SOCIAL, TECHNOLOGICAL AND HEALTH INNOVATION: OPPORTUNITIES AND LIMITATIONS FOR SOCIAL POLICY, HEALTH POLICY, AND ENVIRONMENTAL POLICY

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Editorial: Social, technological and health innovation: Opportunities and limitations for social policy, health policy, and environmental policy

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Editorial on the Research Topic
Social, technological and health innovation: Opportunities and limitations for social policy, health policy, and environmental policy

Overview

Innovation is progressively needed in responding to global challenges. Moreover, the increasing complexity of challenges implies demand for the usage of multisectoral and policy mix approaches. Wicked problems can be tackled by "integrated innovation" that combines the coordinated implementation of social, technological, and health innovation co-created by entities of the public sector, the private sector, the non-governmental sector, and the informal sector (cf. Meissner and Kergroach, 2021).

This Research Topic focuses on filling the knowledge gaps about the selected types of innovation. First, regarding social innovation that can be understood as new strategies, concepts, products, services, and organizational forms that allow the satisfaction of human needs (Murray et al., 2010). Second, a technological innovation that refers to new or remarkably improved products, goods, or services in terms of their technical specifications, components, materials, software, design, or other functional features (Celi et al., 2015). Third, health innovation that focuses on novel or enhanced health policies, systems, products, technologies, services, and care delivery schemes to improve people's health (WHO, 2021). Finally, this Research Topic highlights attempts to develop integrated innovation that can add value to social policy, health policy, and environmental policy by improving efficiency, effectiveness, quality, sustainability, safety, and affordability (Figure 1).

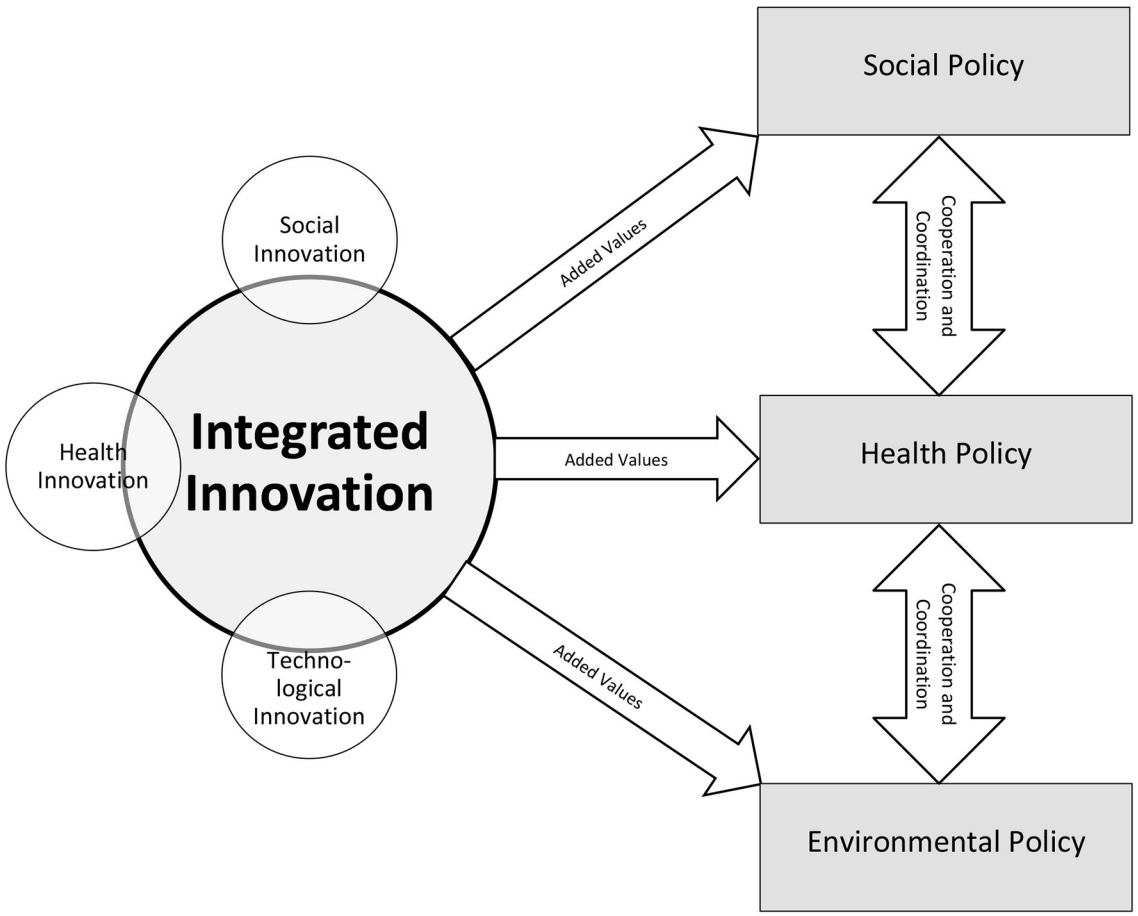

FIGURE 1
Proposed understanding of relationships between selected types of innovation in the context of social policy, health policy, and environmental policy. Source: own elaboration.

The main idea behind the Research Topic "Social, Technological and Health Innovation: Opportunities and Limitations for Social Policy, Health Policy, and Environmental Policy" comes from previous studies of co-editors on the roles of innovation in selected public policies (Klimczuk and Klimczuk-Kochańska, 2019; Klimczuk and Tomczyk, 2020; Felix and Klimczuk, 2021). Four new goals underpinned work on this Research Topic: (1) to identify and share the best current practices and innovations related to social, environmental, and health policies; (2) to debate relevant governance modes, management tools as well as evaluation and impact assessment techniques; (3) to discuss dilemmas in the fields of management, financing, designing, implementing, testing, and maintaining the sustainability of innovative models of delivering social, health and care services; and (4) to recognize and analyze social, technological and health innovation that has emerged or has been scaled-up to respond to crises such as a COVID-19 pandemic.

The presented collection includes 14 articles prepared in total by 100 authors. It also contains five types of articles covering: eight original research articles (Beno; Maresova et al.; Qi and Wang; Sluijs et al.; Enste and Kucharski; Wang et al.; Ma and Gao; Zhang et al.), two perspective articles (El Akoum and El Achi; Ozair and Singh), one conceptual analysis article (Franke et al.), one review article (De Luca et al.), and two opinion articles (Giovanetti et al.; Maravilla and Tan). The papers comprising this set are organized according to three themes.

Theme I: Socioeconomic challenges in the development of social, technological and health innovation

De Luca et al. analyze the regional innovation ecosystem in Campania, Italy, which focuses on ideas of healthy aging, the "silver economy," digitalization, usage of local assets, and

a life-course approach. In the next paper, Ozair and Singh show advances in creating an inclusive and ethically resilient framework for healthcare innovation in India. The subsequent studies focused on China continue the discussion. Qi and Wang provide an example of a targeted rehabilitation assistance system for children with disabilities in which the participants' behaviors exist in a dynamic interaction with the regulatory, normative, and cognitive contexts that generate inclusion and exclusion errors underlying the inaccurate policy implementation. The team of Zhang et al. investigated trends in long-term care insurance funds and factors crucial for establishing a sustainable long-term care insurance financing mechanism in China. The final paper by Wang et al. concentrates on the statistical estimation of catastrophic health expenditure based on data from China's National Health Service Survey. The study recommends developing targeted and multidimensional policies to support identified types of households and vulnerable groups.

Theme II: Innovation in the context of regulatory frameworks of social policy, health policy, and environmental policy

El Akoum and El Achi explore how healthcare innovations can reduce the costs and time associated with responses to the COVID-19 pandemic. The paper analyzes applications received in innovation competitions organized by the World Innovation Summit for Health. In the subsequent study, Maresova et al. investigate how medical device developers respond to regulatory framework requirements in the European Union. On the other hand, Enste and Kucharski present social, legal, and economic challenges implied by the introduction of intelligent wound plaster and the team of Franke et al. discuss diverse effects of assistive robots usage in long-term care facilities. Finally, Maravilla and Tan argue the need for mental health economics and policies that influence not only the quality of life but also the levels of production and consumption.

Theme III: The implementation of social, technological and health innovation: Selected examples

Giovanetti et al., in their article, describe how the Genomic and Epidemiological Surveillance of Arboviruses in Brazil was combined with the dissemination of best practices of emerging movements such as the Open Science and the Responsible Research and Innovation. In the next paper, Ma and Gao provide evidence that there is a need to stimulate social capital that may differently influence self-rated health in distinct types of communities in China. Also, Sluijs et al. focus on targeted intervention. Their study investigates the reduction of type 2 diabetes based on a cost-benefit analysis of various lifestyle programs through dynamic simulations. The last study of this collection, by Beno, analyses how potential financial benefits for e-workers differ in various countries and whether these can increase e-workers' earnings.

Conclusion

The results of the analyzes presented in this Research Topic allow the formulation of three collective lessons derived from these studies. These are: (1) integrated innovation combining social, technological and health innovation needs a high level of cooperation and coordination between various entities and especially well-organized knowledge transfers between research and practice; (2) governance, public management, and organizational management of integrated innovation need an in-depth understanding of multilevel, multistakeholder, and multisectoral approaches; and (3) policy mix related to integrated innovation should cover, among others, investment in research and development, support services and improvement of innovation competencies of policy actors, and the creation of new markets.

Moreover, the articles included in this collection suggest four directions for further research. These are: (1) features of emerging economic systems based on integrated innovation such as the silver economy, longevity economy, social economy, circular economy, green economy, and sharing economy; (2) functions of co-design, co-creation, and co-production schemes in the development of integrated innovation in the areas of social policy, environmental policy, and health policy; (3) disruptions and challenges for integrated public policies and programs on social, environmental, and health issues related to delivering services going beyond digital innovation; and (4) opportunities, criticism, and ethical controversies related to examples of integrated innovation such as digital social innovation, e-health, plant-based innovation, food innovation, artificial intelligence-based solutions, social and service robotics, smart environments, gerontechnology, and welfare technology.

Author contributions

AK outlined and drafted the editorial. MK-K and JF contributed by reviewing and revising the manuscript of editorial and leading editorial work on all manuscripts included in this Research Topic. All authors of the papers listed have made a substantial, direct, and intellectual contribution to the work as well as approved their papers for publication.

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Conflict of interest

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"One Health" Approach for Health Innovation and Active Aging in Campania (Italy)

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This article describes how innovations are exploited in Campania (Italy) to improve health outcomes, quality of life, and sustainability of social and healthcare services. Campania's strategy for digitalization of health and care and for healthy aging is based on a person-centered, life-course, "One Health" approach, where demographic change is considered capable of stimulating a growth dynamic linked to the opportunities of combining the "Silver Economy" with local assets and the specific health needs of the population. The end-users (citizens, patients, and professionals) contribute to the co-creation of products and services, being involved in the identification of unmet needs and test-bed activity. The Campania Reference Site of the European Innovation Partnership on Active and Healthy Aging is a flexible regional ecosystem to address the challenge of an aging population with a life-course approach. The good practices, developed in the context of research and innovation projects and innovative procurements by local stakeholders and collaborations with international networks, have been allowing the transfer of innovative solutions, knowledge, and skills to the stakeholders of such a multi-sectoral ecosystem for health.

Keywords: health policy, digital health, active and healthy aging, health innovation, future health and health care, information and communication technologies, silver economy

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INTRODUCTION

Worldwide demographic change with increasingly aging populations poses a challenge to societies. The Aging Europe report published by the European Commission in 2019 highlighted that the population of older adults (65 years or more) in the European Union (EU) will increase from 101 million in 2018 to 149 million by 2050. The number of people in the EU-28 aged 75–84 years is projected to expand by 60.5%, and those aged 65–74 years to increase by 17.6%, with 9.6% fewer people aged under 55 years living in the EU-28 by 2050 (1). The current COVID-19 pandemic brings an additional challenge for this segment of population, related to the increased risk of adverse outcome in case of infection (2). Furthermore, the deterioration in the quality of life of the older adults as a consequence of loneliness and insufficient treatment resulting from the pandemic imposes health challenges of unknown dimension. Due to the pandemic, health conditions of older adults worsen, and mortality increases, especially among the vulnerable subgroups of populations, setting a country back on its path of human development, and increasing the economic pressure on governments (3). The additional burdens of high unemployment rates among the working-age population and migration will put a strain on health care and welfare systems in southern and eastern European regions (4). The United Nations 2030 Agenda for Sustainable Development (5) calls for a global alliance to address the social challenges that all countries are facing, with a focus on health and training, and in relation to the inequalities that prevent sustainable development for the global society. According to World Health Organization (WHO) Decade for Healthy Aging, if living longer is dominated by poor health, social isolation, or dependency on care, the implications for older people and society are negative in terms of sustainability and development. Poor health for older adults makes them less productive, earn less, retire earlier, and be in greater need for health, care, and social services (6). The impact of social inequalities on population health and mortality has been well-documented, as well as the fact that in many western industrialized nations, there is a gradient between social class position (employment, education, and/or income) and the risk of death (7). This has consequences for individuals, industry, public authorities, health and care organizations, policy makers, and investment communities (8). The term "health inequality" refers to the health differences between individuals or groups (9) that are preventable and unnecessary: allowing them to persist is unfair. Differences between social groups are considered health inequalities because they reflect an unfair distribution of health risks and resources. In fact, to be truly effective, health services must be able to manage the health of the entire population and not only those who need it for specific health conditions. The aging process is not the same for all individuals (10): the loss of ability typically associated with aging differs and is developed throughout a person's life-course. Disability and dependency are not an inevitable consequence of aging, and there is a lot we can do to transform it into an opportunity, by supporting and stimulating active and healthy trajectories of aging along the entire life-course. The WHO indicates three key approaches to align health systems to the needs of older populations:

1. Developing and ensuring access to services that are person centered and integrated;
2. Orienting systems around intrinsic capacity; and
3. Ensuring there is a sustainable and trained health workforce.

In this perspective, there is a need to strengthen health promotion and disease prevention along the entire life-course, while addressing the needs of an aging population by supporting independent living at home, self-management of age-related conditions, and reduction of isolation.

OPPORTUNITIES FROM THE INTERNATIONALIZATION OF THE REGIONAL HEALTH SYSTEMS

The Campania Region follows the indications of the WHO "One Health" approach for the implementation of sustainable development goals across all policies, in an inter-sectoral effort (health, environment, education and training, research, and tourism), including different stakeholders along the quadruple helix of innovation (11, 12). This innovation ecosystem is based on the approach introduced by the European Innovation Partnership on Active and Healthy Aging (EIP on AHA), a stakeholder-driven, voluntary initiative, launched in 2012 to foster innovation and digital transformation in active and healthy aging across countries and regions within the EU (13–15). The EIP on AHA brings together public authorities, health and care providers, researchers, industry, and civic society organizations within, and across, regions to address the challenges of an aging population through the development, implementation, and scaling-up of evidence-based innovative solutions, digital technologies, and models of health and care. One of the biggest challenges for the EIP on AHA is moving innovative solutions to widespread application, beyond projects or test bed environments. The EIP on AHA has been supporting the development and adoption of innovation at scale, either within a region, across a country, or by transferring to other regions and countries. The EIP on AHA Reference Sites (RS) are regional ecosystems that bring together local quadruple helix partners from industry, civil society, academia, and government authorities to focus on a comprehensive, innovation-based approach to active and healthy aging. They are leading regional organizations committed to investing in innovation for active and healthy aging and supporting their transfer and scaling-up across Europe (16). The Reference Site "quadruple helix" structure involves all the stakeholders to work collaboratively and effectively in defining and understanding need; co-creating and co-designing new solutions; offering suitable test bed environments; and evaluating and measuring the impact of innovation on patient, service user, and sustainability. The European Commission (EC) awarded the recognition of "Reference Site" to Campania for the first time in 2012, to

the Research and Development Unit of Federico II University Hospital, as the referent for Campania cluster (**Table 1**). The RS subsequently obtained a first regional recognition (Regional Resolution n. 622/2012), which established a specific coordination group for achieving the objectives of the EIP on AHA. The Federico II University Hospital resubmitted the application to the EC in 2016, obtaining the recognition of "3stars RS." The Regional Resolution n.221/2017 established an interdisciplinary group for the coordination and management of the RS. The latest "4stars RS" award was obtained in 2019, supported by the Department of Public Health of Federico II University. The scale-up of validated innovative solutions is at the core activity of the stakeholders of the Campania RS of the EIP on AHA (17). Campania RS coalition is also connected to the ProMIS (Programma Mattone Internazionale Salute), the Italian Ministry of Health network for internationalization of regional health systems (RHS). Representatives of all Italian regions participate in ProMIS, to address the current and emerging health needs of the Italian population, sharing and exploiting the opportunities provided by innovative good practices (18).

The Health Innovation Division of the Campania Region coordinated and supported the stakeholders of the RHS in the development of the ProMIS regional Network (ProMIS@Campania), including public healthcare organizations of Campania, during the 2017–2020 timeframe. ProMIS@Campania and Campania RS collaboratively designed strategic objectives, through:

1. Periodic dedicated meetings, for the recognition of the needs inherent in procedures, tools, and techniques useful for innovation in healthcare (Focus Groups);
2. Involvement in the activities of the national ProMIS network, with particular reference to European initiatives, projects, and working groups; and
3. Thematic workshops.

The **Supplementary Materials** provide more details on the activities carried out in the framework of the ProMIS@Campania network.

This multidisciplinary, inclusive, and collaborative approach highlighted an asymmetrical progress of the different groups, due to the different levels of maturity of the shared good practices, and to the heterogeneity of the skills expressed by the involved organizations.

The systematic approach described for the strengthening of the ProMIS@Campania regional network has been identified through a decision-making and consensus process integrating evidence gathered from preliminary studies, and an empirical data collection with locoregional stakeholders that was developed iteratively during a 3-year timeframe. This process has allowed the identification of some priority thematic areas for the regional strategies, with respect to which it has been possible to take advantage of the participation in specific European-funded projects, in line with what was developed within the ProMIS@Campania network.

CAMPANIA'S STRATEGIC OBJECTIVES

The results emerging from the activities of the ProMIS@Campania network indicate, as a strategic objective, the repositioning of the offer of services within a person-centered health ecosystem, through the adoption of innovative approaches that allow the implementation of proactive interventions, and use validated innovative good practices. Campania has important research assets, a key element for the development of an economy based on knowledge, as long as the research results are transferred to the market. "Health is the greatest wealth," and it is one of the investment sectors with the strongest drive for innovation. Health has a high turnover of knowledge, and it is one of the most important markets for innovation in a public health context. This is particularly true in Campania, where the RHS is leaving from repayment plan and is investing in the enhancement of service provision to citizens, to improve health outcomes and the system sustainability. A proactive, innovation-driven approach translates into opportunities for regional economic growth that can be triggered by digital transformation, enabling cross-sectoral links. The innovation of the Campania ecosystem for health stimulates multisector and multi-actor collaborations (19). The digital transformation strengthens patient empowerment, increasing the accessibility of services for segments of the population with specific health needs, such as the older adults and people with disabilities. The ProMIS@Campania strategy for innovation is aligned with the objectives of the National Health Plan (20) and the new regional Health Plan (21), aimed at capacity building of the regional stakeholders from the social and health systems, strengthening cross-sectoral collaborations at the locoregional, national, and international levels. In this regard, the digital transformation of health and care offers the opportunity to transform social and health challenges, such as the aging of the population and health inequalities into opportunities for sustainable development, and might be one of the priority areas for investments aimed at bridging infrastructural gaps and digital divide (22).

EMERGING PRIORITY LINES OF INNOVATION NEEDS

The strategic objectives of the ProMIS@Campania network provided a shared vision, facilitating the identification of health needs and supporting the agreement of the local stakeholders on the possible ways to enhance the good practices provided by the collaborative activities within international and national projects. The vision of ProMIS@Campania was aligned with the priorities of the European Commission, allowing the alignment of financial instruments at the regional, national, and European levels for the development of long-term investment plans, to produce structural changes.

Figure 1 represents the directories resulting from the activities carried out within the ProMIS@Campania network, on which the stakeholders of Campania RS have been focusing on, coherently

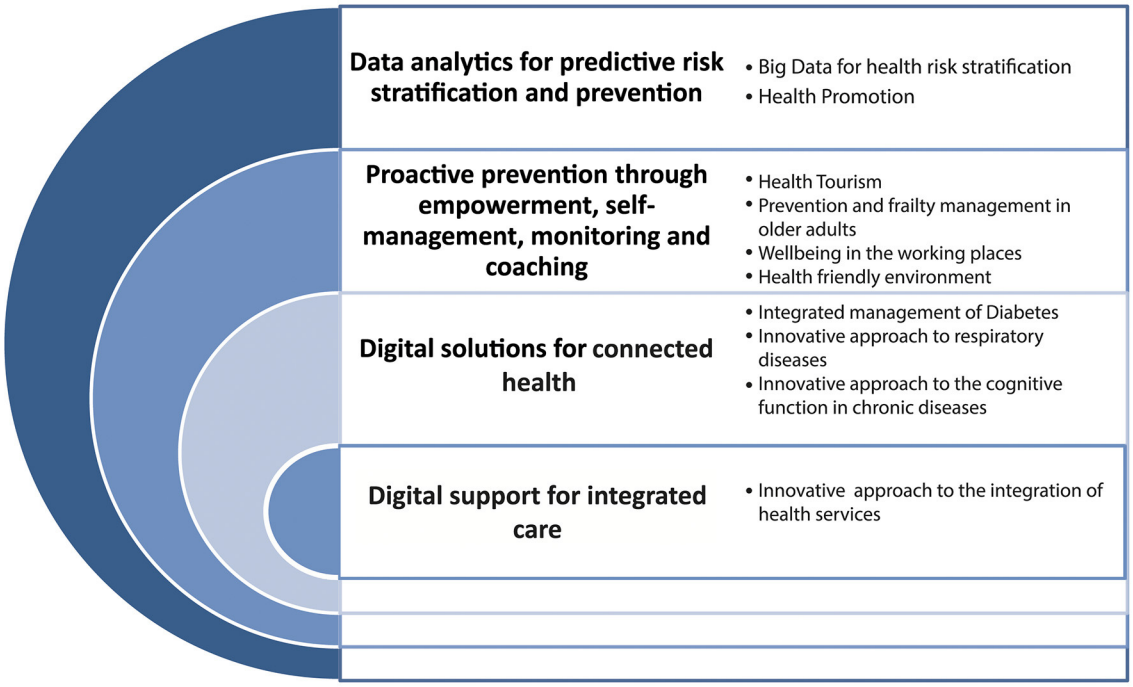

FIGURE 1 | Emerging directories of the health innovation ecosystem in Campania.

with the four priorities of the European Blueprint for the digital transformation of health and care for the aging society (23, 24).

THE GOOD PRACTICES FOR HEALTH INNOVATION IN CAMPANIA

Campania participation in the EIP on AHA community broadened the adoption of digital solutions in health and care, exploiting the good practices available (25) through twinning activities with different European regions (**Table 2**). The twinnings represented an opportunity provided by the EC to exchange knowledge and innovative good practices with high potential for replicability and scaling up (26).

The participation to international collaborative activities also provided the opportunity to be involved in international research projects to design, test, implement, and monitor the impact of innovative good practices. Such projects were coherent with the priority directories identified by the regional focus groups.

Figure 2 provides a list of the European projects that were awarded to the stakeholders of Campania RS ecosystem that were subgrouped according to the strategic lines of the ProMIS regional network and have fostered the stakeholders' engagement at different levels in thematic working groups.

INNOVATIVE PROCUREMENTS

Among the financial instruments for the research and development of digital solutions, a key enabler has been represented by innovative procurements. The EC introduced two forms of public procurement to promote innovation in the public sector: public procurement for innovative solutions (PPI) and pre-commercial procurement (PCP). PPI is a procurement process in which public authorities act as customers for the launch of innovative goods and services that are not yet available on a large-scale commercial basis. PCP is about purchasing research and development (R&D) services rather than ready-to-market products, involving industry players as future suppliers at all stages of solution's development, from research to final product, influencing the market from the demand side, and by stimulating suppliers to develop solutions that respond to well-identified unmet needs of end users (27, 28). The stakeholders of Campania RS community have been taking advantage of the opportunity represented by innovative procurement by joining different consortia, and becoming one of the leading groups in Europe. Innovative procurement supports the improvement of the matchmaking between supply and demand of innovation with the aim of reducing market fragmentation, and promoting a collaborative approach to increase the knowledge sharing and the capacity of the RHS to express its need for innovation in a way that allows interested parties to provide adequate and sustainable solutions. By participating in seven pre-commercial procurements (PCP) (**Table 3**), the stakeholders of Campania RS have been steering the market toward innovative healthcare solutions and the development of demand-driven products (29). Each PCP offers the opportunity for stakeholders and suppliers to develop specific requirements for innovative solutions, to contribute to clinical pilots in healthcare settings, and to offer vendors the possibility to exploit the results of the pilots for the development of new ready-to-market solutions.

TABLE 1 | The stakeholders of Campania RS along the four helixes of innovation.

Government/Health providers	Research and academia	Industry	Civil society
• Campania region, • Local health agency Napoli 1 Centro, • Local health agency Napoli 2 Nord, • Local health agency Napoli 3 Sud, • Local health agency Benevento, • Local health agency Caserta, • Local health agency Avellino, • Local health agency Salerno, • Cardarelli national relevance Hospital, • Pascale national cancer Institute, • Azienda dei Colli national relevance Hospital, • Federico II University Hospital, • Vanvitelli University Hospital, • San Giovanni di Dio e Ruggi d'Aragona University Hospital	• Federico II University of Naples (department of public health, department of advanced biomedical science, department of architecture, department of industrial engineering, department of agricultural science, department of clinical medicine and surgery, department of translational medical science, department of pharmacy, department of molecular medicine and biotechnologies, department of neuroscience, CEINGE advanced biotechnology research center, CIRFF–Interdipartimental research center for pharmacoeconomics and drug utilization), • Parthenope University of Naples (department of physical activities), • University of Salerno (department of medicine and surgery, department of civil engineering), • Suor Orsola Benincasa University of Naples, • Vanvitelli University of Naples (department of medical, surgical and dental specialties) • L'Orientale University of Naples (department of human sciences)	• Digital innovation hub campania (Unione industriali campania), • Federterme (Italian federation of thermal and healing water industries), • Confcooperative Sanità Campania (Confederation of cooperatives–health division)	• Ancel keys institute, • E. Ferrari vocational high school, • Mediterranean federation for advancing vascular surgery, • Italian association Alzheimer disease (AIMA), • Italian cancer association (ANT), • Progetto ALFA association (Health Literacy), • Campus salute (Health promotion), • Federico II University emeritus professors association, • Salute in collina association (general practitioners), • CosmicNet (small and medium municipality network)

TABLE 2 | The good practices exploited by Campania regional health system (RHS) through twinning activities.

Twinnings	Objectives	Originator	Funding scheme
QMCI	Early identification of mild cognitive decline	University of Cork- Ireland RS	EIP-AHA scale up strategy- EC
Gastrological approach to malnutrition	Nutritional intervention in individuals with specific health needs	Center for gastrology- Belgium/The Netherlands	EIP-AHA scale up strategy- EC
MASK-ARIA	Prevention and management of allergic rhinitis	MACVIA- France RS	EIP-AHA scale up strategy- EC
Telerevalidatie	Promotion of adapted physical activity in NCCDs patient	Twente RS	EIP-AHA scale up strategy- EC
Listeo+	Management of waiting list and pre-op recommendations	Andalucia region RS	Digital health Europe CSA
My prescription	Polytherapy management and prescription adherence	Andalucia Region RS	Digital health Europe CSA

INNOVATIVE SOLUTIONS AVAILABLE IN COMPANIA

The innovative solutions tested or under validation concern:

Stratification of the Risk of Adverse Health Outcomes Through a Validated Algorithm, Based on Regional Data Flows (RISK-ER)

RISK-ER aims to identify the risk of adverse health outcomes in the population through a risk stratification tool and to assess the economic impact associated with negative health outcomes. The Risk-ER tool was developed by the Emilia–Romagna Region, and validated in Campania by the Salerno Local Health Agency on the entire resident population, in collaboration with the University of Salerno. The organizational model for collective and individual interventions is under development (30).

Integrated IT-Supported Management of Diabetes, for Patient Empowerment and Self-Monitoring, Supporting Adherence to Healthy Lifestyles, Consistent With the Disease (PROEMPOWER)

The solution consists of a shared care plan allowing both patients and professionals to enter data such as glucose measurements, while giving each of them specific rights to do so and integrating data captured directly from devices. Measurement of parameters used by health professionals and patients to manage the disease are transferable to the main ProEmpower solution, including automatic data transfer from device. The solution is, furthermore, able to deliver messages to the patient, including messages formulated by a professional and those automatically generated through data analysis—notifications of deviation from goals, tips for better management, etc. (31).

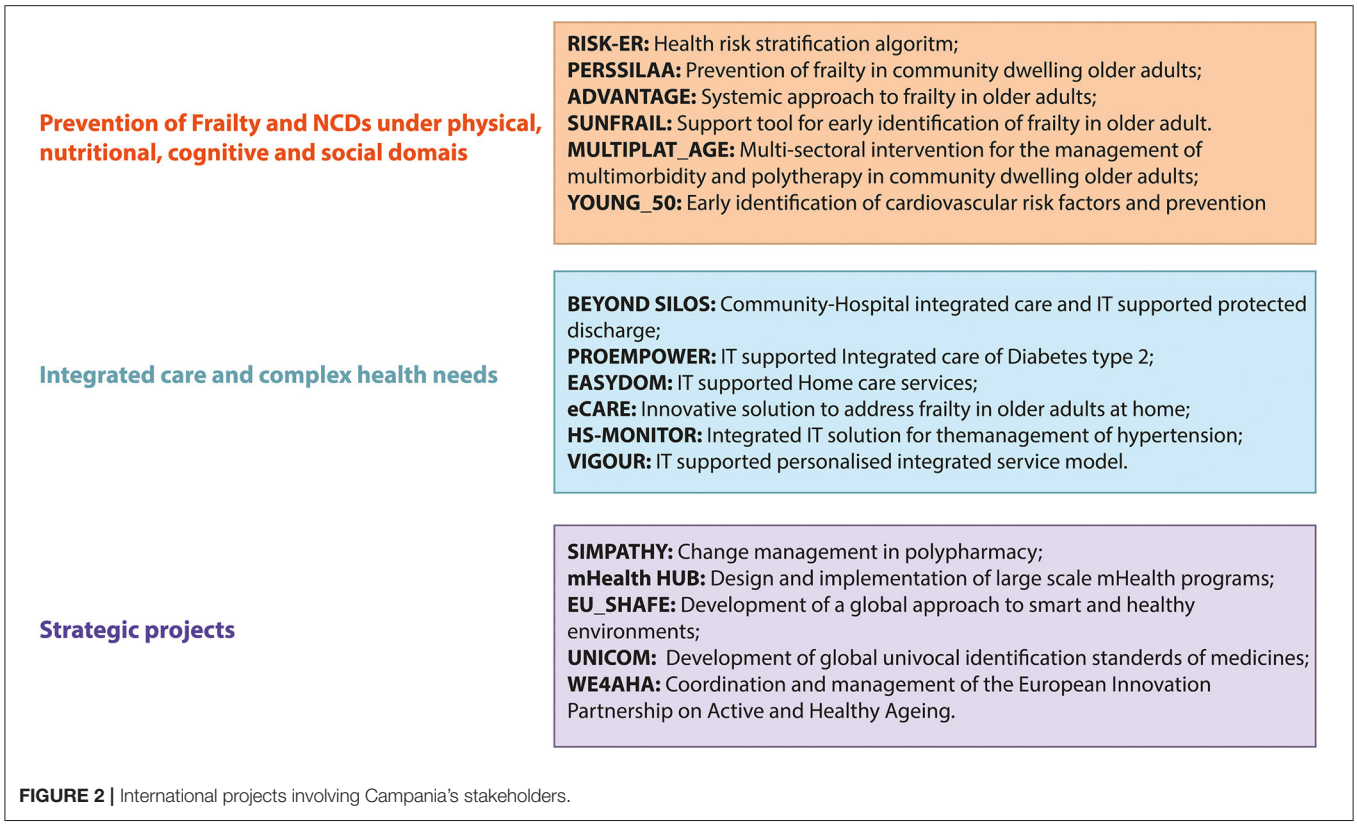

FIGURE 2 | International projects involving Campania's stakeholders.

Integrated Home Care for Subjects With Multi-Morbidity, Including Low and Medium Intensity of Care (Beyond Silos)

Beyond Silos is an innovative practice that consists of an ICT-based home monitoring system provided as a service by a private home care company, which allows hospital staff to follow up patients at home, as if the patient was still in the hospital (32, 33). The Beyond Silos Good Practice will be recalibrated and used as a basis for the pilot phase of the European VIGOR project.

Review of the Polypharmacy Regimens ("Medication Review" and "De-prescribing")

The "FRIENDD" study was implemented to identify cases of prescriptive inappropriateness and report them to the general practitioners connected to a multispecialist team for de-prescribing. The study currently involves experts from different medical areas (pharmacology, geriatrics, neurology, gastrointestinal, and endocrinology) (34).

A Multisectoral Path for Rhinitis and Its Multimorbidity

The MASK-ARIA initiative aims to develop an interprofessional care model (pharmacists, general practitioners, and specialists) for an integrated management of patients with allergic rhinitis. MASK-ARIA in Campania is developed through a smartphone app that allows for rhinitis assessment and uses a clinical decision support system (CDSS) (35–38).

The Gastrological Approach to Malnutrition

The gastrological approach to malnutrition is a primary prevention approach to malnutrition in cases of specific nutritional needs, in all healthcare settings (39). The focus of the gastrological approach is the implementation of personalized ICT-supported nutritional interventions that leverage validated screening, assessment, and monitoring tools, recognizing a coherent set of activities aimed at improving food intake in frail individuals.

Early Identification of Mild Cognitive Decline to Enable Targeted Interventions

A multicenter study was carried out in Campania to validate the Italian version of the Quick Mild Cognitive Impairment (QMCI-I) tool and to obtain normative data. Further studies on Italian patients with MCI (mild cognitive impairment) are underway to investigate the diagnostic properties of QMCI-I, and to use the multidomain structure of the tool to classify the various subtypes of MCI and indicate interventions, including memory training supported by digital tools (40, 41).

PERsonalized ICT Supported Service for Independent Living and Active Aging

PERSSILAA services are offered to older adults through living labs organized in local communities, and are integrated with

TABLE 3 | Pre-commercial procurements in Campania.

Project	Aim	Funding (€)	Funding scheme	Beneficiary
ProEmpower	Self-management and monitoring of diabetes type 2	750,000.00	European commission	Federico II University Hospital
HSMonitor	Early detection and management of hypertension	924,000.00	European commission	Federico II University Hospital
eCARE	Early detection and management of frailty in older adults	980,000.00	European commission	Benevento local health agency
ADCARE	ICT supported integrated services for multimorbidity management	2,008,125.00	Italian ministry of research	Federico II University Hospital
Ingegneria BioMedica	ICT supported management of medical devices	1,347,500.00	Italian ministry of research	Federico II University Hospital
INCAREHEART	Self-management and monitoring of chronic heart failure	930,000.00	European commission	Federico II University
TIQUE	Integrated approach to chronic heart failure management	1,476,358.33	European commission	Avellino local health agency
	Total	8,415,983.33		

healthcare services. This new multimodal service model, focused on nutritional, physical, cognitive, and social dimensions, is supported by an interoperable ICT service infrastructure and by a level of gamification. An extension of the pilot, aimed at Campania rural areas, is currently in the planning and implementation phase (42, 43).

ICT Supported Adapted Physical Activity

The Telerevalidatie.nl® platform supports the physical activity of sedentary patients at their premises. It provides ICT-supported personalized training program with tutorial videos and at the same time allows to track their use of the platform (44). The Federico II University Hospital has activated a clinic for the physical activity on prescription (PAP), to ensure that patients discharged by a rehabilitation pathway are enrolled in a personalized physical activity program. To this aim, patients who are enrolling in the program are subjected to physical need assessments, performed according to the guidelines for exercise testing and prescription of the American College of Sports Medicine (45). Telerevalidatie.nl® is an example of successful transfer of an innovation to current practice. The solution was initially developed in the framework of the PERSILAA project. Its transfer was supported by two international twinnings that support knowledge transfer and adaptations that resulted in the final integration of the program for adapted physical activity into service provision of the Federico II University Hospital.

Early Identification of Frailty in Primary and Secondary Care Settings

The SUNFRAIL tool enables early identification of frailty-risk domains in the elderly, in order to prevent functional decline and adverse health outcomes. The tool is currently being used in pilots at the thematic focus group of the ProMIS@Campania network (46).

TRANSFERABLE ELEMENTS

New Skills for New Jobs

Tackling the challenge of an aging population requires moving from a reactive approach to disease to a proactive one for health and well-being. The Campania RS approach contributed to the connect multidisciplinary skills and knowledge, placing the citizen at the center of healthcare services, improving their quality and accessibility. As COVID-19 emergency demonstrated, digital literacy and training will be essential among professionals across sectors, for e.g., for secondary use of data, hence, the need to make digital tools and solutions accessible to these groups (47), fostering technological skills. Further strengthening of human resources in a regional health system is pivotal to develop capacity building, integrating the enrollment of new professionals in a continuous training courses, as a fundamental tool for maintaining high-quality standards in the provision of health and social services and protecting individual and collective health.

Innovation to Market in Campania

The Campania RS ecosystem has been making efforts to implement the EIP on AHA Innovation to Market (I2M) strategy by establishing a dialogue with industrial stakeholders, such as the Digital Innovation Hub of Campania (DIH) and the HealthTech Innovation Hub. Campania DIH is the regional network of private companies engaged in innovation and digital transformation projects, not only in the health sector. The HealthTech Innovation Hub is the result of the collaboration between the Federico II University of Naples and Medtronic Italy, with the aim of combining academic and industry skills to generate new solutions in healthcare. The shared objective is too contrite to the development of the "Digital Health" market in response to the health needs of citizens. This collaborative and cross-sectorial approach follows the implementation of the European plan for "Innovation to market" (I2M) (48) in Campania and broadens the commitment of local stakeholders in the activities and further progress of the I2M plan. The RS can contribute to the organization of activities aimed at enriching and extending the impact of the I2M plan at the regional level. The alignment between the objectives of interested stakeholders strengthens the strategy of the digital market and extends the priorities of digital development in Campania to the health sector. Through this synergy, Campania RS will stimulate and promote the demand for innovation in the healthcare

system, improving the level of multidisciplinary knowledge and increasing the awareness of the opportunities offered by digitalization to industry and promoting the adaptation and large-scale adoption of validated good practices.

Health, Accessible, and Sustainable Tourism

Health is an important sector of the economy, and health tourism is growing rapidly across Europe. Health tourism refers to any form of tourism development related to health creation that includes health promotion, specific health services, or services addressing health needs related to specific conditions (49). An effective approach needs integration between health, social, and tourism services to make tourist destinations accessible, addressing the different pattern of needs: frailty, dependency, health-specific needs that determine spending priorities of significant parts of the general consumer economy, such as the "Silver Economy" (47). The Collaboration between Italian and European Reference Sites, in the context of the national ProMIS network and the EIP on AHA Reference Sites Collaborative Network (RSCN) (50) led to synergic actions in the field of health, to support the development of accessible and sustainable tourism. This is through sharing validated and innovative experiences that strengthen accessibility to health services in the regional, national, and international contexts. Broad, collaborative activities will allow the identification of shared strategies and priority implementation areas to further drive the development of this emerging sector.

Bottom–Up Approach

Often, the regions adopt a top–down strategy to the development of the local network for innovation, with a centralized definition of priorities, and subsequent collection of good practices on the ground. ProMIS carried out an assessment focusing on the methodology for the development of the local network for the implementation of regional policies in AHA (51). In this study, for example, the strategy of Friuli Venezia Giulia RS is based on the implementation of a regional program for the promotion of healthy aging, with many areas of interventions, such as civil commitment, culture, and social tourism, the access to new technologies, information, and services. A specific panel has been created to implement and manage all those areas of intervention. Liguria RS created a public–private partnership for active aging that collects some of the excellences active in the region in terms of research and innovation (University), social sector, IT companies, training institutions, regional health agencies, and local institutions. Lombardy RS is based on the connection between the regional Directorate for Welfare and the Lombardy Cluster for Technologies in life environments that is a multidisciplinary technological cluster, funded by the Directorate for Productive Activities and Research. In the framework of "Silver Constellation for Health," Piedmont RS developed an operational setting of interlaced good practices on AHA, important experiences contributing to the health policy, adding new professional and community skills. The Emilia–Romagna RS is composed of a wider regional coordination team involving the Department of Health and Social Policies, the Department of Production Trade and Tourism and ASTER, the technological cluster of the Emilia–Romagna Region.

Campania is following Kotter's eight-step change management model to realize the vision of the "One Health" approach (52, 53). The innovation ecosystem, through Campania EIP on AHA RS and ProMIS@Campania network, engaged a group of stakeholders in the identification and uptake of good practices in the region and beyond (Step 1–2). Sharing knowledge and opportunities of collaboration among stakeholders allowed the development of a shared vision and strategy that were appropriately communicated through newsletters, conference presentations, and scientific publications. This approach empowered others to act on the vision (Step 3–4). The involvement of stakeholders in the regional, national, and European level activities empowered and stimulated other stakeholders (Step 5). The generated good practices represent short-term wins (Step 6), for which it is necessary to consolidate the results and produce more changes (Step 7). The wider implementation and the continuous monitoring of the results will connect the solutions together in a single process of change and anchor innovative approaches to the local culture and context (Step 8).

BOTTLENECKS

Innovation of health and care poses many challenges that cannot be addressed timely by an isolated approach, i.e., finance and insurance, technological standards, degree of interoperability of solutions, issues around data security, and solutions for data analytics/data mining, lack of ICT literacy, lack of continuity between different research maturity level (e.g., TLR 1 to 9).

Limited International Collaborations

The quadruple helix of innovation for the digital transformation of health and care includes also research, and indeed, in Campania, an effort was carried out to strengthen interdisciplinary approaches in expert groups, in all projects and twinnings, but further developments are necessary to ensure that horizontal activities succeed in facilitating the mainstreaming along international opportunities, for example, connecting with international networks. This element is pivotal to reduce fragmentation in the procurement of innovative solutions for health services. Strengthening collaborations at international levels is a key enabler to foster national alliances, facilitate peer-to-peer learning and transfer of innovative, validated good practices. Within this approach, networks play a catalytic role to facilitate capacity building.

Absence of Digital Services in Standard Care Pathways

Ensuring appropriateness is pivotal to use digital solutions in healthcare services not at a discretion, as they are included in the standard care pathways (Percorsi Diagnostico-Terapeutico e Assistenziali–PDTA), adapted to the specific needs of the person (Piano Assistenziale Individuale–PAI), hence, the efforts of the national health system to establish a nomenclature of digital services and define new PDTA (health and social) for the integrated management of diseases in the territory, when they

are available as IT-supported services, hence, the introduction of essential levels of digital healthcare in the new Minimum Service Level (Livelli Essenziali di Assistenza–LEA), with reimbursement arrangements specific for digital services, is pivotal (54).

Low Digital Literacy

Large-scale adoption of a digital solution for health and care needs to reach high levels of digital literacy for end users (professionals, patients, and citizens) and to consider how digital tools and solutions can be made completely accessible to these groups (47). Only by starting from the analysis of the needs expressed by citizens and institutions will we be able to enhance the market of innovative solutions, responding to concrete unmet needs of older adults and removing the organizational, technological, and behavioral obstacles that influence large-scale adoption in the locoregional context.

Fragmented Approach to Structural Reform

Health innovation needs strong institutions capable of implementing health reform, with accompanying clear programming objectives and successful projects. Many of the gaps identified are linked to structural reform issues that are difficult to address through project-based funding. Stronger capacity and technical expertise to implement and design reforms can complement the capacity to develop high-quality policies and projects (55).

CONCLUSIONS

The governance approach of Campania RS to address the needs of an aging population translates in strengthening disease prevention and health promotion in the entire life-course through empowerment and digital solutions, and in supporting independent living at home and in community, strengthening self-management of age-related conditions and reducing isolation. Such proactive, user-centered system empowers citizens and informal caregivers to take greater responsibility for health and well-being, by providing information and advising on healthy lifestyles, to stay active and healthy as long as possible (56–58). Similarly, age-friendly environments are beneficial to individuals and society throughout the entire life-course (59) and are enabled by digital solutions. A "Silver Economy," deployed in the framework of a life-course approach, could stimulate sustainable growth in Campania, creating opportunities and jobs, through digital innovation and across sectors such as transportation, constructions, and built environment, as well as supporting patients and older adults to remain independent, active, and live longer in their homes and communities, while increasing the efficiency and effectiveness of health and social care systems (47). End users are at the center of such approach, to accelerate the design of user-friendly products and services, sharing experiences with new generations, and being involved in test-bed activities (60).

AUTHOR CONTRIBUTIONS

MI conceived the presented idea and drafted the table of contents. MI, VDL, and GT wrote the entire manuscript. LR, UT, and PB contributed to the Abstract and the section Strategic Objective. ML, MLC, GB, DT, and AC contributed to the Abstract and the section Health, Accessible, and Sustainable Tourism. GA, UMB, RZ, FC, and MTa contributed to the sections The Good Practices for Health Innovation in Campania, Emerging Priority Lines of Innovation Needs, and Innovative Solutions Available in Campania. GI, AL, and AM contributed to the sections Innovative Procurements and The opportunity of Aging in Campania: new skills, new jobs. GV and MM contributed to section Opportunities From the Internationalization of the RHS. CP and MTr contributed to the section Long-Term Sustainability of Investments in Digital Transformation. CV and GC contributed to the section Innovation to Market in Campania. RR-W and JB contributed to sections Introduction and Conclusions and critical reading. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

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Delivering High-Quality, Equitable Care in India: An Ethically-Resilient Framework for Healthcare Innovation After COVID-19

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Developing countries struggle to provide high-quality, equitable care to all. Challenges of resource allocation frequently lead to ethical concerns of healthcare inequity. To tackle this, such developing nations continually need to implement healthcare innovation, coupled with capacity building to ensure new strategies continue to be developed and executed. The COVID-19 pandemic has made significant demands of healthcare systems across the world—to provide equitable healthcare to all, to ensure public health principles are followed, to find novel solutions for previously unencountered healthcare challenges, and to rapidly develop new therapeutics and vaccines for COVID-19. Countries worldwide have struggled to accomplish these demands, especially the latter two, considering that few nations had long-standing systems in place to ensure processes for innovation were on-going before the pandemic struck. The crisis represents a critical juncture to plan for a future. This future needs to incorporate a vision for the implementation of healthcare innovation, coupled with capacity building to ensure new strategies continue to be developed and executed. In this paper, the case of the massive Indian healthcare system is utilized to describe how it could implement this vision. An inclusive, ethically-resilient framework has been broadly laid out for healthcare innovation in the future, thereby ensuring success in both the short- and the long-term.

Keywords: global health (MeSH [H02.403.371]), health policy, health planning [MeSH], public health, community medicine, digital health (eHealth), digital health

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INTRODUCTION

"There seems to be no limit to the possibilities of scientific medicine, and while philanthropists are turning to it as to the hope of humanity, philosophers see. . . a science from which may come. . . peace over all the earth (1)." Verily, what faith in modern medicine had been expressed by Sir William Osler in 1902, is but reflected in the heroic demands made of it today—to touch more lives than ever before. Such demands warrant innovation at scale and in all aspects of healthcare. Nowhere are they more visible today, than in the worldwide call-to-arms to provide breakthrough treatments and vaccination for COVID-19 (2).

Medicine has had a long history of both scientific and social innovation. The latter, for instance, is evident in the achievements of public health, including in the current pandemic. Therefore, while ranking innovations with the greatest impact on healthcare, the Deloitte Center for Health Solutions used the following, wide-ranging definition:

"Any combination of activities or technologies, that breaks existing performance trade-offs in the attainment of an outcome, in a manner that expands the realm of the possible; defined in health care as providing 'more for less'—more value, better outcomes, greater convenience, access, and simplicity; all for less cost, complexity, and time required by the patient and the provider, in a way that expands what is currently possible (3)."

Attainment of these presumed endpoints is what is expected of healthcare systems across the world, both in developing and developed nations, and both in the current crisis and beyond. This attainment may be either evolutionary, brought on by gradual advances, or revolutionary, which is creative, disruptive, and discontinuous. Such endpoints require one to have, firstly, a short-term strategy for translating innovative strategies into practice; and secondly, a long-term vision and philosophy for future innovation.

Analysis of a single healthcare system, in the context of its unique challenges, provides a foundation to draw lessons from. In this commentary, a broad framework of innovation for the healthcare system in India has been described, which is inclusive, ethically-resilient, and incorporates learning points from patient care experiences at the largest residential hospital in South Asia, both before and during the COVID-19 pandemic (4) (**Table 1**). As discussed below, rectifying health disparities, which have been exposed by the pandemic, and ensuring universal healthcare access must become India's guiding lights for health policy moving forwards.

THE CHALLENGE IN INDIA

Even before COVID-19 struck, the majority of the Indian population was yet to have access to healthcare in its entirety, let alone an excellent one. The public sector was already contributing merely 30% to the cost here, in contrast to 84% in, for instance, the United Kingdom (5). Out-of-pocket expenditure made up over 60% of total healthcare expenses, in a nation having 273 million living below the international poverty line of US$1.90 per person per day (6). Coupled with the average public spending on healthcare per capita, a meager INR 3/- per day, the scale of the economic challenge becomes clear (5). Unfortunately, the above challenge has only been accentuated by the pandemic, with estimates allowing for a possibility of doubling of poverty (7, 8). Issues of unavailability of critical medical equipment and unaffordability of the private sector have also been brought to the fore—issues that can be tackled by innovation and reform as well (9, 10).

A nation that ranks amongst the lowest worldwide for the percentage of its gross domestic product (GDP) spent on healthcare, therefore, requires "frugal innovation," driven by prioritized analysis of population-level healthcare needs. The intent to implement innovation must be with a razor-sharp focus on ensuring that benefits flow to the bottom of the pyramid. In planning for India's future, it must be remembered that even emergency care remains an elusive entity for most, let alone annual health check-ups (11).

Before the COVID-19 pandemic, the biggest killers in India, as per the World Health Organization, in decreasing order of frequency, had been ischemic heart disease, chronic obstructive pulmonary disease, stroke, diarrheal disease, lower respiratory infection, preterm birth complications, and tuberculosis (12). What binds together the top three in this list, together causing a third of all deaths, are the chronic nature of their risk factors, i.e., diabetes, hypertension, dyslipidemia, smoking, visceral obesity, etc. All of these are modifiable or preventable, and thus well-positioned to be the arena of healthcare innovators.

SHORT-TERM STRATEGIES FOR INNOVATION: THE CURRENT BIG IDEAS

Short-term strategies for innovation in India must employ both top-down and bottom-up approaches to succeed, merely one does not succeed alone. The top-down strategy needs a larger number of more enhanced streamlined public-private partnerships, along with a greater public investment in biomedical research. While the latter has been seen in the recent funding provided for developing therapeutics and vaccines against COVID-19, this support needs to be sustained, directed, and unconditional, similar to how the Indian space and aeronautics agencies were provided in their early days. Thus for healthcare, this funding must not merely be contingent on producing a regular stream of publications. The bottoms-up strategy, for instance, needs our finest medical graduates stepping forward for biomedical innovation—the vast majority of them currently pursue clinical practice alone or migrate to greener pastures, where significant incentives for biomedical research exist.

Notably, the twenty-first century is blessed with vast stores of immense, deep, accessible, and ever-growing knowledge, i.e., big data, which can be utilized with great impact in medicine (13). With the explosion of monitoring devices and electronic health records globally, as researchers get access to considerably more patient data than ever before, many conclusions are yet to be drawn by predictive analytics. If crunched with pattern recognition, big data can provide specific, especially regional, epidemiological information, and differential therapeutic responses (14).

Tectonic plates underneath classical healthcare have long been shifting; COVID-19 has greatly accentuated their movement. Particularly, the technologies of telehealth, remote patient monitoring, and consulting by mobile technology (mConsulting), had been leisurely chugging on prior—they have now been thrust into full view because of necessity (15, 16). In our institution, an Electronic COVID Care Support (ECCS) system, where a multidisciplinary team of pulmonologists, intensivists, and internists were available round the clock to advise and guide intensive care units across the province in managing complex COVID-19 patients, especially those with multi-organ dysfunction. This was of crucial value in our province, where fellowship-trained intensive care physicians are but a handful and that too nearly all in the provincial capital. Similarly, the city administration constructed a call center for

TABLE 1 | Broad action items and strategies for healthcare innovation in India after COVID-19.

Short-term strategies		Long-term strategies		
		Pillar 1: creation of ecosystems and incentives	**Pillar 2: manageable risk-taking**	**Pillar 3: capacity building and biomedical education**
Greater public investment	Big data and artificial intelligence	Simplifying regulations and easing creative collaborations	Running of multiple pilot projects	Enhancements in standard pedagogy
Public-private partnership	Targeted therapy or Precision medicine	Developing innovation centers, bio-incubators, and med-tech park	Decentralization of research funding	Engaging professional medical societies
Deep learning and Machine learning	"Local" medical device manufacturing	Ensuring adequate compensation for biomedical researchers	Allowing personal and organizational failures without immediate shutdown	Physician Scientist (MBBS-PhD) and masters in biomedical innovation programs
Telehealth and remote patient monitoring	Utilizing available devices (smartphones) for healthcare delivery	Creating cultures of innovation—less hierarchy, more communication	Promoting social innovation and entrepreneurship	Creating medical schools having purposeful aim of biomedical innovation

medical queries from the general public which junior doctors from our institution staffed, resulting in significant benefit to the general public with regards to managing mild COVID-19 cases at home. Considering how useful such technologies have proved, even in India where the smartphone penetration rate has been rapidly growing, usage of these technologies will likely continue after the pandemic as well (16).

Using machine learning (ML), advanced image-processing capabilities enhanced by artificial intelligence (AI), convolutional neural networks (CNN), deep learning (DL), natural language processing (NLP), many clinically-proven technologies have been described, some approved by regulatory bodies, and a number are rapidly forthcoming (17). Coupling image processing with ML/DL has been especially useful in visual-heavy fields like dermatology, pathology, ophthalmology, and radiology (18). For instance, Arterys Cardio DL, the cloud analytics software recently approved by the U.S. Food and Drug Administration (FDA), helps interpret cardiac MRI, reduces the workload of radiologists, and thus significantly decreases the need for specialists (19).

How will these technologies be implemented in India? Consider a use-case scenario of the "CheXNeXt" algorithm (20). This CNN-based technology utilizes chest x-rays, the most common imaging tool across the world. Built by researchers at Stanford University, it has been proven to diagnose pneumonia in suspected cases better than radiologists of the same institution, historically long-considered one of the top-ten best radiology training centers in the US (21). India, on the other hand, with its immense burden of infectious diseases, sorely lacks radiologists, especially at primary and secondary healthcare centers. However, x-ray diagnostic facilities are often available at community health centers. Therefore, images taken here may be uploaded online for analysis by the algorithm resulting in guidance for the rural physician. This will allow rapid confirmation of the diagnosis in non-complex cases, the majority, by a basic medical doctor leading to an early start of empiric treatment and better patient outcomes. Such innovations, by radically reducing the number of specialists required, hold immense hope for healthcare delivery in the most remote villages. Technology here complements clinical competency, with the algorithm diagnosing the majority of cases and flagging the challenging ones for review and resolution by the expert. Thus, implementing CheXNeXt in a nation where over two-thirds live in villages can have a significant impact (22). Unfortunately, support for this technology was not available in the current pandemic in the majority of India, where doctors in rural areas could have benefitted by getting X-rays of suspected COVID-19 pneumonia cases evaluated by a radiologist or a counterpart.

Furthermore, as part of healthcare innovation, AI can not only diagnose disease under supervision as above; it has been proven to work without the need for a supervising doctor, in selected cases. This gains special relevance in a nation having one of the poorest physician (allopathic) to patient ratios worldwide. Consider IBM's Watson for Oncology, whose independent therapeutic decision-making for breast cancer cases had a 93% concordance with a multi-disciplinary tumor-board (23). Similarly, "IDx Dr," the first FDA-approved AI-based diagnostic system for screening of diabetic retinopathy, also does not require an ophthalmologist for its operation (24). Thus, it is of value to secondary healthcare centers in inaccessible areas, in India, permitting them to screen a large number of diabetics (25). This is crucial for a country having over 70 million diabetics (26), and a current epidemic of retinopathy (27). Another work, published in 2020, promises similar significance by detecting fundal papilledema with over 96% sensitivity (28).

An additional bulwark of an approach would be the leveraging commonly available devices for healthcare delivery, whose built-in technologies would also be utilized for point-of-care (POC) diagnostics. For instance, verified smartphone apps, using AI, can act as personalized, patient advisors: answering their unmet needs, helping adhere to prescribed medications, and encouraging them to implement lifestyle changes (29). This technology has already been utilized by retail industries. Here, this frees up the specialist, especially in overloaded public hospitals, to manage cases of highest acuity. In the current

pandemic, while an app was launched by the federal government for responding to queries of the users, at the backend it required significant manpower to respond to the queries. Innovations using currently available tools, as used successfully prior by suicide prevention hotlines using the ubiquity of landlines, will prove critical in India, having over 300 million smartphone users (30).

Similarly, "AliveCor Kardiaband," the recently FDA-approved sensor (31), delivers a medical-grade six-lead ECG, in conjunction with a smartwatch. The REHEARSE-AF RCT proved its clinical utility by showing that it was better able to detect incident atrial fibrillation, compared to routine care (32). As the electronics industry evolves, appliance costs fall. We believe that as prices of smartwatches compatible with this technology will likely come down, it will lead to its greater adoption by large parts of urban India, with face-to-face consultation expenditures saved and patient outcomes improved.

THE CASE FOR MORE FOR LESS

The reader may return now to one of the sections in the definition of healthcare innovation, used previously, of "more for less." Innovation in India, therefore, must also include efforts to reduce the costs of existing technologies that are currently either inaccessible or pose a considerable challenge to the funding of public hospitals, such as robotic surgery, biosensors, 3D-printed prosthetics, etc. Hospitals here lack reliable alternatives from local manufacturers for equipment such as even endoscopes, let alone surgical robots, and have to purchase these at a premium from foreign manufacturers. This dearth of high-quality, medical-grade manufacturing capacity has been felt acutely in the ventilator shortage during the COVID-19 pandemic as well, with local manufacturers scrambling to develop capacity (33). Had Indian medical corporations been manufacturing ventilators with significantly high enough output and uptake in major hospitals, a period of difficulty may have been averted, where a shortage of ventilators was felt.

What is required is an Indian medical equipment industry, functioning at the level of global standards, such as the economical Jaipur foot that can give the original "SACH foot" a run for the money (34, 35). Such an industry will also help make accessible new POC testing for cancer, stroke, etc., thus greatly assisting in their testing in rural, remote, and disprivileged populations in India, leading to their detection and/or early management. One can envision this similar to the worldwide revolution brought about by the widespread access to POC pregnancy tests (36). Lessons must be learnt from how empowering is the availability of medical equipment in rural areas, evident in the success of "foldscope" in diagnosing parasitic diseases in resource-limited settings (37). Verily, this was a challenge in the current pandemic considering that the reverse transcriptase-polymerase chain reaction (RT-PCR) based testing for COVID-19 could only be carried out in certain laboratories, which were geographically limited in the initial parts of the pandemic. Our own institution performed the maximum number of tests carried out at any single center in India.

Moving away from a one-size-fits-all approach will be another innovation strategy. An NHS report suggests that upto 70% of patients do not benefit from the conventional treatment pathway using mass-manufactured medications (38). Notably, the cost of gene-based studies has been rapidly falling. Low cost, widely-available next-generation sequencing (NGS) and genotyping will enable the prescription of personalized drugs leading to less therapeutic failures and more consistent responses (14, 39). Early recognition of and intervention in high-risk groups also prevents significant costs later in life. This cost-effectiveness has been, for instance, well-demonstrated in familial hypercholesterolemia cases treated with evolocumab (40). As noted in a cost-effectiveness work that looked at universal genetic screening for BRCA1/2 mutations, bringing down the test cost to below 250$ resulted in the ratio of cost per quality-adjusted life-year (QALY) reaching 53,000$/QALY, well-under the commonly cited US-based threshold of 100,000$/QALY (41). A similar hope is enshrined in the 3D-printing of prosthetics tailored to the patient (42). In the current pandemic, several promising drug candidates were looked at, such as hydroxychloroquine, remdesivir, etc. but then largely abandoned due to the majority of studies demonstrating a lack of efficacy. It is useful to consider the idea of whether genotype-based analyses could have helped select patients who found have benefitted from specific agents.

Optimism is also well-placed in economical biosensors. These would ideally allow for continuous, painless, and non-invasive monitoring of vital parameters, and help guide both prevention and treatment. Unfortunately, very few devices like the fingertip pulse oximeter exist, which did have the above attributes and was a valuable tool in the current pandemic both in the home-based and the in-hospital management of COVID-19 cases. These devices are especially useful in patients where long-term monitoring is required. Unfortunately, in India, a large number of such patients are unable to remain in regular follow-up at the often distant tertiary care center due to the issues of cost, time, and lost income therein. Here, such sensors can provide data for remote follow-up and allow for greater time between physical visits. For instance, the "Lumee" biosensor allows for long-term monitoring of tissue oxygen levels, helping in the follow-up of peripheral vascular disease, which tends to also be neglected in rural areas (43).

IS INDIA EQUIPPED TO IMPLEMENT THESE STRATEGIES?

It is important to note the two major bottlenecks for these short-term innovation strategies. These are, first, possession of strong computer science and medical technology industries, and second, deep ability to carry out large clinical trials to prove efficacy. While India's historical competency in the technology arena creates a bedrock of medical innovation to be done in-house, its massive population allows for large-scale careful studies to be conducted at a much lower cost for the latter, without sacrificing any quality paradigms. This is exemplified by the largest clinical trial ever in the world, conducted in India in over two million children (44, 45).

Other limitations to implementing these strategies include the political will to devote support and manpower to enhancing healthcare and increasing the percentage of GDP spent on this sector. Discussion of how to tackle this and how to improve financing into interventions to improve social determinants of health are beyond the scope of this article.

Thus, India is uniquely poised to deliver rapid breakthroughs in its healthcare delivery, provided its research institutions and innovators are specifically tasked with and incentivized to solve this problem. Developing such "disruptive innovation" is vital, as originally described by Bower and Christensen, since it represents a stratagem different from incremental enhancements in good healthcare for those who already have it (46). As a part of a multi-faceted approach to innovation, it gives accessible healthcare to those who entirely lack it.

THE LONG-TERM GAME-PLAN

In grappling with strategies to translate strategies for innovation into practice, it is imperative to have a parallel approach to developing a system that fosters their rise and provides them with a structure to lean on to. *Three* pillars will need to be erected, upon which hopefully the edifice of innovation will transpire (**Table 1**).

The first pillar must be the creation of ecosystems and incentives that promote creative collaboration. Disruptive ideas of the future will emerge at the interface of different fields, as has occurred before, for instance, in the development of the CT scanner (47). This will require cross-pollination of varied concepts and processes of thought, possible only when collaboration between institutions, hospitals and industry happens in interdisciplinary areas such as data capture and analytics, patient engagement, and natural sciences, exemplified by the development of CRISPR for gene editing (48). During the pandemic in India, an example of this was shown in the development and usage of the paper-based rapid diagnostic testing for COVID-19 utilizing CRISPR, named FELUDA (49). To note, such cross-pollination can be facilitated by the creation of innovation centers, bio-incubators, and med-tech parks, some of which have recently been set-up (50).

What else can be done to ensure these creative collaborations? Simplifying and streamlining slow, bureaucratic, regulatory, and administrative processes, all of which hinder collaborative work is critical. To illustrate, consider the challenges encountered in doing multicentric studies in India—for instance, each participating center must separately apply for and complete the entire institutional review board (IRB/IEC) approval process, as per current regulations. Thus, no center can utilize the fact that a study has been already approved by another government-accredited IRB/IEC, so as to have a faster review at their own IRB/IEC. This was a major difficulty faced by our institution and others when conducting multicentric clinical trials in a time-sensitive manner for evaluating interventions for COVID-10. Hindrances such as these slowed down the pace of biomedical research in a period of urgency and contributed to the delay in getting medications approved and to the bedside. Besides this, a rectification of the strict, pervasive, and all-sustaining culture of hierarchy in medicine in India would also help. It has historically stifled collaboration, prevented voices from speaking up, and overemphasized the role of chairpersons and directors at the cost of the team members. Furthermore, cognizance must be taken of the fact that the finest achievements of medicine in the current century have been due to breakthroughs in biology and biotechnology. Scientists of these fields must be better incentivized and recognized for doing biomedical research in India. Institutions here must also further subject the wisdom of their traditional texts to rigorous research, as exemplified by the Nobel-prize-winning discovery of Artemisinin in China (51).

The second pillar must be the espousal of a philosophy that allows for a host of pilot projects to run. Our anecdotal experience suggests that senior, established investigators are heavily rewarded with grants in India, while early career researchers fail to get anything significant. A risk-averse behavior, as has been historically the Indian perspective, must be replaced with conduction of small-scale pilot projects with "manageable risks," allowing a large number of institutions to have funds to experiment and to demonstrate "proof-of-concept." Greater decentralization of research funding would help this as well. Herein, thought must also be given to social innovation and entrepreneurship in medicine, as demonstrated by the success of "Swachh Bharat" with regards to sanitation and hygiene (52). Similarly, considering the prevalence of domestic abuse, malnutrition, and nutritional anemia in Indian women, strategies that empower financially women also indirectly contribute to their healthcare, like the work done by Sakha Consulting Wings (53). These are often harder to implement but produce far more long-lasting impact.

The third pillar must be capacity building and reform in medical education. Firstly, pedagogic teaching of subjects in Indian medical schools today lacks both focus and relevance, since much of it is "teaching to the test." This test is typically either the medical school examination or post-graduate medical entrance examination, both of which strongly focus on rote memorization. This adversely contributed to the current pandemic since final year medical students here could not be well-utilized to care for COVID-19 patients since students in India do not manage patients under supervision till their internship year. It is also well-documented that the content of education imparted molds itself to the testing thereafter, a phenomenon referred to as the "washback" or "backwash" effect (54, 55). Improvements in testing methodology will, therefore, likely result in the enhancement of medical education as a backwash effect. Thus, to realize the intent of imparting scientific curiosity and a spirit of innovation, examinations must become tailored to test relevant issues, coupled with a deliberate attempt at gradual modernization of the entire curriculum (55). Professional medical societies in India must become engaged in this modernization, in addition to having them connecting with and academically mentoring their future trainees, similar to their counterparts in the US and UK.

Furthermore, it would be helpful to start joint physician-scientist (MBBS-PhD) programs, similar to the medical scientist training programs (MSTP), also known as MD/PhD programs,

in the US. Otherwise, an MBBS (Honors) or an MBBS with an intercalated research-based BSc (as is common in the UK) program may be created at apex medical schools. Certain premier medical schools of India may also be designated as those having a novel curriculum merging classical medical training with biomedical innovation. None of these four options currently exists in India. Similarly, an increase is also warranted in the number of institutions offering masters programs in medical innovation, currently, there being few such in the country, for instance, the quite successful Masters in Medical Science and Technology (MMST) program at Indian Institute of Technology Kharagpur, which solely takes in medical school graduates (56).

All of these programs must purposefully aim to create future-ready graduates in fields of innovation, interdisciplinary research, technology advancements, data analytics, statistical capabilities, etc. These programs would mandate additional courses on computer science, molecular biology, rapid prototyping, and/or medical material science, courses that are not part of the current medical school curriculum in India. Finally, these programs must also be in-line with the aspirations of our medical graduates and the health needs of the country, deliberately focusing on "frugal innovation."

CONCLUSION

Healthcare innovation in India will be brought about by a multipronged approach: early-attainable, specific objectives of implementing efficacious new strategies for the priority healthcare needs of the population, i.e., frugal innovation; and a long-term vision for fostering the culture that promotes such advancements; or else worthy intentions will keep getting lost in translation.

AUTHOR CONTRIBUTIONS

AO conceptualized, drafted, and edited the manuscript. KS edited the manuscript. Both authors contributed to the article and approved the submitted version.

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Why Is Rehabilitation Assistance Policy for Children With Disabilities Deviated in Supply-Demand? A Case Study in Mainland China

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Children with disabilities have most potential for salvage rehabilitation, and their rehabilitation results are concerned with their entire life process. Although, the Chinese state has established a targeted Rehabilitation Assistance System for Disabled Children and has expanded the provision of rehabilitation services, a severe deviation between supply and demand remains. Existing studies have focused relatively more on policy content and less on the policy context, at the macro-structural level. However, using the case of the ZW Rehabilitation Center in City J, this study divided the deviation into exclusion errors and inclusion errors, and used the policy context approach to explore the reasons for the deviation. We found that the behaviors of the participants in rehabilitation services exist in a dynamic interaction between the regulatory context, the normative context, and the cognitive context. The joint forces of the three contexts produce both exclusion errors and inclusion errors, which are the underlying reasons for the inaccurate execution of the targeted policy. The results of this research can provide enlightenment for improving rehabilitation policy.

Keywords: rehabilitation assistance system for disabled children, supply-demand deviation, policy context, exclusion error, inclusion error

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INTRODUCTION

Currently, there are 85.02 million persons with disabilities in Mainland China – the maximum number per nation in the world. Rehabilitation has become one of the most important ways to restore or compensate for disabled people's body functions and improve their quality of life, and China is paying increased attention to such rehabilitation efforts. Since 1988, the state has integrated its rehabilitation program for persons with disabilities into national economic and social development plans to protect those individuals (1). Recently, a brief government document also noted that a new targeted rehabilitation program had been implemented (2). Indeed, "targeted" is a hot word in present-day China, having been derived from the term "targeted poverty alleviation," which authorities first proposed in 2013. Targeted rehabilitation refers to the provision of rehabilitation services on the basis of the actual needs and difficulties of each disabled individual, through accurate diagnosis and scientific evaluation (3).

In the full plan for rehabilitation of persons with disabilities, rehabilitation for children is the starting point, and is concerned with the children's entire life process. Studies have shown that the most successful time for the rehabilitation is between 0 and 6 years of age, because during that period the brain has the best flexibility, with the best compensatory effects, for restoring

an injured brain's structure and function (4). For children, grasping the opportunity of early salvage rehabilitation can effectively avoid or decrease later complications and sequelae, thus, creating opportunities for their education, employment, and social integration in the future. Currently, there are 1.678 million children with disabilities in this age range in China (5). Most of those children are faced with different kinds of risks, including poverty, malnutrition, poor health, lack of family protection, and so on (6), and many have extensive demands for medical rehabilitation and care. To satisfy those demands, *the CPC Central Committee* and the *State Council on Promoting the Development of the Cause of Disabled People (2008)* stated the opinion that salvage treatment and rehabilitation for children with disabilities should be given priority and that salvage rehabilitation projects for poor disabled children by the China Disabled Persons' Federation (CDPF) were to be carried out. Beginning in 2018, guided by the concept of targeted rehabilitation and overseen by *the State Council on the Establishment of a Rehabilitation Assistance System for Disabled Children,* rehabilitation services have been provided for children aged 0–6[1] years who have a disability of vision, hearing, speech, limb, intelligence, or who have autism. The content of the services includes operations, assistive devices configuration, and rehabilitation training, with the goals of reducing dysfunction, improving functional status, and raising the individual's ability for self-care and social participation (7).

The interactions between service providers and service users, reported from their experiences of providing and obtaining welfare, can establish a relational understanding of policy (8). From the position of service providers, the Rehabilitation Assistance System for Disabled Children (RASDC) is an inclusive policy that is based on civil rights, and it can effectively address the rehabilitation barriers. However, from the position of service users, this service has not had a strongly positive effect. The rehabilitation provision rate is low, remaining far from the goal of targeted rehabilitation. Survey data have identified that after the implementation of the policy, the supply rate of the service is only 20.33%, whereas, the demand rate is approximately 27% (9). After China has provided a generous rehabilitation service for disabled children, why is there still a severe supply-demand deviation?

To answer that question, this study distinguished between two kinds of deviations and investigated them using the perspective of the policy context. Specifically, studies evaluating the effectiveness of social welfare programs have found that two deviations commonly occur in attempts to "target" public expenditures for poor people in poverty reduction policies. One is an "exclusion error" (also called "undercoverage," or "failure to reach the prime objective"), in which some subjects are eligible to receive benefits but do not receive them, and the other is an "inclusion error" (also called "leakage," or "excessive coverage"), in which those who receive benefits are not eligible to receive them (10, 11). In trying to classify the supply-demand deviation in rehabilitations services, attention has tended to focus on one error and to overlook the other, and that single-error focus has led to a narrow understanding of the supply-demand deviation. In our research, we too found the existence of these two errors in the implementation process of the targeted RASDC. However, relevant extant research on this area is scarce. To explore the reasons for exclusion errors and inclusion errors, we used the policy context, and specifically the regulatory, normative, and cognitive contexts, as a new perspective. That approach gives a much more comprehensive framework that can capture various aspects of the ideology, political interests, cultural norms, social knowledge, rules and regulations, and other features that could have a considerable impact on the administrative process (12, 13). This study, conducted in the local environment of present-day Mainland China, sought to reveal the supply-demand deviation of the RASDC in China, and to enrich the academic community's understanding of how the local political and cultural contexts change the established goals of policy.

LITERATURE REVIEW

In China, the research on rehabilitation has been conducted mainly in the field of medicine, and studies on the rehabilitation policies for disabled children have been carried out only recently. The proposal in China of the RASDC in 2018 was an important watershed event, and the topic gradually became a hot button in academic circles. Although, some scholars have conducted ongoing research on the issues of rehabilitation services for disabled children, most of them have focused on only the service content. From that approach, the findings have shown that the inaccurate implementation of the RASDC has been caused by ideas, methods, and specific contents of provision.

The first aspect of implementation is in regard to the idea of provision, of putting the child first, and maximizing the benefits for the child, but at present in China that idea is not met with consensus among all, and the principle that the state is the supreme guardian and protector of the child is not established. As a result, the RASDC efforts have mainly been survivor-oriented, and have been lacking in inclusive and development-oriented policies (14). Studies have shown that, although state fiscal expenditures are increasing, a lack of funds, the use of strict criteria for rehabilitation assistance, and the problem of rehabilitation demands not being included in the RASDC are still major dilemmas (15).

Second, regarding the methods for provision, medical rehabilitation services for children with disabilities are currently provided by designated agencies, mainly in the form of "government procurement services." Among those services, imperfect service skills in agencies are the most important factor, and that problem produces an exclusion error. Poor rehabilitation service networks, lack of professional staff, low professional levels, and slow updating of rehabilitation technologies have all affected the effectiveness of provision of rehabilitation services (16–18).

[1]It should be noted that ages 0–6 years are not the absolute age limit. In fact, China's 31 provinces (districts, municipalities) and Xinjiang Production and Construction Corps have introduced local RASDC according to local conditions, and among those provinces, 17 provinces (districts, municipalities) have widened the age limit for eligible applicants to varying degrees (data from 2019), such as, ages 0–15 years in Beijing and 0–17 years in Shanghai. City J, the place for investigation in this paper also extended the eligible ages to 0–17 years.

Finally, some research has suggested that the RASDC policy lacks supporting policies (19). The RASDC is mainly aimed at helping poor households to solve the problem of excessive costs in medical care and rehabilitation for children with disabilities. However, those households are faced with more severe parental pressures in the process of rehabilitation, compared with households with disabled people of other ages (20, 21). The long-term care needs of disabled children gradually increase the physical and emotional burdens within families, and those burdens cannot be solved by insufficient support services. That increasing pressure, in turn, can lead the recipients to voluntarily abandon rehabilitation services (22). Additionally, those service providers make medical rehabilitation the main focus, and they ignore the universal demands of community-based and family-based rehabilitation (23, 24).

Those reviews have demonstrated that many exclusion errors occur from the ideas, methods, and specific contents of rehabilitation provision. As a result, a large number of rehabilitation demands of children with disabilities are not satisfied effectively, and that outcome is far from the goal of targeted rehabilitation. The causes of exclusion errors include such main characteristics as insufficient government financial support, a low supply of rehabilitation services, poor quality of rehabilitation services, uneven distribution of services, lack of equipment, large gaps in rehabilitation professionals, inadequate support systems, and so on (19, 25–27). To solve those barriers, government responsibility should be clarified – that is, the stated goal should include such items as the provision of additional services by increasing government fiscal spending, mobilizing social forces, and expanding the participation space of volunteers (28, 29). It is also important to improve rehabilitation technology and increase the delivery of support services, such as, medical screening, exercise rehabilitation, medical and educational integration, community-based rehabilitation, and care support, among others (30–33).

The discoveries made through the service content approach have attracted widespread attention from scholars, but that is a small portion of the policy context, and it can only find exclusion errors. In addition, the existing literature overemphasizes exclusion errors caused by the policy makers and direct providers. In reality, however, policy implementation is always the interaction between individual factors and environmental factors, and that interaction is exactly what the policy context approach emphasizes. From the policy context approach, we found two types of errors – exclusion errors (with additional, different expressions compared with those in the existing research) and inclusion errors – both of which have led to inaccurate results from the RASDC.

Furthermore, the two universally adopted research methods are limited. Existing studies have mainly applied quantitative methods to measure rehabilitation needs (9, 26, 34), along with a few in-depth interviews (18). In regard to the quantitative methods, field research has found that a large number of children with disabilities and their parents are in a passive state of acceptance, and they are not clearly informed about rehabilitation policies and their own needs, so that accurate statistics cannot be obtained by questionnaire. In regard to the in-depth interviews, the studies have focused only on households that have children with disabilities and have not really outlined the entire process of implementation and identified areas where the error occurred. In response, this study, by using a case study method, analyzed behavioral characteristics, and welfare choices of welfare providers and users in specific fields, to answer the question of how the policy context causes well-targeted rehabilitation programs to be implemented inaccurately.

THEORETICAL FRAMEWORK AND METHOD

Theoretical Framework

Social policy's "goal-result" is not a simple linear relationship, and complex mechanisms of intermediate phases – policy implementation systems – cannot be ignored. Some seemingly unrelated events in implementation can interfere with the expression of policy objectives, resulting in an imperfect correspondence between the policies and the services actually provided. What factors can affect policy implementation? From Pressman and Wildavsky's research in 1973 (35), various scholars have investigated the question of influential factors on policy in different ways, including factors in society, economy, technology, and the political environment, among others (36). Hill and Hope offered a detailed explanation, pointing out that the dependent variables that affect the outcome of implementation include policy characteristics, policy formation, vertical public administration, influences on implementation agency responses, horizontal inter-organizational relationships, the impact of responses from those affected by the policy, and the environment or policy context (37). In studying policy implementation in the third world, these factors are resummarized as two elements: the content of the plan and a given political-social context (13). Various scholars have all revealed and affirmed that contexts such as, the legal system, culture, social norms, and the values of an organization have a far-reaching influence on policy implementation. However, in studies on the execution of the RASDC, environmental factors have been ignored, either intentionally, or unintentionally.

Researchers have employed different ways to conceptualize and operationalize the context in which individuals and organizations exist. Parsons was concerned with social norms (38), whereas March and Simon examined cognitive and normative structures (39). Furthermore, Scott's classic study suggested that regulative, normative, and cultural-cognitive are the key features of a national context (40). That theoretical framework has groundbreakingly integrated three basic elements as the main composition of the institution. After Scott, scholars have given more attention to the micro applications of this macro theory. Among those scholars, Kostova effectively overcame the limitations of past work and constructed a comprehensive framework of the external environment with which to study the specific phenomenon of quality management of public services between different countries (12). In her paper, "regulatory component" refers to the mandatory laws and regulations in a particular national environment that promote or restrict certain

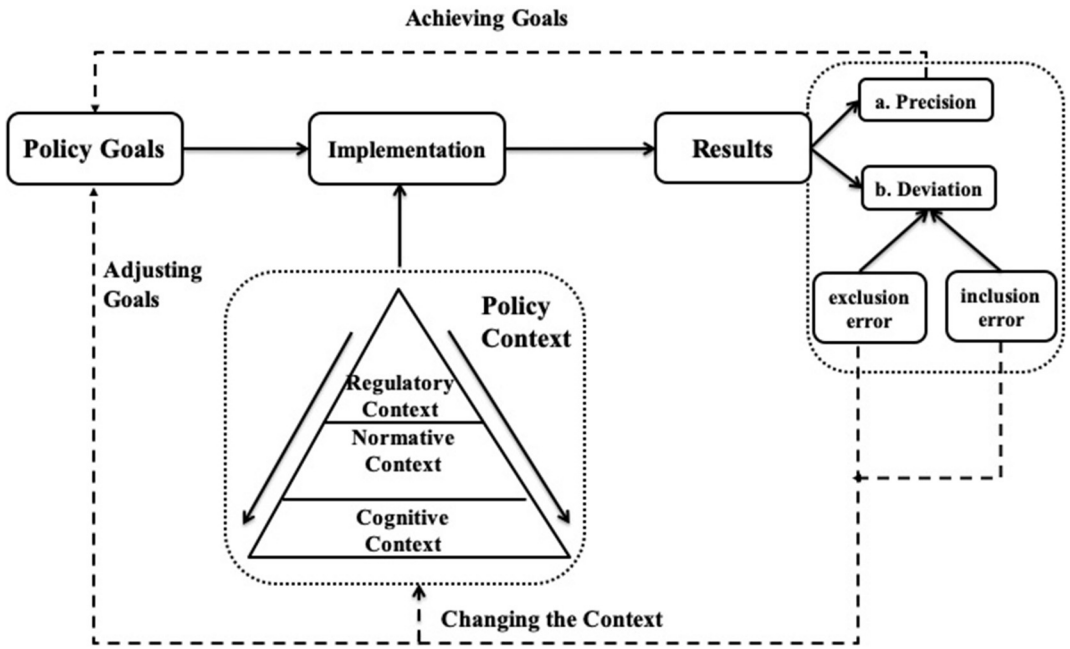

FIGURE 1 | The policy context and its deviations in RASDC implementation.

types of individual and organizational behaviors. "Normative component" consists of social norms, social responsibility, values, beliefs, and assumptions about human nature and human behavior that are socially shared and are carried by individuals and organizations. "Cognitive component" comprises social knowledge and cognitive categories that are widely shared in a country, including the cognitive programs that people use when choosing and interpreting information (12). Although, Kostova studied the particular issue of quality management, the approach that she applied is generalizable and could be used in various studies concerned with other issues.

Well-targeted rehabilitation programs for disabled children will not achieve their goals because of a specific policy context. This study, drawing on the theoretical framework of policy context and taking Chinese local knowledge into full account, anchors these three factors – the regulatory component, the normative component, and the cognitive component – into an investigation of the provision issues of the RASDC. We focused on the complex interactions of local governments, service agencies, and children with disabilities, through their maintenance of the political power, emphasis on self-interest, and reinforcement of the negative role of the disabled, and we constructed a supplementary and comprehensive perspective for understanding policy implementation. We argue that the policy context approach extends beyond the dualism of the supply-oriented model and the demand-oriented model, and we seek to provide adequate evidence regarding how these interactions produce both an exclusion error and an inclusion error in connection with the targeted RASDC. Although, each subcontext involves the participation of multiple subjects, in China's political-social context, the RASDC has been implemented *via* the process of the state distributing tasks through top-down orders and the rehabilitation agencies providing the services. In that light, we define the regulatory context as mainly the laws and regulations of organization, distribution, constraints, and incentives by the local governments that are responsible for implementing the RASDC. The normative context is embodied in the values of social norms and social responsibility that rehabilitation agencies follow when allocating and delivering specific resources. The cognitive context refers to the long-term-disabled culture in China, and the fact that individual cognition and social cognition of the RASDC by families with disabilities and the public have a vital impact on behavioral choices.

The research concept for this study is shown in **Figure 1**. In the implementation stage of the targeted RASDC, the three subelements of regulatory context, normative context, and cognitive context coexist and have a vital impact on the behavior of related individuals and organizations. These lead to two kinds of implementation results: (a) precise implementation – in other words, achieving the policy goals, and (b) deviant implementation, or failure to achieve the policy goals. There are two forms of deviation, called exclusion errors and inclusion errors. To solve them, it is necessary not only to adjust the inappropriate policy objectives, but also through various ways to change any existing unfavorable environment of policy implementation. This two-pronged approach is the key to the problem-solving.

Methods

We used a qualitative study method and selected ZW in City J as the main research site. We collected ethnographic data by

participatory observation, in-depth interviews, and a review of government documents, statistical yearbooks, and other files.

Field Access and Sampling

City J, the provincial capital of Province J, is situated in a rich coastal area of eastern Mainland China. Due to political factors, City J is often the first pilot area for the policy practice by the CDPF. In 2013, the city launched a salvage rehabilitation program for children with disabilities. This city, over time, has moved into the fore front of all of China's cities, and it has rich practical experience.

The field work portion of the study started in the summer of 2020. While visiting the rehabilitation agency, the authors gained access to a list of the names and basic information for 51 designated agencies in City J for the RASDC that had been newly established in 2018. Among the 51 agencies, 49 were private non-enterprise units (non-profit organizations). The ZW Child Rehabilitation Center and ZW Chinese Medicine Clinic (really one agency, with different services; hereinafter referred to as "ZW") was the one with the largest number of disabled children in its services, the largest number of different kinds of disabled children (70 with autism, 90 with mental disability, and 20 with cerebral palsy), and the maximum age range of disabled children (aged 0–17 years). It was also the first designated rehabilitation assistance service agency, approved in 2013, and it has a rich level of experience. Therefore, we selected ZW as the primary research site.

The founder of the ZW organization, after a business failure in 2003 and with no access to converting to Buddhism, decided to make use of his own traditional Chinese medicine skills to do something good for the country and the people, so he established ZW in 2006. The ZW organization developed rapidly by making full use of the characteristic elements of Chinese medicine: acupuncture, massage, medicinal diet, and other traditional Chinese medicine therapies. At present, ZW is a rehabilitation center for cerebral palsy, mental disability, autism, hyperactivity disorder, hemiplegia, and paraplegia, for which it integrates rehabilitation, education, and family-based rehabilitation guidance. It is now engaged primarily in exercise training, homework training, speech training, sensory training, physical therapy, music therapy, guided education, special education, social work, medicinal meals, medicine baths, a spa, massage, acupuncture, near-infrared brain function imaging technology, and other treatment items. The agency is situated in a relatively marginal area of an urban zone in District B, City J, with convenient traffic and low rent, and it covers an area of 2600 square meters. Currently, it has two Chinese medical rehabilitation specialists, 30 therapists, and 22 teachers for special education.

At present, ZW can hold 180 children with disabilities. In July and August, 2020, when we did the research, there were only 139 children at ZW (because of COVID-19, some families had limited movement). The organization primarily receives children with disabilities who live in District B, but some children from other provinces, cities, and districts are also attracted by its reputation. The children range in age from 0 to 17 years, and they have different types and degrees of disability. Their family backgrounds also differ from each other, but they have one thing in common — all are children with disabilities.

Data Collection and Data Analysis

With the help of the head of ZW, we collected ethnographic data in July and August 2020. We used three different methods: participatory observation, in-depth interviews, and a review of government documents, statistical yearbooks, and other files.

To begin, the first author had a nearly one-month-long intense participatory observation period within the ZW organization, closely observing each step, including project-setting, implementation, assessment and adjustment, and so on, in the RASDC. Participating as a university volunteer, the author was responsible for the entire work of the RASDC, chiefly handling the issues for parents of disabled children eligible for assistance and also getting an opportunity to dock with the local Disabled Persons' Federation. During that time, three staff members in the administrative office shared with the author their working experiences, feelings, and attitudes toward the implementation of the RASDC. Data from those interviews also were entered into field records of participatory observation, as an important way of data collection.

Next, we conducted 15 in-depth interviews, each ranging from 30 min to an hour. Our interviewees were divided into two categories: three members in the management team, including the founder and head of ZW, one therapist and the director of the administrative office, and 12 primary caregivers of families with children with disabilities. The caregivers were selected after consideration of factors such as, gender, age, household registration (Hukou), children's age, children's disability type, and willingness to be interviewed. Owing to City J's extended age for rehabilitation services to 17 years, our research was not limited to children 0–6 years old but also included interviewees whose children with disabilities were aged 7–17. Before the interviews, we provided the interviewees with general information related to our research, including the purpose, subjects, process, duration of the study, and the research schedule. The entire research process followed the procedures of the institutional review committee and took into account serious requirements for confidentiality, non-harm, and informed consent of participants. More information about the interviewees can be found in **Tables 1–3**. The authors completed all the one-on-one interviews in Mandarin or dialects, converted all of the interview recordings into Chinese, word by word, and selectively translated some information into English as required in order to present the findings. For confidentiality, all identifying information was anonymized during translation and transcription.

Finally, we also studied government departments guidelines, statistical yearbooks, working documents, and other files related to the RASDC, to supplement our field data. In this investigation, we selected information from multiple sources to improve validity.

We coded the respondents' narratives in two stages: one of open coding and one of theoretical coding. Guided by qualitative analysis techniques (41), we integrated raw data from different sources to generate consistent themes, to reveal

TABLE 1 | Description of research participants – caregivers.

Case	Role of interviewee	Age	Child's age	Child's gender	Child's disability type	Hukou (District B)
Case 1	Mother	30	5	F	Mental disability	Non-local
Case 2	Mother	47	11	F	Mental disability	Non-local
Case 3	Father	38	12	M	Autism	Local
Case 4	Uncle	36	15	M	Mental disability	Local
Case 5	Grandfather	65	6	M	Autism	Non-local
Case 6	Father	32	6	F	Mental disability	Non-local
Case 7	Mother	36	4	M	Autism	Local
Case 8	Mother	31	6	F	Cerebral palsy	Non-local
Case 9	Mother	50	14	F	Mental disability	Local
Case 10	Father	37	7	M	Autism	Non-local
Case 11	Mother	49	10	M	Mental disability	Local
Case 12	Mother	29	4	M	Autism	Local

TABLE 2 | General characteristics of the research participants ($N = 12$).

Variables		*N* (%)
Children's age	0–6	58.3%
	7–17	41.7%
Children's gender	Male	58.3%
	Female	41.7%
Children's disability type	Mental disability	50%
	Autism	41.7%
	Cerebral palsy	8.3%
Hukou	Local	50%
	Non-local	50%

TABLE 3 | Description of research participants – managers.

Case	Age	Gender	Educational attainment	Job title	Years working in ZW
Case 13	50	M	University	Founder & head	16
Case 14	38	M	University	Therapist	14
Case 15	35	F	University	Director	10

the process of implementing the RASDC, and to identify the multiple deviations and their contextual causes in this process. Our purpose was to formulate an extended case study with theoretical and practical meaning (42), that could extend the understanding from the existing literature on the supply-demand dilemma for rehabilitation services and could provide some suggestions for policy practices later. The central administrative work system in China has a high degree of the characteristic of "Isomorphic Responsibility," so the cases selected in this research had a certain expansibility. We try our best efforts to reduce the impact of the limitations of the case method on the results to improve reliability and validity (43).

FINDINGS

The RASDC takes place in a specific field, embedded in local institutional situations and constrained by habitus. The results of our empirical survey indicate that in the process of delivering targeted services for children with disabilities, there is wide interaction among local governments, rehabilitation agencies, and families. That interaction exists in a perpetual, dynamic tension between the regulatory context, normative context, and cognitive context. In the following paragraphs, we will discuss (1) the constrained and incentive rules produced by Chinese local governments in the regulatory context, (2) the strong norms and weak social responsibility of rehabilitation agencies in the normative context, and (3) the identity culture of children with disabilities and their families in the cognitive context. Additionally, we will present our analysis of how the three contexts generated errors of exclusion and inclusion, which then led to an inability to execute the RASDC accurately.

Regulatory Context: Special Executive Rules of the Chinese Local Government

In the targeted RASDC system in present-day China, the local government plays a crucial role in providing services, supervising the operations of agencies, and guiding policy management with official discourses. The RASDC adopts many kinds of local executive rules, from which the target management responsibility system, the administrative subcontract system, and promotion tournaments are the keys to executing policy and are also the root cause of deviant behaviors in the regulatory context.

Exclusion of Types in the Target Management Responsibility System

China assigns and executes tasks through its target management responsibility system, which is a system form created in a highly centralized environment. Its concrete manifestation is to decompose and refine the general administrative goals step by step, forming a set of tasks systems as the basis for management, rewards, and punishments of organizations at all levels (44).

TABLE 4 | Allocation of rehabilitation assistance tasks for children with disabilities in City J (2018).

District	Tasks							Other tasks	Total
	Ages 0–9				Ages 10–17	Corrective surgery	Low-vision surgery		
	Hearing & speech disability	Mental disability	Cerebral palsy	Autism					
A	8	29	26	26	0	0	0	30	119
B	17	70	18	43	24	0	0	20	192
C	15	50	20	18	0	0	0	10	113
D	14	30	12	13	12	0	0	15	96
E	20	53	24	24	20	4	1	10	156
F	15	20	15	15	10	3	0	5	83
G	17	44	40	8	21	0	0	8	138
H	13	15	16	11	5	6	0	0	66
I	19	30	20	4	5	1	0	0	79
J	15	30	8	8	46	0	0	0	107
K	7	19	13	6	4	0	0	10	59
L	8	45	46	1	12	1	0	0	113
Total	168	435	258	177	159	15	1	108	1,321

Indeed, our study showed that the rehabilitation experiences of children with disabilities were extremely closely related to their local Disabled People's Federation, which horizontally is an executive institution that is responsible for the formulation and implementation of all matters concerning persons with disabilities, and which vertically is composed, from the top down, by the China Disabled Person's Federation (CDPF), the Provincial Disabled Person's Federation, the Municipal Disabled Person's Federation, and the District Disabled Person's Federation. Under the target management responsibility system, after the Disabled People's Federation has obtained the tasks of the RASDC from the higher level, then the tasks are refined and assigned to the lower level and finally to rehabilitation agencies, according to the top-down structure. For specific tasks, see **Table 4**. We found that the Disabled People's Federation in City J divides rehabilitation services into four task indexes, thereby assigning the services to children with autism, with limb disability (cerebral palsy), with intelligence disability, and with hearing and speech disability. For visual disability, only low-vision surgery can be provided, and long-term rehabilitation services for children who cannot recover their vision are lacking. That limitation of services deprives children with visual disabilities of access to targeted rehabilitation services, thus, leading to an exclusion error.

In addition, the capacity and preferences of the rehabilitation agencies produce a large number of exclusion errors. The tasks assigned by the target management responsibility system are based not on the number of children with disabilities from District A to L, but on the capacity of rehabilitation agencies to receive children. That is, the capacity is calculated by judging the gross building area, number of therapists, curriculum type, and other factors. The numbers for total tasks in **Table 4** are the sums of the capacity of each agency in City J. However, having arisen only recently, private non-profit rehabilitation agencies in China do not have the capability to cover all of the children with disabilities. In 2018, 1,321 children received rehabilitation services, whereas the number of children with disabilities in City J exceeded 5,000. Even more serious is the fact that, according to the materials of 51 rehabilitation agencies, with the exception of general child rehabilitation hospitals, most of the private non-profit rehabilitation agencies focus on children with autism and mental disability, while ignoring other types of disabilities.

Exclusion of Regions in the Administrative Subcontract System

Another important rule in China's regulatory context is that of the administrative subcontract system. It is a product of the soul of the "contract system" placed under the hierarchical shell, and in it, tasks assigned by the superiors are to be accomplished through administrative power distribution and economic incentives (45, 46). In the process of contracting out the RASDC's tasks, geographic regions serve as the boundaries. Decisions about which region children with disabilities and their families should obtain the source of their services are made through the unique household registration system (hukou system), in which one can only receive the services with the local hukou, and the location of the hukou is based on the person's personal identity card. In China, the flowing population is 245 million people, within which the cross-provincial flowing population is 85.88 million (47). Despite a lack of data on the migrant population of children with disabilities, it is possible to identify a significant number of such groups. The combination of the administrative subcontract and the hukou system results in an exclusion error based on geographic position in the application of the RASDC, when individuals and families whose place of residence and location of hukou are inconsistent. The participant of case 11 left a deep impression on the interviewer because she cried in the interview. She and her family had lived in Tianjin Province for several decades. The family's rehabilitation service was self-financed during the first 3 years, because their hukou was in City

J. In the 4th year, after they learned about the free rehabilitation assistance in City J, the mother rented a room near ZW with her disabled child, which meant that she and the child lived a long distance from her husband and eldest son.

Unfortunately, the boundaries of different services vary. Rehabilitation services for children with disabilities use the province as the boundary, whereas, education services use the city or even the district as the boundary. Children with disabilities who receive rehabilitation in ZW (District B) also face urgent educational needs, which require non-District B families to go back to their local special education school. As a result, some families must choose between education and rehabilitation. The latest rehabilitation method for the integration of rehabilitation and education excludes children whose place of residence is different from their location of hukou, thus, creating an exclusion error.

He cannot do rehabilitation next year. He has to go to school. The special education school in our hometown had been calling us since last year. He will be old to go to school (case 10).

Waste of Sources in Promotion Tournament System

People do not understand why rehabilitation services for disabled children aged 0–6 years differ among age groups in different provinces and cities. The available services are determined not only by the local economic development, but also are closely related to promotion tournaments, the third and distinctly informal rule in the regulatory context. In order to encourage each unit within the five management layers in China to work effectively, a competition mechanism has been formed in which the competition depends on a performance measurement. Distinguishing it from many Western countries, China's performance measurement of the unit is actually an evaluation of the principal person in charge of the unit (48), meaning that leaders of local organizations with good performance in the RASDC greatly enhance their chances of political advancement. The CDPF's leaders at all levels are motivated to gain a competitive advantage by increasing the number of beneficiaries of the RASDC.

The Disabled People's Federation in City J has broadened the policy criteria for outstanding performance in the assessment process. First, the restrictions on the financial conditions of the applicant's family have been canceled, and full coverage is available for all children with disabilities. Second, the age for eligibility of 0–6 years has been broadened to 0–17 years. However, as the director of the administrative office in ZW has demonstrated, the best time to rehabilitate children with disabilities is during the age range of 0–6 years, with children above the age of 7 not experiencing as great an effect from rehabilitation training as children aged 6 years and under do. Therefore, extending the age for eligibility leads to an inclusion error, and to some extent results in a waste of resources. Nevertheless, this conclusion does not mean that rehabilitation services for disabled children aged 7–17 should be canceled. The authors' viewpoint favors providing the older children with services that are more responsive to their specific needs, and thus, realizing an optimal allocation of resources.

For children with disabilities aged 10-17, to be honest, their recovery in rehabilitation will be much worse. Actually, many have given up the rehabilitation. But some parents think that since it is a free service, they should enjoy it, at least the children can have a place to play, with the teacher caring [for] them. But they're crowding out other younger children's resource (case 15).

Normative Context: Strong Norms and Weak Social Responsibility in Rehabilitation Agencies

The normative dimension comprises the social norms and social responsibilities necessary for implementation of the RASDC. Social norms dictate how the policy implementation should be completed and determine the legal methods required to achieve the policy objectives, whereas, social responsibility refers to the preferred values in policy implementation and the attitude toward the obligations that are involved. The normative dimension illustrates the values of the rehabilitation agencies as the basic policy provider for children with disabilities.

Double Errors in Strong Norms

The Communist Party of China's Central Committee and the State Council pay great attention to the RASDC and provide a strong and widely shared norm for rehabilitation agencies, which are the firstline service providers. In present-day China, private non-enterprise units, or non-governmental organizations (NGOs), are often not spontaneous grassroots organizations but instead are heavily influenced by China's policy support and financial support, and therefore, tend to be bureaucratic. That system results in repeated, organized, and institutional norms that emphasize policy outcomes, and such an emphasis creates strong external pressure on the agencies – which are highly dependent on external resources and have the primary task of responding to the requirements of those external organizations. That systemic pressure is not always realistic or effective – on the contrary, in many cases, it only completes the purpose of "ritual" without really meeting the users' needs. In particular, different rehabilitation agencies face different pressures, and the types of deviations that result are also diverse. Our findings revealed that the children's hospital had the largest demands and could only complete its vested tasks through formal or informal methods, such as, modifying standards, screening classifications, and limiting queuing, thus, producing an exclusion error. However, the demands of backward areas or newly established rehabilitation agencies are often small, and they have to fulfill their official tasks by reducing the criteria for eligibility and attracting additional children, thus, generating an error of inclusion. One manager we interviewed described the phenomenon and her ideas about the RASDC.

Free rehabilitation assistance in children's hospitals is limited on quotas. The quota is now 6 months away. The children will be given only charged items after they are diagnosed at the children's hospital. Some parents know that they can go to other agencies, but those who don't know have to go home (case 15).

Selective Neglect in Situations of Weak Social Responsibility

Although, rigid norms have been the guidelines for policy implementation, the criteria for comparing and evaluating the behavior of the RASDC's implementors have been insufficient, and that deficiency has caused rehabilitation agencies to lack social responsibility. Rehabilitation services for children with disabilities currently are provided by a form of "government procurement services." The entities that undertake the government purchasing services are mostly NGOs, which by definition are social organizations organized by enterprises, social groups, and other social forces, as well as individual citizens, using non-state-owned assets to engage in non-profit social service activities. As NGOs, those non-profit organizations still have a "for-profit" need to maintain the operation of the organization. In ZW, "90% of the revenue comes from the support of the RASDC program." Managers complained more than once in our interviews about funding challenges, such as, insufficient government money and unclear government requirements.

One lesson from 2020 has made the head of ZW very cautious this year. That year, a new model, "institution + family + community" rehabilitation, was introduced for children who are more seriously disabled and unable to leave their home. In order to obtain additional public funds, ZW cooperated with a special education school to render rehabilitation services in children's homes. However, the money failed to be delivered at the end of the year, because 3-month centralized institution-based rehabilitation had been lacking (the criteria were emphasized at the time of the assessment). Now, ZW has given up that group of children reluctantly. Clearly, the economic demands of the agency far exceeded the level of social responsibility of the rehabilitation services. The primary aim of the agency was to obtain, as far as possible, children with disabilities who were easily rehabilitated and could acquire the funds from the RASDC. For other children with higher degrees of disability, and inability to provide them with institution-based rehabilitation, and an attitude of neglect, have been adopted toward them. In practice, this behavior that the agencies engaged in to further their own interests was obviously inconsistent with the original purpose of the well-targeted RASDC and has led to numerous cases of exclusion errors.

In addition, no criteria have been developed for evaluating policy implementation from the perspective of the disabled children and their households. On the one hand, the local government's management strategies, from incentives to penalties, still seem focused on shaping the rehabilitation agencies into disciplined and efficient implementors of official discourse and have not offered much autonomy or flexibility for the families with disabled children. On the other hand, influenced by difficulties with social supervision, inadequate development of citizens' participation in politics, and a negative disability culture, few people have the opportunity and willingness to pay attention to the RASDC's implementation. The absence of supervision from service users and the public has further reduced the level of social responsibility in rehabilitation institutions, and that situation fosters an exclusion error. The direct evidence from the managers' narratives reveals that:

> *Now it is mainly [up to] the Disabled Persons' Federation, or a third-party organization invited by the Disabled Persons' Federation, to supervise. They don't understand at all, fill out the form and they're done (case 14).*

Cognitive Context: Identity Culture in Families of Disabled Children

In traditional Chinese society, referring to someone as "canji" or "canfei" means the person is disabled and cannot do anything. These words have obvious derogatory and discriminatory implications and do not place the disabled and the abled on equal footing (49). This notion of inequality about persons with disabilities further influences attitudes on procreation and care, and in so doing leads to another implementation deviation of the RASDC.

The Exclusive Effect of Stigmatization of Children With Disabilities

In ancient China, persons with disabilities did not possess the qualifications to enjoy complete rights. For example, a person with a disability was not allowed to enter the ancestral hall and not allowed to be an official — rules that treated persons with disabilities differently from other people (50). Furthermore, the Chinese words describing disability, such as, "xiazi" (visual disability), "longzi" (hearing disability), "yaba" (speech disability), "quezi" (physical disability), "shazi" (intellectual disability), and "fengzi" (mental disability), are cited in everyday language as acceptable material for teasing, blaming, and reviling, even to the present day. These words are labels that carry serious stigma and create psychological obstacles in the parents. Welfare recipients are often culturally stigmatized; thus, they are not willing to admit that their children are disabled and they are reluctant to receive rehabilitation services that identify the children as being disabled. These concepts lead to subjective exclusion by service recipients.

> *In [our] village, only my child receives rehabilitation service. Others do not and their parents reject rehabilitation, because they don't admit that their child is disabled. They take it to be natural when the child cannot speak at three (case 5).*
> *The child of my wife's classmate is also autis[tic]. My wife told her to take her child for rehabilitation in City J, saying that our child is getting better in the ZW. My wife told her once or twice, and later she [wa]s obviously out of touch with us, without coming to our home or talking to us on the way. She feels that we look down on her by always saying that her child is disabled (case 6).*

One condition by which children with disabilities can obtain free rehabilitation services is to have a disability license, which is an official document for people with disabilities composed of their ID number and two other numbers that refer to their grade of disability and their type of disability. In that negative environment, some parents reject the disability license, which is obtainable after a strict medical diagnosis. Even when they have

the desire to get rehabilitation assistance for their children, they can be persuaded to quit because of this paper identification, thus, causing an exclusion error.

His father is not willing to have the disability license, saying that the child will complain when he grows up. He feels that the disability card is a child's life shame (case 7).

In other cases, family members accept the fact that their children are disabled, but correspondingly, that kind of disability culture fosters a sense of inferiority and shame in those families. A family's interactions with others without disabilities play a significant role in constructing the family members' disabled identities and facilitating their negative perspective toward their lives. Female parents, especially, express fear or anger at the eyes of strangers in their workplace. They always reject parties with friends or relatives, feeling that they are "inferior" and "worse than others." Under this self-cognition, their goal of rehabilitation for their children is to have normal children or children who appear to be normal. If the family members see no hope of recovery for the disabled child, they will refuse to receive rehabilitation.

There is no hope to recovery. It is too tir[ing]. We want to send her to a care center. Once she is there, we can leave it alone and just go to see her once a month (case 9).

Choice of Care in the Traditional Concept of Procreation

The concept of procreation, under the nation's family planning policy, is closely linked to the idea that persons with disabilities are incomplete and inferior. A family planning policy has been carried out in China from 1982 to the present. From 1982 to 2015, a one-couple-one-child policy, or one child in one couple, was strictly enforced. In some special cases, however, two children were allowed, and one such special case was when the first child of the couple was disabled. Since 2016, a one-couple-two-children policy has been adopted, and in some special cases three children are allowed, including the case in which "the couple gives birth to two children, with one of them identified as being handicapped who cannot grow into a normal labor force according to law" (51). With the exception of some households that are afraid of having another child with a disability, most couples do choose to have another child and hope that he/she is normal. Otherwise, the family is not considered perfect.

In Chinese society, the family plays the essential role in providing welfare for disabled children in their living situation and their spiritual life. Throughout the nation's long historical development, the Chinese family system has always preserved great internal stability and formed a solid family care model (52). Research findings have pointed out that the fixed cycle, beginning with "raising children" and ending with "caring for the old," is maintained and reproduced intergenerationally. Of the two parents, the mother is usually the caregiver during the stage of raising the children. In our study, in cases 5, 6, and 10, other family members undertook caregiving duties only because the mothers were disabled. Furthermore, in general, after the birth of the family's second or third child, the mother, as the major caregiver, cannot maintain a balance in taking care of two or even more children, one of whom is disabled. Then, she must choose between two options.

The first choice is to voluntarily abandon the disabled child and to give adequate care to the healthy one, thus, resulting in an exclusion error.

The eldest brother is 23 now and is going to get married soon. I cannot stay here all the time. So next year, we plan to give up rehabilitation. We'll see whether we can send him to a special education school so that I'll have time to manage my family matters (case 11).

The second option is to depend on the system of urgently needed care agencies to provide care for the child with a disability. When care agencies and professional care workers are scarce and expensive, such families are forced to transfer the care pressure to rehabilitation agencies, wherein children can have classes every day. In that way, the care burden of the family can be alleviated, thus, resulting in an inclusion error.

This child is 15 now. To be honest, he cannot make any progress here. He comes just to play. His mother and father are both working without any time to take care of him. I send him here every day. There's a teacher in class, and we don't have to take care of him every minute (case 4).

DISCUSSION AND CONCLUSIONS

This research, based on a case study of ZW, in Mainland China, started with a three-dimensional theoretical framework for policy context and conducted a systematic analytic investigation into supply-demand deviations in the implementation of the RASDC, as well as the reasons behind those deviations. The study's major finding revealed that the failure of the rehabilitation policy was not due to just the policy content itself but was also due to the context of policy implementation, with special aspects of the Chinese environment affecting the final result of implementing the RASDC, which have a negative impact on their health. The empirical data we collected presented exclusion errors, in which those who should enjoy the services did not receive them, and also inclusion errors of wasted resources. To be concrete, in the regulatory context, the local government's implementation of the RASDC policy was affected by formal and informal rules, such as, the targeted management responsibility system, the administrative contracting system, and promotion tournaments, all of which caused barriers such as, the exclusion of disability types, exclusion due to inconsistent service availability in the region of the family's residence, and inclusion errors of extra services being given to those who did not need them. In the normative context, the behavior and activity of rehabilitation agencies were limited by strong norms and weak social responsibility. Priority was given to accomplishing the government's tasks formally, not virtually, by showing preference to those with mild disabilities and neglecting those with severe disabilities. Finally, in the cognitive context,

TABLE 5 | Contexts and types of deviations.

Contexts	Characteristics of contexts	Types of deviations
Regulatory context	Target management responsibility system	Exclusion error
	Administrative subcontract system	Exclusion error
	Promotion tournament system	Inclusion error
Normative context	Strong norms	Exclusion error, inclusion error
	Weak social responsibility	Exclusion error, inclusion error
Cognitive context	Stigmatization	Exclusion error
	Traditional concepts of procreation & care	Exclusion error, inclusion error

children with disabilities were considered as a special group, and were conceived of as being different from healthy people. Households with disabled children felt ashamed and inferior. Those kinds of attitudes prevented the families from actively acquiring the services, or forced them to relinquish the services, or pressured them to transfer the disabled child's care in the dynamic of continuing to have other children. These findings are summarized in **Table 5**.

This research can provide inspiration and suggestions for improving the precision of implementing the RASDC policy's services for children with disabilities. The World Health Organization (WHO) is trying to design international standards for rehabilitation services that can be used everywhere, one of which is *the WHO Global Disability Action Plan 2014-2021: better Health for All People with Disability*. The action plan puts forward 7 actions to achieve the goal of "strengthen and extend rehabilitation, habilitation, assistive technology, assistance and support services, and community-based rehabilitation": providing leadership and management, providing adequate financial resources, developing and maintaining a sustainable workforce, establishing a health care system mechanism for effective coordination, making available appropriate assistive technologies, promoting access to a range of assistance and support services, supporting and building the capacity of persons with disabilities, and their family members and/or informal caregivers (53). According to the findings of this article, combined with the international reform plan, rehabilitation policy in Mainland China needs to be optimized and reduce both exclusion errors and inclusion errors, so as to realize the vision of accurate rehabilitation for all person with disabilities. This action plan specifically includes:

Proposed action 1: Revise policies, standards, and implementation managements. First, the government should strengthen policies, strategies and plans on habilitation, rehabilitation, assistive technology, support and assistance services, community-based rehabilitation, and related strategies based on the actual number and needs of disabled children. Secondly, the government should break geographical boundaries and provide adequate financial resources to increase coverage and access to rehabilitation services for non-local children with disabilities. Finally, the evaluation indicators of the Disabled Persons' Federations at all levels should be reformed by comprehensively evaluating the actual service demand and service quality, rather than the policy texts and supply quantity.

Proposed action 2: Enhance the social responsibility of rehabilitation agencies. To begin with, a rehabilitation assistance network should be built to exchange information between different rehabilitation agencies and, when appropriate, to provide referral services in order to balance the different pressure of rehabilitation agencies. Moreover, third-party supervision and bottom-up public supervision should be strengthened to improve rehabilitation agencies' social responsibility and to achieve a rational allocation of rehabilitation resources. In addition, it is important to train health personnel for early identification, assessment, and referral of children with disabilities, especially in undeveloped areas.

Proposed action 3: Foster an environment of equality, social acceptance, and integration for children with disabilities. We need to internally and culturally change the minds, feelings, and acquired dispositions of the public and families with disabilities, or, in Bourdieu's word, their habitus. During the transformational process, it will be important to build social consensus by publicizing rehabilitation through networks and the media, by popularizing the New Concept toward Persons with Disabilities, and by enhancing people's social sense of responsibility. We also must increase communication with families who have children with disabilities and convince them that those children are not just a drag on the family – that instead, their children can return to their families and society through proper rehabilitation treatments. Psychological support provided for parents with disabled children will improve the quality of care they give to their children and consequently increase the quality of life of children and family (54).

This research had three main limitations. First, it was difficult to obtain much information from the past research, because this was the first qualitative research discussing implementation deviation of the RASDC, and the reasons for it, from the perspective of policy context. Second, the RASDC was a new policy, and there were fluctuations in the task indexes and evaluation methods that might have affected the credibility of the data. Last, this research was based on a single case study, but China's population structure, its urban and rural structures, and its bureaucratic structure are quite complex, meaning that the RASDC differs in different provinces and cities. As a result, the applicability of this study's conclusions to other regions and situations needs further discussion and reflection. In the future, additional qualitative and quantitative research should be conducted to extend the credibility of our existing analysis.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Academic Committee of Jilin University. The

patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

CQ: conceptualization, methodology, investigation, writing the original manuscript, revising the manuscript, and administration. YW: conceptualization, investigation, writing the original manuscript, and revising the manuscript. All authors: contributed to the article and approved the submitted version.

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Research on Financing Mechanism of Long-Term Care Insurance in Xiamen, China: A System Dynamics Simulation

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Objective: This study aimed to predict the changing trend of long-term care insurance (LTCI) funds by clarifying the linkage between revenue and expenditure and its influencing factors and to provide evidence for the establishment of a sustainable LTCI financing mechanism in China.

Method: We have taken Xiamen as an example, based on the data from Xiamen Special Economic Zone Yearbook and field survey. The changing trend of LTCI funds is predicted from 2020 to 2030 based on the system dynamics model (SDM) of the LTCI financing system. Also, through literature research and expert consultation, we found the intervention goals and analyzed their impact on the balance of LTCI funds.

Results : In the current situation, according to the forecast, the revenue and the expenditure of the LTCI funds will increase year by year from 2020 to 2030 in Xiamen, an increase of about 3.7 times and 8.8 times, respectively. After 2029, the expenditure will exceed the revenue of the LTCI funds and the balance will turn into a deficit. From the perspective of fund revenue, by adjusting the individual payment rate, government financial subsidies, and enterprise payment rate, the proportion of LTCI funds can be increased to alleviate the balance deficit under the original forecast. On the contrary, from the perspective of fund expenditure, increasing the proportion of reimbursement and the rate of severe disability will lead to an increase in fund expenditure. In this case, the balance of the funds will turn into a deficit, 7 years in advance. In addition, it was found that the severe disability rate has the greatest impact on the balance of funds.

Discussion: The SDM can objectively reflect the structure and the behavior of the LTCI financing system and has good applicability. By increasing the individual payment rate, government financial subsidies, and enterprise contribution rate, reasonable setting of the reimbursement ratio of nursing services, especially for the prevention of disability among the elderly, to maintain the sustainability of the funds. This study provides strong evidence for policymakers to establish a sustainable LTCI system in China.

Keywords: long-term care insurance, financing mechanism, system dynamic model, sustainability, modeling and simulation

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INTRODUCTION

China has entered a period of rapid development of population aging, facing the severe challenge of deep aging. At the end of 2019, 254 million people were aged over 60 years, accounting for 18.1% of the total population, according to the National Bureau of Statistics of China (1). It is projected that the proportion of elderly people will reach one-third by 2050, exceeding that of most EU countries (2). As the population ages, the number of disabled people also increases (3). With the increasing demand for professional nursing care for the elderly, traditional home-based care is unsustainable. The long-term care insurance (LTCI) system has emerged as an important measure to respond to the needs of social care caused by the aging of the population and to reduce the economic and care burden on the individuals and their families (4). Under the background of the change of family structure and the weakening of traditional support functions, it is critical to establish an LTCI system that suits the national conditions of China.

LTCI in China

At present, the Chinese government is actively implementing the LTCI policy. In June 2016, the Chinese government published the "Guidance on Pilot Cities to Launch Long-Term Care Insurance." At the end of June 2019, the LTCI scheme has been piloted in 15 cities, covering 88.54 million people, and benefiting 426,000 people (5). In September 2020, the National Medical Security Administration published the "Guidance on Expanding the Pilot Cities of the Long-Term Care Insurance" to expand the pilot program of the LTCI; 14 new LTCI pilot cities had been planned to be added to the original 15 pilot cities. The pilot period will be 2 years (6). It can be seen that the establishment and improvement of the LTCI system are the inevitable choices for China to cope with the aging population. Enrolment in LTCI is linked to the medical insurance status of individuals. China currently has two medical insurance schemes, namely, the urban employee medical insurance, covering urban residents with formal employment, and medical insurance for urban and rural residents, covering rural and urban residents without employment. The insured of LTCI must be the insured of the urban employee insurance or the medical insurance for urban and rural residents (7). In addition, according to the disability assessment criteria set by each pilot area, most of the pilot areas guarantee the long-term care (LTC) needs of the severely disabled. The main types of care are home care and institutional care, and the standard of insurance payment is about 50–70%. The operation of LTCI involves many aspects, such as financing, evaluation, service, and supervision. Among them, financing is the core of the LTCI system and is the foundation for the formation of insurance funds, which reflects the internal mechanism of financing. How to build a fair, reasonable, and sustainable financing mechanism is the primary problem when establishing an LTCI system (8).

Previous Research

At present, the research abroad has an early start in which theoretical research and empirical studies have achieved fruitful results. Previous studies mainly focused on the financing model (9, 10), equity (11), and sustainability of financing (12), advantages and disadvantages of public and private LTCI financing (13, 14), and comparison of financing mechanisms (15–17). The quantitative studies on the financing mechanism of LTCI have a wide range of contents and mature methods. The research content includes basic nursing demand forecasting (18, 19), insurance pricing (20), policy simulation (18, 20), and cost control (21), among others, and the system dynamics model (SDM) is introduced to optimize the pension security system (22, 23). These results provide a reference for Chinese scholars.

At present, some domestic scholars focus on analyzing and summarizing the LTCI financing in OECD countries and domestic pilot cities (24, 25) and gradually expanding to financing channels (26), financing models (6), financial supply and demand forecasts (7, 27, 28), LTCI contribution rate (29, 30) and other aspects. The research methods mainly focus on the traditional logistic regression, actuarial model, International Labor Organization financing model, and so on. Few studies have analyzed the financing mechanism of LTCI from a systematic perspective. LTCI financing system involves complex social demography, health management, economics, and other multi-dimensional variables. Research showed that SDM is well-suited to address the dynamic complexity of health-related delivery systems (31). This study considered Xiamen as an example to construct an SDM of the LTCI financing system. As one of the five special economic zones in China, Xiamen is facing the risks and challenges brought by the aging population, such as the high aging rate and the average life expectancy of the population, and it is urgent to maintain the balance between the supply and demand of nursing services for the elderly (32), which is representative and typical.

Therefore, from the perspective of equity, efficiency, and sustainability, this study constructs the SDM of LTCI financing in Xiamen under the background of aging, makes a medium- and a long-term prediction of LTCI financing, which makes the prediction results more scientific and accurate, and observes the changing trend of LTCI funds in the future. Then, by adjusting the key policy indicators, such as individual payment rate, the influence of intervention goals on the financing system of LTCI was analyzed to provide evidence of the need for the establishment of a sustainable financing mechanism for multiple financial supplies.

MATERIALS AND METHODS

Data Sources

Data for this study are taken from field research, expert consultation, the yearbook of Xiamen Special Economic Zone, and published research literature. Based on the principle of typical sampling, four representative LTCI pilot cities (Jiaxing, Shanghai, Chengdu, and Jingmen) were selected from the east, middle, and west of China to conduct the field research. The survey content mainly involves the insured population, the method and level of financing, and payment to reflect the overall construction of the LTCI system. The main data sources are listed in **Table 1**.

TABLE 1 | Summary of main data sources.

Parameters	Value	Unit	Source
Insured population of urban employees	273.88	10,000 people	Xiamen Special Economic Zone Yearbook 2020
Per capita GDP	142,739	Yuan	Xiamen Special Economic Zone Yearbook 2020
Per capita disposable income of urban residents	55,870	Yuan	Xiamen Special Economic Zone Yearbook 2020
Insured population of urban and rural residents	148	10,000 people	Xiamen Special Economic Zone Yearbook 2020
Per capita institutional care costs[b]	30,000	Yuan	Survey data
Per capita home care costs[b]	18,000	Yuan	Survey data
Change rate of insured population of urban employees[a]	6%	Yuan	Xiamen Special Economic Zone Yearbook(2011-2020)
Change rate of insured population of urban and rural residents[a]	5.9%	Yuan	Xiamen Special Economic Zone Yearbook(2011-2020)
Change rate of per capita GDP[a]	5%	Dimensionless	Xiamen Special Economic Zone Yearbook(2000-2020)
Government per capita subsidy standard[b]	0.04%	Dimensionless	Assumed value
Change rate of per capita disposable income of urban residents[a]	8%	Dimensionless	Xiamen Special Economic Zone Yearbook(2015-2020)
Enterprise contribution rate[b]	0.04%	Dimensionless	Assumed value
Individual payment rate[b]	0.06%	Dimensionless	Assumed value
Severe disability rate[b]	0.3%	Dimensionless	Historical literature (33)/Survey data
Proportion of choosing the institutional care[b]	3%	Dimensionless	Historical literature (34)
Proportion of choosing home care[b]	97%	Dimensionless	Historical literature (34)
Reimbursement ratio[b]	70%	Dimensionless	Assumed value

[a]Calculated by using data from Xiamen Special Economic Zone Yearbook. [b]According to the actual operation and investigation of LTCI, the base of severe disability rate is the total number of insured people. The base of individual payment rate is the per capita disposable income of urban residents in 2019; and the enterprise contribution rate and government per capita financing standard base per capita GDP in 2019.

Key Assumptions

At present, Xiamen does not implement the LTCI system. Therefore, according to published research literature, combined with the field research, the key assumptions of this study are as follows: (a) Xiamen implemented LTCI in 2019, and the forecast time of the model is 2020-2030. (b) At present, the enrollment in LTCI is linked to the medical insurance status of individuals' in pilot cities. To ensure the fairness of the implementation of the system, it is assumed that those who participate in LTCI are insured of all medical insurance, and those who enjoy the benefits of LTCI are the severely disabled people in the insured population. (c) Funds for LTCI mainly come from premium payments, without taking into account the investment and operation income of insurance institutions. (d) Xiamen implements a compulsory social LTCI system, which raises funds through various channels such as individual, enterprise contribution and financial subsidies and establishes a diversified financing mechanism, which is not attached to the medical insurance funds. (e) The economic development is relatively stable, and the per capita GDP and wage levels maintain a certain growth rate without major fluctuations.

Model Construction

System Analysis

The modeling process of SDM mainly includes: (a) System subject analysis: Through collecting and analyzing the policy documents and literature related to the LTCI fund, this study identifies the stakeholders of the LTCI financing system. On this basis, the system analysis method is used to determine the main body of the system: individuals, enterprises, and the government. (b) Drawing of the causal diagram: In the SDM, the system structure is composed of the feedback loop, which shows the relationship between variables and the action path. Based on the purpose of the study and the actual operation of LTCI financing, this study makes a loop analysis on the revenue subsystem and the expenditure subsystem of the LTCI funds. The variables of the two subsystems and each subsystem are interrelated and restricted and ultimately affect the balance of the LTCI funds (**Figure 1**). In this figure, the arrow represents the relationship among variables, and the direction of each line shows the direction of the effect. The sign "+" dictates that the variables change in the same direction, while the sign "–" dictates that the variables change in the opposite direction. (c) Model construction: According to the causality diagram, with the help of a literature review and system analysis theory, the relationships between variables in the model are defined (**Figure 2**). The revenue subsystem of LTCI funds includes the revenue of urban employees, retirees, and urban and rural residents. The expenditure subsystem of LTCI funds is affected by the total demand and reimbursement ratio of LTC expenses. Through drawing the system flow diagram and establishing the structural equation, the initial value of variables refers to official statistics, and the functional relationship between the variables are determined by the social insurance actuarial method and the regression analysis method. (d) Simulation and policy optimization: Based on the operation of LTCI, combined with field survey and sensitivity analysis, this study selects five key variables that affect the revenue and the expenditure of the LTCI fund for scenario simulation.

Sensitivity Analysis

Sensitivity analysis determines the influence degree of parameters on the model by changing the parameters and comparing the

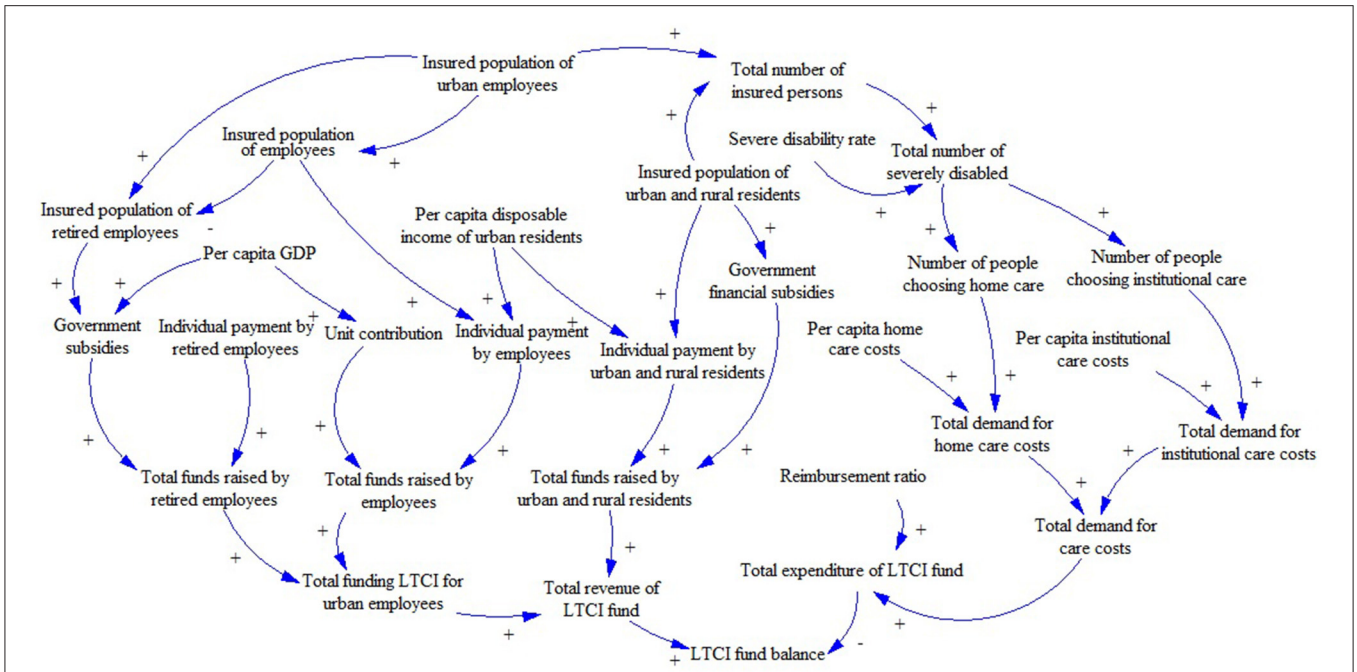

FIGURE 1 | Causality diagram of LTCI financing system.

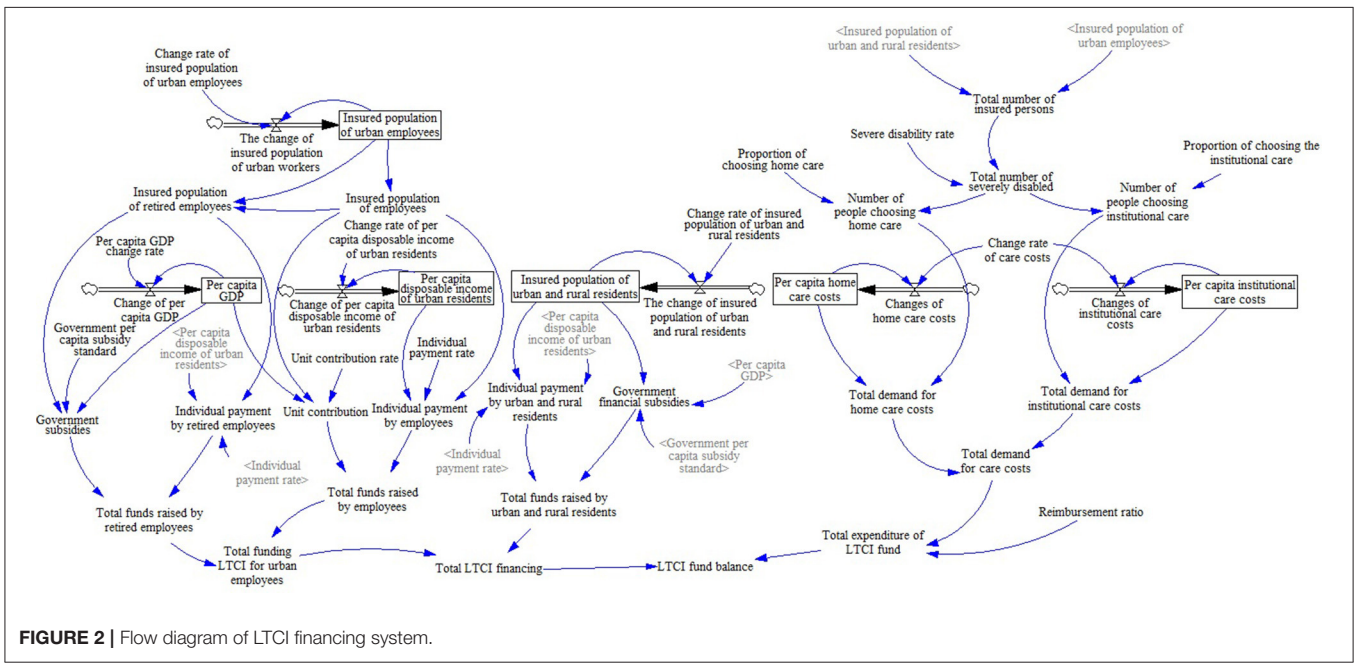

FIGURE 2 | Flow diagram of LTCI financing system.

output of the model. Based on the LTCI operation situation, combined with field investigations, we selected five key variables that affect the revenue and the expenditure of the LTCI funds for sensitivity analysis, namely, individual payment rate, government financial subsidies and enterprise contribution rates, reimbursement ratio of nursing services, and severe disability rate, to verify the influence of parameters on the balance of LTCI funds to achieve sensitivity analysis. We set the number of verifications to 200 and used random uniform distribution to verify. The results show that the LTCI fund balance has changed significantly by adjusting the parameter range (**Figure 3**), which provides a reference for policy intervention.

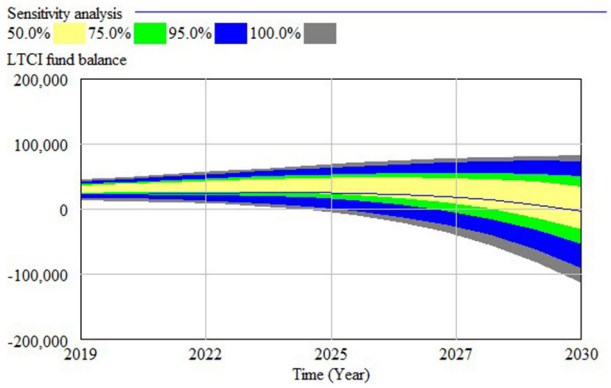

FIGURE 3 | Sensitivity analysis diagram.

Historical Test

The model has passed the dimensional consistency test, the structural test, and the historical test. According to the data availability and the historical tests, the number of insured medical insurance by urban employees in population factors and the per capita disposable income of urban residents in economic factors are selected for the simulation data. By comparing the data of the medical insured population of urban employees and per capita disposable income of urban and rural residents in the yearbook of Xiamen Special Economic Zone (2012-2019), the historical test of the model was carried out. The average error between the actual data and the simulation data is 0.67% (**Table 2**). Within a reasonable range, the model is highly fitting, effective, and reasonable.

RESULTS

The SDM can objectively reflect the structure and the behavior of the LTCI financing system and has good applicability. In this section, first, we analyze the changes in the revenue, expenditure, and balance of the LTCI fund in the current situation and, second, we analyze the future trend of the fund by changing the five key variables that affect the balance of the LTCI fund. Finally, by comparing the impact of these variables on the fund balance, the corresponding conclusions are drawn.

Analysis of the Current Situation

Figure 4 and **Table 1** show the revenue, expenditure, and balance of the LTCI funds from 2020 to 2030. The revenue and the expenditure of the LTCI funds show an increasing trend year by year, an increase of about 3.7 times and 8.8 times, respectively. After 2029, the expenditure of the LTCI funds will exceed the revenue of funds, and the balance of funds will increase first and then decrease; it will reach –¥34.05 million in 2030.

Policy Intervention

Based on the operation of LTCI, combined with field investigation, this study selected five key variables affecting the revenue and the expenditure of LTCI funds, including individual payment rate, reimbursement ratio of nursing services, the rate of severe disability, government financial subsidies, and enterprise contribution rates. Key variables were adjusted to conduct scenario simulations, and the changing trends of LTCI funds revenues, expenditures, and balances were compared under different intervention programs.

Adjust Individual Payment Rate

To ensure the fairness of the implementation of the system, the base of the individual payment rates of urban employees and urban and rural residents is the per capita disposable income of urban residents. Also, to decrease the burden of the individual payment, according to the practice of the pilot area, the proportion of simulated set value was set between 0.06 and 0.1%, which is about ¥30–55 (based on the per capita disposable income of urban residents in 2019).

Test1-1: individual payment rate = 0.06%
Test1-2: individual payment rate = 0.08%
Test1-3: individual payment rate = 0.1%

The results show that in comparison with Test1-1, the revenue of the LTCI funds of Test1-3 increased by ¥416 million to ¥1.819 billion, and the balance increased by 415.75 million to ¥381.7 million. Test1-1 will turn into a deficit in the balance of the LTCI funds in 2030, and after raising the individual payment rate (Test1-2 and Test1-3), the balance of funds did not turn into a deficit in the simulated years (**Figure 5**). Therefore, the increase in individual payment rates can increase the revenue of the LTCI funds and delay the year when the balance of funds turns into a deficit.

Adjust the Reimbursement Ratio of Nursing Services

All of the policy documents pointed out "differentiated treatment guarantee policies are formulated according to the level of care and service delivery methods, and the payment level of funds is generally controlled at about 70% for LTCI expenditure that meets the requirements." According to the practice in the pilot area, the reimbursement ratio of nursing services is about 50–90%. Therefore, this study sets the simulation value of the reimbursement ratio as 50, 60, 70, 80, and 90%.

Test2-1: Reimbursement ratio = 50%
Test2-2: Reimbursement ratio = 60%
Test2-3: Reimbursement ratio = 70%
Test2-4: Reimbursement ratio = 80%
Test2-5: Reimbursement ratio = 90%

The results showed that, with the increase in the reimbursement ratio of nursing services, the expenditure of LTCI funds also increased. In comparison with Test2-1, the expenditure of the LTCI funds in Test2-5 increased by ¥822 million to ¥1.848 billion in 2030, and the balance of funds turns into a deficit earlier than in other situations (**Figure 6**). Therefore, the increase of the reimbursement ratio will increase the expenditure of the LTCI funds and accelerate the deficit of the balance.

TABLE 2 | Historical test.

Year	Medical insured population of urban employees			Per capita disposable income of urban residents		
	Actual data/10,000 people	Simulation data/10,000 people	Error rate/%	Actual data/10,000 people	Simulation data/10,000 people	Error rate/%
2012	182.15	180.7244	−0.78265	37,576	38382.08	−2.1452
2013	192.26	191.4216	−0.43608	41,360	36,772	11.09284
2014	203.64	199.4962	−2.03487	39,625	39539.296	0.216288
2015	212.23	209.7704	−1.15893	42,607	42923.712	−0.74333
2016	223.16	228.185	2.251748	46,254	46417.632	−0.35377
2017	242.75	241.956	−0.32709	50,019	50484.128	−0.9299
2018	257.4	257.4472	0.018337	54,401	51847.36	4.694105

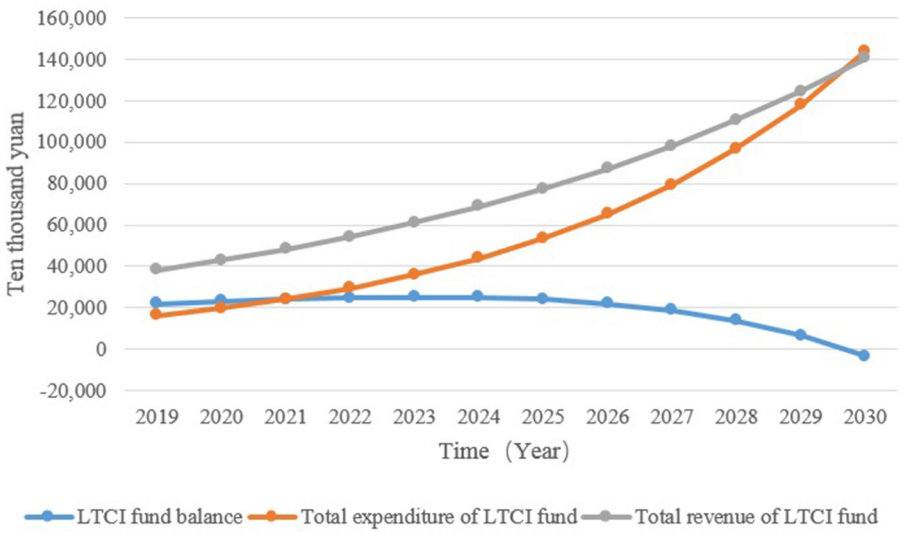

FIGURE 4 | The revenue, expenditure, and balance of LTCI funds.

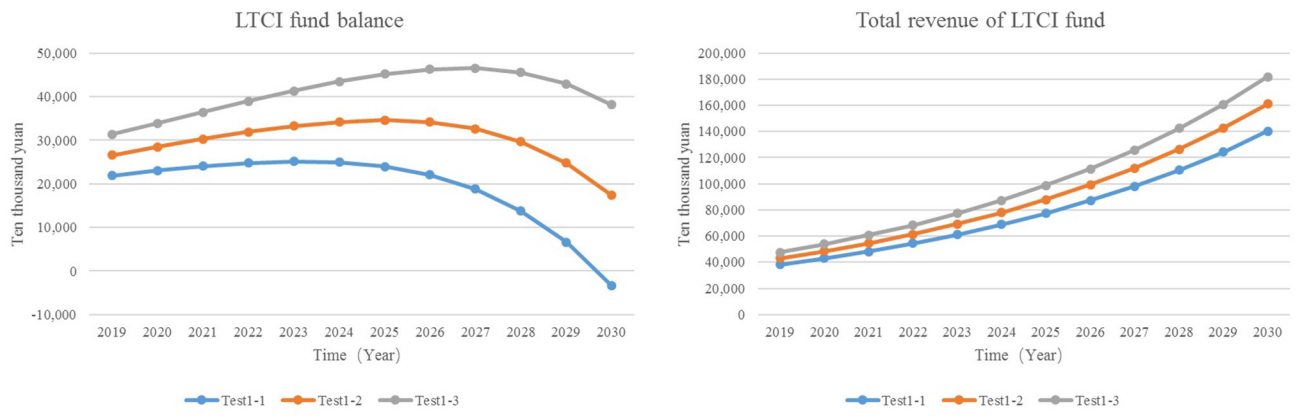

FIGURE 5 | The revenue and balance of LTCI funds.

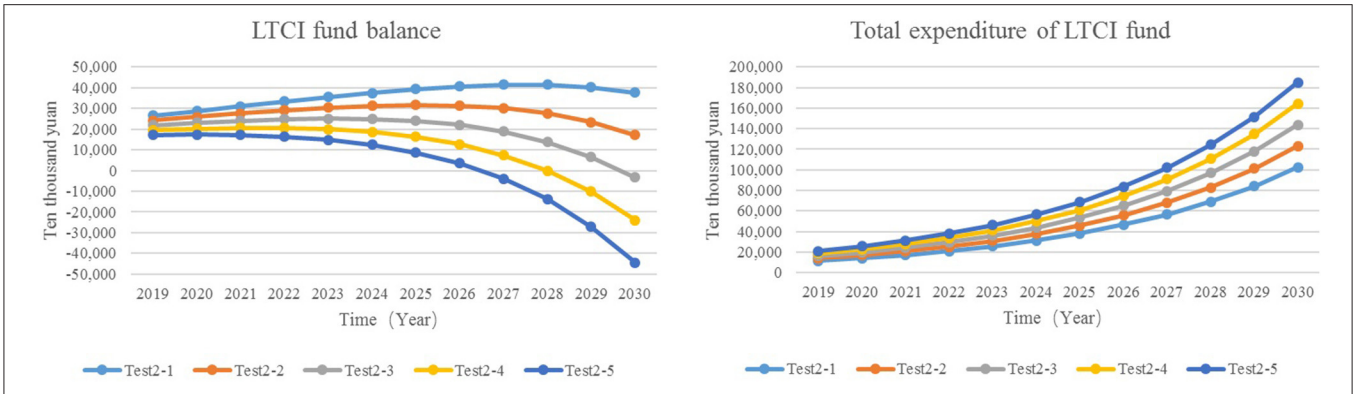

FIGURE 6 | The expenditure and balance of LTCI funds.

Adjust Government Financial Subsidies and Enterprise Contribution Rates

To ensure the fairness of the implementation of the system, the base of government financial subsidies and enterprise contribution rates are both per capita GDP, and the two values are equal. The proportion of the simulation set value is between 0.04 and 0.07%, that is, about ¥55–100 (based on the per capita GDP in 2019).

Test3-1: government financial subsidies and enterprise contribution rates = 0.04%.
Test3-2: government financial subsidies and enterprise contribution rates = 0.05%.
Test3-3: government financial subsidies and enterprise contribution rates = 0.06%.
Test3-4: government financial subsidies and enterprise contribution rates = 0.07%.

The results showed that in comparison with Test3-1, the revenue of the LTCI funds of Test3-4 increased by ¥584 million to ¥1.87 million, and the balance increased by ¥584.45 million to ¥550.4 million. Test3-1 showed a deficit in the balance of the LTCI funds in 2030. After raising the enterprise contribution rate and the per capita financing standard of the government (Test3-2, Test3-3, and Test3-4), the balance of funds did not turn into a deficit in the simulated years (**Figure 7**). It can be seen that raising the financing standard of enterprises and government subsidies can increase the revenue of the LTCI funds and postpone the year when the balance begins to decline.

Adjust the Rate of Severe Disability

All of the policy documents pointed out that the LTCI system takes the insured who has been in a state of disability for a long time as the protection object, focusing on the basic life care of severely disabled people and the medical care closely related to basic life and other expenses. At the beginning of the system, limited resources should be used on the people who are most in need of protection, which not only does not cause a waste of resources but also does not cause excessive pressure on enterprises and individuals to pay fees (35). At present, the beneficiaries of the LTCI in pilot cities of China are mainly severely disabled elderly, and the assessment criteria for disability are mainly based on the Barthel index. According to the practice in the pilot area, due to the slightly different selection of disability assessment criteria, the measured value and real value of the severe disability rate are about 0.3 and 0.5%. Therefore, in this study, the simulation value of the severe disability rate is set to 0.3, 0.4, and 0.5%.

Test4-1: The rate of severe disability = 0.3%.
Test4-2: The rate of severe disability = 0.4%.
Test4-3: The rate of severe disability = 0.5%.

The results showed that the total expenditure of Test4-3 is ¥958 million higher than that of Test4-1 to 2030, reaching ¥2.395 billion (**Figure 8**). Increasing the rate of severe disability, the balance of the LTCI funds turns into a deficit in advance. It can be seen that the lower the severe disability rate is, the lower the expenditure of LTCI funds can be reduced, and the year when the balance presents deficit can be delayed.

Comparison of Intervention Effect

Further analyze the differences in the impact of adjusting individual payment rates, reimbursement ratio of nursing services, severe disability rates, enterprise contribution rates, and government per capita financial subsidies on fund balances. Taking the balance of the LTCI funds as the observation index, the individual payment rate, reimbursement ratio, enterprise contribution rate, and government per capita financial subsidies increase by 10% under the condition of other conditions unchanged.

It can be seen from **Table 3** that when the individual payment rate increases by 10%, the change range of the balance of the LTCI funds from 2020 to 2030 is ∼8.91–54.37%; when the proportion of reimbursement increases by 10%, the change range of fund balance from 2020 to 2030 is ∼-311.42 to −10.16%; when the enterprise contribution rate and the government per capita financial subsidies increase by 10%, the change range of the fund balance from 2020 to 2030 is ∼-144.37 to 1.13%; finally, when the increase rate of severe disability is 10%, the change range of fund balance from 2020 to 2030 is ∼-653.94 to −21.39%. It can be seen that the effects of the four intervention goals on the

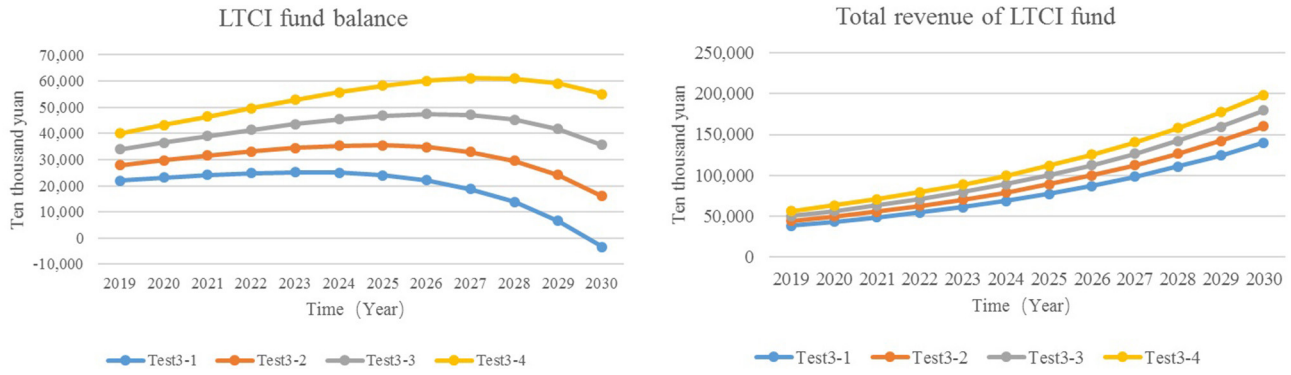

FIGURE 7 | The revenue and balance of LTCI funds.

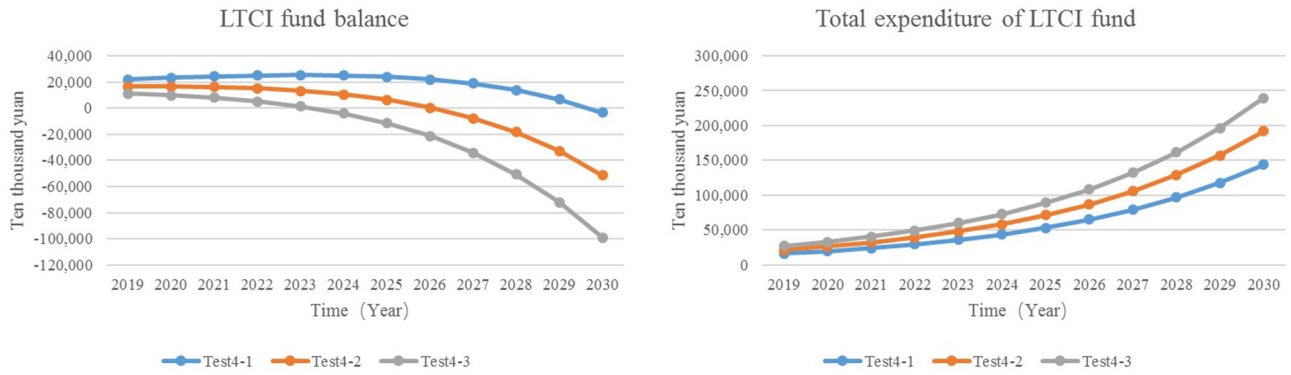

FIGURE 8 | The expenditure and balance of LTCI funds.

balance of LTCI funds are different. The effects on the balance of the LTCI funds from high to low are the rate of severe disability, the reimbursement ratio, the rate of enterprise contribution, the government per capita financial subsidies, and the rate of individual payment rates.

DISCUSSION

The financing system of LTCI involves complex social demography, health management, economics, and other multi-dimensional variables. Regarding it as a large system, its main body includes the government, enterprises, insured persons, and nursing institutions, among others, which also contains multiple subsystems and their influencing factors that affect and restrict each other. This study is based on the SDM of Xiamen LTCI financing to simulate policy intervention strategies. Without any intervention, the revenue and the expenditure of the LTCI funds show an increasing trend year by year, an increase of about 3.7 times and 8.8 times, respectively. After 2029, the expenditure of the LTCI funds exceeds the revenue, and the accumulated balance will turn into a deficit, reaching –¥34.05 million in 2030, at which time the LTCI funds will be insolvent. The results show that, if no intervention measures are taken, the revenue and the expenditure of the LTCI funds will face the risk of imbalance. By predicting the future development trend of LTCI funds, it reflects the necessity and urgency of improving the LTCI financing system and establishing a unified LTCI financing mechanism.

This study introduced the established LTCI financing SDM as an experimental platform to simulate policy interventions and judged the effects and impact of various strategies by observing changes in system behavior. Aiming at the key variable of LTCI funds, first, by setting the individual payment rate of LTCI participants at 0.08–0.1%, it was found that increasing the individual payment rate can delay the balance of funds turn into a deficit; second, the enterprise contribution rate and government per capita financing standard are adjusted to 0.04–0.07%. The results showed that the balance of funds does not turn into a deficit in the simulation period when the government financial subsidies and enterprise contribution rate are increased. By adjusting the pooling funds and personal accounts of basic medical insurance, the LTCI financing mechanism undertaken by individuals, enterprises, and governments can be constructed, without increasing the social security payment burden of the enterprises and individuals (36). With the exploration and improvement of the system, it was recommended to increase the payment capacity of the LTCI funds promptly and further

TABLE 3 | Percentage change of the long-term care insurance funds balance under different intervention schemes (%).

Year	Based on the original research hypothesis, increase 10%, respectively			
	Individual payment rates	Government financial subsidies, and enterprise contribution rate	Reimbursement ratio	Severe disability rate
2019	8.91	1.13	−10.16	−21.39
2020	9.85	0.18	−12.12	−25.46
2021	11.06	−1.09	−14.7	−30.8
2022	12.79	−2.84	−18.23	−38.21
2023	15.36	−5.27	−23.31	−49.01
2024	19.36	−9.32	−31.56	−66.3
2025	26.69	−16.64	−46.73	−98.17
2026	44.55	−34.58	−83.84	−176.08
2027	154.37	−144.37	−311.42	−653.94
2028	95.96	−105.97	−207.69	−436.09
2029	35.29	−45.26	−81.94	−172.04
2030	21.12	−31.12	−52.61	−110.43

increase the government financial subsidies for urban and rural residents in LTCI. At this stage, the people who enjoy the LTCI are the elderly group. To ensure the rationality and fairness of the system, it is recommended to implement a paying policy for urban retired employees. Without causing pressure on the payment of retirees and the government, the payment of premiums by retired employees can increase the revenue of the LTCI funds and maintain its stability and sustainability (37).

In addition, the policy documents all pointed out "differentiated treatment guarantee policies are formulated according to the level of care and service delivery methods, and the funds' payment level is generally controlled at about 70% for LTCI expenditure that meets the requirements (5, 6)". According to the practice of pilot areas, the reimbursement ratio of nursing services is adjusted to be about 50–90%. The results showed that, as the reimbursement ratio increased, the expenditure of the LTCI funds also increased, accelerating the deficit in the balance of funds. Therefore, to maintain the sustainability of the funds, the initial payment standard of nursing service should not be too high and should be reasonably determined according to the principle of "determining expenditure by revenue." In the initial stage of the implementation of the system, through timely analysis of the service content and payment standards formulated in the previous period, the actual application of the service content and payment standards are continuously adjusted according to the actual situation. In the later stage of the implementation of the system, passive protection after the event can be transformed into an active comprehensive protection of "prevention + compensation," which not only guarantees the sustainability of system operation but also helps to build a healthy aging society (38, 39).

Finally, according to the practice of pilot areas, due to the slightly different selection of disability assessment criteria, the adjusted severe disability rate is about 0.3–0.5%. The results show that increasing the severe disability rate will lead to the deficit of the LTCI balance of funds ahead of time. In comparing the effect of four intervention targets on the balance of the fund, it was found that the severe disability rate has the greatest impact on the fund balance. At present, the domestic assessment tools for disability levels are mainly based on the Barthel index, which measures basic daily living ability. The content of the disability assessment is relatively single, only measuring self-care ability, and the disability assessment is not comprehensive enough. If only a single Barthel index scale is used for disability assessment, it may lead to a high disability rate, which is not conducive to maintaining the stability and sustainability of the LTCI funds. Therefore, combined with the current practice in pilot areas, it is suggested that the following points should be considered in the construction of disability assessment tool: (a) at present, China has not yet formed a unified national LTCI system, and the selection of disability assessment content should match with the local LTCI service delivery capacity and scientifically judge the degree of disability; (b) developing the corresponding disability assessment information management system and using the information system to complete the assessment work, which can avoid subjective and human factors in the assessment; and (c) relying on the local medical institutions at all levels and establishing a database of evaluation experts to ensure fairness and justice in the evaluation (40).

Under the current social background, foreign experience shows that it is urgent to build an LTCI system with social insurance as the main body, financial subsidies as the support, and commercial insurance as the supplement. At the same time, policymakers should establish a multi-dimensional and dynamic financing mechanism shared by individuals, enterprises, and government (41). As far as China is concerned, it has become a trend to design LTCI as an independent financing insurance, which is parallel to other social insurance. However, few studies have analyzed the financing mechanism of LTCI from a systematic perspective. Therefore, based on the field research, this study constructs the financing mechanism of the individuals, enterprises, and the government, which can provide the basis for the further implementation and sustainable development of the system and also the reference for other developing countries to establish a sustainable LTCI system (42). Part of the data is based on field investigation and expert consultation conducted in four representative LTCI pilot cities, Jiaxing, Shanghai, Chengdu, and Jingmen, which increased the reliability of the model and enriched the quantitative research on the LTCI system. It provides theoretical support for the construction and optimization of the Xiamen LTCI financing mechanism. However, there are still some limitations to our study. First, due to the lack of relevant data, the parameters are set using the estimation method and lack of dynamic, such as severe disability rate, which may affect the accuracy of the model prediction (43). Second, this study mainly takes Xiamen as an example, lacking a comprehensive study on the national LTCI system, but it provides ideas for the study of the national LTCI financing mechanism. Therefore, in the future, we will carry out research nationwide and set some

parameters accurately to provide a more valuable reference for the development and improvement of the LTCI system in China.

CONCLUSIONS

In summary, the SDM can objectively reflect the structure and the behavior of the LTCI financing system and has good applicability. The results show that the revenue and the expenditure of the LTCI funds display an increasing trend year by year. By increasing the individual payment rate, government financial subsidies, and enterprise contribution rate, reasonable setting of the reimbursement ratio of nursing services, especially the prevention of the elderly disability, to maintain the sustainability of the funds. Therefore, first, it is possible to build an LTCI financing mechanism borne by individuals, enterprises, and government, to further increase the government financial subsidies to urban and rural residents, to implement the payment system for retired employees, to increase the revenue of LTCI funds, and to improve the payment ability of the funds in the future. Second, policymakers should build a fair and effective disability assessment system according to the actual situation of the pilot areas to scientifically judge the degree of disability. In addition, a reasonable standard system of treatment protection should be constructed in accordance with the principle "expenditure is determined by revenue, the balance between revenue and expenditure" to maintain the stability and sustainability of the LTCI funds.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

LZ contributed to the study conception, design, and drafted the manuscript. SF participated in the statistical analysis and drafted the manuscript. YF supervised and revised the manuscript. All authors read and approved the final manuscript.

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Minimizing the Risk of Catastrophic Health Expenditure in China: A Multi-Dimensional Analysis of Vulnerable Groups

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Background: In moving toward universal health coverage in China, it is crucial to identify which populations should be prioritized for which interventions rather than blindly increasing welfare packages or capital investments. We identify the characteristics of vulnerable groups from multiple perspectives through estimating catastrophic health expenditure (CHE) and recommend intervention priorities.

Methods: Data were from National Health Service Survey conducted in 2003, 2008, and 2013. According to the recommendation of WHO, this study adopted 40% as the CHE threshold. A binary regression was used to identify the determinants of CHE occurrence; a probit model was used to obtain CHE standardized incidence under the characteristics of single and two dimensions in 2013.

Results: The total incidence of CHE in 2013 was 13.9%, which shows a general trend of growth from 2003 to 2013. Families in western and central regions and rural areas were more at risk. Factors related to social demography show that households with a female or an unmarried head of household or with a low socioeconomic status were more likely to experience CHE. Households with older adults aged 60 and above had 1,524 times higher likelihood of experiencing CHE. Among the health insurance schemes, the participants covered by the New Rural Cooperative Medical Scheme had the highest risk compared with the participants of all basic health insurance schemes. Households with several members seeking outpatient, inpatient care or with non-communicable diseases were more likely to experience CHE. Households with members not seeing a doctor or hospitalized despite the need for it were more likely to experience CHE. Characteristics such as a household head with characteristics related to low socioeconomic status, having more than two hospitalized family members, ranked high. Meanwhile, the combination of having illiterate household heads and with being covered by other health insurance plans or by none ranked the first place. Cancer notably caused a relatively high medical expenditure among households with CHE.

Conclusion: In China, considering the vulnerability of the population across different dimensions is conducive to the alleviation of high CHE. Furthermore, people with multiple vulnerabilities should be prioritized for intervention. Identifying and targeting them to offer help and support will be an effective approach.

Keywords: catastrophic health expenditure, financial protection, universal health coverage, China, insurance

INTRODUCTION

Throughout the 40 years of "reform and opening up" of China, the country has progressed remarkably in terms of socioeconomic development. Its GDP has increased from 368 billion yuan (USD 53 billion) in 1978 to 83 trillion yuan (USD 13 trillion) in 2019, witnessing an average annual growth rate of 15% (1). In addition to its economic progress, China has also accelerated its goal of improved universal health coverage (UHC). Notably, China set up the biggest medical insurance safety nets in the shortest time so as to cover as many people as possible. Since 2003, China has launched and implemented a series of basic medical insurance schemes, including Urban Employee Basic Medical Insurance (UEBMI), launched in 1998, which was provided mandatorily for employees in urban areas (also including retired and rural-to-urban migrant workers), whose premium is to be borne by both the employer and the employee, with a combined individual account and a socially pooled fund; individual accounts are mainly used for general outpatient services or to purchase drugs in the drug stores. New Rural Cooperative Medical Scheme (NCMS) was launched in 2003 as a voluntary system of mutual assistance through risk pooling to mitigate unaffordable health services and a financial burden in rural areas. The funding is from the contribution of an individual and the government; the Urban Resident Basic Medical Insurance (URBMI), launched 4 years after NCMS, was designed for urban residents not covered by UEBMI or NCMS, including primary and secondary school students, young children, and other unemployed urban residents. It is on a voluntary basis at the household level, and is sponsored by the government and an individual. Different from UEBMI, the individual accounts for URBMI or NCMS participants could not be used in the drug stores. Subsequently, integration of basic medical insurance systems was conducted in succession all over the country; the patterns of integrating URBMI and NRCMS (2) or integrated UEBMI, URBMI, and NRCMS were chosen according to their local conditions (3). Currently, the coverage rate of basic medical insurance is more than 95% (4). Great progress of China has also attracted international attention; a report published in the journal "The Lancet" evaluated and affirmed the progress of China in broadening insurance coverage, stating that Chinese insurance is the most extensive insurance program globally (5). The broad coverage of basic health insurance played a great role in alleviating the major financial barrier hindering smooth access to health services. The problem of seeking medical service, which Chinese often say, "Seeing a doctor is hard" has been improved to some extent (6). However, the strong performance in achieving extensive coverage was not sufficient to realize UHC, as the issue of affordability—"seeing a doctor is expensive"—still exists. UHC aims to ensure that no individual suffers financial hardship (7) when accessing quality health services. A 2010 World Health Organization (WHO) report interpreted UHC along three dimensions (8): breadth of coverage, that is, the proportion of the population that enjoys social health protection; depth of coverage, namely, the range of essential services necessary to effectively address health needs of people; and height of coverage, which refers to the portion of health-care costs covered through pooling and prepayment mechanisms (9).

Financial protection is one of the major aims of health systems (10) and has been, in general, captured by a well-established indicator called "catastrophic health expenditure" (CHE) (11, 12) and also, by the effects of out-of-pocket payments on poverty (13). According to WHO methodology, CHE is defined as out-of-pocket (OOP) spending for health care that exceeds 40% of a capacity of a household to pay (CTP) (14, 15). The CHE proportion in China has been at a high level; a study covering 133 countries revealed that China and some countries with inadequate health insurance coverage or in poverty were all listed at the most serious level (16). Unlike countries, such as Mexico, Thailand, and Vietnam, whose CHE rate has been falling with an increase in the proportion of the population with insurance coverage, the situation in China has not changed in the expected direction despite the launch of the three basic medical insurance schemes and the continuous expansion of coverage (16). According to the findings of the national survey in China, the CHE rate was up to 13% in 2008 and rose to 14.57% in 2012 (17, 18).

Since the health system reform was initiated in 2009, the Chinese government has made numerous efforts, increasing its investment in health care from 929.5 billion yuan in 2013 to 1445.1 billion yuan in 2017, with an increased rate of 55.5% (19). Among these, subsidies for medical insurance of urban and rural residents increased from 328.2 billion yuan to 491.9 billion yuan, at an average annual growth of 10.6% (19). A series of policies to alleviate CHE incidence were also launched, including zero markup policy on drug sales; more specifically, this policy aims to cancel the 15% drug markup when patients purchase drugs directly from hospitals and reduce the medical burden of patients (20), and establishing critical illness insurance. Despite the situation has improved, albeit not significantly, considering the limited available health resources, it is crucial to identify which populations should be prioritized for which interventions and consequently develop appropriate approaches to reach these targeted populations, as well as ensure appropriate allocation of resources and support, rather than blindly increasing welfare

packages or capital investment. Besides, the actual situation of these vulnerable groups is masked by the average rate. It is difficult to address the economic burden of the vulnerable groups solely based on a generalized system of preferences. Being the main source of high CHE, improving the financial protection of vulnerable groups is the key to realize UHC, especially for developing or low-income countries (21).

Many studies have conducted research on CHE in China; however, only a few have reported national representative estimates for the whole population (17, 18, 22, 23). An in-depth analysis of vulnerable populations with high CHE risk is limited as well. Currently, China has just completed the task of eliminating absolute poverty, while the precise and quantitative identification of the mechanism of marginal groups that are prone to fall into poverty due to illness is still insufficient, with policymakers and the general public eager to know the progress of eliminating the risk of CHE in China and where its weakness lies (24, 25). This study examined the progress of China in enhancing financial protection, identifying the main characteristics of the high-risk population that need to be filled to fully achieve UHC. The results would also contribute to the development of healthcare systems in other nations with similar situations.

MATERIALS AND METHODS

Study Design

This study conducted a comparative analysis between 2003 and 2013 to obtain the trend of CHE incidence and the changes of healthcare needs and health service utilization over time. An in-depth analysis was conducted on the fifth NHSS in 2013, identifying the factors with high risk and locking the characteristics with one risk factor, two overlapping risk factors after standardized.

Data Source

Most data were obtained from the fifth National Health Service Survey (NHSS), which was conducted in 2013. Additionally, the data from the third and fourth NHSS were used for supplement. NHSS is a nationally representative survey organized by the Chinese government every 5 years. A multistage, stratified random sampling method was adopted in the NHSS to ensure a representative sample. All the participants were interviewed face-to-face by trained investigators; ultimately, 57,023 households in the third NHSS, 56,456 households in the fourth NHSS, 93,613 households in the fifth NHSS were included in the survey (26–28). After data cleaning, 57,023 households in the third NHSS, 56,433 households in the fourth NHSS, and 93,570 households in the fifth NHSS were respectively used in this study.

Quality Control

The response rate of the fifth NHSS of the adult respondents was 82.1%. The test-retest reliability of the questionnaire reached 97.7%. In reference to the 2010 Sixth National Population Census data, the results show that there is no difference in the family size and the rural-to-urban household ratio between the sample of the fifth NHSS and the whole country; however, the proportion of older adults was higher in the sample than in the general population (26); the data of the third and fourth NHSS also show good consistency in household size between the surveyed population and the general population (27, 28).

Measurement

Catastrophic Health Expenditure

According to the WHO definition, CHE occurs when the total OOP health payments of a household equal or exceed 40% of CTP of the household (15). OOP is the net after reimbursement under any type of insurance, including consulting fees of doctors, drug purchases, and hospitalization expenses, while excluding health-related transportation fees and special nutrition expenses. The CTP of the household is defined as the non-subsistence effective income of the household. The non-subsistence spending of the household was used as a proxy for CTP, and, when food expenditure was less than subsistence spending, CTP was defined as total expenditure minus food expenditure (15), while household subsistence spending was calculated as the poverty line multiplied by standard household size. The poverty line is defined as the food expenditure of the household whose food expenditure share of total household expenditure is within the 45th and 55th percentiles of the total sample (15).

Variables

The dependent variable is whether a household experienced CHE. The independent variables included attributes concerning the household head, such as gender, education level, marital status, employment status, and insurance type; sociodemographic characteristics of households, such as region, economic quintiles (annual household consumption expenditure was ranked into quintiles after adjustment for standard household size), family size, and having family member over 60 years or younger than 5 years; and indicators on need and utilization of health services among household members, such as the number of people with non-communicable diseases (NCDs) in the last 6 months, or the number of people admitted in hospitals in the previous year; a preferred institution grade for common diseases and with members not seeing a doctor or hospitalized despite their need for it; the variables and their codes are detailed in **Table 1**.

Data Analysis

Descriptive statistics were used to reveal the basic characteristics of the respondents and their healthcare needs and service utilization. A time trend approach was conducted to analyze the CHE incidence trend from 2003 to 2013. A logistic regression model was used to identify the determinants of CHE. The metrics for healthcare needs and service utilization and family population structure were standardized in the comparative analysis of the incidence of CHE across 31 provinces, a single-dimension factor, and two-dimension factors, other variables were used as control variables. A probit model was used to standardize the healthcare needs and service utilization (24, 29, 30). All statistical analyses were conducted, using STATA 11.0. Statistical significance was set at the 5% level.

TABLE 1 | Basic information of respondents in the fifth NHSS.

Variable	Variable value	Number (households)	Percentage (%)
Dependent variable			
Experiencing CHE or not	0 = No	80,565	86.10
	1 = Yes	13,005	13.90
Independent variable			
Gender of the head of household	0 = Female	23,744	25.40
	1 = Male	69,826	74.60
Marital status of the head of household	0 = Married	78,751	84.20
	1 = Others	14,819	15.80
Educational level of the head of household	1 = Illiterate	9,904	10.60
	2 = Primary school	26,556	28.40
	3 = Junior high school	33,742	36.10
	4 = Senior high school and technical school	11,800	12.60
	5 = Technical secondary school and above	11,568	12.40
Employment status of the head of household	1 = Employed	64,026	68.40
	2 = Retired	16,164	17.30
	3 = Unemployed and students	13,380	14.30
Medical insurance type of the head of household	1 = UEBMI	23,919	25.60
	2 = URBMI	6,847	7.30
	3 = NCMS	43,362	46.30
	4 = Integration	12,060	12.90
	5 = Mixture	4,811	5.10
	6 = Others and none	2,571	2.70
Region	1 = Eastern	31,201	33.30
	2 = Central	31,186	33.30
	3 = Western	31,183	33.30
Location	0 = Urban	46,798	50.00
	1 = Rural	46,772	50.00
Household size	1 = ≤2	41,633	44.50
	2 = 3–4	39,289	42.00
	3 = ≥5	12,648	13.50
Household with members aged sixty and above	0 = No	52,792	56.40
	1 = Yes	40,778	43.60
Household with members aged five or younger	0 = No	77,239	82.50
	1 = Yes	16,331	17.50
Number of patients with chronic diseases	1 = 0	52793	56.40
	2 = 1	30,316	32.40
	3 = ≥2	10,461	11.20
Number of hospitalized members	1 = 0	74,641	79.80
	2 = 1	16,795	17.90
	3 = ≥2	2,134	2.30
Preferred institution grade for common diseases	0 = Primary hospital	75,833	81.00
	1 = Non-primary hospital	17,737	19.00
Whether there is a member go to clinic in 2 weeks	0 = No	75,006	80.20
	1 = Yes	18,564	19.80
Member not hospitalized despite the need for it	0 = No	89,516	95.70
	1 = Yes	4,054	4.30
Member not seeing a doctor despite the need for it	0 = No	66,440	71.00
	1 = Yes	27,130	29.00

RESULTS

Basic Information Regarding Respondents of the Fifth NHSS

Most household heads were male (74.60%), married (84.20%), junior high school graduates (36.10%), and employed (68.4%). The NCMS was the most common medical insurance among household heads (46.9%). Nearly half of the households had members over 60 years old and members suffering from NCDs in the last 6 months; meanwhile, 44.5% of the households had no more than two family members (**Table 1**).

Catastrophic Health Expenditure Incidence From 2003 to 2013

Table 2 shows the CHE incidences in 2003, 2008, and 2013, which were, respectively 11.7, 13.2, and 13.9%. The result of the time trend approach indicates that, from 2003 to 2013, the CHE incidence shows a general trend of growth over time ($\chi^2 = 150.724$, $P < 0.001$), although the growth rate slowed.

TABLE 2 | Catastrophic health expenditure incidences in 2003, 2008, and 2013.

	Total	Households with CHE	χ^2	*P*-value
	N	*N* (%)		
2003	57,023	6,649 (11.7)	150.724	<0.001
2008	56,433	7,445 (13.2)		
2013	93,570	13,005 (13.90)		

Healthcare Needs and Service Utilization and Hospitalization Expenses From 2003 to 2013

We compared the healthcare needs and service utilization of the recent three NHSS conducted in 2003, 2008, and 2013. The results show that the healthcare needs increased over the years; the prevalence of NCDs was 33.1% in 2013, which was double than that in 2003 (15.1%). The non-admission rate, defined as the percentage of the respondents who had not been admitted to inpatient care in the past year despite being advised by a doctor, decreased from 29.6% in 2003 to 17.1% in 2013. The non-attendance rate, defined as the percentage of the patients who were ill but did not seek medical treatment in the past 2 weeks, decreased from 48.9% in 2003 to 27.3% in 2013.

Although the healthcare needs of residents have been met, this has resulted in higher medical expenses. Expenditure data for 2008 and 2013 are adjusted for movements in the consumer price index and taken 2003 as the basic year. After adjustment, through comparing the average hospitalization expenses of the three NHSS, it was found that the average hospitalization expenses increased over the years, from USD 616 (3,815 yuan) in 2003 to USD 1,273 (8,520 yuan) in 2013, with an annual growth rate of 19.9%. Furthermore, over the past decade, the average hospitalization cost increased by 106.6% (**Figure 1**).

Multidimensional Analysis Based on Characteristics of CHE Risk Households

The Distribution of CHE Rate Among Regions and Provinces

The CHE proportion in the fifth NHSS was 13.9%. From a regional perspective, the proportion of CHE in rural areas is

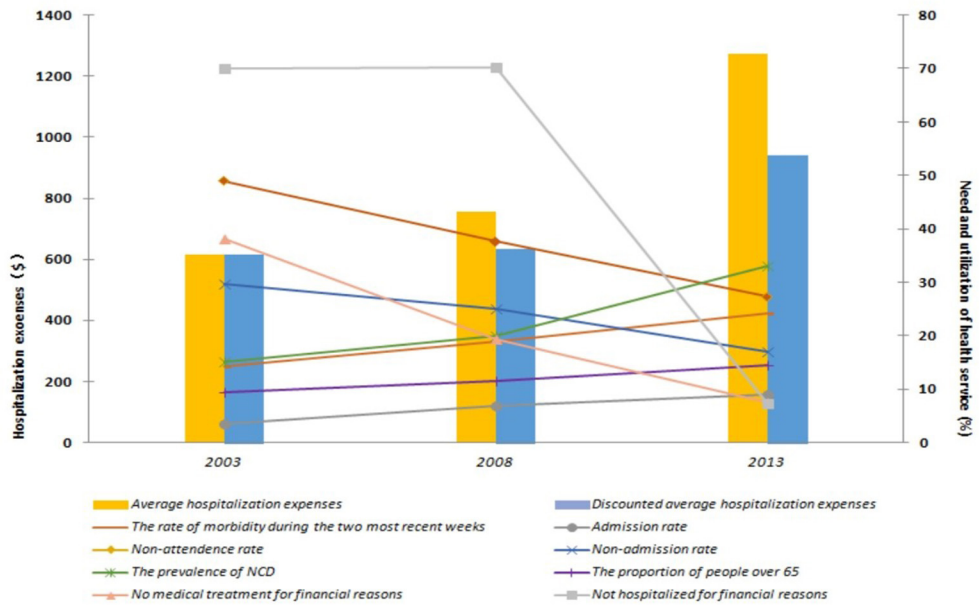

FIGURE 1 | Comparison of health-care needs and service utilization in 2003, 2008, and 2013. $: USD, United States Dollar. According to the exchange rate of 6.1932 yuan to US$ 1.00.

TABLE 3 | Univariate analysis of factors associated with CHE.

Characteristics of the respondents	Total	CHE	Standard error	χ^2	*P*-value
	N (%)	*N* (%)			
Income quintile[a]				766.742	<0.001
Quintile 1	18,714 (20.00)	3,703 (19.80)	0.0029		
Quintile 2	18,714 (20.00)	2,643 (14.10)	0.0025		
Quintile 3	18,714 (20.00)	2,369 (12.70)	0.0024		
Quintile 4	18,714 (20.00)	2,020 (10.80)	0.0023		
Quintile 5	18,714 (20.00)	2,270 (12.10)	0.0024		
Household size				2,379.113	<0.001
≤2	41,633 (44.50)	8,350 (20.10)	0.0020		
3–4	39,289 (42.00)	3,466 (8.80)	0.0014		
≥5	12,648 (13.50)	1,189 (9.40)	0.0026		
Region				33.961	<0.001
Eastern	31,201 (33.30)	4,046 (13.00)	0.0019		
Central	31,186 (33.30)	4,489 (14.40)	0.0020		
Western	31,183 (33.30)	4,470 (14.30)	0.0020		
Location				136.568	<0.001
Urban	46,798 (50.00)	5,886 (12.60)	0.0015		
Rural	46,772 (50.00)	7,119 (15.20)	0.0017		
Gender				24.709	<0.001
Male	69,826 (74.60)	9,476 (13.60)	0.0013		
Female	23,744 (25.40)	3,529 (14.90)	0.0023		
Marital status of the head of household				550.394	<0.001
Married	78,751 (84.20)	10,039 (12.70)	0.0012		
Others	14,819 (15.80)	2,966 (20.00)	0.0033		
Educational level of the head of household				2,327.951	<0.001
Illiterate	9,904 (10.60)	2,548 (25.70)	0.0044		
Primary school	26,556 (28.40)	4,691 (17.70)	0.0023		
Junior high school	33,742 (36.10)	3,867 (11.50)	0.0017		
Senior high school and technical school	11,800 (12.60)	1,120 (9.50)	0.0027		
Technical secondary school and above	11,568 (12.40)	779 (6.70)	0.0023		
Employment status of the head of household				2,635.196	<0.001
Employed	64,026 (68.40)	6,593 (10.30)	0.0012		
Retired	16,164 (17.30)	2,889 (17.90)	0.0030		
unemployed and students	13,380 (14.30)	3,523 (26.30)	0.0038		
Medical insurance of the head of household				404.361	<0.001
UEBMI	23,919 (25.60)	2,779 (11.60)	0.0021		
URBMI	6,847 (7.30)	986 (14.40)	0.0042		
NCMS	43,362 (46.30)	6,816 (15.70)	0.0017		
IBMIUR	12,060 (12.90)	1,774 (14.70)	0.0032		
Mixed medical insurance	4,811 (5.1%)	374 (7.80)	0.0039		
Other types and none	2,571 (2.7%)	276(10.70)	0.0061		
Households including members aged above 60 years				3,593.430	<0.001
No	52,792 (56.40)	4,192 (7.90)	0.0012		
Yes	40,778 (43.60)	8,813 (21.60)	0.0020		
Households including members aged below 5 years				395.525	<0.001
No	77,239 (82.50)	11,534 (14.90)	0.0013		
Yes	16,331 (17.50)	1,471 (9.00)	0.0022		
Number of patients with chronic diseases				4,182.198	<0.001
0	52,793 (56.40)	4,048 (7.70)	0.0012		

(Continued)

TABLE 3 | Continued

Characteristics of the respondents	Total	CHE	Standard error	χ^2	*P*-value
	N (%)	*N* (%)			
1	30,316 (32.40)	6,175 (20.40)	0.0023		
≥2	10,461 (11.20)	2,782 (26.60)	0.0043		
Number of hospitalized members				7,552.608	<0.001
0	74,641 (79.80)	6,711 (9.00)	0.0010		
1	16,795 (17.90)	5,415 (32.20)	0.0036		
≥2	2,134 (2.30)	879 (41.20)	0.0107		
Preferred institutional grade for common diseases				26.674	<0.001
Primary hospital	75,833 (81.00)	10,754 (14.20)	0.0013		
Non-primary hospital	17,737 (19.00)	2,251 (12.70)	0.0025		
Whether there is a member go to clinic in 2 weeks				1,254.815	<0.001
No	18,564 (19.80)	8,930 (11.90)	0.0024		
Yes	75,006 (80.20)	4,075 (22.00)	0.0015		
Member not hospitalized despite the need for it				1,443.631	<0.001
No	89,516 (95.70)	1,382 (34.10)	0.0016		
Yes	4,054 (4.30)	11,623 (13.00)	0.0053		
Member not seeing a doctor despite the need for it				1,875.437	<0.001
No	66,440 (71.00)	5,850 (21.60)	0.0016		
Yes	27,130 (29.00)	7,155 (10.80)	0.0019		

[a]*Quintile 1 is the poorest, 20%, and quintile 5 is the wealthiest, 20%.*

1.2 times higher than that in urban areas; the central (14.4%) and western regions (14.3%) show a higher CHE rate compared with the eastern region (12.9%) (**Table 3**). Of the 31 provinces, 17 exceeded the national average level of the CHE rate, and most of them were concentrated in the central and western regions with lower *per capita* GDP. The number of households who suffered from CHE in the western region was larger than that in the eastern and central regions. Few cities such as Beijing and provinces such as Shandong had a fairly high CHE incidence (**Figure 2**).

CHE Incidence Cross Different Characteristics of Households

Table 3 shows the CHE incidences among households across different characteristics. The univariate analysis results show statistically significant relationships between CHE and factors related to the household head, demographics, and health service needs and utilization (**Table 3**).

Determinants of Households Dropping Into CHE in 2013 in China

In the result of the model, R^2 = 26.9%, and the Hosmer–Lemeshow test showed that the model fits well ($p81> 0.05$), the logistic regression analysis revealed several drivers of CHE. Households in which the head was male (OR = 1.200, 95% CI = 1.138–1.264), unmarried (OR = 1.191, 95% CI = 1.124–1.263), or illiterate (OR = 1.191, 95% CI = 1.124–1.263) had a higher risk of CHE than other groups. Compared with households in the fifth quintile, households in Quintile 1 (OR = 1.483, 95% CI = 1.374–1.600) and Quintile 2 (OR = 1.241, 95%CI = 1.153–1.337) had a higher CHE risk. Compared with the household head with an education level of technical secondary school and above, the groups with an education level of illiterate (OR = 2.351, 95% CI = 2.114–2.616), primary school (OR = 1.779, 95% CI = 1.616–1.957), junior high school (OR = 1.510, 95% CI = 1.377–1.657), and senior high school and technical school (OR = 1.342, 95% CI = 1.208–1.491) were more likely to face CHE. Additionally, the better the employment status of the household head, the lower the risk of CHE in the household: compared with unemployed or student household head groups, employed (OR = 0.522, 95% CI = 0.493–0.552) and retired groups (OR = 0.756, 95% CI = 0.695–0.823) had a lower risk of CHE. Households without inpatient members (OR = 0.123, 95% CI = 0.111–0.136) or only one inpatient member (OR = 0.580, 95% CI = 0.523–0.643) were at a lower risk than those with more than two inpatient members. Compared with households with more than two NCD members, those with no NCD members (OR = 0.509, 95% CI = 0.473–0.548) and only one NCD member (OR = 0.842, 95% CI = 0.793–0.894) were at a lower risk of CHE. Households with outpatient members had a higher CHE risk than the reference (OR = 1.507, 95% CI = 1.433–1.584). Households in rural regions had a higher risk (OR = 1.062, 95% CI = 1.007–1.119) than urban households, while those in western (OR = 1.079, 95% CI = 1.023–1.138) and central regions (OR = 1.052, 95% CI = 0.998–1.109) had a higher risk than those in the eastern region. Households covered by UEBMI had the strongest ability to resist the economic burden of disease. Compared with UEBMI, other types of insurance revealed a higher risk of CHE, and, among these groups, the risk of NCMS was highest (OR = 1.508, 95% CI = 1.382–1.646). Notably, households with members not visiting a doctor (OR =

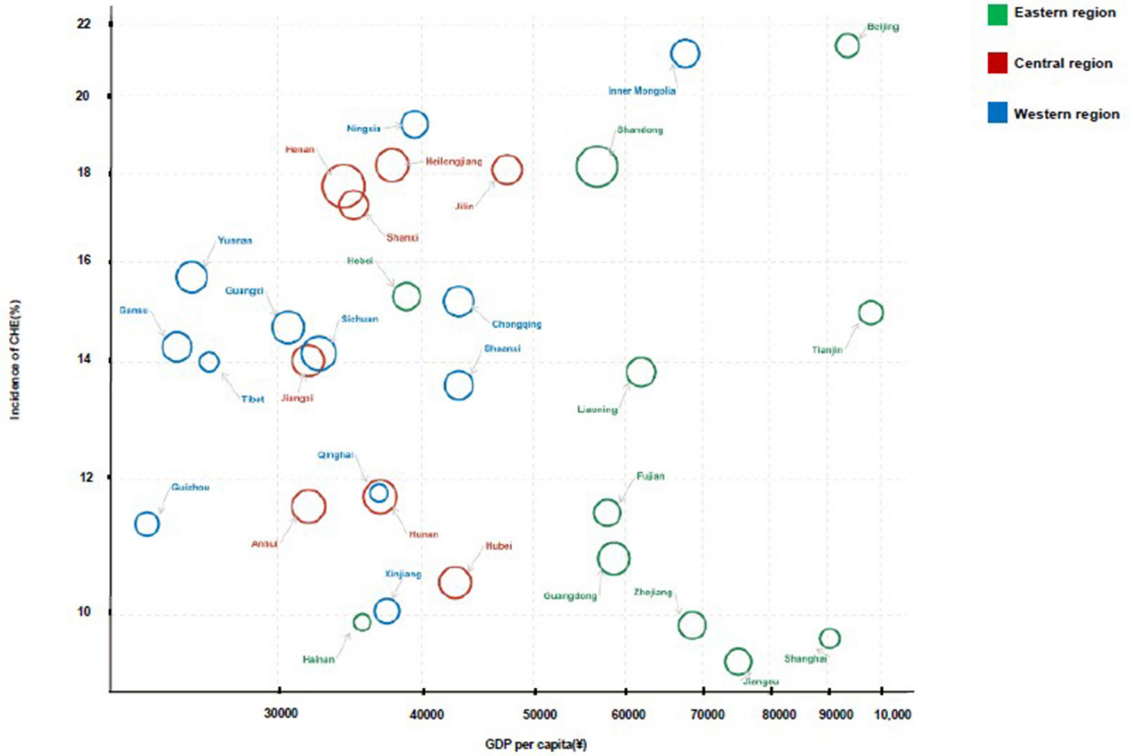

FIGURE 2 | The incidence of CHE across 31 provinces in China.

1.325, 95% CI = 1.256–1.396) or not hospitalized despite the need for it (OR = 1.757, 95% CI = 1.625–1.899) had a higher risk of experiencing CHE (**Table 4**).

The CHE Standardized Rate Under the Characteristics of Single Dimension

Figures 3, **4**, respectively, show the CHE standardized rate under the single dimension of demographic factors and health service needs and utilization factors. Regarding the demographic factors, the top three factors with the highest CHE risk were illiterate household head (23.06%), unemployed or student household head (22.43%), and the poorest household economic status (20.11%). Regarding the factors of health service need and utilization, the top three factors with the highest risk were having two or more hospitalized patients (20.53%), having two or more chronic disease patients (15.93%), and having members who should be hospitalized but are not (14.76%).

CHE Risk Characteristics Under Different Location Levels, Region Levels and Economic Quintile Levels of Households, and Health Insurance Levels of Household Heads

Figures 5–**8**, respectively, show that CHE risk characteristics lied under different location levels and region levels and economic quintile levels of households, and health insurance levels of household heads. Regarding the location level of the household, the CHE rates of rural households were higher than urban households in general. Urban households with illiterate household heads have the greatest risk, with a standardized rate of 22.30%, followed by rural households with the poorest economic status (21.40%). In rural households, those with unemployed or student status household head ranked first (24.50%); those with an illiterate status also had a considerable CHE risk (23.45%).

Regarding household region, eastern, central, and western households with illiterate household heads were all the most vulnerable. In addition, unemployed or student status was also a risk characteristic for households from three regions. The CHE risks of eastern and western households with more than two hospitalized members were quite high at 22.10 and 21.15%, respectively. The poorest households located in eastern and central regions also need to be paid attention to meanwhile.

Regarding economic status, the poorest households with different characteristics show higher CHE rates than other economic groups at over 20%. In the poorest households, those with illiterate household heads ranked first (27.20%), followed by those with unemployed or student household heads (27.09%). For households with sub-poorest economic status, those with household heads who were unemployed or students were the most vulnerable (22.70%). Notably, the richest group with unemployed or student status household head also had a considerably high CHE incidence (21.36%). With the exception

TABLE 4 | Determinants of CHE, using logistic regression.

	Sig.	Exp(B)	95.C.I.	
			Lower	Upper
Income quintile				
Quintile 1 vs. 5	0.000	1.483	1.374	1.600
Quintile 2 vs. 5	0.000	1.241	1.153	1.337
Quintile 3 vs. 5	0.125	1.058	0.984	1.137
Quintile 4 vs. 5	0.008	0.907	0.844	0.974
Household size				
≤2 vs. ≥5	0.000	4.000	3.682	4.344
3–4 vs. ≥5	0.000	1.854	1.712	2.008
Region				
Central region vs. Eastern region	0.061	1.052	0.998	1.109
Western region vs. Eastern region	0.006	1.079	1.023	1.138
Rural vs. Urban	0.025	1.062	1.007	1.119
Gender of the head of household: Female vs. Male	0.000	1.200	1.138	1.264
Marital status of the head of household: Others vs. Married	0.000	1.191	1.124	1.263
Educational level of the head of household				
Illiterate vs. Technical secondary school and above	0.000	2.351	2.114	2.616
Primary school vs. Technical secondary school and above	0.000	1.779	1.616	1.957
Junior high school vs. Technical secondary school and above	0.000	1.510	1.377	1.657
Senior high school and Technical school vs. Technical secondary school and above	0.000	1.342	1.208	1.491
Employment status of the head of household				
Employed vs. unemployed or student	0.000	0.522	0.493	0.552
Retired vs. unemployed or student	0.000	0.756	0.695	0.823
Medical insurance of the head of household				
URBMI vs. UEBMI	0.000	1.293	1.171	1.427
NCMS vs. UEBMI	0.000	1.508	1.382	1.646
Integrated medical insurance vs. UEBMI	0.000	1.316	1.195	1.448
Mixed medical insurance vs. UEBMI	0.337	0.938	0.823	1.069
Other types and none vs. UEBMI	0.003	1.256	1.080	1.459
Having members aged ≥60 years: Yes vs. No	0.000	1.524	1.448	1.605
Having members aged ≤5 years: Yes vs. No	0.162	0.949	0.882	1.021
Members with chronic diseases				
0 vs. ≥2	0.000	0.509	0.473	0.548
1 vs. ≥2	0.000	0.842	0.793	0.894
Inpatients members				
0 vs. ≥2	0.000	0.123	0.111	0.136
1 vs. ≥2	0.000	0.580	0.523	0.643
Preferred institutional grade for common diseases				
Non-primary medical institution vs. primary medical institution	0.065	1.059	0.997	1.126
Whether there is a member go to clinic in 2 weeks: Yes vs. No	0.000	1.507	1.433	1.584
Members not hospitalized despite the need for it: Yes vs. No	0.000	1.757	1.625	1.899
Members not seeing a doctor despite the need for it: Yes vs. No	0.000	1.325	1.256	1.396

of groups in Quintile 1, economic groups with more than two hospitalized members had considerably high CHE risk.

Regarding the health insurance level, households with UEBMI or mixed medical insurance had a lower CHE risk than households with other insurance types. Household heads covered by URBMI with an unstable married relationship were the most vulnerable group (22.44%), followed by those who were illiterate (21.92%). For NCMS households, household heads who were unemployed or students (25.00%) ranked first, and illiterate household heads (23.57%) ranked second. For IBMIUR households, those with more than two hospitalized members had the highest CHE rate (24.46%), and the integrated insurance category shows a lower CHE rate than URBMI or NCMS; the lower rate was largely due to the lower CHE rate

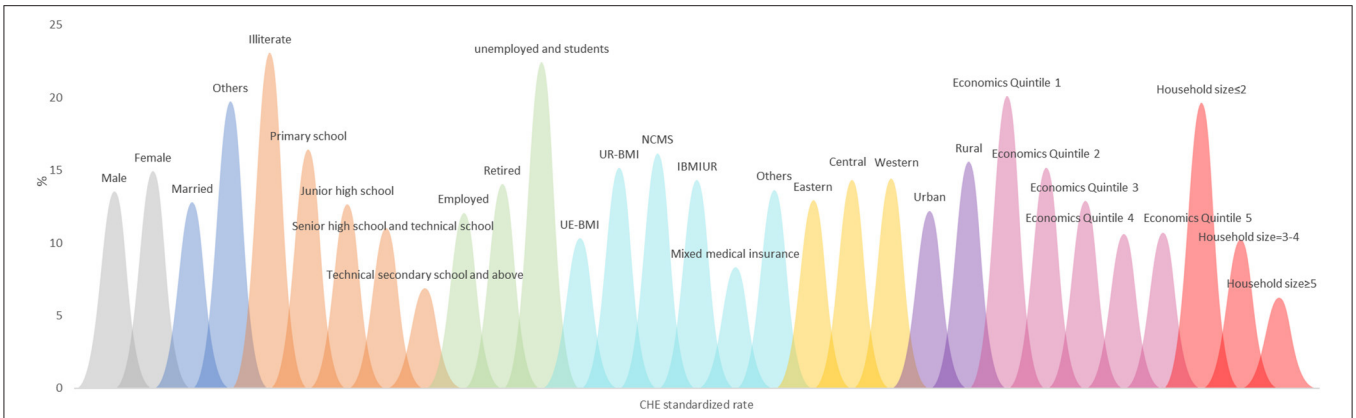

FIGURE 3 | The CHE standardized rate under the characteristics of single dimension related to demographic factors.

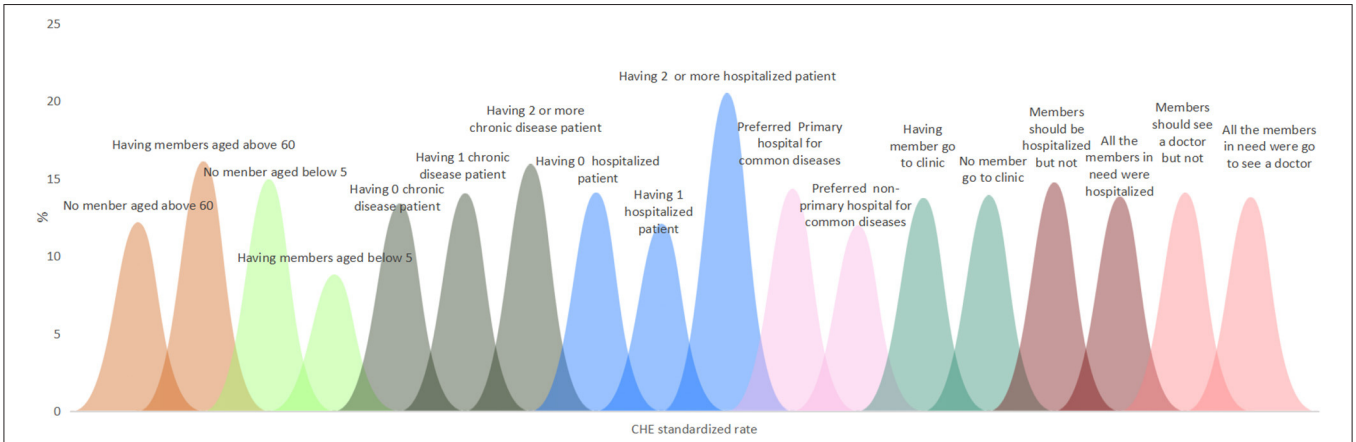

FIGURE 4 | The CHE standardized rate under the characteristics of single dimension related to health service need and utilization factors.

among urban residents, as the value among rural residents was higher. For those with other insurance types or those without medical coverage, the top two risk characteristics were having an illiterate household head (29.71%) and having more than two hospitalized members (27.51%).

Top Five Characteristics of Single or Two Dimensions in Occurring CHE

In order to determine targeted interventions, our analysis listed the top five characteristics of households with a single risk factor and two combined CHE risk factors. In the top five characteristics of households with one risk factor, we found that households whose household heads were illiterate, unemployed or students, whose number of inpatient members was no more than two occupying the top three (23.06, 22.43, 20.53%). Next were households with the poorest economic status and household heads in unstable marriages. Regarding the top five characteristics of households with two combined risk factors, those with an illiterate household head and who were covered by other health insurance types or not covered ranked first, followed by household size was no more than two, combined with the household heads, who were illiterate, and household size was no more than two and the household heads were unemployed or student status (**Table 5**).

Top 10 Diseases of Total Hospitalization Expenses of Households With CHE

This study analyzed the top 10 diseases with the highest total hospitalization expenses for households experiencing CHE. There were four diseases for which the total hospitalization expense exceeded 1,766.14 USD and the highest being 2,099.08 USD for a malignant tumor, congenital heart disease or other congenital abnormalities, and NCDIs. Notably, among the top four diseases, the number of CHE cases caused by a malignant tumor is the highest (768 households), followed by injury and poisoning (753 households) (**Table 6**).

DISCUSSION

The unrelentingly high CHE rate in China has not improved despite the efforts of the Chinese government. It is difficult

		Urban	Rural
Gender of household head	Male	11.84	14.98
	Female	12.96	18.15
Marital status of household head	Married	10.98	14.54
	Others	17.95	21.89
Educational level of household head	Illiterate	22.30	23.45
	Primary school	15.80	16.76
	Junior high school	12.31	12.94
	Senior high school and technical school	10.33	12.37
	Technical secondary school and above	6.59	8.54
Employment status of household head	Employed	9.34	13.92
	Retired	13.66	17.00
	unemployed and students	20.29	24.50
Medical insurance type of household head	UE-BMI	10.36	10.11
	UR-BMI	15.46	13.93
	NCMS	16.19	16.15
	IBMIUR	10.74	16.41
	Mixed medical insurance	6.16	11.11
	Other types and none	12.50	16.52
Region	Eastern	10.34	15.50
	Central	12.83	15.87
	Western	13.42	15.39
Economics quintile	Quintile 1	21.14	19.76
	Quintile 2	16.40	14.51
	Quintile 3	13.14	12.66
	Quintile 4	9.65	12.37
	Quintile 5	8.80	16.32
Household size	≤2	17.74	21.57
	3-4	8.55	12.10
	≥5	4.60	7.49
Households including members aged above 60	No	10.41	13.85
	Yes	14.38	17.97
Households including members aged below 5	No	13.25	16.78
	Yes	6.29	10.73
Number of patients with chronic diseases	0	11.72	14.89
	1	12.37	15.88
	≥2	13.70	19.03
Number of hospitalized members	0	12.56	15.68
	1	9.51	14.54
	≥2	20.42	20.63
Preferred institution grade for common diseases	Primary hospital	12.57	15.65
	Non-primary hospital	11.37	14.67
Whether there is a member go to clinic	No	12.32	15.56
	Yes	11.65	15.67
Members should see a doctor but not	No	12.01	15.37
	Yes	12.56	16.27
Members should be hospitalized but not	No	12.13	15.57
	Yes	13.64	15.89

FIGURE 5 | Factors affecting CHE by different locations of households.

		Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
Gender of household head	Male	19.08	14.55	12.30	10.41	10.92
	Female	23.57	17.38	14.62	11.09	10.09
Marital status of household head	Married	18.33	14.33	11.95	10.00	10.08
	Others	25.76	20.02	18.67	14.36	14.87
Educational level of household head	Illiterate	27.20	22.12	20.06	16.54	19.69
	Primary school	20.15	15.83	14.67	12.32	17.01
	Junior high school	15.79	13.52	11.51	10.69	12.46
	Senior high school and technical school	16.79	13.91	11.11	9.12	9.12
	Technical secondary school and above	13.88	8.54	8.80	7.19	5.65
Employment status of household head	Employed	17.62	13.29	10.92	8.83	8.89
	Retired	19.41	18.18	16.26	12.90	11.78
	unemployed and students	27.09	22.70	18.80	15.72	21.16
Medical insurance type of household head	UE-BMI	16.68	14.97	12.59	9.62	8.31
	UR-BMI	21.02	17.14	14.23	10.57	14.68
	NCMS	19.94	14.99	12.91	13.12	17.94
	IBMIUR	21.93	16.31	13.66	9.45	11.45
	Mixed medical insurance	16.94	10.78	9.74	6.89	5.65
	Other types and none	22.65	15.85	12.20	10.44	10.72
Region	Eastern	22.89	15.75	12.35	9.57	9.16
	Central	20.86	14.71	12.92	10.76	12.37
	Western	18.03	15.19	13.43	11.72	11.53
Location	Urban	21.14	16.40	13.14	9.65	8.80
	Rural	19.76	14.51	12.66	12.37	16.32
Household size	≤2	26.42	21.56	18.88	15.96	14.49
	3-4	14.76	12.29	9.93	7.74	7.47
	≥5	8.51	7.55	5.56	3.32	5.91
Households including members aged above 60	No	16.51	14.09	12.05	9.63	9.77
	Yes	22.97	16.69	14.13	11.99	12.12
Households including members aged below 5	No	21.81	16.43	14.03	11.47	11.28
	Yes	11.59	10.48	8.23	6.10	6.90
Number of patients with chronic diseases	0	19.36	14.28	12.25	10.15	10.45
	1	20.19	15.50	13.28	10.61	10.79
	≥2	24.44	19.77	15.13	12.58	11.29
Number of hospitalized members	0	21.44	15.70	12.80	10.56	9.26
	1	12.88	11.73	12.07	9.31	14.24
	≥2	12.75	22.12	21.90	22.11	20.57
Preferred institution grade for common diseases	Primary hospital	20.14	15.01	12.59	10.53	11.62
	Non-primary hospital	19.56	16.68	14.48	10.77	9.00
Whether there is a member go to clinic	No	20.07	15.41	12.78	10.70	10.62
	Yes	20.28	14.27	13.35	10.11	10.94
Members should see a doctor but not	No	19.76	14.49	12.84	10.51	10.52
	Yes	21.23	17.22	13.01	10.77	10.99
Members should be hospitalized but not	No	20.14	15.02	12.93	10.53	10.68
	Yes	19.48	18.63	12.15	12.06	10.74

FIGURE 6 | The CHE standardized rate by different economic quintile groups.

		Eastern	Central	Western
Gender of household head	Male	12.61	13.86	14.15
	Female	13.82	15.81	15.14
Marital status of household head	Married	11.77	13.30	13.31
	Others	18.80	20.26	20.14
Educational level of household head	Illiterate	24.60	23.72	21.53
	Primary school	16.69	16.39	16.20
	Junior high school	11.57	13.39	13.09
	Senior high school and technical school	9.48	11.86	11.94
	Technical secondary school and above	5.71	7.61	7.35
Employment status of household head	Employed	10.67	12.28	13.05
	Retired	12.31	14.44	16.54
	unemployed and students	23.36	22.81	20.78
Medical insurance type of household head	UE-BMI	9.71	10.71	10.80
	UR-BMI	12.23	17.30	15.28
	NCMS	17.12	16.52	15.26
	IBMIUR	12.87	11.95	18.16
	Mixed medical insurance	8.44	7.30	9.02
	Other types and none	14.31	13.35	13.35
Location	Urban	10.34	12.83	13.42
	Rural	15.50	15.87	15.39
Economics quintile	Quintile 1	22.89	20.86	18.03
	Quintile 2	15.75	14.71	15.19
	Quintile 3	12.35	12.92	13.43
	Quintile 4	9.57	10.76	11.72
	Quintile 5	9.16	12.37	11.53
Household size	≤2	18.98	20.10	19.90
	3-4	8.98	10.23	11.46
	≥5	4.29	7.05	7.40
Households including members aged above 60	No	10.99	12.52	12.89
	Yes	15.10	16.80	16.57
Households including members aged below 5	No	13.97	15.50	15.45
	Yes	7.20	9.05	9.91
Number of patients with chronic diseases	0	12.18	13.75	14.10
	1	13.81	14.19	14.21
	≥2	13.52	17.96	16.89
Number of hospitalized members	0	12.72	14.68	15.00
	1	13.04	12.34	11.05
	≥2	22.10	18.68	21.15
Preferred institution grade for common diseases	Primary hospital	13.48	14.69	14.85
	Non-primary hospital	10.55	12.91	12.48
Whether there is a member go to clinic	No	13.20	14.01	14.53
	Yes	11.93	15.99	13.91
Members should see a doctor but not	No	12.52	14.42	14.35
	Yes	13.68	14.18	14.57
Members should be hospitalized but not	No	12.81	14.29	14.48
	Yes	16.23	15.58	13.06

FIGURE 7 | The CHE standardized rate by different areas.

		UE-BMI	UR-BMI	NCMS	IBMIUR	Mixed medical insurance	Other types and none
Gender of household head	Male	10.10	13.30	15.70	13.73	8.36	13.30
	Female	10.86	17.62	17.99	16.46	8.12	14.43
Marital status of household head	Married	9.32	12.95	15.17	13.09	7.85	11.93
	Others	15.28	22.44	22.11	20.62	12.93	19.67
Educational level of the head of household	Illiterate	18.84	21.92	23.57	23.16	19.60	29.71
	Primary school	14.06	16.85	16.93	16.44	13.55	15.96
	Junior high school	12.13	14.24	13.56	10.78	8.47	12.22
	Senior high school and technical school	10.05	12.86	13.01	8.78	8.55	11.82
	Technical secondary school and above	6.73	11.02	9.83	5.91	2.84	9.78
Employment status of the head of household	Employed	5.68	10.36	14.45	12.68	7.70	10.44
	Retired	13.68	17.28	19.68	12.17	8.85	18.17
	unemployed and students	17.26	20.37	25.00	20.84	14.65	19.33
Region	Eastern	9.71	12.23	17.12	12.87	8.44	14.31
	Central	10.71	17.30	16.52	11.95	7.30	13.35
	Western	10.80	15.28	15.26	18.16	9.02	13.35
Location	Urban	10.36	15.46	16.19	10.74	6.16	12.50
	Rural	10.11	13.93	16.15	16.41	11.14	16.52
Economics quintile	Quintile 1	16.68	21.02	19.94	21.93	16.94	22.65
	Quintile 2	14.97	17.14	14.99	16.31	10.78	15.85
	Quintile 3	12.59	14.23	12.91	13.66	9.74	12.20
	Quintile 4	9.62	10.57	13.12	9.45	6.89	10.44
	Quintile 5	8.31	14.68	17.94	11.45	5.65	10.72
Household size	≤2	14.99	20.85	22.69	21.56	13.30	18.42
	3-4	6.36	11.96	12.57	10.75	5.54	10.80
	≥5	2.42	4.84	8.28	4.97	2.39	3.88
Households including members aged above 60	No	7.88	14.00	14.28	12.61	8.23	11.62
	Yes	12.60	16.77	18.84	16.40	8.50	18.25
Households including members aged below 5	No	11.18	16.35	17.58	15.61	9.16	15.05
	Yes	3.36	8.32	10.92	8.77	4.16	6.83
Number of patients with chronic diseases	0	9.61	14.41	15.31	13.84	8.44	12.96
	1	10.46	16.11	16.50	14.97	8.22	13.13
	≥2	12.14	16.36	20.83	14.95	7.76	21.43
Number of hospitalized members	0	10.77	14.62	16.45	14.23	8.71	14.13
	1	7.47	17.69	14.22	13.67	5.52	9.37
	≥2	18.32	19.13	21.04	24.46	15.83	27.51
Preferred institution grade for common diseases	Primary hospital	10.25	14.45	16.13	14.51	9.14	14.38
	Non-primary hospital	10.44	16.78	16.65	13.28	5.56	12.15
Whether there is a member go to clinic	No	10.45	15.37	16.05	14.78	9.19	13.49
	Yes	9.73	14.21	16.58	12.95	4.65	14.59
Members should see a doctor but not	No	10.04	14.40	15.97	13.57	8.35	12.99
	Yes	10.77	16.84	16.83	15.99	8.18	15.53
Members should be hospitalized but not	No	10.32	15.08	16.15	14.27	8.45	13.17
	Yes	10.74	17.03	16.29	16.32	4.49	23.99

FIGURE 8 | The CHE standardized rate by different health insurance systems. IBMIUR: Integration insurance refers to other basic medical insurance types, which integrate either URBMI and NCMS or UEBMI, URBMI, and NCMS. Mixture medical insurance: It refers to participants covered by basic medical insurance and commercial insurance at the same time.

TABLE 5 | Top 5 family characteristics related to CHE with a single risk factor and two combined CHE risk factors.

Order	Top five types of families with one risk factor	CHE standardized rate (%)
1	Illiterate household head	23.06
2	Household head with unemployed and student status	22.43
3	Household with 2 or more hospitalized members	20.53
4	Poorest households	20.11
5	Household head with unstable marriage	19.72
Order	**Top five types with two combined risk factors**	**CHE standardized rate (%)**
1	Illiterate household head covered by other health insurance types or not covered	29.71
2	Household size was no more than 2 and the household head was illiterate	29.59
3	Household size was no more than 2 and the household head was unemployed or a student	29.25
4	Household with more than two inpatient members and the household size was no more than 2	28.76
5	Household head was illiterate, unemployed, or a student or household had more than 2 inpatient members and an unemployed or student household head	27.92

to achieve the expected effect by increasing welfare and compensation policies indiscriminately, without considering population targeting. This study estimated the CHE rate at the geographic levels (national, regional, and provincial), in addition, exploring factors related to demography, disease, health service need, and utilization to delineate the key risks and vulnerable populations that would help develop dynamic and effective responses aimed at those families experiencing CHE. The analysis shows that the total CHE rate in 2013 (13.9%) was 6.92% higher than that of the previous NHSS in 2008; however, the growth rate was lower than that between 2003 and 2008. Households located in rural areas, in the western region, with members who are NCMS participants, with members over the age of 60, with a female household head or a household head, with low socioeconomic status or unstable married relationship, and with smaller household size, more hospitalization, outpatient, and NCD members were more vulnerable to CHE. In the ranking of single risk factors for CHE, the top five factors leading to the highest CHE incidence were primarily concentrated in households with low socioeconomic status or having more than two inpatient members. Meanwhile, in the overlapping risk factors for CHE, the combination of having illiterate household heads and being covered by other health insurance plans or by none ranked the first.

Compared with other developing countries, the CHE incidence rate in China is relatively high (31). A series of estimates from other countries around 2013 applied 40% as the CHE threshold and found that the CHE incidences of Mongolia and Kenya were lower than that of China, at 1.1% (31) and 4.52% (32), respectively; meanwhile, CHE incidence of Nepal is similar to that of China at 13.8% (33), while that of India is higher than that of China at 18.2% (34).

The increasing economic burden was attributed to several aspects; on the one hand, the aging population and its health service needs, especially the prevalence of chronic NCDs, increased rapidly, leading to a rapid growth of health expenditure (35). On the other hand, the improvement of economic status, the development of medical technology, and the universal coverage of the medical insurance system promoted the utilization of health services. In our study, the hospitalization rate rose to 9%, and the proportion of people giving up treatment or hospitalization for financial reasons decreased to 7.6 and 7.4%, respectively. In the case of surging health service needs, health insurance, in turn, largely stimulated the utilization of health services, thereby leading to higher CHE (which occurs when health insurance does not provide adequate financial protection). Thus, the improvement of the benefits package, reasonable reimbursement standard setting, and effective payment mechanism to control health expenditure were especially crucial to alleviate the risk of CHE and achieve UHC. This study aimed to identify the vulnerable groups and provide targetable strategies that should be prioritized. The study conducted an analysis of the characteristics of multiple vulnerable groups across the following levels.

TABLE 6 | Top 10 diseases with the highest total hospitalization expenses of households with CHE.

Order	Disease	Number (households)	Total hospitalization expenses (USD)
1	Malignant tumor	768	2,099.08
2	Congenital heart disease or other congenital abnormalities	18	2,099.08
3	Benign tumor, tumor *in situ*	204	1,776.14
4	Injury and poisoning	753	1,776.14
5	Urogenital system disease	516	1,291.74
6	Mental disease	60	1,178.71
7	Infectious disease	101	1,130.27
8	Disease of blood and blood forming organ	74	1,130.27
9	Neurological disease	174	1,114.13
10	Other diseases	146	1,106.05

USD, United States dollar, according to the exchange rate of 6.1932 yuan to USD 1.00.

Households Located in the Western Region, Living in the Rural Areas, Were More Easily to Drop Into CHE, the High CHE Rate, Owing to Overutilization in Developed Regions Should Be Paid More Attention

From the perspective of the region, the central and western regions had higher CHE incidence risk than the eastern region, with 13.4 and 13.3%, respectively. It is worth noting that, in the case of no statistical difference between the central and western regions on the CHE rate, the hospitalization rate in the central region (8%) is lower than that in the western region (8.6%), but the average hospitalization expenses were higher in the central region (**Supplementary Material 1**) (26). This illustrates the regional differences in the design of medical insurance schemes lead to different patterns of an economic burden. Through the analysis of CHE proportion in 31 provinces distributed in the eastern, western, and central regions, we found that the CHE rate of most provinces in the eastern region was below the national average and was also generally lower than that of the central and western regions, reflecting that a better economic level contributed to resisting CHE. However, another finding indicated that there exist some eastern provinces with high GDP *per capita* with considerably high CHE rates, such as Beijing, Shanghai, and Tianjin Province, revealing that, when the economic development reaches a certain extent, it results in higher CHE incidence instead, owing to utilization (or even overutilization) of health services. Moreover, a high degree of a gap in financial protection between rural and urban residents still exists. Our study shows that the CHE rate in rural areas is associated with a higher CHE proportion, and rural residents had 1.062 times higher risk than urban residents. Another study also confirmed that the residents in rural areas suffered a greater financial burden from health expenditures; the percentage was 2.4 times higher than that of the urban residents in 2013 (36).

Households With Smaller Household Size and Unstable Married Relationships Were Vulnerable; Medical and Nursing Services for the Older People Would Increase Several Times Risk of CHE for Their Families

Our study shows that the larger the household size was, the lower the possibility of CHE risk was; the likelihood of experiencing CHE in the households with less than two members was ∼4 times compared with the households with more than five members. More family members implies better risk-sharing ability and more working members entering the labor market, and, in turn, this reduces the risk of the household experiencing CHE. A recent study shows that, as the number of household members increases, the risk of impoverishment by medical expenses is reduced by 1.5% points (37). At the same time, we found that marriage is a protective factor, illustrating that existence of stable married relationships in a household is more conducive to reducing the possibility of CHE. The results also indicated a significantly higher probable connection between CHE incidence and households with older adults (OR = 1.524, 95% CI = 1.448–1.605), as reported in other studies in China (17, 22, 38); this is consistent with the results reported by Yardim et al. in Turkey (39) and Kavosi et al. in Iran (40). The reasons for high medical expenses among older adults were listed as follows: first, most older people suffer from NCDs of varying degrees; however, health services and drugs covered by health insurance policies for NCD in clinics were limited (41); thus, they either paid high proportion OOP spending for it or seeking inpatient service, which need not have been carried out, just for reimbursement (42, 43). In addition, during a period of recuperation or self-treatment at home, self-purchased drugs from drugstores are a crucial support for older people. As such purchases were made outside medical institutions, most families covered by insurance other than UEBMI have to bear this part of the high costs alone. Outside medical services, additional nursing expenditures for older adults are also a considerable economic burden, and this is an increasing problem for vulnerable households supporting older adults in China (44). In fact, these costs do not belong to the scale of OOP; thus, the financial risk of households with elderly members was conservatively undervalued in our study. Although the Chinese government has established long-term insurance for those with care needs, the scope of policy implementation is limited to pilot areas, and the policy remains in the pilot stage. Similar in many ways to China, Kenya has also established supplementary insurance to better economically protect the elderly, although this coverage is relatively limited (45). A previous study on calculating a long-term insurance pilot indicated that implementing long-term care insurance may effectively reduce hospitalization and outpatient expenses. Thus, pilot projects should be accelerated and extended to the whole population as soon as possible.

Meanwhile, we must seriously consider the aging population, the level of aging, until this study was conducted, had reached 202 million, and the number is projected to double by 2040 (343.8 million) (46, 47). It is estimated that the healthcare expenditure for Chinese older adults will almost double over the next three decades, which will be up to 263 billion CNY in 2050 (48). Thus, the strategic and tactical reserve for dealing with the aging society should be completed in this period. On one hand, we should implement a positive population policy, promoting relevant economic and social policies to match the current fertility policy to delay the aging process, and, on the other hand, we must strengthen the health management for older adults by establishing health records and providing free physical examination every year to control or delay the development of diseases.

Households With Lowest Capacity to Pay Should Be Provided More Powerful Financial Protection in Medical Health Insurance; A Longer-Term Approach Is Improving the Education Level of the Disadvantaged Families

We found that superior socioeconomic status (a higher household economic level, a higher education level of a household head, and employed status of household heads) could

reduce the odds of experiencing CHE and *vice versa*, which has been comprehensively prove in many studies (17, 22). Our study notably found that only the poorest (OR = 1.483) and the sub-poorest (OR = 1.241) groups show significantly higher risk than the richest, while some previous studies from low- and middle-income countries show a different association between CHE risk and economic status. In India, the poorest households tend to forgo healthcare that might bring them financial hardship, and, thus, relatively poor households are associated with a higher incidence of CHE (33). In Thailand, essential health services are sufficiently covered by social insurance, and the utilization of private high-level health services, resulting in the high CHE rate is more likely to occur in high income populations (49, 50). On the contrary, in China, there is an established health insurance system, covering more than 95% of the population. Health service access, especially among the low-income group, has greatly improved; however, the reimbursement rate is not sufficiently high to protect people from high OOP payments for essential health services (17). In this context, the participants did not have to forgo healthcare services, but as the reimbursement rates of their insurance systems were not sufficient, the lower-income groups were more likely to be associated with a higher incidence of CHE.

In addition, we found that households with household heads who were illiterate or unemployed or students always ranked the highest in each level. This illustrated that, although providing subsidies could alleviate temporary poverty, long-term and radical planning should pay more attention on improving education or providing better employment opportunities, as it is the only way to hinder the intergenerational transmission of poverty (51).

Households Covered by NCMS Had the Highest CHE Risk; the Integration Reform of Basic Health Insurance Was Conducive to Improve Its Financial Protection

Our study shows that in all medical insurance types—URBMI, NCMS, and integrated insurance—the participants show higher CHE incidence than UEBMI, which are 1.1, 1.2, and 1.0 times higher, respectively, than the national level. The participants of NCMS were the most vulnerable, followed by those covered under URBMI, while the integrated insurance participants show a lower rate than those of URBMI or NCMS, indicating that the integrated social health system was probably conducive to provide more financial protection to the beneficiary. However, the integrated insurance participants do not seem to show greater advantages in terms of reducing CHE risk as expected. As of this study, a few districts in China pioneered the integration of the rural and urban schemes and, in an even smaller number of districts (Dongguan and Zhongshan), directly merged the UEBMI, URBMI, and NCMS (52).

Meanwhile, we found that the integrated reform only benefited urban residents, whereas the CHE occurrence among rural residents under integrated insurance is higher than non-integrated insurance. Several studies also proved that, under the integrated insurance, the urban and rural participants experience a larger gap in financial protection (53, 54), and the disparity was caused by a lack of consideration for the propensity of rural residents in medical insurance financing and health service utilization.

Under the integrated insurance, former fixed-point medical institutions were unified under a bigger management scope, and, hence, improvement in convenient off-site medical billing of integrated insurance may increase cases of rural patients going to urban hospitals. Increasing hospitalization rates in tertiary medical institutions and decreasing hospitalization rates in primary and secondary institutions were witnessed in western China after integration, which supports the findings of this study (55). Furthermore, high-quality medical resources are mostly concentrated in urban areas (56, 57), even as rural residents are prompted to use health services and, therefore, enormously increase their medical costs. Among the nationwide financing modes of integrated insurance, most of them have not transformed several financing levels to only one financing level. The problem with setting several financing levels is that rural residents tend to choose a lower financing level, whether limited by income or influenced by past habits (58, 59). However, urban residents tended to receive more health services and enjoy better welfare. This leads to a reverse subsidy (60, 61) and, thus, results in a new inequality. Therefore, in areas with a large gap in urban and rural economic development, the financing subsidy should be provided for rural residents.

Strengthen Financial Protection for Cancer Patients and Ensure Insurance Coverage of Commonly Used Anticancer Drugs and Their Accessibility

Demand and utilization of health services were the necessary conditions for health expenditure. Our results indicated that households with NCD members faced a higher CHE risk. Our analysis of the top 10 diseases for which people in households with CHE were hospitalized revealed that the households with members with a malignant tumor or congenital heart disease or other congenital abnormalities suffered the highest expenses (2,099.08 USD); however, the majority of households (768) experienced CHE due to a malignant tumor. Malignant tumors were found to be a huge challenge not only because they can be life-threatening but also because they have high likelihood of leading to CHE (62). A calculation of cancer costs in different countries shows that, in the US, the proportion of household expenses for cancer patients was only 20.9%, while in China it was as high as 78.8% (63). Many anticancer drugs were not covered in the reimbursement scope or the reimbursement ratio was not so high, and these were the main reasons for high medical costs. Since 2018, the Chinese government has gradually included anticancer drugs in its medical insurance catalog through negotiation; however, barriers related to anticancer drugs arriving at hospitals remain and must be overcome to solve the imbalance in the demand and supply of drugs (64) and enable patients to enjoy the benefits of the policy. Meanwhile, support for chronic disease prevention and cancer screening must also be strengthened.

Pay More Attention to Households With Several Patients and Remove the Obstacles to Treatment Delay

Several previous studies have shown that having inpatient or outpatient members in the household increased the probability of CHE (65). In our result, having more than two hospitalized members was the highest CHE risk factor of the health service and utilization factors. It is necessary to establish a family-based identification mechanism for vulnerable groups in the medical system and provide targeted additional fee relief or subsidies for them.

A surprising finding was that household members who should see a doctor or be hospitalized but had not done so experienced 1.757- or 1.325-times higher risk, respectively, compared with the reference group. One possible explanation was that, because of forgoing medical services that they should have been received, the treatment opportunity was greatly delayed, thereby increasing future medical expenses. Although the value in 2013 is much lower compared with the last survey in 2008, the proportion of those not hospitalized due to financial reasons reached nearly 50% (**Supplementary Material 2**). Thus, the government should make efforts to ensure that all the poverty groups are covered by basic and catastrophic health insurance schemes, appropriately decrease the deductible, increase the cap on hospitalization reimbursement expenses, and increase the reimbursement proportion within the policy scope. Furthermore, the government should take steps to enhance medical assistance to the poverty groups, such as decreasing the thresholds of medical assistance and expanding the medical assistance benefits scope (66). It is necessary to strengthen their regular monitoring to prevent them from returning to poverty.

Priority Intervention Targets and Suggestions

The analysis of characteristics of households with single dimension risk factors for CHE showed that families with factors related to low socioeconomic status ranked a high place; households with more than 2 hospitalized members and those with unstable marriages were also among the top five characteristics. Therefore, these three categories of vulnerable groups in the low socioeconomic-status group are primary concerns. High costs of hospitalization are mainly due to excessive medical treatment and unreasonable hospitalization behavior (24). Thus, measures should be taken for reforming payment mechanism and improving the medical insurance policy for out-patient care to control hospitalization payments, especially for NCDs. Increasing investment in prevention of NCDs and management of NCD patients should also be seriously considered. It is difficult for households with an unemployed household head to resist the risk of CHE, and, thus, policy support is crucial for them. When two risk factors—illiterate household head and lack of health insurance—are combined, the CHE incidence increased to nearly 30%. This is followed by the combinations of household size $\leq$2 and illiterate household head, household size $\leq$2 and employed household head. The disadvantaged groups tend to have multiple vulnerabilities. Identifying the groups with multiple vulnerabilities and taking relevant measures would be an ideal approach to address the persistently high CHE rate. However, capturing the groups with multiple vulnerabilities depends on the degree of realization of household information as well as filing and data sharing among different departments at the national level.

The disadvantaged groups tend to have multiple vulnerabilities. Identifying the groups with multiple vulnerabilities and taking relevant multifaceted measures would constitute an approach to address the high CHE rate, which has been high for a long time. However, capturing the groups with multiple vulnerabilities was up to the realization degree of information filing and data sharing of households among different departments at the national level to a large extent.

The study had two distinctive strengths. First, the data used in this study were obtained from a nationally representative survey organized by the Chinese government. This survey, which included a large-scale sample undertaken with a multistage, stratified random sampling method, reflects the situation of CHE incidence and expenditure accurately. Additionally,we conducted a standardized calculation on the CHE rate under single dimension and two dimensions risk characteristics of Chinese households. The metrics for healthcare needs and service utilization and population structure of a family were standardized in the comparative analysis of the incidence of CHE across 31 provinces, a single-dimension factor, and two-dimension factors. There were also several limitations in our study. First, this was a cross-sectional study; thus, the causal relationship between predictors and CHE is not reflected. Second, the data were self-reported by the respondents, and there may be recall bias in the responses. Third, owing to some respondents being unable to afford health service payment, it might lead to the underestimation of CHE to some extent. Fourth, the data used in this study have their limitation as they restrict this study before 2013, owing to the lack of data availability after that. Fifth, the CHE rate was estimated, using only the ATP approach with the threshold of 40%. Using the definition of 10% of an income (or its proxies) threshold as the SDG use would be more comprehensive.

CONCLUSIONS

This study investigated and identified the high CHE incidence group from the perspective of the region, family structure, socioeconomic status, medical insurance, and needs and utilization of health services. We found that from 2003 to 2013, the CHE incidence shows a general trend of growth over time and the incidence in 2013 was also higher than most developing countries. Households located in western regions and rural areas were more vulnerable, and several provinces located in the eastern regions also had a considerably high CHE incidence, owing to overutilization. Households with smaller size, lower socioeconomic status, unstable married relationship of household heads or members aged over 60 had higher CHE risk. Household heads covered by NCMS had the highest risk

of CHE, and, while the integrated insurance was conducive to provide more financial protection, it performed worse among rural residents. Households with more NCD members or inpatient members had higher CHE risk. And, among these types of NCDs, the number of families with CHE due to cancer was the largest, and their total medical expenditure is the highest. Households with hospitalized members or with members not seeing a doctor /hospitalized despite the need for it increased the likelihood of CHE. Households with characteristics related to low socioeconomic status, having more than two hospitalized family members, were the most vulnerable groups that need immediate attention. When the factor of having more than two inpatient members combined with the characteristics related to low socioeconomic status, household size $\leq$ 2, the CHE rate of these families increased dramatically. Those household heads with characteristics of multiple vulnerabilities should be the priority intervention target, and related stakeholders should cooperate to establish a family information sharing platform and intervene in the issue based on cooperation.

DATA AVAILABILITY STATEMENT

The data analyzed in this study is subject to the following licenses/restrictions: Datasets used in this study are available from Centre of Health Statistics and Information, National Health Commission of the People's Republic of China. The data are not publicly available due to the confidential policy. Requests to access these datasets should be directed to the website of National Health Commission of the People's Republic of China: http://www.nhc.gov.cn/.

ETHICS STATEMENT

The study involving human participants were reviewed and approved by ethics clearance was obtained from the Medical Ethics Committee at Harbin Medical University. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

JW, XT, and QW designed the study. LS contributed to data processing. JW, XQ, and HL contributed to result analysis. JW and XT drafted the manuscript. XZ, KW, SJ, QX, NM, and PC assisted with the collecting literature and providing suggestions for this manuscript. QW, YL, and ZK revised the paper. DA and BI provide great help with providing suggestions and collecting the literature during the revision. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.689809/full#supplementary-material

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Reimagining Innovation Amid the COVID-19 Pandemic: Insights From the WISH Innovation Programme

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The World Innovation Summit for Health (WISH) hosts two innovation competitions as part of its biennial healthcare conference. During the COVID-19 pandemic, WISH received more than 350 applications for both competitions, of which 31 were shortlisted to showcase at the WISH 2020 virtual summit. Of the 31 showcasing innovations, 11 (35.5%) had suggested an alternative use to their innovation as a contribution to the global fight against COVID-19. As such, this article explores the apparent and urgent need for the repurposing of healthcare innovations to reduce the costs and time associated with the conventional approach, in order to best respond to the demands of the global pandemic.

Keywords: innovation, healthcare innovation, cost efficiency, public health, competition

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INTRODUCTION

The world is currently facing one of the greatest social and economic challenges since World War II (1). The key to overcoming the COVID-19 pandemic lies in finding innovative and effective treatments for the disease, further emphasizing the need for an outside-in approach to healthcare innovation (2). The lengthy, conventional path to the diffusion of innovation has been complemented, and in some cases replaced, with an ultrafast approach that focuses on the repurposing of knowledge, ideas, and available technologies in order to provide rapid solutions to the crises at hand (3). In this context, we explore how existing startups and ventures have responded to the lack of available resources and increased pressure on healthcare systems worldwide by reimagining their initial purpose to navigate COVID-19. Through the thorough examination of applications received and shortlisted for the World Innovation Summit for Health (WISH) Innovation Programme, we consider the innovative technologies that have evolved to react efficiently and effectively to this global health emergency.

WISH INNOVATION PROGRAMME

About WISH

WISH is a biennial global gathering of healthcare leaders, policy makers, academics, and innovators based in Doha, Qatar, and charged with building a healthier world through global collaboration. As well as presenting panel discussions and presentations, WISH commissions and undertakes

research and also offers a platform for showcasing innovation in health. At the core of the aim of showing health innovation are two innovation competitions, open to entrepreneurs toward the start of their product development journey.

WISH Innovation Competition 2020

In March 2020, days before the coronavirus outbreak was declared a pandemic by the World Health Organization (WHO), WISH launched two rebranded healthcare innovation competitions: the "Spark Competition" and "Booster Competition." These competitions provided talented and striving entrepreneurs with a platform to promote ideas and products aimed at improving the delivery and quality of healthcare. Applications to the competitions remained open until July 31, 2020.

The WISH Innovation Spark Competition was aimed at entrepreneurs who were seeking to solve healthcare challenges by developing and validating a scalable project. These were typically early-stage innovations or startups. The WISH Innovation Booster Competition was aimed at already existing healthcare solutions with innovators that were looking to scale up and grow. The competitions were open to local and international applicants, aligning with WISH's mission to build a healthier world through global collaboration. Successful applicants for both competitions were required to meet certain criteria, such as an evidence-based market need for the proposed innovation, and demonstrated potential for sustainable future growth.

The panel of judges included healthcare innovation experts, investors, innovation hub representatives, and scientists.

Among its local partners are Qatar Foundation's Qatar Science and Technology Park, Hamad Bin Khalifa University Innovation Center, Qatar Business Incubation Center founded by Qatar Development Bank and Qatar Research, Development and Innovation Council. Global hubs include the United Kingdom–based BMJ New Ventures; the HAG Group, a Brazilian innovation center; Portuguese innovation center Beta-I; and The Helix Centre in the United Kingdom.

METHODS

We examined the applications received for the WISH Innovation Programme to identify which of the applicants had suggested an alternative use of their innovation for COVID-19 diagnosis or treatment of symptoms. This involved the sorting and filtering of applications through the report function of Apply by SurveyMonkey, exporting this to Microsoft Excel and filtering again manually by mention of "COVID." Upon detailed review, two innovations were excluded as the applicant had not mentioned an alternative use or potential use of the product for COVID-19. Ten innovations that were created for the sole purpose of COVID-19 were also excluded so as to focus on the theme of innovative repurposing. For the purpose of this article, only the shortlisted innovations showcased at WISH and that had highlighted and provided evidence for a potential use for COVID-19 either through the online application portal or through personal communication after the summit were considered.

RESULTS

A total of 350 applications were received via the application portal and through email communication. Of those 350, 49 (14%) had suggested a potential for use for COVID-19. Of the 31 innovations that were shortlisted to showcase at WISH 2020, 11 (35.5%) had reported an alternative potential use for COVID-19. The innovations were split into six different categories based on type, function, and mode of care or service delivery. These categories included artificial intelligence (AI) solutions, digital/app-based solutions, medical/scientific equipment, community-based/social solutions, education and training, and telemedicine. **Table 1** lists and describes these innovations in some detail and explores their original function or purpose, and how they were repurposed or could potentially be repurposed, to provide solutions to different aspects of the COVID-19 pandemic. Webpage links have been provided for each of the innovations for more information.

The most common category or field of innovations and technological solutions to suggest an alternative use for COVID-19 was AI, where 4 of the total 11 listed innovations were AI-based. The second most common category was medical/scientific equipment (3 of 11), with the remaining four categories including one innovation each.

DISCUSSION

The COVID-19 pandemic is the first coronavirus pandemic to have a global effect (4). The novelty, speed, and severity of the virus, along with the lack of time and resources available for an effective and timely response, have all been contributing factors behind the race to find innovative therapies and technologies that not only improve health outcomes, but also soften the social and economic impacts of the pandemic. COVID-19 has also revolutionized the way in which solutions are found, developed, and deployed, redefining what it means to innovate. The conventional approach of extensive testing and trialing of new technologies, drugs, and processes has been replaced with a more "frugal" and efficient response that is focused on repurposing technologies and ideas that already exist (2, 3).

This has been evident in the outcome of the WISH innovation competitions whereby more than a third of the shortlisted applicants have demonstrated potential for their innovation to be used in the fight against the COVID-19 pandemic. This reemphasizes the notion that solutions to some complex problems may arise from rather unconventional sources—especially in the middle of a global crisis. Given the size of the crisis at hand, it is imperative that we remove regulatory barriers and facilitate this cost-effective and timesaving approach to healthcare delivery. In order to encourage this, an open innovation culture must be adopted whereby the innovation process involves purposive knowledge flow between organizational boundaries (5).

TABLE 1 | Shortlisted innovations and their potential to help with COVID-19 pandemic.

Name of innovation	Description of its main purpose	COVID-19 implication
Artificial intelligence		
Kalya™	Kalya is an artificial intelligence solution focused on non-pharmacological interventions such as physical interventions, psychological interventions, nutritional Interventions, and digital interventions. This helps address the major health challenges of today and tomorrow (cancer, diabetes, aging, strengthening the immune system, lifestyle). Kalya's expertise enables the design of dedicated digital solutions from the indexing of scientific literature to the exploration and analysis of data to support the decisions of health professionals.	Complementary, non-pharmacological interventions provided digitally are extremely relevant in the treatment context of COVID-19. Especially as the availability of new research findings on interventions for COVID-19 is being updated almost daily, Kalya can help use these new emerging data to help support the decisions of frontline workers—saving them time and providing the patients with the best possible care.
iLoF™: cloud-based library of disease biomarkers and biological profiles	iLoF is a cloud-based library of disease biomarkers and biological profiles based in Oxford, United Kingdom. It uses AI and photonics to build a cloud-based library of diseases and their biomarkers and biological profiled to drastically reduce the cost and time of drug discovery and drug repurposing. Supported by the University of Oxford and Microsoft Ventures, iLoF is being used to find solutions for one of the biggest epidemics of our time, Alzheimer disease. It is also being used to find potential treatments for digestive cancers, stroke, and infectious diseases.	An indicated alternative potential use for iLoF is that it can be used to generate clinical output, operating as a forecast tool that predicts the severity of symptoms for COVID-19 patients.
Botkin™	Botkin.AI is a software platform based on artificial intelligence technologies for the analysis of different types of radiological studies. Main purposes include early detection of lung malignant neoplasms, early detection of breast cancer, detection of lung non-oncological pathologies (tuberculosis, pneumonia, etc.), and COVID-19 detection. Botkin.AI has commercial and pilot integrations in four countries and possesses the best result in terms of lung oncology detection in the world.	Botkin can be used for detection of COVID-19 through radiological analysis. Botkin.ai's X-Ray Analysis function is intended to provide assistance to a radiologist in order to help find pathological changes in chest x-rays. Early detection of medically actionable pathological changes can potentially lead to early hospitalization and treatment and, in turn, a decrease in mortality rate.
Pandexit™	Pandexit is a software that uses an algorithm to predict the evolution of any pandemic weeks in advance. The revolutionary algorithm is used to build a high-granularity model of any pandemic for an entire country. The software then generates the policies needed to fight and end the pandemic, both saving lives and protecting the economy.	Pandexit has successfully been deployed in three countries; it has been used by the special teams in charge of fighting the COVID 19 pandemic to simulate scenarios, model a number of policies, discover their effects on the spread of the pandemic inside the population, and select the most efficient way to save lives and limit the damages to the economy. At the vaccine rollout stage of the pandemic, Pandexit allows the decision makers to model an increasing number of vaccinated people in specific categories of the population and take new variables of the virus into account. Pandexit models are increasingly accurate due to the emerging data on COVID-19 and its variants. It can evaluate the efficiency of an implemented curfew and a lockdown and can predict and recommend the exact number of days needed to reach a specific target.
Digital/app-based		
Dorothy.app™	Dorothy.app is a monitoring system created for dementia patients. Dorothy.app transforms a standard walker into an augmented reality-based navigation assistant for those with dementia using a tablet computer. It allows family to both communicate with and remotely check the well-being of their loved one. Dorothy transmits real-time location data to family members allowing easy communication, maximizing social networks, and care collaboration. It can detect deterioration in general health.	Dorothy increases the independence of those with dementia while also being able to revolutionize how support and monitoring are delivered. It also supports the "recovery" phase of the COVID-19 response, particularly in often quarantined facilities. As language is also often impaired, the telemetry data can initially inform family and clinicians about activity and provide alerts when changes in such data suggest an deterioration in general health allowing for more holistic remote care.
Medical/scientific equipment		
AMSU™: The Airway Medical Suction Unit	AMSU looks like a sports bottle. It incorporates a Venturi that turns positive pressure from a small can of chlorofluorocarbon-friendly gas into negative pressure (suction). Through careful selection of gas (positive) pressure and Venturi size, it is possible to incorporate an effective laryngeal suction device into the cap of the "sports bottle." It is used to clear blocked airways in an emergency. It also helps clear sputum or vomitus on a regular basis in people with chronic brain injury conditions.	CAMSU™, the COVID-19 Airway Medical Suction Unit, is a wall-mounted suction unit that was developed as part of the pandemic response. It can be used to clear some COVID-19 symptoms by preventing sputum from incubating in the laryngeal area and traveling to the lung cavity. This, in turn, would improve outcomes and prevent some ICU admissions for sedation/intubation/ventilation, saving money and freeing up hospital beds.

(Continued)

TABLE 1 | Continued

Name of innovation	Description of its main purpose	COVID-19 implication
We care solar™	Solar suitcase is a compact solar electric system that provides power generation and medical appliances. Some of its features include high-efficiency, water-resistant, long-lasting (70,000 h) LED lights designed for surgical procedures; 12-V DC and 5-V DC power ports for mobile communication; an electronic fetal heart rate monitor; an electronic infrared thermometer, tablets, and e-readers equipped with educational materials.	The no-touch infrared thermometer has been used in COVID-19 assessments. Improved phone charging ensures that emergency referrals happen when needed, especially given that the target population is rural, improvised communities in Africa and Southeast Asia.
QABY biotech™	QABY is a Qatar-based biotech startup that encompasses novel antibodies, innovative assays, unique biomarkers, and the evidence-based knowledge on how to tackle neurodegenerative diseases. QABY can facilitate the early detection of neurodegenerative diseases, assess treatment responses, and monitor disease progression. QABY's key activities include research and development of tools and assays and discovery of new disease targets, providing services through participation in clinical trials, and selling antibodies and kits directly to end users.	QABY received an innovation grant from Hamad bin Khalifa University Innovation Center to develop a serology test for COVID-19. The blood test was successfully completed within 6 months, and the data are strongly correlated with data generated using other well-established technologies, further validating the robustness and usefulness of the in-house kit. Currently, the innovator is also finalizing the development of anther test for COVID-19, named neutralization assay to be added to the QABY portfolio.
Education and training		
Medics.Academy™	Medics.Academy is a technology-enhanced learning and education platform. It uses advanced technologies to scale programs across countries and to reach large-scale audiences of healthcare workers.	Medics.Academy was commissioned by the WHO to help deliver an education and training program to support the WASH agenda as part of the COVID-19 response.
Community based solution		
Charly™	Charly is a speech assistant/speech recognition device that was designed to promote independent communication between people with hearing impairments. Charly recognizes speech and converts it into text.	Charly has been helping people with disabilities at the Employment Center in Moscow to find jobs after having lost them (in some cases due to COVID-19). This has proven to be cheaper, faster, and more efficient than having an interpreter. The founders are also looking at ways to make Charly more useful for distant working. Examples could include help with university lectures for students studying remotely due to the restrictions brought about by the COVID-19 pandemic.
Telemedicine		
Bleepa™	Bleepa is a secure clinical messaging app that facilitates remote image-based communication between clinicians. It allows medical staff to view and discuss high- quality medical-grade imaging on mobile devices.	Since the onset of COVID-19, Bleepa has been helping senior consultants to guide frontline staff and manage cases remotely and safely without face-to-face interaction.

Repurposing in the Pharmaceutical Industry

In the pharmaceutical industry, drug repurposing has been practiced for years. While *de novo* drug development requires substantial financial investments and years of experimentation, drug repurposing allows developers to cut time, cost, and risk by using AI and computational biology to find additional therapeutic uses of drugs that have previously been through these rigorous safety trials and are already on the market (6–8). Traditional methods of drug development require sometimes up to 15 years' worth of preclinical research, clinical studies, safety reviews, US Food and Drug Administration (FDA) review, and post-market monitoring. Many repurposed drugs have already been approved by the FDA saving both time and millions of dollars (9, 10). There have been several successful examples of drugs that have been repurposed across different fields such as diabetes and oncology (11). In the case of the COVID-19 pandemic, as vaccine development and rollout take months, different drugs are being repurposed in order to help alleviate symptoms and prevent deaths. The efficacy of these drugs in achieving favorable outcomes in patients with COVID-19 is still being studied (12–15).

Repurposing in Healthcare and Service Provision

Similar to what has been witnessed from the WISH innovation competitions, other examples of healthcare innovations being repurposed and deployed in the global battle against COVID-19 have been recently recorded in the literature. One example from the United Nations Development Programme Accelerator Lab in collaboration with the Rwandan Ministry of ICT and Innovation included the deployment of five antiepidemic robots to aid frontline workers to fight spread of the COVID-19 virus (16). These robots provided support in detection of the COVID-19 cases, including citizens returning from travel, as well as providing other services in the hospital setting.

Another large-scale example comes from India where railway coaches were converted to isolation wards for COVID-19 patients to meet the increased and unmet demand for hospital beds (17). Such innovative and resourceful tactics have been

practiced by low- and middle-income countries for years and are generally praised for expanding access to care, while fostering a uniquely competitive environment for creating solutions that are increasingly sustainable (18).

Hospitals in their entirety have also been reshaped and repurposed in the fight against the COVID-19 pandemic, where around the world we have witnessed many mitigation strategies deployed at a healthcare system level and within the hospital setting. Examples from South Korea include stratification of patient care, the establishment of COVID-19 hospitals and dedicated COVID-19 emergency centers, the establishment of dedicated community facilities and emergency centers, and the assignment of respiratory care split hospitals (19). These were all applied effectively and have been key in tackling the crisis at hand given the strain on healthcare resources.

The Use of AI During COVID-19

Health systems are coping with the explosive demand through the large-scale adoption of AI and digital operating models (20, 21). AI can be used in a number of significant applications in the fight against the COVID-19 pandemic. These applications range from early detection and diagnosis, treatment monitoring, contact tracing, projection of cases and mortality, development of vaccines and drugs, decreasing healthcare workers' workload, and disease prevention (22).

One example of AI being used for detection and diagnosis purposes includes Providence St. Joseph Health system in Seattle, whereby in partnership with Microsoft, Providence developed an online screening and triage solution. This tool could help detect and differentiate, at a rapid rate, the difference between a patient with COVID-19 and a patient with another, less threatening ailment (20). This same partnership, together with University of British Columbia, has also provided other AI-driven solutions to monitor the compliance and effectiveness of social distancing measures, as well as personal protective equipment (PPE) usage (23).

Similar to "Pandexit" mentioned in **Table 1**, another innovation that has also been deployed in the use of virus tracking is Metabiota. Metabiota, a company that provides services for the US Department of Defense and intelligence agencies, has been used to detect the risk of spread of disease, calculating its predictions from factors such as symptoms, availability of treatment, and mortality (24).

The Rise of Telehealth During the COVID-19 Pandemic

The use of telehealth or telemedicine technologies to combat the current COVID-19 crisis, as well as the overall management of communicable diseases as a whole, is ideal. Telehealth solutions decrease the need for person-to-person contact, so for COVID-19 patients, or patients who are concerned about getting infected, telehealth can provide an effective alternative solution for remote assessment and delivery of care (25, 26).

Other advantages of telehealth include increased access and availability to specialists and subspecialists. These can sometimes be doctors in different hospitals, providing care in different regions. The Mount Sinai system, for example, leverages specialists across eight hospitals to provide emergency consultations and make referrals where needed (27). The limitation of these types of solutions is usually related to issues to do with payment, staffing, and credentialing. It is also argued that nurses, medical assistants, and physician assistants all contribute to the overall experience of in-person care provision, and telemedicine could not possibly replicate this (27).

Telemedicine can also take the format of a messaging app between doctors to facilitate discussions and shared experiences and recommendations when it comes to more challenging medical cases. Such is the case of "Bleepa," one of the WISH 2020 shortlisted innovators mentioned in **Table 1**. Here the challenge is avoiding the leak of confidential and sensitive information, such as the patient's condition and medical history.

Lessons From Other Industries

Other industries, sometimes with no clear links to the healthcare industry, are also following suit. Several firms, for example, have exapted their capacities and capabilities to produce PPE (28). In addition, a number of cosmetic brands have started manufacturing hand sanitizers to meet the increase in demand. These brands include the likes of L'Oreal and Nivea (29). Another example is Dyson, a producer of household items such as air purifiers, vacuum cleaners, and hair dryers. Dyson announced in March 2020 that it had initiated the design and production process of 10,000 ventilators, following the United Kingdom's National Health Services' predictions of an increased demand for ventilators amid the COVID-19 pandemic (30). This type of innovative cross-industry collaboration to respond to the global demand for healthcare is an approach to be applauded and encouraged.

CONCLUSION

It is without a doubt that the COVID-19 pandemic has emphasized the need for an accelerated, cross-sectorial, and frugal approach to healthcare innovation. The innovation competitions at WISH further emphasized this need through direct response, where more than a third of the applicants suggested an alternate use for their innovation. While repurposing products is a practice that has been going on for years before the onset of the current pandemic, it has been mostly been practiced by other industries such as drug development. Solutions that make use of AI and digital-based technologies for delivery of services and care are especially helpful during a global crisis such as this one where social distancing plays a great role in stopping the spread of the virus. It is also evident that not all solutions must be high-tech in order for them to provide sufficient answers and deliver impact. Innovations such as AMSU, mentioned in **Table 1**, provide relatively low-tech, yet highly effective solutions. Finally, it is imperative that lessons are learned from this pandemic at a global level and that this fast and frugal method of responding to an increase in demand, especially in the time of crisis, becomes mainstream and runs in parallel to

the more traditional approach to innovation and product development. In order for repurposing to become mainstream practice in healthcare innovation, there is a need for systems worldwide to facilitate this through the adoption of open innovation mechanisms.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

AUTHOR CONTRIBUTIONS

MahaE wrote the draft with input from MahmE. Both authors contributed to the article and approved the submitted version.

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Do Regulatory Changes Seriously Affect the Medical Devices Industry? Evidence From the Czech Republic

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Background: Within the EU, some of the challenges and perceived risks now facing medical device (MD) developers result from changes in the regulatory framework, emphasizing safety. Therefore, medical technology companies must adopt stricter quality assurance measures so that individual devices can be speedily tracked and retrieved in emergency situations.

Objectives: We highlight the challenges and risks faced by the European medical devices industry, particularly those faced by SMEs in the Czech Republic. We address two important research questions: Q1. Do advantages from increased regulation outweigh the additional expenses? Q2. As many MD developers are SMEs, will the new regulatory regime result in some of those companies going out of business and therefore impede future innovation?

Methods: The paper focuses on a single case study, with the situation and outcomes discussed in the context of the financial results of a further 50 medical device manufacturers marketing in the Czech Republic.

Results: Our findings suggest that the new legislation will result in improved safety, facilitate product recalls, but the cost and administrative burden may be high. The evidence also indicates that some SMEs may be forced to diversify to "non-medical" products, with the inevitable loss of innovative MDs being made available to patients and healthcare providers.

Keywords: risk, patient safety, regulation, innovation, SME, medical devices

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INTRODUCTION

The European trade association for the medical technology industry (MedTech) state that "medical technologies can save lives, improve health, and contribute to sustainable healthcare" (1). The medical health literature (2) states, "Medical devices are used for the diagnosis, monitoring, and treatment of virtually every disease or condition, and include familiar objects such as simple bandages to high-end MRI scanners" regulated by Council Directive (3, 4). European manufacturers now face the new Regulation (EU) 2017/745 to be introduced in 2021. This new legislation not only presents issues concerning health and risk but also for society in general.

Attitudes toward regulations are perceived differently. Concern has been expressed in the literature that the current regulatory regime for medical devices (MDs) is inadequate, biased toward commercial interests, that innovation outpaces the development of regulatory controls, resulting in

social and patient risk implications (5–7). de Mol (8) argues (p. 735) that "medical devices are considered to be a cornerstone of medical technology and to enable progress in healthcare for millions of patients." The current regulatory regime may, however, be putting patients at risk (9). With respect to innovation theories, a strict interpretation of the Porter hypothesis implies that challenging factors in the form of heavy regulations can induce innovation because established technologies get to be replaced by newer, more effective and safer alternatives (10). This may be particularly true of the medical device market, which is highly regulated, and new entrants must fulfill many conditions. These conditions involve mainly safety regulations but also environmental protection requirements, and they affect multiple aspects of the development process: technical, clinical, as well as biological. While the demanding conditions may be seen as an obstacle, they may also prove stimulating for innovation (11).

This industry's characteristics are the exceptionally high innovation potential (11), the above-average number of innovations successfully applied to the market, the high added value of products, and the high export potential (12). The manufacturers of medical technologies have high-level research and development capacities. They are also vocal in expressing their expertise and knowledge toward the continuous development of innovative and accelerated development (13). As a result, such development activities in the Czech Republic often result in products with unique properties, which are considered innovative globally. The research, development, and production of MDs have a long tradition in the Czech Republic (14). In addition to the positive impact on the economic development of the Czech Republic, the development and production of MDs also have a direct positive impact on other sectors, especially the health services sector (13).

The main change under the new MDR regulations focuses on safety and risk reduction, which is to be achieved by strict processes that lead to market authorization (15). Medical technology companies must adopt more stringent quality assurance measures so that individual devices can be speedily tracked and retrieved in emergencies. Among the new requirements introduced by the MDR is creating a unique position to be filled by a candidate with proof of experience in medical device regulations. This person is to be entrusted with managing all matters related to regulatory requirements (16). For SMEs in the Czech Republic, it can be challenging to find an employee with such expertise. Moreover, "to obtain MDR authorization for class III, implantable devices and high-risk class IIb, MedTech companies will be required to present a notified body with a large volume of clinical data that supports their products' clinical performance" (17).

However, from an SME perspective, the new European legislation (highlighted in this paper) may result in a significant proportional increase in costs and an increased administrative burned, resulting in the impossibility for some companies to continue developing new products and, therefore, restrain innovation for the development of MDs.

This paper aims to highlight the challenges and risks faced by the European medical devices industry due to recent legislation changes, particularly those faced by SMEs in the Czech Republic. We address two important research questions:

Q1. Do advantages from increased regulation outweigh the additional expenses?
Q2. As a large proportion of MD developers are SMEs, will the new regulatory regime result in some of those companies going out of business and therefore restrict future innovation?

It is essential to highlight and bring to the literature the perceived risks (as a result of the proposed new legislation) facing SME companies that currently develop innovative MDs.

Firstly, sector analysis provides an overview of the medical device market and MD companies' structure in the Czech Republic. Secondly, the case study of an SME company describes and analyses the situation from the point of view of regulation and the impact on the functioning of this company. Regardless of the company's size, these problems or requirements will have to be solved by every company.

THEORETICAL BACKGROUND

The importance of innovation in the medical device market and the actual impact on society, the market and the economy is often linked to regulations at national and global levels. It is essential to state the context of the current legislative conditions in force and to acquaint them with their possible impacts, which, for example, some authors have mentioned in the past, both negative and positive.

R&D, Innovation, and Regulation in the Field of Medical Device Development

Success in medical device development is determined by the variables of innovativeness, financial analysis and planning, user input in the development process, and company employees' engagement in the new product development (NPD) goals. It follows that successful product development and placement on the market depends on a complex interplay of factors relating equally to business strategies, technological solutions, human resources, and end-user involvement. Additionally, a survey found that new global innovations accounted for only 4.4 per cent of NPD projects in larger companies and 9.3 per cent of NPD projects in SMEs (18).

The medical device sector is a rapidly developing industry (19) subjected to pressures from all sides. New technologies emerge in fast succession. They are widely publicized, which results in patients increasing demands for the latest inventions that are still in the early stages of development and may require years of honing and testing before they can be introduced to the market. Therefore, the ever-increasing challenge of small high-tech firms (HTSFs) is to keep up with the latest breakthroughs and come up with ways to leverage their potential (20).

Hourd and Williams (21) conducted a case study on a sample of 14 UK-based SMEs operating in the medical device sector. The researchers compared the individual companies' business strategies and practices to determine the factors most important

for these enterprises' success. It was found that each stage of the development process presents its peculiar challenges and that all the stages are equally essential to the overall success. This involves obtaining funding, securing partners, recruiting staff, and setting up development milestones in the preparation stage. Further on, success depends on conducting clinical trials, obtaining approvals, launching the product and conducting post-market surveillance.

Numerous obstacles can hinder the success of the enterprise. These include external cost-related issues, such as lack of funding (22), high implementation cost (22, 23) and the cost of verification or certification (22). Furthermore, barriers may present themselves in the form of unethical regulatory authorities (24) and the difficulty of obtaining information (22).

The Importance of Regulation for Innovation

The manufacturers of MDs cooperate with clinical workplaces to research and develop new devices and then in the application phase. This co-operation is essential for a high level of medical and nursing care. Therefore, modern MDs represent a fundamental and irreplaceable area for contemporary medicine, which needs to be further developed and innovated (25). An essential prerequisite for the use of innovative MDs for increasing the level of the healthcare provided is to create, in particular, optimal legislative conditions for their market launching.

It is difficult to draw any definitive conclusions when it comes to the relationship between regulation and innovation. The association is a highly complex one, and the impact of regulation on innovation is not always immediately apparent. This impact may be manifested indirectly and gradually, such as in subtle shifts in market structure in competition, business strategies and investment priorities (11).

The new legislation's key goal, highlighted in this paper, is to provide a more transparent, efficient and "consumer-oriented" approach and increase patient safety. The effects of regulation on product quality have been frequently researched in the past. While many theoretical models illustrate the relationships between product quality, competition on the market, and price regulation, only a few studies describe the relationship between regulatory policies and technological innovation. However, a positive relationship between heavy regulation and innovation was established in the Porter hypothesis (10), which proposed the innovation effect of introducing innovative environment-friendly processes as a result of heavy environmental regulations. Simultaneously, innovative technologies are cost-efficient, compensating for any costs incurred in achieving compliance with new regulations. Furthermore, innovations stimulated through regulations can be further utilized through patenting, which ultimately serves as a competitive advantage over companies that are not subjected to such strict regulations.

In contrast, studies that illustrate a negative impact of regulations on innovation (26) highlight that hospitals' regulatory obligations significantly slowed down the spread of CT scans, which eventually became more prevalent in individual physicians' offices than in hospitals. Peltzman (27), researching the effects of new FDA regulations on the drug industry, reports that the regulations led to a significant drop in the number of new drugs introduced in the market and that the costs exceeded any potential savings. Finally, some studies (28, 29) confirm that the new FDA regulations resulted in companies cutting down investments in innovation, hence decreasing the number of new drugs introduced.

What will be the possible consequences of the new medical device regulations [(MDR) 2017/745]? Will it support or hinder innovation?

Regulatory

Medical technologies are characterized by a constant flow of innovation, resulting from a high level of research and development within the industry and co-operation with users. New product development can take from 1 to 2 years in terms of their risk class. Health means are divided into classes I, IIa, IIb, III. The placing on the market of a new or innovated product depends on the complexity of meeting the essential requirements and, above all, on time required for the conformity assessment by the notified body (NB).

The following risk classifications and descriptions are taken from (17).

Class I [I (low-risk non-sterile), Is (sterile), Im (measure), Ir (reusable)] – Provided sterile "and/or have a measuring function (low/medium risk) or reusable low-risk Class I devices placed on the market in a sterile condition, have a measuring function or are reusable surgical instruments: assessment of the technical documentation relating only to those specific features of the device, such as sterility, measurement, or reprocessing" [see also (30)].

Class IIa (medium risk) "Class IIa devices: Assessment of the technical documentation for at least one representative device for each category of devices" [see also (31)].

Class IIb (medium/high risk) Class IIb "implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors) and Class IIb active devices intended to administer and/or remove a medicinal product: Assessment of the technical documentation for" [see also (32)].

Class III (high risk). Class III devices: "Assessment of the technical documentation for every device."

Within the European Union, the medical device industry, from development through manufacturing to distribution, is subject to EU directives and regulations. The difference between the two is that directives must be embedded in each member state's national legislative system, whereas regulations apply directly. Legislation concerning medical devices (in the Czech Republic, where our study is based) is spread across a number of different directives, decrees and laws issued by the Ministry of Health of the Czech Republic. These documents apply to medical devices in general or to specific types of devices, such as active implants or *in vitro* diagnostic devices. As an example of legislative conditions, the European manufacturers face the new Regulation (EU) 2017/745 (33) of the European Parliament and the Council on Medical Devices (MDR). Currently, MDs in the

Czech Republic are regulated by Act No. 268/2014 Coll. Like the national laws of the other member states of the European Union, this law incorporates Council Directive 93/42/EEC (MDD) on MDs (34).

After placing on the market, MDs must be monitored, and their clinical benefit and, where appropriate, the risks arising from their use must be continuously evaluated. According to Article 10 of the MDR, the manufacturer must set up a so-called proactive way to establish, document, implement, and periodically update the risk management system or conduct a clinical trial under the requirements of Article 61 of the MDR, including post-market clinical follow-up (PMCF) (35). The PMCF is a requirement included in the current MDD, allowing manufacturers to start PMCF studies before the end of the MDD. The clinical data from these studies will be used for MDR clinical trials, thus partially avoiding costly clinical trials. However, manufacturers often have only a post-market surveillance (PMS) process, which they understand as a summary of sales and production; the collection of clinical data is only marginally included here. For this reason, manufacturers lack clinical data that they could rely on in their MDR clinical trials, which can mean high financial demands, not only for the implementation of clinical trials.

The factors mentioned above highlight the European MDs industry's challenges due to recent legislation changes, especially by SMEs. MDR was due to come into force in May 2020, but due to the COVID-19 situation, it has been postponed until May 2021. This gives manufacturers more time and the opportunity to start taking steps to facilitate the transition to MDR. Even though the certificate will be issued and supervised according to the MDD until the end of the transitional period, manufacturers will already be obliged to meet the requirements of the MDR.

General View of the Medical Device Industry, Specifically in Europe

The development of a new medical device typically starts in a small, innovation-driven company. Small companies tend to stand at the beginning of technological progress in medical devices for several reasons (36). Small-sized companies move forward faster because they are easier to manage than large corporates. The inventor and innovator is often the leader and decision-maker, unlike in larger companies, where research, leadership, and management form different levels. With the innovator and executive in one person, it is significantly easier to make informed decisions and assess possible risks.

This fact is also supported by the number of companies and the structure of the market in Europe. There are 25,000 MedTech enterprises in Europe, 95 per cent of them being SMEs (37, 38). These enterprises are at the greatest risk of exiting the market because administrative costs are often too high for them.

The Czech market is still relatively small compared to other European markets. Demand for medical devices in the Czech Republic in 2016-2020 is relatively constant. In 2016, market growth was 1.3%. In 2019 it was estimated at 2%. Demand for medical devices in the Czech Republic by type of device is highest in areas: Catheters, cannulae and needles, orthopedic and fracture appliances, Medical furniture, Electro-diagnostic equipment, and medical instruments and appliances (39).

The Czech market's opportunities lie in the aging population connected with chronic diseases; there is also demand for innovative products that improve efficiency and health outcomes, such as mini-invasive surgery systems, digital image processing, or home-care equipment (40).

RESEARCH METHODOLOGY

This paper is partly based on a single case study, considering that a "Case study is the study of the particularity and complexity of a single case, coming to understand its activity within important circumstances" (41). The popularity of case study research is increasing, especially in corporate research, as case studies can provide insights that might not be achieved with other approaches. However, "The important issue is to have a clear objective, involve the right people and have access to the right information" (42). Case studies can focus on a single case or several cases. There are no formal requirements in a multi-case study as to a minimum number of cases required, and neither is there a requirement of a random selection of cases (43). Therefore, a case study may not be representative since the researcher simply examines such material as is available. Although generalizations from a single case study may be limited, this does not distract from their importance. "Case studies can be used to explain, describe or explore events or phenomena in the everyday contexts in which they occur" (44). Analyzing a particular case in detail may prove to be helpful in discovering and describing cause-and-effect relationships and eventually estimating possible tendencies that may apply to similar cases. This research follows the main steps in preparing and conducting a case study, including successively identifying a specific case, collecting data, interpreting data, and drawing conclusions (45). On top of that, we have performed the industry analysis in the Czech Republic to assess how representative is the case of the selected company in question, medical device producers, which further enhance the usability of the performed case study.

Design

Our research is based on a single case study supported by data from a further 50 companies. The case study SME company is a representative of Czech manufacturers, listed in the Register of Medical Devices, which since 2015 is a unified system for comprehensive data management in medical devices in the Czech Republic (46). We chose an SME company focusing on the production of several types of MD class IIb, including pacemakers. The fact that many studies confirm the importance of SME companies played a role in selecting the company for our detailed case study. Initially, we looked at the register of the Association of Manufacturers of Medical Technology (47), the total number of 140 companies available. We excluded *in vitro* Diagnostic (IVD) manufacturers (these companies are not affected by the examined change in legislation) and distributors. Sixty-eight companies remained for further analysis. In the next step, economic data were found in the database of Albertina companies' Economic data (48) (profit, revenues and number of

TABLE 1 | Number of MD manufacturers by size of company.

Company category	Number of companies	The average number of active MDs in the registry
Micro	13	19.25
Small	18	44.75
Medium-sized	16	63,62
Large	6	57

employees) were not available for all companies. Our final set contains 53 companies in total **(Table 1)**.

Generally, our study was performed in the following steps:

- Sector analysis based on data of medical device companies in the Czech Republic to;
  - A list of MD companies was used from the register of the Association of Manufacturers of Medical Technology.
  - For each company information of the production of medical devices according to the risk classes available in the database the National Register of Medical Devices (available at: https://eregpublicsecure.ksrzis.cz/Registr/RZPRO/) Class I-III were included;
  - For the included companies, economic data were added using the Albertina database (48), and economic analysis was done;
- Case study elaboration to show possible scenarios of the impact of new legislation.

Data

We obtained a sizable dataset from accounting statements and internal company information obtained directly from the company's representative. Our dataset covers the period of 2002–2018, containing a total of 36 variables. Information about company revenues corresponding to the various product classes or services is present, alongside cost categories: salaries, material costs, and specific costs directly related to MD developments and their continual market approval (certification costs). Total revenues, costs, and gross profit are also included.

The dataset is, however, not without its limitations. Since it covers a relatively long time period, many accounting standards changed over the analyzed period; namely, the method for reporting employee numbers (given by full-time vs. part-time contrasts in reporting) changed three times. This made it difficult to obtain comparable data for the entire period.

The company representative was repeatedly interviewed, and the selected financial variables (**Table 2**) were refined and interpreted. Additionally, an interview was conducted in May 2019 to determine the company's strategy in the reporting period.

We used IBM SPSS version 24 was to forecast the main variables for the future company development scenario. SPSS Time Series Modeler was used to select the most appropriate method (exponential smoothing, univariate autoregressive integrated moving average and multivariate) based on the best fit to the historical data (49).

RESULTS

Innovation in the field of MDs is undertaken by SME companies. Therefore, sector analysis which shows the medical device market in the Czech Republic, is done. Then possible scenarios of the impact of new regulations are shown in a single case study.

Analysis – Part 1 - Medical Device Industry in the Czech Republic

The major problem of MDR implementation is in the field of innovation. Specifically, most innovative research in MDs is not undertaken by big companies but by SMEs (37, 38). "Such companies usually focus on the production of a small number of products, meaning their margin does not allow them to pay for all the necessary costs connected with MDR compliance" (11). The estimated costs for SMEs to launch a new class III MD will be between EUR 1–4 million or EUR 7–28 million if the device must fulfill the centralized pre-market authorization procedure requirements. A specific expert estimate associated with the legislative conditions is given in **Table 3**.

The above data are an overall estimate for the MD market. However, there are no data available on the impact of new legislation on business results (50). Therefore, we have prepared our specification based on several sources. We have selected companies listed as members of the two MD producer associations in the Czech Republic for our analysis. Our final list consists of 50 companies whose data were relevant and available. See section Design for detailed information. Data are displayed in **Table 4**.

Increases in certification costs for conformity assessment were quantified by a domain expert to be approximately 2.5 points multiple of the current costs, except the MD of safety class I, where there are no increases expected.

We used a combination of data regarding revenues, profit, and the number of MDs in each company's safety classes. Estimates of the increase in certification costs were obtained by multiplying the number of MDs in each respective safety class by the expected rise in certification costs for that class. For companies having multiple MD in the same safety class, coefficients were used to lower estimated certification costs reflecting the fact that producers often certify MD in larger batches (coefficients used were 0.17 for safety class I; 0.26 for class IIa; 0.27 for class IIb and 0.3 for class III). Estimated certification cost increases were further compared with total revenues to obtain a percentage share in revenues to create a reasonable estimate of the significance of this increase for the company. Column 5 in **Table 4** displays these results for the groups of companies in our set.

Results show clearly that the estimated burden of certification cost increases falls disproportionately on small and micro-companies. This is because they have a relatively high share of MDs in higher safety classes, IIb in particular, for which certification costs are quite considerable, but total revenues are relatively small. On top of that, **Table 4** shows that profit margins are increasing in line with the company size. The smallest companies, on average, are even recording losses. The red curve in **Figure 1** depicts the decreasing estimated increase in certification costs as the percentage of revenues. It is higher than

TABLE 2 | Monitored variables.

Revenue from the resale of consumable material	Purchase of material	Cashflow
Sales of safety technical control (STC)	Purchase of material for resale	Foreign sources ("debt")
Number of performed STC	Purchase of material for product	Goods (stock of products for sale and material for resale)
Revenue for product	Average adjusted employee count	Stock of material
Number of sold pieces (product)	Employee wages total	Total value of stored stocks (products and material)
Sales of own products and services	Purchase of services, total	Net Capital
Revenue for total sales	Purchase of services, product certification	Subsidy granted by the Ministry of Industry and Trade for the development of a cardio stimulator
Total revenues	Purchase of services, system certification	Subsidy granted by the Ministry of Industry and trade for marketing
Profit before taxes	Total costs	Costs of marketing activities and international exhibitions (fairs)

TABLE 3 | Approximate costs related to the development of MDs (EUR).

		Inactive	Active		Active/implants		Comments
		I	I	IIa	IIb	III	
Time of development [year]		1	1	2	2	2	
Employees	HW	0	17,771	35,542	35,542	35,542	With a salary of 1,500EUR per month
	SW	0	17,771	35,542	35,542	35,542	With a salary of 1,500EUR per month
	other	35542	17,771	71,085	71,085	71,085	With a salary of 1,500EUR per month
Sterilization validation		0	0	1,851	1,851	1,851	
Measurement validation		0	1,851	1,851	1,851	1,851	
Tests el. Security		0	3,702	5,553	5,553	5,553	Not for implantable ones (joints, for stimulators)
EMC		0	1,851	3,702	3,702	3,702	EMC is not implantable (joints, it is a stimulator), but again they have a higher price for biological evaluation
Biological evaluation		1,851	1,851	5,553	5,553	5,553	Based on type of MD
Clinical evaluation		740	740	1,851	3,702	3,702	If the clinical trial is based on a clinical trial, even millions
Type test		740	740	3702	5,553	5,553	
CE Conformity Declaration		0	0	7,405	9,256	11,107	Abroad: notified body: it is IIa - 20 thousand €; IIb - 25 thousand €, III - 30 thousand €, plus supervision every year about 5 thousand €. According to the MDR, it is expected that it should be up to 25% more.
QMS		5,553	5,553	5,553	5,553	5,553	
PMCF		After placing a product on the market, the cost depends on the type of product, its use and the complexity of the study itself (large price range); estimate for IIb is part of the Appendix.					
Total		44,428	69,604	17,9193	184,746	186,598	

the profit margins for the lower three groups of companies (1–19 employees, 16 companies total) with a relatively small estimated impact on the larger companies (20–199 employees, 27 in total) and negligible impact on the even larger companies (200–999 employees, 7) where it declines significantly to below one per cent of revenues. Only the group of companies with the number of employees in the range of 100–199 show a slight divergence from the trend. This can be explained by the fact that companies in this group have the highest average amount of registered MD's (34) concentrated in the safety classes IIb and III.

Analysis – Part 2 - Case Study

Our case study is based on an SME (Mediatrade – pulse generators) operating and regulated in the Czech Republic. In the context of the change in legislative conditions in the European Union, the company's crucial concern is related to its economic development under the new legislative conditions.

Company Characteristics and Strategy

The company's primary focus, which was established in 1994, is external pacemakers' EPG 10 production and medical devices of risk class IIb. However, it is relatively new to the MD industry, having entered the field in 2012. Secondary activities include the sale of materials for usage in the areas of gastroenterology, specially boot sets for endoscopic stents (guiding, integral and pusher), disposable injector varices; double and triple lumen catheter for ERCP, endoscope catheters, guidewires, Nazo-biliar catheters. In area of cardiology it produce device, cardiostimulation catheter, loader sets, accessories, neurostimulation.

TABLE 4 | Medical device market in the Czech Republic – MD type, production, economic indicators.

Number of employees	Number of firms	Average number of active MD in the national MD list	I*	IIa*	IIb*	III*	Average weighted profit share in revenues [% of revenues]	Expected increase of certification costs as percentage of revenues
1,500–1,999	1	9				9	10.50%	0.03
1,000–1,499	1	34	34				11.31%	0
250–499	3	14	5	3.5	0.8	1.3	14.04%	0.1
200–249	2	9	1,5	0.5	7	0	15.52%	0.25
100–199	8	34	12	0.8	8.1	5.8	5.42%	1.16
50–99	6	20.2	8,8	5.7	2.7	3	9.96%	0.86
25–49	9	21	17	0.9	1.9	0.8	6.04%	0.78
20–24	4	9.25	3.3	0.5	3.8	1.5	4.69%	2.02
10–19	5	14.5	3.2	1.2	5.6	0	2.12%	5.63
6–9	7	10	6	2.1	1.4	0.9	−16%	5.3
1–5	4	9.25	0	1.3	5	3.3	−169%	10.13

**Average sum(count) of MD's in a given safety class and group of companies.*

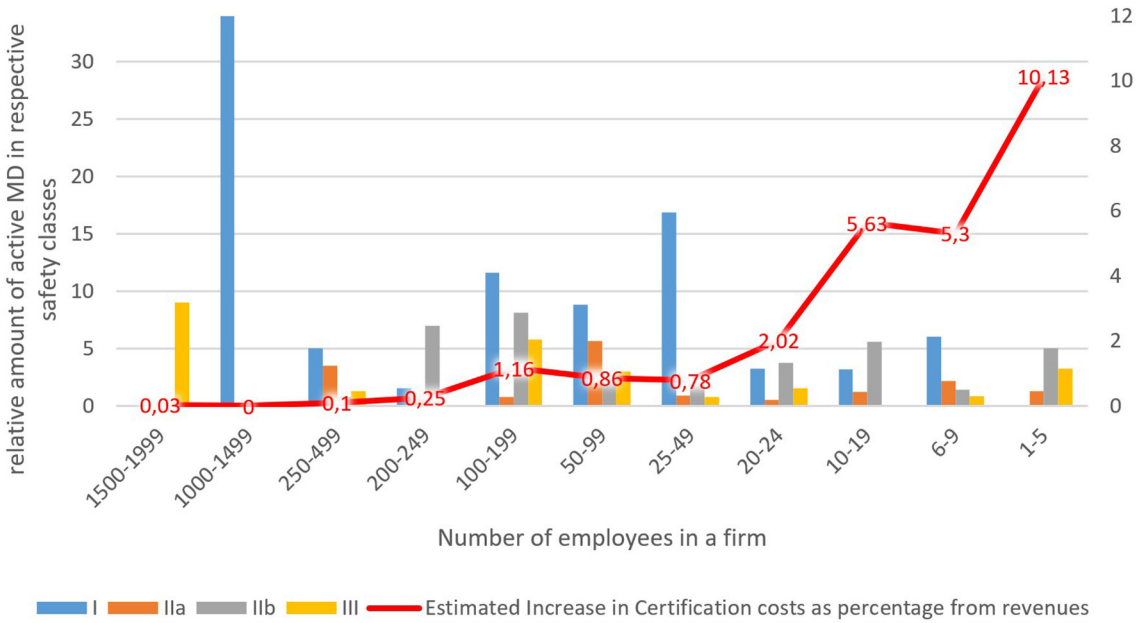

FIGURE 1 | Certification costs.

Innovation plays a large part in its product development strategy. Since the company's inception, it launched the first-generation analog products, which it innovated into digital form in 2013, launching its second-generation pacemaker. Based on market demand, the third-generation product with biphasic stimulation impulse was launched in 2017.

Gradually, with increased production, the domestic market was largely saturated (in particular, regional hospitals were fully secured by Mediatrade). The company also provides service for each device in the form of an annual safety check (the historical revenue trend is shown in **Supplementary File 1B**. Expansion to foreign markets has partially been achieved.

In their business activities, various development problems relating to certification and legislative have been addressed. The company also faced complications in product testing or testing in laboratories for compliance. Another challenge was the compilation of documentation for the new product to be satisfactory in the Czech Republic's legislation. The solution to these problems was partially achieved, in the early years, through certification using external assistance. In later years, professional activities were also dealt with by recruiting external experts.

The product's price was determined based on the market competition with the maximum target price of CZK 40,000. This was because hospitals, if interested in the product, did not have

TABLE 5 | Economic indicators in 2017.

Debt 77.41 percent	**The share of receivables in current assets 144.00 percent**	**Return on EBIT 1.31 percent**
Inventory turnover time 55.00 days	Current liquidity 0.37	Increase/decrease in sales in−13.74 percent
Receivables turnover time 859.00 days	Return on equity 0.53 percent	Average monthly salary 1,519 EUR/month

Converted at the historical rates for the given years; data are from https://www.kurzy.cz/kurzy-men/historie/EUR-euro/2008/.

to issue a tender for the product up to and including CZK 40,000. This resulted in reduced administrative costs for hospitals.

Economic Indicators of the Company

Mediatrade's financial results show long-term growth between 2002 and 2018, with partial declines in 2007, 2012, and 2017. The revenues follow the development GDP from 2011 to 2017. Despite the economic crisis between 2007 and 2009, the company registered rising revenues (**Supplementary File 1C**. This corresponds to the healthcare and pharmaceutical industries' performance in the Czech Republic, which did not show a decline in the added value over this same period.

The company has a high debt ratio and a long turnover of inventory and receivables. Its current liquidity points to the ability to repay its short-term liabilities (**Table 5**). Mediatrade has a value that is more typical for immediate liquidity, that is, very low. The profitability of less than half a percentage point and other indicators adds to an unfavorable economic prospect under the current economic and legislative conditions.

Expected Development

To assess the company's possible future development, we have defined four scenarios based on the forecasts of three key variables – revenues for consumption material, amount of performed pacemaker safety – technical controls (STC), and the number of products sold. The analysis of consumption material revenues with exponential smoothing and the prediction of growing revenues resulted in EUR 114,708, EUR 120,760, and EUR 126,813 for 2020, 2021, 2022, respectively. This is based on the historical data for the same variable with observed growth of roughly 150% in the last 10 years and represents a simple trend extrapolation, i.e., analyst estimate. The level of uncertainty concerning this estimate is quite considerable, at around 50% of the forecasted mean value (Upper confidence limit of 148 118 EUR, lower confidence limit of 81 298 EUR on the 95% confidence level for the year 2020). Based on historical data for the amount of performed STC's (usually performed once a year for each device to verify that it functions correctly, i.e., output signal precision is within defined bounds), the SPSS Time-series modeler selected ARIMA (0,0,0) was used for this data series, which equals an interpolation data series in terms of its mean value. In terms of model fit, R-squared was negligible. The prediction does not seem helpful, and consequently, it was not used for further analysis. Fortunately, we know that the amount of performed safety – technical controls each year – is determined by the total number of pacemakers in the Czech Republic hospitals. Mediatrade already reached a cap of 270 active pacemakers in Czech hospitals, so the constant forecast of the 342 performed STC is relevant for the Czech market, given current safety regulations regarding this MD's maintenance. For the last variable, the number of sold pacemakers, the simple exponential smoothing method was used, with a constant predicted value of 48 pieces sold each year. This again corresponds relatively well to our expectations because Mediatrade has already captured the Czech market, and any further growth in product sales may have to come from foreign markets. It is necessary to point out that the trajectories mentioned above of the three primary sources of revenue for the company do not represent exact statistical projections but more so analyst estimates, based on the knowledge of the company inner workings and processes accompanied by an understanding of the Czech market for this particular kind of MD. Costs were calculated using historical data for the corresponding categories; for details, please see the collected data on Mediatrade in **Supplementary File 2.**

The first scenario is the business-as-usual scenario (BAU), in which there are no significant changes regarding the costs related to MD certification and the sales volume is based on the forecasts explained in the previous paragraph. In the second scenario, the company is faced with increased certification expenditures (CERT) to maintain its MD sales on the Czech medical market. Two following scenarios are based on possible mitigation strategies the company could adopt to offset impacts of CERT scenario – CERT+EXP based on a pro-export company orientation, where it expands on foreign markets with the help of increased marketing expenditures, and CERT+PRIC, where it tries to mitigate the increased certification costs through an increase of 15 per cent in the price of its services and products. We assume inelastic demand for the MD, so the predicted volumes of the units sold and service check-ups decrease by 7.5 per cent overall. The results of this exercise are shown in **Figure 2**.

Under the BAU scenario, the company generates a small profit over the 3-year forecast period. However, once the increased certification expenditures are included in the CERT scenario, the firm incurs a significant loss, which further impairs its financial standing (EUR 195,160 in debt in 2016). The first mitigation strategy, CERT+EXP, somewhat improves the situation. However, the company still incurs a loss, as the increased volume of sales abroad requires higher marketing expenses and slightly higher employee costs. The last strategy, CERT+PRIC, is the closest to zero, with a small loss of EUR 2,444.

Regarding identified uncertainty around forecasted sales of consumption material, the risk is disproportionally skewed to the downside of the forecasted mean value in the post COVID-19 world. A lower confidence limit for the first forecasted year represents a decline of EUR 27,649, enough to wipe out the whole profit in the BAU scenario and significantly deepen the losses in

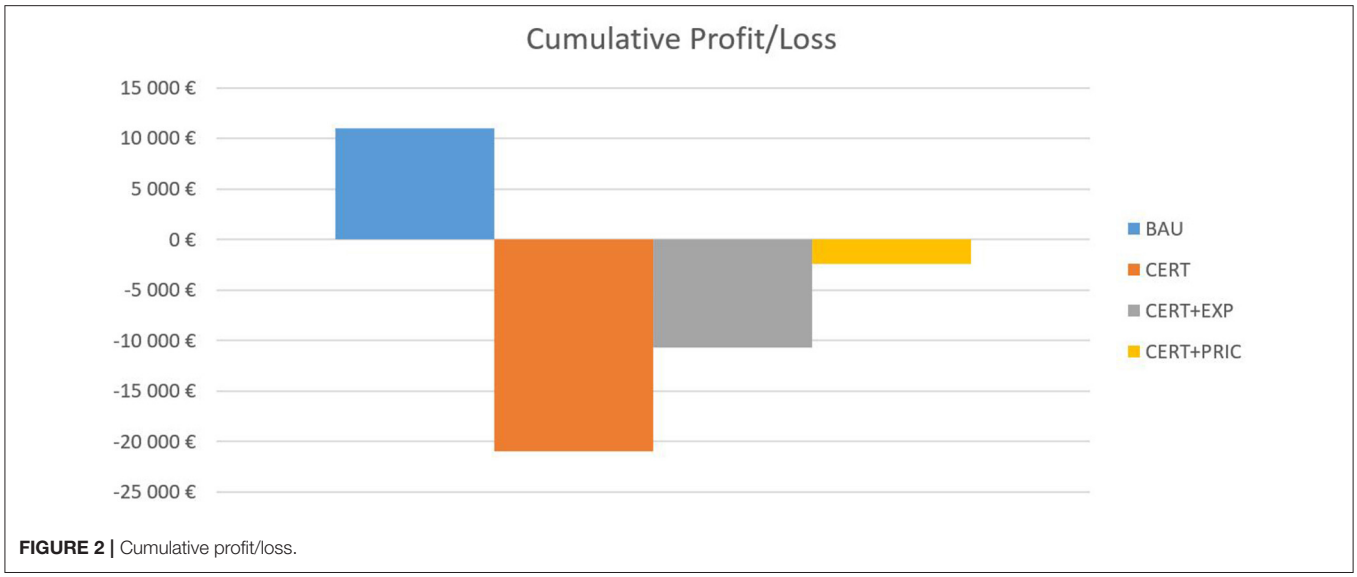

FIGURE 2 | Cumulative profit/loss.

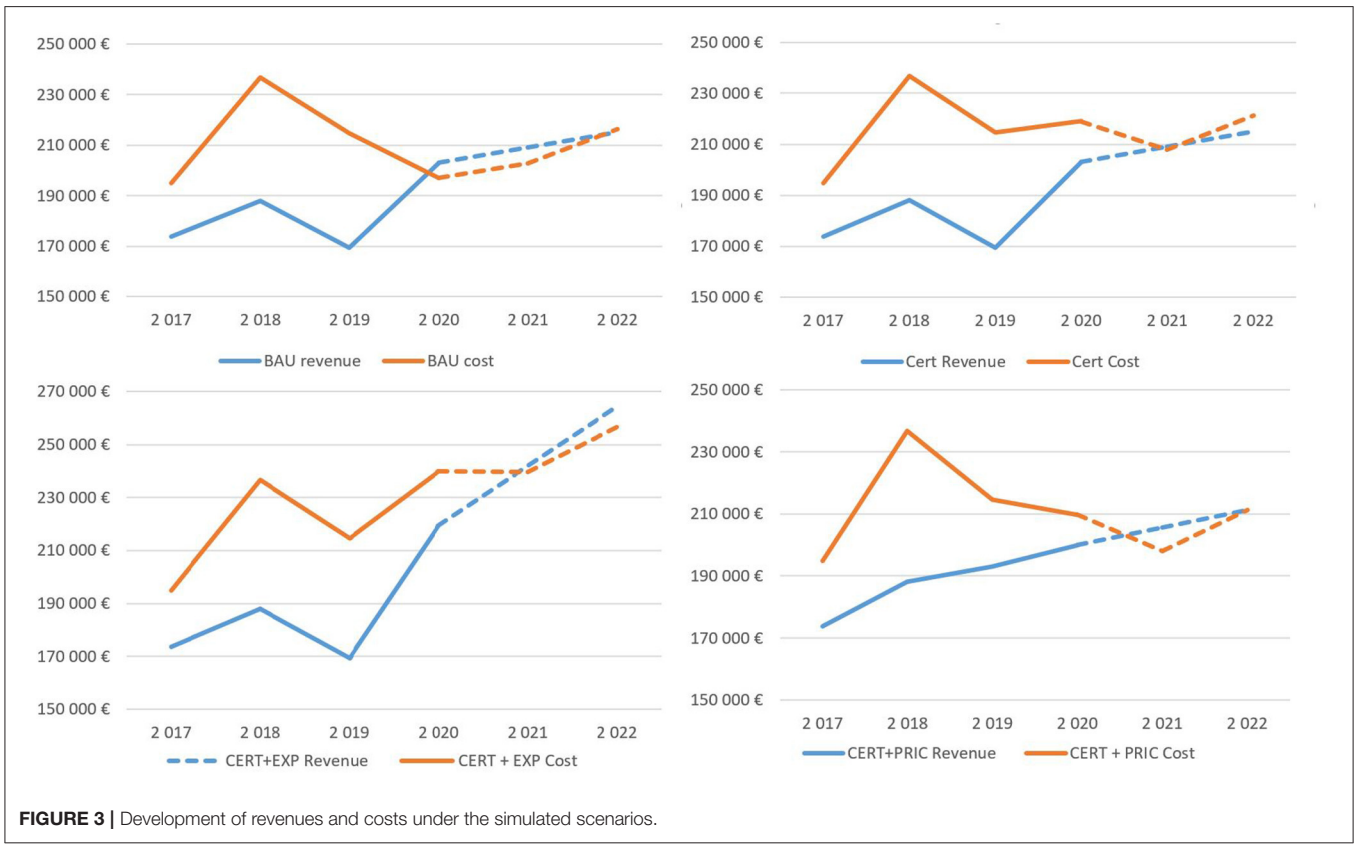

FIGURE 3 | Development of revenues and costs under the simulated scenarios.

the rest of the scenarios. Also important is the distribution of the results over time due to cashflow consideration; the temporal distribution is depicted in **Figure 3**.

The first 3 years are based on the historical data obtained from financial statements, and the simulation results are presented for 2020–2022. In all scenarios, losses are concentrated in the first simulation year, but in the two final scenarios, the firm generates a slight profit, except for the BAU scenario.

DISCUSSION

Previous studies [see, for example, (7)] highlight the need for regulatory change. The current regime appears to be biased toward MD producers and not the end users' safety and risk assessment. Kent and Faulkner (5) argue (p. 189), "that there are weaknesses in the regulation of medical devices and that commercial interests have dominated regulatory policy," and

(p. 191), "The processes of innovation outpace the development of regulatory controls." There has also been concern expressed about the increasing number of MD recalls (2). Leiter and White (6) argue that "medical devices are increasingly being implanted in human bodies, constituting manufactured risks."

One of the biggest problems for companies appears to be in acquiring clinical data, which will enable them to succeed in the conformity assessment or certification process, according to MDR 2017/745. Until now, MDD 93/42/EC requirements were perceived differently; the MEDDEV recommendations specified them. However, they were still recommendations. Within the MDR 2017/745, it is no longer a recommendation but a regulation. Thus, there is an obligation for manufacturers to demonstrate clinical data. However, it is not entirely clear whether clinical data from clinical trials or data from PMCF studies will suffice. Manufacturers believe that a well-designed PMCF process will provide them with sufficient quality clinical data to demonstrate their product's clinical safety. However, the rightly set PMCF process is an intervention in the economic situation of the company. It is the right time for manufacturers to decide what changes they will make to their processes and business model to avoid the financial impact on their business.

As the new regulations come into effect, 2021 will be a challenging year for many companies in the MD market. The legislative changes aim to make MDs safer for patients throughout their lifetime. For companies, this means additional control costs, even after an MD has been launched and also new clinical trials for MDs with a lower risk class than in the past.

From our research, it is clear that SMEs will be most affected by the change in legislation. Larger companies are better positioned to adapt to legislation changes because they already have a regulatory department to monitor and update the legislative requirements for their currently manufactured medical devices. Article 15 of MDR 2017/745 specifies that a manufacturer is required to have at least one person within his organization demonstrating his expertise in regulatory affairs, but at the same time admits that small firms may have such a person employed externally. From this point of view, the response to legislative changes in small companies will not be as dynamic as in companies that have established an internal regulatory department. These companies will be forced to make many changes that will impact their economic indicators.

Our market analysis shows that the larger the company the lower the percentage change in increased costs caused by the MDR new requirements. In our dataset, it was also apparent that, in general, micro-cap companies are specialized in the production of a few MDs in higher safety classes. Therefore, they will be disproportionately affected by new regulations, estimates of increases in certification costs as % of revenues are height. Larger companies focus on the large-scale production of class I MD's where it is harder to compete by small companies due to the economies of scale. That leads to specialization on MD's in more demanding safety classes, which will, unfortunately, be harder hit by increases to certification costs. The above-mentioned leads to a potentially threatening situation for SME's. The performed sectoral analysis further showed that the results obtained in the case study of Mediatrade are relevant in the Czech Republic case, as micro-cap companies (see **Figure 1**) share many of the same characteristics in general.

Overall, there is another problem in the medical device market, corruption. According to Transparency International's Index, the Czech Republic is one of the countries with a higher level of corruption. In the CR are identified illegal and non-standard methods of tendering and vendor lock-in Competitive Procedures Without Negotiation (CPWN). It allows to get the contract to a single bidder without a competition (Act 134/2016 Coll., § 63). In its reports, the Supreme Court repeatedly draws attention to CPWN's practices in securing public procurement, including at the level of ministers and institutions responsible for the purchase of medical devices and equipment. In the years 2011-2016, the share of these contracts ranged from 31 to 62% of their total volume. A common problem with non-standard methods in the health sector is the vendor lock-in, it means propriety lock-in or customer lock-in that makes a customer dependent on a vendor for products and services. Then the contracting authority often tends to compete for long-term contracts in closed procedures, for higher prices on the account of public funds. One of the specific examples in the field of healthcare is the creation of a cartel for the supply of medical equipment and modern technologies to the Czech hospitals (50). There is also pressure from the pharmaceutical and medical device industry toward the use of more profitable products. There is no definition of the standard health care covered by the insurance as guaranteed by the law. It happened in the past that the regulation was *ad-hoc* and usually even retrospective (51). This fat is confirmed by the European Research Centre for Anti-Corruption and State-Building (ERCAS), the Czech Republic has been one of the most successful Centre and Eastern European countries in the fight against corruption in all areas, including the healthcare sector. Nowadays, its administrative simplicity and transparency are comparable to European standards as a result of the harmonization of laws within the European Union (52).

CONCLUSIONS

Concerning the development of MDs, the EU regulations' changes present many challenges to the MD industry. The new stricter (heavy) regulations aim to improve patient safety through more rigorous quality assurance measures, but there is concern that this may adversely affect SMEs.

The Porter hypothesis implies that heavy regulation induces innovation while, on the other hand, there is a contrary view that heavy regulation is a barrier to innovation. Within the context of the new MD development regulations discussed in this paper, it would appear that, with respect to SMEs, heavy regulation may be a barrier to the innovation of new MDs. In contrast, with regard to larger organizations, such regulation may prove to stimulate innovation. However, while some SMEs may move away from MD development to non-MD products, they may transfer their innovative skills to these products to the medical profession's detriment.

Regarding research question Q1, our research shows that the new regulations should ensure improved MD safety. However, the economic load may be excessive both to the producer and healthcare provider. A problem is not only the price of the conformity assessment process, which in the Czech Republic varies with regard to the type and risk class of MD in the range of CZK 150–600 thousand within the assessment according to MDD 93/42/EEC but another difficulty for the manufacturer is the obligation to submit clinical data for conformity assessment. Obtaining clinical data that can be used for MDs' clinical trials and subsequently setting up the PMCF system in clinical trials may also be beyond small companies' power. The evidence also indicates that some SMEs may be forced to diversify to "non-medical" products, with the inevitable loss of some innovative MDs being made available to patients and healthcare providers. Q2 has partly been answered under Q1, but as the number of MD developers reduces so will the number of innovative MDs, thus restricting future MD innovation. Following the introduction of the new regulations, further research should be undertaken to verify our findings and perceived implications for the development of MDs by SMEs. On a more positive note, due to the effect of COVID-19, the implementation of the regulations has been delayed until 2021, giving companies the chance to manage the transition more positively and even seek out benefits through the opportunity of a competitive advantage.

Limitations regarding our study may arise from two perspectives; (i) the paper deals only with the production of MDs subject to MDD 93/42/EC, resp. MDR 2017/745 and does not, therefore, include MDs in class IVD, and (ii) it is based mainly on a single case study – Mediatrade. Due to the specifics of the selected company, namely its unique business model, previously received state subsidies and historical changes in the Czech accounting practices disallow exact replication of this case study. We have addressed this issue by supporting our research with a comprehensive analysis of the whole industry, which confirms the results obtained from Mediatrade. Nevertheless, we believe that the paper provides a valuable contribution to the literature concerning the innovative development of medical devices.

We believe the paper is timely in that it addresses an important current issue regarding the MD industry's future. In further support of the timely relevance of our paper is the concern regarding the current crisis over coronavirus (COVID-19), where innovation in medical devices, especially in the field of personal protective equipment (PPE) and respiratory/intensive care ventilator equipment, should be encouraged and not suppressed through restrictive legislation, although safety must be paramount. This article can also be a basis for further research and addressing issues such as what has happened after that date to confirm the concerns expressed before introducing the new regulations or refute them. How have the SMEs reacted to the new regulations? Has there been a decline in MD innovations? Have some SMEs gone out of business or moved away from MD development? What impact could Covid 19 have on the MD industry?

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

AUTHOR CONTRIBUTIONS

PM, LP, and FL contributed to conception and design of the study. LR performed the statistical analysis and graphical outputs. PM and LH wrote the first draft of the manuscript. PM, FL, LH, LR, and LP wrote sections of the manuscript. All authors contributed to manuscript revision, read, and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.666453/full#supplementary-material

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Social, Legal and Economic Implications for the Implementation of an Intelligent Wound Plaster in Outpatient Care

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Background: The care of chronic wounds is one of the core tasks of inpatient and outpatient care. The correct timing of changes has a significant impact on the positive course of wound healing. The VulnusMON project developed an intelligent wound plaster to determine the optimum time to change the plaster in hospital. Against the background of implementing the solution also in the outpatient sector, this article focuses on the following research questions: What is the legal framework for wound care in outpatient care? What are the differences in wound care between inpatient and outpatient care? What obstacles and barriers arise for the VulnusMON project when it is implemented in the outpatient sector? Can initial economic estimates be made for the transfer to the outpatient sector?

Method: Due to the complexity of the different research questions, a mixed method design was used. The qualitative part of the study includes both focus groups and expert interviews. As part of the quantitative analysis, a data set on outpatient wound care was analyzed (n = 463).

Results: In summary, it can be stated that the project VulnusMON and its intelligent wound plaster, which aims to determine the ideal time to change a wound plaster is viewed very positively by the professionals. However, there are a number of barriers that inhibit the potential transfer of the new digital solution to the outpatient setting. From an economic point of view, implementation in the outpatient sector makes sense, as travel times can be reduced. However, the study also points out important social implications, that pose several challenges for the actual transfer of the plaster to the outpatient sector.

Keywords: outpatient care, digital health, ELSI, wound management, health care

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INTRODUCTION

The care of chronic wounds is one of the core tasks of inpatient and outpatient care. The correct timing of changes has a significant impact on the positive course of wound healing. Especially in the outpatient setting, infection control is a particular challenge because the environment does not provide the same hygienic conditions that exist in a hospital (Payne and Peache 2021). In addition, several studies show that the treatment of chronic wounds is a hereditary cost factor in the health system that is very often underestimated. At the same time, the studies point to an urgent need for action in the optimization of wound care so that, on the one hand, the quality of life of patients is

improved and, on the other hand, the costs in the area of wound care do not increase uncontrollably in the future (Olsson et al., 2019; Nussbaum et al., 2018; Bates 2020). Against this background three main factors can be identified through which better wound management can be achieved: Shortening the wound healing time, optimizing the frequency of dressing changes and reducing the prevention of wound infections. By achieving these goals, the quality of life of patients can be improved on the one hand and the costs in the context of wound care can be significantly reduced on the other (Lindholm and Searle 2016).

Around 3.4 million people living in Germany need care services. Three quarters of these are cared for at home. A large part of the care for the approximately 830,000 people in need of care is provided by the approximately 14,100 outpatient care services. This does not include people who only receive home care according to the Fifth Book of the German Social Code (SGB V). A further 820,000 people in need of care are cared for in the 14,500 nursing homes licensed under SGB XI (Federal Statistical Office, 2018, 2019). The quality of inpatient facilities and outpatient care is assessed and recorded through regular systematic evaluation. According to this, 6.6% of those in need of care in nursing homes and 7.3% in outpatient care suffer from chronic wounds, such as diabetic foot ulcers, decubitus ulcers or vascular leg ulcers (Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen, 2017).

Wound management is understood to be much more than just wound care. In fact, wound care is a part of wound management. The spectrum ranges from uniform diagnostics, the determination of wound types, healing and treatment, pain management to wound documentation. Experts from various medical professions are involved, including nurses with special training, the so-called wound managers or wound experts.

Effective wound management is an enormous challenge and is based on the complete documentation of the healing process by the wound experts and enables appropriate treatment adapted to the respective stage of the wound. Rapid intervention and transfer to safe treatment pathways increases the chances of accelerating wound healing, prevents complications, reduces pain and improves the quality of life of those affected. A distinction is made between acute and chronic wounds. In the case of the latter, both wound care and support for wound healing are considerably more complex. Wounds are described as chronic if they persist for more than eight weeks without therapy or do not heal within one to three months with the right therapy (Storck et al., 2019; Dissemond et al., 2017).

Against this background, it is clear that digital products can make a significant contribution to improving the quality of care in the health sector (Haggerty 2017; Alami et al., 2017; Kraus et al., 2021). However, it is also evident that the digital transformation in the health sector has started later than in other industries and has to overcome a number of barriers and acceptance problems (Herrmann et al., 2018). The evidence on digital transformation in care can be described as rather abstract at this point in time, because in the context of reviews, trends are usually paraphrased that have little empirical evidence, are based on expert opinions, or do not systematically correlate subjective assessments and objective outcome effects (Johnson et al., 2019; Robert 2019). Studies that examine the perspectives of professional nurses on the use of digital technology in the work process focus in particular on the aspects of attitudes, acceptance and setting-specific readiness for technology. The results vary. While the spectrum of attitudes among caregivers ranges from skepticism to interest, more in-depth questions with a view to concrete obstacles to use reveal problems in completely different areas: For example, the technological infrastructures and possibilities for use are not always available, especially in elderly care facilities, and at the same time the age of the caregiver plays a central role (Papadopoulos et al., 2018; Rantanen et al., 2018; Coco et al., 2018; Hülsken-Giesler et al., 2019). In this context, ELSI research can make an important contribution to identifying problems and barriers already in the development process and to developing solution strategies for the further course of the project. (Goldenberg et al., 2019; Parker et al., 2019).

This paper describes part of the ELSI research, i.e., focusing on the social, legal and economic implications, using a concrete example. As part of the VulnusMON project, an intelligent wound plaster was developed that uses sensors as part of continuous monitoring to determine the optimal time when the plaster should be changed to optimize the wound healing process. For this purpose, parameters such as temperature, pH value, impedance and humidity are continuously measured and analyzed. The data from the local wound sensors are processed with further information and data from the patient's file. In this way, the wound healing process and the therapy are optimally supported. The patch was used in a German hospital as part of the project. The aim of this paper is to review the framework conditions that describe the potential use of the developed wound plaster in the ambulatory care sector. With this in mind, this paper describes the framework that characterizes the implementation of inpatient use in the outpatient sector. A practical implementation did not occur during the project period. Therefore, no conclusions about patient acceptance can be made at this time. For the ambulatory care sector there are some special features, so that a transfer and the associated requirements have to take certain aspects into account: Legal framework conditions that regulate the prescription of dressing materials, the place of use in the patient's household, which requires flexibility in standardized care processes, and a sometimes not yet high level of digitalization in the area of outpatient services, combined with a different form of work organization, present new challenges for the expansion of the VulnusMON project.

For the outpatient sector, there are two options, which are described below:

- Option I: Measurement and data transmission take place continuously in the patient's household. For this purpose, both the transmitter and receiver of the data are installed in the patient's household. The time of change is determined in real time.
- Option II: The transmission of data is done by a device that the outpatient care service carries with them. Accordingly, the care provider must be on site to transfer the data. The determination of the optimal time of change can therefore be delayed under certain circumstances.

TABLE 1 | Research design.

Topic		Method
Legal framework	Qualitative	Literature review
Differences in wound care between inpatient and outpatient		Focusgrups
Obstacles and barriers		Focusgroups
Economic	Quantitative	Data analysis

In order to develop targeted solution strategies in good time so that implementation in the outpatient sector can succeed, the overarching main question of the paper can be formulated as follows: What contribution can ELSI research make to support an implementation of a digital application in ambulatory care? This raises the following questions:

- What is the legal framework for wound care in outpatient care?
- What are the differences in wound care between inpatient and outpatient care?
- What obstacles and barriers arise for the VulnusMON project when it is implemented in the outpatient sector?
- Can initial economic estimates be made for transfer to the outpatient sector?

METHODS

Due to the complexity of the different research questions, it was decided to use a combination of different research methods. The methodological approach is based on the principles of mixed methods, in which both quantitative and qualitative research methods are used.

This raises the question of what goal is pursued by pursuing the research question with both quantitative and qualitative methods, if this results in a considerable additional expenditure of time and not infrequently also material and financial resources. There is agreement in the research landscape that the combination of the two approaches should balance out the respective strengths and weaknesses (Creswell 2014; Baur und Blasius 2014; Kelle 2014).

In this study, too, the main question is therefore the added value of combining methods to answer the question. If one orients oneself to the five basic functions (validation, complementarity, initiation, development and extension) to which a mixed methods approach can be assigned, the function of extension is identified for the present expertize. This function is characterized by the fact that the quantitative and qualitative approach refer to two different areas in connection with one object (Schreier and Odağ). The subject matter is ambulatory wound care, the quantitative approach refers to economic issues while the qualitative approach refers to the experiences and evaluations by the nursing staff. This research design can be called Convergent Parallel Mixed Methods (Creswell 2014) and can be presented as displayed in **Table 1**.

In the first step of the study, a literature review was conducted, which took into account both the state of the art in outpatient wound care and the legal basis in Germany. The qualitative part of the study includes focus groups as well as expert interviews. A total of two focus groups were conducted. In the first focus group, a special focus was placed on outpatient wound care and the associated challenges for the wound patch. The focus group consisted of eight wound experts who work in ambulatory care. The second focus group dealt with general questions about digitalization in the outpatient care sector. This focus group consisted of management and nursing staff as well as people from the technical sector. Furthermore, five expert interviews were conducted with managers of outpatient care. The content of the focus groups was as follows: At the beginning, the process of wound care in outpatient wound care was addressed (only in focus group 1); in the further course, the impact of digitalization on the outpatient sector was discussed. In the last part, the digital solution was presented in order to discuss questions of potential practicability and acceptance. The expert interviews included the same thematic aspects and served to sharpen the content of the results.

The instrument of qualitative content analysis was chosen as the evaluation method. It stands as an evaluation method for data that accrued within the framework of qualitative research projects and is characterized by the fact that it is also able to handle large data volumes and to structure them through a rule-guided procedure (Mayring and Fenzl 2014). Within the framework of the quantitative analysis, a data set on outpatient wound care of an outpatient nursing service was analyzed. Descriptive methods were used for the analysis, all calculations were carried out with the statistical software SPSS.

RESULTS

The Legal Framework for Outpatient Wound Care

Successful treatment of chronic wounds often takes place with the involvement of several medical professional groups to ensure proper wound care. The treatment usually extends over a longer period of time. Professional assessment and treatment of wounds is crucial for wound healing and can be carried out by doctors as well as by qualified nursing staff, the so-called wound managers. The doctor is initially responsible for diagnosis. When deciding on therapy, which is also part of his or her area of responsibility, he or she decides whether and to what extent treatment care activities should be delegated to nursing staff (Reibnitz and Skowronsky 2018).

Should it prove medically necessary from the doctor's point of view, he or she can refer the patient to a specialist or even to hospital for inpatient treatment. Wounds are treated with dressings specially developed for wound care, which can be redeemed by a prescription from the doctor at a pharmacy and a medical supply store. As with medicines, the statutory co-payment applies here for each dressing prescribed.

The dressings are changed at a prescribed interval according to the instructions of the attending physician. The doctor can issue a prescription for the outpatient nursing service. As a rule, the wound managers are responsible here, whose goal is to promote the quality of life of the affected person through appropriate wound care, to support wound healing and to prevent a recurrence of the wound. If necessary, wound managers can also instruct patients to take over wound care independently in the long term. Dressing changes by an ambulatory care service are a service of home health care and are subject to reimbursement. In general, the expenses for the necessary measures for wound care are prescriptive according to §31 SGB V and are covered by the health insurance funds. The professional wound and photo documentation is part of the nursing documentation and therefore falls under the responsibility of the wound managers. The physician's task is to document the course of treatment in the medical records (Deutsches Netzwerk fü; Reibnitz und Skowronsky 2018).

In order to successfully carry out wound healing, further medical products, so-called aids, may be necessary in certain cases. Aids to support the healing process of wounds can also be prescribed by the doctor. These can be obtained from a medical supply store.

When prescribing services and products, the doctor is bound by the principle of economic efficiency according to §12 Para. One SGB V, i.e., the services must be sufficient, appropriate and economical and must not exceed what is necessary. For this reason, not all available services and products are reimbursable for wound treatment and can only be reimbursed after prior individual approval by the health insurance fund. If they are not included in the catalog of benefits of the health insurance funds, they must be financed by the patients themselves.

Outpatient wound care is subject to specific courses of action and legal framework conditions that must be taken into account for the appropriate care of patients, but also for the protection of service providers. The legal and contractual stipulations in the Social Code Book XI and Social Code Book V define the range of services of outpatient care that are available in Germany for the management of problem situations in connection with illness and the need for care in the home environment. The Federal Joint Committee has expanded the specifications for the care of patients with chronic and difficult-to-heal wounds in the area of home care in 2019. According to this, the care of chronic and difficult-to-heal wounds should primarily take place in the household of the insured person or, according to §2, in other suitable places where the insured person frequently spends time.

If this is not likely to be possible in the insured person's home due to the complexity of the wound care or the circumstances in the home, the wound care should then take place in specialized facilities. However, this must be evident from the regulation. For the care of chronic and difficult-to-heal wounds, the service is to be prescribed according to the procedures for no. 31a. According to §3, every home nursing measure requires a medical prescription. The service providers who carry out the measures within the framework of home nursing care are first bound by the prescription and then by it if approval is given.

According to §7, the care provider reports to the treating contractual doctor on changes in the home care situation, in particular home nursing care, or upon request by the doctor, if necessary also by transmitting extracts from the care documentation. The doctor decides on the necessary measures resulting from this (Gemeinsamer Bundesausschuss 2019). Accordingly, the legal framework clearly specifies that the prescription for treatment is made by the general practitioner. For the VulnusMon project, this means that, especially in the outpatient sector, GPs must be included in the supply chain and they must also have the necessary infrastructure.

Differences in Wound Care Between Inpatient and Outpatient Care Settings

In the focus group discussion, the ordinary process of wound care is discussed. The usual care process is as follows: A wound expert goes out to the patient and looks at the wound and takes a photo. The expert then contacts the primary care physician because he or she must issue the prescription. The wound expert makes a recommendation on how to treat the wound. The doctor then makes the decision on how to treat. Ideally, there is subsequently regular contact with the family doctor's office with photo documentation of the wound healing:

> "*Normally, if the wound deteriorates, contact is made with the primary care physician or the physician specifies a time period where the status of the wound should be reported. If there are changes or deterioration, an alternative treatment method can be discussed.*"

Most wounds that occur are pressure ulcer treatments, leg ulcers, unhealed surgical wounds, and wounds related to falls. In this regard, the wound managers note that there is a specific treatment method for each wound. This also means that there are different dressing materials and certain materials are contraindicated for certain wounds. This results in a wide range of patients with different ages. In general, the average age of patients with wound care only tends to be lower than in the outpatient setting. There are many patients with wound healing disorders after surgery. As already described above, these are usually patients for whom only the wound is treated and who, after healing, are no longer part of the nursing service's clientele. Regarding the task of wound experts, however, it must be noted that their duties do not exclusively include the care of wounds. The nurse must also perform the other tasks of care. In everyday life, it can always be the case that other nursing staff who are not so well versed in wound care consult the wound experts.

The group clearly states that there is no such thing as "typical wound care" in outpatient care. The care processes are much less

standardized here than in inpatient care, because the nurses have to adapt to the home situation and the associated environment.

Wound care in the outpatient setting is very different from care in the inpatient setting. There is significantly less time available: For example, there are wound irrigation solutions that are supposed to soak in for 15 min. In outpatient care, there is no time for this. On average, dressing changes in outpatient care take 8 min. In this situation, the nurse must therefore assess whether to reduce the exposure time and thus accept that the solution will not achieve its full effect, or whether the specified time will not be adhered to, which can, however, result in the entire time and tour schedule being disrupted. In general, it is noted that the time allowance is a major problem: if the preparation time of the workplace, the careful disinfection and the changing into appropriate protective clothing are included, there is effectively very little time left for the actual assessment, documentation, and care of the wound.

There are also significant fluctuations in the amount of wound care that is provided to patients: There are times when there are very few patients with wounds to care for, but then it can also happen that five new patients with wound care are added in one fell swoop. Very often it is the case that only the wound needs to be treated and no further nursing care is provided. Typical examples of this are wound care after operations or secondary wound healing. For the nursing staff, this means that they must constantly adapt to new situations and environments.

Regarding the actual care process, the focus group notes that there are many differences compared to wound care in the inpatient area. In the inpatient setting, the entire process can be observed with better accuracy, because there is constant contact and exchange with the patients. In outpatient care, for example, dressing changes are prescribed three times a week, and the patient is then visited on these days. However, nurses often are unaware of what is happening on the other days. If the patient is unable to report if something is wrong with the dressing, the wound healing process can be adversely affected. Such problems and difficulties can occur repeatedly. Therefore, outpatient nurses must be prepared to react very flexibly.

The actual work process is also influenced by the situation on site. It very often happens that the hygienic conditions are not the same as in the hospital:

> "That doesn't even mean that households are particularly dirty. Of course, that happens, too, but that's a completely different issue. There are just things that are just different than in the hospital. There isn't always a closet where we can store the material. In many households, there are also pets, so you have to pay special attention. In inpatient care, if you don't have enough material or need something else, you can go to the material storage. In outpatient care, however, you have to make do with what's on hand. That's where improvisation is often needed."

The group goes on to say that in many cases the workspace is significantly limited, and one must improvise because the work surface is much smaller than in the hospital. In addition, the lighting conditions are not always optimal.

A very central distinction from inpatient care is the role of the caregiver, which is taken in outpatient care:

> "*The role of the nurse is also different. You are a guest in someone's home and if a patient wants something done a certain way, even though it doesn't make sense from a professional point of view, you do it the way he or she wants it done. That may sound more dramatic than it is. Generally, there are few problems, but you have to keep reminding yourself that you are invading their privacy much more intensively than you would in inpatient care.*"

This aspect applies not only to wound care, but to the entire nursing process and is very closely linked to adherence to specific times. The group states that a steady routine of care is very important for many patients:

> "*Many patients are used to fixed times when we visit them. They adjust to this and set up their daily routine that way. If we then come at other times because there is a postponement, because an emergency has come up or the tour had to be changed, some become impatient quickly.*"

In the focus group it emerged that in several cases there are problems with the communication with primary care physicians. Although all participants in the focus group have further training as wound managers, in certain cases they feel that they are not taken seriously in the discussion with the primary care physician when the treatment process is coordinated:

> "*Doctors never discuss with us at eye level, but many doctors have no idea about wound care.*"

Problems always arise when primary care physicians prescribe treatment that is out of date and not conducive to the wound healing process. In such a situation, the wound expert is allowed to say if he or she does not agree with a treatment and can refuse to perform it. A continuing education program ensures that wound experts are always aware of the latest advances in care. They usually have a significant knowledge advantage over primary care physicians, although some practices now have wound experts. Additionally, a very common problem is prescribing high-cost materials because it impacts the primary care practice's budgeting. In general, one has to be much more economical with materials in outpatient care because much less is prescribed and one always has to obtain a new prescription from the practice, combined with the difficulties just described. Very often, these disputes are fought out at the expense of the patients, because they do not receive the most effective care:

> "*In one specific case, a doctor refused to prescribe dressing material, this was all documented and the*

wound actually worsened considerably. It was then suggested to the practice that the patient should be transferred to a wound outpatient clinic, and that ultimately happened."

Relatives also play a very important role in the outpatient care setting. This does not only apply to wound care, but it also rather refers to the entire care process. Sometimes relatives make a lot of effort, but sometimes they don't. For example, they apply ointments that don't help at all and sometimes even contribute to worsening the wound. This is often well-intentioned on behalf of the relatives because they want to support the nursing staff in their work. Very often, however, the exact opposite is achieved, as the wound healing process is halted. In this situation, it is very difficult for nurses to find the correct words so as not to offend the relatives. Some relatives also want to observe and document every step of the process. The nursing staff consider this to be very disturbing, because they cannot concentrate on their work and are distracted:

"*It has also happened several times that I have ordered a relative out of the room because he was disturbing too much. Of course, he is offended at first, but you have to find the right words and make it clear that you can't do your job properly like that.*"

Obstacles and Barriers

The focus group agrees that digitization has not yet made much of an impact on outpatient care. The care documentation that is carried out at the care service, for example, is still done handwritten. The group knows that it is already different at other services. They state that in a few years, complete documentation will certainly be done digitally. However, the group cannot judge when a digital transition will take place. However, a conversion to digital documentation requires a lot of time and requires a complete reorganization in many processes. Above all, the documentation is viewed very critically:

"*A digital care plan is very inflexible, you can't react as flexibly to changes as you can with handwritten documentation. It lacks all the individuality of the patients. It is much too rigid. Wound documentation in particular has to happen very individually. I have great doubts as to whether digital documentation can reflect this individuality.*"

However, some processes are already being done digitally today. Tour planning is already done digitally today. A central PC creates the plan, which is then transferred to the nurse's cell phone. In addition, the photo function of the cell phone is used for documentation, especially for wound care, because this allows the healing process to be recorded at regular intervals:

"*In rare cases, it even happens that the doctors have the wound history sent to them via WhatsApp. They can then respond with their prescriptions and adjust the material if necessary. However, this does not happen very often.*"

The focus group finds it very difficult to make a general assessment of whether digitization has a positive or negative impact on outpatient care. In many cases, data protection hinders work in outpatient care (e.g., fetching prescriptions). A lot depends on how user-friendly the programs are. The group describes the impression that many functions are not always useful. In addition, there are also fears and doubts among the patients:

"*On the street, everyone is just walking around with a cell phone. Now the nurses also come with cell phones and start clicking around.*"

In the further course of the focus group discussion, the VulnusMon project, i.e., the intelligent wound plaster, is presented to the participants and it is discussed with them how sensible it is to use it in outpatient care. The group notes that many patients find digital devices very impersonal. There are also doubts as to whether patients agree to their data being transmitted:

"*Many patients see this as an intrusion on their autonomy and do not want to relinquish control over their bodies in this way. They will certainly feel a kind of surveillance.*"

Another problem is that cell phones already have many gaps in coverage in many regions. Whether smooth data transmission is guaranteed in all households is highly doubted. If a Wi-Fi connection has to be available in the household, there are further problems, because at the present time many people do not yet have Wi-Fi in their homes and do not intend to acquire this technology. This is especially true for senior households. In addition, the fixed daily structure of the patients mentioned above is seen as a possible barrier to implementation:

"*The patient needs communication. It is difficult not to be able to tell the patient exactly when you will be back. These fixed appointments play an important role.*"

The experts further note that the patient's condition plays an important role in whether such a system can be used. There are very often restless patients who move around a lot, so the dressing can slip due to scratching or movement. The group is sure that these effects will certainly influence the measurement. On size and material, the experts note that there are very different sized wounds. And on dressing material, it has already been said above that there is different material for certain types of wounds:

"*One for all does not work!*"

Many wounds are also dressed with compression, so the plaster must also be able to withstand pressure and must not negatively affect the wound in the process. This aspect must

TABLE 2 | Total number of patients and patients with wound care.

	Number	Share
Total number of patients	463	100%
Patients with wound care	75	16.2%
Patients ONLY with wound care	21	4.5%

TABLE 3 | Age structure of the patients.

Age	Patients with wound care (%)	Patients only with wound care (%)
Under 60	7	8
60–69 years	14	19
70–79 years	19	24
80 years and older	60	49

TABLE 4 | Average duration of care services in minutes.

	Avg	Min	Max
Total number of patients	10.9	5.1	20
Patients only with wound care	12.5	6.6	20
Patients with wound care	10.2	5.1	18.3

definitely be taken into account in further development, as the wound often remains unseen for several days, especially in the outpatient area. If the transmission does not work and the sensor causes unnecessary pressure points, this can have serious consequences for the wound healing process.

Determining the ideal time to change dressings is seen as very useful, although it is associated with difficulties when implemented in outpatient care. However, it would be conceivable for the data to go directly to the primary care physician. This relieves the nursing service and reduces errors in the transmission of information.

Economic Estimations for Outpatient Wound Care

During the expert interviews with managers of outpatient care services, the aspect of the economic dimension was addressed:

> "It can be assumed that, from an economic point of view, pure wound care is not lucrative for the nursing service. You travel to the patient every other day to treat the wound, regardless of whether the plaster needs to be changed or not. The nurse spends a lot of time in the car, which cannot be billed."

This statement will be verified in the following using quantitative methods. For this purpose, the patient data set of the nursing service involved in the project will be used. The data set contains all patients who received nursing care in 2017. Accordingly, the project does not collect its own data material, but rather concentrates on the analysis of secondary data material. The data set includes information on gender, age, type of care, and duration of care.

In 2017, a total of 463 patients were cared for by the outpatient nursing service (**Table 2**). Of these, 75 patients received wound care, which corresponds to a share of 16.2%. An analysis of the data shows that a large proportion of patients who receive wound care also receive other nursing services from the nursing service. This is the case for 54 patients, consequently 21 patients received only wound care from the ambulatory care service in 2017. More than 70% of the patients who receive wound treatment also receive other nursing care. The proportion of patients who are cared for exclusively by the outpatient nursing service for wound care is thus just under five percent (4.5%).

If we look at the age structure of the patients, the following picture emerges: The average age of patients receiving only wound care is 69.8 years (SD 15.88). For patients who receive other nursing services in addition to wound care, the value is 78.9 years (SD 11.01). The difference is significant ($t(63) = 2.710$, $p = 0.009$). **Table 3** shows how the proportions are distributed within the age groups.

The age structure of all patients with wound care shows that the majority of patients can be attributed to the group of the very old (80 years and older): With 60%, clearly more than every second patient with wound care is 80 years and older. One fifth of the patients form the group of persons who are between 70 and 79 years (19%). With decreasing age, the proportion becomes smaller: 14% of the patients can be assigned to the age group 60–69 years. Only 7% of the patients are younger than 60 years. If one looks at the age structure of patients for whom only wound care is performed, the assumption that these patients are younger than patients for whom additional nursing services are performed is confirmed: The proportion of persons younger than 60 years increases by one percentage point. The increase in the next age group is already clearer: with 19%, the share value in the age group 60–69 years is clearly higher than in the patients for whom a nursing measure is also carried out in addition to wound care. To assess the correlation Cramer V was calculated. There is a medium correlation between the variables age group and wound care ($V = 0.396$).

In the following, it will be shown how long an intervention at the patient's home usually takes. Here, a differentiation is made between patients with additional nursing care and pure wound care.

From **Table 4** it can be deduced that there is a slight difference in the average duration of care: While the average duration of care for patients with only wound care is 12.5 min, it is slightly shorter at 10.2 min for patients who receive care in addition to wound care. At the same time, both types of care show a very wide range. If we look at wound care alone, the minimum is 6.6 min, compared to a maximum of 20 min. The difference is significant ($t(61) = -2.806$, $p = 0.007$).

In a further step, it will now be examined which economic statements can be made about outpatient wound care on the basis of the patient data. For this purpose, the following hypothesis is formulated: H_1: Pure wound care is not effective for the nursing service from an economic point of view.

The following key figures will be used for this purpose:

TABLE 5 | Economic framework for outpatient wound care.

22 Patients with wound care only		
Number of deployments	767	
Revenue per deployment	14.19 €	
Total revenue	14.19 € × 767	10.884 €
Total operating times (without route)	158	
Travel times in hours	128	
Total effort in hours	286	
Hourly rate (incl. Material and overhead costs)	45 €	
Total cost	45 € × 286	12.872 €
Difference	Defizit	1.988 €

- Number of patients
- Number of operations
- Revenue per operation and total
- Total operating times in hours
- Total travel time in hours
- Total costs

As seen in **Table 5**, it can be concluded that the pure care of wounds in outpatient care without additional nursing services is associated with deficits for the nursing service presented here. These deficits can be explained above all by the high time expenditure of travel: In one year, 767 missions were made in which only wound care was administered to the patient. This corresponds to a time expenditure of 286 h. Of these, 128 h were spent in the car alone, which corresponds to a share of almost 45%. The driving time is not billable for the nursing service, so a large part of the working time incurred is not billable for the nursing service via the health insurance. The other 55% of the total time is spent on wound care in the patient's home. Here, one service is remunerated at €14.19. If the costs for the nursing service are calculated using an hourly rate of €45, which includes material and overhead costs in addition to personnel costs, this results in a total deficit of almost €2,000 per year. The results clearly show that the hypothesis formulated at the beginning is agreed with.

Against the background of this calculation, it becomes clear that the introduction of the digital wound plaster makes sense from an economic point of view. The area of wound care has so far been running at a deficit. With the determination of the optimal time for changing the plaster, travel times can be reduced, as it can be assumed that the number of interventions will also be reduced. This calculation assumes that the wound healing process is better with the use of the digital wound plaster than with conventional wound treatment.

DISCUSSION

In this section, the identified barriers are now discussed with possible solutions for a successful implementation in the outpatient setting: The central person in outpatient care in wound care is the wound manager, who contacts the general practitioner after inspecting the wound. He makes suggestions for treatment, the final decision is made by the general practitioner. The general practitioner then issues the prescription for the wound treatment. This process does not run smoothly in practice. In many cases, communication with the general practitioner is not on an equal footing, so that the wound manager's recommendation is not always put into practice. The GPs are not always up to date with the latest developments in wound treatment. In addition, low budgeting for reimbursement often leads to treatment steps not being prescribed in a timely manner. For this reason, a follow-up project is recommended in which the inpatient solution is transferred to the outpatient sector. In this follow-up project, a network of nursing services, general practitioners and specialists should be created, in which a joint training can be implemented and evaluated.

It should also be noted that there is a specific treatment method for each type of wound, combined with the correspondingly different dressing materials. The sensors must therefore be applied to different dressing materials. An alternative would be to separate the sensors and the plaster material so that both can be combined individually for the corresponding wound type. A number of wounds are treated with compression bandages that apply pressure to the wound. The material of the sensors must be chosen so flexibly that no pressure points can develop.

In outpatient care, wound treatments often occur where only the wound is treated, and no other nursing services are performed. Very often, the patients are younger on average than the other patients in outpatient care. Many elderly people do not yet have a Wi-Fi-connection in the house. A mobile solution that the care service brings with them is less suitable because the data cannot be passed on continuously. As part of a follow-up project, the households should be equipped with the technical infrastructure. In the course of the increasing digitalization of households, however, this barrier will become smaller in the near future.

The work processes in wound care in outpatient care differ significantly from the processes in inpatient care: The situation alone of being a guest in the patient's household is a challenge for the nursing staff. Furthermore, the working conditions (cleanliness, hygiene, material, workplace) are not at the same level as in inpatient wound care. The use requires a rethinking in the entire area of outpatient care: This applies to the operative level as well as to the planning and management level. When using the digital solution, the nursing staff must be able to react flexibly when a dressing change is indicated.

In general, the effects of digitalization on the field of outpatient care are perceived as rather difficult: Experiences with digital documentation have not provided any relief; rather, it has not been able to map the complexity and individuality in outpatient care. At the same time, it is also evident that there has been very little experience with digital products in outpatient care so far. The overall goal of the VulnusMON project is positively received, but the high degree of digitalization and further barriers (e.g., plaster must be able to treat different types and sizes of wounds) ensure that the use of the digital wound plaster in care is assessed as rather unlikely

at the present time. The effectiveness of the application must be proven by clinical studies. This will make the benefits more transparent for nursing staff and patients. Furthermore, a participatory method should be chosen within the framework of a research project for implementation in the outpatient sector, so that nursing staff and doctors' practices are involved in the development and adaptation process at an early stage.

In summary, the integration of ELSI questions in the context of an exploratory study turns out to be very useful. Thus, barriers and obstacles could be identified at a very early stage, which can be taken into account in further project planning. It has been shown, for example, that implementation will lead to major changes in established work processes. As a result, the qualification process, which is absolutely necessary for successful implementation, should include not only nursing staff but also physicians and patients, because their routines will also change significantly. At the same time, it shows that it makes a lot of sense to look at all aspects of ELSI research together in order to point out apparent contradictions and to develop measures in time that can resolve the contradictions. The example of the intelligent wound plaster, for example, has shown that implementation makes sense from an economic point of view, but that social implications present a number of challenges that need to be addressed in the actual implementation phase.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

AUTHOR CONTRIBUTIONS

PE was responsible for the research design. PE was also responsible for data collection and analysis. The writing of the manuscript was done in collaboration between PE and AK.

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CONCEPTUAL ANALYSIS
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Implementation of Assistive Technologies and Robotics in Long-Term Care Facilities: A Three-Stage Assessment Based on Acceptance, Ethics, and Emotions

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Assistive technologies including assistive robots (AT/AR) appear to be a promising response to the increasing prevalence of older adults in need of care. An increasing number of long-term care facilities (LTCFs) try to implement AT/AR in order to create a stimulating environment for aging well and to reduce workload for professional care staff. The implementation of new technologies in an organization may lead to noticeable cultural changes in terms of social interactions and care practices associated with positive or negative emotions for the employees. This applies especially for LTCFs with high rates of vulnerable residents affected by increasing care needs and specific ethics in nursing and cultural rules within the setting. Thus, systematic consideration in leadership management of emotions and ethical aspects is essential for stakeholders involved in the implementation process. In this article, we explicitly focus on the emotions of the employees and leaders within LTCFs. We relate to direct consequences for the organizational well-being and culture, which is of course (indirectly) affecting patients and residents. While aspects of technology acceptance such as safety and usefulness are frequently discussed in academic literature, the topic of emotion-management and ethical questions during the organizational implementation process in LTCFs received little attention. Emotional culture entails affective values, ethical norms and perceptions of employees and further investigation is needed to address the importance of transformational leadership during implementation process. For this purpose, we developed a three-staged assessment tool for implementation of AT/AR in long-term care institutions. Acceptance (A), ethical acceptability (A) and emotional consequences (E) are considered as comprehensive assessment, in which emotional consequences comprise management aspects of transformational leadership (T), emotion-management (E) and organizational culture (O). Based on AAE and TEO, this paper presents an integrated framework illustrated with a illustrative example and aims to combine established approaches with ethical insights in order to unfold potentials of AT/AR in LTCSs.

Keywords: assistive technologies, assistive robotics, care homes, long-term care, ethics, organization, emotion management, quality of life

INTRODUCTION

Digitalization 4.0 and assistive technology including assistive robotics (AT/AR) evoke certain aspirations in health care with regard to well-being and economic arguments (Magsamen-Conrad and Checton, 2014). In March 2018, the World Health Organization (WHO) promoted the access to AT/AR for all member states:

"The impact of assistive technology goes far beyond the benefits of health and well-being to individual users and their families. It also has socioeconomic benefits, by reducing direct health and welfare costs (such as hospital admissions or state benefits), enabling a more productive labor force, and stimulating economic growth" [World Health Organization (WHO), 2018, p. 3].

AT/AR embrace various dimensions of interesting products, aids, devices or software which enable persons with functional losses, e.g., communication boards, screen readers, positioning devices or service robots[1] [International Federation of Robotics (IFR), 2021]. In 2019, the market for professional service robots increased by 32% [International Federation of Robotics (IFR), 2020]. Growing potential can be assumed, when more robots could overcome the prototype stage (Bedarf et al., 2015; Hersh, 2015; Scassellati and Vázquez, 2020).

Within the last decades information, communication and assistive technologies seem to find their unstoppable way into (health-)care facilities, even when many institutions in residential care—compared to technological pioneers in long-term care like Japan—are still struggling with general preconditions for new technologies (e.g., access to wireless internet) (Moyle et al., 2018; Seifert et al., 2020; Grüneberg, 2021; Tan et al., 2021).

Especially for decision makers in long-term care facilities (LTCFs)[2] AT/AR suggests new opportunities related to preserving activities and personal well-being for residents, lower health care costs, reduced workload for professional caregivers and solutions for nursing shortage (Sharkey and Sharkey, 2012; Bonaccorsi et al., 2016; Scassellati and Vázquez, 2020; Tan et al., 2021).

Robots are supposed to be used in long-term care for different purposes: to solve logistical challenges, as supportive aid for basic needs, for safeguarding and monitoring, and for instrumental tasks like cleaning or social interaction (Tan et al., 2021). At the same time, LTCFs represent particular challenging settings including self-image of care and specific vulnerable clients. In Germany for example, about a quarter of all persons in need of care are living in LTCFs, of whom more than 70% suffer from severe impairment of independence (Destatis, 2020).

In this respect, AT/AR may lead to fundamental organizational changes in LTCFs and the question is not if or when, but "how best to shape and direct our efforts to optimize the development and application of new technologies" (Schulz et al., 2015, p. 725).

AT/AR already posed a controversial discussion about safety, social justice, usefulness and appropriateness in long-term care. In addition, discussions arose on questions of economic viability, customer acceptance, co-design and user impact (e.g., stress level) (Berkowsky et al., 2017; Chu et al., 2017; Kwon, 2017; Meyer and Fricke, 2017; Diefenbach, 2018; Merkel and Kucharski, 2019; Peine and Neven, 2020). All these aspects have already been explored in current research literature, even though a deeper understanding, for example, of ambivalent user acceptance is still needed (Hersh, 2015). In this respect, Krick et al. (2019), provide a systematic review on three core outcome dimensions concerning digital technologies for all participants involved in the care sectors by focusing on *acceptance, effectiveness and efficiency* (AEE) of new technologies.

While these dimensions of AT/AR in long-term care are frequently discussed in academic literature, *emotional and ethical* acceptance and acceptability, and the *role of leadership* within organizations received little attention so far. Even though some studies underline the importance of implementation circumstances and management practices (e.g., further education of employees) (Tan et al., 2021), deeper investigations are required in terms of management approaches as Melkas et al. (2020, p. 5) point out: "Robotic research has so far focused on technical implementation, technology development, and clinical applications, but there has been limited discussion on social and managerial issues that might be equally important for successful robot use."

The aim of this article is to address stakeholders and management staff in LTCFs in their strategic leadership role in the AT/AR implementation process. From our perspective, it is important for this target group to examine "emotion-management," which means the recognition of ethics and emotions (explicitly from staff and implicitly from LTC-residents) within the organization (Thiel et al., 2012). As the majority of LTC-residents experience multimorbidity, cognitive impairments, functional decline and decreasing quality of life (e.g., lower levels of loneliness) (Boggatz, 2020), LTCFs represent a specific workplace environment, where the demanding conditions of residents and social norms frame multiple dimensions of emotionality (Bolton, 2001). Fulfillment of professional care tasks like conversations, lifting or washing by different kinds of robots, has emotional and ethical consequences for both patients and staff in care homes. This applies in particular in consideration of nursing values like autonomy, beneficence, justice and non-maleficence (Beauchamp and Childress, 2001; Sharkey and Sharkey, 2012; Haddad and Geiger, 2020 Tan et al., 2021). In addition, anxiety and skeptical expressions of nursing staff can be assumed in the fear to become replaced by technology (Feil-Seifer et al., 2007; Broekens et al., 2009; Wolbring and Yumakulov, 2014; Coco et al., 2018; Mitzner et al., 2018). From a practical perspective, this means that strategic planning and understanding of significant affects

[1] Defined as a robot "that performs useful tasks for humans or equipment excluding industrial automation applications." Service robots can be categorized as medical robots, logistic robots or field robots (ibid). Further categorizations of robot-based services differ between (1) assistive robots primarily used for physical applications, (2) socio-emotional robots for companionship and (3) robots for health and safety monitoring (Sharkey and Sharkey, 2012; Prabuwono et al., 2017; Meyer et al., 2020).

[2] Defined as "a facility that provides room and board, as well as management of chronic medical conditions and 24-h assistance with ADLs in patients who are physically and/or cognitively impaired" (Klein et al., 2013; Sanford et al., 2015: p. 182).

and emotions are critical to the ongoing success of a modern organizations (Thiel et al., 2012).

We therefore combine Bolton (2005) idea of "*emotion-management*" and the concept of "*transformational leadership*" according to Bass and Avolio (1994). Bolton developed a multidimensional approach to emotionality in organizations with specific focus on nurses, in critical engagement with Hochschild (1989) distinction on emotional work and emotional labor. For Bolton, feelings and motivations are central in interactions within an organization, where actors (leaders as well as workers) are able to channel emotions in their workplace to achieve organizational goals. Workers are purposive agents of their emotions, but constrained by organizational emotion rules and embedded in broader cultural beliefs and values. Bolton provides a typology of four dimensions of emotion-management, from which we depict "prescriptive emotion-management" as most relevant for our topic (= emotion-management according to organization/professional rules). This means, that organizational power is related to emotional rules, as Bolton (2005, p. 8) labels "nurses as multi-skilled emotion managers" (see also Cranford and Miller, 2013). The approach of transformational leadership we refer to, underlines the role model function of leaders, setting attractive goals and fostering motivation and stimulation for employees (Bass and Avolio, 1994). Leaders and management staff express themselves through aspects such as inspiration, vision or personal role model action and thus deliberately appeal to emotions of their employees.

Drawing on both concepts, two questions arise as relevant for this paper: (1) How can emotion-management and transformational leadership fruitfully contribute to AT/AR implementation within LTCFs? (2) How can a holistic assessment of emotional and ethical aspects be designed as part of the change management process for AT/AR implementation in LTCFs without neglecting the acceptance-perspective?

To address these questions, we apply the AEE system by Krick et al. (2019) as an assessment tool and develop it further with regard to ethics and emotionality in organizations. First, we present an ideal-typical, but concrete illustrative example of such technology, which we see as the central thread of our presentation (2). After that we outline general practical consequences of AT/AR implementation in the care sector for organizational culture in view of our illustrative example (3). In the following section, we systematically illustrate our assessment criteria with regard to emotions and ethics (4, 5), and apply it to the illustrative example in three stages (6). We conclude with a look at our contribution to the discussion, followed by an outlook (7).

ILLUSTRATIVE EXAMPLE

Some hurdles and opportunities of negative emotions and concerns of acceptance and acceptability are typical challenges for AT/AR implementation processes (Diefenbach, 2018). An inpatient LTCFs is planning on implementing the "Care Assist Robot" (CAR, **Figures 1**, **2**; Toyota, 2021). The facility has 61 bed spaces, of which 21 patients are cognitively impaired and in need of severe care, and predominantly require 24-h assistance. CAR is to be used for people with multimorbid diseases as well as physical limitations during early and late duty. As **Figures 1**, **2** show, it will be used in work processes such as transfers and lifting, e.g., from bed to wheelchair, or in personal hygiene processes from the wheelchair to the bathtub. CAR is thereby operated by a caregiver. Nursing staff, nursing assistants and care assistants are to be supported and relieved (and, among other things, skeletal and muscular disorders on the part of the nursing staff are to be reduced preventively), because lifting and transfer services are physically very strenuous (Future of Occupation, 2015).

The organization also expects a significant reduction in costs and compensation for the existing shortage of nursing staff through the use of CAR. Furthermore, the implementation is supposed to increase the quality of work and the job satisfaction of the employees. The robot is expected to be implemented within the next months.

FIGURE 1 | Care Assist Robot (Source: Future of Occupation, 2015).

FIGURE 2 | Care Assist Robot (Source: Future of Occupation, 2015).

Employees in management positions (nursing service management and residential area management) were included in the selection process as well as in the discussion with the company, which manufactured CAR. In doing so, they were able to consider the suitability in terms of content and function on the basis of a catalog of criteria as well as the price-performance ratio. The acquisition costs for three CAR amount to € 28,600.

The implementation process, which is going to take about 3 months, will be supported by the manufacturer, who will hold a workshop every 6 weeks to inform employees about the use of the robot, how to handle it, how to document data, and how to change processes and workflows. Four weeks after the implementation the manufacturer will hold an additional workshop.

Several employees report anxiety, anger, bewilderment and disappointment. While some of them are frustrated and will not accept that management is buying robots instead of creating new jobs, others are concerned about being replaced by a robot, with potential job loss. In addition, some nurses are afraid of their patients with dementia, who could possibly be confused by CAR and perceive additional stress caused by technology-generated overload for sensory and motoric functions (hearing, collision with CAR in the room).

For some nurses CAR appears like a dystopian scenery with hybrid and blurring boundaries between humans and machines ("Who is taking care of a person? The robot or the person, who is pushing the button? And what comes next?"). Even when some persons are also curious and excited to try CAR, they hesitate whether they can operate the machine.

The consequence, or possible unexpected reactions of staff, could be that more negative emotions arise within the organization and this could result in, for example, a disturbed relationship of trust with the home's management and leaders, increased illness-related absence or even increased staff turnover. On the other hand, however, some other colleagues report a rather positive attitude toward robots and are looking forward to possibly having more joy and meaning in performing their tasks again.

With our example, we tried to point out the possible dynamics of emotionality, which are important for our further argumentation. For the next step, we have to focus on organization consequences of AT/AR implementation in care homes to get a broader picture and better understanding of the upcoming assessment part.

CONSEQUENCES OF AT/AR IMPLEMENTATION FOR ORGANIZATIONAL CULTURE IN THE CARE SECTOR

In practical implementations, it has so far mostly been assumed that AT/AR "only needs to be activated" in order to have a positive effect (Beimborn et al., 2016; Gallistl and Wanka, 2019; Merkel and Kucharski, 2019). However, many hurdles with regard to individual characteristics, participatory design or contextual factors can be observed in connection with the implementation of digital technologies in professional everyday (health-)care:

Granja et al. (2018) examined in their systematic review major facilitators and barriers of eHealth-implementation in a total of 221 included studies. On the one side, *"Quality of healthcare"* turned out to be the most relevant category contributing to the success of eHealth interventions in clinical practice. This embraces *inter alia* better communication with the patient, improved diagnosis and provided patient-centered care. The determinant *"workflow"*—i.e., the manner people interact with their work, other people and communication pathways—plays a critical role in affecting the adoption at this point. It is imperative to mold the new work processes after the intervention in a way that increased workload, workflow disruption, undefined roles, undermined face-to-face communication as well as staff turnover are prevented (Granja et al., 2018). However, *"costs"* was the category most mentioned adding to the failure of eHealth interventions due to the fact that the shortage of financial resources inhibits the AT adoption or rather implementation. It becomes clear that a national policy for investment in eCare-Technologies—especially establishing financial mechanisms to support organizational changes—is required for successful product launches (Granja et al., 2018, p. 4–5).

Kruse et al. (2018) analyzed 30 articles and identified 33 different barriers of which the most occurred and important ran as follows: "*technically challenged staff,*" "*resistance to change,*" "*cost,*" "*reimbursement,*" "*age of patient,*" as well as "*level of education of patient.*" Against this backdrop, the reviewers come to conclusion that individual training and organizational change-management techniques are essential to overcome the outweighing technology-specific barriers (Kruse et al., 2018, p. 4).

Papadopolous et al. (2020) explored implementation-enablers and -barriers in a systematic review for the field of socially assistive humanoid robots in health and social care. The 12 in the analysis included studies suggest that *"personalization"* and *"enjoyment"* seem to be crucial adoption-enablers. In contrast, *"technical problems"* and the *"limited capabilities of the robots"* were summarized as the two most important obstacles. It should be noted that the evidence of investigated studies was limited, whereby a generalization of these initial findings is excluded (ibid.).

Melkas et al. (2020) identified six types of impacts on care personnel (five types of impacts on care residents) concerning the use of "Zora," a care robot for personal cognitive and social assistance. For employees changes have been experienced in terms of "*work atmosphere,*" "*meaningfulness,*" "*workload,*" "*professional development,*" "*competences,*" and "*work ethics*" and the authors underline the importance of organizational leadership and information policy within the organization (ibid.).

The study of Mitzner et al. (2018) also focused on the perception of professional caregivers with a mobile manipulator robotic assistant. The participants reported some positive experiences of AR, e.g., *"time efficacy"* and *"productivity,"* but at the same time skepticism in terms of *"reliability," "appropriate tasks"* for individual difficulties, and the question if the robot *"might be a hazard"* for some patients.

Attitudes of healthcare staff which come into conflict with the AT and AR-adoption potentially result in skepticism, frustration, negative thoughts and bad feelings (Magsamen-Conrad and Checton, 2014; Melkas et al., 2020). Slightly or strongly negative emotions of patients and healthcare professionals appear as underestimated barriers resulting in the AT/AR never completely integrated into the workflow, whereby the implementation fails overall (Nielsen and Mathiassen, 2013; Sølling et al., 2014).

As a way of summarizing, elected key implementation dimensions being based on the illustrated articles are synoptically organized by the perspectives of patients, healthcare professionals as well as home and nursing management staff (**Table 1**).

Notably, not merely the organizational environment influences the deployment (at best, in a positive way) but the implementation itself affects the institution. In this light, Kuziemsky et al. (2016) investigated in a systematic review the phenomenon of so called *"unintended consequences"* (UICs) as well as organizational and social issues related to these effects.

The term UICs was established as crucial factors, which can be beneficial and/or adverse with a lack of purposeful action of causation. Although the relationship between collaborative teams and individual providers were determined as the main source of UICs, there is a need to study and substantiate the reason and manner of their occurrence. Beside this, the UICs are contributing to diverse organizational and social sub-themes, namely: process change and evolution, individual-collaborative interchange, context of use as well as (proactive) approaches to model, study, and understand UICs (Kuziemsky et al., 2016).

A particular highlight was the realization that UICs go beyond errors and also include changes in workflow, communication and emotions (Ash et al., 2007; Borycki et al., 2012). Moreover, UICs can beneficially elicit positive processes and thus improve care delivery (Ash et al., 2007; Melby and Hellesø, 2014). For this purpose, UICs should be better explored to anticipate the consequences and then to specifically, proactively use them in the phase of pre-implementation on the micro and meso level of a care institution (Kuziemsky, 2015).

In summary, it can be emphasized that the nursing staff in management positions should constantly be aware of the potential development of UICs during AT/AR implementation. On that account it is important to know which enablers or obstacles are decisive for an accomplished deployment. In this way in the case of suboptimal or faltering implementation progresses high priority categories (i.e., the category "workflow") can be particularly analyzed and influenced by organizational and emotional aspects.

ORGANIZATIONS AS EMOTIONAL ARENAS FOR TRANSFORMATIVE LEADERSHIP

One of the most prominent perceptions of emotionality and management leads to a distinct divide between private and public spheres, where emotions may occur. For example, Hochschild (1989) distinguishes between unpaid "emotion work" and paid "emotional labor." She argues, that emotion work can be defined as a person's management of her or his internal feelings, with the aim to evoke a specific emotional reaction from another person (private context). Translated into a professional context, for example when leaders ask their employees to do "emotion work" in contact with their clients, this "emotion work" turns into "emotional labor." In general, Hochschild's concept refers to service activities or activities related to people. Emotional labor for example entails frequent telephone or personal contact with clients or customers and requires a certain emotional expression toward them. However, if feelings are suppressed systematically and for a longer period of time or employee and client indicate different feelings and unequal exchange of emotions, this leads to negative effects on mental health of the employees and impaired organizational well-being.

Fineman (1993) places emotions explicitly in the workplace. He denotes organizations as "emotional arenas." Everyday dissatisfactions and disillusions, as well as devotion and passion, such as boredom, envy, fear, love, anger, guilt, infatuation, etc., bring about the potential to unite, but also to separate the workforce. They determine, how roles are appropriated and implemented, how positions of power are exercised, trust is lived, acceptance and commitment is developed and how judgments are made in a way, that they cannot simply be excluded from organizational processes (ibid.).

With her concept of "emotion-management" primarily based on gynecologic nursing practice, Bolton (2005) underlines the difficulties to separate private and public emotional dimensions in interactions between employees. In doing so, she criticizes Hochschild's distinction of emotion work and emotional labor:

> *"Emotion is a lived, interactional experience with traffic rules of interaction framing how it is expressed and shared. Employees draw on both professional, organizational and commercial codes of conduct and social feeling rules in their interactions with others. The fragile accomplishment of social interaction is continually maintained through, not only formal exchanges, but also through episodes of compassion and shared laughter"* (Bolton, 2005, p.2).

The approach assumes that emotions do not simply "happen" in organizations, but are the result of controlled processes in which employees are depicted as active agents. Accordingly, managing emotions does not mean imposing unauthentically emotions, but rather creating the possibility for emotional compliance. Bolton's model of "emotion-management" is based on four categories:

- *"presentational"* (emotions are handled according to social rules),
- *"philanthropic"* (emotion-management as a "donation"),
- *"prescriptive"* (with regard to organization or professional rules),
- *"pecuniary"* (emotion-management is commercialized).

Drawing on employees in LTCFs, emotion-management is framed by specific social norms on acceptance and acceptability of AT/AR. "*[I]n this way nurses are portrayed as multi-skilled emotion managers who both comply with and resist the organizational constraints which exist around them.*" (Bolton, 2005, p.8). Aside organizational rules, Cranford and Miller (2013)

TABLE 1 | Elected key dimensions influencing the success or failure of AT-implementation by perspective (own elaboration).

	Perspective		
Outcome	**Patients**	**Healthcare professionals**	**Home and nursing management staff**
Success	Patient empowerment and self-management Enjoyment Personalization	Quality of healthcare Usability Familiarization	Costs Privacy Data and effectiveness policies Successful change management
Failure	Age Level of education (esp. AT literacy) Privacy and security	Technically-challenged staff Resistance to change Workflow Perception of impersonal care	Costs/reimbursement Privacy/confidentiality Data security Effectiveness

underline the role of organizational "signals" as important for persons in need of care.

For example, Smollan and Sayers (2009) focus on the affective organizational culture, which shapes how emotions are experienced and expressed. The results of their study show an interconnection of cultural change and emotions: the greater the congruence between the values of the employees and the organization, the more positive are reactions of the employees with regard to change. If the emotions of employees are treated with respect and appreciation during an organizational culture change process, employees will participate more in the change process (ibid.). Kaplan et al. (2014) developed a theoretical model which highlights eight specific categories of leader emotion-management behavior like interacting and communicating in an interpersonally tactful manner, demonstrating consideration and support for employees or structuring work tasks with consideration for employees' emotions (ibid.). In addition, the authors address dimensions that include knowledge (e.g., self-awareness, knowledge of emotions and their consequences, etc.), skills (e.g., emotion recognition, perspective taking, etc.) as well as proximal outcomes (psychological safety, satisfaction with the leader, etc.), and ultimate outcomes (cohesion, satisfaction and organizational commitment).

Also the study from Höld et al. (2020) shows, that cooperation with the team and supervisors is one of the most significant aspects of job satisfaction among professional nurses. A good team can create professional and ideal support for nurses and improve their professional development and quality of care. These positive aspects of job satisfaction should be integrated in emotion-management and play a significant role in the implementation of AT/AR. In this respect, leaders are requested, who are able to perceive emotions in a targeted manner within the framework of their management behavior, who are able to show these emotions and to evoke them in employees. A mutual exchange or implementation of emotions within emotion-management for prospective change management processes is therefore desirable.

If we now focus on leadership within the organization and specifically on theories of leadership, it becomes apparent that emotions also play a significant role here (Kaplan et al., 2014; Schein and Schein, 2018). Stakeholders and management staff have to shape the implementation process in a way that it matches the assumptions and values of the employees, their organizational culture, to ensure their acceptance. Emotions are interwoven in leadership theories and are at the heart of many leadership mechanisms, such as inspired employees, sustainable interpersonal relationships and investment in employee development, performance and satisfaction, etc. (MacGregor Burns, 2007; Little et al., 2016). As a result, a large number of academics understand persons in leadership roles as managers of group emotions (Brotheridge and Lee, 2008; Ashkanasy and Humphrey, 2011; Little et al., 2016).

"Transformational leadership" according to Bass and Avolio (1994) provides a model for emotion-management based on four principles:

(1) "*Idealized influence*" represents the role model function of leaders. A clear orientation of values, which is reflected in the attitude of the leader, provides orientation for employees. Furthermore, the authors emphasize that in this form of leadership, managers put their own interests behind those of the organization as a whole. Such leadership behavior triggers respect, admiration and trust among employees.
(2) "*Inspirational motivation*" is about motivating employees through challenging and attractive goals. The meaning of these goals must be made clear. By pursuing a common goal, team spirit, optimism and commitment can be fostered.
(3) The approach also emphasizes the role of "*intellectual stimulation*" of employees. Creativity and problem-solving skills of employees should be promoted. In the long term, employees should acquire the ability to critically question outdated assumptions, routines and habits and find new approaches to solutions.
(4) Within the framework of "*individualized consideration,*" employees should be individually supported according to their personal strengths, weaknesses and expectations. The leader acts as a kind of coach and promotes the development of the professional perspectives and potentials of the individual to a higher level (ibid.).

Transformational leaders express themselves through aspects such as inspiration, vision or personal role model action and thus deliberately appeal to emotions of their employees in order to support them as well as consecutively raise their acceptance, aspirations, motives and goals (Bolton, 2005). Transformational leadership behavior is intended to generate optimism, confidence

and belief in their employees by suggesting to them that although their challenges seem immense (Bass, 1985; Yukl, 2012).

The implementation of new technologies in an emotional-sensitive setting like LTCFs require specific leader behavior in respect of the identity and stability of the care personnel. Following the approaches of emotion-management and transformational leadership, the successful implementation and realization of profound change and innovation processes can be decisively supported by shaping an emotional relationship between leaders and those led (Tichy and Ulrich, 1984). In light of the aforementioned concepts, an integrated acceptance model could be useful, which comprises key dimensions for assessment of AT/AR implementation in long-term care institutions.

A MULTI-PERSPECTIVE MODEL OF ACCEPTANCE, ETHICAL ACCEPTABILITY AND EMOTIONAL CONSEQUENCES

Following the work of Krick et al. (2019), which used the three outcome dimensions acceptance, effectiveness and efficiency (AEE) in terms of AT/AR evaluation, we present a modified approach based on the three perspectives *acceptance (A)*, *ethical acceptability (A)* and *emotional consequence (E)*. Together, they form the acceptability and emotional consequences (AAE) model according to our perspective. In a subsequent step, we apply this model to our illustrative example and use it to arrive at a holistic evaluation of the implementation for the organizational culture.

Acceptance (A)

When addressing the issue of technology acceptance, it is important to consider the needs and characteristics of potential users. Persons in LTCFs are more frequently confronted with experienced functional losses and decreased coordinative and sensory abilities. These difficulties cause individuals to perceive, use and accept technology differently.

One of the most prominent concepts is the "Technology Acceptance Model (TAM)" by Davis (1986). This model highlights the usefulness of a technology (degree to which a person believes that using a particular system would enhance her or his performance) and the perceived ease of use (degree to which a person believes that using a particular system would be free of effort) which together with external factors influence the attitude toward using and the behavioral intention to use (ibid., 320). Critical arguments, however, address the limited practical implications of this approach and the influence of professional or occupational use of a system (King and He, 2006).

The further developed TAM2-Model (Venkatesh and Davis, 2002) considers the social and cognitive instrumental factors influencing the perception of usefulness such as norms, image, job relevance and voluntariness. Thus, TAM2 underlines that both, social and cognitive-instrumental variables, have an impact on technology acceptance and use. In this context, the model is sufficient, when a person, even if he or she does not support a certain behavior, still engages in it if he or she assumes that someone personally important approves of it.

Venkatesh et al. (2003) developed the Unified Theory of Acceptance and Use of Technology (UTAUT) by integrating several other concepts such as TAM, theory of planned behavior (TPB) or theory of reasoned action (TRA). The concept underlines the importance of social influence and facilitating conditions in acceptance of technologies whereas variables as age, gender or experience only have a moderating effect. The most important variable for behavior and use of technology represents the own performance expectancy of a person. In the TAM3-Model, Venkatesh and Bala (2008) focused on the perceived ease of use, which is influenced by factors such as computer self-efficacy, computer anxiety or results demonstrability.

All TAM-models in their modification are considered to have been empirically tested many times. However, these models have hardly been applied in relation to persons in need of care or in care homes.

In the Almere model, Heerink et al. (2010) used the items of the former UTAUT questionnaire adaptively with regard to animal-like social robotics and older persons as their users. Instead of expected performances and expected effort, the authors renamed the variables with "perceived usefulness" and "perceived ease of use." In addition to the existing assumptions that usefulness and voluntariness play a significant role in how a person accepts AR, Almere also emphasizes the importance of affective and cognitive attitude. Thus, acceptance variables have been added to the UTAUT model like perceived enjoyment, confidence, or perceived adaptability. In total, 12 different dimensions determine technology acceptance such as anxiety (for using social robotics), (positive or negative) attitude toward technology, facilitating conditions (adequate introduction in functions of the robot), intention to use, perceived adaptiveness (of the robot with regard to specific needs of the patient), perceived enjoyment, perceived ease of use, perceived sociability, perceived usefulness, social influence (related to the acceptance of others), social presence (as perceived social interaction with the robot) and trust (integrity and reliability of the robot). Central to the model is thus not only the individual perspective, but also the idea that acceptance is embedded in social contexts, like in our example in an organizational setting.

In summary, these prominent and empirical tested models for technology acceptance focused on various aspects of acceptance such as perceived usefulness, ease of use, or voluntary in use. In the prominent triangle of caregivers, care recipients and technology, organizational culture and ethics were, however, mentioned only in passing.

Ethical Acceptability (A)

For an ethical evaluation acceptance alone is not a sufficient criterion. A humane perspective does not first ask about the usefulness of a technology for solving concrete practical problems or a mere acceptance. It asks about acceptability against the background of the consequences of a technology's use for the image of humanity and coexistence. First of all, AT/AR in care contexts are undoubtedly something good, if what they help to achieve in turn produces something good in the end.

Justice, self-determination, privacy, etc., and the criteria for nursing formulated by Beauchamp and Childress (2001) like justice and autonomy are only a first approach here. Going to the root of the ethical question, self-determination is by no means the fulfillment of one's own desires. With Immanuel Kant, autonomy means: reason, free from egoistic willing, recognized what a person should do. If a person makes this ought her/his ought, she/he is ultimately autonomous and free. But this has little to do with the common understanding of self-determination; for it is the obligated freedom in responsibility. Thus, there is a significant need to semantically fill the ethical generalities and to substantially question, evaluate and responsible implement the use of technology to avoid unintended consequences. The possible reference to the distinction that robots can only achieve predetermined goals but cannot set goals for themselves is no longer sufficient when algorithms inspire and control each other even without human intervention (Matsuzaki and Lindemann, 2016). Is the care robot seen as a colleague or is it even allowed to determine work processes of human employees? This, however, contradicts our notion of humanum and also implies highly complex liability issues in case of robot errors (Kaplan, 2004; Bartneck et al., 2019; Nass, 2020). Who will take responsibility for this?

We first take a look at already existing instruments of ethical evaluation of AT/AR before we sharpen and propose our position. An ethical evaluation-model popular in the context of Ambient-Assisted-Living (AAL) is the MEESTAR-Model (Model for the Evaluation of Socio-Technical Arrangements) (Weber, 2015, 2020). It takes an explicit ethical view on the consequences of AAL-adoptions and interventions like privacy, security or justice and tries to balance responsibility and ability in this context. These aspects are remarkably necessary with regard to clients with cognitive impairments in order to provide appropriate information and tools for a sensitive adoption of technology. In the course of further development, less "practical" approaches and more questions of attitude, participation, trust and values have flowed into the development of the model. However, from a psychological and ethical point of view, some essential aspects are still disregarded as positive or negative affection, authenticy, autonomy or resonance (Beimborn et al., 2016; Rosa, 2019). And MEESTAR is a procedural model, which does not represent its own ethical position, but only brings different ones into discussion with each other.

Beyond procedural ethics, we have to refer to models with a strong concept of acceptability (Jaensch and Nass, 2019), like for example a Kantian or a Christian perspective—equally legitimate in terms of scientific theory to start from secular or religious postulates. Therefore, we choose for the criterion of acceptability as a semantically substantial position with a transparent humanistic view of dignity. The focus lies independently of economically measurable acceptance, on the consequences for the image of man, responsibility and social coexistence. Against a legal positivist view in which laws and ethics coincide, we do not derive our ethical arguments from legal provisions, which, moreover, also vary widely internationally. It is precisely this perspective that enables a critical evaluation of rules and laws as well.

According to this view, the use of technology is acceptable if it enables every human being to live up to the responsibility given to her/him (by God or by reason) before herself/himself, before each other (and before God or before reason). The unconditional human dignity as the basis of humanity and thus of ethics is then justified, for example, in the idea of the image of God in man (Christianity), the idea of the substitution of God by man (Islam) or in the necessities of reason (Kant). Autonomy understood in this way is thus always linked to given tasks or duties, which could be justified in Kantian or religious terms (Westphal, 2016; Frick, 2019). Equal dignity belongs to every human being, but not to machines, virtual realities, cyborgs or the like. The use of technology in care must then always be a service value for the development of human beings in their individuality, sociality and triple responsibility. Such humanity should absolutely frame the logic of self-referential technology.

Emotional Consequence and the TEO-Model (E)

Drawing on the idea of emotion-management and transformative leadership, organizational changes as AT/AR implementation in LTCFs are emotional challenges, which can trigger uncertainty, mistrust or fear within the setting. The competence of the nurse to establish a safe and healing connection with the person in need of care symbolizes a central ethical and emotional content of the care profession. On the other hand, the effects of technology use could facilitate the daily work routine/process of nurse-skilled employees and promote a pleasant organizational culture.

If certain emotions are successfully fostered (not manipulated!) by leaders in the long term, the corporate culture may also change in this direction over time and contribute to individual and organizational well-being. For leaders in the care sector it is a matter of accepting and reflecting on existing emotions within the workforce, but also of creating framework conditions that positively support the change process on an emotional level (Goleman et al., 2002; Bolton, 2005).

As described in section "Acceptance (A)," several models on technology acceptance embrace factors as attitude and behavior shaped by structural and cognitive factors. Purchasing behavior and positive emotions about AT/AR implementation are, however, susceptible to manipulation and misinformation. Concerning the legitimacy and emotional consequences for the image of caregivers as human beings, this means concretely that the use of technology is only legitimate if it does not lead to the isolation or anonymization of human contacts. If technology replaces human interaction and feelings of belonging and agency, the social nature of human beings is misled.

Collective emotions are part of the corporate culture and generally to accept. This may mean that in an organization where cautious, protective behavior has reliably led to success in the past, implementation should be undertaken in particularly slow steps, staff should be able to try out the new solution first in test settings, where mistakes do not mean serious consequences and where they have the opportunity to express concerns openly.

Furthermore, leaders—as distinct role models—should be aware of their own emotions regarding the change and reflect

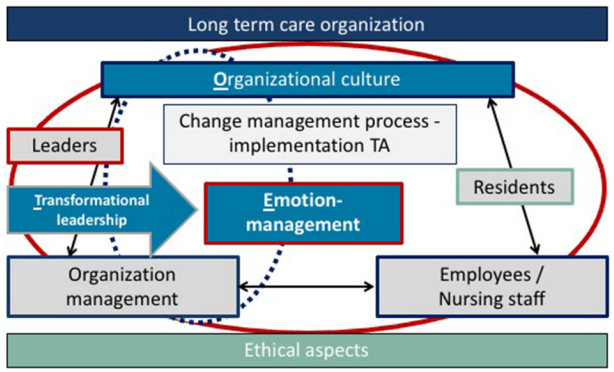

FIGURE 3 | Implementation of technical assistance and transformational leadership with emotion-management in nursing practice—TEO (own elaboration).

emotions that new tools and practices trigger in them, even before the actual implementation. However, emotions such as satisfaction or anticipation are naturally more conducive to the implementation process than fear, anger or sadness. Therefore, it is helpful to create framework conditions that promote positive emotions regarding the change of nursing practice. This can be, for example, the possibility of co-determination in the choice of technology or the co-design of the adaptation of work processes, but it can also initially mean giving space for the articulation of negative emotions on their workflow.

Since AT/AR is added as a supporting factor, the former dyadic "two-way relationship" between care receiver and care giver becomes a "three-way relationship" (see **Figure 3**). We call this framework "TEO" for the integration of **t**ransformational leadership, **e**motion-management and **o**rganizational culture as diagnosis and iterative assessment instrument of the dimension "emotional consequence."

In **Figure 3**, measures in TEO are presented that are significant for emotion-management in organizations. It should be designed like leadership around AT/AR, e.g., with regard to the question, how emotions can be created around the technology, like trust, joy, peace, harmony etc. It is also necessary, that the employees/nursing staff feel accepted and creative. The ethical aspects shed light on the iterative process of implementing a technical assistance system from the beginning. The aspects of AT/AR implementation are structured by the leader/organization management within the framework of transformational leadership and include the essential aspects of the organizational culture, management, the personnel in LTCFs and implicitly also the persons in need of care. A possible tool for implementation are workshops in which leaders and organization management specifically address how the care tasks may be changing and redistributed within the framework of change management.

To summarize, measures for an AT/AR implementation should address the following key questions:

1. What is the emotional *status quo* before running the change management process within the organization or among employees we have to consider in order to create a corresponding emotional culture?
2. What changes—especially in the caregiving relationship, communicative behavior, and health status—could each result from the use of technology?
3. To what extent may these positive/negative effects influence workflow and job satisfaction of the nursing staff as well as the organizational culture and thus promote/impair the implementation?

Under this assumption, an intended implementation would necessarily have to take into account the patient-nurse relationship, general ethical-human assessment criteria, and their interactions.

AAE-APPLICATION TO THE PRACTICAL EXAMPLE

Having presented our specific assessment tool of AAE, we now would like to illustrate this model along the illustrative example introduced earlier: A LTCF and the implementation of the "Care Assist Robot" (CAR).

Acceptance (A)

According to important models of user acceptance [see section "Acceptance (A)"], this dimension represents the willingness of the employees to include CAR in their daily routines. As the TAM model and its modifications or the Almere model indicate, the acceptance depends for example on the tasks, CAR is designed for—in this context physical assistance in care work—and its perceived usefulness and how easy CAR can be operated. In this case, greater acceptance can be assumed, as CAR is supposed to reduce physical burden for caregivers and therefor performs an important care tasks that doesn't replace social or emotional interactions between caregiver and care receiver (as, for example, it would possibly be the case with social assistive robots).

Nursing staff's concerns about insufficient functions (like taking too much time for moving a patient) or loss of control could be addressed in terms of specific workshops for introduction and peer-to-peer-education, which relates to specific user characteristics, realistic scenarios and the social context in which the robot is used. The opportunity to try out CAR and its functions in a workshop setting (and not in urgent situations) allows employees a prevention-oriented culture in respect of shortcomings but also as arenas for experienced self-efficacy and confidence. In addition, it is important to consider the voluntariness to use CAR and if resistance (by employees but also by residents) against the robot is acceptable for leaders. Possibilities of participation in the implementation process (as mentioned in this example) and transparent information policy by the leaders are also crucial to avoid negative attitudes and perceptions of replacement.

Ethical Acceptability (A)

Ethical acceptability in our example is more likely as CAR provides physical tasks to reduce physical impairments and

mobile difficulties for the persons in need of care. However, staff members in our example are concerned about the possibility to become removed by CAR in their personal assistance.

In respect to ethics in nursing social interactions and non-maleficence of patients are roles, which cannot be compensated by a AT/AR. However, conflicts between patients and care staff in the ethical evaluation of CAR use may arise, for example, where patients prefer the use of technology to a human nursing service, while nurses see this specific service as essential to their job description and identity. Or, vice versa, a nurse may want to get rid of unpleasant care services that the patient prefers to see provided by a human. Such conflicts have consequences for organizational culture when nurses' issues of conscience affect their motivation, job satisfaction, and identification with their work. The criterion of ethical acceptability of CAR use does not require smoothing out all such conflicts. If the use of technology with all its consequences leads to the fact that thereby the human relationship between them and patients wins, then it is acceptable. The concrete evaluation in individual cases depends on the semantics of the idea of humanity, which can be shaped differently for cultural or ideological reasons.

In our example, it is possible that patients in specific care contexts prefer the use of CAR to care by humans, for example out of shame, and therefore regard this arrangement as morally preferable. For the self-image of nursing staff, the use of CAR can then also be seen as a facilitation, because encounters with shame can be avoided. Such a substitution of human care by robotics is acceptable in principle, if it is always clear that an ethical evaluation on the use of CAR does not itself attribute a moral quality to this concrete robotics. The use may be acceptable, but the robotics itself is never morally good or bad. Other positions are conceivable here, for example in animism (Kaplan, 2004; Hornyak, 2016).

Who is CAR in comparison to the nurse and other employees in terms of human image and nursing ethics? How is responsibility in care tasks attributed between staff and CAR? Once such questions have been clarified in the organization (clear limits have been set for the use of robots; there is no replacement of human communication; machines are not colleagues and questions of liability have been clarified), the use of CAR could be ethically supported in principle under these conditions if it actually relieves the workload of the scarce nursing staff and if this robotics is easy to operate.

Emotional Consequences (E)

In our illustrative example employees reported various emotions with regard to CAR: anxiety, anger, confusion but also curiosity. While some of them are frustrated and disappointed, because the management is buying robots instead of creating new jobs, others are worried about being replaced by a CAR with the possible loss of their job. Possible unexpected reactions could arise on the part by generating even more negative emotions among the staff, developing a disturbed trust relationship with the management, leading to for example increased sick days or staff turnover.

The application of TEO (including transformative leadership, emotion-management and organizational culture) in its practical feasibility means that leadership is associated with an emotional reaction of the employees and has corresponding emotional effects that have presumably hardly been perceived in leadership management.

In the illustrative example of a LTCF, knowing exactly what contributes to a professional workflow and satisfaction of care staff in their job, are significant steps to move together positively in the direction of change management (e.g., implementation of AT/AR). In the case of the existing negative emotions with regard to CAR, it is important that the manager promotes positive emotions and has a calming effect with less intensity, satisfaction and serenity and that their role model function again exemplifies trust through authentic, honest and beneficial communication processes as well as the emphasis on joint positive performances, so that a change from negative can be converted into positive emotions.

With the focus particularly on *emotion-management*, timing and emotions must be thought together. The change management process in our example starts a long time before the implementation process of the AT/AR (e.g., planning budget for CAR, negotiation with the manufacturers). In workshops (as already mentioned with regard to *Acceptance*) the transformational leadership has to create an emotional vision of CAR implementation. Caregivers want to be informed and active part of the process and transparent, authentic and communicative information policy by the leading management. This means to create emotions around the robot, like trust, joy, peace, harmony etc., were caregivers feel accepted, creative and are able to flourish.

The application of our three-stage system for the introduction of the Care Assist Robot has shown that acceptance, ethical acceptability and emotions each make criteria for an implementation transparent, which allow a holistic evaluation also in a human perspective. These critical criteria can now be easily merged. They are the compass for the management of LTCF to design a responsible transformational change process in response to AT/AR implementations.

DISCUSSION AND OUTLOOK

In the future, residential care will increasingly face the challenge of successfully implementing digital technologies. This can especially be expected for LTCFs, as multiple assistive technologies and robots promise new possibilities for maintaining the quality of life of vulnerable residents as well as facilitation for professional caregivers in their daily work. Several studies underlined the importance of different acceptance dimensions in the care sector and specific outcomes for different user groups.

From our perspective, successful implementation by organizational leaders also has to take into account the existing organizational culture and to support employees in these changes beyond traditional concepts of technology acceptance, especially on an emotional level and in respect of ethical values in nursing. Compared to other industries, the implementation of AT/AR in LTCFs has to consider specific emotional conditions in care settings in terms of vulnerable residents with daily care

needs, shortage of professional caregivers and ethical social rules in nursing. In the context of facilitators and barriers contributing to the AT/AR deployment, the stakeholder-entities are decisive too: The aim of AT/AR implementation is frequently to evoke positive emotionality in patients and employees and thus to support the health balance of older or cognitively impaired people. Ideally, these generated effects would have an equally positive effect on professional caregivers and, in a broader sense, the entire organization, including the prevailing work culture.

Thus, we argue here for a more ethical and emotion-led leadership and management strategies in care institutions to enable modern organizations to adopt a constructive and reflexive attitude toward technology without, however, being manipulative. We offer a humanistic compass with the evaluation criterion of AAE (acceptance, ethical acceptability and emotional consequences), which includes the idea of humanity and social coexistence for the solution of concrete individual questions in care practice. In doing so, we avoid a paternalistic narrowing, as local norms and organizational cultures should be considered.

To avoid unpredictable/unintended results and resistance, employees should be stimulated by change and involved in a participative way. In this respect, an intentional utilization of factors which foster facilitator-categories is very beneficial for the entire institution. While the concept of "emotion-management" explores human emotions at the workplace and conceptualize a new management approach (Bolton, 2005), "transformational leadership" underlines the role model function of leaders, attractive goals and motivation, or stimulation for employees (Bass and Avolio, 1994). We have translated the emotional consequences in the AAE approach into a three-perspective heuristic model "TEO" that integrates previous prominent approaches on transformative leadership, prescriptive emotion-management and organizational culture on the issue of technology implementation. Emotional consequences captured by the perspective of TEO can potentially support organizations in developing appropriate implementation guidelines and provide ideas for a common value discussion. In addition, adapted to the respective institutional framework conditions, it can represent an initial diagnostic or rather iterative assessment blueprint for understanding and improving change management during the hole implementation process. For example, ethical and emotional-based questions could be included in internal surveys and emotional resources could be considered in the evaluation.

Our findings should be interpreted while considering certain limitations. We are aware that our AAE-model is initially a working hypothesis that deserves further development. Thus, a fourth or fifth essential perspective could be added to AAE as other acceptance logics could be applied. The ethical acceptability model could be given a different semantics than ours (humanistic-Christian-Kantian), i.e., utilitarian, anthroposophical, etc. In addition, the specific organizational context (funding principles, ethical codex, number and skills of employees and clients, number of residents with cognitive decline) plays an important role for the debate around the priority of robots vs. human care providers. In addition, leadership styles like transformational leadership can be taught to leaders by individual coaching or peer counseling, but it needs to be practiced and internalized, which takes time and support. Another limitation lies in the implementation of the model, which first of all means an additional effort (time, costs, intensity) for the management.

In addition, there is still a need for research regarding the question which contextual conditions in the care sector shape a resonant relationship between leading attitudes and behavior by the management and emotions by employees (Plummer, 2018; Rosa, 2019). A deeper insight here could explore, which emotions are particularly helpful and which ones hinder technology implementation. Here, comprehensive empirical analyses of successful and unsuccessful implementation attempts in care organizations are recommended.

AUTHOR CONTRIBUTIONS

AF prepared the general concept and outline of the publication, the introduction, the theoretical part on relevant concepts of technology acceptance as well as discussion and conclusions. EN, A-KP, AZ, and CH prepared the whole theoretical part on emotion-management, change management and role of leadership. All authors made comments, suggestions and corrections to the rest of the article.

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Philippine Mental Health Act: Just an Act? A Call to Look Into the Bi-directionality of Mental Health and Economy

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INTRODUCTION

It may seem intuitive to say that a healthy economy makes people happy, but little is said about the converse of this statement. Perhaps, we should look into how happy people make an economy healthy. The nature of happiness has been debated on by philosophers for thousands of years, but a benchmark for it that has been accepted by many social and behavioral scientists in the past few decades has been Diener's Subjective Well-being (SWB) (Diener, 2009). Studies that employ the use of SWB show that individuals who report high levels of it tend to live longer with healthier lives, have healthier social relationships, and work more productively (Montagnoli, 2019). Hence, higher levels of SWB could mean good mental health among individuals. Poli et al. (2020) described good mental health as "a state of well-being that allows individuals to cope with the normal stresses of life and function productively." However, the definition of *good mental health* may vary among cultures, values and traditions. Culture affects how people manifest symptoms, express these symptoms, deal with psychological problems, and decide whether to seek care (Eshun and Gurung, 2009). Because of these differences, the best way to enrich our understanding of mental health might be to evaluate the different perspectives of mentally healthy populations toward it (Vaillant, 2003). Further understanding of mental health is significant because it greatly affects the economy as economies appear to crucially depend on the population's mental health. And so, good mental health is significant for economic growth. According to Knapp and Wong (2020), the economy has a bi-directional relationship with mental health. Economic decline may lead to a greater likelihood of mental-illness due to exposure to risk factors such as social exclusion, poor education, treatment costs, unemployment, and poverty. Mental health problems may also lead to a significant decline in economic activity that results from productivity losses and limited resources for treatment. Thus, the study of economics, particularly mental health economics (MHE), is significant in identifying ways to improve mental health and mental healthcare production and consumption. Unfortunately, to the best of our knowledge and understanding, there are currently no existing studies written on Philippine MHE. And so to help address the economic and mental health crises in the Philippines, we hope to spark discussions that will promote the study of MHE for the good of all Filipinos.

THE STATE OF MENTAL HEALTH IN THE PHILIPPINES

The Philippines is an archipelago of over 7000 islands, with over 120 languages, and numerous religions. The country has been occupied and colonized by many foreign powers since 1545 and it only gained full independence in 1946. This colonial history has contributed to the unique Filipino culture, yet the country remains poorly understood because of its late independence and of it being one of only two Christian-majority countries in the Far East (Lally et al., 2019). The cultural beliefs of Filipinos vary in almost every respect. One of the popular beliefs is that depression and anxiety are non-existent, and that mental illnesses are something to be ashamed of. A qualitative study conducted by Tanaka et al. (2018) showed that this stigma is considered to be an effect of the public belief about mental disorders which consist of three themes: First is *familial problems*, wherein the family rejects or disowns the family member who suffers from a mental disorder because they believe that it can be inherited. Second is *unrealistic pessimism and optimism* about the severity of the disorder, wherein the mentally ill either would certainly suffer from severe functional impairment or would be able to overcome any psychological suffering by themselves. Last is the *oversimplified chronic course*, wherein people without mental illnesses apply an acute illness model to those ill, and expect full recovery in the short term.

Because of this stigma, mental health has been given very little attention by the Philippine government and public sectors. Even after the country has recently passed its first Mental Health Act and Universal Health Care Law, only 5% of the healthcare expenditure is directed toward mental health. Also, there are only 7.76 hospital beds and 0.41 psychiatrists per 100,000 people (World Health Organization—Assessment Instrument for Mental Health Systems, 2007; Department of Health, 2018). This ratio was known to be lower than other Western Pacific countries with similar economic statuses, like Malaysia and Indonesia (Lally et al., 2019). The Philippine government does not even provide economic support for organizations that have been involved in the formulation and implementation of mental health policies and legislation (World Health Organization—Assessment Instrument for Mental Health Systems, 2007). Consequently, mental illness has become the third most common disability in the Philippines, wherein six million Filipinos live with depression and anxiety. Because of this, the country has the third highest rate of mental disorders in the Western Pacific (Martinez et al., 2020). Also, the Philippine World Health Organization (WHO) Special Initiative for Mental Health conducted in 2020 showed that ≥3.6 million Filipinos suffer from at least one kind of mental, neurological, or substance use disorder (Department of Health, 2020). Suicide rates are reported to be at 3.2 per 100,000 population with higher rates among males (4.3/100,000) than females (2.0/100,000). However, these numbers may be underreported because suicide cases may sometimes be misclassified as "undetermined deaths" (Lally et al., 2019; Martinez et al., 2020). The WHO estimated that 154 million Filipinos suffer from depression, 1 million from schizophrenia,

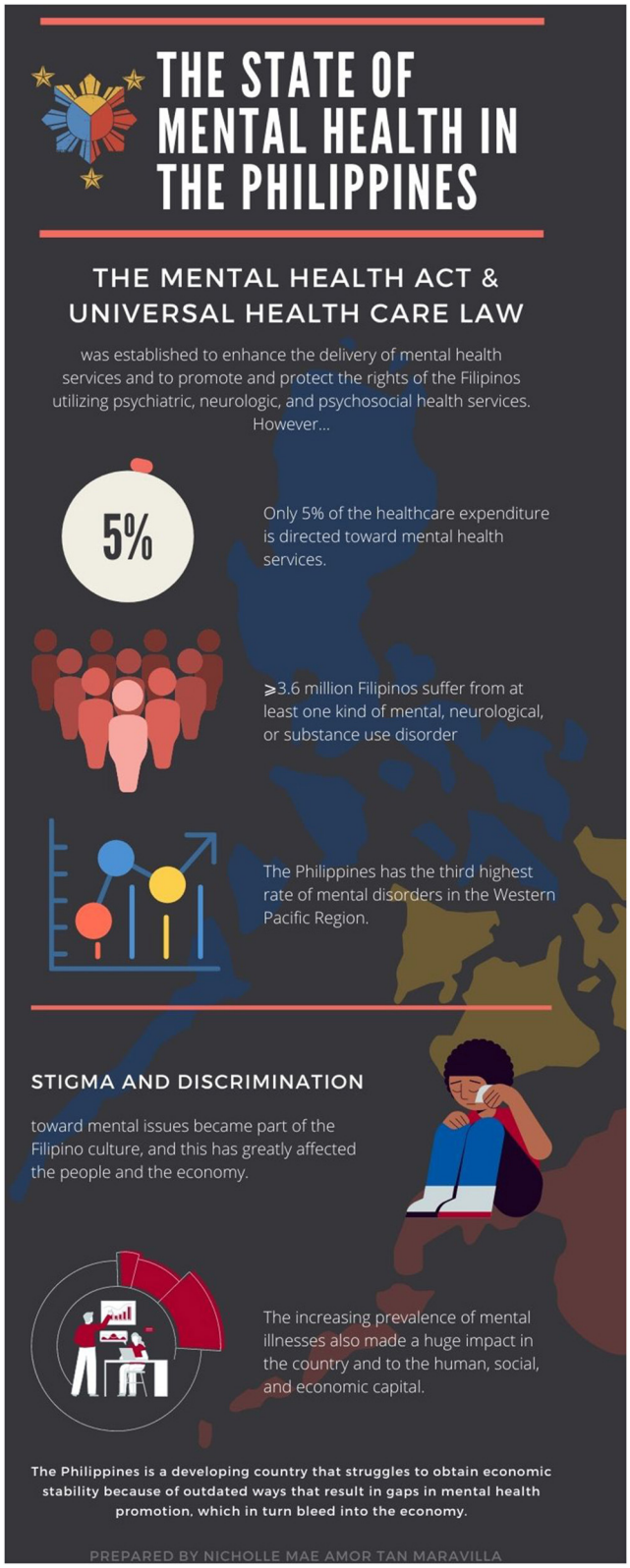

FIGURE 1 | An infographic that summarizes the state of mental health in the Philippines.

and 15.3 million from substance use disorders, while 877,000 die due to suicide every year (Department of Health, 2018). Thus, mental disorders could greatly affect employment and levels of education, most especially in ages 25 to 52 years (Hakulinen et al., 2019). It was found in a study by Hakulinen et al. (2020) that individuals with a severe mental disorder had notably lower levels of employment before, and more especially after, the diagnosis of their disorder. Their overall incomes came primarily from transfer payments, and the most affected were those diagnosed with schizophrenia. After receiving a mental disorder diagnosis, more than half of these individuals received no employment earnings.

Filipinos are generally unhappy not only because of poor economic conditions (unemployment, low salary, etc.), but also because of pressures arising from high expectations from family and society. In the study by Palaganas et al. (2017), it was shown that 24% of midwives, 29% of doctors, 51% of nurses, and 61% of physical therapists desired to migrate to the United States, Canada, Australia, and the United Kingdom to work as health professionals. Their migrations resulted in shortages of health workers, reductions in the provision of health services, poor quality of health care service provision, longer waiting times for patients, and increased work overtime. Their decisions to migrate were mainly influenced by the greater number of employment opportunities and high salaries abroad where they are given more respect and quality of practice, which greatly develop their wellbeing.

The state of mental health in the Philippines in summarized in **Figure 1** (World Health Organization—Assessment Instrument for Mental Health Systems, 2007; Department of Health, 2018; Tanaka et al., 2018; Martinez et al., 2020).

A HAPPY NORTHWESTERN EUROPE

Here, we talk about the condition in Northwestern European countries to establish a basis with which to compare that in the Philippines.

Mental health is associated with either happiness or unhappiness, and is significant to Nordic life. A good reason why Nordics are happy is their system that provides security, free education, and a reasonable balance of work and personal time (Andreasson and Birkjaer, 2018). Humanitarianism is the root of their culture that has led to economic growth and reconversion of cities. Innovation and development were also attributed to their kindness toward the multicultural neighborhoods of their country (European Economic and Social European, 2016). Aside from culture, the government also plays an important role in developing these countries. Since the late 19th century, independent court systems that handle corruption-related matters have been distinctive features of Nordic legal systems. These have made their governments more trustworthy and reliable, and have given their citizens the assurance of effective reforms that fulfill their purpose (World Happiness Report, 2021). This explains why Northwestern European countries have among the highest scores in the World Governance Indicator. Moreover, they use digital tools to optimize management, service delivery, and overall state capacity. National websites are established to allow citizens' participation in policymaking and to provide feedback on public services. Thus, the collaboration between governments and their citizens is able to strengthen research, monitoring, and the evaluation framework of policymaking. It also promotes transparency and trust between them (World Health Organization, 2018b). In addition, health has always been their top priority. Therefore, public services such as healthcare and disability services are supported by the government (World Bank Group, 2021).

THE PHILIPPINES AND NORTHWESTERN EUROPE—A COMPARISON

The World Bank Group (2021) has emphasized that mental health is part of the strategy to improve disadvantaged economies. In order to achieve this, people should be in positive mental and emotional states of enjoyment and contentment, *id est* "happiness" (Richards et al., 2015). However, according to Hart et al. (2018) and Wahlbeck (2015), socioeconomic factors like poverty, poor education, unemployment, and high debt, which are mostly experienced by Filipinos, affect happiness.

Economic crises can produce secondary mental health effects that lead to increased suicide and substance abuse mortalities (World Health Organization—European Region, 2020). The Philippines has faced multiple financial crises since the 1980s. In fact, the 1980s and 1990s saw a dramatic decline in the country's banking system that caused Filipinos and financial intermediaries to lose trust in it. This has been known as the *lost decade* for the whole Philippine economy. Fortunately, bank earnings recovered in the 2000s due to the economic, financial, and structural reforms that were implemented. This provided a strong economic foundation for the country, especially during the 2009 Global Financial Crisis. The country also continued to carry out policy reforms that further enhanced the various sectors of the economy. However, severe and shifting weather patterns, and disease, have increasingly become a source of downside risks to the financial system (Bangko Sentral ng Pilipinas, 2020). In the study by Montagnoli and Montagnoli (2019), it was shown that financial crises bring about micro- and macroeconomic changes in countries that affect SWB and lead to major and long-lasting psychological losses. However, these losses can be counteracted by social welfare and other policy measures (World Health Organization—European Region, 2020). Thus, measures of the same nature should be carried out to counteract the effects of financial crises in the Philippines and in turn, alleviate the plight of low-wage earners who are more prone to psychological distress (Kronenberg et al., 2017). These measures can be achieved by investing a greater deal in health and education.

However, Filipinos migrate to other countries because of the persistent economic crises and unemployment. Palaganas et al. (2017) showed that the decision of the workers to migrate is mainly influenced by their job dissatisfaction with income, workload, and infrastructure. However, increasing the wages of low-wage earners would not entirely enhance their mental health (Kronenberg et al., 2017). According to Martinez et al. (2020), although Filipinos enjoy more opportunities and higher wages abroad, mental health issues still exist among Overseas Filipino Workers due to language barriers, immigration status, lack of

insurance, and discrimination. This may be explained by the happiness-income paradox presented by Easterlin et al. (2010). According to them, "at a point in time both among and within nations, happiness varies directly with income, but over time, happiness does not increase when a country's income increases." This is evidence of the incompleteness of the unidirectional perspective of the effects of the economy on happiness, and in turn, mental health. While there is truth in this perspective, the perspective in the other direction, i.e. that the effect of mental health on the economy, is probably equally as important.

Being that mental health issues have been widely neglected in the Philippines and migration has resulted in the loss of investments in human capital (Palaganas et al., 2017), it would be best to take steps to attempt to adopt the mental health promotion strategy of Europe as nine of the 10 happiest countries in the world—Finland, Denmark, Switzerland, Iceland, Netherlands, Norway, Sweden, Germany, and Austria are in Northwestern Europe (World Happiness Report, 2021). This is perhaps because of their good economic status and quality healthcare. Mental health promotion in these countries proved to be more effective because it was introduced into the political agenda using a different approach. Neither the prevalence of mental illness nor the need for resources was emphasized. Instead, mental health was highlighted as a fundamental component of public health, and as having a significant effect on individual countries and their human, social, and economic capital (Wahlbeck, 2015). If the Department of Health in the Philippines would use this approach, the government would view the bottomline of the economic crisis in a different light. Realizing this would provide a new perspective to managing the economy.

However, the unresponsive governance has made Filipino people of all socio-demographic profiles distrust the government. This leads to a disunity between the two groups. According to Montagnoli (2019), uncertainty and distrust in financial and political institutions caused by financial crises may result in psychological losses that shape decision making. These crises exacerbate disapproval and distrust in the Philippine government. This is contrary to the experiences in Northwestern Europe, where individuals trust and socially interact with their neighborhoods. Finland, for instance, which ranked highest on measures of mutual trust, enjoys the sentiment that their lives and livelihoods are protected even during times of the pandemic (Hart et al., 2018; World Happiness Report, 2021).

As regards psychiatric services provided in Northwestern European countries, there are 39 to 130 psychiatric beds per 100,000 inhabitants and over 80,000 psychiatrists. Of these countries, those with the highest numbers of psychiatrists were Germany (27 per 100,000 inhabitants), Finland (24 per 100,000), the Netherlands (23 per 100,000), and Sweden (23 per 100,000) (Eurostat, 2020). However, suicide and mental disorders still exist in these countries. In 2015, it was reported that there were 56,000 deaths due to suicide in the European Union. And, among Northwestern European countries, Belgium recorded the highest suicide rate (17 per 100,000 population) while Demark recorded the lowest (10 per 100,000) (Eurostat, 2018). The prevalence of mental disorders are also very high in Europe, where Finland (18,800 per 100,000) and the Netherlands (18,600 per 100,000) ranked the highest in the continent. In all European countries, especially in Northwestern Europe, the most common mental health problem is anxiety disorder (25 million people), followed by depressive disorders (21 million), alcohol and drug use disorders (11 million), bipolar disorders (5 million), and schizophrenia (1.5 million) (OECD/European Union, 2018). It certainly appears that mental health problems are significantly more prevalent in Northwestern European countries than in the Philippines. However, this is probably because mental disorders go underdiagnosed in the Philippines owing to lack of mental health providers and facilities in the country.

Moreover, the economic and social burden of mental illnesses, unemployment, and worker productivity losses amount to over 600 billion Euros or 4% of the gross domestic product (GDP) across 28 European countries. The government has already spent around three-quarters of its health funds, and the country's national budget may be affected if large healthcare spending continues. There would also be challenges on the fiscal sustainability of health and long-term care systems. For these reasons, health sectors have made major strides to promote good mental health and to prevent mental illnesses. Moreover, many more European countries have ensured the implementation of comprehensive plans and policies that address mental health promotion and suicide prevention. The European Mental Health Action Plan 2013-2020 is strong evidence of this (OECD/European Union, 2018) and the fruits of these efforts are manifested by their favorable SWB scores (De Neve and Sachs, 2020) and by the findings of the World Happiness Report (2021). The architects of the mental health program of the WHO in Europe, its member states, and their partners worked together to develop and implement mental health policies and legislations that reflect the vision of the WHO that there is "no health without mental health" (World Health Organization—European Region, 2018). If the Philippines were also to endeavor toward this sense of solidarity, there, too, would be improvements in the healthcare system that would send ripples throughout the economy.

Although there were years of slow health economic growth across Europe following the economic crisis in 2008, nearly all European countries were able to rise in recent years. Yet, there are variations observed in the level and growth of health spending across Europe. For instance, high-income European countries, such as Luxembourg, Norway, and Switzerland, have the highest health expenditures per capita at EUR 4,713 (approximately USD 5715 in today's exchange rates), while Romania (EUR 983 or USD 1,192) and Bulgaria (EUR 1,234 or USD 1,496) have the lowest (OECD/European Union, 2018). Nevertheless, the mental health expenditure per capita in Europe is higher than all other countries at EUR 17.89 (USD 21.70). Also, 77% of the countries in Europe have stand-alone mental health laws, while 64% of them have updated these legislations since 2013. Meanwhile, in the Philippines,mental health and other economic problems are hardly addressed because of undeveloped mental health legislations, plans and policies (World Health Organization, 2018a), and annual net fiscal loss (Department of Finance, 2021). Even though the country's Current Health Expenditure (CHE) reached 792.6 billion (USD 16.5 billion) in 2019, 10.9% higher than 714.8 billion (USD 14.9 billion) in 2018, the total mental health expenditure per person is only

12.19 (USD 0.25). This is only 1/87 that of Europe. Moreover, only 0.22% of the government's total expenditure is allotted to mental health. The bulk of the CHE was spent on hospitals (43.6%), followed by pharmacies (30.3%), and providers of health care system administration and financing (7.4%). There are also stand-alone laws and policies for mental health in the country but there are no reports that monitor their implementation. Neither are there authorities that assess the compliance of mental health legislations in the Philippines with international human rights (World Health Organization—Assessment Instrument for Mental Health Systems, 2007; Philippine Statistics Authority, 2020). Evidently, mental health economists are needed to best resolve the mental health issues of the country.

Mental health is not well-established in the Philippines because of the dearth of investments channeled toward research. Thus, Filipino mental health workers cannot fully utilize their skills due to outdated practice guidelines and inappropriate curricula (Palaganas et al., 2017) unlike in Europe where guidance on economic crises and mental health are based on carefully reviewed research (Carrasco et al., 2016). The implementation of community mental health services are also based on empirical clinical evidence. Through this, they are able to recognize gaps that exist between the needs of the population and actual service provision (Semrau et al., 2011). This commitment has led to technological innovations such as e-Mental Health after evaluating the efficacy of delivering mental health services (Gaebel et al., 2020).

DISCUSSION

Thus far, the Philippine Mental Health Act has been nothing more than "just an act." Nonetheless, there is still hope that the provision of mental healthcare will be recognized as a significant need to ameliorate life and economy. However, gradual change should begin with norms ingrained in culture before governmental reforms could be enjoyed, as these, too, are products of social norms themselves. Moreover, social stigma and discrimination are the toxic traits that misshape Filipino culture.

Furthermore, this is the time to drop the romanticization of Filipino resiliency because the truth is that the average Filipino is not genuinely happy. A picture of a smiling Filipino does not equate to a happy Filipino because the mentally ill know how to smile too. The Philippines is a developing country that struggles to obtain economic stability because of outdated ways that result in gaps in mental health promotion, which in turn, bleed into the economy. The increasing prevalence of mental illnesses bears a great impact on human, social, and economic capital. This may be true not only in the Philippines, but also in other developing countries. Moreover, depression and anxiety should be recognized as disorders, not mere illusions. Families must be listeners and comforters of the mentally ill, not castigators. Filipinos must also understand that there is a complex process in managing mental health issues and full recovery could not be achieved over a short period of time.

This article is a call for Filipinos to view mental health issues in a different light and to impel government and public sectors to prioritize them and to set the Philippine Mental Health Act into motion. Below is a prescription for the realization of a mentally healthy Philippines.

First, mental health professionals must be mobilized to educate families about mental health and mental disorders to eliminate stigma and discrimination. They must participate in and contribute to the development of mental health policy and service delivery guidelines. And very importantly, "family group conferencing" skills should be included in the training and practice of psychiatry.

Second, since mental disorders usually begin in adolescence, much attention on the mental health of individuals in this age group must be given. Suicide intervention, prevention, and response strategies with particular attention to the concerns of the youth should be implemented.

Third, the quality of mental health services should be based on the findings of medical and scientific research. By doing so, a comprehensive and effective mental health care system could be developed and established to provide the psychological, psychosocial, and neurologic needs of the Filipino. Family members should also be encouraged to participate in research, in formulating and developing mental health policies, and in promoting mental health in the workplace and communities.

And finally, because suicide and substance abuse continue to be prevalent in the country, it would be best for legislators to review the Mental Health Act in order to identify any lapses in the law for its improvement.

Through these efforts, we hope that the Philippine Mental Health Act would be able to effectuate happiness, contentment, and healthier social relationships. These will be good not only for the mental health of the individual, but also for those around him or her. The mentally healthy Filipino population that emerges through these changes could reverse the effects of financial crises, unresponsive governance and unproductivity in the country. The economy will continue to grow, employment and salaries will increase, and Filipinos will no longer need to migrate abroad to seek greener pastures.

As earlier mentioned, MHE is a subject that cries out for exploration in the Philippines. Alas, here, mental health and the economy are considered to be two separate concepts that appear to exclude each other. Be that as it may, we hope that this article sparks conversations that will draw the indubitable connection between these correlated concepts in academe, government, and industry. We hope that it becomes a discipline in itself and investigations in the discipline are carried out for the good of the country. We hope that this paper would interest future researchers to look into verifying the converse of the seemingly intuitive idea that a healthy economy makes people happy as it is our belief that happy people will make our economy healthy.

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Conceived the work: MT and NM. Drafted the article: NM. Critically revised the manuscript: MT. Both authors read and approved the final manuscript.

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Promoting Responsible Research and Innovation (RRI) During Brazilian Activities of Genomic and Epidemiological Surveillance of Arboviruses

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Scientific advances have been accompanied by great achievements and also great societal expectations with respect to research and innovation. In fact, the scientific scenario is reconfiguring itself. If research was previously limited to academy, now it is present in companies and has a direct relationship with economics and politics, playing an important role on social issues such as gender, accessibility, and opportunities (1).

In this sense, some world movements are emerging, as the Open Science and the Responsible Research and Innovation (RRI) (2, 3). These movements are transforming scientific practice, integrating and aligning the interests between science and technology, society and environment. The main aim is to expand the number of agents that think and execute these ideas, in addition to promoting greater accessibility to the results of scientific research and, consequently, performing a more popular science (4).

The European Commission defines RRI as "a process for better aligning research and innovation with the values, needs and expectations of society. It implies close cooperation between all stakeholders in various strands comprising science education, access to research results and the application of new knowledge in full compliance with gender and ethics considerations." In practice, the RRI search for "science with and for society" and is guided by education as a promoter of scientific propagation (5). Actually, the information itself is not the same of a useful and critical knowledge. To become knowledge, it is necessary to disseminate the information, always based on open access. In this sense, continued training and the dissemination of technology are essential for

a growing range of professionals to bring research and innovation to places where opportunities are usually scarce. In addition, the popularization of science and technology provides an increase in interest in issues that are usually away from routine, such as the genomic and epidemiological surveillance (1, 4).

Currently, the genomic and epidemiological surveillance of arboviruses seems to play a crucial role in Brazilian context. Seasonally outbreaks of dengue, chikungunya, zika, and yellow fever occurs in Brazil, disproportionately affecting the poorest population and overwhelmed the public health system (6). Coupling genomic diagnostics and epidemiology to innovative digital disease detection platforms allowed an open, global and digital viral pathogen surveillance system (7–10). In this context, considering viral pathogen surveillance in mind, real-time sequencing, bioinformatics tools and the combination of genomic and epidemiological data from viral infections can give essential information for understanding the past and the future of an epidemic, making possible to establish an effective surveillance framework on tracking the spread of infections to other geographic regions. These actions can be even more relevant if carried out in conjunction with educational actions, such as technology transfer and training courses.

In this sense, in order to assist the Brazilian Ministry of Health (BMoH), we carry out a real-time genomic monitoring of the arbovirus circulating and co-circulating in Brazil, during the 2016–2020 epidemics, applying the RRI concepts. These concepts involve five principal keys: (i) Gender; (ii) Open Access; (iii) Education; (iv) Public Engagement; and (v) Ethics. The following strategies were established: (i) a team based on achieving gender equality (the team comprised 24 people of which 12 male and 12 female); (ii) an open access database to make data available as soon as they were produced; (iii) technology transfer and capacity building for the health workers to track the spread of emerging viral pathogens; (iv) the publications of the obtained results in local and international open access journals to make available final data for the scientific community and the general population; and (v) all steps were carried out based on the application of fundamental ethical principles and legislation to scientific research (**Figure 1**). Our real-time genomic activities started in 2016 when Brazil and the Americas experienced the emerging of a new international concern the Zika virus infection. At that time in collaboration with National and International institutions we started our sequencing mission in Northeast Brazil. During this project, called ZiBRA (Zika in Brazil Real Time Analysis), we were capacitated on the use of the nanopore sequencing, to get more insight regarding the dispersion dynamics of this emerging viral treat in Brazil. Using a mobile lab in 15 working days we generate a substantial number of complete and near complete ZIKV genomes and all data were also shared in real time on a free online website platform (http://www.zibraproject.org) (11).

Considering the success obtained using this novel technology we decided to extend those activities to track the emergence and the re-emergence of other viral pathogens circulating in Brazil and Americas (https://www.zibra2project.org). For this purpose, we lunched the second phase of those real-time genomic activities, called ZIBRA-2 project, where we characterized all the arboviruses currently circulating and co-circulating, including ZIKV, chikungunya virus (CHIKV), dengue virus (DENV) and yellow fever virus (YFV).

We investigated the spread of the CHIKV—East/Central/South/African genotype (CHIKV-ECSA) in different Brazilian regions (North, Southeast and Southeast), as well as we followed the spread of ZIKV in the Amazon region (12–14). Between 2016 and 2018 we were also fully dedicated to track the re-emergence of YFV in Southeast, Brazil. In this context, we extended our real-time genomic surveillance activities to understand the origins of this outbreak firstly detected in the state of Minas Gerais and then follow the YFV spreading in other southeastern (Rio de Janeiro, Espírito Santo, and São Paulo) and Northeastern (Bahia). Those activities gave us the possibility to generate 200 complete and/or near YFV complete genome sequences from those regions, and highlighted the importance of genomics-based methods to infectious disease surveillance and control (9, 15). During these activities we also applied the RRI concepts, by targeting public health and higher-education institutions. We generate and analyze most of the data in real-time within training programs, and we provide a proof-of-concept of the unique opportunities that portable sequencing technologies offer for local capacity building.

In 2019, we take advantage of the experiences obtained and innovated upon such field surveillance initiatives by including real-time training sessions in the surveillance schedule under 2 formats: in the field, using a mobile nanopore sequencing laboratory inside a motorhome for 17 days in the Midwest, training personnel from local public health laboratories; and in the classroom, under a 2 week workshop (Belo Horizonte city, Southeast) attended by a large number of participants from public health laboratories from across Latin America.

The course had 62 students from 34 national and international institutions (age range of participants between 25 and 50 of which half of them were male and half female). In addition to post-graduate students, course participants included laboratory technicians and health practitioners in universities and laboratories from several institutions responsible for laboratory-based surveillance of emerging and reemerging diseases, such as the Central Public Health Laboratories of the Brazilian states from the BMoH's network and public health laboratories from Paraguay, Argentina, Panama, Chile, Mexico, Uruguay, Costa Rica, and Ecuador. In both formats, training included all surveillance tasks, from sequencing to computational analyses and research writing. Employing genomic surveillance in the field and in the classroom, we generated and analyzed 227 novel complete genome sequences of Dengue 1–2 (16).

In order to disseminate those experiences in our institution (FIOCRUZ), at the end of 2019 we promoted the meeting "Structural Transformations for Responsible Research and Innovation." During this event we had the opportunity to discuss with researchers and graduate students ways to apply the RRI concepts, in addition to emphasizing the need of promote structural change in this field, in research institutions. Considering that Fiocruz is mainly involved in producing, disseminating and sharing knowledge and technologies, we had no problems in proposing measures to disseminate RRI

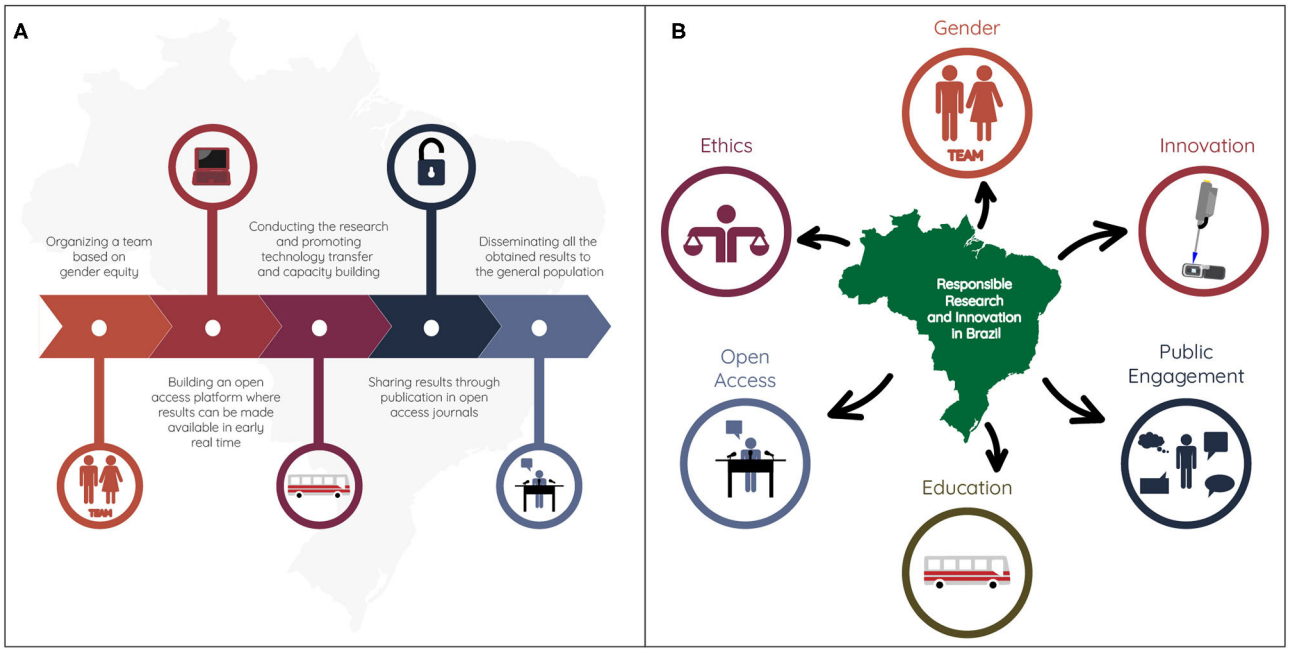

FIGURE 1 | Illustrative diagram representing the strategy used to implement RRI concepts during real-time genomic surveillance activities of circulating arboviruses carried out in Brazil. **(A)** Timeline showing the strategy steps. **(B)** The RRI principles applied during the research.

concepts in the institution. People, researcher, students involved were really receptive to try to come together to make those structural changes happen. It is important to note that, part of the Fiocruz's mission, as stated before, is promoting the scientific dissemination to the general population. In this sense, we used to share in nearly real time all the obtained results with the general public, using social midia (video and television platforms) including: (i) YouTube, (ii) Twitter, and (iii) Brazilian open TV channels (more details can be found here: https://www.zibra2project.org/zibra-press/).

Overall, the surveillance outputs and training initiative carried out during those activities also served as a proof-of-concept for the utility of real-time portable sequencing for research and local capacity building in the genomic surveillance of emerging viruses. More recently, in March 2020, the Coronavirus Disease 2019 (Covid-19) pandemic, caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus, was declared by The World Health Organization (WHO). In February, the Brazilian Ministry of Health confirmed the first case in the country and in April the LACEN from Minas Gerais state worked in collaboration with our team to sequence and analyze 40 complete SARS-CoV-2 genomes (17). This work can be seen as an example of the RRI impact on the interactions between science and society in Brazil and demonstrates the importance of the RRI concepts application during all research activities for social and health policy. A similar project of sequencing SARS-CoV2 genomes has been required by the Ministries of Health of the Republic of Chad and of the Republic of Cameroon (Central Africa). Two of the authors (M.G. e V.C.) are ready to move to Central Africa for capacity building, viral sequences and bioinformatics training in the context of the RRI approach.

CONCLUSION

The data presented here reinforce the need for real-time and continued genomic surveillance strategies to better understand and prepare for the epidemic spread of emerging viral pathogens and fortify that this is only possible through the spread of science and technology combined with social and environmental awareness. This implies harm reduction and intensification of benefits for society, the economy and the environment, in addition to equipping the scientific community to act more quickly in times of crisis.

The participation in Structural Transformation to Attain Responsible BIOSciences (https://starbios2.eu), a European project that received funding from the Horizon 2020 and aims to implement the RRI approach in research institutions, provided us with the ideal environment to reflect our research projects, as well as facilitates the practical insertion of RRI into bioscience. We hope that this report can help the scientific community to promote structural changes in their research, in order to practice and disseminate the Responsible Research and Innovation.

AUTHOR CONTRIBUTIONS

MG, LA, and FB: conception and design and draft preparation. MG, LA, AD, QF, WM, JJ, TA, ST, HF, FI, MM-G, AS, VF, JX, EL, GS, MC, VA, AK, GC, LP-D, CC, AB, CM, VC, and

FB: methodology. LA: resources. All authors contributed to the article and approved the submitted version.

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The Association of Social Capital and Self-Rated Health Between Urban Residents and Urbanized Rural Residents in Southwest China

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China has seen an accelerated process of urbanization in the past 30 years. The influence of urbanization on health is complex and primarily influenced by changes in social capital. The purpose of this research was to compare the social capital between urban residents and urbanized rural residents of southwest China and its relationship with self-rated health. It is of great significance to study the difference of social capital between urban and urbanized rural residents to help urbanized rural residents improve their social adaptability and health. Data was collected from 1,646 residents between November and December of 2017 in Chengdu. Three logistic regressions were used to investigate the association between social capital and self-rated health by controlling for demographic variables, lifestyles factors, and health status factors. We observed that urban residents' self-rated health had a higher proportion of "good" than that of urbanized rural residents ($P = 0.017$). After controlling for factors such as health status and demographic characteristics, participants with higher social capital had better self-rated health. Urbanized rural residents with higher community trust and belonging had better self-rated health (OR = 0.701, 95% CI = 0.503∼0.978), however urban residents with higher personal social networks and family relationships had better self-rated health (OR = 0.676, 95% CI = 0.490∼0.933 and OR = 0.666, 95% CI = 0.450∼0.987, respectively). Different types of communities should focus on the types of social capital from different sources, so as to take more targeted measures to improve the social support of residents and improve their health. Improving residents' social trust and sense of belonging may help urbanized rural residents better adapt to the new living environment and help them complete the identity transformation.

Keywords: social capital, self-rated health, urbanization, urbanized rural residents, Southwest China

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INTRODUCTION

In the past 30 years, China has seen an accelerated process of urbanization (1). In general, urbanization is a form of migration of a country's population from rural to urban areas (2). The expansion of Chinese cities has been dramatic. In 2011, the proportion of the urban population (51.3%) exceeded that of the rural population for the first time in history (3). In 2020, China's

urbanization rate has reached 63.9%. Due to the rapidity of urbanization, in many rural areas that have become urban districts. The impact of urbanization on individual health outcomes has both positive and negative consequences. On the one hand, changes in living environment and lifestyle are all related to the rapid growth of urbanization (4). Many factors, such as deteriorating air quality, increased high-calorie intake, and reduced social interaction with neighbors, affect the health of the residents. On the other hand, people tend to have better access to quality health services and other community resources, including health information (5). The influence of urbanization on health is complex and primarily influenced by changes in reciprocity and trust, social structure and networks, which are mentioned in most definitions of social capital (6).

Social capital has been defined as "those features of social organization that facilitate cooperation for mutual benefit, such as the extent of interpersonal trust between citizens, norms of reciprocity, and density of civic associations" (7, 8). More and more researches have been conducted on the role of social capital on personal health in these two decades (9). A study based on data from 39 states in US found that lack of social capital was strongly correlated with higher total mortality, death rate of heart disease and infant mortality (10). Moreover, a review illustrates that the association between social capital and personal health outcome may differ depending on the specific aspects of social capital being explored (11).

There are many indicators for evaluating the health of the population, including physical health, mental health and disease status. Various assessments of health status frequently ask respondents to rate their overall health with the categories of excellent, good, fair, and poor (12). Self-rated health appears to have a significant, independent association with mortality risks in numerous studies, when included medical, behavioral, or other health-related indicators (13). Ou et al. found that poor self-rated health was related to premature mortality and chronic health conditions (14). In addition, self-rated health is susceptible to many external factors, such as material, psychosocial, behavioral, workplace environmental and social capital (15, 16). A substantial body of literature assessed on the association of social capital on individuals' self-rated health in developed countries. For instance, Kawachi and colleagues detected a contextual effect of low social capital on the risk of poor self-rated health among US residents, after controlling for certain individual-level factors, such as low income, low education, smoking (7). Snelgrove showed that a protective relationship with current self-rated health and social trust after adjusting for individual characteristics, baseline self-rated health and individual social trust in Britain (17). Nevertheless, a few researches paid attention to the influence of social capital on self-rated health among Chinese residents. Using multilevel analysis, Meng et al. found that trust in social capital indicators was beneficial to self-rated health in China (6). Research by Zhu et al. showed that there is inequality in objective health outcomes between the floating population and local hypertensive patients, but there is no inequality in subjective health outcomes (18). These studies have examined the relationship between social capital and self-rated health in urban or rural areas. Taking into account the particularity of China's urban-rural dual structure, comparisons between different groups of people may help us better understand the impact of social capital on China's self-rated health.

In the context of China's urbanization policy, the government collectively collects the farm land that was originally cultivated by rural residents in the villages around the city. These residents were concentrated in the apartment community and their household registration status was converted from rural to urban (19). These are called urbanized rural residents (3). They left the original land and faced the problem of re-establishing a living circle. The lives of these policy immigrants have changed in many ways compared to their original lives. There are three main changes: first, their careers were no longer farmers. But because of their low level of education and lack of necessary work skills, this created a serious economic burden. Second, the type of social medical insurance had changed. There were some differences in the payment standard, reimbursement ratio and reimbursement scope between rural residents' medical insurance and urban residents' medical insurance. Third, their living space changed from scattered brick house to single-family high-rise apartments. Urbanized rural residents may experience challenge due to changes in their living environment and lifestyle. As rural-to-urban migration may influence migrants' health or well-being by exposing to new environmental risk and benefits, stimulating changes in patterns of behavior and connection of social network, and providing access to resources which were unavailable at the original place (20, 21). In the new living environment, how to help them establish new social connections and social support and improve their health level has become an urgent problem to be solved.

However, in the background of China's urbanization development, empirical evidence on the relationship between social capital and self-rated health is very limited (22). This study mainly addresses two objectives: first, to study the health status of urbanized rural residents and the differences among urbanized rural residents and urban residents. Second, to explore the differences in the relationship between social capital and self-rated health of these two groups?

MATERIALS AND METHODS

Study Setting

Our cross-sectional study was conducted between November and December of 2017. The face-to-face questionnaire survey was conducted in the community of Chengdu, which is one of the most developed cities in Southwest China. As the urbanization speed of Chengdu city continues to accelerate, a large number of urbanized rural residents swarm into the city, which poses many challenges to urban management. Meanwhile, it also provides a good opportunity and conditions for us to study its social capital and health status. Since 2004, Chengdu has transferred an average of nearly 200,000 farmers to cities and towns each year, and the city has built a total of 630 farmers' concentrated residential areas and new rural communities, with a total area of more than 28 million square meters (23). Urbanized rural residents are important human resource in the process of

urbanization. Establishing and improving public services such as education, culture, and medical care, and the old-age security and employment security systems are of great significance to help urbanized rural residents better integrate into urban life and promote social equity. Chengdu's reform experience has important implications for urbanization development policies in other regions of the country.

Study Participants

The selection criteria for the respondents were: (1) 15 years of age and older; (2) residents who lived in the selected community for half a year or more (to exclude some temporarily rented residents); (3) no mental illness and hearing impairment, able to express themselves; (4) respondents must answer the questions themselves; (5) urbanized rural resident: their land were levied because of the urbanization policy and their rural hukou (official registration) were converted into urban hukou within 15 years. Urban residents: their urban hukou period were more than 15 years because of urban planning.

Sampling and Sample Size

The survey used a multi-stage stratified random sampling method. First, Chengdu was divided into central urban areas and suburbs according to economic level, and one district was randomly selected in the central urban area and the suburbs. Then, we randomly selected an urban residential community and an urbanized rural residential resettlement community in each district, and uniformly codes the buildings in the selected community. According to the family, we surveyed all eligible family members present in each household.

We calculated the sample size using the following formula: $n = [\mu^2\alpha/2\pi\ (1\text{-}\pi)]/\delta^2$ (24), where $\pi = 33.2\%$ [which was 2-week prevalence rate in the population aged 15 and over in the fifth National Health Service Survey of Sichuan Province in 2013 (25)], $\delta = 1.5\%$ (δ is the allowable error, determined by the researcher based on previous experience), $\alpha = 0.05$, $\mu^2\alpha/2 = 1.96$. Based on this formula, the sample size was calculated to be 1,739. A total of 1,740 community residents were surveyed face-to-face by trained investigators. Excluding questionnaires with too much missing information, 1,646 valid questionnaires were finally obtained, and the effective rate was 94.6%. The study protocol was approved by the Institutional Review Board of School of Public Health, Sichuan University. Informed consent was obtained from each participant following a detail explanation about the purpose of the study.

Variables

The questionnaire included three parts, (a) demographic characteristics, health-related factors, and health status, (b) social capital, (c) self-rated health.

Demographic Characteristics, Health-Related Factors, and Health Status

Demographic characteristics mainly included gender, age, marital status, education, income, and employment status. Health-related factors was considered to include these questions, "Are you currently smoking?," "Are you currently drinking alcohol?," and "How many times have you exercised on average every week for the past 6 months?." Health status of participants was measured by two indices, the past 2 weeks of any diseases, and diagnosis of chronic diseases (0 = No, 1 = Yes). History of chronic diseases included hypertension, diabetes, chronic bronchitis, chronic gastritis, coronary heart disease, rheumatism and other diseases.

Social Capital Measurement

There is an ongoing debate about how to measure social capital. On the basis of a large number of theoretical studies on social capital in the early stage, we referred to domestic and foreign measure instruments (26, 27), and formed this social capital scale through the Delphi method. The questionnaire of social capital (see **Supplementary Table 1**) has 23 items, divided into five domains, Personal Social Network (SC1, 4 items), Interpersonal Support (SC2, 4 items), Family Relationship (SC3, 5 items), Community Participation (SC4, 3 items), Community Trust and Belonging (SC5, 7 items). SC1 mainly measures the number of people who are close to each other in daily life and economics, and the number of social activities with them. SC2 represents the support of others, for example, "when you are sick or uncomfortable, can you always get the care of others?" SC3 indicates whether family relationships are harmonious, including relationships with spouses, parents, and children. SC4 measures the individual's community participation, such as "The number of times you have participated in a community activity in the last year." SC5 represents the individual's sense of belonging to the community and the trust of the community residents. For example, "If you have to move away from where you live now, do you feel uncomfortable?" (Specific items for the Social Capital Scale and scoring methods are provided in **Supplementary Table 1**.) The answers consisted of 2-, 4-, and 5-point Likert scales, with the higher score indicating a higher level of social capital. The sum of the scores for all items in each domain was the score for that domain. Each respondent's SC1, SC2, SC3, SC4, and SC5 scores were dichotomized by the cutoff point of the median of the corresponding social capital scores: scores lower than median scores meant low social capital. The reliability of this scale can be acceptable (Cronbach's alpha 0.681, SC1 = 0.539, SC2 = 0.602, SC3 = 0.609, SC4 = 0.411 and SC5 = 0.788).

Self-Rated Health

We used an item to reflect the self-rated health of the respondents: would you say that in general your health is excellent, very good, good, fair, or poor? From this question, we created a dichotomous outcome measure (0 = excellent, very good, or good; 1 = fair or poor) (7).

Data Quality Control

During the data collection phase, undergraduate or graduate students with a medical background were selected as investigators, and they were trained intensively before the survey. After the daily survey, the investigator cross-checked the questionnaire on that day and signed and confirmed it. At

TABLE 1 | Characteristics of the participants.

	Total (%)	Urban residents (%)	Urbanized rural residents (%)	χ^2	*P*
Gender				18.498	<0.001**
Male	511(31.0)	315(35.6)	196(25.8)		
Female	1,135(69.0)	570(64.4)	565(74.2)		
Age(years)				23.089	<0.001**
<45	214(13.0)	147(16.6)	67(8.8)		
45–54	422(25.6)	215(24.3)	207(27.2)		
55–64	389(23.6)	209(23.6)	180(23.7)		
65+	621(37.7)	314(35.5)	307(40.3)		
Marital status				35.017	<0.001**
Single	100(6.1)	69(7.8)	31(4.1)		
Married	1,294(78.6)	713(80.6)	581(76.3)		
Divorced	35(2.1)	22(2.5)	13(1.7)		
Widowed	217(13.2)	81(9.2)	136(17.9)		
Education				240.193	<0.001**
Primary school and below	635(38.6)	218(24.6)	417(54.8)		
Secondary school	473(28.7)	243(27.5)	230(30.2)		
High school	297(18.0)	219(24.7)	78(10.2)		
College and above	241(14.6)	205(23.2)	36(4.7)		
Personal monthly income (CNY)				297.404	<0.001**
<2,000	965(58.6)	348(39.3)	617(81.1)		
2,000~	230(14.0)	174(19.7)	56(7.4)		
3,000~	184(11.2)	141(15.9)	43(5.7)		
4,000+	267(16.2)	222(25.1)	45(5.9)		
Employment status				223.205	<0.001**
Employed	470(28.6)	309(34.9)	161(21.2)		
Retired	464(28.2)	341(38.5)	123(16.2)		
Unemployed	712(43.3)	235(26.6)	477(62.7)		

***P < 0.001.*

the data collation and analysis stage, the verifier cleaned up the database and deleted missing records.

Statistical Analysis

The database was set up with EpiData 3.0 (Denmark). Descriptive statistics were used to illustrate demographic characteristics of participants. And we used chi-square test to undertake an analysis of participants' social capital by each indicator of demographic characteristics. Logistic regression was used to describe the relationship between social capital and self-rated health by controlling for demographic variables. In the first model (Model 1), odds ratios (ORs) and 95% confidence intervals (95% CIs) were calculated for the relationship of five dimensions of social capital and self-rated health. Model 1 only included five dimensions of social capital as independent variables. In the second model (Model 2), the OR (95% CI) was adjusted by controlling for demographic variables, including gender, age, education, marital status, income, employment status. The third model (Model 3) controlled the health-related factors and health status based on Model 2, including smoking, drinking, physical exercise, the past 2 weeks of any diseases, and chronic diseases. We used the forward method to filter variables. The social capital contents were also considered in Model 2 and Model 3. We used the forward method to filter variables. **Tables 3**, **4** showed the variables that eventually enter the model. The goodness of fit about these models were estimated by Hosmer-Lemeshow test (see **Supplementary Table 5**). All statistical analyses were performed with IBM SPSS 21.0. P<0.05 was considered to indicate a statistically significant difference.

RESULTS

Characteristics of the Participants

The descriptive information of 1,646 participants were presented in **Table 1**. There were 885 urban residents (53.8%) and 761 urbanized rural residents (46.2%). The average age of urban residents and urbanized rural residents was 55.6 years (SD = 16.9) and 58.7 years (SD = 14.9). More than half of the respondents were women. The vast majority of the participants were married (80.6 and 76.3%, respectively). Urbanized rural residents reported lower education levels and income than urban residents. More than half of the urbanized rural residents were unemployed (62.7%).

The Distribution of Health-Related Factors, Self-Rated Health and Social Capital

The current smoking and drinking behavior were not significantly different between the two groups of participants

TABLE 2 | The distribution of health-related factors, self-rated health and social capital between urban residents and urbanized rural residents.

	Urban residents (%)	Urbanized rural residents (%)	χ^2	*P*
Current smoker			0.262	0.626
No	698(78.9)	608(79.9)		
Yes	187(21.1)	153(20.1)		
Current drinker			1.028	0.322
No	701(79.2)	618(81.2)		
Yes	184(20.8)	143(18.8)		
Exercise/week(times)			6.635	0.036*
6+	550(62.1)	518(68.1)		
1∼5	153(17.3)	105(13.8)		
<1	182(20.6)	138(18.1)		
Chronic disease			4.147	0.045*
No	587(66.3)	468(61.5)		
Yes	298(33.7)	293(38.5)		
Ill within the past 2 weeks			3.945	0.047*
No	604(68.2)	484(63.6)		
Yes	281(31.8)	277(36.4)		
Self-rated health			5.823	0.017*
Good	626(70.7)	496(65.2)		
Bad	259(29.3)	265(34.8)		
SC1			0.923	0.348
High	443(50.1)	399(52.4)		
Low	442(49.9)	362(47.6)		
SC2			1.627	0.213
High	484(54.7)	440(57.8)		
Low	401(45.3)	321(42.2)		
SC3			5.589	0.019*
High	520(58.8)	403(53.0)		
Low	365(41.2)	358(47.0)		
SC4			2.454	0.125
High	475(53.7)	379(49.8)		
Low	410(46.3)	382(50.2)		
SC5			15.131	<0.001**
High	408(46.1)	424(55.7)		
Low	477(53.9)	337(44.3)		

*$P < 0.05$, **$P < 0.001$. SC1: Personal Social Network, SC2: Interpersonal Support, SC3: Family Relationship, SC4: Community Participation, SC5: Community Trust and Belonging. Use the median as a criterion for dividing high and low group of social capital.*

($P > 0.05$), while it seemed better for urbanized rural residents to participate in physical exercise every week ($P = 0.036$). It can be seen from the chronic disease and 2-week illness that the health status of urban residents was better than that of urbanized rural residents (**Table 2**). The distribution of self-rated health was different between urban residents and urbanized rural residents ($P = 0.017$). The self-rated health of urbanized rural residents was worse than that of urban residents. By comparing the five dimensions of social capital, it showed that the urban residents had better family relationships ($P = 0.019$). However, the community trust and sense of belonging of urbanized rural residents was higher ($P < 0.001$).

Associations Between Social Capital and Self-Rated Health

The logistic regression models were established with self-rated health as the dependent variable, social capital, demographic characteristics and health status factors as independent variables. After testing, the VIF values between social capital and other socio-economic factors were <10, and there was no collinearity between the variables. The relationships between social capital and self-rated health in different logistic regression models are presented in **Tables 3**, **4** among urbanized rural residents and urban residents. For urbanized rural residents, higher SC5 was significantly associated with self-rated health in Model 2 and Model 3 (OR = 0.676, 95% CI = 0.491∼0.931 and OR = 0.701, 95% CI = 0.503∼0.978, respectively). For urban residents, SC1 was significantly associated with self-rated health all three models. People with higher SC1 had better self-rated health in Mode 1 (OR = 0.683, 95% CI = 0.505∼0.923), Model 2 (OR = 0.669, 95% CI 0.487∼0.918), and Model 3 (OR = 0.676, 95% CI = 0.490∼0.933). In addition, SC3 was also protective factors after controlling variables of demographic characteristics and health status (OR = 0.598, 95% CI = 0.407∼0.878 in Model 2 and OR = 0.666, 95% CI = 0.450∼0.987 in Model 3).

DISCUSSION

This research is dedicated to exploring social capital among urban residents and urbanized rural residents of West China and its relationship with self-rated health.

In the past 10 years, China's urbanization process has been very rapid, and Chengdu is also undergoing a process of rapid urbanization. Chengdu, the capital city of Sichuan Province, has a population of 17 million permanent residents, of which nearly 2 million are migrants. At present, the urbanization rate in Chengdu is 71.9% (28). Urbanized rural residents do not have urban hukou or have obtained urban hukou in recent years. The urban health service facilities and subsidized health care were better than the rural areas under the urban-rural dual structure (29). We found that urban residents and urbanized rural residents have statistically significant differences in 2-week illness, chronic disease, and self-rated health. The health status of urban residents was better than that of urbanized rural residents. And urbanized rural residents' self-rated health had a lower proportion of "good." Many literatures have reported that socioeconomic status (30), health status (31), health-related behaviors (32), social capital (33) and other factors may have an impact on self-rated health. The differences between these two types of residents may cause differences in their own health assessments.

By investigating the social capital of residents, we found that the community trust and belonging of urbanized rural residents were better than those of urban residents. It showed that these participants had maintained the original community contact, and the resettlement community was mostly an acquaintance.

TABLE 3 | Associations of social capital to self-rated health among urbanized rural residents.

	Model 1			Model 2			Model 3		
	OR	**95% CI**	***P***	**OR**	**95% CI**	***P***	**OR**	**95% CI**	***P***
SC1(Low)									
High	1.083	0.792, 1.481	0.617	1.056	0.770,1.448	0.736	1.085	0.781,1.507	0.626
SC2(Low)									
High	0.821	0.598,1.128	0.223	0.774	0.560, 1.068	0.119	0.778	0.557, 1.088	0.142
SC3(Low)									
High	0.775	0.568, 1.056	0.107	0.872	0.627, 1.212	0.413	0.951	0.674, 1.341	0.775
SC4(Low)									
High	1.115	0.821, 1.515	0.487	1.113	0.816, 1.519	0.497	1.119	0.810, 1.547	0.495
SC5(Low)									
High	0.740	0.542, 1.012	0.060	0.676	0.491, 0.931	0.017*	0.701	0.503, 0.978	0.036*
Age (<45)									
45-54				1.691	0.872, 3.280	0.120	1.352	0.688, 2.657	0.381
55∼64				2.702	1.393, 5.239	0.003*	1.639	0.824, 3.261	0.159
65+				2.453	1.297, 4.641	0.006*	1.420	0.729, 2.767	0.303
Ill within the past 2 weeks (No)									
Yes							1.904	1.328, 2.731	<0.001*
Chronic disease (No)									
Yes							2.204	1.521, 3.194	<0.001*

*SC1: Personal Social Network, SC2: Interpersonal Support, SC3: Family Relationship, SC4: Community Participation, SC5: Community Trust and Belonging. Model 1 only included five dimensions of social capital as independent variables. Model 2 controlled the influence of demographic characteristics (gender, age, marital status, education, income, and employment status), and Model 3 adjusted for risk factors (2-week illness, chronic diseases, smoking, drinking, and physical exercise) based on Model 2. Use the median as a criterion for dividing high and low group of social capital. *$P < 0.05$. The control group is marked in brackets.*

However, the family relationship of urbanized rural residents was not so close, which was reflected in the relationship with parents and the relationship between husband and wife was lower than that of urban residents. In the urbanization process, the residential mode of centralized resettlement changed the former courtyard-style decentralized living mode, which led to the decomposition of the original joint family into a nuclear family, which may also weaken the intergenerational relationship. In addition, urbanized rural residents faced new life issues arising from urbanization, including employment, medical care, education for their children, etc. Due to the pressure of life, their time spent with their spouses and parents had decreased, leading to family tensions (34). This suggests that policies should pay more attention to various social insurance issues of urbanized rural residents to alleviate their living pressure and promote the stability of their family relationships.

Our study showed that a significant positive association between social capital and self-rated health. After controlling for factors such as health risk factors and demographic characteristics, participants with higher social capital had better self-rated health. The social capital factor that affects the self-rated health of urbanized rural residents was mainly the sense of community trust and belonging. In the former rural life in China, the neighborhood relationship between the residents was very close, and the neighbors often exchanged or helped each other. In urbanized communities, most residents in the same settlement were former neighbors, so their community belonging and trust were still significantly related to self-reported health. However, modern urban life may reconstruct their social networks after they moved in. These urbanized rural residents may tend to decrease social interaction and feel lonely or isolated as they moved into modern or high-rise apartment (35). It should be noted that the proportion of urbanized rural residents who are over 65 years old reaches 40.3%. Most of them do not have formal and stable work. Their focus of life is mainly in the communities where they live, so they have a strong dependence on the community environment. As a large marginal population concluding on unemployed rural migrants has been created, the urban community area will become an important resource of social capital for them in providing neighborhood-based mutual help or job information (36). The lack of neighboring relationships and long-term isolation, loneliness, the pressure of life may affect their assessment of health (37, 38). Schultz et al. found that social capital measures, such as informal socializing, formal group involvement, organized group interaction and volunteer activity, were the significant predictor of self-rated health (39). Evidence from an urban renewal scheme in Hong Kong has shown that the establishment of good community policing and affinity neighborhood committees can greatly enhance residents' trust and well-being in the community (38). By carrying out various meaningful community activities, enhancing the emotional exchanges between residents, increasing the community participation of residents, and creating a family atmosphere for them, they can feel more social support and social trust, reduce the pressure on life, and thus enhance individual health (17).

However, we found that the social capital factors that affect the self-rated health of urban residents were primarily personal social

TABLE 4 | Associations of social capital to self-rated health among urban residents.

	Model 1			Model 2			Model 3		
	OR	**95% CI**	***P***	**OR**	**95% CI**	***P***	**OR**	**95% CI**	***P***
SC1(Low)									
High	0.683	0.505,0.923	0.013*	0.669	0.487,0.918	0.013*	0.676	0.490,0.933	0.017*
SC2(Low)									
High	0.745	0.548,1.013	0.060	0.812	0.588, 1.121	0.205	0.804	0.579, 1.116	0.192
SC3(low)									
High	0.757	0.559, 1.027	0.073	0.598	0.407, 0.878	0.009*	0.666	0.450, 0.987	0.043*
SC4(low)									
High	1.174	0.866, 1.593	0.302	1.105	0.800, 1.526	0.545	1.081	0.778, 1.501	0.642
SC5(low)									
High	1.006	0.747, 1.354	0.971	0.832	0.604, 1.146	0.260	0.830	0.599, 1.150	0.262
Gender (male)									
Female				1.479	1.039, 2.106	0.030*	1.458	1.019, 2.086	0.039*
Age (<45)									
45–54				0.516	0.301, 0.883	0.016*	0.473	0.274, 0.818	0.007*
55–64				0.449	0.237, 0.853	0.014*	0.347	0.179, 0.671	0.002*
65+				0.765	0.410, 1.427	0.400	0.532	0.278, 1.018	0.057
Marital status (no)									
Yes				1.991	1.231, 3.220	0.005*	1.981	1.216, 3.229	0.006*
Employment status (employed)									
Retired				2.509	1.446, 4.354	0.001*	2.257	1.293, 3.940	0.004*
Unemployed				2.015	1.040, 3.902	0.038*	1.909	0.980, 3.719	0.057
Income (<2,000)									
2,000∼				2.110	1.209, 3.685	0.009*	1.995	1.133, 3.512	0.017*
3,000∼				1.166	0.645, 2.110	0.611	1.121	0.614, 2.046	0.711
4,000+				1.400	0.783, 2.503	0.257	1.302	0.724, 2.339	0.378
Ill within the past 2 weeks (No)									
Yes							1.465	1.030, 2.084	0.034*
Chronic disease (No)									
Yes							1.951	1.337, 2.847	0.001*

SC1: Personal Social Network, SC2: Interpersonal Support, SC3: Family Relationship, SC4: Community Participation, SC5: Community Trust and Belonging. Model 1 only included five dimensions of social capital as independent variables. Model 2 controlled the influence of demographic characteristics (gender, age, marital status, education, income, and employment status), and Model 3 adjusted for risk factors (2-week illness, chronic diseases, smoking, drinking, and physical exercise) based on Model 2. Use the median as a criterion for dividing high and low group of social capital.

$^{*}P < 0.05$. The control group is marked in brackets.

networks and family relationships, which referred to individual-level social capital. Different from urbanized rural communities, residents' neighborhood relationships were relatively stable in the urban community. Most urban residents were forced to put most of their energy into their work, and rarely had time to communicate with their neighbors. Their sources of social support and social networks were more extensive from family, friends, and associates, but less on social capital at the community level (40). The findings from the current multivariate analysis showed that the relationship between individual social capital and health outcome had backing from other studies (41). For example, an analysis from older Americans found that social networks were associated with a lower presence of depressive symptoms (42). Verhaeghe et al. suggested there was a positive relationship between network social capital and self-rated health, and social connections from different classes provided people different sets of resources. Network social capital from strong ties was more important to self-rated health than network social capital from weak ties (43). Generally, urban residents had higher socioeconomic status, and social capital at individual level such as personal social networks and family relationships, was stronger social capital for them. Their self-rated health was more strongly affected by individual social capital. In addition, we found that, after controlling for other factors, marital status, employment status, and income of urban residents were significantly associated with self-rated health, while this relationship was not significant for urbanized rural residents. This also implied that socioeconomic factors had an important impact on self-rated health of urban residents.

The main limitation of this study is that it is a cross-sectional survey, it does not validate the causal relationship between social capital and self-rated health. Therefore, prospective

researches are needed to confirm our finding. In addition, the questionnaire for measuring social capital was not an international questionnaire, while it was developed to fit the Chinese cultural background. Also, this study didn't consider the interaction of social capital and other socio-economic factors.

CONCLUSIONS

This research found a significant positive relationship between self-rated health and social capital. In the case of controlling factors such as health status and demographic characteristics, participants with higher social capital had better self-rated health. At the same time, we observed that urbanized rural residents with higher community trust and belonging had better self-rated health, however urban residents with higher personal social networks and family relationships had better self-rated health. The influence of social trust and sense of belonging on the health of urbanized rural residents cannot be ignored. In the process of urbanization, improving residents' social trust and sense of belonging will help urbanized rural residents better adapt to the new living environment and help them complete the identity transformation. In the future research on social capital, different types of communities should focus on the types of social capital from different sources, so as to take more targeted measures to improve the social support of residents and improve their health.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Institutional Review Board of School of Public Health, Sichuan University. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

TM and BG conceptualized the idea. TM collected the data, performed the statistical analyses, and wrote the first draft of the manuscript. BG critically revised the manuscript. All the authors checked and approved the final manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.718793/full#supplementary-material

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An Innovative Approach for Decision-Making on Designing Lifestyle Programs to Reduce Type 2 Diabetes on Dutch Population Level Using Dynamic Simulations

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The number of individuals suffering from type 2 diabetes is dramatically increasing worldwide, resulting in an increasing burden on society and rising healthcare costs. With increasing evidence supporting lifestyle intervention programs to reduce type 2 diabetes, and the use of scenario simulations for policy support, there is an opportunity to improve population interventions based upon cost–benefit analysis of especially complex lifestyle intervention programs through dynamic simulations. In this article, we used the System Dynamics (SD) modeling methodology aiming to develop a simulation model for policy makers and health professionals to gain a clear understanding of the patient journey of type 2 diabetes mellitus and to assess the impact of lifestyle intervention programs on total cost for society associated with prevention and lifestyle treatment of pre-diabetes and type 2 diabetes in The Netherlands. System dynamics describes underlying structure in the form of causal relationships, stocks, flows, and delays to explore behavior and simulate scenarios, in order to prescribe intervention programs. The methodology has the opportunity to estimate and simulate the consequences of unforeseen interactions in order to prescribe intervention programs based on scenarios tested through "what-if" experiments. First, the extensive knowledge of diabetes, current available data on the type 2 diabetes population, lifestyle intervention programs, and associated cost in The Netherlands were captured in one simulation model. Next, the relationships between leverage points on the growth of type 2 diabetes population were based upon available data. Subsequently, the cost and benefits of future lifestyle intervention programs on reducing diabetes were simulated, identifying the need for an integrated adaptive design of lifestyle programs while collecting the appropriate data over time. The strengths and limitations of scenario simulations of complex lifestyle intervention programs to improve the (cost)effectiveness of these programs to reduce diabetes in a more sustainable way compared to usual care are discussed.

Keywords: system dynamic model, type 2 diabetes, lifestyle, cost-benefit, patient journey modeling, decision support model

INTRODUCTION

Diabetes mellitus (DM) is a complex disorder (1–3), and the number of individuals suffering from DM is dramatically increasing worldwide from over 360 million individuals in 2015, expected to be 500 million individuals in 2030 (3–5). Nine out of 10 individuals of the total DM population suffers from type 2 diabetes (T2DM) (6), which is characterized by a systemic metabolic disorder of which fasting blood glucose concentration slowly increases over years (1), and a major cause of slow healing foot ulcers, kidney failure, blindness, heart attacks, stroke, and lower limb amputation (3). T2DM can be treated and prevented, and as such, its consequences can be avoided or delayed by means of diet, physical activity, medication, as well as regular screening and treatment for complications (7). Without effective lifestyle intervention programs, DM results in an increasing burden on society and a substantial rise in healthcare costs (8, 9).

Also in The Netherlands, there is talk of an emerging epidemic, as over the years, the total population of DM patients increased from 3.9% in 2007 to 6.6% in 2019 (10, 11). Today, with a population of ∼18.2 million people, 1.2 million people (6.6%) are estimated to suffer from diabetes, and it is estimated that this prevalence will increase ∼30% by 2030 (12, 13). In latest calculations, the direct care costs of DM accumulated to a staggering 1.6 billion euros in 2017, accounting for around 1.8% of the total healthcare budget of The Netherlands (6, 14). There is an urgent need to explore how this rising societal burden can be reduced (cost)effectively. Recently, nutrition and lifestyle intervention programs focusing on treatment and especially reversing T2DM patients to a healthy state have been described in the literature (3, 15–17). Nevertheless, despite having access to intervention programs and knowledge of lifestyle on the onset and progression of T2DM and on total cost, only limited long-term policies on early prevention of pre-diabetes or T2DM patients are being implemented in the Dutch healthcare system. A clear understanding of the "T2DM patient journey," our denomination of the journey from being healthy to becoming pre-diabetic and eventually becoming diabetic over time and possibly recovering from T2DM could support decision makers to optimize current policy including weigh-offs in social cost that is inferred through the accumulation of this (pre)diabetic population over time. An easily accessible simulation tool to bridge the gap between all these dimensions and to simulate interconnected effects of different programs on the outcome prior to the implementation of intervention strategies appears to be hardly existent in the literature.

Currently available simulation models for cost effectiveness or cost–benefit analysis of intervention programs on diabetes are often based upon Markov-type simulations of healthcare costs (18, 19). However, these Markov-type simulations do not offer an opportunity to estimate the consequences of unforeseen dynamic interactions over multiple years in the prescription of actions/interventions based on scenarios tested through "what-if" experiments (20). As such, dynamic simulation modeling could be a more effective method for designing especially high-leverage policy population lifestyle programs in the context of a complex problem such as type 2 diabetes. A small number of system dynamics (SD) models simulating the onset and progression of diabetes on population level over time have been described (21, 22). However, these SD models focus on the United States and therefore lack specific parameters for The Netherlands. The models were constructed for the purpose of explaining the progression of the number of patients with type 2 diabetes and did not take into account any form of dynamic simulation of the costs and benefits of lifestyle policies.

Therefore, in the present study, we aim to develop an SD model of the T2DM patient journey visualizing and exploring the consequences via "what-if" scenarios. To achieve this, we aim to simulate the costs and benefits of lifestyle programs over time via coupling three interconnected elements, i.e., (1) the dynamic journey from healthy (normoglycemic) to type 2 diabetes at population level, (2) the effect of lifestyle programs focusing on either prevention, treatment, and/or reversing T2DM, and (3) their associated total cost for society. The resulting simulation model does not have the aim to be 100% accurate in predicting the future, as this will not be possible. It aims to support the decision-making on T2DM pre- and intervention strategies by society and policy makers by means of a scenario-simulation tool of the cost and benefit analyses of type 2 diabetes lifestyle programs.

To develop a T2DM patient journey SD model, a thorough understanding of the core concepts of the onset and progression of the disease and associated costs of this complex social issue is crucial, which is described in section Background. The Methods section elaborates on the methods used to collect the appropriate data, model building, and addresses the role of feedback governing the system's behavior. The Result section provides an overview of the T2DM patient journey model, followed by the validation process of the model and the resulting scenarios. The Discussion section describes the limitations of the study and summarizes the most important insights resulting from the present study, followed by section Conclusion.

BACKGROUND

The T2DM Patient Journey

T2DM is a complex disease, slowly evolving and both genetic and lifestyle related (1, 3). The individual is diagnosed with T2DM when fasting blood glucose or 2-h post-load blood glucose reaches values $\geq$ 7.0 and $\geq$11.1 mmol/L, respectively (23). The individual is referred to as "pre-diabetic" or "having pre-diabetes" when the fasting blood glucose or 2-h post-load blood glucose is higher than the blood glucose levels of healthy individuals but lower than the standard set to receive the diagnosis DM (2, 24, 25). Researchers have shown that T2DM and pre-diabetes results from an interaction of heritable risk factors and non-heritable risk factors (2, 5, 26–28). The non-heritable risk factors indicate the possibility of T2DM patients, and diagnosed pre-diabetes patients could be reversed to healthy individuals.

In line with this interaction, Loos and Janssens (29) argued that most individuals develop T2DM as a consequence of suffering from a metabolic syndrome or obesity, which predominantly occurs due the combination of an unhealthy

lifestyle and a genetic susceptibility for gaining weight. In The Netherlands, the Heart Foundation and the Rotterdam R cohort study suggest that one out of three obese Dutch individuals will develop T2DM over time (30). The number of DM patients in The Netherlands has increased from 160,000 individuals in 1990 to 1.2 million in 2018 (12). In more recent years, Dutch healthcare is seemingly regaining control over the T2DM disease. Statistics Netherlands (31) has published data concerning the number of T2DM patients of the total Dutch population from 2014 to 2018 showing a steady change from 3.7% in 2014 to 4.0% in 2019. A faster rate of increase was observed in the two decades before (from 1990 to 2011), the number increased from 160,000 to 830,000 (10, 31), which is 1% to around 4.9% of the total population (31). A unified scientific explanation for this is not yet present; however, explanations might be found in more awareness of unhealthy lifestyle via media and success rates of the installment of local integrated lifestyle programs and bariatric surgery for especially obese T2DM patients (32). Nevertheless, the number of T2DM and pre-diabetes patients is foreseen to grow (25, 33), largely as a result of two factors. Besides the effect of increasing obesity (29, 33), an increasing aging population also results in an increasing T2DM population, as insulin resistance increase with obesity (34) and age (35). Currently, 51% of the Dutch population above 20 years old are overweight, of which 15% are obese. Both populations have increased over the past 5 years (31), and with the knowledge that one of three obese people develops T2DM, these numbers indicate that combined (cost)effective lifestyle programs may have extensive positive implications for society.

Treatment of T2DM and Lifestyle Programs Aiming to Reverse T2DM

In The Netherlands, T2DM treatment is performed in compliance with the guidelines of the NHG-standard (de Nederlandse Huisartsen Genootschap Standaard in Dutch). Patients with T2DM are primarily treated in primary care by general practitioners (GPs) and their practice staff, including practice nurses (PNs). After medical treatment and lifestyle advice, every 3–6 months, routine diabetes consultations are performed, including physical examinations, blood glucose checks, and other laboratory tests, and the results discussed with patients. Both GPs and PNs perform medical and lifestyle counseling according to generally acknowledged criteria (36, 37). Besides treatment, researchers suggest that non-heritable risk factors are modifiable, and hence, assuming that individuals are able to make sustainable lifestyle changes, T2DM patients could be helped to permanently lower their blood glucose levels to normal levels. This process is referred to as "reversing the T2DM patient" (2). However, to achieve an actual reversal of T2DM patients, long-term behavioral changes are needed to restore normal, sustainable blood glucose levels (2, 3, 38–40). Reversal programs of T2DM are focused on providing treatment with limited use of insulin, as early routine use of insulin therapy can have negative consequences such as increased mortality, weight gain, increased risks of cancer, and hypoglycemia (41). In the beginning, T2DM intervention programs ranged from programs focusing on improving current treatment programs in The Netherlands, as approved by the NHG-standard, by re-evaluating the screening process resulting in the possibility to intervene earlier (10). As knowledge increased, other T2DM programs were developed focusing on changing lifestyle factors, such as personalized nutrition (40, 42), enhancing physical exercise (43), or after bariatric surgery for individuals with severe obesity (32, 44).

Treatment effectiveness, however, is highly dependent on the patient's intrinsic motivation to deliberately make lifestyle changes. Long-term coaching is often outside of the GP's role, with the development of several coaching tools as a result (45). Additionally, through current advancements of technology, the possibility of determining pre-diabetes gives the ability to reduce the causes earlier instead of fighting the consequences. Overweight and obesity for instance are very well-known to increase the incidence of T2DM (34). Early reversals are to reduce the potential long-term cost due to the development of the T2DM population. Hence, the present study argues that lifestyle programs should focus on the pre-diabetes population as well.

The Construction and Calculation of Total Cost Arising From T2DM

The total cost associated with T2DM are costs resulting from individuals suffering from undiagnosed pre-diabetes, diagnosed pre-diabetes, and T2DM. These contributions in healthcare cost are abatable and/or even preventable, as research suggests that non-genetic obesity is relatively preventable in the assumption that individuals can make sustainable long-term behavior changes (46). There are multiple types of costs that arise from T2DM.

First, as The Netherlands is a welfare state, the public authorities provide unemployment benefits to the disabled (47). In case of a T2DM patient becoming disabled, the individual may claim for benefits according to the Work and Income Act (WIA). Within the invalidity scheme (the WIA scheme), a distinction is made between full, permanent disability (in Dutch "Inkomensvoorziening Volledig Arbeidsongeschikten," IVA benefit) and partial disability (in Dutch "Werkhervatting Gedeeltelijk Arbeidsgeschikten," WGA benefit).

Second, the employer develops cost arising due to labor productivity loss of the individual suffering from T2DM, which eventually may result in absenteeism of the T2DM patient (9). Additionally, the cost resulting from an obligatory salary payment for disabled employees is considered. When an employee is declared partially or fully disabled in The Netherlands, the employer is obligated to pay the salary of the employee up to 2 years as regulated in the Employee Insurance Agency (47).

Lastly, every person is insured under the Healthcare Insurance Act (ZVW) and the Long-Term Care Act (Wlz). Both medical as well as non-medical cost arise due to the need for primary care, hospitalization, and medical support. The present study, therefore, recognizes medical costs resulting from ambulatory care, hospitalization, physiotherapy, tools and devices use, general practitioner care, and medical treatment (the latter

being separated for the elderly as insulin in an elderly body adjusts differently and therefore needs additional treatment). Furthermore, cost arising from comorbidities of T2DM (48–51) are taken into account. Additionally, costs arising from managing organizations concerned with T2DM by T2DM patients' foundation associations are included.

Connecting the Elements

To explore the effectiveness of policy interventions, these three interconnected elements (the development of type 2 diabetes, lifestyle programs focused on reversing T2DM, and associated cost) need to be coupled to each other to provide a holistic view on the likely development of interventions on the T2DM stock and subsequent cost over time. The possibility of reversing type 2 diabetes and reducing its subsequent number of patients, the evidence of the effectiveness of lifestyle programs, and the subsequent cost for society should be treated as a combination of direct and indirect costs. Additionally, these pre- and intervention programs are financially heavy and require long-term commitment of (health) professionals and patients. To put all these aspects in a computer model, simulating the dynamics of the future trend of type 2 diabetics and associated cost could possibly guide the way for a more informed decision-making as to which programs decisionmakers can consider implementing in a certain context for optimal result.

METHODS

Choosing SD for Computational Modeling

To model the T2DM patient journey in The Netherlands, an SD modeling approach was applied for the following reasons. In 2016, Alouki et al. reviewed that many of the public health interventions fall short of their larger goals, as these interventions usually are based upon linear projections of retrospect data (52). Current economic evaluation methods are often insufficient to simulate dynamics of complex phenomena involved and to visualize the outcome of "what if?" experiments. Environment, behavior, and population change over time, where risk factors, states of uncertainty, healthcare professions, and intervention resources are continuously interacting with one another. When the latter phenomena result in chronic problems, these can be defined as "wicked problems" (53, 54). To address wicked problems to an extent in which they might become manageable, this research argues the need of a holistic, integral approach, easily accessible for stakeholders, that captures non-linear behavior of the complex system over time. SD modeling is well-suited to address this complexity and an appropriate method for identifying important leverage points and examination of possible interventions in complex problems in advance of real-life implementation and subsequent evaluation, which would otherwise be too costly (21, 55). Therefore, with the ultimate aim to develop a simulation tool, SD was used to build a first version of an SD model to gain insights in the development of the T2DM patient journey in The Netherlands under the current policy, under lifestyle programs as several intervention policies, and under programs that combine lifestyle intervention policies.

Basics of SD Methodology Explained

SD modeling simulates complex dynamic behavior over time and works with interrelationships, which are represented in multiple linked differential equations (56–59). The method predominantly makes use of stocks and flows. A simplified population model and its respective behavior, illustrating stocks and flows, are presented in **Figure 1A**. A stock, indicated with a square, represents a (accumulation of a) quantity at a certain point in time. A flow, however, indicated with a double-lined arrow, models the change in a stock over time (and therefore "flows" in or out of the stock). Variables, indicated by words preceding single arrows, add detail to the relations between stocks and flows. These variables mostly are endogenized within the system. Ultimately, the interaction and feedback (known as "loops") between multiple endogenous variables, stocks, and flows create the dynamics over time (**Figure 1B**).

Building the T2DM Patient Journey Model

A participatory process was used to develop the SD model, as illustrated in **Figure 2**, and described below.

The current SD model finds its origins in the systemic analysis of diabetes performed by the Center for Disease Control and Prevention in the USA. The aim of this research by Homer et al. was to model the key drivers of population flows and inputs amenable to policy intervention (21). In a further adaptation of Homer's work, Jones et al. (22) redefined the model to a "patient journey." A large focus point in the study of Jones et al. was the division of complicated and uncomplicated diabetes, and no attention was paid to associated costs. In the current study, we chose to focus on the impact of lifestyle intervention programs, which has the most impact on early prevention and reversal of diabetes, and as such, we did not distinguish between complicated T2DM and uncomplicated T2DM but focused on four additional factors affecting the early onset and actual emergence of T2DM. The factors were (1) the effect of an aging population (indicated in the model as Elderly fraction of adult population), (2) the effect of obesity on the emergence of T2DM (indicated in the model as Obese fraction of adult population), (3) the effect of population growth (indicated in the model as Adult growth rate), and (4) the T2DM death rate compared to death rate of the normoglycemic population (indicated in the model as Death rates for diabetic- and non-diabetic population, respectively). Multiple improvements were made due to new information available on the effect of prevention and lifestyle intervention programs changing the recovery rates of the subpopulations due to further evidence of reversing T2DM patients by nutrition and lifestyle. The structure of the T2DM model was parameterized toward the current situation and data available in The Netherlands.

Data Collection to Build the Final T2DM Patient Journey Model

To collect the appropriate data, experts were iteratively interviewed to elicit their knowledge on T2DM and lifestyle intervention programs and to validate the relationships presented in the preliminary model, as described by Vennix (57).

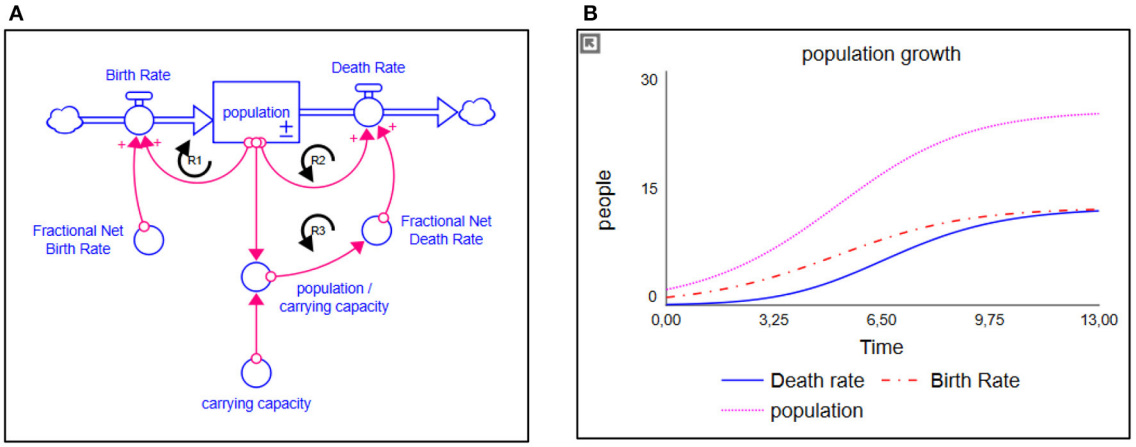

FIGURE 1 | (A) Simplified population model and **(B)** its respective behavior. The stock is represented as a square; the flows are represented as double-lined arrows. The more people there are, the higher the birth rate is over time; a reinforcing loop (R1). Given a fixed carrying capacity, the more people there are, the more people will die; a counteracting reinforcing loop (R2). If the birth rate remains larger than the death rate, we will experience population growth. Population growth, however, has its limits due to all kinds of factor. Therefore, a balancing structure is built in, indicated by limiting variable "carrying capacity." The closer the population gets to its respective carrying capacity, the more deaths will occur (a second counteracting reinforcing loop (R3), eventually stabilizing population growth where the amount of deaths equals the amount of births.

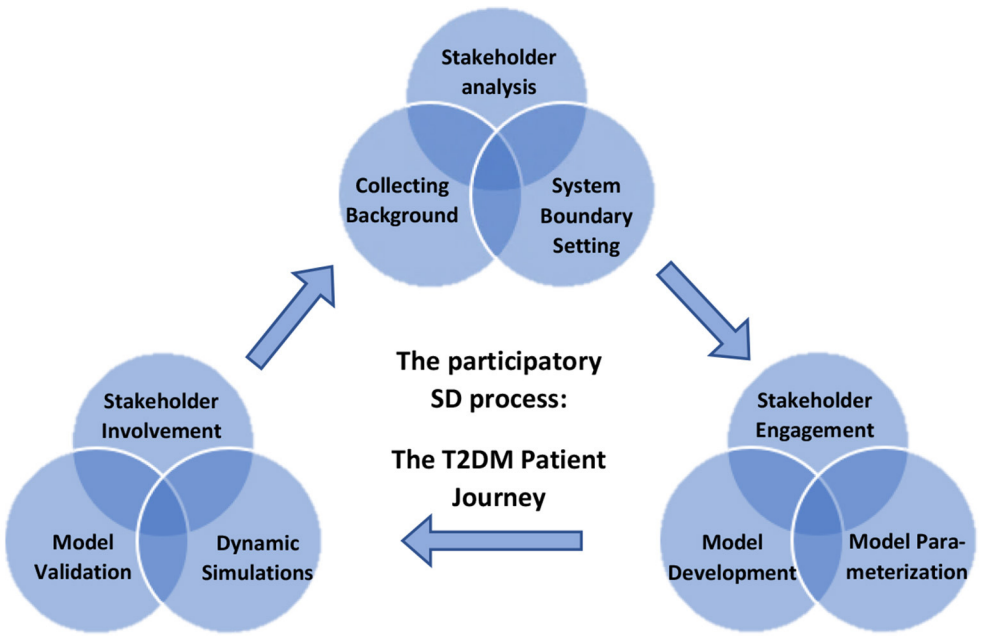

FIGURE 2 | Overview of the participatory process of building a system dynamic (SD) model for decision-making on designing lifestyle programs to reduce type 2 diabetes on Dutch population level using dynamic simulations.

Accordingly, interviews were held with five scientific experts working at The Netherlands Organisation for Applied Scientific Research (TNO). All experts had detailed scientific knowledge and/or together more than 40-year experience on T2DM as well as its lifestyle programs in The Netherlands. Background of the experts were in biomedical sciences, health sciences, molecular biology, economics, and social history with a female/male ratio of 2/3. The expert interviews were conducted according to an interview guide approach, audio-recorded and analyzed for overall themes, as described by Vennix (57, 60). During the expert interviews, some changes in the preliminary model were suggested. For example, in contrast with Jones et al. (22), an outflow from the T2DM population to the normoglycemic population was suggested, as experts argued the possibility

of reversing both pre-diabetics and T2DM patients. After crosschecking with the relevant literature review and background information as described the modules *The T2DM Patient Journey, Treatment of T2DM and Lifestyle Programs Aiming to Reverse T2DM*, and *The Construction and Calculation of Total Cost Arising From T2DM*, the preliminary model was modified accordingly. Thereafter, the modified preliminary SD model was validated by the experts. Finally, after several critical discussions, a final structure of the model was generated and inserted in Stella Architect software version 2.0.1 (iSee Systems, 2020). For parameterizing the model, data were extracted from scientific literature, World Bank, and Dutch databases of Statistics Netherlands (CBS), Dutch Healthcare Authority (NZa), The National Health Care Institute (ZIN), Netherlands Institute for Health Services Research (NIVEL), National Institute for Public Health and the Environment (RIVM), Dutch Diabetes Research Foundation (Diabetes Fonds), Dutch Diabetes Association (DVN), and the Netherlands Organization for Applied Scientific Research (TNO). Based on these data, the model was adjusted to represent the baseline scenario. Details of the data used are given in **Supplementary Data**.

RESULTS

The Construction of the T2DM Patient Journey Model

The T2DM patient journey model displays the journey of individuals developing T2DM and the possibilities to reduce T2DM via interventions programs, coupled to the costs associated with T2DM and these subsequent programs in The Netherlands (**Figure 3**). The more type 2 diabetics, the higher the cost for society. Details of the model are given in **Supplementary Data**.

The model, as presented in **Figure 3**, is constructed via the following rationale. The initial stock is the "Normoglycemic population" of The Netherlands, consisting of all individuals able to develop T2DM. That is, the total Dutch population minus the T2DM population as T1DM patients are able to develop insulin resistance (61). Individuals are recruited to this population because of being born, migration, and passing away (formed as an exogeneous variable to keep the scope of focus on T2DM development: the variable "Dutch population trend"). A small fraction of this stock is already diabetic, whereas a small but growing fraction develops T2DM over time. Therefore, the initial values of the normoglycemic population plus type 2 diabetic population must equal the number of citizens in The Netherlands at the model's initial starting time. Under the circumstance when the Dutch population growth is equal to the growth projections of CBS, the model portrays the following behavior: the more diabetics, the larger the group of diabetics becomes, and the more the stock of normoglycemic population depletes; a reinforcing (+) relationship. On the other hand, the more type 2 diabetic people recover (or differently said, the stock "type 2 diabetics" reduces), the larger the normoglycemic group: a balancing (–) relationship. To reduce the amount of type 2 diabetics, one can "adjust" these flows with intervention strategies. We can reduce the amount of type 2 diabetics by either implementing a prevention program, which will reduce the amount of people becoming diabetic (slow down the reinforcing structure) or we can accelerate the type 2 diabetic recoveries by implementing intervention strategies (increase the balancing structure). From normoglycemic to diabetic, most individuals undergo generally the following process: first, one becomes overweight or even obese (outliers are represented as "non-obese") and becomes a pre-diabetic. Either the person gets diagnosed or does not, represented as the "Diagnosed pre-diabetics" and "Undiagnosed pre-diabetics" stocks. Over time, a small fraction of both stocks "reverts" and flows back to the Normoglycemic population stock. Hence, individuals who suffered from either pre-diabetes or T2DM are again recruited to the normoglycemic population through "recovery." However, a large part of these groups becomes type 2 diabetic, flowing into the "Type 2 diabetics" stock. A percentage of this type 2 diabetics population can be reversed, flowing back to the "Normoglycemic" stock. The according differential equations can be found in the **Supplementary Data**; the equations follow the rational:

(1) Diabetes population = (fraction of diagnosed pre-diabetics that become diabetic/time it takes to become diabetic for diagnosed pre-diabetics + fraction of undiagnosed pre-diabetics that become diabetic/time it takes to become diabetic for undiagnosed pre-diabetics).
(2) Normoglycemic population = [initial normoglycemic population + (fraction of type 2 diabetics that recovers/time it takes to recover)].

Pre-diabetics

Individuals experiencing symptoms of pre-diabetes per definition first develop undiagnosed pre-diabetic and are thus recruited to the "Total persons that become pre-diabetics." These pre-diabetes patients either can see a general practitioner and receive either the diagnosis impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) (diagnosed pre-diabetes population, depicted in **Equation 2**), or leave the diagnosis to rest. The diagnosis rate (IFG and IGT) is determined by combining the fraction incidence (IFG) and the fraction incidence (IGT). Individuals suffering from either IFG or IGT are recruited from the total pre-diabetes population to the diagnosed pre-diabetes population when receiving the diagnosis IFG or IGT. Both individuals who are diagnosed and undiagnosed (or who are not visiting a general practitioner) can experience symptoms of T2DM, as the disease progresses over time. Fractions of both the diagnosed and undiagnosed pre-diabetes patients recover from pre-diabetes and is recruited to the normoglycemic population again; the latter has a smaller percentage of returning as people simply do not know they have pre-diabetes.

Reversing the T2DM Population

Individuals are recruited over time to the T2DM population from the undiagnosed and diagnosed pre-diabetes population (IFG/IGT). T2DM patients leave the T2DM stock in two ways: first, passing away due to T2DM when reaching the average

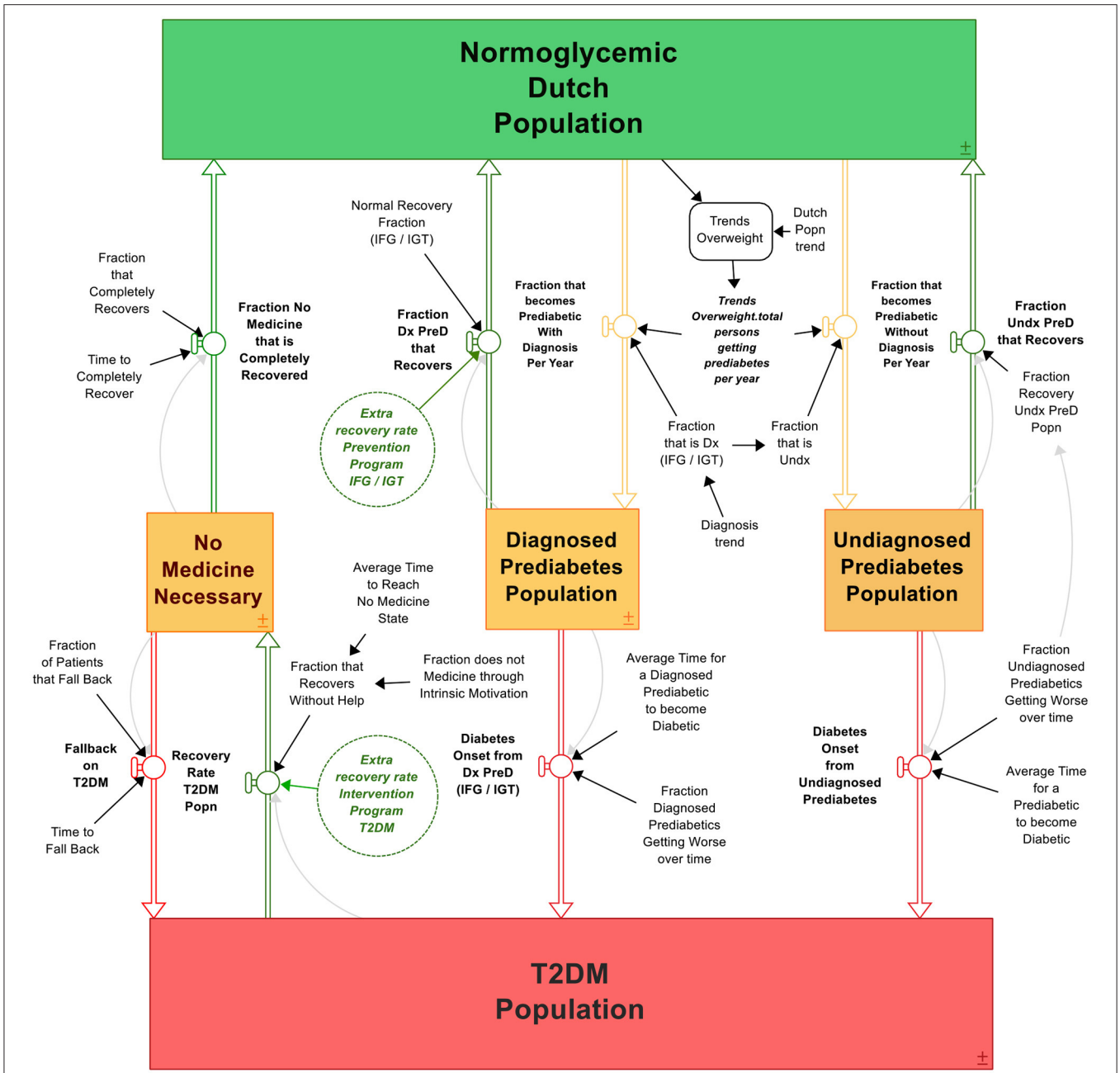

FIGURE 3 | The T2DM patient journey. Boxes are stocks that accumulate over time, double arrows are in- or outflows that either give input or take output of the stock. Circles are variables that affect the in- or outflows, containing parameter values. Clouds are outputs that "flow out of the system" like deaths. The process is visualized from green (healthy) to orange (likely to develop T2DM) to red (developed T2DM), with multiple possibilities to bounce back in the system to "healthy" (green arrows). The system contains the differential equations as described in section The Construction of the T2DM Patient Journey Model.

life expectancy of a T2DM patient; second, by recovering from T2DM. The fraction that recovers from T2DM determines the recovery rate of the T2DM population and thus the number of people recruited again to the normoglycemic population. Furthermore, a fraction of T2DM patients that are reversed to a state in which they do not need any medicine experience a relapse into the type 2 diabetes stock. This percentage is around 65% and heavily affects the follow-through of the success rates of a certain lifestyle program (48). With a bariatric surgery, however, this relapse percentage is only 5% (62). As CBS only provides data of T2DM from 2011 onwards, the initial value ($t = 0$) is defined by the Dutch population trend multiplied by the fraction of T2DM over the total population in 2011. Following the equations, the resulting SD model can be found in **Figure 3**.

TABLE 1 | Model values used that determine the time and fraction of individuals to transit from one stock to another.

Transition		Average time (years)	Fraction of stock from A to B, divided by average time (DT)
From stock A	**To stock B**		
Normoglycemic population (non-overweight)	Total persons that become pre-diabetics	2	0.01
Normoglycemic population (overweight)	Total persons that become pre-diabetics	3	0.33
Diagnosed pre-diabetics	Type 2 diabetics	4	0.70
Undiagnosed pre-diabetics	Type 2 diabetics	7	0.90
Diagnosed pre-diabetics	Normoglycemic population	2	0.30
Undiagnosed pre-diabetics	Normoglycemic population	4	0.10
Type 2 diabetics	Normoglycemic population	3	0.01
No Medicine necessary	Type 2 diabetics	2	0.65
No Medicine Necessary	Type 2 diabetics (Bariatric Surgery)	10	0.05

Data are based upon assumptions made from the literature, reports, and discussion with experts. Fractions of stocks are indicated between 0 and 1, in which 1 indicates 100%. Data are based upon assumptions made from the literature, reports and discussion with experts.

Dynamics Over Time

As SD modeling is a method to capture behavior over time, these differential equations are constructed accordingly by dividing the difference over a certain time step (dt) in this study in months. In the SD model, certain time factors are crucial for the behavior of the model, namely, the time a person takes on average to become pre-diabetic, the average onset and recovery times from (un)diagnosed pre-diabetics to either type 2 diabetic or normoglycemic population, and the recovery time for a type 2 diabetic to revert to a normoglycemic person. The time and fraction in which one transitions from one stock to another (in years) are represented in **Table 1**.

Submodules

In order to perform (cost)effectiveness analyses with the SD model, two types of submodules were developed and connected to the dynamics of the T2DM population: the submodule on effectiveness of the lifestyle intervention programs on reducing the pre-diabetic and T2DM population and a submodule on the costs and benefits of the lifestyle intervention programs. The submodules run simultaneously of each other and complement themselves with elements of the "larger" T2DM model. The T2DM model forms merely an input for the cost for society (the more patients, the more the cost, and the more program cost, the more total cost). The effectiveness of the lifestyle programs, however, enjoys its input through the T2DM population (for example, the higher the T2DM population, the more people to treat) and, in turn, provides a feedback for the T2DM population dynamics (the more effective the lifestyle program, the more people recover from T2DM).

Submodule 1: Intervention and Prevention Programs

The structure enabling the implementation of intervention programs is presented in the **Supplementary Data**. This module serves as an input for a possible higher recovery rate of T2DM patients (prevention programs) as well as a lower onset rate from the non-glycemic to pre-diabetic stock. The rationale is as follows. Assuming that individuals are able to make sustainable lifestyle changes, the present study argues that T2DM patients (either IFG or IGT) can either recover without intervention program (normal recovery rate) and with the support of one (recovery rate intervention program). The recovery rate intervention program is determined by the program recruitment rate and the program success rate. The number of individuals recruited to participate in a certain intervention program is determined by the potential recruitment rate or the indicated recruitment rate, as it is initialized with the special-function MIN. The potential recruitment rate can only be determined by the maximum patients able to receive treatment over time. Furthermore, the indicated recruitment rate represents the actual number of T2DM patients who are recruited to participate in the certain program, which is determined by investments. Thereafter, the model with implementation of a certain lifestyle intervention program is connected to the associated costs and benefits.

Submodule 2: Total Cost of Type 2 Diabetes

The total cost of type 2 diabetes in The Netherlands consist of costs for the Dutch authorities, the health insurer, the employer, and, more implicitly to a certain extent, the patient. In **Figure 4**, a schematic and static overview is given of the costs, as they have been incorporated in the model and their respective mathematical relationships. The total accumulative costs are represented in the **Supplementary Data**. In order to couple the costs to the development and scenario setting of T2DM and lifestyle programs over time, it is required to couple elements as the T2DM development over time (the type 2 diabetics stock) to these static equations.

Model Validation

In SD modeling, model validation is a combination of a social, qualitative process as well as formal testing (63). Therefore, it is argued that model validity should be judged considering the model's purpose (63). Accordingly, the T2DM patient journey model's validity was judged considering its purpose by conducting several structure tests and structure-behavior-oriented tests as described earlier (26, 64). Within structural behavior testing, an extreme condition test was used to examine whether the model still rationally portrays the right behavior when being put to extreme measures. In the model, the normoglycemic population was set to both 0 and 100 million, whereas the model adequately portrayed reality in for example cost: 0 T2DM patients resulted in 0 costs, 100 million

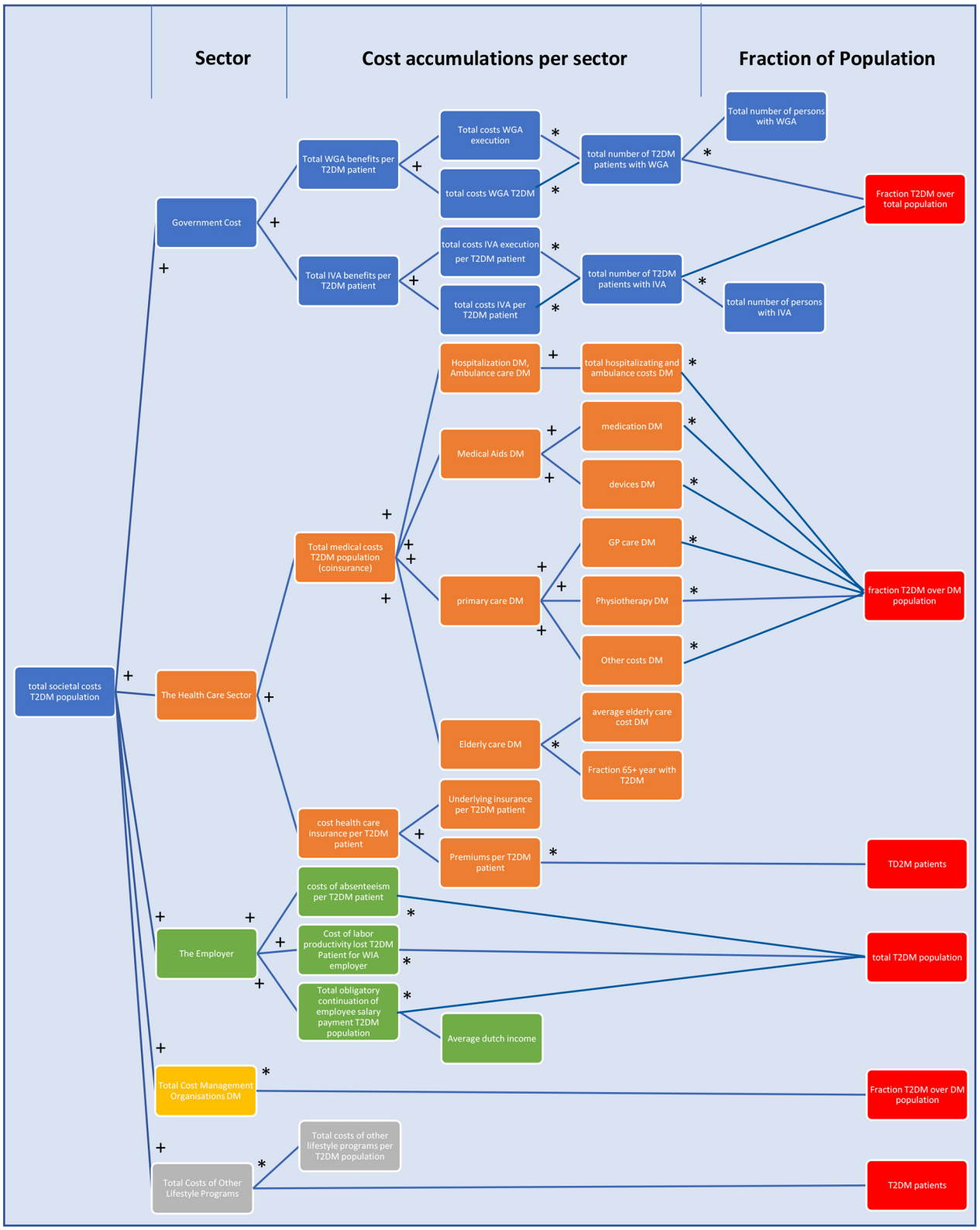

FIGURE 4 | A schematic overview of the total costs of T2DM in The Netherlands as incorporated in the model. The figure follows the logic: from the portion of the Dutch population that has T2DM, in whichever way that fits for the equation (red), multiple costs to society are calculated via multiplications (*) and cumulations (+). Blue = costs for Dutch authorities, orange = costs for the financial health care sector, green = costs for the employer, yellow = total costs for management of DM, and gray = total costs of other lifestyle programs. For details of WGA, WIA, and IVA, see section The Construction and Calculation of Total Cost Arising From T2DM (47).

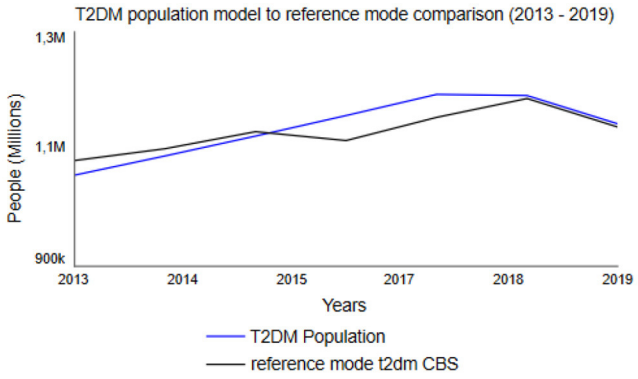

FIGURE 5 | Dutch T2DM Population between 2013 and 2019, based upon Statistics Netherlands (CBS) data (31) as reference mode (black line) and simulated change using the T2DM patient journey model (blue line).

T2DM patients resulted in a few billion euros in costs. By conducting behavior sensitivity analysis, all exogenous variables were examined based on their impact on the model's behavior (59). When conducting behavior sensitivity analysis on *Fraction Individuals Developing Pre-diabetes* (see **Supplementary Data**), for example, the simulations showed that all five populations are very sensitive to changes in the fraction. The model appears to be very sensitive for changes regarding the fraction of individuals determining the number of overweight and obese individuals who develop diabetes [*Fraction Overweight Developing Pre-diabetes (BMI)*]. Furthermore, the behavior reproduction test examined the model's ability to replicate the reference mode of behavior (59) on CBS published data on the normoglycemic population and the T2DM population from 2013 to 2019 (31). When comparing the model's behavior and the CBS data, roughly the same behavior was observed (**Figure 5**). Hence, the model is able to replicate the reference mode of behavior.

Scenario Simulation of the Cost and Benefits of Future Lifestyle Programs

The T2DM patient journey model is simulated for a 45-year time period from 1990 to 2035 to enable comparison with results presented in the relevant literature (10). Following the current policy, simulation shows that the total costs of T2DM increase as a result of an increase in the type 2 diabetics stock, as shown by the relationship between the T2DM population and the total costs for society T2DM population. As all the elements are interconnected and validated to "sufficiently correct with reality," policy levers are implemented in the model to examine dynamic cost–benefit interactions in the model. The current policy levers are five-fold: First, one can choose to "activate" a certain program, either prevention or an intervention (pre-diabetes program and T2DM program). Second, one can determine the success rate of the program. Realistically, this is usually a trade off with cost: the more it is effective, the more people are needed so the more cost, which is another policy lever (cost multiplier). The potential amount of people that will be focused on can also be determined with "potential patients to recruit in program." A program can choose to either focus on a small group and make this extremely efficient or draw it to a wider group with the risk of being less efficient.

Using different "what-if?" experiments, the development of the T2DM population and the total costs for society of T2DM were simulated under hypothesized multiple policy scenario runs: current policy ("No lifestyle program") and policy options 1–4 (activated in the year 2020), as to be seen in **Table 2**, followed by the outcomes of these particular policy parameterizations to total cost for society of all the interventions (**Figure 6A**) and its subsequent T2DM population (**Figure 6B**).

Scenario Run 1: No Intervention Policy

In the "no intervention policy" situation, we simulate that no additional lifestyle program is yet installed. Therefore, the program activations remain 0. The model shows that the inflows diabetes onset rate from undiagnosed and pre-diabetes, diabetes onset rate from diagnosed pre-diabetes (IFG/IGT) continuously exceed the outflows recovery rate T2DM population and recovery rate (un)diagnosed pre-diabetes, resulting in a steadily increasing T2DM population. The total cost for society associated with T2DM follow the trend of the T2DM population and result in current setting to a cost for society in the Netherlands that increases to 13 billion euros in 2035.

Additional Intervention Policies

When an additional intervention program is implemented, it will always incur an extra cost. However, T2DM patients can also fully recover via a lifestyle change without the support of any additional lifestyle programs (current policy), although rare. To determine (cost)effectiveness of additional lifestyle programs as offset under increased cost, several policy scenarios (different lifestyle programs) are run on the framework of the T2DM patient journey and its subsequent societal costs. Multiple aspects are being taken into account in all these additional lifestyle interventions: the success rate of a program, the choice of a focused (T2DM population only) or an integrated program (both T2DM and pre-diabetes population), the potential amount of patients (either T2DM only or T2DM and pre-diabetes) that can be recruited in the program, and the cost per person of the program. All lifestyle programs contain trade-offs. For example, to have a lifestyle program with success rate while still "keeping it cheap," one needs a focused approach with a selective group as personalized care is expensive. Another example is the trade-off of having an integrated approach that covers most of the society; in order to not make the lifestyle program too expensive, one needs to make trade-offs in the success and recruitment rates of the program.

Scenario Run 2: Bariatric Surgery

Scenario run 2 is one where a bariatric surgery is performed on patients. The success rates are based on Yska et al. (44), and the cost for this surgery is based on RIVM data (62). In this policy, an adaptation on the relapse rate and time from the "no medicine necessary" stock is made. The parameter values for this group are set on relapse rate of 5% (0.05 as compared to 0.65) with a delay of 10 years instead of 2. The cost of this bariatric

TABLE 2 | Hypothesized intervention scenarios and their parameter values used in scenario simulation.

Simulated intervention scenarios	T2DM program				Pre-diabetes program			
	Yes/no	Fraction recruited	Success rate	Cost multiplier	Yes/no	Fraction recruited	Success rate	Cost multiplier
No Intervention policy	No	–	–	–	No	–	–	–
Policy 1 "Bariatric Surgery"	Yes	0.28	0.95	17	No	–	–	
Policy 2 "ReverseDiabetes2Now"	Yes	0.002	0.28	1	No	–	–	–
Policy 3	Yes	0.3	0.3	1.0	No	–	–	–
Policy 4	Yes	0.45	0.3	2.0	Yes	0.3	0.3	1.0
Policy 5	Yes	0.6	0.5	3.0	Yes	0.4	0.5	3.0

Parameter values are indicated between 0 and 1, in which 1 indicates 100%. Data are based upon assumptions made from literature, reports and discussion with experts.

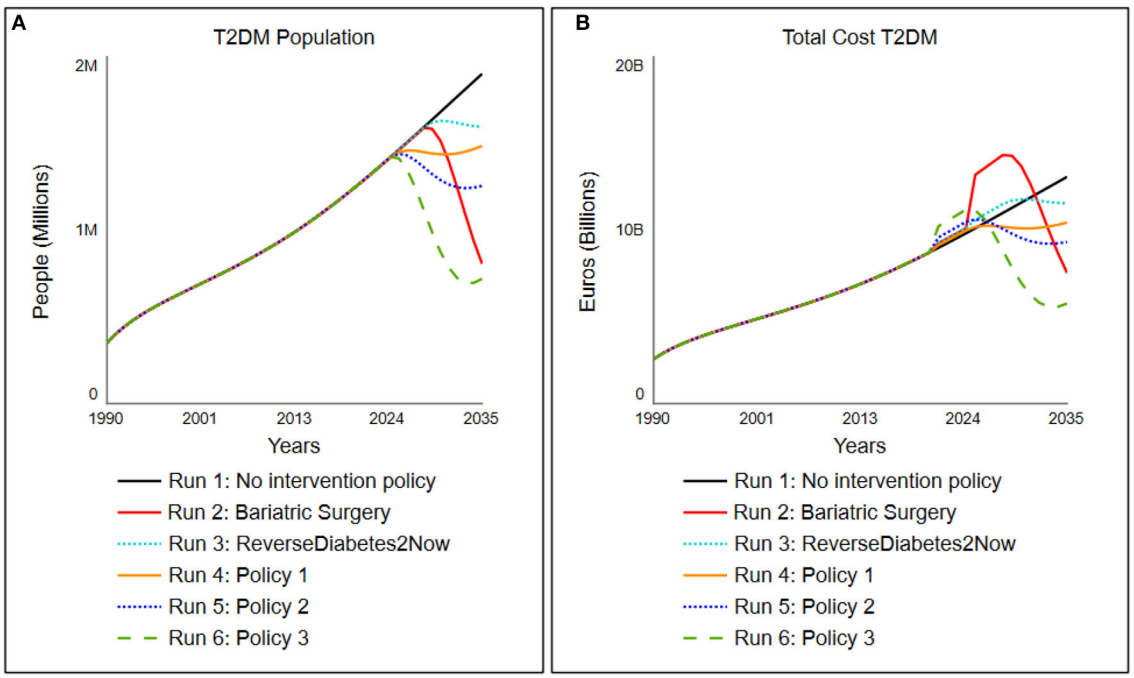

FIGURE 6 | Simulated change in **(A)** the total cost for society associated with T2DM population and **(B)** the total T2DM under five different scenarios tested, which are activated in 2020 (details of scenarios indicated in **Table 2**).

surgery, however, accumulates to around 17 times the amount of a lifestyle intervention, ranging from 15,000 to 20,000 euros (62). The success rate of this policy is set on 95%. Since only people with BMI above 35 are eligible for bariatric surgery due to Dutch care regulations, the percentage of people recruited is set to 28%, which roughly accounts for the percentage of people who have a BMI above 35. The policy portrays that, however extremely effective, this is a very expensive policy option when it is deployed over the larger population (**Figure 6**, run 2).

Scenario Run 3: The "ReverseDiabetes2Now" program

In scenario run 3, the program of "ReverseDiabetes2now" is simulated with its current success rates (40) and gradually increased in population treatment over 10 years. The program currently has a success rate of 28% where no medicine is necessary, and around 2,500 people are treated yet (roughly 0.002% of T2DM population in 2020). Pricing is assumed to be set on "average." The model simulates, when the treated population is gradually increased over 10 years to 30% of the entire T2DM population, that the type 2 diabetes population will stagnate and subsequently its cost (**Figure 6**, run 3).

Scenario Run 4: Policy Option 1

Policy option 1 is a moderately successful additional lifestyle program (success rate of the program is 30%, or 0.3) but merely focuses on the T2DM population. To keep the cost down (average cost), the program can only focus on 30% of the T2DM population. As a result, the program turns out to level off the costs in the year 2025 (for a closer look, simulation of the

cost for society of the policy run is presented in **Figure 6**, run 4). Although it practically levels off the growth of the T2DM population, the program is still a high societal burden in terms of cost.

Scenario Run 5: Policy Option 2

Policy option 2 is a fairly successful additional integrated program (success rate of the program is 45% or 0.45 for both T2DM patients as well as 30% or 0.3 for pre-diabetes billion by 2) for T2DM patients and standard (1.0) for pre-diabetes patients. As a result, the program brings down the T2DM population to a far extent and is a relatively small investment for the benefit it brings (**Figure 6**, run 5: a small bump in 2020, which is being corrected through an extensively lower T2DM population and thus a decrease in total cost for society of around two billion euros in 7 years). The combination turns out to be successful for total cost for society in the long run while ensuring that only a small investment needs to be made for the society to implement this integrated program.

Scenario Run 6: Policy Option 3

Policy option 3 is an expensive (pricing multiplied by 4) yet very successful additional program focused on the T2DM population (success rate of the program is 60% or 0.6 for T2DM patients). As mentioned, personalized care is expensive, hence four times the standard costs. One can see a drastic decrease in the T2DM population. In terms of long-term gain, this is the most successful option for both reduction in T2DM population as total cost, but more practically, this comes at a price. The stakeholders need to preinvest as much as 1 billion euros in this program (**Figure 6**, run 6: a large bump in 2020 of 1 billion euros compared to current policy) to get this result, which likely will result in large resistance of stakeholders.

DISCUSSION

This study was performed to demonstrate how dynamic simulations can be used to explore the consequences of policies in order to design lifestyle intervention programs of a complex disease like T2DM based on scenarios tested through "what-if" experiments. At first, understanding of the patient journey from a normoglycemic and/or obese health state toward pre-diabetes toward type 2 diabetes, and vice versa, was based upon literature data, databases, and expert interviews. Thereafter, a detailed study to capture available cost for society, current policy, and available T2DM intervention programs were collected. The combination of literature and empirical data, discussions with knowledge experts, and several publicly accessible data sources in The Netherlands, appeared to be successful for developing a first version of an SD-based simulation tool focusing on the patient journey of type 2 diabetes as a complex reversal disease, and the associated total cost for the society. The analyses presented in this study demonstrate the insights and conclusions one could draw from building an SD model and use it for simulation experiments. The experiments improved understanding of some characteristic dynamics of the simulated diabetes population in The Netherlands: (1) obesity is a major factor driving the growth of pre-diabetes and as such T2DM prevalence; (2) the inability of the current policy to reduce T2DM prevalence in the long term; (3) lifestyle intervention programs focusing on T2DM alone reduce T2DM population on short term but is less effective over longer time; and (4) the significant delays between primary prevention efforts and downstream improvements in diabetes outcomes. These results indicate the need for additional intervention programs focusing on pre-diabetics.

The participatory process of building simulation models can help improve our understanding of a complex chronic disease dynamics like type 2 diabetes. In addition, it can also identify the missing data needed to improve the model and our knowledge and may enhance the commitment of collaborative participatory action research to collect longitudinal data for evaluation of the intervention programs. As a consequence, this may result in more cost-effective lifestyle intervention designs. However, all simulation models have several inherent limitations. All models remain incomplete simplifications of the reality, and their conclusions are affected both by structural boundaries and by the uncertainties of the data with which they are calibrated (59). Techniques such as boundary critique and sensitivity testing (59, 64) can be used to assess the extent to which models may be affected by these simplifications and uncertainties. In the case of the type 2 diabetes patient model, sensitivity testing suggests that the magnitudes of its simulated futures, such as those seen in **Figure 1**, are subject to some imprecision because of uncertainties about input parameters but that the directions of change and thus our general findings are unaffected by these uncertainties.

Limitations

To calibrate the model, accessible databases in The Netherlands of, among others, CBS, KPMG, Nederlandse Zorgautoriteit, NIVEL, RIVM, and TNO were used. For some concepts, data estimates and assumptions in trends and rate had to be made due to limited data availability or conflicting datasets. No distinction in age groups was made, as specific data for all other variables per age group were scarce. Age is considered to have a limited effect, as the fraction of individuals below the age of 20 years old suffering from T2DM is close to 0 (31). The average life expectancy of a healthy individual in The Netherlands is 81.7 years (31). Assuming that undiagnosed individuals unaware of their T2DM condition pass away sooner than individuals aware of their condition, a shortened lifespan of 10 and 8 years was considered for the undiagnosed pre-diabetes population and the diagnosed pre-diabetes population, respectively. For the T2DM population, a shortened lifespan of 9 years was assumed.

Publicly accessible data on sustainable recovery rates are not available yet. It is assumed that already recovered individuals and normal healthy individuals develop T2DM at the same pace. For both diagnosed pre-diabetes populations, as the disease has not yet progressed as much, it is assumed that the motivation to recover of diagnosed pre-diabetes patient suffering from IFG or IGT is present, and thus, the recovery fraction for the IFG/IGT diagnosed pre-diabetes population was set at 10%. Furthermore, it was assumed that undiagnosed pre-diabetes patients are

unaware of their condition and thus are the least motivated to recover or simply do not know about their disease until it is too late. Therefore, the recovery for undiagnosed pre-diabetes population was set at 5%.

In the submodule total cost for society, some costs were determined for the total DM population in accordance with the relevant literature, the costs for the T2DM population were determined by taking the product of the total cost for society of the total DM population and the fraction that 9 out of 10 DM patients suffer from T2DM (6, 31). Additionally, it was assumed that all T2DM patients and all pre-diabetes patients are employed.

Suggestions for Future Work

For the full potential of the T2DM patient journey model, it is clear that extra longitudinal data need to be collected to improve the prognostic value for decision-making on designing lifestyle programs to reduce type 2 diabetes on Dutch population level. However, based upon the available data, the model showed that compared with the current situation, the policy options 3 and 4 are observed to be the most effective in terms of decrease in T2DM population and reduction in total cost for society. This is due to these policy options having the highest reference frame—these programs apply to the entire diabetes patient journey. Therefore, we believe that future research should focus on identifying the most optimal policy options under a similar approach. That is, conducting scenario analysis with individual policy success rates per group in the patient journey in a certain context taking constrictions into account, while collecting the data as indicated in **Table 2** over time to evaluate the lifestyle program while improving the T2DM patient journey model.

The present study argues that both creation of awareness on pre-diabetes, combined lifestyle programs, and collective actions are important to reduce T2DM, as besides the current expenditure of billions of euros that are largely avoidable, it could contribute to positive societal change and reverse obesogenic tendencies in Dutch society. Policy should not only focus on medication or lifestyle intervention programs in the case of severe symptoms but also focus on early prevention programs by supporting sustainable change toward a healthy diet, exercise, sleep pattern, and reduction in chronic stress, for a full remission toward a healthy state. Currently, individuals deliberately need to make lifestyle changes to manage their blood glucose levels, whereas a more supportive role from society and public authorities to reduce unhealthy stressors would be beneficial. Over the years, some changes have been made, such as promoting daily exercise and installing bike lanes. At the same time, however, grocery stores sell unhealthy products at eye level, and too often, stairs are installed behind doors while elevators are prominently placed at the main entrance of office buildings. Dutch citizens are therefore receiving contradictory prompts from their social environment, and a tension appears to exist between incentives that promote healthy and unhealthy lifestyles.

To parameterize the model to reality, assumptions had to be made. In accordance with (65), each assumption is explicitly stated in the **Supplementary Data** and open for criticism. Therefore, future studies should be focused on discussion of these assumptions by gaining knowledge and longitudinal data on the development of (un)diagnosed pre-diabetes and the recovery process of (un)diagnosed pre-diabetes patients. This will also result in less parameter sensitivity in the behavior sensitivity analysis.

Additionally, when assessing the effectiveness of the policy options, the underlying assumption is that that all individuals are able to make sustainable lifestyle changes that continue beyond the timeframe of the model. However, future studies should focus on including the effect of this assumption for two reasons. First, the majority of T2DM patients are elderly (35). Consequently, those individuals have practiced unhealthy lifestyles for a long period of time. Hence, it could be argued that this limits the success of adopting a new lifestyle. Second, as T2DM is more progressed than (un)diagnosed pre-diabetes (1), it is arguable that it is harder to make behavioral lifestyle changes for T2DM patients than for (un)diagnosed pre-diabetes patients. Another assumption that should be challenged in future research is to measure the effect of stakeholders' budget to investment in lifestyle programs.

Moreover, future studies should include the effect of gender, education level, social status, migration background, and culture, as research suggests the factors to be of significant influence in the development of T2DM (66, 67). With more accurate data of the local situation, the model has the potential to support local policy makers with new insights and hypotheses *ex ante* implementation of prevention and lifestyle intervention programs for more sustainable (cost)effectiveness in their own region. However, even with their inevitable imprecision and incompleteness, simulation models can enhance learning and decision-making, which is their primary purpose (59).

CONCLUSION

In the present study, we used SD modeling to build a prototype model to be implemented into a simulation tool to gain a clear understanding of the type 2 diabetes mellitus patient journey and to assess the impact of lifestyle intervention programs on total cost for society associated with developing, preventing, and lifestyle treatment of pre-diabetes and diabetes. We were able to capture the extensive knowledge of diabetes, current available data on both population level, lifestyle intervention programs, and associated cost for society in The Netherlands into one simulation model. The model was able to visualize and measure the relationship between leverage points on the different outcomes of lifestyle programs. When assessing the policy options' effectiveness in terms of their total cost for society reductions, the model shows that simulation runs 5 and 6 prove to be most effective in terms of long-term societal cost reduction and simulation run 1 is the least effective one. As the systemic approach shows, this is due to focus points in the model: Simulation runs 2–4 are merely focused on the reduction in current T2DM cases, which is largely increasing cost as personalized care is expensive. Simulation runs 5 and 6 take the entire client journey into account and addresses a personalized option to both pre-diabetics and T2DM. In this way, more

individuals with diversified problems get treated, preventing the number of individuals developing T2DM to a large extent and thus, with more focused effort, lower cost for society. However, a crucial remark on practicality should be made in the assessment. In simulation runs 2 and 6, although more effective for the T2DM population as well as cost in the long run, large sums of money are required to initiate and maintain the programs. Simulation run 5, however, although lower in success, requires a far lower initial investment and is still very effective in terms of reduction in the T2DM population. Simulation run 5 (or Policy option 4) is therefore, in a practical sense, considered the most effective policy option that is presented in this study.

To our knowledge, this is the first integrated simulation model of the type 2 diabetes patient journey in The Netherlands from the normoglycemic to the diabetes population. We believe that through scenario simulations of complex lifestyle intervention programs in an early stage of design and implementation process, the (cost)effectiveness of lifestyle intervention programs for diabetes scan be improved.

DATA AVAILABILITY STATEMENT

The datasets presented in this study can be found in online repositories. The names of the repository/repositories and accession number(s) can be found below: World Bank,Dutch databases of Statistics Netherlands (CBS), Dutch Healthcare Authority (NZa), The National Health Care Institute (ZIN), Netherlands Institute for Health Services Research (NIVEL), National Institute for Public Health and the Environment (RIVM), Dutch Diabetes Research Foundation (Diabetes Fonds), Dutch Diabetes Association (DVN) and the Netherlands Organization for Applied Scientific Research (TNO).

AUTHOR CONTRIBUTIONS

TS and LL: framework and model. HW, LL, and TS: literature review. TS, GV, and LL: methodology. SÖ: input. HW: supervision. TS: results, graphs, analysis, and conclusion. TS and HW: discussion and final edits. HW, GV, and SÖ: review. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2021.652694/full#supplementary-material

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Analysis of Three Potential Savings in E-Working Expenditure

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The aim of this research study is to contribute to the sustainability of e-working initiatives, specifically by exploring three employee-financial impacts. The study adopted a two-step methodological approach: firstly, a comprehensive review of the existing literature was done and, secondly, secondary data analysis was carried out. The study analyses how three potential financial benefits for e-workers differ in various countries and whether these can increase e-workers' earnings. It was found that there are significant benefits. Regarding the affordability of a home, e-working presents a useful tool to move to less costly regions. This reduces the struggle with housing. Aside from housing, commuting is one of the largest time and cost consuming expenses. Based on our calculations, all employees can save commuting time and money by using public transport or their own vehicles. Important considerations here are the costs, such as fuel, insurance, tolls, time, health and environment. Making cappuccino or coffee at home is a useful way to decrease expenses compared to buying them at a café. Generally, the results indicate that an increase of e-working tends to decrease selected expenses of employees. This paper point outs that, on the basis of average costings, e-working decreases selected expenses of employees. The findings also indicate that more long-term and comprehensive studies are needed, especially in relation to other benefits, such as lunch, childcare and clothing. This study has contributed to highlighting the e-working financial benefits for e-workers by not commuting to work.

Keywords: E-working expenditure, affordability of home, commuting, cappucino, coffee

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INTRODUCTION

E-working (teleworking, telecommuting), in brief, working from home, is not a new concept. The ILO has estimated that 7.9% of the global workforce (5.6% men and 11.5% women) work from home (this includes face-to-display workers) on a permanent basis (ILO, 2021). With the Covid-19 pandemic, the number of employees working from home has increased dramatically, especially in the white-collar workers' sector (Belzunegui-Eraso and Erro-Garcés, 2020), but people with the lowest incomes and educational attainment have been disproportionately affected (Lund et al., 2020). Recent results of a survey from *Argentina* show that 80% of the workforce was engaging in telework as a policy of social isolation (Sanchéz Zinny, 2020).

Since the pandemic outbreak, there have been some attempts to determine the teleworkability potential. Sostero et al. (2020) estimate that 37% of dependent employment in the EU is currently teleworkable. Dingel and Neiman (2020) found that in the United States the same percentage of jobs is performed entirely at home. Additionally, Saltiel's (2020) results show that only 13% of workers in developing countries could work from home, yet this share ranges from 5.5% in Ghana to 23% in

Yunnan (China). In Australia, almost 40% of all jobs can be done from home (Ulubasoglu and Onder, 2020).

In the literature, a great deal of attention is paid to the potential benefits of e-working from the employee's perspective (Bernardino and Ben-Akiva, 1996; Mokhtarian and Salomon, 1997; Mokhtarian et al., 1998; Kitou and Horvath, 2003; Shafizadeh et al., 2007).

The object of this research is to contribute to the sustainability of e-working initiatives, specifically by exploring the employee-financial impacts. The impact of the costs for employees varies. Employees can save considerably by e-commuting but, other costs for employees, so-called direct costs (fuel, electricity and air-condition use, mobile phones), increase. The impact of e-working is not equally distributed among different types of employees, employers and countries. To achieve the object of this research, we set out to understand this impact by analyzing secondary data of variables, namely housing, commuting and cappuccino/coffee. The affordability of housing has long been a global problem (Makridis, 2019; Eurostat, 2021). Secondly, commuting has also been tied to increases in labor costs and losses in productivity (Grinza and Rycx, 2020). Finally, coffee is a typical employee habit during an ordinary working day (Coffee and Health, 2017) and increases the expenses (So Pure, 2019) of different generations, genders and industry sectors (PBFY, 2019). This analysis will show the increased disparity between e-workers and intensive face-to-face workers who are generally paid less.

The main research questions in this study were:

- to analyze how three potential financial benefits for e-workers differ in various countries

and

- whether these can increase e-workers' earnings.

The next section presents a literature review. In the second part, the methodology is introduced. The results of the study are presented in the following section. The fourth section is the discussion, and the last part concludes with a summary.

THEORETICAL BACKGROUND

In the pre-Covid 19 period, European countries were reluctant to implement e-working (Beno and Hvorecky, 2021). But e-working has been a growing phenomenon in the advanced world compared to developing countries (Ansong and Boateng, 2018). This is revealed in recent studies, where it is shown that nearly 100 million workers in 35 advanced and emerging countries could be at high risk because they are not able to work remotely. The poor, the young and women are most at risk (Brussevich et al., 2020). Dingel and Neiman (2020) indicate that the developed world has a low prevalence of jobs that are compatible with working from home compared to the advanced world. Saltiel (2020) estimated that only 13% of employees from ten developing countries could work from home. Delaporte and Pena (2020) evaluated the share of individuals working from home from 7% in Gautemala to 16% in the Bahamas. This is caused by occupational structures [higher-skilled vs. lower-skilled jobs (Watson, 2020)], age, gender and education (Brussevich et al., 2020), and income level (ILO, 2020).

Telecommuting, virtual office and telework are a few of the terms used to describe the same phenomenon (Siha and Monroe, 2006). Simply, e-workers are those workers who are working outside the organisation's premises using modern technology. Beňo and Ferenčíková, (2019) believe that e-working is a triple-win option.

Working from home has various benefits. According to data from Citrix (2019), potential United States economic gains from a flexible working culture could amount to approximately $2.36 trillion per annum. Possible employee benefits can be brought about by employers encouraging their employees to do telework (Deloitte, 2011). E-working can reduce costs for both employer and employee (Madsen, 2003). But Bernardino (1996) suggested that the expected perceived savings and the actual savings may differ. In this study, the financial benefits have been examined.

According to Riswadkar and Riswadkar (2009), employees can derive a range of cost savings through teleworking. Lister and Harnish (2011) report that e-working saves employees time and money. These authors also say that telework could save employees between $250 and $2700 a year (Lister and Harnish, 2013).

Some of the employees' work related expenses decrease (Kanellopoulos, 2011), e.g., travel or professional work outfits (Riswadkar and Riswadkar, 2009), office clothing and lunches (Ford and Butts, 1991). Another study showed that over half of the participants (57.1%) indicated somewhat of a reduction in monthly expenses (Baard and Thomas, 2010). Saving money is possible by dispensing with the commute to the office (Wienclaw, 2020, *p*. 2). Additionaly, savings are derived from a reduction in fuel and wear and tear of the vehicle (Ford and Butts, 1991) or costs for parking and other transport (Wienclaw, 2020). This confirms the ILO paper (ILO, 2016) that teleworkers can reduce all these costs, including insurance. According to data collected by Garg and van der Rijst (2015), employees could save an average of 822.06 rands per month if they do not travel to work. Dell employees who on average work remotely 10 days a month save about $350 a year in commuting costs (Sahadi, 2016). Furthermore, working remotely on average 2.4 days per working week would amount to cost savings of $44.4 billion on commuting spent on tickets or fuel (Citrix, 2019). Swink (2008), *p*. 862 also adds that homeworking employees may enjoy reduced expenses for work attire, less stress and reduced transportation expenses. Another financial benefit, especially for the sandwich generation (middle-aged adults who are caring for their elderly parents and their own children), is the decreased cost for babysitting/kindergartens/nurses (Lupu, 2017) and after-school activities (Wienclaw, 2020).

METHODOLOGY

In this paper, a two-step methodological approach has been used. Firstly, a comprehensive review of the available existing literature

on the financial benefits of e-working is done because a substantive and thorough literature review is the basis for any good research project (Boote and Beile, 2005).

Next, a secondary data analysis was implemented to create a starting point for future analysis. In this study, secondary sources were used to answer the research question because they offer a good collection of existing data. Furthermore, since the material being investigated comprises a large studying unit, it is impractical to study it directly. Sources of secondary data included journals, newspapers, websites and government and other organization records. This includes the relationship between variables and the cause of a particular variable in relation to e-working. Following the exigencies of settled research questions, inquiries were made about appropriate existing archival sources. The research questions were "the dictatorship of the problem" (Vogt, 2008).

On the basis of research questions, we identified appropriate secondary data in these steps: identification, selection, examination, conducting analyses and interpreting results. In contrast to primary data (individual/team of researchers designs, collects and analyses data), analysis of data collected by others was also used. The United States dollar, as the world's leading currency, was used for the calculations. In order to perform commuting analyses, it is necessary to consider the amount and pattern of travel of the population in the cities surveyed. In London, 27% of workers typically traveled to work by car, 44% by rail, 13% by bus, 9% on foot and 5% by bicycle (GOV.UK, 2019). The 2011 Hong Kong population census shows that there was more mass transport, 70.1% (bus and train), than travel by car and taxi, 10.5% (Census, 2011). Hong Kong has always been less car-dependent than other cities (Cullinane and Cullinane, 2003; Dawda et al., 2019). Moreover, to be efficient, available and productive (Dawda et al., 2019), a commuting system must serve different requirements in the form of multimodal transportation modes, e.g. Kuhnimhof et al. (2006) found that multimodal individuals in Germany tend to use cars several times per week and use public transport less regularly, preferring to commute. Nobis (2007) presented an extensive overview of multimodality (car/bike, car/public transport, bike/public transport, car/bike/public transport). Heinen and Bohte (2014) point to public transport (rail or underground) and cycling as resulting multimodal groups. Cycling as a multimodal option is affected by positive weather conditions (Heinen et al., 2011). The City of London has a long tradition of a multimodal integrated system (Dawda et al., 2019).

The utilization of available data to answer research questions has several benefits (less time and resources are required, access is obtained to large and wide-ranging data sets). Some limitations do occur, including a lack of knowledge of the existence of rich data sets and how to obtain and evaluate the contents, insufficient or outdated data, and lack of funds to hire staff to assist with the work (Dunn et al., 2015).

This analysis strategy is geared toward producing actionable findings. Furthermore, these findings also provide information for further research.

FINDINGS

Recent articles draw the attention to the most costly elements of e-working. For example, remote work will cost business in Japan more than 1.3 trillion yen (Nakafuji, 2020). Munk (2020) stresses that despite the potential savings (commuting, dry-cleaning bills, shopping for work attire), there are some hidden expenses, such as electricity bills, phone data plans, supplies for the home office and wear and tear of personal devices. Interestingly, a recent CreditCards.com survey shows that working from home due to the pandemic costs households about $108 more per month (Segal, 2020).

Housing

The main benefit of e-working is that one works from home or another location instead of working in a cubicle. A recent study by Redfin revealed that a quarter of participants move for reasons of affordability, and almost 60% said their ability to afford non-housing expenses and leisure activities improved after their relocation (Katz, 2020).The latest data reveal that 14 million to 23 million Americans are planning to benefit from e-working by seeking housing in more affordable markets, with the biggest out-migration occurring in major cities (Upwork, 2020).

Generally, people choose where to live on the basis of their workplace and try to avoid long commutes. But times have changed due to the high housing prices around the world. Based on a Demographia International Housing Affordability Survey, the 10 least affordable international housing markets ranked by house price to income ratio were Hong Kong, Vancouver, Sydney, Melbourne, Los Angeles, Toronto, Auckland, San Jose, San Francisco and London (Cox and Pavletich, 2020). Notably, New Zealand, Hong Kong, the United States, the United Kingdom and Australia are the top regions doing business (WBG, 2020), but they are at the top of those with the least affordable housing. Through e-working, doing business remotely offers employees the opportunity to participate/work without being present. Conversely, baby boomers, on account of their age and children, were considering downsizing and moving back into cities where walkability and urban living are more appealing. E-working seems to be the catalyst (Schreiber, 2016). This is in accordance with the life course rather than economic motives in residential relocation decisions (Nijkamp et al., 1993). As technology continues to improve and these housing trends increase, more employees will recognize the benefits of working remotely. The empirical evidence indicates that using the home as a workplace has become a substantial feature of labor markets in many western economies and that this has increased significantly in recent years (Doling and Arundel, 2020).

Commuting

One of the benefits of e-working is the decrease of traffic congestion and lower carbon emissions (Kitou and Horvath, 2003; Shafizadeh et al., 2007). But transport costs have a significant impact on the structure of economic activities as well as on international trade. Empirical evidence underlines

TABLE 1 | Commuting (London).

Commuting days	Tickets per week	Monthly ticket public transport	Monthly savings	Annual savings
5	10	$179.40	$0	$0
4	8	$143.52	$35.88	$430.56
3	6	$107.64	**$71.76**	**$861.12**
2	4	$71.76	$107.64	$1291.68
1	2	$35.88	$143.52	$1722.24
0	0	$0	$179.40	**$2152.80**

Source, Author's own calculation based on Deutsche Bank, 2019.

TABLE 2 | Commuting by car (Hong Kong).

Commuting days	Average distance km[a]	Monthly savings spent on fuel[b,c]	Monthly savings spent on parking[d]
5	308.40	$0	$0
4	246.72	$147.91	$138.44
3	185.04	$295.82	$276.88
2	123.36	$443.73	$415.32
1	61.68	$591.93	$553.76
0	0	**$739.54**	**$692.20**

[a]*Average distance 15.42 km (Numbeo, 2021).*
[b]*20 working days.*
[c]*Average cost per gallon of fuel $2.40 (GPP, 2021).*
[d]*Daily parking cost $34.61 (Spacer, 2021).*
Source, Author's own calculation.

that raising transport costs by 10% reduces trade volumes by more than 20% (Rodrigue and Notteboom, 2020).

Commuting is seen as one of the largest time-consuming (traffic or waiting for delayed public transport modes) and recurrig expenses (fuel, parking, tolls, montly transit passes) that mankind faces. One study presented the best and worst commute cities among 74 worldwide cities (Expert Market, 2019). In **Table 1**, cost-saving calculations show that London's monthly ticket public transport is the most expensive one, and also show that besides long commutes and barriers, cost savings could be the reason for further e-working expansion. Researchers found that an extra minute of commuting time reduces both job and leisure-time satisfaction, but increases strain and worsens mental health for workers. Additionally, 20 min of commuting to and from work each working day have the same effect on job satisfaction as a 19% reduction in personal income (UWE, 2017). Recently it was found that Londoners commute 74 min each day (NE, 2020) and spend $179.40 each month for a ticket pass (Deutsche Bank, 2019).

Based on this calculation, Londoners who choose hybrid working (partly at home and partly in cubicles) at least 2 days could save $71.76 monthly and $861.12 annually, compared to $2152.80 annually by working remotely full-time, an almost threefold difference (see highlighted data in **Table 1**).

By commuting, drivers incur a number of costs. In **Table 2**, calculations of overall savings for Hong Kong are presented.

Commuters spend on average 42.42 min (Numbeo, 2021) a day commuting - 14 h a month or 170 h per year - which is almost comparable to the United States rate (Vasel, 2015). The average Hong Kong commuter driver spends over $739.54 monthly on fuel and $692.20 monthly (as highlighted in **Table 2**) on daily parking (28% of men's monthly income and 37% of female's monthly income (Stotz, 2021)), or $352 on a monthly basis (Spacer, 2021) on parking alone (14% of men's monthly income and 19% of females' monthly income (Stotz, 2021)), which could be saved in its entirety by e-working, but only 3.12% of employees in Hong Kong work from home (Numbeo, 2021). Saving money on cost components such as fuel, insurance, tolls, time, health and the environment should be further considered.

Coffee

Coffee is celebratory. Its consumption is uncommon, and its uncommonness imbues it with a unique mystique associated with a wealthy, refined and intellectually evolved class. Coffee is predominantly an outside drink, it derives its utility from a social, esthetic and emotional role (Verma, 2013). Coffee has become an important part of societal norms across the globe (Waxman, 2004; Almqvist et al., 2007; Moretti, 2017).

Millennials spend $2008 a year at coffee shops (Mckenzie, 2020), and the average American spends about $1100 a year on coffee (Acorns, 2020). Furthermore, the data highlight that 41% of them admitted to spending more on coffee in the past year than they had invested in their retirement savings (Mckenzie, 2020).

Generally, we save money by making things to eat or to drink at home (Thorpe, 2012). McClean et al. (2020) found that something as simple as missing one's regular morning cup of coffee can cause that employee to begin the workday less calm and

TABLE 3 | Morning cappuccino and coffee.

Commuting days	Monthly cappuccino at a cafe	Monthly cappuccino at home	Monthly coffee at a cafe	Monthly coffee at home
5	**$126.00**	$0	**$124.80**	$0
4	$100.80	$2.00	$99.84	$0.80
3	$75.60	$4.00	$74.88	$1.60
2	$50.40	$6.00	$49.92	$2.40
1	$25.20	$8.00	$24.96	$3.20
0	$0	$10.00	$0	$4.00

Source, Author's own calculation.

more mentally exhausted. The costs for coffee or cappuccino vary from country to country and from continent to continent (CCM, 2019; Deutsche Bank, 2019). A cappuccino in Copenhagen costs $6.30 (Deutsche Bank, 2019), and a coffee costs $6.24 in Doha (CCM, 2019). We have calculated that making morning cappuccino at home costs $0.50 and coffee costs $0.20. As shown in **Table 3**, making morning cappuccino and coffee at home is cheaper than buying it. An employee in Copenhagen who drinks one morning cappuccino on 5 days a week spends $126 per month, but when e-working full-time he/she saves $116 monthly and $1392 annually. Furthermore, when drinking one morning coffee an employee spend $124.80 per month, but when e-working full-time he/she saves $120.80 monthly and $1449.60 annually. Making one's own cappuccino or coffee is clearly a way to save money with working remotely, whether it is full-time or not.

DISCUSSION

E-working can help to reduce the employee's expenses, as shown in this study. Is it possible for e-working to affect housing choices? The rise of e-working (developing economies adapt more easily (Bana et al., 2020)) enables employees to live and work away from the organisation's premises, even a long way away. The data in this study confirm that the shift to working remotely has changed and will continue to change housing patterns. A world in which e-workers work at home may not only affect the form and choices of housing, but also implies a potential transformation of the physical structure of cities, the distribution of property values and the broader labor and housing markets themselves (Doling and Arundel, 2020). While the pandemic may have made offices less accessible, hybrid working, co-working and e-working will be much appreciated in the future. Wilsker (2008) states that the average full-time e-worker, regardless of salary scale, receives the equivalent of an annual salary increase of $8400 due to the reduced expenses that result from e-working (vehicle, clothing, parking, food and insurance costs). Some of these expenses were examined in this study with positive potential savings for employees. What does it mean in the long term? As also shown in this study, some trends are already emerging. E-workers are more likely than commuters to reside in more peripheral areas, such as urban green settings or town and rural areas, as stated in an analysis from the Netherlands (Muhammad et al., 2007), where the rate of e-working is very high.

CONCLUSION

In the pre-Covid era, very few employees worked from home (and this was usually on a casual basis). Suddenly, e-working exploded even in developing countries. To work from home situation is expected to continue. The impact of e-working is not equal divided around the globe among different types of employees including age, gender, education, skills and occupational structures.

In this study, we discussed and analyzed three financial benefits of e-working. Three dependent variables were used: housing, commuting and cappuccino/coffee. The study was conducted in two stages. The first stage investigated the financial benefits for e-working. In the second stage, dependent variables were analyzed.

The main research question investigated in this paper is:

How three potential financial benefits for e-workers differ in various countries and whether these can increase e-workers' earnings? Our analysis considers both quantifiable and non-quantifiable considerations. It is clear that e-workers can reduce their expenses compared to regular commuters, even in hybrid or full-time work from home. We set out to research how, in terms of costs and benefits (housing, commuting and cappuccino/coffee) a permanent increase in working from home would influence overall employee expenses. It was found that increasing the period of working from home is driven by cost savings for employees. This translates to a reduction of the struggle for housing, less commuting and saving money by drinking a cappuccino/coffee at home. However, in those countries with a greater share of informal economy and a low prevalence of remote jobs, the result can be the reverse.

As modern technology continues to improve, housing trends will accelerate, commuting will become more expensive and time consuming, and prices will increase. More employees are likely to recognize the savings potential that comes from working from home instead of commuting to work. Offering a flexible work culture including e-working can be a profitable long-term strategy. If costs continue to be lower than those for on-location, more employers will increase at-home work. The latest data of one study indicate that when workers experience higher WFH efficiency, they have a higher preference for WFH even after the pandemic. Additionally, female workers preferred WFH twice per week, while the male workers more often preferred WFH once per week. Finally, workers from the management and the self-employed levels demonstrated a lower preference for WFH, compared to the front-line and

middle-grade workers (Wong et al., 2020). Obviously, however, some jobs still have to be carried out on site.

The limitations of the study arise mainly from not taking into consideration mitigating, location-cultural specific expenses in relation to dependent variables explored in this study (e.g., air conditioning, electricity, free snacks or lunches). Moreover, the modality of groups described in the methodology give rise to further limitations. Nobis (2007) notes that most adolescents are multimodal, and Kuhnimhof et al. (2006, 2012) determined that single people are multimodal.

FURTHER RESEARCH

The labor market impact of Covid-19 still need to be examined. Aspects not covered by this research are the analysis of lunch, childcare and clothing variables. These issues could be dealt with in future research. This is needed in order to understand how additional data can throw further light on e-working as a beneficial option. But companies and organisations that allow their employees to work remotely can reap benefits too. More research should be done on the benefits for employers in the future.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

AUTHOR CONTRIBUTIONS

MB conceived of the presented idea, was engaged in the investigation, literature search and selection, verified the analytical methods, writing original draft, preparation, and finishing the last version.

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