THE USE OF ERROR REPORTING DATA IN PATIENT SAFETY RESEARCH

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DECLARATION

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ABSTRACT

Background: Error reporting is the only data source designed specifically to generate patient safety data, yet its ability to report comprehensively on patient safety has not been assessed. This study aimed to assess the capability of error reporting data to report comprehensively on adverse events. The research question that guided this study was: "What are the perceptions of patient safety experts regarding the use of error reporting data in patient safety?" The objectives of the study were set to determine the demographic characteristics of those who use error reporting in patient safety, i.e., their professional backgrounds, area of practice, countries, languages and years of experience with error reporting data. The study also aimed to determine how they perceive error reporting`s capability to report comprehensively on patient safety and assess whether their professions or areas of practice influenced their choice to work with error reporting and not with other data sources also used in patient safety.

Methods: A cross-sectional survey using an online questionnaire was conducted. This was a descriptive study design with a quantitative approach. Reliability and validity of the study were assured through a pilot test and in consultation with the project leader (who was the researcher's supervisor and an expert in epidemiology research), and experts in patient safety field at the University of Frankfurt. This study was conducted with approval from the University of Frankfurt (see annexure 1b) and University of Stellenbosch ethics committees. Ethics reference number: S15/11/267. Sixty-two experts in patient safety research were surveyed using a 15-item online questionnaire. Error reporting was measured against other data sources on its availability, accessibility, time consumption, annual report generation, ability to report on all causes and level of harm to patients, uniqueness, independence and adaptability to different health organisations. Data were analysed using Statistical Analysis Software 9.4.

Results: Error reporting was the most widely used patient safety data source with 36 (58%) participants indicating a preference for using it, as opposed to 13 (21%) for chart review, 10 (16%) for claims data, 9 (15%) for routine data and 8 (13%) for survey data. Experts felt it was the best in reporting on all levels of harm (61.1%) and generating annual patient safety reports (44.4%), but it was the most inaccessible data source (37.2%). Both profession (p = 0.25) and area of practice (p = 0.79) had no influence on experts' choice for error reporting as a data source.

The difference between error reporting's overall performance in patient safety and the other data sources, measured using a *t*-test was not statistically significant (between error reporting and claims data source (p = 0.92), between error reporting and routine data source (p = 0.74) and between error reporting and survey data source (p = 0.61).

Conclusion: Error reporting, although the most widely used, had shortcomings in several areas currently complemented by other data sources. Thus, relying on it alone could be inadequate, and ways to integrate data sources should be explored further.

Keywords: Patient safety, Error reporting, Chart review, Claims data, Routine data, Survey data

OPSOMMING

Agtergrond: Fout-aanmelding is die enigste databron wat spesifiek vir die generasie van pasiënt veiligheid data ontwerp is, en tog is dié bron se vermoë om omvattend oor pasiënt veiligheid te rapporteer, nie geëvalueer nie. Die doel van die studie was om te beoordeel of die fout-aanmelding data volledig kan rapporteer op ongunstige gebeure, aangesien dit die enigste databron ontwerp is vir pasiënt veiligheid. Die navorsing vraag wat die studie gelei het was: "Wat was die persepsie van pasiënt veiligheid kenners met betrekking tot die verteenwoordiging en evaluasie van fout-aanmelding data in pasiënt veiligheid?" Die objektief van die studie was om die demografiese eienskappe te bepaal van die wat fout-aanmelding in pasiënt veiligheid gebruik. Hulle professionele agtergrond, praktyk-gebied, lande, tale en jare van ondervinding wat fout-aanmelding data rapporteur bepaal hoe hulle fout-aanmelding sien en die vermoë om dit te rapporteur volledig op pasiënt veiligheid en dit beoordeel of hulle beroep praktyk beïnvloed die keuse of hulle fout-aanmelding en nie ander databronne gebruik in pasiënt veiligheid.

Metodes: In 'n opname oor pasiënt veiligheid was 62 deskundiges geraadpleeg en 'n aanlyn vraelys bestaande uit 15 items gebruik. Fout-aanmelding in verhouding tot ander databronne was gemeet, met inagneming van die beskikbaarheid, toeganklikheid, tydverloop, jaarlikse verslag generasie, vermoë om oor alle oorsake en vlakke van pasiënt bedreiging te rapporteer, uniekheid, onafhanklikheid, asook die aanpasbaarheid daarvan by verskillende organisasies. Data is met behulp van die rekenaarsagteware Statistical Analysis Software 9.4 ontleed.

Resultate: Fout-aanmelding was die algemeenste pasiënt veiligheid databron by 36 (58%) van die deelnemers, in vergelyking met 13 (21%) se voorkeur aan kaart hersiening, 10 (16%) se voorkeur aan eise data, 9 (15%) se voorkeur aan roetine data en 8 (13%) se voorkeur aan opname data. Kundiges was van mening dat foutopsporing die beste presteer het wat rapportering op alle vlakke van bedreiging (61.1%) betref, asook vir die skep van jaarlikse pasiënt veiligheid verslae (44.4%), maar dat fout-aanmelding die ontoeganklikste databron (37.2%) was. Daar is bevind dat sowel beroep (p = 0.25) as praktyk gebied (p = 0.79) geen invloed op die deskundiges se keuse van fout-aanmelding as 'n databron gehad het nie. Volgens 'n toets wat fout-aanmelding en ander bronne se oorhoofse prestasie ten opsigte van pasiënt veiligheid gemeet het, was die verskil statisties

onbeduidend (tussen fout-aanmelding en eis databron (p = 0.92), tussen fout-aanmelding en roetine databron (p = 0.74), en tussen fout-aanmelding en opname databron (p = 0.61)).

Gevolgtrekking: Alhoewel fout-aanmelding die algemeenste gebruik is, het dit tekortkominge op verskillende gebiede getoon, wat tans deur ander databronne aangevul word. Deur alleenlik op fout-aanmelding staat te maak kan ontoereikend wees, en maniere om databronne te integreer behoort gevolglik verder verken te word.

Sleutelwoorde: Pasiënt veiligheid, fout-aanmelding, kaart hersiening, eise data, roetine data, opname data

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LIST OF ABBREVIATIONS AND ACRONYMS

AHRQ	Agency for Healthcare Research and Quality
CDC	Centre for Disease Control
DoH	Department of Health
IOM	Institute of Medicine
KK	Kerstin Klemp (the project leader and the researcher's supervisor at University of Frankfurt)
LINNEAUS	Learning from International Networks about Errors and Understanding Safety in Primary Care
m	Mean
NHS	National Health Service
P	*p*-value
SAS	Statistical Analysis System
SPSS	Statistical Package for the Social Sciences
SOP	Standard Operations Procedures
USA	United States of America
UK	United Kingdom
WHO	World Health Organization
X^2	Chi-square test

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CHAPTER 1: INTRODUCTION

This chapter gives the background information on medical errors in healthcare and the data sources used to report on these medical errors. It further gives the rationale of this study and concludes with a relevant literature review on the subject.

1.1 Background

According to the World Health Organization (WHO), one in every ten patients is harmed while receiving healthcare. There are 43 million incidents per year of which medicine errors alone cost about 42 billion US dollars (1). In 1999, it came as a shock when the "To Err is Human" report revealed that 98 000 deaths caused by medical mistakes exceeded deaths caused by breast cancer or motor vehicle accidents (75). Unfortunately, in 2013, the Institute of Medicine (IOM) still reported an alarming number of 400 000 deaths due to medical mistakes (2).

The WHO defines patient safety as the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum (1). Patient harm is mostly caused by human error or systems error (3). Human error is when a health professional does or omits an act from the plan or follows a wrong plan or no plan at all, e.g. wrong-side surgery. Systems errors happen due to the way in which things are done in that particular healthcare facility, e.g. when an Intensive Care Unit fails to implement processes that reduce infections. Errors can happen at any step in patient management, including diagnosis, treatment, and prevention (4). Laharia et al. documented the same findings that patients can be harmed at all levels of healthcare, i.e. in primary, secondary and tertiary care. An error may or may not cause an adverse event (5).

Vincent defined an adverse event as an unintended injury caused by medical management rather than by the disease process. This event is serious enough to lead to the prolongation of hospitalisation or to temporary or permanent impairment or disability to the patient at the time of discharge or both (3). The WHO defines an adverse event as an incident that resulted in harm to a patient (1).

Adverse events can be classified according to the severity of harm suffered by the patient ranging from no harm (also known as “near misses”) or minor harm needing only minor treatment with minimal or no financial losses at all to severe harm (6,7). They can also be classified according to how frequently they are most likely to occur ranging from less to most likely to occur (8).

Several factors influence medical errors in healthcare, with human factors being the main cause of errors (9,10). Human factors include but are not limited to fatigue, lack of knowledge, distractions and forgetfulness. The types of errors differ according to whether one receives their care in a primary setup or hospital. In primary care, the errors will mostly be because of delayed or incorrect diagnosis with the wrong medication (76). In hospitals, diagnosis and medication errors apply and in addition, a lack of prevention against infections leading to nosocomial infections, falls and faulty medical equipment. A study by Angheluta indicated that errors are usually approached at an individual level with a punitive action forgetting that systems contribute greatly to errors (11).

It is estimated that the aggregate cost of harm in the Organisation of Economic Cooperation and Development (OECD) countries alone amounts to trillions of US dollars every year (1). The HARM study on medication-related hospital admissions indicated that medical costs were not the only concern. Instead, they estimated a total production loss of €181 528 or US$263 723 for all 331 studied admissions (12). “Patient harm is the 14th leading cause of the global disease burden, comparable to diseases such as tuberculosis and malaria” (1). Besides having to pay for long hospital stays, litigation and loss of lives, the society also suffers a loss of productivity at work and schools while health professionals slide into depression and lose confidence in caring for their patients (11).

It was the ever-increasing litigation claims against doctors by patients and families of the deceased that triggered the need to look into the quality of healthcare patients received in the United States of America (USA). South Africa has also experienced a rise in litigation claims, as patients increasingly become aware of their rights resulting in medical practitioners to look at their patients as potential litigation risks. To protect themselves, they practice defensively, running all possible unnecessary medical tests, which in turn increases medical costs (13). The scale of the medico-legal claims is staggering. According to a BusinessLIVE report, by the end of the 2016-2017 fiscal

year, government faced contingent liabilities of about R56.1bn. That equates to close to a third of the R170.9bn consolidated health budget for 2016-2017 (14).

The ethical principles of beneficence (doing good) and non-maleficence (preventing harm) are violated when errors are not reported or disclosed (15). This ugly picture of our healthcare system can only be mitigated by capturing all the medical errors, investigate them and correct their causes to prevent them from recurring. Patient safety, therefore, has become a growing focus for researchers and practitioners in healthcare. Patient safety research seeks to understand the causes of unsafe care and to identify potential solutions (1). We, therefore, depend on reliable, representative and relevant data to report on patient safety, to learn from and prevent errors from occurring in the future.

Currently, many different poorly coordinated sources of data are being used, with no consensus of how the adverse events should be collected, which is time-consuming, difficult and costly (16). It would be possible to report comprehensively on patient safety if these data sources could be standardised and reduced to one or two. Data sources used for collecting information on adverse events include but are not limited to chart review, claims data, error reporting data, routine data and survey data.

1.2 Problem statement

Error reporting data, as the only data source designed to report on patient safety, should be more representative, relevant and must report comprehensively on all adverse events. All healthcare providers should be able to use this information to prevent the same mistakes from recurring in the future to save costs and human lives. Hospitals, pharmacies and doctors' rooms should be safe places for patients. People should not need to pay exorbitant amounts of money on medical complications that subsequently result in increased premiums for medical insurances. Though error reporting data is the only data source designed to report on patient safety, its capability to report on adverse events comprehensively have not been assessed. Currently, many data sources used in patient safety are non-coordinated and costly; therefore, many adverse events remain unreported.

For the reason mentioned, the researcher decided to evaluate the perceptions of the patient safety researchers on error reporting as a data source with the hope to use the findings of this study to improve its shortfalls.

1.3 Significance of the study

By assessing the use of error reporting, its strengths and weaknesses were identified and compared to chart review, claims data, routine data and survey data sources. The researcher hopes that this will form the basis for its improvement and healthcare providers will utilise it more. It will be the main patient safety data source providing a platform for healthcare providers to learn from their mistakes and preventing the same from recurring. Patient harm will be reduced; healthcare institutions will be safer places; and costs on hospitalisations, litigation against healthcare providers and absenteeism from work and schools will also decrease. By understanding the data sources, relevant data to safeguard safety interventions will be generated. It will be easier, faster and cheaper for patient safety researchers to source data on medical errors from one major data source.

1.4 Research question

The research question that guided this study was: “What are the perceptions of patient safety experts regarding the use of error reporting data in patient safety?’’

1.5 Literature review

1.5.1 Expert perceptions of error reporting as a data source used to report patient safety

A selective literature search was done on Medline via Pubmed. A combination of a ‘data source and patient safety’ was entered in the search box, e.g., ‘(survey data) AND patient safety’. This was repeated for all five data sources. Filters were activated to include only human species and articles written in English only. Google scholar and organization-based websites related to patient safety like Agency for Healthcare Research and Quality, World Health Organization and the National Patient Safety Agency (UK) were also searched. Abstract screening to select relevant literature was done by both the researcher and the project leader. Literature was considered relevant if it contained information or compared any of the five data sources being studied. This

study sought to explore patient safety experts' perceptions of error reporting data in patient safety as opposed to other data sources also used in this field. Their opinions on error reporting data relevance to patient safety, its availability, accessibility, user-friendliness, time consumption, independence, adaptability to different organisations, ability to report on all harm including "near misses" (i.e., harm that could have happened but did not happen), causes of harm, whether it had unique information and whether information sourced from it could be used to train employees on patient safety were assessed. There is no doubt that error reporting data is relevant in-patient safety since it is the only one designed to report on it.

Comparing its performance in patient safety to other data sources is not the simplest task since the terminology used in classifying the adverse effects and errors are not necessarily the same (15). Marodin et al. encouraged the importance of harmonising the vocabulary in reporting adverse events to avoid confusion (17). A study by Rostami et al. confirmed how difficult it is comparing safety data across organisations, practice domains, and applications, as data are usually specific for a certain safety application and organisation, which limits the shareability of patient safety data (18).

1.5.1.1 Accessibility

The authors' views regarding error reporting data accessibility and other data sources were somehow similar. There are varying degrees as to how accessible the health information is to a health researcher. Most of them require medical expertise for the researcher to extract the relevant information needed. Sometimes there were no computers or forms on which to report errors. As much as some institutions depend entirely on error reporting to report on patient safety, some authors mentioned that this was not available in primary care. A study by Hoffmann and Rohe indicated that error reporting systems as internal systems might be accessible only to the employees of a specific hospital and not necessarily in all hospitals (19). Some data sources such as routine data involve a fee before a health professional can access them (20).

1.5.1.2 User-friendliness

A study by Gong et al. mentioned a lack of reporter-friendliness as a barrier to healthcare professionals successfully adopting error reporting systems (21). Error reporting was also blamed

for lack of consistency in the terminology used (15) making it more difficult to extract information relevant to patient safety. Claims data were also considered difficult to work with, especially since data was collected by law professionals for litigation purposes and not necessarily for patient safety (22). Chart review data sources were considered the most difficult to work with, as the information was as good as the person who entered it (77). Chart review data is not collected for patient safety, but it is about every activity of care by all healthcare professionals on the patient (78).

1.5.1.3 Cost-effectiveness

Patient safety professionals desire that error reporting systems should also be cost-effective. A study by Stavropoulou suggests that health care organisations should carefully consider the opportunity costs of error reporting systems and whether they provide value for money (23). The study further recommends that more work on the cost-effectiveness of error reporting systems should be done to shed more light on this issue. Murff et al. highlighted that even though manual chart review has been considered the "gold standard" for identifying adverse events in many patient safety studies, this methodology is expensive and imperfect (24). Wickson-Griffiths et al. also showed the imperfection of chart reviewing, needing data extractors to be trained on how to extract data, which could be costly (25).

1.5.1.4 Ability to report on all levels of harm

Regarding the ability of error reporting data source to report comprehensively on all levels of harm, some authors felt that error reporting data was biased towards severe cases and neglecting "near misses". A study by Marella indicated how an incident of a patient who was nearly not resuscitated due to a yellow wristband indicating that he is a risk for falling but mistaken for no resuscitation, would not be recorded anywhere since no harm happened (26). In contradiction, a study by Crane et al. indicated how error reporting made it possible for healthcare professionals to report "near misses" anonymously without any fear of being persecuted (27). While a study by Ajri-Khameslou et al. showed that nurses were most likely to report minor harm than severe harm due to fear for losing their jobs and their reputation (79). Anonymous reporting of errors can be good and bad. Good in a sense that it would promote an error reporting culture without fear, and bad in that health professionals get to choose whether to report an incident or not, which leads to underreporting.

A study by McCall showed a decrease in the number of medication errors reported and it was not clear whether this was due to an actual decrease in the number of medication errors made, or due to a decrease in the number of nurses and health care professionals who report errors (28).

1.5.1.5 Unique information

Authors felt that information sourced from error reporting overlapped to other data sources. Among the data sources used in patient safety, only claims data has unique information. A study by Wilson mentioned that it is only through claims data that a holistic view of the patient's interactions with the healthcare system can be seen (29). A study by Croke revealed that it was possible to track down which doctors and nurses are involved in harm and to identify risky units through malpractice payments (30). This would be impossible with data sources such as error reporting and survey data since healthcare professionals are allowed to remain anonymous. Winslade et al. indicated how useful pharmacy claims data were in addressing medication use problems within communities (31).

1.5.1.6 Ability of error reporting information to be used in training

Authors had mixed reactions regarding the ability of error reporting information usefulness in the organisational training of employees, where they learn from the mistakes and prevent them from happening in the future. A study by Stavropoulou et al. found some evidence of single-loop learning, that is, changes to clinical settings or processes as a consequence of learning from error reporting systems (23). In addition, a study by Cooke et al. suggested that the greatest opportunity for improving organisational learning might not lie in improving employees' willingness to report incidents but in the ability to respond to them (32). It was recommended that organisations provide training to employees on how to effectively communicate (written) incidents to supervisors, and to supervisors on how to report/summarise incident learning back to employees (32).

1.5.1.7 Ability of error reporting data to report comprehensively on patient safety on its own

Even though error reporting is the only data source designed to report on patient safety, a study by Murff et al. considered chart review data as the "gold standard" in reporting patient safety (24). This is probably because all healthcare institutions have medical records, unlike error reporting systems that are not necessarily available in all healthcare areas, for example, in primary healthcare

where the need to invest in error reporting systems might not be recognised. Germany`s "Jeder Fehler zählt!" a national error reporting system for family doctors, is one example of a system that works well in primary care (33).

A study by Stavropoulou et al. also raised the concern of not having found strong enough evidence that error reporting systems performed better than other methods do (23). In fact, even in areas where error reporting systems were available, some physicians opted to use other methods to report medication errors, while nurses were noted to utilise error reporting systems more (15). A study by Rosenthal argued that error reporting systems should complement and not replace practices used by hospitals to review and analyse their health safety incidents (34).

1.5.2 Expert professional background influence on their choice for error reporting data

A study by Wolf and Hughes indicated that nurses were more likely to submit written reports or use error-reporting systems than physicians (15). The same findings were found by Rowin et al. who indicated that out of 266 224 adverse events reported in hospitals over 7.3 million inpatient days, physicians only reported 1.1% of the total events, nurses 45.3%, and other hospital employees 53.6% (35). This was further confirmed in a study by Garbutt et al. where physicians indicated that they relied on informal discussions with colleagues about errors instead of reporting them on error reporting systems, as they considered current systems to be inadequate (36).

In addition, a study by Carmichael indicated that at least 66% of physicians regarded poor error reporting systems to be their main barrier in medical error reporting (37). However, nurses, doctors and other clinicians were preferred in sourcing patient safety data from chart reviewing, as they are familiar with medical terminology and understand what information needs to be extracted. This is usually a challenge when ordinary people are trained to extract patient safety information from chart reviews.

Several studies indicated the role played by pharmacists in reporting medication errors and using medication error data to improve patient safety. In a study by Kang et al. pharmacists thought that medication errors were a critical issue and that they should play a role in preventing them, even though they confessed their lack of active participation in reporting these errors (38).

Teoh et al. noted similar findings where both doctors and pharmacists stated that prevention of medication errors is a high priority in their workplace, even though their medication error reporting remained low (39). A medication error reporting system such as Medmarx has been in use since 2000. However, a 2018 medication safety community pharmacy report by Discern Health indicated that in practice, many pharmacists still do not report medication errors, citing factors such as fear of punishment and ridicule as one of the main causes of low error reporting (40).

Although pharmacists tended to report medication errors less, they were condoned for using pharmacy claims data to control medication problems in communities. This applied mainly to the elderly who tend to collect treatment with the same active ingredients but different trade names from different pharmacies within the same area and risking overdose. For example, in Quebec, pharmacists are also authorised and paid to provide specific professional services to address such medication use problems, and one can measure their rate of performance of these services (31). Pharmacists used same claims data to track patients in possession of medications that needed to be recalled due to newly observed severe adverse effects. The key role for professionals in patient safety research is to report on patient safety using data sourced from different data sources.

1.5.3 Experts healthcare speciality influence on their choice for error reporting data

Authors agreed that error reporting systems were not readily available in primary healthcare, which translated into medical error reporting in this section of healthcare being biased to severe cases only. Crane et al. were of the same opinion indicating that error and event reporting systems can be implemented in primary care. They, however, were concerned that these rarely focused on near-misses or the coordination of near-miss reports with quality improvement (27). A study by Kaprielian et al. showed how less attention has been paid to outpatient settings regarding increasing patient safety as opposed to inpatient settings (41). Khoo et al. echoed that there is a lack of studies published on medical errors in primary care (42).

It was only recently that LINNEAUS Germany seriously engaged in finding factors to improve their error reporting system in ambulatory settings, which so far seems to be working well (43). Both ambulatory facilities and hospitals, however, keep patients' files with medical information that include, doctors' and nurses' notes, medicine prescriptions, laboratory and radiology results. This information later is used in chart reviewing to answer any research questions on patient safety.

This is in line with chart review being considered the gold standard in detecting errors and adverse events.

A study by Hogg et al. indicated that physician behaviour, which is a constant area of inquiry for primary care researchers, is often best measured by auditing medical charts. It is from these chart audits that clinicians' daily activities on patients, for example, physical examination, prescribing, laboratory procedures, and specialist referrals can be measured (44).

Other than error reporting and chart reviewing, authors identified several other methods to detect errors and adverse events in hospitals, including malpractice claims analysis, routine data and survey data analysis. As much as they agreed that medical malpractice claims data were used in hospital settings, it was also appreciated that these were used in primary settings too. A study by Bonetti et al. presented the number of medical malpractice claims in Italy, broken down into the hospitals where the incidents occurred, departments, type of harm sustained by the patient and the total monetary value claimed for compensation (45). Another study confirming the use of medical malpractice claims in hospitals to detect adverse events was in Taiwan by Hwang et al. (46). A systematic review study by Wallace et al. demonstrated that malpractice claims were also used in primary care to detect diagnosis and medication error as areas that needed to be prioritised in developing educational strategies and risk management systems (47).

Authors believed hospitals used survey data to detect adverse events. Some hospitals made it a routine to ask patients and families to complete a patient satisfaction survey on discharge from the hospital (48,49). It is from such surveys where some of the adverse events would be detected. Womack et al. indicated that employees could be surveyed concurrently to understand the organisational factors regarding using data to identify and measure quality, patient safety, or service line efficiencies and improvement (50). In addition, a study by Bodur and Filiz also demonstrated that nurses, doctors and other healthcare professionals in primary care were surveyed to determine the safety culture in Turkish primary healthcare services (51).

Authors believed that routinely collected data such as birth rates, mortality rates, and socio-economic data in both primary and hospital settings can be successfully used to identify adverse events. A study by Davies et al. indicated how routinely collected data in hospitals remained their main source of information on the diagnosis and treatment received by patients in secondary and

tertiary care settings (52). Sprenger et al. indicated how Austrian primary care routinely collected data was used to reduce low-value services, unnecessary diagnostic tests and ineffective therapeutic procedures to improve patient safety and quality of care (53). Adding to this, a study in Germany among four hospitals confirmed that ICD codes from routine data can provide an important contribution to the development and improvement of Adverse Drug Events monitoring systems (54).

1.6 Research aim

This study aimed to assess the capability of error reporting data to report comprehensively on adverse events, since it is the only data source designed for patient safety.

1.6.1 Research objectives

The researcher identified the following research objectives:

to assess the demographic characteristics of the users of patient safety data sources for reporting on patient safety;
to determine the perception of experts on error reporting as a data source for reporting patient safety; and
to assess the influence of professional background or area of practice on error reporting utilisation.

1.7 Conceptual framework based on study concepts

Figure 1.1: The relationship between data source and patient safety

Patient safety remains a global concern as patients continue to be harmed within the hands of health professionals. For harm to be reduced, all adverse events need to be collected, researched and used to learn from them to prevent the same mistakes from happening again. Information on adverse events can be sourced from various sources, including but not limited to patients' medical files, error reporting systems, medical malpractice claims and pharmacy claims, routine and survey data. The data from these different sources are used by professionals like doctors, nurses, pharmacists and others in different facilities of healthcare to study the most common types of medical errors relevant to their units. This information is used to improve quality of care and to train staff in order to improve patient safety. Collecting data from different data sources has, however, proved to be laborious, uncoordinated and expensive, hence the researcher's decision to undertake this study to determine whether one can rely only on error reporting data to comprehensively report on patient safety.

1.8 Definition of concepts/operational definitions

Patient safety: The WHO defines patient safety as the absence of preventable harm to a patient during the process of health care and the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum (1).

Adverse event: Is defined as an unintended injury caused by medical management rather than by the disease process and which is serious enough to lead to the prolongation of hospitalisation or to temporary or permanent impairment or disability to the patient at the time of discharge or both (3).

Error reporting: Is the system used by health professionals to report patient harm that occurred during healthcare voluntarily and anonymously (6). Nurses, doctors and pharmacists who have been directly involved in causing harm to the patient, capture the details of the incident in the error reporting system specifically designed for their departments. This is however not the only way of reporting errors, as observed in the American "Just culture approach" where medical employees are encouraged to openly report their mistakes to patients (16).

Chart review: This is pre-recorded medical information about the patient such as physician and nursing notes, out of hospital report and diagnostic test results from both radiology and laboratory departments (55).

Claims data: It is information regarding payments made for healthcare services received by the patient. It consists of the billing codes that physicians, pharmacies, hospitals, and other health care providers submit to payers, for example, insurance companies and Medicare (29). Such information can be useful to track down all patients who received medication that has been found to be harmful and needs to be recalled.

Routine data: It is information collected routinely about the population, for example, registration of births and deaths as required by the law in many countries (20,56). Causes of deaths are studied from such data.

Survey data: Is information collected through surveys where opinions about a specific issue are collected nationally or from patients and health professionals (57,58). Some hospitals routinely

provide these surveys to patients and family to comment on the care received during their stay in the hospital.

Patient safety research: Patient safety research is defined as an action-oriented field of scientific enquiry that aims to determine: 1) the type and magnitude of harm caused by unsafe care; 2) the contributing factors and causal pathways that are potentially modifiable, including unsafe systems, processes and behaviours; and 3) cost-effective and locally adapted interventions that can successfully prevent, reduce or mitigate unsafe care to reduce harm (59).

Patient safety experts: An expert is defined as a person who is deeply knowledgeable about or skilful in a particular area (in this case in the patient safety field) (60).

CHAPTER 2: RESEARCH METHODS

The previous chapter provided an introduction and background to the study. This chapter will describe the study design, study population, study setting, sampling and measurements. The definition of variables used for this study together with data management, data analysis and ethical considerations will also be discussed.

2.1 Study design

A cross-sectional survey using an online questionnaire was conducted. This was a descriptive study design with a quantitative approach. This study design was chosen because it allows one to gather information about different groups and compare them at the same time. This design was appropriate for this study, as it needed information about different data sources from the patient safety experts to be collected to later compare them on specific measures.

The benefits of a cross-sectional survey are that it can be used to prove or disprove assumptions, it is cost-effective and requires a short time to complete. It contains several variables that can be used for several types of research, but this doesn't mean that it is without shortcomings. Compared to other study designs, it is known to be prone to bias due to low response and misclassification due to recall bias (61).

2.2 Study setting

This study was conducted through the Institut für Allgemeinmedizin Uni-Frankfurt, Germany, a partner in the LINNEAUS project (funded by European Union Framework 7), which focused on researching, networking and developing tools for improving patient safety in primary care. The purpose of the sub-study was to assist in determining the usability of different data sources in healthcare for patient safety research.

2.3 Study population

The study population were health professionals who are experts in patient safety research from different countries, who have experience with one or more of the data sources used in reporting on

patient safety across all levels of healthcare. These data sources included chart review, claims data, error reporting, routine data and survey data.

2.4 Sampling and sample size

There were 326 safety experts in total that were identified. Seventeen (17) of them were identified by each of the LINNEAUS partner countries (Austria, Germany, The Netherlands, Poland, Denmark, Greece, Spain, Scotland and England) and their details were forwarded to the researcher at the Institut für Allgemeinmedizin Uni-Frankfurt. Another 309 safety experts were further identified through a literature search. These were the first authors of patient safety publications accessed through Pubmed. Online questionnaires were sent to all experts, and of the 326 experts, 73 completed the survey representing a 22% response rate. The questionnaire was distributed to all the identified experts hence no specified sample was selected. This was done to improve the power of the study to detect a significant difference.

2.4.1 Inclusion criteria

This study included persons experienced in patient safety research who work with one or more data sources used in patient safety.

2.4.2 Exclusion criteria

There were no specific exclusion criteria set out; participants only needed to have worked with one or more data source in the patient safety field to be included in the study.

2.5 Data collection tool and data collection

The researcher collected data using an online questionnaire. The demographic characteristics section of the questionnaire was adapted from a previously validated LINNEAUS questionnaire that was used for “Patient Safety Incident Classification for Primary Care research”, with permission from the researcher’s supervisor who had developed that questionnaire (47). The researcher, under the supervisor’s guidance, developed the rest of the questions.

The questionnaire was divided into two parts. The first part of the questionnaire concentrated on the participants’ demographic data. The demographic section comprised of questions regarding

the participants' country, native language, professional background, years of experience working with their respective data source(s) and the area of healthcare where they are currently employed (see Annexure 3). The second part concentrated on the participants' opinions about the data sources with which they worked. The participants had to use a five-point Likert scale to indicate their agreement or disagreement with the 11 statements made about their respective data sources.

The questionnaire was loaded on Survey Monkey software, an online survey tool that enables a collection of responses from participants and can download results on an advanced excel spreadsheet compatible for use with statistical analysis software like SPSS and SAS. This method was preferred to paper methods due to it being cheaper, saves time, easy to track responses, flexible, stores data securely in a password-protected environment and allows for easy consultation of persons on widespread locations.

The data collection was conducted through The Institut für Allgemeinmedizin Uni-Frankfurt, Germany under the supervision of the Project Leader Mrs Kerstin Klemp (KK) from 13 November 2012 to 31 January 2013. Information was given to participants as described in paragraph 2.13 Ethics Consideration. Participants who partially answered the questionnaire and those who did not respond at all were electronically reminded twice to do so.

2.6 Pilot study

Pilot tests sometimes referred to as pilot studies, are small-scale versions of a research investigation that lacks sample size to fully calculate statistics or answer the research question. Pilot studies are conducted to assess the study design, its feasibility, and evaluate the methodology and procedures of the investigation (63). In this study, a pilot test was conducted on three (3) patient safety researchers at the University of Frankfurt. They were selected because they were familiar with the patient safety field and they could easily detect whether there were any errors with the questionnaire. The following parameters were tested: clarity of instructions to ensure that they did not confuse the participants, that the questions asked what they were meant to and the timing for each question and the overall research was correct.

2.7 Reliability and validity

Reliability and validity of the study were assured through a pilot test and consultation with the project leader (who was an expert in epidemiology research and was also my research supervisor) and other patient safety experts at the University of Frankfurt. These experts in epidemiology research assured content validity, face validity and construct validity. A test-retest reliability was conducted to assess the reliability of the measurement instrument. Three experts were asked same questions at two different times and responses were compared to assess if they gave the same answer to the questions. The questionnaire was revised accordingly based on observation from the test-retest.

2.8 Outcome variables

The outcome variables in this study were the five data sources used in collecting information on adverse events in patient safety. These were chart review, claims data, error reporting, routine data and survey data sources. The probability of an expert using either one of these data sources depending on their professional backgrounds and their area of practice was assessed.

2.9 Exposure variables

The exposure variables in this study were the experts' profession and their healthcare area where they worked. This study assessed the influence of someone's profession or healthcare area on their choice to work with either chart review data or any of these five data sources.

2.10 Definition of main variables used in this study

2.10.1 Definition of outcome variables used in this study

The probability of an expert using error reporting data source or any of the other data sources used in patient safety, including chart review, claims data, routine data and survey data sources, depending on their professional backgrounds or their area of practice, was assessed. The data sources were defined under operational definitions in section 1.8.

The variables ("chart", "claim", "error", "routine" and "survey") represented the different data sources as outcome variables while variables "profession" and "healthcare area" were exposure variables.

2.10.2 Definition of exposure variables used in this study

Healthcare area: The variable "healthcare area" was created from the question, "In what area of healthcare do you primarily work (Multiple selections are possible)?" Participants had an option of selecting the division in which they primarily work from the list of different healthcare areas provided in the questionnaire. In addition, they could also select other and then specify their choice. It was possible to select more than one choice for those who work in different healthcare areas simultaneously. At least 40 options were pre-listed for the participants, for example, primary care, emergency care, pharmacy and medicine.

Profession: The variable "profession" was created from the question, "What is your professional background?" There were no specific professions pre-listed, so participants were free to type in their respective professions in the text box provided in the questionnaire. All medical doctors were grouped together and coded "1". Nurses were coded "2", pharmacists "3", Law "4", research and academics "5", psychologists "6", and physiotherapists were coded "7".

2.10.3 Demographic variables

Country: The variable "country" was obtained from the question, "In which country are you working?" Participants were expected to be primarily from the nine European LINNEAUS project partner countries, (Austria, Germany, The Netherlands, Poland, Denmark, Greece, Spain, Scotland and England). For comparison purposes, the option "other and please specify your country" was added, which made it possible for other European and non-European countries not necessarily taking part in the LINNEAUS project to also take part in the study.

Language: This variable was created to determine the participants' native languages.

Years: This variable was created from the question, "How long have you been working with this data source already?" At least six categories were created, namely, less than 5 years was labelled

as “1”, 5–9 years “2”, 10–14 years “3”, 15–19 years “4”, 20–24 years “5” and 25+ years was labelled “6”.

2.10.4 Five-point Likert scale variables

A number of statements meant to assess the experts’ perceptions of their data sources used to report on patient safety were made. They had to comment on their respective data sources accessibility, availability, user-friendliness, time consumption, ability to report on all causes and levels of harm, whether their information was unique and could be used in employee training in different organisations and the data sources’ ability to report comprehensively on all adverse events and generate an annual report. The participants had to show their agreement or disagreement using a five-point Likert scale. I strongly agree = 1, I agree = 2, I am not sure = 3, I disagree = 4 and I strongly disagree = 5. Eleven variables were created from these 11 questions. These variables would normally attach the specific data source name, for example, Chart_Widelyused, Claims_Widelyused, Error_Widelyused, Routine_Widelyused and Survey_Widelyused (see Annexure 4).

2.11 Data management

Data was directly captured into a password-protected Survey Monkey software as participants completed an online survey. This was made available on excel, which was exported to SAS V9.4 statistical software for analysis. A plausibility check on the data was done by the project leader and the researcher to correct any mistakes and to note missing values (see Figure: 3.1 Flowchart). Access to data was limited to the study team only. New variables necessary for the analysis were created from the existing data.

2.12 Data analysis

2.12.1 Descriptive and inferential statistics

Descriptive analysis of the demographic variables included “Country” (which shows the countries where these data sources are being used), “Healthcare_area” (shows whether it is in a primary setting, hospital, pharmacy), “Profession” (nurse, pharmacist, lawyer,), “Chart”, “Claims”, “Error”, “Routine” and “Survey” (shows which data source was being used among chart review,

claims data, error reporting, routine data or survey data respectively), "Language" (shows the participants` languages) and "Years" (shows how many years of experience the participants have with their respective data sources). This analysis indicated which data sources are mainly used, where, by whom, for how long and for what purpose. These were described numerically and presented in frequency tables.

Univariate analysis of variables created from the Likert scale questions was conducted to describe the participants' perceptions of their respective patient safety data sources. Responses from the 11 Likert scale questions were dichotomised into "I strongly agree/agree" vs "I am not sure/I strongly disagree/disagree". This dichotomisation placed primary analytic focus on positive responses; therefore, responses for "I strongly agree" and "I agree" were combined and analysed. Results were presented graphically on histograms.

A bivariate analysis was done to assess associations between participants' characteristics and their preference for a specific data source, being whether someone's profession or his healthcare area of practice had an influence on him choosing a specific data source with which to work. The dependent variables involved were Error, Chart, Claims, Routine and Survey, each modelled against the independent variables, Profession and Healthcare_area. Their relationship was tested using the Chi-square test (x^2) with the significance of their association determined using a *p*-value of 0.05. Fisher's exact test was used where there were sparse data of less than five observations in cells.

To determine the difference in error reporting data source's overall performance in patient safety from the other four data sources, a two-sample *t*-test with a *p*-value of 0.05 was used. Results only considered responses from participants who answered that specific question. Data were analysed using Statistical Analysis System 9.4 (SAS Institute, Cary, N.C.).

2.13 Ethics consideration

The University of Frankfurt and the University of Stellenbosch ethics committees approved this study. Ethics Reference number: S15/11/267. (Appendix 1a &1b)

Beneficence means to do no harm to patients and is one of the core principles in ethical research. This study was non-experimental, data was collected online and posed no threat to the participants' lives; therefore, the researcher assures that no harm was caused to the participants.

Consent: Taking part in this study was voluntary. Prior to completing the questionnaire, the purpose of the research was explained to the participants (See annexure 2). Their confidentiality was assured, and they were made aware that they could stop completing the questionnaire at any time they felt they did not want to continue with the study by clicking on a link on the survey. The signing of consent forms was not necessary, completion of the online questionnaire indicated that consent was given voluntarily.

Confidentiality: The LINNEAUS project leader and the researcher made sure that participants' confidentiality was maintained. As a Principal Investigator (PI), data was saved in the researcher's password-protected Personal Computer. Data did not include personal identification details such as participants' names, date of birth, home address and telephone numbers.

CHAPTER 3: RESULTS

The preceding chapter discussed the research methods employed in this study. This chapter presents the results and interpretation thereof following each objective of the study. The demographic characteristics of the participants, their opinions regarding their respective data sources and the influence of either their professional backgrounds or their area of practice have been described.

3.1 Participants' demographic characteristics

Of the 17 experts identified through partners in the LINNEAUS project, 15 completed the survey. From the additional 309 experts identified through the literature, 58 completed the survey. These two sources provided a total of 73 experts who completed the survey. Of the 73 experts, eleven provided incomplete data and were excluded from the analysis.

Of the remaining 62, 13 worked with and responded to questions on more than one data source. Error reporting data was the most widely used with n = 36 (58%) participants indicating a preference for using it, as opposed to n = 13 (21%) for chart review, n = 10 (16%) for claims data, n = 9 (15%) for routine data and n = 8 (13%) for survey data as presented in Figure 3.1.

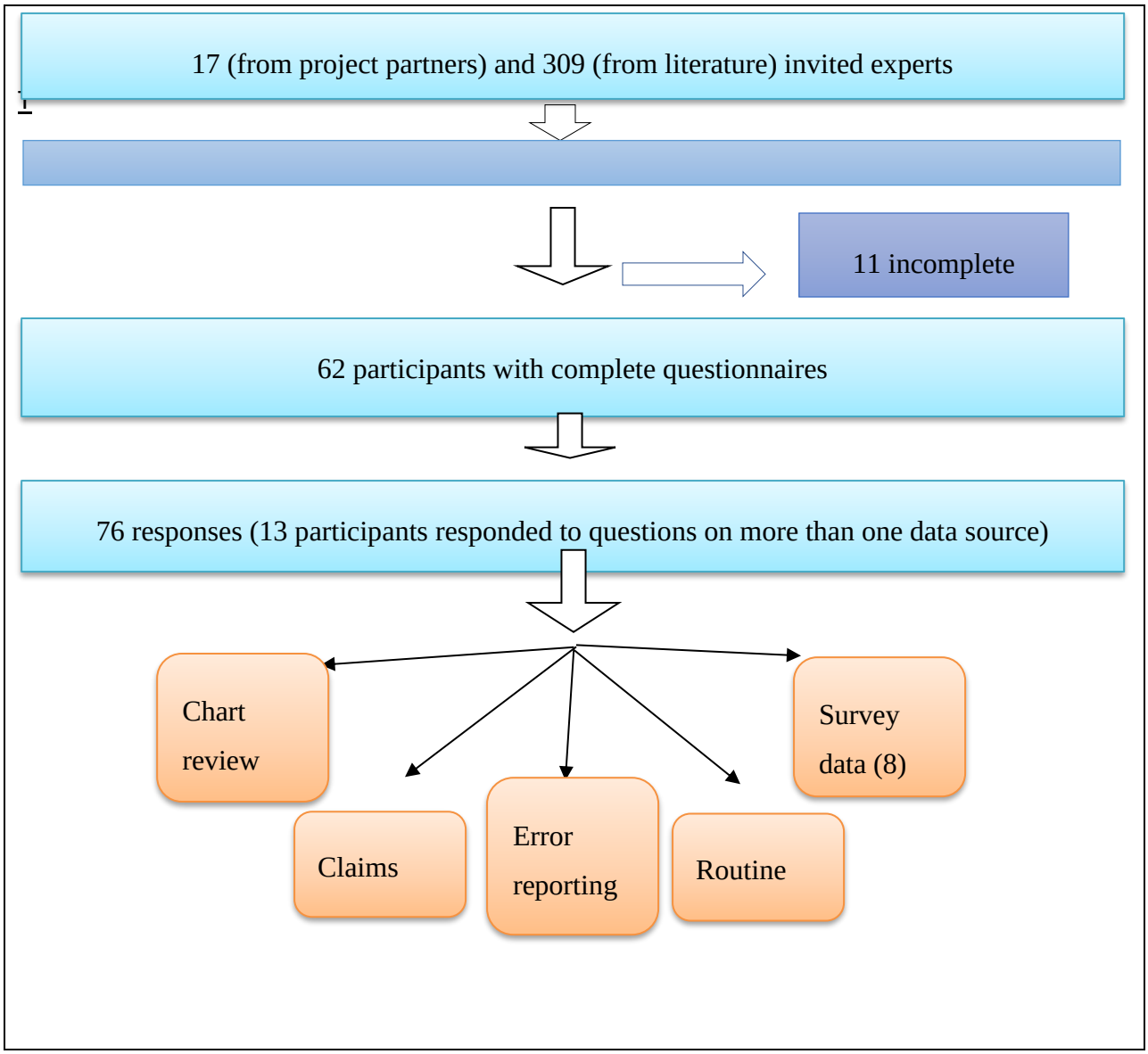

Figure 3.1: Flowchart/Data source breakdown (*n* = 62)

The experts worked in four different regions classified according to the WHO region classification as presented in Table 3.1. The majority of them, *n* = 37 (59.7%) worked in Europe and the USA (33.9%). They spoke 10 different languages with English being the main spoken language (59.7%), German (11%) and Dutch (8%). The rest of the other languages were Korean, French, Finnish, Italian, Persian, Danish, Catalan and Greek. They were from different professional backgrounds with medical doctors being the majority *n* = 25 (40.3%), research and academics (21%) and nurses (17.7%). Other professions like pharmacists (8.1%), physiotherapists (1.6%), psychologists

(8.06%) and lawyers (3.2%) had to be combined due to small numbers. The majority of them worked in public health *n* = 27 (43.5%), clinical science (33.8%) and critical care (14.5%). They had much experience working with their respective data sources with those between 5–9 years' experience being the majority, as it appears in Table 3.2.

Table 3.1. Participants' demographic characteristics

Characteristic	**Frequency (*n* = 62)**	**Percentage (%)**
WHO Region		
Europe	37	59.7
Americas	21	33.9
Western Pacific	3	4.8
Eastern Mediterranean	1	1.6
Language		
English	37	59.7
French	3	4.8
German	7	11.3
Dutch	5	8.1
Finnish	1	1.6
Italian	1	1.6
Persian	1	1.6

Danish	3	4.8
Catalan	2	3.2
Greek	2	3.2
Profession		
Medical doctors	25	40.3
Nurses	11	17.7
Research and academics	13	21.0
Others	13	21
Healthcare specialty		
Clinical science	21	33.9
Critical care	9	14.5
Public health	27	43.5
Biomedical science	2	3.2
Pharmacy	3	4.8

Table 3.2. Experts` years of experience with their respective data sources

Experts' years of experience	**Chart review** *n* **(%)**	**Claims data** *n* **(%)**	**Error reporting data** *n* **(%)**	**Routine data** *n* **(%)**	**Survey data** *n* **(%)**
Less than 5 yrs.	1 (7.7)	1 (10)	6 (16.7)	-	-
5–9 yrs.	6 (46)	3 (30)	15 (41.7)	4 (44)	2 (25)
10–14 yrs.	2 (15.4)	2 (20)	9 (25)	2 (22)	3 (38)
15–19 yrs.	1 (7.7)	2 (20)	2 (5.6)	-	2 (25)
20–24 yrs.	2 (15.4)	1 (10)	2 (5.6)	1 (11)	-
25 yrs. +	1 (7.7)	1 (10)	2 (5.6)	2 (22)	1 (13)

(Explanatory note: These are the total number of observations used per data source "Chart review n=13, Claims data n=10, Error reporting data n=36, Routine n=09 and Survey data n=08")

3.2 Patient safety experts' perceptions of error reporting as a data source

Several statements on error reporting data, chart review, claims data, routine data and survey data sources were made. The experts were requested to indicate their agreement or disagreement with the statements for their respective data sources using a five-point Likert scale.

3.2.1 Wide use of data sources for patient safety research in various countries

Only 58.3% (*n* = 21/36) of experts who used error reporting data thought that it was widely used in their countries. The best in this category was survey data where 75% (*n* = 06/08) of its experts believed that it was widely used in their countries. See Figure 3.2.

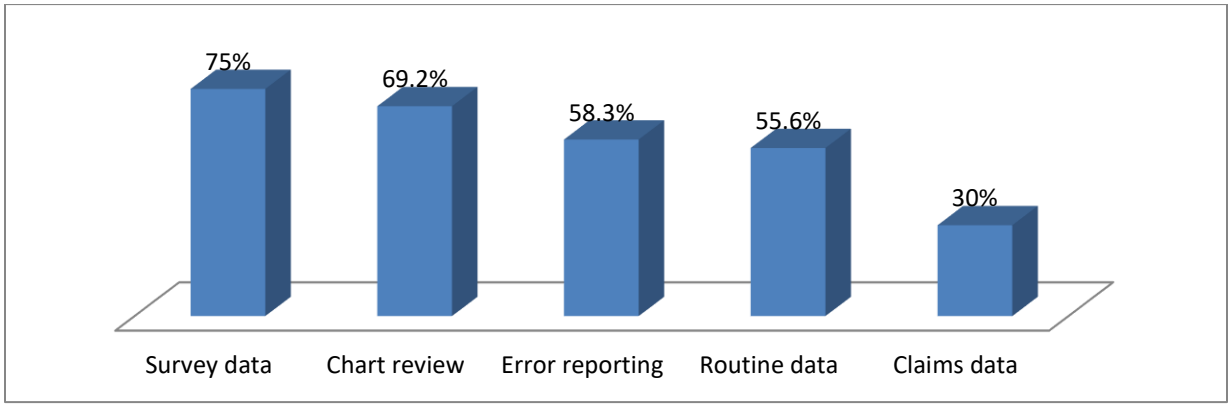

Figure 3.2: Description of the extent of use of data sources

(Chart review n = 13, Claims data n = 10, Error reporting n = 36, Routine data n = 09 and Survey data n = 08, N=76)

3.2.2 Ease of access of data sources by researchers

Error reporting data was considered the most inaccessible data source. Only 37,2% of its users thought differently, while chart review had the majority n = 7 (54%) of its users considering it to be easily accessible.

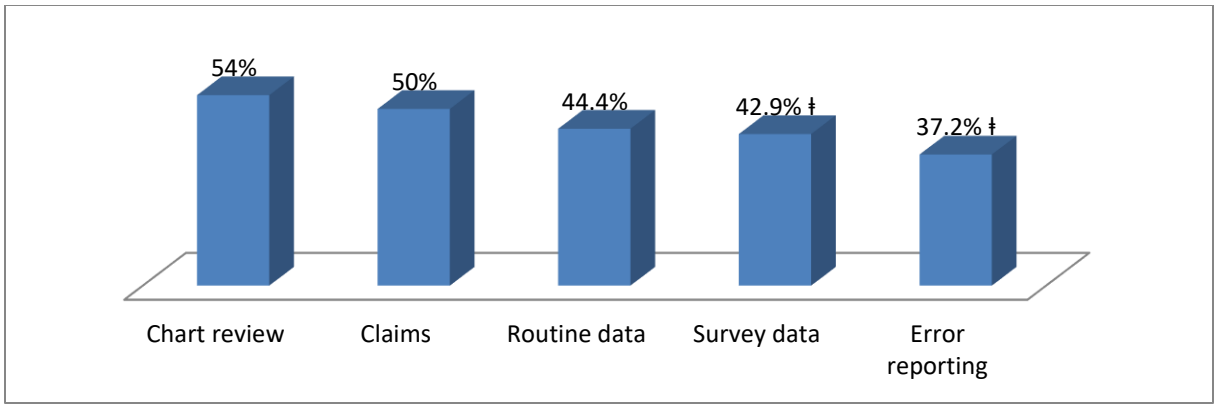

Figure 3.3: Description of information accessibility from these data sources

(Chart review n = 13, Claims data n = 10, Error reporting n = 35, Routine data n = 09 and Survey data n = 07; N=74,ǂ = 1 missing observation)

3.2.3 User-friendliness and cost-effectiveness of data sources for research

Error reporting data again scored low on its user-friendliness. Only 30.6% of its users thought it was user-friendly while survey data had the majority (62.5%) of its experts considering it to be the most user-friendly data source to work with.

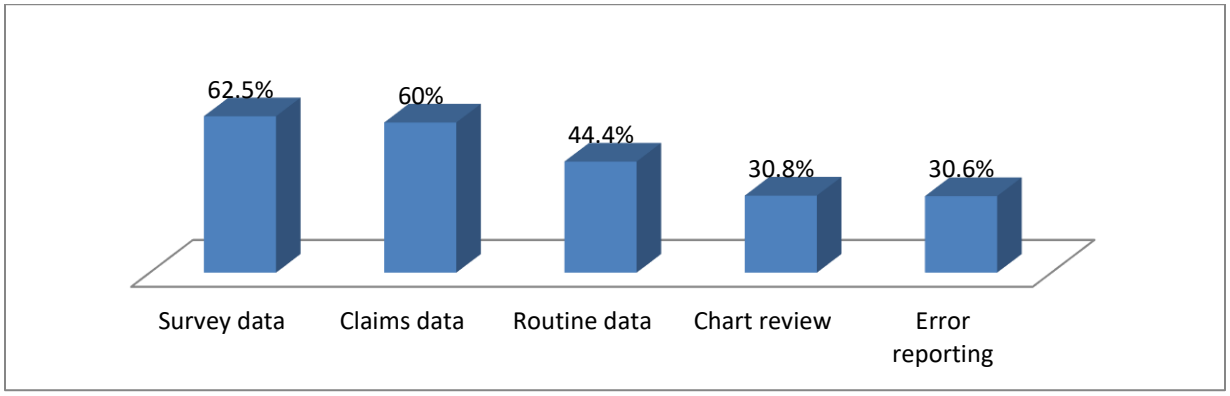

Figure 3.4: Description of the user-friendliness of these data sources

(Chart review n = 13, Claims data n = 10, Error reporting n = 36, Routine data n = 09 and Survey data n = 08, N=76)

3.2.4 Timeliness regarding utility of data sources

About 64% of error reporting experts considered working with it to be time-consuming, while the worst was chart review with at least 84.6% of its experts considering it to be the most time-consuming data source to work with. See Figure 3.5.

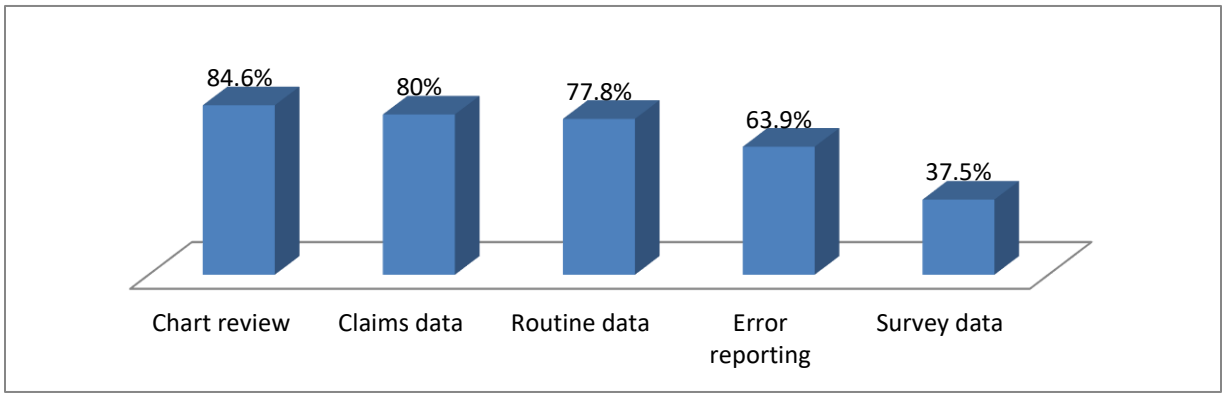

Figure 3.5: Description of how time-consuming these data sources are

(Chart review n = 13, Claims data n = 10, Error reporting n = 36, Routine data n = 09 and Survey data n = 08, N=76)

3.2.5 Using data sources to generate annual reports on patient safety in various countries

Both error reporting experts (44.4%) and routine data experts (44.4%), considered their data sources to be the best in generating annual reports on patient safety in their countries. Survey data scored the least in this category with only 12.5% of its experts reporting to generate an annual report from it.

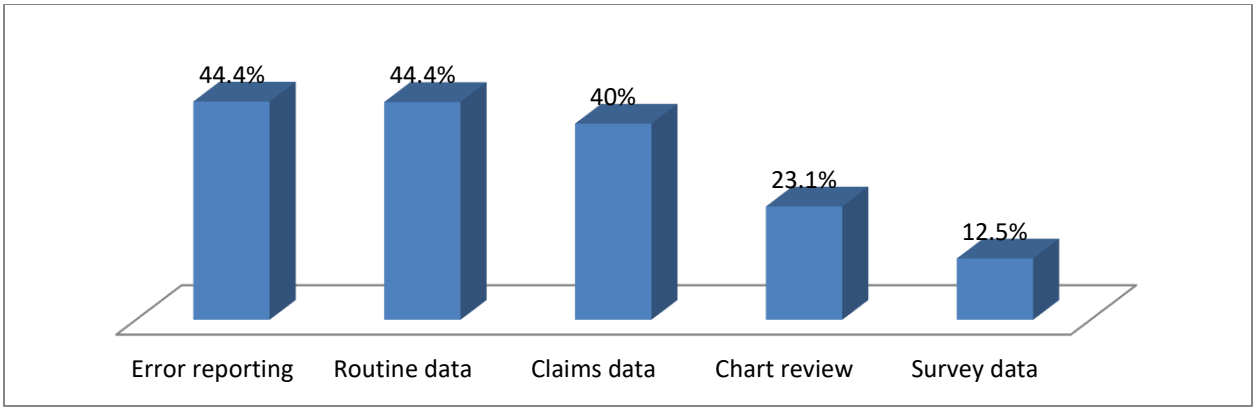

Figure 3.6: Ability to generate annual report from these data sources

(Chart review n = 13, Claims data n = 10, Error reporting n = 36, Routine data n = 09 and Survey data n = 08, N=76)

3.2.6 Using data sources for reporting all causes of patient safety-related events

At least 38.9% of error reporting experts considered it to be able to report on all causes of patient safety-related events, namely, failures by healthcare professionals or patients. The best in this category was chart review with 53.9% of its experts considering it to be the best in reporting all causes of patient safety-related events.

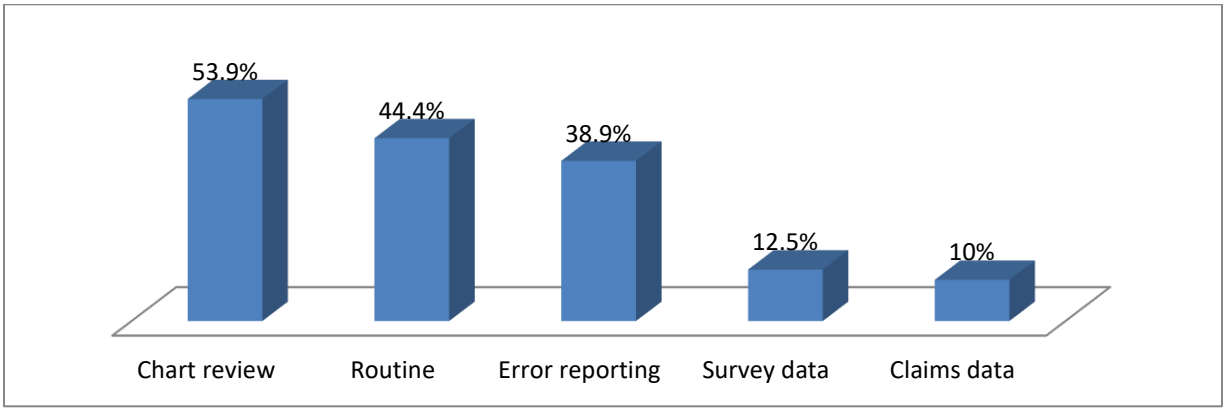

Figure 3.7: Data sources' ability to report on all causes of patient safety-related events

(Chart review n = 13, Claims data n = 10, Error reporting n = 36, Routine data n = 09 and Survey data n = 08, N=76)

3.2.7 Using data sources to report various levels of patients' harm including near-misses

Error reporting was the best in reporting on all levels of harm to patients, including near misses according to 61.1% of its users, while claims data was the worst in this category with only 10% of its experts stating that it can actually report on all levels of harm. See Figure 3.8.

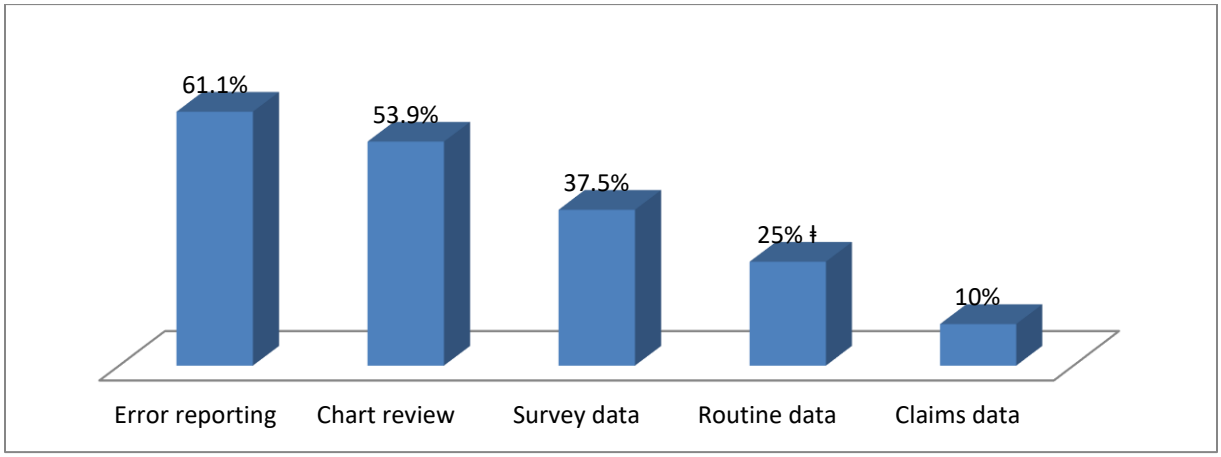

Figure 3.8: Data sources' abilities to report on all levels of harm

(Chart review n = 13, Claims data n = 10, Error reporting n = 36, Routine data n = 08 and Survey data n = 08; N=75, ǂ = 1 missing observation)

3.2.8 Using data sources for future training of healthcare professionals

At least 75% of error reporting experts considered its information useful in training healthcare professionals to avoid recurrence of the same mistakes in the future. The best in this category was survey data with all (100%) its experts considering its information useful in training employees, as presented in Figure 3.9.

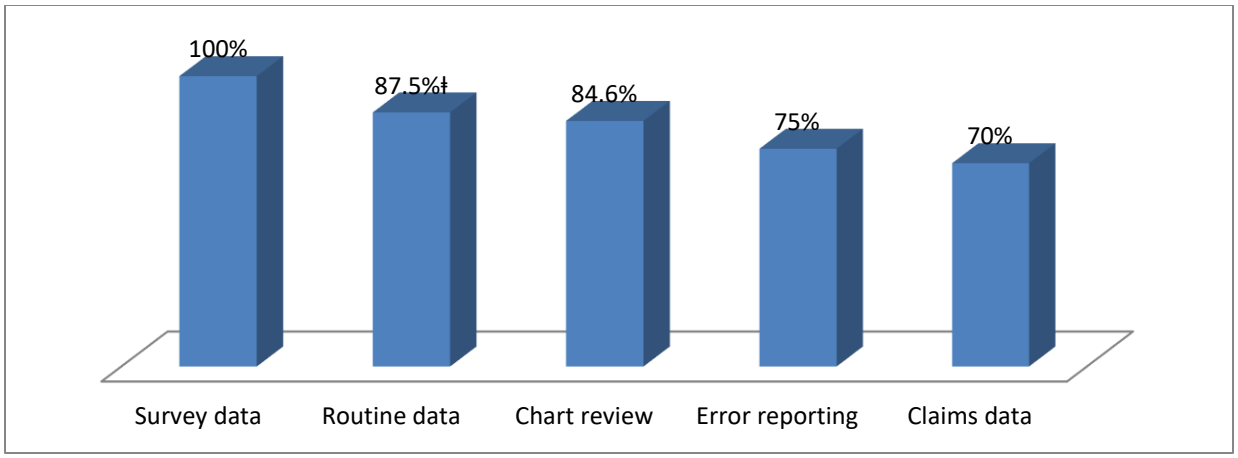

Figure 3.9: Data source information usefulness in future training of healthcare professionals

(Chart review n = 13, Claims data n = 10, Error reporting n = 36, Routine data n = 08 and Survey data n = 08;N=75, ł = 1 missing observation)

3.2.9 Using data sources for comprehensive reporting of patient safety

Only 41.7% of error reporting experts thought it could be used on its own to report comprehensively on patient safety. Survey data was the best here with 62.5% of its experts reporting that it is capable of reporting comprehensively on patient safety.

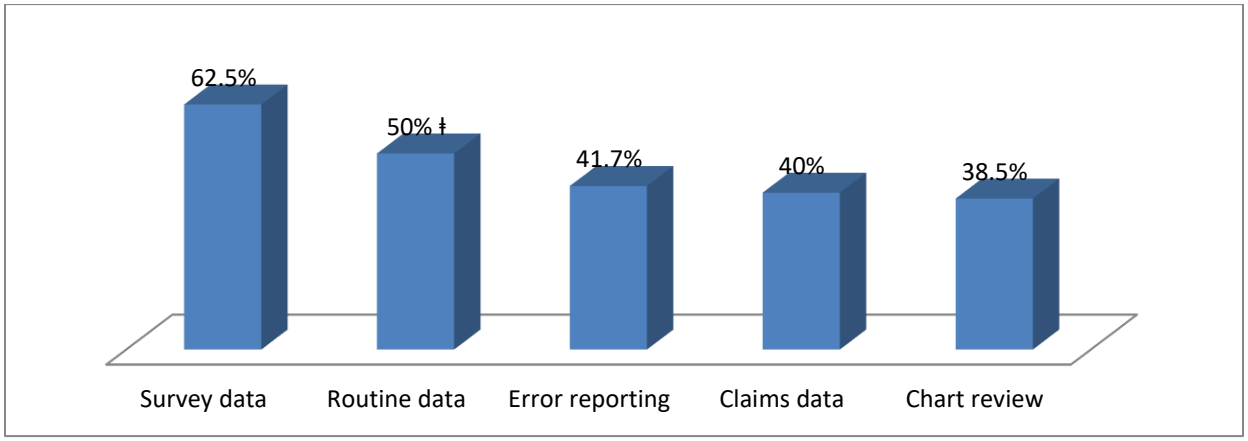

Figure 3.10: Data sources' abilities to report comprehensively on patient safety by themselves

(Chart review n = 13, Claims data n = 10, Error reporting n = 36, Routine data n = 08 and Survey data n = 08; N=76, ł = 1 missing observation)

3.2.10 No overlap of information between the data source under study and others

Error reporting was reported to have the least unique information, with only 2.8% of its experts believing that it had unique information. Its information overlapped to other data sources. While 60% of claims data experts considered it to have the most unique information.

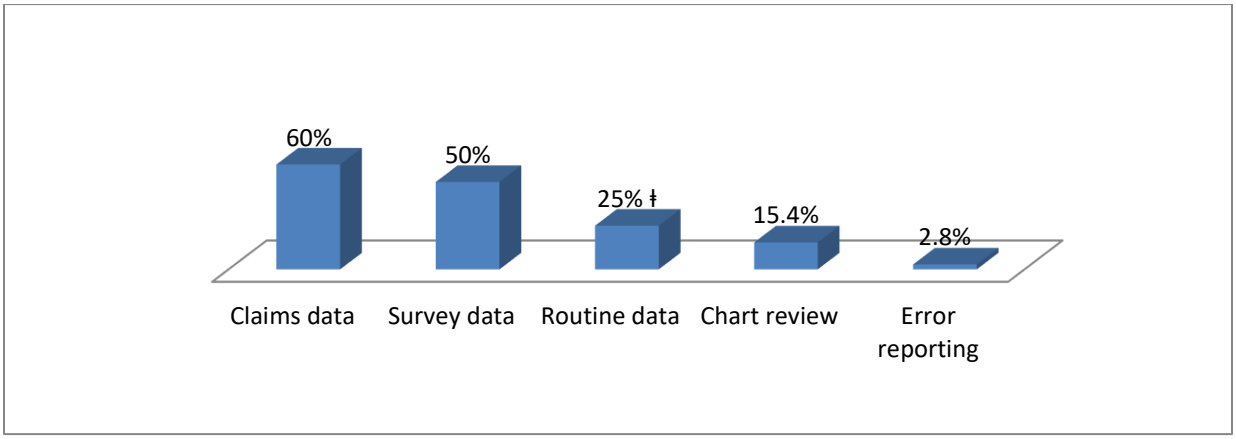

Figure 3.11: Uniqueness of the information derived from these data sources

(Chart review n = 13, Claims data n = 10, Error reporting n = 36, Routine data n = 08 and Survey data n = 08; N=75, ŧ = 1 missing observation)

3.2.11 Using data sources for both big and small organisations

Seventy-five per cent of error reporting experts considered it appropriate in all organisations, while all (100%) survey data experts considered survey data to be appropriate for both big and small organisations, as it appears in Figure 3.12.

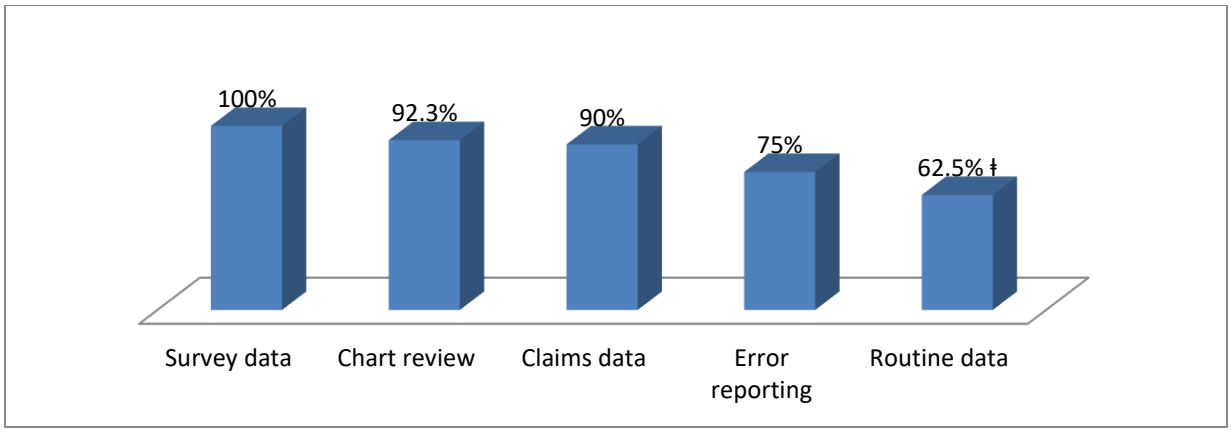

Figure 3.12: Appropriateness of data sources in all organisations

(Chart review n = 13, Claims data n = 10, Error reporting n = 36, Routine data n = 08 and Survey data n = 08; N=75, ł = 1 missing observation)

3.2.12 Proportions of different professions per data source

The use of each data source by different professionals was assessed, as it appears in Table 3.3. All professional groups preferred error reporting to other patient safety data, with doctors 14/36 (39%) and nurses 8/36 (22%) expressing their greatest preference and researchers/academics at 6/36 (17%). Due to the small numbers, all the other professional groups were combined into one category and they showed preference for error reporting data 8/36 (22%).

3.3 Healthcare speciality/professional background influence on data source usage

The Chi-square (X^2) test was done to assess the association between experts' profession or experts' area of practice and their choice to work with a specific data source. No significant associations were found between profession and choice of data sources: error reporting (p = 0.25), claims data (p = 0.29), routine data (p = 0.42) and survey data sources (p = 0.13), although chart review (p = 0.05) was almost significant with more doctors showing preference for it. Experts' area of practice also had no influence on the data sources they used, with non-significant results for error reporting (p = 0.79), chart review (p = 0.67), claims data (p = 0.27), routine data (p = 0.17) and survey data (p = 0.56).

A two-sample *t*-test was used to further compare the overall performance of the error reporting data source to each of the other four data sources. The difference in means between error reporting and chart review data sources was not statistically significant ($p = 0.53$). The difference in means was also not statistically significant between error reporting and claims data source ($p = 0.92$) or between error reporting and routine data source ($p = 0.74$) and between error reporting and survey data source ($p = 0.61$).

Table 3.3. Proportions of different professions per data source

Profession	**Medical doctors'** *n* **(%)**	**Nurses** *n* **(%)**	**Research academics** *n* **(%)**	**All the other professions combined** *n* **(%)**	X^2 ***p*-value ****
Chart review	**9 (69)**	2 (15)	-	2 (15)	0.05
Claims data	**5 (50)**	-	2 (20)	3 (30)	0.29
Error reporting	**14 (39)**	8 (22)	6 (17)	8 (22)	0.25
Routine data	3 (33)	-	3 (33)	3 (33)	0.42
Survey data	2 (25)	1 (12.5)	**3 (37.5)**	2 (25)	0.13
Total responses/profession	33* (43)	11 (15)	14* (18)	18* (24)	-

(Explanatory note: Total number of observations were 62 of which medical doctors were $n = 25$, nurses $n = 11$, research and academics $n = 13$ and all other professions combined $n = 13$.

*Some participants selected more than one category

***p*-value < 0.05 was considered significant)

CHAPTER 4: DISCUSSION

4.1 Introduction

This study was conducted to determine experts' opinions on the respective data sources they used to report on patient safety (i.e., chart review, claims data, routine data, error reporting and survey data sources). The aim was to determine whether error reporting data, being the only one designed for patient safety, was capable of reporting comprehensively on adverse events, to an extent where one could rely solely on it to do so. It was not clear whether error reporting data contained similar information with the other data sources or not, and whether it reported better on adverse events than the others did. The findings are based on both experts' opinions and information extracted from the selected literature.

4.2 Systematic overview of the study findings

4.2.1 Demographic characteristics of the users of patient safety data in patient safety

A range of professionals from different backgrounds (medical doctors, nurses, research and academics, psychologists, physiotherapists, pharmacists, and lawyers) responded on using these data sources to generate patient safety information at all levels of healthcare, for example, in primary healthcare, hospitals, pharmacies and in the courts of law. Most responses were from doctors, nurses, researchers and academics from 20 different countries. They were predominantly English, German or Dutch speaking and were working in the US, UK and the Netherlands. They were all well experienced with their respective data sources with the majority of them (48%) having between 5–9 years' experience.

4.2.2 Patient safety experts' perceptions of error reporting as a data source

This study showed that error reporting data had both similarities and differences when compared to other data sources also used to report on patient safety. A patient safety researcher would normally go through different data sources searching for incidents related to procedures performed on patients, medication and systems errors.

Depending on the research question and the design, one or more data sources would be relevant for the topic while others would not be. Most of these data sources would have information regarding the patient's demographic details, and the care provided to the patient by healthcare providers, except in situations where one is allowed to remain anonymous, for example, error reporting and survey data.

4.2.3 Wide use of data sources for patient safety research in various countries

This study showed that error reporting data was the most widely used in patient safety research by all categories of professionals. This is in keeping with it being regarded as the only data source designed to report on patient safety (71). It is designed to meet the specific needs of different healthcare facilities. The actual users of error reporting data did, however, not perceive it as the most widely used data source. They felt that error reporting systems were not readily available in all healthcare areas, for example, in primary care where the need to invest in error reporting systems might not be recognised. Countries such as Germany, where their national error reporting system for family doctors, "Jeder Fehler zählt!", is one example of a system that works well in primary care (33). In some areas that had error reporting systems, Wolf and Hughes (15) found using them was not mandatory. Some professionals, such as doctors, preferred to use registers for their incidents and not necessarily error reporting systems (15).

4.2.4 Ease of access of data source by researchers and its user-friendliness

Error reporting data was considered the least accessible and the least user-friendly data source with which to work. This was in line with a study by Hoffmann and Rohe, which indicated that error reporting systems as internal systems might be accessible only to the employees of a specific hospital and not necessarily to all hospitals (19). Password-protected environments, and lack of consistency on the terminology used made error reporting data inaccessible and less user-friendly.

This was consistent with a study by Wolf and Hughes where error reporting data was blamed for lack of consistency in the terminology used and a study by Gong et al. that mentioned lack of reporter-friendliness as a barrier to healthcare professionals' successful adoption of error reporting systems (15, 21). It is a legal requirement to keep health data confidential; therefore, there are policies in place on how these can be acquired. Some data sources such as routine data involved a

fee before a health professional could access them (20). There are varying degrees to how accessible the health information is to a health researcher. Most of them require medical expertise knowledge for the researcher to extract the relevant information needed.

The chart review data source was considered the most difficult to work with, as the information was as good as the person who entered it (77). This was expected, especially because there are no standard operations procedures (SOP) on how this data must be collected. This data is not collected for patient safety, it is about all healthcare professionals' every activity of care on the patient (78). Some data is in text form while some are electronically available (63). This was in line with a study by Wickson-Griffiths et al. who showed how imperfect chart reviewing was, needing data extractors to be trained on how to extract data that could be costly (25).

Even though a study by Davy et al. considered it difficult to work with claims data, especially since data was collected by law professionals for litigation purposes and not necessarily for patient safety (22), the findings in this study were different. Sixty per cent of the experts who worked with claims data considered it to be user-friendly.

4.2.5 Timelines regarding utility of data sources

This study revealed that working with all these data sources consume time, as one would have expected. Only 63% of error reporting experts considered working with it to be time-consuming while the worst was chart review with at least 84.6% of its experts considering it to be the most time-consuming data source with which to work. In this study, chart review was considered the most difficult data source to work with, but it was also considered the most time-consuming compared to the other four data sources. This was particularly so when information was not available electronically.

The results are in line with a study by Rosen that showed that a medical record review, particularly when the records are paper-based rather than electronic, is costly, labour-intensive, and typically involves one or more clinicians (72). Survey data was considered the least time-consuming to work with, but this only applies if one is working with secondary data. Otherwise, survey data also takes more time if primary data is collected, especially if planned and conducted properly. On the other hand, secondary data is less time-consuming to work with, since data is readily available.

Considering the fact that litigation claims are not within healthcare facilities, one would expect the whole procedure of acquiring them to be time-consuming. “Collecting a large volume of data about cases of clinical negligence is difficult or impossible to access, held in unstructured paper records, distributed across a number of organisations, fragmented across multiple sets of records for the same cases, and not collected consistently using common data definitions and standards” (22). This study confirmed this with 80% of the experts considering it to be time-consuming. It was the second most time-consuming data source to work with after chart review data.

4.2.6 Using data sources to generate annual reports on patient safety in various countries

For error reporting data to report comprehensively on patient safety, there should be at least a report generated from it. This study revealed that there are low proportions of annual reports generated from these data sources. None of these data sources received more than 50% confirmation from their experts that there are annual reports generated from them annually. Some experts could not tell if there were any reports on patient safety generated from one of these data sources in their countries at all. However, error reporting together with routine data sources were the best in this category with at least 44% of their experts considering them to can generate an annual report on patient safety.

4.2.7 Using data sources to report on all causes of patient safety-related events

For error reporting to report comprehensively on patient safety, it must be able to report on all causes of patient safety-related events, for example, failures by healthcare professionals or patients. It must be able to tell if harm was due to human error, (i.e. any mistake by the healthcare professional or the patient himself) or systems error (i.e. when an error happens due to the way in which things are done in that particular healthcare facility). Only 38.9% of error reporting experts considered it to can report on all causes of patient safety-related events. This was in line with the study by Classen et al. that indicated that voluntary reporting fared poorly as opposed to other methods and missed 90% of the adverse events (68).

The best in this category was chart review with 53.9% of its experts considering it the best in reporting all causes of patient safety-related events. This was expected since healthcare givers recorded all activities on patients in this data source. Chart review also allows for a very long

follow up with the patients so that harm occurring now can be linked to some exposure that happened previously. Both claims and survey data sources were seen by most of the experts not to report on all causes of patient safety-related events. This might be mainly since both these data sources tend to concentrate mainly on unique information, for example, litigation claims and people's perceptions, respectively.

4.2.8 Using data sources to report on all levels of harm to patients including near-misses

Error reporting was the best in reporting on all levels of harm to patients, including near-misses according to 61.1% of its users. This was consistent with a study by Crane at al. that indicated how error reporting made it possible for healthcare professionals to report near-misses anonymously without any fear of being persecuted (27). In this study, only error reporting (61.10%) and chart review (53.90%) data sources were considered by the majority of their experts to have abilities to report on various levels of harm to patients including near-misses. This does not guarantee that all near-misses are recorded by these data sources, especially when one considers the fact that error reporting tends to be biased towards severe cases, as indicated by Marella (26). Claims data was the worst in this category with only 10% of its experts stating that it can actually report on all levels of harm.

4.2.9 Using data sources for future training of healthcare professionals

The main reason behind collecting data on adverse events is to make sure that healthcare professionals learn from these experiences so that they are not repeated in the future. In this study, all data sources received no less than 70% confirmations from their experts that they contained information that could be used in future training of healthcare professionals. This was in line with a study by Stavropoulou et al. who found some evidence of single-loop learning, that is, changes to clinical settings or processes as a consequence of learning from error reporting systems (23).

Survey data topped the list with all its experts saying that its information is useful for future training to prevent further harm. One of the reasons for this might be that survey data can be collected from both patients and healthcare professionals, therefore, giving a complete picture of both patients' and healthcare givers' perceptions on patient safety. This does not apply with other data sources.

4.2.10 Using data source for comprehensive reporting of patient safety

Only 41.7% of error reporting experts thought it could be used on its own to report comprehensively on patient safety. This did not come as a surprise since error reporting was already blamed for not being accessible or user-friendly since it is not necessarily found in all healthcare facilities, especially in Primary care. It was also not easily accessible due to security and non-standardised terminology used. As argued by Stavropoulou et al., error reporting systems did not perform better than other methods (23). Survey data was the best here with 62.5% of its experts reporting that it is capable of reporting comprehensively on patient safety.

4.2.11 No overlap of information between the data source under the study and others

This study showed that information extracted from error reporting systems was not necessarily unique. It was the worst in this category with only 2.8% of its experts thinking that its information did not overlap to other data sources. This suggests that error reporting can be adapted or extended to incorporate information from other data sources to complement it and extend its use as the main data source in patient safety. A study by Rosenthal, however, argued that error reporting systems should complement and not replace practices used by hospitals to review and analyse their health safety incidents (34).

Claims data was the best in this category with 60% of its experts considering it to have unique information, which was in line with a study by Wilson who believed that it was only through claims data that a holistic view of the patient's interactions with the health care system can be seen. Both Croke and Winslade et al. showed how possible it was to track down healthcare professionals involved in harm and to identify medication problems through litigation and pharmacy claims data (30,31). This would be impossible with data sources such as error reporting and survey data since healthcare professionals are allowed to remain anonymous. In this study, half of the survey data experts (50%) also believed that it had unique information.

Only survey data allows for the assessment of patients' and providers' perceptions regarding errors/adverse events. Through surveys, one is able to accurately express one's feelings and attitudes toward patient safety, which is not possible with other data sources. Survey data, therefore, has been used by the patient safety researchers to not only source information from the

patients and healthcare professionals regarding their awareness of patient safety issues, but to measure individuals' comfort with the culture of safety at their health care organisation (70) while only routine data allows for the calculation of standardised mortality ratios. It has the ability to capture information necessary in patients' safety such as the patient's educational level, employment status, environment and housing, birth, death, primary and hospital data (20). Since data is collected routinely and categorically compiled, for example, one can tell later if the cause of death was due to injury or poisoning for example.

Even though in this study chart review was not necessarily considered to have unique information, a study by Rosen considered it a "gold standard", in measuring patient safety since it contains rich, detailed clinical information (72). Sometimes it is necessary to look into the patient's laboratory or radiological results to determine the cause of harm. This information can only be found in a chart review. Most care provided to the patient by all healthcare professionals in that institution are recorded in this data source. It allows a long follow-up; therefore, it is able to report better on all levels of harm including near-misses.

4.2.12 Using data source for both big and small organisations

Patients are harmed at all levels of healthcare, for instance in both primary and secondary care (73). To use a data source on its own to report comprehensively on patient safety, it would have to be available in all healthcare facilities, irrespective of their sizes. Seventy-five per cent of error reporting experts considered it appropriate in all organisations. The best in this category was survey data with all (100%) its experts considering it appropriate for both big and small organisations. This is the only question where all data sources received not less than 62.50% confirmations from their experts. All these data sources are suitable for use in both small and big organisations.

When comparing error reporting's overall performance to other data sources using a two-sample *t*-test, it did not outperform them. This finding was in line with a study by Stavropoulou et al. who also raised its concern of not having found convincing evidence that error reporting systems **performed** better than other methods (23). Even though the results should be treated with caution due to the small sample, only survey data scored better in at least six aspects. Experts who used survey data felt that it was the most widely-used, user-friendly, least time-consuming and cost-

effective data source to work with. Its information could be used in employee training, it was adaptable to all organisations and at least half of its experts believed it reported comprehensively on patient safety. Experts also mentioned that collecting primary survey data can be time and resource intensive if carefully planned and conducted. Long survey tools, low response rates and lack of honesty among participants are some of its shortfalls. Error reporting data did well on reporting on all levels of harm and producing annual reports, but its accessibility, user-friendliness, time consumption and other aspects need to be improved.

4.3 Healthcare speciality or professional background influence on data source usage

4.3.1 Healthcare speciality or professional background influence on chart review usage

There was no statistically significant association between the experts' area of practice ($p = 0.67$) or their professional background ($p = 0.05$) and their usage of chart review data to report on patient safety. Medical doctors, however, showed more interest in working with chart review data when compared to nurses and other professionals. They consider chart review data to be rich in medical information since all medical information about the patient by various healthcare professionals is kept in this data source. It contains answers to various questions on patient safety. Nurses and other professionals find working with chart review data to be expensive and imperfect as indicated by both Murff et al. and Wickson-Griffiths et al. (24, 25).

4.3.2 Healthcare speciality or professional background influence claims data usage

There was no statistically significant association between the experts' area of practice ($p = 0.27$) or their professional background ($p = 0.29$) and their use of claims data in patient safety. Medical doctors showed more interest in working with claims data when compared to nurses and other professionals. In the US, it was the ever-increasing litigation claims against doctors that probed the interest in patient safety research. As patients and their family members become more aware of their rights, litigation claims against doctors increase, and they find themselves having to learn more from those malpractice claims to prevent the same mistakes from recurring. Medical doctors were followed by pharmacists in their utilisation of claims data. As indicated in a study by Winslade et al., although pharmacists tended to report medication errors less, they used pharmacy claims data to control medication problems in communities. This helped to prevent elderly people

from collecting treatment with the same active ingredients but different trade names from different pharmacies within the same area and risking overdose (31).

4.3.3 Healthcare speciality or professional background influence on error reporting data usage

There was no statistically significant association between the experts' area of practice (0.79) or their professional background (0.25). In this study, all professionals showed more interest in working with error reporting data when compared to other data sources also used in patient safety. Medical doctors showed more interest in working with error reporting data when compared to the professionals. These findings were different from a study by Wolf ZR and Hughes RG which indicated that nurses used error reporting more than medical doctors (15). This might be a good indication that medical doctors are beginning to see the benefit of error reporting and using it accordingly.

4.3.4 Healthcare speciality or professional background influence on routine data usage

No statistically significant association was found between the experts' area of practice (0.17) or their professional background (0.42) and the use of routine data to report on patient safety. Medical doctors and professionals in research and academics showed similar interests in working with routine data. As indicated in studies by Davies et al., Sprenger et al. and Kuklik, routine data contained information on birth rates, mortality rates and socio-economic data in both primary and hospital settings from which adverse events could be identified and used to improve adverse drug events monitoring systems, patient safety and quality of care (52-54).

4.3.5 Healthcare speciality or professional background influence on survey data usage

No statistically significant association was found between the experts' area of practice ($p = 0.56$) or their professional background ($p = 0.13$) and the use of survey data to report on patient safety. This study showed that researchers use survey data more to report on patient safety. This was in line with a study by Zipper et al. who indicated that patient safety researchers used surveys to source information from the patients and healthcare professionals regarding their awareness of patient safety issues and to measure individuals' comfort with the culture of safety at their health care organisation (70).

4.4 Potential study biases

This was a cross-sectional study design from a sample of purposively selected experts and such studies are usually prone to researcher bias. In order to increase the power of the study, questionnaires were sent to the total population and not doing sampling, this might have introduced researcher bias. In purposive sampling, participants are selected based on their expertise for the topic at hand, and this might have exposed this study to selection bias.

4.5 Study limitations

A low response rate is one of the limitations of this kind of study; therefore, it might not be representative. Doing data collection electronically poses a challenge as return rates are very low and this was observed in this study. This study was done in high-income countries only, which leaves out the low- income countries with their different setup. The small sample size resulted in small numbers in some strata, which limits the ability to demonstrate statistical differences.

4.6 Study strengths

The findings reflect the views of knowledgeable experts from several countries with many years of experience working with these data sources to report on patient safety. Although the study was conducted in high-income countries, both low- and middle-income countries pursuing research in patient safety will also benefit from these results.

4.6 Generalisability

The results should be treated with caution due to the small sample size, and that the study only included high-income countries.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

This study revealed that several data sources are relevant in patient safety research and a wide range of professionals at all levels of care in different countries use it. They indicated that although error reporting data is widely used, relying on it alone is inadequate. It did well on reporting on all levels of harm and producing annual reports but its accessibility, user-friendliness and time consumption need to be improved. The experts' area of practice or their professional backgrounds had no influence on the experts' choice to work with a specific data source to report on patient safety. Currently, there is no single data source that can be used on its own to report on patient safety comprehensively. In this study, no data source got 100% affirmation from its experts when asked if it could be used on its own to report comprehensively on patient safety or not. Error reporting data overlapped to other data sources and only claims data had unique information; therefore, error reporting could be improved to consolidate all other information from various sources and be supplemented with claims data to give a true picture of our patient safety.

5.2 Recommendations

Error reporting data source is the most widely used in generating patient safety information, as was confirmed by most of our participants (36/62, 58%) showing their preference for it. Although it is the only data source designed specifically for patient safety reporting, the most widely used and preferred by patient safety professionals, it is not without flaws. This study revealed three aspects of error reporting data that need to be improved, its accessibility, user-friendliness and time consumption.

Accessibility: Error reporting data was blamed for not being easily accessible to patient safety researchers and users, mainly because it was not available in some areas and where it was available, passwords were needed. Ways of protecting the privacy and confidentiality of patients and health care providers, which does not preclude the use of error reporting to improve patient safety, should be explored.

User-friendliness: There was no consensus on the terminology used in error reporting data making it difficult to work with it. Initiatives to standardise patient safety terminology by using codes could improve the user-friendliness of error reporting data systems.

Time consumption is linked to the fact that error reporting systems are healthcare area specific, without the use of standardised terminology and being password protected. Employee training on how to use these systems, standardising the terminology used and making issuing of password processes to be faster would resolve this problem. The ability of error reporting data to generate annual patient safety reports is important in improving the quality of care, as it enables clinicians and health managers to identify areas of healthcare with high levels of incidents and the most common types of incidents needing attention.

These recommendations would be presented to Policy makers for them to incorporate them in their new policies.

5.3 Further research

Error reporting data source did well in several aspects on which it was measured but its accessibility, user-friendliness and time consumption need to be improved. Further research could look into ways of improving these aspects and can be done in developing countries as well, as they also experience patient harm while receiving healthcare. This study did not include any experts from Low Middle Income Countries (LMIC) and insufficient research has been done on patient safety in LMIC.

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ANNEXURES

Uni Stellenbosch ethics clearance letter (a)

Uni Frankfurt ethics clearance letter (b)

Invitation letter to study participants

Questionnaire used for the study

Likert scale questions with created variables

Annexure 1(a): Uni Stellenbosch ethics clearance letter

UNIVERSITEIT·STELLENBOSCH·UNIVERSITY
jou kennisvennoot · your knowledge partner

Approval Notice
Response to Modifications- (New Application)

23-Mar-2016
Swana, Nelisiwe N

Ethics Reference #: S15/11/267

Title: **The representativeness and relevance of Error reporting data source in generating patient safety data as compared to chart review, claims data, routine data, and survey data sources.**

Dear Mrs Nelisiwe Swana,

The **Response to Modifications** - *(New Application)* received on **26-Feb-2016**, was reviewed by members of **Health Research Ethics Committee 1** via Expedited review procedures on **23-Mar-2016** and was approved.
Please note the following information about your approved research protocol:

Protocol Approval Period: **23-Mar-2016 -22-Mar-2017**

Please remember to use your **protocol number** (**S15/11/267**) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:
Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.
Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel:

[redacted]Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.
For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at 0219389657.

Included Documents:
Curriculum Vitae Swana
Informed Consent Letter
Curriculum Vitae Klemp
Curriculum Vitae Dudley
Investigator Declaration Klemp
20160308 MOD Ethikkomm_2016_Waiver
Research Protocol
Checklist
Investigator Declaration Swana
Protocol Synopsis
Research Protocol
20160308 HREC Mods letter
20160308 MOD Protocol
Investigator Declaration Dudley
20160308 MOD Protocol Synopsis

Sincerely,

[redacted]
HREC Coordinator
Health Research Ethics Committee 1

Annexure 1(b): Uni Frankfurt ethics clearance letter

GOETHE UNIVERSITÄT FRANKFURT AM MAIN

Zentrum der Pharmakologie

Institut für Klinische Pharmakologie
Direktor: Prof. Dr. Dr. [redacted]

Dipl.Soz. [redacted]
Institut für Allgemeinmedizin / Institute of General Practice
Johann Wolfgang Goethe University
Theodor-Stern-Kai 7
D-60590 Frankfurt

[redacted]

Arzt für Klinische Pharmakologie

e-mail [redacted]

Telefon (Durchwahl) [redacted]

Telefax [redacted]

Datum 10.02.2016

Dear Dr. [redacted]

No ethical concerns are raised over the following survey study: " The representativeness and relevance of Error reporting data source in generating patient safety data as compared to chart review, claims data, routine data, and survey data sources."

However, questionnaires to Healthcare Professionals do not require a formal IRB statement according to §15 Berufsordnung Hessische Ärzte as they are not deemed as biomedical research in the scope if the Declaration of Helsinki.

Sincerely yours

[redacted]

Vorsitzender der Ethikkommission
des Fachbereiches Medizin
der Goethe Universität Frankfurt

Annexure 2: Invitation letter to study participants

Sent invitation

from: [redacted] via surveymonkey.com
date: Tuesday, October 30, 2012 1:04 PM
sent to: 0 recipients
subject: Invitation to a panel of experts on patient safety data sources
message:

Dear [FirstName] [LastName],

The European project Learning from International Networks about Errors and Understanding Safety in Primary Care (LINNEAUS-EURO PC) was set up specifically to address issues related to improving patient safety, whereby our focus is on primary care and the interface between primary and secondary care. The LINNEAUS-EURO PC is a co-operation project consisting of 11 research groups in 9 EU countries : the UK, Scottland, Greece, The Netherlands, Germany, Austria, Denmark, Poland, and Spain. For further project details please visit our homepage at http://www.linneaus-pc.eu.

We, at the German research group, are concerned with the comparison of different data sources (error reporting, chart review, claims data, routine data, and survey data) that are used in the European countries to generate patient safety data. Their representativeness and relevance for a comprehensive picture of patient safety is often not clear. Therefore we conduct a survey with persons experienced with the data sources.
As you are an expert in this field, we would like to kindly invite you to be a member of our panel and to support our undertaking with your experience and opinions.
Herewith we send you a personal link to the survey and we kindly ask you to take some time to fill in the questions. It will take you approximately 20 to 30 min. It is possible to interrupt your answering session and to continue later. Questions requiering an answer are flagged by an asterix (*).

The survey will be closed on December 5, 2012.
Here is the link to the survey:

[SurveyLink]

(This link is uniquely tied to your email address. Please do not forward this message).
If you have any problem with the message display or access to the survey, please don't hesitate to contact us.

Thanks for your participation!

The project team Kerstin Klemp and Nelisiwe Swana

Institute of General Practice
Goethe University
Theodor-Stern-Kai 7
60590 Frankfurt am Main
Germany
Tel.: [redacted]

Please note: If you do not wish to receive further emails from us, please click the link below, and you will be automatically removed from our mailing list.

[RemoveLink]

Annexure 3: Questionnaire used for the study

Experts opinions on the data sources used in patient safety research.

INTRODUCTION

Dear Sir/Madam

As a valued expert in one or more of the following data sources used to report on patient safety (namely: chart review, claims data, error reporting, routine data and survey data), you have been selected to participate in this survey. Information gathered from this survey will be used to determine how valid and representative these data sources are, in reporting patient safety in Europe.

It will take you approximately 15 to 20 min to fill in the questionnaire. It is possible to interrupt your answering session and to continue later from another computer. Questions requiring an answer are flagged by an asterix (*).

The first page of this questionnaire will be about your personal background. Subsequent pages will focus on specific data sources you currently use. Your personal information is confidential and we will strictly treat it that way. The results of this survey will be accessible to you via email.

Your contribution is highly valued.

Thank you.

The Patient Safety Team

***1. In which country are you working?**

Gemany

Austria

Scottland

England

Poland

Denmark

The Netherlands

Greece

Spain

Other

Please specify "other"

***2. What is your native language?**

***3. What area of healthcare do you primarily work in?(Multiple selections are possible)**

Administrative Services
Allied Health
Dietetics
Cardiology
Care of the Elderly (Geriatrics)
Clinical Immunology and Allergy
Dental Medicine and Surgery
Dermatology
Diagnostic Services
Emergency Medicine
Endocrinology
Gastroenterology
General Medicine
General Nursing
General Surgery
Genetics
Gynaecology
Haematology
Infectious Diseases
Medical Oncology
Nephrology/Renal
Neurology
Obstetrics
Ophthalmology
Orthopaedics
Otolaryngology
Pain Services
Palliative Medicine
Paediatrics
Pharmacy
Physiotherapy (Physical Therapy)
Podiatry
Primary Care

Psychiatry

Public Health

Rehabilitation

Rheumatology

Speech and Language Therapy

Thoracic/Respiratory Medicine

Urology

Other (please specify)

***4. What is your professional background?**

***5. Which data source are you an expert for? (If you are working on more than one data source, you will have a chance to answer for the other data source at the end)**

Chart review

Claims data

Error reporting

Routine data

Survey data

Other source

Please specify "other source"

CHART REVIEW

***6. For how long have you been working with chart review data source already?**

- less than 5 yrs
- 5-9yrs
- 10-14yrs
- 15-19yrs
- 20-24yrs
- 25 yrs and more

CHART REVIEW

***7. A number of statements on chart review data source will be made, and your opinion requested. For each of these we kindly ask you to indicate your agreement or disagreement on a five-point Likert scale.**

	I strongly agree	I agree	I am not sure	I disagree	I strongly disagree
Chart review data source is widely used for patient safety research in your country.					
It is easily accessible to researchers.					
It is user friendly and enables cost effective research.					
Working with this data source is rather time consuming.					
There is an annual report on patient safety generated from this data source in your country.					
It reports on all causes of patient safety related events, e.g. failures by healthcare professional or patient.					
It reports on different levels of harm to patients including near misses.					
Information derived from this data source can be used in future to train healthcare professionals and prevent further occurrence of the identified problems.					
This data source can be used on its own to report comprehensively on patient safety.					

Information found on this data source does not overlap to other data sources.					
This data source can be used for both big and small organizations.					

***8. For how long have you been working with claims data source already?**

- less than 5 yrs
- 5-9yrs
- 10-14yrs
- 15-19yrs
- 20-24yrs
- 25 yrs and more

CLAIMS DATA

***9. A number of statements on claims data source will be made, and your opinion requested. For each of these we kindly ask you to indicate your agreement or disagreement on a five-point Likert scale.**

	I strongly agree	I agree	I am not sure	I disagree	I strongly disagree
The claims data source is widely used for patient safety research in your country.					
It is easily accessible to researchers.					
It is user friendly and enables cost effective research.					
Working with this data source is rather time consuming.					
There is an annual report on patient safety generated from this data source in your country.					
It reports on all causes of patient safety related events, e.g. failures by healthcare professional or patient.					
It reports on different levels of harm to patients including near misses.					
Information derived from this data source can be used in future to train healthcare professionals and prevent further occurrence of the identified problems.					
This data source can be used on its own to report comprehensively on patient safety.					

Information found on this data source does not overlap to other data sources.					
This data source can be used for both big and small organizations.					

***10. For how long have you been working with error reporting data source already?**

ess than 5 yrs

5-9yrs

10-14yrs

15-19yrs

20-24yrs

25 yrs and more

ERROR REPORTING

***11. A number of statements on error reporting data source will be made, and your opinion requested. For each of these we kindly ask you to indicate your agreement or disagreement on a five-point Likert scale.**

	I strongly agree	I agree	I am not sure	I disagree	I strongly disagree
Error reporting data source is widely used for patient safety research in your country.					
It is easily accessible to researchers.					
It is user friendly and enables cost effective research.					
Working with this data source is rather time consuming.					
There is an annual report on patient safety generated from this data source in your country.					
It reports on all causes of patient safety related events, e.g. failures by healthcare professional or patient.					
It reports on different levels of harm to patients including near misses.					
Information derived from this data source can be used in future to train healthcare professionals and prevent further occurrence of the identified problems.					
This data source can be used on its own to report comprehensively on patient safety.					

Information found on this data source does not overlap to other data sources.					
This data source can be used for both big and small organizations.					

***12. For how long have you been working with routine data source already?**

- less than 5 yrs
- 5-9yrs
- 10-14yrs
- 15-19yrs
- 20-24yrs
- 25 yrs and more

ROUTINE DATA

***13. A number of statements on routine data source will be made, and your opinion requested. For each of these we kindly ask you to indicate your agreement or disagreement on a five-point Likert scale.**

	I strongly agree	I agree	I am not sure	I disagree	I strongly disagree
Routine data source is widely used for patient safety research in your country.					
It is easily accessible to researchers.					
It is user friendly and enables cost effective research.					
Working with this data source is rather time consuming.					
There is an annual report on patient safety generated from this data source in your country.					
It reports on all causes of patient safety related events, e.g. failures by healthcare professional or patient.					
It reports on different levels of harm to patients including near misses.					
Information derived from this data source can be used in future to train healthcare professionals and prevent further occurrence of the identified problems.					
This data source can be used on its own to report comprehensively on patient safety.					

Information found on this data source does not overlap to other data sources.	○	○	○	○	○
This data source can be used for both big and small organizations.	●	●	●	●	●

***14. For how long have you been working with survey data source already?**

- less than 5 yrs
- 5-9yrs
- 10-14yrs
- 15-19yrs
- 20-24yrs
- 25 yrs and more

SURVEY DATA

***15. A number of statements on survey data source will be made, and your opinion requested. For each of these we kindly ask you to indicate your agreement or disagreement on a five-point Likert scale.**

	I strongly agree	I agree	I am not sure	I disagree	I strongly disagree
Survey data source is widely used for patient safety research in your country.					
It is easily accessible to researchers.					
It is user friendly and enables cost effective research.					
Working with this data source is rather time consuming.					
There is an annual report on patient safety generated from this data source in your country.					
It reports on all causes of patient safety related events, e.g. failures by healthcare professional or patient.					
It reports on different levels of harm to patients including near misses.					
Information derived from this data source can be used in future to train healthcare professionals and prevent further occurrence of the identified problems.					
This data source can be used on its own to report comprehensively on patient safety.					

Information found on this data source does not overlap to other data sources.					
This data source can be used for both big and small organizations.					

Thank you!

Dear panel member,

thank you for your contribution!

Best wishes from the patient safety team.

Experts opinions on the data sources used in patient safety research.

Annexure 4: Likert scale questions with created variables

QUESTIONS AND CREATED VARIABLES

QUESTION	**VARIABLE**
This data source is widely used for patient safety research in your country.	Widely used
It is easily accessible to researchers.	Accessibility
It is user-friendly and enables cost effective research.	User-friendly
Working with this data source is rather time-consuming.	Time-consuming
There is an annual report on patient safety generated from this data source in your country.	Report
It reports on all causes of patient safety-related events, e.g. failures by healthcare professional or patient.	All causes
It reports on various levels of harm to patients including near-misses.	All harm
Information derived from this data	Training usability

source can be used in future to train healthcare professionals and prevent further occurrence of the identified problems.	
This data source can be used on its own to report comprehensively on patient safety.	Alone
Information found on this data source does not overlap to other data sources.	Unique
This data source can be used for both big and small organisations.	Organisation