Restraint use in somatic acute care hospitals

Restraint use in somatic acute care hospitals: do we need to care?

Silvia Thomann

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Silvia Thomann

Supervisors

Prof. Dr. S.M.G. Zwakhalen

Prof. Dr. S. Hahn (Bern University of Applied Sciences)

Assessment committee

Prof. Dr. J.P.H. Hamers (Chair of the Committee)

Dr. L.L. Berring (University of Southern Denmark)

Prof. Dr. C.G. Faber

Prof. Dr. H.R. Haak (Maastricht University, Máxima Medical Center)

Prof. Dr. R. Möhler (Heinrich Heine University Düsseldorf)

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CONTENTS

CHAPTER 01

GENERAL INTRODUCTION

Restraints are “interventions that may infringe [on] a person’s human rights and freedom of movement, including observation, seclusion, manual restraint, mechanical restraint and rapid tranquillisation” [1]. Restraining means applying freedom-restricting measures without patient consent [2]. As the definition shows, the term restraint includes not only movement-restricting measures such as the use of fixation belts or bed rails, but also any other forms of restriction of freedom like sedative medication. More controlling, less restrictive measures such as sensor mats for electronic observation are also included. Restraints should be used as a last resort in all health care settings, as their use violates basic human rights and can have negative consequences for patients (e.g. functional decline, increased length of stay, trauma or even death due to strangulations or other causes) and health care professionals (moral distress, psychological and physical harm) [3-10].

Reality shows that restraints are still (frequently) used in health care – often with the intention of ensuring patient safety (e.g. for preventing falls) or to prevent the patient from endangering him/herself or third parties (e.g. in the case of self-aggression and aggression towards others) [6, 11-14]. Whether restraint use is effective for these purposes is questionable (with some exceptions, e.g., as a last resort to control dangerous situations in forensic psychiatric care). Benefits do not seem to outweigh the harms, thus violating a fundamental ethical principle of restraint use [7]. For these reasons, it is internationally recommended to reduce restraint use in all health care settings or even assure restraint-free care, whenever possible [11, 15-17]. Efforts to meet this demand started decades ago in mental health care and have received more and more attention in long-term care [18-22]. Far fewer studies have investigated restraint use in the somatic acute care hospital (henceforth referred to as “hospital”) setting. As a result, knowledge about the need and possibilities to reduce restraint use especially in hospitals is limited. Therefore, the present thesis examines the current situation of restraint use in the hospital setting and discusses possible approaches to meet the demand to reduce restraint use in this setting.

RESTRAINT USE IN THE HOSPITAL SETTING

Studies investigating restraint use in hospital have often focussed on subpopulations (e.g. intensive care units) and most of them have included only mechanical (physical) restraint (belts and bed rails) [11]. The reported prevalence of restraint use in hospitals varies between 0% and 100% depending on the discipline

studied, the definition of restraints used and the data collection method [23, 24]. The most commonly given reason for the use of restraints in hospital is patient safety. Restraint is applied most often to prevent falls, to prevent the removal of catheters or tubes or to manage agitated or disturbing behaviour due to cognitive impairment such as delirium [6, 11, 25, 26]. There is no evidence that restraints are effective and justifiable for these reasons [6, 11, 27-29]. On the contrary, there is evidence for the negative effects of restraint use in hospital on patients, such as increased risk of falls, functional decline, intensification of delirium, traumatisation, strangulation and higher mortality [3, 11, 16, 25, 27, 28]. These negative effects can result in a longer hospital stay, which in turn leads to higher costs. Furthermore, negative effects on health professionals have been identified, especially the feeling of distress when restraints have to be applied [6, 11]. This is very understandable because the use of restraints occurs in an ethical area of tension as health professionals have to balance the ethical principles (autonomy, beneficence, non-maleficence and justice). Moreover, from a legal point of view, there is growing pressure on health professionals to not use restraint. In many countries, the legal framework has been adapted in order to comply with the United Nations (UN) Convention on Human Rights and the Convention on the Rights of Persons with Disabilities (CRPD, see below) [9, 30]. Thus, the use of restraint occurs in an ethical as well as legal area of tension.

Patient- and hospital-related influencing factors on restraint use

Among patients, older age, cognitive impairment, agitation, limited mobility, fall risk, polypharmacy and the use of medical devices (e.g. feeding tubes, mechanical ventilation) are reported as being associated with more frequent restraint use in hospitals [11, 23, 31-33]. However, one has to realise that the few studies available are often based on a cross-sectional design and small sample sizes and, as mentioned, often examine subpopulations, which limits causality. With regard to certain patient characteristics, the studies are contractionary – for example, whether restraint use is influenced by the patient's gender [34, 35]. However, given the demographic trends and patient characteristics associated with higher use of restraint, the proportion of patients at risk for restraint use in hospitals is likely to increase.

Although evidence is limited, restraint use also seems to be influenced by conditions within hospitals. There are indications that the institutional culture/

attitude towards restraint use and corresponding routines, the availability of guidelines and staff training and systematic monitoring of restraint use play a role [11, 14, 25, 36, 37]. For example, restraint use in certain situations may be an implicit standard in a hospital. Thus, an institutional culture may prevail that favour restraint use. Improved structural conditions such as the provision of regular staff training, monitoring and restraint guidelines have been discussed as approaches to reduce restraint use. In addition, although there are very few studies, nursing skill mix and nursing hours per patient day seem to be related to restraint use [38]. More nursing hours per patient day as well as a higher proportion of registered nurses (higher skill mix) are associated with less restraint use. The skill mix seems to be more relevant than nursing hours. Researchers have also observed that more restraints tend to be used at night, a phenomenon that might be associated with staffing levels [25, 33]. Overall, there are indications that similar patient situations may be treated with restraint use in one hospital and without it in another depending on the conditions in the respective hospital. Such practice variation would be unwarranted from ethical, legal, professional and patient points of view. In addition, many hospitals lack standardised and systematically implemented processes that help to ensure that restraints are only used as a last resort and only for as long as absolutely necessary [25]. As a result, restraint use is often insufficiently documented and, accordingly, not regularly evaluated [6, 39, 40].

Decision-making and the role of nurses in restraint use

Within the interprofessional team, nurses play a key role in restraint use. They are key decision-makers as well as the main responsible parties for the prevention and usage of restraints [6, 25, 41]. They are in a subjectively perceived ethical area of tension (e.g. preserving personal freedom of a patient vs prevent the patient from falling) that is shaped by external circumstances. Although they have an important role to play in an ethically and legally sensitive topic, it is evident that nurses in hospitals often receive little specific education and training regarding restraint use, which is why their knowledge and expertise are often considered insufficient [6, 14, 42-44]. Hence, restraint use is perceived by nurses as a routine nursing intervention and preventive and alternative interventions are not known or thought to be unavailable [25, 45, 46]. In the decision-making process, nurses may also be confronted with expectations of relatives [14]. It is possible that relatives demand the use of restraint or that they are critical of it. Despite these aggravating

circumstances, it is evident that nurses receive little support in the decision-making process – whether by physicians, who in many countries continue to bear responsibility for patient care, or by management and senior staff [14, 25, 47].

In addition, decisions usually have to be made under high workload and time pressures [25, 46]. Such conditions can favour intuitive decisions that correspond to one's own attitude [25, 48, 49]. Attitude means "the stored evaluations of or feelings toward persons, objects, events, situations, routines, instructions, goals, positions, ideas, behaviours, and issues" [49]. The attitude one adopts is an essential condition (in any) decision-making process. Indeed, attitude guides the appraisal of situations and consideration of the different options in the situation, especially if there is little time and motivation to analyse the situation in an effortful, feature-based manner [49]. Thus, the decision of nurses may also depend on whether they generally adopt a more restraint-critical or favourable attitude. Because routine, as it applies to restraint use for nurses [45], tends to correspond to a favourable attitude [49], it must be assumed that an intuitive decision under time pressure is more likely to be made in favour of restraint use. A correlation between restraint use and workload/time pressure has already been demonstrated [25, 42, 47]. Hence, restraint practice may vary not only among hospitals, but also among nurses [6, 50].

RESTRAINT REDUCTION FROM A THEORETICAL POINT OF VIEW AND ITS IMPLEMENTATION

It is known that restraint reduction, and corresponding improvements in quality of care, requires changes at different levels [11, 51-54]. The theoretical framework illustrated in Figure 1 was used to identify and study these different levels. On the one hand, this theoretical framework is based on the widely used model on quality of care according to Donabedian. By 1980, he had already expressed that quality of care can be described in the dimensions of structure, process and outcome, which in turn influence each other [55]. The structure dimension refers to the structures that prevail within an institution (e.g. availability of restraint materials, guidelines or qualified staff). The process dimension refers to the way in which care is effectively delivered (e.g. interventions to prevent restraint use or regular evaluation to stop restraint use as early as possible). The dimension outcome, as the name implies, includes the patient outcome, that is, its effect on the patient (e.g. whether restraints are used). Even though showing causal relationships between these dimensions is difficult, the model is considered helpful for measuring and improving quality in health care. Donabedian's model focusses on quality of care within the health

care institution. However, it is known that health care provision, and restraint use in particular, is also dependent on the health care system in which it takes place (e.g. depending on the legal framework) [51]. Therefore, quality assessment and improvement can be undertaken at a macro level (health care system), a meso level (health care providers, including structures according to Donabedian's model) and a micro level (direct clinical practice, including processes and outcome according to Donabedian's model). Accordingly, this thesis investigated restraint use and possible approaches for its reduction at the macro level, the meso level (including structures according to Donabedian) and the micro level (including processes and outcome according to Donabedian). More detailed information can be found in the concluding section of this general introduction.

So far, initiatives to reduce restraint use at the different levels (macro, meso, micro) have mostly focussed on mental health and to some extent on institutional long-term care settings. In the mental health setting, for example, the Safewards model to reduce aggressive events [56] and the six core strategies to reduce seclusion and restraint use [57] have proved to be effective. Both models rely on a multi-strategy approach and address different levels (within the institution, micro and meso levels). In the long-term care setting, researchers have combined approaches at the micro and meso levels to successfully reduce restraint use [18, 58, 59]. These approaches in the long-term care setting mostly involved a combination of knowledge building among nursing staff (micro level) and organisational policy change (meso level). On a system level (macro level), most measures for restraint reduction also address the mental health and long-term care sectors. For example, restraint use has been monitored in terms of a (national) quality indicator in mental health care and more and more in the long-term care setting [5, 60-62]. In addition, the legal framework for restraint use has become stricter in many countries in recent years to comply with the UN Convention on Human Rights and the Convention on the Rights of Persons with Disabilities [9, 30], to which many (Western) countries have subscribed. However, regulatory conditions are often more explicit for the mental health and long-term care sector than for the hospital sector. In other respects, it is also evident that the hospital sector has received far less critical attention than other settings regarding the use of restraint and its reduction [22]. There are recommendations on how to deal with and reduce restraints in hospital settings [11, 63]. For example, the Swiss Academy of Medical Sciences [63] gives more general recommendations regarding required processes: they emphasise that the patient's decision-making capacity must be clarified for

every restraint, that an individual ethical assessment of risk-benefit must take place and that preventive and alternative measures must always precede restraint use. If restraint use is unavoidable, it must be documented in detail, the patient and relatives must be informed, a regular evaluation must take place and the patient must be monitored regularly. In addition, they point out that restraint should only be used in an appropriate environment, including not in front of other patients. Lach et al. [11] distinguish between restraint reduction measures that can be applied by nursing staff (micro level) and those that the institution can contribute (meso level). They recommend that nurses make a differentiated assessment as to why the patient is behaving "unsafely" and take appropriate interventions to address the underlining causes for the "unsafe behaviour" (e.g. reduce pain or eliminate noise). At the institutional level, they recommend that monitoring for restraint use be installed, staff education be offered, adequate staff equipment be ensured, preventive and alternative measures be made readily available (e.g. puzzles for distraction, adapted furniture) and consultations by experts be offered. However, the data on the implementation of these recommendations is rather limited and the evidence on the effectiveness of the restraint reduction approaches developed and recommended so far is low [16, 64]. This might also be related to the generally limited data based on restraint use in hospitals, making it difficult to comprehensively understand the use of restraint in hospitals and to derive appropriate reduction interventions [22].

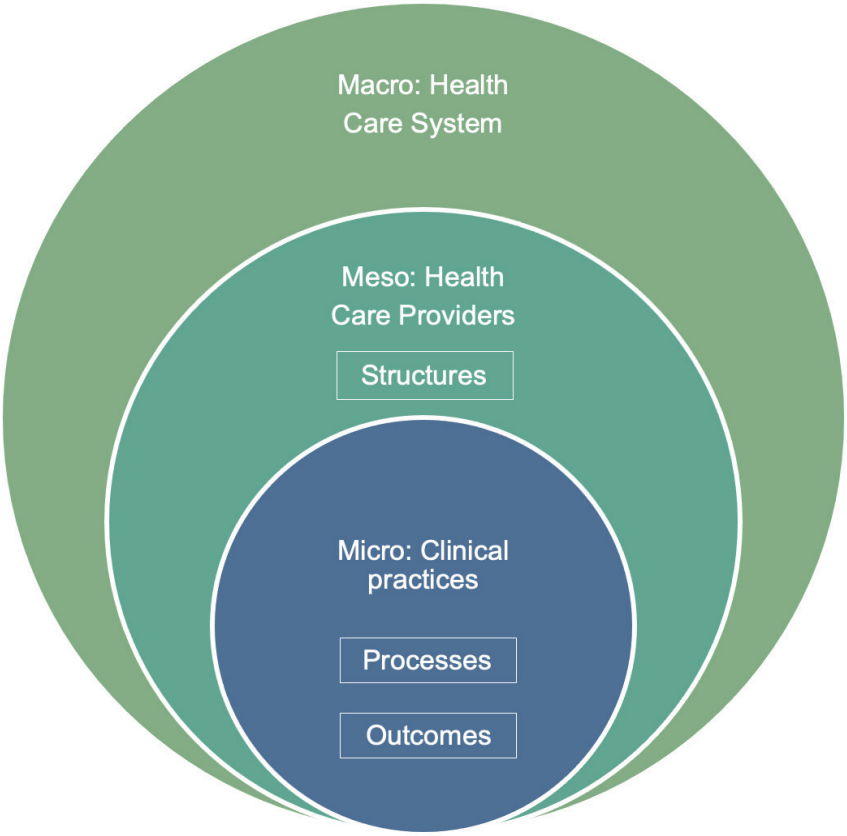

Figure 1: Illustration of the theoretical framework used to investigate restraint use and possible approaches for its reduction in the hospital setting

AIM AND OUTLINE OF THIS THESIS

To reduce restraint use in hospital settings and to ensure restraint management in line with ethical and legal requirements, it is important to first describe the current restraint practice in hospitals comprehensively. That is, it is necessary to examine the use of restraint independently of the type of restraint and specific subpopulations. This includes the frequency of use as well as the implementation of processes, the availability of structures and the attitude of the nursing staff. This endeavour will help to identify areas that have potential for improvement and/or can be addressed through specific preventive initiatives. In addition, it is important to investigate the influence of the different levels (macro, meso and micro) on the use of restraints so that interventions can be targeted where they have the greatest

potential impact. Therefore, this thesis aims to describe restraint use in hospital settings comprehensively, independently of subpopulations and specific restraint types, and to identify influencing factors on different levels.

Chapters 2 and 3 report restraint use at the micro and meso levels according to Donabedian quality dimensions based on quantitative data collected at three measurement points in several hospitals in Switzerland and Austria. In Chapter 2, the focus lies on the outcome and processes at the micro level, with an investigation on how often restraint is used in hospitals, what restraint types are used most frequently, what reasons for restraint use are given, what patients are most affected and how the processes around restraint use are implemented. Chapter 3 focusses on the structures within hospitals (meso level). It examines the degree of fulfilment of various structural indicators in the hospital and whether these contribute to explain the variance in restraint use. In addition, it examines how much variance in restraint use is explained at the patient and hospital levels, respectively.

Chapter 4 is based on data from a qualitative observational study. Daily restraint practice in hospital and influencing factors were examined from an outsider's perspective – that is, from someone who is not part of the institution. At the time the study was conducted, restraint use in hospitals had been studied primarily by means of quantitative assessments and interviews with health professionals. However, the quantitative assessment instruments can only be as comprehensive as the current state of research allows. The perspective of health professionals might be potentially biased, given the indications of the relevance of individual attitudes and institutional culture/routines in restraint use. Therefore, it was hypothesised that the outsider perspective could be used to generate new insights into restraint practice in hospitals primarily at the micro level, and to some extent at the meso level. These insights, in turn, can inform the development of quality improvement measures.

Chapter 5 is based on quantitative data from a cross-sectional study on the attitudes of nursing staff in hospitals towards restraint use. As described, the attitudes of nurses are likely to be relevant to restraint use at the micro level because they are the main decision-makers and are often under time pressure and face a high workload. Accordingly, it is relevant to include the attitude of nurses when designing and implementing restraint reduction programmes. In addition, the instrument used, which was originally developed for measuring nursing staff attitudes in long-term care settings, was examined for construct validity for use in hospital settings.

Chapter 6 is based on quantitative, multicentre data from Switzerland. The focus was on whether restraint use has potential to be established as a national quality indicator in the hospital setting and thus might represent a possible macro-level quality improvement measure. The investigation involved determining whether restraint use varies among hospitals in Switzerland, taking into account that hospitals care for different groups of patients (risk-adjusted hospital comparison).

Chapter 7 completes the thesis with a general discussion on restraint use in hospitals independent of subpopulations and specific restraint types as well as influencing factors on the different levels (macro, meso [including structures according to Donabedian's model] and micro [including processes and outcomes according to Donabedian's model]). The findings of this thesis are summarised, and theoretical and methodological reflections are presented. Implications and recommendations for (clinical) practice and for future research are derived.

Figure 2 gives an overview of the different chapters and their content along the different levels of the theoretical framework used (macro, meso [including structures] and micro [including processes and outcome]) for investigating restraint use and possible approaches for its reduction in the hospital setting.

Chapter 6: restraint use as a national quality indicator

Chapters 3 and 4: structures within institutions, practice variation among providers

Chapters 2, 4 and 5: processes surrounding restraint use, outcome, attitude of the nursing staff

Chapter 7: general discussion of findings

Figure 2: Overview of the chapters and their content along the different levels of the theoretical framework used to investigate restraint use and possible approaches for its reduction in the hospital setting

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CHAPTER 02

RESTRAINT USE IN THE ACUTE-CARE HOSPITAL SETTING: A CROSS-SECTIONAL MULTI-CENTRE STUDY

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ABSTRACT

Background: Restraints are likely to negatively affect patients' health and therefore a reduction in their usage is recommended for all health-care settings. To date, research on restrictive practices has concentrated on mental health and long-term care settings. In the acute-care hospital setting few studies have been published and these studies mainly focus on physical/mechanical restraints in specific subpopulations and/or on intensive care units. However, to ensure restraints are used as little as possible in the acute-care hospital setting, it seems important to investigate more comprehensively the use of restraints, to include all types of restraints irrespective of ward type or subpopulations and to identify factors associated with restraint use.

Objective: The aim of this study was to investigate restraint use regardless of ward type in the acute-care hospital setting, including restraint type, reasons for restraint use, process indicators when using restraints and restraint use-associated patient characteristics.

Methods: Using a cross-sectional multi-centre design, data were collected by means of an annual international prevalence measurement in acute-care hospitals in Switzerland and Austria. All hospitalized patients aged 18+ who gave informed consent were included. Data were collected at three measurement points between 2016 and 2018. Descriptive and multivariate logistic regression analyses were performed.

Results: A total of 29,477 patients hospitalized in 140 hospitals were included in this study. The prevalence rate for the use of at least one restraint over a 30-day period was 8.7% (n=2,577), with mechanical restraints representing the highest proportion of restraint type used (55.0%, n=1,417). The main reason for restraint use was fall prevention (43.8%, n=1,129), followed by confusion or delirious behaviour (20.4%, n=525). In 64.3% of the cases (n=1,657), restraint use was documented in the patient file. Regular evaluation occurred in 42.9% of the cases (n=1,105). Care dependency had the strongest association with restraint use (odds ratio [OR] 25.00, 95% confidence interval [CI] 21.01–29.78 for completely dependent patients in comparison to completely independent patients), followed by mental and behavioural disorders (OR 2.36, 95% CI 2.15–2.59).

Conclusions: Restraints are often utilized in hospitals in complex care situations

such as with patients at risk of falling or with delirium. When using restraints the consideration of processes like documentation and evaluation shows great potential for improvement. Standardization of these processes and education of the interprofessional team could be beneficial for raising awareness and for the sustainable reduction of restraint use.

Tweetable abstract: In hospitals restraints are often used in complex care situations. However, their use seems to be insufficiently documented and evaluated.

WHAT IS ALREADY KNOWN ABOUT THE TOPIC?

- A reduction in restraint use is recommended for all health-care settings due to their negative effects on patients.
- With regard to the acute-care hospital setting, little is known internationally as few studies have been published, and these studies mainly focus on physical/mechanical restraints in specific subpopulations and/or on intensive care units.
- To reduce restraint use in the acute-care hospital setting as much as possible, it seems important to investigate more comprehensively the use of restraints.

WHAT THIS PAPER ADDS

- The 30-day prevalence of patients with at least one restraint was 8.7%, including different restraint types such as bed rails and electronic or pharmacological measures.
- The main reasons for restraint use were the prevention of falls and the management of confusion or delirious behaviour.
- Documentation was part of restraint use in 64.3% of the cases and evaluation in 42.9%.

KEYWORDS

health-care outcome and process assessment, hospitals, prevalence, restraints, risk factors

BACKGROUND

Restraints can have negative effects on patients' physical and mental health, therefore a reduction in their use is recommended for all health-care settings [1]. To date, research and regulations on restraint use have focused on mental health and long-term care settings [2-4]. However, in the somatic acute-care hospital setting (henceforth referred to as "hospital") little is known internationally about the use of restraints and clear regulations are lacking [5]. Nevertheless, restraints may be used for various reasons in hospitals. To ensure that restraints are used as little as possible in this setting as well it is important to describe the restrictive practices. Thus, more information will be available to identify and develop quality improvement approaches.

Restraints are defined as "interventions that may infringe [on] a person's human rights and freedom of movement, including observation, seclusion, manual restraint, mechanical restraint and rapid tranquillisation" [National Institute for Health and Care Excellence [NICE], 6]. Previous studies on the prevalence of restraint use in hospitals showed that rates range between 0% and 100% [7, 8]. These large differences in the prevalence rates may be influenced by varying conditions, such as the restraint definition used, the legal situation in the country of origin or the availability of equipment (for example, for body fixation) [9-12]. In general, the few published studies in the hospital setting have mainly focused on physical/mechanical restraints in specific subpopulations and/or in intensive care units (ICUs). Comprehensive research on restraints, including various interventions limiting a person's human rights and irrespective of specific ward types and subpopulations, is lacking [5].

The reasons for using restraints have been studied in various settings, and within the long-term care and hospital setting similar reasons for their usage were found in the research. The most frequently stated reasons were patient safety (especially fall prevention), cognitive impairment, , and particularly in the hospital setting the prevention of therapy interruption (for example, preventing self-extubation) [4, 13-17]. However, various studies reveal that restraints have no impact or even a negative impact on patient safety, fall prevention and self-extubation [16, 18-25]. Thus, one of the basic ethical principles governing restraint use (that the expected benefit must exceed the damage) appears to be violated.

To reduce restraint use in the hospital setting as much as possible it seems important to investigate more comprehensively the use of restraints, including all types of restraints regardless of ward type [5], and to determine predictors for their

usage [14, 26, 27]. This would support the identification of at-risk patients, raise awareness among health professionals regarding restrictive practices and reveal possible alternatives to their usage.

Therefore, the aim of this study was to investigate the use of restraints in the somatic acute-care hospital setting, including restraint type, reasons for restraint use and process indicators when using restraints. Additionally, the patient characteristics associated with restraint use will be examined.

METHODS

Study design

Utilizing a cross-sectional multi-centre design, data on the use of restraints were collected from hospitals in Switzerland and Austria. These countries are participants in "LPZ (Landelijke Prevalentiemeting Zorgkwaliteit) International". LPZ International performs an annual international prevalence measurement for different quality of care indicators (such as pressure ulcers, falls and restraints) in various settings, including hospitals [28, www.lpz-um.eu]. As well as Switzerland and Austria, the Netherlands, the United Kingdom and Turkey are also participants in LPZ International. However, in these three countries, very few (or no) hospitals collect data on restraints. Therefore, only LPZ data from Switzerland and Austria were included in this study.

Setting and sample

For the LPZ International measurement, the national coordinator invites health-care institutions annually (via email, flyer, et cetera) to participate on a voluntary basis. In the hospital setting, all ward types (medical specialities) were eligible. Hospitalized patients aged 18+ with informed oral (Switzerland) or written (Austria) consent were included. Patients who were not available on the ward during the measurement (for example, as they were undergoing surgery) or who could not give informed consent (for instance, due to cognitive impairment or language barriers) and where no legal representative was available were excluded.

Variables and measurements

The LPZ 2.0 instrument, which is the revised version of the LPZ instrument, was used for data collection [28]. It consists of a multi-module questionnaire with predefined

answer options conceived as an online data entry program. For this study, data from the module on general patient characteristics and data from the module on restraints at three measurement points (08.11.2016, 14.11.2017 and 13.11.2018) were analysed.

The module on general patient characteristics included age, sex, surgical intervention in the two weeks prior to data collection, length of stay since admission to hospital, medical diagnosis groups according to ICD-10 (International Statistical Classification of Diseases and Related Health Problems 10th Revision) [29] and care dependency. Care dependency was assessed using the Care Dependency Scale (CDS) [30]. The CDS consists of 15 items (for example, eating and drinking or mobility) that are rated on a Likert scale from 1 to 5 (sum score 15–75). Lower scores indicate higher care dependency.

In the module on restraints the use of restraints within the institution was assessed regardless of restraint type for each patient retrospectively over a maximum period of 30 days (yes, no). Restraints were defined according to NICE [6 – see background section]. In regard to patients who had any restraint applied, the following criteria were surveyed:

- restraint type applied (multiple responses possible): mechanical (within this category – bed rails, belt fixation, tabletop/chair table, other), electronic, pharmacological, physical, one-to-one supervision, locked ward or building, other (for definitions see Supplemental Material Table A)
- main reason for restraint use (single response possible): (preventing) falls, (preventing) wandering around, (preventing) aggressive behaviour, confusion or delirious behaviour, agitation, non-compliance with treatment, request of the patient and/or the family, other motive, unknown
- process indicators regarding restraint use (multiple responses possible): documentation, informing the patient/legal representatives about the entire process, evaluation, monitoring, use of alternatives, none.

The questionnaires are reviewed annually by the international research group of LPZ International and adapted where indicated, therefore answer options may differ across time. Because of this, the following restraint types were not available for all measurement points between 2016 and 2018 for the present study: the different types within mechanical methods (only assessed in 2018) and the answer option one-to-one supervision (only available for 2017 and 2018).

Data collection

All participating hospitals were requested to document restraint use during the 30-day period prior to the measurement (in case this was not normally completed in the patient's file or any other documentation system). On the measurement day data were collected by trained registered nurses on-site at the patient's bedside and/or through the patient's documentation (retrospective assessment). Training of the data collectors (the nurses) included recruitment of the patients for the measurement; information regarding the definitions, questions and answer options; and the use of the online data entry program. Additionally, a manual with all of the educational information, including a more detailed description, was available for the data collectors. Through their training along with the aid of the manual a uniform answering of the questions was ensured. The data collectors entered the data into the online data entry program, which only allowed questionnaire completion once all questions had been answered.

Country-specific regulations on restraint use

In the two countries (Switzerland and Austria) restraint use is regulated as follows. In Switzerland only the use of movement restriction measures for individuals in nursing and care homes who lack decision-making capacity, as well as for those with compulsory admission, is regulated by law [31]. As well as legal regulation, a medical-ethical guideline on coercive measures in medicine for all settings was developed [32]. This guideline provides recommendations on coercive measures along with all other types of restraints. It focuses on ethical decision-making and considerations, as well as on process indicators such as evaluation and documentation. In Austria the use of restraints is regulated by the Nursing Home Residence Act and the Hospitalization Act [33, 34]. These acts regulate under which conditions, and by whom, restraints can be ordered and applied. The acts are applicable for mental health and long-term care settings, as well as for persons who have a mental illness or disability in hospital care. The reason, type, start and duration of the restraint must all be documented and immediately reported to the "Residential Advocacy Service".

Statistical analysis

The data from the two countries and the different measurement points were pooled into one data set. Descriptive statistics (numbers, percentages, 95% confidence interval [CI], median, interquartile range [IQR]) were used to describe the sample,

the prevalence rate and types of restraints, the main reason for using restraints and the process indicators. Additionally, the results regarding restraints were analysed for differences according to country utilizing cross tables.

Multivariate logistic regression analysis with a stepwise backwards procedure, based on the Akaike information criterion (AIC) [35], was used to investigate the associations between patient characteristics and restraint use. The independent variables female sex, surgical intervention in the two weeks prior to data collection and each ICD-10 diagnosis group [29] were included dichotomously (yes, no). Two ICD-10 diagnosis groups (congenital malformations, deformations and chromosomal abnormalities; certain conditions originating in the perinatal period) and the answer option unknown/no diagnosis had to be excluded because they were only present in less than 1% of patients. The inclusion of these variables would have led to convergence problems concerning the regression model. Age in years and number of days since admission to hospital were included as interval variables. In terms of care dependency, the five verified categories according to the Care Dependency Scale were utilized (15–24 completely dependent, 25–44 dependent to a great extent, 45–59 partially dependent, 60–69 independent to a great extent, 70–75 completely independent) [30]. Country was included as a character variable. Multicollinearity was tested using the variance inflation factor (VIF).

Since data were collected using an online data entry program in which all questions had to be answered in order to finish the survey there were no missing data. The statistical analysis was conducted utilizing R Version 3.6.1 [36] and the R Packages “compareGroups” [37], “jtools” [38], “MASS” [39], “questionr” [40], “tableone” [41], “tidyverse” [42] and “vcd” [43]. For data cleaning and pooling SPSS version 25 [44] was used.

Ethical considerations

In Switzerland the Ethics Committee of the Canton of Bern declared that the present study did not fall under the Swiss Human Research Act (April 2019, BASEC-Nr: Req-2019-00259), therefore ethical approval was not required. In Austria the Ethics Committee of the Medical University of Graz approved the study protocol (approval nr. 20-192 ex08/09). All patients or their legal representatives received written information about the measurement and gave their oral (Switzerland) or written (Austria) informed consent. Data were collected pseudonymously so that identification of individual patients is almost impossible. Participation was voluntary.

RESULTS

Sample

A total of 29,477 patients hospitalized in 140 hospitals were surveyed regarding the use of restraints in Switzerland (CH) and Austria (AT) at three measurement points between 2016 and 2018. The sample consisted of 20,561 (69.8%) patients from Switzerland and 8,916 (30.2%) patients from Austria (Table 1). The 29,477 participants corresponded to 75.4% (95% confidence interval [CI] 74.9%–75.8%) of all patients hospitalized (N=39,106) on the measurement days in the 140 hospitals (CH 76.3% [95% CI=75.8%–76.8%] N=26,934; AT 73.3% [95% CI=72.5%–74.0%] N=12,172).

Approximately half of the patients were female (49.2%, n=14,504) and 35.8% (n=10,542) had had a surgical intervention in the two weeks prior to data collection. Their median age was 70 years, their median length of stay since admission to the hospital was 5 days and the median score of the CDS was 71 (indicating that most of the patients were completely independent in their care). The three most frequent ICD-10 diagnosis groups were diseases of the circulatory system (55.1%, n=16,245), endocrine, nutritional and metabolic diseases (33.5%, n=9,886) and diseases of the musculoskeletal system and connective tissue (33.4%, n=9,834). Differences between countries are shown in Table 1.

Prevalence rate and type of restraints

The 30-day prevalence rate of patients with at least one restraint was 8.7% (n=2,577), with differences between countries being detected (CH 10.6%, n=2,171; AT 4.6%, n=406). Mechanical methods were the most frequently used type of restraint (55.0%, n=1,417). Within this category (data available only for the measurement point in 2018 n=10,305, mechanical restraint n=570), bed rails were most commonly cited (86.7%, n=494). Apart from mechanical methods, electronic (33.2%, n=856) and pharmacological (24.6%=633) methods were frequently used (see Table 2). Differences between countries were evident. For example, in Switzerland more electronic methods were used but there were fewer locked wards or buildings than in Austria.

Table 1: Patient characteristics

Characteristics	Total (n=29,477)		Switzerland (n=20,561)		Austria (n=8,916)	
	median	IQR	median	IQR	median	IQR
Age in years	70	24	70	23	69	23
Number of days since admission to hospital	5	9	5	9	5	10
Care Dependency Scale (sum score)	71	15	70	15	74	11
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Female sex	14,504	49.2 (48.6–49.8)	9,902	48.2 (47.5–48.8)	4,602	51.6 (50.6–52.7)
Surgical intervention in the two weeks prior to data collection (yes)	10,542	35.8 (35.2–36.3)	8,318	40.5 (39.8–41.1)	2,224	24.9 (24.0–25.9)
ICD-10 diagnosis groups (multiple responses)						
Diseases of the circulatory system	16,245	55.1 (54.5–55.7)	11,756	57.2 (56.5–57.9)	4,489	50.3 (49.3–51.4)
Endocrine, nutritional and metabolic diseases	9,886	33.5 (33.0–34.1)	7,023	34.2 (33.5–34.8)	2,863	32.1 (31.1–33.1)
Diseases of the musculoskeletal system and connective tissue	9,834	33.4 (32.8–33.9)	7,543	36.7 (36.0–37.3)	2,291	25.7 (24.8–26.6)
Diseases of the genitourinary system	8,333	28.3 (27.8–28.8)	6,389	31.1 (30.4–31.7)	1,944	21.8 (21.0–22.7)
Diseases of the digestive system	7,214	24.5 (24.0–25.0)	5,185	25.2 (24.6–25.8)	2,029	22.8 (21.9–23.6)
Diseases of the respiratory system	7,137	24.2 (23.7–24.7)	5,224	25.4 (24.8–26.0)	1,913	21.5 (20.6–22.3)
Neoplasms	6,118	20.8 (20.3–21.2)	4,540	22.1 (21.5–22.7)	1,578	17.7 (16.9–18.5)
Mental and behavioural disorders	5,831	19.8 (19.3–20.2)	4,249	20.7 (20.1–21.2)	1,582	17.7 (17.0–18.6)
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	4,283	14.5 (14.1–14.9)	3,539	17.2 (16.7–17.7)	744	8.3 (7.8–8.9)
Diseases of the nervous system	4,118	14.0 (13.6–14.4)	3,064	14.9 (14.4–15.4)	1,054	11.8 (11.2–12.5)
Certain infectious and parasitic diseases	3,559	12.1 (11.7–12.5)	2,997	14.6 (14.1–15.1)	562	6.3 (5.8–6.8)
Diseases of the skin and subcutaneous tissue	2,450	8.3 (8.0–8.6)	1,712	8.3 (8.0–8.7)	738	8.3 (7.7–8.9)
Factors influencing health status and contact with health services	2,413	8.2 (7.9–8.5)	1,641	8.0 (7.6–8.4)	772	8.7 (8.1–9.3)
Injury, poisoning and certain other consequences of external causes	1,800	6.1 (5.8–6.4)	1,462	7.1 (6.8–7.5)	338	3.8 (3.4–4.2)
Diseases of the eye and adnexa	1,769	6.0 (5.7–6.3)	1,247	6.1 (5.7–6.4)	522	5.9 (5.4–6.4)
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	1,304	4.4 (4.2–4.7)	1,100	5.3 (5.0–5.7)	204	2.3 (2.0–2.6)
Diseases of the ear and mastoid process	684	2.3 (2.2–2.5)	551	2.7 (2.5–2.9)	133	1.5 (1.3–1.8)
External causes of morbidity and mortality	491	1.7 (1.5–1.8)	448	2.2 (2.0–2.4)	43	0.5 (0.3–0.6)
Pregnancy, childbirth and the puerperium	290	1.0 (0.9–1.1)	171	0.8 (0.7–1.0)	119	1.3 (1.1–1.6)
Congenital malformations, deformations and chromosomal abnormalities	148	0.5 (0.4–0.6)	114	0.6 (0.5–0.7)	34	0.4 (0.3–0.5)
Unknown/no diagnosis	112	0.4 (0.3–0.5)	78	0.4 (0.3–0.5)	34	0.4 (0.3–0.5)
Certain conditions originating in the perinatal period	28	0.1 (0.1–0.1)	25	0.1 (0.1–0.2)	3	<0.1 (<0.1–0.1)

IQR=interquartile range, 95% CI=95% confidence interval, ICD-10=International Statistical Classification of Diseases and Related Health Problems 10th Revision

Reasons for restraint use

The main reason for restraint use was fall prevention (43.8%, n=1,129), followed by confusion or delirious behaviour (20.4%, n=525). Patient or family request was far more often the main reason for restraint use in Austria than in Switzerland (see Table 3).

Process indicators

Overall, the use of restraints was documented in the patients' files for 64.3% (n=1,657) of patients affected by restraint use (n=2,577). In 51.0% (n=1,315) of the cases the patient and/or the legal representatives were informed about the entire process surrounding the use of the restraint. A regular evaluation with all persons involved, including the patient, was part of the restraint procedure in 42.9% (n=1,105) of the cases. In 42.1% (n=1,084) of the cases, in each shift someone was responsible for monitoring the patient undergoing the restraining. Alternatives to minimize the use of restraints (for example, delirium prevention) were primarily used in 37.1% (n=957) of the cases. There were small differences between countries, as shown in Table 4.

Associated patient characteristics

In the multivariate analysis with AIC backward selection the strongest association with restraint use was detected for patients' care dependency, with an almost exponentially increasing odds ratio (OR). Completely dependent patients, according to the Care Dependency Scale, had a 25-fold higher risk (OR=25.00, 95% CI=21.01–29.78) of undergoing restraint during their hospital stay than completely independent patients. Various ICD-10 diagnosis groups were associated with a slightly higher risk of being restrained (see Table 5). The most important ICD-10 diagnosis group with an OR of 2.36 (95% CI=2.15–2.59) was mental and behavioural disorders. The variables female sex, diseases of the digestive system and diseases of the musculoskeletal system and connective tissue were found to be significant risk-decreasing variables with ORs of around 0.8. The different prevalence by country described above is also reflected in the regression analysis. In Switzerland the risk of experiencing the use of a restraint is 2.23 times higher (95% CI 1.98–2.51) than in Austria. The model fit is 0.28 according to Cragg-Uhler, or 0.22 according to McFadden ($p<0.000$).

Table 2: Prevalence rate and type of restraint

	Total (n=29,477)		Switzerland (n=20,561)		Austria (n=8,916)	
	n	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**
Restraint (yes)	2,577	8.7 (8.4–9.1)	2,171	10.6 (10.1–11.0)	406	4.6 (4.1–5.0)
Proportion restraint type (multiple responses)						
Mechanical restraints	1,417	55.0 (53.0–56.9)	1,224	56.4 (54.3–58.5)	193	47.5 (42.6–52.5)
Proportion type of mechanical restraint (multiple responses, only 2018)						
n participants 2018		*10,305*		*6,923*		*3,382*
n restraint (yes) 2018		*570*		*495*		*75*
Bed rails	*494*	*86.7 (83.6–89.3)*	*428*	*86.5 (83.1–89.4)*	*66*	*88.0 (78.4–94.4)*
Other mechanical restraint	*100*	*17.5 (14.5–20.9)*	*92*	*18.6 (15.3–22.3)*	*8*	*10.7 (4.7–19.9)*
Belt fixation	*65*	*11.4 (8.9–14.3)*	*48*	*9.7 (7.2–12.7)*	*17*	*22.7 (13.8–33.8)*
Tabletop/chair table	*56*	*9.8 (7.5–12.6)*	*49*	*9.9 (7.4–12.9)*	*7*	*9.3 (3.8–18.3)*
Electronic restraints	856	33.2 (31.4–35.1)	798	36.8 (34.7–38.8)	58	14.3 (11.0–18.1)
Pharmacological restraints	633	24.6 (22.9–26.3)	549	25.3 (23.5–27.2)	84	20.7 (16.9–25.0)
Other	388	15.1 (13.7–16.5)	302	13.9 (12.5–15.4)	86	21.2 (17.3–25.5)
One-to-one supervision[1]	227	8.8 (7.7–10.0)	223	10.3 (9.0–11.6)	4	1.0 (0.3–2.5)
Locked ward or building	164	6.4 (5.5–7.4)	82	3.8 (3.0–4.7)	82	20.2 (16.4–24.4)
Physical restraints (keeping someone restrained with human physical force)	75	2.9 (2.3–3.6)	70	3.2 (2.5–4.1)	5	1.2 (0.4–2.9)

[1]Answer option was only available for 2017 and 2018 (n participants=20,012)

95% CI=95% confidence interval; for definitions of the different restraint types see Supplemental Material Table A

Table 3: Main reason for restraint use

		Total		Switzerland		Austria
Patients with restraint (n)		2,577		2,171		406
Main reason for restraint use (single response)	**n**	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**
(Preventing) Falls	1,129	43.8 (41.9–45.8)	1,029	47.4 (45.3–49.5)	100	24.6 (20.5–29.1)
Confusion or delirious behaviour	525	20.4 (18.8–22.0)	465	21.4 (19.7–23.2)	60	14.8 (11.5–18.6)
Other motive	308	12.0 (10.7–13.3)	211	9.7 (8.5–11.0)	97	23.9 (19.8–28.3)
Request of the patient and/or family	188	7.3 (6.3–8.4)	119	5.5 (4.6–6.5)	69	17.0 (13.5–21.0)
Agitation	123	4.8 (4.0–5.7)	111	5.1 (4.2–6.1)	12	3.0 (1.5–5.1)
Non-compliance with treatment	71	2.8 (2.2–3.5)	68	3.1 (2.4–4.0)	3	0.7 (0.2–2.1)
(Preventing) Wandering around	56	2.2 (1.6–2.8)	42	1.9 (1.4–2.6)	14	3.4 (1.9–5.7)
(Preventing) Aggressive behaviour	33	1.3 (0.9–1.8)	19	0.9 (0.5–1.4)	14	3.4 (1.9–5.7)
Unknown	24	0.9 (0.6–1.4)	19	0.9 (0.5–1.4)	5	1.2 (0.4–2.9)
95% CI=95% confidence interval						

Table 4: Process indicators

		Total		Switzerland		Austria
Patients with restraint (n)		2,577		2,171		406
Process indicators (multiple responses)	**n**	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**
The restraining was documented in the patient file	1,657	64.3 (62.4–66.2)	1,403	64.6 (62.6–66.6)	254	62.6 (57.7–67.3)
The patient and/or the legal representatives were informed about the entire process surrounding the use of restraints	1,315	51.0 (49.1–53.0)	1,093	50.3 (48.2–52.5)	222	54.7 (49.7–59.6)
The use of restraints was evaluated with all persons involved (including the patient)	1,105	42.9 (41.0–44.8)	919	42.3 (40.2–44.4)	186	45.8 (40.9–50.8)
In each shift a person/nurse was appointed to monitor the patient undergoing restraining regularly, according to the defined prescription	1,084	42.1 (40.1–44.0)	954	43.9 (41.8–46.1)	130	32.0 (27.5–36.8)
Primarily alternatives were used to minimize the use of restraints	957	37.1 (35.3–39.0)	821	37.8 (35.8–39.9)	136	33.5 (28.9–38.3)
None	265	10.3 (9.1–11.5)	229	10.5 (9.3–11.9)	36	8.9 (6.3–12.1)
95% CI=95% confidence interval						

Table 5: Patient characteristics associated with restraint use

Model p<0.000; Pseudo-R^2 Cragg-Uhler=0.28, McFadden=0.22; AIC=13657.27	
Patient characteristics	**OR (95% CI)**
(Intercept)	0.01 (0.01–0.01)*
Country Austria	Reference
Switzerland	2.23 (1.98–2.51)*
Age in years	1.00 (1.00–1.01)*
Female sex	0.80 (0.73–0.87)*
Number of days since admission to hospital	1.00 (1.00–1.00)*
Care Dependency Scale (CDS) ≥70 completely independent	Reference
≥60–69 independent to a great extent	2.56 (2.22–2.96)*
≥45–59 partially dependent	6.36 (5.53–7.32)*
≥25–44 dependent to a great extent	14.84 (12.78–17.25)*
≤24 completely dependent	25.00 (21.01–29.78)*
Mental and behavioural disorders	2.36 (2.15–2.59)*
External causes of morbidity and mortality	1.46 (1.12–1.88)*
Factors influencing health status and contact with health services	1.29 (1.12–1.48)*
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	1.24 (1.04–1.47)*
Diseases of the eye and adnexa	1.24 (1.05–1.46)*
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	1.18 (1.06–1.32)*
Injury, poisoning and certain other consequences of external causes	1.14 (0.97–1.33)
Diseases of the nervous system	1.10 (0.98–1.23)
Diseases of the digestive system	0.85 (0.76–0.94)*
Diseases of the musculoskeletal system and connective tissue	0.78 (0.71–0.86)*
*statistically significant based on the 95% CI	
OR=odds ratio, 95% CI=95% confidence interval, AIC=Akaike Information Criterion	

DISCUSSION

In our cross-sectional study on restraint use in Swiss and Austrian hospitals, we found that approximately every 11th patient was affected by restraint use. Most frequently mechanical methods (for example, bed rails) were applied followed by electronic and pharmacological restraints. Restraints seem to be used in complex care situations such as with patients at risk of falling or with delirium. When using restraints, processes such as documentation and regular evaluation do not appear to be systematically implemented. The strongest association for restraint use was found with patients' care dependency and mental and behavioural disorders. This indicates that a very vulnerable patient group was most affected by restraint use.

Prevalence rate and type of restraints

The prevalence rate for the use of at least one restraint over a 30-day period was 8.7%. Since this rate includes different restraint types and does not, as in most other studies (in the hospital setting), include only mechanical (physical) methods a comparison of the prevalence rates is not possible. Internationally there seems to be conceptual ambiguity concerning restraints [5]; an international consensus in regard to a research definition only exists for physical (mechanical) restraints [45]. However, the results show how important comprehensive research on restraints is, especially regarding various interventions limiting a person's human rights.

Both in the literature [19, 46] and in this study bed rails are the most common restraint type. The frequent use of bed rails could be related to the fact that bed rails are increasingly often permanently installed on the bed [11, 47] and that they are (therefore) viewed as a standard operational procedure [46]. However, there is no evidence regarding the benefit of bed rails (for instance, in fall prevention) [21, 25]. In contrast, there is intense discussion about the risks of bed rail use [25, 47]. For example, more severe fall injuries could occur if a patient tried to climb over the bed rail and then fell from a higher level than if the bed rail were down, therefore frequent use of bed rails should be critically reflected.

Two forms of restraint other than bed rails that were identified in this study as being frequently used were electronic and pharmacological restraints. To date, electronic restraints in hospitals have hardly been investigated. There are indications that bed/chair alarms, for example, are often used to prevent falls. However, a positive effect regarding fall rate or reduced use of mechanical restraints has yet to be detected [25]. Pharmacological restraints have to some extent been

described in the literature. They seem to be frequently applied measures, even though side effects from the medication and a negative impact on rehabilitation (after hospitalization) have been reported [48, 49]. Often pharmacological restraints are not recorded as restraints, for example the off-label use of antipsychotic medication to address agitation in people with delirium or dementia. However, in the long-term care setting an association was found between the (off-label) use of antipsychotic medication and various adverse events such as hip fractures and infections [50].

Reasons for restraint use

Findings showed that fall prevention is the main reason for restraint use in this study, which is consistent with the literature [13-16]; however, there is growing evidence that restraints are ineffective for preventing falls [19, 21, 25]. Interestingly the second-most common reason for using restraints was confusion or delirious behaviour. This is contrary to the literature, in which the avoidance of therapy interruption is mentioned as the second-most common reason for restraint use [13-16]. As confusion or delirious behaviour is often linked with a risk of therapy interruption the difference in results could be influenced by definitions/personal interpretations of what the main reason for restraint use is. However, similarly to fall prevention there are negative indications regarding the use of restraints in that they could lead to the development of delirium [12, 24]. Therefore their use could be counterproductive in terms of therapy interruption, prevention, et cetera, at least over the longer term. Overall, there are indications that restraints are often used in complex care situations (fall risk, delirium), in which preventive measures and/or alternative approaches would be challenging and difficult to implement. Since the reasons for restraint use are similar to those in the long-term care setting [2, 4, 17] it would be worth examining whether restraint reduction strategies in this setting could be adapted to the hospital setting [51].

Process indicators

The process indicators for restraint usage show great potential for improvement since even the documentation of restraint use in the patients' files is complete in only 64.3% of the cases. This supports the assumption that there is a lack of knowledge regarding legal and ethical regulations when using restraints [9, 13, 24, 47, 52, 53]. This is especially evidenced by the incomplete or sometimes

totally missing documentation of the use of restraints, which is widely discussed in the literature [15, 16, 54-56]. Indeed, Freeman et al. [14] emphasize that poor documentation also leads to a lack of systematic reassessment/evaluation of the use of restraints. The even lower occurrence (42.9%) of regular evaluations of restraint use with all individuals involved could be related to this assumption.

Findings showed that alternatives to restraints (for example, for fall prevention) were used in only 37.1% of cases. Möhler and Meyer [53] state that restraints are routine nursing interventions and that because of this routine, alternatives are not sufficiently considered, even though it is a legal and ethical requirement. Additionally, since health professionals often see restraints as solely a mechanical fixation with a belt, it may be assumed that not all measures are correctly identified as being a restraint [57]. If health professionals do not realize that a certain intervention is a restraint they likely will not document and evaluate its use or consider alternatives before using it. Standardization of the processes along with education could help to ensure that ethical and legal requirements are met and at the same time promote awareness. Those health professionals who have to evaluate restraint use regularly and document their decisions are then required to think about the necessity of the use of restraints. In this respect, interprofessional training programmes for all health professionals, which focus on the different restraint types, their use and their possible alternatives, could be beneficial for a more conscious restraint management [12, 51].

Associated patient characteristics

The results of the regression analysis are highly relevant from an ethical point of view. They show that very vulnerable and care-intensive patients (older, completely care dependent, with mental and behavioural disorders) have an increased risk of being restrained. This means that the patients who are most affected are those who often cannot speak up for themselves, therefore ethical considerations become even more important. In view of the demographic trend, an increase in the number of patients at risk of restraint use in the hospital setting must be assumed. It is therefore essential that health professionals show increased awareness of restrictive practices and use restraints in a more reflective and targeted manner (including for the long term) instead of basing practice on routine and intuition [5, 53, 58]. The results of this study can contribute to stimulating (critical) discussions about restrictive practice and to identifying possibilities for quality improvement approaches.

The differences between Switzerland and Austria could have been influenced by the availability of the different restraint equipment (for example, for body fixation) in the hospital and on the ward [11], as well as by their different legal situations [57]. Although more restraints were used in Switzerland these tended to be potentially less restrictive than those in Austria. For example, the proportion of electronic measures and one-to-one supervision is considerably higher in Switzerland, whereas the proportion of locked wards and buildings is higher in Austria. However, these potentially less drastic measures have hardly been studied to date, either in terms of benefits or risks. As regards fall prevention, LeLaurin and Shorr [25] state that alarms and sitters (one-to-one supervision) seem to be ineffective.

In regard to the legal situation in the two countries, in Switzerland only movement restriction measures for a subpopulation and/or specific settings are regulated. In Austria, however, all restraint types are included in the legislation and there is also a focus on subpopulation and/or specific settings. Furthermore, in Austria the documentation of restraints is mandatory, whereas in Switzerland only recommendations from the Swiss Academy of Medical Sciences [32] exist. Interestingly in this study there was no difference regarding the documentation of restraint use between the countries. However, in both countries clear legal regulations that are independent of specific populations and settings are lacking, especially for the hospital setting. It is therefore uncertain whether the different regulations had an influence on the differences in restraint use detected between these two countries (for instance, restraint type or reason for restraint use). Nevertheless, in terms of restraint reduction, it is important to have clear policies and to monitor and benchmark the use of restraints [4, 12].

Strengths and limitations

The strengths of the study are the large sample sizes of the two countries and their many similarities (including their health-care systems), the inclusion of all medical specialities of all hospital types, the annually reviewed questionnaire and the highly standardized data collection. There are also some limitations, however. The first is the exclusion of a potentially very vulnerable patient group and thus the possibility of a selection bias. Patients who could not give their informed consent (for instance, due to cognitive impairment) and where no legal representative was present had to be excluded from the study, therefore it is possible that the restraint prevalence was underestimated and that the results might be biased with respect to restraint

types and the main reasons for their use. In both countries for a variety of reasons approximately a quarter of all hospitalized patients on the measurement days did not participate in the survey. In addition, the results also depend on the data quality within the hospital. Since data were collected retrospectively over a period of the previous 30 days, patient files were also used as a data source. However, as the results show, documentation is only available for about two-thirds of restraints, therefore it is possible that a documentation and/or recall bias exists, and again that the restraint prevalence is underestimated. Additionally, it is also possible that only hospitals that were already engaged in restraint reduction participated in the study. However, due to the large sample size and the high participation rate it can be expected that the results of this study will be generalizable.

In the regression analysis based on the model fit it must be assumed that there are additional factors influencing restraint use that are not represented in this model (for example, contextual factors such as nurse-to-patient ratio and skill mix are not assessed with LPZ 2.0). Additionally, the cross-sectional study design favours fluctuations in the group of patients examined and limits the causality of the results. At this point it should also be mentioned that due to the cross-sectional design, the direction of the association of the patient characteristics with the restraint use is not clear. For example, care dependency can be the cause and/or the consequence of restraint use.

One limiting condition of the survey is the answer option “other”, which represents a large number of responses in all questions. Since this response option is not very meaningful in terms of quality improvement efforts, future studies should investigate what has been recorded under “other”. On the one hand, a more refined picture of restraint use could be obtained, while on the other hand, the questionnaire could be adapted. Given these limitations, longitudinal designs and/or observational studies seem to be necessary in future research.

CONCLUSIONS

Restraints are frequently used in hospitals, even though there is growing evidence regarding their negative effects on patients and on their lack of benefits (for instance, with fall prevention). This study reveals that a very vulnerable patient group (older, completely care dependent and/or with mental and behavioural disorders) is most affected by restraint use. Therefore, and in light of the demographic trend, a more conscious usage of restraints based upon the legal

and ethical requirements will become even more important. The standardization of processes such as documentation and evaluation as well as the education of the interprofessional team could be beneficial for raising awareness and for ensuring the sustainable reduction of restraint use. Overall, this first study on different restraint types, irrespective of medical specialities in hospitals, provides insight into possibilities for quality improvement approaches.

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CONFLICT OF INTEREST

None.

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SUPPLEMENTAL MATERIAL

Table A: Definitions of the different restraint types

Mechanical restraints	Mechanical restraining is a method of physical intervention involving the use of authorised equipment applied in a skilled manner by health professionals. Its purpose is to safely immobilise or restrict movement of part(s) of the body of the patient.
• Bed rails	Bed rails prevent the patient for example from standing up independently or from falling off bed. The patient cannot leave the bed on her/his own. Bed rails are not considered as restraints, if they are used only on one side of the bed/ if the patient could leave the bed without restriction. Semi-raised bed rails are considered as restraint, because the patient cannot leave the bed without risk. Semi-continuous bed rails are not considered as restraints if the patient can leave the bed without restriction or if she/he can remove the bed rail by her-/himself.
• Belt fixation	This concerns belt fixation for example in bed or on chairs as well as the fixation of extremities. The belt is used to restrict freedom of movement. The restraint prevents the patient for example from standing up independently or from removing medical devices. The restraint measure can only be removed or opened with the help of another person using specific equipment.
• Tabletop/chair table	The tabletop/chair table prevents the patient for example from standing up independently. The restraint measure can only be removed with the help of another person.
• Other	Any other mechanical interventions.
Physical restraints (keeping someone restrained with human physical force)	Physical restraints are skilled, hands-on methods performed by trained health professionals to prevent patients from harming themselves, endangering others or compromising the therapeutic environment. The purpose of physical restraints is to safely immobilise the patient, keeping her or him restrained with human physical force for as long as necessary.
Pharmacological restraints	In this form of restraints, the patient receives oral or parenteral application of sedative and/or psychotropic drugs with the aim of restricting the freedom or the movement of a patient. For example, rapid tranquillization or sedation in an emergency.
Electronic restraints	Electronic restraints include technological supervision such as camera surveillance, fall devices, sensor mats, and alert systems (movement detection) with the aim of restricting the patient's freedom of movement.
One-to-one supervision	One-to-one supervision means constantly supervising the patient through direct observation.
Locked ward or building	A locked ward or building is a ward or building which has locked doors that can only be opened by authorised persons. Patients cannot leave the ward or building without authorisation. The aim of these locked wards or buildings is to restrict freedom of movement.
Other measures	Any other restraints.

CHAPTER 03

VARIATION IN RESTRAINT USE BETWEEN HOSPITALS: A MULTILEVEL ANALYSIS OF MULTICENTRE PREVALENCE MEASUREMENTS IN SWITZERLAND AND AUSTRIA

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ABSTRACT

Background: In restraint use in the somatic acute-care hospital setting, routine and institutional culture seem to play an important role. This implies that similar patient situations would be managed with restraints in one hospital, while in another hospital the situation would be managed without restraints. This practice variation appears to be ethically and legally questionable. The influence of organisation-specific factors such as the availability of guidelines is discussed. However, the relevance of such factors at the hospital level has been rarely investigated to date. Therefore, the aims of this study were a) to determine how much variance in restraint use can be explained on the hospital level (hospital general effect) and b) to examine the impact of organisational factors on restraint use (specific contextual effects).

Methods: A secondary data analysis of cross-sectional multicentre data was performed. Data were collected during three quality measurements (2016-2018) in acute-care hospitals in Switzerland and Austria. Hospitalised patients from different medical specialties aged 18+ with informed consent were included. Descriptive analysis and multilevel logistic regression analysis were performed.

Results: The study included 29,477 patients from a total of 140 hospitals. The 30-day prevalence rate of patients with at least one restraint was 8.7% (n=2,577). The availability of guidelines regarding restraint use and refresher courses for nursing staff were associated with less restraint use (odds ratios = 0.60 and 0.75). By adding the hospital as a random effect, the explained variance of the model increased from 24% to 55%.

Conclusions: The use of restraints varies widely between hospitals, even considering patient characteristics. The identification of situations in which restraints were used out of routine or institutional culture appears to be an important approach in restraint reduction. Investments in appropriate structures and employee knowledge can facilitate providing restraint-free care as much as possible.

KEYWORDS

Hospitals, Multilevel Analysis, Organisational Culture, Quality of Health Care, Restraint

BACKGROUND

Restraint use in health care often leads to negative effects for patient health, such as functional decline, higher mortality, distress or trauma [1-4], and to moral distress for health professionals [5, 6]. Therefore, a reduction in restraint use is recommended [7-9].

To date, quality improvement initiatives regarding restraint use are mainly known in the long-term care and mental health setting [10, 11]. Nevertheless, restraints are frequently used in the somatic acute care hospital setting (henceforth referred to as 'hospital') as well. Prevalence rates up to 100% are reported [1, 12, 13]. Large differences in restraint prevalence rates can be detected depending on the ward type studied (intensive care units often have a much higher prevalence rate) and by the definition of restraints used (e.g. only restraint belts; alternatively, bed rails and electronic monitoring can also be considered as restraints).

Frequently stated reasons for restraint use in the hospital setting are patient safety (e.g. fall prevention or prevention of therapy interruption) and patient characteristics like cognitive impairment [5, 14, 15]. However, evidence for the effectiveness of restraints for these reasons is lacking [5, 16, 17]. Nevertheless, restraints also seem to be used out of routine according to the tradition on the ward or local habits [18-21]. This implies that practice variation may exist. Consequently, in a similar patient situation, restraints may be used in one hospital, while in another hospital this situation would be managed without restraints. These differences in restraint use among hospitals independent of evidence or professional recommendations appear to be ethically and legally questionable. In this context, the relevance and role of organisational factors such as structures, policies/guidelines, education for staff, monitoring of restraint use and organisational attitudes are discussed [18, 20-24].

Surprisingly, the practice variation in restraint use among hospitals (hospital general effect) and the impact of organisational factors (specific contextual effects) has rarely been investigated to date. Nevertheless, in order to promote a professional management of restraints and, thus, to develop and implement effective measures for restraint reduction, it is crucial to know the influencing factors on different levels and their impact on the use and non-use of restraints. Therefore, the aims of this study were a) to determine how much variance in restraint use can be explained on the hospital level (hospital general effect) and b) to examine the impact of organisational factors (specific contextual effects) on restraint use; both aspects considered the influence of patient characteristics on restraint use.

METHODS

Study design and setting

A secondary data analysis of cross-sectional multicentre studies was performed. Data were collected within the International Prevalence Measurement of Quality of Care, called LPZ (Landelijke Prevalentiemeting Zorgkwaliteit) International [25, 26]. LPZ International performs an annual international quality measurement for a variety of care indicators (like pressure ulcers, falls and restraints) in various settings and countries. Healthcare institutions are invited annually by a national coordinator in several countries to participate on a voluntary basis in the measurement. For the present study, data from the hospital setting of Switzerland and Austria from three one-day measurement points in the years 2016 to 2018 were included. Other countries in the LPZ consortium were not able to provide data as very few hospitals measured restraint use.

Sample

In the LPZ measurement, hospitalised patients from different medical specialties (ward types) aged 18+ with informed verbal (Switzerland) or written (Austria) consent were included. Patients were excluded from the LPZ measurement if they were not available on the ward during the measurement (e.g. since they were undergoing surgery) or could not give informed consent (e.g. due to cognitive impairment or language barriers) and where no legal representative was available. There were no additional exclusion criteria for this secondary analysis.

Instrument and data collection

For data collection, the LPZ 2.0 instrument was used. It is the 2016 revised version of the LPZ instrument [25]. With LPZ 2.0, general and care indicator specific information is assessed on the institutional, ward and patient levels. For this secondary data analysis, information regarding restraints of different levels was included (for details, see Table 1). Restraints were defined as ‘interventions that may infringe [on] a person’s human rights and freedom of movement, including observation, seclusion, manual restraint, mechanical restraint and rapid tranquillisation’ [27].

Table 1: Variables

Level	Information
National	Country (Switzerland, Austria)
Institutional	Availability of a protocol/guidelines regarding restraints (based on a(n) (inter) national guideline) within the institution (yes, no)
	Availability of a multi-disciplinary expert committee regrading restraints within the institution (yes, no)
Ward	Regular audits are performed on the ward level to ensure compliance with the protocol/guidelines regarding restraints (yes, no)
	Refresher course regarding restraints for at least 80% of ward nursing staff in the last two years (yes, no)
Patient	Age in years (interval)
	Female gender (yes, no)
	Surgical intervention in the two weeks prior to data collection (yes, no)
	Number of days since admission to hospital (interval)
	Medical diagnosis groups according to International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10; for each diagnosis group yes, no) [28]
	Care dependency assessed with the Care Dependency Scale (CDS) (15 items [e.g., eating and drinking or mobility] are rated on a Likert scale from 1 to 5 [sum score 15-75]. Lower scores indicate higher care dependency resulting in five verified categories: 15-24 completely dependent, 25-44 dependent to a great extent, 45-59 partially dependent, 60-69 independent to a great extent, 70-75 completely independent) [29]
	Restraint use within the institution retrospectively over a maximum period of 30 days (yes, no)

Within LPZ 2.0, the data collection process is highly standardised. The whole process (e.g. recruitment and information of patients, preparing data collection including documentation of restraint use 30 days prior to data collection) and all questions and answer options are internationally defined and described in a measurement manual. Additionally, the questionnaire was conceived as an online data entry program leading the questionnaire completion. To ensure uniform execution of the measurement and uniform answering of the questions, data collectors were trained. Using the train-the-trainer procedure, the national coordinator trained the responsible person within each hospital (called the institutional coordinator). The institutional coordinator then trained the data collectors (registered nurses) within the hospital. Additionally, the measurement manual with all the information was made available for the data collectors directly in the data entry program.

On the predetermined measurement day, the patient level data were collected by the trained data collectors on-site at the patient's bedside and/or through patient documentation (retrospective assessment). The questions on the institutional and ward level were answered by the institutional coordinator.

Statistical analysis

The data from the different measurement points and the two countries (Switzerland and Austria) were pooled into one dataset. Descriptive statistics (numbers, percentages, 95% confidence intervals [CI], median, interquartile range [IQR]) were used to describe the organisational factors, the sample and the restraint prevalence rate.

A multilevel modelling approach was used in order to determine how much variance in restraint use can be explained on the hospital level (hospital general effect). This means that the analysis took into account that patients are clustered in hospitals with their organisational factors. Such methodological approaches are particularly well known from public health research where, for example, the influence of neighbourhoods on certain behaviours is studied [30, 31]. The baseline (before variable selection) of the multilevel logistic regression model of our study was built as shown in Figure 1. We could not include the ward level due to patient transfers between wards and potential misclassification as the exact ward where the restraint has happened was not recorded during data collection.

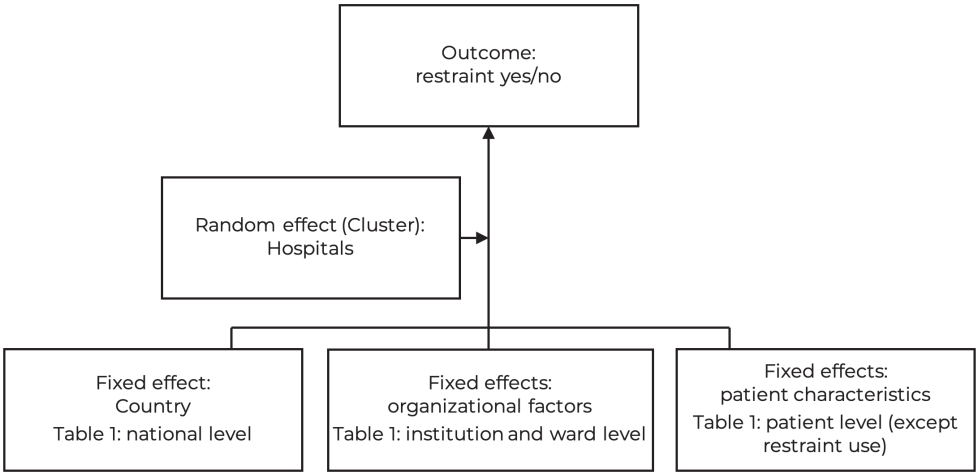

Figure 1: Baseline multilevel regression model

Due to the limited data on restraint use in the hospital setting (with partial exception of the ICU), designing a purely theory-based model was not possible, respectively, the insufficient theoretical basis entailed the risk of inaccurate assumptions for including or excluding patient level data. Given that the "blind" inclusion of all possible fixed effects carries the risk of overadjustment, we decided on a data-driven model with variable selection (explorative design).

For variable selection, we used the Akaike information criterion (AIC) [32] backwards procedure implemented in the R package MASS [33]. Here, however, the hospital random effect had to be treated as a fixed effect. During development of the analysis, we also considered using similar variable selection procedures for logistic multilevel models, but the few software implementations we found were not practicable for our problem. Since the hospital general effect is an explicit part of the question, the AIC procedure was employed such that the hospital variable cannot be unselected. Further, to enhance the stability of the variable selection, i.e. to reduce the number of noisy variables selected due to the large sample size, we used a split-half approach where the AIC procedure was applied on both of two subsets from a random split of the data, and then only the variables included in both selections were used for the final multilevel model. The model then was built as a generalised linear mixed model fit by maximum likelihood (Laplace approximation) implemented in the R package lme4 [34]. The ICC (intraclass correlation coefficient) was estimated, and a log-likelihood ratio test was performed to evaluate the relevance of the random effect. However, as the ICC is difficult to interpret for logistic multilevel models we calculated the median odds ratio (MOR) of the random effect [30, 31]. The MOR allows to translate the hospital level variance into the same scale as the fixed effects are reported (OR). In addition, the 80% interval odds ratio (IOR) was calculated for the organisational factors (specific contextual effects) included in the fixed effects. Using the 80% IOR it can be better considered that these characteristics can take on only one value per hospital (cluster) [31]. These two calculations were performed using the calculation sheet provided by Merlo et al. [30]. The R codes of the multilevel analysis are available in the Additional File 1. Three ICD-10 diagnosis groups (congenital malformations, deformations and chromosomal abnormalities; certain conditions originating in the perinatal period; pregnancy, childbirth and the puerperium) and the answer option unknown/no diagnosis were present in less than 1% of patients and would have led to convergence problems of the regression model. Therefore, these variables had to be excluded. For similar reasons, the variables Age in years and Number of days since admission to hospital had to be standardised. Since there is a non-linear association of age and restraint use the variable Age in years was also included as quadratic (squared) term (second-order polynomial) in the multilevel model. Multicollinearity was tested using the variance inflation factor (VIF). There were no missing data as the online data entry program only allowed for finishing the survey when all questions were answered.

The statistical analysis was conducted utilising R Version 4.0.1 [35] and the R Packages compareGroups [36], Hmisc [37], lme4 [34], jtools [38], MASS [33], MuMIn

[39], sjPlot [40], tableone [41] and tidyverse [42]. For data cleaning and pooling, SPSS version 25 was used [43].

Ethical considerations

In Switzerland, the Ethics Committee of the Canton of Bern declared that the present study is not subject to the Swiss Human Research Act and ethical approval was not required (April 2019, BASEC-Nr: Req-2019-00259). In Austria, the Ethics Committee of the Medical University of Graz approved the study protocol (approval nr. 20-192 ex08/09). All patients or their legal representatives received written information about the measurement and gave their verbal (Switzerland) or written (Austria) informed consent. Data were collected pseudonymously so that no conclusions can be made regarding the individual patients. Participation was voluntary.

RESULTS

The study included 29,477 patients from a total of 1,117 wards in 140 hospitals (Table 2). Of these, 20,561 (69.8%) patients were assessed at 84 hospitals in Switzerland and 8,916 (30.2%) patients at 56 hospitals in Austria. The number of participating patients per hospital ranged from 2 to 1,718 with a median of 102 (Switzerland: range from 2 to 1,718, median 146; Austria: range from 16 to 979, median 73). Response rate of all patients hospitalized (N=39,106) on the measurement days in the 140 hospitals was 75.4% (95% confidence interval [CI] 74.9%–75.8%; Switzerland: 76.3% [95% CI=75.8%–76.8%] N=26,934; Austria 73.3% [95% CI=72.5%–74.0%] N=12,172).

The 30-day prevalence rate of patients with at least one restraint was 8.7% (n=2,577). Differences between countries were evident. In Switzerland, the prevalence rate was much higher (10.6%, n=2,171) than in Austria (4.6%, n=406). A more refined description about the differences on patient level between Switzerland and Austria as well as about the restraint type used, reasons for restraint use and process indicators is available in a publication by Thomann et al. [15].

Overall, 73.6% (n=21,694) of all patients were treated in a hospital with guidelines regarding restraints. A multi-disciplinary expert committee regarding restraints was implemented in the hospitals of 42.7% (n=12,575) of all patients assessed. On the ward level, regular audits to ensure compliance with the guidelines regarding restraints was performed in 68.3% (n=20,126) of all patients surveyed. In 21.1% (n=6,209) of all patient situations, nursing staff attended a refresher course on restraints.

Table 2: Sample description

Characteristics	Total (n=29,477)		Switzerland (n=20,561)		Austria (n=8,916)	
Institutional level	**n**	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**
Guidelines regarding restraint use (yes)	21,694	73.6 (73.1-74.1)	14,318	69.6 (69.0-70.3)	7,376	82.7 (81.9-83.5)
Multi-disciplinary expert committee (yes)	12,575	42.7 (42.1-43.2)	7,302	35.5 (34.9-36.2)	5,273	59.1 (58.1-60.2)
Ward level						
Regular audits (yes)	20,126	68.3 (67.7-68.8)	13,893	67.6 (66.9-68.2)	6,233	69.9 (68.9-70.9)
Refresher course (yes)	6209	21.1 (20.6-21.5)	2,280	11.1 (10.7-11.5)	3,929	44.1 (43.0-45.1)
Patient level	**median**	**IQR**	**median**	**IQR**	**median**	**IQR**
Age in years	70	24	70	23	69	23
Number of days since admission to hospital	5	9	5	9	5	10
Care Dependency Scale (sum score)	71	15	70	15	74	11
	n	**% (95% CI)**	**n**	**% (95% CI)**	**n**	**% (95% CI)**
Female gender	14,504	49.2 (48.6-49.8)	9,902	48.2 (47.5-48.8)	4,602	51.6 (50.6-52.7)
Surgical intervention in the two weeks prior to data collection (yes)	10,542	35.8 (35.2-36.3)	8,318	40.5 (39.8-41.1)	2,224	24.9 (24.0-25.9)
Three most frequent ICD-10 diagnosis groups (multiple responses)						
Diseases of the circulatory system	16,245	55.1 (54.5-55.7)	11,756	57.2 (56.5-57.9)	4,489	50.3 (49.3-51.4)
Endocrine, nutritional and metabolic diseases	9,886	33.5 (33.0-34.1)	7,023	34.2 (33.5-34.8)	2,863	32.1 (31.1-33.1)
Diseases of the musculoskeletal system and connective tissue	9,834	33.4 (32.8-33.9)	7,543	36.7 (36.0-37.3)	2,291	25.7 (24.8-26.6)
Restraint (yes)	2,577	8.7 (8.4-9.1)	2,171	10.6 (10.1-11.0)	406	4.6 (4.1-5.0)

IQR=interquartile range, 95% CI=95% confidence interval, ICD-10=International Statistical Classification of Diseases and Related Health Problems 10th Revision

Based on the multilevel regression analysis, several factors associated with restraint use were found (Table 3). The strongest association was found for patients' care dependency: completely dependent patients in comparison to completely independent patients had an almost 40 times higher risk of being restrained (odds ratio [OR] 39.74, 95% confidence interval [CI] 32.72-48.26). A strong association was also found for patients with mental and behavioural disorders: the risk for them to be restrained was more than two times higher than for patients without such disorders (OR 2.31, 95% CI 2.09-2.56).

With regard to the organisational factors (specific contextual effects), the availability of guidelines regarding restraints (OR 0.60, 95% CI 0.49-0.74, 80% IOR 0.04-9.30) and refresher courses for at least 80% of ward nursing staff (OR 0.75, CI 0.64-0.89, 80% IOR 0.05-11.64) were associated with less restraint use. The availability of a multi-disciplinary expert committee and regular audits to ensure compliance with the protocol/guidelines regarding restraints were not selected for the model, indicating that these factors are not relevant concerning restraint use, from a statistical point of view. Also, the variable country was not selected for the model, despite large descriptive differences in prevalence rates.

Only considering the fixed effects (patient characteristics and organisational factors), the model could explain 24% of the variance in restraint use (marginal R^2=0.24). By adding the random effect (hospital as cluster variable), the model explains 55% of the variance in restraint use (conditional R^2=0.55). The log-likelihood ratio test was statistically significant (p-value < 0.000), indicating that adding hospital as a random effect (cluster) does improve the model. Additionally, the ICC (0.41) shows that the random effect is also relevant from a clinical point of view. This means that a relevant part of the variance in restraint use can be explained at the hospital level. The MOR (4.22) also highlights that there is rather large heterogeneity between hospitals.

Table 3: Multilevel logistic regression model

Model: AIC 12568.9; marginal R^2=0.24; conditional R^2=0.55; ICC=0.41, MOR=4.22	
Random effect	**Variance (SD)**
Hospital (intercept)	2.28 (1.51)
Fixed effects	**OR (95% CI)**
(intercept)	0.02 (0.01-0.03)*
Organisational factors (specific contextual effects)	
Guidelines regarding restraint (yes)	0.60 (0.49-0.74)*
	80% IOR: (0.04-9.30)
Refresher course regarding restraints (yes)	0.75 (0.64-0.89)*
	80% IOR: (0.05-11.64)
Patient characteristics	
Age in years (1st degree)	1.21 (1.14-1.29)*
Age in years squared (2nd degree)	1.11 (1.06-1.15)*
Female gender	0.74 (0.67-0.81)*
Care Dependency Scale (CDS) ≥ 70 completely independent	Reference
≥ 60-69 to a great extent independent	3.20 (2.74-3.72)*
≥ 45-59 partially dependent	8.83 (7.59-10.28)*
≥ 25-44 to a great extent dependent	23.81 (20.17-28.10)*
≤ 24 completely dependent	39.74 (32.72-48.26)*
Mental and behavioural disorders	2.31 (2.09-2.56)*
Factors influencing health status and contact with health services	1.42 (1.22-1.65)*
Diseases of the genitourinary system	0.90 (0.81-1.00)
Diseases of the digestive system	0.85 (0.76-0.95)*
Diseases of the musculoskeletal system and connective tissue	0.78 (0.70-0.86)*
*statistically significant based on the 95%CI	
AIC= Akaike information criterion, ICC=intraclass correlation coefficient, OR=odds ratio, 95% CI=95% confidence interval, MOR=median odds ratio, 80% IOR=80% interval odds ratio	

DISCUSSION

In this secondary data analysis of cross-sectional data on restraint use in Swiss and Austrian hospitals, we analysed the impact of organisational factors (specific contextual effects) on the use of restraints in the somatic acute care hospital setting, as well as whether a hospital general effect exists . Overall, the restraint prevalence rate was 8.7%. We found that the availability of guidelines regarding restraint use on the institutional level and refresher courses for at least 80% of ward nursing staff

in the last two years are associated with less restraint use. However, the wide 80% IORs put the impact of these organisational factors in perspective. No association was found for the availability of a multi-disciplinary expert committee regarding restraint use within the institution and regular audits on the ward level to ensure compliance with the guidelines regarding restraint use. Furthermore, the findings show that a relevant part of the variance in restraint use is explained at the hospital level (random effect), suggesting that a hospital general effect exists regarding restraint use. The difference between hospitals also appears to be greater than that between countries, as might have been expected given the much higher restraint prevalence rate in Switzerland (the country variable was not selected for the model). Thus, there is evidence that, in similar patient situations, restraints are used more frequently in some hospitals than in others (up to 4 times). This finding supports assumptions from the literature that, regarding restraint use, local habits, routine and institutional culture seem to play an important role [18-21, 44]. Such routine or habitual restraint use, independent of an objective and evidence-based evaluation, violates professional values and fundamental human rights. Therefore, critical interprofessional reflections on the current restrictive practice within hospitals are needed to minimise non-professional, non-legal and non-ethical restraint use. However, based on well-known safety models, like the Swiss cheese model, we know that patient safety is not only influenced by health professionals involved in direct patient care (micro level) [45]. The conditions within an institution (meso level) and on a national level (macro level) also have a significant impact on patient safety. For this reason, critical reflection on current restraint practices should take place on micro, meso and macro level.

On the micro level, a critical interprofessional reflection of practice is only possible with appropriate knowledge about the topic of interest. Regarding restraint use, it is widely discussed that health professionals in the hospital setting do not have sufficient knowledge and expertise [21]. As a result, restraints are often applied in situations that are not appropriate [14, 19, 22, 46]. For example, restraints are used for fall prevention, even though there is growing evidence that restraints are ineffective in preventing falls [16, 17]. Also, in this study, indications could be found that knowledge influences the use of restraints, since attending a refresher course is associated with less restraint use. Thus, in line with the recommendations of a review related to a Cochrane protocol regarding restraint reduction in general hospitals [47], education of health professionals seems to be a relevant component for restraint reduction. In this regard, it seems important that an interprofessional approach is

taken, as this is the only way to change the institutional culture, the perception of risk-taking and the work ethic [44]. In particular, the results of this study show how important these institution-specific aspects seem to be (hospital general effect).

However, changes in these institution-specific aspects also require a strong commitment from the meso level. First of all, there is a need for open discussion within an institution, for example to clarify responsibilities for safety [44]. Especially in the care of elderly people, the assessment of security issues needs different perspectives [48]. For example, functional needs must also be weighed in the decision-making process in terms of using or not using restraints. This is even more important as, like the findings show, older and more care-dependent patients have an increased risk of being restrained during their hospital stay, and as restraint use is associated with functional decline [1]. In addition, mental and behavioural disorders are associated with a higher use of restraints. This means that a very vulnerable patient group is most affected, i.e. patients who often cannot stand up for themselves; therefore, ethical considerations are even more important. In this regard, the management has the responsibility to support front-line staff by influencing the structural conditions for example, as also shown in this study, by providing policies/ guidelines that support decision-making or at least restraint management in line with legal and ethical requirements [18, 20-22, 24, 47]. In addition, they can adapt the infrastructural conditions, for example by removing restraint equipment from the wards, as it is known that the availability of restraint equipment influences its use [23]. It seems interesting that, in this study, regular audits and the availability of an expert committee were not found to be associated with restraint use. A possible explanation might be that, for both tasks, the individual person (who conducts the audit or is a member of the expert committee) must be able to critically reflect on the situation in which restraints are used and, in particular, to take an outsider perspective in order to identify restraint use due to the institutional culture or attitudes. However, as discussed above, the knowledge and expertise of the individual person might be insufficient and therefore no effect of these two organisational factors could be measured.

To support critical reflection on the micro and meso level and thus to support the change in restrictive practice in order to protect human rights of personal freedom and to ensure professional restraint use, interventions should also be taken on the national (macro) level [45, 49, 50]. For example, in both included countries (Switzerland and Austria), clear legal regulations regarding restraint use in the hospital setting are lacking [15]. However, clear regulations, professional

statements of nurses or medical associations and national guidelines would help institutions to clarify their policies, would support the uniform education of health professionals and would provide a basis for national quality improvement programs in the hospital setting. Such programs often lead to more uniform monitoring of restraint use within institutions and thus enable comparison, which are both important aspects in restraint reduction [24, 51].

As restraint use is a very sensitive issue, in this respect, a national quality measurement with a risk-adjusted comparison should be considered. This is the only way to guarantee that the different patient mix of institutions is taken into account and that a fair statistical comparison can be made [45]. Moreover, there is otherwise a risk that institutions with a higher restraint prevalence rate will only see their patient mix (e.g. older, more care-dependent) as the reason for the higher rate and will then reflect on the institution-specific aspects insufficiently. However, as described, this critical reflection seems to be essential for less restrictive practice. In addition, such efforts on the national level could stimulate a more open information policy regarding restraint use in hospitals, more critical thinking about restrictive practice in general and open discussions both within institutions but also in society. These aspects are well-known from similar approaches in the mental health or long-term care setting [52, 53].

Limitations

Beside its relevant findings, this study has some limitations. Firstly, there are limitations related to the LPZ 2.0 instrument. Some organisational factors expected to be associated with restraint use (e.g. nurse to patient ratio) and health professional-related factors were not assessed with LPZ 2.0. It is, therefore, possible that the impact of the included organisational factors (specific contextual effects) is over- or underestimated as is the relevance of the hospital general effect. Also, the ward level could not be included in the models, since using the LPZ 2.0 instrument restraint use is assessed over a 30 day period in the corresponding hospital without taking into account on which ward the restraint was used (current ward or other). This seems particularly relevant to us, as previous evidence suggests that there are differences in restraint use depending on ward (type) [54]. Thus, future studies should address the inclusion of the ward level. Additionally, data on medical diagnoses are not satisfactorily collected within the LPZ 2.0 instrument. From a statistical point of view, the assessment of ICD-10 diagnosis groups instead of

specific ICD-10 diagnosis codes may lead to an over- or underestimation of each diagnosis group. In addition, clinical interpretation and implication is hampered by these very broad and imprecise groups.

Secondly, it is possible that a selection bias exists. Patients who could not give informed consent and had no legal representative available had to be excluded. It could be that these patients were at high risk for restraint use and, therefore, the prevalence rate might be underestimated. Also, the impact of the predictors might be slightly different when including these patients in the analysis. Similar consequences could also be caused by a potential recall or documentation bias because restraint use was assessed over a period of 30 days. However, it is known that, regarding restraint use, the documentation is often incomplete [5, 15]. Thirdly, the cross-sectional design has its limitations; on the one hand, the patient situations under investigation can fluctuate strongly within institutions on the measurement day and, on the other hand, no causal correlations can be identified using a cross-section design. For example, greater care dependency could lead to restraint use, but could also be a consequence of restraint use. Fourth, possibilities and limitations of different methodological approaches for variable selection are controversially discussed as well as for our chosen approach using AIC selection [55]. With our approach there is a risk that variables are incorrectly excluded from the model (false negatives). However, in comparison to the full model (Additional File 2) our results with variable selection (Table 3) differs only slightly. In terms of an exploratory design, the AIC approach seemed to us to be a useful way of obtaining an initial overview of the topic, reduced in complexity. Nevertheless, in order to improve modelling possibilities/strategies and to obtain more comparable and robust results in general, intensified research attention on restraint use in the hospital setting must be established. Despite these limitations, the results are expected to be generalisable due to the large sample of two countries using the same data collection method. They provide important indications for future quality development efforts. In this context, it seems to be of interest to investigate explanations for the additional 31% of explained variance on the hospital level (hospital general effect). The inclusion of further structural characteristics in data collection and a subsequent analysis or a qualitative approach, for example by observing the (interprofessional) processes surrounding restraint use, could be helpful in this regard.

CONCLUSIONS

Regarding restraint use, a hospital general effect exists. This indicates that restraints are used more frequently in certain hospitals than in others, even when considering the different patient mix. To provide restraint-free care as much as possible requires both specific knowledge and appropriate structures. Based on these findings, considerable potential for restraint reduction appears to exist in the interprofessional critical reflection of decision-making processes within a hospital; especially, the identification of situations in which restraints were used out of routine or institutional culture. This critical reflection ideally goes along with addressing the knowledge and attitudes towards restraints of the interprofessional team as well as of the management. A clear national (legal) regulation regarding restraint use could support a change in practice.

LIST OF ABBREVIATIONS

LPZ: Landelijke Prevalentiemeting Zorgkwaliteit

ICD-10: to International Statistical Classification of Diseases and Related Health Problems 10th Revision

CDS: Care Dependency Scale

95% CI: 95% confidence intervals

IQR: Interquartile range

AIC: Akaike information criterion

ICC: Intraclass correlation coefficient

VIF: Variance inflation factor

OR: Odds ratio

MOR: median odds ratio

80% IOR: 80% interval odds ratio

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

As the study was conducted in two countries, there is one ethical approval per country. In Switzerland, the Ethics Committee of the Canton of Bern declared that the present study is not subject to the Swiss Human Research Act and ethical approval was not required (April 2019, BASEC-Nr: Req-2019-00259). In Austria, the Ethics Committee

of the Medical University of Graz approved the study protocol (approval nr. 20-192 ex08/09). All patients or their legal representatives received written information about the measurement and gave their verbal (Switzerland) or written (Austria) informed consent. In Switzerland, only verbal and no written consent was required, since in 2012 Swissethics and the cantonal ethics committees classified the annual LPZ data collection as a quality measurement for which no written consent of the patients is required. The decisive factors were the aim of the data collection (ensuring and further developing the quality of care), the data collection method, the type of data collected (only data of the regular care process) and the fact that no intervention is carried out. The documentation of the verbal consent was in the responsibility of the participating hospitals. It was recommended that consent be recorded in the patient documentation or centrally for all patients in a separate document. Data were collected pseudonymously so that no conclusions can be made regarding the individual patients. Participation was voluntary. The whole study was performed in accordance with the Declaration of Helsinki.

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA AND MATERIALS

The data that support the findings of this study are available from Swiss National Association for Quality Development in Hospitals and Clinics (Swiss data) and Department of Nursing Science from the Medical University of Graz (Austrian data) but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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AUTHORS' CONTRIBUTIONS

ST contributed to the conceptualization, methodology, data collection, data curation, data analysis, data interpretation and writing of the manuscript. SH supervised the project and contributed to the conceptualization, acquisition, data interpretation as well as reviewing and editing of the manuscript. SB contributed to the data collection, data interpretation and reviewing and editing of the manuscript. DR contributed to the methodology and the validation of the data analysis, the data interpretation as well as reviewing and editing of the manuscript. SZ supervised the project and contributed to the conceptualization, data interpretation as well as reviewing and editing of the manuscript. All authors read and approved the final manuscript.

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ADDITIONAL MATERIAL

Additional file 1: R Codes of the multilevel model

Below the R codes used for the multilevel model are provided for transparency (1. variable selection and 2. multilevel modeling).

1. Variable selection on two subsets from a random split of the data

```
library(tidyverse)

library(Hmisc)

library("jtools")

library(MASS)
```

sample splitting

```{r first and second random data subset}

set.seed(20200124)

#generate first and second random data subset

CH_AT <- CH_AT %>% mutate(id = row_number())

head(CH_AT$id)

first <- CH_AT %>% sample_frac(.50)

second  <- anti_join(CH_AT, first, by = 'id')

#Check proportion outcome

tab2=table(first$Rest_Prev)

prop.table(tab2)

tab2=table(second$Rest_Prev)

prop.table(tab2)
```

first data subset: logistic regression keep IDresponsible

```{r first}

glm_first_all_s <- glm(Rest_Prev ~ ProjectID + Age_stand + Age_quadr + G_gender + Length_stand + G_pat_surgery + BFH_PAS_Kat + BFH_diag_infect + BFH_diag_canc + BFH_diag_blood + BFH_diag_endo + BFH_diag_psych + BFH_diag_nerve + BFH_diag_eye + BFH_diag_ear + BFH_diag_cardio + BFH_diag_lung + BFH_diag_digest + BFH_diag_skin + BFH_diag_motor + BFH_diag_urogen + BFH_diag_other + BFH_diag_accident + BFH_diag_external + BFH_diag_influence + InstitutionForm_QI_Inst_Rest_1 + InstitutionForm_QI_Inst_Rest_2 + QI_Ward_Rest_1 + QI_Ward_Rest_4 + IDresponsible, family = binomial, data=first)

#summary(glm_first_all_s)

#summ(glm_first_all_s, vifs = TRUE)

#exp(coef (glm_first_all_s))

#exp(confint (glm_first_all_s))

#AIC backwards procedure

glm_first_all_s_step <- glm_first_all_s %>% stepAIC(scope = list(lower = ~IDresponsible), trace = FALSE)

summ(glm_first_all_s_step, vifs = TRUE)

#exp(coef (glm_first_all_s_step))

#exp(confint (glm_first_all_s_step))

```

second data subset: logistic regression keep IDresponsible

```{r second}

glm_second_all_s <- glm(Rest_Prev ~ ProjectID + Age_stand + Age_quadr + G_gender + Length_stand + G_pat_surgery + BFH_PAS_Kat + BFH_diag_infect + BFH_diag_canc + BFH_diag_blood + BFH_diag_endo + BFH_diag_psych + BFH_diag_nerve + BFH_diag_eye + BFH_diag_ear + BFH_diag_cardio + BFH_diag_lung
```

+ BFH_diag_digest + BFH_diag_skin + BFH_diag_motor + BFH_diag_urogen + BFH_diag_other + BFH_diag_accident + BFH_diag_external + BFH_diag_influence + InstitutionForm_QI_Inst_Rest_1 + InstitutionForm_QI_Inst_Rest_2 + QI_Ward_Rest_1 + QI_Ward_Rest_4 + IDresponsible, family = binomial, data=second)

#summary(glm_second_all_s)

#summ(glm_second_all_s, vifs = TRUE)

#exp(coef (glm_second_all_s))

#exp(confint (glm_second_all_s))

AIC backwards procedure

glm_second_all_s_step <- glm_second_all_s %>% stepAIC(scope = list(lower = ~IDresponsible), trace = FALSE)

summ(glm_second_all_s_step, vifs = TRUE)

#exp(coef (glm_second_all_s_step))

#exp(confint (glm_second_all_s_step))

```

2. Multilevel model with variables included in both selections

library("tidyverse")

library("Hmisc")

library("lme4")

library("jtools")

library("MuMIn")

```

Interceptonly model

```{r}
```

interceptonly<-glmer(Rest_Prev ~ 1 + (1|IDresponsible), family = binomial, data=CH_AT)

summary(interceptonly)

confint(interceptonly)

```

Multilevel model full dataset

```{r}

final_all<-glmer(Rest_Prev ~ poly(Age_stand, degree=2, raw=T) + G_gender + BFH_PAS_Kat + BFH_diag_psych + BFH_diag_digest + BFH_diag_motor + BFH_diag_urogen + BFH_diag_influence + InstitutionForm_QI_Inst_Rest_1 + QI_Ward_Rest_4 + (1 | IDresponsible), family= binomial, data=CH_AT, control = glmerControl(optimizer = “optimx”, optCtrl = list(method = “nlminb”)))

summary(final_all)

se <- sqrt(diag(vcov(final_all)))

(tab <- cbind(Est = fixef(final_all), LL = fixef(final_all) - 1.96 * se, UL = fixef(final_all) + 1.96 *

se))

exp(tab)

```

Explained variance Multilevel model and intercept only

```{r}

r.squaredGLMM(final_all)

r.squaredGLMM(interceptonly)

```

check for significance of random effect
```

```{r}

# H0 model without random effect

m0 <- glm(Rest_Prev ~ poly(Age_stand, degree=2, raw=T) + G_gender + BFH_PAS_Kat + BFH_diag_psych + BFH_diag_digest + BFH_diag_motor + BFH_diag_urogen + BFH_diag_influence + InstitutionForm_QI_Inst_Rest_1  + QI_Ward_Rest_4, family= binomial, data=CH_AT)

logLik(m0)

## model with random effect

m1 <- final_all

logLik(m1)

## log-Likelihood ratio test

t <- as.numeric(2 * (logLik(m1) - logLik(m0)))

df <- as.numeric((attr(logLik(m1), "df") - attr(logLik(m0), "df")))

pval <- 2 * (1 - pchisq(q = t, df = df))

pval

```

ICC

```{r}

library(sjPlot)

tab_model(final_all, show.df = TRUE)

```

Additional file 2: Multilevel full model

A multilevel full model, including all possible fixed effects, is provided.

Table A: Multilevel logistic regression full model

Model: AIC 12564.0; marginal R^2=0.29; conditional R^2=0.57; ICC=0.39, MOR=3.98	
Random effect	**Variance (SD)**
Hospital (intercept)	2.09 (1.45)
Fixed effects	**OR (95% CI)**
(intercept)	0.01 (0.01-0.02)*
Country Austria	Reference
Switzerland	2.70 (1.54-4.75)*
Organisational factors (specific contextual effects)	
Guidelines regarding restraint (yes)	0.60 (0.49-0.75)* 80% IOR: (0.04-8.33)
Multi-disciplinary expert committee (yes)	0.93 (0.79-1.09) 80% IOR: (0.07-12.80)
Regular audits (yes)	1.15 (0.98-1.34) 80% IOR: (0.08-15.79)
Refresher course regarding restraints (yes)	0.77 (0.65-0.90)* 80% IOR: (0.06-10.53)
Patient characteristics	
Age in years (1st degree)	1.20 (1.12-1.27)*
Age in years squared (2nd degree)	1.10 (1.06-1.15)*
Number of days since admission to hospital	1.03 (0.99-1.07)
Female gender	0.74 (0.67-0.81)*
Surgical intervention in the two weeks prior to data collection (yes)	1.04 (0.94-1.16)
Care Dependency Scale (CDS) ≥ 70 completely independent	Reference
≥ 60-69 to a great extent independent	3.11 (2.67-3.63)*
≥ 45-59 partially dependent	8.56 (7.34-9.98)*
≥ 25-44 to a great extent dependent	22.96 (19.40-27.17)*
≤ 24 completely dependent	37.79 (31.00-46.07)*
Mental and behavioural disorders	2.29 (2.06-2.54)*
Factors influencing health status and contact with health services	1.36 (1.17-1.59)*
External causes of morbidity and mortality	1.35 (1.02-1.78)*
Diseases of the eye and adnexa	1.22 (1.02-1.46)*
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	1.15 (0.95-1.39)
Diseases of the ear and mastoid process	1.09 (0.83-1.45)
Injury, poisoning and certain other consequences of external causes	1.09 (0.92-1.30)
Diseases of the nervous system	1.09 (0.96-1.23)
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	1.08 (0.96-1.22)
Diseases of the circulatory system	1.06 (0.94-1.19)
Diseases of the respiratory system	1.05 (0.94-1.17)
Certain infectious and parasitic diseases	0.97 (0.85-1.11)
Neoplasms	0.97 (0.86-1.09)
Endocrine, nutritional and metabolic diseases	0.94 (0.85-1.04)
Diseases of the skin and subcutaneous tissue	0.89 (0.75-1.05)
Diseases of the genitourinary system	0.89 (0.80-0.99)*
Diseases of the digestive system	0.85 (0.76-0.95)*
Diseases of the musculoskeletal system and connective tissue	0.77 (0.69-0.85)*
*statistically significant based on the 95%CI	
AIC= Akaike information criterion, ICC=intraclass correlation coefficient, OR=odds ratio, 95% CI=95% confidence interval, MOR=median odds ratio, 80% IOR=80% interval odds ratio	

CHAPTER 04

RESTRAINT PRACTICE IN THE SOMATIC ACUTE CARE HOSPITAL: A PARTICIPANT OBSERVATION STUDY

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ABSTRACT

Aims and Objectives: we aimed to describe daily restraint practices and the factors which influence their use, from an outsider's perspective.

Background: a reduction in restraint use is recommended in healthcare. However, somatic acute care hospital settings currently lack effective reduction strategies. Thus far, hospital restraint practice is described in terms of quantitative assessments and the 'insider' view of healthcare professionals. However, as factors such as routine or personal beliefs seem to play a relevant role in restraint use, these approaches might be incomplete and biased.

Design: a qualitative observation study design was employed.

Methods: fieldwork with unstructured participant observation was conducted at a department of geriatrics and a department of intensive care in Switzerland between November 2019 and January 2020. Data were recorded as field notes. The analysis was conducted iteratively in two coding cycles using descriptive coding followed by pattern coding. We adhered to the Standards for Reporting Qualitative Research (SRQR).

Results: a total of 67 hours of observation was conducted. We found that daily restraint practice can be described in three categories: the context in which restraints are used, the decision-making process on the use and continued use of restraints, and the avoidance of restraint use. Most processes and decisions seem to take place unconsciously, and their standardisation is weak.

Conclusions: the lack of standardisation favours intuitive and unreflective action, which is prompted by what is also known as heuristic decision-making. To transform daily restraint practice, a technical solution that leads restraint management in line with ethical and legal requirements might be useful.

Relevance to clinical practice: The outsider perspective has allowed daily restraint practice to be described independently of existing routines, departmental cultures, and personal attitudes. This is important to comprehensively describe restrictive practices, which is a prerequisite for the development of effective restraint reduction strategies.

WHAT DOES THIS PAPER CONTRIBUTE TO THE WIDER GLOBAL CLINICAL COMMUNITY?

- The broader understanding of restraints, which includes any restriction of personal freedom, is still poorly established in hospitals, leading to a wide variation of how restraints are dealt with, depending on the type of restraint.
- Heuristic decision making is used in daily restraint practice, but seems to have more of a negative impact, as health professionals lack the appropriate knowledge and expertise in restraint use.
- Promoting consistent implementation of guidelines in combination with expanded and targeted application of existing prevention approaches could positively change restraint practice in hospitals.

KEYWORDS

Restraint, Hospitals, Qualitative Research, Decision Making, Evidence-Based Practice

INTRODUCTION

Restraints are used in healthcare with the intention of providing safety for patients, professionals and/or third parties [1-3]. Prevalence rates vary widely depending on (sub)population, country, and setting, and may differ depending on the definition of restraint used (e.g. whether only mechanical fixations with belts and seclusion, or also chemical and electronic ones, are considered to be restraints), and the legal situation [3]. However, due to negative effects on patients' physical and mental health, as well as moral distress and its consequences for health professionals, it is recommended that restraints are used as little as possible, and only for a limited period of time [4, 5, 6].

To date, restraint reduction programmes or strategies are mainly known from the mental health setting, and, to some extent, from the long-term care setting [7-9]. For the somatic acute care hospital setting (henceforth referred to as 'hospital'), effective reduction programmes or strategies are still lacking [10]. In order to be able to develop and implement suitable restraint reduction strategies, or to adapt strategies from other settings, it is important to gain insight into actual daily hospital restraint practice and its influencing factors. Therefore, this study has focussed on the observation and interpretive description of daily restraint practice in hospitals.

BACKGROUND

Restraints are defined as 'interventions that may infringe [on] a person's human rights and freedom of movement, including observation, seclusion, manual restraint, mechanical restraint and rapid tranquillisation' [11]. Obviously, restraint use affects human rights, and thus might have a legal and ethical dimension, which further underlines the importance of using restraint only when necessary. In the hospital setting, the use of the following types of restraint is described: mechanical (incl. bed rails, belts, chair tables), electronic (incl. sensor mats, video surveillance, motion sensor), pharmacological, physical (keeping someone restrained with human physical force), one-to-one supervision, and locked wards or buildings [12].

Restraint use in the hospital setting is often justified by health professionals in terms of patient safety (e.g. to prevent falls or therapy interruption); however, to date, evidence for its effectiveness is lacking [1, 13]. Several studies indicate that, in addition to patient-dependent factors like cognitive impairment [12], non-objective factors such as routine, local habits, intuition, or personal beliefs/

opinions seem to play an important role in restraint use [6, 14-16]. In the decision-making process regarding the use or non-use of restraints, a lack of knowledge, assessment tools, and interprofessional support is reported [1, 17]. As a result, the decision making of nurses (as the key decision makers) is often based on intuition and personal perceptions rather than objective (evidence-based) factors [15, 18]. Moreover, restraints sometimes seem to be such ordinary nursing interventions that alternatives are not even considered [19].

Once the decision to use restraint has been made, it is important that its use is documented, and that a regular evaluation of necessity and harm/benefit takes place to ensure that restraints are used only for as long as necessary. However, even these processes are not systematically implemented, and therefore documentation is often lacking; in addition, regular evaluation rarely occurs [1, 12, 20].

In summary, a complex interplay of multiple factors influences restraint use, with nurses playing a decisive role. So far, research has focussed on quantitative assessments of restraint use, and on the 'insider' view of healthcare professionals on restrictive practices within the hospital. However, since factors such as routine or personal beliefs seem to play a relevant role in restraint use, these approaches might be incomplete and biased against adequately reflecting daily practice and in order to identify the most important influencing factors. Therefore, it seems important to include an 'outsider's' perspective (that of someone who is not involved in the daily practice, and whose perception is therefore not shaped by routine, institutional culture, etc.) on restraint use to comprehensively describe the restrictive practice, as a prerequisite for the development or adaptation and implementation of effective restraint reduction strategies. Consequently, we aimed to describe daily restraint practices and their influencing factors from an outsider's perspective.

METHODS

Study design

A qualitative observation study design was chosen to investigate daily hospital restraint practice, independent of restraint type. Fieldwork with participant observation was performed, since this method is known to be suitable for examining 'everyday activities in context' [21]. The methodological approach used Thorne's interpretive description [22] as orientation. Interpretive description is an applied inductive research approach designed to investigate clinical health and illness phenomena. Using interpretive

research strategies, the phenomenon of interest can be described in its context and associations, allowing relationships and patterns to be discovered. The strength of Thorne's interpretive description lies in its focus on applied, practice-oriented knowledge production in the context of healthcare provision [22]. The Standards for Reporting Qualitative Research (SRQR) [23] have been used to ensure high quality research and transparency in reporting (see Supplementary File 1).

Setting and Sample

The participant observation was conducted at the department of geriatrics and the department of intensive care medicine of a public multisite university hospital in Switzerland that treats around 60,000 inpatients annually. The selection of the departments was purposive and data-driven: departments with a higher restraint rate based on a prevalence measurement were selected, as this increased the possibility of observing daily hospital restraint practices. The department of geriatrics operates 40 beds at the corresponding site for the acute-geriatric care of patients over 70 years of age. The department of intensive care medicine has 37 beds at the corresponding site for intensive care, and 20 beds for high-dependency care.

In Switzerland, the "adult protection law regulates the use of coercive measures in specific areas, i.e. in connection with an involuntary committal or the detention of patients admitted voluntarily, or during stays in residential or nursing institutions; in particular, it includes provisions designed to strengthen legal protection for the persons concerned" [5]. For the hospital setting, there are no clear legal regulations. However, there is a national guideline on the use of coercive measures in medicine, which also contains recommendations for restraint use in general (incl. all restraint types e.g. also electronic restraints, recommendations on processes to be fulfilled etc.) [5].

Each observation period consisted of shadowing, as an outsider, a nurse during their shift (full shift = 8.4h). The nurse and shift to be monitored was determined by the unit manager and was mainly driven by organisational possibilities and the availability of the observer. For example, there was no requirement that a particular restraint type must be in use during an observation. To ensure anonymity, no personal data of healthcare professionals (age, work experience, etc.) were registered. From our point of view, explicitly assuring anonymity to participants was important to foster the observation of authentic daily restraint practice without anyone having to fear doing something supposedly wrong in this ethically and legally loaded arena. Thus, there is no closer description of the sample available. In addition, no patient-related

information was collected. This would have required the consent of the patients or their legal representatives. Since obtaining consent can be difficult, and the practice could therefore not have been observed comprehensively, this was dispensed with in favour of an unlimited insight into the restraint practice.

Data collection

For data collection, the first author (ST) conducted an open, unstructured participant observation of nurses in their daily practice in November and December 2019 in the department of geriatrics, and in January 2020 in the department of intensive care medicine. The data collection was based on the procedure described by Allen [21]: data generation and data analysis were carried out in parallel in an iterative process. At the beginning, a very broad observation of as many aspects as possible potentially related to restraint practice (e.g. spatial/material aspects or communication among professionals and with patients) was made. Subsequently, during the data collection process, it was increasingly better differentiated which aspects were related to restraint use and needed a special focus. In addition, it was brought out more clearly who was being talked to and what questions were being asked. These interactive conversations (also known as ethnographic interviewing) with nurses and with other involved staff were used to deepen what was observed or get insight in aspects that would have been difficult to observe directly, such as existing documentation. The data on the various aspects of the daily restraint practice (e.g. environment, staff, restraint type, processes of documentation and evaluation), as well as information on date and place, were recorded as field notes in a logbook. The role of the observer was reflected throughout the entire data collection and field note writing process. Thus, it was, for example, documented when a situation seemed to be influenced as a result of an observation. In addition, all the interpretations of the observer were clearly identified as such in the field notes, which were written out in continuous text shortly after the observations to ensure their richness of detail. It was established that no observations would be carried out after data saturation had become apparent.

The observer (ST) is a nurse with professional experience in acute psychiatry and outpatient care. She has a Master of Science degree in nursing and is a PhD student in health science. In preparation for the observation, the observation process was defined in detail together with an expert in qualitative research and aspects to be considered (behaviour, communication, involvement, etc. during the observation periods) were reflected upon with the expert.

Data analysis

As described, a first data analysis step took place concurrently with the data collection. This first data interpretation was noted as such in the field notes. After the data collection was completed, a systematic data analysis was performed. The analysis was conducted iteratively in two coding cycles guided by Saldaña [24]. For the first cycle, a descriptive coding was used. The topic of a passage was summarised in one word or a short phrase. Subsequently, pattern coding was used for the second cycle. This allowed the summary of the first cycle codes into meaningful units (see figure 1). Data analysis was conducted using the MAXQDA software [25].

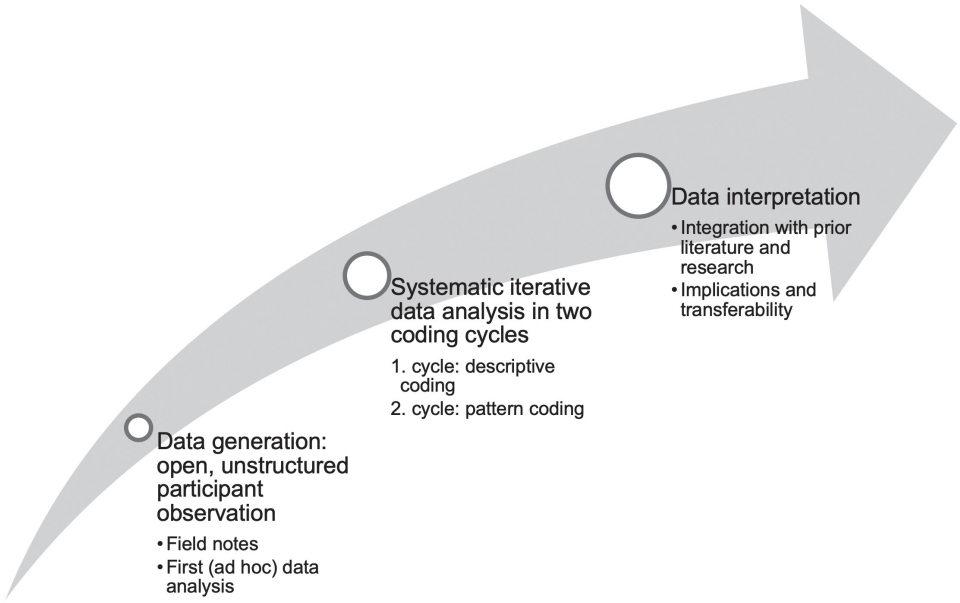

Figure 1: From field notes to conclusions – data generation and analysis processes

A quarter of the data was independently analysed by a peer researcher (SSD) familiar with the research topic in order to control for potential bias in the interpretative lens of the first author/observer. The results of the independent analysis were then discussed, and differences clarified. As a consensus was predominantly found in the results, the remaining data was only analysed by the first author. In addition, the entire second cycle coding was validated with another co-author (SH), as well as some randomly selected codings from the first cycle.

Ethical considerations

The responsible ethics committee declared that the present study did not fall under the Swiss Human Research Act (April 2019, BASEC-Nr: Req-2019-00259). Therefore, applying for ethical approval was not required. The nursing and medical management of the respective departments and units were informed about the study in advance, and gave their consent. For ethical reasons, the nursing teams were informed about the study too. The nurses of the acute geriatric unit were informed about the study by the first author at a team meeting. In the intensive care area, the nursing teams were informed by the nursing expert. Written information about the study and contact details for questions and queries were made available to the nursing teams. Additional staff members were directly informed during the observation if they would be involved in the observed situations. Patients potentially involved in participant observations were informed that a researcher would accompany the responsible nurse to examine their work processes, but that no personal data would be documented. As no personal data was collected, no written consent was necessary.

For transparency, the observer introduced herself; this included mentioning her own background as a registered nurse and researcher, and she explained (again) the aim of the observations to the nurse she was accompanying on their shift at the beginning of each observation period. Nurses were explicitly informed, for example, that with respect to restraint practice, notes would be taken as to whether and how restraints were used, but not on which person said or decided what. All nurses agreed to be accompanied by a researcher for this study.

RESULTS

A total of around 67 hours of observation during eight observation periods were conducted to examine daily restraint practice in two different departments of a university multisite hospital. Three observation periods took place in the department of geriatrics (two dayshifts from 7am to 4pm and one late shift from 3pm to 11pm [observations 1–3]) and there were five observation periods in the department of intensive care medicine (two dayshifts in the area of high-dependency care [observations 4–5], and two dayshifts and one late-shift in the area of intensive care [observations 6–8]). During the observations, the use of the following restraint types could be observed: mechanical restraints including fixation with different kinds of belts, wheelchair tables, and bed rails; electronic restraints; and pharmacological restraints. Two-part bed rails were frequently used, where the bed had rails at the

head and the leg part, with a gap between them. On these units, restraints were mainly used in cases where there was a fall risk, confusion (e.g. delirium), cognitive impairment, and/or psychiatric disorders. In the area of intensive care, an additional reason for restraint was the risk of therapy interruption (e.g. self-extubation). The following fieldnote describes the start of an observation period:

> Today, I [the observer] am accompanying a nurse who is responsible for a delirious patient with a new tracheostoma after a period of intubation. At the beginning of the shift, the patient's hands are mechanically (physically) restrained because the nurse is afraid of a disconnection of the tracheostoma when the patient is getting agitated. Next to the patient, there is a room divider where the date and the place where he stays are noted and a clock has been hung up (the utensils seem to be part of the equipment of the intensive care unit [ICU]). In addition, there are photos of children, probably the grandchildren. (Observation 7)

Based on analysis of the fieldnotes, three categories emerged to describe daily restraint practice in the two departments from an outsider's perspective: the context in which restraints are used, the decision-making process on the use and continued use of restraints, and the avoidance of restraint use.

The context in which restraints are used

While observing the daily restraint practice on the units involved, several aspects of the context in which this practice takes place became apparent. In our analysis, we identified these as standardisation of processes, architectural/environmental factors, the staff's skill and grade mix, and the availability of restraint equipment.

> In the opened patient file, we [the nurse and observer] could see that the motion sensor was prescribed today by the physician. However, yesterday the motion sensor was already in use. For this patient, there were also a wheelchair table and bed rails in use. Both were not documented anywhere in the patient file. The nurse explained that all applied restraints should be visible in the patient file. However, this is not implemented rigorously. The prescription by the physicians is often only carried out upon request by the nursing staff. (Observation 2)

Differences could be observed in the standardisation of processes, depending on the restraint type. For mechanical restraints with belts, practices involving documentation and prescription were perceived as consistent across units and between health professionals. For the other restraint types, such as bed rails or electronic monitoring, hardly any standardisation of processes could be observed. Irrespective of the restraint type, the observations showed that the indication for restraint use was often missing from the patient file or was only imprecisely recorded. For example, in the intensive care area, the electronic patient file only offered the possibility of selecting between self-harm and harm to others as a justification for the restraint.

In addition to prescription and documentation, it remained unclear to an outsider when an evaluation of restraints should take place in daily practice, who should be involved in this evaluation, and what form the evaluation should take. The only thing that became apparent was that discussions about restraints were mostly initiated by nurses. However, the fact that it was the nurses who were accompanied during the observations may have influenced this impression. There was also a wide variation in how restraints were reported and discussed during a handover report, or at rounds (mono- or interprofessional); the reporting (or lack of it) ranged from not addressing it, to clearly explaining why the restraint was still necessary and why other measures would be less suitable.

Other influencing contextual factors on restraint practice were observed in these departments. Architectural or environmental conditions, for example, seem to make alternatives to, or prevention of, restraint more difficult. A nurse very aptly described the difficulties on the ICU and high-dependency unit, summarising them as follows:

> It's always beeping somewhere. It is never quiet. The other patients are only behind curtains [on the high-dependency unit]. I.e. one hears everything that is going on there. When they moan, cry, scream … Or the reactions of the families. There is also a lot of motion around the patient. For example, the curtains that always flutter when someone passes by on one side or the other. In addition, one is regularly awakened for monitoring [of vital and/or neurological parameters], which is not beneficial. For the patients, there is hardly an opportunity for orientation anywhere. There are devices, cables, infusions, feeding tubes, etc. everywhere. (Observation 4)

This contrasts with the need of stimulus reduction for patients with delirium. Daylight is important for orientation and especially for the day–night rhythm. However, in some areas of the participating ICU there was no daylight.

At the staff level, the relevance of the skill and grade was evident, as this observation of the reactions of a young physician reflects:

> A young patient with a psychiatric disorder is restrained and sedated for most of the time. As the sedation eases, she screams and is very agitated. A young physician approaches the patient's bedside but does not seem to know how to react. He is speechless and seems completely overwhelmed with the situation. (Observation 8)

Staff turnover, which is linked to skill and grade mix, also influences restraint use:

> A nurse explained that she used to work full-time in the high-dependency unit and knew most of the team members and their strengths well. However, due to staff turnover during her maternity leave and now working part-time, she no longer knows the strengths of all team members. Accordingly, it is much more challenging for her to efficiently use the strengths of the team members in the daily shift planning, for example in dealing with delirious patients. (Observation 5)

According to the nurses, a psychiatric consultation focussing on nursing issues is newly available in the ICU and high-dependency unit to provide support in challenging situations; the consultation is seen as very promising by the nursing staff. However, during the observations, no such consultation took place.

The availability of the restraint equipment played a role too. The two-part bed rails were permanently installed on the bed. From an outsider's perspective, this encouraged their use, as they were often pulled up intuitively rather than consciously. There was a sign on the cupboard containing the restraining belts saying that they were not to be used on regular units or outside the intensive care area. Thus, no mechanical fixation with a belt could take place on a regular unit. According to the nurses' explanations, pharmacological restraints were more often used in the intensive care area than in regular units, as they facilitate the continuous monitoring of vital parameters.

The decision-making process on the use and continued use of restraints

Analysis of the field notes has shown that a crucial factor in the decision-making process is whether healthcare professionals are even aware that they are using

measures that have an ethical and legal dimension. Furthermore, the analysis revealed that the decision to (continue) using restraints was influenced by the expected benefits of the restraints; the nurses' attitude and perception of safety, as well as work experience; routine; the patients' judgement ability; a lack of knowledge; overwhelming demands and health professionals' emotional condition in the situation; and the level of inhibition of healthcare professionals for using restraints.

> A motion sensor is installed in a patients' room because he showed signs of delirium. The nurse evaluated that the patient has always behaved calmly and, therefore, the motion sensor is no longer needed. She removes it. The nurse says she is aware that the motion sensor is an electronic restraint. (Observation 2)

Among the accompanied nurses, the first association they made with the topic of restraints was usually mechanical fixation with belts. However, in conversations during the observations it became clear that they were aware that bed rails, medication, or electronic monitoring might be restraints. Our analysis showed that this awareness of restraints among nurses was a basic prerequisite for being conscious of the decision-making process in the first place. We found that it was not only a matter of deciding whether or not to use a restraint, but often also about whether to continue using a restraint based on a conscious and purposeful evaluation (e.g. whether or not the expected benefit was achieved). For example, electronic monitoring was often used in acute geriatrics. However, it could be observed that due to limited staff resources, there was sometimes a certain delay in the response to an alarm generated by the electronic monitoring. This led to patients moving independently from the bed or chair despite electronic monitoring; 'A patient with electronic monitoring installed is standing alone in the corridor looking for the restroom.' (Observation 3) Thus, from an outsider's perspective, the benefit was not always obvious. Similar observations were made with regard to the mechanical fixations, for instance, in the case of the delirious patient with a tracheostoma mentioned at the beginning, whose hands were mechanically restrained: 'The tracheostoma repeatedly disconnects during mobilisation and positioning in the morning. The patient becomes increasingly agitated but has no influence on the repeated disconnection of the tracheostoma.' (Observation 7)

In general, nurses played an important role in the decision-making process, with individual attitude and perception of safety, as well as work experience identified as being influential. The following example illustrates the differences between nurses:

> [On the ICU] Nurse B looks after nurse A's patient because nurse A has to leave for a moment. When nurse A returns, her patient has his hands on the tube. Nurse A is immediately a bit nervous and not pleased, Nurse B has no worries. (Observation 6)

Differences could be observed, for example, at the start of a shift: sometimes the bed rails were raised for (almost) all patients, while at other times when a shift started all bed rails were down. Some mentioned during the observations that bed rails were raised without reflection and because of routine, as also illustrated by the following example:

> The nurse has raised the bed rail almost completely and then asks the patient if he wants the bed rial to be raised. The patient hesitates for a moment and then says he does not really care but no, actually, it is fine without the bed rail. I [observer] suspect that my presence prompted the nurse to ask. (Observation 1)

Such patient involvement in the decision-making process was only rarely observed. A reason for this could be that patients' judgement was often perceived as limited, and this was partly combined with a language barrier. Whether a standardised assessment of patients' judgement ability takes place at a certain point in the treatment (e.g. at admission) was not observed.

A feeling of being overwhelmed and a lack of knowledge was found to be related to restraint use. Tranquillising medication was regularly discussed, especially for agitated patients, but hardly any other measures were taken to counteract this agitation. From outsider's perspective and assessment, these medications were a pharmacological restraint. However, it should be mentioned that, even for the outsider, the restlessness/agitation of patients was sometimes hard to bear. Additionally, the health professional's emotional condition in the situation appeared to influence the decision-making. Thus, on a stressful day, it seemed that restraints were more likely to be used to prevent self-extubation, for example, because the additional stress could not be endured.

From the perspective of an outsider, differences were perceived in the decision-making process according to restraint type. Potentially less drastic restraints seem to be used more easily, in other words, the inhibition level seemed to be lower. In acute geriatrics, this perception was particularly gained in connection with electronic restraints, and in the ICU in relation to equipment that appeared

to be 'loose fixation straps'. These still allowed the patient a certain freedom of movement, and could be perceived to be less drastic, compared to a mechanical fixation with the appropriate belts. Pharmacological restraints may also be viewed as less drastic than mechanical fixations, as the following observation implies:

> In the morning report among the nursing staff in the ICU, it is mentioned who is mechanically restrained with belts/ straps. In passing, the comment is made that "the others are sedated". I [observer] think this was meant in a rather exaggerated way. On this day, many patients were mechanically restrained with belts/straps. It is difficult to judge to what extent sedation is in the consciousness as a restraint. (Observation 8)

Interestingly, multiple restraints were often used simultaneously: 'The patient is restrained in bed with an abdominal belt. At the same time, the two-part bed rails are raised.' (Observation 4)

The avoidance of restraint use

During the observations, various approaches to prevent the use of restraints, as well as alternative strategies to their use, were observed. They mostly addressed the basic problem (e.g. the risk of falling due to confusion), and were summarised in our analysis as follows: patient-orientation approach, proactive communication, promotion of orientation and self-awareness, relatives' involvement, a need-oriented approach, the distraction and occupation of the patient, and a lack of documentation.

> The nurse tries to provide verbal guidance and touches the delirious patient's hands and shoulder while talking to him, which seems to be helpful. The patient reacts positively to being addressed directly by name and to the physical contact and calms down. (Observation 7)

On the units involved, patients often (nonverbally) expressed anxiety and feelings of being overwhelmed, presumably due to the unfamiliar situation in the hospital and, in some cases, confusion or delirium. In such situations, a patient-oriented approach in combination with proactive communication were observed as valuable attempts to reduce the patient's agitation, as well as to promote orientation and self-awareness, as is illustrated in the following observation: 'The tracheotomised patient touches his face with his hands. The nurse seems a little tense but allows

it to happen in order to promote the patient's self-awareness.' (Observation 7) Orientation-promoting approaches were part of the environmental design. In the acute geriatric unit, for example, clearly visible clocks were installed in each room, and the names of the responsible nurse and physician were noted next to each patient's bed. In the intensive care area, specific considerations were made as to which patients would benefit most from a place directly by the window, so that they could experience the benefit of daylight. During the observations, it became apparent that relatives usually had a positive effect on the patient's orientation, but a systematic approach to the involvement of the relatives could not be identified

A needs-oriented approach was clearly observable, too. For example, attention was directed towards adequate pain management. Moreover, the need for potentially intrusive devices, like the peripheral venous catheter, was regularly evaluated.

In addition, it was repeatedly observed on the units involved that distraction and occupation was used, or that the patients were placed near the responsible nurse, as illustrated in the following observations:

> [On the acute geriatric unit] The nurse has placed the confused patient, who is at risk of falling, next to her at a table as she works on the documentation. The patient is calm. This gives the nurse the opportunity to react immediately if the patient wants to get up. (Observation 3)

> A nurse reported that they once had a patient with dementia who was often restless. For many years, this patient had played brass band music. So, they let him watch YouTube videos with brass music on a tablet. He enjoyed it, was calm and busy. (Observation 2)

In general, attempts were made to address the basic problem with regard to prevention of, and alternatives to, restraints. Many good approaches were observed, but difficulties emerged too. For example, in the case of a patient with a language barrier who was at risk of falling, 'the nurse suspects that smoking cigarettes tempts the patient to walk away' (Observation 4). However, due to the smoking ban in the hospital and limited staff resources, it was not possible to fulfil this need for the patient. Additionally, it was observed that alternatives were often insufficiently documented, or not at all, so that the next shift, or at least the one after that, did not know which alternatives had been useful.

DISCUSSION

Participant observation was used to examine daily restraint practice in the field of university acute geriatrics and intensive care medicine. Findings showed that from an outsider's perspective, restraint practice can be classified primarily into three areas: (1) the context in which restraints are used; (2) the decision-making process on the use and continued use of restraints; and (3) the avoidance of restraint use.

The observations showed that the awareness of nurses and other health professionals that certain measures entail a restriction of the patients' freedom, and that this restriction has ethical and legal aspects, is a basic prerequisite. To promote this awareness, clear definitions of what is and what is not a restraint are necessary [15, 26]. However, thus far, most research activities have been conducted on physical (mechanical) restraints, and attempts to develop an internationally uniform definition have only been undertaken for this type of restraint [27]. During the observations, the first association that nurses had with the topic of restraints was fixation with belts. On the one hand, this could be an indication that nurses' awareness has been created and focussed on belt use due to longer existing research activity and related practice development projects compared to other restraint types [e.g. 28]. One the other hand, it is known that restraints with belts are perceived as much more restrictive, and cause greater discomfort than other restraints (e.g. bed rails, electronic monitoring) [29, 30], which is probably why they are more memorable for health professionals. The relevance of a uniform understanding of restraints was shown in this study too. The accompanied nurses mentioned, for example, that they knew that sensor mats are restraints. However, the processes (such as the decision for or against restraint use, evaluation, and documentation) seemed to be less consciously considered and systematically implemented for these kinds of restraints than for fixation belts.

Although various definitions of restraint include any restriction of personal freedom and human rights [5, 11], in clinical practice, it is evident, that a broader understanding of restraint has hardly been established yet. A difficulty in this respect could be that the existing definitions offer room for interpretation, and also depend on how a person is involved (e. g. whether they are a health professional, patient, or family member). Furthermore, it can often depend on the circumstances how a person perceives an individual restriction. Even as an outsider, it was difficult in some situations to assess whether a particular measure was a restraint or not. For example, the two-part bed rails could be considered a restraint for a poorly mobile

patient, as it would be impossible for this patient to get out of bed through the gap between the two parts without assistance. For a physically mobile patient, however, this would be possible without any problem, and thus it would not be a restraint in this situation. Due to the limited insight in patient files, it was also difficult to assess whether medication (e.g. psychotropic drugs) was used for sedation/ tranquilisation (restraint), or for treatment of a specific disease (no restraint). Our findings underline the importance of having a uniform understanding of restraints in order to enable staff to reflect on the potential restriction of a measure in any situation, and to act in accordance with ethical and legal requirements in cases of measures restricting personal freedom.

Regarding the decision-making process, it was observed that decisions on the use and continued use of restraints are primarily made by nurses. This is consistent with previous findings [1, 15]. The results of our study further support previous findings that the decision-making process is based on personal views, intuition, and attitudes rather than on a standardised, comprehensible assessment or reflections [17, 18]. When balancing safety and (promoting) patients' independence (e.g. in performing activities of daily living, mobilisation, body- and self-awareness/ orientation), we found that patients' security seemed to be given greater importance in a rather unconscious decision-making process, despite the lack of evidence for the effectiveness of restraints [1, 13]. In the situations observed, the benefit was sometimes hardly recognisable to an outsider. The lack of the effectiveness of restraints might be linked with a kind of false sense of security on the part of the health professional, which can lead to less attentiveness and consideration of alternative measures. For example, if the nurse relies on being alerted by the motion sensor when the patient leaves the bed, she might visit the patient's room less often. Additionally, in the case of electronic restraints, alarm fatigue has been described as a recognised phenomenon [13]. This can lead to a delayed reaction to the alarm, which is why falls (and other reasons for using this kind of restraint) cannot be prevented. Thus, the benefit of the electronic restraint becomes questionable.

Reflecting on this false sense of security may be hampered by routine and institutional culture (e.g. 'everyone does it this way' or 'we have always done it this way'), which is known to contribute to restraint use [6, 14, 31], along with health professionals lacking knowledge about restraint and its consequences for patients [1, 32, 33]. In addition, as shown in this study, restraints are often used in acute situations that are overwhelming and/or when the emotional burden is high. In the

context of the lack of standardisation found in our study, intuitive and unreflective action is likely to be favoured, which is prompted by what is also known as heuristic decision-making [17, 34]. Although this type of decision-making is often useful in daily clinical practice, it can also have a negative impact on patient safety, as shown here with restraint use [34]. Lack of appropriate knowledge, qualifications, and professional experience, as described in this and other studies on restraints, particularly in relation to nurses [1, 32, 35] further promotes a negative result when using heuristic decision-making. However, in the case of restraint use, it remains unclear in our view as to whether more professional experience would favour better heuristic decision-making. On the one hand, increasing experience can lead to a better assessment of which situations require restraint, and which do not. On the other hand, with increasing experience, routines are consolidated, and the institutional culture is internalised, which may, in our view, reduce critical reflection on restrictive practice. Moreover, the evident influence of institutional culture on daily restraint practice carries the risk of fears of repercussions if the common view is contradicted (this is known as the bandwagon heuristic [34]). Nonetheless, since there is no evidence to date for the effectiveness of restraint but only for its risks, heuristic decision-making in the case of restraint use needs to be reflected upon and transformed. The moral distress that nurses feel when they use restraint offers a starting point, but so far, the (false) sense of security has prevailed [1, 19]. It is therefore essential to improve the evidence on restraint use in hospitals, to teach it, and to systematically implement the findings in practice.

Besides health professional related factors, infrastructural conditions were also shown to influence restraint practice [15]. For example, it could be shown that permanently installed bed rails increase their use [36]. On the observed units, the bed rails were permanently installed, and the impression was gained that this fixed installation favours an intuitive, unreflective raising, instead of a conscious decision to raise them. In some cases, the bed rails were raised even for persons who were hardly physically mobile, because it seemed to be such a routine procedure for patients who were care dependent. Thus, the permanent installation was interpreted as being associated with a lowering of the inhibition threshold for their use. Also, with regard to the 'fixation straps' previously described, which leave more room for movement than fixation belts and can thus be seen as a potentially less drastic measure in terms of ethical decision-making, the question arose as to whether an inhibition threshold is lowered here as well. On the one hand, from an outsider's perspective, it remained questionable as to whether the same number

of patients would have been restrained if only fixation belts had been available. On the other hand, it is possible that the regular use of the 'fixation straps' reduces the inhibition threshold to use fixation belts.

Besides the use of restraints, this study also identified various measures that could be potentially associated with the reduction of restraint use. These measures mostly addressed the underlying problem that led to restraint, such as patients' confusion, but did not seem to be systematically and specifically applied in terms of restraint reduction. A more conscious and systematic use of such measures might, therefore, lead to a further reduction of restraint use. This assumption is in line with Möhler and Meyer [19] who found that alternatives are not considered sufficiently often. It could be beneficial to highlight these associations, and the obligation that restraint should only be used when no other way is possible. Based on the observations, there seems to be great potential for communication and involvement of patients' relatives in the reduction of restraint use. As described, it can be a challenge for patients to feel (locally) oriented in a hospital, and this can lead to anxiety and the sense of being overwhelmed. It is important that these feelings are recognised by nurses and other health professionals, and alleviated by providing orientation through communication and infrastructural modifications. The systematic involvement of relatives could further encourage orientation, and help to reduce fear and the sense of being overwhelmed. Given that older people are more often affected by restraint use [12], it can be assumed that relatives might be over retirement age, and therefore would be potentially available.

In order to move from routine use to a more reflective restraint management, a central element should be the promotion of documentation and evaluation according to certain criteria, for example by means of technical solutions. This means that the documentation system automatically reminds staff of the evaluation, and requests a justification for the continuation. A technical solution that leads restraint management in line with defined processes could also address the known lack of adherence to existing protocols [1]. For example, the need for proper documentation, including the reason for restraint use, alternative methods tried, and reassessment of the need for restraint use, is undisputed [Joint Commission and American College of Emergency Physicians in 37]. In the intensive care department observed, the system offered a standardised recording of the reason for restraint use. However, the only distinction made for the reasons for restraint was between self-harm and harm to others. From an outsider's perspective, this distinction appeared unhelpful for a profound evaluation or, in particular, for the consideration of alternatives and

preventive measures (e.g. in the case of self-harm due to the risk of falling vs. the risk of therapy interruption, other preventive measures would probably be used). Better documentation quality would further improve monitoring and thus enable data-based reflection, and later on evaluation of measures taken. Bellenger et al. [26] recommended the involvement of a team of specialists for the reduction of restraints in nursing homes, which may also be relevant for the hospital setting. It is conceivable that a technical solution could trigger the direct notification of a team of specialists according to certain criteria, so that an evaluation of the restraint use could also be carried out by these specialists. This, in turn, would lead to a shift from decisions made by individuals according to their personal preferences to standardised decision-making that builds on a constant team, and can thus relieve individuals of sole responsibility for restraint decisions. In the mental health setting, shared decision-making approaches have been shown to be beneficial [38]. Such an approach not only relieves health professionals of sole responsibility for decision-making, but also leads to more patient involvement. Based on our findings, patient involvement seems to be rather low, whereby cognitive impairments and language barriers may have made patient involvement more difficult. In our view, better patient involvement might be conceivable in the sense of a prospective approach, i.e. that the possibility of restraint use is already discussed at the time of admission. This can ensure that the patient's views and wishes are known (and documented), so that some kind of patient consent can be obtained in this way.

Based on the findings of this study, the following three core recommendations for clinical implications can be derived:

- the promotion of conscious decision-making including a clear definition of restrictive measures, interprofessional staff education, reflection vessels, and support through a technical solution.

- 'Walking in the patient's shoes': providing staff training to enable nursing staff, physicians and other involved health professionals to reflect and acknowledge the unfamiliar situation for patients and their feeling of fear and being overwhelmed in the hospital setting; to communicate more proactively (e.g. addressing the patient by name, purposeful touching, regular interactions to proactively pick up on patients' needs, experience for oneself what it feels like to be restrained) in order to convey orientation and security, thus counteracting fear and feelings of being overwhelmed; and to actively and intentionally involve relatives to further promote feelings of security and orientation.

- Systematic monitoring regardless of measures (not) taken, in order to conduct a data-based and objective discussion on restraint practice and culture at departmental and institutional levels (ongoing auditing of restraints); generating a baseline of data for profound evaluation of future reduction measures; the standardisation of processes, since monitoring requires a definition of what needs to be documented and how that in turn is likely to have a beneficial effect on conscious restraint management, as decisions must be documented accordingly.

In our view, these recommendations can be implemented even within the context of scarce (human) resources, and can serve as a kind of preliminary stage for more complex interventions to reduce restraint use. Since elderly and mentally ill people are particularly affected by restraints in hospital [12], it might be worth considering concepts from the long-term care and mental health fields to reduce restraint use in hospitals and to develop alternatives. These concepts are unlikely to be applicable one-to-one in the hospital setting due to different basic conditions, but could provide important information on effective and potentially adaptable approaches to restraint reduction. In addition, there appears to be a need for policy makers to revise the legal framework regarding restraint use in the hospital setting, as changes in the law have been shown to positively influence clinical practice in the psychiatric setting, for example [38, 39]. Furthermore, it should be examined on a macro level whether restraint use should be established as a (national) quality indicator for the hospital setting, as measuring and benchmarking restraint use in other settings has proven to stimulate quality improvement [40, 41].

Limitations

The following limitations must be considered: first, the participants were informed that the restraint practice would be observed. In addition, the nurses to be accompanied were allocated by the unit management. It is therefore possible that only exemplary restraint practice was observable. However, the participants were very interested in the topic, and the impression was gained that there was a great openness to show the restraint practice as it is because the participants seemed to be aware of the potential for improvement. In some cases, it was suggested that other nurses should be accompanied, as more restraints were in use with their patients. During one observation period, this offer was taken up, as the nurse who was supposed to be accompanied had to spend a large part of the shift with the

patient in examinations, and thus the restraint practice on the unit could not be observed. If a situation seemed to have been influenced by the observer it was also recorded in the field notes. Furthermore, no night shift could be accompanied, although more restraints are often used at night [15]. For future studies, it would be interesting to investigate whether restraint practice differs between day and night shifts. However, the recommendations derived from this study may also lead to an improvement in restraint management at night.

Second, in addition to nurses, other health professionals are involved in restraint management. In particular, physicians have an important role, as in the Swiss healthcare system they primarily bear the legal responsibility for the treatment of patients. Thus, their attitude is crucial in relation to daily practice. However, as nurses were accompanied during the observations, the description of restraint practice in this study is primarily based on the view of the nurses. For future studies, it would be advisable to direct more attention towards the interprofessional aspect of restraint practice, as this has generally been barely explored so far. Furthermore, patients with restraints are also cared for by nursing assistants, whose role is only partially represented in this study, although there were indications that qualifications play a role in restraint practice.

Third, due to reduced insight into the patient file, the indication for measures and medications could often not be determined. Particularly in the case of medications, lack of access made it difficult to distinguish between whether a medication was used for restraint or for therapeutic purposes. In future studies, an analysis of the patient file could contribute additional evidence. Furthermore, it became apparent that the distinction of restraints from involuntary treatment, if there is one, was also a challenge. For example, a patient was compelled to go to bed because of low blood pressure and the resulting danger of syncope, even though he did not want this, and medication was mixed with food and administered in this way.

It is also important to reflect on the role of the observer. For the data collection, an open, unstructured perspective was intended to enable the description of restraint practice as comprehensively as possible. As the observer had prior knowledge of restraint, and had worked for some time in a mental health setting, which gave her experience in dealing with restraints, in this respect, there could be a bias. However, the observer's prior knowledge and practical experience were perceived as more beneficial, as it enabled certain aspects to be recognised as being related to restraints, which would hardly have been assessed as relevant without this prior knowledge and practical experience. This was particularly the case because the

observer's practical experience was gained in a mental health setting, where dealing with restraints, and especially their avoidance, is more advanced.

Different approaches were taken to ensure the trustworthiness of the data. First, data saturation became apparent during data collection. Secondly, the observations were discussed with the participants at certain points, thus deepening the insights, and so that a kind of participant validation took place within this process. Third, parts of the analysis were conducted independently by a co-author, and the final analysis was discussed with the co-authors. Finally, the results were supported by field notes.

CONCLUSION

The daily restraint practice in a hospital setting shows potential for improvement in terms of the standardisation of processes for restraint management in accordance with ethical and legal requirements. Digitalisation could be used to guide the processes, and at the same time raise awareness and conscious decision-making among healthcare professionals. In combination with targeted and proactive communication, this could be a contribution to restraint reduction that could be integrated into daily practice with little additional investment.

RELEVANCE TO CLINICAL PRACTICE

While the benefits of restraints have not yet been proven, there is evidence for their risks, which is why a reduction in their use is recommended. This study is relevant to clinical practice because it brings a new perspective to a topic dominated by routine and attitude. The outsider perspective allowed daily restraint practice to be described independently of existing routines, departmental cultures, and personal attitudes. It was shown that the restraint practice in the hospital can be positively changed by demanding and promoting consistent implementation of guidelines, in combination with expanded and targeted application of existing prevention approaches.

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CONFLICT OF INTEREST

All authors declare no conflict of interest.

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AUTHORS CONTRIBUTION

ST: study design, data collection, data analysis, data interpretation, and writing of the manuscript. SSD: data analysis, data interpretation, and reviewing and editing the manuscript. SZ: study design, data interpretation, reviewing and editing the manuscript, and supervision. SH: study design, data interpretation, reviewing and editing the manuscript, and supervision. All authors read and approved the final manuscript.

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CHAPTER 05

ATTITUDES OF NURSING STAFF IN HOSPITALS TOWARDS RESTRAINT USE: A CROSS-SECTIONAL STUDY

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ABSTRACT

The attitude of nursing staff towards restraint use can be decisive for whether restraints are used. So far, nursing staff's attitudes have been studied primarily in long-term and mental health care settings, while findings from somatic acute care hospital settings are largely lacking. Therefore, we aimed to investigate (a) the attitudes of hospital nursing staff towards restraint use, and (b) the construct validity and reliability of a measurement instrument for use in hospital settings that was developed and validated in long-term care settings (Maastricht Attitude Questionnaire (MAQ)). Using a cross-sectional design, the attitudes of 180 nursing staff towards restraint use were assessed. The data were analysed descriptively and by means of regression analysis and factor analysis. We found that nursing staff in hospitals have a neutral attitude towards restraint use and that the MAQ, with minor adaptations, can be used in hospital settings, although further testing is recommended. Neutral attitudes of nursing staff have also been observed in long-term and mental health care settings, where changing attitudes were found to be challenging. Interventions at the national level (e.g., legal regulations) and management level (e.g., providing alternatives and changing institutional culture) are suggested.

KEYWORDS

attitude; hospitals; nursing; restraint

INTRODUCTION

Internationally, it is undisputed whether restraint use should be reduced as much as possible [1-3]. Restraints are 'interventions that may infringe [on] a person's human rights and freedom of movement, including observation, seclusion, manual restraint, mechanical restraint and rapid tranquillisation' [4]. The use of restraints is an encroachment of basic human rights and has negative consequences for patients (e.g., increased risk of falls, delirium, strangulation, and re-traumatisation) and (in-)formal caregivers (e.g., distress) [5-8].

In inpatient settings, nursing staff play crucial roles in the decision-making process as well as in the application of restraint, as they are most intensively involved in patient care [7,9,10]. It is well known that the decision-making process for the use of restraint is influenced not only by contextual (e.g., availability of guidelines) and patient-related factors (e.g., aggressive behaviour) but also by the individual conditions of the staff [7,11,12]. An essential condition (in any) decision-making process is the attitude one adopts, as this attitude guides the appraisal of the situation and the selection of the given options in the situation [9]. Attitude is defined as 'the stored evaluations of or feelings toward persons, objects, events, situations, routines, instructions, goals, positions, ideas, behaviours, and issues' [9]. Attitude becomes particularly relevant in the decision-making process when there is little time and motivation to conduct an effortful, feature-based analysis of the situation. Given the high workload that nurses in the inpatient setting also describe as a contributing factor to restraint use [10-12], it becomes apparent that time is often scarce and, therefore, a decision based on attitude is more likely to be made. Indeed, whether nursing staff have a favourable or critical attitude toward restraint can influence its use. Thus, knowing and addressing the attitude of nursing staff may be an important contributor to restraint reduction [13].

To date, research on nursing staff's attitudes towards restraint use in the inpatient setting has focused mainly on long-term and mental health care. In the long-term care field, the findings about nursing staff's attitudes are inconsistent. Using qualitative approaches, negative feelings were expressed, while surveys with standardised questionnaires indicated a slightly favourable attitude of nursing staff towards restraint use. Furthermore, it was reported that attitudes have hardly changed in the past decades [14-16]. In the mental health care field, it was found that attitudes have tended to become slightly more critical over the past decades, although the change in attitude was not highly pronounced [13]. Rather,

it has been shown that the view is changing from a therapeutic paradigm to a safety paradigm [17]. In the somatic acute care hospital (henceforth referred to as 'hospital') setting, little is known about the attitudes of the nursing staff. Some studies have been conducted in the intensive care area [e.g., 18, 19-21]); however, these focused more on reasons for the use of restraints (e.g., using the Perception of Restraint Use Questionnaire), on knowledge and application practices (partly using questionnaires designed for the study), or on attitudes assessed only using qualitative methods. Therefore, the aim of the current study is to assess nursing staff's attitudes in a hospital setting using a standardised questionnaire and to identify their associations with staff characteristics. Since, to our knowledge, no validated instrument has been used to assess attitudes towards restraint use in hospital settings, we also aimed to test the construct validity and reliability of an instrument validated in long-term care settings for use in hospital settings.

MATERIALS AND METHODS

Study Design, Setting, and Sampling

Using a cross-sectional design, nursing staff in a department of a Swiss university hospital were surveyed regarding their attitude towards restraint use. The department operates with 146 patient beds distributed over seven 'general' inpatient, two outpatient, and three high-dependency care units. All nursing staff at all qualification levels, including those still in training, were eligible. There were no exclusion criteria. In order to test the construct validity and reliability of a questionnaire, 5–10 participants per item (question) of a scale are recommended [22]. The highest number of items is found in the attitude scale (see Section Instrument), which contains 22 items. Accordingly, we aimed for a sample size of 110–220 participants.

Instrument

The Maastricht Attitude Questionnaire (MAQ, German version) was used with the developers' permission [23, 24]. So far, the MAQ has been used solely in long-term care settings and has proven to be valid and reliable [25-27]. The MAQ includes socio-demographic information (age and gender), work-specific information (workplace, highest professional qualification, and work experience), and three scales dealing with the attitude and perception of nursing staff regarding the use of restraints in health care. We chose this questionnaire as it was the only one

known to us at the time of measurement that had been translated into German to measure attitudes of nursing staff towards restraint use. In addition, it has been shown that the patient group most affected by restraint use in hospitals are older, care-dependent, and cognitively impaired [28]; thus, this is a patient group more closely resembling patients in long-term care than in psychiatry. There is another scale, the Physical Restraint Knowledge, Attitude, and Practice Scale, that has also already been used to measure the attitude of nurses in hospital (ICU) [21]. This scale is also based on a scale further developed in the long-term care setting. In this scale, however, attitude is only a subscale. Moreover, this scale was not available in German at the time our study was conducted.

The first scale of the MAQ assesses the general attitude towards restraint use with 22 items (see Table 3). The internal consistency of the attitude scale is reflected by a Cronbach's alpha of 0.81 [25]. This scale consists of three subscales:

- Consequences of restraint use for the patient (10 items, e.g., *Patients experience the use of physical restraints as safe*; Cronbach's alpha = 0.71)
- Reasons for restraint use (8 items, e.g., *Restraints reduce the risk of serious injury to patients*; Cronbach's alpha = 0.77)
- Appropriateness of restraint use (4 items, e.g., *If we use physical restraints it is always necessary*; Cronbach's alpha = 0.58)

The items were answered on a Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The interpretation of the results is based on the mean score of all 22 items (sum of all items divided by the number of items): the higher the score, the more favourable the attitude is towards the use of restraints.

In the second scale of the MAQ, the perceived degree of restrictiveness for the patient and, in the third scale of the MAQ, the extent of own discomfort with the use of the specific restraint were assessed (both 16 items, see Table 4). The answers were given on a Likert scale ranging from 1 (not restrictive/not discomforting) to 3 (highly restrictive/highly discomforting). The interpretation of the results is based on the mean score. Higher scores indicate a higher perception of the degree of restrictiveness for the patient, and higher scores indicate a greater degree of discomfort in using restraints for nursing staff.

As the MAQ was developed for long-term care settings, minor adjustments were made to the wording based on the setting and context. The word 'resident'

was replaced with the word 'patient'. Likewise, the word 'hospital' was used instead of 'nursing home'. For the qualifications, the nomenclature typical of the educational qualifications in the field of nursing and care of the Swiss Health Observatory [29] were used. Otherwise, no changes were made to the content or to the number of items of the questionnaire. As the questionnaire was used for the first time in a hospital setting, the construct validity and reliability was tested (see Section Data analysis). This resulted in a slight adaptation of the factor structure and, accordingly, in the calculation of the mean scores of each scale (see Section Results). In this study, the Attitude scale comprised 19 items (see Table 3), the Discomfort scale comprised 14 items, and the Restrictiveness scale comprised 10 items (for both, see Table 4). All results presented in this study (e.g., mean scores of the scales in Table 1) were derived from the adapted scales.

Data Collection

Data collection took place between October and December 2020. Information on the study along with a link to the online questionnaire (using the platform SoSci Survey) were sent to all nursing staff in the department via their employee email. To increase the response rate, a total of 3 reminder emails were sent (after 2, 4, and 6 weeks) to all eligible participants. To prevent missing data, mandatory fields were marked for the items of the scales but not for the socio-demographic and work-specific information.

Data Analysis

The software R 4.1.0 [30] was used to analyse the gathered data. By means of descriptive analyses (number and percentages with 95% confidence interval for nominal variables; mean and standard deviation, median and interquartile range, and range for ratio variables), the sample was described in terms of socio-demographic and work-specific characteristics as well as its attitude, perceived restrictiveness, and discomfort (R packages used: tableone [31] and compareGroups [32]). In addition, the correlation among the mean scores of the three scales were analysed using Pearson's correlation coefficients. As the MAQ was used in a hospital setting for the first time, construct validity was tested by means of factor analyses. We initially intended to perform a confirmatory factor analysis for the scale on attitude, as it can be assumed that the population examined was similar to the population in which the questionnaire was validated. However, we found that the data did not fit the theoretical construct (e.g.,

one item was negatively correlated with the factor). In such a case, it is recommended to conduct an exploratory factor analysis (EFA) [33]. In addition, in previous scientific publications using the MAQ, only information about reliability (Cronbach's alpha) of the Attitude scale was published. Information on construct validity is lacking. For the two other scales (Discomfort and Restrictiveness), no statistical parameters based on factor analysis could be identified. Therefore, an EFA was carried out for all three scales of the MAQ, starting with the original number of items per scale (Attitude n items = 22; Discomfort n items = 16; Restrictiveness n items = 16).

For the EFA, the following analyses and cut-off values were used [34, 35]: we identified factorability computing the correlation matrix, the Bartlett test of sphericity (p-value < 0.05), and the Kaiser–Meyer–Olkin (KMO) criterion (>0.5). In addition, we checked the measure of sampling adequacy (MSA) for each item (>0.5). To determine the number of factors to retain, we used several approaches: we interpreted the scree plot and used parallel analysis and the minimum average partials (MAP). We started the analysis with the highest recommended number of factors. If a factor had <3 items or if the allocation of the items to the factors did not make sense in terms of content, the next-smallest number of factors was trialled, up to the final number of factors. For the factor analysis, we used the "oblimin" rotation method, as earlier analyses of the attitude scale of the MAQ showed that these factors are correlated [27]. For item-factor loading, a cut-off value of >0.3 was used. In the case of an exclusion of items due to too-low factor loading, the above steps were repeated. Finally, internal consistency/reliability for each factor as well as for the full scale was calculated by means of the Cronbach's alpha. Cases with missing values in one item of the scale were excluded. The results of the EFA on the Attitude scale were additionally compared with the original version. The R packages used were psych [36], corrplot [37], dplyr [38], and GPArotation [39].

Multiple linear regression analyses were carried out to identify associations between each of the three scale mean scores and staff characteristics. Attitude, discomfort, and restrictiveness were defined as the dependent variables, and the staff characteristics listed in Table 1 were defined as independent variables. Since years of work experience and age were correlated, only work experience was included in the model. Cases with missing values were excluded. The R packages used were MASS [40], tidyverse [41], and jtools [42].

As the professional qualification was highly heterogeneous, with very few answers per qualification in some cases, these had to be grouped for a meaningful analysis. This grouping was also based on the nomenclature typical of the

educational qualifications in the fields of nursing and care of the Swiss Health Observatory [29]. For our analyses, the following four categories were used:

1. RN BSc/MSc: Registered nurse (RN) with a Bachelor of Science (BSc) or Master of Science (MSc) in nursing;

2. RN+: RN with a degree from a college of higher education (so-called Advanced Federal Diploma of Higher Education in Nursing; European Qualifications Framework: Level 6 [43]), and further education as an intensive care, anaesthesia, or emergency care nurse;

3. RN: RN with a degree from a college of higher education (so-called Advanced Federal Diploma of Higher Education in Nursing; European Qualifications Framework: Level 6 [43]);

4. Non-RN: Staff working in the field of nursing but not having an RN qualification (including 3-year vocational training in nursing (European Qualifications Framework: Level 4 [43]); staff with other degrees in the field, such as nursing assistants; students; trainees; and staff with other professional degrees outside the nursing field).

Ethical Considerations

The ethics committee assessed the project as not being subject to the Swiss Human Research Act (BASEC-Nr: Req-2020-01204). Participation in the survey was voluntary and anonymous. In order to participate in the survey, the participants provided informed consent before the start of the survey, as this was the first question. The survey could be stopped at any time without giving reasons.

RESULTS

Sample and Attitude

A total of 351 nursing staff were invited to participate in the survey. Of these, 182 completed the survey, including all items of the general Attitude scale. Two participants gave implausible information about their age (−1 and 1); hence, these cases were excluded. Thus, 180 questionnaires could be included in the analysis, corresponding to a participation rate of 51.3%. There were further missing responses in both the Discomfort (n = 9) and Restrictiveness scales (n = 2) (Figure 1).

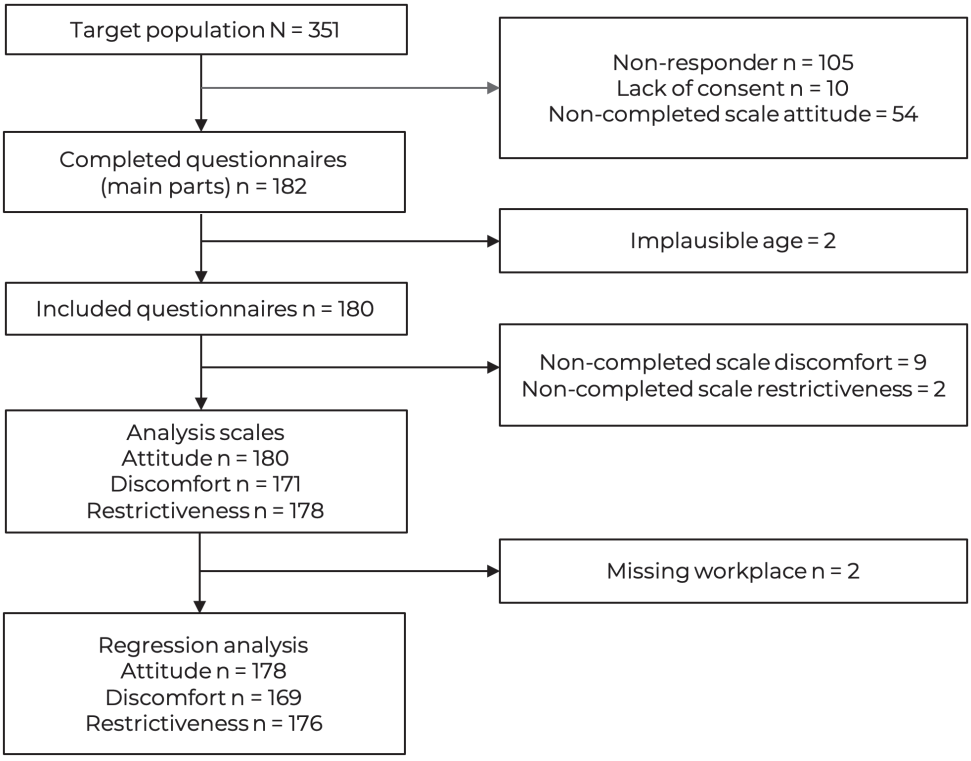

Figure 1: Flowchart detailing the number of participants per analysis step and scale

The majority of participants were female (91.7%), worked in an inpatient unit (51.7%) and were registered nurses with a qualification from a college of higher education (RN 48.9%; see Table 1). The median age of the participants was 35 years, and the median number of years of work experience was 13 years. The participants tend to have a neutral general attitude towards restraint use (mean 3.2 on a scale of 1–5) and to perceive the restrictiveness of restraints (mean 2.1 on a scale of 1–3) and the discomfort in their use (mean 2.2 on a scale of 1–3) as being moderate. However, the discomfort as well as the perceived restrictiveness differ greatly depending on the restraint type (Table 4). The sensor alarm was perceived by the participants as being both the least uncomfortable (mean 1.2) and least restrictive restraint (mean 1.4). The abdominal belt in bed was perceived to be the most discomforting (mean 3.0), and the ankle belt was perceived to be the most restrictive restraint (mean 2.9). Furthermore, the mean scores of the three scales are correlated: the greater the discomfort in the use of restraints, the more critical the attitude towards restraints ($r = -0.22$; $p = 0.003$);

the stronger the perceived restrictiveness of restraints, the more critical the attitude towards restraints (r = −0.28, p = 0.000); and the greater the discomfort in the use of restraints, the more restrictive they are perceived (r = 0.52; $p \leq 0.000$).

Table 1: Sample description

Characteristics (*n* Answers)		**n (% [95% CI])**
Sex (180)		
	Female	165 (91.7 [86.6–95.3])
	Male	15 (8.3 [4.7–13.4])
Workplace (180)		
	Inpatient unit (*excluding the high-dependency care unit*)	93 (51.7 [44.1–59.2])
	Outpatient unit	39 (21.7 [15.9–28.4])
	High-dependency care unit	46 (25.6 [19.4–32.6])
	No response	2 (1.1 [0.1–4.0])
Professional qualification (180)		
	RN BSc/MSc	29 (16.1 [11.1–22.3])
	RN+	24 (13.3 [8.7–19.2])
	RN	88 (48.9 [41.4–56.4])
	Non-RN	39 (21.7 [15.9–28.4])
	Mean (SD)	**Median (IQR)**	**Range**
Age in years (178)	36.7 (12.8)	35 (26–46)	16–69
Work experience in years (180)	16.0 (12.0)	13 (6–25)	0–45
Attitude (180)	3.2 (0.5)	3.2 (2.9–3.5)	1.5–4.6
Restrictiveness (178)	2.1 (0.2)	2.1 (1.9–2.3)	1.5–2.5
Discomfort (171)	2.2 (0.3)	2.2 (2.0–2.4)	1.4–2.8

n = number; 95% CI = 95% confidence interval; SD = standard deviation; IQR = interquartile range; RN BSc/MSc = Registered nurse with a Bachelor of Science (BSc) or Master of Science (MSc) in nursing; RN+ = Registered nurse with a degree from a college of higher education + further education as an intensive care, anaesthesia, or emergency care nurse; RN = Registered nurse with a degree from a college of higher education. Non-RN = staff with 3-year vocational training in nursing; staff with other degrees in the field, such as nursing assistants; students; trainees; or staff with other professional degrees outside the nursing field.

The linear regression analysis showed that the general attitude is associated with work experience. With increasing work experience, a more restraint-favouring attitude is taken (β 0.01). Other staff characteristics did not show a statistically significant association with the general attitude. The perceived discomfort in using restraints is associated with the staff's workplace. Nursing staff who work in the high-dependency care unit feel less discomfort with the use of restraints than nursing staff in 'general' inpatient units (β −0.17). All other associations were not statistically significant. The perceived restrictiveness of restraints is associated with work experience, workplace, and professional qualification. Increasing work experience is associated with a lower perceived restriction of restraints (β −0.00). Nursing staff who work in the high-dependency care unit perceived restraints as being less restrictive than nursing staff

in a 'general' inpatient unit (β −0.09). RN+ (β 0.20) or RN (β 0.11)-qualified staff tend to perceive restraints as being more restrictive than non-RN staff. Our models explain between 7% and 9% of the variance (R^2; see Table 2).

Construct Validity and Reliability of the MAQ

For the general Attitude scale, we found that the factor structure of the original scale is largely similar to that in the hospital setting. Four items showed deviating results. Items 10 (*I always question why a restraint is applied on a patient (recoded)*) and 21 (*I would rather risk falling than be physically restrained in a chair all day (recoded)*) did not load sufficiently on any factor and were, therefore, excluded. Item 15 (*The adverse effects of physical restraints do not outweigh the increase in safety*) was negatively correlated with the factor and was, therefore, excluded. Item 13 (*Applying physical restraints usually has a calming effect on patients*) was loaded on Factor 2 (Reasons for restraint use) instead of Factor 1 (Consequences of restraint use for the patient), as in the original scale. Item 2 (*If we use physical restraints it is always necessary*) additionally showed cross-loadings. Here, the allocation to the factors of the original scale was considered appropriate from a content point of view. We also considered the factor naming to be appropriate (Factor 1 = Consequences of restraint use for the patient, α = 0.83; Factor 2 = Reasons for restraint use, α = 0.77; and factor 3 = Appropriateness of restraint use, α = 0.55). The adapted scale comprising 19 items explains 37% of the variance and has an internal consistency of α = 0.83.

For the Discomfort and Restrictiveness scales, we found that both scales contain two factors (see Table 4). However, some items were loaded below the required value (0.3) and were, therefore, excluded. For the Discomfort scale, this applies to items 14 and 15, and for the Restrictiveness scale, this applies to items 6, 7, 9, 11, 14, and 15. For the Discomfort scale, items 2, 4, and 11 were loaded on multiple factors with >0.3. Assignment to a factor was based on content. The two factors were named as follows: Fixation belts in bed (Factor 1) (items 10, 13, and 16; α = 0.90), and Mechanical and electronic restraint except fixation belts (Factor 2) (items 1–9, 11, and 12; α = 0.78). The Discomfort scale explained 38% of the variance in perceived discomfort and had an internal consistency of α = 0.78. For the Restrictiveness scale, there were no cross-loadings. The two factors were named as follows: Restraining the patient to the bed (Factor 1) (items 8, 10, 13, and 16; α = 0.66) and Safety measures in the chair when leaving the bed or place (Factor 2) (items 1–5 and 12; α = 0.63). The Restrictiveness scale explained 35% of the variance in perceived restrictiveness and shows an internal consistency of α = 0.65.

Table 2: Associations between participants' characteristics and their general attitude towards restraints, their discomfort in using restraints, and their perceived restrictiveness of restraints

Predictor	Attitude (n = 178) $F(7, 170) = 2.31$, $p = 0.028$ R^2/R^2 Adjusted 0.09/0.05				Discomfort (n = 169) $F(7, 161) = 1.65$, $p = 0.126$ R^2/R^2 Adjusted 0.07/0.03				Restrictiveness (n = 176) $F(7, 168) = 1.97$, $p = 0.037$ R^2/R^2 Adjusted 0.08/0.04			
	β	SE	95% CI	*p*	β	SE	95% CI	*p*	β	SE	95% CI	*p*
(Intercept)	3.04	0.08	2.88–3.19	**<0.001**	2.23	0.05	2.13–2.33	**<0.001**	2.09	0.04	2.01–2.17	**<0.001**
Sex male	0.08	0.12	−0.17–0.33	0.525	−0.06	0.08	−0.21–0.10	0.459	0.03	0.06	−0.09–0.16	0.591
Work experience in years	0.01	0.00	0.00–0.02	**0.003**	−0.00	0.00	−0.01–0.00	0.305	−0.00	0.00	−0.01–0.00	**0.011**
Workplace												
Inpatient unit			Reference				Reference				Reference	
Outpatient unit	−0.04	0.09	−0.21–0.13	0.628	−0.06	0.06	−0.17–0.05	0.281	−0.01	0.04	−0.09–0.08	0.877
High-dependency care unit	−0.10	0.08	−0.27–0.07	0.230	−0.17	0.05	−0.27–0.06	**0.002**	−0.09	0.04	−0.18–0.01	**0.033**
Qualification												
Non-RN			Reference				Reference				Reference	
RN BSc/MSc	0.16	0.11	−0.06–0.38	0.141	0.01	0.07	−0.13–0.14	0.933	0.09	0.06	−0.03–0.20	0.131
RN+	−0.13	0.14	−0.41–0.14	0.337	0.14	0.09	−0.03–0.31	0.114	0.20	0.07	0.06–0.34	**0.004**
RN	0.05	0.09	−0.13–0.23	0.575	0.05	0.06	−0.07–0.16	0.450	0.11	0.05	0.01–0.20	**0.026**

n = number; F = F statistics; p = p-value (bold if significant); β = coefficients, SE = standard error, 95% CI = 95% confidence interval; SD = standard deviation; IQR = interquartile range RN BSc/MSc = Registered nurse with a Bachelor of Science (BSc) or Master of Science (MSc) in nursing; RN+ = Registered nurse with a degree from a college of higher education + further education as an intensive care, anaesthesia, or emergency care nurse; RN = Registered nurse with a degree from a college of higher education. Non-RN = staff with a 3-year vocational training in nursing; staff with other degrees in the field, such as nursing assistants; students; trainees; and staff with other professional degrees outside the nursing field.

Table 3: Descriptive and factor analysis for the Attitude scale

Attitude Bartlett's χ2 = 86.98, df = 18, *p*-Value < 0.000 KMO 0.84 α Full Scale (95% CI): 0.83 (0.79–0.86) Explained Variance 37% (F1 16%; F2 15%; F3 6%)							
Item nr.	Label	Mean (SD)	Median (IQR)	Factor Original Scale	F1 (α 0.83 [95% CI 0.79–0.87])	F2 (α 0.77 [95% CI 0.71–0.82])	F3 (α 0.55 [95% CI 0.45–0.66])
					factor loading (α if item is dropped)		
01	My ward/unit uses physical restraints far too often (recoded)	4.3 (0.8)	4.0 (3.0–5.0)	Appropriateness			0.51 (0.49)
02	If we use physical restraints it is always necessary	4.3 (0.9)	4.0 (4.0–5.0)	Appropriateness		0.35	0.35 (0.49)
03	Physical restraints are used too quickly (recoded)	4.1 (0.9)	4.0 (4.0–5.0)	Appropriateness			0.62 (0.43)
09	Physical restraints are applied as a result of convenience of nursing staff (recoded)	4.4 (0.8)	5.0 (4.0–5.0)	Appropriateness			0.36 (0.50)
04	I'm afraid of falls if I do not apply physical restraints	2.7 (1.0)	3.0 (2.0–3.0)	Reasons		0.60 (0.73)	
05	It's better to tie up patients than risk accidents	2.2 (1.0)	2.0 (1.0–3.0)	Reasons		0.47 (0.75)	
06	Falls in older adults often cause serious injury	3.6 (0.8)	4.0 (3.0–4.0)	Reasons		0.40 (0.77)	
07	Restraints reduce the risk of serious injury to patients	3.3 (0.9)	3.0 (3.0–4.0)	Reasons		0.66 (0.72)	
08	Failure to restrain puts individuals and facilities at risk for legal liability	2.9 (1.0)	3.0 (2.0–4.0)	Reasons		0.61 (0.73)	
11	Restraint-free care is impossible	2.3 (1.1)	2.0 (1.0–3.0)	Reasons		0.51 (0.76)	
12	The moral duty to protect people from harm requires restraint	2.8 (1.0)	3.0 (2.0–3.0)	Reasons		0.77 (0.70)	
21	I would rather risk falling than be physically restrained in a chair all day (recoded)	2.8 (1.2)	3.0 (2.0–4.0)	Reasons			
13	Applying physical restraints usually has a calming effect on patients	2.1 (0.8)	2.0 (2.0–3.0)	Consequences		0.32 (0.76)	
10	I always question why a restraint is applied on a patient (recoded)	3.0 (1.5)	3.0 (2.0–4.25)	Consequences			
15	The adverse effects of physical restraints do not outweigh the increase in safety	2.8 (0.9)	3.0 (2.0–3.0)	Consequences			

Attitude
Bartlett's $\chi 2 = 86.98$, df = 18, *p*-Value < 0.000
KMO 0.84
α Full Scale (95% CI): 0.83 (0.79–0.86)
Explained Variance 37% (F1 16%; F2 15%; F3 6%)

Item nr.	Label	Mean (SD)	Median (IQR)	Factor Original Scale	F1 (α 0.83 [95% CI 0.79–0.87])	F2 (α 0.77 [95% CI 0.71–0.82])	F3 (α 0.55 [95% CI 0.45–0.66])
					factor loading (α if item is dropped)		
14	Applying physical restraints is a major cause of pressure ulcers (recoded)	3.6 (0.9)	4.0 (3.0–4.0)	Consequences	0.41 (0.82)		
16	Most patients suffer adverse effects from physical restraints (recoded)	3.4 (0.9)	3.0 (3.0–4.0)	Consequences	0.70 (0.80)		
17	Physical restraints reduce a patient's quality of life (recoded)	2.8 (1.0)	3.0 (2.0–4.0)	Consequences	0.68 (0.79)		
18	Patients experience the use of physical restraints as a form of punishment (recoded)	2.9 (1.0)	3.0 (2.0–4.0)	Consequences	0.88 (0.79)		
19	Patients experience the use of physical restraints as safe	2.7 (0.8)	3.0 (2.0–3.0)	Consequences	0.55 (0.82)		
20	If I end up in a hospital, I hope staff use physical restraints on me if they deem it necessary	3.1 (1.1)	3.0 (2.0–4.0)	Consequences	0.41 (0.83)		
22	Application of physical restraints is inhumane (recoded)	3.3 (0.9)	3.0 (3.0–4.0)	Consequences	0.61 (0.81)		

df = degree of freedom; KMO = Kaiser–Meyer–Olkin criterion, α = Cronbach's alpha, 95% CI = 95% confidence interval; SD = standard deviation; IQR = interquartile range; F1 = Consequences of restraint use for the patient; F2 = Reasons for restraint use; F3 = Appropriateness of restraint use; grey background = allocation factor.

Table 4: Descriptive and factor analysis for the Discomfort and Restrictiveness scales

		Discomfort Bartlett's $\chi2$ = 402.71, df = 13, *p*-Value < 0.000 KMO 0.77 α Full Scale (95% CI): 0.78 (0.74–0.83) Explained Variance 38% (F1D 19%; F2D 20%)				Restrictiveness Bartlett's $\chi2$ = 386.46, df = 9, *p*-Value < 0.000 KMO 0.66 α Full Scale (95% CI): 0.65 (0.58–0.72) Explained Variance 35% (F1R 19%; F2R 16%)			
Item nr.	Label	MW (SD)	Median (IQR)	F1D (α 0.90 [95% CI 0.88–0.93])	F2D (α 0.78 [95% CI 0.73–0.83])	MW (SD)	Median (IQR)	F1R (α 0.66 [95% CI 0.58–0.74])	F2R (α 0.63 [95% CI 0.54–0.71])
				factor loading (α if item is dropped)				factor loading (α if item is dropped)	
10	Wrist belt	2.9 (0.3)	3.0 (3.0–3.0)	0.89 (0.85)		2.0 (0.2)	2.0 (2.0–2.0)	0.99 (0.49)	
13	Abdominal Belt in bed	3.0 (0.3)	3.0 (3.0–3.0)	0.88 (0.86)		1.9 (0.2)	2.0 (2.0–2.0)	0.65 (0.51)	
16	Ankle belt	2.9 (0.3)	3.0 (3.0–3.0)	0.86 (0.87)		2.9 (0.3)	3.0 (3.0–3.0)	0.50 (0.66)	
08	Special sheet (fitted sheet including a coat enclosing the mattress)	2.7 (0.5)	3.0 (3.0–3.0)		0.47 (0.76)	2.8 (0.4)	3.0 (3.0–3.0)	0.34 (0.73)	
01	Sensor alarm (in bed/chair, on the floor)	1.2 (0.4)	1.0 (1.0–1.0)		0.40 (0.78)	1.4 (0.5)	1.0 (1.0–2.0)		0.34 (0.63)
02	(Wheel)Chair with table	1.8 (0.6)	2.0 (1.0–2.0)		0.66 (0.75)	2.3 (0.6)	2.0 (2.0–3.0)		0.77 (0.49)
03	Tensioning system in (wheel)chair	2.0 (0.7)	2.0 (2.0–2.0)		0.62 (0.75)	2.2 (0.6)	2.0 (2.0–3.0)		0.56 (0.57)
04	Bilateral bedrails	1.9 (0.6)	2.0 (1.0–2.0)		0.62 (0.75)	2.3 (0.5)	2.0 (2.0–3.0)		0.39 (0.58)
05	Unilateral bedrail	1.3 (0.5)	1.0 (1.0–2.0)		0.55 (0.76)	1.5 (0.5)	2.0 (1.0–2.0)		0.36 (0.61)
12	Abdominal Belt in (wheel)chair	2.6 (0.5)	3.0 (2.0–3.0)		0.40 (0.77)	1.6 (0.5)	2.0 (1.0–2.0)		0.45 (0.60)
06	Deep (wheel)chair (Siesta)	1.9 (0.7)	2.0 (1.0–2.0)		0.50 (0.76)	1.9 (0.6)	2.0 (2.0–2.0)		
07	Surveillance system	1.5 (0.6)	1.0 (1.0–2.0)		0.41 (0.77)	1.7 (0.7)	2.0 (1.0–2.0)		
09	Sleep suit (clothing that deters a person from self-undressing)	2.1 (0.7)	2.0 (2.0–3.0)		0.45 (0.77)	2.1 (0.7)	2.0 (2.0–3.0)		
11	Tightly tucked sheet (over belly and upper legs)	2.8 (0.5)	3.0 (3.0–3.0)	0.45	0.30 (0.77)	1.8 (0.4)	2.0 (2.0–2.0)		
14	Bedroom door locked	2.7 (0.6)	3.0 (3.0–3.0)			2.7 (0.5)	3.0 (2.0–3.0)		
15	Ward door locked	1.9 (0.7)	2.0 (1.0–2.0)			2.0 (0.6)	2.0 (2.0–2.0)		

df = degree of freedom; KMO = Kaiser–Meyer–Olkin criterion, α = Cronbach's alpha, 95% CI = 95% confidence interval; SD = standard deviation; IQR = interquartile range; F1D = Fixation belts in bed; F2D = Mechanical and electronic restraint except fixation belts; F1R = Restraining the patient to the bed; F2R = Safety measures in the chair when leaving the bed or place; bold = highest/lowest descriptive scores; grey background = allocation factor.

DISCUSSION

In this cross-sectional study, we investigated the attitudes of nursing staff in hospitals towards restraints and the association of attitudes with staff characteristics. Based on data gathered from 180 participants, we found that nursing staff have a rather neutral attitude towards restraints in general and perceive the discomfort in the use and restrictiveness of restraints as being moderate. These three constructs are, furthermore, correlated as expected: the greater the discomfort or the stronger the perceived restrictiveness, the more critical the attitude towards restraint use, and the greater the discomfort, the more restrictive the restraints are perceived to be. The following associations between attitude/discomfort/restrictiveness and staff characteristics were found: general attitude and work experience; discomfort and working in the high-dependency care unit; and restrictiveness and working in the high dependency care unit, work experience, and qualification. In addition, we tested the construct validity and reliability of the MAQ for its use in hospital settings. We found that, with minor adaptations, the MAQ can also be used in hospital settings, although further testing is necessary.

The Attitudes of Nursing Staff

A neutral attitude of nursing staff towards restraint use has also been observed in studies using questionnaires in long-term care and mental health care settings. By using qualitative methods, more critical attitudes were identified [9,17,20,27]. With regard to associations, there are no consistent findings so far. Our model also explained little of the variance, and we only identified professional experience as being positively associated with the general attitude, i.e., with increasing professional experience, an attitude slightly favouring restraint use evolves. It is known that routine and institutional culture play important roles in restraint use in hospitals [12, 14, 44-46]. It is possible that with more professional experience, the prevailing routines will become internalised and the practice will be less critically scrutinised. However, the association is not pronounced and should be further investigated.

Both the discomfort in the use of restraints and the perceived restrictiveness show that nursing staff working in a high-dependency care unit perceive both to be less pronounced, compared with nursing staff in ‘general’ inpatient units. This is possibly related to a habituation effect, since in these units, as the name indicates, more complex patient situations are cared for, which has been shown to be related to the use of restraints [28]. The restrictiveness is also perceived to

be less pronounced when nursing staff have more work experience. This, in turn, could be due to similar effects as with the general attitude, i.e., one questions the practice less critically and legitimises the use of restraints for oneself as a kind of coping strategy against distress that may occur when using restraints [7]. With regard to qualification, it can be seen that staff with an RN or RN+ degree perceive restraints as more restrictive than non-RN staff. One explanation may be found in the requirements for the different qualification levels. According to the European Qualifications Framework [43], non-RN staff (level 4 and below) are responsible for predictable situations and perform their work according to predefined guidelines. In contrast, RN staff (level 6) are responsible for complex, unpredictable situations and must be able to make decisions in these situations. In addition, at this qualification level and above, a critical reflection on theories and practices is expected. However, no significant difference in the perception of restraints could be identified between those with an RN BSc/MSc degree and those with non-RN degrees, which limits this interpretation. It is possible that the merger of the various qualification degrees into groups plays a role here.

With regard to the perception of discomfort in the use and the restrictiveness of the individual restraint types, the results are in line with previous findings in long-term care settings using the same questionnaire [25, 27]. In general, it can be summarised that the more obvious the movement restriction, the more uncomfortable its use and the more restrictive the restraint is perceived to be. From our point of view, however, the results also imply that it is primarily the restriction of movement that is perceived, and the other forms of restriction of freedom are perceived less. On the one hand, it has been pointed out in previous studies that not all restraints are recognised as such because, among other reasons, clear and/or broader definitions of restraints seem to be little established in practice [14, 47]. On the other hand, in many countries, it is primarily the restriction of movement that is regulated by law. In Switzerland, for example, the law only clearly regulates the restriction of movement for persons with compulsory admission and for persons who lack judgmental capacity and live in a care facility [48]. Thus, it seems important not only to raise awareness about the different forms of restraints but also to have clear legal regulations [49].

In the long-term care and mental health care settings, where restraint use has been researched for a longer time, it is evident that the attitude has hardly changed over the past decades [13, 14]. Nursing staff's attitudes tend to be neutral. However, given the growing evidence that the benefits of restraint do not outweigh

the harms and the ethical guidelines that have been in place for some years, one would expect attitudes to become increasingly critical. That this does not happen could, in our view, be related to the following two aspects in relation to the concept of attitude [9]. First, it is described that evidence that does not correspond to one's own attitude is often rejected or discounted. Second, restraint use is a routine practice [14, 47] and routine is accompanied by a favourable attitude towards the practice. Nevertheless, it is also important to note that decision-making also means weighing different options. With regard to restraint use, it is known that alternatives are not very common or known [14, 50]. The lack (of awareness) of these alternative options in the decision-making process may be another reason why the attitude of nursing staff towards restraint use is neutral and hardly changes. Therefore, it seems important to develop alternatives on the one hand and to change the perception of restraint use as a routine intervention or as being part of the job on the other hand. Indeed, changing attitudes proves that challenging, and neutral or even favourable attitudes toward restraint use also pose a barrier to the successful implementation of restraint reduction programs [15, 51]. Therefore, it seems that both management and policy makers are required to promote the process of change with appropriate measures [52]. Management can ensure that options are available (alternatives/prevention options) or that they are not available (restraint material) in the decision-making process. In addition, management can play an active role in shaping the institutional culture of restraint use. Policy makers can further promote or stimulate these processes by providing clear and binding regulations and by monitoring their implementation in practice. In this way, it may be possible to change nursing staff's attitudes towards restraint use over time.

Construct Validity and Reliability of the MAQ

Regarding the construct validity and reliability of the Attitude scale for its use in hospital settings, we found similar results to those previously reported [25]. Differences were primarily found for Factor 1 (Consequences of restraint use for the patient): two items were removed (item 15 and item 10) and one item (item 13) changed to Factor 2 (Reasons for restraint use), resulting in a higher reliability compared with the original scale (α = 0.83 vs. 0.71). The Discomfort and Restrictiveness scales have so far been analysed and interpreted mostly at the single item level [25-27]. Two of the studies also calculated a mean score of all items [25, 26]. However, information on a possible factor structure or internal consistency is missing. Our factor analysis

shows that there is a two-factor solution for both scales. The internal consistency (α) of the Discomfort scale is 0.78, and that of the Restrictiveness scale is 0.65. Two restraint types were not considered in the factor structure of either scale (*Bedroom door locked and Ward door locked*). These restraint types are unlikely to be used in hospital settings, which might explain the result.

While the scales were only tested for construct validity and reliability in this study, it seems advisable to further develop them. As the data from long-term care and mental health care settings show, changing attitudes towards restraint use seems to be challenging. The measurement of attitude could, therefore, be of use for raising awareness as well as for training purposes, or as a secondary outcome in intervention studies to reduce restraint use. From a content point of view, it should be reviewed whether the scale should be extended/adapted even further to other forms of restraint (e.g., pharmacological) or even extended to the broader concept of involuntary treatment. From a psychometric point of view, it is recommended to use a large sample size for further development and validation of the MAQ since the item-factor loadings are rather low [53, 54]. Moreover, the scales only explain between 35% and 38% of the variance, which also indicates that further development of the scales is suggested. Aside from the instrument-related limitations, it is important to note the rather low participation rate, which limits the generalisability of the results.

CONCLUSIONS

Nursing staff in hospitals have a rather neutral attitude towards restraint use, as has already been found in mental health care and long-term care settings. Although the use of restraint is being critically scrutinised internationally and corresponding ethical guidelines have been developed, hardly any change could be observed in the long-term care setting and only a slight change in attitude has occurred in the mental health care setting over the past several decades. Policy makers and management are obliged to establish conditions that favour a change in attitude. In addition, the further development of instruments for the valid measurement of attitudes towards restraint use is recommended. This could help to monitor whether restraint-reduction initiatives also reach attitudes as an important component in the decision-making process. Such instruments may also be useful in education in order to raise awareness or to take appropriate initiatives early on so that nursing staff develop a critical attitude toward restraint use from the very beginning of their career.

AUTHOR CONTRIBUTIONS

Conceptualization, S.T. and G.G.; Data curation, S.T. and G.G.; Formal analysis, S.T. and G.G.; Investigation, G.G.; Methodology, S.T. and G.G.; Project administration, S.T. and G.G.; Supervision, S.T., S.H., and S.Z.; Visualization, S.T.; Writing—Original draft, S.T.; Writing—Review and editing, G.G., S.H., and S.Z. All authors have read and agreed to the published version of the manuscript.

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INSTITUTIONAL REVIEW BOARD STATEMENT

This study was conducted in accordance with the Declaration of Helsinki. The Ethics Committee of the Canton of Bern approved that the the Swiss Human Research Act (BASEC-Nr: Req-2020-01204, date of approval 21 October 2020) does not apply to this project.

INFORMED CONSENT STATEMENT

Informed consent was obtained from all subjects involved in the study.

DATA AVAILABILITY STATEMENT

The data presented in this study are available from the corresponding author upon reasonable request. The data are not publicly available due to ethical and privacy restrictions.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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CHAPTER 06

RESTRAINT USE AS A QUALITY INDICATOR FOR THE HOSPITAL SETTING: A SECONDARY DATA ANALYSIS

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SUMMARY

Introduction: A reduction in restraint use is recommended for all health care settings. For this purpose, local or national quality measurement and improvement initiatives have been implemented in various countries, primarily in the mental health and long-term care settings. However, restraints are also frequently used in the somatic acute care hospital setting and strong fluctuations in the prevalence rate have been reported. Therefore, the aim of this study was to reanalyse existing data regarding restraint use in Swiss hospitals, to assess the potential of restraint use as a national quality indicator for the hospital setting.

Methods: Data were collected utilising a cross sectional multicentre design in the national 'ANQ (Swiss National Association for Quality Development in Hospitals and Clinics) Prevalence Measurement Falls and Pressure Ulcers' in acute care hospitals in Switzerland, from 2016 to 2018. The hospitals measured restraint use on a voluntary basis, in addition to falls and pressure ulcers. All medical specialities and patients aged 18 and older with informed consent were included in the measurement. Descriptive and multilevel regression analyses were performed using institutional, ward and patient level data, in relation to restraint use.

Results: The sample consisted of 18,938 inpatients from 55 hospitals. The 30-day prevalence rate of patients with at least one restraint was 10.2% (n=1,933). The risk-adjusted hospital comparison revealed that hospitals in Switzerland differed significantly in restraint use, even after adjusting for patient characteristics. In total, 10 hospitals differed positively and 12 hospitals differed negatively from the national average.

Conclusion: Restraint use differs significantly in Swiss hospitals; 40% of all hospitals differed either positively or negatively from the average. In comparison to the other quality indicators, this is a very high value, indicating potential for quality improvement. Since restraint use is associated not only with quality of care, but also with human rights, these large differences seem to be questionable from a professional, ethical and legal point of view. Clearer and binding regulations in combination with monitoring and benchmarking of restraint use in hospitals, such as with a national quality indicator, seem to be necessary. They would help to ensure that restraint use is in alignment with professional values as well as ethical and legal requirements.

KEYWORDS

Restraint, Hospitals, Prevalence, Health Care Quality Indicators, Risk Adjustment

INTRODUCTION

Restraints have been used in health care settings for centuries. In mental health care, there is an increasing awareness of the negative consequences of restraints and, therefore, restraint use is more and more regulated. It has, for example, also become an important quality indicator for inpatient psychiatry for many years [1-3]. Also in the nursing home setting, this restrictive practice is increasingly viewed critically. In Australia, for example, stricter regulations regarding restraint use in residential care settings were introduced in 2019 [4]. In Switzerland, movement restrictive interventions in nursing homes have been monitored at the national level since 2019 [5]. However, with regard to somatic acute-care hospitals (subsequently referred to as 'hospitals'), clear regulations are lacking in most countries and often only recommendations exist. In Canada, for example, recommendations from the Canadian Agency for Drugs and Technologies in Health (CADTH) are available [6]. In Switzerland, a medical-ethical guideline regarding coercive measures in medicine exists, including recommendations for restraint use in general [7].

Restraints are indeed used frequently in hospitals. Internationally, prevalence rates range from 0% to 100% [e.g. 8, 9, 10]. These large differences may primarily be influenced by different definitions of the restraints used, the setting (e.g. intensive care units or general wards), the legal situation in the corresponding country, or the availability of equipment within the institution or on the ward (e.g. belts for mechanical fixation) [11-14]. In hospitals, restraints are frequently used to prevent adverse events such as falls or therapy interruption [10, 15-18]. However, the effectiveness of restraints for these reasons is increasingly being questioned. Various studies reported that restraints had no effect on fall prevention or self-extubation [18-22]. In contrast, there is evidence that restraints in hospitals are associated with negative consequences for patients' physical and mental health [23-25] and with moral distress for health professionals [18, 26]. Thus, based on the available evidence, it cannot be ensured for the hospital setting that the benefits of restraint use exceed the harms, which is a basic ethical requirement for restraint use. Therefore, it is recommended to reduce restraint use as much as possible [6, 27]

In various health care settings, different measures for restraint reduction have been examined. Many studies concluded that individual measures such as education of health professionals can be beneficial; however, national approaches might have an even greater impact [28, 29]. Local or national measurement and quality improvement initiatives are known in the nursing home and mental health

care settings [3, 30-32]. However, national approaches regarding restraint reduction might also be relevant for hospitals. Apart from the considerable differences in prevalence rates described above, there is increasing evidence that restraint use in hospitals also depends on patient-independent factors such as routine, local habits, organisational attitude, hospital structures and policies [11-14, 33-35]. Such factors may be subject to efforts for change when they are recognised by hospital management and staff as being relevant in the reduction of restraint use.

Often, a key aspect of national programs is the measurement and benchmarking of certain clinical performance [36]. Such a comparison can help to critically reflect upon the restraint practice within the ward/institution, and to identify potential for improvement. However, such quality measurements are only meaningful if risk-adjusted differences between hospitals (that take into account the different patient mix) are identified, because this reveals potential for quality improvement [36].

Therefore, the aim of this study was to reanalyse existing data regarding restraint use in Swiss hospitals, in order to assess the potential of restraint use as a national quality indicator for the hospital setting.

MATERIALS AND METHODS

Study design and setting

Data used for the secondary analysis were collected utilising a cross-sectional multicentre design within the national 'ANQ (Swiss National Association for Quality Development in Hospitals and Clinics) Prevalence Measurement Falls and Pressure Ulcers' in Switzerland [37]. The annual measurement of these two indicators is mandatory for all hospitals in Switzerland. In addition to these two indicators, hospitals can measure restraint use on a voluntary basis. For the present study, data from hospitals measuring restraint use at the following three measurement points were included: 08.11.2016, 14.11.2017 and 13.11.2018.

Sample

The sample consisted of patients aged 18 and older, who were hospitalised on one of the reference dates when the measurement took place, and who (or whose legal representative) gave informed oral consent to participate in the overall quality measurement. The documentation of oral consent was the responsibility of the hospitals. It was recommended that consent be recorded in a central document or

in the patient documentation. All medical specialties (ward types) were included, except for maternity, the emergency department and post-anaesthesia care units. Patients who were not available on the ward during the measurement (e.g., undergoing surgery) were excluded. We did not apply any other exclusion criteria for this secondary analysis.

Instrument and data collection

Data were collected utilising the LPZ 2.0 (Landelijke Prevalentiemeting Zorgkwaliteit) instrument (version 2016), which was developed by an international consortium led by Maastricht University in the Netherlands [38, www.lpz-um.eu]. This instrument assesses general and care indicator specific information on institutional, ward and patient levels. In this study, we conducted a secondary data analysis with variables regarding restraint use at all three levels (see Table S1 in the supplementary material). Restraints were defined as 'interventions that may infringe [on] a person's human rights and freedom of movement, including observation, seclusion, manual restraint, mechanical restraint and rapid tranquillisation' [39]. This definition largely corresponds to that of the Swiss Academy of Medical Sciences (SAMS), from which the national language translation for the LPZ 2.0 measurement emerges [7].

The LPZ 2.0 instrument utilises standardised data collection procedures. The entire procedure (e.g., recruitment and information of patients, preparing data collection including documentation of restraint use 30 days prior to data collection) and all questions and answer options are defined across the participating LPZ consortium nations and are described in a manual. Data are collected via an online tool that guarantees completion of the questionnaire. To ensure a uniform execution of the measurement across participating hospitals, data collectors were trained prior to the measurement. Utilising the concept of train-the-trainer, the national coordinator trained a responsible person within each hospital (the institutional coordinator). The institutional coordinator eventually trained the data collectors (registered nurses) on the wards. Additionally, the measurement manual containing all of the information was readily available to the data collectors (directly in the data entry program).

Statistical analysis

The data from the different measurement points from 2016 to 2018 were pooled. Descriptive statistics (numbers, percentages, 95% confidence intervals [CI], median, interquartile range [IQR]) were used to describe the sample.

With regard to benchmarking, a multilevel modelling approach was used. This approach allows for the adjustment of '...patient-level risk factors that are outside the control of providers' [36]. In other words, the different patient mix and, thus, the risk of using more or fewer restraints due to the complexity of the patient situations of each hospital, were considered in benchmarking. A very similar approach is used for the national ANQ Prevalence Measurement Falls and Pressure Ulcers [37]. The model was built according to the following: restraint use was defined as the dependent variable; hospitals were used as a random effect; the variables on the institutional and ward level as well as the general information on patient level were used as fixed effects (see Table S1 in the supplementary material). The ward level could not be included in terms of a third level for the model (i.e. a three-level model could not be built), as restraint use was assessed over a period of 30 days at the hospital level and not at the ward level. Since patient transfers from one ward to another are frequent, there was a risk of misclassification and, thus, bias when including the ward level.

Given the insufficient theoretical database available on restraint use in the hospital setting (with partial exception for mechanical restraint use in the intensive care area), determining the inclusion/exclusion of all possible fixed effects was not possible in a purely theory-driven manner. Since including all possible fixed effects might have led to an overadjustment, we decided on a data-driven model. For the data-driven modelling, we considered variable selection procedures for logistic multilevel models. However, the very few software implementations available were not applicable to our problem. Therefore, we used the Akaike information criterion (AIC) [40] backwards procedure, implemented in the R package 'MASS' [41]. Consequently, the hospital random effect had to be treated as a fixed effect for variable selection. In addition, the AIC procedure was employed so that the hospital variable could not be unselected, as hospital comparison is an explicit part of this study. To reduce the number of noisy variables selected due to the large sample size and thus to enhance the stability of the variable selection, we used a split-half approach, in which the AIC procedure was applied to both of two subsets from a random split of the data. For the final multilevel model, we used only the variables included in both selections. Afterwards, a generalised linear mixed model fit by maximum likelihood (Laplace approximation) was built using the R package 'lme4' [42]. To assess the relevance of the random effect, the Intraclass Correlation Coefficient (ICC) was estimated, and a log-likelihood ratio test was performed. Afterwards, a caterpillar plot was built with all hospitals on the x-axis and their residuals and 95%-confidence intervals on the y-axis.

The ICD-10 diagnosis groups [43], 'Pregnancy, childbirth and the puerperium'; 'congenital malformations, deformations and chromosomal abnormalities'; and 'certain conditions originating in the perinatal period', as well as the answer option unknown/no diagnosis, had to be excluded, as they were present in less than 1% of the patients. The inclusion of these variables would have led to convergence problems in variable selection. In addition, the variables 'age in years' and 'number of days since admission to hospital' had to be centred for similar reasons. Multicollinearity was tested using the variance inflation factor (VIF). There were no missing data, as the online data entry program allowed the finishing of the survey only if all questions were answered.

The statistical analysis was conducted utilising R Version 4.0.1 [44] and the R Packages 'compareGroups' [45], 'Hmisc' [46], 'lme4' [42], 'jtools' [47], 'MASS' [41], 'MuMIn' [48], 'sjPlot' [49] and 'tidyverse'[50].

Ethical considerations

The Ethics Committee of the Canton of Bern declared that the present study was not subject to the Swiss Human Research Act (April 2019, BASEC-Nr: Req-2019-00259); therefore, ethical approval was not required. All patients or their legal representatives received written information about the measurement and gave their oral informed consent. Data were collected pseudonymously, so that no conclusions could be made regarding the individual patients. Participation was voluntary.

RESULTS

The sample consisted of 18,938 patients who were hospitalised in 55 hospitals (see Table 1). The participation rate was 76.6% (n=18,938/24,736) across all three years. The 30-day prevalence rate of patients with at least one restraint was 10.2% (n=1,933/18,938). Detailed information regarding restraint type (e.g. mechanical, pharmacological or electronical) used; reason for restraint use (e.g. fall prevention or aggression); and processes surrounding restraint use (e.g. documentation or evaluation) as well as the distribution of the sample across hospital and ward types are available in the supplementary material.

For 68.7% (n=13,016/18,938) of the patients there were guidelines regarding restraints in the respective hospitals on an institutional level and for 34.3% (n=6,503/18,938) of the patients there was a multi-disciplinary expert committee regarding restraints available. At the ward level, 66.7% (n=12,635/18,938) of the

patients surveyed were hospitalised in wards where regular audits were carried out to ensure compliance with the guidelines regarding restraints. Nursing staff had attended a refresher course regarding restraints in 10.5% (n=1,980/18,938) of all patient situations.

Table 1: Sample description

Characteristics	**Total (n=18,938)**	
Institutional level	**n**	**% (95% CI)**
Availability of a guideline regarding restraints (yes)	13,016	68.7 (68.1-69.4)
Availability of a multi-disciplinary expert committee regarding restraints (yes)	6,503	34.3 (33.7-35.0)
Ward level		
Performance of regular audits to ensure compliance with the guideline regarding restraints (yes)	12,635	66.7 (66.0-67.4)
Refresher course regarding restraints in the last two years for at least 80% of the wards' nursing staff (yes)	1,980	10.5 (10.0-10.9)
Patient level	**median**	**IQR**
Age in years	70	24
Number of days since admission to hospital	5	9
Care Dependency Scale (sum score)[a]	70	15
	n	**% (95%-CI)**
Female gender	9,031	47.7 (47.0-48.4)
Surgical intervention in the two weeks prior to data collection (yes)	7,667	40.5 (39.8-41.2)
Three most frequent ICD-10 diagnosis groups (multiple responses)		
Diseases of the circulatory system	10,757	56.8 (56.1-57.5)
Diseases of the musculoskeletal system and connective tissue	6,829	36.1 (35.4-36.7)
Endocrine, nutritional and metabolic diseases	6,432	34.0 (33.3-34.6)
Restraint use (yes)	1,933	10.2 (9.8-10.6)

IQR=interquartile range, 95% CI=95% confidence interval,
ICD-10=International Statistical Classification of Diseases and Related Health Problems 10th Revision [43], [a]Care dependency assessed utilising the Care Dependency Scale (CDS) [51]. In the CDS, 15 items (e.g., eating and drinking or mobility) are rated on a Likert scale from 1 (completely dependent) to 5 (completely independent). It results in a sum score of 15-75 (higher score indicating higher care independency) or five categories (5-24 completely dependent, 25-44 dependent to a great extent, 45-59 partially dependent, 60-69 independent to a great extent, 70-75 completely independent)

Several factors associated with restraint use were found in the multilevel regression analysis (see Table 2). Patients' care dependency showed the strongest association with restraint use (odds ratio [OR] 52.65, 95% confidence interval [CI] 41.71-66.48 for completely dependent patients in comparison to completely independent patients). Furthermore, a strong association between mental and behavioural

disorders and restraint use was found (OR 2.22%, 95% CI 1.97-2.49). Regarding the organisational factors, no factor was selected for the model.

In total, 35% of the variation in restraint use could be explained by fixed effects (selected patient characteristics; marginal R^2 0.35). The full model, including the random effect (hospital as cluster variable), explained 43% of the variation in restraint use (conditional R^2 0.43). Based on the ICC (0.12) and the log-likelihood ratio test (*p*-value < 0.000), there was relevant and significant between-hospital variability underlining the relevance of hospital as random effect, thus indicating great potential for benchmarking the use of restraint across hospitals.

Table 2: Multilevel logistic regression model

Model: AIC 9025.02; Marginal R^2 = 0.35; Conditional R^2= 0.43; ICC=0.12	
Random effect	**Variance (SD)**
Hospital (Intercept)	0.45 (0.67)
Fixed effects	**OR (95% CI)**
(Intercept)	0.02 (0.01-0.02)*
Age in years	1.01 (1.01-1.02)*
Female gender	0.71 (0.64-0.79)*
Number of days since admission to hospital	1.01 (1.01-1.01)*
Care Dependency Scale (CDS) ≥ 70 completely independent	Reference
≥ 60-69 to a great extent independent	3.37 (2.80-4.07)*
≥ 45-59 partially dependent	9.74 (8.11-11.71)*
≥ 25-44 to a great extent dependent	27.42 (22.50-33.42)*
≤ 24 completely dependent	52.65 (41.71-66.48)*
ICD-10 diagnosis group: Mental and behavioural disorders	2.22 (1.97-2.49)*
ICD-10 diagnosis group: Factors influencing health status and contact with health services	1.33 (1.12-1.58)*
*statistically significant based on the 95% CI	
AIC= Akaike information criterion, ICC=intraclass correlation coefficient, SD=standard deviation, OR=odds ratio, 95% CI=95% confidence interval ICD-10=International Statistical Classification of Diseases and Related Health Problems 10th Revision	

The risk-adjusted hospital comparison (Figure 1) showed that hospitals in Switzerland differ significantly in restraint use even when adjusting for patient characteristics. In Figure 1, it is shown that 10 hospitals differed positively (i.e. showed lower restraint rates in comparison to other institutions), and 12 hospitals differed negatively (i.e. showed higher restraint rates), in a clinical sense, from the average.

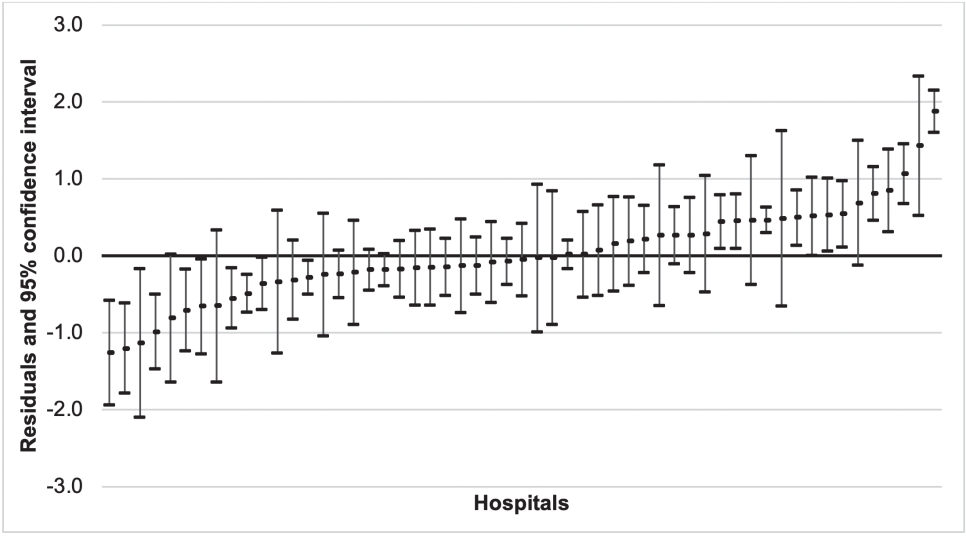

Figure 1: Risk-adjusted restraint use hospital comparison (residuals and 95% CI)

DISCUSSION

In this secondary data analysis of cross-sectional data regarding restraint use in Swiss hospitals, we found a restraint prevalence of 10.2%. A strong association was detected between restraint use and care dependency of patients, as well as for patients with mental and behavioural disorders. Furthermore, Swiss hospitals differed significantly regarding restraint use, even after the adjustment for risk (taking into account the different patient-mix and, thus, the different risk of hospitals for using restraints). Overall, 22 out of 55 hospitals differed significantly, either positively or negatively, from the average.

The 55 participating hospitals reflect about one quarter of all hospitals in Switzerland. The characteristics of the patients included are comparable to those of the mandatory fall and pressure ulcer measurements, carried out using the same methodology [37]. Consequently, it can be assumed that the sample is likely to be representative for Swiss hospitals. The restraint prevalence of 10.2% also includes electronic measures such as sensor mats or video surveillance, whereas most other studies in the hospital setting only examined mechanical restraint with belts. Therefore, a comparison of the prevalence rates is not possible. However, as reported by Thomann et al. [10], mechanical restraint with belts consists of only 9.7% of all mechanical restraints used in Swiss hospitals.

Based on the multilevel regression analysis, a very vulnerable patient group, i.e. older, more care dependent and with mental and behavioural disorders, seemed to be most affected by restraint use. This result is ethically highly relevant, as restraint use affects a group of patients who are often unable to defend their own rights. Therefore, it seems even more important that any use of restraints is critically analysed from both an ethical and a legal point of view. In this context, it is important to note that restraint use often violates a basic ethical principle: the expected positive health effects must exceed the harm. The positive effects of restraints in the hospital setting have not yet been proven [14, 18, 22].

Based on the risk-adjusted benchmarking, we found that restraint use differs significantly in Swiss hospitals. The caterpillar plot shows that 40% of all hospitals differ significantly either positively or negatively from the average. In comparison to other quality indicators, this is a very high value. For example, the same data collection and a very similar statistical method was utilised for the national 'ANQ Prevalence Measurement Falls and Pressure Ulcers'. In these measurements the number of outliers only varied between 0% and 8% during the past measurements [37]. In other words, the care quality regarding falls and pressure ulcers differed only slightly between Swiss hospitals. In contrast, there are relevant differences in restraint use. Such differences indicate potential for improvement [52]. Based on the results of this study, it remains unclear as to how the differences can be explained, especially as none of the included structural characteristics (guideline, expert committee, audits, refresher course) were selected for the model. Thus, it remains unclear as to which quality improvement measures could be effective in reducing restraint use.

Nevertheless, as mentioned above, factors that are difficult to measure, such as routine, institutional culture or attitudes, may have an influence on the results. Since restraint use is associated not only with quality of care but also with human rights, it seems legally and ethically problematic if decision-making is based on (individual) opinions, attitudes or culture. Clearer, binding regulations and the promotion of critical scrutiny of hospital internal restraint practice could help to address the dilemma of legal certainty versus practical challenges (e.g., patients with cognitive impairment) [26]. Thus, there seems to be a lot of potential for restraint use as a quality indicator for hospitals.

Restraint use is a very sensitive issue and clear, binding legal regulations for hospitals are lacking [10]. Therefore, a national approach for quality measurement and development seems to be indicated. Firstly, such an approach would

encourage discussion of the issue among policymakers, professional organisations and society. This would result in the establishment of the necessary structures at a macro level, which is an important element of quality development [36]. Secondly, a national approach consisting of monitoring and benchmarking would stimulate critical interprofessional discussions both at different management levels within institutions and in direct patient care. Such interprofessional discussions throughout the organisation of a hospital are needed to reflect and address the institutional culture or routine, which seem to play an important role in the use of restraints [14, 53]. Thirdly, a national approach could also contribute to improving the current lack of data and evidence on restraint use in hospitals [54]. This would then enable the development and implementation of a (national) quality improvement program. Consequently, interprofessional decision-making based on evidence would be promoted, instead of decision-making being based on personal opinions, intuition or institutional culture. An adequate database would also allow the examination as to what extent concepts for better restraint prevention and management from long-term care or mental health settings could be adapted for the hospital setting.

CONCLUSION

Although restraint use potentially violates human rights, there are no clear and binding legal regulations for their application in hospitals, although it is well-known that they are frequently used in this setting. This study highlights large risk-adjusted differences between Swiss hospitals regarding restraint use. These differences seem questionable from a professional, ethical and legal point of view. Therefore, monitoring and benchmarking restraint use in hospitals in terms of a national quality indicator seems to be needed. This would help ensure that restraint use is in alignment with professional values as well as ethical and legal requirements. Additionally, this would stimulate quality improvement in this area and guarantee high quality care among Swiss hospitals.

LIMITATIONS

A first limitation might be the definition of restraints used. As can be expected, not all restraint types restrict freedom and human rights to the same extent, so it would be worth examining whether restraints should be analysed separately for each restraint type. Nevertheless, even measures such as a sensor mat are a restrictive intervention for which the evidence has not yet been proven [7, 22]. On the contrary, it is currently

a topic of discussion as to whether the risk of undesirable events increases when such electronic measures are used without reflection, thereby causing 'alarm fatigue' [22]. Furthermore, the Swiss Academy of Medical Sciences guidelines in Switzerland also include electronic restraints, emphasising the need for critical reflection regarding their use and, therefore, the need to measure them as with all other restraint types [7]. We were not able to comprehensively cover the complexity of the diversity of restraint measures. Different restraint measures have different impacts on the affected patients, both objectively and subjectively. It is, however, for example unclear whether mechanical restraints are felt subjectively worse than pharmacological interventions. Much more sophisticated research is needed to gain more insight into this matter.

A second limitation within this measurement is that a potentially very vulnerable patient group who is predominantly affected by restraint use (older patients, more care dependent patients and/or patients with cognitive impairment) might have been excluded, as they were not able to give informed consent. Therefore, a selection bias may exist. A third limitation could be the possibility of a recall or documentation bias, as restraint use was assessed over a period of 30 days within the institution. It is known that the use of restraints is often not well-documented; therefore, it would not have been assessed within this measurement [10, 18]. Consequently, the results could have been underestimated. The assessment of restraint use over a 30-day period at the hospital level also had the consequence that the ward level could not be included in the multilevel modelling (i.e. a three-level model could not be built; see the Methods section). Since restraint use might differ depending on ward type and thus would give important information on intra-hospital variation, future studies should assess restraint use on the ward level.

Some limitations must also be expected due to the cross-sectional design and the instrument used. The cross-sectional design favours fluctuations in the population assessed, and a detection of causal associations and/or the direction of the association is not possible. For example, care dependency could be the reason for, but also a consequence of restraint use. The instrument utilised included only certain organisational factors that were not selected for the model. In order to stimulate quality improvement, it would be worth examining which organisational factors are associated with restraint use. Due to the limited evidence available, some relevant patient characteristics for risk-adjustment might also be missing. A more in-depth investigation of risk factors to ensure adequate risk adjustment is necessary.

In addition, the hospital types were not considered in this analysis. However, we assumed that the care dependency acted as a kind of proxy variable in this

context, as the complexity of the patient cases and consequently the extent of (medical) care needed is relevant for the differences between hospital types. Also, due to hospital mergers, there is a risk of inadequate classification, as the hospital group classification may not be accurate for all hospital sites in a hospital group.

Apart from these limitations, the results are likely to be generalisable for Swiss hospitals, as the large sample studied is comparable with the population assessed in the national 'ANQ Prevalence Measurement Falls and Pressure Ulcers' in Swiss hospitals [37]. In addition, the data collection method is well-established in Swiss hospitals and is expected to have a positive impact on data quality.

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POTENTIAL COMPETING INTERESTS

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the Swiss National Association for Quality Development in Hospitals and Clinics; however, restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available.

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SUPPLEMENTARY MATERIAL

Detailed information regarding variables (Table S1), hospital and ward types (Table S2), restraint type (Table S3), reason for restraint use (Table S4) and processes surrounding restraint use (Table S5). A discussion of restraint type, reason for restraint use and process surrounding restraint use can be found in Thomann et al. [10].

Table S1: Variables

Level and variable	Details
Institutional level	
– Availability of a protocol/guideline regarding restraints (based on a national/international guideline) within the institution	Yes/no
– Availability of a multi-disciplinary expert committee regarding restraints within the institution	Yes/no
Ward level	
– Performance of regular audits to ensure compliance with the protocol/guideline regarding restraints	Yes/no
– Assessment regarding if at least 80% of the ward's nursing staff had attended a refresher course regarding restraints in the last two years	Yes/no
Patient level	
– Age in years	Continuous
– Sex	Female, male
– Surgical intervention in the two weeks prior to data collection	Yes/no
– Number of days since admission to hospital	Continuous
– Medical diagnosis groups according to ICD-10 (International Statistical Classification of Diseases and Related Health Problems 10th Revision) [43]	For each diagnosis group yes/no
– Care dependency assessed utilising the Care Dependency Scale (CDS) [51]. In the CDS, 15 items (e.g., eating and drinking or mobility) are rated on a Likert scale from 1 (completely dependent) to 5 (completely independent). It results in a sum score of 15-75 (higher score indicating higher care independency) or five categories (5-24 completely dependent, 25-44 dependent to a great extent, 45-59 partially dependent, 60-69 independent to a great extent, 70-75 completely independent)	Continuous or ordinal
– Restraint use within the institution retrospectively over a maximum period of 30 days	Yes/no

Table S2: Sample description - hospital and ward type

Characteristics	**Total (n=18,938)**	
Hospital type[a]	**n**	**% (95% CI)**
Centre care hospital	8,642	45.6 (44.9-46.3)
University hospital	7,384	39.0 (38.3-39.7)
Primary care hospital	2,537	13.4 (12.9-13.9)
Specialised hospital	375	2.0 (1.8-2.2)
Ward type		
Surgical	8,576	45.3 (44.6-46.0)
Non-surgical (medical)	7,154	37.8 (37.1-38.5)
Acute geriatrics	950	5.0 (4.7-5.3)
Intensive care	784	4.1 (3.9-4.4)
High dependency care	411	2.2 (2.0-2.4)
Gynaecology	409	2.2 (2.0-2.4)
Other	401	2.1 (1.9-2.3)
Short stay	147	0.8 (0.7-0.9)
Palliative care	106	0.6 (0.5-0.7)
[a]hospital types (specialisation) according to the Swiss Federal Office of Public Health [55]		

Table S3: Restraint type

Patients with restraint (n)		1,933
Proportion restraint type (multiple responses)	**n**	**% (95% CI)**
Mechanical restraints	1,125	58.2 (56.0-60.4)
Proportion type of mechanical restraint (multiple responses, only available for 2018)		
n participants 2018		*6,344*
n mechanical restraint (yes) 2018		*454*
Bed rails	*397*	*87.4 (84.0-90.4)*
Other mechanical restraint	*85*	*18.7 (15.2-22.6)*
Belt fixation	*43*	*9.5 (6.9-12.5)*
Tabletop/chair table	*43*	*9.5 (6.9-12.5)*
Electronic restraints	694	35.9 (33.8-38.1)
Pharmacological restraints	504	26.1 (24.1-28.1)
Other	281	14.5 (13.0-16.2)
One-to-one supervision[a]	202	10.5 (9.1-11.9)
Physical restraints (keeping someone restrained with human physical force)	67	3.5 (2.7-4.4)
Locked ward or building	57	2.9 (2.2-3.8)
[a]Answer option was only available for 2017 and 2018 (n participants=12,560)		
95% CI=95% confidence interval		

Table S4: Reasons for restraint use

Patients with restraint (n)		1,933
Main reason for restraint use (single response)	**n**	**% (95% CI)**
(Preventing) Falls	935	48.4 (46.1-50.6)
Confusion or delirious behaviour	419	21.7 (19.9-23.6)
Other motive	190	9.8 (8.5-11.2)
Agitation	106	5.5 (4.5-6.6)
Request of the patient and/or family	99	5.1 (4.2-6.2)
Non-compliance with treatment	68	3.5 (2.7-4.4)
(Preventing) Wandering around	37	1.9 (1.4-2.6)
Unknown	18	0.9 (0.6-1.5)
(Preventing) Aggressive behaviour	15	0.8 (0.4-1.3)
95% CI=95% confidence interval		

Table S5: Processes surrounding restraint use

Patients with restraint (n)		1,933
Process indicators (multiple responses)	**n**	**% (95% CI)**
The restraining was documented in the patient file	1,270	65.7 (63.5-67.8)
The patient and/or the legal representatives were informed about the entire process surrounding the use of restraints	985	51.0 (48.7-53.2)
In each shift a person/nurse was appointed to monitor the patient undergoing restraining regularly, according to the defined prescription	858	44.4 (42.2-46.6)
The use of restraints was evaluated with all persons involved (including the patient)	836	43.2 (41.0-45.5)
Primarily alternatives were used to minimise the use of restraints	724	37.5 (35.3-39.7)
None	208	10.8 (9.4-12.2)
95% CI=95% confidence interval		

CHAPTER 07

GENERAL DISCUSSION

The aim of this thesis was to describe restraint use in hospital settings comprehensively, independently of subpopulations and specific restraint types, and to identify influencing factors on different levels (micro, meso and macro). This included prevalence, reasons for restraint use, the implementation of processes, the availability of structures, influencing patient characteristics, hospital characteristics and the attitude of the nursing staff towards restraint use. The findings revealed areas that have potential for restraint reduction and practice improvement. In this general discussion, the findings of this thesis are summarised, then methodological and theoretical reflections are presented including corresponding recommendations and implications for (clinical) practice and future research.

MAIN FINDINGS

- Restraints are used frequently in the hospital setting and affect a vulnerable patient group (micro level)

This thesis highlighted that restraint use is common in the hospital setting in Switzerland and Austria. Almost 1 out of 11 patients admitted were restrained. More precisely, the prevalence of restraint use for the hospital setting in general, regardless of subpopulations or restraint type, was 8.7%. Bed rails were the most commonly used restraint in the hospital setting. However, electronic restraints (e.g. sensor mats) and pharmacological restraints (e.g. psychotropic medication) were also used frequently. Restraints were mainly used to prevent falls. In general, a very vulnerable hospital patient group is most affected by restraint use: higher care dependency and mental and behavioural disorders are associated with a significantly higher use of restraints. [Chapter 2]

- Processes to ensure that restraint is used as a last resort and in accordance with ethical and legal requirements are not implemented systematically (micro and meso levels)

Although restraint is used frequently, the required ethical and legal processes were not implemented systematically, had a weak standardisation and varied depending on the restraint type. There is a tendency that the more obvious the restriction of movement the better the standardisation and implementation of processes. Besides processes that take place during restraint use (documentation, evaluation, monitoring, information), the implementation of preventive and alternative measures to reduce restraint use was poor. Alternatives were only used in 1 out of 3 restrained patients to minimise the use of restraints. Nevertheless, nurses seem to use many interventions in their daily practice that are potentially related to the prevention/reduction of restraint. These include distraction and

occupation of the patient or promotion of orientation and self-awareness, among others. However, these preventive interventions appear to be hardly perceived and used purposefully for restraint reduction. [Chapters 2 and 4]

- The decision to (not) use restraint depends on nurses and their personal and professional background and corresponding assessment of the patient's situation (micro level)

Nurses play an essential role in the decision-making process and implementation of restraints. Their actions seem to be shaped by their awareness of using measures that have ethical and legal dimensions, the expected benefits of restraints, knowledge about restraint use, their personal well-being in the situation and their attitude towards restraints. With regard to the latter, nursing staff in hospitals seem to adopt a neutral attitude towards restraint – they neither favour nor critically question its use. Basically, there is a strong individual component in restraint management depending on the respective nurse and his/her routines and intuition. [Chapters 4 and 5]

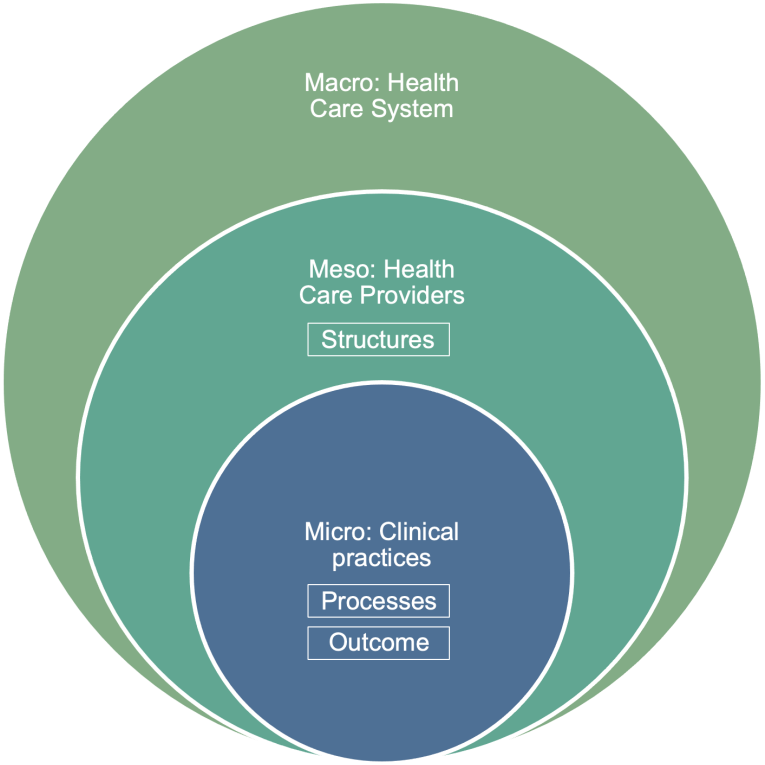
- The conditions within hospitals have a relevant influence on restraint use and show potential for improvement (meso level)

A relevant part of the variance in restraint use could be explained at the hospital level. The availability of a guideline on restraint use and a refresher course on restraint use for nursing staff are associated with a significantly lower use of restraint. While 3 out of 4 patients were treated in a hospital that has a guideline regarding restraint use, only 1 out of 5 patients was treated in a hospital where nursing staff had received recent training regarding restraint use. [Chapter 3]

- Restraint use might be a relevant national quality indicator for the hospital setting (macro level)

We found that 2 out of 5 hospitals use significantly more or less restraints than the average even when adjusted for the different patient mix. Thus, there are hospitals that should strive for internal quality improvements because they use more restraints than the average. However, an overall quality improvement also seems possible, as there are also hospitals that use even fewer restraints than the average. Therefore, and also in relation to the improvement possibilities regarding the degree of fulfilment of structural and process characteristics, restraint use could be suitable as a national quality indicator for the hospital setting. [Chapters 2, 3 and 6]

The main findings are summarised in the following Figure 1 in relation to the theoretical framework used at the three levels (macro, meso [including structures according to Donabedian's model] and micro [including processes and outcomes according to Donabedian's model]).



- Restraint use differs significantly among hospitals even when considering the different patient mix
- Restraint use might be a relevant national quality indicator for the hospital setting

[Chapter 6]

- Conditions within hospitals have a relevant impact on whether restraints are used
- Structures within hospitals show potential for improvement

[Chapters 3 and 4]

- Nurses and their individual assessment of the patient's situation lead the restraint use decision
- Restraints were used in 8.7% of patients
- Patients with higher care dependency and/or mental and behavioural disorders have an increased risk for being restrained
- Processes that include ethical and legal requirements are not implemented systematically

[Chapters 2, 4 and 5]

Figure 1: Summary of main findings along the different levels of the theoretical framework used

METHODOLOGICAL REFLECTIONS

The aim of this thesis was to describe restraint use in hospitals as comprehensively as possible, as the limited available data could have been part of the reason why previous reduction measures in hospitals have hardly been effective. Accordingly, a certain degree of generalisability was pursued in this thesis. To assess how the methodological approach complied with this goal and how trustworthy and meaningful the results are, the internal and external validity of the findings are discussed below.

Internal validity of the findings

The use of an internationally established and proven instrument for data collection (LPZ 2.0 [Landelijke Prevalentiemeting Zorgkwaliteit]) [1] and the combination of different methodological approaches had a positive effect on the internal validity of this thesis findings. The LPZ 2.0 instrument was used for data collection in three out of the five studies (Chapters 2, 3 and 6). In addition to its scientific validation, this instrument has been used in hospital settings in Switzerland and Austria for several years. Thus, the people responsible for data collection in the hospitals are experienced in using this instrument, which is likely to have had a positive effect on data quality. Quantitative data collection was supplemented with qualitative data collection, namely an unstructured participant observation (Chapter 4). This participant observation made it possible to investigate restraint practice independently of institutional culture and routines, an endeavour in line with the aim of describing restraint use in hospitals as comprehensively as possible. Thus, aspects and associations in daily restraint practice could be detected that previously had not been or had hardly been described. In addition, the Maastricht Attitude Questionnaire (MAQ) [2, 3] was used in Chapter 5 to assess the attitude of the nursing staff towards restraint use. To improve the internal validity of the findings, this instrument was reviewed with regard to construct validity, as the instrument originates from the long-term care setting. This triangulation of methods brought different perspectives to describe restraint use in hospitals. In addition, this approach helped to prevent observer bias because data were collected from different perspectives (data collection by trained nurses in practice, survey of nursing staff and direct observation). Furthermore, all data were analysed by a team of researchers, meaning that a kind of investigator triangulation took place. This prevents findings from being biased based on the expectations of individual researchers. The findings of this thesis, resulting from this approach with triangulation, proved to be complementary. No contradictions emerged.

However, some limitations regarding the internal validity of the findings of this thesis have to be considered. The data collection with the LPZ 2.0 could be subject to recall/documentation bias and selection bias. Using the LPZ 2.0 for data collection on restraint use, the patient documentation can be used as a data source. However, the results of this thesis (Chapter 2) as well as previous findings [4-8] show that restraint use is not systematically documented. Thus, restraint use might be underestimated in this thesis. In addition, data collection with the LPZ 2.0 requires patient consent. Patients who could not give their consent due to their health condition and where no legal representative was available had to be excluded. Thus, patients potentially at high risk for restraint use had to be excluded from the data collection, which in turn could have also led to underestimation of restraint use in this thesis. Furthermore, the quantitative data are based on cross-sectional studies, which limits the ability to establish causality of the discovered associations. Based on the available findings, it cannot be determined whether, for example, a higher care dependency increases the risk of restraint use or whether a higher care dependency is a consequence of restraint use. Limitations with regard to triangulation also have to be considered. In the indicated investigator triangulation, most of the people involved had a nursing background. The perspectives of patients, relatives and other health professionals involved in restraint use were missing.

More from a theoretical-methodological point of view, reflection is needed on the definition of restraint use and its influence on the findings. So far, the majority of research in hospital settings has focussed on mechanical restraint, and corresponding clinical guidelines have been developed. Consequently, hospitals may define restraint in their guidelines only as mechanical restraint, and accordingly, only mechanical restraint may be recorded in a standardised way in their patient documentation systems. Therefore, the non-systematic implementation of process indicators identified in Chapter 2 could be attributed to the definition of restraint. In hospitals whose documentation systems only allow recording mechanical restraint, no systematic recording of, for example, electronic restraint can take place. Furthermore, assessment of the attitude of nurses and their perception of the restrictiveness of different types of restraint for patients in Chapter 5 could be related to the definition of restraint. For a long time, and often even today, awareness has been raised about the problem of mechanical restraint, and other restraint types such as sensor mats have been recommended as alternatives [9, 10]. Thus, these findings could be influenced by socialisation of health professionals in education and practice as to what restraint encompasses. As

this broader definition was applied to all studies, they could have been influenced similarly. Hence, it is possible that the findings are particularly indicative of potential for improvement in restraint types other than mechanical ones.

These reflections on internal validity indicate that the extent of restraint use might have been underestimated in several respects in this thesis. Restraints are probably used more frequently and affect a group of patients that may be even more vulnerable than described in this thesis. In addition, the majority of the findings represent the nursing perspective. However, restraints are used in an interprofessional context and with the involvement of relatives and patients. Their perspective is not sufficiently represented in this thesis.

External validity of the findings

The external validity of the findings of this thesis was positively influenced by data triangulation. The multicentre approach helped prevent the results from being biased by the conditions of individual hospitals (meso level, Chapters 2, 3 and 6). The inclusion of data from two countries minimised to an extent the potential influence of the conditions at the macro level (health care system) on the results (Chapters 2 and 3). In addition, data from different measurement points were pooled, an approach that at least partially counteracts the limitations of the cross-sectional designs (Chapters 2, 3 and 6). This data triangulation resulted in findings based on large data sets that represent the range of hospital care. Furthermore, in accordance with the aim of this thesis, there were no further specifications with regard to patients and restraint types. Thus, the findings not only included more studied disciplines and restraint types such as fixation with belts in intensive care, but all restraint types and disciplines. In addition, all nursing staff were included in Chapters 4 and 5 – not only registered nurses. This reflects the reality that restraints are used by registered nurses as well as nursing staff of other qualification levels. Therefore, the findings can be generalised to an extent to the hospital setting.

However, when considering generalisability, it is important to recognise that legal regulations at the macro level can have a substantial influence on restraint use. Thus, generalisability might be limited if there are relevant legal conditions that are different than what are present in Switzerland and Austria. In addition, restraint use is an interprofessional topic, but the findings of this thesis refer primarily to the nursing profession. Because there are few comparable studies, the assessment of external validity in this thesis is limited. It will become even more differentiated when the body of knowledge on restraint use in hospitals is expanded.

THEORETICAL REFLECTIONS

The title of this thesis *"Restraint use in somatic acute care hospitals: do we need to care?"* raises the question of whether we need to care about restraint use in hospitals. Based on the findings of this thesis, the answer is yes. However, to understand its implications, theoretical reflections are needed regarding three key themes: 1) the definition of restraints, 2) advocacy as a key nursing role in restraint use and 3) starting points for changing restraint practice. These three somewhat interconnected themes are discussed below.

The definition of restraints

In this thesis, restraint was defined as "interventions that may infringe [on] a person's human rights and freedom of movement, including observation, seclusion, manual restraint, mechanical restraint and rapid tranquillisation" [11]. This definition is not limited to mechanical restraint such as fixation belts or bed rails; it also includes any form that restricts the freedom of patients in hospitals. However, the findings of this thesis show that this broader understanding of restraint has not yet been fully implemented in practice. On the one hand, this was shown in Chapter 4 by the different degree of process standardisation depending on restraint type: the more obvious a restraint restricts the free body movement the better the standardisation was. On the other hand, nursing staff perceived some restraint types as not being restrictive for patients, in particular sensor alarms (Chapter 5). These differences in implementation and perception by restraint type may be driven by research, regulation and quality improvement initiatives that have focussed on mechanical restraints for a long time. Indeed, electronic restraints such as sensor alarms have often been suggested as an alternative to mechanical restraints [9, 10]. A problem that could arise from focussing on mechanical restraints is that the use of restraints is not reduced. Rather, there could be a shift in the type of restraint, as an example from the United Kingdom highlights [12]. After the rates of mechanical restraints were publicly reported, there was a reduction in the use of mechanical restraints in nursing homes between 1999 and 2008. Importantly, there were differences between nursing homes that were subject to reporting restraint use and those that were not. The rate of mechanical restraint decreased more in the nursing homes that had to report their rates than in the other nursing homes. At the same time, the proportion of antipsychotic use – that is, potential pharmacological restraint – increased more in the nursing homes reporting their rates than in the others.

The problem of a shift in restraint type instead of a reduction in restraint use is increasingly being recognised. For example, since 2020 any form of involuntary treatment (including restraint use) for people who receive care has been regulated by law in the Netherlands [13]. In Switzerland, medical-ethical guidelines regarding coercive measures in medicine that includes any form of freedom restriction – for example, permanent (electronic) observation – was introduced 2015 [14]. In Australia, a 2021 legislative change replaced the term restraint with restrictive practice to strengthen the regulation for any restriction of personal freedom [15]. What these developments have in common is that they have all been in place for only a short time. Accordingly, most research and practice development are still focussed on mechanical restraints [9, 16, 17]. However, the findings of this thesis have revealed that a relevant proportion of restraints in hospitals reverts to restraint types other than mechanical restraints, like electronic restraints (Chapter 2). Furthermore, given digital and technological progress, such electronic restraints are increasingly available in very subtle forms such as infrared systems. Moreover, new devices are regularly being developed with the intention of making care easier and safer. However, there are devices that will be recognised as forms of restraint according to ethical and legal assessment. To take this ongoing development of devices into account and to prevent a shift from a device that has already been recognised as a form of restraint to a device that has not yet been recognised as a form of restraint, it seems important that research, education and practice apply a broad definition of restraint that includes any form that restricts a patient's freedom. This is the only way to ensure that any form of restraint is used only as a last resort in patient care.

Advocacy as a key nursing role in restraint use

Restraint use potentially violates a patient's human rights – and it is the task of nurses to protect a patient's rights and to advocate on behalf of a patient's interest [11, 18]. In particular, the lack of evidence for the effectiveness of restraint use in hospital settings demands a critical reflection of restraint use from ethical and legal points of view [6, 9, 19-21]. Moreover, the present thesis confirms previous findings that a very vulnerable patient group (older, care dependent, with cognitive and behavioural disorders) is most affected by restraint use in hospitals [Chapters 2 and 3; 5, 9, 22, 23, 24]. Thus, the patients most affected by restraint are likely unable to advocate themselves. Furthermore, due to demographic trends, an increase in the number of patients at risk for restraint use in hospitals is to be expected if practices

do not change. In this context, nurses play an important role in several respects: on the one hand, according to the definition of nursing of the International Council of Nurses [18], it is their task to advocate for the patient's interests. On the other hand, they are the main decision-makers for restraint use in hospitals [Chapter 4; 6, 25, 26]. Thus, it is their task to prevent restraint use in the interest of the patient and at the same time, as the main decision-makers, they are in a position to do so.

To enable nurses to use their position as decision-makers in favour of restraint-free care, it is important that they are appropriately trained and qualified. So far, research has indicated that nurses in hospitals often have insufficient knowledge about restraint use [6, 27-30]. However, this knowledge is essential for making a differentiated ethical assessment of benefits and harms. In addition, it is important that nurses are aware of what alternatives or preventive measures are available. Here, too, it is evident that nurses are often unaware of alternatives or consider them to be unavailable [26, 31, 32]. However, as the findings show (Chapter 4), nurses use many preventive and alternative interventions in daily care, but hardly with the intention of reducing restraint use (e.g. promotion of orientation and self-awareness, proactive communication or distraction and occupation of the patient). This means that within the existing possibilities and knowledge, a change in restraint practice could be achieved if these interventions were used more systematically and purposefully to reduce restraint. Besides knowledge about restraint use, it is also important that nurses have the appropriate qualifications. As studies from the long-term care sector show, expectations of relatives might be a barrier for not using restraints [33]. In addition, there might be different assessments within the (interprofessional) team as to whether restraints are necessary in a certain patient's situation. Therefore, it is important that nurses can convincingly argue why restraint use is not appropriate in a patient's situation and what other measures could be used to ensure the patient's safety. According to the European Qualifications Framework [34], such requirements can be fulfilled from the qualification of registered nurse (level 6) onwards. Thus, it is obvious that a change in restraint practice requires well-qualified nurses who can critically question practice and make and argue decisions that are in the best interest of the patient.

Advocating for the patient requires nurses to recognise the patient's interests. Patients at risk for restraint use are often cognitively impaired and they may have difficulty verbalising their own wishes. Therefore, nurses need to be enabled to determine the patient's perspective and by doing so identify trigger for as well as

consequences of restraint. For example, they could recognise when the patient is overwhelmed with the situation in the hospital, leading to agitation (Chapter 4), or when a patient feels disturbed by constant electronic monitoring, even if he/she cannot express this verbally. This insight allows nurses to implement effective solutions to promote the patient's well-being. In addition, advocating for the patient demands the nurse to critically reflect on his/her own attitudes and routines. It is well known that restraint use is considered a routine nursing intervention, and routine is associated with positive attitudes [31, 35]. Accordingly, there is a risk that nurses would make decisions according to their routine and attitude rather than in the best interest of the patient. Thus, it is important that nurses critically reflect their own practices to advocate for the patient.

Starting points for changing restraint practice

This thesis provides insight into two aspects of where to start changing restraint practice, namely 1) in terms of the theoretical framework used to identify starting points and 2) how change should be approached from a content theoretical perspective based on the findings. These two aspects are reflected below.

- The theoretical framework used to identify starting points for changing restraint practice

The theoretical framework was useful in identifying areas that have potential to improve restraint practice in hospitals. This thesis relied on the framework that quality of health care provision depends on direct clinical practice (micro level), the conditions within hospitals (meso level) and the prerequisites on a national/health care system level (macro level) [36]. In addition, this thesis integrated Donabedian's structure-process-outcome model, which demonstrates that structures within hospitals (meso level) influence the processes of implementation, which are crucial for the patient outcome (micro level) [37]. Donabedian's model was helpful as a starting point to examine restraint practice. It contains concrete indications on what to assess to obtain an overview of restraint practice and to identify areas of improvement. For example, results from this thesis (Chapter 2) confirm previous findings [4, 6, 38] that required ethical and legal processes such as documentation and regular evaluation are not implemented systematically in daily practice (micro level). However, these processes are elementary to ensure that restraints are used only as a last resort, only for as long as absolutely necessary, in a safe manner and

in the best interest of the patient. Improving such processes can be promoted by improving structures at the meso level – for example, by implementing an electronic documentation system that promotes and demands the necessary processes. Such a system could always require a justification for restraint use and could require a re-evaluation after a defined time. The increased use of such information technology is seen as one of the most prominent developments for guideline implementation [36]. As an example, push notifications can be used to facilitate guideline adherence.

However, the findings of this thesis also show why it was meaningful to embed Donabedian's model in the broader context of health care to investigate influencing factors on restraint use and possible starting points to improve restraint practice. Indeed, better structures do not necessarily have an impact on restraint use. For example, in Chapter 3 two out of four structural characteristics were not associated with whether restraints are used. Nevertheless, there are other, potentially non-objective and hardly measurable factors at the meso level that have an influence on restraint use (as a relevant part of variance in restraint use is explained at the hospital level, Chapter 3 and 6). Based on the findings of this thesis (Chapters 3, 4 and 6) as well as earlier assumptions by other researchers [9, 26, 27, 39, 40], institutional culture and prevailing routines seem to play an important role in this respect. Thus, all processes might be implemented as intended, but restraints are still used (longer than necessary) because it has become an implicit standard in the hospital to maintain (a feeling of) safety. This example demonstrates that the different levels also influence each other, which was rather implicitly represented in the theoretical framework. Apart from that, the chosen theoretical perspective enabled a comprehensive description of restraint use and influencing factors at the different levels and allowed deducing how improvements in restraint practice in hospitals could be approached, as will be reflected on in the following.

- Changing restraint practice from a content theoretical perspective based on the findings

Based on the findings of this thesis (Chapters 3-6), a change in institutional culture and addressing the perception of safety/the demand to feel safe are relevant starting points to improve restraint practice in hospitals. Without such changes, implicit standards could, as mentioned above, undermine any efforts to reduce restraint use. Efforts at the meso level are crucial to trigger changes in the institutional culture and safety feelings. At this level, restraint-free care can be

defined and established as a standard. Establishing restraint-free care as standard care in hospitals, includes enabling but also demanding new experiences in (not) using restraints as well as sharing the responsibility.

The findings of this thesis (Chapter 4) have revealed that the benefits of restraint tend to be overestimated by nurses. Nurses use restraints for a combination of reasons, including a lack of knowledge [6, 27-30] and the demand to ensure patient safety and to protect themselves from being held responsible if something happens [27]. In addition, as discussed in Chapter 4, the decision-making process for or against restraint use seems to be heuristic. Decisions often have to be made immediately and in stressful situations. It is known that in such situations, people resort to habitual processes [35]. Thus, if one does not have much experience with restraint-free care, it is very likely that one would seldom decide against restraint use in this situation. Furthermore, restraint use gives health professionals a (false) sense of security and deciding against restraint use may be perceived as a risk [Chapter 4; 27]. The willingness to take a risk can vary among health professionals [41], another factor that could make it even more difficult to apply an alternative to restraints [27]. Therefore, it is important that management defines restraint-free care as standard and make concrete efforts to establish restraint-free care. Some examples are no longer recognising a risk of falling as a reason for restraint use, reporting and independently reviewing every use of restraint or making decisions against restraint use together with the staff and sharing the risk accordingly. However, management can also decide to remove restraint material or to make access to it more difficult. In addition, it is also the task of management to ensure that no one is blamed/held responsible (e.g. if a patient falls) who has decided against using restraint according to the evidence. The implementation of such different experiences with (no) restraint use and a corresponding cultural change requires, of course, the involvement of all stakeholders as well as analysis of the evidence [9]. In many countries, physicians are still responsible for patient care. As such, they are key stakeholders in implementing this change. Overall, new experiences can help health professionals in hospitals to feel safe when not using restraint, to change their routine in the longer term and thereby to contribute to a changed restraint culture.

This required change in restraint culture can further be promoted by improvements at the macro level [Chapters 3 and 6; 36, 42, 43]. Policymakers and professional organisations are responsible for raising awareness of the topic, adopting a position and making recommendations [44]. Legal clarity that is

translated into guidelines and recommendations for clinical practice can help reassure hospitals that restraint-free care is the right way to go. Furthermore, society can be sensitised to restraint use in hospitals. Anyone can suddenly become a patient or relative and therefore be involved in the decision on whether to use restraints. In this case, it can be helpful to have been sensitised regardless of the current situation and independent of the restraint routines prevailing in the respective hospital. By raising awareness in society, the confidence of patients and relatives in restraint-free care can be promoted. In addition, clear guidelines would allow for even more differentiated education on restraint use in hospitals during professional formation of nurses and other health professionals. As a result, nurses and other health professionals start their careers with a potentially more critical attitude towards restraint use and are therefore more supportive of the implementation of restraint-free care.

In summary, a change in hospital restraint practice is indicated. To achieve this change at the micro level, investments are needed at the meso level with the support of the macro level. These findings have parallels to those of the mental health and the long-term care sectors. In the Six Core Strategy, which researchers have found to be effective in the mental health sector for reducing restraint use, three of the six recommendations address the meso level (leadership for institutional culture change, monitoring and appropriate use of data, staff development) [45]. In the long-term sector, the EXBELT study in the Netherlands laid the basis for a change in practice. In this study too, the researchers discussed that the policy change in nursing homes has had a significant influence on the success of the programme [46]. A multi-centre project in the United States also showed that a combination of the introduction of new legislation (Nursing Home Reform Act 1987, macro-level) and involvement of nursing management (meso level) was relevant to change restraint practice in nursing homes [47]. Although these projects and successes often refer only to mechanical restraint (some even exclusively to fixation belts), there might be great potential to learn from these experiences to change restraint practice in hospitals. The extent to which similar effects can be achieved if all forms of restraint are taken into account, such as alarm systems, which have often been listed as alternatives in previous projects, needs to be explored.

IMPLICATIONS AND RECOMMENDATIONS

Based on the findings of this thesis and the corresponding methodological and theoretical reflections, the implications of *"yes"* to the question raised in the thesis title *"Restraint use in somatic acute care hospitals: do we need to care?"* can be derived. The implications and recommendations for future research and (clinical) practice are presented below.

Implications and recommendations for future research

Based on this thesis, there are three main implications and corresponding recommendations for future research: 1) inclusion of all restraint types, 2) development of restraint reduction strategies at the different levels and 3) involve all health professions concerned with restraint use as well as the patients directly affected and their relatives.

– Inclusion of all restraint types

While completing the work described in this thesis, the number of studies on restraint use in the hospital setting has increased, but it is evident that the majority of studies still focus on mechanical restraint. However, to achieve restraint-free care as standard in hospitals, it is important that every form of restraint is taken into account. Otherwise, as explained, there is a risk of a shift in the type of restraint instead of a real reduction. Therefore, for future research it is recommended that restraint use be defined according to the broader definitions of restraint/restrictive practice. The more uniform the definition, the better the comparability of findings will be in the future, which will ultimately allow for more differentiated assessments of generalisability and the derivation of reliable recommendations.

– Development of restraint reduction strategies at the different levels

So far, there is a lack of effective evidence-based restraint reduction strategies for the hospital setting [10, 16, 17], although as this thesis and other studies have shown, there seems to be potential for a reduction. One reason for this could be that previous restraint reduction approaches have paid too little attention to the relevance and influence of the conditions at the various levels and the interplay between the levels. Therefore, it is recommended that the (mutual) influence of these conditions on restraint use be further investigated and incorporated when developing restraint reduction strategies. In this respect, the impact of the meso

level on restraint use in hospitals, which was identified in this thesis (Chapters 3-6), should be validated and refined. Given the similar findings in this thesis to those previously reported in the long-term care and mental health fields, it is recommended that inspiration be sought in other settings when developing restraint reduction strategies in the hospital setting. Because the reasons for using restraints, as well as the patient population most affected, are more similar to the long-term care field, it seems particularly advisable to investigate similarities and possibilities for intervention adaptation in this area.

– Involve all health professions concerned with restraint use as well as the patients directly affected and their relatives

This thesis, like many other studies on restraint use, focusses on the nursing profession. However, restraints are implemented by an interprofessional team. Furthermore, restraint use is influenced by the institutional culture, which in turn is also shaped by the interprofessional team. Hence, changing restraint practice requires that future research focus more on interprofessional dynamics. As mentioned previously, in many countries physicians remain responsible for patient care. Accordingly, their involvement in a cultural change is essential. However, physiotherapists and occupational therapists could also play an important role in the prevention of restraint use, and therefore their perspectives should be considered. In addition, patients affected by restraint use and their relatives should be included in future research. As this thesis has shown (Chapters 2 and 4), they hardly seem to be involved in the decision-making process, even though this is required from ethical and legal points of view. Their expectations and concerns are largely unknown. Moreover, involving patients and their relatives might represent great potential for the prevention of restraint use. The possibilities and roles need to be explored in future research.

Implications and recommendations for (clinical) practice

The implications and recommendations for practice are presented in line with the theoretical framework using the three levels (micro, meso, macro) and are thus directed at both direct clinical practice as well as superordinate structures and preconditions.

At the macro level, a clear legal framework for the hospital setting that includes clear definitions of restraint is needed. Such a framework would raise awareness

across hospitals and help them to get better oriented regarding ethical and legal requirements, and thus critically question their own restraint practice. Indeed, the World Health Organization (WHO) points out that legislative reforms are needed to ensure that (mental) health care is provided in accordance with the Convention on the Rights of Persons with Disabilities (CRPD) for example also in Switzerland, as the UN report "Convention on the Rights of Persons with Disabilities. Concluding observations on the initial report of Switzerland" has shown [48, 49]. Second, quality development should be initiated at the macro level in various ways, including:

- developing and providing evidence-based guidelines for the reduction and management of restraints in hospitals as well as strategies for their implementation in practice;
- making evidence-based education about restraint use in hospital care mandatory in any nursing or other health professional curriculum;
- raising public awareness of restraint use in hospitals;
- implementing restraint use as a national quality indicator for the hospital setting including risk-adjusted hospital-comparison.

These recommendations are already being implemented for mental health and long-term care in many countries. However, the inclusion of the hospital setting is largely missing. For example, as discussed earlier, the legal framework is much clearer for mental health and long-term care than for the hospital care. Similarly, national monitoring of restraint use has so far been installed primarily in mental health and long-term care. Based on the findings in this thesis (Chapter 6), however, the potential for stimulating quality improvement through national monitoring of restraint use with risk-adjusted hospital comparison is considerable. There are some hospitals that use significantly more restraint as well as some that use significantly less restraint. The latter indicates that quality development cannot only take place in individual hospitals; rather, there is potential for a reduction in restraint use on a national level that should be stimulated accordingly.

At the meso level, it is essential that management assumes its responsibilities and exerts its influence. They are responsible for ensuring that restraints are (not) used in their institution in accordance with ethical and legal requirements. Based on the findings in this thesis, the most effective possibilities for changing restraint

practice are identified at this level. This eventuality requires management that defines and establishes restraint-free care as standard and creates corresponding structural conditions for this change. Based on the findings of this thesis, the following structural changes are essential and could be implemented to a large extent within the existing possibilities.

- Promote guideline adherence by embedding ethically and legally defined processes in the electronic documentation system:

Required ethical and legal processes help to ensure that restraints are only used as a last resort and, if so, only for as long as absolutely necessary (see Box 1). The electronic documentation system should be programmed to remind and require the implementation of these processes.

- Adapt the available options in the decision-making process

Decision-making means weighing options [35]. In this regard, nurses report that they often do not have any alternatives available [26, 31, 32]. Thus, management has the responsibility to ensure that preventive and alternative measures are available (e.g. stimulus shielding or occupation options for confused patients, appropriate signage and lighting to prevent falls, etc.). However, management can also actively decide against providing restraint material so that it is not available at all in the decision-making process, or hamper access to restraint material.

- Monitor restraint use at the ward and hospital levels

Monitoring restraint use produces objective data that could facilitate an exchange about restraint use in the interprofessional team, including management, as it could be easier for health professionals to talk about data than about their own practice when dealing with such an ethically and legally sensitive topic as restraint use. In addition, it makes it possible to react promptly to changes (e.g. above-average use of restraints in a ward) or to evaluate restraint reduction intervention taken.

- Establish interprofessional training including management on restraint use

According to the findings in this thesis, institutional culture has a significant influence on restraint use (Chapter 3). Changing this culture requires the participation of all stakeholders [9]. Therefore, interprofessional training should not only focus on knowledge transfer but also on active exchange about restraint

use and differences in its implementation in everyday practice and enable to experience restraint-free care in daily practice. In this way, trust can be built up that restraint-free care is possible and safe.

Management faces challenging tasks in restraint reduction. Accordingly, it is recommended that not only the staff in direct patient care must be well trained and qualified, but also the management. With reference to the European Qualifications Framework [34], the transformation of work processes can be expected from level 7, which corresponds to a master's degree qualification. Accordingly, for the implementation it is necessary to consider which person could be deployed for which task in line with his/her qualification. In reality, many employees working in lower management likely do not have a master's degree. Thus, these people should be involved as multipliers rather than as change leaders.

At the micro level, nurses and all other health professionals should be sensitised to the ethical and legal dimensions and corresponding requirements of the use of any restraint type. The findings indicate that there is much more awareness of more obvious movement-restricting restraints, such as fixation belts, than of restraints that restrict personal freedom in other ways, such as permanent electronic surveillance. However, considering the definition, both types are restraints and ethical and legal processes must be fulfilled accordingly. As shown in Box 1, their systematic implementation could help to reduce restraint use and to ensure restraint management that is as safe as possible. Therefore, in addition to creating a more comprehensive understanding and awareness of restraint, the systematic implementation of required ethical and legal processes is recommended. Furthermore, it is important that the use of restraint is recognised as routine and that this routine is critically reflected at the micro level. Routine use indicates that the benefits and harm of restraint use are not reviewed individually for each patient and alternatives or preventive interventions are hardly considered. However, many alternative or preventive interventions, such as pain management, targeted communication and promoting self-awareness, are part of the nursing tasks. Based on the findings of this thesis, such approaches are already being implemented in practice, but hardly ever with the intention of reducing restraint use (Chapter 4). For clinical practice, this means that more awareness should be created for the importance and effect of such interventions for restraint reduction. A systematic collection of daily restraint prevention interventions in an easily accessible overview could be helpful for nurses in their direct practice and increases

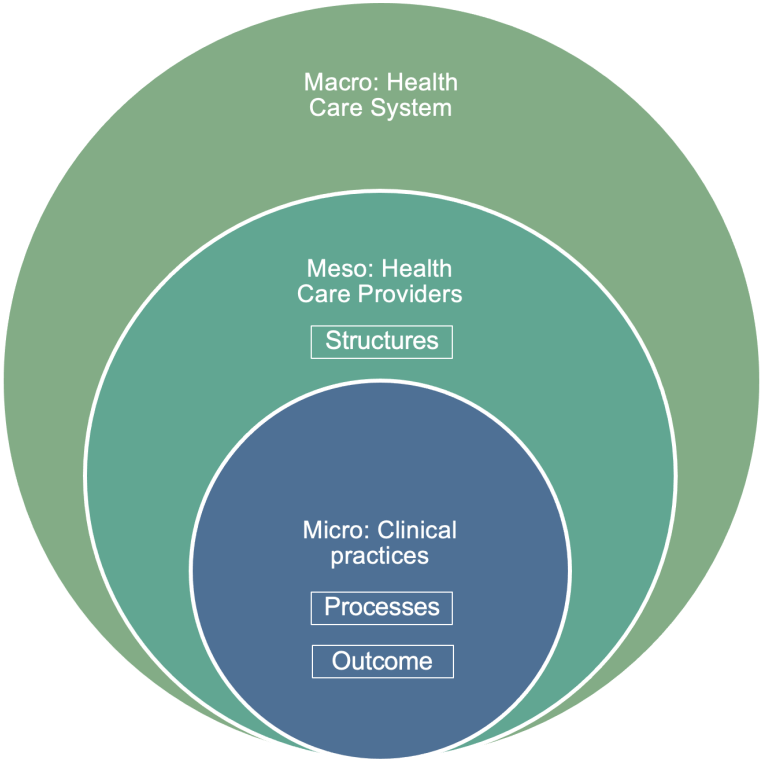
its implementation. However, as the findings highlight, identifying (effective) restraint prevention interventions requires taking the patient's perspective (Chapter 4). As discussed, the reason for restraint use may be fall prevention, but the risk of falling is actually based on agitation. Thus, in addition to fall prevention measures, restraint prevention requires interventions that address the reasons for agitation. To identify these reasons, nurses need to consider the patient's perspective, as their own perspective may be influenced by their own routine. For example, they may not recognise that the hecticness, noise, regular disturbances and inadequate guidance in daily procedures could overwhelm the patient.

Box 1

Implementing required ethical and legal processes to ensure that restraints are used as a last resort and only for as long as absolutely necessary, in a safe manner and in the best interest of the patient

Implementing required ethical and legal processes ensures that preventive measures have been used and exhausted beforehand (restraint as a last resort). Subsequently, the indication for restraint use and weighing different options in the decision-making process needs to be documented in a comprehensible way. This approach allows the health professionals who are subsequently responsible for the patient to determine whether restraint use is still necessary. A regular differentiated evaluation ensures that restraints are discontinued at the earliest possible time – and thus are only in place for as long as necessary. Regular monitoring ensures that negative effects for patients are detected and minimised as early as possible. For example, if the patient becomes more restless due to restraint or if the alarm system is bypassed, a new risk-benefit assessment can be conducted. Ideally, the patient or, if the patient's cognitive condition does not allow it, his/her legal representatives should be involved in the entire process. On the one hand, this ensures that the patient's interests are respected. On the other hand, individual preventive measures in terms of biographical work (e.g. as described in Chapter 4, having a patient who played brass band music for a long time watch YouTube videos of brass band music calmed him down and kept him busy) or risks can be identified in this way.

The implications and recommendations for (clinical) practice are summarised in Figure 2 according to the levels (macro, meso and micro).



- Provide a clear legal framework including definition
- Provide guidelines for the reduction and management of restraints
- Raise awareness among health professionals during training as well as society
- Establish restraint use as a national quality indicator for the hospital setting

- Use information technologies to promote guideline adherence
- Influence options in decision-making
- Monitor restraint use
- Establish interprofessional training (including management)

- Raise awareness on the ethical and legal dimensions of the use of any restraint type
- Systematically implement required ethical and legal processes
- Reflect on the routine use of restraint
- Raise awareness of preventive intervention
- Include the patient's perspective in (preventing) restraint use

Figure 2: Summary of implications and recommendations for (clinical) practice along the different levels of the theoretical framework used

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SUMMARY

The title of this thesis questions whether we need to care about restraint use in the hospital setting. Based on five studies and a subsequent general discussion, restraints are frequently used in the hospital setting, affect a vulnerable patient group and there are opportunities for improving practice. Therefore, it is evident that we need to care about restraint use in the hospital setting. A more comprehensive summary of each chapter is presented below.

Chapter 1 includes a general introduction to the topic. Restraint use is a potential human rights violation and can have negative effects on patients and health professionals; therefore, a reduction in restraint use is recommended. Initiatives to meet this demand have long focussed on the mental health and long-term care settings. For the hospital setting, most of the evidence has related to intensive care and emergency care and mostly involved only mechanical restraints. However, to ensure that any type of restraint is reduced as much as possible and only used as a last resort in the whole hospital setting, it is important to first fully describe the current situation. Therefore, the aim of this thesis was to describe restraint use in hospital settings comprehensively, independently of subpopulations and specific restraint types, and to identify influencing factors on different levels. With the background, it will be possible to identify in the future whether an improvement in restraint practice is indicated and, if so, in which area interventions could potentially have the greatest impact on reducing restraints. In addition, Chapter 1 presents the theoretical framework and the outline of the thesis.

In **Chapter 2**, restraint use was investigated independently of ward type in terms of prevalence, restraint type used, reasons for restraint use, process indicators when restraints are used and patient characteristics associated with restraint use based on a multicentre cross-sectional design. The findings involving 29,477 patients from 140 hospitals in Switzerland and Austria showed that 8.7% of all patients were restrained during their hospital stay (retrospectively over a maximum of 30 days). The largest proportion was due to mechanical restraint (55.0%). The main reason for restraint use was fall prevention (43.8%). The required ethical and legal processes were not implemented systematically. Hence, the documentation of restraint use in the patient documentation was the most frequently implemented process indicator (64.3%). All other process indicators (e.g. regular evaluation of restraint use, information of the patient/relatives) were implemented even less frequently. Regarding patient characteristics, care dependency followed by mental and behavioural disorders proved to be most strongly associated with restraint

use. The conclusion from this study was that restraints are used in complex patient situations and there is great potential to improve the implementation of ethical and legal processes. Standardisation of these, combined with appropriate training of staff, could be beneficial in promoting awareness of restraint and the corresponding potential for reduction.

In **Chapter 3,** variation in restraint use between hospitals was investigated. A secondary analysis of the same data as in Chapter 2 was performed to determine how much variance in restraint use can be explained on the hospital level and to examine the impact of organisational factors (structures) on restraint use. Based on a multilevel logistic regression analysis, the availability of guidelines regarding restraint use and refresher courses for nursing staff were associated with less restraint use. In addition, the total explained variance of restraint use increased from 24% to 55% when hospital was added to the regression model as a random effect. From this study it was concluded that restraint use varies widely among hospitals, even when considering the different patient mix of hospitals. Accordingly, the findings emphasise earlier assumptions by other researchers that routine and institutional culture may play a role in restraint use. Thus, identifying situations where restraints are used based on routine or due to institutional culture could be relevant to reduce restraint use. Investing in structures and staff knowledge could further promote restraint reduction.

In **Chapter 4**, daily restraint practices and the factors which influence their use were investigated from an outsider's perspective. Fieldwork with unstructured participant observation was conducted. Before this study was performed, restraint use had mostly been described only quantitatively and from the perspective of health professionals. Quantitative assessment tools can only be as good as the current state of knowledge allows. The view of health professionals might be biased by routine and personal beliefs that seem to play an important role in restraint use. Therefore, the perspective of someone who is not involved in the daily restraint practice was considered to be useful to describe the restraint practice as comprehensively as possible. Based on 67 hours of observation, daily restraint practice can be described in three categories: the context in which restraints are used, the decision-making process on the use and continued use of restraints and the avoidance of restraint use. In addition, processes and decisions on restraint use often seem to be executed unconsciously and in a poorly standardised manner. The conclusion from this study was that the low standardisation of restraint

practice favours intuitive and unreflective actions. Therefore, the decision to use restraints seems to be a heuristic process. Digitalisation could be used to improve daily restraint practice and, thus, reduce restraint use – for example, by making the electronic documentation system promote and demand the implementation of required ethical and legal processes.

In **Chapter 5**, the attitudes of hospital nursing staff towards restraint use were investigated by means of a survey. This information is critical because the attitude one adopts is an essential condition in any decision-making process. In addition, the construct validity and reliability of a measurement instrument that was developed and validated in long-term care settings (Maastricht Attitude Questionnaire [MAQ]) was tested for its use in the hospital setting. Based on the data of 180 participants, nursing staff in hospitals had a neutral attitude towards restraint use. Furthermore, it was found that the MAQ can be used in the hospital setting with minor adaptations, even though further testing is recommended. Based on the findings of this study, and given that attitudinal change has already been identified as a challenge in mental health and long-term care settings, interventions at a national and institutional level are indicated to change nursing staffs attitudes towards restraint use and to change restraint practice in the longer term.

In **Chapter 6**, the potential of restraint use as a national quality indicator for the hospital setting was investigated based on cross-sectional data of 18,938 patients from 55 Swiss hospitals. Across the sample, the 30-day restraint prevalence was 10.2%. Based on multilevel regression analyses, Swiss hospitals differed significantly in their restraint use, even after adjusting for patient mix. In total, 40% of all included hospitals used either significantly more or less restraints than the average. In comparison to the other quality indicators in the hospital setting, the 40% outlier is a very high value indicating potential for quality improvements. Because such large differences in restraint use seem questionable from professional, ethical and legal points of view, the findings indicate the need for national monitoring and benchmarking of restraint use in hospitals, such as with a national quality indicator. This monitoring, combined with clearer and binding regulations, would help to ensure restraint management that is in line with ethical and legal requirements (as a last resort).

Chapter 7 completes the thesis with a general discussion of the findings. First, the findings of Chapters 2-6 are summarised. Second, methodological and theoretical reflections are presented. The methodological reflections focus on the internal and external validity of the findings. The theoretical reflections address three key, relatively interconnected themes: 1) the definition of restraints, 2) advocacy as a key nursing role in restraint use and 3) identifying starting points for changing restraint practice. Third, implications and recommendations for (clinical) practice and future research are presented.

SAMENVATTING

Het toepassen van vrijheidsbeperking in de somatische acute zorg in ziekenhuizen: moeten we daar zorg aan besteden?

De titel van dit proefschrift stelt de vraag of onze zorg nodig is als het gaat om het gebruik van vrijheidsbeperking in ziekenhuizen. Uit vijf studies en een daaropvolgende algemene discussie blijkt dat vrijheidsbeperkende maatregelen vaak worden gebruikt in ziekenhuizen, een kwetsbare patiëntengroep betreffen en dat er mogelijkheden zijn om de toepassing ervan te verbeteren. Daarom is het duidelijk dat we zorg moeten besteden aan het gebruik van vrijheidsbeperkende maatregelen in ziekenhuissituaties. Hieronder volgt een uitgebreidere samenvatting van elk hoofdstuk.

Hoofdstuk 1 bevat een algemene inleiding tot het onderwerp. Het toepassen van vrijheidsbeperkende maatregelen vormt een potentiële schending van de mensenrechten en kan negatieve gevolgen hebben voor patiënten en zorgprofessionals; daarom wordt aanbevolen het toepassen van vrijheidsbeperkende maatregelen te beperken. Initiatieven om aan deze behoefte te voldoen, zijn lange tijd gericht geweest op de geestelijke gezondheidszorg en de langdurige zorg. Voor de ziekenhuissituaties heeft het meeste bewijsmateriaal betrekking op de intensive care en de spoedeisende hulp en betreft het meestal alleen mechanische vrijheidsbeperkende maatregelen. Om er echter voor te zorgen dat elke vorm van vrijheidsbeperking zoveel mogelijk wordt beperkt en alleen als laatste redmiddel in de gehele ziekenhuissetting wordt gebruikt, is het van belang eerst de huidige situatie volledig te beschrijven. Daarom was het doel van dit proefschrift het gebruik van vrijheidsbeperking in ziekenhuissettingen uitgebreid te beschrijven, onafhankelijk van sub-populaties en specifieke soorten van vrijheidsbeperkende maatregelen, en beïnvloedende factoren op verschillende niveaus te identificeren. Met die achtergrond kan in de toekomst worden nagegaan of een verbetering van de toepassing van vrijheidsbeperking gewenst is en, zo ja, op welk gebied interventies het grootste effect zouden kunnen hebben op het terugdringen van vrijheidsbeperking. Daarnaast worden in hoofdstuk 1 het theoretisch kader en de opzet van het proefschrift gepresenteerd.

In **hoofdstuk 2** wordt het gebruik van vrijheidsbeperking onafhankelijk van het type afdeling onderzocht op prevalentie, type vrijheidsbeperkende maatregel, redenen voor het gebruik van vrijheidsbeperking, procesindicatoren wanneer vrijheidsbeperking wordt gebruikt en patiëntkenmerken die verband houden met het toepassen van vrijheidsbeperking op basis van een multicentrisch cross-sectioneel ontwerp. De bevindingen waarbij 29.477 patiënten uit 140 ziekenhuizen in Zwitserland en Oostenrijk betrokken waren, tonen aan dat bij 8,7% van alle patiënten

tijdens hun ziekenhuisverblijf (retrospectief over een periode van maximaal 30 dagen) vrijheidsbeperking werd toegepast. Het grootste deel had betrekking op mechanische vrijheidsbeperking (55,0%). De belangrijkste reden voor het toepassen van vrijheidsbeperking was valpreventie (43,8%). De vereiste ethische en juridische procedures werden niet systematisch toegepast. Documentatie van het toepassen van vrijheidsbeperking in de patiënten documentatie was dan ook de meest toegepaste procesindicator (64,3%). Alle andere procesindicatoren (bijvoorbeeld regelmatige evaluatie van het toepassen van vrijheidsbeperking, informatie van de patiënt/verwanten) werden nog minder vaak toegepast. Wat de kenmerken van de patiënten betreft, bleek zorgafhankelijkheid, gevolgd door psychische en gedragsstoornissen, het sterkst samen te hangen met het toepassen van vrijheidsbeperking. De conclusie van deze studie was dat vrijheidsbeperking wordt toegepast in complexe patiëntsituaties en dat er een groot potentieel is om de uitvoering van ethische en wettelijke processen te verbeteren. Standaardisatie daarvan, in combinatie met een passende opleiding van het personeel, zou bevorderlijk kunnen zijn voor de bewustwording inzake vrijheidsbeperking en de bijbehorende mogelijkheden tot vermindering.

In **hoofdstuk 3** is de variatie in het gebruik van vrijheidsbeperking tussen ziekenhuizen onderzocht. Een secundaire analyse van dezelfde gegevens als in hoofdstuk 2 werd uitgevoerd om te bepalen hoeveel variantie in het toepassen van vrijheidsbeperking kan worden verklaard op ziekenhuisniveau en om de invloed van organisatorische factoren (structuren) op het toepassen van vrijheidsbeperking te onderzoeken. Uit een multi-level logistische regressieanalyse bleek dat de beschikbaarheid van richtlijnen voor het toepassen van vrijheidsbeperking en opfriscursussen voor verplegend personeel samenhingen met het minder toepassen van vrijheidsbeperking. Bovendien nam de totale verklaarde variantie van het toepassen van vrijheidsbeperking toe van 24% tot 55% wanneer het ziekenhuis als willekeurig effect aan het regressiemodel werd toegevoegd. Uit deze studie werd geconcludeerd dat het toepassen van vrijheidsbeperking sterk varieert tussen ziekenhuizen, zelfs wanneer rekening wordt gehouden met de verschillende patiëntenmix van ziekenhuizen. De bevindingen onderstrepen dan ook eerdere veronderstellingen van andere onderzoekers dat routine en institutionele cultuur een rol kunnen spelen bij het toepassen van vrijheidsbeperking. Het identificeren van situaties waarin vrijheidsbeperking wordt toegepast op basis van routine of als gevolg van de institutionele cultuur zou dus van belang kunnen zijn voor de vermindering van het toepassen van vrijheidsbeperking. Investeren in structuren en kennis van het personeel zou bevorderlijk kunnen zijn voor het terugdringen van vrijheidsbeperking.

In **hoofdstuk 4** werden de dagelijkse vrijheidsbeperkende maatregelen en de factoren die het gebruik ervan beïnvloeden onderzocht vanuit het perspectief van een buitenstaander. Er werd veldwerk verricht met ongestructureerde observatie van deelnemers. Voordat deze studie werd uitgevoerd, was toepassing van vrijheidsbeperking meestal alleen kwantitatief en vanuit het perspectief van zorgprofessionals beschreven. Kwantitatieve beoordelingsinstrumenten kunnen slechts zo goed zijn als de huidige stand van de kennis toelaat. Het idee dat zorgprofessionals beïnvloed kunnen zijn door routine en persoonlijke overtuigingen lijkt een belangrijke rol te spelen bij het toepassen van vrijheidsbeperking. Daarom werd het perspectief van iemand die niet betrokken is bij de dagelijkse toepassing van vrijheidsbeperkende maatregelen nuttig geacht om de toepassing ervan zo volledig mogelijk te beschrijven. Op basis van 67 uur observatie kan de dagelijkse toepassing van vrijheidsbeperkende maatregelen worden beschreven in drie categorieën: de context waarin vrijheidsbeperking wordt toegepast, het besluitvormingsproces over de toepassing en de voortgezette toepassing van vrijheidsbeperking en het vermijden van vrijheidsbeperking. Bovendien lijken processen en beslissingen over de toepassing van vrijheidsbeperking vaak onbewust en op een weinig gestandaardiseerde manier te worden uitgevoerd. De conclusie van deze studie was dat de lage standaardisering van de toepassing van vrijheidsbeperking intuïtief en ondoordacht handelen in de hand werkt. Daarom lijkt de beslissing om vrijheidsbeperkende maatregelen toe te passen een heuristisch proces. Digitalisering zou kunnen worden gebruikt om de dagelijkse toepassing van vrijheidsbeperking te verbeteren en zo de toepassing van vrijheidsbeperking te verminderen - bijvoorbeeld door de uitvoering van vereiste ethische en juridische processen te bevorderen en vereisen middels het elektronisch documentatiesysteem.

In **hoofdstuk 5** werd de houding van het verplegend personeel in ziekenhuizen ten aanzien van het gebruik van vrijheidsbeperkende middelen en maatregelen onderzocht door middel van een enquête. Deze informatie is van cruciaal belang omdat de houding die men aanneemt een essentieel gegeven is bij elk besluitvormingsproces. Bovendien werden de constructvaliditeit en -betrouwbaarheid van een meetinstrument dat ontwikkeld en gevalideerd werd in langdurige zorgsettingen (Maastricht Attitude Questionnaire [MAQ]) getest voor gebruik in de ziekenhuissetting. Op basis van de gegevens van 180 deelnemers had het verplegend personeel in ziekenhuizen een neutrale houding ten opzichte van de toepassing van vrijheidsbeperking. Voorts is gebleken dat de MAQ met kleine aanpassingen in de ziekenhuissetting kan worden gebruikt, hoewel verdere tests

worden aanbevolen. Op basis van de bevindingen van deze studie, en aangezien een mentaliteitsverandering reeds als een uitdaging is aangemerkt in instellingen voor geestelijke gezondheidszorg en langdurige zorg, zijn interventies op nationaal en institutioneel niveau aangewezen om de houding van het verplegend personeel ten aanzien van de toepassing van vrijheidsbeperkende maatregelen te veranderen en de toepassing van vrijheidsbeperking op langere termijn te verbeteren.

In **hoofdstuk 6** werd het potentieel van vrijheidsbeperkende maatregelen als nationale kwaliteitsindicator voor de ziekenhuissetting onderzocht op basis van cross-sectionele gegevens van 18.938 patiënten uit 55 Zwitserse ziekenhuizen. In de gehele steekproef bedroeg de prevalentie van vrijheidsbeperkende maatregelen gedurende 30 dagen 10,2%. Op basis van multi-level regressieanalyses verschilden de Zwitserse ziekenhuizen aanzienlijk in de toepassing van vrijheidsbeperking, zelfs na een correctie voor de patiëntenmix. In totaal werd in 40% van alle betrokken ziekenhuizen aanzienlijk meer of minder vrijheidsbeperking toegepast dan gemiddeld. In vergelijking met de andere kwaliteitsindicatoren in de ziekenhuissetting is de uitschieter van 40% een zeer hoge waarde die wijst op potentieel voor kwaliteitsverbetering. Omdat dergelijke grote verschillen in het gebruik van vrijheidsbeperkende maatregelen twijfelachtig lijken vanuit professioneel, ethisch en juridisch oogpunt, wijzen de bevindingen erop dat er behoefte is aan nationaal toezicht op en benchmarking van de toepassing van vrijheidsbeperking in ziekenhuizen, bijvoorbeeld met een nationale kwaliteitsindicator. Dit toezicht, in combinatie met duidelijkere en bindende voorschriften, zou ertoe bijdragen dat het beheer van vrijheidsbeperking in overeenstemming is met ethische en juridische vereisten (als laatste redmiddel).

Hoofdstuk 7 rondt het proefschrift af met een algemene bespreking van de bevindingen. Eerst worden de bevindingen uit hoofdstukken 2-6 samengevat. Ten tweede worden methodologische en theoretische beschouwingen gepresenteerd. De methodologische beschouwingen richten zich op de interne en externe validiteit van de bevindingen. De theoretische beschouwingen behandelen drie belangrijke, relatief met elkaar verbonden thema's: 1) de definitie van vrijheidsbeperking, 2) belangenbehartiging als cruciale verpleegkundige rol bij de toepassing van vrijheidsbeperking en 3) het vaststellen van uitgangspunten voor het veranderen van de toepassing van vrijheidsbeperking. Ten derde worden implicaties en aanbevelingen voor de (klinische) praktijk en toekomstig onderzoek gepresenteerd.

IMPACT

In health care, the use of measures restricting personal freedom, so-called restraints, is increasingly viewed critically as a potential violation of human rights. Their use in almost all circumstances is unacceptable from scientific, societal and patient points of view – on the one hand, because the effectiveness for most of the reasons restraints are used (like patient safety) has not been proved [1-5], and on the other hand, because the negative consequences for both patients and health professionals are evident [1-4, 6-8]. While this critical view and corresponding strategies to reduce restraint use, or even to provide restraint-free care, have received attention for decades in mental health and long-term care, restraint use in hospitals has remained a side issue. A limited amount of research has been done in hospitals, most often with a focus on belt restraint and partly also pharmacological restraint in intensive care units and emergency departments. Little information had been available on the other disciplines (ward types) of the hospital setting and other forms of restraining. This thesis has provided new and comprehensive insights into restraint use in hospitals, independent of subpopulations and specific restraint types. Moreover, influencing conditions on restraint use within direct clinical practice as well as on a hospital and health care system levels have been identified. The main finding is that about 1 in 11 patients in somatic acute care hospitals is restrained. These patients are most often vulnerable. There are large differences among hospitals and among health professionals as to whether restraints are used in similar patient situations. Such differences should not exist from ethical and legal points of view, and also from professional and social perspectives. The findings facilitated the identification of approaches that could improve practice and thus reduce restraint use. The findings of this thesis had an impact on both society and science, as demonstrated below.

SOCIETAL IMPACT

This thesis provides a basis for the various players across the health care system to recognise their responsibility for ethically and legally appropriate restraint management and to take corresponding initiative to contribute to restraint reduction in hospitals. Based on this thesis, restraint use occurs in the entire range of hospital care and vulnerable patients are most affected. Thus, people who can hardly advocate for their own rights and interests are most affected. Hence, it is crucial that the various players in the health care system do everything within their control to protect this group of patients. This thesis highlights that it is not sufficient

to question only mechanical restraints in intensive care or emergency care. Rather, a critical discourse across disciplines as well as regarding any form of restriction of freedom is needed to protect the human rights of vulnerable patients in hospitals. The demographic trend, which is likely to increase the number of patients in hospitals who may be affected by restraint use, reinforces the urgency. On the one hand, the findings of this thesis provide society with a source to critically review restraint use as well as reduction initiatives (not) taken in hospitals. On the other hand, the various players in the health care system are informed regarding how they could help to ensure that restraints are only used as a last resort in the future. The impact of the findings of this thesis for regulatory bodies, professional bodies, management in hospitals, nurses in direct hospital patient care, patients and relatives and nursing education as well as the ways to reach these target groups are described below.

For the regulatory bodies in the health care sector, the findings of this thesis point to their possibilities to initiate a reduction in restraint use in hospitals at a system level. Specifically, this thesis indicates that restraint use in hospitals should be monitored at a national level to identify differences in restraint practice among hospitals. This monitoring could detect when a hospital uses more restraint than others, and thus encourage it to change its restraint practices. In the longer term, the findings of this thesis may also influence the improvement of legislation on restraint use. In some countries, such as Switzerland, legislation is focussed on mechanical restraint use in mental health and long-term care [9]. However, this thesis shows that restraint is also frequently used in hospitals and that a relevant proportion of restraint occurs via electronic monitoring and pharmacological restraint. Thus, the findings of this thesis advise the regulatory bodies as to the direction in which legislation should be revised.

For the professional bodies, these findings have an impact in that they have to take a clear position against the use of restraint in hospitals and formulate corresponding recommendations. The findings show that restraint use is considered a routine intervention. Here, professional organisations have the opportunity to draw attention to this critical practice and to recommend a change in practice to their members.

This thesis emphasises that management of hospitals is not merely responsible for creating structures and processes for the most restraint-free care possible. Much more importantly, management is responsible for transforming the restraint culture and providing employees with the confidence not to use restraint. This is a challenging

but – based on the findings in this thesis – fundamental task for management to improve restraint practice. Without changing culture, it is likely that any improvements in structures and processes will have little impact on restraint use.

For nurses in direct clinical practice, this thesis provides a database to reflect on their own restraint practice in terms of their own routines, their own implementation of ethical and legal processes, and especially the influence of their own attitudes on their decisions about restraint use. The thesis also underlines the relevance for nurses to consider the patient's perspective to prevent restraint use as effectively as possible. In addition, the responsibility of nurses towards patients in terms of respecting human rights is emphasised. The thesis stresses that the nursing profession must increasingly make use of its scope of action and advocate on behalf of patients in an interprofessional environment. With the academisation and professionalisation of the nursing profession, many nurses in practice are now also formally qualified; hence, they have an ethical and legal obligation to recognise potential human rights violations and to counteract them.

This thesis also impacts patients and relatives, as the findings indicate that their active involvement is relevant to change restraint practice. In the longer term, this will strengthen their position in the entire process of (not) using restraint. In addition, this thesis can contribute to a future reduction in the use of restraints, thereby improving patient safety and autonomy. An important finding that has emerged from this thesis is that differences in restraint use among hospitals are not dependent on the patient groups receiving care. This factor, combined with the lack of evidence for the benefits of restraint, gives patients even more of a right to advocate for human rights in hospitals and to demand a reduction in restraint use or – even better – restraint-free care.

The findings of this thesis emphasise that education has great responsibility in the socialisation of nurses. Education must define restraint broadly from the beginning and enable nurses to think critically and act appropriately within the interprofessional team, even on ethically and legally sensitive issues. Specifically, the findings of this thesis call for education to sensitize nurses to human rights and the evidence and prevention of restraints. However, this thesis could also have an impact on education provided to management, because this group has great influence on promoting restraint-free care. Education is responsible for equipping management with the leadership skills needed for cultural change.

To ensure that these findings also reach this wider audience, they have been disseminated through various channels. The findings concerning the political

level were presented at the Q-Day presented by the Swiss National Association for Quality Development in Hospitals and Clinics (ANQ). This event promotes an active dialogue on quality measurement and quality development in Switzerland and addresses policymakers as well as (quality) managers and (nursing) experts in health care institutions. Furthermore, the findings were presented to the participating practice partners in two presentations: once in an interprofessional exchange at a participating site and once at a training session on restraint use for all nursing experts of the practice partners. This dissemination could allow the results to be applied in direct clinical practice. In addition, some of the results could be integrated into a presentation at a symposium of the regional association of nurses on the topic of aggression and thus reached clinically active nurses from various settings in the Bern region. Regarding education, the findings of this thesis could be incorporated into a module of a Certificate of Advanced Studies (CAS) course on quality in medicine, whereby a broader field of clinically active health professionals could be reached. Moreover, several exchanges have taken place with the responsible lecturer, who teaches restraint in the bachelor programme for nurses at the Bern University of Applied Sciences. All results and publications have been shared with her so that the findings could be integrated into the basic training of nurses. Finally, (parts of) the findings were presented at a public online event, which was open to all interested parties free of charge. The invitation was distributed via the network of the School of Health Professions of the Bern University of Applied Sciences as well as via the professional and personal networks of the involved researchers. Participants included people from direct clinical practice, education as well as privately interested people. Furthermore, the first findings of this thesis were represented at the “Rendenz-vous Forschende im Gespräch” 2019. This event takes place regularly in the Bern city centre: people passing by are invited to talk with researchers. In this way, the wider community was invited to talk about restraint use in hospitals.

SCIENTIFIC IMPACT

The scientific impact of this thesis includes 1) the relevance of recognising restraint use as a phenomenon influenced by conditions throughout the health care system and 2) the need to investigate restraint by using a broad definition of restraint and across disciplines.

For the first aspect, the findings of this thesis add knowledge that interventions to change restraint practice in hospitals must be conceptualised by

considering influences outside of the nurse-patient interaction. Previous restraint reduction interventions in hospital settings have had limited effectiveness [7, 10, 11]. One possible reason for this might be that too little attention has been paid to the influence of conditions at different levels. However, the findings of this thesis clearly highlight the relevance of conditions at the hospital level such as prevailing routines or cultures. Thus, the findings of this thesis provide a basis for developing effective restraint reduction strategies for the hospital setting in the future. In addition, these findings show parallels to results obtained from long-term care as well as the mental health field. Thus, if these indications are confirmed, synergy in the development of restraint reduction interventions could be exploited in the future. For example, concepts from one of the other settings could be adapted to the hospital setting instead of having to develop completely new concepts. It would also be possible to develop and validate training programmes that can be offered across settings.

For the second aspect, it is evident from this thesis how important it is to study restraint in all its forms and in all disciplines in hospitals to ensure restraint is used as a last resort. Previous research on restraint use in hospitals has focussed on mechanical restraints (in subpopulations). However, the findings of this thesis have clearly shown that a relevant proportion of restraint use is attributable to forms other than mechanical restraint. In addition, this thesis has demonstrated that restraint use is a relevant topic in the entire hospital sector. Hence, all disciplines in hospitals and all forms of restraints have to be considered to reduce the use of restraint in the hospital setting and to avoid a shift in the type of restraint. Overall, these findings impact research in that it is imperative to apply the newer definitions of restraint, which encompass all forms of restrictions on freedom.

In general, this thesis indicates the necessity to investigate restraint use in hospitals further and in a differentiated way. For this purpose, this thesis impacts the possibilities of future research by having the Maastricht Attitude Questionnaire (MAQ) to assess the attitude of nurses towards restraint reviewed for its use in the hospital setting. In addition, this thesis adds knowledge regarding future investigation into restraint use and possibilities for changing practice, in particular to better understand the role of patients, their relatives and other involved health professionals.

Different dissemination strategies have been chosen to have an immediate impact on science. First, all articles have been published as open access. Two articles were published in nursing-specific journals (*International Journal of Nursing Studies* and *Journal of Clinical Nursing*) and three articles were published in

interdisciplinary journals (*Swiss Medical Weekly*, *BMC Health Services Research* and *International Journal of Environmental Research and Public Health*). Publication in both profession-specific and interdisciplinary journals means that this research has reached a wide audience including nurses, other health care professionals, policymakers, etc. In addition, one of these articles was part of a special issue on "The Use of Physical Restraints in Clinical Practice". This has increased the visibility of the work in the interested community. Second, (parts of) the findings have been presented at four conferences with different target audiences: 1) the International Society for Quality in Health Care (ISQua) 37th international conference target at an international community for quality development in health care; 2) the high-noon?! 2021 target at health care professionals and researcher in German-speaking countries focussing on aggression and restraint use in health care; and 3) the European Doctoral Conference in Nursing Sciences (EDCNS) 2019 and EDCNS 2022 target for PhD students in health and nursing sciences, thus addressing especially the scholars of the future. In addition, the publications have been distributed via ResearchGate and linked to the personal profile on the website of the Bern University of Applied Sciences. The strategies have already had an impact. For example, even though the articles have not been published for very long, they have already been cited by other researchers, including in the introduction to a Cochrane Review on the reduction of restraint use in hospitals [10]. In addition, a proposal for an intervention study on the reduction of restraint use through the preventive involvement of patients was developed, among others, based on the findings of this thesis. The proposal is still under review for acquisition; however, the first half of the necessary financial resources for this intervention study have already been approved by a foundation.

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ABOUT THE AUTHOR

Silvia Thomann was born on 28 March 1991 in Erlenbach im Simmental, Switzerland. She received her Bachelor of Science in Nursing from the University of Applied Sciences and Arts of Western Switzerland in 2013. Afterwards, she worked as a registered nurse in acute psychiatry and outpatient care before starting her Master of Science in Nursing at the Bern University of Applied Sciences in 2016. With the start of the Master of Science, she changed from direct nursing practice to the Division of Applied Research and Development Nursing at the Bern University of Applied Sciences as a research assistant. She completed the Master of Science in Nursing in 2018 and was subsequently employed as a research associate at the Bern University of Applied Sciences. Beginning in summer 2018, she became co-project leader of the national prevalence measurement of falls and pressure ulcers in Switzerland, which she still co-leads today. Some of the data analysed in this thesis originate from this measurement. In addition to this co-project leadership, she has worked in and/or led various other research projects related to quality and quality development in healthcare. Among other projects, she has been involved in the project Free Me^{akut}, which addressed restraint use in somatic acute care hospitals. Her PhD project developed out of this project. In March 2019, she started as an external PhD candidate at the Care and Public Health Research Institute (CAPHRI), Faculty of Health, Medicine and Life Sciences at Maastricht University. Under the supervision of Prof. Dr. Sandra Zwakhalen (Maastricht University) and Prof. Dr. Sabine Hahn (Bern University of Applied Sciences), she investigated restraint use in the somatic acute care hospital setting and the need and possible approaches for improving practice.

Besides research, she has been involved in various teaching activities since 2018. She has been teaching in the Bachelor of Science as well as in the Master of Science in Nursing at the Bern University of Applied Sciences and supervised numerous Bachelor and Master theses. In addition, as part of her PhD, she was head of the organising committee of the 19th European Doctoral Conference in Nursing Science (EDCNS), which was held in Bern in 2022 under the motto Designing the Future of Healthcare – Nurses Taking the Lead.

Since 2021, she has held a management position as co-leader of the innovation field Quality in Health Care of the Applied Research and Development Nursing of the Bern University of Applied Sciences. Her responsibilities include the acquisition, execution and dissemination of (applied) research projects as well as the coaching of junior researchers at different levels of qualification.

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