Scientific Contribution

Influenza vaccination in Dutch nursing homes: Is tacit consent morally justified?

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Abstract. Objectives: Efficient procedures for obtaining informed (proxy) consent may contribute to high influenza vaccination rates in nursing homes. Yet are such procedures justified? This study's objective was to gain insight in informed consent policies in Dutch nursing homes; to assess how these may affect influenza vaccination rates and to answer the question whether deviating from standard informed consent procedures could be morally justified. Design: A survey among nursing home physicians. Setting & Participants: We sent a questionnaire to all (356) nursing homes in the Netherlands, to be completed by one of the physicians. Results: We received 245 completed questionnaires. As 21 institutions appeared to be closed or merged into other institutions, the response was 73.1% (245/335). Of all respondents 81.9% reported a vaccination rate above 80%. Almost 50% reported a vaccination rate above 90%. Most respondents considered herd immunity to be an important consideration for institutional policy. Freedom of choice for residents was considered important by almost all. Nevertheless, 106 out of 245 respondents follow a tacit consent procedure, according to which vaccination will be administered unless the resident or her proxy refuses. These institutions show significantly higher vaccination rates (p < 0.03). Conclusions: In our discussion we focus on the question whether tacit consent procedures can be morally justifiable. Such procedures assume that vaccination is good for residents either as individuals or as a group. Even though this assumption may be true for most residents, there are good reasons for preferring express consent procedures.

Key words: ethics, influenza vaccination, informed consent, nursing homes, tacit consent

Introduction

In the Netherlands as well as in many other countries, it is advised to offer influenza vaccination to elderly persons above 65 of age as well as to other risk groups (Health Council, 1998; Harper et al., 2004). Practically all nursing home residents belong to these risk groups, hence all are advised to receive influenza vaccination. Influenza viruses impose large risks to elderly persons (Gross et al., 1988, 1995; Govaert et al., 1994; Patriarca et al., 1986). Vaccination may halve the incidence of serological and clinical influenza (Patriarca et al., 1986) and it can prevent loss of quality of life as a result of the flu as well (Arden et al., 1995; Ligthart, 1995). The average vaccination rate among all Dutch risk groups is estimated to be 75% (Tacken et al., 2003). Evidently, it will be easier to produce high vaccination rates in nursing homes, only if the nursing home staff responsible for vaccination have numerous possibilities to approach target persons and their proxies; to convince them to accept vaccination; and ultimately to administer the vaccine on the basis of tacit consent. Moreover, nursing home physicians may have stronger reasons than family physicians to aim at high vaccination rates in their practice, because they may consider it desirable and possible to realise herd immunity (Coles et al., 1992; Drinka et al., 1997).

From a medical ethical point of view it is important to explore to what extent nursing homes actually aim at high vaccination rates in nursing home residents, and to assess whether deviating from standard informed consent procedures could be morally justified. As part of a research project on collective values in preventive medicine, we did a survey of influenza vaccination practices in Dutch nursing homes. We have reported some of the results concerning vaccination rates in a short paper (Verweij and van den Hoven, 2002). In this paper we focus on the nature of the information and consent processes and on the central considerations in nursing home vaccination policies.

Method

In October 2000 we sent a questionnaire, to be completed by one of the nursing home physicians, to all nursing homes in the Netherlands. The questionnaire involved questions about a nursing home policy and about the way information is disclosed and consent is obtained. We also enquired into the vaccination rate (the exact rate when possible or, if the respondent could not produce exact numbers, an estimation of the vaccination rate). Another part of the questionnaire involved questions about the various reasons physicians give (or encounter) for deciding not to vaccinate certain residents. Respondents were also asked for their opinion towards various arguments they think important for vaccination policies. A third part addressed the immunisation of health care workers. We also requested some information about pneumococcal vaccination but these (limited) results are not discussed in this paper. We sent a total of 356 questionnaires, based on the information of the "Adresgids Ouderenzorg 1999". Two weeks later we sent a reminder including a back-up questionnaire. We used SPSS 9.0 for descriptive statistics and comparisons of means between subsets. We assumed differences in vaccination rates among subgroups to be significant if p < 0.05.

Results

Response

We received 251 questionnaires, of which 6 were blank. A brief non-response survey showed that we had sent too many questionnaires (21): two nursing homes appeared to be shut down and several others appeared to have merged into larger insti-

tutions. Some questionnaires were sent to two different departments within the same organisation. Therefore we counted the final response to be 74.9% (251/335); the effective response (completed questionnaires) was 73.1% (245/335).

Institutional policies

First we addressed the issue whether the respondent's nursing home had a written policy for influenza vaccination among residents. Only a minority (n = 98; 40%) of all respondents answered that they had a written institutional policy for influenza vaccination; 135 (55%) answered they had no written policy available and 9 nursing home physicians (5%) did not know whether there was a written policy.

We also enquired whether nursing homes have a vaccination policy towards employees. Of 245 respondents, 120 (49.0%) reported that their institution does not have such a policy. Fifty-three nursing homes (21.6%) offer vaccination to employees and explicitly request them to accept this offer. In 70 institutions (28.6%) vaccination is available for employees who ask for it.

Vaccination rates

Not all nursing home physicians have exact information about the number of residents that have been immunised. Therefore we asked respondents to report the exact percentage if possible or else to estimate the vaccination rate. One hundred and eighty respondents were able to produce an exact percentage of vaccinated residents. Ninety-five respondents indicated 5 categories in which they estimated the vaccination rates in their institution (0–30%; 30–50%; 50–70%; 70–80%; 80–90%; 90–100%). The results are presented in Table 1.

Table	1	Vaccination	rates	written	nolicies	and	informed	consent*
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	N		Mean vaccination	Vaccination rate			
			rate (N) [†]	≥80% [‡]		≥90%‡	
Total # responding nursing homes	245	100%	85.8% (180)	199/243	81.9%	120/243	49.4%
Institutions with written policy	98	40%	83.7% (73)	74/98	75.5%	48/98	49.0% [§]
Institutions without written policy	135	55%	87.5% (100)	118/133	88.7%	68/133	51.1% [§]
Always express consent required	100	40.8%	82.3% (73)	74/98	75.5%	41/98	41.8%
Always tacit consent sufficient	106	43.3%	89.3% (81)	96/106	90.5%	64/106	60.3%

^{*} Differences between institutions with written policy and without written policy and between 'express consent' and 'tacit consent' are significant p < 0.03.

[†] Based on exact vaccination rates per nursing home.

[‡] Based on exact and estimated vaccination rates.

[§] Not significant.

The average vaccination rate (based on exact information) in nursing homes is 85.8%. If exact data and estimations are combined, it appears that almost half of all the nursing homes report a vaccination rate of 90% and higher.

Most Dutch nursing homes house somatic as well as psychogeriatric patients. Only 28 of the responding institutions provide psychogeriatric care only. In these nursing homes, the level of vaccination is extremely high. As much as 20 out of 28 (71%) respondents report a vaccination rate of 90% or higher.

Relation with written policies

We expected that nursing homes with a written policy for influenza vaccination would show a higher vaccination rate (Smalbrugge, 1995; Nickol et al., 1996). To our surprise, the survey produced a different picture. Institutions without a written policy on average have a significantly higher vaccination rate.

Informed consent procedures

We also expected to find a clear relation between the way informed consent is obtained and the level of vaccination. We indicated two types of consent procedures to the respondents: "express consent" procedures imply that no vaccination is administered unless the resident (or her proxy or legal representative) has consented: in a "tacit consent" procedure, vaccination will be administered unless the resident or her proxy refuses. One may expect that if a tacit consent procedure is followed, it will be easier to realise a high vaccination rate. Many institutions follow a tacit (proxy) consent procedure for influenza. This holds especially with respect to incompetent residents: 56.4% of all respondents report assuming tacit consent of proxies of incompetent residents. Competent residents are most often expected to give express consent (54.2%).

Out of 245, 106 nursing homes follow a tacit consent procedure both for competent and (proxies of) incompetent residents; in 100/245 institutions only express (proxy) consent procedures are followed. Institutions that explicitly require express consent show a significantly lower level of vaccination among residents than institutions that assume tacit consent. On the basis of our data on exact numbers, the average immunisation rates are, respectively, 82.3 and 89.3%.

Could there be a correlation between institutional choices for tacit or express consent procedures and the existence of a written policy within the institution? Especially if written policies more often involve express consent procedures, this could have explained the somewhat unexpected result that institutions with a written vaccination policy show lower vaccination rates. However, we did not find such differences.

Information disclosure

The information process is a crucial element in any consent procedure. Residents and proxies can be informed in different ways (Table 2). We distinguished four sorts of information disclosure: personal oral information, personally addressed written information, written group information (e.g. notice on the bulletin board) and oral group

Table 2. Information procedures

	*				
	One procedure for competent residents and proxies of incompetent residents $(n = 158)$	Different policies for competent residents and proxies of incompetent residents			
		Competent residents $(n = 79)$	Proxies of incompetent residents (n = 88)		
Personal information at start of the vaccination	season				
Oral	86 (54.4%)	65 (82.3%)	21 (23.9%)		
In writing	57 (35.8%)	10 (12.7%)	48 (54.5%)		
Group information at start of the vaccination se	eason				
Oral	2 (1.3%)	1 (1.3%)	0 (0%)		
In writing	40 (25.3%)	23 (29.1%)	25 (28.4%)		
Institutions that <i>only</i> offer group information	17 (10.8%)	5 (6.3%)	14 (15.9%)		
Information disclosure at other moments	19 (12%)	4 (5.1%)	15 (17.0%)		
Other information procedures	3 (1.9%)	7 (8.9%)	8 (9.1%)		

information (e.g. during a meeting in the living room). These types of information are supposed to be given annually. Apart from these information procedures, respondents could also indicate non-yearly ways of informing residents, for example at admission in the nursing home or during a consulting hour.

Many nursing homes (159/245) follow one information procedure for both competent residents and proxies of incompetent residents. In these cases, residents or proxies are most often informed personally (orally: 54.4% and/or in writing: 35.8%). Personal information is often combined with "group information", like "public" announcements on the bulletin board, a newsletter or in the living rooms. In some institutions (10.8%) residents and proxies are not personally informed; all information is directed at the whole group.

The institutions (82/245) that have different information policies towards competent residents and towards proxies of incompetent residents, mostly inform competent residents by personal oral communication (82.3%). Proxies are more often informed in a personally addressed letter (56.8%). What is remarkable is that in 15.9% of these institutions, proxies are not personally informed about vaccination; information is only provided in, for example, a newsletter, or on a bulletin board.

Reasons to abstain from vaccination

As shown above, only few residents of Dutch nursing homes are not immunised. We asked the respondents what reasons they encounter to with-hold vaccination. Almost all respondents (239/245) have been confronted with explicit refusals of residents or proxies during the last several years. Another frequently mentioned reason (232) is that a resident is expected to die within a short time. Other reasons for withholding vaccination are less paramount: the fact that decisions about limitation of treatment have been made (148) and religious objections of residents or proxies against vaccination (115). Some physicians report decisions to refrain from vaccination because an (incompetent) resident resisted against administration of the vaccine (139) or because a resident or proxy was afraid of side effects of vaccination (106).

The physician's opinion about arguments in a vaccination policy

The high prevalence of tacit consent policies and the high vaccination rates suggest that influenza vaccination in nursing homes is considered to be very important. Which considerations do respondents see as most relevant for an institutional policy (Table 3)? Respondents could score the importance of several considerations on a scale of 1 (not at all important) to 5 (very important). We mark a consideration to be important (unimportant) if more than 50% of all respondents scored "1" or "2", (unimportant: if more than 50% scored "4" or "5"). The freedom of choice for residents (and their proxies) is considered very important (88.6%), together with prevention of loss of quality of life as a result of influenza

Table 3. Considerations for the institutional vaccination policy

	Percentage of respondents who consider this important or very important	Percentage of respondents who consider this not important or not at all important
Important considerations		
Prevention of loss of quality of life as a result of influenza	92.6	1.6
Residents' freedom to refuse or accept vaccination	88.6	1.6
The protective effect of herd immunity for the weakest residents	73.4	13.1
Unimportant considerations		
The financial costs of influenza vaccination	4.1	81.6
Possible side-effects of influenza vaccination	12.9	58.3
The official policy for influenza vaccination in the Netherlands	18.2	50.4
Considerations raising diverging reactions		
Preventing that the quality of care decreases as result of an outbreak	21.7	47.3
Preventing premature death	25.3	45.4
Preventing that the workload increases as a result of an outbreak	36.1	32.3

(92.6%). The protective effect of herd immunity for the weakest residents was also considered an important criterion for influenza policies (73.4%). Two items were considered extremely unimportant: most respondents did not think that the financial costs of influenza vaccination should influence a policy concerning influenza (81.6%) and did not consider the side effects of influenza vaccination as important (58%). Three other considerations received quite diverging evaluation of the responding physicians. These considerations involved the idea that vaccination may prevent negative effects of an outbreak on the quality of nursing home care; the prevention of premature death; and the increased workload of caregivers during outbreaks.

Discussion

The influenza immunisation rate among nursing home residents in the Netherlands has risen considerably during the last decade. A 1993 survey in the Netherlands showed a mean vaccination rate in Dutch nursing homes of 71% (Smalbrugge, 1995). According to our data the mean level of immunisation in 2000 is 85.5%. The most plausible explanation of this development is that in the Netherlands, since 1996, immunisation is recommended to persons of 65 years and older (Health Council, 1998). Most nursing home residents fall within this group. In 2002, the immunisation rate among healthy Dutch elders was 78% (Tacken et al., 2003). Normally, these persons do not live in institutions. It will not come as a surprise that in long term care institutions a considerably higher immunisation level can be attained. Physicians in nursing homes have numerous possibilities to bring vaccination to the attention of residents and proxies and hence to develop efficient policies. The procedure of obtaining informed consent is an important element of such policies. Many residents in a nursing home may not be competent to consent themselves; in these cases consent should be obtained from a family member or other representative (proxy consent). Either way, the standard procedures of consent involve (1) that information is disclosed to the resident or proxy, who (2) should understand the information and (3) voluntarily decide whether or not to consent. Finally (4), this decision should be communicated to the person who requested consent (Beauchamp and Childress, 2001; Faden and Beauchamp, 1986). Legal rules will sometimes require written consent. From a moral point of view however, it is less relevant whether written or oral consent is

obtained, as long as these four conditions are satisfied. On the other hand, a choice between express consent and tacit consent is highly relevant. If express consent is obtained, health care workers have ample opportunities to see whether the four conditions are satisfied. Tacit consent procedures leave much room for possibilities that the resident or her proxy (1) did not receive the information or (2) did not adequately understand it. Moreover, (3) the health care worker has no basis to believe that a decision has been made at all and, if it has been made, whether it was a voluntary choice. This is because (4) no consent is communicated to the health care worker: consent is assumed. Obviously, the quality of any consent procedure depends on the quality of communication between caregivers and residents or proxies. If caregivers see to it that residents and proxies are well informed, and that they are aware they can make a decision themselves, both express and tacit consent procedures might be sufficient. Yet an important feature of express consent is that this procedure helps to secure communication and consent (although obviously it does not guarantee autonomous choice). In this context it is salient that in a number of institutions, proxies are not personally informed about vaccination; which means for example that the yearly vaccination is only announced on a bulletin board or in a newsletter. Arguably, in such cases the communication and information will often be incomplete, if only because the communication seems to be a one-way process, and caregivers who assume tacit consent cannot reasonably expect that all proxies will have read the information and made a decision. Hence, such procedures might well violate these persons' right to informed consent.

This is not to say that tacit consent procedures can never constitute justified forms of informed consent. A minimum requirement should be that there is a high quality information and communication process. Yet even then, a choice for tacit instead of express consent requires a strong and explicit justification.

Our survey shows that approximately 43% of Dutch nursing homes follow tacit consent procedures for both competent and proxies of incompetent residents. Thirty-nine percentage follow express consent procedures towards both groups. Most of the remaining institutions obtain express consent of competent residents and assume tacit consent of incompetent residents' proxies.

One obvious reason for a tacit consent policy is that it requires, when compared with express consent, less time and efforts of nursing home personnel. Tacit consent procedures are efficient and may therefore contribute to a high vaccination rate. Indeed, our survey makes clear that institutions with tacit consent procedures show higher vaccination rates than institutions in which express consent is required. Is this a sufficient justification for tacit consent? Choosing for tacit consent may involve the assumption that it is in the best interest for the resident to be vaccinated. This assumption is appealing but not self-evident. First, there is the underlying assumption that the individual resident will always benefit from vaccination: vaccination protects vaccinees against the burdens of illness and against lethal complications of influenza, notably pneumonia. This is of course worthwhile. However, for some nursing home residents who have gone through a long process of deterioration, death due to pneumonia may be considered relatively mild and well acceptable. This is why sometimes pneumonia is considered "the old man's friend." (Hensel, 2000). Indeed, the question whether prevention of premature death is important for influenza vaccination policies raises diverging reactions among our respondents. Now it would be highly simplistic to resist immunisation because of the "friendly" character of the lethal complications of influenza. Yet, if one accepts that at least in some cases pneumonia might be a friend rather than a foe, one has reasons to be open for discussion whether influenza immunisation is the best choice for each resident. If so, tacit consent may not be the most suitable procedure.

A potentially stronger argument for striving for high immunisation rates (and hence justifying tacit consent procedures) however, does not refer to the individual benefits but to collective interests and values (Verweij, 2001). High immunisation rates may result in herd immunity, involving increased protection for all residents, including the weakest amongst them (Coles et al., 1992; Drinka et al., 1997; Fox et al., 1971). Moreover, realising herd immunity may be the best way to prevent an influenza outbreak that will have devastating effects on daily life and care within the institution. Most respondents in our study consider herd immunity to be an important goal of vaccination policies. Herd immunity will require vaccination levels of at least 80% (Drinka et al., 1997). This level is reached in most responding institutions. However, the level of immunisation among residents is not the only relevant factor for herd immunity. Immunisation of health care workers is also important, because of their possible role in introducing and spreading the virus among the nursing homes (Carman et al., 2000; Coles et al.,

1992; Drinka et al., 1997; Fox et al., 1971; Nicholson, 2000; Potter et al., 1992). We have no data about the level of immunisation of health care workers in Dutch nursing homes, but, apparently, occupational immunisation is not given high priority: only 21.6% of the responding institutions in our survey explicitly request their personnel to get vaccination. Now, if a low vaccination rate among health care workers obstructs the realisation of herd immunity, then it becomes more difficult to justify tacit consent procedures towards residents.

Conclusion

Influenza vaccination policies that favour efficient non-express consent procedures but neglect the importance of nursing staff immunisation, lack a coherent moral justification. Instead, we recommend institutional immunisation campaigns that favour express consent and stimulate education and discussion among residents, families and nursing staff. Reflecting on the meaningfulness of immunisation may lead residents, families and staff to recognise that, by choosing for immunisation, they contribute to the protection of others as well.

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