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# **SAFE or SORRY?**

A programme to implement multiple guidelines simultaneously

Betsie van Gaal

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simultaneously**

Betsie van Gaal

Nijmegen, 2011

The studies presented in this thesis have been performed at the Scientific Institute for Quality of Healthcare of the Radboud University Nijmegen Medical Centre. The Scientific Institute for Quality of Healthcare is part of the Nijmegen Centre for Evidence Based Practice (NCEBP), one of the approved research institutes of the Radboud University Nijmegen and the Netherlands School of Primary Care Research (CaRe), acknowledged by the Royal Dutch Academy of Science (KNAW).

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**SAFE or SORRY?**  
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**simultaneously**

Een wetenschappelijke proeve op het gebied van de  
Medische Wetenschappen

**Proefschrift**

ter verkrijging van de graad van doctor  
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## **Chapter 1**

### **General introduction**

Quality and safety in health care is a prime concern for health care professionals. Over the last two decades, several studies have shown that patients are at risk for injuries or even death as a result of care delivered in hospitals.<sup>1-9</sup> One current gauge for judging the safety of health care is the occurrence of adverse events.<sup>1</sup> The definition of adverse events used in studies varies.<sup>1</sup> Often, an adverse event is defined as 'an unintended injury that results in prolonged stay, disability at the time of discharge, or death and is caused by health care management rather than by the patient's underlying disease process'.<sup>10</sup> Several international studies have shown that 3 to 17% of patients in acute care hospitals experienced at least one adverse event.<sup>2,3,6-8</sup> In 5 to 13% of these events, the patients died.<sup>2-8</sup> A similar Dutch study showed that 6% of the 1.3 million hospital patients admitted in 2004 experienced at least one adverse event.<sup>11</sup> One out of four patients with an adverse event experienced a minor disability from which they had recovered by the time of discharge. Nevertheless, 5% of the patients with an adverse event had a permanent disability or died as a result of the adverse event.<sup>11</sup> Patient safety can be improved, as half of all events are considered preventable.<sup>2,4,7-9,12</sup> The Dutch study collected data on the causes of the adverse events, and results showed that 41% of the adverse events had an unknown cause. Of the other adverse events, most were caused by human factors (56%) (e.g. lack of knowledge, attitude or skills) and patient factors (39%) (e.g. co-morbidity, age, compliance or communication). Fewer adverse events were caused by breaking the rules (15%), and organisational factors (14%) (e.g. protocols, communication, culture).<sup>12</sup>

While the studies mentioned above were not performed in nursing homes, other studies show that adverse events, such as urinary tract infections, pneumonia, falls, pressure ulcers and medication errors, also occur frequently in nursing homes.<sup>13-18</sup> An earlier Dutch study on the twenty most frequently occurring adverse events during patients' stay in a nursing home showed an incidence of 9% adverse events per 1000 patient days.<sup>15</sup> Urinary tract infections, side effects of medication, constipation, pneumonia and pressure ulcers were the most frequently diagnosed adverse events.<sup>15</sup> In a more recent study, the incidence of healthcare-associated infections in nursing homes was studied and showed an incidence of 1% infections per 1000 patient days.<sup>17</sup> Urinary and lower respiratory tract infections were the most common.<sup>17</sup>

In hospitals and nursing homes, a proportion of the adverse events is related to suboptimal nursing care. Nurses taking care of patients 24 hours a day, seven days a week have an important role in preventing adverse events. Examples of adverse events which can often directly be linked to suboptimal nursing care, and generally are considered preventable are certain medication errors, pressure ulcers, infections and falls.<sup>11,13,14,19-21</sup> Evidence based guidelines are available for the prevention of several adverse events. They are an important aid in translating research evidence into daily practice.<sup>26</sup> In nursing, the use of research evidence is referred to as evidence-based practice, which can be defined as 'the conscientious, explicit, and judicious use of current best evidence in making decisions about the care for individual patients'.<sup>22</sup> Unfortunately, numerous examples show that evidence based guidelines are often not implemented in daily nursing care and it is difficult to change nurses' behaviour in order to implement evidence based guidelines. For example, the study of De Laat et al. (2006) showed that it was very difficult to implement the policy of effective measures for pressure ulcer prevention.<sup>23</sup> Another example is the non-compliance of hospital workers to hand hygiene prescription.<sup>24</sup> The overall low compliance rate of nurses with these guidelines is a serious threat to patient safety. This situation is similar in nursing homes<sup>25</sup> and implementing new evidence such as ineffective use of restraints for preventing falls is difficult.<sup>26</sup> As a result, many patients do not receive optimal care.<sup>19,28,29</sup>

### *Implementation of guidelines*

Implementation of guidelines can be described as a planned process and systematic introduction of innovations and/or changes of proven value.<sup>30</sup> Wensing and Grol (2005) developed a model for effective implementation of change in healthcare practice.<sup>32</sup> In general, many factors or barriers may influence compliance -or non compliance- with a guideline.<sup>27</sup> These general barriers may be related to the individual healthcare professional, the individual's social context, or the system, i.e. the organisational setting (Table 1).<sup>31</sup>

**Table 1. General barriers for changes**

Element	Possible barriers
<b>Individual barriers</b>	
Competence	Knowledge and skills for use, insight into own routines, ability to learn new insights
Attitudes	Opinion on the innovation and its feasibility in practice
Motivation for change	Dissatisfaction with current routines
Individual characteristics	Age, gender, membership of professional organisations, self-efficacy and learning style
<b>Social setting barriers</b>	
Patients	Needs and preferences, personal characteristics and perceptions of wishes of the patient
Colleagues	Opinions of colleagues, opinion leaders and professional network
<b>Organisational barriers</b>	
Organisation and/or structure	Structural conditions, volume, bounded rationality, interests and resources
Financial reimbursements	Fee for service or fixed payment system, financial interest and targeted financial incentives

The table is reproduced from chapter 6 written by Wensing & Grol (2005).<sup>32</sup>

*Individual barriers:* barriers related to the individual care professional are competence, attitude, motivation for change, and individual characteristics. Examples of the barriers regarding the individual's competence are lack of knowledge and skills. These are important barriers, since the use of a guideline often requires specific knowledge and skills. Therefore, these attributes are necessary to ascertain the success of the implementation.<sup>34</sup> Also, the attitude of an individual towards a guideline may influence the implementation of guidelines. In this light, the complexity (how difficult it is to do) and visibility (how obvious any change is and how quickly it will occur) of a guideline are important characteristics of guidelines in judging the features of guidelines.<sup>32</sup> An individual's motivation for change can be another barrier and relevant to the achievement of change. In many cases, the motivation to change grows gradually under the influence of experiences in practice or information about a specific routine.<sup>32</sup>

*Social setting barriers:* barriers related to the social setting are for instance patients and colleagues. Patient characteristics can stimulate or inhibit change of professional routines and professionals can be influenced by opinions of colleagues in their direct environment.<sup>31</sup>

*System barriers:* Barriers related to the system are organisation and/or structure and financial reimbursements. The unavailability of the necessary materials is also an important organisational barrier.<sup>32</sup>

To gain a clear insight into these general barriers, it is important in each implementation process to analyse the target group and setting before the implementation of a guideline.

Besides these general barriers that inhibit implementation, specific problems exist with the implementation of guidelines, such as lack of insight into actual performance of guideline based care. To overcome this, recently developed guidelines mostly include guideline based indicators. These indicators can support the evaluation of the performance of the implementation process and stimulate the use of guidelines.<sup>35</sup> Yet, organisations are not always familiar with the principle of monitoring these indicators when implementing a guideline. Another problem is the large number of guidelines. As there are guidelines on so many topics, organisations can never implement all existing guidelines. They have to decide which guidelines have priority. This means that guidelines are competing for attention and cannot all be implemented, at the same time. A further problem is the time consuming process of implementing guidelines. Implementation includes translating each guideline to the target group, and developing and organising targeted information and education.

### *The programme*

A major challenge for organisations would be to move beyond "single project thinking". Single project thinking refers to the sequence of performing one implementation after another, each implementation aiming at the introduction of a single guideline or innovation (i.e. an implementation on fall prevention, followed by an implementation on pain management, followed by an implementation on pressure ulcer prevention). Several risks come with this single project approach. First, other improvements cannot be accomplished during the course of an implementation (e.g., this year we focus on pain management). Second, the sequence of projects could be inefficient and does not recognise other topics related to overall quality of care and requiring similar processes.

We wanted to support organisations with the implementation of guidelines by developing a programme that would simplify guidelines into workable instructions and structure the implementation process. We set out to develop a general framework aiming at the integration of guidelines in daily work. With such a general and structural programme we assumed that it would be possible to implement multiple guidelines

simultaneously. In order to find out if such programmes already existed, we started a literature search on the effectiveness of programmes that focus on the prevention of different adverse events simultaneously (chapter 2), in hospitals or nursing homes. As we could not find any such publications, we assumed that no such studies have been done previously, and we decided to develop a programme that allows organisations to implement multiple guidelines, simultaneously.

Besides developing a programme that allows organisations to implement multiple guidelines, it was also challenging to implement such a programme. Reviews by Grol and Grimshaw (2003)<sup>28</sup> and Grimshaw and Eccles (2004) provide overviews of evidence regarding implementation strategies in medicine.<sup>33</sup> The studies of Halfens and Van Linge (2003) and Van Achterberg et al. (2008) show many different kinds of implementation strategies used in nursing studies.<sup>19,29</sup> Often investigated implementation strategies are education and performance feedback as single strategies.<sup>19</sup> In nursing studies, multifaceted implementation strategies always consist of education, with one or more other added strategy(ies).<sup>19</sup> In an implementation process, education is often a necessary first step to implement a guideline or innovation, but the effects of education on behaviour are limited.<sup>34</sup> A multifaceted implementation strategy is probably more effective, as it addresses multiple barriers and needs, but it is not a guarantee for success.<sup>28,36</sup> It is important to tailor the implementation activities to the relevant barriers and needs of the target group.<sup>28</sup> For this reason, we wanted to develop a multifaceted implementation strategy for the implementation of our multiple guideline programme and additionally tailor the implementation activities to the relevant barriers and needs of the different wards. Therefore, we involved the target group in the development of the multifaceted implementation strategy.

We wanted to develop a patient safety programme (SAFE or SORRY?) that allows organisations to implement multiple guidelines simultaneously. Since this is the first study that investigates the implementation of multiple guidelines at the same time, it is unknown how many guidelines could effectively be implemented at the same time. Therefore, we chose to develop the SAFE or SORRY? programme for three frequently occurring nursing care related adverse events which had evidence based guidelines for preventive care: pressure ulcers, urinary tract infections and falls. The occurrence of pressure ulcers and falls are both often investigated adverse events. The prevalence and incidence of pressure ulcers grade 2 or worse varies from 3 to 12% in hospital and

nursing home patients in the Netherlands,<sup>37,38</sup> and the incidence of falls varies from 1 to 6% in hospitals and nursing homes.<sup>38-44</sup> For urinary tract infections, the prevalence of bacteriuria varies from 18-28% in nursing homes<sup>43</sup> and the incidence of a symptomatic urinary tract infection is about 1% in hospitals and nursing homes.<sup>15-17,46</sup>

To investigate whether this patient safety programme would decrease the number of adverse events, we tested the effectiveness of this programme in hospitals and nursing homes.

### **Aim of the thesis**

The aim of this thesis is to develop and test a patient safety programme that addresses implementation of multiple guidelines simultaneously in hospitals and nursing homes. Our primary outcome was the incidence of the three adverse events. We wanted to investigate whether the patient safety programme decreased the incidence of the three adverse events (sum of the incidence of pressure ulcers, urinary tract infections and falls) in hospitals and nursing homes. We wanted to know whether the patient safety programme increased the preventive care given and whether it increased the knowledge of nurses regarding the prevention of the three adverse events. Therefore the secondary outcomes of the study were 1) the percentage of patients that received preventive care and 2) nurses' knowledge regarding the three adverse events.

### **Outline of the thesis**

Chapter 2 describes a review on the effectiveness of programmes that focus on the prevention of different adverse events simultaneously, in hospitals or nursing homes. The databases of Pubmed, CINAHL, EMBASE, Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects were searched for the period 1980 to 2009. Chapter 3 reports on the development of the patient safety programme (SAFE or SORRY?) and the design of the SAFE or SORRY? study, in which we have tested the effect of this patient safety programme in hospitals and nursing homes. Chapter 4 describes the incidence of the three concurrent adverse events and the preventive care given in hospitals and nursing homes. Chapter 5 describes whether our patient safety programme decreased the incidence of adverse events. The outcome was the incidence of the three adverse events per patient week, which is the primary outcome of our study. Chapter 6 describes whether our patient safety programme increased preventive care to patients at risk for these three adverse

events. In chapter 7, we describe whether our educational programme improved the nurses' knowledge on the prevention of pressure ulcers, urinary tract infections and falls. The outcome was the score on a test regarding the prevention of pressure ulcers, urinary tract infections and falls. Finally, in chapter 8, we discuss the findings, conclusions methodological considerations, and implications for practice and future research and in chapter 9 and 10, we end with a summary in English and Dutch.



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## Chapter 2

**SAFETY IN NURSING – where comprehensive efforts in the prevention of adverse events are lacking**

Lisette Schoonhoven

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**Abstract**

*Aim:* To identify publications describing trials on the effectiveness of programmes that focus on the prevention of different adverse events simultaneously, in hospital patients or nursing home residents.

*Background:* Although guidelines are available, nursing care often remains suboptimal, resulting in adverse events. As developing separate implementation programmes for every guideline is not feasible, a major challenge for nursing practice is to develop innovations aimed at more than one adverse event at a time.

*Data Sources:* Pubmed, CINAHL, EMBASE, Cochrane Database of Systematic Reviews (CDSR) and Database of Abstracts of Reviews of Effects (DARE) between 1980 and 2009.

*Review Methods:* Inclusion criteria: studies in adult hospital patients or nursing home residents; describing programmes that aim at the prevention of  $\geq 2$  adverse events simultaneously; nurses involved in the programme; comparison of outcomes with either baseline data in the same group or outcome data in a comparison group or reviews of these trials; one out of four possible outcomes: 1) incidence or prevalence of adverse events, 2) knowledge or skills of care givers, 3) performance of adequate preventive measures, 4) degree of monitoring or registration of adverse events.

Two reviewers independently assessed retrieved studies for inclusion.

*Results:* No studies aimed at the prevention of  $\geq 2$  adverse events simultaneously were found.

*Conclusion:* Integrated programmes for the prevention of multiple adverse events are urgently needed. They could be effective and efficient, and could reduce 'project tiredness' caused by many subsequent, single problem focused guideline projects.

## Introduction

Patients in health care settings are at risk for adverse events. Retrospective studies of hospital case records have shown that 2.9% to 16.6% of the patients in acute care hospitals experienced at least one adverse event during admission.<sup>1-5</sup> Approximately 50% of the adverse events were considered preventable. There are no major analyses of nursing home records available. However, several studies showed that adverse events such as pressure ulcers, falls, and medication errors frequently occur in nursing homes.<sup>6,7</sup>

Current attention for patient safety has resulted in various (research) projects attempting to improve patient safety. While many of these projects focus on medical procedures, i.e. medication prescription<sup>8</sup>, or surgical procedures<sup>9</sup>, improvement of patient safety is equally relevant to nursing care. Prevention of adverse events such as pressure ulcers, accidental falls, and infections is mainly the responsibility of nurses.

Despite the fact that there is (strong) evidence for several interventions<sup>10</sup>, nursing care often remains suboptimal, i.e. is not evidence informed. This has several reasons. First, although the interventions are often made available through guidelines, guidelines contain many recommendations, thus complicating straightforward implementation in practice. Moreover, many organizations do not have policies for the introduction of new guidelines.<sup>11</sup> Also, guidelines often compete for attention as every guideline requires a considerable amount of resources and attention from the organization and the health care workers involved. Implementing multiple guidelines thus leads to 'project-tiredness' in clinical practice. This hampers the ability to implement all relevant guidelines in practice, and therefore the possibility to improve the prevention of several adverse events simultaneously.

The challenge for nursing practice is to develop a way of dealing with these problems in order to improve nursing care on more than one adverse event at a time.

## Aim

The aim of this systematic literature search was to identify publications that describe reviews and trials on the effectiveness of prevention programmes that focus on the prevention of different adverse events simultaneously, in hospital patients or nursing home residents.

## Methods

First, computerised databases of Pubmed, CINAHL, EMBASE, Cochrane Database of Systematic Reviews (CDSR) and Database of Abstracts of Reviews of Effects (DARE) were searched using the search strategy described in Table 1. The sub-searches for population, intervention and outcome were combined using the Boolean operator 'AND'. The search was limited to papers with the search terms in the title or abstract. Next, the search was combined with a methodological filter limiting the search to literature reviews and (controlled) trials. The search was then limited to papers concerning adult patients, published between 1980 and April 2009, for which an abstract was available. Second, when relevant papers were found we planned to check the references to identify additional studies.

**Table 1. Search strategy**

<i>Population:</i>	patient OR resident OR hospital OR nursing home OR care facility OR institution
<i>Intervention:</i>	(prevent* OR manage* OR control* OR assess* OR monitor) AND (safe* OR complicat* OR risk* OR accident* OR hazard* OR adverse event OR adverse outcome OR pressure sore* OR pressure ulcer* OR infect* OR malnutrit* OR dehydrat* OR fall* OR injury)
<i>Outcome:</i>	incidence OR prevalence OR relative risk OR rate OR ratio OR event* OR knowledge OR skill* OR adher* OR monitor* OR registrat*
<i>Methodological filters:</i>	review OR randomized controlled trial OR trial
<i>Other limits:</i>	year of publication $\geq$ 1980, adult, search terms in title or abstract, nurs* in title or abstract, only publications with abstract

Terms for population, intervention and outcome combined with AND

### *Inclusion criteria*

The studies that were retrieved were independently assessed for inclusion by two reviewers (LS and TvA) and included when all of the inclusion criteria were met. Inclusion criteria were:

- Studies in (subgroups of) adult hospital patients or nursing home residents
- Studies describing programmes that aim at improving the prevention of  $\geq 2$  adverse event simultaneously
- Studies involving nurses in the programme (independently or as members of multidisciplinary teams)
- Studies fulfilling the minimum criterion of comparison of outcomes with either baseline data in the same group or outcome data in a comparison group; or reviews of these studies

- Studies describing one out of four possible outcomes:
  - incidence or prevalence of adverse events
  - knowledge or skills of care givers
  - performance of adequate preventive measures
  - degree of monitoring or registration of adverse events

Disagreement over inclusion between the reviewers was to be resolved through discussion. When no consensus could be achieved, a third researcher (BvG) had to decide.

## Results

The search identified a total of 2132 publications (Table 2). No studies aimed at the prevention of  $\geq 2$  adverse events simultaneously were found.

**Table 2. Databases**

	Hits	Included
National Library of Medicine (PubMed)	1286	0
CINAHL	556	0
EMBASE	440	0
Cochrane Database of Systematic Reviews (CDSR)	57	0
Database of Abstracts of Reviews of Effects (DARE)	5	0
Subtotal	2344	0
Duplicates	212	-
Total	2132	0

## Discussion

Given the increased attention for patient safety and the subsequent focus on preventing adverse events by evidence informed nursing and working according to guidelines, we were surprised that we did not find any studies that addressed the issue of prevention of different adverse events simultaneously.

There are several possible explanations for this result. First, nurses and managers may lack an integral vision on patient safety. Two mechanisms may be underlying this lack of vision. Nurses and managers may work ad-hoc, i.e. only solving emerging problems without anticipating on future problems. Others may be focused on individual nursing safety issues such as preventing pressure ulcers or accidental falls, or individual medical

safety issues such as preventing medication prescribing errors, thus missing the larger picture. Second, studies looking at more than one safety issue are probably more large-scale, expensive and labour intensive. Researchers may not be willing to take the risk of undertaking such a study, as these projects could be difficult to manage and finance. Also, there could be a problem concerning interaction between the interventions, resulting in synergism or opposing effects, which are difficult to analyse. Third, barriers to implementation are often perceived as unique to the project at hand, while in fact many determinants for success are common to many innovations, e.g. knowledge, skills, motivation and social influence amongst colleagues.<sup>12</sup> Finally, guidelines contain a large amount of information and recommendations, and more recent guidelines also contain guideline specific recommendations for implementation. Organisations could find it too difficult and time consuming to aim their attention at two or more guidelines at the same time, specifically if they recommend different implementation strategies. While this is understandable, aiming at only one guideline at a time is not an advisable policy when an organisation wants to drive the number of adverse events back.

There are two solutions worth exploring: simplification of guideline recommendations and developing a standard framework for implementation.

Simplification of guideline recommendations could be achieved by developing so-called bundles. The concept of bundles was introduced by the Institute for Healthcare Improvement (IHI) for the improvement of critical care ([www.ihl.org](http://www.ihl.org)). A bundle is defined as "a structured way of improving the processes of care and patient outcomes: a small, straightforward set of practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes". The practices in a bundle are evidence based, focusing on how the care should be delivered and not on which care should be delivered. These practices are often not new, they are just not performed uniformly and often enough, increasing unreliability of prevention or treatment. A bundle ties all the practices together into a package of interventions that health care workers know must be followed for every patient, every single time. Examples are the severe sepsis bundle and the ventilator bundle developed for critical care ([www.ihl.org](http://www.ihl.org)). Developing bundles for adverse events commonly associated with nursing care, e.g. pressure ulcers, accidental falls, based on the available guidelines, allows summarising the relevant information per guideline, and could thus be an improvement when dealing with the extent of information per guideline. Although standardization of care holds the risk that care becomes poorer, bundles



could be a first step in improving patient safety, particularly in organisations where preventive care is delivered poorly.

A standard framework for implementation could facilitate implementation of new guidelines. As stated before, barriers to implementation are often wrongfully perceived as unique to the project at hand. Knowledge, skills, motivation and social influence amongst colleagues are determinants for success in many innovations.<sup>12</sup> This implies that education, training, feedback and reminders, and social influences strategies such as team discussions or role modelling should always be considered a part of any implementation strategy. Developing standards for these strategies, e.g. a standard format for group education, followed by individual education via a standard website, a standard format for posters to deliver feedback, etc., allows organisations to easily adapt the content of the material for every new guideline, without the need to design the entire implementation strategy again. It also gives organisations the opportunity to build on their own experiences about what works in their organisation.

A subsequent step would be to implement bundles in practice simultaneously, and evaluate their effect on the prevention of adverse events as well as the effectiveness of the approach.

### *Conclusion*

Although developing and testing programmes for preventing several adverse events simultaneously makes perfect sense from a practical nursing perspective, this has never been described in the international literature of the last 28 years.

We believe that integrated programmes for the prevention of multiple adverse events could be both effective and efficient, and could end 'project tiredness' caused by many subsequent, single problem focused guideline projects in current practice. Therefore, we conclude that this area deserves to be explored.

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## Chapter 3

### **The design of the SAFE or SORRY? study: a cluster randomised trial on the development and testing of an evidence based inpatient safety programme for the prevention of adverse events**

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**Abstract**

*Background:* Patients in hospitals and nursing homes are at risk of the development of, often preventable, adverse events, which threaten patient safety. Guidelines for prevention of many types of adverse events are available, however, compliance with these guidelines appears to be lacking. Besides general barriers that inhibit implementation, this non-compliance is associated with the large number of guidelines competing for attention. As implementation of a guideline is time-consuming, it is difficult for organisations to implement all available guidelines. Another problem is lack of feedback about performance using quality indicators of guideline based care and lack of a recognisable, unambiguous system for implementation. A programme that allows organisations to implement multiple guidelines simultaneously may facilitate guideline use and thus improve patient safety.

The aim of this study is to develop and test such an integral patient safety programme that addresses several adverse events simultaneously in hospitals and nursing homes. This paper reports the design of this study.

*Methods and design:* The patient safety programme addresses three adverse events: pressure ulcers, falls and urinary tract infections. It consists of bundles and outcome and process indicators based on the existing evidence based guidelines. In addition it includes a multifaceted tailored implementation strategy: education, patient involvement, and a computerised registration and feedback system. The patient safety programme was tested in a cluster randomised trial on ten hospital wards and ten nursing home wards. The baseline period was three months followed by the implementation of the patient safety programme for fourteen months. Subsequently the follow-up period was nine months. Primary outcome measure was the incidence of adverse events on every ward. Secondary outcome measures were the utilization of preventive interventions and the knowledge of nurses regarding the three topics. Randomisation took place on ward level. The results will be analysed separately for hospitals and nursing homes.

*Discussion:* Major challenges were the development of the patient safety programme including a digital registration and feedback system and the implementation of the patient safety programme.

## Background

Over the past seventeen years several studies showed that patients are at risk of injuries or even death as a result of care delivered in hospitals.<sup>1-11</sup> These studies show that 2.9 to 16.6% of patients in acute care hospitals experienced at least one adverse event (Table 1).<sup>1,2,9-11</sup> In 5 to 13% of these events the patients died.<sup>1-3,7,9-11</sup> Half of all events are considered preventable.<sup>1,3,6,9-11</sup> While these studies did not include nursing homes, other studies show that adverse events, such as urinary tract infection, pneumonia, falls, pressure ulcers and medication errors, also occur frequently in nursing homes.<sup>12-14</sup> These events can often be linked directly to suboptimal nursing care, and they are generally considered preventable.

Many guidelines for the improvement of nursing care are available, however compliance with these guidelines appears to be lacking.<sup>15</sup> Generally, many factors or barriers may influence compliance -or noncompliance- with a guideline. These general barriers may be related to the individual (e.g. knowledge, skills, attitudes, motivation) or the individual's social context (e.g. patients, colleagues, culture), and the organisational setting (e.g. financial, equipment). Moreover, the large number of guidelines competing for attention makes it difficult to keep track of all of them. In addition, organisations must translate each guideline to their own target group, and develop and organise their own information and education, which is a time-consuming process. Also, there is a lack of insight into actual performance of guideline based care, e.g. by using quality indicators.<sup>16</sup> As a result, it is difficult to implement all available guidelines necessary for good quality daily nursing care. This situation is at odds with the responsibility of professionals to ensure patient safety. A programme that allows organisations to implement multiple guidelines simultaneously may facilitate guideline use and thus improve patient safety.

The aim of this study is to develop and test such an integral patient safety programme that addresses several adverse events simultaneously in hospitals and nursing homes.

In this paper we will report on the design of this study, which has two phases. The first phase concerns the development of the patient safety programme for three frequently occurring nursing care related adverse events: pressure ulcers, falls and urinary tract infections. The second phase describes the evaluation of the patient safety programme in a cluster randomised trial.

## Methods and design

### *Phase 1: the development of the patient safety programme*

#### *General focus of the programme*

From September 2005 through July 2006 we developed the integral patient safety programme (SAFE or SORRY?) for the prevention of pressure ulcers, falls and urinary tract infections in hospitals and nursing homes. The programme consists of bundles<sup>18</sup> (Table 1) and outcome and process indicators based on evidence based guidelines for pressure ulcers, falls and urinary tract infections.

For the implementation of guidelines, multifaceted implementation strategies are probably more effective than single strategies, as multifaceted strategies address multiple barriers to guideline adherence.<sup>17</sup> Therefore, we aimed at developing a multifaceted strategy for the implementation of these bundles.

**Table 1. Definitions**

<b>Adverse event</b>
An adverse event is defined as an unintended injury that results in prolonged stay, disability at the time of discharge, or death and is caused by health care management rather than by the patient's underlying disease process. <sup>1,3,9,11</sup>
<b>Bundle</b>
A bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of practices - generally three to five - that, when performed collectively and reliably, have been proven to improve patient outcomes. <sup>18</sup>

#### *Development*

We developed the patient safety programme with experts on each topic by collecting the existing guidelines<sup>19-27</sup> and supplementary material.<sup>28-41</sup> Based on this information the research group and the experts achieved consensus about the essence of the guidelines and formulated the bundles and indicators (Table 2). They developed a multifaceted implementation strategy consisting of education, patient involvement, feedback through a computerised registration programme and an implementation plan for every ward (Table 3).

#### *Tailoring*

We discussed the bundles and indicators with the user group. This group consisted of two researchers (LS and BvG), seventeen future users of the patient safety programme, two medical doctors and an implementation expert (MH) and met five times. During the first meeting everyone was informed about the aim and work methods. During the next three meetings the group was split up into two smaller groups: a group with users

from the hospitals and a group with users from the nursing homes. In each group we had focus discussions about the use of the bundles and indicators and the expected barriers for implementation. During the fifth meeting the group tested the computerised registration programme. With this information, and the outcome on the knowledge test from the baseline measurement (phase 2), we tailored the education for the nurses to each individual ward in the intervention group. In a last meeting, the users of the intervention group tested the final educational material and the patient information. In order not to contaminate the control group with the elaborated education material and patient information, the users of this group were not invited to this last meeting.

**Table 2. Process (P) and outcome (O) indicators**

<b>Pressure Ulcers</b>
% patients where nurses assessed pressure ulcer risk (P)
% patients at risk for pressure ulcers (O)
% patients with pressure ulcers grade 2 or worse (O; prevalence)
% patients developing nonblanchable erythema (O; incidence)
% patients developing pressure ulcers grade 2 or worse (O; incidence)
% patients developing pressure ulcers grade 2 or worse at the heels (O; incidence)
% patients at risk receiving permanent adequate preventive measures (P)
% patients developing pressure ulcers despite the preventive measures (O)
% patients with pressure ulcers increasing in grade and/or becoming more serious (O)
<b>Urinary tract infection</b>
% patients where nurses assessed risk for urinary tract infection (P)
% patients at risk for urinary tract infections (O)
% patients with urinary tract infections (O; prevalence)
% patients with fecal incontinence with urinary tract infections (O; prevalence)
% patients with urinary tract infections who have of had a bladder catheter (O; prevalence)
% patients developing urinary tract infections (O; incidence)
% patients at risk receiving permanent adequate preventive measures (P)
% patients with an appropriate/correct indication for indwelling bladder catheter (P)
<b>Falls</b>
% patients where nurses assessed risk for falling (P)
% patients at risk for falls (O)
%patient falls (O; prevalence)
% patients at risk that received multi-factorial measures (P)
% patients in which both risk factors and multi-factorial measures were evaluated regularly (P)
% patient that fell despite multi-factorial measures (O)

Table 3 describes the concrete implementation strategies for the patient safety programme. In addition, every intervention ward appointed two key nurses to the study. Together with the head nurse they were responsible for the implementation of the patient safety programme on their ward. At the start of the implementation period these key nurses received a training in the use of the patient safety programme. We also discussed the results of the baseline measurements (phase 2) and the educational

material, and all educational activities on the wards were planned and organised. The key nurses and the researcher had periodical contact about the progress on the ward, throughout the implementation period.

**Table 3. Operational implementation strategies**

<b>Education</b>
Group lesson on the wards for all nurses
A CD-ROM with education material and a knowledge test
Case discussions on every ward
<b>Patient involvement</b>
An information folders for the prevention of pressure ulcers, urinary tract infection and falls, separately. In addition to giving oral information nurses were asked to give the folder to patients at risk for the specific adverse event.
<b>Feedback</b>
The nurses register the patient's daily care and the presence or absence of an adverse event in a computerised registration system. This digital programme generates feedback by charts on the process and outcome indicators.

## ***Phase 2: cluster randomised clinical trial to evaluate the patient safety programme***

### *Study design and setting*

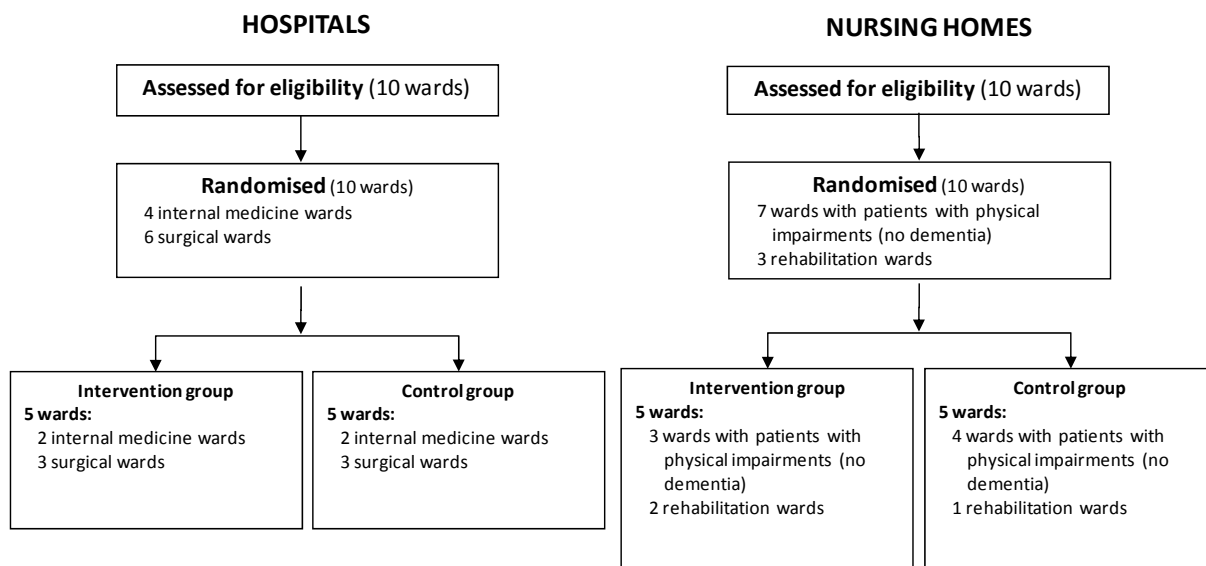
A cluster randomised trial was conducted between September 2006 and November 2008 in the Netherlands. Hospitals and nursing homes were asked to participate with two or four, more or less comparable, wards. The hospital wards (n=10) were internal medicine wards (n=4) and surgical wards (n=6) from four hospitals. The nursing home wards (n=10) were wards with patients with physical impairments (no dementia n=7) or rehabilitation wards (n=3) from six nursing homes. The randomisation of the wards was stratified for centre and type of ward (Figure 1) and took place prior to baseline data collection.

Baseline data collection took place from September through November 2006. Subsequently, the patient safety programme was implemented on the intervention wards: five hospital wards and five nursing home wards from December 2006 through February 2008. The wards of the control group continued care as usual. The follow-up period was nine months and continued until the end of November 2008.

The Medical Ethics Committee of district Arnhem – Nijmegen assessed the study and waived the need for complete evaluation of the study.



Figure 1. Flow diagram



### *Study population*

Adult patients ( $\geq 18$  years) admitted to the hospitals or the nursing homes during our study, were asked to participate. Hospital patients with an expected stay of at least five days were asked within 48 hours after admission. After a written informed consent the research assistants visited the patients once a week. All patients with at least a second visit were included in this study.

All (clinical) nurses at the wards participated in our study.

Nurses' aids and students were excluded.

### *Outcome measures*

The primary outcome measure was the incidence of adverse events (sum of the incidence of pressure ulcers, urinary tract infections and falls).

A *pressure ulcer* is an area of localised damage to the skin and underlying tissue caused by a combination of pressure and shear.<sup>22</sup> Pressure ulcers are classified in four grades according to the guidelines.<sup>20,22,41</sup> Pressure ulcers were considered present if a patient developed a pressure ulcer grade 2 or worse. If a patient had a pressure ulcer grade two or worse at the first visit, that pressure ulcer lesion was excluded from the registration of pressure ulcers until the pressure ulcer healed. Patients with an already present pressure ulcer grade two or worse were only registered if they developed additional pressure ulcer lesions.

A *urinary tract infection* is bacteriuria with clinical symptoms as: frequent urinating, pain while urinating, abdominal pain, fever and delirium, urinary incontinence.<sup>19,25</sup> During this study we defined a urinary tract infection as present if it was diagnosed by a medical doctor. Patients were excluded from the registration of urinary tract infection for a period of three weeks if they had a urinary tract infection until the infection was cured.

A *fall* is an unexpected event in which the participant comes to rest on the ground, floor, or lower level.<sup>21,42</sup> In this study the falls were measured by examining the patient files, assuming that if a patient fell it was reported in his or her file.

The secondary outcome measures were 1) the percentage of patients that received preventive care and 2) the knowledge of nurses regarding the three topics.

*Prevention* is important in patients at risk for one of the adverse events. Preventive measurements were considered present when the care was performed according to the guideline.

The risk of *pressure ulcers* was measured with the PrePURSE<sup>28</sup> and the Braden scale<sup>43</sup> in hospitals and nursing homes, respectively. Next, preventive care was measured: position while lying or sitting; if patients' heels were lifted; use of pressure-reducing material or alternating pressure material in bed or chair; presence of a repositioning scheme.

Hospital patients were at risk for a *urinary tract infection* if they had at least one of the next four risk factors<sup>19,24</sup>: 1) a urinary catheter in situ or the week before, 2) incontinence of faeces, 3) urinary retention or 4) a urinary tract infection in the last two years. According to the guideline, all nursing home patients were considered at risk for a urinary tract infection.<sup>19</sup> Next, preventive care was measured: personal hygiene, frequent toilet visits, unnecessary indwelling catheter and unobstructed urine flow.

To identify hospital patients at risk for *falls* we used the STRATIFY.<sup>44</sup> According to the guideline all nursing home patients were considered at risk for falls, except those who were totally immobile.<sup>21</sup> Next, preventive care was measured: if the file had a written multidisciplinary plan with multi-factorial preventive interventions; a periodic

evaluation of the multidisciplinary plan; a periodic evaluation of the multi-factorial risk factors for falls.

The *knowledge of nurses* about risk assessment and effective preventive care was measured using a written knowledge test. Each topic had twenty questions, on which nurses could answer 'correct', 'not correct', or 'do not know'.

The knowledge test was developed from questionnaires<sup>45</sup> (knowledge test used in an implementation study of a pressure ulcer guideline in the Netherlands<sup>46</sup> and geriatric educational material of the prevention of falls, 2007) and student tests of the HAN University of Applied Sciences on the three topics. The face validity was tested by sending the questionnaire to the members of the research group (LS, JM, RK and TvA), and the expert on each topic. Finally, nurses in hospitals and nursing homes were asked to pre-test the questionnaire.

## Data collection

During the baseline and follow-up period, the patient data were collected in two ways. To measure adverse events and preventive care, the research assistants read the patient files and observed the patients during a weekly visit. To measure the utilisation of preventive care, wards were visited three times by research assistants. At each visit they observed a sample of at least five patients and nurses during their daily activities for five hours.

All nurses were asked to fill out a questionnaire at the start of the baseline period and the follow-up period.

## Statistics

Power calculation was based on the primary outcome, with a two-sided alpha of 0.05 and 80% power for the analysis of both the hospital and the nursing homes data.

As randomisation was on ward level, a ward was considered to be a cluster. To account for these clusters an intra class correlation coefficient of 0.01 was used in the calculation.

In hospitals, the incidence of pressure ulcers (10%) will be the highest contributor to our combined adverse event measure. The incidence of urinary tract infection and falls in the same patients is unknown. Therefore we assumed that the count of these three adverse events will be 12% (an additional 1% for falls and 1% for urinary tract

infections). We aimed to achieve a reduction of 50% as studies on the prevention of pressure ulcers have shown this is attainable.<sup>47,48</sup> To detect a decrease in adverse events (from 12%–6%) 1250 patients had to be included in each hospital group.

In the nursing homes, the incidence of falls will be the highest (60%). We assume that the additional contribution of pressure ulcers and urinary tract infection to adverse events will be negligible. We aimed to achieve a reduction of 60% as a study on the prevention of falls showed this was attainable.<sup>49</sup> Therefore this study wanted to achieve a reduction of adverse events from 60–36%. To detect this decrease in the nursing homes, 100 patients had to be included in each group.

The results will be analysed separately for hospitals and nursing homes, as patient characteristics, length of stay and nurse characteristics differ between hospitals and nursing homes.

The difference in incidence of adverse events between the intervention and the control group during the follow-up period will be analysed using a random effects Poisson regression analysis, including the following covariates: ward (random effect), institution and the baseline results of the ward.

The secondary outcomes will be evaluated in a similar way, using linear and logistic random effect models.

## **Discussion**

As implementation of a guideline is time-consuming, it is difficult for organisations to implement all available guidelines. Also, lack of feedback about performance using quality indicators of guideline based care and lack of a recognisable, unambiguous system for implementation often impede guideline implementation. A programme that allows organisations to implement multiple guidelines simultaneously may facilitate guideline use and thus improve patient safety.

This study posed several challenges concerning the development of the complex intervention, the implementation of this intervention and the design of the trial. For the development of our intervention we used available guidelines on each topic. Translating three extensive guidelines into a manageable proposal for improving patient care is not

easy. We chose to combine the essence of each guideline into a recognizable simple structural approach, and reduced the guidelines on each topic into two or three bundles. These bundles were easier to use in daily practice.

The aim of the digital registration and feedback system was to provide the nurses on the ward with feedback on the performance of guideline based care. As we anticipated that nurses have limited computer skills and limited time to register all patients daily, we paid extra attention to the accessibility and performance of the digital programme. This programme was subsequently pre-tested during the first phase of this study in a group of future users and it was obvious that we had managed to develop a digital registration and feedback system that was user-friendly for all nurses on the wards. Also, the time it takes to register all patients on the wards was considered acceptable.

Our next challenge was the implementation of our intervention. Many factors may enhance or inhibit implementation. Therefore it is important to analyse the target group.<sup>51</sup> To be successful, we developed a multifaceted implementation strategy that could be tailored to each specific ward. By tailoring the strategy to the barriers of the individual wards we developed an individual implementation plan for each ward that considered the context of that particular ward.

The implementation of the digital registration and feedback system was even more complex. Currently, registration of patient care in a computer is not a standard procedure in the Netherlands. The nursing files are still mainly paper files. Moreover, not all nurses of the participating wards were used to working with a computer and on some wards the nurses did not even have access to a computer or the internet. We explored these barriers in a very early stage of the implementation process. This allowed us to remove the practical barriers, i.e. attaining access to a computer and the internet, and organise training programmes for nurses to improve computer skills. Also, it gave the wards the opportunity to adopt the idea of registration of patient care on a computer. By the time they had to work with the digital registration and feedback system they were already used to the idea of using a computer.

Unfortunately it was not possible to prevent double registration of patient data: nurses had to write patient files and also register the patient daily care in the computer. This is only worthwhile when the digital programme is of benefit to the nurses. Therefore, nurses were trained and encouraged to use the feedback provided by the digital programme to evaluate and adjust daily care.

The final challenge we want to discuss is the design of the cluster randomised trial. Cluster randomised trials are more complex to perform, as they require more participants,<sup>50</sup> due to the correlation between individuals in the same ward. In this study we took this into account by including an intra cluster correlation coefficient in the power calculation. As a result we had to include many hospital patients: 1250 in each group. To include and follow-up that many patients in such a short time is ambitious, but we are convinced that it is achievable. Also, analyses of cluster randomised trials are complex. For analysing the effect of an intervention, a regression analysis including covariates should be used to account for the influence of the wards. Therefore this study will consider the following covariates: ward (random effect), institution and the baseline results of the ward.

Dissemination of the results of this study is planned for 2009.

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## **Chapter 4**

### **Incidence of three adverse events in the Netherlands: a prospective cohort study**

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**Abstract**

*Background:* Patients in hospitals and nursing homes are at risk for preventable adverse events. unknown is the concurrent incidence of these three nursing care related adverse events in hospital and nursing home patients.

*Objective:* To describe the concurrent incidence of pressure ulcers, urinary tract infections and falls, and the preventive care given to patients at risk for the three adverse events.

*Design and setting:* A prospective, three-month, cohort study on ten hospital- and ten nursing home wads in the Netherlands. Weekly visits and additional observations were used to assess the incidence of adverse events and preventive care.

*Participants:* 687 hospital and 241 nursing home patients.

*Main outcome measure(s):* The incidence of three adverse events and preventive care given to patients at risk.

*Results:* Seventy seven hospital patients (11%) and 111 nursing home patients (46%) developed one or more adverse events. The incidence rate for both was 9% adverse events per patient week.

In hospitals, 34% of the patients at risk for pressure ulcers, 47% of the patients at risk for urinary tract infections and none of the patients at risk for falls received adequate preventive care. In nursing homes, 18% patients at risk for pressure ulcers, 42% patients at risk for urinary tract infections and less than 1% patients at risk for falls received adequate preventive care.

*Conclusion:* There was a high incidence of adverse events in both hospitals and in nursing homes. The majority of the patients at risk did not receive adequate preventive care.

## Introduction

Patients in hospitals and nursing homes are at risk for the development of often preventable adverse events<sup>1</sup>, which compromise patient safety. Guidelines for prevention of many types of adverse events are available. Three frequently occurring nursing care related adverse events in hospitals and nursing homes for which guidelines on preventive care are available are pressure ulcers, urinary tract infections and falls.

An important outcome for the effect of preventive care for adverse events is the incidence rate i.e. the number of new adverse events per period of time. It is to be expected that when patients receive adequate preventive care, incidence rates will be low. Many studies investigated the incidence of individual adverse events, but there is a lack of insight into the concurrent incidence of adverse events for institutionalised patients. Therefore, the aims of this study are to describe the concurrent incidence of pressure ulcers, urinary tract infections and falls as well as the preventive care given to patients at risk for these three adverse events in hospitals and nursing homes.

## Methods

### *Design*

This prospective cohort study included patients from four hospitals (one university hospital, two large teaching hospitals and one small hospital) and six nursing homes in the Netherlands. The hospital wards (n=10) were internal medicine wards (n=4) and surgical wards (n=6). The nursing home wards (n=10) were wards for patients with physical impairments (no dementia) (n=7) or rehabilitation wards (n=3) (Figure 1). Between September and November 2006 all adult patients ( $\geq 18$  years) admitted to the wards were asked to participate. In hospitals, 867 patients with an expected stay of at least five days were asked to participate within 48 hours after admission. In nursing homes 308 patients were asked to participate at the start of the data collection period or within two weeks after admission. After written informed consent, research assistants visited the patients once a week until discharge, death or the end of the three month data collection period (Figure 1). All patients with a minimum of two visits were included in this study.

### *Outcome measures*

The main outcome was the incidence of adverse events (the sum of the incidents of pressure ulcers, urinary tract infections and falls divided by the total patient weeks). *Pressure ulcers*<sup>2-4</sup> were measured by observing the patients' skin and were considered present if a patient developed a pressure ulcer grade two or worse according to the EPUAP-classification system.<sup>4</sup> If a patient had a pressure ulcer grade two or worse at the first visit, this pressure ulcer lesion was excluded when calculating incidence rates until the pressure ulcer healed; all new pressure ulcer lesions were included. The presence of a *urinary tract infection*<sup>5</sup> needed to be confirmed by a physician. Patients with existing urinary tract infections were excluded from the calculation of the incidence rates of urinary tract infections for a period of three weeks until the infection was cured. *Falls*<sup>6,7</sup> were measured by examining the patient files. Consequently, all falls that occurred after the first visit of the research assistant and that were documented in the patient's file were included.

The second aim of the study was the assessment of the percentage of patients who received adequate preventive care according to the existing guidelines. This outcome was calculated for each adverse event separately, and only in patients who were considered to be at risk for the particular adverse event.

Patients at risk for *pressure ulcers* were patients with mobility or activity impairments according to the Braden subscales "mobility" and "activity" (score less than 3) and/or who were at risk according to a risk assessment tool. We used risk assessment scales that were developed for the various settings, i.e. the PrePURSE scale in hospitals<sup>8</sup> and the Braden scale<sup>9</sup> in nursing homes. Hospital patients were considered at risk, if they had a score of twenty or more on the PrePURSE scale. Nursing home patients were considered at risk if they had a score of 17 or less on the Braden scale. Preventive care was registered as "adequate" preventive care if the care for patients at risk who were lying in bed and/or sitting in a chair and who received the combined preventive activities described in Figure 2.<sup>2,3,10</sup>

Hospital patients were at risk for a *urinary tract infection* if they had at least one of the following four risk factors: 1) an indwelling catheter (urethra- or suprapubic catheter), currently or within the last seven days, 2) faecal incontinence, 3) urinary retention or 4) a urinary tract infection in the last two years.<sup>11,12</sup> All nursing home patients were considered at risk for a urinary tract infection.<sup>11</sup>

Preventive care was registered as "adequate" preventive care if the care for patients at risk and who received the combined preventive activities described in Figure 2.<sup>11,12</sup> To identify hospital patients at risk for *falls* the STRATIFY tool<sup>13</sup> was used. According to the CBO guideline, all nursing home patients were considered at risk for falls, except those who were totally immobile.<sup>6</sup> Preventive care was registered as "adequate" preventive care if patients at risk and who received the combined preventive activities described in Figure 2.

### *Data collection*

The data were collected during a weekly visit and by additional observations on every ward. During the weekly visits, we screened the patients' file for data on the occurrence of urinary tract infections and falls, and the preventive care given. We observed the patient for the presence of preventive measures and the patients' skin for the occurrence of pressure ulcer.

Through additional observations, we collected information on applied preventive measures (Figure 2). We performed the additional observations for at least five consecutive hours in a random sample of at least five patients per ward who participated in the study.

The data were collected by trained research assistants who were appointed to this study and trained in reading the patients' files, observing patients' skin and paying attention to signals that could point at adverse events, such as antibiotic use.

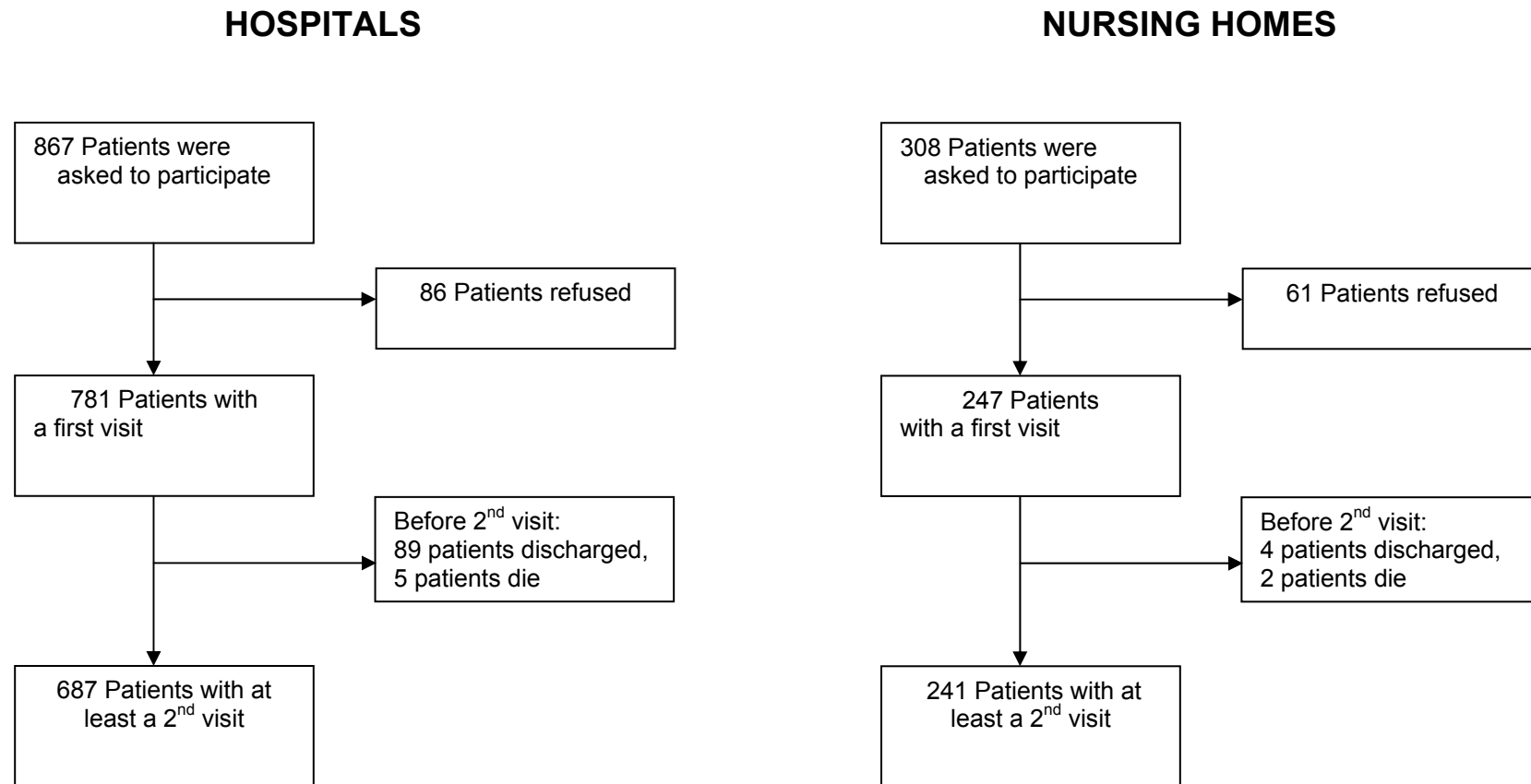
### *Statistical analysis*

The results for hospitals and nursing homes were analysed separately, as patient characteristics and length of stay differ. The incidence rate of adverse events was defined as the number of adverse events per patient week. We also calculated the incidence rate of adverse events per ward. Data were analysed using SPSS 15.0.

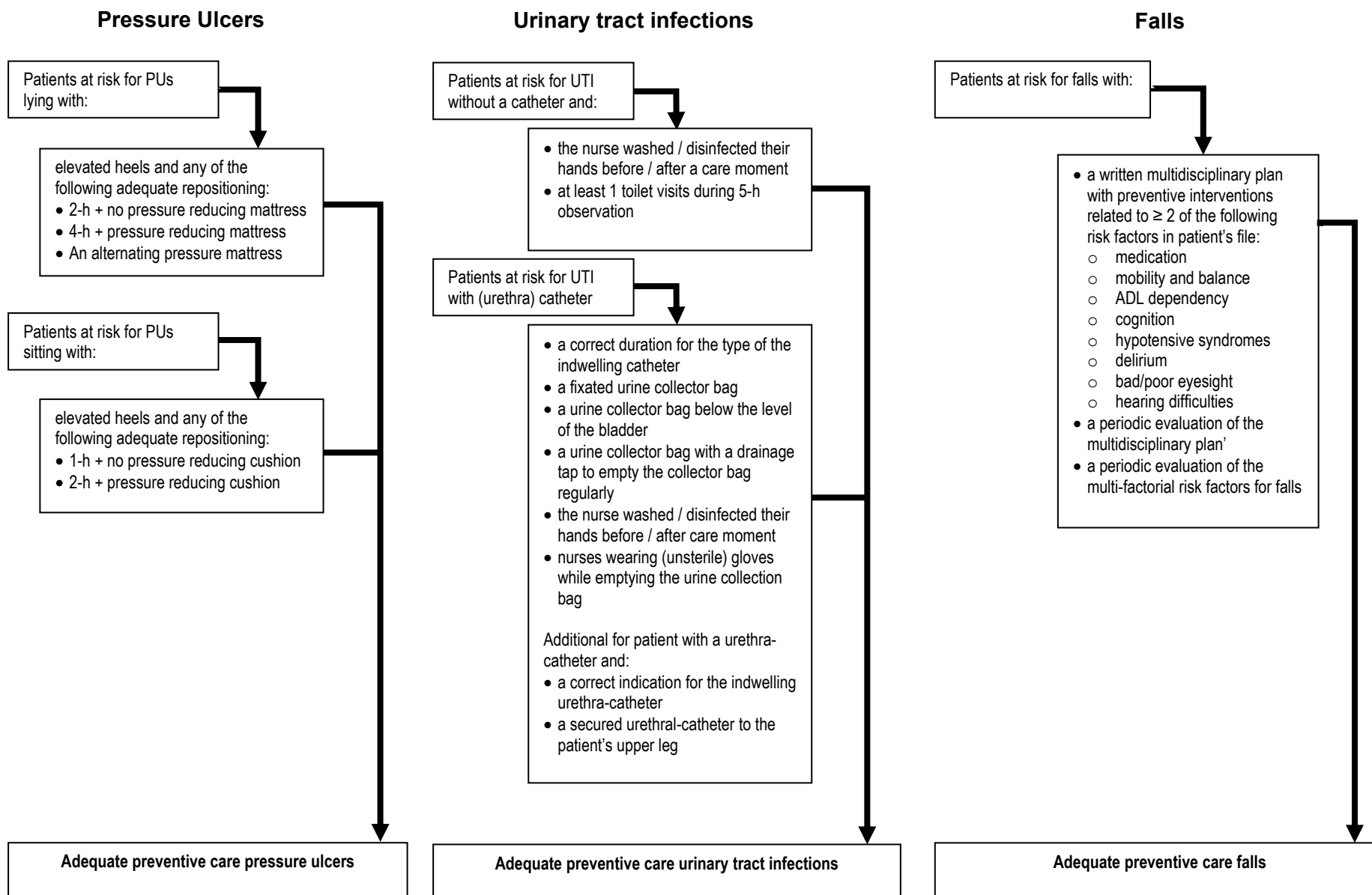
### *Ethical considerations*

The local Medical Ethics Committee (of district Arnhem – Nijmegen) assessed the study and waived the need for complete evaluation of the study. Patients received verbal and written information about the study's content and aim. All participating patients signed a written consent.

Figure 1. Patient flow



**Figure 2.** Adequate preventive care consist of



## Results

In this study 687 hospital patients were included (Figure 1). Their mean age was 65 years (SD: 15.7) and 388 patients were females (57%). Patients were admitted for a median of one week (interquartile range: 1-2) (Table 1).

Two hundred and forty one nursing home patients were included (Figure 1). Patients had a mean age of 78 years (SD: 10.3) and 159 were females (66%). Patients were admitted for a median of five weeks (interquartile range: 3-8) (Table 1).

**Table 1. Characteristics of the patients**

Hospitals	
n	687
Age in years (mean (SD))	64.8 (15.7)
Female (%)	388 (56.5)
Total visits	1717
Patient weeks	1030
Median admitted weeks (interquartile range)	1 (1-2)
Nursing homes	
n	241
Age in years (mean (SD))	77.9 (10.3)
Female (%)	159 (66.0)
Total visits	2232
Patient weeks	1991
Median patient weeks (interquartile range)	5 (3-8)

Values represent number unless stated otherwise

### *Adverse events in hospitals*

The total number of adverse events in hospitals was 90: 32 pressure ulcers, 41 urinary tract infections and 17 falls. The overall incidence rate was 0.09 adverse events per patient week, i.e. 90 adverse events in 1030 patient weeks. Seventy seven (11%) of the 687 patients developed one or more adverse events. Sixty four patients had one adverse event and 13 patients had two adverse events (Table 2). Most patients with two adverse events had a combination of pressure ulcers and urinary tract infections (n=6) or a combination of urinary tract infections and falls (n=4). Analysis at ward level showed a highly variable incidence rate from 0.04 adverse events to 0.27 adverse events per patient week.

### *Adverse events in nursing homes*

The total number of adverse events in nursing homes was 172: 59 pressure ulcers, 51 urinary tract infections and 62 falls. The overall incidence rate was 0.09 adverse events per patient week, i.e. 172 adverse events in 1991 patient weeks. One hundred and



eleven (46%) of the 241 patients developed one or more adverse events. Seventy patients had one adverse event, 30 patients had two adverse events, seven patients had three adverse events, and four patients had four or more adverse events (Table 2). Of the patients with two or more adverse events (17%), 17 patients had a combination of two different adverse events. Most of these patients had a combination of a pressure ulcer and a urinary tract infection (n=7) or a urinary tract infection and a fall (n=6). Incidence rates varied between wards from 0.06 to 0.12 adverse events per patient week.

**Table 2. Number of adverse events**

Hospitals	Total	PU	UTI	Falls	PU+UTI	PU+Falls	UTI+Falls
Patients with 1 AE	64	25	31	8			
Patients with 2 AEs	13			2	6	1	4
Nursing homes	Total	PU	UTI	Falls	PU+UTI	PU+Falls	UTI+Falls
Patients with 1 AE	70	25	24	21			
Patients with 2 AEs	30	7	5	7	5	3	3
Patients with 3 AEs	7	2	1	0	1	0	3
Patients with 4 AEs	1			1			
Patients with 5 AEs	2				1	1	
Patients with 7 AEs	1			1			

PU= pressure ulcers, UTI= Urinary tract infections, AE(s) = adverse event(s)

### *Preventive care in hospitals*

We found that 74% of the hospital patients were at risk for one or more adverse events, 48% were at risk for pressure ulcers, 48% were at risk for urinary tract infections and 19% were at risk for falls.

Ninety seven percent of the hospital patients at risk for *pressure ulcers* were chair – and/or bedbound. Thirty eight percent of these patients had elevated heels while sitting on a chair or lying in bed and 34% of the patients who were chair- and/or bedbound received adequate repositioning as well. Almost all patients at risk for pressure ulcers had a pressure reducing mattress (97%), but few patients had a pressure reducing cushion (2%) (Table 3).

**Table 3. Preventive measures in hospitals and nursing homes**

	HOSPITALS	NURSING HOMES
<b>Pressure ulcers:</b> Patients at risk	48	66
Patients at risk:		
sitting or lying with elevated heels	38	27
sitting or lying with elevated heels and adequate repositioning	34	18
with pressure reducing material:		
pressure reducing cushion	2	56
pressure reducing mattress	97	31
alternate mattress	2	17
<b>Urinary tract infections:</b> patients at risk	48	100
Patients at risk without a catheter and:		
nurses' hand hygiene	51	37
at least 1 toilet visit during 5-h observation	52	53
Patients at risk without a catheter and with above mentioned preventive measures	51	45
Patients at risk with a catheter and:		
nurses' hand hygiene	53	35
a correct duration of use of indwelling catheter conform the type of catheter	55	57
a fixated urine collector bag	86	52
a urine collector bag with a drainage tap to empty the collector bag regularly	59	78
a urine collector bag below the level of the bladder	87	26
nurses wearing (unsterile) gloves while emptying the urine collector bag	53	36
with a urethra-catheter and:	89	40
a secured urethra-catheter to patients' upper leg	24	1
a correct indication for the indwelling urethra-catheter	73	24
Patients at risk with a catheter and with above mentioned preventive measures	33	20
Overall: patients with and without a catheter and with all above preventive measures	47	42
<b>Falls :</b> patients at risk	19	66
Patients at risk with a written multidisciplinary plan:	<1	12
and preventions related to $\geq 2$ risk factors	0	2
and periodic evaluation of the multidisciplinary plan	0	2
and periodic evaluation of the risk factors for falls	0	<1

Values represent %

Of the hospital patients at risk for *urinary tract infections* without an indwelling catheter (77%), 51% received adequate preventive care.

Twenty three percent of the patients at risk for urinary tract infections had an indwelling catheter. In these patients, nurses did not always comply with hygienic measures, e.g. nurses' hand hygiene compliance was 53% and 53% of the nurses wore unsterile hand gloves while emptying the urine collector bag. Most of the patients with an indwelling catheter had a urethra-catheter (89%). Only 24% of the patients with an indwelling urethra-catheter had the catheter secured to the upper leg. Of all patients with an indwelling catheter (urethra- or suprapubic catheter) 33% received all adequate

preventive measures. Overall, 47% of the patients at risk for urinary tract infections received adequate preventive care according to the guidelines (Table 3).

Of the hospital patients at risk for *falls*, less than 1% of the patients' files contained a written multidisciplinary plan specifically addressed at prevention or treatment of falls, and none of them (0%) had multi-factorial preventive interventions in place. No multidisciplinary plan was evaluated and there was no evaluation of risk factors for falls (Table 3).

#### *Preventive care in nursing homes*

All nursing home patients were at risk for at least one adverse event. Sixty six percent were at risk for pressure ulcers, all were at risk for urinary tract infections, and 66% were at risk for falls.

Ninety nine percent of the nursing home patients at risk for *pressure ulcers* were chair- and/or bedbound. Twenty seven percent of these patients had elevated heels while sitting on a chair and/or lying in bed and only 18% of the patients who were chair and/or bedbound received adequate repositioning. Fifty two percent of the patients at risk for pressure ulcers did not have a pressure reducing mattress (Table 3).

By definition all the nursing home patients were at risk for *urinary tract infections*. Of the patients without an indwelling catheter (87%), 45% received preventive care.

Thirteen percent of all patients had an indwelling catheter. Our results showed that nurses did not always comply with hygienic measures, e.g. nurses' hand hygiene compliance was 35% and 36% of the nurses wore unsterile hand gloves while emptying the urine collector bag. Only 26% of the patients' urine collector bags were positioned below the level of the bladder. Forty percent of the patients with an indwelling catheter had a urethra-catheter. Of these patients only 1% had the catheter secured to the upper leg. Of all patients with an indwelling catheter (urethra- or suprapubic catheter) 20% received all adequate preventive measures. Overall, 42% of the patients received adequate preventive care according to the guidelines (Table 3).

In the nursing home setting, 12% of the patients at risk for *falls* had a written multidisciplinary plan, specifically addressing the prevention or treatment of falls: 2% of the patient's files contained multi-factorial preventive interventions and all of these

were evaluated (2%). Moreover, less than 1% of the patients' files contained an evaluation of the risk factors for falls (Table 3).

## Discussion

This prospective cohort study showed an alarming frequency of adverse events, even during relatively short periods of hospital admission. Eleven percent of the hospital patients developed a single adverse event; 2% developed two adverse events. Forty six percent of the nursing home patients developed an adverse event and nearly one in five patients (17%) developed two or more adverse events.

Less than 50% of the hospital patients at risk for pressure ulcers or urinary tract infections and none of the patients at risk for falls received adequate preventive care according to existing guidelines. In nursing homes less than 20% of the patients at risk for pressure ulcers, 41% of the patients at risk for urinary tract infections and 5% of the patients at risk for falls received adequate preventive care according to the guidelines.

Since this is the first study to describe the combined incidence of three adverse events, a comparison of our results with those of other studies is difficult. Most incidence studies investigated a single adverse event, in a particular population. Therefore, a comparison with other investigators' results was only possible for the individual adverse events.

Four studies have recently investigated the incidence of *pressure ulcers* in more or less comparable populations in hospitals<sup>14,16</sup> and nursing homes<sup>17</sup>. The results of our hospitals are similar to Vanderwee *et al.*<sup>16</sup> who showed an incidence rate of 0.03 pressure ulcers per patient week. Schoonhoven *et al.*<sup>15</sup> measured a much higher incidence rate (0.06 pressure ulcers per patient week). Although the incidence rate of 0.03 pressure ulcers per patient week in the study by Gehrlach *et al.*<sup>14</sup> seems similar to our finding, it is in fact lower as they included grade 1 pressure ulcers in their outcome. In the nursing homes Defloor *et al.*<sup>17</sup> showed a higher incidence rate (0.05 pressure ulcers per patient week), which can be explained by the difference in inclusion criteria. Defloor *et al.*<sup>17</sup> only included patients who were at risk for pressure ulcers, while we included all patients.

Four studies investigated infections, including *urinary tract infections* in hospitals<sup>18</sup> and nursing homes.<sup>19-21</sup> Our study showed a higher incidence rate of urinary tract infections compared to these studies. In hospitals we measured an incidence rate of 0.04 urinary tract infections per patient week, while Mintjes *et al.*<sup>18</sup> showed a mean incidence rate of 0.01 urinary tract infections per patient week over the studied thirteen years. In nursing homes we found an incidence rate of 0.03 urinary tract infections per patient week, while the three nursing home studies all showed a lower incidence rate of 0.01 urinary tract infections per patient week.<sup>19-21</sup> These differences in incidence rates can possibly be explained by differences in the populations. In hospitals, we only included surgical and internal medicine wards, where the surveillance study by Mintjes *et al.*<sup>18</sup> assessed all hospitals wards. In the nursing homes, we only included wards for patients with physical impairments (no dementia) and rehabilitation wards. Most of these patients were able to communicate or express their symptoms. In contrast Engelhart *et al.*<sup>19</sup> and Eriksen *et al.*<sup>20</sup> included a substantial number of residents with dementia or confusion, who were not able to communicate or express their symptoms. Moreover, these studies used a strict consensus definition for urinary tract infections<sup>22</sup> which, according to Engelhart *et al.*<sup>19</sup> possibly led to an underestimation of the true incidence of urinary tract infections. Koopmans *et al.*<sup>21</sup> only included nursing home patients with dementia.

Nine studies recently investigated *falls* in hospitals<sup>23,24,24-28</sup> and nursing homes.<sup>29-32</sup> Our study showed comparable results to those studies. The incidence rate of falls varies from 0.01 to 0.06 falls per patient week, for all hospital wards<sup>26</sup> and the subgroups of internal medicine ward patients<sup>25</sup> respectively, while our study showed an incidence rate of 0.02 falls per patient week. The high incidence rate found by Semin-Goossens *et al.*<sup>25</sup> can be explained since they only included high risk wards. In nursing homes the incidence rate varies from 0.03<sup>29,31</sup> to 0.06 falls per patient week,<sup>30</sup> and our study showed an incidence rate of 0.03 falls per patient week.

To comprehend our results some aspects should be discussed. First, the study had a strict timeframe in which to include hospital patients, i.e. within 48-hours after admission. This posed a limitation for inclusion on two groups of patients: patients admitted via the emergency department who had to undergo several check-ups or even an operation, and patients who could not understand or read our informed consent. Although we included the majority of the admitted patients it is possible that this has caused some minor selection bias. Secondly, to identify patients at risk for an adverse

event –who should receive preventive care– we used recommended risk assessment scales.<sup>8,9,13</sup> Despite the use of the most accepted and most validated risk assessment scales, we acknowledge that the currently available scales have limitations. The risk assessment scales are known to classify patients incorrectly into both the 'at risk' and 'not at risk' groups.<sup>33-35</sup> Therefore it is possible that we incorrectly identified a certain percentage of patients as either at risk or not at risk for developing an adverse event. Last but not least, we – as many other investigators – have used patient files to collect incidence data. Patient files have been found to notoriously underreport the incidence of events. To ensure the validity of the results, all data were collected by independent, research assistants who were trained in reading the patients' file and paying attention to signals which could point at adverse events in order to indirectly find evidence of adverse events that were not incompletely documented. The research assistants were supervised by the senior investigator (BvG).

One could argue that we missed a number of urinary tract infections because we did not monitor the urinary tract infections that were detected after discharge. However, we assume that the rate of urinary tract infections is fairly correct (hardly or no underreporting) since the proportion of urinary tract infections occurring after discharge is extremely low.<sup>36</sup>

Next to concerns with regard to underreporting of outcome measures (adverse events), one has to consider underreporting of preventive measures. In order to minimise this we combined two data collection methods. If the data would have been collected during the weekly visits only, it would be impossible to measure typical preventive interventions, e.g. adequate repositioning for patients at risk for pressure ulcers or hand hygiene for patients at risk for urinary tract infections. By using the combined data collection methods (namely the inclusion of observation) we obtained a better impression of the given preventive care by the nurses on the wards.

The three adverse events in this study are frequently occurring nursing care related adverse events in hospitals and nursing homes. In some countries, these three adverse events are used as important and sensitive quality indicators.<sup>37</sup> To improve patient safety on these three topics, organisations can improve the preventive care given by the nurses. This study showed that less than 50% of the patients at risk received adequate preventive care according to existing evidence based guidelines. To improve these three

topics, organisations have to implement three guidelines. Organisations normally implement one guideline at a time, which compromises patient safety, because by implementing one guideline, the other important guidelines cannot be implemented and have to 'wait'. The implementation of multiple guidelines simultaneously will have a greater contribution to the improvement of patient safety and deserves to be studied.

### *Conclusion*

This study showed that a substantial part of the patients developed an adverse event, both in hospitals as well as in nursing homes. A small percentage of the patients even developed more than one adverse event. The majority of the patients at risk for an adverse event did not receive adequate preventive care, neither in hospitals nor nursing homes. This shows that hospitals and nursing homes have a significant chance to improve preventive care and thus their patients' safety.

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## Chapter 5

### **Fewer adverse events as a result of the SAFE or SORRY? programme in hospitals and nursing homes: a cluster randomised trial**

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**Abstract**

*Background:* Usually, patient care guidelines are implemented one at a time, while patients are at risk for multiple, often preventable, adverse events simultaneously.

*Objective:* This study aimed to test the effect of the SAFE or SORRY? programme on the incidence of three adverse events (pressure ulcers, urinary tract infections and falls) and the preventive care given. This paper describes the effect on the incidence of adverse events.

*Design:* A cluster randomised trial was conducted between September 2006 and November 2008. After a 3-month baseline period the intervention was implemented followed by a 9-month follow-up period.

*Settings:* Ten wards from four hospitals and ten wards from six nursing homes were stratified for institute and ward type and then randomised to intervention or usual care group.

*Participants:* During baseline and follow-up, patients ( $\geq 18$  years) with an expected length of stay of five days at least, were asked to participate.

*Methods:* The SAFE or SORRY? programme consisted of the essential recommendations of guidelines for the three adverse events. A multifaceted implementation strategy was used for the implementation: education, patient involvement and feedback on process- and outcome indicators. The usual care group continued care as usual. Data were collected on the incidence of adverse events and a Poisson regression model was used to estimate the rate ratio of the adverse events between the intervention and usual care group at follow-up.

*Results:* At follow-up, 2201 hospital patients with 3358 patient weeks and 392 nursing home patients with 5799 patient weeks were observed. Poisson regression analyses showed a rate ratio for the development of an adverse event in favour of the intervention group of 0.57 (95% CI: 0.34 to 0.95) and 0.67 (95% CI: 0.48 to 0.99) for the hospital patients and nursing home patients respectively.

*Conclusion:* This study showed that implementing multiple guidelines simultaneously is possible, which is promising when aiming at improving patient safety. Patient outcomes in the intervention groups were better, as was demonstrated by 43% and 33% fewer adverse events compared to the usual care groups in hospitals and nursing homes respectively.

## Introduction

Patients in hospitals and nursing homes are at risk for the development of often preventable adverse events<sup>1</sup> (Table 1), compromising patient safety. Although guidelines for nursing care are available, compliance appears to be lacking.<sup>2-4</sup> Several factors may influence compliance with guidelines, such as the large number of guidelines competing for attention, making it difficult to keep track of all of them. Another barrier is the lack of policies for the introduction of new guidelines in organisations.<sup>5</sup> Each guideline requires translation into the target group, and development and organisation of targeted information and education, which is a time-consuming process. As a result, it is difficult to implement all available guidelines necessary for good quality nursing care. This situation is at odds with the responsibility of professionals to ensure patient safety. Integration of recommendations of guidelines in a comprehensive programme may facilitate the implementation of guidelines. Therefore, we developed a patient safety programme that allows organisations to implement multiple guidelines simultaneously, facilitate guideline use and thus improve patient safety.

**Table 1. Definitions**

<b>Adverse events</b>
An adverse event is defined as an unintended injury that results in prolonged stay, disability at the time of discharge, or death and is caused by health care management rather than by the patient's underlying disease process. <sup>1</sup>
<b>Pressure ulcers</b>
A pressure ulcer is an area of localized damage to the skin and underlying tissue caused by a combination of pressure and shear. <sup>12</sup> Pressure ulcers are classified in four grades. <sup>12-14</sup>
<b>Urinary tract infections</b>
A urinary tract infection is bacteriuria with clinical symptoms such as: frequent urinating, pain while urinating, abdominal pain, fever, delirium and urinary incontinence. <sup>15</sup>
<b>Falls</b>
A fall is an unexpected event in which the participant comes to rest on the ground floor, or lower level. <sup>16,17</sup>

### *The patient safety programme*

The patient safety programme (SAFE or SORRY?) was directed at three frequently occurring nursing care related adverse events for which guidelines are available: pressure ulcers, urinary tract infections and falls. It consists of the essential recommendations of each guideline and outcome- and process indicators. For the implementation of this patient safety programme, we developed a multifaceted implementation strategy, tailored to the related barriers and needs of the individual wards. We used a multifaceted implementation strategy because this seems more

effective than a single strategy, as it addresses multiple barriers to guideline adherence.<sup>6,7</sup> Our strategy consisted of education, patient involvement, feedback through a computerised registration programme and an implementation plan for every ward. Educational activities are necessary components of any implementation strategy and can lead to changes in professional behaviour.<sup>6</sup> Patient involvement can be used to enhance the implementation of innovations or improvements.<sup>8</sup> Feedback through a computerised registration programme provided timely feedback on the performance of guideline based process- and outcome indicators.<sup>6</sup>

The development of the patient safety programme (SAFE or SORRY?) is described in detail in an earlier article.<sup>9</sup>

The aim of this study was to test the effect of this comprehensive patient safety programme (SAFE or SORRY?) on the incidence of three adverse events and the preventive care given to patients at risk for pressure ulcers, urinary tract infections and/or falls in hospitals and nursing homes. In this article we describe, the effect of this programme on the incidence of adverse events (the incidence of pressure ulcers, urinary tract infections and falls). Besides the incidence of adverse events (primary outcome), we undertook an additional study with separate data collection methods which investigated whether the programme increased the preventive care given to the patients at risk for these adverse events. These results will be described in a separate article.<sup>10</sup>

## Methods

### *Design and setting*

A cluster randomised trial was conducted between September 2006 and November 2008. In a cluster randomised trial, groups of individuals rather than individuals are randomised.<sup>11</sup> In our study the intervention addressed the entire team of nurses rather than individual patients. Therefore the results were clustered to the wards.<sup>11</sup> The detailed design of this study is described elsewhere.<sup>9</sup> We included a purposive sample from four hospitals (one university hospital, two large teaching hospitals and one small hospital) and six nursing homes in the Netherlands. Hospitals and nursing homes were asked to participate with two or four, more or less comparable internal medicine or surgical wards. The hospital wards were internal medicine wards (n=4) and surgical wards (n=6). The nursing home wards were wards for patients with physical impairments (no dementia) (n=7) and need for rehabilitation (n=3). The randomisation

of the wards was stratified for institute and type of ward and each ward was considered as a cluster. The ten hospital wards and ten nursing home wards were assigned to an intervention or usual care group (Figure 1). After the randomisation, baseline data were collected during three months at all wards, followed by the implementation of the patient safety programme in the intervention group from December 2006 to February 2008. During this period the usual care group continued care as usual. The subsequent follow-up period was nine months for all wards (Figure 1).

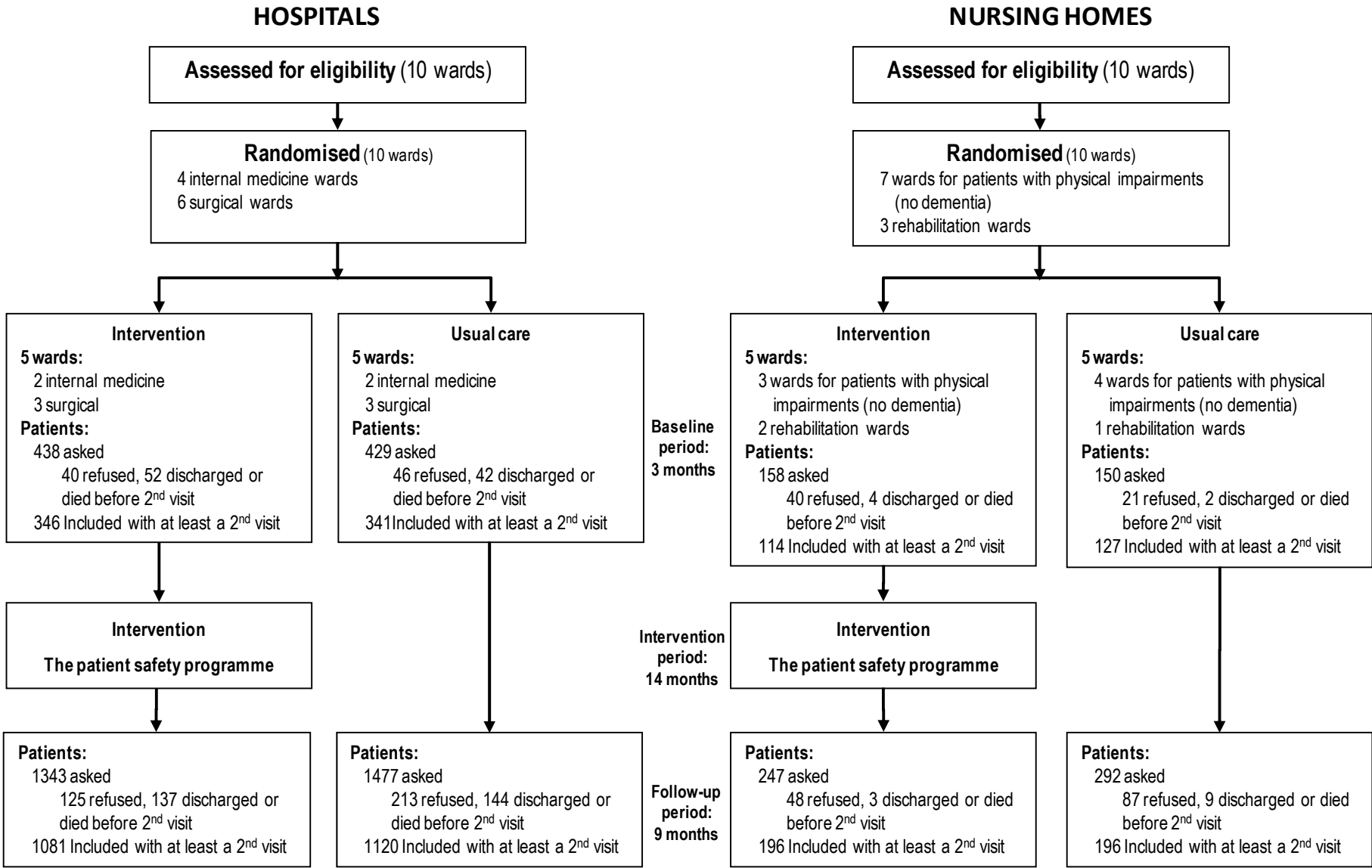
### *Study population*

During baseline and follow-up data collection periods, all adult patients ( $\geq 18$  years) admitted to the wards were asked to participate. Hospital patients with an expected length of stay of at least five days were asked to participate within 48 hours after admission. Nursing home patients were asked to participate at the start of the data collection periods, or within two weeks after admission. After written informed consent, research assistants visited the patients weekly, until discharge, death or the end of the data collection period to monitor incidence of pressure ulcers, urinary tract infections and falls. All patients with two or more visits were included in the study (Figure 1).

### *The intervention*

We implemented the patient safety programme on the wards in the intervention group between December 2006 and February 2008. At the start of the implementation period, every intervention ward appointed two key nurses to the study. Together with the ward manager, they were responsible for the implementation of the patient safety programme on their ward. Table 2 illustrates the specific implementation activities on the intervention wards. Every intervention ward started with small-scale educational meetings for all nurses and the introduction of the information leaflet for the patients at risk for the specific adverse event. Additionally, the wards received the CD-ROM with educational material. Within two to three months, case discussions were held twice on every intervention ward. At last, the digital computerised registration and feedback system was introduced in the wards. The usual care group continued care as usual.

Figure 1. Trial profile of study





**Table 2. Operational implementation strategies with the activities****Education**

*Small-scale educational meetings* for all nurses (1.5 hours). The main subjects during these meetings were: causes of adverse events, assessment of patients at risk for adverse events and how to prevent the adverse events.

*Two case discussions* on every ward (30 minutes). During these case discussions the nurses and the researcher reviewed patients on their ward regarding the causes of adverse events, assessment of risk for adverse events and preventive care. A CD-ROM with education material. Besides the theoretical items (causes of the adverse events, assessment of patients at risk and prevention of adverse events), a test with feedback (for nurses to test their own knowledge) was included.

**Patient involvement**

An information leaflet for the prevention of pressure ulcers, urinary tract infection and falls, separately. In addition to giving oral information, nurses were asked to give the folder to patients at risk for the specific adverse event.

**Feedback**

The nurses register the patient's daily care and the presence or absence of an adverse event in a computerised registration system. This digital programme generates feedback by charts on the process- and outcome indicators.

*Outcome measure*

The primary outcome was the incidence of adverse events per patient week (the sum of the incidents of pressure ulcers, urinary tract infections and falls divided by the total patient weeks).

*Pressure ulcers*<sup>12-14</sup> were measured by observing the patient's skin. Pressure ulcers (Table 1) were considered present if a patient had developed a pressure ulcer grade two or worse according to the EPUAP-classification system.<sup>14</sup> If a patient had a pressure ulcer grade two or worse at the first visit, this pressure ulcer lesion was excluded when calculating incidence rates until the pressure ulcer had healed; all new pressure ulcer lesions were included.

The presence of a *urinary tract infection*<sup>15</sup> (Table 1) needed to be confirmed by a physician. Patients with existing urinary tract infections were excluded from the calculation of the incidence rates of urinary tract infections for a period of three weeks until the infection was cured.

*Falls*<sup>16,17</sup> (Table 1) were measured by examining the patient files. Consequently, all falls that occurred after the first visit of the research assistant and that were documented in the patient's file were included.

The number of patients at risk for an adverse event were the patients at risk for pressure ulcers, urinary tract infections and or falls. Patients at risk for *pressure ulcers* were the patients at risk according to the PrePURSE scale<sup>18</sup> (score more than 19) in hospitals and patients at risk according to the Braden scale<sup>19</sup> (score less than 18) in nursing homes. Hospital patients were at risk for a *urinary tract infection* if they had at least one of the following four risk factors: 1) an indwelling catheter (urethra- or suprapubic catheter), currently or within the last seven days, 2) faecal incontinence, 3) urinary retention, or 4) a urinary tract infection in the last two years.<sup>20</sup> All nursing home

patients were considered at risk for urinary tract infections.<sup>21</sup> To identify hospital patients at risk for *falls*, the STRATIFY tool<sup>22</sup> was used. All nursing home patients were considered at risk for falls, except those who were totally immobile.<sup>16</sup>

### *Data collection*

Data on adverse events and risk status were collected by screening the patient files and inspecting the patient's skin, weekly. Data were collected by trained research assistants who were appointed to this study and trained in reading the patients' files, observing patients' skin and paying attention to signals that could indicate adverse events, such as antibiotic use.

### *Statistical analysis*

The results for hospitals and nursing homes were analysed separately, as patient characteristics and length of stay differ between hospital and nursing home patients. In an earlier article we described the sample size calculation for this study.<sup>9</sup>

The incidence rate of adverse events was defined as the number of new adverse events per patient week. The results were clustered at ward level and we used a random effects Poisson regression model to estimate the rate ratio of the adverse events for the intervention versus the usual care group at follow-up (MLwiN version 2.02). The Poisson model had ward as random factor and the offset was the patient weeks. Covariates were institution, number of patients at risk for an adverse event at the first visit and the incidence of adverse events at each ward at baseline. The Poisson analyses yielded an incidence rate ratio that reflected the change in event rate for the intervention relative to the usual care group. Additionally, we checked for outliers and we repeated the analyses with the values of the outliers Winsorised to various levels.

Analyses was performed by intention to treat. Ninety five percent confidence intervals were calculated and results were considered statistically significant if the confidence interval did not include unity.

The study is registered with clinicaltrials.gov, number NCT00365430.

*Ethical considerations*

The Medical Ethics Committee of district Arnhem – Nijmegen assessed the study and concluded that our study was deemed exempt from their approval, as it did not involve research covered by the Medical Research Involving Human Subjects Act.

**Results***General*

Figure 1 illustrates the trial profile, and table 3 presents the characteristics of the patients included in the intervention and usual care group at baseline and at follow-up. During the follow-up, we observed 1576 patient weeks in 1081 hospital patients in the intervention group (5 wards) and 1782 patient weeks in 1120 patients in the usual care group (5 wards). In nursing homes both groups comprised 196 patients with 2754 patient weeks in the intervention group (5 wards) and 3045 patient weeks in the usual care group (5 wards).

**Table 3. Characteristic of the patients**

<b>HOSPITALS</b>	<b>Baseline</b>		<b>Follow-up</b>	
	<b>INT</b>	<b>UC</b>	<b>INT</b>	<b>UC</b>
n	346	341	1081	1120
Age in years, mean (SD)	66 (14.5)	64 (16.9)	66 (14.7)	67 (16.1)
Female	184 (53.2)	204 (59.8)	570 (52.7)	646 (57.7)
Total visits	842	875	2657	2902
Patient weeks	496	534	1576	1782
Patient weeks, median (interquartile range)	1 (1–2)	1 (1–2)	1 (1–2)	1 (1–2)
1 <sup>st</sup> visit patients at risk of PUs	189 (57.6)	149 (47.2)	694 (66.9)	616 (57.2)
1 <sup>st</sup> visit patients at risk of UTIs	120 (34.7)	131 (38.4)	402 (37.2)	511 (45.6)
1 <sup>st</sup> visit patients at risk of falls	52 (15.0)	67 (19.6)	139 (12.9)	215 (19.2)
<b>NURSING HOMES</b>	<b>Baseline</b>		<b>Follow-up</b>	
	<b>INT</b>	<b>UC</b>	<b>INT</b>	<b>UC</b>
n	114	127	196	196
Age in years, mean (SD)	78 (9.9)	78 (11.7)	80 (10.9)	79 (10.5)
Female	70 (61.4)	89 (66.0)	131 (66.8)	126 (64.3)
Total visits	1047	1185	2950	3241
Patient weeks	933	1058	2754	3045
Patient weeks, median (interquartile range)	5 (3–8)	5 (3–8)	10 (4–9)	11 (5–20)
1 <sup>st</sup> visit patients at risk of PUs	64 (56.1)	74 (58.3)	70 (35.7)	86 (43.9)
1 <sup>st</sup> visit patients at risk of UTIs	114 (100)	127 (100)	196 (100)	196 (100)
1 <sup>st</sup> visit patients at risk of falls	78 (68.4)	77 (60.6)	165 (84.2)	110 (56.1)

Values represent number (percentages) unless stated otherwise

Abbreviations: INT = intervention group. UC = usual care group. PUs = pressure ulcers. UTIs = urinary tract infections

*Patient outcomes in hospitals and nursing homes*

Table 4 shows the total numbers of adverse events with (between brackets) the incidence rate per patient week in each group. In the follow-up period, hospital patients in the intervention group developed 0.06 adverse events per patient week (total number of adverse events = 97), while hospital patients in the usual care group developed 0.09 adverse events per patient week (total number of adverse events = 152). Nursing home patients in the intervention group developed 0.06 adverse events per patient week (total number of adverse events = 174), while nursing home patients in the usual care group developed 0.09 adverse events per patient week (total number of adverse events = 272).

**Table 4. Incidence of adverse events**

HOSPITALS	Baseline		Follow-up		Incidence rate ratio <sup>a</sup>	95% CI*
	INT	UC	INT	UC		
Incidence of AEs	46 (0.09)	44 (0.08)	97 (0.06)	152 (0.09)	0.57	0.34 – 0.96
Incidence of PUs	14 (0.03)	18 (0.03)	45 (0.03)	66 (0.04)	0.92	0.39 – 2.15
Incidence of UTIs	22 (0.05)	19 (0.04)	23 (0.02)	60 (0.04)	0.39	0.15 – 1.02
Incidence of falls	10 (0.02)	7 (0.01)	29 (0.02)	26 (0.02)	0.67	0.17 – 2.58
NURSING HOMES	Baseline		Follow-up		Incidence rate ratio <sup>a</sup>	95% CI*
	INT	UC	INT	UC		
Incidence of AEs	79 (0.09)	93 (0.09)	174 (0.06)	272 (0.09)	0.67	0.47 – 0.97
Incidence of PUs	29 (0.03)	30 (0.03)	36 (0.01)	97 (0.03)	0.34	0.15 – 0.76
Incidence of UTIs	23 (0.03)	28 (0.03)	58 (0.02)	57 (0.02)	0.85	0.43 – 1.67
Incidence of falls	27 (0.03)	35 (0.03)	80 (0.03)	118 (0.04)	0.63	0.35 – 1.16

Values represent number (incidence rate / patient week) unless stated otherwise

Abbreviations: INT = intervention group. UC = usual care group. AEs = adverse events. PUs = pressure ulcers. UTIs = urinary tract infections. a: Results incidence rate ratio from a Poisson regression, with ward as random factor, the offset was the duration of observation and institution, patients at risk for an AE at the first visit and the incidence of AEs from each ward at baseline

Results from Poisson regression showed that the incidence rate ratio for the hospital patients in the intervention group for developing adverse events was 0.57 (95% CI: 0.34 to 0.95), compared to the patients in the usual care group. In nursing homes the incidence rate ratio for patients in the intervention group was 0.67 (95% CI: 0.48 to 0.99), compared to the usual care group. In hospitals this difference in the occurrence of adverse events was especially accounted for by fewer urinary tract infections per patient week (incidence rate ratio = 0.39) and falls per patient week (incidence rate ratio = 0.67). In nursing homes, this difference in the occurrence of adverse events was mainly accounted for by the fewer pressure ulcers per patient week (incidence rate ratio = 0.34) and falls per patient week (incidence rate ratio = 0.63).

The Winsorised analyses confirmed the results of the primary analyses and showed that potentially influential outliers, such as patients with an excessively high number of falls, had no relevant impact on the results.

## **Discussion and conclusion**

This is the first study in which a patient safety programme, allowing organisations to implement multiple safety guidelines simultaneously, was developed and studied on its effects. The results show that simultaneous implementation of multiple guidelines is not only possible, but it can be effective as well. In both hospitals and nursing homes, patients in the intervention groups developed fewer adverse events compared to the patients in the usual care groups.

While it seemed that in both health-care settings one type of the adverse events was more effectively targeted (in hospitals fewer urinary tract infections and in nursing homes fewer pressure ulcers), our study was not powered for this kind of conclusion. The wide confidence intervals in table 4 illustrate this. The confidence intervals of the three adverse events largely overlap, so it is impossible to decide whether the results differed between the types of adverse events. Conversely, it is impossible to determine whether there was an effect of the intervention on any of the individual types of adverse events. We can only be sure that overall, there is a positive effect and all rates for the three adverse events separately contributed positively to the result. To explore this, further studies would be necessary.

We assumed an effect size when designing this study, and nearly achieved the desired result. This study aimed at a reduction of adverse events of 50% (corresponding with a rate ratio of 0.50) in hospitals and 40% (rate ratio of 0.60) in nursing homes.<sup>9</sup> We achieved a reduction of 43% (rate ratio of 0.57) in hospitals and 33 % (rate ratio of 0.67) in nursing homes. Again, the confidence intervals are important however. In our study, the upper and lower limits of the confidence intervals of the estimated rate ratios were approximately 0.34–0.96 (hospitals) and 0.47–0.97 (nursing homes), respectively. This shows that, although we found a somewhat smaller result than anticipated, the rate ratios that we used in the power calculation are well within the confidence intervals that we found.

We measured the incidence of three outcome indicators, and all three are considered as nursing sensitive quality indicators.<sup>23,24</sup> A quality indicator is “a measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality, and hence change in the quality of care provided”.<sup>25</sup> An advantage of outcome measures is that they reflect all aspects of the process of care and not simply those that are measurable or measured.<sup>26</sup> However, differences in outcomes could be explained by case mix, differences in data collection, chance, or differences in quality of care.<sup>26</sup> As a result comparing outcomes remains problematic. In this study, we adjusted for the differences in type of patient by analysing the results separately for hospitals and nursing homes and stratifying the randomisation for institute and ward. Additionally, we standardised the measurements and the study was powered on the outcome indicator.

An outcome indicator will not give detailed insight into the differences in care. We chose to measure an outcome that is more sensitive to differences in preventive care; the incidence of adverse events. Incidences measures the number of patients developing a (new) adverse event during a period in time and incidence may allow inferences to be made regarding the effectiveness of preventive care and the adherence to prevention guidelines.<sup>27</sup> Therefore, we believe that the positive results on the outcomes, can be explained by the difference in quality of care.

Comparing our results with those of other studies investigating the implementation of guidelines proved to be very complicated. Most other studies compare the effect of a single intervention on a single adverse event, which is only a part of the overall process. Others used prevalence measures rather than incidence as done in this study. Furthermore, most importantly, we could not find another rigorous study investigating the effectiveness of the implementation of multiple guidelines simultaneously. There are studies on pressure ulcers and falls, which describe the effectiveness of the implementation of one guideline on patient outcomes. For urinary tract infection, most implementation studies do not investigate the introduction of single guidelines, but investigate a single intervention from a guideline. For example, implementation studies aimed at the prevention of urinary tract infections often investigate the effect on catheter associated urinary tract infections. These are mostly single intervention studies, e.g. comparing different types of catheters, in a specific population. In contrast, our intervention comprised multiple recommendations for all patients at risk.

This study used a multifaceted implementation strategy for the implementation of multiple guidelines. There is no consistent evidence on the effectiveness of single versus multifaceted implementation strategies.<sup>28,29</sup> The choice for a single or a multifaceted implementation strategy depends on the topic, the setting, the target group and the problems encountered.<sup>30</sup> We chose to use a multifaceted strategy, because this might address multiple barriers to guideline adherence.<sup>6,7</sup> It is not possible to specify which combinations of strategies are most effective in which situation.<sup>31</sup> We combined tailored education, patient involvement and feedback through a computerised registration programme. As the implementation of multiple guidelines can be considered to be a complex intervention, this study showed that a complex intervention can effectively be implemented with a multifaceted implementation strategy that tailored the implementation activities to the individual wards. This is promising for the implementation of other complex interventions.

To comprehend our results, some methodological aspects need to be discussed. First, the study had a strict timeframe in which to include hospital patients, i.e. within 48 hours after admission. This posed a limitation for inclusion on two groups of patients: those admitted via emergency departments who had to undergo several check-ups or even surgery, and those who could not understand or read our informed consent. Although we included the majority of the patients admitted, it is possible that this caused some minor selection bias. Second, we used patient files to collect incidence data on urinary tract infections and falls. Patient files have been found to notoriously underreport the incidence of events.<sup>32</sup> To ensure the validity of the results, all data were collected by independent research assistants who were trained in reading patient files and finding clues that could indicate adverse events, such as antibiotic use. The research assistants were trained and supervised by the senior investigator (BvG). Data on incidence of pressure ulcers were gathered by examining patients' skin weekly. We are confident that we did not miss the incidence of a pressure ulcer grade two or worse as these are irreversible and older lesions of the skin would still have been visible as a scab at a subsequent visit. We may have missed a number of urinary tract infections because we did not monitor those detected after discharge. However, we assume that the rate of urinary tract infections is fairly correct -hardly or no underreporting- since the proportion detected after discharge is extremely low.<sup>33</sup> Moreover, the underreporting would be present in both the intervention and usual care group. It is possible that frequent fallers -patients with a high incidence of falls- could have influenced the results

of our study, because with a count outcome –as in this study– the incidents were added up, we counted the falls and not the faller). In analysing the results, we checked for outliers and they did not influence the outcome of our study. Lastly, the follow-up in this study took place one and a half years after the start of the intervention period. This long period potentially opened the study to external influences. For instance, if hospitals and nursing homes had decided to start special quality improvement programmes on one of our adverse events, this would have influenced our results. During the study period we monitored - intervention and usual care - wards for other interventions that could possibly influence the outcome on the adverse events. This inventory made it possible to prevent two hospitals from organising separate courses on the subject of falls. Instead, they organised courses on other important subjects (delirium and use of restraints). From the inventory we know that there were no activities regarding our three adverse events.

In conclusion, this study showed that it is possible and effective to implement multiple guidelines simultaneously. In hospitals, patients in the intervention group had 43% fewer adverse events compared to the usual care group. In nursing homes, intervention group patients had 33% fewer adverse events. These results are promising for the future, but more research is necessary to underline these results. A programme for the simultaneous implementation of multiple guidelines can give organisations the opportunity to improve patient safety.



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## **Chapter 6**

### **The effect of the SAFE or SORRY? programme on preventive care in hospitals and nursing homes: a cluster randomised trial**

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**Abstract**

*Background:* Usually, patient care guidelines are implemented one at a time, while patients are at risk for multiple, often preventable, adverse events simultaneously.

*Objective:* This study aimed to test the effect of the SAFE or SORRY? programme on the incidence of three adverse events (pressure ulcers, urinary tract infections and falls) and the preventive care given. This paper describes the effect on the preventive care given.

*Design:* A cluster randomised trial was conducted between September 2006 and November 2008.

*Settings:* Ten wards from four hospitals and ten wards from six nursing homes were stratified for institute and ward type and randomised to intervention or usual care groups.

*Participants:* Patients ( $\geq 18$  years) with an expected length of stay of five days at least.

*Methods:* The SAFE or SORRY? programme consisted of the essential recommendations of guidelines for pressure ulcers, urinary tract infections and falls. A multifaceted implementation strategy was used to implement these guidelines including: education, patient involvement and feedback on process and outcome indicators. The usual care group continued care as usual. Data were collected on preventive care given to patients at risk for the adverse events and the difference between the intervention and usual care group at follow-up was analysed.

*Results:* The study showed no overall difference in preventive pressure ulcer measures between intervention and usual care group in hospitals (Estimate = 6%, CI = -7 to 19) and nursing homes (Estimate = 4%, CI = -5 to 13). For urinary tract infections, even statistically significantly fewer hospital patients at risk received preventive care (Estimate 19%, CI = 17 to 21). For falls in hospitals and nursing homes, no more patients at risk received preventive care.

*Conclusion:* The implementation of multiple guidelines is feasible, but an increase of preventive care given to patients at risk was not measured in hospitals nor in nursing homes. We even measured a decrease of preventive care given to patients at risk for urinary tract infections in hospitals. More research is needed to explore possibilities to measure the implementation of multiple guidelines.

## Introduction

### *Background*

Over the past seventeen years, several studies showed that patients are at risk for injuries or even death as a result of care delivered in hospitals.<sup>1-4</sup> These studies show that 3 to 17% of patients in acute care hospitals experienced at least one adverse event (Table 1). Half of all events are considered preventable.<sup>1-4</sup> While these studies did not include nursing homes, other studies show that adverse events, such as infections, pneumonia, falls, pressure ulcers and medication errors also occur frequently in nursing homes.<sup>5-8</sup> A proportion of the adverse events, such as medication errors, pressure ulcers, infections, falls, is related to suboptimal nursing care, and often considered preventable. For the prevention of such events, guidelines are available. Unfortunately, the utilisation of these guidelines in daily practice is lacking.<sup>9-11</sup>

**Table 1. Definitions**

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#### **Adverse events**

An adverse event is defined as an unintended injury that results in prolonged stay, disability at the time of discharge, or death and is caused by health care management rather than by the patient's underlying disease process.<sup>3</sup>

#### **Pressure ulcers**

A pressure ulcer is an area of localized damage to the skin and underlying tissue caused by a combination of pressure and shear.<sup>19</sup> Pressure ulcers are classified in four grades.<sup>19,20</sup>

#### **Urinary tract infections**

A urinary tract infection is bacteriuria with clinical symptoms such as: frequent urinating, pain while urinating, abdominal pain, fever, delirium and urinary incontinence.<sup>22</sup>

#### **Falls**

A fall is an unexpected event in which the participant comes to rest on the ground floor, or lower level.<sup>25</sup>

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Generally, many factors or barriers may influence compliance -or noncompliance- with a guideline.<sup>9</sup> These general barriers may be related to the individual professional (e.g. knowledge, skills, attitudes, motivation), the individual's social context (e.g. patients, colleagues, culture) and the organisational setting (e.g. financial, equipment).<sup>12</sup> As there are so many important nursing care related guidelines, they are competing for attention and it is difficult to keep track of all of them. In addition, organisations must translate each guideline to their own target group, and develop and organise their own information and education, which is a time-consuming process. All this combined makes it difficult for organisations to implement all available guidelines that are necessary for good quality nursing care. Integration of recommendations of guidelines in a comprehensive programme may facilitate the implementation of guidelines. Therefore, we developed a comprehensive patient safety programme that allows

organisations to implement multiple guidelines simultaneously, may facilitate guideline use, and thus improve patient safety.

### *The patient safety programme*

The patient safety programme (SAFE or SORRY?) was directed at three frequently occurring nursing care related adverse events for which guidelines are available: pressure ulcers, urinary tract infections and falls. It consists of the essential recommendations of each guideline and outcome- and process indicators. For the implementation of this patient safety programme, we developed a multifaceted implementation strategy, tailored to the related barriers and needs of the individual wards. We preferred a multifaceted implementation strategy because this seems more effective than a single strategy, as it addresses multiple barriers to guideline adherence.<sup>9,13</sup> Our strategy consisted of education, patient involvement, feedback through a computerised registration programme and an implementation plan for every ward. Educational activities are necessary components of any implementation strategy and can lead to changes in professional behaviour.<sup>9</sup> Patient involvement can be used to enhance the implementation of innovations or improvements.<sup>14</sup> Feedback through a computerised registration programme provided timely feedback on the performance of guideline-based process- and outcome indicators.<sup>9</sup> The development of the patient safety programme (SAFE or SORRY?) is described in detail in an earlier article.<sup>15</sup>

The aim of this study was to test the effect of a comprehensive patient safety programme (SAFE or SORRY?) on the incidence of three adverse events and the preventive care given to patients at risk for pressure ulcers, urinary tract infections and/or falls in hospitals and nursing homes. In this article, we describe the effect of this programme on the preventive care. The effect of this programme on the incidence of adverse events is reported in a separate paper.<sup>16</sup>

## **Methods**

### *Design and settings*

A cluster randomised trial was conducted between September 2006 and November 2008.<sup>15</sup> It included a purposive sample from four hospitals (one university hospital, two large teaching hospitals and one small hospital) and six nursing homes in the Netherlands. The hospital wards were internal medicine wards (n=4) and surgical wards (n=6). The nursing home wards were wards for patients with physical impairments (no

dementia) (n=7) and need for rehabilitation (n=3). The randomisation of the wards was stratified for institute and type of ward and each ward was considered as a cluster. The ten hospital wards and ten nursing home wards were assigned to an intervention or usual care group (Figure 1). After the randomisation, baseline data were collected during three months at all wards, followed by the performance of the patient safety programme in the intervention group from December 2006 to February 2008. During this period the usual care group continued care as usual. The subsequent follow-up period was nine months for all wards (Figure 1).

### *Study population*

During baseline and follow-up data collection periods, all adult patients ( $\geq 18$  years) admitted to the wards were asked to participate. Hospital patients with an expected length of stay of at least five days were asked to participate within 48 hours after admission. Nursing home patients were asked to participate at the start of the data collection periods, or within two weeks after admission. After written informed consent, research assistants visited the patients weekly, until discharge, death or the end of the data collection period to monitor the preventive care given. All patients with two or more visits were included in the study (Figure 1).

### *The intervention*

The implementation of the patient safety programme on the wards in the intervention group was between December 2006 and February 2008. The development of the patient safety programme (SAFE or SORRY?) is described in detail in an earlier article.<sup>15</sup> At the start of the implementation period, every intervention ward appointed two key nurses to the study. Together with the ward manager, they were responsible for the implementation of the patient safety programme on their ward. Table 2 illustrates the specific implementation activities on the intervention wards. Every intervention ward started with small-scale educational meetings for all nurses and the introduction of the information leaflet for the patients at risk for the specific adverse event. Additionally, the wards received the CD-ROM with educational material. Within two or three months, case discussions were held twice on every intervention ward. At last, the digital computerised registration and feedback system was introduced in the wards. The usual care group continued care as usual.

**Table 2. Operational implementation strategies with the activities****Education**

*Small-scale educational meetings* for all nurses (1.5 hours). The main subjects during these meetings were: causes of the adverse events, assessment of patients at risk for the adverse events and how to prevent the adverse events.

*Two case discussions* on every ward (30 minutes). During these case discussions the nurses and the researcher reviewed patients on their ward regarding the causes of the adverse events, assessment of risk for adverse events and preventive care.

*A CD-ROM* with education material. Besides the theoretical items (causes of the adverse events, assessment of patients at risk and prevention of the adverse events) a test with feedback (for nurses to test their own knowledge) was included

**Patient involvement**

An information folders for the prevention of pressure ulcers, urinary tract infection and falls, separately. In addition to giving oral information nurses were asked to give the folder to patients at risk for the specific adverse event.

**Feedback**

The nurses register the patient's daily care and the presence or absence of an adverse event in a computerised registration system. This digital programme generates feedback by charts on the process and outcome indicators.

*Outcome measures*

The outcome measures were the process indicators: the percentage of patients at risk who received preventive care according to the guidelines.

*Patients at risk for pressure ulcers* were defined as the patients with mobility or activity impairments according to the Braden subscales "mobility" or "activity" (score less than 3) and/or were at risk according to a risk assessment tool. In hospitals, we used the PrePURSE scale (score more than 19)<sup>17</sup> and in nursing homes we used the Braden scale (score less than 18).<sup>18</sup> Preventive care was registered as "adequate" preventive care for patients at risk who were lying in bed and/or sitting in a chair and who received the combined preventive activities for pressure ulcers as described in Figure 2.<sup>19-21</sup>

Hospital patients were defined as being *at risk for a urinary tract infection* if they had at least one of the following four risk factors: 1) an indwelling catheter or an indwelling catheter less than one week before, 2) fecal incontinence, 3) urinary retention or 4) a urinary tract infection in the last two years.<sup>22,23</sup> Nursing home patients at risk for a urinary tract infection included all nursing home patients.<sup>22</sup> Preventive care was registered as "adequate" preventive care for patients who were at risk and who received the combined preventive activities for urinary tract infections as described in Figure 2.<sup>22,23</sup>



Figure 1. Trial profile of study

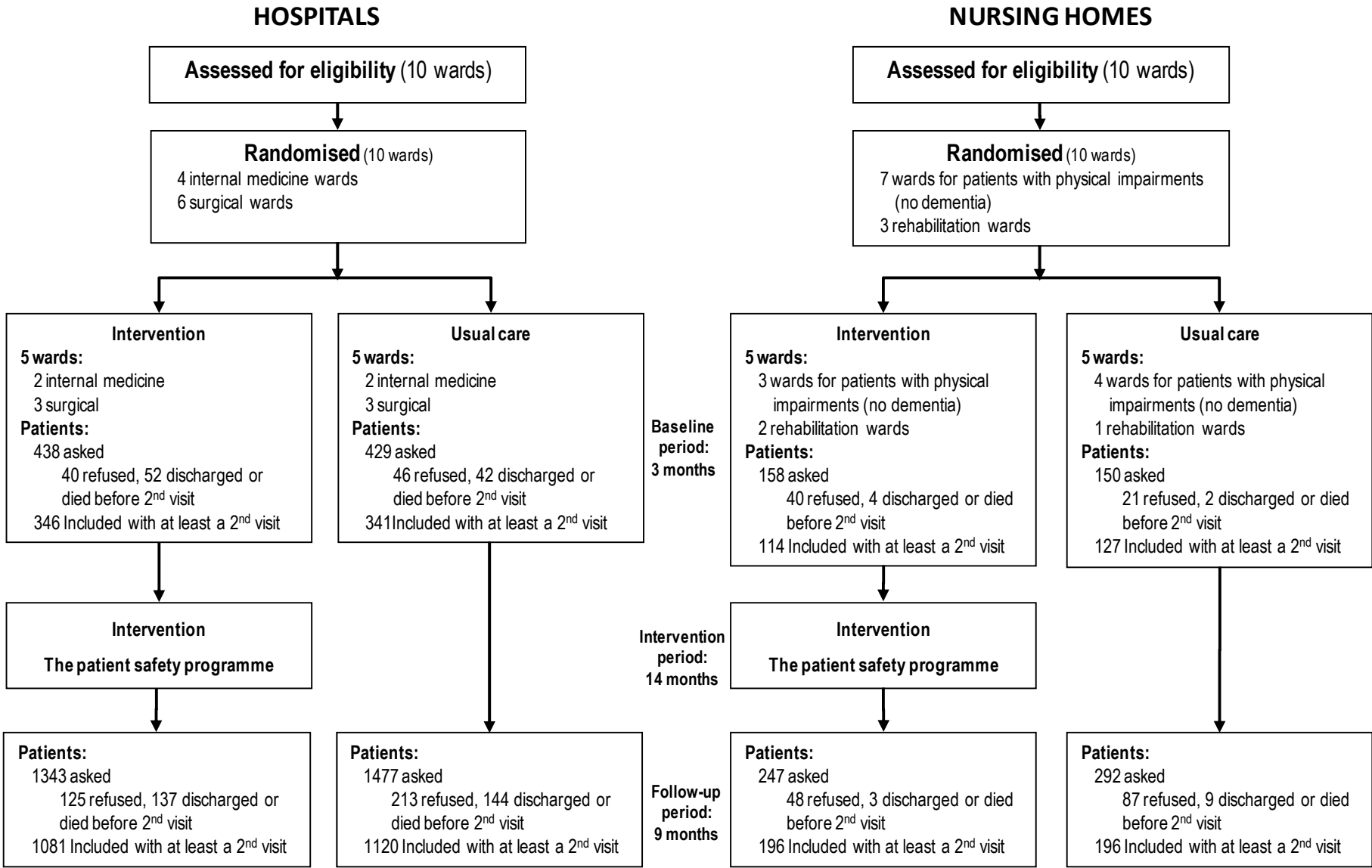
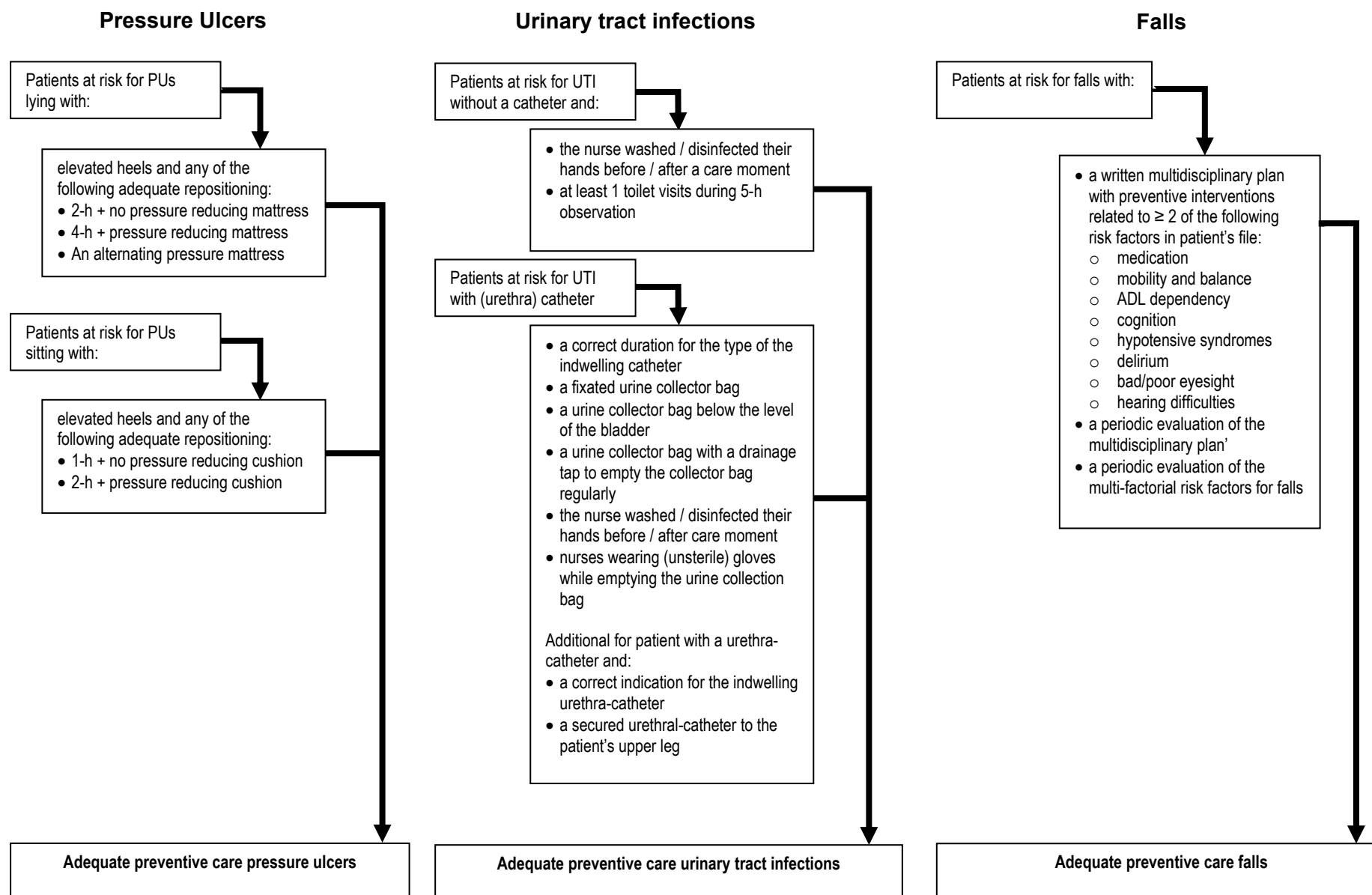


Figure 2. Adequate preventive care consists of



To identify hospital *patients at risk for falls*, the STRATIFY tool (score more than 1) <sup>24</sup> was used. In nursing homes all patients were considered at risk for falls, except those who were totally immobile. Preventive care was registered as "adequate" preventive care if patients at risk and who received the combined fall preventive activities as described in Figure 2.<sup>25</sup>

### *Data collection*

Trained independent research assistants collected the data in 1) a weekly visit, and 2) by three additional observations on every ward.

During the weekly visits, we collected data from the patient files and we observed the patients for the presence of preventive measures (Figure 2).

Through additional observations, we collected information on applied preventive care measures (Figure 2). We performed the additional observations for at least five consecutive hours in a random sample of at least five patients per ward who participated in the study.

### *Statistical analysis*

The outcome the preventive care given was calculated for each adverse event separately, and only in patients who were considered to be at risk for the particular adverse event. The results for hospitals and nursing homes were analysed separately, as patient characteristics and length of stay differ.

The patient characteristics were analysed using descriptive statistics. The results of this study were clustered to ward level, so we used random effects analyses with ward as random factor. Group, institution and the baseline results of the ward were fixed covariates. To analyse the difference in preventive care with respect to falls, we calculated the odds ratio, using a logistic model. For the other outcomes, odds ratios were less appropriate, because the incidences were above 20%, which makes odds ratios difficult to interpret. As a result, we were more interested in absolute differences, so we used a generalised linear model with Bernoulli distribution and linear link function. This linear analysis yielded a mean percentage that reflected the differences in mean percentage of preventive care between the intervention and usual care group at follow-up. Ninety five percent confidence intervals were calculated and results were considered significant if the confidence interval did not include unity.

The study is registered with [clinicaltrials.gov](https://clinicaltrials.gov), number NCT00365430.

### *Ethical considerations*

The Medical Ethics Committee of district Arnhem – Nijmegen assessed the study and concluded that our study was deemed exempt from their approval, as it did not involve research covered by the Medical Research Involving Human Subjects Act.

## Results

### *General*

Figure 1 shows the trial profile, and Table 3 the characteristics of the patients on the wards included in the intervention and usual care group at baseline and follow-up period. At follow-up, 1081 hospital patients on the five wards in the intervention group and 1120 hospital patients on the five wards in the usual care group were included. In nursing homes, 196 patients on the five wards were included in both the intervention and usual care group. The next sections show the difference in the adequate preventive care given between the intervention and usual care group during follow-up.

**Table 3. Characteristics of the patients**

HOSPITALS	Baseline		Follow-up	
	INT	UC	INT	UC
n	346	341	1081	1120
Age in years (mean (SD))	66 (14.5)	64 (16.9)	66 (14.7)	67 (16.1)
Female	184 (53.2)	204 (59.8)	570 (52.7)	646 (57.7)
Total visits	842	875	2657	2902
Patient weeks	496	534	1576	1782
Median admitted weeks (interquartile range)	1 (1–2)	1 (1–2)	1 (1–2)	1 (1–2)
Patients at risk for PUs <sup>b</sup>	46	50	49	52
Patients at risk for UTIs <sup>b</sup>	44	53	44	54
Patients at risk for falls <sup>b</sup>	15	23	16	22
Observed patients <sup>a</sup>	77	70	100	109
Mean observed hours/day <sup>a</sup>	6 (1.3)	6 (1.1)	4.9(0.6)	4.7(0.6)
NURSING HOMES	Baseline		Follow-up	
	INT	UC	INT	UC
n	114	127	196	196
Age in years (mean (SD))	78 (9.9)	78 (11.7)	80 (10.9)	79 (10.5)
Female	70 (61.4)	89 (66.0)	131 (66.8)	126 (64.3)
Total visits	1047	1185	2950	3241
Patient weeks	933	1058	2754	3045
Median patient weeks (interquartile range)	5 (3–8)	5 (3–8)	10 (4–9)	11 (5–20)
Patients at risk for PUs <sup>b</sup>	64	58	47	52
Patients at risk for UTIs <sup>b</sup>	100	100	100	100
Patients at risk for falls <sup>b</sup>	68	65	78	52
Observed patients <sup>a</sup>	89	88	151	148
Mean observed hours/day <sup>a</sup>	5.6 (0.7)	5.4 (0.5)	5.4 (0.6)	5.4 (0.5)

Values represent numbers (%) unless stated otherwise. INT=intervention group. UC=usual care group.

PUs = pressure ulcers. UTIs = urinary tract infections

a: number of patients with mean observed hours per day during additionally observations; b: values represent %

*Preventive care in hospitals*

*Pressure ulcers.* Forty nine percent of the hospital patients in the intervention group and 52% of the patients in the usual care group were at risk for pressure ulcers (Table 3). Ninety eight percent of these patients were in bed or in a chair at the time of the visit in both the intervention and the usual care group. In both groups, 27% of the patients at risk received "adequate" preventive care, i.e. they had elevated heels while sitting on a chair or lying in bed and received "adequate" repositioning as well (Table 4). No statistically significant difference in patients at risk receiving "adequate" preventive care was found between the intervention and usual care group (Estimate = 6%, CI = -7 to 19).

*Urinary tract infections.* Forty four percent of the hospital patients in the intervention group and 54% of the patients in the usual care group were at risk for urinary tract infections (Table 3). Thirty eight percent of these patients in the intervention group and 47% of these patients in the usual care group received "adequate" preventive care. Statistically significant fewer patients at risk in the intervention group received "adequate" preventive care (Estimate 19%, CI=17 to 21).

*Falls.* Sixteen percent of the hospital patients in the intervention group and 22% of the patients in the usual care group were at risk for falls (Table 3). In the intervention group, only 1% of these patients had a written multidisciplinary plan with multi-factorial preventive interventions, specifically addressed at prevention of falls. These multidisciplinary plans and the risk factors for falls were evaluated. In the usual care group, no patients at risk had a written multidisciplinary plan with multi-factorial preventive interventions, specifically addressed at prevention of falls. The numbers were too low for statistical analysis, but it seems obvious that there was no difference between the intervention and usual care group in "adequate" preventive care given.

**Table 4. Adequate preventive care in hospitals**

HOSPITALS	Baseline		Follow-up	
	INT	UC	INT	UC
	n	346	1081	1120
<b>Pressure ulcers</b>				
Patients at risk:				
with pressure reducing material:				
pressure reducing cushion	1%	2%	2%	2%
pressure reducing mattress	97%	97%	86%	98%
alternate mattress	2%	3%	1%	1%
sitting or lying with elevated heels	35%	40%	29%	40%
sitting or lying with elevated heels and "adequate" repositioning	31%	36%	27%	27%
sitting or lying with elevated heels and turning scheme or alternate mattress while lying	0	<1%	2%	1%
<b>Urinary tract infections</b>				
Patients at risk without a catheter and:				
nurses' hand hygiene	59%	44%	52%	66%
at least 1 toilet visit during 5-h observation	61%	44%	33%	33%
Patients at risk without a catheter and with above mentioned preventive measures	60%	44%	43%	50%
Patients at risk with a catheter:				
nurses' hand hygiene	24%	22%	35%	32%
a correct duration of use of indwelling catheter conform the type of catheter	56%	50%	53%	66%
a fixated urine collector bag	44%	64%	51%	58%
a urine collector bag with a drainage tap to empty the collector bag regularly	86%	85%	84%	90%
a urine collector bag below the level of the bladder	61%	57%	75%	80%
a urine collector bag below the level of the bladder	91%	84%	88%	92%
nurses wearing (unsterile) gloves while emptying the urine collector bag	39%	64%	85%	61%
with a urethra-catheter and:				
a secured urethra-catheter to patients' upper leg	83%	95	75%	95%
a correct indication for the indwelling urethra-catheter	18%	29%	17%	31%
a correct indication for the indwelling urethra-catheter	74%	71%	61%	65%
Patients at risk with a catheter and with above mentioned preventive measures	32%	34%	30%	40%
Overall: patients with and without a catheter and with all above preventive measures	53%	42%	38%	47%
<b>Falls</b>				
Patients at risk:				
with a written multidisciplinary plan:	1%	0	4%	3%
and preventions related to $\geq 2$ risk factors	0	0	1%	0
and periodic evaluation of the multidisciplinary plan	0	0	1%	0
and periodic evaluation of the risk factors for falls	0	0	1%	<1%

Values represent % unless stated otherwise

### *Preventive care in nursing homes*

**Pressure ulcers.** Fifty eight percent of the nursing home patients in the intervention group and 71% of the patients in the usual care group were at risk for pressure ulcers (Table 3). In the intervention group, 99% of patients and all patients in the usual care group were in bed or in a chair at the time of the visit. In the intervention group, 19% of the patients at risk had elevated heels while sitting on a chair or lying in bed and

received "adequate" repositioning as well, compared to 13% in the usual care group (Table 5). Statistically, no difference in patients at risk who received "adequate" preventive care was found between the intervention and usual care group (Estimate = 4%, CI=-5 to 13).

*Urinary tract infections.* All nursing home patients were at risk for urinary tract infections in both groups (Table 3). Forty three percent of these patients in the intervention group received "adequate" preventive care compared to 41% in the usual care group. Statistically, no difference in patients at risk receiving "adequate" preventive care was found between the intervention and usual care group (Estimate 6%, CI=-13 to 26).

*Falls.* Seventy eight percent of the nursing home patients in the intervention group and 52% of the patients in the usual care group were at risk for falls (Table 3). In the intervention group, 22% of these patients at risk had a written multidisciplinary plan with multi-factorial preventive interventions, specifically addressed at prevention of falls. One percent of these multidisciplinary plans was evaluated periodically. The risk factors for falls were also evaluated in 1% during admission. Thus overall 1% of the patients received "adequate" preventive care. In the usual care group, 3% of the patients at risk had a written multidisciplinary plan with multi-factorial preventive interventions, specifically addressed at prevention of falls. In one percent of the patients at risk, the multidisciplinary plan was evaluated and in less than 1% the risk factors for falls were evaluated. Thus overall less than 1% of the patients received "adequate" preventive care. The percentage of patients receiving "adequate" preventive care were too low for statistical analysis. Instead, we analysed the difference in patients with a written multidisciplinary plan with multi-factorial preventive interventions between the intervention and usual care group. Results showed that in the intervention group more patients at risk for falls had a multidisciplinary plan with multi-factorial preventive interventions (22%) compared to the usual care group (3%)  $P<0.01$ .

Table 5. Adequate preventive care in nursing homes

NURSING HOMES	Baseline		Follow-up	
	INT	UC	INT	UC
n	114	127	196	196
<b>Pressure ulcers</b>				
Patients at risk:				
with pressure reducing material:				
pressure reducing cushion	38%	50%	33%	55%
pressure reducing mattress	36%	25%	38%	57%
alternate mattress	14%	20%	18%	23%
sitting or lying with elevated heels	28%	27%	28%	21%
sitting or lying with elevated heels and "adequate" repositioning	19%	17%	19%	13%
sitting or lying with elevated heels and turning scheme or alternate mattress while lying	2%	3%	8%	8%
<b>Urinary tract infections</b>				
Patients at risk without a catheter:				
nurses' hand hygiene	42%	32%	33%	38%
at least 1 toilet visit during 5-h observation	40%	65%	58%	53%
Patients at risk without a catheter and with above mentioned preventive measures	41%	48%	46%	46%
Patients at risk with a catheter:				
nurses' hand hygiene	44%	27%	38%	39%
a correct duration of use of indwelling catheter conform the type of catheter	36%	64%	35%	62%
a fixated urine collector bag	81%	76%	76%	74%
a not routinely replaced (not daily) urine collector bag	32%	22%	51%	17%
a urine collector bag below the level of the bladder	65%	79%	74%	72%
nurses wearing (unsterile) gloves while emptying the urine collector bag	26%	41%	42%	34%
with a urethra-catheter:	39%	41%	82%	54%
a secured urethra-catheter to patients' upper leg	0	2%	3%	2%
a correct indication for the indwelling urethra-catheter	34%	16%	32%	34%
Patients at risk with a catheter and with above mentioned preventive measures	27%	15%	20%	21%
Overall: patients with and without a catheter and with all above preventive measures	39%	44%	43%	41%
<b>Falls</b>				
Patients at risk:				
with a written multidisciplinary plan:	9%	15%	45%	17%
and preventions related to $\geq 2$ risk factors	1%	3%	22%	3%
and periodic evaluation of the multidisciplinary plan	0	4%	1%	1%
and periodic evaluation of the risk factors for falls	0	<1%	1%	<1%

Values represent % unless stated otherwise

## Discussion and conclusion

To facilitate the implementation of multiple guidelines, we developed a comprehensive patient safety programme including education, patient involvement, and computerised timely feedback on process- and outcome indicators. The effect was tested on the preventive measures applied to patients at risk. We found that the percentage of patients at risk for pressure ulcers that received preventive measures did not differ



between the intervention and the usual care group, in both hospitals and nursing homes. For urinary tract infections, we only found a difference in hospitals, but this difference was in favour of the usual care group. For falls, there was no difference between the intervention and the usual care group, in hospitals or in nursing homes. In nursing homes, more patients at risk for falls in the intervention group had a written multidisciplinary plan with multi-factorial preventive interventions, specifically addressed at prevention of falls, but too few patients had an evaluated multidisciplinary plan or had an evaluation of the risk factors for falls, which are both essential in "adequate" preventive care for falls. Despite these findings, the strength of the patient safety programme lies in the fact that it is a comprehensive programme for the implementation of multiple guidelines and applicable for many guidelines in health care, particularly by the structural approach of each topic and the computerised programme that gave timely feedback on the indicators.

In the SAFE or SORRY? study, we measured both outcome- and process indicators. There is an ongoing discussion about whether processes or outcomes should be measured in quality assessment.<sup>26</sup> An advantage of outcome measures is that they reflect all aspects of the process of care and not simply those that are measurable or measured.<sup>27</sup> In another article of this study, we reported the results of the patient safety programme on the incidence of the three adverse events (we found 43% and 33% fewer adverse events for patients in the intervention group in hospitals and nursing homes, respectively). Differences in outcome cannot simply be explained by differences in care. They can be explained by case mix, differences in data collection methods, chance, or differences in quality of care.<sup>27</sup> An outcome indicator will not give detailed insight into the differences in care. Therefore, we chose an outcome that is more sensitive to differences in preventive care; the incidence of adverse events.

An advantage of process indicators is that they are more sensitive to differences in the quality of care than outcome measures.<sup>27</sup> Process indicators are easier to formulate and are less affected by confounders, but their relationship with specific patient outcomes may be less certain.<sup>26</sup> Therefore, we not only measured process indicators, but we too measured outcome indicators.

In this study, we adjusted for the differences in type of patient (we analysed the results separately for hospitals and nursing homes and stratified the randomisation for institute and ward). Additionally, we standardised the measurements and the study was powered on the outcome indicator. We assumed that the positive results on the outcome, were

related to the differences in quality of care and we expected to find positive results on the preventive care. Surprisingly, we did not find more prevention. How do we match the positive results on the incidence of the adverse events to the results presented in this paper?

A first reason may lie in the guideline based outcome and process indicators used in the computerised registration and feedback system of the patient safety programme. Per topic we developed outcome and process indicators which were meant to give insight into the quality of care regarding the three adverse events to the nurses on the intervention wards. However, the feedback on the process indicators in our patient safety programme may not have been sufficient. The feedback form process indicators differed from the outcome indicators in two ways. First, we developed more outcome – prevalence and incidence- indicators than process indicators per topic and second, the nurses received daily feedback on the outcome indicators while the feedback on the process indicators was provided weekly. As a result of that, nurses only 'saw' how they provided preventive care once a week but they immediately (the next morning) 'saw' whether patients on the ward developed (incidence) or had an adverse event (prevalence). Furthermore, the feedback for each of the three topics on the process indicators was summarised into a single 'adequate prevention score' indicator per topic. By doing this, nurses could monitor preventive care rather roughly but did not get detailed insight into their preventive care performance. For instance, if patients did not have a repositioning scheme (and no alternating pressure mattress), but received all the other preventive activities, it was not registered as good preventive care. As a result, nurses were not able to see which activity they had to give more attention, e.g. repositioning. Nurses only saw -in a graphic- the percentage of patients who received "adequate" preventive care. In future, this can be improved by giving feedback on the several process indicators per topic so that professionals gain insight into the preventive activities given and the preventive activities withheld.

Another possible explanation concerns some methodological considerations and the data collection in this study. We measured the combined process indicator per topic and therefore, used a rigorous standard of what we considered as "adequate" preventive care. Only patients who met the combination of preventive activities given (Figure 2) at every observation moment were registered as receiving "adequate" preventive care. As a result, quite a few preventive activities were not registered as "adequate" preventive

care, because they were not combined with other preventive activities. It is questionable whether it is necessary to combine the activities in order to be effective in preventing the specific adverse events, and if all these preventive activities are necessary all the time. Maybe it is enough to receive 80% of all the activities or to receive the preventive activities in four out of five observation moments and not five out of five, as we have performed in this study. By using this rigorous standard, we probably registered a lot of preventive activities as inadequate preventive care and therefore missed them in our results.

A further point is the identification of patients at risk for adverse events, i.e. those who should receive preventive care. We used recommended risk assessment scales for pressure ulcers and falls.<sup>17,18,24</sup> Despite the use of accepted and validated risk assessment scales, we acknowledge that the currently available scales for pressure ulcers and falls have limitations. The risk assessment scales are known to classify patients incorrectly into both the 'at risk' and 'not at risk' groups.<sup>28-30</sup> In this study, we used a risk assessment scale for pressure ulcers in combination with the Braden subscales 'mobility' (score less than 3) and 'activity' (score less than 3), because immobile (Braden subscale less than 3) and/or inactive patients (Braden subscale less than 3) are unable to move sufficiently of their own accord and are therefore at risk for pressure ulcers. The risk assessment scales used did not classify all the immobile or inactive patients as 'at risk'. Therefore, we combined the risk assessment scales used in hospitals and nursing homes with the Braden subscales 'mobility' and 'activity'. As a result of this, we may have overestimated the patients at risk for pressure ulcers and thus the patients who should receive prevention.

Furthermore, the nurses on the intervention wards were trained in assessing the patients at risk with a risk assessment tool (PrePURSE and STRATIFY in hospitals and Braden in nursing homes), in combination with their clinical judgement. As a result, nurses in daily practice may have adjusted the classification of the risk status of the patients based on their clinical judgement. Therefore, nurses probably will not give preventive care to every patient at risk according to a risk assessment scale.

An additional explanation concerns the data collection, patient files have been used to collect the data. They have been found to notoriously underreport the care given.<sup>31</sup> Underreporting could have occurred in the prevention given on falls, as fall prevention prescribes a written multidisciplinary plan which should be part of the patient file. Especially in hospitals where patient turnover is high, a written multidisciplinary plan was often not found in patient files. To limit underreporting, we combined two data

collection methods. Besides the data from the patient files, we collected data by observing the preventive care given to the patients at risk. If the data had been collected during the weekly visits only, it would be impossible to measure typical preventive interventions, e.g. "adequate" repositioning for patients at risk for pressure ulcers or hand hygiene for patients at risk for urinary tract infections. Therefore, three observations were performed on every ward in addition to the weekly visits. By using combined data collection methods, we obtained a better impression of the preventive care given.

Another point is that preventive care is a continuous process: 24 hours a day and seven days a week. Despite the combined data collection, we could only give a random indication of the continuous process of preventive care given, which is a limited impression and not the continuous process.

Based on this study we come to a few recommendations. The first concerns the development of process indicators. Process indicators can be used to measure quality improvement, but they should be tested for their validity, reliability, as well as sensitivity to change. A second suggestion concerns monitoring quality improvement by using process indicators. To gain insight into the process of guideline based preventive care, it is essential to develop several process indicators reflecting the essential guideline based recommendations. Finally, collecting data on the preventive care given is not easy, because it is a continuous complex process and it is impossible to measure such care 24 hours a day and seven days a week. To obtain an accurate impression of the preventive care, we recommend collecting this kind of data by frequent observations.

In conclusion, this study showed no positive effect of the patient safety programme on the preventive care delivered to patients at risk for an adverse event. These results emphasise the difficulties in measuring the compliance to guidelines. More research is needed to explore possibilities to measure the implementation of multiple guidelines using process indicators.

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## Chapter 7

### **The effect of the SAFE or SORRY? programme on patient safety knowledge of nurses in hospitals and nursing homes: a cluster randomised trial**

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**Abstract**

*Background:* Patients in hospitals and nursing homes are at risk for the development of often preventable adverse events. Guidelines for the prevention of many types of adverse events are available, however compliance with these guidelines appears to be lacking. As a result many patients do not receive appropriate care. We developed a patient safety programme that allows organisations to implement multiple guidelines simultaneously and therefore facilitates guideline use to improve patient safety. This programme was developed for three frequently occurring nursing care related adverse events: pressure ulcers, urinary tract infections and falls. For the implementation of this programme we developed educational activities for nurses as a main implementation strategy.

*Objectives:* The aim of this study is to describe the effect of interactive and tailored education on the knowledge levels of nurses.

*Design:* A cluster randomised trial was conducted between September 2006 and July 2008.

*Settings:* Ten hospital wards and ten nursing home wards participated in this study. Prior to baseline, randomisation of the wards to an intervention or control group was stratified for centre and type of ward.

*Participants:* All nurses from participating wards.

*Methods:* A knowledge test measured nurses' knowledge on the prevention of pressure ulcers, urinary tract infections and falls, during baseline and follow-up. The results were analysed for hospitals and nursing homes separately.

*Results:* After correction for baseline, the mean difference between the intervention and the control group on hospital nurses' knowledge on the prevention of the three adverse events was 0.19 points on a zero to ten scale (95% CI: -0.03 to 0.42), in favour of the intervention group. There was a statistically significant effect on knowledge of pressure ulcers, with an improved mean mark of 0.45 points (95% CI: 0.10–0.81). For the other two topics there was no statistically significant effect. Nursing home nurses' knowledge did neither improve (0 points, CI: -0.35 to 0.35) overall, nor for the separate subjects.

*Conclusion:* The educational intervention improved hospital nurses' knowledge on the prevention of pressure ulcers only. More research on long term improvement of knowledge is needed.



## Introduction

### *Background*

Recent studies showed that patients in hospitals and nursing homes are at risk for the development of, often preventable, adverse events (Table 1).<sup>1</sup> An adverse event is defined as "an unintended injury that results in prolonged stay, disability at the time of discharge, or death and is caused by health care management rather than by the patient's underlying disease process".<sup>1</sup>

**Table 1. Definitions**

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An **adverse event** is an unintended injury that results in prolonged stay, disability at the time of discharge, or death and is caused by health care management rather than by the patient's underlying disease process.<sup>1</sup>

A **pressure ulcer** is an area of localised damage to the skin and underlying tissue caused by a combination of pressure and shear. Pressure ulcers are classified in four grades.<sup>11,12</sup>

A **urinary tract infection** is bacteriuria with clinical symptoms as: frequent urinating, pain while urinating, abdominal pain, fever, delirium and urinary incontinence.<sup>13</sup>

A **fall** is an unexpected event in which the participant comes to rest on the ground floor, or lower level.<sup>14,15</sup>

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Although many guidelines are available, compliance with these guidelines appears to be lacking.<sup>2-4</sup> As a result, many patients receive inappropriate care.<sup>5</sup> Generally, many factors or barriers may influence compliance – or noncompliance – with a guideline.<sup>5</sup> These general barriers may be related to the individual (e.g. knowledge, skills, attitudes, motivation) or the individual's social context (e.g. patients, colleagues, culture), and the organisational setting (e.g. financial, equipment).<sup>6</sup> Moreover, the large number of guidelines competing for attention makes it difficult to keep track of all of them. In addition organisations must translate each guideline to their own target group, and develop and organise their own information and education, which is a time-consuming process. All this combined makes it difficult for organisations to implement all relevant guidelines. This situation is at odds with the responsibility of professionals to ensure patient safety. To facilitate hospital and nursing home organisations in guideline implementation, we developed a patient safety programme (SAFE or SORRY?) that allows organisations to implement multiple guidelines simultaneously.<sup>7</sup> We developed this programme for three frequently occurring nursing care related adverse events, for which guidelines on preventive care are available: pressure ulcers, urinary tract infections and falls. For the implementation of this patient safety programme we developed educational activities as a main implementation strategy.

Education is a necessary component of any implementation strategy<sup>8</sup> and can lead to changes in professional behaviour,<sup>5</sup> although the effects of most types of education are

small.<sup>5</sup> In general, passive approaches (written material and large-scale educational meetings) are ineffective and unlikely to result in behaviour change.<sup>9</sup> To improve the effectiveness of an educational strategy, the activities should have specific characteristics.<sup>9</sup> Education that is interactive and personal, such as small-scale educational meetings and educational outreach visits, is more effective.<sup>5</sup> Therefore we developed interactive and personal educational activities which were tailored to the needs of the nursing ward. Subsequently, we assessed the effect of this educational implementation strategy on nurses' knowledge.

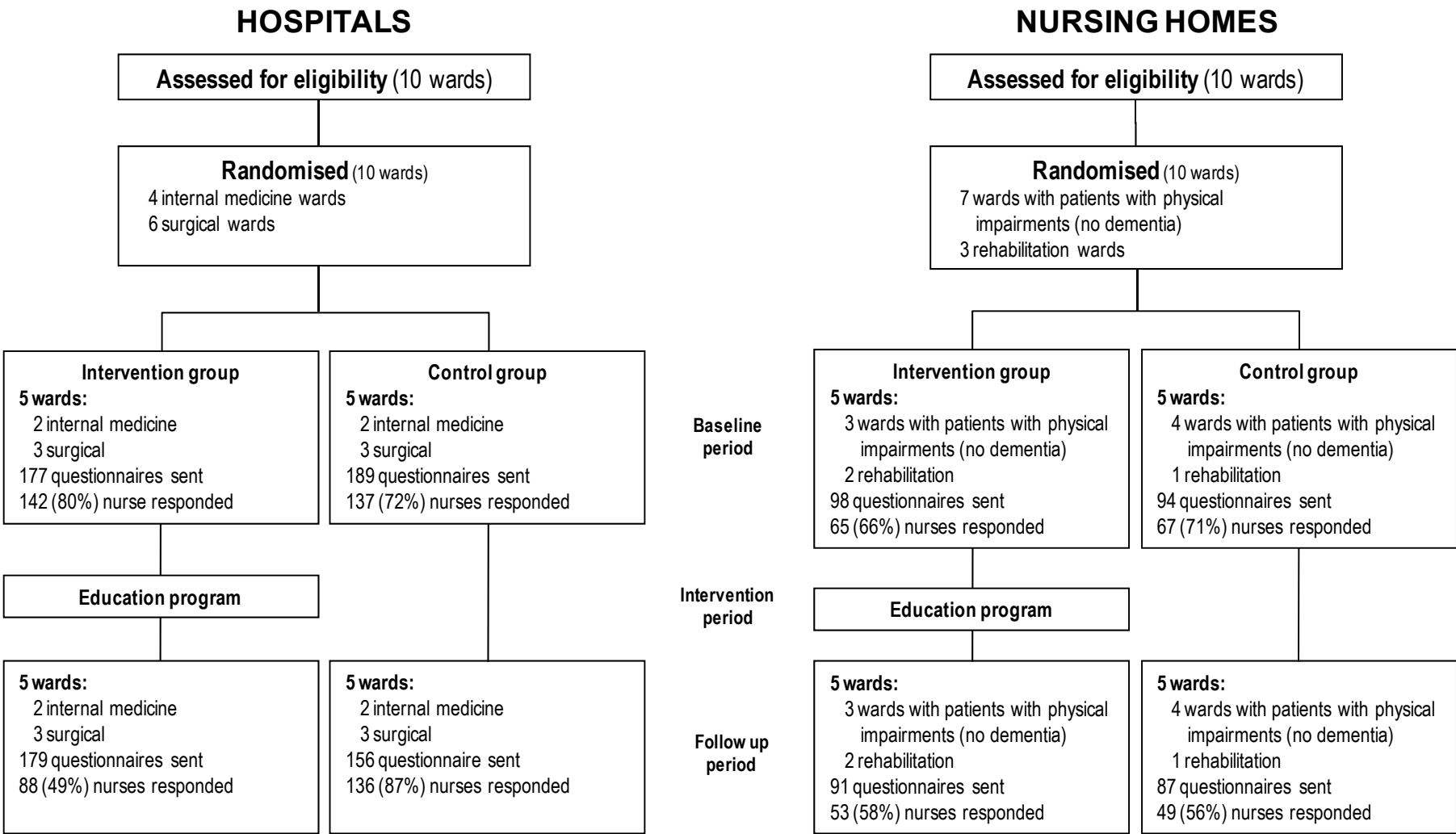
In this article we will describe the effect of interactive and tailored education on the knowledge levels of the nurses.

## Methods

### *Design and settings*

The study was embedded in the SAFE or SORRY? study, which is a cluster randomised trial.<sup>7</sup> The effectiveness of our educational intervention was tested within this trial. In a cluster randomised trial, groups of individuals rather than individuals are randomised.<sup>10</sup> In our study the intervention involved the entire team of nurses and not individual nurses on nursing wards. Therefore nurses within the same ward were considered to be a cluster.<sup>10</sup> The current study was conducted between September 2006 and July 2008. It included a purposive sample of 20 wards from four hospitals (one university hospital, two large teaching hospitals and one small hospital) and six nursing homes in the Netherlands. Hospitals and nursing homes were asked to participate with two or four, more or less comparable wards. The hospital wards were internal medicine wards (n=4) and surgical wards (n=6). The nursing home wards were wards with patients with physical impairments (no dementia) (n=7) and rehabilitation wards (n=3). The randomisation of the wards was stratified for centre and type of ward and took place prior to baseline data collection (Figure 1). The baseline period was in September 2006 and follow-up measurement was performed from May to July 2008, 1 year after the end of the intervention period. Five hospital wards and five nursing home wards were randomised to the intervention group.

Figure 1. Flow diagram



### *Outcome*

The score on a test regarding the three topics: pressure ulcers<sup>11,12</sup>, urinary tract infections<sup>13</sup> and falls.<sup>14,15</sup>

### *Data collection*

All registered and licensed nurses working within the 20 participating wards were invited to participate in the study. Data were collected using questionnaires. At each ward, one nurse was responsible for the distribution and collection of the questionnaires.

### *Development of the questionnaire*

The questionnaire contained a knowledge test and seventeen demographic questions: e.g. age, gender, work experience on the present ward. The knowledge test contained 20 statements per topic, addressing aetiology of the adverse events, risk assessment and preventive care. With each statement, nurses could answer 'correct', 'incorrect', or 'do not know'. The test was based on existing knowledge tests<sup>16-19</sup> and tests on the three adverse events used at the HAN University of Applied Sciences. The face validity was tested by sending the knowledge test to the members of the research group (LS, JM, RK and TvA), and an additional expert per topic. Based on their feedback, we changed suggestive statements into more objective statements and reformulated statements that were considered too easy. Finally, we asked four nurses in hospitals and nursing homes to pre-test the knowledge test. No changes were made after this test.

### *Intervention*

The nurses from the intervention wards received the educational interventions of the patient safety programme between December 2006 and June 2007. Nurses from the control wards did not receive educational interventions.

The content of the educational intervention was based on the existing guidelines for the prevention of pressure ulcers, urinary tract infections and falls,<sup>13,15,20-22</sup> and supplementary material<sup>12,23-25</sup> and tailored to each individual ward. The education consisted of small-scale educational meetings, educational materials and outreach visits. The development of this intervention was described in an earlier article.<sup>7</sup>

The implementation period started with two to three small-scale educational meetings (1.5 h). All nurses had to attend one meeting. The main subjects during these meetings

were: causes of adverse events, assessment of patients at risk for adverse events and how to prevent the adverse events. After 2–3 months, every ward planned two case discussions (30 min). During these case discussions the nurses and the researcher reviewed patients on their ward regarding the causes of adverse events, assessment of risk for adverse events and preventive care.

The educational material consisted of an educational compact disc for every ward. Besides the theoretical items (causes of the adverse events, assessment of patients at risk and prevention of adverse events) a test with feedback (for nurses to test their own knowledge) was included. At most wards the educational compact disc was copied onto the desktop of the computer, allowing nurses to look up the information during their work. Where this was not possible, the nurses received a copy of the compact disc and took it home.

Additionally, every intervention ward appointed two key nurses to the study. Together with the ward manager they were responsible for the implementation of the intervention on their ward. In the hospitals these key nurses were all registered nurses. In the nursing homes key nurses were registered and licensed nurses. They all received training in managing the different types of educational interventions. Also, the result of the baseline test was discussed and all educational activities on the wards were planned and organised. During the intervention period the researcher planned two outreach visits (5 h) with key nurses at every ward for training on the job. The key nurses had periodical contact with the researcher about the progress of the intervention.

#### *Ethical considerations*

The local Medical Ethics Committee assessed the study and waived the need for complete evaluation of the study. The anonymity of both the wards and the nurses in the hospitals and nursing homes was assured. Ref. No.: CMO nr: 2005/121.

#### *Statistical analysis*

For the current study, all nurses working on the participating wards during baseline and follow-up, were invited to participate. In the Netherlands the majority of the hospital nurses are bachelor or registered nurses, while in nursing homes very few bachelor or registered nurses are employed. Here, the majority of the nurses are licensed nurses. Because nurses' characteristics differ between hospitals and nursing homes, the data

were analysed for hospital wards and nursing home wards separately. With the knowledge test, every correct answer scored one point, every incorrect answer scored minus one point and the 'do not know' answers and omitted answers were given zero points. To calculate an overall mark for the three topics we first added up the scores for each topic to obtain a number between -20 and 20. Second, to get a mark between 0 and 10 we calculated as follows:  $(\text{the result of a topic} + 20)/4$ . Third, the overall mark was subsequently calculated in the following way:  $(\text{mark pressure ulcers} + \text{mark urinary tract infections} + \text{mark falls})/3$ .

We used a linear random effects model to analyse the difference in the results on the knowledge test between the intervention and the control wards at follow-up. This model was used because of the hierarchical structure of the data (nurses were clustered within wards. Data were analysed with the baseline values as covariate, centre as fixed factor and ward as random factor. Ninety-five percent confidence intervals were calculated and results were considered significant if the confidence interval did not include zero.

## Results

### *Hospitals*

In hospitals, 503 nurses (72%) returned the knowledge test. The response rate in all groups was high (>70%) with the exception of the intervention group at follow-up (49%) (Table 2), yet in each group every ward had an equal percentage of nurses who returned the questionnaire. The mean age of the nurses was 38 years (SD = 10.7) and 411 (89%) were females. There were no differences in hospital nurses' characteristics between the intervention and the control group at baseline or follow-up (Table 2).

At follow-up, multilevel analysis showed that for the intervention group the mean overall mark on the knowledge of the three adverse events improved with 0.19 points (on a zero to ten scale). However, this improvement was statistically non-significant (95% CI: -0.03 to 0.42). The knowledge on two topics (urinary tract infections and pressure ulcers) showed a positive trend in favour of the intervention group (Table 4). Improved knowledge on pressure ulcers was statistically significant (0.45 points (95% CI: 0.10–0.81)).

Table 2. Characteristics of hospital nurses

HOSPITALS	Baseline		Follow-up	
	Intervention	Control	Intervention	Control
<b>n</b>	142	137	88	136
<b>Age</b> <i>mean</i> yr (SD)	37.0 (9.9)	38.2 (11.3)	36.9 (10.0)	38.1 (11.5)
<b>Female</b>	119 (92)	109 (87)	76 (91)	107 (85)
<b>Highest education</b>				
Primary school	1 (1)	1 (1)	0	0
Secondary school	63 (50)	61 (48)	41 (53)	57 (46)
High school	63 (50)	62 (49)	36 (47)	64 (52)
University	0	2 (2)	0	2 (2)
<b>Position on ward</b>				
Bachelor nurses	59 (42)	67 (50)	36 (41)	66 (49)
Registered nurses	80 (57)	66 (49)	50 (57)	67 (50)
Licensed nurses	2 (1)	2 (2)	2 (2)	1 (1)
<b>Work experience</b>				
Current ward <i>mean</i> yr (SD)	8.8 (7.6)	8.4 (7.0)	9.4 (7.9)	8.4 (7.5)
Work hours/week	26.2 (8.1)	27.2 (7.2)	27.1 (7.6)	28.8 (6.4)
<b>Post registration education last 3 yr:</b>				
Pressure ulcers	64 (45)	74 (55)	48 (55)	53 (39)
Urinary tract infections	1 (1)	5 (4)	17 (20)	13 (10)
Falls	22 (20)	12 (9)	20 (23)	13 (10)

Values represent number (percentages) unless stated otherwise

### *Nursing homes*

In nursing homes 234 (63%) nurses returned the knowledge test. The response rate at baseline was higher (69%) than at follow-up (57%). The mean age of the nurses was 39 years (SD = 10.2) and 214 (96%) were females. There were no differences in nurses' characteristics for the intervention and the control group at either baseline or follow-up (Table 3).

At follow-up, multilevel analysis showed no difference in the mean overall mark between the intervention and the control group (Table 4). The knowledge on one topic improved in the intervention group (0.17 points (95% CI: -0.31 to 0.65)) on a zero to ten scale, however this improvement was statistically non-significant.

Table 3. Characteristics of nursing home nurses

NURSING HOMES	Baseline		Follow-up	
	Intervention	Control	Intervention	Control
<b>n</b>	65	67	53	49
<b>Age</b> <i>mean</i> yr (SD)	38.1 (10.0)	38.4 (10.0)	41.3 (10.3)	37.4 (10.1)
<b>Female</b>	58 (97)	59 (95)	45 (98)	43 (94)
<b>Highest education</b>				
Primary school	4 (7)	2 (3)	0	1 (3)
Secondary school	49 (85)	53 (90)	38 (88)	32 (84)
High school	5 (9)	4 (7)	5 (12)	4 (11)
University	0	0	0	1 (3)
<b>Position on ward</b>				
Bachelor nurses	0	0	1 (2)	1 (2)
Registered nurses	13 (21)	13 (20)	7 (14)	11 (22)
Licensed nurses	49 (79)	51 (80)	43 (84)	37 (76)
<b>Work experience</b>				
Current ward <i>mean</i> yr (SD)	9.0 (7.8)	7.2 (5.8)	7.4 (7.5)	6.9 (5.8)
Work hours/week	24.5 (8.9)	25.8 (8.0)	24.5 (7.8)	26.4 (8.1)
<b>Post registration education last 3 yr</b>				
Pressure ulcers	15 (23)	28 (42)	25 (48)	17 (36)
Urinary tract infections	8 (13)	5 (8)	21 (41)	4 (9)
Falls	6 (9)	5 (8)	17 (33)	4 (9)

Values represent numbers (percentages) unless stated otherwise

Table 4. Mean marks of nurses' knowledge in hospitals and in nursing homes

HOSPITALS	Baseline		Follow-up		Estimate	95% CI
	Intervention	Control	Intervention	control	*	*
Overall	6.8 (0.60)	6.9 (0.57)	7.2 (0.78)	7.1 (0.64)	0.19	-0.03 to 0.42
Pressure ulcers	5.4 (0.95)	5.7 (0.94)	6.0 (1.10)	5.7 (0.99)	0.45	0.10 to 0.81
Urinary tract infections	7.1 (0.78)	7.1 (0.85)	7.4 (0.95)	7.3 (0.87)	0.15	-0.15 to 0.45
Falls	7.9 (0.88)	7.9 (0.90)	8.3 (1.03)	8.2 (0.87)	-0.03	-0.35 to 0.29
NURSING HOMES	Baseline		Follow-up		Estimate	95% CI
	Intervention	Control	Intervention	control	*	*
Overall	6.4 (0.73)	6.1 (0.58)	6.7 (0.81)	6.4 (0.67)	0.00	-0.35 to 0.35
Pressure ulcers	5.0 (0.84)	4.8 (0.78)	5.4 (0.96)	5.1 (0.76)	-0.05	-0.48 to 0.39
Urinary tract infections	6.9 (0.97)	6.5 (0.89)	7.1 (0.97)	6.6 (0.94)	0.17	-0.31 to 0.65
Falls	7.3 (1.23)	7.1 (1.05)	7.7 (1.23)	7.6 (1.13)	-0.12	-0.71 to 0.48

Values represent mean marks (st dev) unless stated otherwise; \* Results from multilevel analysis

## Discussion en conclusion

This study showed that the educational intervention of the patient safety programme did not improve nurses' knowledge on the three adverse events in hospitals and nursing homes. There was a small positive overall effect on hospital nurses' knowledge, but this effect was statistically non-significant and too small to be relevant for daily practice. Of the three topics, only the knowledge on pressure ulcers showed a statistically significant improvement that is also relevant for daily practice. For the other topics there were no effects. Nursing home nurses' knowledge on the three adverse events did not improve. Of the three topics, the knowledge of urinary tract infections showed a small



improvement, but this effect was statistically non-significant and too small to be relevant for daily practice.

To appreciate our results some aspects need to be discussed. For this study we wanted to develop an effective educational intervention. Therefore, we avoided passive education (written material and large-scale educational meetings), because this kind of education is less effective than education which is interactive and personal.<sup>5,9</sup> For that reason our educational intervention employed small-scale educational meetings, which were all interactive and tailored to the wards.<sup>7</sup> We further developed an interactive compact disc with an additional knowledge test to avoid written and standard material. Also the outreach visits had an interactive and personal character.

While many studies describe the effectiveness of an educational intervention to change health care professional practice and behaviours,<sup>26-32</sup> fewer studies describe the effectiveness of an educational intervention on knowledge of health care professionals.<sup>33-36</sup> Most of these pre- and post-test studies on knowledge did describe an increase of knowledge, but none of these studies had a control group. Moreover, knowledge was usually measured immediately after the intervention. One study measured knowledge at intervals, i.e. immediately after the intervention, 3 months and 6 months after the intervention.<sup>34</sup> This study showed that indeed there was an increase of knowledge immediately and 3 months after the intervention, but the positive changes did not sustain for more than 6 months.<sup>34</sup> This could be a possible explanation for the lack of significant increase in knowledge in our study, as our follow-up measurement took place one and a half year after the start of the educational intervention. Unfortunately, we could not measure knowledge at intervals, because our evaluation was part of a larger study<sup>7</sup> and measuring knowledge at intervals could have caused bias in other outcomes. In this light, the positive effect on hospital nurses' knowledge of pressure ulcers might even imply that the increase in nurses' knowledge is a long term improvement, which is promising for further development of this educational intervention. However, more research into the short- and long term effects of this type of education is needed.

Another explanation for the limited effects could lie in the knowledge test. We chose to use a self-constructed knowledge test because we did not find an existing test that fitted our intervention. Although good knowledge tests are available for each of the topics

separately, there was no test that addressed all topics simultaneously. Combining three existing knowledge tests would have resulted in too many questions. Moreover, as the existing knowledge tests focussed on both prevention and treatment, we would have posed irrelevant questions, as our intervention focussed on prevention only. Therefore, we selected the relevant questions on the prevention of the three adverse events from several sources and constructed our own knowledge test. Unfortunately we were not able to fully validate the self-constructed knowledge test. While we did test the face validity in an expert panel, we did not extensively assess the knowledge test in our population. We were concerned that we developed a knowledge test too difficult for nursing home nurses, but the results showed that nursing home nurses had more or less comparable marks for the tests in relation to the hospital nurses. However, we did not test the responsiveness. Possibly, this could have biased our results.

There are a few methodological issues which should be considered. First there is the issue of data collection. In our study it was not possible to fill in the knowledge test under exam conditions. Despite the fact that the wards were asked to organise these exam conditions they did not succeed in doing so. It is possible that nurses who received the knowledge test looked up the answers, e.g. on the internet, or in a protocol, or that they asked each other for the correct answers. Therefore it is possible that the results of our study are biased. To avoid this type of bias in future studies, it is advisable to organise exam condition when filling in this kind of knowledge test.

Another methodological consideration is that fewer nurses returned the knowledge test during the follow-up period, hospital nurses in the intervention group especially. We assume that these nurses were less motivated, due to the higher turnover rate of the hospital nurses (in two hospitals) and the extra workload for the nurses that came with this study. Possibly, nurses who had affinity with the subject were more likely to respond. This may have resulted in selection bias, as we do not know whether the nurses were representative for the nurses of their ward. We do know that every ward had an equal percentage of nurses who returned the questionnaire. In nursing homes more nurses with a lower position on the ward (licensed nurses) returned the questionnaire at follow-up in the intervention group compared to the control group, which could explain the lower result at follow-up for the intervention group in nursing homes.

We did not systematically measure staff turnover, but we know from the periodic contact with the key nurse and ward manager on the intervention wards, that nurses had left and other nurses were employed. Consequently, staff turnover may have influenced the results of this study especially given the length of time to follow-up. To minimise this kind of influence, 'new' nurses who were employed on the ward after the educational interventions, were offered the opportunity to access the educational information about the patient safety programme by using the CD-ROM with the theoretical items and the tests with feedback. The key nurse and ward manager on the intervention wards were responsible for acquainting 'new' nurses with the patient safety programme.

The follow-up of this study took place one and a half year after the start of the intervention period. This long period potentially opened the study up to external influences. If hospitals and nursing homes decided to start special quality improvement programmes on one of our adverse events for instance this would have influenced our results. To monitor for this kind of influence, we interviewed every ward manager (intervention and control wards) about (their plans to organise) educational activities on the three adverse events prior to baseline and follow-up measurement. We were able to prevent that two hospitals organised separate courses on the subject of falls. Instead they organised courses on other important subjects (delirium and use of restraints). From the inventory we know that there were no educational activities on our three adverse events.

As we studied different wards in the same centre, contamination across wards could have occurred. However, we are convinced that contamination is not an issue in our study. First, we agreed with the intervention wards that the educational material (CD-ROM) could only be used by the intervention wards, and the other educational activities (educational meetings and case discussions) were only organised for the nurses of the intervention wards, other nurses were not invited. Thus, the control wards did not have access to the educational material and did not know the content of the educational activities. We promised the control wards that they would receive the educational activities (if they wanted) after the study. Second, although nurses from the intervention ward (occasionally) worked on the control ward and vice versa, this only occurred in one hospital ward and in one nursing home ward. Moreover, when nurses did work across wards this was due to nursing shortage, which means that there was not much time for extra activities, as all time was needed for the most essential/basic

activities such as taking care of the patient (washing, eating). Therefore, there would not have been much time to discuss issues from the education and contamination was unlikely.

A last methodological consideration is the sensitivity of our test. Ninety-five percent of the scores in hospitals were between 5.6 and 8.0 and between 5.0 and 7.6 in nursing homes. There was not much variation, as all the scores were between 5.0 and 8.0, which corresponds to 25% of our total scale (a zero to ten scale). This might indicate that our scale was not sensitive enough to measure improvements.

There are a few recommendations we want to make. First, knowledge about the content of a guideline is an important prerequisite for the use of a guideline. In this study the mean score on guideline related knowledge was a seven (on a zero to ten scale). We consider this score to be too low, and take the view that a nine is the minimally desired score, because if nurses have insufficient knowledge of a guideline they cannot give appropriate care. Second, to improve this knowledge our interactive and personal educational intervention should become a continuous activity.<sup>5</sup> Since acquired knowledge will not sustain overtime,<sup>34</sup> education should be a continuous activity to guarantee a long term effect on knowledge. Third, we suggest to develop a web based learning/training programme (instead of a CD-ROM) including a knowledge test with personal feedback on the results.<sup>5</sup> A web based programme makes it possible for ward managers (or teachers) to identify the nurses who have or have not studied the information and give the individual nurse and the whole team feedback on the results and their performance. Finally, we recommend to measure the effect of such an intervention at intervals, in order to capture both short- and long term improvements.

In conclusion, we found a long term effect of our educational intervention on hospital nurses' knowledge on the prevention of pressure ulcers only. It is possible that there were short term effects, but we did not measure these. More research is necessary to expand this educational intervention so it can have a long term effect on nurses knowledge.

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## **Chapter 8**

### **General discussion**

In this thesis, we wanted to move beyond "single project thinking" and wanted to develop a patient safety programme which helps organisations to implement multiple guidelines simultaneously. Usually, patient care guidelines are implemented one at a time, while patients are at risk for multiple, often preventable, adverse events simultaneously. The aim of this study was to investigate whether it is possible to develop and implement a multiple guideline based patient safety programme. We tested the effectiveness of the programme in a cluster randomised trial on ten wards in four hospitals and ten wards in six nursing homes in the Netherlands.

In this chapter, we present the primary and secondary outcomes described in the general introduction of this thesis, followed by the discussion of the main findings of this study. Subsequently, we describe some implications for future research and practice and we end this chapter with the final conclusion of the study.

The primary outcome of this study was the incidence of three adverse events. We investigated whether the patient safety programme (SAFE or SORRY?) decreased the incidence of the three adverse events in hospitals and nursing homes. We found (chapter 5) that patients in the intervention group developed 43% and 33% fewer adverse events compared to the usual care group in hospitals and nursing homes, respectively. In hospitals, this difference in the occurrence of adverse events was mainly accounted for by fewer urinary tract infections. Patients in the intervention group developed 61% fewer urinary tract infections compared to the usual care group. In nursing homes, this difference was mainly accounted for by fewer pressure ulcers. The patients in the intervention group developed 66% fewer pressure ulcers compared to the usual care group.

The secondary outcomes were 1) the percentages of patients that received preventive care and 2) nurses' knowledge regarding the three adverse events. We investigated whether the patient safety programme increased the preventive care given to patients at risk in hospitals and nursing homes and whether it increased nurses' knowledge on preventive care regarding the three topics. We could not demonstrate that more patients at risk in the intervention groups received preventive care, neither in hospitals nor in nursing homes (chapter 6). We even found that fewer hospital patients at risk for urinary tract infections in the intervention group received preventive care. Furthermore, we found that the patient safety programme improved hospital nurses' knowledge on



the prevention of the three topics, with a small non-significant mean difference of 0.19 points (on a zero to ten scale) in favour of the intervention group (chapter 7). It only improved hospital nurses' knowledge on the prevention of pressure ulcers. In nursing homes, the patient safety programme neither improved nurses' knowledge on the prevention of the three topics in general, nor on the knowledge on one of the three topics.

### **How to interpret the results on the primary outcome?**

This study showed that patients in the intervention group developed fewer adverse events compared to the usual care group in both hospitals and nursing homes. This implies that not only is it possible to implement multiple guidelines, but implementation can also be effective. Actually, by analysing the results separately for hospitals and nursing homes, we performed two studies in one, and in both the results were the same. We not only found a positive effect on the total of the three incidence-rates of pressure ulcers, urinary tract infections and falls, but all three adverse events separately had a positive contribution to the result. It looks as if the programme was more effective on one type of adverse event in hospitals –fewer urinary tract infections– and in nursing homes –fewer pressure ulcers–, but we must be very cautious about this interpretation, since our study was not powered for this conclusion. The result of this study is promising for the implementation of multiple guidelines simultaneously, but more research is needed to underline the results of this study.

This study found differences in the main outcome between the intervention and control groups. However, differences in outcome cannot only be explained by the difference in quality of care, they could also be explained by case mix, differences in ways of collecting the data, and chance.<sup>1</sup> To ensure that the differences in outcome could be explained by the differences in quality of care, we adjusted for the differences in type of patient by analysing the results for hospitals and nursing homes separately and by performing a stratified randomisation of the wards with the patients nested to the wards. Additionally, we standardised the way we collected the data and the study was powered on the main outcome –the incidence of the adverse events– of this study. Therefore, positive results on this outcome are highly likely to be explained by the difference in quality of care.

The results of this study are very important for the patients in hospitals and nursing homes. Patients are at risk for the development of preventable adverse events.<sup>2 3</sup> With this integral patient safety programme, organisations which want to improve their quality of care on several topics, do not have to 'wait' until other projects are rounded off, they can improve their quality of care on several topics at the same time. It is conceivable that even more guidelines can be implemented at the same time. Regarding the three preventable adverse events, this study showed that every week patients are admitted to a hospital or nursing home, nine percent adverse events –pressure ulcers, urinary tract infections and falls– occurred (chapter 4). After the implementation of the patient safety programme we found that in the intervention groups every week patients are admitted to the wards, six percent adverse events occurred (chapter 5). This is an important step in the right direction. The impact for patients who experience adverse events is often great. A recent review of the impact of pressures ulcers showed that pressure ulcers and pressure treatment interventions have a significant impact on health-related quality of life.<sup>4</sup> Pressure ulcers cause a great burden to patients. The major burdens identified in the review were related to severe pain; patients' health care professionals ignoring views and concerns; early warning signs (e.g. pain) not prompting action; treatments increasing discomfort and pain and reducing health-related quality of life; and the physical, social and psychological aspects of patient's needs not being met.<sup>4</sup> Every adverse event has his own specific impact. Urinary tract infections are the most common infections in hospitals and nursing homes.<sup>5 6</sup> Although of all hospital infections they have the lowest costs and mortality,<sup>5</sup> they can cause severe complications. In general, patients with a urinary tract infection experience discomfort caused by frequent and painful urinating (voiding) but some patients are seriously ill. Elderly patients can easily develop a delirium caused by the infection. Also, resistance to antibiotics is a well known complication. For patients with unrecognised urinary tract infections or suboptimal treatment, this infection can even develop into a urosepsis with high mortality rates.<sup>7</sup> Falls may have serious consequences for patients. Fortunately, most falls are not serious, but a small proportion, 1-4%, results in a serious injury like fractures or even death.<sup>8-10</sup> Even if a fall does not result in physical injury, falls can have severe psychological impact and result in fear of falling. This may lead to decreased mobility, activities of social functioning and increased dependency.

The reduction of adverse events is promising, taking into account that we did have some limitations in our study. To avoid contamination of the usual care wards, we

could not perform organisational implementation activities necessary for embedding the guidelines into a ward. As the randomisation of this cluster randomised trial was stratified for centre and took place at ward level, every hospital and nursing home had one or more intervention and usual care wards. As a result, we could not, for example, involve the quality management and management of the organisation into the implementation process, which normally is important for embedding guidelines. If we had been able to involve them in the implementation process, they could have set goals with the wards on the improvement of patient safety, based on the regular feedback provided by the computerised programme. These organisational activities probably would have improved the outcome of the patient safety programme.

Another limitation of the design of this study was that we could not implement all recommended preventive activities required according to the guidelines. For instance, the unavailability or inaccessibility of equipment, was an important barrier for the implementation of the guidelines. It was difficult to organise special equipment solely for the intervention ward(s), e.g. type of indwelling catheter recommended for patients with a long term indwelling catheter, type of urine collector bag to avoid disconnection of a urine collector bag, unavailability of special pressure relief cushions for elevating patients' heels.

A final limitation was that most guidelines require adjustment of some procedures of an organisation. For instance, for the prevention of falls, it was necessary to discuss and evaluate the risk factors for falls and the multidisciplinary plan for patients at risk for falls in a multidisciplinary meeting. Not all wards had a multidisciplinary meeting. Within the scope of this study, it was not possible to organise such a meeting on those wards just to discuss the patients at risk for falls.

We believe that implementation of this programme in organisations as a whole, allowing for the enforcement of implementation through organisational measures, will further improve the effectiveness of the integral patient safety programme.

### **How to interpret the results on the secondary outcomes?**

Given the positive result on the primary outcome, we also expected to find positive results on the secondary outcomes. Surprisingly, we did not find more preventive care in the intervention groups and no significant improvement of nurses' knowledge on the

prevention of these three adverse events. We propose three possible explanations for these contradictory findings. The first explanation lies in the use of evidence based guidelines, the second lies in the potential shortcomings of the implementation strategy used in this study and the last explanation concerns the validity of the data collected in this study.

### *Evidence based guidelines*

In this study we implemented the essential recommendations of the existing guidelines and collected data on whether preventive care was given according to these guidelines. We used the best available existing evidence based guidelines.<sup>11-15</sup> One may question how evidence based these guidelines are and if it is necessary to apply all recommendations in a patient to improve patient outcome. Guidelines mostly consist of various recommendations, some of them based on rigorous studies, others mainly based on expert consensus. We implemented the recommendations from the guidelines with the best evidence e.g. use of pressure reducing devices and frequency of repositioning in combination with pressure reducing devices,<sup>16</sup> unnecessary indwelling catheter use<sup>17</sup> and maintaining a closed drainage system for patients with an indwelling catheter.<sup>18</sup> However, we also had to use recommendations based on expert consensus e.g. frequency of repositioning in combination with pressure reducing cushions,<sup>19</sup> the regime and advises on personal hygiene.<sup>12</sup> It is generally assumed that implementing an entire guideline will lead to improved patient outcomes.<sup>20</sup> However, there are only a few rigorous randomised controlled trials that actually test the effectiveness of implementing an entire guideline, but none of them tested the implementation of a guideline on preventive care.<sup>20</sup> Additionally, it is still unknown whether all essential recommendations are necessary to fulfil to improve patient outcomes, or if for instance it is enough to apply 60 to 80% of the essential recommendations. This may have contributed to our findings and perhaps partial compliance with recommendations of the guidelines led to the improved patient outcome we found.

### *Potential shortcomings of the implementation strategy*

As part of the multifaceted implementation strategy, a computerised registration and feedback system was used. Per topic we developed outcome and process indicators which were meant to give insight into the quality of care regarding the three adverse events to the nurses on the intervention wards. However, the feedback on the process indicators in our patient safety programme may not have been sufficient. The feedback

from process indicators differed from the outcome indicators in two ways. First, we developed more outcome –prevalence and incidence- indicators than process indicators per topic and second, the nurses received daily feedback on the outcome indicators while the feedback on the process indicators was provided weekly. As a result of that, nurses only 'saw' how they provided preventive care once a week but they immediately (the next morning) 'saw' whether patients on the ward developed (incidence) or had an adverse event (prevalence). Furthermore, the feedback for each of the three topics on the process indicators was summarised into a single 'adequate prevention score' indicator per topic. By doing this, nurses could monitor preventive care rather roughly but did not get detailed insight into their preventive care performance. For instance, if patients did not have a repositioning scheme (and no alternating pressure mattress), but received all the other preventive activities, it was not registered as good preventive care. As a result, nurses were not able to see which activity they had to give more attention, e.g. repositioning. Nurses only saw -in a graphic- the percentage of patients who received "adequate" preventive care. In future, this can be improved by giving feedback on the several process indicators per topic so that professionals gain insight into the preventive activities given and the preventive activities withheld.

### *Validity of data*

The third possible explanation concerns some methodological considerations and the limitations of data collection in this study.

In this study, we used a set standard for "adequate" preventive care, as we measured the combined performance in relation to recommendations of the guidelines per adverse event. Only when care for patients met the combination of preventive activities given at every observation moment, we registered this as receiving "adequate" preventive care. As a result, quite a few preventive activities were not registered as "adequate" preventive care, because they were not combined with other preventive activities. By using this high standard, we probably registered a lot of preventive activities as inadequate preventive care and therefore missed them in our results.

A further limitation of our data collection lies in the moments in time at which we collected the data. We had to collect data on the incidence of three adverse events and on the preventive care given to prevent these adverse events. We did not want to collect the data solely from the patients' files. Therefore, independent research

assistants observed the patients. Since our data collection method was intensive, we had to be efficient with the time it took to measure these data. The research assistants visited the patients included to observe the patient's skin, observe the preventive care given, and collect data from the patients' file, each week. Especially in nursing homes, but also in the seriously ill hospital patients, we wanted to minimise the burden of data collection for the patients. Therefore, we chose to observe the patient and the preventive care given at the time the nurses were washing or nursing the patients before they were getting dressed. These moments are not ideal to observe preventive care and they occur not more than 15 minutes a day, while preventive care is given 24-hours a day and seven days a week. To get a better impression on the preventive care given, we additionally observed the patient included on the wards three times for five continuous hours. Despite these efforts to gather additional data on the weekly visits, we probably only got a limited impression on the preventive care given to the patients at risk.

Another limitation was that the data collection on nurses' knowledge took place one and a half year after the start of the educational intervention. Most studies, which investigate knowledge improvements, investigate these improvements shortly after an educational intervention.<sup>21-24</sup> One study showed that the effect of an educational intervention will decrease over time.<sup>22</sup> In this study, we could not measure nurses knowledge immediately or shortly after the educational activities, because we did not want to bias the usual care group during the intervention period. We decided on forehand to measure the knowledge of the nurse of the intervention and usual care group after the intervention period. As a result, this long term measurement could be a possible explanation for the lack of significant increase in knowledge in our study.

### **Implications for future research and practice**

Evidence based guidelines are important for the quality of care in daily practice. More research is needed to investigate the effectiveness of the guidelines on patient outcomes and the process of care.

We developed outcome and process indicators based on the recommendations of the evidence based guidelines used. When these indicators are used for monitoring or measuring quality improvement, they should be tested for their validity, reliability, as well as sensitivity to change. When developing process indicators that aim to get insight into the process of for example guideline based care, it is essential to develop several process indicators reflecting the different essential guideline based recommendations.

To test the effectiveness of guidelines, a randomised clinical trial is the "gold standard" in implementation research.<sup>25</sup> The implementation of a guideline is a complex intervention. Testing the effectiveness of a guideline is not easy and a randomised clinical trial is not always the best suitable design.<sup>26</sup> There are more experimental designs, which are appropriate for evaluating complex interventions. In this study we performed a cluster randomised trial, because randomisation of individual patients was not possible. When it is important to implement a guideline on all wards in an organisation, a cluster randomised trial may not have been the best design. A stepped wedge design might be more suitable.<sup>26</sup> It is important to choose the best suitable design for evaluating the complex intervention.

In this study, we did not perform a process evaluation on the implementation of the patient safety programme. Performing a process evaluation can provide valuable insight into why an intervention has unexpected consequences.

Collecting data on the preventive care given is not easy, because it is a continuous complex process and it is impossible to measure such care 24 hours a day and seven days a week. To obtain an accurate impression of the preventive care, we recommend collecting this kind of data by frequent observations.

Implementing multiple guidelines will give organisations the opportunity to improve patient safety on several adverse events, simultaneously. The effect of our patient safety programme can be improved by adding organisational implementation activities. One important subject is the unavailability of equipment, a vital barrier in the implementation of a guideline. Influencing these kind of barriers mostly requires activities at the organisational level.

## **Final conclusion**

In conclusion, it is possible to develop and implement a multiple guideline based patient safety programme in hospitals and nursing homes. The result of this study is promising for the future, because it allows organisations to implement more than one guideline simultaneously, and thus improve patient safety. Since this is the first study which investigates the effectiveness of such a comprehensive programme, more research is necessary to underline the results of this study.

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## Summary

Patients in hospitals and nursing homes are at risk for the development of often preventable adverse events, compromising patient safety. Although evidence based guidelines for nursing care are available, compliance appears to be lacking. In general, many factors may influence compliance –or non compliance- with a guideline. These general factors may be related to the individual healthcare professional, the individual's social context, or the system, i.e. the organisational setting. Besides these general factors, specific problems exist with the implementation of guidelines, such as the large number of guidelines competing for attention, making it difficult to keep track of all of them. Another barrier is the lack of strategies for the introduction of new guidelines in organisations. Each guideline requires translation into the target group, and development and organisation of targeted information and education, which is a time-consuming process. As a result, it is difficult to implement all available guidelines necessary for good quality nursing care.

In this thesis, we wanted to move beyond "single project thinking". Usually, patient care guidelines are implemented one at a time. We wanted to know if it is possible to implement multiple guidelines for the prevention of adverse events simultaneously. First, we searched the literature on existing programmes that focus on the prevention of different adverse events simultaneously (chapter 2). This review showed, that no studies aimed at the prevention of two or more adverse events simultaneously were found. Therefore, we decided to develop such a programme. We developed this patient safety programme for three frequently occurring nursing care related adverse events for which evidence based guidelines for preventive care were available: pressure ulcers, urinary tract infections and falls (chapter 3). The programme consisted of the essential recommendations from the guidelines and we developed guideline based outcome and process indicators. In addition, the programme included a multifaceted tailored implementation strategy that consisted of educational activities, patient involvement, and a computerised registration and feedback system.

## Methods

### *Design and settings*

To test the effectiveness of this programme we designed a cluster randomised trial (chapter 3) that was conducted between September 2006 and November 2008. The

study was performed on ten wards in four hospitals (one university hospital, two large teaching hospitals and one small hospital) and ten wards in six nursing homes, in the Netherlands. Hospital wards were internal medicine (n=4) and surgical wards (n=6). Nursing home wards included patients with physical impairments (no dementia) (n=7) and need for rehabilitation (n=3). The ten hospital wards and ten nursing home wards were randomly assigned to an intervention or usual care group. The randomisation of the wards was stratified for institute and type of ward and each ward was considered to be a cluster. After the randomisation, baseline data were collected during three months at all wards, followed by the implementation of the patient safety programme for fourteen months on the intervention wards. The usual care wards continued care as usual. Subsequently the follow-up period was nine months.

### *Study population*

During baseline (chapter 4) and follow-up (chapter 5 and 6) data collection periods, all adult patients ( $\geq 18$  years) admitted to the wards were asked to participate. Hospital patients with an expected length of stay of at least five days were asked to participate within 48 hours after admission. Nursing home patients were asked to participate at the start of the data collection periods, or within two weeks after admission. After written informed consent, research assistants visited the patients weekly, until discharge, death or the end of the data collection period.

During both data collection periods all (clinical) nurses at the wards were asked to participate in a knowledge test (chapter 7). Nurses' aids and students were excluded.

### *Outcome measures*

The primary outcome was the incidence of pressure ulcers, urinary tract infections and falls (chapter 4 and 5). Pressure ulcers were measured by observing the patients' skin. Pressure ulcers were considered present if a patient developed a pressure ulcer grade two or worse according to the EPUAP-classification system. The presence of a urinary tract infection needed to be confirmed by a physician and falls were measured by examining the patient files.

The secondary outcome measures were 1) the percentage of patients that received preventive care (chapter 4 and 6) and 2) nurses' knowledge regarding the three topics (chapter 7). The percentage of patients that received preventive care was calculated for each adverse event separately, and only in patients who were considered to be at risk for the particular adverse event.

The knowledge of nurses about risk assessment and effective preventive care was measured using a written knowledge test.

### *Data collection*

During the baseline (chapter 4) and follow-up (chapter 5 and 6) period, the patient data were collected in two ways: by a weekly visit and by additional observations on every ward. During the weekly visits, we screened the patients' file for data on the occurrence of urinary tract infections and falls, and the preventive care given. We observed the patients for the presence of preventive measures and the patients' skin for the occurrence of pressure ulcer. During the additional observations we collected data to estimate the utilisation of adequate preventive care. Research assistants visited every ward three times. During these visits, a random sample of at least five patients who participated in the study and the nurses on the ward were observed for at least five consecutive hours.

The data on nurses' knowledge were collected by asking all the nurses to fill in a questionnaire at the start of the baseline period and during the follow-up period (chapter 7).

### *Statistics*

The results for hospitals and nursing homes were analysed separately (chapter 4 – 7), as patients' and nurses' characteristics differ between hospitals and nursing homes. The incidence rate of adverse events was defined as the number of new adverse events per patient week. The results were clustered at ward level and we used a random effects Poisson regression model to estimate the rate ratio of the adverse events in the intervention and usual care group at follow-up. To analyse the difference in adequate preventive care given between the intervention group and usual care group we used a random effects linear and logistic regression model. We used a linear random effects model to analyse the difference in the results on the knowledge test between the intervention and the usual care wards at follow-up.

## **Results**

The baseline period was from September to the end of November 2006 (chapter 4). Eight hundred and eighty seven hospital patients and 241 nursing home patients participated. Regarding the incidence of the three adverse events, this study showed that 77 hospital patients (11%) and 111 nursing home patients (46%) developed one or

more adverse events. The incidence rate for both was 9% adverse events per patient week. Regarding the preventive care given, this study showed that in hospitals, 34% of the patients at risk for pressure ulcers, 47% of the patients at risk for urinary tract infections and none of the patients at risk for falls received adequate preventive care. In nursing homes, 18% of the patients at risk for pressure ulcers, 42% of the patients at risk for urinary tract infections and less than 1% of the patients at risk for falls received adequate preventive care.

Following the baseline period, the patient safety programme was implemented on the intervention wards from December 2006 to February 2008. During this period the usual care group continued care as usual.

The nine-month follow-up period started in March 2008. A total of 2201 hospital patients with 3358 patient weeks and 392 nursing home patients with 5799 patients weeks were observed during the follow-up of the study. The results showed an incidence rate ratio for the development of an adverse event in favour of the intervention group of 0.57 (95% CI: 0.34 to 0.95) and 0.67 (95% CI: 0.48 to 0.99) for the hospital patients and nursing home patients, respectively. Patients in the intervention groups had 43% and 33% fewer adverse events compared to the usual care group in hospitals and nursing homes respectively (chapter 5). The study showed no overall difference in preventive pressure ulcer measures between intervention and usual care group in hospitals and nursing homes. For urinary tract infections, even statistically significantly fewer hospital patients at risk received preventive care. For falls in hospitals and nursing homes, no more patients at risk received preventive care (chapter 6).

The results from the knowledge test (chapter 7) showed that, after correction for baseline, the mean difference between the intervention and the usual care group on hospital nurses' knowledge on the prevention of the three adverse events was 0.19 points on a zero to ten scale (95% CI: -0.03 to 0.42), in favour of the intervention group. There was a statistically significant effect on knowledge of pressure ulcers, with an improved mean mark of 0.45 points (95% CI: 0.10 to 0.81). For the other two topics there was no statistically significant effect. Nursing home nurses' knowledge neither improved (0 points, CI: -0.35 to 0.35) overall, nor for the separate subjects. These

results showed that, only the hospital nurses' knowledge on the prevention of pressure ulcers was improved.

## **Discussion and conclusion**

This study showed that patients in the intervention group developed 43% and 33% fewer adverse events compared to the usual care group in hospitals and nursing homes, respectively. We did not find better preventive care given to patients at risk in the intervention groups, neither in hospitals nor in nursing homes. Furthermore, we found that the patient safety programme improved hospital nurses' knowledge on the prevention of the three topics, with a small non-significant mean difference in favour of the intervention group. In nursing homes, the patient safety programme did not improve nurses' knowledge on the prevention of the three topics.

Given this positive result on the primary outcome, we also expected to find positive results on the secondary outcomes. Surprisingly, we did not find more preventive care in the intervention groups and no significant improvement of nurses' knowledge on the prevention of these three adverse events. We discussed three possible explanations for these contradictory findings (chapter 8). Firstly, we discussed how evidence based the guidelines used are and if it is necessary to apply all recommendations in a patient to improve patient outcome. Secondly, a shortcoming of the implementation strategy could have caused lack of insight into the preventive care given to the patients at risk. The last possible explanation concerns some methodological considerations and the limitation of the data collection in this study.

In conclusion, it is possible to develop and implement a multiple guideline based patient safety programme in hospitals and nursing homes. The result of this study is promising for the future, because it allows organisations to implement more than one guideline simultaneously, and thus improve patient safety. Since this is the first study that investigates the effectiveness of such a comprehensive programme, more research is necessary to underline the results of this study.



## Samenvatting

Patiënten in ziekenhuizen en verpleeghuizen lopen risico op, vaak vermijdbare zorggerelateerde schade (adverse events), waardoor de patiëntveiligheid in gevaar komt. Richtlijnen ter preventie van veel adverse events zijn beschikbaar, maar deze worden niet altijd opgevolgd.

Veel factoren beïnvloeden het al dan niet opvolgen van richtlijnen. Algemene factoren kunnen gerelateerd zijn aan de individuele zorgprofessional, de sociale context of de organisatie waarin men werkt. Naast deze algemene factoren zijn er ook specifieke problemen die de implementatie van richtlijnen beïnvloeden. Zo is het grote aantal om aandacht concurrerende richtlijnen een serieus probleem. Daarnaast ontbreekt het vaak aan feedback over de op richtlijnen gebaseerde kwaliteitsindicatoren en aan een herkenbare eenduidige systematiek van implementatie. Daarbij komt dat een richtlijn, voorafgaand aan implementatie, vertaald dient te worden naar de doelgroep, waarna informatie- en scholingsmateriaal moet worden ontwikkeld. Iedere richtlijn vraagt van zowel organisaties als zorgprofessionals veel aandacht, waardoor implementatie van alle relevante richtlijnen in de praktijk geen haalbare kaart lijkt.

In dit proefschrift wilden we verder gaan dan het denken in individuele projecten. Normaliter worden richtlijnen in de gezondheidszorg één voor één geïmplementeerd. Wij wilden weten of het mogelijk is om meerdere richtlijnen tegelijkertijd te implementeren. Hiervoor voerden we allereerst een literatuuronderzoek uit naar bestaande programma's voor de preventie van twee of meer adverse events tegelijkertijd (hoofdstuk 2). Het literatuuronderzoek liet geen studie zien voor de preventie van twee of meer adverse events tegelijkertijd. Hierdoor ontstond het idee om zelf zo'n programma te ontwikkelen. Een programma dat organisaties de mogelijkheid geeft om meerdere richtlijnen tegelijk te implementeren kan het gebruik van richtlijnen bevorderen en verbetert daarmee de patiëntveiligheid. Het idee voor dit patiëntveiligheidsprogramma, werkten we uit voor drie veel voorkomende verpleegkundig gerelateerde adverse events: decubitus, urineweginfecties en vallen (hoofdstuk 3). Het programma bevat de essentiële aanbevelingen uit de beschikbare richtlijnen voor de preventie van deze drie adverse events. Vervolgens ontwikkelden we uitkomst- en procesindicatoren gebaseerd op de bestaande richtlijnen. Voor de implementatie van dit programma ontwikkelden we tevens een gecombineerde implementatiestrategie bestaande uit: onderwijsactiviteiten met voor elke afdeling een

aangepast implementatieplan, patiënteninformatie over de adverse events en een digitaal registratie- en feedback systeem gebaseerd op de geformuleerde uitkomst- en procesindicatoren.

## **Methode**

### *Onderzoeksdesign en instellingen*

In een cluster gerandomiseerd onderzoek testten we de effectiviteit van het patiëntveiligheidsprogramma (hoofdstuk 3) tussen september 2006 en november 2008. Het onderzoek vond plaats op tien afdelingen in vier ziekenhuizen (één universitair ziekenhuis, twee grotere algemene ziekenhuizen en één kleiner ziekenhuis) en tien afdelingen in zes verpleeghuizen in Nederland. In de ziekenhuizen waren dit vier interne en zes chirurgische afdelingen en in de verpleeghuizen zeven somatische en drie revalidatieafdelingen. De tien ziekenhuis- en tien verpleeghuisafdelingen werden gerandomiseerd naar een interventie- en een controlegroep. Hiervoor werd gestratificeerd voor instelling en soort afdeling. Elke afdeling was in dit onderzoek een cluster. Na de randomisatie startte de voormeting gedurende drie maanden op alle afdelingen. Aansluitend vond gedurende veertien maanden de implementatie van het patiëntveiligheidsprogramma plaats op alle interventieafdelingen. Op de controleafdelingen vonden geen activiteiten plaats en ging men door met de gebruikelijke zorg op het gebied van deze drie adverse events. Na de implementatieperiode volgde de negen maanden durende nameting op alle afdelingen.

### *Onderzoekspopulatie*

Gedurende de voor- (hoofdstuk 4) en nameting (hoofdstuk 5 en 6) werden alle volwassen patiënten ( $\geq 18$  jaar) gevraagd of ze aan het onderzoek wilden deelnemen. In de ziekenhuizen werd aan patiënten die naar verwachting vijf dagen of langer zouden blijven binnen 48 uur na opname gevraagd of ze aan het onderzoek wilden meedoen. Aan verpleeghuispatiënten werd bij de start van de voor- en nameting of binnen twee weken na opname gevraagd of ze aan het onderzoek wilden meedoen. Na de schriftelijke instemming bezocht de onderzoeksverpleegkundige de patiënten wekelijks. Alle patiënten met minimaal een tweede bezoek werden in het onderzoek opgenomen. Tijdens beide meetperioden namen alle verpleegkundigen en verzorgenden van de deelnemende afdelingen aan het onderzoek deel. Studenten, verpleegassistenten en verpleeghulpverleners werden uitgesloten.



### *Uitkomsten*

De primaire uitkomst was de incidentie van adverse events, de optelling van de incidentie van decubitus, urineweginfecties en valincidenten (hoofdstuk 4 en 5). Decubitus werd gemeten door de huid van de patiënt te observeren en decubitus werd geregistreerd als een patiënt een decubitus graad 2 of ernstiger ontwikkelde. Had een patiënt tijdens het eerste bezoek een decubitus graad 2 of ernstiger, dan werd dat decubitusletsel geëxcludeerd van de registratie van decubitus. Van patiënten met decubitus graad 2 of ernstiger werden alleen nieuw ontwikkelde decubitusletsels geregistreerd.

Tijdens dit onderzoek registreerden we een urineweginfectie als die door een arts was gediagnosticeerd. Patiënten met een urineweginfectie werden voor een periode van drie weken geëxcludeerd van de registratie van urineweginfecties totdat de urineweginfectie was genezen.

Valincidenten werden gemeten door het patiëntendossier te lezen.

Naast de primaire uitkomst had het onderzoek ook secundaire uitkomsten: 1) het percentage patiënten met preventieve maatregelen (hoofdstuk 4 en 6) en 2) de kennis van de verpleegkundigen en verzorgenden over de preventie van deze drie adverse events (hoofdstuk 7).

Het percentage patiënten dat preventieve maatregelen krijgt werd berekend voor elke adverse events afzonderlijk en alleen voor de risicopatiënten van het betreffende adverse event.

De kennis van de verpleegkundigen en verzorgende over het bepalen van het risico en preventieve maatregelen werd gemeten met een schriftelijke kennistoets.

### *Verzamelen van gegevens*

Tijdens de voor- (hoofdstuk 4) en nameting (hoofdstuk 5 en 6) werden de patiëntengegevens op twee manieren verzameld.

Voor het meten van de adverse events en preventieve maatregelen lazen de onderzoeksverpleegkundigen het patiëntendossier en observeerden ze de patiënt tijdens de wekelijkse bezoeken. Aanvullend werden voor het toepassen van preventieve maatregelen de afdelingen drie keer bezocht door een onderzoeksverpleegkundige. Tijdens elk bezoek werd een selectie van minimaal vijf geïncludeerde patiënten en de verpleegkundigen bij de uitvoer van de dagelijkse zorg gedurende vijf aaneengesloten uren geobserveerd.

Voor het meten van de kennis werd tijdens de voor- en nameting aan alle verpleegkundigen gevraagd of ze de vragenlijst in wilden vullen (hoofdstuk 7).

### *Analyse*

De resultaten voor de zieken- en de verpleeghuizen werden apart geanalyseerd, omdat de patiëntenkenmerken, de opnameduur en de kenmerken van de verpleegkundigen en verzorgenden in de zieken- en de verpleeghuizen verschillen (hoofdstuk 4–7).

De incidentie-rate van adverse events is gedefinieerd als het aantal nieuwe adverse events per patiëntweek. De resultaten werden geclusterd naar afdelingniveau en een random-effects Poisson regressie model is gebruikt om het verschil tussen de incidentie-rate van adverse events uit de interventie en controlegroep tijdens de nameting te analyseren.

Om het verschil in preventieve maatregelen tussen de interventie- en controlegroep te analyseren, gebruikten we lineaire en logistische random-effects regressie modellen. Het verschil in de behaalde resultaten op de kennistoets tussen de interventie- en controlegroep tijdens de nameting analyseerde we met een linear random-effects model.

### **Resultaten**

De voormeting vond plaats van september tot eind november 2006 (hoofdstuk 4). Aan deze meting deden 887 ziekenhuispatiënten en 241 verpleeghuispatiënten mee. Tijdens deze drie maanden durende voormeting ontwikkelden 77 ziekenhuispatiënten (11%) en 111 verpleeghuispatiënten (46%) één of meer adverse events. De incidentie-rate voor de ontwikkeling van adverse events was 9% per patiënt week. Verder werd duidelijk dat in de ziekenhuizen 34% van de patiënten met risico op decubitus, 47% van de patiënten met risico op een urineweginfectie en geen enkele patiënt met risico op vallen preventieve maatregelen volgens de richtlijnen ontving. In de verpleeghuizen ontving 18% van de patiënten met risico op decubitus, 42% van de patiënten met risico op een urineweginfectie en minder dan 1% van de patiënten met risico op vallen preventieve maatregelen volgens de richtlijnen.

Na de voormeting werd het patiëntveiligheidsprogramma op de interventieafdelingen geïmplementeerd tussen december 2006 en februari 2008. Tijdens deze periode ging de controlegroep door met de gebruikelijke zorg op het gebied van deze drie adverse events.

Tijdens de nameting deden in totaal 2201 ziekenhuispatiënten met 3358 patiëntweken en 392 verpleeghuispatiënten 3358 patiëntweken mee aan het onderzoek. Voor de ziekenhuizen was de rate-ratio, het verschil tussen de incidence-rate voor de ontwikkeling van een adverse events tussen de interventie- en controlegroep, 0,57 (95% CI: 0,34 to 0,95) en voor de verpleeghuizen was dit 0,67 (95% CI: 0,48 to 0,99), beiden in het voordeel van de interventiegroep. Dit betekent dat in de ziekenhuizen patiënten in de interventiegroep 43% minder adverse events ontwikkelden dan de patiënten in de controlegroep. In de verpleeghuizen was dit verschil 33% (hoofdstuk 5). De resultaten voor de preventieve maatregelen bij patiënten met risico op deze adverse events waren in dit het onderzoek als volgt.

Zowel in de zieken- als in de verpleeghuizen was er geen verschil te zien in decubituspreventie tussen de interventie- en controlegroep. Voor urineweginfecties kregen risicopatiënten in de interventiegroep in de ziekenhuizen zelfs significant minder preventieve maatregelen in vergelijking de risicopatiënten in de controlegroep. Voor vallen was er in de zieken- en verpleeghuizen geen verschil in preventieve maatregelen tussen de interventie- en controlegroep (hoofdstuk 6).

Het resultaat van de kennistoets (hoofdstuk 7) liet zien dat de ziekenhuisverpleegkundigen in de interventiegroep gemiddeld een iets hoger cijfer haalden dan de verpleegkundigen in de controlegroep. Dit verschil in gemiddeld behaald cijfer tussen deze beide groepen was 0,19 (95% BI: -0,03 tot 0,42), waarbij een nul het laagste te behalen cijfer was en een tien het hoogste. In de analyse corrigeerden we voor de behaalde resultaten in de voormeting. Voor de kennistoets over de afzonderlijke adverse events liet het onderzoek een kleine maar significante toename van kennis zien over de preventie van decubitus (95% BI: 0,10 to 0,81) in het voordeel van de interventiegroep. Voor de andere twee onderwerpen was er geen noemenswaardig verschil in kennis tussen de interventie- en controlegroep.

In de verpleeghuizen hadden de verpleegkundigen en verzorgenden in de interventiegroep na correctie voor de resultaten uit de voormeting, noch voor de kennis over alle drie de adverse events (verschil tussen de gemiddelden = 0; 95% BI: -0,35 tot 0,35) noch voor elk afzonderlijke adverse event een toename aan kennis.

## **Discussie en conclusie**

Dit onderzoek laat zien dat patiënten in de interventiegroep 43% en 33% minder adverse events ontwikkelden in vergelijking met de controlegroep in respectievelijk de zieken- en de verpleeghuizen. Zowel in de zieken- als de verpleeghuizen konden we niet aantonen dat de risicopatiënten in de interventiegroep meer preventieve maatregelen kregen. Verder zagen we dat het patiëntveiligheidsprogramma de kennis van de ziekenhuisverpleegkundigen over de preventie van deze drie adverse events gemiddeld iets verbeterde in vergelijking met de controlegroep, dit was echter een niet significant klein verschil. In de verpleeghuizen verbeterde de kennis van de verpleegkundigen en verzorgenden over de preventie van deze drie onderwerpen niet.

Uitgaande van het positief effect op de primaire uitkomst van dit onderzoek hadden we ook een positief resultaat verwacht voor de secundaire uitkomsten. Tot onze verbazing kregen echter de risicopatiënten in de interventiegroep niet meer preventieve maatregelen en was er geen significante verbetering van de kennis over de preventie van deze drie adverse events in zowel de zieken- als verpleeghuizen. In de discussie (hoofdstuk 8) beschrijven we drie mogelijke verklaringen voor deze onverwachte bevindingen. Als eerste stellen we de vraag hoe evidence based de richtlijnen zijn die we voor de ontwikkeling van het patiëntveiligheidsprogramma gebruikten. Daarbij vroegen we ons af of het altijd nodig is alle aanbevelingen in de praktijk op te volgen. Het tweede punt is de mogelijke tekortkoming van de gebruikte implementatiestrategie, concreet het digitaal registratie- en feedback systeem, waardoor de verpleegkundigen en verzorgenden mogelijk onvoldoende inzicht kregen in de gegeven preventieve maatregelen. Als laatste benoemen we enkele methodologische overwegingen en tekortkomingen van de dataverzameling tijdens dit onderzoek.

Concluderend laat dit onderzoek zien dat het mogelijk is een patiëntveiligheidsprogramma te ontwikkelen en te implementeren waarmee zieken- en verpleeghuizen meerdere richtlijnen tegelijk kunnen implementeren. Het resultaat van dit onderzoek is veelbelovend voor de toekomst, omdat organisaties hiermee meerdere richtlijnen tegelijk kunnen implementeren, wat de patiëntveiligheid ten goede komt. Aangezien dit het eerste onderzoek is dat de effectiviteit van zo'n veelomvattend programma onderzoekt is meer onderzoek nodig om deze resultaten te bevestigen.

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Diverse studenten van de Hogeschool van Arnhem en Nijmegen (HAN) hebben aan dit onderzoek meegewerkt. Zo ontwikkelde een student van de Informatica, Media en Communicatie van de HAN de scholings Cd-rom en ontwikkelden twee HBOV-studenten de informatiefolders over de preventie van de drie onderwerpen. Andere studenten hebben geholpen om de verpleegkundigen en verzorgenden in de zieken- en verpleeghuizen bekend te maken met het digitaal registratie systeem. Hierdoor was het mogelijk om een zo'n omvangrijk patiëntveiligheidsprogramma op de afdelingen te introduceren. De samenwerking had voor alle partijen zeer leerzame momenten.

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## Curriculum Vitae

Betsie van Gaal was born on November 23, 1964, in Ravenstein, the Netherlands. After Graduating secondary school, she began her in-service nursing education at the St. Anna Hospital, the current Bernhoven Hospital, in Oss in 1983. Following her graduation in 1987, she worked at the Pediatric department of this hospital for four years. In 1990 she successfully completed her training as a registered pediatric nurse. In 1991, she moved to the Pediatric Oncology / Pediatric Nephrology department of the Radboud University Nijmegen Medical Centre, where she worked for five years. In 1994, she graduated as a registered nurse in Pediatric Oncology. Additionally, she followed a Master in Management at the HAN University of Applied Sciences, from which she graduated in 1996.

In 1995, Betsie continued her professional career in Pediatric at the General Pediatric / Pediatric Nephrology/ Pediatric Heart Surgery / Pediatric Urologic Surgery department of the Radboud University Nijmegen Medical Centre. During this period, she started her Master Degree in Health Sciences at the Maastricht University, where she graduated in 2004. In the mean time, she worked from 2000 – 2005 as a project manager at the Childrens' outpatient clinic of the Radboud University Nijmegen Medical Centre.

In May 2005, Betsie moved to a research position at the Scientific Institute for Quality of Healthcare of the Radboud University Nijmegen Medical Centre. Started working on the SAFE or SORRY? study described in this thesis. As from September 2009, she holds a part-time position as a researcher in Nursing Science at the Scientific Institute for Quality of Healthcare, and since December 2009 she also holds a part-time position as coordinator in the Nijmegen University Network of Nursing Homes, a collaborative network between twelve Nursing Home Organisations and the department of Primary Care, Centre for Family Practice, Geriatric Care and Public Health.