

## PAPER

# Sharing the benefits of research fairly: two approaches

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**ABSTRACT**

Research projects sponsored by rich countries or companies and carried out in developing countries are often described as exploitative. One important debate about the prevention of exploitation in research centres on whether and how clinical research in developing countries should be responsive to local health problems. This paper analyses the responsiveness debate and draws out more general lessons for how policy makers can prevent exploitation in various research contexts. There are two independent ways to do this in the face of entrenched power differences: to impose restrictions on the content of benefit-sharing arrangements, and to institute independent effective oversight. Which method should be chosen is highly dependent on context.

**INTRODUCTION**

Research projects sponsored by rich countries or companies are often described as exploitative. Western researchers may be accused of ‘parachute’ or ‘safari’ research, in which they swoop into a country, test their drugs or collect their samples, and then exit with their spoils.<sup>1</sup> Companies looking for valuable chemical compounds in areas of high biodiversity are often accused of ‘bio-piracy’.<sup>2</sup> Even nation states may feel exploited. Controversy persists, for example, over the use of the influenza samples shared through the WHO’s Global Influenza Surveillance Network. In 2007, Indonesia stopped sharing H5N1 (avian flu) samples with the network because it judged that its population was highly unlikely to get access to a vaccine in the event of a flu pandemic, despite its contributions.<sup>3 4</sup>

This paper analyses one debate about the ethics of clinical research in developing countries—the *responsiveness debate*, which concerns whether only research whose results are expected to benefit local populations should be permitted in developing countries. I draw lessons from that debate about the ways in which policy makers can prevent exploitation in a variety of research contexts. Exploitation can be avoided if the benefits and burdens of research are distributed in a way that does not take unfair advantage of people’s vulnerability. I argue that there are two independent ways to do this in the face of entrenched power differences: to impose restrictions on the content of benefit-sharing arrangements, and to institute independent effective oversight. Which method should be chosen is highly dependent on context.

**EXPLOITATION AND FAIRNESS**

Exploitation occurs when one party takes ‘unfair advantage’ of another.<sup>5</sup> Consequently, one party can exploit another even if both benefit from their interaction. Indeed, such ‘mutually advantageous exploitation’ has been the locus of discussion about exploitation in research.<sup>6</sup> The problem explored in this paper arises because of the vulnerability of some of the parties affected by research. Whether this vulnerability is a consequence of poverty, illness, ignorance, or a lack of alternatives, it means that these parties have much less power, and so are liable to agree to unfair distributions of the benefits and burdens of research. For example, an HIV-infected South African woman who cannot access treatment outside of a research study is likely to agree to almost any terms in order to enrol. Likewise, a community with little contact with the modern world might freely share knowledge of a native plant’s healing properties with foreign scientists because the true prospects for commercialisation are kept hidden from them.

Exploitation can be prevented if the benefits and burdens of a research project are shared fairly among the people affected by it. However, except for the simplest of cases, there are no accounts of what constitutes a fair agreement for benefit sharing that command any degree of consensus. For example, would a fair agreement distribute the benefits of a research project according to the amount people contribute to the project, how much effort they expend, what value the market would assign to their labour, or some other factor? If it is a matter of contribution, how do we weigh the different contributions made by, for example, people who donate samples, the healthcare workers who collect them, the scientists who analyse them, the governments that trained the scientists, and the companies who pay them? Despite the absence of general principles for working out which distributions of benefits and burdens are fair, however, people have strong intuitions about fairness in particular cases. For example, most people think that the wages paid to workers in ‘sweatshops’ are unfairly low, even though they might not be able to say exactly how much would be fair.

**THE RESPONSIVENESS DEBATE**

The most detailed discussion of how to prevent exploitation in research has taken place in arguments about whether clinical research with poor populations in developing countries should be *responsive* to the health problems of those countries. Several different conceptions of a *responsiveness*

requirement have been proposed. They have in common that they restrict the type of research permitted on the basis of whether the information gained from the research has a sufficient prospect of benefiting the population from which research participants are drawn. So any responsiveness requirement would prohibit a research project that involved testing an experimental hepatitis A vaccine on rural inhabitants of Tanzania if the only benefits that accrued to the local population were that the research team built a clinic and a school. Most responsiveness requirements would permit such research if there were a commitment from the Tanzanian government to supply a successful vaccine to its citizens.

Responsiveness requirements impose *content restrictions* on the ways that the benefits and burdens of research may be distributed. That is, they rule out certain benefit-sharing arrangements whose content does not include certain *types* of benefit. Many guidance documents that pertain to the ethics of clinical research in developing countries include a responsiveness requirement. For example, the *Declaration of Helsinki* states:

Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.<sup>7</sup>

As the commentary on Guideline 10 of the Council for International Organisations of Medical Sciences' *International Ethical Guidelines for Biomedical Research Involving Human Subjects* and a recent summary of academic literature on the responsiveness debate make clear, it is generally assumed that the function of responsiveness requirements is the prevention of exploitative research.<sup>8,9</sup> Though it is possible that their proponents also have other goals in mind, such as increasing the bargaining power of developing countries or increasing the total amount of research on neglected diseases,<sup>10</sup> this paper considers the appropriateness of responsiveness requirements only insofar as they are intended to prevent exploitation.

If the intention behind responsiveness requirements is to prevent exploitation, the imposition of any responsiveness requirement is vulnerable to the following criticism. Exploitation involves one party taking unfair advantage of another; it is therefore impossible for exploitation to take place if the benefits and burdens of a transaction are distributed fairly. But whether a distribution is fair or not is a matter of *how much* the parties to the transaction receive, not what *type* of benefit they receive. Clinical research can therefore be non-exploitative even if the benefits received by participants and host communities are wholly unconnected to the knowledge gained by the research. For example, the provision of ancillary medical care, or the donation of medical equipment, if sufficiently valuable, could be enough to constitute a fair level of benefits. As a result, any responsiveness requirement will prohibit some research projects that are actually ethical.

This objection was originally lodged against conceptions of the responsiveness requirement that include the provision that a clinical trial that results in a successful intervention should ensure that the intervention is made 'reasonably available' to host populations after the trial.<sup>11,12</sup> However, the criticism can be applied to any conception of responsiveness. Indeed, any restriction on the *type* of benefits that must accrue to some party affected by clinical research will rule out as 'unethical' some research that is actually ethical. This point does not take us very far in practice, however. The principles stated in codes of ethics

for the use of research ethics committees (RECs) normally admit exceptions. For example, the requirement that the risks of research be minimised may have an exception if a slightly more risky procedure would yield much more accurate data. In general, it is better to take these principles as ethical rules of thumb—they are likely to get us to the right answer most of the time and exceptions must be very carefully thought through.<sup>13,14</sup> So, even though the critics of responsiveness are right in principle, this does not yet tell us that responsiveness requirements should not be promulgated for use by RECs.

The main proponents of the criticism just noted proposed an alternative way to prevent exploitation in clinical research—the *Fair Benefits* framework. According to this framework, rather than having to provide benefits derived from the results of the research, research projects must simply provide a fair amount of benefits to the participants and population at risk of exploitation. In addition, they proposed two restrictions on the process by which agreements about the distribution of the benefits and burdens of research should be reached: *collaborative partnership*, so that the population at risk of exploitation must freely decide that the level of benefits offered is sufficient; and *transparency* about the terms of agreements, so that comparisons can be made with other agreements that have been judged fair.<sup>11</sup>

The Fair Benefits framework was widely interpreted as accepting no restrictions on the type of research that may be conducted in developing countries. It was heavily criticised as a consequence.<sup>15–17</sup> The more compelling criticisms share a concern about whether attempts to implement the Fair Benefits framework would lead to research participants and host communities being exploited in practice. For example, Alex John London and Kevin J S Zollman interpret the Fair Benefits framework as a procedural approach to determining the fairness of transactions and argue that its implementation would likely lead to a race to the bottom as research sponsors and contract research organisations played off different communities against each other.<sup>17</sup> As Udo Schuklenk puts the concern: 'The idea that severely impoverished, frequently undereducated, communities could readily be empowered to the point that they would be able to extract fair benefits from developed-world for-profit trial sponsors is unrealistic.'<sup>18</sup>

In summary, critics of responsiveness charge that a responsiveness requirement is liable to prohibit some ethical research. Critics of an alternative that would not place restrictions on the types of benefits that should accrue to participants and host communities claim that it would lead to unfair distributions of benefits and burdens in practice. Which ought RECs to require?

Which is preferable depends on the context in which the rules for evaluating the ethics of clinical research will be applied. To see why, we must take a step back and analyse how each approach is supposed to prevent exploitation.

## RESPONSIVENESS AND THE PREVENTION OF EXPLOITATION

There is something intuitive about the judgement that it is wrong to conduct research on a poor population to gather data that will only help a rich population, while it would not be wrong to conduct the same research to gather data to help other members of the poor population. But what explains this judgement? The most plausible explanation draws an analogy with the relationship between medical research and the healthcare system in developed countries that have universal healthcare.

When working properly, the system for developing, testing and supplying new healthcare interventions in developed countries

with universal healthcare is not exploitative. It is not exploitative because almost all members of these societies contribute to the healthcare system and all benefit from it. In particular, the medical research that is conducted in such societies addresses important health problems that affect people within them, and the fruits of the research are generally available to people who need them.<sup>i</sup> Likewise, it may be supposed, if research sponsored from abroad is carried out in a developing country, it will not be exploitative if it addresses important health problems that affect people in that country and the fruits of the research are generally available to people in that country who need them. For example, US researchers trying to develop a cheap, heat-stable malaria vaccine by studying experimental vaccines in subjects from malaria-endemic regions of West Africa seem to be engaged in a noble effort. By contrast, studying an expensive drug designed to protect travellers to these regions against malaria using the same subjects seems ethically suspect, since the drug would likely be too costly for most West Africans, and chemical prophylaxis is generally not recommended for people living in malaria-endemic regions. A just West African government with the will and resources to fund medical research itself would, plausibly, sponsor the first study, but not the second. In brief, we can interpret responsiveness requirements as attempts to mimic in an international context the features of research in the national context that make it non-exploitative.

It is illuminating to look at the form of this argument by analogy. We do not have a general principle for working out whether or not transactions are fair (and consequently we do not have a general way to show that a transaction is non-exploitative). However, there are particular cases where we are confident in our judgements about fairness or exploitation. The case of research participation in a developed country with universal healthcare is one. Consequently, if we take features of that case that render it non-exploitative and replicate them in another context, we have good reason to think that exploitation will be avoided in the new context. The responsiveness requirement therefore provides a heuristic with which to ensure that the benefits provided by a research project are sufficient to render it non-exploitative.<sup>ii</sup>

### FAIR BENEFITS AND THE PREVENTION OF EXPLOITATION

In contrast with the responsiveness requirement, the Fair Benefits framework does not give explicit guidance on the content of agreements—that is, what is agreed to. It therefore faces an epistemological problem: how should the fairness of agreements be ascertained?

This is not an insurmountable problem. I have noted already that we are able to make confident judgements about the fairness of agreements in some cases. Indeed, the effectiveness of responsiveness at preventing exploitation is premised on an

<sup>i</sup>Notice that, as we get further from an ideal healthcare system that is embedded in a just society, our confidence that it is non-exploitative is likely to drop. So, for example, in the USA, where many people still lack medical insurance, some people are uncomfortable with the idea of testing new drugs on people who don't have health insurance and may therefore be both desperate (and so vulnerable to exploitation) and unlikely to benefit from new interventions that are developed.<sup>19</sup>

<sup>ii</sup>This makes use of just one of the features that makes most research in developed countries non-exploitative. Another is that research participants can access good-quality healthcare outside of research studies. This reduces their vulnerability to exploitation by increasing their bargaining power (though it does not eliminate it—for example, cancer patients in developed countries for whom all existing treatments have failed may judge that they have no good options outside of research participation). Since exploitation entails taking unfair advantage of another's vulnerability, it can be prevented by *either* eliminating the vulnerability or ensuring that the distribution of benefits and burdens is fair.

intuitive judgement that research in developed countries with universal healthcare is non-exploitative. We should not think it impossible, therefore, for an ethics committee to make accurate judgements about fairness.

It is not impossible, but it will require more work and greater expertise than applying a responsiveness requirement. The REC will have to search for novel analogies to help it make judgements, rather than having one readymade. It may have to spend time talking with representatives of communities, examining data, and comparing proposed benefit arrangements with arrangements elsewhere. And it is harder for outside observers to check the performance of an REC with regard to fulfilling a requirement that the benefits given to affected parties be 'fair', than to check whether a more explicit content requirement about the type of benefits has been fulfilled. Consequently, the independence of the REC from parties with an interest in the research going ahead is more crucial. In short, in the absence of guidance on the content of agreements, the system of oversight for clinical trials must meet higher standards of effectiveness and independence in order to ensure that a clinical research project does not exploit the vulnerable. Since it allows considerable flexibility regarding the type of research that may be conducted, it therefore makes sense that the original Fair Benefits framework outlined substantial procedural safeguards.

### RESPONSIVENESS VERSUS FAIR BENEFITS

It is possible that some RECs can provide the effective independent oversight that the Fair Benefits framework would require. But it is likely that some cannot. In particular, in developing countries where RECs are overworked, underfunded, undervalued, short of staff, lacking in training, and under pressure from their home institutions to approve research, it is reasonable to be concerned about their ability to ensure that agreements are fair.<sup>20</sup> If effective independent oversight would be impractical or too expensive, a content restriction, such as a responsiveness requirement, could be promulgated. To be worthwhile, implementing such a requirement would need to require less of RECs than the Fair Benefits framework. Consequently, the conception of the responsiveness requirement promulgated should combine the virtues of being easy to apply and reasonably successful at ruling out exploitative research.

The above analysis of how responsiveness requirements prevent exploitation suggests a conception of responsiveness that might have these virtues. According to that analysis, a research project in a society will be non-exploitative if (hypothetically) conducting it within that society's healthcare system alone would be ethically justified. The implied conception of responsiveness would say that a research project is responsive just in case its results are expected to have sufficient *local* social value to justify the local resources used and the risks and burdens to which research participants are subjected.

This conception provides a heuristic for ruling out exploitative research. There are also three reasons to think that it would be significantly easier to apply than a requirement that simply stipulated that the distribution of benefits and burdens from the research should be fair. First, there are many cases in which it is clear whether a research project would be responsive or non-responsive, such as the examples of malaria vaccine and chemotherapeutic research given above. Second, because a Fair Benefits approach requires that we account for all the benefits and burdens of research, it requires that many more ethical considerations be analysed. The difficult questions about what is owed for different types of contribution (eg, provision of samples versus expert labour) raised above are not usually

answered by RECs. Third, all ethical reviews of research projects are supposed to include a judgement of whether the social value of the research is sufficient to justify its burdens.<sup>21</sup> In this case, it just requires a narrower judgement to be made—whether the *local* social value is sufficient. Thus, this responsiveness requirement would not substantially add to the work that RECs are already expected to do.

Space does not permit the full development of this conception here. However, it should suffice to show that a practical conception of responsiveness is possible. Since even the best conception of responsiveness will be vulnerable to criticisms such as those raised by the proponents of Fair Benefits, a national body deciding whether to promulgate such a content restriction should take into account the relative costs and benefits of having RECs implement this responsiveness requirement versus those of ensuring that they can provide effective independent oversight. Since research review capacity and resources differ widely from country to country, it is unlikely that this decision would be the same everywhere. Where there are reasonable doubts about the possibility of effective independent oversight, a responsiveness requirement should be the default presumption.<sup>iii</sup> Where there is greater confidence in the oversight system, something like the Fair Benefits framework could be tried.

### LESSONS FROM THE RESPONSIVENESS DEBATE

The foregoing analysis implies that whether or not clinical research in a poor population should be required to be responsive depends on contextual factors. In particular, it depends on whether the costs of implementing an effective oversight system are outweighed by the benefits of the research that a responsiveness requirement would otherwise prohibit. This analysis can be generalised to the other research contexts mentioned at the beginning of this paper. We can draw out several lessons.

First, it is sometimes possible to find rules of thumb that would rule out unfair or exploitative arrangements by stipulating content restrictions. This is very helpful, since otherwise it can be difficult to know if a particular distribution of benefits and burdens is fair or not. One way to work out content restrictions is to draw an analogy with the context of interest from a context or case about which we have confident ethical judgements.

Second, content restrictions that are designed to prevent exploitative agreements are liable to also rule out some agreements that are not exploitative (since the rules of thumb used are unlikely to map exactly on to fair and unfair agreements). Policy makers should therefore look for content restrictions only when they have reason to think that exploitative research is otherwise probable. It is more likely in contexts where two conditions are met: the relative bargaining powers of the different parties to the research enterprise are very different, making some people vulnerable to being taken advantage of; and there is not a system of effective independent oversight capable of ensuring that the benefits and burdens of research projects are shared fairly. The examples mentioned in the introduction to this paper all fit this pattern. In some cases, the attempted solution has been to impose systems of oversight. For example, the *Convention on Biological Diversity*, which requires 'fair and

equitable sharing' of the benefits of research using non-human biological resources, has so far resulted in a number of benefit-sharing arrangements, but no substantive content restrictions have been worked out for future arrangements.<sup>22</sup> In the absence of rules determining what should be given to whom, elaborate systems of oversight have been set up in several countries to oversee the use of their natural resources.<sup>23</sup> In other cases, some parties are pushing for content restrictions. For example, following the H5N1 controversy, developing countries, including Indonesia, have argued that, when viral samples are shared across national borders, they should be accompanied by a Standard Material Transfer Agreement. The Standard Material Transfer Agreement should include binding arrangements for benefit sharing, including access to data, the transfer of technology, and the provision of royalty-free licences to developing countries to use any intellectual property that results.<sup>24</sup>

Finally, this suggests that, even when content restrictions that can prevent exploitation have been identified, a cost–benefit analysis is still necessary. If policy makers want to prevent exploitation, and are not in a position to correct the power imbalances that allow it, then they can choose between at least two strategies. First, content restrictions could be imposed. Second, a system of effective oversight could be put into place. Depending on the context, each of these will vary in its ease and cost of implementation, and each will vary in its effectiveness at ruling in and out exploitative transactions.<sup>iv</sup> For example, the systems of oversight that have been introduced to implement the *Convention on Biological Diversity* in some countries have been criticised for unnecessarily impeding research.<sup>25</sup> It is an open question whether it would be better to try to develop content restrictions for these agreements instead, or whether this is just a matter of bureaucratic inefficiency, which could be cured while preserving an oversight system.

### CONCLUSIONS

Exploitation in international collaborative research can be prevented by sharing the benefits and burdens of the research fairly, whether we are concerned about clinical research with human subjects, bio-prospecting for natural products, or the sharing of biological samples. But there is no consensus about what counts as a fair agreement. Analysis of the responsiveness debate suggests that, despite the difficulty of identifying general principles of fairness, we can sometimes identify context-specific content restrictions that would rule out unfair or exploitative agreements. We should look for such content restrictions when there are inequalities of power between the people affected by research and when effective independent oversight of how the benefits of research are shared is lacking. In deciding whether to impose content restrictions, we should compare the relative ease and effectiveness of implementing those content restrictions with implementing an effective independent oversight system.

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<sup>iii</sup>Exploitative research could still be approved with a responsiveness requirement in place. For example, an REC might mistakenly judge a study to have sufficient local social value when it did not (just as an REC anywhere might make an error about the global social value of a study). The point is just that such REC errors are less likely if a responsiveness requirement is used.

<sup>iv</sup>This is a simplification. It would also be open to policy makers to strike a balance between more or less flexible content restrictions and the resources they put into systems of oversight.

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