

Influenza vaccination rates and informed consent in Dutch nursing homes: survey of nursing home physicians

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Influenza is a major cause of morbidity and mortality among residents of nursing homes.¹ Many nursing homes therefore aim at high vaccination rates. To meet this aim some homes use tacit consent policies, in which the vaccine is given unless residents or their proxies state that they do not want it. Such policies deviate from standard (express) consent procedures, which require that vaccination occurs only if the resident or his or her proxy gives consent. Is this deviation from standard informed consent procedures justified? We explored consent procedures and vaccination rates in Dutch nursing homes to determine the effects of current practice.

Participants, methods, and results

In October 2000, we sent a questionnaire to all 353 nursing homes in the Netherlands for completion by one of the nursing home physicians. Doctors were asked to provide exact vaccination rates or, if that was not possible, to estimate the rate within 10% ranges (90-100%, 80-90%, etc). The questionnaire also asked about vaccination and consent policies. We analysed data using SPSS-9. Differences were considered significant if $P < 0.05$.

We received 245 completed questionnaires. Eighteen nursing homes seemed to have shut down or merged into other institutions. We therefore counted the response rate as 73% (245/335). The average vaccination rate (based on exact information) in nursing homes was 86%. When we combined exact and estimated data, 120 homes (49%) had a vaccination rate of 90% or higher (table).

Ninety eight homes had a written vaccination policy. These institutions had lower vaccination rates than homes without written policies. Only 53 (22%) nursing homes asked healthcare workers to be vaccinated.

In all, 106 institutions followed tacit consent procedures for all residents. Nursing homes with tacit consent procedures had higher vaccination rates than

institutions that required express consent from all residents (mean rate 89% *v* 82%, $P < 0.001$).

Comment

We have shown that homes that use tacit consent have higher vaccination rates than those which require express consent, but the difference may not be sufficient to justify the use of such a policy. Tacit consent implies that residents and their proxies are informed about vaccination and are vaccinated unless they refuse. This procedure deviates from standard informed consent procedures² and therefore raises ethical problems. If tacit consent is presumed, the health professional will often not be certain whether the person received the relevant information or whether the information was adequately understood. Moreover, it is unclear that a voluntary choice was made.

There is a potentially strong collective argument for aiming at high vaccination rates and hence for preferring tacit consent.³ High immunisation rates may result in herd immunity, which increases protection for all residents, including the weakest patients. Moreover, it may reduce the risk of an influenza outbreak that will disrupt daily institutional life and care. However, there are some problems with this argument. Firstly, our survey shows that many nursing homes that use express consent procedures have vaccination rates (>80%) that may be sufficient for herd immunity. Hence, tacit consent is not necessary for herd immunity. Secondly, tacit consent can be valid only if everyone is aware that they have a choice. This puts far reaching demands on the information process. Lastly, only 53 of the 245 institutions asked employees to be vaccinated. We suspect that vaccination rates among nurses are low, and this will frustrate herd immunity within the institution.^{4,5} If vaccination of healthcare workers is inadequate, the aim of herd immunity is not a sufficient argument to deviate from standard consent procedures.

Vaccination rates of Dutch nursing homes according to policies on vaccination and consent*

	No (%) of homes	Mean vaccination rate (No of homes)†	No (%) with ≥80% vaccination‡	No (%) with ≥90% vaccination‡
All responding nursing homes	245 (100)	86% (180)	199/243 (82)	120/243 (49)
Institutions with written policy¶	98 (40)	84% (73)	74/98 (76)	48/98 (49)§
Institutions without written policy	135 (55)	88% (100)	118/133 (89)	68/133 (51)§
Always required express consent**	100 (41)	82% (73)	74/98 (76)	41/98 (42)
Tacit consent always sufficient**	106 (43)	89% (81)	96/106 (91)	64/106 (60)

*Differences between institutions with and without written policy and between those requiring express 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.

¶Nine residents did not know whether the home had a written policy and three gave no information.

**35 homes had different policies on consent for competent and incompetent residents and one gave no information.

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1 Gross PA, Hemogenes AW, Sacks HS, Lan J, Levandavski RA. The efficacy of influenza vaccine in elderly persons. A meta-analysis and review of the literature. *Ann Intern Med* 1995;123:518-27.

2 Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 4th ed. New York: Oxford University Press, 1994.

3 Verweij M. Individual and collective considerations in public health: influenza vaccination in nursing homes. *Bioethics* 2001;15:536-46.

4 Drinka PJ, Gravenstein S, Krause P, Schilling M, Miller BA, Shult P. Outbreaks of influenza A and B in a highly immunized nursing home population. *J Fam Pract* 1997;45:509-14.

5 Nicholson KG. Should staff in long-stay hospitals for elderly patients be vaccinated against influenza? *Lancet* 2000;355:83-4.

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Commentary

Sahaya Josephine takes you through this paper and explains the implications

The paper addresses two important issues, one being uptake of vaccination for influenza and the other being informed consent. Increasing vaccine uptake rates is a top priority in the effort to prevent winter crises.

Why was it done?

The authors set out to find out what types of consent procedures were in place for influenza vaccination in Dutch nursing homes and what effect it had on the overall uptake rates.

How was it done?

This was a postal survey of nursing home physicians done in a set period or at one point in time and so is called a cross sectional or prevalence study. The authors wished to obtain a snapshot of the vaccination rates and consent policies. A postal questionnaire is usually considered to be a simple and convenient method for collecting this type of information. The information was collected to discover whether deviation from standard informed consent procedures was justified.

The questionnaires were sent to all nursing homes in the Netherlands and therefore this was an all inclusive approach avoiding any selection bias. Selection bias would normally occur if the sample selected was not representative of the nursing home population.

The authors requested nursing home physicians to provide exact vaccination rates or close estimates. An element of information bias or observer bias could be possible, as it is not clear if there was a standard method of collecting data in all the nursing homes.

What did they find?

The survey had a response rate of about 73%, which is reasonable considering the difficulties in conducting a survey. The response rate could have been better if the non-responders had been sent a reminder or contacted by telephone. As more than 25% of the homes did not respond, this could have a significant effect on the overall results. Nursing homes that do not have explicit policies may have failed to respond. Also, where there were problems or complications in homes due to inadequate vaccination rates, there may have been a poor response or no response.

There is no information on what proportion of nursing homes provided exact rates and how many provided

only estimates. The estimates were within 10% ranges and it is not known if the number of nursing homes providing estimates was substantially higher. This could also have an effect on the apparent differences noted between the homes using different consent policies.

The authors conclude that homes that use tacit consent have higher vaccination rates. This was statistically significant, with a P value of <0.001. This means that the difference in the uptake rates may be attributable to a tacit consent policy. But is this sufficient justification for introducing such a policy? The authors themselves agree it is not.

It is essential to distinguish between what is statistically significant and clinically significant. Ideally it would have been more useful to know the clinical effects of inadequate vaccination rates before reaching a conclusion about what type of consent procedure is justified. However, this is not something which can be measured easily or accurately, and another type of study would be required. The authors rightly point out that other issues like vaccinating healthcare staff are also important to achieve good herd immunity.

What are the implications?

In the United Kingdom, although uptake of influenza vaccine is increasing, there are instances when individuals in high risk groups may not be vaccinated. The single most important factor in patients accepting influenza immunisation is that their doctor recommends they have it. The Department of Health's reference guide to consent for examination or treatment states that it is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care for a patient.¹ The consent needs to be given voluntarily by an appropriately informed person.

In general practice, if an individual attends a clinic for vaccination, that could be considered as giving implied consent. The nursing home setting is different, and many patients may not have the mental capacity to make an informed choice. In such instances, for both ethical and legal purposes it is essential that explicit written policies are in place to guide the staff. Therefore, using a tacit consent policy may not be the preferred alternative. This study emphasises that the debate on consent issues is vital and that it is something that all healthcare professionals need to be well informed about at all stages of their career.

1 Department of Health. *Reference guide to consent for examination or treatment*. London: DoH, 2001.

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