Effect of non-response bias in pressure ulcer prevalence studies

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Aim. This paper reports a study to determine the prevalence of pressure ulcers in German hospitals and nursing homes for national and international comparison, and analyses the influence of non-response bias.

Background. Outcome rates are often used to evaluate provider performance. The prevalence of pressure ulcers is seen as a possible parameter of outcome healthcare quality. However, the results from different pressure ulcer prevalence studies cannot be compared, because there is no standardized methodology and terminology. Observed and published prevalence rates may reflect variations in quality of care, but differences could also relate to differences in case-mix or to random variation.

Methods. A point prevalence survey was carried out for 2002 and 2003 using data from 21,574 patients and residents in 147 different kinds of institutions throughout Germany. Participation rates and reasons for not participating in the study were documented. Non-responders were considered in different calculations to show the range of possible prevalence rate for a hypothetic 100% participation.

Results. In 2002 and 2003, the calculated prevalence rate (among participating persons at risk) in hospitals was 25·1% and 24·2% respectively, while in nursing homes it was 17·3% and 12·5% respectively. Non-response varied from 15·1% to 25·1%. The majority of non-responders in hospitals and nursing homes had not been willing to participate in the study. Based on different assumptions about the characteristics of the non-responders, we calculated minimum and maximum prevalence rates as if 100% participation was achieved.

Conclusions. Calculating the non-response bias of prevalence rates is an inconvenient but necessary thing to do because its influence on calculated prevalence rates was high in this study. High participation rates in clinical studies will minimize non-response bias. If non-response cannot be avoided, the formula provided will help researchers calculate possible minimum and maximum prevalence rates for the total sample of both the responding and non-responding groups.

Keywords: Germany, non-response bias, nursing, point prevalence survey, pressure ulcers, prevalence

Introduction

Outcome rates are often used to evaluate provider performance. The prevalence of pressure ulcers is seen as a possible parameter of outcome healthcare quality (Dealey 1997, Tsokos *et al.* 2000), with lower rates indicating better quality of care (Haalboom 2000). Despite the international popularity of conducting prevalence surveys (Barczak *et al.* 1997, Hopkins *et al.* 2000, Jacksich 1997, Meehan 1994, Pearson *et al.* 2000, Scott & Newens 1999), in the Federal Republic of Germany only few published studies are available. They are usually limited to individual institutions (Gruen *et al.* 1997, Schumacher & Eveslage 1999) or restricted to one state/district (Leffmann *et al.* 1998, Steingass *et al.* 2002) with results between 2% and 10%, which seemed exceptional in comparison with internationally published results. However, the results from different pressure ulcer prevalence studies cannot be used for comparisons, because there is no standardized methodology and terminology (Lake 1999). Observed and published prevalence rates may reflect some quality of care, but differences could also relate to differences in case-mix or to random variation (Berlowitz *et al.* 1998). Therefore, recommendations for standardization of prevalence measures often relate to case-mix (Berlowitz *et al.* 1996, Bours *et al.* 2003, Perneger *et al.* 1998), quantity of risk (Lake 1999) and the use of a recognized severity index for the classification of pressure ulcer (Healey 1996).

Background

Even if there was a generally accepted procedure for these issues, another important problem remains unsolved, i.e. the influence of non-response bias on pressure ulcer prevalence rates. Although research has been undertaken in other clinical settings (Korkeila *et al.* 2001, Lahaut *et al.* 2002), many researchers recommend more studies on the topic (Hoeymans *et al.* 1998, Rupp *et al.* 2002). Up to now, few articles have been published about these methodological problems in pressure ulcer prevalence surveys. As every clinical study requires the informed consent of the participating population, it is quite natural that only few will have a 100% response rate. Existing statistical procedures, such as the confidence interval (Bortz & Döring 2002), that take into account the non-responders, are generally used. However, these procedures require the participating sample to be a randomized sample of the total population. There has been some research on this issue, but for obvious reasons empirical knowledge of a group that cannot be examined is very limited or controversial. Some researchers examining non-responder groups have been unable to identify a constant or homogeneous group (Schnell 1997), while other studies have shown possible differences in demographic and risk factor rates (Solberg *et al.* 2002) of non-responder populations. The survey population very often differs from the target population because of lack of coverage and response (Frankel 1983). There has not been enough evidence so far to justify the conclusion that the responding group can be regarded as representative of the non-responding group.

According to Scheuch (Scheuch 1974), three different reasons for non-response can be distinguished in questionnaire surveys:

- Not present during survey (absent).
- Not willing to participate (unwilling to give informed consent).
- Not capable of participating (incapable to give informed consent).

When conducting pressure ulcer prevalence studies, it becomes evident that lack of data is mainly caused by organizational matters within the participating institutions, i.e. missing data may be explained by a patient's absence during the survey because of therapeutic or diagnostic procedures (X ray, theatre, etc.), or by loss of questionnaires. The latter reasons relate to the patient or resident. It can be concluded that being unwilling or not capable of participating may have a major impact on clinical studies. Unconscious and disoriented patients or those unable to comprehend the aims of a pressure prevalence study may be the very old, very sick and high-risk patients.

The study

Aims

The aim of this study was to provide information about a survey on pressure ulcer prevalence rates in German nursing homes and hospitals in 2002 and in 2003 and the effect of non-response bias on the results. The specific research questions were:

- What was the pressure ulcer prevalence in German nursing homes and hospitals in 2002 and 2003?
- What was the participation rate and what were the reasons for not participating in the study?
- What was the effect on the prevalence rate of pressure ulcers when non-responders were taken into account?

Design

Point prevalence studies for pressure ulcers were conducted in April 2002 and 2003. The data collection methods and questionnaire formats were based on those developed by the

Dutch National Registration Project on Pressure Ulcers (Bours *et al.* 1999). Derived from the Dutch version, the instrument was translated into German and modified following group discussions between researchers and practitioners. After a pilot study in 2000, a survey in 11 Berlin hospitals was conducted in April 2001. The instrument contained questions about patient demographics, occurrence and characteristics of pressure ulcers, and methods of prevention and therapy. The Braden scale was used to measure the risk of developing pressure ulcers, while the degree of pressure ulcers was determined using the National Pressure Ulcer Advisory Panel grading system (NPUAP 2003).

In order to measure the quantity of response bias, another instrument – the 'response questionnaire' – was used to obtain information about the number of non-responding patients or residents at ward level and their reasons for not responding. The questionnaire contained questions about the total number of patients and residents on the day of the study. In cases of non-response, the reason had to be stated (i.e. did patients and residents not wish to give informed consent, or were they unable to do so because of unconsciousness, confusion, no understanding, etc?).

Sample

In April 2002 and 2003, hospitals and nursing homes throughout Germany were invited to participate anonymously in the study. In 2002, 15 nursing homes and 40 hospitals participated; in 2003, the sample consisted of 45 nursing homes and 47 hospitals. The average age of respondents in 2002 was 66·2 years, whilst in 2003 it was 68·6 years. The average age of hospital patients in 2002 was 63·6 years (63·9 in 2003), while the average age of residents in nursing homes was higher (83·6 in 2002, 81·2 in 2003). In both years, there were slightly more female than male patients in the hospitals (56·0% in 2002, 55·7% in 2003) in comparison with nursing homes, where there was predominantly female participation (81·3% in 2002; 78·3% in 2003).

Data collection

Researchers trained the co-ordinators in all participating hospitals and nursing homes. Then each co-ordinator trained ward nurses in gathering the data required for the survey. Only fully qualified staff nurses on the wards were trained. Standard pictures and definitions of each grade of pressure ulcer were given to every nurse who was trained. In each of the participating institutions, the prevalence study was carried out on a set day of the second week of April 2002

and 2003. The specially trained ward nurses examined all patients or residents in the selected wards of the institution. The same nurses completed the response questionnaires and gave the reasons for non-response. The questionnaires were then returned to the university, checked for remarks and completeness, and prepared for data analysis.

Ethical considerations

Permission to conduct the study was obtained from the Berlin medical ethics committee.

Prior to data collection, informed consent was obtained from patients, either personally or on their behalf from a relative.

Data analysis

To determine the prevalence rate, the NPUAP definition was used: 'prevalence measures all cases of a condition (e.g. pressure ulcers) among those at risk of developing the condition. Measures of prevalence are made at one point in time' (NPUAP 2003) (see Formula 1, Figure 1).

1. Prevalence rate definition:

(Formula 1) Prevalence $(p) = \dfrac{PU}{AR} \times 100$

2. Non-responders representative

(Formula 2) $\Lambda_{krit\,(95\%)} = p \pm 1.96 \times \sqrt{\dfrac{p \times (1-p)}{R}}$ (Bortz & Döring 2002)

3. Non-responders not representative

(Formula 3) If (NR = AR)

absolute maximum / minimum prevalence rates:

(3a) $p_{(ab\_max)} = \dfrac{PU + NR}{AR + NR} \times 100$ (3b) $p_{(ab\_min)} = \dfrac{PU}{AR + NR} \times 100$

Maximum possible prevalence rate

(Formula 4) If $\left(\dfrac{AR}{R} = \dfrac{AR^*}{NR}\right) \rightarrow : AR^* = NR \times \dfrac{AR}{R}$

4. likely maximum and minimum prevalence rates

(4a) $p_{(lik\_max)} = \dfrac{PU + AR^*}{AR + AR^*} \times 100$ (4b) $p_{(lik\_min)} = \dfrac{PU}{AR + AR^*} \times 100$

Figure 1 Formulae.

The populations in different institutions were standardized using the Braden scale, with a cut-off of 20 or less defining a risk of developing a pressure ulcer (Halfens 2000). Non-response is shown for each kind of institution in both years. Non-response data for patients and residents included data for those who were absent, unwilling or incapable to participate in the study. Descriptive analysis of these data is displayed for each year and each kind of institution. Apart from the reasons for non-response, no further information was available about those who did not respond. The two different general assumptions about non-responders were made:

- Assumption A: the non-responding group is a sample representative of the total sample.
- Assumption B: the non-responding sample is not a sample representative of the total sample.

Based on assumption A, the confidence interval can be calculated (Formula 2, Figure 1). To calculate a possible maximum (minimum) prevalence rate, the confidence interval was added to (deducted from) the prevalence rate of the responding group.

Based on assumption B, a variety of further assumptions can be made. In this paper, we will provide an assumption B1 for the case of an absolute possible maximum and minimum prevalence rate $P_{(abs)}$ and an assumption B2 for the case of a likely possible maximum and minimum prevalence rate $P_{(lik)}$:

- B1. All non-responders are considered at risk (NR = AR) and all non-responders at risk suffer from at least one pressure ulcer. In this case, Formula 3 (Figure 1) can be used.
- B2. The assumption that all are at risk is rather unlikely. It is therefore assumed that the risk group (AR) size in the responder group (R) and the unknown risk group (AR*) size in the non-responder group (NR) are the same. Therefore, the unknown risk group size (AR*) can be calculated.

Finally, using Formula 4 (Figure 1), a more likely possible maximum/minimum prevalence rate can be calculated if all non-responders in this defined risk group suffered from at least one/no pressure ulcer.

Results

Measured prevalence rates (responders only)

In the following presentation of results, all calculations also include pressure ulcer grade 1. It should be noted that results are usually presented without grade 1 pressure ulcers; however, the issue of this paper is the influence of non-participating patients/residents on calculated prevalence

Table 1 Measured prevalence rates (responders only)

Institution	2002		2003	
	AR	PU (prevalence, %)	AR	PU (prevalence, %)
Nursing homes	861	149 (17·3)	2052	257 (12·5)
Hospitals	2598	653 (25·1)	3236	783 (24·2)
Total	3459	801 (23·2)	5288	1040 (19·7)

AR, at-risk (Braden score 20 points or less); PR, prevalence rate.

rates. Different possible minimum and maximum prevalence rates are displayed, and therefore presentation of all these figures with the exclusion of pressure ulcer grade 1 might be confusing.

Firstly, the at-risk group was determined using the Braden-scale with a cut-off of 20 points or less to achieve a standardized comparable risk group in each kind of institution. According to this procedure, 3459 participants in 2002 and 5288 in 2003 were considered to be at risk. Table 1 shows the prevalence rates for both kinds of institution in each year. In 2002, there were 801 participants with pressure ulcers (149 nursing home residents and 653 hospital patients). Thus, the prevalence among those at risk is 25·1% in hospitals, which is approximately one-third higher than in nursing homes (17·3%). In 2003, the results in hospitals revealed only minor differences, with about 1% lower prevalence; however, the prevalence rate in nursing homes was only about half of the hospital rate.

Non-response

Table 2 shows that the total number of patients/residents in all participating institutions was 10,683 in 447 U/wards in the year 2002 and 17,074 in 773 U/wards in 2003. In 2002, more than 2000 patients and residents did not respond; in 2003, there were more than 4000 non-responders. This means that approximately one-fifth to one-quarter of all patients/residents did not respond. In 2002, participation was higher than in 2003. The lowest non-response (15·1%) was occurred in nursing homes in 2002 ($n = 1347$), and the highest participation (24·4%) in hospitals in 2003 ($n = 9503$).

Table 2 Non-response

Institution	2002		2003	
	Total	Non-response	Total	Non-response
Nursing homes	1586	239 (15·1%)	4453	954 (21·4%)
Hospitals	9097	1872 (21·6%)	12,574	3071 (24·4%)
Total	10,683	2111 (19·8%)	17·074	4072 (23·7%)
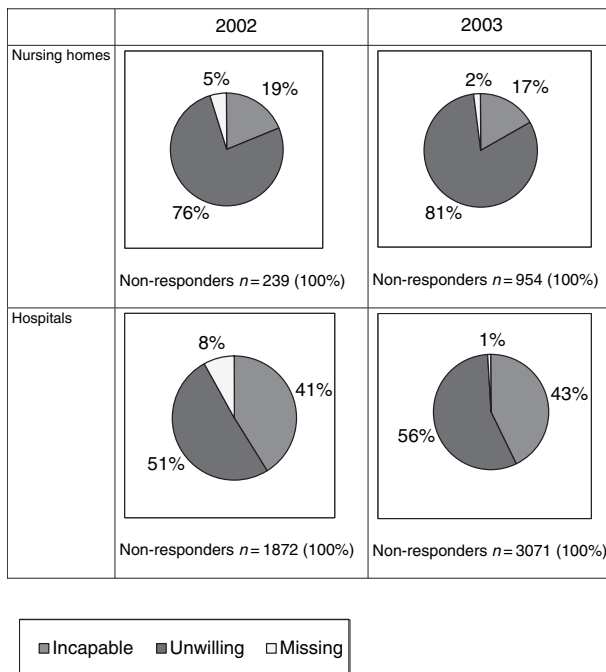
Figure 2 Reasons for not responding.

Table 3 Minimum and maximum prevalence rates (including non-responders)

	2002		2003	
	Min–max %	Range	Min–max %	Range
Confidence interval ($P < 0.05$)				
Nursing homes	17·1–17·6	0·5	12·3–12·5	0·2
Hospitals	24·9–25·3	0·4	24·1–24·3	0·2
Total	23·1–23·3	0·2	19·6–19·8	0·2
Absolute possible minimum/maximum prevalence				
Nursing homes	13·5–35·3	21·8	8·5–40·3	31·8
Hospitals	14·6–56·5	41·9	12·4–61·1	48·7
Total	14·4–52·3	37·9	13·8–67·9	54·1
Likely possible minimum/maximum prevalence				
Nursing homes	14·7–29·9	15·2	10·0–30·3	20·3
Hospitals	19·8–41·0	21·2	18·3–42·7	24·4
Total	18·6–38·4	19·8	19·7–38·1	18·4

Reasons for non-response

The reasons for not participating in the study are shown in Figure 2. The percentage of non-responders because of absence, incapability or unwillingness to participate is shown for each year and kind of institution. The reasons for absence (missing) related to organizational or institutional matters, and varied between 1% and 8%. In each year, more than three-quarters of the non-participating residents were unwilling to participate, while in hospitals these were just over half of all patients. The highest percentage of those incapable of participating was 43%, which occurred in hospitals in 2003.

Calculation of minimum and maximum prevalence rates

Finally, the maximum and minimum prevalence rates were calculated for assumptions A (participants are a sample representative of the whole sample) and B1 and B2 (participants are not a sample representative of the total sample). As these figures are rather theoretical, no absolute numbers are shown, but just the potential prevalence rates. If assumption 'A' was applied, the possible confidence interval would be very close to the calculated results in Table 3. The deviation from the calculated values ranges between 0·1 and 0·3 points. On the other hand, assumption B1 (no representative sample) actually shows a very wide range of possible prevalence rates. The possible prevalence rates in nursing homes could range from a possible minimum of 8·5% to up to 40·3%. In

hospitals, this value could be very high, ranging from 12·4% to up to more than 60% in 2003. Assumption B2, therefore, is a much more probable assumption. According to this, the possible minimum prevalence rate was 10·0% in nursing homes in 2003. This is 2·5% less than the calculated value of the responding group and is therefore a more reasonable outcome. Hospitals in 2003 could have had a very probable possible maximum prevalence rate of 42·7%, which is about 18% more than the calculated value of the responding group, but still more than 25% less than the absolute possible maximum prevalence rate according to assumption B1.

Discussion

Throughout Germany, 27,757 patients and residents in 147 institutions were asked to take part in this pressure ulcer survey. No data were obtained for 6183 persons. These figures provided a good starting point for further investigation. However, the sample was not representative of German hospitals and nursing homes because participation was voluntary and no random or quota sampling procedure was used.

When analysing the results of the two annual prevalence pressure ulcer surveys, it is worthy of note that the non-response in nursing homes was generally lower than in hospitals. The majority of residents in nursing homes failing to give informed consent were unwilling to participate in the study. This was probably because of some of them having problems in comprehending the aims and issues of the study or having no confidence in the appropriate handling of sensitive personal data. It might be possible to increase participation if there were more and better explanations of the necessity of conducting these studies; however, some

potential participants might still remain sceptical. In hospitals, more than 40% of the patients were not capable of giving informed consent. This incapability might have been for a variety of reasons. The causes can only be speculated upon; however, no personal data were available for the individuals concerned. Patients had perhaps undergone surgery, were suffering from a serious condition, were unconscious or confused, or spoke a different language and therefore did not understand what the survey was about. However, the majority of non-responders in hospitals and nursing homes were not willing to participate in the study. This should make researchers more aware of the information needs of participants. It can be concluded that information about a study should be clear and easy to understand to enable more patients and residents to overcome any initial scepticism.

The different calculations show that it is quite difficult to deal with the 'non-responder problem'. The calculated values for possible minimum and maximum prevalence rates are very different, depending on the assumptions and calculations used. Assumption A and assumption B1 are rather extreme and therefore not very probable. There is no evidence to justify the assumption that non-responders are representative of the responding sample; therefore, assumption A is rather difficult to adhere to. Alternative B1 – everyone failing to give informed consent is (a) at risk and (b) suffers from a pressure ulcer – is also very unlikely. Therefore, assumption B2 gives a more reasonable range of possible prevalence rates. According to this, the possible prevalence rate in nursing homes in Germany ranges from a probable possible minimum of about 15% to a maximum of about 30%, whilst ranging from about 20% to more than 40% in hospitals. The fact that all

findings from 2002 to 2003 only vary slightly makes the results more important.

Conclusion

Calculating the non-response bias of prevalence rates is necessary in order to provide comparable pressure ulcer prevalence data. As this study showed, non-response bias was high for calculated prevalence rates. The possible range of prevalence rates depends to a great extent on the response rate of the study sample. The higher the response rate in pressure ulcer prevalence studies, the smaller the possible range of pressure ulcer prevalence rate will be. Therefore, it is extremely important to gain consent from as many patients and residents as possible in order to maximize the response rate. The fact that most non-responder were unwilling to participate rather than being unable because of unconsciousness and disorientation suggests that non-response could be minimized by providing adequate information about the aims and reasons for the study for this group of patients and residents.

Nevertheless, no clinical study will ever achieve a 100% response rate. All researchers who do descriptive research will face this problem and should therefore take this issue seriously. It is possible to use our formula to calculate non-response bias. By comparing not only the calculated figures for the participating sample but also the range of possible figures for the total (participating and non-participating) sample, the internal validity of the data will be increased. It has to be acknowledged that non-response bias can be quite significant, and it is not sufficient just to compare rates of responders of prevalence ulcer surveys. The consideration of the non-response bias helps increase the comparability and interpretation of data. This is important for researchers, healthcare planners and other clinical professionals who (not only) deal with pressure ulcer prevalence data.

Author contributions

NL, RH and TD were responsible for the study conception and design and drafting of the manuscript. NL performed the data collection and data analysis. TD provided administrative support. NL provided statistical expertise. RH and TD made critical revisions to the paper. RH and TD supervised the study.

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