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Defining the Patient Safety Trajectory of Breast Cancer at a National Cancer Centre.

Thesis presented by

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for the degree of

Master of Research in Medical Sciences

University College Cork

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Declaration

This is to certify that the work I am submitting is my own and has not been submitted for another degree, either at University College Cork or elsewhere. All external references and sources are clearly acknowledged and identified within the contents. I have read and understood the regulations of University College Cork concerning plagiarism and intellectual property.

Signed:



Date: 06/01/2023

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Abstract

Introduction: One in seven Irish women will develop breast cancer in their lifetime. A well-researched management pathway commences thereafter, involving multiple treatment modalities and specialities. In contrast, there is sparse research examining the patient safety trajectory that mirrors this clinical journey. Learnings from previous events can illuminate this otherwise unknown patient safety trajectory of those with breast cancer. Furthermore, there is little known of patients' and doctors' views and experiences of this patient safety trajectory.

Aims: This study aimed to characterise patient safety incidents that have occurred during breast cancer care, their contributory and preventative factors, outcome and impact. Using this data, patient safety trajectories were created. In addition, this paper aimed to explore the patient safety views and concerns of patients receiving and doctors providing breast cancer care.

Methods: Anonymous, quantitative patient and doctor questionnaires were used. In addition, data related to medical negligence claims involving breast cancer and handled by the State Claims Agency was analysed. Pearson chi-squared test and Fisher's exact test were utilised for categorical data. The median degrees of harm were used to construct trajectories.

Results: 83 patient safety incidents were included (61 medical errors and 22 medical negligence claims). Failure or delay to correctly diagnose was the most commonly implicated adverse event type overall (n=32/83, 38.6%) and was involved in a higher proportion of medical negligence claims than medical errors (p=0.01). Forty percent of events occurred in the outpatient department (n=33/83) and 31% of events took place before a patient's formal breast cancer diagnosis (n=26/83). Inadequate communication was the most common contributory factor. Events during neoadjuvant chemotherapy and after discharge from follow-up had the highest median degree of harm of 4 (Q1-Q3:3.5-4.5 and Q1-Q3:4.0-4.5). More doctors felt patient safety has worsened in the past five years compared to patients (41.4% vs 13.0%) (p<0.001). Twice as many doctors reported that there were inadequate measures in place to prevent medical error compared to patients (54.3% vs 27.2%) (p<0.001).

Conclusion: Patient safety incidents during breast cancer care occur in a variety of settings and during all clinical stages but often occur before diagnosis and involve inadequate communication. Doctors who provide breast cancer care have a more pessimistic outlook on patient safety compared to patients and are more concerned about medical error in breast cancer care. Addressing and acting on the experiences and concerns of those involved in breast cancer care is vital to improve patient safety trajectories for breast cancer patients.

Introduction

Breast Cancer Care in Ireland

Internationally, breast cancer is the most common malignancy diagnosed in women (excluding skin cancer) and it is the leading cause of cancer death (1). This is also the case in Ireland, with one in seven Irish women developing breast cancer at some point during their life (2). The presentation and outcome of breast cancer differs from person to person. Its management can require multiple treatment modalities and many medical specialities.

Navigating cancer services can be daunting for patients and healthcare practitioners alike. 'A Strategy for Cancer Control in Ireland' was published in 2006 and it advocated for a comprehensive cancer control policy programme (3). In response to this, the National Cancer Control Programme (NCCP) was established in 2007 with the aim of reorganising the delivery of cancer care in Ireland and improving cancer survival rates. An early priority for the NCCP was to establish designated cancer centres for oncological surgery of which there are now nine throughout Ireland. A further 17 public hospitals provide systemic anti-cancer therapy. The aim of this reorganisation was to ensure adequate case volumes, develop expertise and specialist skills as well as the formation of multidisciplinary teams (3).

Central to the NCCP is evidence-based guidelines which intend to cover "the whole patient journey from early detection, diagnosis, treatment, monitoring and end of life care" (4). An abnormality on imaging or a symptom experienced by the patient can set a person's breast cancer trajectory in motion. It moves from assessment to formal diagnosis to treatment. It can involve radiology, pathology, surgery, radiotherapy, chemotherapy, physiotherapy, genetic counselling and reproductive medicine to name but a few components. Patients may require hormonal therapy and regular follow-up for many years and a person's breast cancer trajectory can span up to a decade or more.

Medical Error and Its Consequences

National and international evidence-based guidelines outline and define the clinical stages of a patient's breast cancer trajectory. However, there is an undefined and unseen trajectory parallel to each clinical stage, one whose components relate to safety, risk and error. Guidelines and research rarely look at a patient's path with a safety and risk lens. The World Health Organisation's defines patient safety as "the prevention of errors and adverse effects to patients associated with healthcare" (5). From that stems the description of medical error which is "an adverse event or near miss that is preventable with the current state of medical

knowledge" (6). The definitions which naturally follow are that of an adverse event, "an incident which resulted in harm to a patient" and a near miss, "an incident that did not reach the patient" (6). In essence, patient safety is the twenty-first century version of 'primum non nocere' ('first do not harm').

Abiding by this ethical principle is becoming increasingly complex, in part due to the fact that knowledge is expanding faster than our ability to apply it. The doubling time of medical knowledge in 1950 was estimated to be 50 years but by 2020, it was just 73 days (7). Owing to new treatment options and more effective treatments, expectations of care have appropriately increased. However, this has been paralleled by growing complexity of care and therefore increasing risk. It is critical that patient safety remains a fundamental aspect of healthcare because "every point in the process of care can contain an inherent risk" (8).

Nevertheless, errors and adverse events are common. A report by the Organisation for Economic Co-Operation and Development found that up to four in ten patients are harmed in primary and outpatient healthcare settings with as much as 80% of harm being preventable (9). The Irish National Adverse Events Study (INAES) was published in the BMJ Quality & Safety in 2016 and it reviewed the charts of over 1,500 randomly selected inpatient admissions from eight hospitals. The prevalence of adverse events in hospital admissions was reported by the INAES to be 12.2% (10). A follow-on study, The Irish National Adverse Event Study-2 (INAES-2) published in 2021, found that the prevalence of adverse events was 14%. The authors described this relatively unchanged figure as reflective of a lack of national progress in improving patient safety (11). Ireland is not unique as these figures are comparable with many high-income countries (12, 13).

While some medical errors do not result in harm, morbidity and mortality can occur. An adverse event can cause physical or psychological harm and the severity can range from mild harm to irreversible harm or, in rare circumstances, death. Over 21 years ago, the pioneering report by the United States' Institute of Medicine presented evidence that thousands of deaths each year were the result of inadequate patient safety practices (14). Another milestone study extrapolated that up to 250,000 deaths per year were attributable to medical error, ranking it the third leading cause of death in the United States (15). Common adverse events such as wrong-site surgery, medication errors or nosocomial infections for example can cause significant, long-lasting consequences for patients (16).

The resources allocated to improving patient safety should match the magnitude of the issue. While general expenditure on healthcare services will have an indirect positive impact on patient safety, only €36.5 million of the €22 billion 2022 Irish health budget was earmarked to be spent specifically with the aim of 'enhancing the quality and clinical safety' of health services (17). In contrast, the cost of adverse events in Irish hospitals is estimated at €194 million annually (10).

In the United Kingdom, longer hospital admissions caused by adverse events are estimated to cost over £2 billion (€2.3 billion) annually (12). In the Australian state of Victoria, an adverse event added, on average, $6826 AUD (€4374) to the cost of each admission. In one year, the cost of adverse events was estimated to total $460,000,000 AUD (€294 million) which represented 15.7% of total expenditure on direct hospital costs (18). Preventable adverse events were estimated to be responsible for 300,000 bed days in a Dutch study (19). Adverse events are costing countries across the globe hundreds of millions of euros annually but resources allocated to mitigate risks often pale in comparison.

The Current Status of Medical Negligence Litigation in Ireland and Internationally

If a medical error causes harm to a patient, legal action may be pursued by the patient to establish that negligence occurred and that compensation should be awarded (20). In Ireland, the State Claims Agency (SCA) manages medical negligence claims on behalf of the Health Service Executive, the publicly funded healthcare system in Ireland. The SCA is the indemnifier in 90% of all clinical negligence cases in Ireland (21). The other 10% of cases include those arising from private practice which are covered by private indemnity providers.

Medical negligence claims are increasing in both quantity and subsequent cost across the globe. In the United Kingdom (UK), £2.4 billion (€2.8 billion) was spent by the National Health Service (NHS) on negligence claims in 2021 - 2022, representing an 8.7% increase from the previous year (22). £83.4 billion (€96.9 billion) is the predicated cost of outstanding claims making it the second largest public sector liability (23). Italy and Poland face increasing medical negligence costs and similarly in the Netherlands, average claims' costs have quadrupled since 2007 (24-27). Countries in Europe are not alone, with the number and costs of medical malpractice claims in China increasing since 2008 (28). In contrast to the United Kingdom and many European countries, the United States operates a public-private healthcare system and is governed by common law. However, the current state of the medicolegal environment does not differ vastly with the average amount paid per claim increasing year on

year (29). Taking into account all cost components, it has been estimated that the medical liability system in the US costs more than $55 billion (€55.09 billion) a year (30).

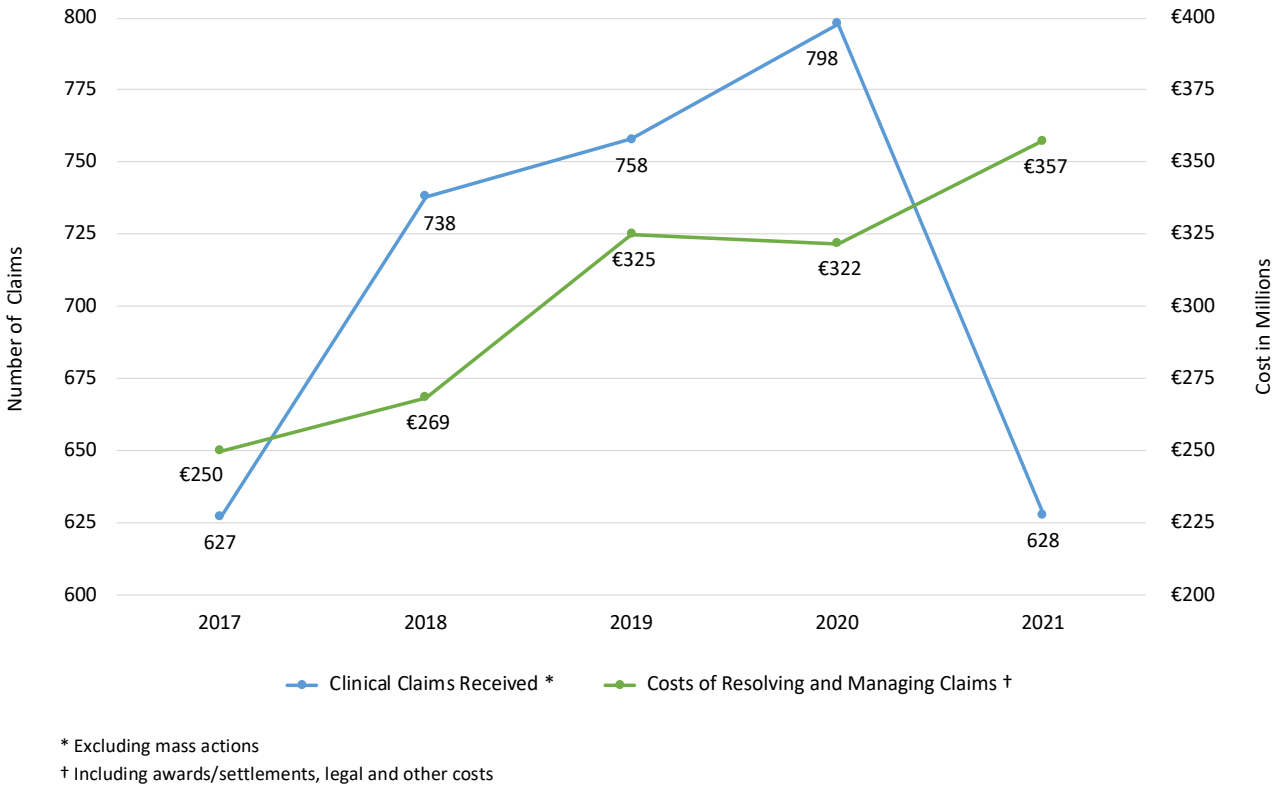


Figure 1: Number of clinical claims received and costs of resolving and managing claims 2017-2021 in Ireland

Ireland's medicolegal environment does not compare favourably. The number of clinical claims and their costs have been increasing for over a decade (Figure 1) (31, 32). The year 2021 is an outlier and likely reflects decreased clinical activity due to COVID-19 (32). Between 2010 and 2020, the number of claims (excluding mass actions) increased 46.7% from 544 to 798. Concurrently, the amount spent on resolving and managing clinical claims (which includes awards/settlements and legal costs) claims increased 297%, from €81 million to €321.8 million (31, 33).

The number of outstanding clinical claims at the end of each year that are yet to be resolved, as well as their estimated costs, are also growing (Figure 2). There were 3,626 outstanding clinical claims associated with an estimated cost of €3.41 billion by the end of 2021 (32). These trends are financially unsustainable and the estimated amount needed for outstanding claims is a substantial public sector liability which represents money that cannot be spent on the provision of healthcare. Improving patient safety has the potential to reduce both patient harm and subsequent medical litigation. However, making this improvement a

reality needs adequate funding and dedicated resources (23). Investing in other areas of healthcare will indirectly contribute to patient safety, but €36.5 million set aside to specifically enhance clinical safety in the 2022 health budget was insufficient (17).

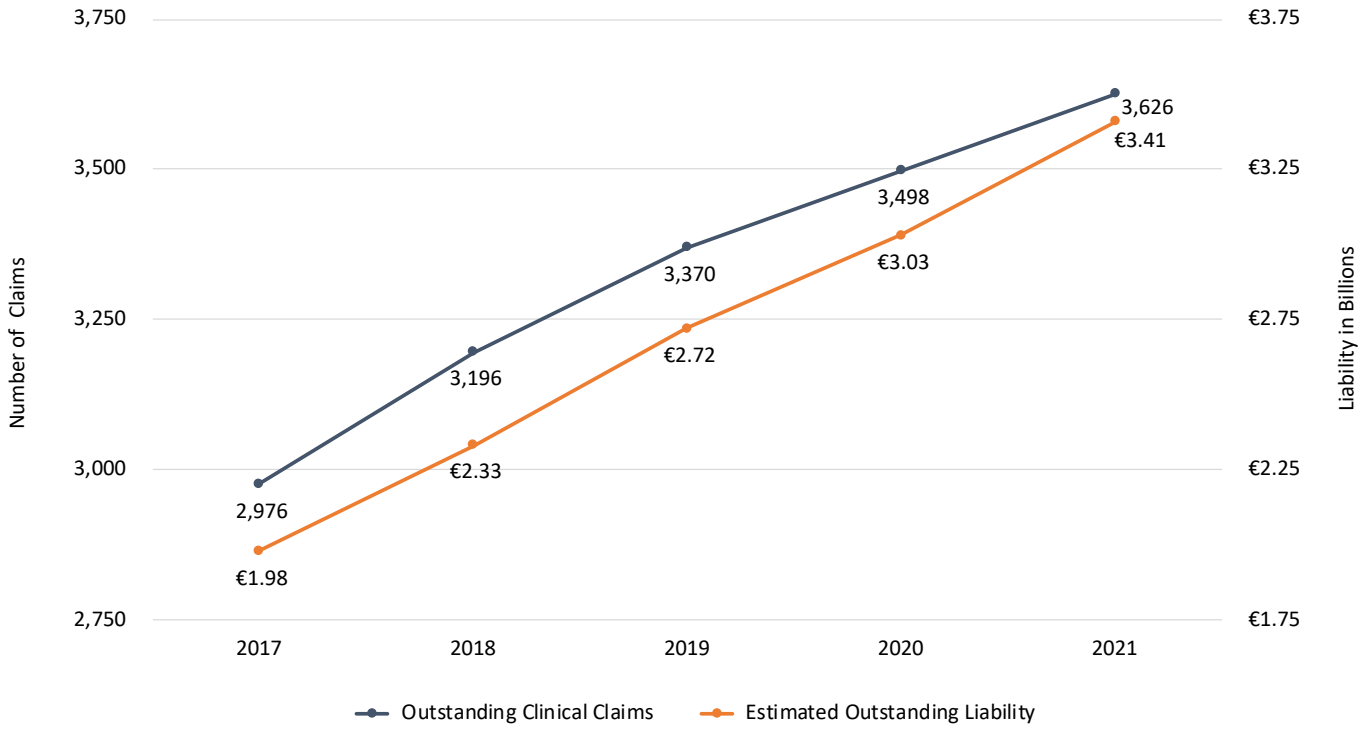


Figure 2: Number of outstanding clinical claims and associated estimated outstanding liability at the end of each year 2017-2021 in Ireland

Consequences of Medical Negligence Litigation

The aim of medical negligence litigation is to identify and hold accountable a provider who has breached their duty of care which has resulted in harm and to compensate the injured party (34). However, this justification was challenged by a landmark paper published in the New England Journal of Medicine which examined the relationship between malpractice claims and adverse events caused by negligence. It found that medical-malpractice litigation "infrequently compensates patients injured by medical negligence and rarely identifies, and holds providers accountable for, substandard care" (35). If litigation does not always provide accountability and compensation, then greater consideration should be given to the negatives of medicolegal proceedings.

The financial burden of medical negligence litigation in Ireland is undeniable and is often a rationale for reform of the legal system (36). Other arguments include the fact that court

hearings are often adversarial in nature and the entire process can span many years. Owing to the negative impacts on both plaintiff and defendant alike, the process is been said to have no winners (37). Aside from the financial aspect, a recent Irish study explored the emotional burden. One barrister commented that they had never seen "a plaintiff come out and say 'God, that was really worth it'" (36). This can, in part, be due to the system's failure to address extra-legal aims such as a desire for communication, openness, an explanation or an apology. Counter-intuitively, these extra-legal aims can often be the reasons patients turn to litigation (21, 36).

Without doubt, the patient and their families are the most directly impacted by medical negligence as any harm that was preventable is deeply distressing. The second victim of medical error is the professional involved. They too need recognition (38). For the medical practitioner, the emotional impact can progress from shock and worry to profound numbness, guilt and isolation (36). The protracted legal process can lead to 'arrested healing', preventing those from moving on and during that time, medical practitioners are expected to continue with their regular work (21, 36).

The practice of medicine can also be affected by litigation. In research examining the impact of the medicolegal environment on surgical practice in Ireland, all respondents reported practising at least one defensive medicine behaviour (39). Over a third were considering early retirement and one in five would consider emigrating as a result of the current medicolegal climate (39). McCarthy et al. evaluated the influence of the medicolegal environment on Irish obstetrics and gynaecology trainees and found it had a negative impact on patient interactions, patient perception, recruitment and retention with one trainee commenting that "the current litigation-heavy, fear-inducing, undermining system makes me reconsider my life choice almost every day" (40). Research published in the Journal of the American Medical Association found that physicians were altering their practice due to risk of litigation such as avoidance of complication-prone procedures or complex patients (41).

As mentioned, redress for patient safety incidents which have resulted in harm can be pursued through medical negligence litigation which is under civil law. Internationally, there has been increasing attention on gross negligence manslaughter (42, 43). This is the prosecution for patient safety incidents under criminal law and can result in medical professionals facing imprisonment. High profile cases include that of Michael Jackson's cardiologist Dr Conrad Murray and those involved in the care of internationally renowned soccer player, Diego

Maradona (44, 45). In the UK the prosecution of Dr Bawa-Garba, a specialist registrar in her sixth year of paediatric postgraduate training, for manslaughter raised concerns about personal culpability versus systemic failures and had negative implications on improving learning from errors (46). In Ireland, there has been one criminal prosecution of a doctor for gross negligence manslaughter in 2016, however they were later found not guilty (39). Such cases spark debate regarding the precedent they set for the criminal prosecution of healthcare workers and the deterrent effects on open disclosure, patient safety culture and learning from error (47).

The Medicolegal Climate of Cancer Care

How are these medicolegal trends impacting on cancer care? A number of specialities are often seen as classically 'high-risk' for malpractice claims: obstetrics and gynaecology, surgery and emergency medicine (41, 48). Relatively low medical malpractice insurance premiums for oncologists in the US reflects the belief that they are less likely to be sued than their counterparts in other specialties (49). However, on average 9% of oncology physicians in the US faced a malpractice claim annually, which is higher than the 7.4% average rate for physicians and ranked third after gastroenterology and pulmonary medicine, both of which are procedure based (50). Despite oncology not being classed as a stereotypically 'high-risk' field of medicine, surgical oncology disciplines have high medicolegal exposures with 19.1% of neurosurgeons, 18.9% of cardiothoracic surgeons and 15.3% general surgeons facing malpractice claims annually (50).

Breast cancer is the most common malignancy involved in malpractice claims in the United States (51). Breast cancer claims have been found to arise most often from delay in diagnosis, most commonly involve radiologists followed by general surgeons and median award amounts varied from $978,858 to $1,800,000 (51-54). A 20-year review of colorectal cancer cases highlighted that diagnostic error was the commonest cause for litigation. Primary care physicians were most commonly named followed by gastroenterologists and general surgeons (55). In dermatological, head and neck, oral, and oropharyngeal malignancies failure to diagnose was again the most commonly alleged reason for litigation (56, 57).

While under or delayed diagnosis is a significant medicolegal risk, the fear of litigation can lead to defensive medical practices and over diagnosis. Surveys of pathologists have shown that concerns regarding malpractice increased their likelihood of diagnosing malignancy in equivocal lesions such as breast or pigmented skin lesions (58, 59). Defensive medicine is hypothesised to be a major cause of unnecessary diagnostic testing and subsequent

overdiagnosis of thyroid cancer (60). A review of malpractice cases involving pancreaticoduodenectomies found the most common cause of alleged negligence was unnecessary surgery and as well as alleged misdiagnosis (61).

Malpractice litigation has a profound impact on the feasibility of cancer screening programmes. Wilson & Jungner's 1968 principles of screening remain the foundation of many global screening programmes. One of the ten principles states that "the cost of case-finding (including a diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole" (62). Balancing this cost is difficult and the growing financial burden of malpractice claims threaten the viability of cancer screening programmes.

Mammography is one of the most common areas of medical litigation among adults and this is impacting breast cancer screening negatively due to its increasing costs and its deterrent impact on recruitment of radiologists. Survey-based studies have found that one in three radiologists are considering withdrawing from mammogram interpretation due to medical malpractice concerns (63-66). In Ireland, there have been over 360 claims filed against the National Cervical Cancer Screening Programme, CervicalCheck (67). Consequently, due to concerns that both erosion of public trust and litigation pose a threat to the viability of screening services globally, the International Agency for Research on Cancer, is conducting a review into Ireland's cancer screening programmes (68).

Learning from Litigation and Regulatory Body Complaints

In theory, examining the characteristics of malpractice claims can improve our understanding of the current medicolegal climate and provide a foundation from which further risk management and prevention strategies can be developed (69). However, in practice there are limited examples of studies' findings translating into tangible improvement of care, reduction of error and subsequent litigation. (70). Anaesthetics, arguably the leading speciality in patient safety improvement, has been the most successful. A prime example is the findings of the American Society of Anaesthetists Closed Claims Project which contributed significantly to the formulation of standards regarding endotracheal intubation, ulnar nerve injury, spinal cord injury and airway trauma (71).

In the UK in May 2021, 'Learning from Litigation Claims: The Getting It Right First Time (GIRFT) and NHS Resolution best practice guide for clinicians and managers' was released as part of the drive for better patient safety (72). As pointed out by John Machin, co-

leader of GIRFT's litigation workstream, 'historically, claims learning has not had the attention it needs to maximise the potential improvements for patient care.' (73). Since then, the GIRFT litigation workstream has improved access to claims data and provided a structured, standardised way of analysing claims which in turn has allowed practical recommendations to be applied to clinical practice (74-76). Central to the GIRFT litigation workstream is practicality, structure and standardisation. Furthermore, there is guidance on disseminating learnings at local and national levels to facilitate data-driven improvements patient safety and care (72).

Only through system-wide improvements can harm be reduced, safer care provided and spending on clinical negligence minimised (23, 77). In Ireland, a recent review of patient safety research found "a modest, but growing, body of patient safety research" but only one study involved a review of medicolegal claims (78). In its recent publication, the Expert Group on Tort Reform and Management of Clinical Negligence stated that "our current legal system urgently requires reform" and that "a key element in improving patient safety is learning from past errors and mistakes" (21). However, as outlined by Minister Seán Fleming, "there is no evidence of a functioning systems-wide approach to incorporate learnings from associated incidents across the entire health sector" (79). The analysis of claims can uncover latent errors, reveal background causes of harm and educate safety improvement (70, 71) (80).

If a medical error occurs, accountability can also be sought by patients from regulatory bodies such as the Irish Medical Council. Similar to experiences of medical negligence litigation, the outcome of a fitness to practise inquiry can be catastrophic for a practitioner's ability to continue. The fear of a complaint or receiving a complaint can have negative psychological consequences on doctors, drive defensive practices and increase the cost of healthcare (81, 82). Nevertheless, analysing complaints can uncover key learning points to support good professional practice. An in-depth qualitative review of complaints received by the Irish Medical Council between 2008 and 2012 explored the most frequently cited causes of concern. Areas and themes highlighted in the review were then considered by the Council during revision of the 'Guide to Professional Conduct and Ethics' (81). A review such as this demonstrates the utility of learning from previous negative experiences and errors in order to improve doctors' practice and patients' care.

Stakeholder Engagement in Safety Improvement

As outlined, medical errors are common and they can result in harm for both patient and practitioner, but lessons can be learnt from past errors in order to prevent future ones. This error prevention is at the crux of patient safety improvement. However, patient safety cannot improve without engagement from those involved. This is why it is pertinent to understand patients' and doctors' views on aspects of safe healthcare as well as on past, current and future error prevention. In Ireland, there is little known of the patient safety opinions and concerns of those with breast cancer and of doctors who provide breast cancer care.

With regards to the former, patients have a unique knowledge of their own healthcare pathways and are the most attentive spectators of the care they receive (83, 84). As a result, their opinions can be used to identify when, where and how there may be patient safety risks along the trajectory and result in a reduction of adverse events and improvement of services (85, 86). Many tools can be used to involve patients in safety improvement including interviews and designated patient incident reporting systems (87). Patient surveys have been used in numerous studies to assess medical error as well as the safety of healthcare (83, 85, 86, 88-96). Using patients' perspectives to characterise safety risk and adverse events has many benefits. One example is that it captures concerns or events which were not documented in the medical record and would have been missed in chart reviews (89). Another is that patients can offer different perspectives to healthcare professionals and have been found to report different types of concerns, events and outcomes compared to healthcare workers (85, 87, 97).

Data about patient safety and medical error has long relied on the reporting of healthcare professionals and unfortunately, the level of reporting is often far below the incidence of events (11, 98, 99). However, there is little knowledge of the patient safety views and experiences of doctors who provide breast cancer care. Previous Irish studies assessing medical error and patient safety have examined specific specialities which is not conducive to the multi-disciplinary format of breast cancer care (39, 40). An understanding of the patient safety trajectory of breast cancer can be better achieved by a movement towards the analysis of the journey across different settings and specialities (100). As a result, there is a need to examine and characterise doctors' perspectives of patient safety and medical error in relation to breast cancer care.

Contemporary medical practice involves a continuous cycle of learning from the inputs of clinical trials and evidence-based medicine (Figure 3). This cycle of information integration

does not routinely include learnings from the experiences and concerns of stakeholders. However, these experiences and concerns represent modifiable, teachable moments in improving patient care. The greater the attempt to understand the perspective of those involved, the greater the strength of claims analyses compared with other methods of examining adverse events (80, 101).

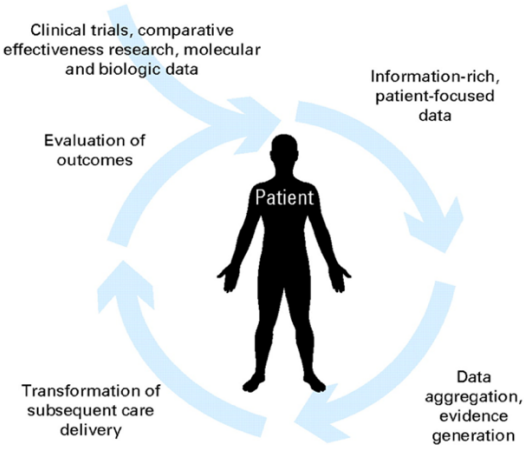


Figure 3: The cycle of reflective learning (102)

Conclusion

Firstly, this project uses data from previous patient safety incidents during breast cancer care with the aim of defining the patient safety risks faced by those undergoing treatment. Data from these previous incidents inform the mapping of patient safety trajectories with vulnerabilities illustrated chronologically. Trajectory mapping is an emerging novel approach to describe care pathways and has been utilised in both palliative care and oncology previously. Its benefits lie in the fact it encapsulates a patient's journey. It contains data to educate and a story to motivate (100, 103-105).

A deeper understanding of patients' and doctors' perceptions of patient safety and medical error, as well as differences between the two groups, can be used by to improve healthcare services, contribute to policy discussion and promote participation in patient safety improvement (84, 106). Therefore the second aim of this project to establish doctors' and patients' current perceptions of patient safety and concerns about medical error.

Methods

Study One

Study Design

The aim of study one was to characterise patient safety incidents experienced during breast cancer care and define the patient safety trajectory of breast cancer. The aftermath of each medical error can differ, for example some are unreported while others may result in a regulatory body compliant or medical negligence claim (20, 81, 99). This heterogenicity is one of the challenges of patient safety data (12). The World Health Organisation's (WHO) Global Patient Safety Action Plan 2021–2030 outlines different approaches to identifying, quantifying and characterising errors. Among them are reporting systems, malpractice claims, patient-reported measures, clinical care audits, medical record reviews and surveys (8).

Each of these sources has advantages and disadvantages. For example, medical record reviews are the gold standard for measuring the prevalence of medical error but do not capture the experiences of those involved (107). Incident reporting systems improve standardisation of the data collected but are reliant on the uptake of staff (99). Surveys can offer insights into the more intangible aspects of clinical care including patient and provider perspectives that are often not evident in other sources (108).

To maximise the advantages of different approaches and capture the different outcomes of events, this study intended to use four data sources. The first source was patient and doctor questionnaires. The second was data from the State Claims Agency (SCA) related to closed medical negligence cases. The third was complaints submitted to the Irish Medical Council. The final source was incidents reported to the National Incident Management System (NIMS). Despite much pre-emptive planning there were many bureaucratic barriers to accessing much of this data.

The study intended to utilise national data from the SCA. Despite engaging two years before the project was intended to begin and gaining the support of the National Cancer Control Programme for national data, it was not made available within the timeframe of this project. In order to provide data on a local level, the SCA required a data request from the Chief Executive Officer of the hospital. Once this was provided, the SCA provided a report on breast cancer claims related to a geographical location which corresponded with one of the nine national designated cancer centres.

The Irish Medical Council cited privacy and confidentiality issues as a barrier to providing data. Finally, access to NIMS data was limited by the inability to filter incidents to just those undergoing breast cancer care at the time of the incident. Patients could only be filtered based on the primary consultant and as mentioned previously, consultants often care for multiple cancer types. To filter patients with breast cancer would have required a manual examination of thousands of incidents under many consultants of different specialities who care for a variety of cancer types. Unfortunately, that was beyond the capacity of this study. Therefore, only two of the four data sources were viable for the timeframe over which this study was conducted. They were patient and doctor questionnaires as well as non-national closed claims data from the SCA.

Survey Design

This research employed a predominantly quantitative approach by using anonymous questionnaires which had 39 questions for patients and 42 questions for doctors. Based on whether the respondent had experienced an error or a medical negligence claim, the maximum number of questions answered by any one patient was 25. Similarly for doctors, the maximum was 27 questions. One open-ended question was included regarding consequences of the event for the patient. This was to allow for a degree of harm to be assigned to each incident by the PI. The degree of harm was defined by the WHO's International Classification for Patient Safety which is outlined in data analysis. All other questions were closed-ended.

A predominantly quantitative approach was chosen for a number of reasons. The first being that experiences of error and litigation can be an emotional and sensitive experience. For this reason a qualitative Irish study assessing the emotional impact of medical negligence litigation on plaintiffs and medical practitioners felt that involving supportive representative groups would be more appropriate than individual participants (36). Answering a close-ended questionnaire allows a degree of detachment for the respondent and affords them complete anonymity.

The findings of a quantitative approach are independent of the principal investigator (PI). This is particularly relevant because if a qualitative approach had been adopted, patients would have been interviewed by the PI who is a healthcare professional. This may have prevented patients from being honest in their views or experiences for fear they would reflect negatively on their doctor or the care they received. Quantitative research also allows replicability which would enable similar research to be conducted for patients with other cancer

types. Quantitative research in general allows for larger sample sizes and is less time consuming for participants and researchers (109).

At the time of this study, there were no surveys designed specifically for patients with breast cancer and doctors who provide breast cancer care. Therefore, the surveys utilised were designed by the PI in conjunction with an experienced medical oncologist and a professor with extensive experience in the medicolegal field from the Department of Law at University College of Cork. The surveys were kept short and questions were phrased without complex language or medical jargon for the patients' survey (110). Their design was informed by much of the literature discussed in the introduction however, the majority of questions were based on an 'analysis of claims form' designed by Vincent et al. with minor adaptations to ensure relevance to an Irish cohort (70). This form was the basis for a large claims analysis study which looked at 155 cases. Vincent et al. designed this form using three sources: retrospective record review studies (13, 107, 111-113), speciality-specific review instruments (114) and the 'Protocol for Investigation and Analysis of Clinical Incidents' which is used widely in the United Kingdom and internationally (115, 116).

One limitation of the Vincent et al. form is that it was designed in 2006. Therefore minor adaptions were made using the best practice guide 'Learning from Litigation Claims: The Getting It Right First Time (GIRFT) and NHS Resolution best practice guide for clinicians and manager' which was published in 2021 and ensures relevance to current practice (72). The questionnaires distributed to patients and doctors were very similar except for the use of lay-man's terms in the former and medical terms in the latter. In addition, the questions about the demographics and characteristics of the participant were different to ensure relevance to patients and doctors. Lastly, doctors' questionnaires had two additional questions about early retirement and emigration. The questionnaires were initially piloted with five patients and three doctors. Their feedback was used to improve the clarify and functionality of the questionnaires. Patients could choose to fill out the questionnaire electronically or in paper form with all opting for the latter.

Medical Negligence Claims Data

An 'analysis of claims form' was designed by the PI in conjunction with an experienced medical oncologist which essentially mirrored the questionnaires distributed to patients and doctor. This was to ensure standardisation of data collected. An additional field was included

which was concerned with the degree of harm associated with the event as defined by the WHO's the International Classification for Patient Safety (6).

The data provided by the SCA included "record number, date of incident, claim creation date, claim finalised date, case outcome, sub hazard type, problem / cause, service, summary of the incident, paid total". The level of detail provided was insufficient to complete the claims analysis form and the SCA were not in a position to dedicate more resources to provide additional data. Instead, the record number was utilised to identify closed cases locally. Approval was requested and subsequently granted from the relevant local patient safety and quality assurance department to access the records related to the closed cases. This resulted in sufficient information for the five cases to be included in the study. The questionnaires and the analysis of claims form utilised in this study are available in appendices A, B and C.

Study Population & Recruitment - Patients

Non-probability sampling was utilised in the form of convenience sampling as it is time and cost effective. Methods were employed to reduce non-response bias. The PI had no relationship with patients prior to distribution of the study and no further contact with them thereafter. The PI stayed with each participant for until they completed the survey. This allowed a prompt response to any participants' questions. To diversify recruited patients, distribution occurred over two hospital sites and over a period of eight weeks, from April to June 2022.

Patients with breast cancer who had undergone or were currently undergoing treatment and doctors who work in breast cancer care comprised the study population. Patients with breast cancer who attended a medical oncology outpatient appointment for the management of breast cancer were identified at the beginning of the clinic. The basis for the study and the completion process was explained. Thereafter, they were invited to participate and complete the questionnaire while they waited for their appointment.

The anonymity and sensitivity of their answers was emphasised and patients were informed that the doctor who they were attending would not know if they had partaken or not to ensure they did not feel their choice would influence their care. An outline of the study and instructions on how to complete the questionnaire were included on the first page. Participants were informed they could withdraw their answers or decide to no longer participate at any point.

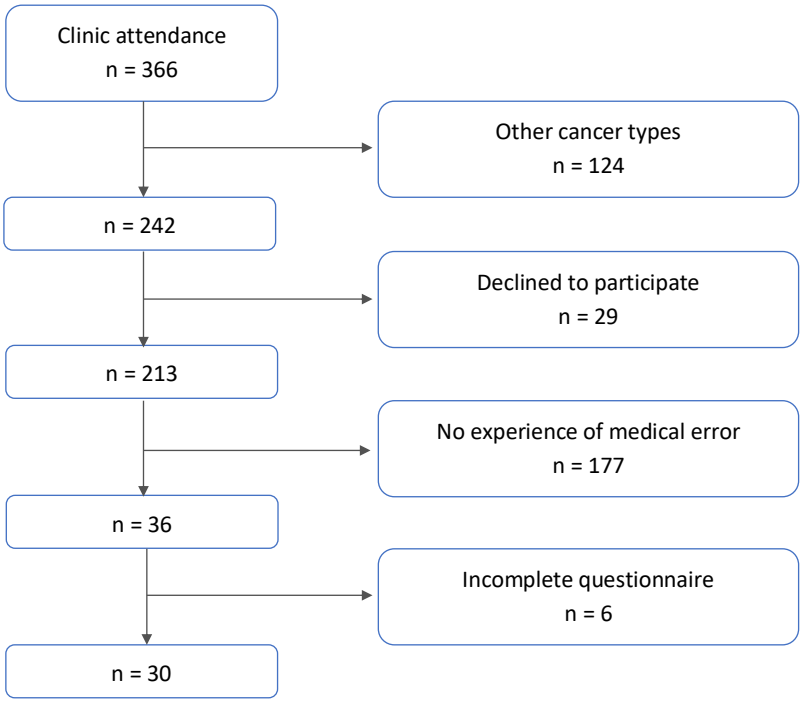


Figure 4: Recruitment process of patients for study one

Study Population & Recruitment - Doctors

Doctors who provide breast cancer care were invited to participate in an online version of the questionnaire using Smart Survey. Convenience sampling was again used for the survey for doctors, however distribution was in the format of an email. One consultant from each of the following specialities was responsible for distribution among colleagues who work in breast cancer care: medical oncology, radiation oncology, breast surgery, palliative care, pathology and radiology. Distribution occurred over a period of eight weeks from May to July 2022. Each consultant sent a participation invite using an email distribution list to colleagues in their field who also provide breast cancer care. Unfortunately, due to nature of the distribution the exact number of recipients who received the questionnaire was not recorded but an effort was made to circulate it as widely as possible.

Exclusion criteria for events included insufficient data, incomplete questionnaires and errors which did not directly relate to breast cancer care. A timeframe for when the medical error occurred was not an exclusion criterion.

Data Collection

As mentioned, two sources of data were utilised to identify medical errors experienced during breast cancer care. They were patient and doctor questionnaires as well as data related to closed claims handled by the SCA. Data from the completed questionnaires was recorded

by one person into a password protected excel sheet. Demographic information was gathered from patients and doctors (Appendix A and B).

The WHO definition of patient safety, medical error, adverse event and near miss were provided. Participants where then asked if they had been involved in an event where they felt a medical error had occurred over the course of their breast cancer journey for patients or when caring for breast cancer patients for doctors. They were then asked if the error had resulted in a medical negligence claim. Respondents proceeded to answer questions about the error (Appendix A and B).

The second data source was related to closed claims involving breast cancer care. The 'analysis of claims form' (Appendix C) was completed by the PI. Variables collected mirrored all of those collected about medical errors identified in the questionnaires. Data was then input by the PI into a password protected excel sheet.

The last element of data collection related to the degree of harm. This was determined for the claims relating to the SCA during the completion of the 'analysis of claims form'. For events identified from patient and doctor questionnaires, the PI assessed the qualitative response to the question regarding harm and determined the degree of harm as defined by the WHO's the International Classification for Patient Safety which is as follows (6):

- None – patient outcome is not symptomatic or no symptoms detected and no treatment is required.
- Mild – patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g. extra observation, investigation, review or minor treatment) is required.
- Moderate – patient outcome is symptomatic, requiring intervention (e.g. additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long term harm or loss of function.
- Severe – patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function
- Death – on balance of probabilities, death was caused or brought forward in the short term by the incident.

Data Analysis

Statistical analysis was performed using IBM SPSS Statistics software version 28.0. Categorical data was analysed using descriptive statistics such as frequencies and percentages. Pearson Chi-squared analyses were performed for categorical variables where all cells had an expected count of over five (117). Otherwise, Fisher's Exact test was utilised (118). A $p < 0.05$ was considered statistically significant for all variables. Z-test analysis was performed for pairwise comparisons of proportions (119). Bonferroni method of adjustment of *p*-value was applied to correct for type one error (120).

Descriptive statistics produce results that are straightforward to interpret and understand due to its intuitive nature. However, numbers and statistics are limited in describing variables over a period of time, such as a breast cancer journey. Therefore, previously mentioned trajectory mapping was utilised in this study. The varying levels of the degree of harm were transformed into corresponding numbers: none = 1, mild = 2, moderate = 3, severe = 4 and death = 5. Thereafter, the median, first and third quartiles (Q1-Q3) were calculated.

A trajectory was constructed by placing clinical stages on the x-axis and the median degree of harm for events on the y-axis. A box and whisker plot was then constructed using the median degree of harm of events which occurred at different clinical stages as well as the first and third quartiles and the absolute range. A second trajectory was constructed by placing healthcare settings on the x-axis in an order which mirrored those most commonly encountered at various clinical stages. The median degree of harm for events was placed on the y-axis and a box and whisker plot was constructed.

Study Two

Study Design

Study two is a cross-sectional, quantitative questionnaire study which examined the patient safety views of those with breast cancer and doctors involved in breast cancer care. Study two also assessed the concerns of patients and doctors about medical error who had not previously been involved in a medical error or medical negligence claim. This study adopted a predominantly quantitative approach by using an anonymous questionnaire which had 22 questions for patients and doctors. All questions were closed-ended. Three questions also provided respondents with the opportunity to provide a free-text comment. This resulted in a small amount of qualitative data. Four questions utilised Likert scales.

A predominantly quantitative approach was chosen to facilitate comparability to results in study one. Another reason was to allow for a larger sample size as engagement in a quantitative study is less time-consuming for respondents (109).

At the time of this study, there were no surveys designed specifically for patients with breast cancer and doctors who provide breast cancer care. Therefore, the survey utilised was designed by the PI as well as an experienced medical oncologist and a professor with extensive experience in the medicolegal field from the University College of Cork's Department of Law. The design process is identical to that for the questionnaires used in study one and almost all of the questions are the same except for minor alterations in terminology to ensure applicability to the two groups.

Four additional questions were added to this questionnaire compared to that in study one which related to views on patient safety in the healthcare environment. These questions were from a survey conducted by NORC at the University of Chicago and the Institute for Healthcare Improvement which assessed experiences of medical errors and views on patient safety (121, 122). The questionnaires were trialled on seven patients and four doctors whose feedback was used to improve the practicality and applicability of the survey.

Similar to the questionnaires above, convenience sampling was used and the same steps were taken to reduce non-response bias. Patient and doctor questionnaire distribution was in the same format outlined above in study one during the same time period. The full version of the questionnaires are available in Appendix D and E.

Study Population

The study population consisted of patients with breast cancer who had undergone or were currently undergoing treatment and doctors who work in breast cancer care. Participants were recruited using the same methods as outlined. Unfortunately, due to nature of the distribution the exact number of doctors who received the questionnaire was not recorded but it was circulated as widely as possible.

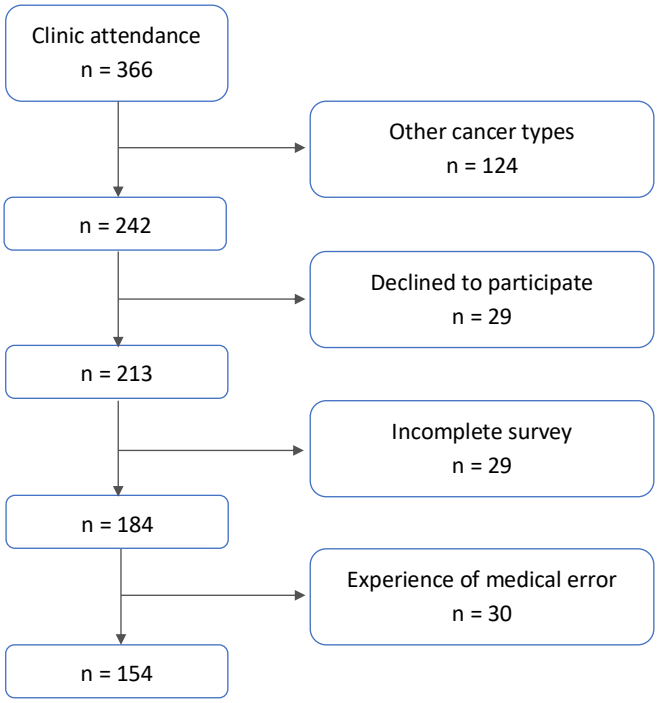


Figure 5: Recruitment process of patients for study two

Data Collection

Data from the completed questionnaires was recorded by the PI into a password protected excel sheet. Participants answered questions on the importance of aspects of care, opinions on medical error and patient safety, levels of concern about adverse events, patient safety in different healthcare settings and at different clinical stages. Data was also collected about respondents' views on potentially contributory and remediating factors as well as experiences of reporting concerns.

Data Analysis

Statistical analysis was performed using IBM SPSS Statistics software version 28.0. All variables were categorical and were analysed using descriptive statistics such as frequencies and percentages. Pearson Chi-squared analyses were performed for categorical variables where all cells had an expected count of over five (117). Otherwise, Fisher's Exact test was utilised (118). A $p < 0.05$ was considered statistically significant for all variables. Z-test analysis was performed for pairwise comparisons of proportions (119). Bonferroni method of adjustment of *p*-value was applied to correct for type one error (120).

Four questions had qualitative data from the free-text comment box. All comments that were provided by respondents were included in results. Thematic analysis was conducted in

order to highlight themes within the qualitative data. The data was read by the PI and codes were developed based on themes evident in the comments.

Ethics

Ethical approval was received from the Clinical Research Ethics Committee of the Cork Teaching Hospitals. A data request was submitted to the State Claims Agency and subsequently granted. Permission to access data was given by the appropriate quality and patient safety department.

All data was stored and utilised in accordance with the European General Data Protection Regulation and Irish Data Protection Act 2018. The data in this project is of a sensitive nature as it relates to potential medical errors, patient safety incidents and medical negligence claims. As such, care was taken to ensure all participants were anonymous and all patient identifiers were omitted from data collection.

Participants were provided with information outlining the rationale for the study, its ethical approval and oversight prior to commencing the questionnaire. They were assured of their right to withdraw their participation at any point prior to submission.

There are no personal interests to disclose. This project was supported by a research bursary to the amount of €2,000 co-funded by the Health Service Executive National Doctors Training and Planning body and University College Cork via the National Academic Track for Internship in Ireland.

Data Management

An excel spreadsheet was created with steps to minimise the limitations of excel. Naming conventions were decided on and rules for empty cells employed. There was an automated back-up to a secure cloud storage to which the PI had access to. As mentioned, data was managed and stored in adherence to both Irish Data Protection Act 2018 and the European General Data Protection Regulation. All data will be kept for the statutory limited period of time. Given the sensitive nature of this data, it will not be made open access.

Results

Study One

This study aimed to characterise patient safety incidents which occurred during breast cancer care. In order to identify relevant events, two sources of data were utilised which were questionnaires and medical negligence claims handled by the State Claims Agency (SCA).

Demographics

Questionnaires were completed by 30 patients with breast cancer and by 48 doctors who provide breast cancer care. Table 1 shows the demographics of patient respondents. Involvement in a medical error was reported 6.5 times more than involvement in a medical negligence claim. All patients were female and more than half were aged 55 years old or over (n = 17/30, 56.7%). The split between those diagnosed less than five years ago and those diagnosed five years ago or more is close to even (n = 16/30, 53.3% and n = 14/30, 46.7% respectively). Almost a quarter of patients were unsure of their type of breast cancer (n = 7/30, 23.3%). There was no statistically significant difference between the demographics of patients who were involved in a medical error compared to those involved a medical negligence claim ($p > 0.05$). In addition, there was no significant difference in the proportions of all other variables for all respondents ($p > 0.05$).

Table 2 outlines the demographics of doctors in study one. Over a quarter of doctors reported involvement in a medical negligence claim (n = 13/48, 27.1%). The female to male ratio for those involved in a medical error was 1.4:1 compared to 0.86:1 involved in a medical negligence claim. All those involved in a medical negligence claim were aged 45 or older as opposed. Radiology was involved in a greater proportion of medical negligence claims than medical errors ($p = 0.03$).

No other variable differed significantly between those involved in a medical error compared to those involved a medical negligence claim (all $p > 0.05$). Furthermore, there was no significant difference in the proportions of all other variables for all respondents (all $p > 0.05$) . The distribution of the number of years' experience doctors had caring for breast cancer patients was similar. The majority of doctors involved in a medical error had ten or more years' experience caring for breast cancer patients (n = 25/35, 71.4%) while all doctors involved in a medical negligence claim had ten or more years' experience.

Table 1: Demographics of patients in study one

	Medical error	Medical negligence claim	Total
Number	26	4	30
Gender (%)			
Female	26 (100.0)	4 (100.0)	30 (100.0)
Male	0	0	0
Age groups (%)			
18-34	3 (11.5)	0	3 (10.0)
35-39	2 (7.7)	0	2 (6.7)
40-44	4 (15.4)	0	4 (13.3)
45-49	3 (11.5)	0	3 (10.0)
50-54	1 (3.8)	0	1 (3.3)
55-59	4 (15.4)	2 (50.0)	6 (20.0)
60+	9 (34.6)	2 (50.0)	11 (36.7)
Patient or family member work in healthcare (%)			
Yes	10 (38.5)	0	10 (33.3)
No	16 (61.5)	4 (100.0)	20 (66.7)
Residence (%)			
Rural area	6 (23.1)	2 (50.0)	8 (26.7)
Small town	11 (42.3)	1 (25.0)	12 (40.0)
Suburb	7 (26.9)	1 (25.0)	8 (26.7)
City	2 (7.7)	0	2 (6.7)
Currently have private health insurance (%)			
Yes	15 (57.7)	2 (50.0)	17 (56.7)
No	11 (42.3)	2 (50.0)	13 (43.3)
First diagnosed with breast cancer (%)			
< 1 year	5 (19.2)	0	5 (16.7)
1-2 years	5 (19.2)	0	5 (16.7)
3-4 years	6 (23.1)	0	6 (20.0)
5-6 years	2 (7.7)	1 (25.0)	3 (10.0)
7-8 years	1 (3.8)	1 (25.0)	2 (6.7)
9-10 years	1 (3.8)	0	1 (3.3)
> 10 years	6 (23.1)	2 (50.0)	8 (26.7)
Breast cancer type (%)			
Hormone sensitive invasive ductal carcinoma	4 (15.4)	0	4 (13.3)
Ductal carcinoma in-situ	1 (3.8)	0	1 (3.3)
HER2 positive carcinoma	2 (7.7)	0	2 (6.7)
Triple negative carcinoma	4 (15.4)	2 (50.0)	6 (20.0)
Invasive lobular carcinoma	1 (3.8)	0	1 (3.3)
Metastatic carcinoma	6 (23.1)	1 (25.0)	7 (23.3)
Unsure	7 (26.9)	0	7 (23.3)
Other	1 (3.8)	1 (25.0)	2 (6.7)

Table 2: Demographics of doctors in study one

	Medical error	Medical negligence claim	Total
Number	35	13	48
Gender (%)			
Female	20 (57.1)	6 (46.2)	26 (54.2)
Male	14 (40.0)	7 (53.8)	21 (43.8)
Prefer not to say	1 (2.9)	0	1 (2.1)
Age groups (%)			
25-34	5 (14.3)	0	5 (10.4)
35-39	3 (8.6)	0	3 (6.3)
40-44	8 (22.9)	0	8 (16.7)
45-49	6 (17.1)	2 (15.4)	8 (16.7)
50-54	5 (14.3)	4 (30.8)	9 (18.8)
55-59	2 (5.7)	2 (15.4)	4 (8.3)
60+	6 (17.1)	5 (38.5)	11 (22.9)
Job title (%)			
Consultant	30 (85.7)	13 (100.0)	43 (89.6)
Senior/ specialist registrar	5 (14.3)	0	5 (10.4)
Junior registrar	0	0	0
Field of medicine			
Medical oncology	11 (31.4)	2 (15.4)	13 (27.1)
Radiation oncology	9 (25.7)	1 (7.7)	10 (20.8)
Radiology	4 (11.4)	8 (61.5)	12 (25.0)
Surgery	6 (17.1)	2 (15.4)	8 (16.7)
Palliative medicine	1 (2.9)	0	1 (2.1)
Pathology	4 (11.4)	0	4 (8.3)
Experience with breast cancer patients (%)			
< 1 year	0	0	0
1-2 years	3 (8.6)	0	3 (6.3)
3-5 years	2 (5.7)	0	2 (4.2)
5-10 years	5 (14.3)	0	5 (10.4)
10-20 years	13 (37.1)	5 (38.5)	18 (37.5)
> 20 years	12 (34.3)	8 (61.5)	20 (41.7)
Practice in a private capacity (%)			
Yes	15 (42.9)	9 (69.2)	24 (50.0)
No	20 (57.1)	4 (30.8)	24 (50.0)

Characteristics of Events

Sixty-one events involving medical error were included, 26 from patients' questionnaires and 35 from doctors' questionnaires. 22 events which resulted in a medical negligence claim were included, four from patients' questionnaires, 13 from doctors' questionnaires and five from the State Claims Agency's data. This resulted in a total of 83 events included in this study. The characteristics of the events are outlined in Table 3.

As shown in Figure 6 and Table 3, failure or delay to correctly diagnose was most commonly implicated (n = 32/83, 38.6%). However, it was involved in a higher proportion of medical negligence claims than medical errors (n = 14/22, 63.6% and n = 18/61, 29.5%) (p = 0.01). Furthermore, failure or delay to provide treatment in a timely manner was reported in a greater proportion of medical negligence claims than medical errors (n = 7/22, 31.8% and n = 7/61, 11.5%) (p = 0.045). Almost one in five events involved communication errors (n = 16/83, 19.3%) and one in eight involved administrative errors (n = 10/83, 12.0%). No medical negligence claims were concerned with errors related to infection, prescribing of medications or equipment malfunctions (Table 3).

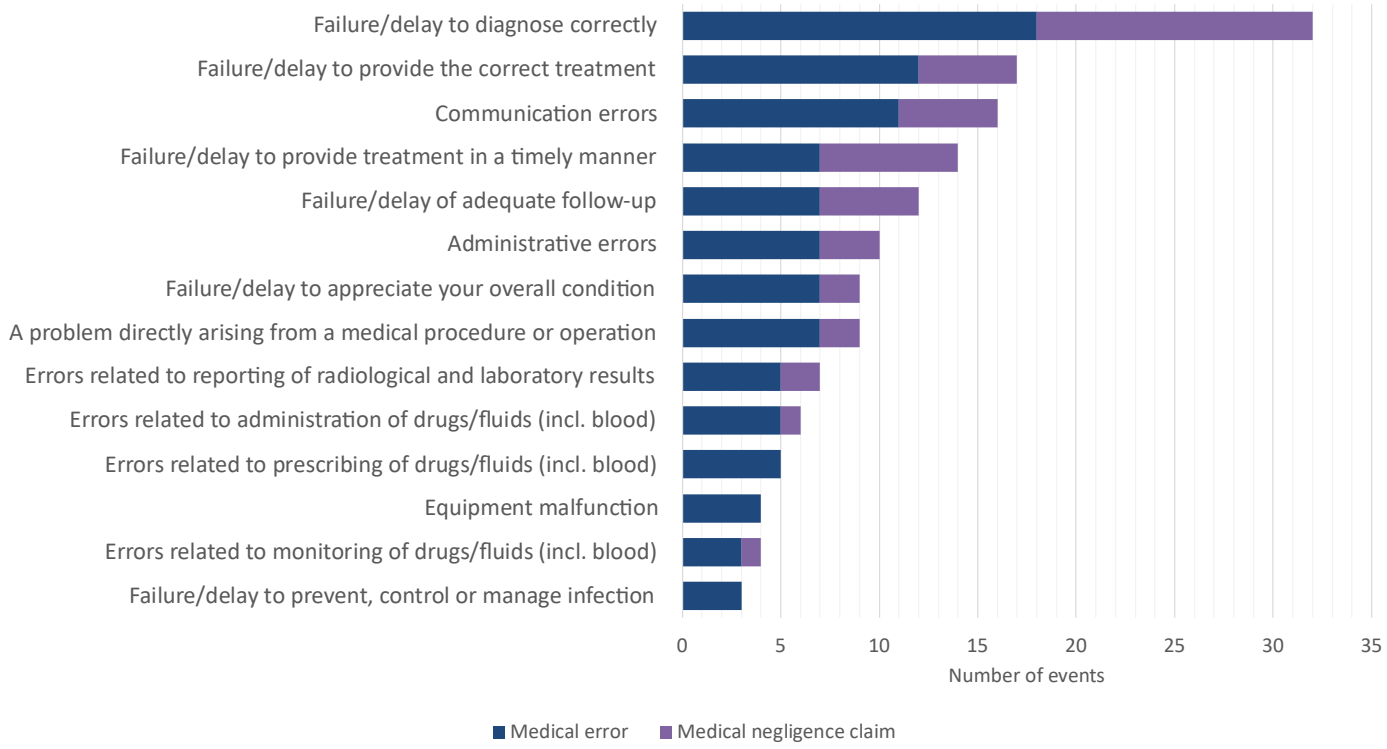


Figure 6: Nature of patient safety incidents which occurred during breast cancer care

Almost two in five events occurred in the outpatient department (n = 33/83, 39.8%) (Figure 7 and Table 3). This was followed jointly by radiology department and general practice (n = 7/83, 8.4%). A procedure-related setting was reported for 11 events and nine events occurred in inpatient settings (admission on a ward, emergency department and high dependency unit).

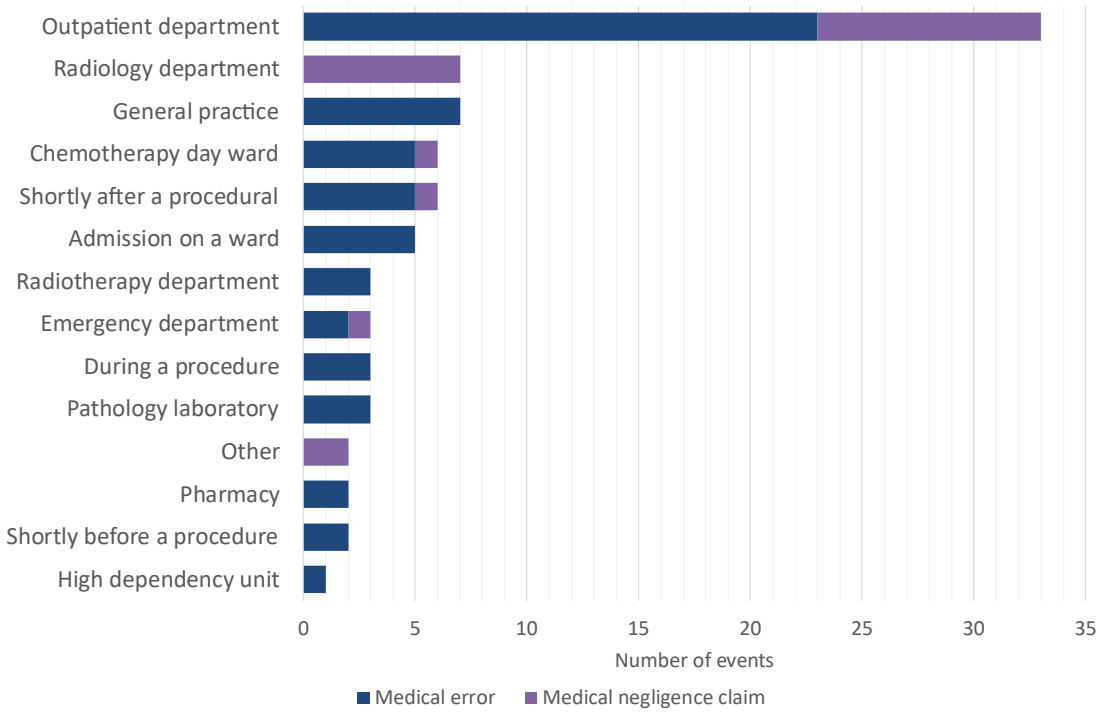


Figure 7: Healthcare setting of patient safety incidents which occurred during breast cancer care

Twenty-six events took place before a patient's formal diagnosis of breast cancer. Therefore, it was the clinical stage which accounted for the highest proportion of events (n = 26/83, 31.3%) as demonstrated in Figure 8 and Table 3. When events which occurred during chemotherapy, irrespective of whether it was neoadjuvant, adjuvant or for palliation, were combined they accounted for 20.4% of all events (n = 17/83). One in ten events occurred either during follow-up or after the patient was discharged from follow-up (n = 9/83, 10.8%).

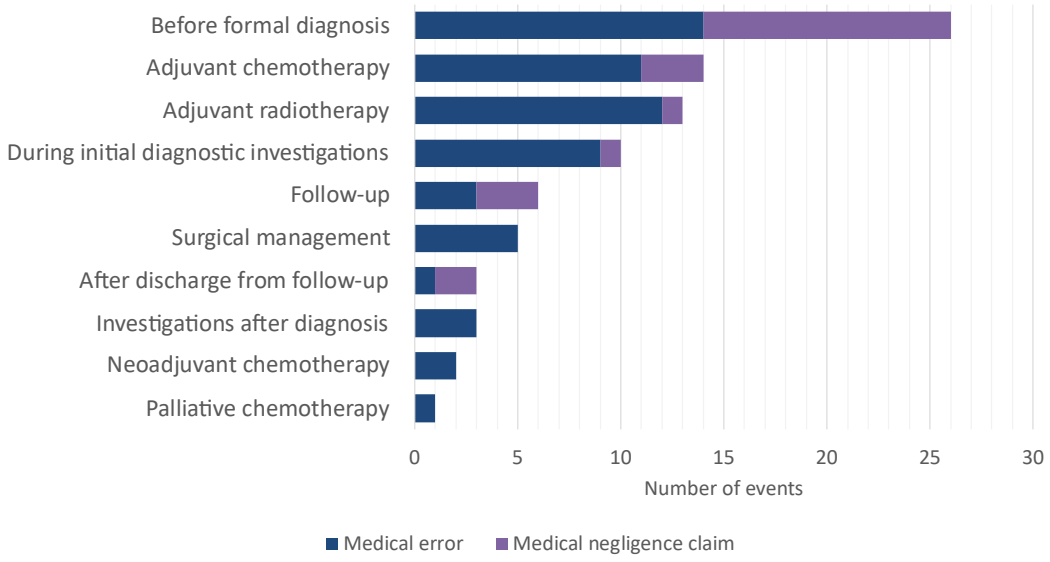


Figure 8: Clinical stage during which patient safety incidents occurred during breast cancer care

The majority of events occurred in the past four years (n = 49/83, 59.1%). As evident in Table 3, the event was discovered by either the patient or the healthcare professional involved in the same number of cases (n= 27/83, 32.5%).

Table 3: Characteristics of patient safety incidents which occurred during breast cancer care

	Medical error	Medical negligence claim	Total
Number	61	22	83
Nature of the event (%)			
Failure/delay to diagnose correctly	18 (29.5)	14 (63.6)	32 (38.6)
Failure/delay to provide the correct treatment	12 (19.7)	5 (22.7)	17 (20.5)
Failure/delay to provide treatment in a timely manner	7 (11.5)	7 (31.8)	14 (16.9)
Failure/delay of adequate follow-up	7 (11.5)	5 (22.7)	12 (14.5)
A problem directly arising from a medical procedure or operation	7 (11.5)	2 (9.1)	9 (10.8)
Errors related to prescribing of drugs/fluids (incl. blood)	5 (8.2)	0	5 (6.0)
Errors related to administration of drugs/fluids (incl. blood)	5 (8.2)	1 (4.5)	6 (7.2)
Errors related to monitoring of drugs/fluids (incl. blood)	3 (4.9)	1 (4.5)	4 (4.8)
Failure/delay to appreciate your overall condition	7 (11.5)	2 (9.1)	9 (10.8)
Failure/delay to prevent, control or manage infection	3 (4.9)	0	3 (3.6)
Administrative errors	7 (11.5)	3 (13.6)	10 (12.0)
Communication errors	11 (18.0)	5 (22.7)	16 (19.3)
Errors related to reporting of radiological and laboratory results	5 (8.2)	2 (9.1)	7 (8.4)
Equipment malfunction	4 (6.6)	0	4 (4.8)
When the event occurred (%)			
Within the past year	11 (18.0)	0	11 (13.3)
1 - 2 years ago	11 (18.0)	3 (13.6)	14 (16.9)
3 - 4 years ago	17 (27.9)	7 (31.8)	24 (28.9)
5 - 6 years ago	2 (3.3)	4 (18.2)	6 (7.2)
7 - 8 years ago	7 (11.5)	5 (22.7)	12 (14.5)
9 - 10 years ago	4 (6.6)	0	4 (4.8)
Over 10 years ago	9 (14.8)	3 (13.6)	12 (14.5)
Who discovered the event (%)			
The patient	21 (34.4)	6 (27.3)	27 (32.5)
The healthcare professional involved	16 (26.2)	6 (27.3)	22 (26.5)
Another healthcare professional	22 (36.1)	5 (22.7)	27 (32.5)
Management at the site where it occurred	2 (3.3)	1 (4.5)	3 (3.6)
At a multidisciplinary meeting	1 (1.6)	0	1 (1.2)
Letter from solicitor	0	4 (18.2)	4 (4.8)
Unsure	1 (1.6)	0	1 (1.2)
Setting of event (%)			
General practice	7 (11.5)	0	7 (8.4)
Radiology department	0	7 (31.8)	7 (8.4)
Pathology laboratory	3 (4.9)	0	3 (3.6)
Outpatient department	23 (37.7)	10 (45.5)	33 (39.8)
Shortly before a procedure	2 (3.3)	0	2 (2.4)
During a procedure	3 (4.9)	0	3 (3.6)
Shortly after a procedural	5 (8.2)	1 (4.5)	6 (7.2)
Admission on a ward	5 (8.2)	0	5 (6.0)

Table 3 continued: Characteristics of patient safety incidents which occurred during breast cancer care

	Medical error	Medical negligence claim	Total
Number	61	22	83
Setting of event (%)			
High dependency unit	1 (1.6)	0	1 (1.2)
Emergency department	2 (3.3)	1 (4.5)	3 (3.6)
Pharmacy	2 (3.3)	0	2 (2.4)
Chemotherapy day ward	5 (8.2)	1 (4.5)	6 (7.2)
Radiotherapy department	3 (4.9)	0	3 (3.6)
Other	0	2 (9.1)	2 (2.4)
Clinical stage when event occurred (%)			
Before formal diagnosis	14 (23.0)	12 (54.5)	26 (31.3)
During initial diagnostic investigations	9 (14.8)	1 (4.5)	10 (12.0)
Investigations after diagnosis	3 (4.9)	0	3 (3.6)
Neoadjuvant chemotherapy	2 (3.3)	0	2 (2.4)
Surgical management	5 (8.2)	0	5 (6.0)
Adjuvant chemotherapy	11 (18.0)	3 (13.6)	14 (16.9)
Adjuvant radiotherapy	12 (19.7)	1 (4.5)	13 (15.7)
Follow-up	3 (4.9)	3 (13.6)	6 (7.2)
After discharge from follow-up	1 (1.6)	2 (9.1)	3 (3.6)
Palliative chemotherapy	1 (1.6)	0	1 (1.2)

Causative, Contributory and Preventative Factors

Figure 9 illustrates the most commonly reported causative or contributory factors involved in events. Of the top five most frequently implicated, four are concerned with communication. Inadequate verbal communication with the patient was reported to have caused or contributed to nearly a third of events (n = 26/83, 31.3%) (Table 4). Organisational and management factors were commonly listed as causative or contributory with poor co-ordination of overall service, lack of essential infrastructure, poorly organised systems for record-keeping and poorly organised systems for appointments and follow-up ranking sixth to ninth respectively (Figure 9). Staff contending with a very high workload was frequently reported as a causative or contributory factor with it being implicated in 18.1% of events (n = 15/83) (Table 4).

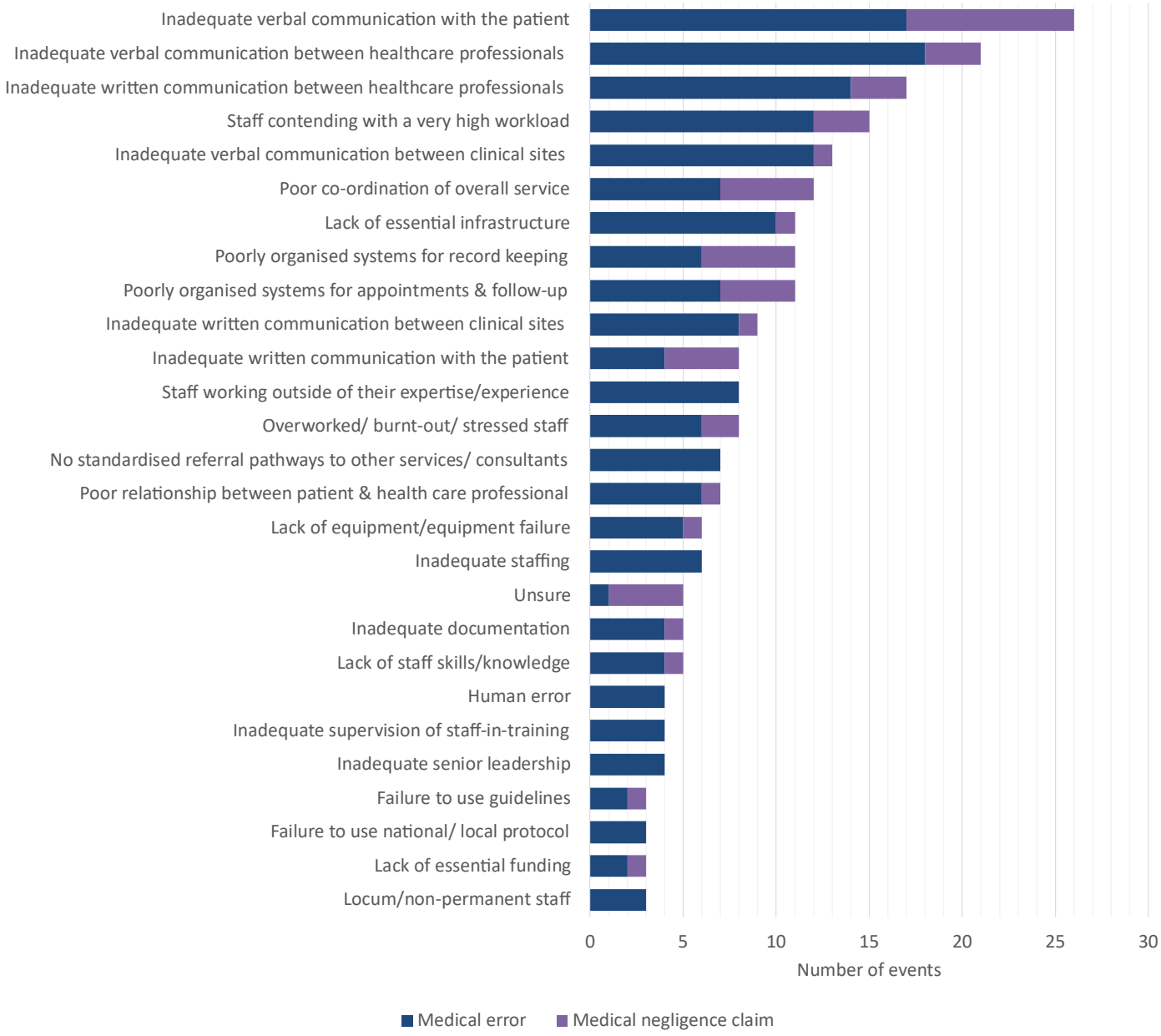


Figure 9: Causative/ contributory factors to patient safety incidents which occurred during breast cancer care

The most frequently reported factors that could have prevented the event from occurring are demonstrated in Figure 10. As may be expected, three factors concerned with improved communication are among the top four. Improved communication with the patient would have helped prevent the error in over one third of events (n = 32/83, 38.6%) (Table 4). Organisational and management factors such as better systems for record keeping, appointments and follow-up and increased infrastructure ranked third and sixth respectively (Figure 10). Staffing considerations such as increased recruitment of staff and more training for staff in specific departments or specialities were also among the top factors that could have helped to prevent the event from occurring (Figure 10).

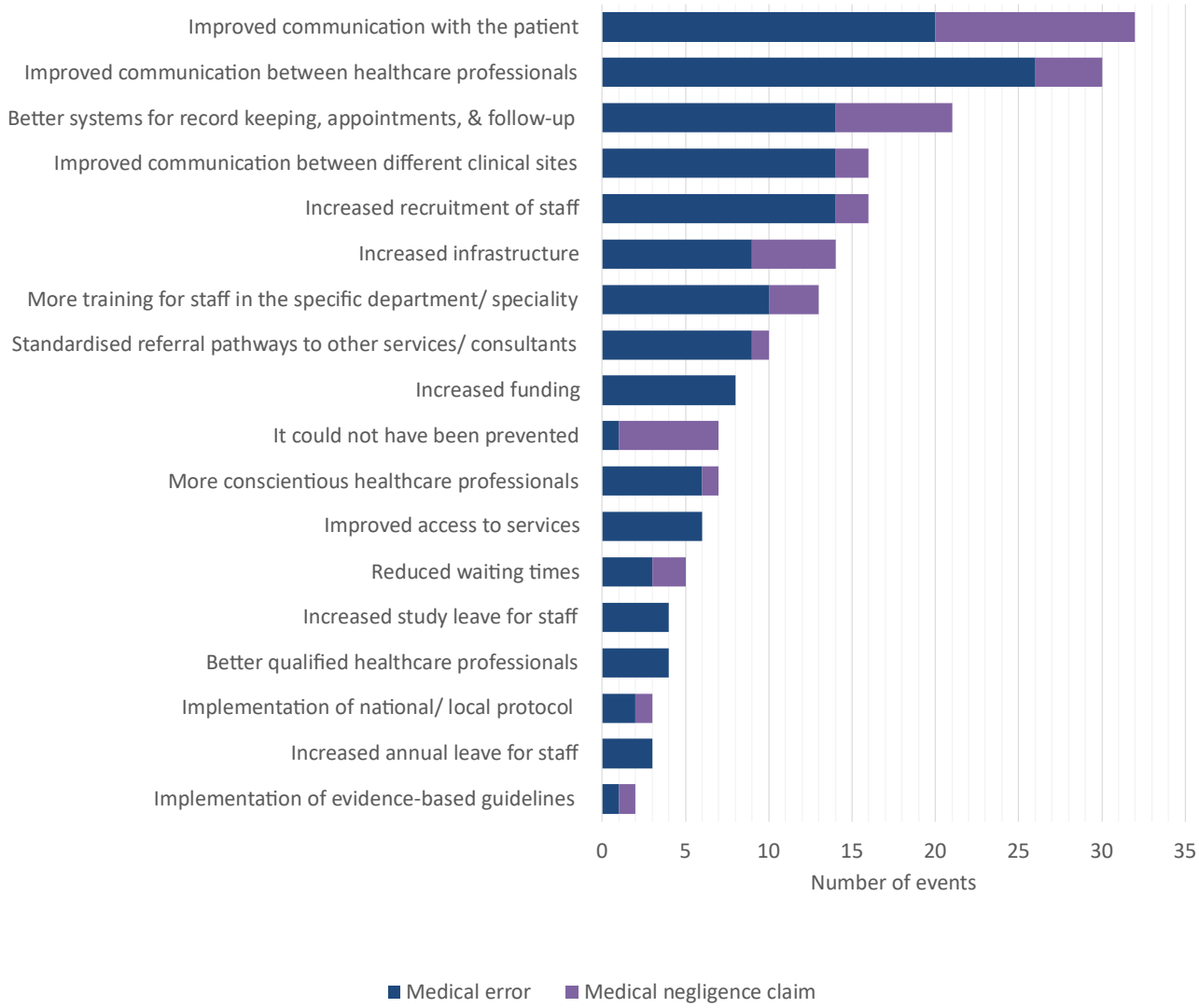


Figure 10: Preventative factors to patient safety incidents which occurred during breast cancer care

Consequences of Events

Table 5 details the consequences of all events. Additional medications were required in over a quarter of events (n = 23/83, 27.7%) and additional procedures in more than two in five events (n = 38/83, 45.8%). As classified by the International Classification for Patient Safety (ICPS), approximately one third of events resulted in mild harm and another third resulted in moderate harm (n = 30/83, 36.1% and n = 28/83, 33.7%). Severe harm and death combined accounted for 11 events representing 13.2% of all events.

Table 4: Causative/ contributory factors and preventative factors of patient safety incidents which occurred during breast cancer care

	Medical error	Medical negligence claim	Total
Number	61	22	83
Contributory/ causative factors (%)			
Staff contending with a very high workload	12 (19.7)	3 (13.6)	15 (18.1)
Overworked/ burnt-out/ stressed staff	6 (9.8)	2 (9.1)	8 (9.6)
Inadequate staffing	6 (9.8)	0	6 (7.2)
Lack of staff skills/knowledge	4 (6.6)	1 (4.5)	5 (6.0)
Staff working outside of their expertise/experience	8 (13.1)	0	8 (9.6)
Inadequate senior leadership	4 (6.6)	0	4 (4.8)
Inadequate supervision of staff-in-training	4 (6.6)	0	4 (4.8)
Locum/non-permanent staff	3 (4.9)	0	3 (3.6)
Poor relationship between patient & healthcare professional	6 (9.8)	1 (4.5)	7 (8.4)
Inadequate verbal communication between clinical sites	12 (19.7)	1 (4.5)	13 (15.7)
Inadequate written communication between clinical sites	8 (13.1)	1 (4.5)	9 (10.8)
Inadequate verbal communication between healthcare professionals	18 (29.5)	3 (13.6)	21 (25.3)
Inadequate written communication between healthcare professionals	14 (23.0)	3 (13.6)	17 (20.5)
Inadequate verbal communication with the patient	17 (27.9)	9 (40.9)	26 (31.3)
Inadequate written communication with the patient	4 (6.6)	4 (18.2)	8 (9.6)
No standardised referral pathways to other services/ consultants	7 (11.5)	0	7 (8.4)
Poor co-ordination of overall service	7 (11.5)	5 (22.7)	12 (14.5)
Poorly organised systems for appointments & follow-up	7 (11.5)	4 (18.2)	11 (13.3)
Inadequate documentation	4 (6.6)	1 (4.5)	5 (6.0)
Poorly organised systems for record keeping	6 (9.8)	5 (22.7)	11 (13.3)
Lack of essential funding	2 (3.3)	1 (4.5)	3 (3.6)
Lack of essential infrastructure	10 (16.4)	1 (4.5)	11 (13.3)
Lack of equipment/equipment failure	5 (8.2)	1 (4.5)	6 (7.2)
Human error	4 (6.6)	0	4 (4.8)
Unsure	1 (1.6)	4 (18.2)	5 (6.0)
Failure to use national/ local protocol	3 (4.9)	0	3 (3.6)
Failure to use guidelines	2 (3.3)	1 (4.5)	3 (3.6)
Remediating factors (%)			
Better qualified healthcare professionals	4 (6.6)	0	4 (4.8)
More conscientious healthcare professionals	6 (9.8)	1 (4.5)	7 (8.4)
Increased recruitment of staff	14 (23.0)	2 (9.1)	16 (19.3)
Increased annual leave for staff	3 (4.9)	0	3 (3.6)
Increased study leave for staff	4 (6.6)	0	4 (4.8)
More training for staff in the specific department/ speciality	10 (16.4)	3 (13.6)	13 (15.7)
Improved communication between different clinical sites	14 (23.0)	2 (9.1)	16 (19.3)
Improved communication between healthcare professionals	26 (42.6)	4 (18.2)	30 (36.1)
Improved communication with the patient	20 (32.8)	12 (54.5)	32 (38.6)
Standardised referral pathways to other services/ consultants	9 (14.8)	1 (4.5)	10 (12.0)
Better systems for record keeping, appointments, & follow-up	14 (23.0)	7 (31.8)	21 (25.3)
Reduced waiting times	3 (4.9)	2 (9.1)	5 (6.0)
Improved access to services	6 (9.8)	0	6 (7.2)
Increased funding	8 (13.1)	0	8 (9.6)
Increased infrastructure	9 (14.8)	5 (22.7)	14 (16.9)
It could not have been prevented	1 (1.6)	6 (27.3)	7 (8.4)
Implementation of national/ local protocol	2 (3.3)	1 (4.5)	3 (3.6)
Implementation of evidence-based guidelines	1 (1.6)	1 (4.5)	2 (2.4)

Table 5: Consequences of patient safety incidents which occurred during breast cancer care

	Medical error	Medical negligence claim	Total
Number	61	22	83
Additional procedures required (%)			
Yes	27 (44.3)	11 (50.0)	38 (45.8)
No	30 (49.2)	7 (31.8)	37 (44.6)
Not relevant	3 (4.9)	2 (9.1)	5 (6.0)
Unsure	1 (1.6)	2 (9.1)	3 (3.6)
Additional medications required (%)			
Yes	15 (24.6)	8 (36.4)	23 (27.7)
No	38 (62.3)	10 (45.5)	48 (57.8)
Not relevant	6 (9.8)	3 (13.6)	9 (10.8)
Unsure	2 (3.3)	1 (4.5)	3 (3.6)
Additional treatment required (%)			
Yes	18 (29.5)	11 (50.0)	29 (34.9)
No	33 (54.1)	7 (31.8)	40 (48.2)
Not relevant	7 (11.5)	1 (4.5)	8 (9.6)
Unsure	3 (4.9)	3 (13.6)	6 (7.2)
ICPS extent of harm (%)			
None	13 (21.3)	1 (4.5)	14 (16.9)
Mild	26 (42.6)	4 (18.2)	30 (36.1)
Moderate	19 (31.1)	9 (40.9)	28 (33.7)
Severe	1 (1.6)	4 (18.2)	5 (6.0)
Death	2 (3.3)	4 (18.2)	6 (7.2)

Abbreviations: ICPS = International Classification for Patient Safety

Impacts on the Respondent

As mentioned, 78 questionnaires identified events which involved medical errors and events which resulted in medical negligence claim. These were completed by 30 patients with breast cancer and by 48 doctors who provide breast cancer care. Table 6 outlines the impact of events on respondents. Patients had longer lasting effects on their physical health and finances compared to doctors. Conversely, more doctors reported a short-term effect on their emotional health due to their experience of a medical error than patients.

A larger proportion of patients who experienced a medical error reported that it had a permanent effect on their physical health compared to doctors (n = 8/26, 30.8% and n = 1/35, 2.9%) ($p < 0.001$). This was also the case for patients who had experienced a medical negligence claim compared to doctors who had (n = 3/4, 75.0% and n = 1/13, 7.7%) ($p < 0.001$). A higher proportion of doctors reported experiencing no effects due to their experience of a medical error compared to patients (n = 20/35, 57.1% and n = 5/26, 19.2%) ($p < 0.001$). The proportion of doctors who reported that their experience of a medical error had a short-term impact on their emotional health was higher compared to patients (n = 23/35, 65.7% and n = 8/26, 30.8%) ($p = 0.004$).

A greater percentage of patients reported that their experience of a medical error had a long-term effect on their finances when compared to doctors (n = 8/26, 30.8% and n = 0/35) ($p < 0.001$). The experience of a medical error had no effect on finances for a higher proportion of doctors than patients (n =34/35, 97.1% and n = 14/26, 53.8%) ($p < 0.001$). This was also the case for the finances of doctors who had experienced a medical negligence claim compared to patients (n = 13/13, 100% and n = 1/4, 25.0%) ($p < 0.001$).

One in four doctors' experiences have prompted them to consider early retirement (n = 12/48, 25.0%). One in six doctors would consider working abroad due to their experiences (n = 8/48, 16.7) and one in ten would consider changing careers (n = 5/48, 10.4%).

Table 6: Impact of patient safety incidents on the respondent

	Patient			Doctor			Total
	Medical error	*Medical negligence claim*	*Total*	*Medical error*	*Medical negligence claim*	*Total*	
Number	26	4	30	35	13	48	78
Physical health (%)							
Permanent effect	8 (30.8)	3 (75.0)	11 (36.6)	1 (2.9)	1 (7.7)	2 (4.2)	13 (16.7)
Long-term effect	7 (26.9)	0	7 (23.3)	2 (5.7)	0	2 (4.2)	9 (11.5)
Short-term effect	6 (23.1)	0	6 (20.0)	12 (34.3)	5 (38.5)	17 (35.4)	23 (29.5)
No effect	5 (19.2)	1 (25.0)	6 (20.0)	20 (57.1)	7 (53.8)	27 (56.3)	33 (42.3)
Emotional health (%)							
Permanent effect	7 (26.9)	3 (75.0)	10 (33.3)	2 (5.7)	2 (15.4)	4 (8.3)	14 (17.9)
Long-term effect	9 (34.6)	0	9 (30.0)	6 (17.1)	5 (38.5)	11 (22.9)	20 (25.6)
Short-term effect	8 (30.8)	0	8 (26.6)	23 (65.7)	4 (30.8)	27 (56.3)	35 (44.9)
No effect	2 (7.7)	1 (25.0)	3 (10)	4 (11.4)	2 (15.4)	6 (12.5)	9 (11.5)
Finances (%)							
Permanent effect	3 (11.5)	1 (25.0)	4 (13.3)	1 (2.9)	0	1 (2.1)	5 (6.4)
Long-term effect	8 (30.8)	1 (25.0)	9 (30.0)	0	0	0	9 (11.5)
Short-term effect	1 (3.8)	1 (25.0)	2 (6.6)	0	0	0	2 (2.6)
No effect	14 (53.8)	1 (25.0)	15 (50.0)	34 (97.1)	13 (100)	47 (97.9)	62 (79.5)

	Doctor		Total
	Medical error	Medical negligence claim	
Number	35	13	48
Experience prompted consideration of early retirement (%)			
Yes	6 (17.1)	6 (46.2)	12 (25.0)
No	27 (77.1)	6 (46.2)	33 (68.8)
Other	2 (5.7)	1 (7.7)	3 (6.3)
Experience prompted consideration of working abroad (%)			
Yes	6 (17.1)	2 (15.4)	8 (16.7)
No	29 (82.9)	11 (84.6)	40 (83.3)
Other	0	0	0
Experience prompted consideration of career change (%)			
Yes	3 (8.6)	2 (15.4)	5 (10.4)
No	32 (91.4)	11 (84.6)	43 (89.6)
Other	0	0	0

Outcome of Events

As evident in Table 7, the majority of all medical negligence claims were settled out of court (n = 14/22, 63.6%). Three of the four medical negligence claims described by patients are currently still ongoing. Of the 61 events involving a medical error, the majority were reported as shown in Table 8 (n = 38/61, 62.3%). Medical errors which were described in patients' surveys were reported in 11 cases out of 26 (42.3%). In comparison, the proportion of medical errors described in doctors' surveys that were reported was greater at 74.3% (n = 26/35) ($p < 0.001$). Medical errors described in doctors' surveys were reported by another healthcare professional in more cases than those in patients' surveys (n = 12/35, 34.3% and n = 1/26, 3.8%) ($p < 0.001$).

The majority of the medical errors described in patients' surveys were reported to the healthcare professional involved (n = 9/11, 81.8%). In comparison, medical errors which were described in doctors' surveys were most often reported to the management at the site involved (n = 19/26, 73.1%) followed by the National Incident Management System (n = 10/26, 38.5%). Improved communication between healthcare professionals was the most common outcome after reporting a medical error (n = 11/37, 29.7%). This was followed by both improved communication with the patient and nothing (n = 8/37, 21.6%) (Table 8).

Twenty-three medical errors went unreported (n = 23/61, 37.7%). The most commonly cited barriers to reporting were uncertainty about how to report (n = 13/23, 56.5%), uncertainty who to report them to (n = 10/23, 43.5%) and no established culture of reporting (n = 10/23, 43.5%). Patients reported the emotional burden as a barrier in four cases while no doctors did (Table 8).

Table 7: Outcome of medical negligence claim which occurred during breast cancer care

	Patient	Doctor	State Claims Agency	Total
Number	4	13	5	22
Outcome of claim (%)				
Withdrawn	0	1 (7.7)	1 (20.0)	2 (9.1)
Settled out of court	1 (25.0)	9 (69.2)	4 (80.0)	14 (63.6)
Proceeded to trial	0	0	0	0
Mediation	0	1 (7.7)	0	1 (4.5)
Claims' proceedings ongoing	3 (75.0)	2 (15.4)	0	5 (22.7)

Table 8: Reporting of patient safety incidents which occurred during breast cancer care

	Patient	Doctor	Total
Number	26	35	61
Reporting of event (%)			
No, the event was not reported	14 (53.8)	9 (25.7)	23 (37.7)
Yes, by the patient	7 (26.9)	2 (5.7)	9 (14.8)
Yes, by the healthcare professional involved	3 (11.5)	12 (34.3)	15 (24.6)
Yes, by another healthcare professional	1 (3.8)	12 (34.3)	13 (21.3)
Unsure	1 (3.8)	0	1 (1.6)
	Patient	Doctor	Total
Number	11	26	37
Who the event was reported to (%)			
Management at the site involved	4 (36.4)	19 (73.1)	23 (62.2)
Healthcare professional directly involved	9 (81.8)	0	9 (24.3)
Lawyer	0	1 (3.8)	1 (2.7)
Another healthcare professional	1 (9.1)	7 (26.9)	8 (21.6)
Medical Protection Society/ Medical Defence Organisation	0	1 (3.8)	1 (2.7)
Serious Adverse Events report	0	1 (3.8)	1 (2.7)
Radioprotection	0	1 (3.8)	1 (2.7)
National incident management system (NIMS)	0	10 (38.5)	10 (27.0)
Outcome of reporting (%)			
Improved communication with the patient	4 (36.4)	4 (15.4)	8 (21.6)
Improved communication between healthcare professionals	2 (18.2)	9 (34.6)	11 (29.7)
Improved communication between different clinical sites	1 (9.1)	3 (11.5)	4 (10.8)
Better organised systems for record keeping, appointments, and follow-up	0	2 (7.7)	2 (5.4)
Implementation of standardised referral pathways to other services or consultants	0	1 (3.8)	1 (2.7)
Increased recruitment of staff	0	1 (3.8)	1 (2.7)
More training for staff in the specific department/speciality	1 (9.1)	4 (15.4)	5 (13.5)
Nothing	3 (27.3)	5 (19.2)	8 (21.6)
Unsure	3 (27.3)	2 (7.7)	5 (13.5)
Root Cause Analysis process	0	1 (3.8)	1 (2.7)
Changes to medication prescribing/ administration/ monitoring	0	2 (7.7)	2 (5.4)
Implementation of evidence-based guidelines	0	1 (3.8)	1 (2.7)
Implementation of a national and/or local protocol	0	4 (15.4)	4 (10.8)
	Patient	Doctor	Total
Number	14	9	23
Barriers to reporting (%)			
Unsure of how to report your concerns	8 (57.1)	5 (55.6)	13 (56.5)
Unsure of who to report your concerns to	8 (57.1)	2 (22.2)	10 (43.5)
Worried it will impact on the care patient receives	4 (28.6)	0	4 (17.4)
Worried it will change the healthcare professional's opinion of the patient	2 (14.3)	0	2 (8.7)
No opportunity for the patient to choose an alternative healthcare professional	2 (14.3)	0	2 (8.7)
Worried it will impact on the doctor's current job/career	0	2 (22.2)	2 (8.7)
Worried it will change the doctors' colleagues' opinion of them	0	1 (11.1)	1 (4.3)
No established culture of reporting	4 (28.6)	6 (66.7)	10 (43.5)
Lack of confidence in the difference it would make	3 (21.4)	5 (55.6)	8 (34.8)
Emotional burden	4 (28.6)	0	4 (17.4)

Patient Safety Trajectories

The median degree of harm, as defined by the International Classification for Patient Safety (ICPS), for events which occurred during different clinical stages is outlined in Table 9. These are illustrated in Figure 11. There is a peak at chemotherapy before surgery, a trough around surgical management and adjuvant therapy followed by a peak thereafter. The clinical stages with the highest median degree of harm were neoadjuvant chemotherapy (median: 4, Q1 – Q3: 3.5 – 4.5) and after discharge from follow-up (median: 4, Q1 – Q3: 4.0 – 4.5). Follow-up rated second with a median degree of harm of 3.5 (Q1 – Q3: 2.25 – 2.75).

Table 10 contains the median degree of harm for events which occurred at different healthcare settings. Four settings had the same median degree of harm of 3: general practice (Q1 – Q3: 2.5 – 3), radiology department (Q1 – Q3: 3 – 3.5), emergency department (Q1 – Q3: 2 – 3.5) and chemotherapy day ward (Q1 – Q3: 2.25 – 4.5). 'Other' refers to two specific claims which did not occur in a healthcare setting. Figure 12 illustrates the patient safety trajectory for breast cancer patients at various healthcare settings.

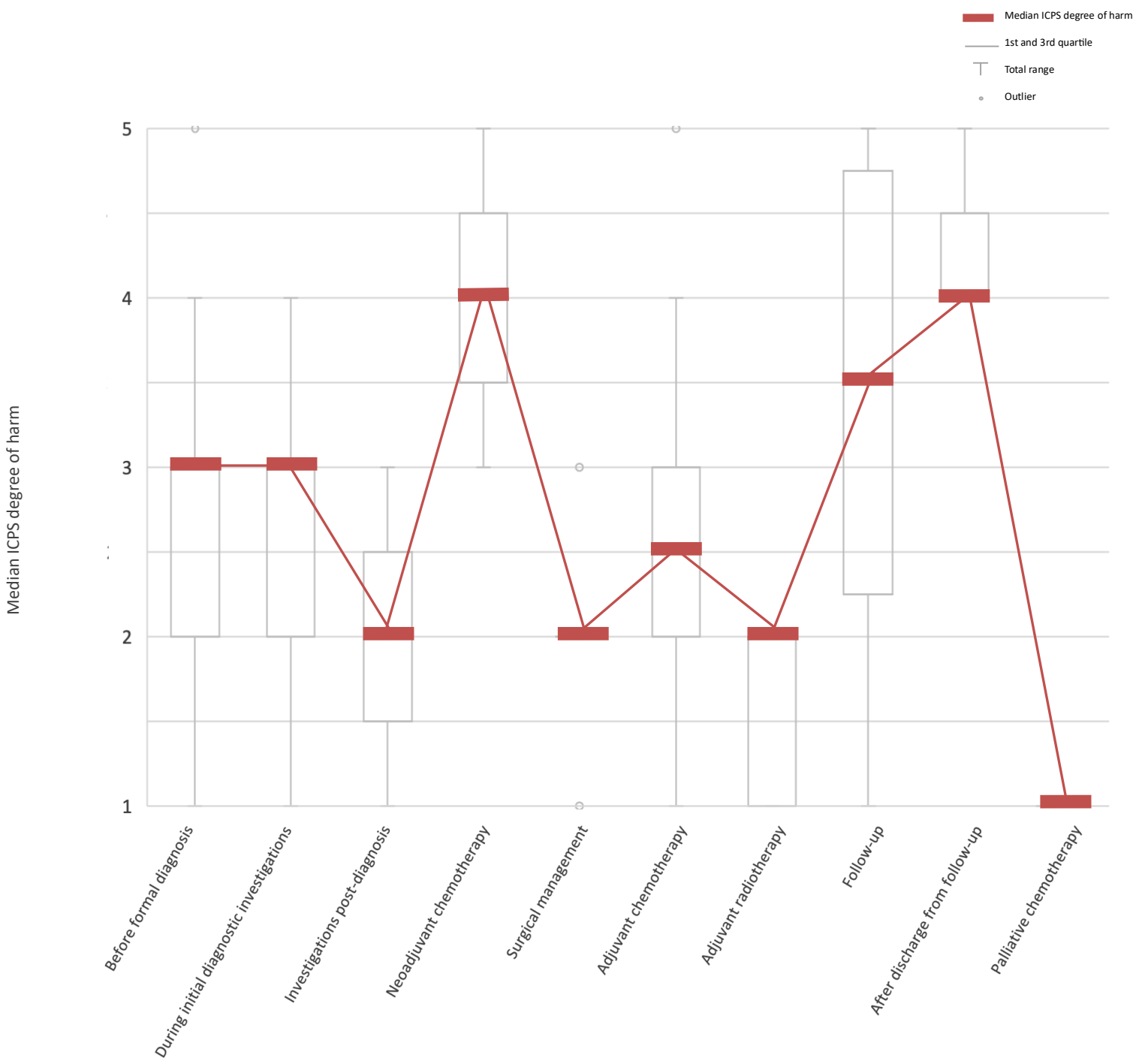


Figure 11: Patient safety trajectory one: median degree of harm of patient safety incidents at clinical stages

Table 9: Median degree of harm of patient safety incidents at clinical stages

	Total	Median ICPS degree of harm	Q1 – Q3	Range
Before formal diagnosis	26	3	2 – 3	1 – 5
During initial diagnostic investigations	10	3	2 – 3	1 – 4
Investigations after diagnosis	3	2	1.5 – 2.5	1 – 3
Neoadjuvant chemotherapy	2	4	3.5 – 4.5	3 – 5
Surgical management	5	2	2 – 2	1 – 3
Adjuvant chemotherapy	14	2.5	2 – 3	1 – 5
Adjuvant radiotherapy	13	2	1 – 2	1 – 2
Follow-up	6	3.5	2.25 – 2.75	1 – 5
After discharge from follow-up	3	4	4 - 4.5	4 – 5
Palliative chemotherapy	1	1	1 – 1	1 – 1

Abbreviations: Q1 – Q3 = first quartile and third quartile values

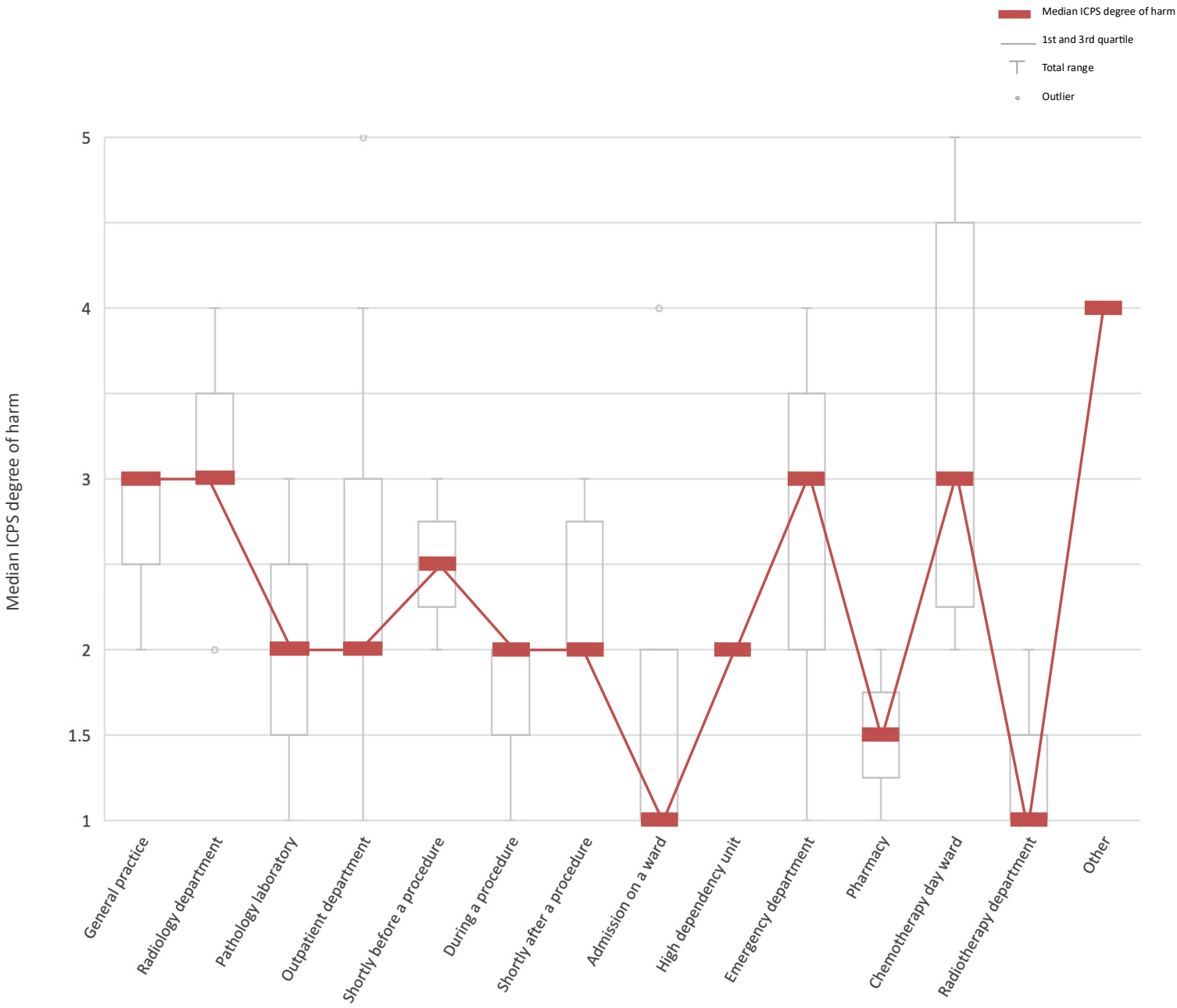


Figure 12: Patient safety trajectory two: median degree of harm of patient safety incidents at healthcare settings

Table 10: Median degree of harm of patient safety incidents at healthcare settings

	Total	Median ICPS degree of harm	Q1 – Q3	Range
General practice	7	3	2.5 – 3	2 – 3
Radiology department	7	3	3 – 3.5	2 – 4
Pathology laboratory	3	2	1.5 – 2.5	1 – 3
Outpatient department	33	2	2 – 3	1 – 5
Shortly before a procedure	2	2.5	2.25 – 2.75	2 – 3
During a procedure	3	2	1.5 – 2	1 – 2
Shortly after a procedural	6	2	2 – 2.75	2 – 3
Admission on a ward	5	1	1 – 2	1 – 4
High dependency unit	1	2	2 – 2	2 – 2
Emergency department	3	3	2 – 3.5	1 – 4
Pharmacy	2	1.5	1.25 – 1.75	1 – 2
Chemotherapy day ward	6	3	2.25 – 4.5	2 – 5
Radiotherapy department	3	1	1 – 1.5	1 – 2
Other	2	4	4 – 4	4 – 4

Abbreviations: Q1 – Q3 = first quartile and third quartile values

Study Two

184 patients with breast cancer and 116 doctors responded to part one of study two. Part one explores their opinions of varying aspects of breast cancer care as well as their thoughts on the patient safety environment and the likelihood of experiencing or causing a medical error. Of those respondents, 154 patients and 44 doctors progressed to part two of this study as they had not been involved in a patient safety incident. In this section, respondents rated their concerns around different adverse events, clinical stages and healthcare settings. In addition, respondents' views on factors that could contribute to or remediate against medical error were explored. Descriptive and inferential analysis was conducted on all valid responses received for each of the two parts.

Part One: Views on Aspects of Care, Patient Safety and Medical Error Prevention

Table 11 and Table 12 show the demographics of patients and doctors respectively. The female to male ratio was 45:1 for patients and 1.7:1 for doctors. More than a third of patients (n = 66/184, 35.9%) were over the age of sixty, while the age group which accounted for the highest proportion of doctors was 45 to 49 years old (n = 25/116, 21.6%). A total of 64.1% (n = 116/184) of patients were first diagnosed with breast cancer within the past four years and 66.4% (n = 77/116) of doctors had over ten years' experience working with breast cancer patients. A higher percentage of patients reported having private insurance (n = 103/184, 56.0%) than doctors reported working in private practice (n = 53/116, 45.7%).

Consultants accounted for over three quarters of respondents (n = 92/116, 79.3%). The most common field of medicine was medical oncology (n = 34/116, 29.3%) followed by radiation oncology (n = 28/116, 24.1%) and radiology (n = 25/116, 21.6%). Patients came from varied rural and urban settings. A quarter of patients were unsure of their breast cancer type (n = 46/184, 25.0%). Invasive ductal carcinoma was the most common breast cancer type (n = 39/184, 21.2%).

Table 11: Demographics of patients in part one of study two

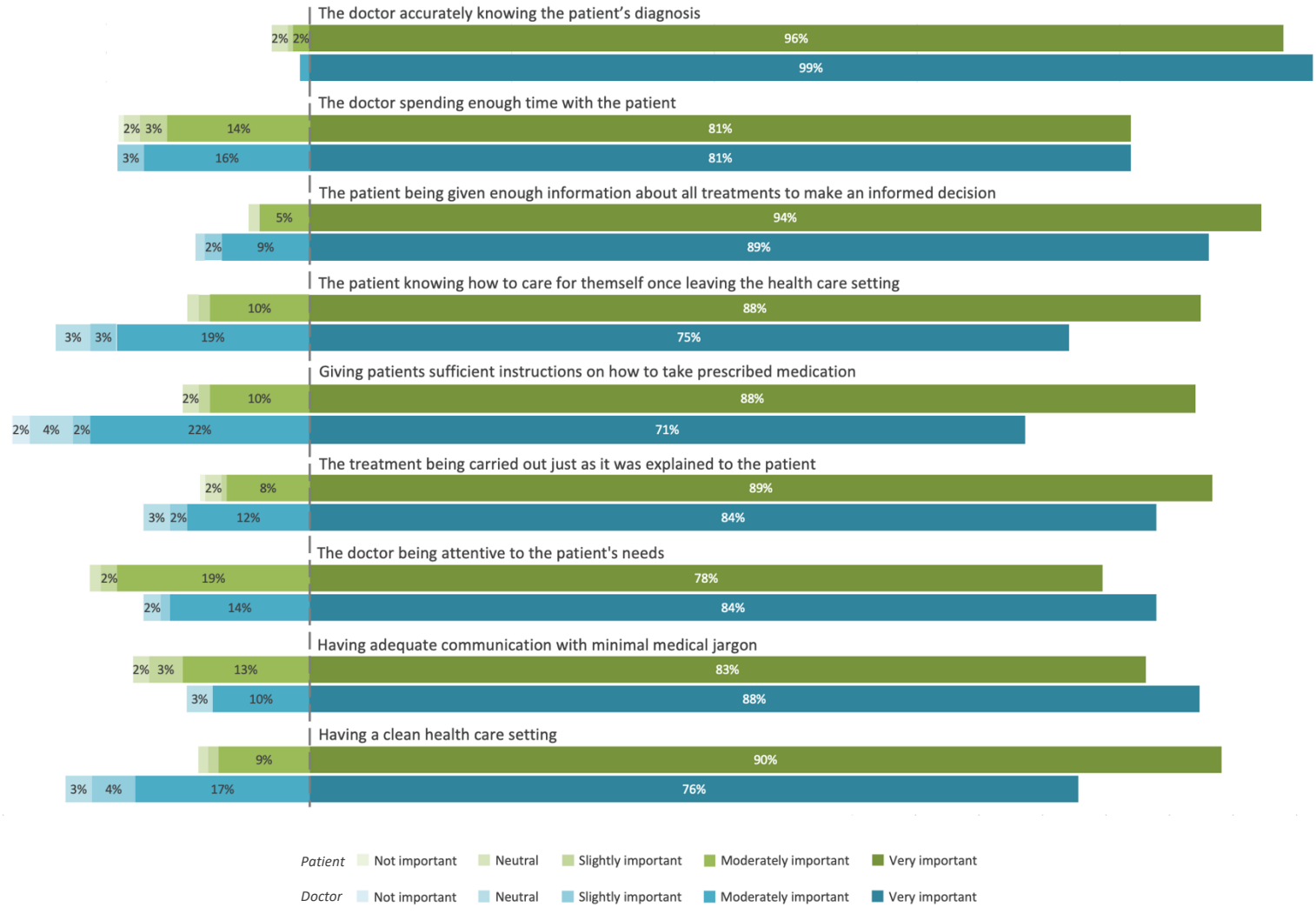
Number	184
Gender (%)	
Female	180 (97.8)
Male	4 (2.2)
Age groups (%)	
18-34	5 (2.7)
35-39	10 (5.4)
40-44	22 (12.0)
45-49	19 (10.3)
50-54	25 (13.6)
55-59	37 (20.1)
60+	66 (35.9)
Patient or family member work in healthcare (%)	
Yes	42 (22.8)
No	142 (77.1)
Residence (%)	
Rural area	60 (32.6)
Small town	53 (28.8)
Suburb	38 (20.7)
City	31 (16.8)
Other	2 (1.1)
Currently have private health insurance (%)	
Yes	103 (56.0)
No	78 (42.2)
Other	3 (1.6)
First diagnosed with breast cancer (%)	
< 1 year	36 (19.6)
1-2 years	31 (16.8)
3-4 years	51 (27.7)
5-6 years	17 (9.2)
7-8 years	8 (4.3)
9-10 years	7 (3.8)
> 10 years	33 (17.9)
Unsure	1 (0.5)
Breast cancer type (%)	
Hormone sensitive invasive ductal carcinoma	39 (21.2)
Ductal carcinoma in-situ	11 (6.0)
HER2 positive carcinoma	29 (15.8)
Triple negative carcinoma	16 (8.7)
Invasive lobular carcinoma	7 (3.8)
Metastatic carcinoma	29 (15.8)
Unsure	46 (25.0)
Other	7 (3.8)

Table 12: Demographics of doctors in part one of study two

Number	116
Gender (%)	
Female	72 (62.1)
Male	42 (36.2)
Prefer not to say	2 (1.7)
Age groups (%)	
25-34	20 (17.3)
35-39	9 (7.8)
40-44	23 (19.8)
45-49	25 (21.6)
50-54	15 (12.9)
55-59	10 (8.6)
60+	14 (12.1)
Job title (%)	
Consultant	92 (79.3)
Senior/ specialist registrar	21 (18.1)
Junior registrar	3 (2.6)
Field of medicine	
Medical oncology	34 (29.3)
Radiation oncology	28 (24.1)
Radiology	25 (21.6)
Surgery	20 (17.2)
Palliative medicine	5 (4.3)
Pathology	4 (3.4)
Experience with breast cancer patients (%)	
< 1 year	4 (3.4)
1-2 years	6 (5.2)
3-5 years	10 (8.6)
5-10 years	19 (16.4)
10-20 years	42 (36.2)
> 20 years	35 (30.2)
Practice in a private capacity (%)	
Yes	53 (45.7)
No	63 (54.3)

Figure 13 and Table 13 illustrate the importance of different aspects of breast cancer care to patients and doctors based on a five point Likert scale ranging from not important to very important. Patients and doctors were in agreement with what were the most important aspects of care however their opinions differed on two variables. Those that were ranked as very important by a higher proportion of patients than by doctors were ‘the patient knowing how to care for themself once leaving the healthcare setting’ and ‘giving patients sufficient instructions on how to take prescribed medication’ ($p = 0.021$ and $p = 0.002$).

Almost all doctors felt knowing the patient's diagnosis accurately was very important (n= 115/116, 99.1%). Patients were in agreement as this was also rated as very important by the greatest proportion of patients (n = 177/184, 96.2%). Furthermore, the patient being given enough information about all treatments to make an informed decision was rated as very important by the second highest proportion of both patients and doctors (n = 173/184, 94.0% and n = 103/116, 88.8% respectively). Adequate communication with minimal jargon was rated as very important by the third highest proportion of doctors (n = 102/116, 87.2%) while it was having a clean healthcare setting for patients (n = 165/184, 89.7%).



* Numbers may not equal 100 due to rounding

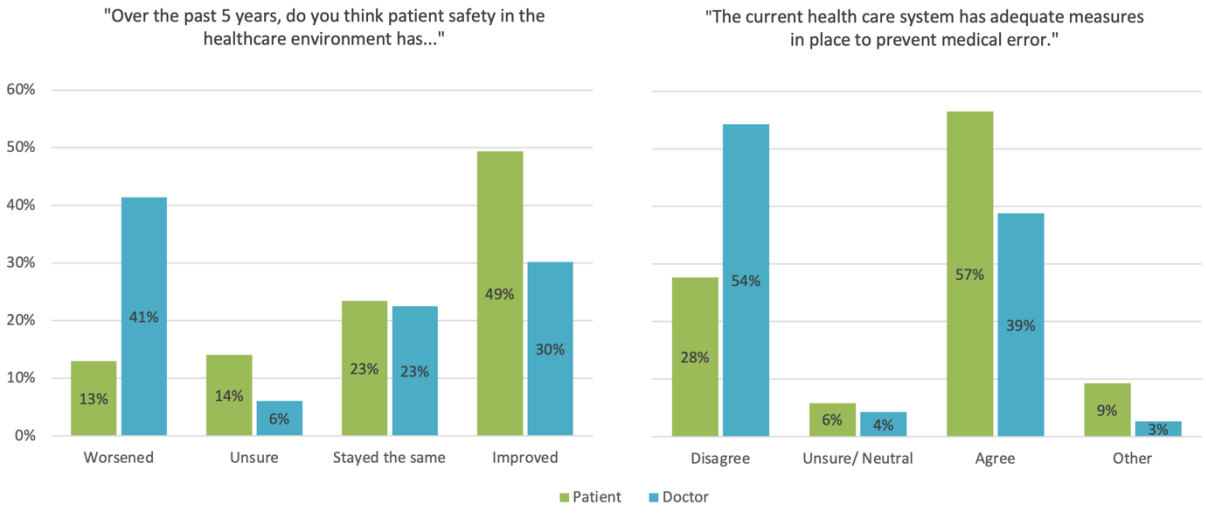
Figure 13: Patients' and doctors' views on the importance of aspects of breast cancer care

Table 13: Patients' and doctors' views on the importance of aspects of breast cancer care

		Total	Not important (%)	Neutral (%)	Slightly important (%)	Moderately important (%)	Very important (%)	P-value
The doctor accurately knowing the patient's diagnosis	*Patient*	184	0	3 (1.6)	1 (0.5)	3 (1.6)	177 (96.2)	0.576
	Doctor	116	0	0	0	1 (0.9)	115 (99.1)	
The doctor spending enough time with the patient	*Patient*	184	1 (0.5)	3 (1.6)	5 (2.7)	26 (14.1)	149 (81.0)	0.356
	Doctor	116	0	3 (2.6)	0	19 (16.4)	94 (81.0)	
The patient being given enough information about all treatments to make an informed decision	*Patient*	184	0	2 (1.1)	0	9 (4.9)	173 (94.0)	0.168
	Doctor	116	0	1 (0.9)	2 (1.7)	10 (8.6)	103 (88.8)	
The patient knowing how to care for themself once leaving the healthcare setting	*Patient*	184	0	2 (1.1)	2 (1.1)	18 (9.8) $_a$	162 (88) $_a$	0.021
	Doctor	116	0	4 (3.4)	3 (2.6)	22 (19.0) $_b$	87 (75) $_b$	
Giving patients sufficient instructions on how to take prescribed medication	*Patient*	184	0	3 (1.6)	2 (1.1)	18 (9.8) $_a$	161 (87.5) $_a$	0.002
	Doctor	116	2 (1.7)	5 (4.3)	2 (1.7)	25 (21.6) $_b$	82 (70.7) $_b$	
The treatment being carried out just as it was explained to the patient	*Patient*	184	1 (0.5)	3 (1.6)	1 (0.5)	15 (8.2)	164 (89.1)	0.472
	Doctor	116	0	3 (2.6)	2 (1.7)	14 (12.1)	97 (83.6)	
The doctor being attentive to in the patient's needs	*Patient*	184	0	2 (1.1)	3 (1.6)	35 (19)	144 (78.3)	0.637
	Doctor	116	0	2 (1.7)	1 (0.9)	16 (13.8)	97 (83.6)	
Having adequate communication with minimal medical jargon	*Patient*	184	0	3 (1.6)	6 (3.3)	23 (12.5)	152 (82.6)	0.179
	Doctor	116	0	3 (2.6)	0	11 (9.5)	102 (87.9)	
Having a clean healthcare setting	*Patient*	184	0	2 (1.1)	1 (0.5)	16 (8.7) $_a$	165 (89.7) $_a$	0.005
	Doctor	116	0	3 (2.6)	5 (4.3)	20 (17.2) $_b$	88 (75.9) $_b$	

Each subscript letter denotes a subset of the variable whose row proportions differ significantly from each other at the .05 level.

Overall, doctors have an unfavourable view on the current status of patient safety compared to patients (Figure 14, Table 14). Three times as many doctors (n = 48/116, 41.4%) feel patient safety has worsened in the past five years compared to patients (n = 24/184, 13.0%) ($p < 0.001$). Twice as many doctors (n = 63/116, 54.3%) felt there were inadequate measures in place to prevent medical error compared to patients (n = 51/184, 27.2%) ($p < 0.001$).



* Numbers may not equal 100 due to rounding

Figure 14: Patients' and doctors' views on patient safety and medical error prevention

Table 14: Patients' and doctors' views on patient safety and medical error prevention

		Total	Worsened (%)	Unsure (%)	Stayed the same (%)	Improved (%)	P-value
Over the past 5 years, do you think patient safety in the healthcare environment has:	*Patient*	184	24 (13.0) $_a$	26 (14.1)	43 (23.4)	91 (49.4) $_a$	< 0.001
	Doctor	116	48 (41.4) $_b$	7 (6.1)	26 (22.5)	35 (30.2) $_b$	
			Disagree (%)	Unsure/ Neutral (%)	Agree (%)	Other (%)	
'The current healthcare system has adequate measures in place to prevent medical error.' Do you agree or disagree?	*Patient*	184	51 (27.2) $_a$	11 (5.8)	104 (56.5) $_a$	18 (9.3)	<0.001
	Doctor	116	63 (54.3) $_b$	5 (4.3)	45 (38.8) $_b$	3 (2.7)	

Each subscript letter denotes a subset of the variable whose row proportions differ significantly from each other at the .05 level.

Four patients included narrative comments for the first question as seen in Table 15. All focused on the impact COVID-19 has had on patient safety in the healthcare environment however two argued that the pandemic had improved patient safety while two supported the opposite argument.

Table 15: Patients' views on patient safety in the healthcare environment

Comment (C)	Theme	Quotation
C1	COVID-19	From my own experience as I am already in 'the system', it has improved with COVID-19 restrictions making healthcare workers and patients more health and safety conscious.
C2	COVID-19	Improved - cleanliness I expect has improved with COVID-19.
C3	COVID-19	Worsened - due to COVID.
C4	COVID-19	Worsened - due to doctors not being able to see patients due to COVID.

Table 16: Doctors' views on medical error prevention

Comment (C)	Theme	Quotation
C1	System factors	Practitioner absorbs system deficiencies that can lead to error.
C2	System factors	With high volume of patients seen, a degree of error is inevitable. System measures may reduce the severity of the error, but are unlikely to eliminate error.
C3	Remediating factors	MDM discussion is helpful. Lack of time and workload are concerns. More double reading may be useful.

Abbreviations: MDM – multidisciplinary meeting

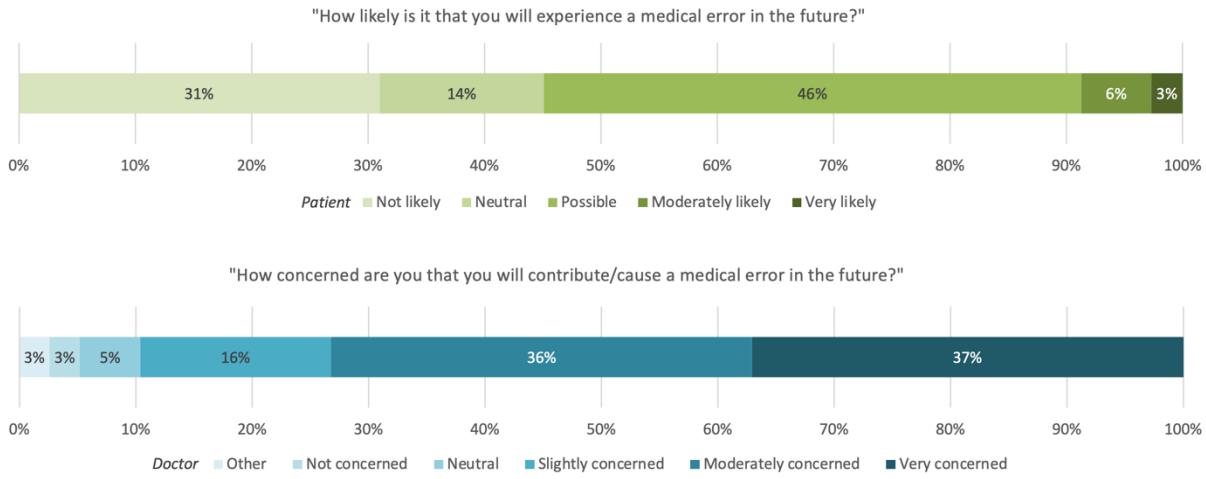
Narrative comments were left by three doctors in relation to the second question as evident in Table 16. A focus on system factors were evident in all three. One also commented on the inevitability of error and another proposed remediating factors.

Sixteen patients provided narrative comments in response to the second question which were grouped into the following themes: COVID-19, staffing, inevitability, system factors, compliance, differing areas of medicine and patient unawareness. These are seen in Table 17.

Table 17: Patients' views on medical error prevention

Comment (C)	Theme	Quotation
C1	COVID-19	COVID might have undermined it.
C2	Staffing	Agree - but staff shortages challenge these.
C3	Staffing	Understaffed = potential medical error.
C4	Inevitability	Human error happens.
C5	Inevitability	There is always a % of medical error.
C6	Inevitability	Mistakes are possible but should not happen
C7	Inevitability	Measures are there but error can always happen
C8	Inevitability	In most areas but people do make mistakes and doctors can only do their best
C9	System factors	Disagree - I believe the healthcare system is under pressure and needs more resources to alleviate potential issues and put in place better designated areas, resources and information outlets
C10	Compliance	Measures in place must be followed
C11	Compliance	If systems followed agree but often systems/ current protocols not followed so medical errors can occur example prescription legible for all
C12	Different areas of healthcare	Certain field - emergency care/ ED need more attention
C13	Different areas of healthcare	In breast cancer and bone, medical error is not a problem, same cannot be said in other areas of the system
C14	Unawareness	As a patient we do not have knowledge of what measures are in place
C15	Unawareness	Difficult to know
C16	Unawareness	Impossible for me to say

While those questions reveal opinions on the past and present, Figure 15 and Table 18 show there are similar sentiments for the future. The minority of patients (n = 13/184, 8.7%) feel it is moderately to very likely they will experience a medical error in the future with a further 46.2% (n = 85/184) reporting it is possible. In contrast, almost three quarters of doctors (n = 85/116, 73.3%) are moderately to very concerned that they will contribute to or cause a medical error in the future with a further 16.4% (n = 19/116) reporting slight concern.



* Numbers may not equal 100 due to rounding

Figure 15: Patients' and doctors' views on future medical error

Table 18: Patients' and doctor's views on future medical error

		Total	Not likely (%)	Neutral (%)	Possible (%)	Moderately likely (%)	Very likely (%)
How likely is it that you will experience a medical error in the future?	*Patient*	184	57 (31)	26 (14.1)	85 (46.2)	11 (6.0)	2 (2.7)

			Other (%)	Not concerned (%)	Neutral (%)	Slightly concerned (%)	Moderately concerned (%)	Very concerned (%)
How concerned are you that you will contribute/cause a medical error in the future?	*Doctor*	116	3 (2.6)	3 (2.6)	6 (5.2)	19 (16.4)	42 (36.2)	43 (37.1)

Three doctors provided narrative comments with regard to causing or contributing a medical error in future as outlined in Table 19. All focused on the inevitability of error, a theme which was also common in narrative comments from the previous question.

Table 19: Doctors' views on future medical error

Comment (C)	Theme	Quotation
C1	Inevitability	Certain; intrinsic to all human processes
C2	Inevitability	I know for a fact that a mistake will happen. Otherwise is statistically impossible
C3	Inevitability	With high volume of patients seen, a degree of error is inevitable

Part Two: Patient Safety and Medical Error Concerns

The second part of study two assessed concern levels about different adverse events, clinical stages and healthcare settings as well as views on contributing and remediating factors of medical error. Respondents to this section of the study constituted 154 patients and 44 doctors who had not experienced a patient safety incident during breast cancer care.

Table 20: Demographics of patients in part two of study two

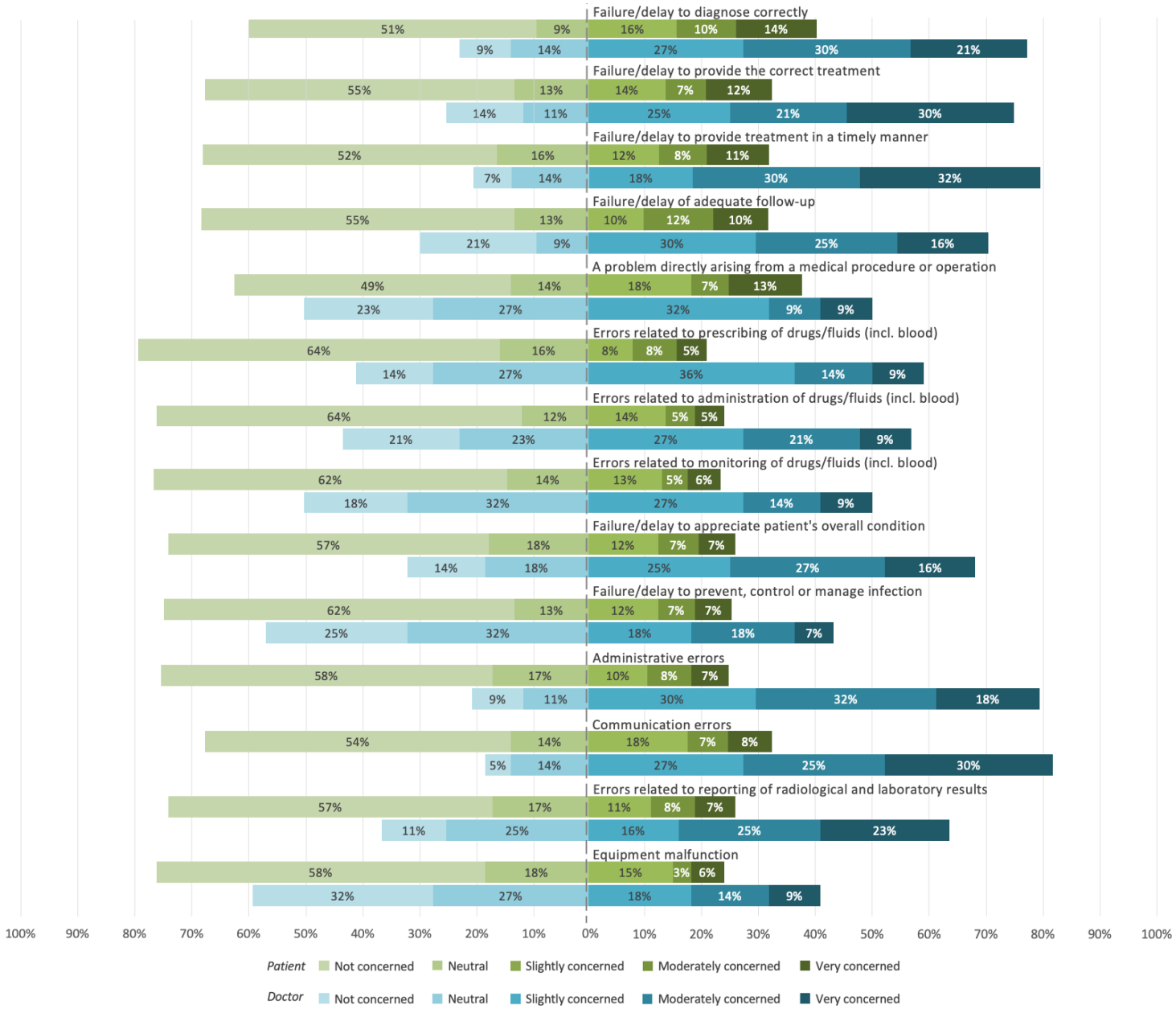
Number	154
Gender (%)	
Female	150 (97.4)
Male	4 (2.6)
Age groups (%)	
18-34	2 (1.2)
35-39	8 (5.2)
40-44	18 (11.7)
45-49	16 (10.4)
50-54	24 (15.6)
55-59	31 (20.1)
60+	55 (35.7)
Patient or family member work in healthcare (%)	
Yes	32 (20.8)
No	122 (79.2)
Residence (%)	
Rural area	52 (33.8)
Small town	41 (26.6)
Suburb	31 (20.1)
City	28 (18.2)
Other	2 (1.3)
Currently have private health insurance (%)	
Yes	86 (55.8)
No	65 (42.2)
Other	3 (1.6)
First diagnosed with breast cancer (%)	
< 1 year	31 (20.1)
1-2 years	26 (16.9)
3-4 years	45 (29.2)
5-6 years	14 (9.1)
7-8 years	6 (3.9)
9-10 years	6 (3.9)
> 10 years	25 (16.2)
Unsure	1 (0.6)
Breast cancer type (%)	
Hormone sensitive invasive ductal carcinoma	35 (22.7)
Ductal carcinoma in-situ	10 (6.5)
HER2 positive carcinoma	27 (17.5)
Triple negative carcinoma	10 (6.5)
Invasive lobular carcinoma	6 (3.9)
Metastatic carcinoma	22 (14.3)
Unsure	39 (25.3)
Other	5 (3.1)

Table 21: Demographics of doctors in part two of study two

Number	44
Gender (%)	
Female	31 (70.5)
Male	12 (27.3)
Prefer not to say	1 (2.3)
Age groups (%)	
25-34	10 (22.7)
35-39	5 (11.4)
40-44	9 (20.5)
45-49	8 (18.2)
50-54	4 (9.1)
55-59	6 (13.6)
60+	2 (4.5)
Job title (%)	
Consultant	31 (70.5)
Senior/ specialist registrar	12 (27.3)
Junior registrar	1 (2.3)
Field of medicine	
Medical oncology	14 (31.8)
Radiation oncology	11 (25.0)
Radiology	7 (15.9)
Surgery	8 (18.2)
Palliative medicine	4 (9.1)
Pathology	0 (0)
Experience with breast cancer patients (%)	
< 1 year	3 (6.8)
1-2 years	1 (2.3)
3-5 years	7 (15.9)
5-10 years	7 (15.9)
10-20 years	15 (34.1)
> 20 years	11 (25.0)
Practice in a private capacity (%)	
Yes	18 (40.9)
No	26 (59.1)

The patients' demographics outlined in Table 20 are similar to those described in part one of this study (Table 11). Doctors' demographics in this part of the study are evident in Table 21. They differ from those in part one of this study (Table 12) in that the female to male ratio was higher in this part of the study at 2.6:1 compared to 1.7:1. The doctors who responded to part two of the study are slightly younger than those in part one. The proportion of doctors aged 60 and over in this part was lower than that of part one (n = 2/44, 4.5% compared to n =

14/116, 12.1%). The two most common fields of medicine were unchanged. The third and fourth in this section were surgery (n = 8/44, 18.2%) and radiology (n = 7/44, 15.9%) which is the inverse from the first part of this study. Those with over ten years' experience working with breast cancer patients accounted for 59.1% (n = 26/44) of respondents.



* Numbers may not equal 100 due to rounding

Figure 16: Patients' and doctors' levels of concern for adverse events

All respondents rated their level of concern on a Likert scale which ranged from not concerned, neutral, slightly concerned, moderately concerned and very concerned. Patients were asked to respond in the context of their breast cancer journey while doctors were instructed to respond in the context of when they provide breast cancer care to patients. Figure 16 and Table 22 outline the varying levels of concerns reported by patients and doctors about different adverse events occurring.

Doctors reported higher levels of concern for every adverse event compared to patients (Table 22). 'Communication errors' ranked the highest for doctors with 81.8% (n = 36/44) reporting some level of concern compared to 32.4% of patients (n = 50/154). Almost a third of doctors (n = 13/44, 29.5%) were very concerned that communication errors could occur while providing breast cancer care compared to less than a twelfth of patients (n = 12/154, 7.8%) ($p < 0.001$).

'Administrative errors' and 'failure or delay to provide treatment in a timely manner' were both ranked second by doctors with 79.5% (n = 35/44) of doctors reporting any level of concern compared to 24.7% (n = 38/154) and 31.7% (n = 49/154) of patients respectively. Half of doctors (n = 22/44, 50.0%) were moderately to very concerned about the occurrence of administrative errors which is over three times the proportion of patients reporting the same level of concern (n = 22/ 154, 14.3%) ($p < 0.001$). 'Failure or delay to provide treatment in a timely manner' had the highest percentage of doctors ranking it as very concerning (n = 14/44, 31.8%).

'Equipment malfunction' followed by 'failure or delay to prevent, control or manage infection' had the least concern with 31.8% (n = 14/44) and 25% (n = 11/44) of doctors reporting no concern respectively. Both patients and doctors had higher levels of concerns for adverse events that related to diagnosis, timely and correct treatment compared to errors related to medications or equipment.

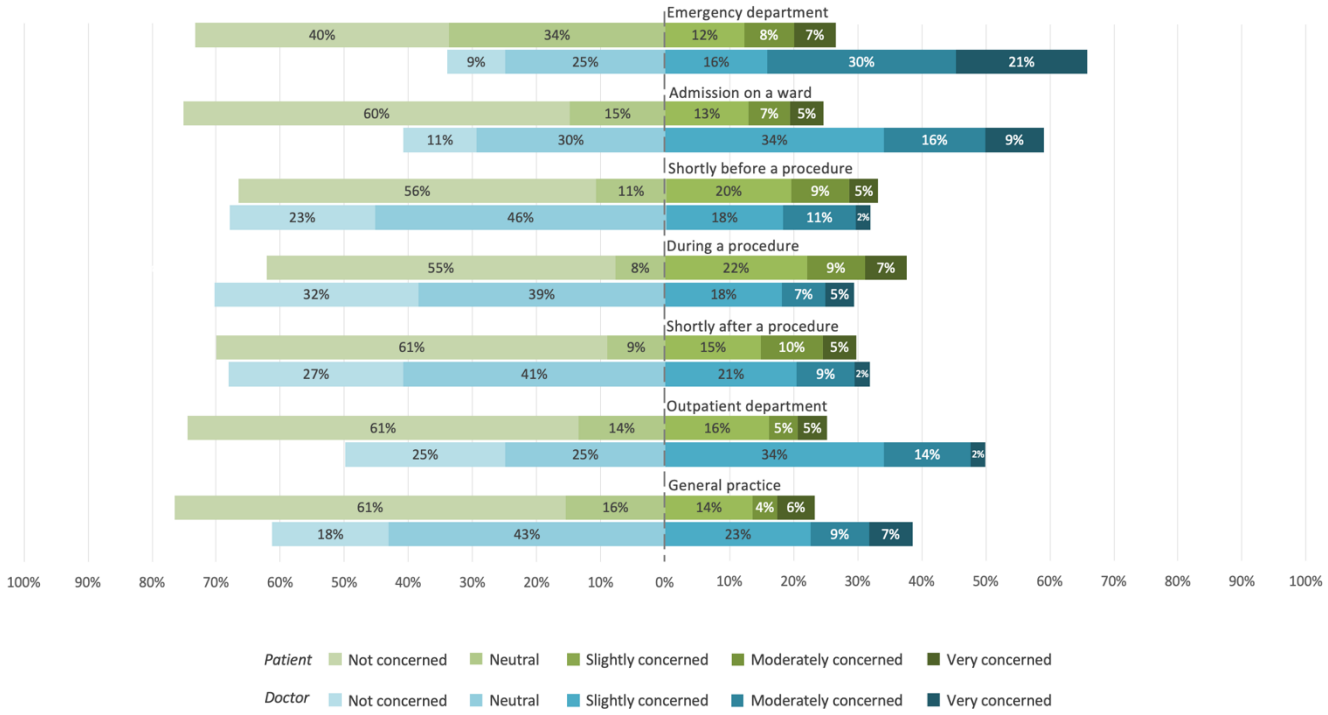
Patients were most concerned with failure or delay to diagnose correctly (n = 62/154, 40.3%) followed by 'a problem directly arising from a medical procedure or operation' (n = 58/154, 37.7%). Patients were least concerned about 'errors related to administration of drugs or fluids (including blood)' and 'errors related to prescribing of drugs or fluids (including blood)' with 64.3% (n = 99/154) and 63.6% (n = 98/154) reporting no concern respectively.

Table 22: Patients' and doctors' levels of concern for adverse events

		Total	Not concerned (%)	Neutral (%)	Slightly concerned (%)	Moderately concerned (%)	Very concerned (%)	P -value
Failure/delay to diagnose correctly	*Patient*	154	78 (50.6) $_a$	14 (9.1)	24 (15.6)	16 (10.4) $_a$	22 (14.3)	< 0.001
	Doctor	44	4 (9.1) $_b$	6 (13.6)	12 (27.3)	13 (29.5) $_b$	9 (20.5)	
Failure/delay to provide the correct treatment	*Patient*	154	84 (54.5) $_a$	20 (13.0)	21 (13.6)	11 (7.1) $_a$	18 (11.7) $_a$	< 0.001
	Doctor	44	6 (13.6) $_b$	5 (11.4)	11 (25.0)	9 (20.5) $_b$	13 (29.5) $_b$	
Failure/delay to provide treatment in a timely manner	*Patient*	154	80 (51.9) $_a$	25 (16.2)	19 (12.3)	13 (8.4) $_a$	17 (11.0) $_a$	< 0.001
	Doctor	44	3 (6.8) $_b$	6 (13.6)	8 (18.2)	13 (29.5) $_b$	14 (31.8) $_b$	
Failure/delay of adequate follow-up	*Patient*	154	85 (55.2) $_a$	20 (13.0)	25 (9.7) $_a$	19 (12.3) $_a$	15 (9.7)	< 0.001
	Doctor	44	9 (20.5) $_b$	4 (9.1)	13 (29.5) $_b$	11 (25) $_b$	7 (15.9)	
A problem directly arising from a medical procedure or operation	*Patient*	154	75 (48.7) $_a$	21 (13.6) $_a$	28 (18.2)	10 (6.5)	20 (13.0)	0.011
	Doctor	44	10 (22.7) $_b$	12 (27.3) $_b$	14 (31.8)	4 (9.1)	4 (9.1)	
Errors related to prescribing of drugs/fluids (incl. blood)	*Patient*	154	98 (63.6) $_a$	24 (15.6)	12 (7.8) $_a$	12 (7.8)	8 (5.2)	< 0.001
	Doctor	44	6 (13.6) $_b$	12 (27.3)	16 (36.4) $_b$	6 (13.6)	4 (9.1)	
Errors related to administration of drugs/fluids (incl. blood)	*Patient*	154	99 (64.3)	18 (11.7)	21 (13.6) $_a$	8 (5.2) $_a$	8 (5.2)	< 0.001
	Doctor	44	9 (20.5)	10 (22.7)	12 (27.3) $_b$	9 (20.5) $_b$	4 (9.1)	
Errors related to monitoring of drugs/fluids (incl. blood)	*Patient*	154	96 (62.3) $_a$	22 (14.3) $_a$	20 (13.0) $_a$	7 (4.5) $_a$	9 (5.8)	< 0.001
	Doctor	44	8 (18.2) $_b$	14 (31.8) $_b$	12 (27.3) $_b$	6 (13.6) $_b$	4 (9.1)	
Failure/delay to appreciate your overall condition	*Patient*	154	87 (56.5) $_a$	27 (17.5)	19 (12.3) $_a$	11 (7.1) $_a$	10 (6.5) $_a$	< 0.001
	Doctor	44	6 (13.6) $_b$	8 (18.2)	11 (25.0) $_b$	12 (27.3) $_b$	7 (15.9) $_b$	
Failure/delay to prevent, control or manage infection	*Patient*	154	95 (61.7) $_a$	20 (13.0) $_a$	19 (12.3)	10 (6.5) $_a$	10 (6.5)	< 0.001
	Doctor	44	11 (25.0) $_b$	14 (31.8) $_b$	8 (18.2)	8 (18.2) $_b$	3 (6.8)	
Administrative errors	*Patient*	154	90 (58.4) $_a$	26 (16.9)	16 (10.4) $_a$	12 (7.8) $_a$	10 (6.5) $_a$	< 0.001
	Doctor	44	4 (9.1) $_b$	5 (11.4)	13 (29.5) $_b$	14 (31.8) $_b$	8 (18.2) $_b$	
Communication errors	*Patient*	154	83 (53.9) $_a$	21 (13.6)	27 (17.5)	11 (7.1) $_a$	12 (7.8) $_a$	< 0.001
	Doctor	44	2 (4.5) $_b$	6 (13.6)	12 (27.3)	11 (25.0) $_b$	13 (29.5) $_b$	
Errors related to reporting of radiological and laboratory results	*Patient*	154	88 (57.1) $_a$	26 (16.9)	17 (11.0)	12 (7.8) $_a$	11 (7.1) $_a$	< 0.001
	Doctor	44	5 (11.4) $_b$	11 (25.0)	7 (15.9)	11 (25.0) $_b$	10 (22.7) $_b$	
Equipment malfunction	*Patient*	154	89 (57.8)	28 (18.2)	23 (14.9)	5 (3.2) $_a$	9 (5.8)	0.01
	Doctor	44	14 (31.8)	12 (27.3)	8 (18.2)	6 (13.6) $_b$	4 (9.1)	

Each subscript letter denotes a subset of the variable whose row proportions differ significantly from each other at the .05 level.

Patients and doctors were asked how concerned they were about a medical error occurring in different healthcare settings during their breast care journey or when proving breast cancer care respectively (Figure 17 and Table 23). A larger proportion of patients were not concerned about every healthcare setting when compared to doctors (Table 23). The emergency department accounted for both the highest proportion of doctors reporting any level of concern (n = 29/44, 65.9%) as well as the highest percentage of doctors who were very concerned (n = 9/44, 20.5%). A higher proportion of doctors reported being moderately to very concerned about the emergency department compared to patients ($p < 0.001$) (Table 23).



* Numbers may not equal 100 due to rounding

Figure 17: Patients' and doctors' levels of concern for medical error in healthcare settings

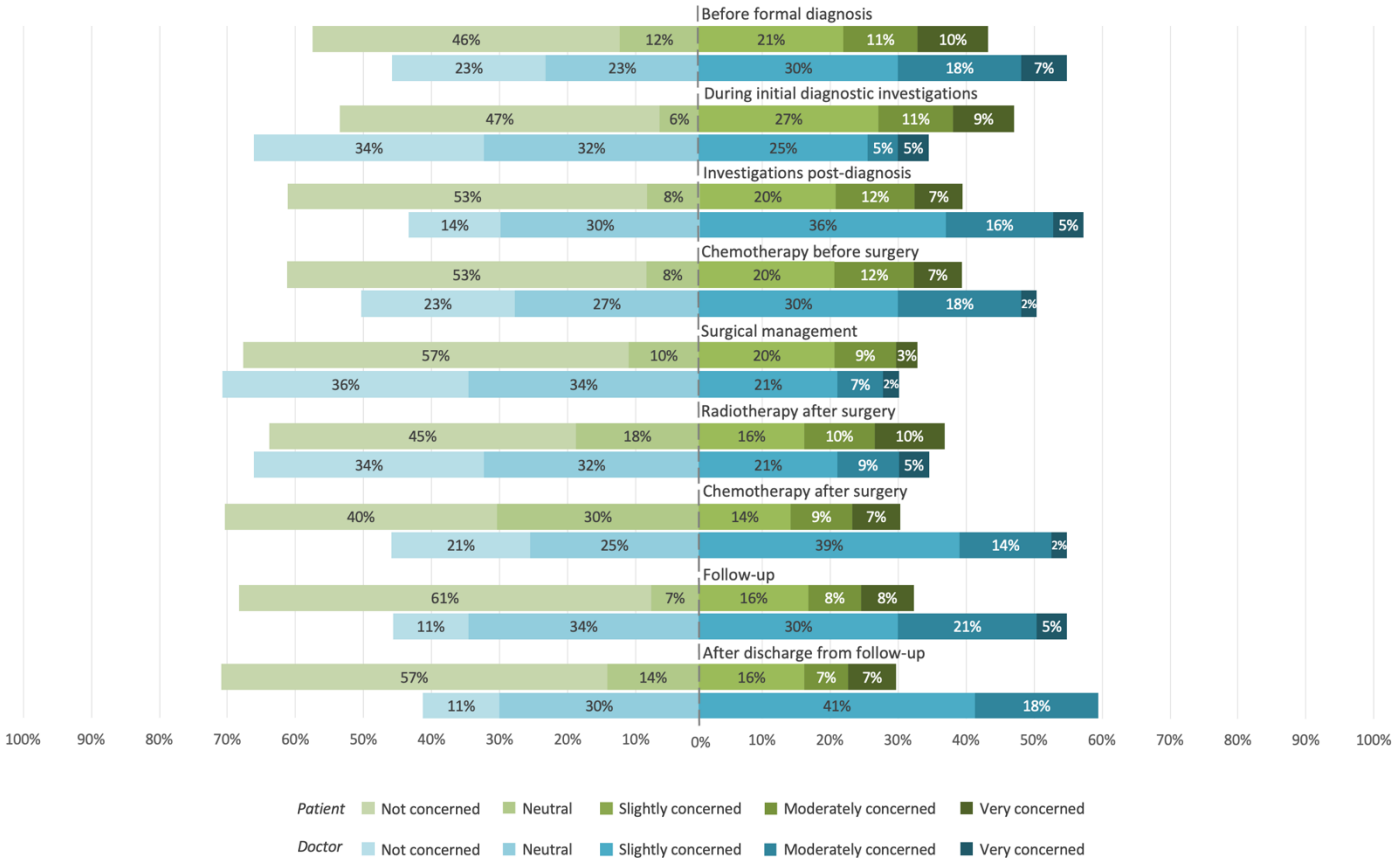
The second and third most concerning settings as rated by doctors were admission on a ward and outpatient department (n = 26/44, 59.1% and n = 22/44, 50%). The settings which caused the most concern for patients were those involving with a procedure: shortly before (n = 51/154, 33.1%), during (n = 58/ 154, 37.7%) and shortly after (n = 46/ 154, 29.8%).

Table 23: Patients' and doctors' levels of concern for medical error in healthcare settings

		Total	Not concerned (%)	Neutral (%)	Slightly concerned (%)	Moderately concerned (%)	Very concerned (%)	P -value
Emergency department	*Patient*	154	61 (39.6) $_a$	52 (33.8)	19 (12.3)	12 (7.8) $_a$	10 (6.5) $_a$	< 0.001
	Doctor	44	4 (9.1) $_b$	11 (25.0)	7 (15.9)	13 (29.5) $_b$	9 (20.5) $_b$	
Admission on a ward	*Patient*	154	93 (60.4) $_a$	23 (14.9) $_a$	20 (13.0) $_a$	10 (6.5) $_a$	8 (5.2)	< 0.001
	Doctor	44	5 (11.4) $_b$	13 (29.5) $_b$	15 (34.1) $_b$	7 (15.9) $_b$	4 (9.1)	
Shortly before a procedure	*Patient*	154	86 (55.8) $_a$	17 (11.0) $_a$	30 (19.5)	14 (9.1)	7 (4.5)	< 0.001
	Doctor	44	10 (22.7) $_b$	20 (45.5) $_b$	8 (18.2)	5 (11.4)	1 (2.3)	
During a procedure	*Patient*	154	84 (54.5) $_a$	12 (7.8)) $_a$	34 (22.1	14 (9.1)	10 (6.5)	0.011
	Doctor	44	14 (31.8) $_b$	17 (38.6) $_b$	8 (18.2)	3 (6.8)	2 (4.5)	
Shortly after a procedure	*Patient*	154	94 (61.0) $_a$	14 (9.1) $_a$	23 (14.9)	15 (9.7)	8 (5.2)	< 0.001
	Doctor	44	12 (27.3) $_b$	18 (40.9) $_b$	9 (20.5)	4 (9.1)	1 (2.3)	
Outpatient department	*Patient*	154	94 (61.0) $_a$	21 (13.6)	25 (16.2) $_a$	7 (4.5) $_a$	7 (4.5)	< 0.001
	Doctor	44	11 (25.0) $_b$	11 (25.0)	15 (34.1) $_b$	6 (13.6) $_b$	1 (2.3)	
General practice	*Patient*	154	94 (61.0) $_a$	24 (15.6) $_a$	21 (13.6)	6 (3.9)	9 (4.5)	< 0.001
	Doctor	44	8 (18.2) $_b$	19 (43.2) $_b$	10 (22.7)	4 (9.1)	3 (6.8)	

Each subscript letter denotes a subset of the variable whose row proportions differ significantly from each other at the .05 level.

Patients and doctors reported how concerned they were about a medical error occurring at different clinical stages of the breast cancer care journey. Responses are illustrated in Figure 18. On average, doctors reported higher levels of concern compared to patients at the majority of clinical stages. A greater proportion of patients were not concerned compared to doctors at every clinical stage except radiotherapy after surgery (Table 24).



* Numbers may not equal 100 due to rounding

Figure 18: Patients' and doctors' level of concern for medical error at clinical stages

After discharge from follow-up and during investigations post-diagnosis were the clinical stages which the highest proportion of doctors reported some level of concern (n = 26/44, 59.0% and n = 25/44, 56.8%). For patients, the highest percentage reported concern for a medical error occurring during initial diagnostic investigations (n = 72/154, 46.8%) followed by before formal diagnosis (n = 66/154, 42.9%). A greater percentage of doctors reported having moderate concern for the occurrence of a medical error during follow-up or after discharge from follow-up compared to patients (p = < 0.001 and p < 0.001) (Table 24).

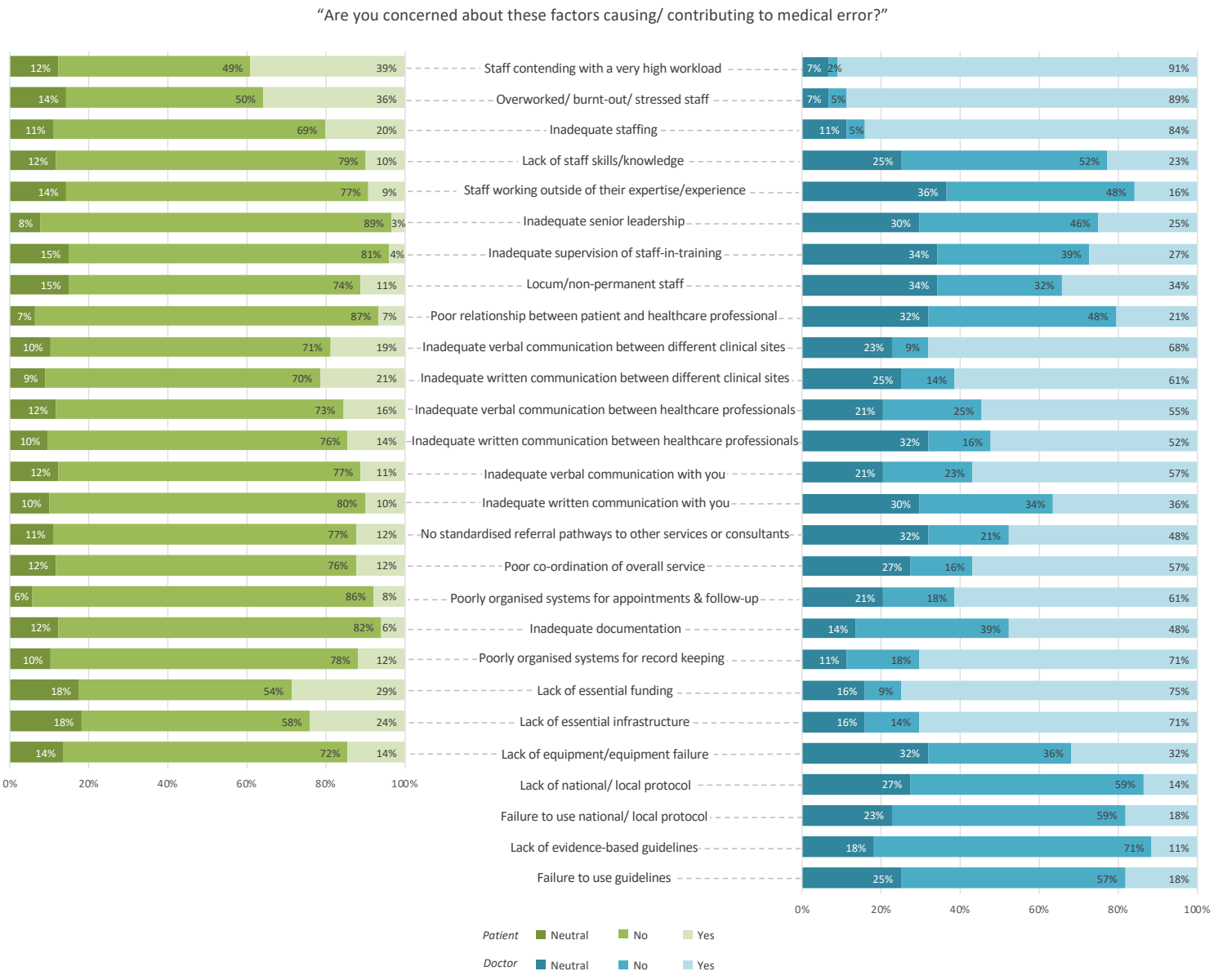
Table 24: Patients' and doctors' levels of concern for medical error at clinical stages

		Total	Not concerned (%)	Neutral (%)	Slightly concerned (%)	Moderately concerned (%)	Very concerned (%)	P -value
Before formal diagnosis	*Patient*	154	70 (45.5) $_a$	18 (11.7)	33 (21.4)	17 (11.0)	16 (10.4)	0.037
	Doctor	44	10 (22.7) $_b$	10 (22.7)	13 (29.5)	8 (18.2)	3 (6.8)	
During initial diagnostic investigations	*Patient*	154	73 (47.4)	9 (5.8) $_a$	41 (26.6)	17 (11.0)	14 (9.1)	< 0.001
	Doctor	44	15 (34.2)	14 (31.8) $_b$	11 (25.0)	2 (4.5)	2 (4.5)	
Investigations post-diagnosis	*Patient*	154	82 (53.2) $_a$	12 (7.8) $_a$	31 (20.1) $_a$	18 (11.7)	11 (7.1)	< 0.001
	Doctor	44	6 (13.6) $_b$	13 (29.5) $_b$	16 (36.4) $_b$	7 (15.9)	2 (4.5)	
Chemotherapy before surgery	*Patient*	154	82 (53.2) $_a$	12 (7.8) $_a$	21 (20.1)	18 (11.7)	11 (7.1)	< 0.001
	Doctor	44	10 (22.7) $_b$	12 (27.3) $_b$	13 (29.5)	8 (18.2)	1 (2.3)	
Surgical management	*Patient*	154	88 (57.1) $_a$	16 (10.4) $_a$	31 (20.1)	14 (9.1)	5 (3.2)	0.006
	Doctor	44	16 (36.4) $_b$	15 (34.1) $_b$	9 (20.5)	3 (6.8)	1 (2.3)	
Radiotherapy after surgery	*Patient*	154	70 (45.4)	28 (18.2)	24 (15.6)	16 (10.4)	16 (10.4)	0.212
	Doctor	44	15 (34.1)	14 (31.8)	9 (20.5)	4 (9.1)	2 (4.5)	
Chemotherapy after surgery	*Patient*	154	62 (40.3) $_a$	46 (29.9)	21 (13.6) $_a$	14 (9.1)	11 (7.1)	0.002
	Doctor	44	9 (20.5) $_b$	11 (25.0)	17 (38.6) $_b$	6 (13.6)	1 (2.3)	
Follow-up	*Patient*	154	94 (61.0) $_a$	11 (7.1) $_a$	25 (16.2) $_a$	12 (7.8) $_a$	12 (7.8)	< 0.001
	Doctor	44	5 (11.4) $_b$	15 (34.1) $_b$	13 (29.5) $_b$	9 (20.5) $_b$	2 (4.5)	
After discharge from follow-up	*Patient*	154	88 (57.1) $_a$	21 (13.6) $_a$	24 (15.6) $_a$	10 (6.5) $_a$	11 (7.1)	< 0.001
	Doctor	44	5 (11.4) $_b$	13 (29.5) $_b$	18 (40.9) $_b$	8 (18.2) $_b$	0	

Each subscript letter denotes a subset of the variable whose row proportions differ significantly from each other at the .05 level

A greater proportion of doctors were concerned about almost all of the causative or contributory factors of medical error compared to patients, except for staff working outside of their expertise or experience (Table 25).

As demonstrated in Figure 19, the factors which concerned the greatest proportion of both patients and doctors were those involving staff workload. Approximately two in five patients and four in five doctors were concerned that staff contending with a very high workload could contribute to a medical error (n = 60/154, 39.0% and n = 40/44, 90.9%). One in three patients and close to four in five doctors reported concern about overworked or burnt-out or stressed staff (n = 55/154, 35.7% and n = 39/44, 88.6%) contributing to a medical error. More doctors were concerned about inadequate staffing than patients ($p < 0.001$).



* Numbers may not equal 100 due to rounding

Figure 19: Patients' and doctors' views on causative/ contributory factors of medical error

The third and fourth greatest proportion of patients and doctors were concerned about the same factors. These were predominantly of an organisational and management nature. Lack of essential funding was reported to be concerning for 28.6% of patients (n = 44/154) and 75.0% of doctors (n = 33/44). A lack of essential infrastructure was concerning for 24.0% of patients (n = 37/154) and 70.5% of doctors (n = 31/44). Fewer doctors were concerned about staff knowledge, expertise, leadership, supervision and locum staff contributing to medical error as illustrated in Figure 19. In addition, a smaller proportion of doctors were concerned about a lack of or failure to use either protocols or guidelines as contributing factors to errors.

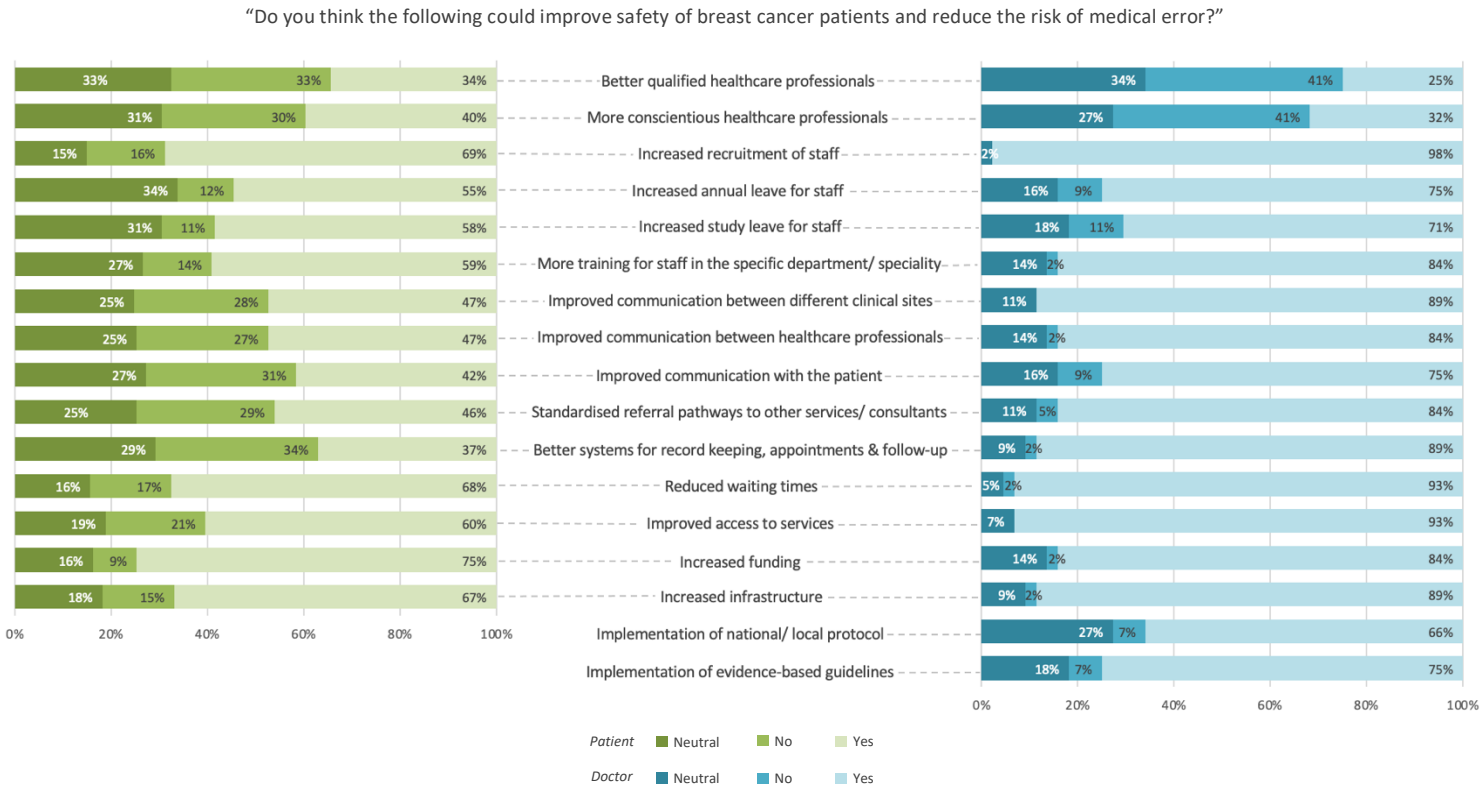
Table 25: Patients' and doctors' views on causative/ contributory factors of medical error

		Total	Neutral (%)	No (%)	Yes (%)	P -value
Staff contending with a very high workload	*Patient*	154	19 (12.3)	75 (48.7) $_a$	60 (39.0) $_a$	< 0.001
	Doctor	44	3 (6.8)	1 (2.3) $_b$	40 (90.9) $_b$	
Overworked/ burnt-out/ stressed staff	*Patient*	154	22 (14.3)	77 (50.0) $_a$	55 (35.7) $_a$	< 0.001
	Doctor	44	3 (6.8)	2 (4.5) $_b$	39 (88.6) $_b$	
Inadequate staffing	*Patient*	154	17 (11.0)	106 (68.8) $_a$	31 (20.1) $_a$	< 0.001
	Doctor	44	5 (11.4)	2 (4.5) $_b$	37 (84.1) $_b$	
Lack of staff skills/knowledge	*Patient*	154	18 (11.7) $_a$	121 (78.6) $_a$	15 (9.7) $_a$	0.002
	Doctor	44	11 (25.0) $_b$	23 (52.3) $_b$	10 (22.7) $_b$	
Staff working outside of their expertise/experience	*Patient*	154	22 (14.3) $_a$	118 (76.6) $_a$	14 (9.1)	< 0.001
	Doctor	44	16 (36.4) $_b$	21 (47.7) $_b$	7 (15.9)	
Inadequate senior leadership	*Patient*	154	12 (7.8) $_a$	137 (89) $_a$	5 (3.2) $_a$	< 0.001
	Doctor	44	13 (29.5) $_b$	20 (45.5) $_b$	11 (25.0) $_b$	
Inadequate supervision of staff-in-training	*Patient*	154	23 (14.9) $_a$	125 (81.2) $_a$	6 (3.9) $_a$	< 0.001
	Doctor	44	15 (34.1) $_b$	17 (38.6) $_b$	12 (27.3) $_b$	
Locum/non-permanent staff	*Patient*	154	23 (14.9) $_a$	114 (74) $_a$	17 (11) $_a$	< 0.001
	Doctor	44	15 (34.1) $_b$	14 (31.8) $_b$	15 (34.1) $_b$	
Poor relationship between patient & healthcare professional	*Patient*	154	10 (6.5) $_a$	134 (87.0) $_a$	10 (6.5) $_a$	< 0.001
	Doctor	44	14 (31.8) $_b$	21 (47.7) $_b$	9 (20.5) $_b$	
Inadequate verbal communication between clinical sites	*Patient*	154	16 (10.4) $_a$	109 (70.8) $_a$	29 (18.8) $_a$	< 0.001
	Doctor	44	10 (22.7) $_b$	4 (9.1) $_b$	39 (68.2) $_b$	
Inadequate written communication between clinical sites	*Patient*	154	14 (9.1) $_a$	109 (69.5) $_a$	33 (21.4) $_a$	< 0.001
	Doctor	44	11 (25.0) $_b$	6 (13.6) $_b$	27 (61.4) $_b$	
Inadequate verbal communication between healthcare professionals	*Patient*	154	18 (11.7) $_a$	112 (72.7) $_a$	24 (15.6) $_a$	< 0.001
	Doctor	44	9 (20.5) $_b$	11 (25.0) $_b$	24 (54.5) $_b$	
Inadequate written communication between healthcare professionals	*Patient*	154	15 (9.7)	117 (76) $_a$	22 (14.3) $_a$	< 0.001
	Doctor	44	14 (31.8)	7 (15.9) $_b$	23 (52.3) $_b$	
Inadequate verbal communication with the patient	*Patient*	154	19 (12.3)	118 (76.6) $_a$	17 (11) $_a$	< 0.001
	Doctor	44	9 (20.5)	10 (22.7) $_b$	25 (56.8) $_b$	
Inadequate written communication with the patient	*Patient*	154	16 (10.4) $_a$	123 (79.9) $_a$	15 (9.7) $_a$	< 0.001
	Doctor	44	13 (29.5) $_b$	15 (34.1) $_b$	16 (17.6) $_b$	
No standardised referral pathways to other services/ consultants	*Patient*	154	17 (11.0) $_a$	118 (76.6) $_a$	19 (12.3) $_a$	< 0.001
	Doctor	44	14 (31.8) $_b$	9 (20.5) $_b$	21 (47.7) $_b$	
Poor co-ordination of overall service	*Patient*	154	18 (11.7) $_a$	117 (76) $_a$	19 (12.3) $_a$	< 0.001
	Doctor	44	12 (27.3) $_b$	7 (15.9) $_b$	25 (56.8) $_b$	
Poorly organised systems for appointments & follow-up	*Patient*	154	9 (5.8) $_a$	133 (86.4) $_a$	12 (7.8) $_a$	< 0.001
	Doctor	44	9 (20.5) $_b$	8 (18.2) $_b$	27 (61.4) $_b$	
Inadequate documentation	*Patient*	154	19 (12.3)	126 (81.8) $_a$	9 (5.8) $_a$	< 0.001
	Doctor	44	6 (13.6)	17 (38.6) $_b$	21 (47.7) $_b$	
Poorly organised systems for record keeping	*Patient*	154	16 (10.4)	120 (77.9) $_a$	18 (11.7) $_a$	< 0.001
	Doctor	44	5 (11.4)	8 (18.2) $_b$	31 (70.5) $_b$	
Lack of essential funding	*Patient*	154	27 (17.5)	83 (53.9) $_a$	44 (28.6) $_a$	< 0.001
	Doctor	44	7 (15.9)	4 (9.1) $_b$	33 (75.0) $_b$	
Lack of essential infrastructure	*Patient*	154	28 (18.2)	89 (57.8) $_a$	37 (24.0) $_a$	< 0.001
	Doctor	44	7 (15.9)	6 (13.6) $_b$	31 (70.5) $_b$	
Lack of equipment/equipment failure	*Patient*	154	21 (13.6) $_a$	111 (72.1) $_a$	22 (14.3) $_a$	< 0.001
	Doctor	44	14 (31.8) $_b$	16 (36.4) $_b$	14 (31.8) $_b$	
Lack of national/ local protocol	*Doctor*	44	12 (27.3)	26 (59.1)	6 (13.6)	
Failure to use national/ local protocol	*Doctor*	44	10 (22.7)	26 (59.1)	8 (18.2)	
Lack of evidence-based guidelines	*Doctor*	44	8 (18.2)	31 (70.5)	5 (11.4)	
Failure to use guidelines	*Doctor*	44	11 (25.0)	25 (56.8)	8 (18.2)	

Each subscript letter denotes a subset of the variable whose row proportions differ significantly from each other at the .05 level

A greater proportion of doctors felt that the majority of remediating factors listed shown in Figure 20 would improve patient safety and reduce the risk of medical error compared to patients (Table 26). Increased recruitment of staff was viewed by 97.7% of doctors (n = 43/44) as a way in which patient safety could be improved and medical error reduced which was a significantly higher proportion than patients ($p < 0.001$).

Reduced waiting times and improved access to service (n = 41/44, 93.2%) were rated as joint second by doctors. Improved communication between clinical sites, increased infrastructure and better systems for record keeping appointments and follow-up were all ranked third by doctors (n = 39/44, 88.6%).



* Numbers may not equal 100 due to rounding

Figure 20: Patients' and doctors' views on preventative factors of medical error

Increased funding and increased recruitment of staff were the two factors which the highest proportion of patients felt would improve patient safety and reduce the risk of medical error (n = 115, 74.7% and 106, 68.8%). One third of patients felt that better organised systems for record keeping, appointments and follow-up would not contribute to improved patient safety or reduced medical error risk (n = 52/144, 33.8%) which is significantly higher compared to doctors ($p < 0.001$) (Table 26).

Table 26: Patients' and doctors' views on preventative factors of medical error

		Total	Neutral (%)	No (%)	Yes (%)	P -value
Better qualified healthcare professionals	*Patient*	154	50 (32.5)	51 (33.1)	53 (34.3)	0.489
	Doctor	44	15 (34.1)	18 (40.9)	11 (25.0)	
More conscientious healthcare professionals	*Patient*	154	47 (30.5)	46 (29.9)	61 (39.6)	0.372
	Doctor	44	12 (27.3)	18 (40.9)	14 (31.8)	
Increased recruitment of staff	*Patient*	154	23 (14.9) $_a$	25 (16.2) $_a$	106 (68.8) $_a$	< 0.001
	Doctor	44	1 (2.3) $_b$	0 $_b$	43 (97.7) $_b$	
Increased annual leave for staff	*Patient*	154	52 (33.8) $_a$	18 (11.7)	84 (54.5) $_a$	0.041
	Doctor	44	7 (15.9) $_b$	4 (9.1)	33 (75.0) $_b$	
Increased study leave for staff	*Patient*	154	47 (30.5)	17 (11.0)	90 (58.4)	0.262
	Doctor	44	8 (18.2)	5 (11.4)	31 (70.5)	
More training for staff in the specific department/ speciality	*Patient*	154	41 (26.6)	22 (14.3) $_a$	91 (59.1) $_a$	0.007
	Doctor	44	6 (13.6)	1 (2.3) $_b$	37 (84.1) $_b$	
Improved communication between different clinical sites	*Patient*	154	38 (24.7)	43 (27.9) $_a$	73 (47.4) $_a$	< 0.001
	Doctor	44	5 (11.3)	0 $_b$	39 (88.6) $_b$	
Improved communication between healthcare professionals	*Patient*	154	39 (25.3)	42 (27.3) $_a$	73 (47.4) $_a$	< 0.001
	Doctor	44	6 (13.6)	1 (2.3) $_b$	37 (84.1) $_b$	
Improved communication with the patient	*Patient*	154	42 (27.3)	48 (31.2) $_a$	64 (41.6) $_a$	< 0.001
	Doctor	44	7 (15.9)	4 (9.1) $_b$	33 (75.0) $_b$	
Standardised referral pathways to other services/ consultants	*Patient*	154	39 (25.3) $_a$	44 (28.6) $_a$	71 (46.1) $_a$	< 0.001
	Doctor	44	5 (11.4) $_b$	2 (4.5) $_b$	37 (84.1) $_b$	
Better systems for record keeping, appointments, & follow-up	*Patient*	154	45 (29.9) $_a$	52 (33.8) $_a$	57 (37.0) $_a$	< 0.001
	Doctor	44	4 (9.1) $_b$	1 (2.3) $_b$	39 (88.6) $_b$	
Reduced waiting times	*Patient*	154	24 (15.6)	26 (16.9) $_a$	104 (67.5) $_a$	0.003
	Doctor	44	2 (4.5)	1 (2.3) $_b$	41 (93.2) $_b$	
Improved access to services	*Patient*	154	29 (18.8)	32 (20.8) $_a$	93 (60.4) $_a$	< 0.001
	Doctor	44	3 (6.8)	0 $_b$	41 (93.2) $_b$	
Increased funding	*Patient*	154	25 (16.2)	14 (9.1)	115 (74.7)	0.275
	Doctor	44	6 (13.6)	1 (2.3)	37 (84.1)	
Increased infrastructure	*Patient*	154	28 (18.2)	23 (14.9) $_a$	103 (66.9) $_a$	0.013
	Doctor	44	4 (9.1)	1 (2.3) $_b$	39 (88.6) $_b$	
Implementation of national/ local protocol	*Doctor*	44	12 (27.3)	3 (6.8)	29 (65.9)	
Implementation of evidence-based guidelines	*Doctor*	44	8 (18.2)	3 (6.8)	33 (75.0)	

Each subscript letter denotes a subset of the variable whose row proportions differ significantly from each other at the .05 level

Of the 154 patients, only 13 reported their concerns about patient safety and risk of medical error. Figure 21 shows who concerns were reported to as well as the outcome. The three most frequent outcomes were all related to improved communication. Patients most frequently cited lack of confidence on the difference it would make as a barrier to reporting which was the same for doctors who did not report their concerns (Figure 21).

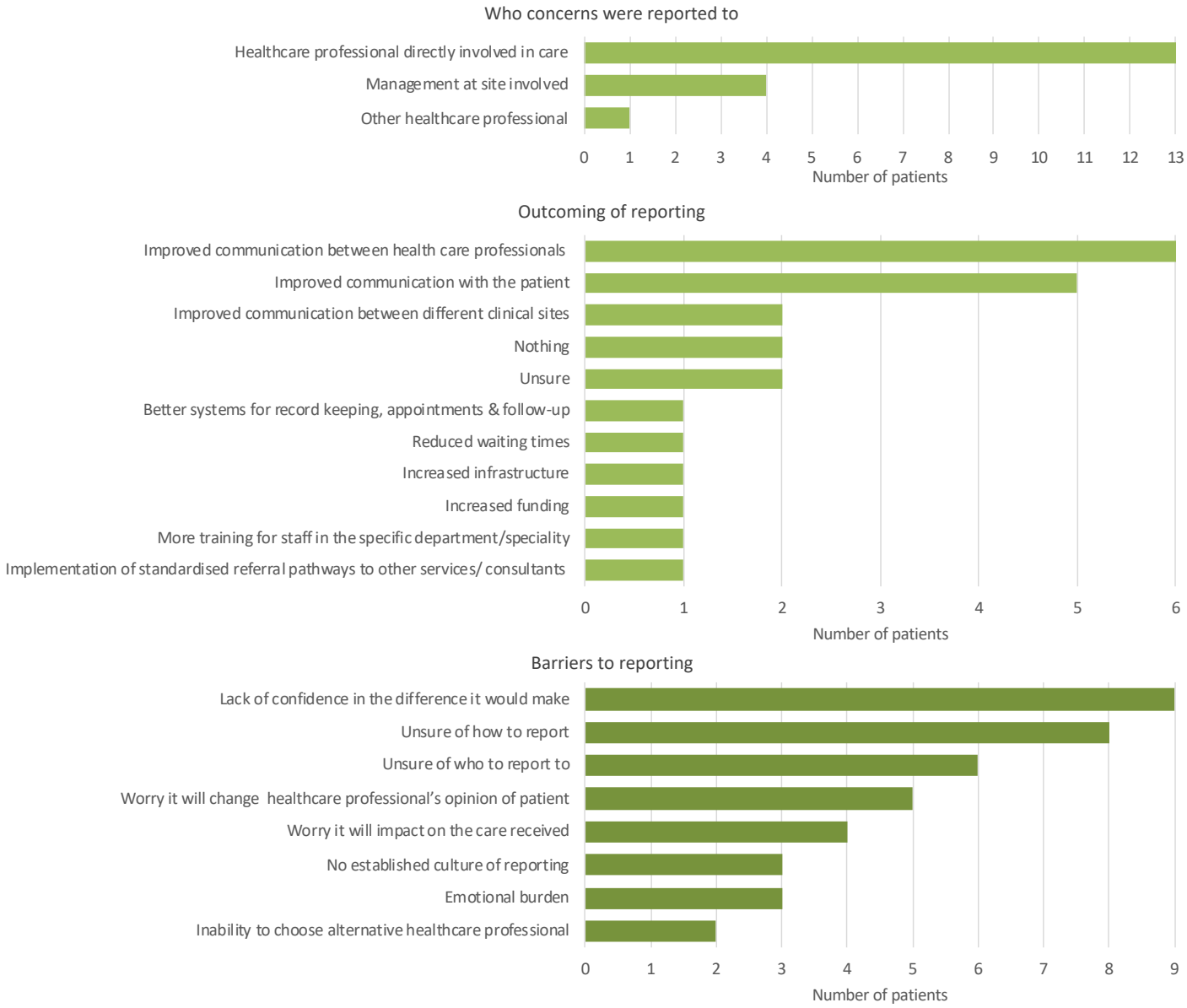


Figure 21: Patients' experiences of reporting patient safety concerns

Fifteen of the 44 doctors reported their concerns. As illustrated in Figure 22, most doctors reported their concerns to management at the site involved. Unfortunately, 'nothing' was the most frequently reported outcome. Uncertainty regarding who to report to or how to report concerns was also commonly reported by both patients and doctors (Figure 22).

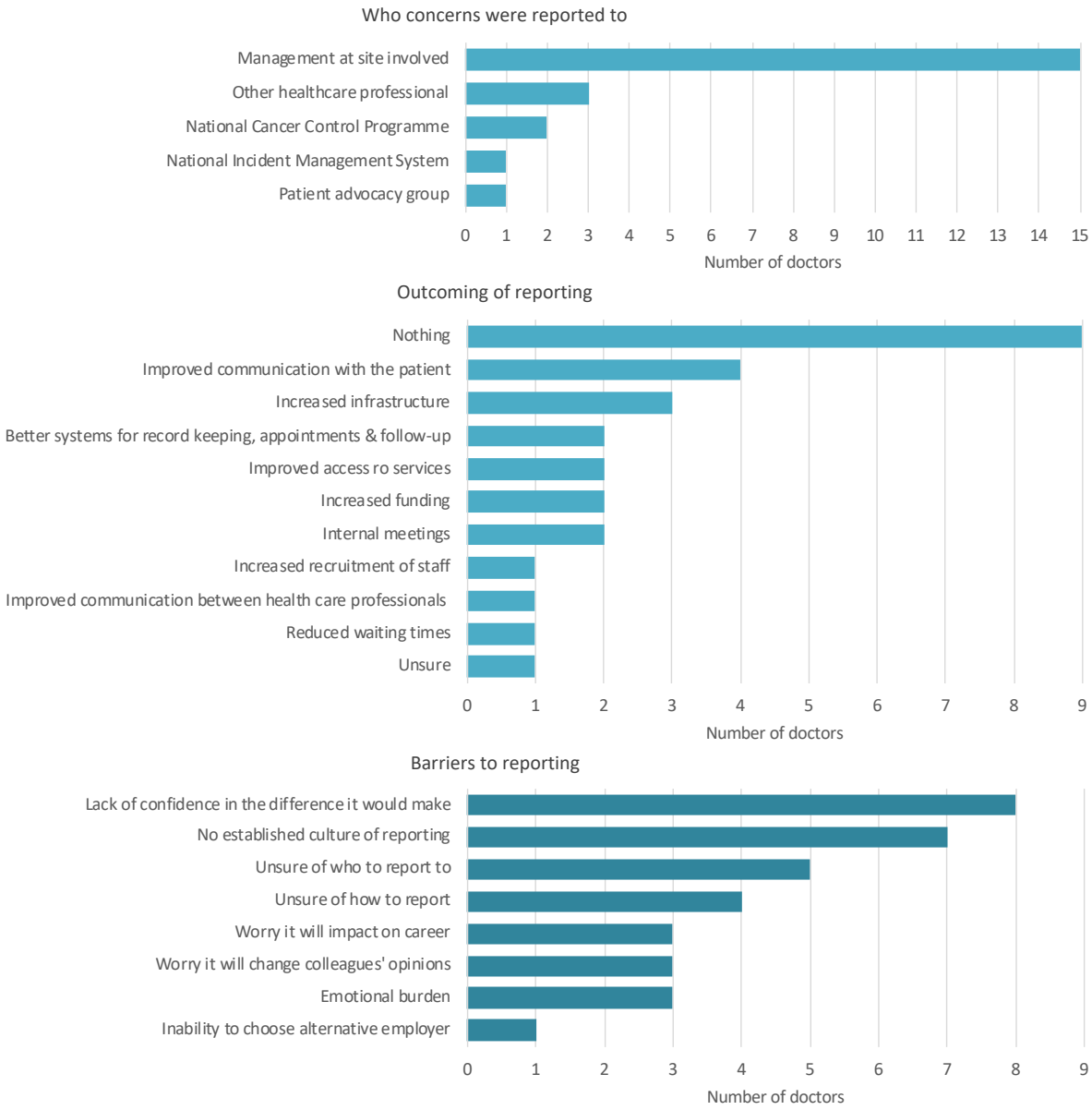


Figure 22: Doctors' experiences of reporting patient safety concerns

Figure 23 and Figure 24 illustrate the impact that patient safety concerns have had on doctors who completed the questionnaire. One in five doctors have been prompted to consider early retirement due to their concerns regarding patient safety for breast cancer patients (n = 9/44, 20.5%). Their concerns have prompted almost three in ten doctors to consider working abroad (n = 13/44, 29.5%).

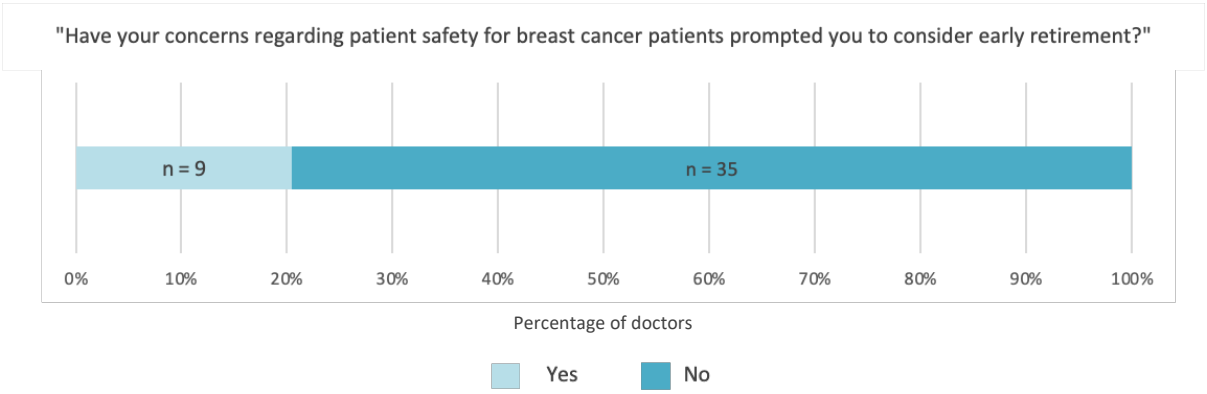


Figure 23: Impact of patient safety concerns on doctors' early retirement

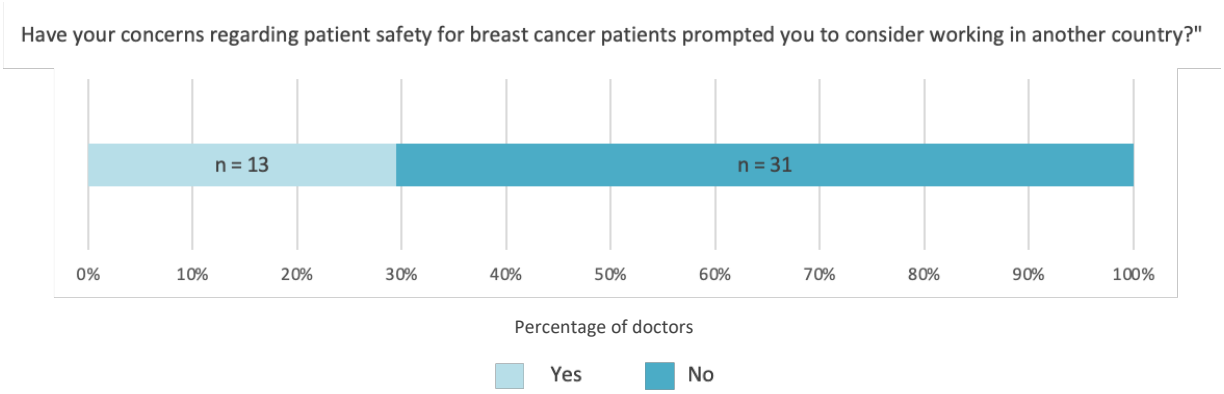


Figure 24: Impact of patient safety concerns on doctors' emigration

Discussion

Breast cancer can be a life-altering diagnosis. Its management has innumerable impacts on the patient's physical health and psychological wellbeing (123, 124). Often, a breast cancer diagnosis affects the entire family unit and can cause financial strain for years to follow (125-127). The potential occurrence of a medical error is an additional burden that no person wishes to experience. However, medical errors are common. Their prevention, which can be described by the term 'patient safety', can only be achieved when there is specific knowledge about patients receiving breast cancer care.

There are benefits to using patient surveys to assess medical error and patient safety. The Organisation for Economic Co-operation and Development (OECD) published a report in 2018 titled 'The Economics of Patient Safety in Primary and Ambulatory Care' which highlighted the importance of patient involvement in patient safety improvement (9). The report discussed how "patient reporting must be part of a safety measurement and improvement system" (9) Their unique perspective and observations can identify different types of events and errors. Patient engagement has a positive impact on safety by preventing or reducing adverse events (9, 87, 97, 101, 128, 129). This study's strength lies in highlighting patients' experiences and opinions.

While patient involvement is a key aspect of safety improvement, ultimately the responsibility to provide safe care rests with healthcare professionals. As a result, much of the research in patient safety and medical error relies on information from them. This study utilised the perspectives of both patient and healthcare providers in order to present a rounded picture as often the two groups identify different types of events, contributing factors and outcomes (85, 87). As outlined earlier, a growing number of patient safety incidents are being pursued in the legal system (31-33). Only through examining previous claims, can future ones be prevented (70, 72). Therefore, a strength of this study is the inclusion of data related to medical negligence claims.

Study One

The 'What' of Patient Safety Events during Breast Cancer Care

This study identified and analysed 83 patient safety events involving breast cancer care. Of these, 35 were medical errors reported by doctors, 26 medical errors reported by patients, 13 medical negligence claims reported by doctors, 4 medical negligence claims reported by patients and five medical negligence claims from State Claims Agency data.

The most common description of the nature of events was 'failure or delay to correctly diagnose' as 32 events were concerned with correct diagnosis. It was implicated in twice as high a proportion of medical negligence claims compared to medical errors. Previous studies examining medical negligence claims involving breast cancer claims have also found that delays or failures of diagnosis were the most common cause of litigation (51-54). A large study conducted in the United States which examined over 550 breast cancer claims found that more than half involved delays in diagnosis (130).

This study's findings that the most common error related to failures or delays regarding diagnosis and that that the highest proportion of events occurred before formal diagnosis highlight the importance of diagnostic pathways from start to finish. There must be clear guidelines for patients who present asymptomatically and are detected through screening as well as those who present symptomatically and are referred from primary care.

The current National Cancer Control Programme's referral guidelines were deemed the gold standard for referral to symptomatic breast services, however this was over a decade ago (131). A study which examined interval cancer rates in the Irish national breast screening programme between 2000 and 2007 found that while the programme achieved the minimum standard in the first 12 months after screening, it did not attain the "achievable" standard, especially in the second year after screening (132). An updated assessment on the current symptomatic and asymptomatic diagnostic pathways is due and should be used to inform ongoing service and guideline development.

Other types of events which were commonly reported in this study included failure or delay to provide the correct treatment and failure or delay to provide treatment in a timely manner which were again reported in a greater proportion of medical negligence claims than medical errors. This may be in keeping with the fact that if a diagnosis is delayed, it is natural that treatment cannot start at a desired time resulting in delayed and untimely treatment. Therefore, improving the diagnostic pathways will result in a timely diagnosis and the correct treatment which will have positive impacts on patient care (133, 134).

The 'Why' of Patient Safety Events during Breast Cancer Care

Communication

Communication errors were the third most commonly described nature of event and were reported in approximately one in five events. In addition, this study found that four of the top five cited causative or contributory factors to all events were concerned with

communication. Therefore, even if the nature of the event is not a communication error per-say, there is a high likelihood that issues with inadequate communication were involved. Previous studies in patients with cancer have found that communication is a common concern for patients and often contributes to perceived errors (135-137). This sentiment is not specific to oncological medicine as poor communication in healthcare in general has been found to compromise patient safety (138).

In this study, inadequate verbal communication with the patient was the most commonly implicated causative or contributory factor. It was reported to be involved in almost one in three events. This finding is notable for a number of reasons. Firstly, the pursuit of an explanation or an apology can be a reason for litigation as previously mentioned (21, 36). However, legal action seldom addresses these aims with patients often left feeling unheard (36). A potential solution is the concept of open disclosure which prioritises communication in a honest and timely manner.

Another reason the finding is notable is due to Ireland's substandard relationship with transparent communication. The significance of open disclosure grew after a controversy involving Ireland's cervical cancer screening programme, CervicalCheck, which resulted in over 360 legal claims (67). In 2015, internal audits were conducted to retrospectively re-analyse previous cytology of women who had developed interval cervical cancer. In the case of 206 women, cytology previously classified as normal was reclassified. The intention of the audits was quality improvement and the women involved were not informed of the process nor the reclassification (139).

In 2018, a scoping inquiry into this controversy was conducted and it found that CervicalCheck was operating at international standards and there was no evidence of laboratory underperformance (67). However, the inquiry did find that Ireland's "policy and practice in relation to open disclosure is deeply contradictory and unsatisfactory" (67). Thereafter, the Patient Safety Bill 2019 was published providing the legislative underpinning for mandatory open disclosure (140). Further work is required to implement mandatory open disclosure in practice as doing so has different challenges in various healthcare contexts (141). This study highlights the importance of improving communication between healthcare practitioner and patient in order to improve patient safety.

The two next most frequently cited causative or contributory factors were inadequate verbal and written communication between healthcare professionals. This emphasises the need

for improvement of communication between healthcare professionals which is particularly important in cancer care as so much of it depends on a multidisciplinary team. Good communication at multidisciplinary meetings facilitate healthcare professionals to work in unison and deliver optimal care (142). On the flipside, inadequate communication within the team can lead to conflicts, uncertainty and ambiguity which can ultimately negatively impact patient care (143). Another aspect of multidisciplinary care is the legal implications that group decisions may have for individual members (144). This is an area that warrants further research.

Staffing of the Health Service

Staff contending with a high workload was the fourth most commonly reported causative or contributory factor, being superseded only by factors involving communication. In study two, patients and doctors who had not experienced a medical error or medical negligence claim also reported concern about the contributory and causative nature of staffing to medical error. Thirty-six percent of patients and 87% of doctors were concerned that overworked or burnt-out or stressed staff could contribute to a medical error. Thirty-nine percent of patients and 91% of doctors were concerned about staff contending with a very high workload. This is highly relevant as Ireland is currently in the midst of a staffing crisis.

According to the Irish Hospital Consultants Association, there are 728 unfilled consultant posts nationally which is reported to be 45% more than previously believed (145). These vacancies post a risk to patient safety (146). An increasing number of doctors are choosing to emigrate based on experiences of training and working in an "an over-stretched, under-staffed health system" (147). In study two, 98% of doctors who had not experienced a medical error or medical negligence claim felt that increased recruitment of staff could improve patient safety and reduce the risk of medical error.

Remaining staff are now dealing with unprecedented pressures in a healthcare system which is overburdened. On the 3rd of January 2023, the highest ever number of admitted patients without beds in Irish hospitals was recorded with 931 patients on trolleys (148). This is an issue that will only escalate in the future if no action is taken. A recent report by the Economic and Social Research Institute in Ireland forecasts that an additional 15,000 healthcare staff are required by 2035 (149). It is well known that understaffing and overworked staff are risks to patient safety (150-153). This study has demonstrated that the unmanageable workload faced by staff is causing, or at least contributing, to patient safety incidents.

Organisational and Management Factors

Organisational and management factors were frequently reported as causative or contributory factors. Among them were poor co-ordination of overall service, lack of essential infrastructure, poorly organised systems for record-keeping and poorly organised systems for appointments and follow-up. While systematic problems within an organisation and its management can be multifaceted and difficult to address, one step that can improve service co-ordination as well as systems for record-keeping and appointments would be the implementation of an electronic health record (154, 155).

In a study which looked at the development of 'Interoperable Electronic Health Records' in European Union member states (as well as Norway and the UK), Ireland was one of just four countries which does not have a fully functioning EHR system and one of five countries which does not have an ePrescription system in place. Along with five other countries (Cyprus, Germany, Luxembourg, Poland, and Romania), Ireland showed among the lowest overall level of use across all EHR data types (156). In this study, better systems for record keeping, appointments and follow-up was the third most commonly reported preventative factor. Moving away from paper-based healthcare and toward an integrated electronic healthcare record would be one step toward achieving this.

The 'Where' of Patient Safety Events during Breast Cancer Care

The most common healthcare settings for events to occur in this study was the outpatient department and this was the case for both medical errors and incidents that lead to a medical negligence claim. In total, 39.8% of events occurred here and the joint next most common settings were the radiology department and general practice both of which accounted for 8.4% of events. It is worth noting that respondents' interpretations of what constitutes outpatient department may vary. For example, some may have interpreted undergoing scans or receiving radiotherapy as occurring in the outpatient department while others may have considered these as having occurred in the radiology department and during a procedure respectively.

Nevertheless, just nine events occurred in definite inpatient settings (admission on a ward, emergency department and high dependency unit), seven in general practice, eleven were in a procedure-related setting and two in 'other' locations. This leaves 54 events, constituting a majority, as occurring in what are classically outpatient settings. Literature comparing medical error in different healthcare settings is sparse. However, a large study in the United

States which looked at patient-reported medical errors had a similar finding whereby more than half of adults with experience of a medical error say that it occurred in an outpatient setting (121). Much of patient safety research in Ireland is focused around inpatient care such as slips, trips and falls, medication errors and perioperative incidents (78). This study's finding that the majority of events occurred in an outpatient setting is surprising and more research should be focus on examining, characterising and improving patient safety in outpatient care.

The 'When' of Patient Safety Events during Breast Cancer Care

As mentioned, this study found the clinical stage during which the highest proportion of events occurred was before formal diagnosis. Adjuvant chemotherapy and adjuvant radiotherapy were the second and third most common clinical stages. Every patient will go through many of the same clinical stages such as before formal diagnosis and follow-up but whether they undergo surgery, radiotherapy or chemotherapy can differ from patient to patient and this can impact how many events occur at each clinical stage.

However, most patients undergo surgical management and the majority of patients with breast cancer will undergo adjuvant chemotherapy (which in this study includes hormonal therapy and immunotherapy as the term systemic anti-cancer treatments which better reflects this group of treatments is not yet used widely as a layman's term) or adjuvant radiotherapy or both (157). Therefore, variations in patient's individual clinical journeys are limited in those with breast cancer.

The Trajectory of Patient Safety during Breast Cancer Care

A report by the World Health Organisation on patient engagement commented that "the person using healthcare services is the only consistent factor throughout the care pathway" (158). Creating trajectories with a patient safety lens using the events in this study exploit the unique benefit that the patients who completed the questionnaire are the only consistent in their care pathway. The analysis of the patient journey in its entirety, rather than singular events, is essential to better understand the patient safety aspects of breast cancer care (100).

The median degree of harm as defined by the International Classification for Patient Safety was calculated for events at each clinical stage and plotted on the y-axis with the corresponding clinical stage on the x-axis (6). Despite the highest proportion of events in this study occurring before formal diagnosis it was not that clinical stage in which events resulted in the greatest harm. Events which occurred during neoadjuvant chemotherapy, after discharge from follow-up and during follow-up had the highest median harm. Surprisingly, despite a

greater number of events occurring during adjuvant chemotherapy and adjuvant radiotherapy, the median harm caused by those events was relatively lower at 2.5 and 2 respectively. As a patient journeys along their breast cancer management, it can be beneficial for themselves and healthcare professionals alike to have an awareness of the clinical stages in which a medical error can result in the greatest harm.

This is also the case for different healthcare settings. Events which occurred in general practice, radiology department, emergency department and chemotherapy day ward had the same median degree of harm. Both general practice and the radiology department play central roles in the patient's initial diagnosis, therefore the finding that events in those settings result in a higher degree of harm is congruent with the finding that the most common error involves failures or delays to correctly diagnose as previously discussed. Once again, this patient safety trajectory through the varying healthcare settings emphasises the importance of initial diagnostic pathways.

The median degree of harm for events at the chemotherapy day ward is in keeping with the finding that clinical stage of neoadjuvant chemotherapy had a high median degree of harm, however it is worth noting that this is based on the lowest number of events. Adjuvant chemotherapy in comparison had a relatively high number of events but a lower median degree of harm. Additional research about the nature and severity of medical errors which occur in the chemotherapy day ward is justified.

An event can occur in the emergency department at almost any clinical stage of a patient's journey. It has been estimated that up to 44% of cancer patients visit the department within a year of diagnosis (159). However, its high median degree of harm in this study warrants further investigation. Recently, a major tertiary hospital in the south of Ireland has opened an Acute Oncology Services Unit which is the first of its kind nationally. It is an alternative pathway to the emergency department which provides urgent hospital care to patients with a side effect or unexpected symptom by staff who are familiar with their cancer care and treatment. A potential area of future research would be to examine medical errors in cancer care in the emergency department compared to in a dedicated service such as was described.

The Impact of Patient Safety Events during Breast Cancer Care

The Impact on Patients

Two thirds of events in this study resulted in mild to moderate harm and no harm was caused in 15% of events which is similar to the number of events having a mild to moderate impact in the Irish National Adverse Events Study, although their definition differs slightly (10). Three medical errors and eight medical negligence claims resulted in severe harm. However, it is worth mentioning that these outcomes are not based on in-depth, multisource reviews and have no applicability to assumptions about the incidence of severe harm or death caused by medical error.

In many cases, additional procedures, medication and treatment were required. These utilise scarce resources such as labour, finances and time. However, the most important consequence of needing these additional interventions is the impact on the patient. Harm that was potentially preventable is distressing. For patients who experienced an incident, approximately 37% reported a permanent effect to their physical health, 63% reported a long-term or permanent impact on their emotional health and 43% experienced a long-term impact on their finances. These rates differ compared to a study which specifically examined cancer patients' perceptions of problematic events. Mazor et al. reported a higher rate of psychological or emotional harm at 96.2% but a lower rate of uncompensated financial costs at 37.2% (137).

The rates reported in this study are similar to a study conducted by NORC at the University of Chicago and the Institute for Healthcare which examined the general population. They found the rate of long-term or permanent impact on emotional health was 53% which compares more closely to 63% in this study. They also reported that the long-term or permanent impact on financial well-being was 41% which is similar to 43% in this study (121). In this study across all domains, substantially higher proportions of patients experienced effects compared to doctors. This is not surprising and it emphasises the importance of prevention of medical error and the improvement of patient safety.

The Impact on Doctors

A patient safety incident invariably involves two parties, the patient and the healthcare professional. An error does not have to be pursued in the legal system for it to have an impact on the doctor. The perception of having made a mistake alone can lead to significant emotional distress which can last the rest of a doctor's career and often there is a feeling that this cannot by disclosed to colleagues, family, or friends (160). This is despite the fact that needing

someone to talk to was found to be the most valued form of support (161). In an article examining how residents cope with medical errors during training, it was found that barriers to disclosing and discussing error included fear of judgement and shame (162). However, recovery and learning from medical errors can be supported by ensuring that an integral part of residents' training is having various forums which allow residents to reveal their experience of error to others, a process known as self-disclosure (163).

One in four doctors were prompted to consider early retirement due to their experiences of medical error or medical negligence claims. When examining just those who had experienced a medical negligence claim, this increased to 46% which is higher than the rate reported in a recent study looking at the impact of the medicolegal environment on surgical practice nationally. Conducted by Dr Mary-Elizabeth Tumelty of University College Cork, the study found that over a third of respondents were considering early retirement as a result of the current medicolegal climate in Ireland (39). It also reported that one in five would consider emigrating due to fear of being sued which is similar to the rate of 17% of respondents in this study (39).

Even doctors who have not experienced a medical error or medical negligence claim in study two have been prompted to consider early retirement because of their patient safety concerns. Twenty-one percent have been prompted to consider early retirement and 30% would consider working abroad. This is relevant for two reasons. As mentioned, Ireland faces significant issues with staff recruitment and retention currently (145-149). It cannot afford to lose more of its staff due to early retirement or relocation. Furthermore, in this study staffing concerns have been implicated as causative or contributory factors to medical errors and yet the experience of medical errors are causing doctors to consider leaving the profession in Ireland. Policymakers cannot underestimate the importance of addressing the issues they face regarding staff recruitment and retention in order to improve patient safety for the multiple of reasons outlined.

The Reporting of Patient Safety Events during Breast Cancer Care

The number of medical errors that went unreported was 23 out of a total of 61 (37.7%). Events identified in doctors' questionnaires were more likely to have been reported than those identified in patients'. A survey-based study of the public found a similar medical error reporting rate of 31% (121). The reporting rate of medical error in this study is higher than the HSE's rate of reporting incidents that resulted in clinical claims received between 2017 and

2021 to National Incident Management System (NIMS) which was 25% (164). However, this study's rate of reporting is lower than the estimated rate of patient safety incidents recorded in NIMS which is approximately 50% of incidents that are estimated to occur (11).

Barriers to reporting in this study included uncertainty about how to report and who to report to. Factors which may impact that are a lack of standardisation between different clinical sites resulting in a poor awareness about how to report (99). However, lessons cannot be learnt from incidents that are not captured. In a governance review, the Health Information Quality Authority (HIQA) recommended that the HSE and the SCA "formalise the governance structures for collaborative work on projects…to ensure the NIMIS data are used to their maximum potential" and that there is scope for an improved approach to the use of incident data to improve patient safety (165). Policymakers in both the HSE and SCA could focus on creating greater cohesion between the agencies to maximise incident data collection, analysis and distribution. As demonstrated in this study, positive outcomes can occur when events are reported. In 30% of reported incidents, improved communication between healthcare professionals was described as an outcome. In over 20% of cases, communication between the doctor and the patient improved.

The 'Who' of Patient Safety Events during Breast Cancer Care

Of those experienced an event, there was a mix of breast cancer subtypes. However the proportions of each subtype are different to official national figures (157). This may be due to the fact that almost one quarter of patients were unsure of their cancer type in this study. The level of awareness that patients have around their diagnosis can vary due to personal preference or receiving insufficient information. While the proportion of patients who were unsure seems significant, it compares well to international studies which have demonstrated that only approximately half of patients know their diagnosis accurately (166-168). Nevertheless, patient health literacy and awareness should be improved because it is estimated that aggregate harm could be reduced by up to 15% through health literacy improvement strategies (9).

With regards to doctors, radiologists were involved in a greater proportion of claims than errors. This finding reflects the international trend that breast cancer claims most commonly involve radiologists (52, 53). As mentioned, mammography is one of the most common areas of medical litigation among adults with international studies showing that up to a third of radiologists are considering withdrawing from mammogram interpretation due to medical malpractice concerns (63-66). Given that radiologists in this study were involved in a

greater proportion of claims than errors, further research would be warranted to explore the potentially negative consequences this may have on Ireland's national breast cancer screening programme.

Study Two

Representativeness of the Study Populations

The demographics and characteristics of the 184 patients who expressed their opinions on patient safety reflected the target national population of any person with breast cancer. The percentage of respondents who were female and male was 97.8% and 2.2% respectively which reflects the rarity of breast cancer in men (169). The proportion of patients under 50 years old was 30% and nationally this age group account for one quarter of patients with breast cancer (157). Patients were distributed across rural, suburban and urban destinations and both those with and without private insurance were represented. Thirty-six percent of patients were diagnosed in the past two years, 37% between three and six years ago and 26% seven or more years ago.

Other than those who were unsure of their breast cancer diagnosis, the subtype which accounted for the highest proportion was hormone-sensitive invasive ductal carcinoma. The percentage of those with HER2 positive breast cancer reflects the national average of 15% (157). Those who identified as having triple negative breast cancer are similar to internationally reported figures of between 10% and 15% (170). The demographics of the 154 patients who proceeded to answer questions in part two about their patient safety concerns were unchanged.

With regards to doctors, females accounted for 62.1% and therefore were over-represented as females account for 47% of doctors registered with the medical council (171). Forty-five percent of doctors were under 45. However, the majority were consultants and therefore 66% had ten or more years' experience. Those that did and did not work in private practice were evenly represented. Medical oncology, radiation oncology, radiology and surgery were represented similarly. Both palliative care medicine and pathology were underrepresented compared to the number of doctors on the Irish Medical Council registry (171).

Patients' and Doctors' Contrasting Views on Breast Cancer Care

The views of patients differed from doctors with regards to the importance of various aspects of breast cancer care. A greater proportion of patients rated 'knowing how to care for themself once leaving the healthcare setting' and being given 'sufficient instructions on how

to take prescribed medication' as moderately to very important compared to doctors. Both of these variables are concerned with 'patient engagement' which is defined by the World Health Organisation as "the process of building the capacity of patients, families, carers, as well as healthcare providers, to facilitate and support the active involvement of patients in their own care" (158). Another aspect that a higher proportion of patients found important was 'being given enough information about all treatments to make an informed decision'. This study found that patients place importance in aspects of healthcare that would enable and empower them to become involved in their own care. Healthcare settings should give greater consideration to providing support and greater access to information to facilitate patients engagement in their care.

Patient-centered care, though a complex area, can be succinctly defined as 'treating the patient as a unique individual' (172). The aspects of healthcare that doctors rated as important could be considered as fitting this definition. The included being attentive to the patient's needs', 'knowing the patient's diagnosis accurately', 'and 'having adequate communication with minimal medical jargon'. In recent years, there has been an increasing awareness of how medical terminology and confusing jargon can prevent patient understanding and lead to medical error (173). With two in five people calling for Irish healthcare professionals to reduce their use of jargon, it is positive that doctors find this important (174).

Patients' and Doctors' Contrasting Views on Patient Safety

Doctors have a pessimistic view of the current status of patient safety with over 40% feeling as though it has worsened in the healthcare environment in the past five years. This was a substantially higher proportion than just 13% of patients. However, patients in this study were more positive than those which took part in a large survey-based study conducted in the United States. Almost half of patients in this study reported that it had improved compared to 9% in the American study (121). In an Australian study of the public, an even smaller proportion of just 7.6% of respondents felt patient safety in healthcare had improved (84).

Patients were positive about medical error prevention measures with 57% agreeing they were adequate. This is similar to a finding in a study with over 1,500 Americans, where half of respondents felt that the health care system did have adequate measures in place (122). In this study, many more doctors than patients disagreed with the sentiment. In fact, half of doctors felt that were not adequate measures in place to prevent medical error. Greater research is warranted to investigate the reasons behind this pessimistic view and the consequences of it.

This study's findings that most doctors feel patient safety has worsened and that there are inadequate prevention measures in place should function as a canary in a coal mine for policy makers whose responsibility it is to improve patient safety, as if there is no action now an increase in medical errors may be inevitable.

In fact, in the narrative comments left by doctors in response to this question and the following question the inevitability of a degree of error was described as well as the ability of system measures to reduced, but not eliminate error. One doctor mentioned how error is intrinsic to all human processes and another commented that it would be statistically impossible not to err. Inevitability was a common theme in narrative comments made by patients also. There is a recognition that despite preventative measures and doctors' best efforts, errors will and do occur. This attitude is becoming more prevalent in recent years. The landmark report published in 1999 titled 'To Err Is Human: Building a Safer Health System' brought patient safety issues to the forefront and increased international awareness about medical error prevention (14).

Patients also commented on system factors such as a lack of resources as well as the importance of the preventative measures that are in place being followed. As previously described, staffing has been shown to impact patient safety and it is highlighted once again in this study with patients describing a lack of staffing as a challenge to medical error prevention. Some patients noted that certain areas of medicine may have inadequate measures or require additional attention while others simply did not have enough knowledge to comment one way or the other in response to the question. Engaging patients and improving their awareness of patient safety can advance improvement and learning and reduce adverse events (158).

Finally, one doctor described multidisciplinary meeting discussions as a remediating factor. As mentioned earlier, the multidisciplinary team is a central part of breast cancer care and it plays a key role in improving treatments, decision making and the overall quality of care (175). To what extent and by what means multidisciplinary meetings impact on medical error reduction is an area which could be investigated further.

The Impact of COVID-19 on Patient Safety

Four patients left narrative comments concerned with the impact of COVID-19 on patient safety. Two patients felt as though the pandemic had positively affected patient safety by improving cleanliness and increasing awareness for both patients and healthcare workers about health and safety concerns. However, two patients felt that the pandemic had left a

negative impact on patient safety with one citing the inability of doctors to physically see patients. The World Health Organisation conducted a rapid review of 'Implications of the COVID-19 pandemic for patient safety' and found that the pandemic had "revealed a range of safety gaps across all core components of health systems, at all levels" and that "disruptions to systems and processes of care affected previously known safety risks and sources of harm in health care and introduced new ones" (176). However, it noted that the true extent of avoidable harm attributable to the pandemic is yet to be fully understood. Assessing in detail its impact on patients' perceptions and experiences of breast cancer care is an area that could be further researched.

Patients' and Doctors' Contrasting Views on Medical Error

The generally positive outlook of patients is evident again in their views on experiencing a medical error in the future. Less than 9% of patients felt it was moderately to very likely they would experience a medical error. Perhaps a testament to a growing acknowledgment of the inevitability of error, 46% felt it was possible. However, close to one in three patients felt it was not likely.

Doctors in this study were worried about causing or contributing to a medical error in the future with almost nine in ten doctors reporting some level of concern. Just three of the 116 doctors were not concerned. In contrast, 43 described themselves as very concerned. An awareness for the potential of occurrence of a medical error is important. However, excessive or extreme fear of causing a medical error can lead to negative defensive medical practices such as over-investigation, excessive prescribing and unnecessary hospitalisation which have implications for the patient as well as the finite resources of a healthcare system (39, 177). Therefore, it is important to prepare doctors, particularly those in their early stages of their career, about how to manage with medical error so that maladaptive, defensive coping strategies are not adopted (178).

Doctors' Concerns About Medical Error

Part two of study two measured the levels of concern of 44 doctors with regards the occurrence of medical error. The most common error doctors were concerned about was communication errors with four in five reporting some level of concern. As outlined in study one, communication was implicated in four of the five most highly rated causative or contributing factors to incidents. Therefore, even those who have not experienced a medical error recognise that problems with communication are a risk to patient safety. Unsurprisingly,

the internationally recognised importance of adequate and appropriate communication is once again highlighted in this study (20, 67, 136, 138, 141, 179).

For doctors who had not experienced a medical error, inadequate verbal communication between different clinical sites was the communication factor that was most concerning, followed by inadequate written communication between different clinical sites. Prior to the introduction of the National Cancer Control Programme (NCCP), cancer care services were fragmented across the country. Since its establishment, nine designated centres for oncological surgery now exist in which the majority, but not all, oncological surgery takes place. Furthermore, 17 additional public hospitals provide systemic anti-cancer therapy (4). While progress has been made to unify and standardise Irish cancer care, concern among doctors about communication between clinical sites contributing to medical error may reflect that there is still room to improve coordination and communication of care across cancer services.

The introduction of a national electronic medical record would be one step toward addressing this and should be considered a priority for policymakers (154, 155). In fact, almost 90% of doctors in this study believed that better systems for record-keeping, appointment and follow-up as well as increased infrastructure would improve patient safety and reduced the risk of medical error. Unfortunately, significant gaps in Ireland's data infrastructure and health information systems have been highlighted by a report by the Economic and Social Research Institute (180). With just 0.85% of the healthcare budget being spent on health technology compared to the European average of 2% to 3%, it is unsurprising that the long-standing aspirations of introducing individual health identifiers and electronic health records are yet to be realised (180).

The settings which the most doctors were concerned about a medical error occurring were the emergency department followed by admission on a ward and the outpatient department. The emergency department was the setting of a small number of events in study one, however was among the few settings with a median degree of harm of three. Therefore, doctors' concerns could be seen as warranted. In contrast, admission on a ward was the setting for five events out of a total of 83 in study one and had one of the lowest median degrees of harm of just one. The reasons behind a negative perception of patient safety on inpatient wards could be a topic of further research.

In nine cases where doctors reported their concerns the outcome was, unfortunately, 'nothing'. A review of studies looking at the influencing factors of healthcare professionals

speaking up about patient safety concerns noted that the perceived efficacy of doing so, such as "lack of impact" was a common barrier (181). A study which looked specifically at the reporting of safety concerns by oncology nurses and doctors found that "remaining silent about safety concerns is a common phenomenon in oncology" (182). Reporting concerns about and experiences of medical error and patient safety risk is essential if healthcare systems are to learn and improve. Achieving improvement in the prevalence of reporting can be achieved by addressing this perceived lack of impact, giving feedback to reporters and simplifying the process (181).

Patients' Concerns About Medical Error

This study measured the levels of concern of 154 patients with regards to the occurrence of medical error. The type of event which concerned the greatest number of patients was failure or delay to correctly. Therefore, patients who have not experienced a medical error or medical negligence claim are most concerned about the type of event that was statistically most common in study one. The clinical stage which the highest proportion of patients were concerned about was during initial diagnostic investigations. Once again, the importance of diagnostic pathways is emphasised (131-134).

Only 13 of the 154 patients reported concerns. The most common barrier for reporting was a lack of confidence in the difference it would make. However, the importance of patients voicing their concerns is evident in the fact that when they did, communication was reported to have improved. A study which examined the impact of an intervention of active outreach to patients undergoing cancer treatment found that it "can provide healthcare teams and systems the opportunity to offer a real-time response to the patient, identify where system improvements are needed, and implement policies, procedures, or programs to prevent recurrences" (135). The introduction of an outreach programme such as this might encourage reporting and increase patient engagement.

Challenges Faced During this Study

As mentioned in the methodology section, this study intended to utilise national data from the SCA, data from Irish Medical Council (IMC) complaints and data from the NIMS system. Limited resources within the SCA were cited as the reason for not being able to provide national data despite support from the National Cancer Control Programme (NCCP). Confidentiality constraints were a barrier to the IMC providing data despite reassurances that all identifiers would be removed and the study was quantitative in nature thus could maintain

anonymity. Lastly, the NIMS database's user face and functionality is archaic and it was not technologically feasible to filter the incidents to include those which occurred during breast cancer care.

Despite attempted engagement with multiple agencies at local and national levels, the quantity and quality of data sources for this study were less than what had been hoped for. In other countries, including the UK, there is a greater emphasis on the dissemination and use of national incident data. The NHS Resolution, which is the UK's equivalent of the SCA, launched 'Learning from Litigation Claims: GIRFT and NHS Resolution best practice guide for clinicians and managers' (72). Since then, access to data related to claims and standardised analyses have improved. The GIRFT programme advocates and facilitates practical, clinical changes based on learnings and recommendations from NHS claims (72, 74-76). Implementing a similar programme here could allow learnings from previous claims to inform patient safety improvement strategies.

As well as the GIRFT litigation workstream, the NHS has data from their National Reporting and Learning System available online in accessible formats with an emphasis on consistency across all data users. In addition, Organisation Patient Safety Incident Reports are published every six months (165). Data sharing is key to facilitating system-wide improvements and the HIQA governance review has advised that "the HSE, with support from the SCA, to develop an overarching data quality framework" (165). The SCA has a unique position in that it manages 90% of all clinical claims in Ireland and therefore has large amounts of data related to patient safety though a claims perspective (21). The SCA has an obligation to advise and assist the HSE on the management of litigation risks and improving patient safety in order to minimise national clinical claims and their liabilities. Despite having the legislative remit, the SCA does not routinely evaluate the implementation of their recommendations. These evaluations, either conducted primarily by the SCA or through support for national data for studies such this, could reduce clinical claims and improve patient safety (23, 77).

Strengths and Limitations

Patient safety research is vital to reduce the incidence and subsequent harm caused by medical error. However, barriers to progress include a lack of internationally agreed approaches and standardised measures (12). This study is subject to the limitations of much of patient safety research which include outcome and hindsight bias (70). The retrospective nature of this proposal was felt to be more time and cost effective than if it were conducted

prospectively, however as a result it was sensitive to selection bias. Another limitation is this study's reliance on self-reported events from patients and doctors (183, 184)

The strength of this study lies in its originality. Patient-reported events and concerns have been explored in those with cancer (83, 135). Studies have reported that up to a quarter of patients with cancer believe something in their care has gone wrong (137, 185, 186). However, to our knowledge, there are no studies assessing the experiences and views of patients with breast cancer specifically. Secondly, this study examines patient safety incidents that have occurred during the care of multiple specialities and highlights these through a novel approach of trajectory mapping. Patients with breast cancer must navigate through many modalities of treatment in many clinical settings. There has been one large study of medical oncology outpatients' perceived experiences of errors but this is one medical specialty in one healthcare setting (187). Doctors who provide breast cancer care face unique challenges that other clinicians don't such as screening, toxic therapies, partaking in multidisciplinary care and managing the psychosocial aspects of cancer. This study illuminates the types of medical errors in cancer care. Through awareness, cognisant preventative measures can be explored and implemented.

This study's participants are largely representative of the target population of people who have breast cancer. Almost all patients were female which is in keeping with the national finding that male breast cancer is rare. Annually, 37 men are diagnosed in Ireland compared to approximately 3,600 women (169). Nationally one quarter of breast cancer patients are under 50 years old and in this study that proportion was two fifths (157). The percentage of patients who had private health insurance in this study was 56.7% which is similar to the percentage of Irish population which is 47.1% (188). The characteristics of doctors within this study were reasonably well balanced. The involvement of doctors in private practice were closely split. Palliative care was underrepresented given that there are 144 doctors on the Irish Medical Council registry who have reported as working in palliative care (171). Females are slightly over-represented in this study given that 47% of doctors registered with the Irish Medical Council are female (171). The vast majority of respondents were consultants which would account for the length of their experience with breast cancer patients being skewed toward longer time periods. With regards to relevance, approximately 60% of all events in this study occurred in the past four years and only 14% occurred over ten years ago, ensuring the relevance to current clinical practice.

Conclusion

The characteristics of patient safety incidents which occurred during breast cancer care are varied and reflect the multifaceted nature of breast cancer management. Communication and diagnostic pathways have been shown in this study to be important areas of patient safety risk which require dedicated attention and resources. Doctors reported high levels of concern about many aspects of breast cancer care compared to patients and addressing these should be a priority for all cancer services in order to improve patient safety and reduce medical error.

How can healthcare systems better learn from previous patient safety incidents? An initial step could be the development of a best practice guide for clinicians and managers to aid learning from patient safety incidents. This may address how to access comprehensive and reliable incident and claims-related data as often this initial step presents bureaucratic challenges as demonstrated in this study. The guide could suggest methods for assessing the data in a standardised manner by relevant senior clinicians and with the assistance of experienced medical lawyers so actionable recommendations can be made and that comparisons can be made across different groups. Implementing system-wide improvements can lead to reduced harm and safer care (23, 77). Healthcare organisations must also tackle the 'paradox plaguing patient-centred care' as described by Mazor et al. This is that, despite the many calls for patient engagement, their views and perceptions are often ignore and seldom translate into tangible change (189). This study is a step in the right direction, however greater research should be done to include all stakeholders. Without significant action, the patient safety trajectories of breast cancer patients will suffer.

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Appendices

Appendix A – Patient Questionnaire for Study One

Medical Error and Patient Safety in Breast Cancer Care - Patient Survey

This short survey is conducted by a research team from Cork University Hospital and University College Cork working under Professor Seamus O'Reilly (National Specialty Director, Medical Oncology) as part of a study titled 'Defining and Remediating the Patient Safety Trajectory of Breast Cancer at a National Cancer Centre'.

Our aim is to investigate the nature and consequences of medical error as well as the patient safety environment for breast cancer patients in Ireland. We very much appreciate your participation in this short survey which will take 5-10 minutes.

Please note that this survey is completely anonymous. Respondents will not be identifiable in any way. All answers are confidential and will not be shared or distributed to any third party.

The study has been granted ethical approval by the Clinical Research Ethics Committee of the Cork Teaching Hospitals. All data will be held for the statutory period in password protected cloud-based storage and is untraceable back to the individual respondents. Data will be treated in accordance with GDPR legislation and UCC's Code of Research Conduct.

Participation in this survey is voluntary. If you give your consent to take part in the study continue on to answer the first question. If you do not give consent, please return the survey; no information has been collected. Please note once you have completed the study and submitted your answers it will not be possible to withdraw your data as it will be anonymised.

* Required

Section 1

1. How would you describe yourself? * *(Tick only one circle)*

- ○ Female
- ○ Male
- ○ Prefer not to say

2. What age are you? * *(Tick only one circle)*

- ○ 18 - 24
- ○ 25 - 29
- ○ 30 - 34
- ○ 35 - 39
- ○ 40 - 44
- ○ 45 - 49
- ○ 50 - 54
- ○ 55 - 59
- ○ 60 +

3. Do you, or any member of your household, work in a medical or health-related field? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Other

4. How would you describe where you live? * *(Tick only one circle)*

- ○ City
- ○ Suburb
- ○ Small town
- ○ Rural area
- ○ Other

5. As of today, are you covered by a private health insurance plan? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Unsure

6. When were you first diagnosed with breast cancer? * *(Tick only one circle)*

- ○ Within the past year
- ○ 1 - 2 years ago
- ○ 3 - 4 years ago
- ○ 5 - 6 years ago
- ○ 7 - 8 years ago
- ○ 9 - 10 years ago
- ○ Over 10 years ago
- ○ Other

7. What type of breast cancer do you have? * *(Tick only one circle)*

- ○ Ductal carcinoma in situ
- ○ Lobular carcinoma in situ
- ○ Invasive ductal carcinoma - oestrogen receptor and progesterone receptor positive
- ○ Invasive ductal carcinoma - HER2 positive
- ○ Invasive ductal carcinoma - triple negative
- ○ Invasive lobular carcinoma
- ○ Inflammatory breast cancer
- ○ Metastatic breast cancer
- ○ Unsure

Section 2: Your Experience of Medical Error in Breast Cancer Care

These are the World Health Organisation definitions for terms utilised in this section:

Patient safety is the prevention of errors and adverse effects to patients associated with healthcare

A **medical error** is an adverse event or near miss that is preventable with the current state of medical knowledge

An **adverse event** is an incident which resulted in harm to a patient

A near miss is an incident that did not reach the patient

8. Over the course of your breast cancer journey, have you been involved in an event where you feel a medical error occurred? * *(Tick only one circle)*

- ○ Yes
  → ***Proceed to question 9 on this page***
- ○ No

9. Regarding the most memorable medical error during your breast cancer journey, did the following it result in a medical negligence claim (i.e. lawsuit)? * *(Tick only one circle)*

- ○ Yes
  → ***Skip Section 3***
- ○ No
  → ***Skip to Section 4***

Section 3: Your Experience of Medical Error in Breast Cancer Care

These are the World Health Organisation definitions for terms utilised in the following questions:

Patient safety is the prevention of errors and adverse effects to patients associated with healthcare

A **medical error** is an adverse event or near miss that is preventable with the current state of medical knowledge

An **adverse event** is an incident which resulted in harm to a patient

A near miss is an incident that did not reach the patient

Please answer the following questions based on ***one*** event where you feel a medical error occurred during your breast cancer journey and had the ***greatest impact on you***.

10. Did harm occur as a result of the event? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Other

11. Describe briefly the harm caused by the event for you. *

_____

_____

_____

_____

12. When did the event occur? * *(Tick only one circle)*

- ○ Within the past year
- ○ 1 - 2 years ago
- ○ 3 - 4 years ago
- ○ 5 - 6 years ago
- ○ 7 - 8 years ago
- ○ 9 - 10 years ago
- ○ Over 10 years ago
- ○ Other

13. How did you become aware that the event had occurred? * *(Tick only one circle)*

- ○ You discovered it yourself
- ○ The healthcare professional involved informed you
- ○ A family member/ friend informed you
- ○ Another healthcare professional informed you
- ○ The site where it occurred informed you
- ○ Other

14. What was the nature of the event? * *(Tick all that apply)*

- ○ Failure/delay to diagnose correctly
- ○ Failure/delay to provide the correct treatment
- ○ Failure/delay to provide treatment in a timely manner
- ○ Failure/delay of adequate follow-up
- ○ A problem directly arising from a medical procedure or operation
- ○ Errors related to prescribing of drugs/fluids (incl. blood)
- ○ Errors related to administration of drugs/fluids (incl. blood)
- ○ Errors related to monitoring of drugs/fluids (incl. blood)
- ○ Failure/delay to appreciate your overall condition
- ○ Failure/delay to prevent, control or manage infection
- ○ Administrative errors
- ○ Communication errors
- ○ Errors related to reporting of radiological and laboratory results
- ○ Equipment malfunction
- ○ Other

15. Where did the event occur? * *(Tick only one circle)*

- ○ Emergency department
- ○ Admission on a ward
- ○ Shortly before a procedure
- ○ During a procedure
- ○ Shortly after a procedural
- ○ Outpatient department
- ○ Intensive care unit
- ○ General practice
- ○ Other

16. At what point during the your breast cancer journey did the event occur? * *(Tick only one circle)*

- ○ Before formal diagnosis
- ○ During initial diagnostic investigations
- ○ Investigations post-diagnosis
- ○ Chemotherapy before surgery
- ○ Radiotherapy before surgery
- ○ Surgical management
- ○ Chemotherapy after surgery
- ○ Radiotherapy after surgery
- ○ Follow-up
- ○ After discharge from follow-up
- ○ Other

17. Which of the following factors caused or contributed to the event? * *(Tick all that apply)*

- ○ Inadequate verbal communication with you
- ○ Inadequate written communication with you
- ○ Inadequate verbal communication between healthcare professionals involved in your care
- ○ Inadequate written communication between healthcare professionals involved in your care
- ○ Inadequate verbal communication between different clinical sites involved in your care
- ○ Inadequate written communication between different clinical sites involved in your care
- ○ Poor relationship between you and your healthcare professional
- ○ No standardised referral pathways to other services or consultants
- ○ Staff working outside of their expertise/experience
- ○ Lack of staff skills/knowledge
- ○ Inadequate senior leadership
- ○ Inadequate supervision of staff-in-training
- ○ Locum/non-permanent staff
- ○ Inadequate documentation
- ○ Inadequate staffing
- ○ Staff contending with a very high workload
- ○ Poorly organised systems for record keeping
- ○ Poorly organised systems for appointments and follow-up
- ○ Lack of essential funding

- ○ Lack of essential infrastructure
- ○ Poor co-ordination of overall service

18. How could the event have been prevented?* *(Tick all that apply)*

- ○ Improved communication with you
- ○ Improved communication between healthcare professionals
- ○ Improved communication between different clinical sites involved in your care
- ○ Better organised systems for record keeping, appointments, and follow-up
- ○ Standardised referral pathways to other services or consultants
- ○ Increased recruitment of staff
- ○ Increased annual leave for staff
- ○ Increased study leave for staff
- ○ More training for staff in the specific department/ speciality
- ○ Improved access to services
- ○ Reduced waiting times
- ○ Increased funding
- ○ Increased infrastructure
- ○ More conscientious healthcare professionals
- ○ Better qualified healthcare professionals
- ○ It could not have been prevented

19. Were additional procedures performed as a result of the event? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Not relevant
- ○ Other

20. Were additional medications administered as a result of the event? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Not relevant
- ○ Other

21. Was additional treatment given as a result of the event? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Not relevant

- ○ Other

22. Was the event reported? * *(Tick only one circle)*

- ○ No
- ○ Yes, by you
- ○ Yes, by the healthcare professional involved
- ○ Yes, by another healthcare professional
- ○ Yes, by your family member/ friend
- ○ Other

23. If yes, who was the event reported to? *(Tick all that apply)*

- ○ Management at the site involved
- ○ A healthcare professional directly involved in your care
- ○ Lawyer
- ○ The Medical Council or appropriate national regulatory body
- ○ Another healthcare professional
- ○ Patient advocacy group
- ○ Other

24. If yes, what was the outcome of reporting the event? *(Tick all that apply)*

- ○ Improved communication with you
- ○ Improved communication between healthcare professionals
- ○ Improved communication between different clinical sites involved in your care
- ○ Better organised systems for record keeping, appointments, and follow-up
- ○ Implementation of standardised referral pathways to other services or consultants
- ○ Increased recruitment of staff
- ○ Increased annual/ study leave for staff
- ○ More training for staff in the specific department/speciality
- ○ Improved access to services
- ○ Reduced waiting times
- ○ Increased funding
- ○ Increased infrastructure
- ○ Nothing
- ○ Unsure
- ○ Other

25. If no, what were the barriers to reporting the event? *(Tick all that apply)*

- ○ Unsure of how to report your concerns
- ○ Unsure of who to report your concerns to
- ○ Worried it will impact on the care you receive
- ○ Worried it will change the healthcare professional's opinion of you
- ○ No opportunity to choose an alternative healthcare professional
- ○ No established culture of reporting
- ○ Lack of confidence in the difference it would make
- ○ Emotional burden
- ○ Financial burden
- ○ Other

26. Regarding the event, what was the effect on your physical and emotional health as well as your finances? * *(Tick one circle for each row)*

	No effect	Short-term effect	Long-term effect	Permanent effect
Physical health	○	○	○	○
Emotional health	○	○	○	○
Finances	○	○	○	○

18

If you have completed Section 3, this is the end of the survey.

Section 4: Your Experience of Medical Negligence Litigation in Breast Cancer Care

These are the World Health Organisation definitions for terms utilised in the following questions:

Patient safety is the prevention of errors and adverse effects to patients associated with healthcare

A **medical error** is an adverse event or near miss that is preventable with the current state of medical knowledge

An **adverse event** is an incident which resulted in harm to a patient

A near miss is an incident that did not reach the patient

27. Briefly describe the consequence(s) of the event on you. *

_____

_____

_____

_____

28. When did the event occur? **(Tick only one circle)*

- ○ Within the past year
- ○ 1 - 2 years ago
- ○ 3 - 4 years ago
- ○ 5 - 6 years ago
- ○ 7 - 8 years ago
- ○ 9 - 10 years ago
- ○ Over 10 years ago
- ○ Other

29. How did you become aware that the event had occurred? * *(Tick only one circle)*

- ○ You discovered it yourself
- ○ The healthcare professional involved informed you
- ○ A family member/ friend informed you
- ○ Another healthcare professional informed you
- ○ The site where it occurred informed you
- ○ Other

30. What was the nature of the event? * *(Tick all that apply)*

- ○ Failure/delay to diagnose correctly
- ○ Failure/delay to provide the correct treatment
- ○ Failure/delay to provide treatment in a timely manner
- ○ Failure/delay of adequate follow-up
- ○ A problem directly arising from a medical procedure or operation
- ○ Errors related to prescribing of drugs/fluids (incl. blood)
- ○ Errors related to administration of drugs/fluids (incl. blood)
- ○ Errors related to monitoring of drugs/fluids (incl. blood)
- ○ Failure/delay to appreciate your overall condition
- ○ Failure/delay to prevent, control or manage infection
- ○ Administrative errors
- ○ Communication errors
- ○ Errors related to reporting of radiological and laboratory results
- ○ Equipment malfunction
- ○ Other

31. Where did the event occur? * *(Tick only one circle)*

- ○ Emergency department
- ○ Admission on a ward
- ○ Shortly before a procedure
- ○ During a procedure
- ○ Shortly after a procedural
- ○ Outpatient department
- ○ Intensive care unit
- ○ General practice
- ○ Other

32. At what point during the your breast cancer journey did the event occur? * *(Tick only one circle)*

- ○ Before formal diagnosis
- ○ During initial diagnostic investigations
- ○ Investigations post-diagnosis
- ○ Chemotherapy before surgery
- ○ Radiotherapy before surgery
- ○ Surgical management

- ○ Chemotherapy after surgery
- ○ Radiotherapy after surgery
- ○ Follow-up
- ○ After discharge from follow-up
- ○ Other

33. Which of the following factors caused or contributed to the event? * *(Tick all that apply)*

- ○ Inadequate verbal communication with you
- ○ Inadequate written communication with you
- ○ Inadequate verbal communication between healthcare professionals involved in your care
- ○ Inadequate written communication between healthcare professionals involved in your care
- ○ Inadequate verbal communication between different clinical sites involved in your care
- ○ Inadequate written communication between different clinical sites involved in your care
- ○ Poor relationship between you and your healthcare professional
- ○ Poorly organised systems for record keeping
- ○ Poorly organised systems for appointments and follow-up
- ○ No standardised referral pathways to other services or consultants
- ○ Staff working outside of their expertise/experience
- ○ Lack of staff skills/knowledge
- ○ Inadequate senior leadership
- ○ Inadequate supervision of staff-in-training
- ○ Locum/non-permanent staff
- ○ Inadequate documentation
- ○ Inadequate staffing
- ○ Staff contending with a very high workload
- ○ Overworked/ burnt-out/ stressed staff
- ○ Lack of equipment/equipment failure
- ○ Lack of essential funding
- ○ Lack of essential infrastructure
- ○ Poor co-ordination of overall service
- ○ Other

34. How could the event have been prevented?* *(Tick all that apply)*

- ○ Improved communication with you
- ○ Improved communication between healthcare professionals
- ○ Improved communication between different clinical sites involved in your care
- ○ Better organised systems for record keeping, appointments, and follow-up
- ○ Standardised referral pathways to other services or consultants
- ○ Increased recruitment of staff
- ○ Increased annual leave for staff
- ○ Increased study leave for staff
- ○ More training for staff in the specific department/ speciality
- ○ Improved access to services
- ○ Reduced waiting times
- ○ Increased funding
- ○ Increased infrastructure
- ○ More conscientious healthcare professionals
- ○ Better qualified healthcare professionals
- ○ It could not have been prevented
- ○ Other

35. Were additional procedures performed as a result of the event? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Not relevant
- ○ Other

36. Were additional medications administered as a result of the event? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Not relevant
- ○ Other

37. Was additional treatment given as a result of the event? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Not relevant
- ○ Other

38. What was the outcome of medical negligence litigation/ claim (i.e. lawsuit)? * *(Tick only one circle)*

- ○ It was withdrawn
- ○ It was settled out of court
- ○ It proceeded to trial
- ○ It went to mediation
- ○ Other

39. Regarding the event and the subsequent medical negligence litigation/ claim (i.e. lawsuit), what was the effect on your physical and emotional health as well as your finances? * *(Tick one circle for each row)*

	No effect	Short-term effect	Long-term effect	Permanent effect
Physical health	○	○	○	○
Emotional health	○	○	○	○
Finances	○	○	○	○

If you have completed Section 4, this is the end of the survey.

Appendix B – Doctor Questionnaire for Study One

Medical Error and Patient Safety in Breast Cancer Care - Healthcare Professional Survey

This short survey is conducted by a research team from Cork University Hospital and University College Cork working under Professor Seamus O'Reilly (National Specialty Director, Medical Oncology) and Mr Martin O'Sullivan (Lead of the Breast Cancer Group National Cancer Control Programme) as part of a study titled 'Defining and Remediating the Patient Safety Trajectory of Breast Cancer at a National Cancer Centre'

Our aim is to investigate the nature and consequences of medical error as well as the patient safety environment for breast cancer patients in Ireland. We very much appreciate your participation in this short survey which will take a few minutes.

Please note that this survey is completely anonymous. Respondents will not be identifiable in any way. All answers are confidential and will not be shared or distributed to any third party.

The study has been granted ethical approval by the Clinical Research Ethics Committee of the Cork Teaching Hospitals. All data will be held for the statutory period in password protected cloud-based storage and is untraceable back to the individual respondents. Data will be treated in accordance with GDPR legislation and UCC's Code of Research Conduct.

Participation in this survey is voluntary. If you give your consent to take part in the study continue on to answer the first question. If you do not give consent, please exit the page; no information has been collected. Please note once you have completed the study and submitted your answers it will not be possible to withdraw your data as it will be anonymised.

How would you describe yourself? *

- [ ] Female
- [ ] Male
- [ ] Prefer not to say

What age are you? *

- [ ] 18-24
- [ ] 25-29

- [ ] 30-34
- [ ] 35-39
- [ ] 40-44
- [ ] 45-49
- [ ] 50-54
- [ ] 55-59
- [ ] 60+

What is your job title? *

- [ ] Consultant
- [ ] Senior registrar
- [ ] Junior registrar
- [ ] Specialist registrar
- [ ] Senior house officer
- [ ] Intern
- [ ] Other

What field of medicine do you work in? *

- [ ] Medical oncology
- [ ] Radiation oncology

- [ ] Surgery
- [ ] Radiology
- [ ] Pathology
- [ ] Palliative medicine
- [ ] Other

How many years' experience with breast cancer do you have? *

- [ ] Less than 1 year
- [ ] 1 - 2 years
- [ ] 3 - 5 years
- [ ] 5 - 10 years
- [ ] 10 - 20 years
- [ ] >20 years

Do you also work in a private capacity? *

- [ ] Yes
- [ ] No
- [ ] Other

Section 2: Your Experience of Medical Error in Breast Cancer Care

The following are the World Health Organisation definitions for terms utilised in this section:

Patient safety = the prevention of errors and adverse effects to patients associated with healthcare

Medical error = an adverse event or near miss that is preventable with the current state of medical knowledge

An adverse event = an incident which resulted in harm to a patient

A near miss = an incident that did not reach the patient

When caring for breast cancer patients, have you been involved in an event where a medical error has occurred? *

- [ ] Yes
- [ ] No

Regarding the most memorable medical error involving a breast cancer patient, did it result in a medical negligence claim? *

- [ ] Yes
- [ ] No

Section 3: Your Experience of Medical Error in Breast Cancer Care

Please answer all questions based on one medical error which had the greatest impact on you.

Did harm occur as a result of the medical error? *

- [ ] Yes
- [ ] No
- [ ] Other

If yes, describe briefly the harm caused by the medical error.

When did the medical error occur? *

- [ ] Within the past year
- [ ] 1 - 2 years ago
- [ ] 3 - 4 years ago
- [ ] 5 - 6 years ago
- [ ] 7 - 8 years ago
- [ ] 9 - 10 years ago

- [ ] Over 10 years ago
- [ ] Other

How did you become aware that the medical error had occurred? (Check all that apply) *

- [ ] You discovered it yourself
- [ ] The patient involved informed you
- [ ] A family member/friend of the patient informed you
- [ ] Another healthcare professional informed you
- [ ] The site where it occurred informed you
- [ ] Letter from solicitor
- [ ] Other

What was the nature of the medical error? (Check all that apply) *

- [ ] Failure or delay to diagnose correctly
- [ ] Failure or delay to provide the correct treatment
- [ ] Failure or delay to provide treatment in a timely manner
- [ ] Failure or delay in adequate follow-up
- [ ] A problem directly arising from a medical procedure or operation
- [ ] Errors related to **prescribing** of drugs/fluids (incl. blood)
- [ ] Errors related to **administration** of drugs/fluids (incl. blood)

- [ ] Errors related to **monitoring** of drugs/fluids (incl. blood)
- [ ] Failure or delay to appreciate patients' overall condition
- [ ] Failure or delay to prevent/control/manage infection
- [ ] Administrative errors
- [ ] Communication errors
- [ ] Errors related to reporting of radiological and laboratory results
- [ ] Equipment malfunction
- [ ] Other

Where did the medical error occur? *

- [ ] Emergency department
- [ ] Admission on a ward
- [ ] Shortly before a procedure
- [ ] During a procedure
- [ ] Shortly after a procedure
- [ ] Outpatient department
- [ ] Intensive care unit
- [ ] General practice
- [ ] Other

At what point during the patient's breast cancer journey did the medical error occur? *

- [ ] Before formal diagnosis
- [ ] During initial diagnostic investigations
- [ ] Investigations post-diagnosis
- [ ] Neoadjuvant chemotherapy
- [ ] Neoadjuvant radiotherapy
- [ ] Surgical management
- [ ] Adjuvant chemotherapy
- [ ] Adjuvant radiotherapy
- [ ] Follow-up
- [ ] After discharge from follow-up
- [ ] Other

Which of the following factors caused or contributed to the medical error? (Check all that apply) *

- [ ] Inadequate **verbal** communication **with the patient**
- [ ] Inadequate **written** communication **with the patient**
- [ ] Inadequate **verbal** communication **between healthcare professionals** involved in patients' care
- [ ] Inadequate **written** communication **between healthcare professionals** involved in patients' care

- [ ] Inadequate **verbal** communication **between differing clinical sites** involved in patients' care
- [ ] Inadequate **written** communication **between differing clinical sites** involved in patients' care
- [ ] Poor patient-healthcare professional relationship
- [ ] Poorly organised systems for record keeping
- [ ] Poorly organised systems for appointments and follow-up
- [ ] No standardised referral pathways to other services or consultants
- [ ] Staff working outside of their expertise/experience
- [ ] Lack of staff skills and knowledge
- [ ] Inadequate senior leadership
- [ ] Inadequate supervision of staff-in-training
- [ ] Locum/non-permanent staff
- [ ] Lack of evidence-based guidelines
- [ ] Failure to use guidelines
- [ ] Lack of national and/or local protocol
- [ ] Failure to use national and/or local protocol
- [ ] Inadequate documentation
- [ ] Inadequate staffing
- [ ] Staff contending with a very high workload
- [ ] Overworked/ burnt-out/stressed staff
- [ ] Lack of equipment/equipment failure

- [ ] Lack of essential funding
- [ ] Lack of essential infrastructure
- [ ] Poor co-ordination of overall service
- [ ] Other

How could the medical error have been prevented? (Check all that apply) *

- [ ] Improved communication **with patients**
- [ ] Improved communication **between healthcare professionals**
- [ ] Improved communication **between differing clinical sites** involved in patients' care
- [ ] Better organised systems for record keeping, appointments, and follow-up
- [ ] Standardised referral pathways to other services or consultants
- [ ] Increased recruitment of staff
- [ ] Increased annual leave for staff
- [ ] Increased study leave for staff
- [ ] More training for staff in the specific department/speciality
- [ ] Implementation of evidence-based guidelines
- [ ] Implementation of a national and/or local protocol
- [ ] Improved access to services
- [ ] Reduced waiting times
- [ ] Increased funding

- [ ] Increased infrastructure
- [ ] More conscientious healthcare professionals
- [ ] Better qualified healthcare professionals
- [ ] It could not have been prevented
- [ ] Other

Were additional procedures performed as a result of the medical error? *

- [ ] Yes
- [ ] No
- [ ] Not relevant
- [ ] Other

Were additional medications administered as a result of the medical error? *

- [ ] Yes
- [ ] No
- [ ] Not relevant
- [ ] Other

Was additional treatment given as a result of the medical error? *

- [ ] Yes

- [ ] No
- [ ] Not relevant
- [ ] Other

Was the medical error reported? *

- [ ] No -> skip next two questions
- [ ] Yes, by you
- [ ] Yes, by the patient involved
- [ ] Yes, by family member/ friend of the patient
- [ ] Yes, by another healthcare professional
- [ ] Other

If yes, who was the medical error reported to? (Check all that apply)

- [ ] Management at the site involved
- [ ] National incident management system (NIMS)
- [ ] Lawyer
- [ ] The Medical Council or appropriate national regulatory body
- [ ] Another health care professional
- [ ] Patient advocacy group
- [ ] Medical Protection Society/ Medical Defence Organisation

- [ ] Other

If yes, what was the outcome of reporting the medical error? (Check all that apply)

- [ ] Improved communication with patient
- [ ] Improved communication between healthcare professionals
- [ ] Improved communication between differing clinical sites involved in patients' care
- [ ] Better organised systems for record keeping, appointments, and follow-up
- [ ] Implementation of standardised referral pathways to other services or consultants
- [ ] Increased recruitment of staff
- [ ] Increased annual/ study leave for staff
- [ ] More training for staff in the specific department/speciality
- [ ] Implementation of evidence-based guidelines
- [ ] Implementation of a national and/or local protocol
- [ ] Improved access to services
- [ ] Reduced waiting times
- [ ] Increased funding
- [ ] Increased infrastructure
- [ ] Nothing
- [ ] Unsure
- [ ] Other

If no, what were the barriers to reporting the medical error? (Check all that apply)

- [ ] Unsure of how to report your concerns
- [ ] Unsure of who to report your concerns to
- [ ] Worried it will impact on your current job/career
- [ ] Worried it will change your colleagues' opinion of you
- [ ] No opportunity to choose an alternative employer
- [ ] No established culture of reporting
- [ ] Lack of confidence in the difference it would make
- [ ] Emotional burden
- [ ] Financial burden
- [ ] Other

Regarding the medical error, what was the effect on your physical and emotional health as well as your finances? *

	No effect	Short-term effect	Long-term effect	Permanent effect
Physical health	☐	☐	☐	☐
Emotional health	☐	☐	☐	☐
Finances	☐	☐	☐	☐

Have your experiences of medical error involving breast cancer patients prompted you to consider early retirement? *

- [ ] Yes

- [ ] No
- [ ] Other

Have your experiences of medical error involving breast cancer patients prompted you to consider working in another country? *

- [ ] Yes
- [ ] No
- [ ] Other

Have your experiences of medical error involving breast cancer patients prompted you to consider changing careers? *

- [ ] Yes
- [ ] No
- [ ] Other

Section 4: Your Experience of Medical Negligence Litigation in Breast Cancer Care

Please answer the following questions based on one medical negligence claim which had the greatest impact on you.

Briefly describe the consequence(s) of the medical error for the patient.

*

When did the medical error occur? *

- [ ] Within the past year
- [ ] 1 - 2 years ago
- [ ] 3 - 4 years ago
- [ ] 5 - 6 years ago
- [ ] 7 - 8 years ago
- [ ] 9 - 10 years ago
- [ ] Over 10 years ago
- [ ] Other

How did you become aware that the medical error had occurred? *

- [ ] I discovered it myself
- [ ] The patient involved informed me
- [ ] A family member/ friend of the patient informed me
- [ ] Another healthcare professional informed me
- [ ] The site where it occurred informed me
- [ ] Letter from solicitor
- [ ] Other

What was the nature of the medical error? (Check all the apply) *

- [ ] Failure or delay to diagnose correctly
- [ ] Failure or delay to provide the correct treatment
- [ ] Failure or delay to provide treatment in a timely manner
- [ ] Failure or delay in adequate follow-up
- [ ] A problem directly arising from a medical procedure or operation
- [ ] Errors related to **prescribing** of drugs/fluids (incl. blood)
- [ ] Errors related to **administration** of drugs/fluids (incl. blood)
- [ ] Errors related to **monitoring** of drugs/fluids (incl. blood)
- [ ] Failure/delay to appreciate patients' overall condition
- [ ] Failure or delay to prevent/control/manage infection

- [ ] Administrative errors
- [ ] Communication errors
- [ ] Errors related to reporting of radiological and laboratory results
- [ ] Equipment malfunction
- [ ] Other

Where did the medical error occur? *

- [ ] Emergency department
- [ ] Admission on a ward
- [ ] Shortly before a procedure
- [ ] During a procedure
- [ ] Shortly after a procedure
- [ ] Outpatient department
- [ ] Intensive care unit
- [ ] General practice
- [ ] Other

At what point during the patient's breast cancer journey did this medical error occur? *

- [ ] Before formal diagnosis
- [ ] During initial diagnostic investigations

- [ ] Investigations post-diagnosis
- [ ] Neoadjuvant chemotherapy
- [ ] Neoadjuvant radiotherapy
- [ ] Surgical management
- [ ] Adjuvant chemotherapy
- [ ] Adjuvant radiotherapy
- [ ] Follow-up
- [ ] After discharge from follow-up
- [ ] Other

Which of the following factors caused or contributed to the medical error? (Check all that apply) *

- [ ] Inadequate **verbal** communication **with the patient**
- [ ] Inadequate **written** communication **with the patient**
- [ ] Inadequate **verbal** communication **between healthcare professionals** involved in patients' care
- [ ] Inadequate **written** communication **between healthcare professionals** involved in patients' care
- [ ] Inadequate **verbal** communication **between differing clinical sites** involved in patients' care
- [ ] Inadequate **written** communication **between differing clinical sites** involved in patients' care
- [ ] Poor patient-healthcare professional relationship
- [ ] Poorly organised systems for record keeping
- [ ] Poorly organised systems for appointments and follow-up

- [ ] No standardised referral pathways to other services or consultants
- [ ] Staff working outside of their expertise/experience
- [ ] Lack of staff skills and knowledge
- [ ] Inadequate senior leadership
- [ ] Inadequate supervision of staff-in-training
- [ ] Locum/non-permanent staff
- [ ] Lack of evidence-based guidelines
- [ ] Failure to use guidelines
- [ ] Lack of national/local protocol/ policy
- [ ] Failure to use national/local protocol/policy
- [ ] Inadequate documentation
- [ ] Inadequate staffing
- [ ] Staff contending with a very high workload
- [ ] Overworked/ burnt-out/stressed staff
- [ ] Lack of equipment/equipment failure
- [ ] Lack of essential funding
- [ ] Lack of essential infrastructure
- [ ] Poor co-ordination of overall service
- [ ] Other

How could this medical error have been prevented? (Check all that apply) *

- [ ] Improved communication **with patients**
- [ ] Improved communication **between healthcare professionals**
- [ ] Improved communication **between differing clinical sites** involved in patients' care
- [ ] Better organised systems for record keeping, appointments, and follow-up
- [ ] Standardised referral pathways to other services or consultants
- [ ] Increased recruitment of staff
- [ ] Increased annual leave for staff
- [ ] Increased study leave for staff
- [ ] More training for staff in the specific department/speciality
- [ ] Implementation of evidence-based guidelines
- [ ] Implementation of a local protocol/ policy
- [ ] Improved access to services
- [ ] Reduced waiting times
- [ ] Increased funding
- [ ] Increased infrastructure
- [ ] More conscientious healthcare professionals
- [ ] Better qualified healthcare professionals
- [ ] It could not have been prevented
- [ ] Other

Were additional procedures performed as a result of the medical error? *

- [ ] Yes
- [ ] No
- [ ] Not relevant
- [ ] Other

Were additional medications administered as a result of the medical error? *

- [ ] Yes
- [ ] No
- [ ] Not relevant
- [ ] Other

Was additional treatment given as a result of the medical error? *

- [ ] Yes
- [ ] No
- [ ] Not relevant
- [ ] Other

What was the outcome of the medical negligence claim? *

- [ ] Withdrawn

- [ ] Settled out of court
- [ ] Proceeded to trial
- [ ] Mediation
- [ ] The claim is ongoing

Regarding the medical error and the subsequent medical negligence claim, what was the effect on your physical and emotional health as well as your finances? *

	No effect	Short-term effect	Long-term effect	Permanent effect
Physical health	☐	☐	☐	☐
Emotional health	☐	☐	☐	☐
Finances	☐	☐	☐	☐

Has your experience of medical negligence claims involving breast cancer patients prompted you to consider early retirement? *

- [ ] Yes
- [ ] No
- [ ] Other

Has your experience of medical negligence claims involving breast cancer patients prompted you to consider working in another country? *

- [ ] Yes
- [ ] No

- [ ] Other

Has your experience of medical negligence claims involving breast cancer patients prompted you to consider changing careers? *

- [ ] Yes
- [ ] No
- [ ] Other

Appendix C – Analysis of Claims Form

Claims Analysis Form

1. When did the medical error occur?
    - ○ Within the past year
    - ○ 1-2 years ago
    - ○ 3-4 years ago
    - ○ 7-8 years ago
    - ○ 9-10 years ago
    - ○ Over 10 years ago
    - ○ Other: _____

2. Describe briefly the subsequent consequence(s) for the patient involved.

_____

_____

_____

_____

3. How did it come to light that the medical error had occurred?
    - ○ The healthcare professional involved discovered it
    - ○ The patient involved discovered it
    - ○ A family member/ friend of the patient discovered it
    - ○ Another healthcare professional discovered it
    - ○ Management at the site where it occurred discovered it
    - ○ Other_

4. What was the nature of the medical error?
    - ○ Failure or delay to diagnose correctly
    - ○ Failure or delay to provide the correct treatment

- ○ Failure or delay to provide treatment in a timely manner
- ○ Failure or delay in adequate follow-up
- ○ A problem directly arising from a medical procedure or operation
- ○ Errors related to prescribing of drugs/fluids (incl. blood)
- ○ Errors related to administration of drugs/fluids (incl. blood)
- ○ Errors related to monitoring of drugs/fluids (incl. blood)
- ○ Failure/delay to appreciate patients' overall condition
- ○ Failure or delay to prevent/control/manage infection
- ○ Administrative errors
- ○ Communication errors
- ○ Errors related to reporting of radiological and laboratory results
- ○ Equipment malfunction
- ○ Other_

5. Where did the medical error occur?
    - ○ Emergency department
    - ○ Admission on a ward
    - ○ Immediately pre-procedural
    - ○ Procedure-related
    - ○ Immediate post-procedural
    - ○ Outpatient department
    - ○ Intensive care unit
    - ○ General practice
    - ○ Other_

6. At what point during the patient’s breast cancer journey did this medical error occur
    - ○ Before formal diagnosis
    - ○ During initial diagnostic investigations
    - ○ Investigations post-diagnosis
    - ○ Neoadjuvant chemotherapy

- ○ Neoadjuvant radiotherapy
- ○ Surgical management
- ○ Adjuvant chemotherapy
- ○ Adjuvant radiotherapy
- ○ Follow-up
- ○ After discharge from follow-up
- ○ Other

7. Which of the following factors caused or contributed to the medical error? Check all that apply.
    - ○ Inadequate verbal communication with the patient
    - ○ Inadequate written communication with the patient
    - ○ Inadequate verbal communication between healthcare professionals involved in patients' care
    - ○ Inadequate written communication between healthcare professionals involved in patients' care
    - ○ Inadequate verbal communication between differing clinical sites involved in patients' care
    - ○ Inadequate written communication between differing clinical sites involved in patients' care
    - ○ Poor patient-healthcare professional relationship
    - ○ Poor organisation of system for record keeping
    - ○ Poor organisation of system for appointments/ follow-up
    - ○ Lack of standardised referral pathways to another service/specialty/consultant/team member
    - ○ Staff working outside of their expertise/experience
    - ○ Lack of staff skills and knowledge
    - ○ Inadequate senior leadership
    - ○ Inadequate supervision of staff-in-training
    - ○ Locum/non-permanent staff
    - ○ Lack of evidence-based guidelines

- ○ Failure to use guidelines
- ○ Lack of national/local protocol/ policy
- ○ Failure to use national/local protocol/policy
- ○ Inadequate documentation
- ○ Inadequate staffing
- ○ Staff contending with a very high workload
- ○ Overworked/ burnt-out/stressed staff
- ○ Lack of equipment/equipment failure
- ○ Lack of essential funding
- ○ Lack of essential infrastructure
- ○ Poor co-ordination of overall service
- ○ Other

8. How could this medical error have been prevented?
    - ○ Improved communication with patients
    - ○ Improved communication between healthcare professionals
    - ○ Improved communication between differing clinical sites involved in patients' care
    - ○ Improved standardised organisation of systems for record keeping and appointments/follow-up
    - ○ Standardised referral pathways to another service/specialty/consultant/team member Increased recruitment of staff
    - ○ Increased annual leave for staff
    - ○ Increased study leave for staff
    - ○ More training for staff in the specific department/speciality
    - ○ Implementation of evidence-based guidelines
    - ○ Implementation of a local protocol/ policy
    - ○ Improved access to services
    - ○ Reduced waiting times
    - ○ Increased funding

- ○ Increased infrastructure
- ○ Healthcare professional more conscientious
- ○ Better qualified healthcare professionals
- ○ It could not have been prevented
- ○ Other

9. Were additional procedures performed as a result of the medical error?
   - ○ Yes
   - ○ No
   - ○ Not relevant
   - ○ Other

10. Were additional medications administered as a result of the medical error?
    - ○ Yes
    - ○ No
    - ○ Not relevant
    - ○ Other

11. Was additional treatment given as a result of the medical error?
    - ○ Yes
    - ○ No
    - ○ Not relevant
    - ○ Other

12. What was the outcome of the medical negligence litigation claim?
    - ○ The claim was withdrawn
    - ○ The claim was settled out of court
    - ○ The claim proceeded to trial
    - ○ Mediation
    - ○ Other

13. What was the degree of harm associated with the event as per the ICPS?

- ○ None
- ○ Mild
- ○ Moderate
- ○ Severe
- ○ Death

Appendix D – Patient Questionnaire for Study Two

Medical Error and Patient Safety in Breast Cancer Care - Patient Survey

This short survey is conducted by a research team from Cork University Hospital and University College Cork working under Professor Seamus O'Reilly (National Specialty Director, Medical Oncology) as part of a study titled 'Defining and Remediating the Patient Safety Trajectory of Breast Cancer at a National Cancer Centre'.

Our aim is to investigate the nature and consequences of medical error as well as the patient safety environment for breast cancer patients in Ireland. We very much appreciate your participation in this short survey which will take 5-10 minutes.

Please note that this survey is completely anonymous. Respondents will not be identifiable in any way. All answers are confidential and will not be shared or distributed to any third party.

The study has been granted ethical approval by the Clinical Research Ethics Committee of the Cork Teaching Hospitals. All data will be held for the statutory period in password protected cloud-based storage and is untraceable back to the individual respondents. Data will be treated in accordance with GDPR legislation and UCC's Code of Research Conduct.

Participation in this survey is voluntary. If you give your consent to take part in the study continue on to answer the first question. If you do not give consent, please return the survey; no information has been collected. Please note once you have completed the study and submitted your answers it will not be possible to withdraw your data as it will be anonymised.

* Required

Section 1

1. How would you describe yourself? * *(Tick only one circle)*

- ○ Female
- ○ Male
- ○ Prefer not to say

2. What age are you? * *(Tick only one circle)*

- ○ 18 - 24
- ○ 25 - 29
- ○ 30 - 34
- ○ 35 - 39
- ○ 40 - 44
- ○ 45 - 49
- ○ 50 - 54
- ○ 55 - 59
- ○ 60 +

3. Do you, or any member of your household, work in a medical or health-related field? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Other:_____

4. How would you describe where you live? * *(Tick only one circle)*

- ○ City
- ○ Suburb
- ○ Small town
- ○ Rural area
- ○ Other

5. As of today, are you covered by a private health insurance plan? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Unsure

6. When were you first diagnosed with breast cancer? * *(Tick only one circle)*

- ○ Within the past year
- ○ 1 - 2 years ago
- ○ 3 - 4 years ago
- ○ 5 - 6 years ago
- ○ 7 - 8 years ago
- ○ 9 - 10 years ago
- ○ Over 10 years ago
- ○ Other

7. What type of breast cancer do you have? * *(Tick only one circle)*

- ○ Ductal carcinoma in situ
- ○ Lobular carcinoma in situ
- ○ Invasive ductal carcinoma - oestrogen receptor and progesterone receptor positive
- ○ Invasive ductal carcinoma - HER2 positive
- ○ Invasive ductal carcinoma - triple negative
- ○ Invasive lobular carcinoma
- ○ Inflammatory breast cancer
- ○ Metastatic breast cancer
- ○ Unsure
- ○ Other

8. When attending a healthcare professional during your breast cancer journey, how important are the following to you? * *(Tick one circle for each row)*

	Not important	Neutral	Slightly important	Moderately important	Very important
The healthcare professional knowing your diagnosis accurately	○	○	○	○	○
The healthcare professional spending enough time with you	○	○	○	○	○
Being given enough information about all treatments to make an informed decision about your care	○	○	○	○	○
Knowing how to care for yourself once you left the health care setting	○	○	○	○	○
Being given sufficient instructions on how to take prescribed medication	○	○	○	○	○
Having the treatment carried out just as it was explained to you	○	○	○	○	○
Those involved in your care being attentive to your needs	○	○	○	○	○
Receiving adequate communication with minimal medical jargon	○	○	○	○	○
Having the health care setting clean	○	○	○	○	○

Section 2: Your Opinions on Medical Error and Patient Safety

These are the World Health Organisation definitions for terms utilised in this section:

Patient safety is the prevention of errors and adverse effects to patients associated with healthcare

A **medical error** is an adverse event or near miss that is preventable with the current state of medical knowledge

An **adverse event** is an incident which resulted in harm to a patient

A near miss is an incident that did not reach the patient

9. Over the past 5 years, do you think patient safety in the healthcare environment has ___? * *(Tick only one circle)*

- ○ Improved
- ○ Stayed the same
- ○ Worsened
- ○ Unsure
- ○ Other: _____

10. How likely is it that you will experience a medical error in the future? * *(Tick only one circle)*

- ○ Not likely
- ○ Neutral
- ○ Possible
- ○ Moderately likely
- ○ Very likely
- ○ Other: _____

11. 'The current healthcare system has adequate measures in place to prevent medical error.' Do you agree or disagree? * *(Tick only one circle)*

- ○ Agree
- ○ Disagree
- ○ Other: _____

Section 3: Your Experience of Medical Error in Breast Cancer Care

These are the World Health Organisation definitions for terms utilised in this section:

Patient safety is the prevention of errors and adverse effects to patients associated with healthcare

A **medical error** is an adverse event or near miss that is preventable with the current state of medical knowledge

An **adverse event** is an incident which resulted in harm to a patient

A near miss is an incident that did not reach the patient

12. Over the course of your breast cancer journey, have you been involved in an event where you feel a medical error occurred? * *(Tick only one circle)*

- ○ Yes
- ○ No

→ ***Continue to the next page***

Section 4: Your Concerns About Patient Safety in Breast Cancer Care

13. Over the course of your breast cancer journey, how concerned have you been about the following happening? * *(Tick one circle for each row)*

	Not concerned	Neutral	Slightly concerned	Moderately concerned	Very concerned
Failure/delay to diagnose correctly	○	○	○	○	○
Failure/delay to provide the correct treatment	○	○	○	○	○
Failure/delay to provide treatment in a timely manner	○	○	○	○	○
Failure/delay of adequate follow-up	○	○	○	○	○
A problem directly arising from a medical procedure or operation	○	○	○	○	○
Errors related to prescribing of drugs/fluids (incl. blood)	○	○	○	○	○
Errors related to administration of drugs/fluids (incl. blood)	○	○	○	○	○
Errors related to monitoring of drugs/fluids (incl. blood)	○	○	○	○	○
Failure/delay to appreciate your overall condition	○	○	○	○	○
Failure/delay to prevent, control or manage infection	○	○	○	○	○
Administrative errors	○	○	○	○	○
Communication errors	○	○	○	○	○
Errors related to reporting of radiological and laboratory results	○	○	○	○	○
Equipment malfunction	○	○	○	○	○

These are the World Health Organisation definitions for terms utilised in the following questions:

Patient safety is the prevention of errors and adverse effects to patients associated with healthcare

A **medical error** is an adverse event or near miss that is preventable with the current state of medical knowledge

An **adverse event** is an incident which resulted in harm to a patient

A near miss is an incident that did not reach the patient

14. Over the course of your breast cancer journey, how concerned were you about a medical error occurring in the following locations? * *(Tick one circle for each row)*

	Not concerned	Neutral/ not applicable	Slightly concerned	Moderately concerned	Very concerned
Emergency department	○	○	○	○	○
Admission on a ward	○	○	○	○	○
Shortly before a procedure	○	○	○	○	○
During a procedure	○	○	○	○	○
Shortly after a procedure	○	○	○	○	○
Outpatient department	○	○	○	○	○
Intensive care unit	○	○	○	○	○
General practice	○	○	○	○	○

15. Over the course of your breast cancer journey, how concerned were you about a medical error occurring during these points of your journey? * *(Tick one circle for each row)*

	Not concerned	Neutral/ not applicable	Slightly concerned	Moderately concerned	Very concerned
Before formal diagnosis	○	○	○	○	○
During initial diagnostic investigations	○	○	○	○	○
Investigations post-diagnosis	○	○	○	○	○
Chemotherapy before surgery	○	○	○	○	○
Radiotherapy before surgery	○	○	○	○	○
Surgical management	○	○	○	○	○
Chemotherapy after surgery	○	○	○	○	○
Radiotherapy after surgery	○	○	○	○	○
Follow-up	○	○	○	○	○
After discharge from follow-up	○	○	○	○	○

16. Over the course of your breast cancer journey, were you concerned that the following factors may contribute to a medical error?* *(Tick one circle for each row)*

	No	Neutral	Yes
Inadequate verbal communication with you	○	○	○
Inadequate written communication with you	○	○	○
Inadequate verbal communication between healthcare professionals involved in your care	○	○	○
Inadequate verbal communication between different clinical sites involved in your care	○	○	○
Inadequate written communication between healthcare professionals involved in your care	○	○	○

Inadequate written communication between different clinical sites involved in your care	○	○	○
Poor relationship between you and your healthcare professional	○	○	○
Poorly organised systems for record keeping	○	○	○
Poorly organised systems for appointments and follow-up	○	○	○
No standardised referral pathways to other services or consultants	○	○	○
Staff working outside of their expertise/experience	○	○	○
Lack of staff skills/knowledge	○	○	○
Inadequate senior leadership	○	○	○
Inadequate supervision of staff-in-training	○	○	○
Locum/non-permanent staff	○	○	○
Inadequate documentation	○	○	○
Inadequate staffing	○	○	○
Staff contending with a very high workload	○	○	○
Overworked/ burnt-out/ stressed staff	○	○	○
Lack of equipment/equipment failure	○	○	○
Lack of essential funding	○	○	○
Lack of essential infrastructure	○	○	○
Poor co-ordination of overall service	○	○	○

17. Do you think the following could improve your safety as a breast cancer patient and reduce the risk of medical error? * *(Tick one circle for each row)*

	No	Neutral	Yes
Improved communication with you	○	○	○
Improved communication between healthcare professionals	○	○	○
Improved communication between different clinical sites involved in your care	○	○	○
Better organised systems for record keeping, appointments, and follow-up	○	○	○
Standardised referral pathways to other services or consultants	○	○	○
Increased recruitment of staff	○	○	○
Increased annual leave for staff	○	○	○
Increased study leave for staff	○	○	○
More training for staff in the specific department/ speciality	○	○	○
Improved access to services	○	○	○
Reduced waiting times	○	○	○
Increased funding	○	○	○
Increased infrastructure	○	○	○
More conscientious healthcare professionals	○	○	○
Better qualified healthcare professionals	○	○	○

18. Over the course of your breast cancer journey, have you voiced or reported your concerns about patient safety? * *(Tick only one circle)*

- ○ Yes
- ○ No
- ○ Other

19. If yes, who did you voice or report your concerns to? *(Tick all that apply)*

- ○ Management at the site involved
- ○ A healthcare professional directly involved in your care
- ○ Lawyer
- ○ The Medical Council or appropriate national regulatory body
- ○ Another healthcare professional
- ○ Patient advocacy group
- ○ Other

20. If yes, what was the outcome(s) of voicing or reporting your concerns? *(Tick all that apply)*

- ○ Improved communication with you
- ○ Improved communication between healthcare professionals
- ○ Improved communication between different clinical sites involved in your care
- ○ Better organised systems for record keeping, appointments, and follow-up
- ○ Implementation of standardised referral pathways to other services or consultants
- ○ Increased recruitment of staff
- ○ Increased annual/ study leave for staff
- ○ More training for staff in the specific department/speciality
- ○ Improved access to services
- ○ Reduced waiting times
- ○ Increased funding
- ○ Increased infrastructure
- ○ Nothing
- ○ Unsure
- ○ Other

21. If no, what were the barriers to voicing or reporting your concerns? *(Tick all that apply)*

- ○ Unsure of how to report your concerns
- ○ Unsure of who to report your concerns to
- ○ Worried it will impact on the care you receive
- ○ Worried it will change the healthcare professional's opinion of you

- ○ No opportunity to choose an alternative healthcare professional
- ○ No established culture of reporting
- ○ Lack of confidence in the difference it would make
- ○ Emotional burden
- ○ Financial burden
- ○ Other

22. Regarding the concerns you have had about patient safety, what was the effect on your physical and emotional health as well as your finances? * *(Tick one circle for each row)*

	No effect	Short-term effect	Long-term effect	Permanent effect
Physical health	○	○	○	○
Emotional health	○	○	○	○
Finances	○	○	○	○

If you have completed Section 4, this is the end of the survey.

Appendix E – Doctor Questionnaire for Study Two

Medical Error and Patient Safety in Breast Cancer Care - Healthcare Professional Survey

This short survey is conducted by a research team from Cork University Hospital and University College Cork working under Professor Seamus O'Reilly (National Specialty Director, Medical Oncology) and Mr Martin O'Sullivan (Lead of the Breast Cancer Group National Cancer Control Programme) as part of a study titled 'Defining and Remediating the Patient Safety Trajectory of Breast Cancer at a National Cancer Centre

Our aim is to investigate the nature and consequences of medical error as well as the patient safety environment for breast cancer patients in Ireland. We very much appreciate your participation in this short survey which will take a few minutes.

Please note that this survey is completely anonymous. Respondents will not be identifiable in any way. All answers are confidential and will not be shared or distributed to any third party.

The study has been granted ethical approval by the Clinical Research Ethics Committee of the Cork Teaching Hospitals. All data will be held for the statutory period in password protected cloud-based storage and is untraceable back to the individual respondents. Data will be treated in accordance with GDPR legislation and UCC's Code of Research Conduct.

Participation in this survey is voluntary. If you give your consent to take part in the study continue on to answer the first question. If you do not give consent, please exit the page; no information has been collected. Please note once you have completed the study and submitted your answers it will not be possible to withdraw your data as it will be anonymised.

How would you describe yourself? *

- [ ] Female
- [ ] Male
- [ ] Prefer not to say

What age are you? *

- [ ] 18-24
- [ ] 25-29
- [ ] 30-34

- [ ] 35-39
- [ ] 40-44
- [ ] 45-49
- [ ] 50-54
- [ ] 55-59
- [ ] 60+

What is your job title? *

- [ ] Consultant
- [ ] Senior registrar
- [ ] Junior registrar
- [ ] Specialist registrar
- [ ] Senior house officer
- [ ] Intern
- [ ] Other

What field of medicine do you work in? *

- [ ] Medical oncology
- [ ] Radiation oncology
- [ ] Surgery

- [ ] Radiology
- [ ] Pathology
- [ ] Palliative medicine
- [ ] Other

How many years' experience with breast cancer do you have? *

- [ ] Less than 1 year
- [ ] 1 - 2 years
- [ ] 3 - 5 years
- [ ] 5 - 10 years
- [ ] 10 - 20 years
- [ ] >20 years

Do you also work in a private capacity? *

- [ ] Yes
- [ ] No
- [ ] Other

Section 2: Your Opinions on Medical Error and Patient Safety

The following are the World Health Organisation definitions for terms utilised in this section:

Patient safety = the prevention of errors and adverse effects to patients associated with healthcare

Medical error = an adverse event or near miss that is preventable with the current state of medical knowledge

An adverse event = an incident which resulted in harm to a patient

A near miss = an incident that did not reach the patient

When providing healthcare to a breast cancer patient, how important are the following to you? *

	Not important	Neutral	Slightly important	Moderately important	Very important
Accurately knowing the patient's diagnosis	☐	☐	☐	☐	☐
Spending enough time with the patient	☐	☐	☐	☐	☐
Giving enough information to enable the patient to make an informed decision about their care	☐	☐	☐	☐	☐
Ensuring the patient knows how to care of themselves once they have left the healthcare setting	☐	☐	☐	☐	☐
Giving sufficient instructions on how to take prescribed medications	☐	☐	☐	☐	☐
Carrying out the treatment as it was explained to the patient	☐	☐	☐	☐	☐
Being attentive to the needs voiced by the patient	☐	☐	☐	☐	☐
Communicating with the patient adequately and with minimal medical jargon	☐	☐	☐	☐	☐
Having a clean health care setting	☐	☐	☐	☐	☐

Over the past 5 years, do you think that patient safety in the healthcare environment has __? *

- [ ] Improved
- [ ] Stayed the same
- [ ] Worsened
- [ ] Unsure
- [ ] Other (please specify):

How concerned are you that you will contribute/cause a medical error in the future? *

- [ ] Not concerned
- [ ] Neutral
- [ ] Slightly concerned
- [ ] Moderately concerned
- [ ] Very concerned
- [ ] Other (please specify):

'The current healthcare system has adequate measures in place to prevent medical error.' Do you agree or disagree? *

- [ ] Disagree
- [ ] Neutral
- [ ] Somewhat agree

- [ ] Moderately agree
- [ ] Strongly agree
- [ ] Other (please specify):

Section 3: Your Experience of Medical Error in Breast Cancer Care

When caring for breast cancer patients, have you been involved in an event where a medical error has occurred? *

- [ ] Yes
- [ ] No

Section 4: Your Concerns About Patient Safety in Breast Cancer Care

When caring for breast cancer patients, how concerned have you been about the following? *

	Not concerned	Neutral	Slightly concerned	Moderately concerned	Very concerned
Failure or delay to diagnose correctly	☐	☐	☐	☐	☐

	Not concerned	Neutral	Slightly concerned	Moderately concerned	Very concerned
Failure or delay to provide the correct treatment	☐	☐	☐	☐	☐
Failure or delay to provide treatment in a timely manner	☐	☐	☐	☐	☐
Failure or delay in adequate follow-up	☐	☐	☐	☐	☐
A problem directly arising from a medical procedure or operation	☐	☐	☐	☐	☐
Errors related to prescribing of drugs/fluids (incl. blood)	☐	☐	☐	☐	☐
Errors related to administration of drugs/fluids (incl. blood)	☐	☐	☐	☐	☐
Errors related to monitoring of drugs/fluids (incl. blood)	☐	☐	☐	☐	☐
Failure or delay to appreciate patients' overall condition	☐	☐	☐	☐	☐
Failure or delay to prevent/control/manage infection	☐	☐	☐	☐	☐
Administrative errors	☐	☐	☐	☐	☐
Communication errors	☐	☐	☐	☐	☐
Errors related to reporting of radiological and laboratory results	☐	☐	☐	☐	☐
Equipment malfunction	☐	☐	☐	☐	☐

When caring for breast cancer patients, how concerned have you been about patient safety in the following locations? *

	Not concerned	Neutral	Slightly concerned	Moderately concerned	Very concerned
Emergency department	☐	☐	☐	☐	☐

	Not concerned	Neutral	Slightly concerned	Moderately concerned	Very concerned
Admission on a ward	☐	☐	☐	☐	☐
Shortly before a procedure	☐	☐	☐	☐	☐
During a procedure	☐	☐	☐	☐	☐
Shortly after a procedure	☐	☐	☐	☐	☐
Outpatient department	☐	☐	☐	☐	☐
Intensive care unit	☐	☐	☐	☐	☐
General practice	☐	☐	☐	☐	☐

When caring for breast cancer patients, how concerned have you been about patient safety at these points of their journey? *

	Not concerned	Neutral	Slightly concerned	Moderately concerned	Very concerned
Before formal diagnosis	☐	☐	☐	☐	☐
During initial diagnostic investigations	☐	☐	☐	☐	☐
Investigations post-diagnosis	☐	☐	☐	☐	☐
Neoadjuvant chemotherapy	☐	☐	☐	☐	☐
Neoadjuvant radiotherapy	☐	☐	☐	☐	☐
Surgical management	☐	☐	☐	☐	☐
Adjuvant chemotherapy	☐	☐	☐	☐	☐
Adjuvant radiotherapy	☐	☐	☐	☐	☐

	Not concerned	Neutral	Slightly concerned	Moderately concerned	Very concerned
Follow-up	☐	☐	☐	☐	☐
After discharge from follow-up	☐	☐	☐	☐	☐

When caring for breast cancer patients, have you been concerned that the following factors may cause/contribute to patient safety risk? *

	No	Neutral	Yes
Inadequate verbal communication with the patient	☐	☐	☐
Inadequate written communication with the patient	☐	☐	☐
Inadequate verbal communication between healthcare professionals involved in patients' care	☐	☐	☐
Inadequate written communication between healthcare professionals involved in patients' care	☐	☐	☐
Inadequate verbal communication between differing clinical sites involved in patients' care	☐	☐	☐
Inadequate written communication between differing clinical sites involved in patients' care	☐	☐	☐
Poor patient-healthcare professional relationship	☐	☐	☐
Poorly organised systems for record keeping	☐	☐	☐
Poorly organised systems for appointments and follow-up	☐	☐	☐

	No	Neutral	Yes
No standardised referral pathways to other services or consultants	☐	☐	☐
Staff working outside of their expertise/experience	☐	☐	☐
Lack of staff skills and knowledge	☐	☐	☐
Inadequate senior leadership	☐	☐	☐
Inadequate supervision of staff-in-training	☐	☐	☐
Locum/non-permanent staff	☐	☐	☐
Lack of evidence-based guidelines	☐	☐	☐
Failure to use guidelines	☐	☐	☐
Lack of national and/or local protocol	☐	☐	☐
Failure to use national and/or local protocol	☐	☐	☐
Inadequate documentation	☐	☐	☐
Inadequate staffing	☐	☐	☐
Staff contending with a very high workload	☐	☐	☐
Overworked/burnt-out/stressed staff	☐	☐	☐
Lack of equipment/equipment failure	☐	☐	☐
Lack of essential funding	☐	☐	☐
Lack of essential infrastructure	☐	☐	☐
Poor co-ordination of overall service	☐	☐	☐

Do you think the following could improve patient safety and reduce the risk of medical error? *

	No	Neutral	Yes
Improved communication with patients	☐	☐	☐
Improved communication between healthcare professionals	☐	☐	☐
Improved communication between differing clinical sites involved in patients' care	☐	☐	☐
Better organised systems for record keeping, appointments, and follow-up	☐	☐	☐
Standardised referral pathways to other services or consultants	☐	☐	☐
Increased recruitment of staff	☐	☐	☐
Increased annual leave for staff	☐	☐	☐
Increased study leave for staff	☐	☐	☐
More training for staff in the specific department/ speciality	☐	☐	☐
Implementation of evidence-based guidelines	☐	☐	☐
Implementation of a local protocol/policy	☐	☐	☐
Improved access to services	☐	☐	☐
Reduced waiting times	☐	☐	☐
Increased funding	☐	☐	☐

	No	Neutral	Yes
Increased infrastructure	☐	☐	☐
More conscientious healthcare professionals	☐	☐	☐
Better qualified healthcare professionals	☐	☐	☐

When caring for breast cancer patients, have you reported concerns you have had about patient safety? *

- ☐ Yes
- ☐ No
- ☐ Other

If yes, who did you report your concerns to? (Check all that apply)

- ☐ Management at the site involved
- ☐ National incident management system (NIMS)
- ☐ Lawyer
- ☐ The Medical Council or appropriate national regulatory body
- ☐ Another healthcare professional
- ☐ Patient advocacy group
- ☐ Other

If yes, what was the outcome(s) of reporting your concerns? (Check all that apply)

- [ ] Improved communication with patients
- [ ] Improved communication between healthcare professionals
- [ ] Improved communication between differing clinical sites involved in patients' care
- [ ] Better organised systems for record keeping, appointments, and follow-up
- [ ] Implementation of standardised referral pathways to other services or consultants
- [ ] Increased recruitment of staff
- [ ] Increased annual/ study leave for staff
- [ ] More training for staff in the specific department/speciality
- [ ] Implementation of evidence-based guidelines
- [ ] Implementation of a national and/or local protocol
- [ ] Improved access to services
- [ ] Reduced waiting times
- [ ] Increased funding
- [ ] Increased infrastructure
- [ ] Nothing
- [ ] Unsure
- [ ] Other

If no, what were the barriers to reporting your concerns? (Check all that apply)

- [ ] Unsure of how to report your concerns

- [ ] Unsure of who to report your concerns to
- [ ] Worried it will impact on your current job/career
- [ ] Worried it will change your colleagues' opinion of you
- [ ] No opportunity to choose an alternative employer
- [ ] No established culture of reporting
- [ ] Lack of confidence in the difference it would make
- [ ] Emotional burden
- [ ] Financial burden

Regarding the concerns you have had about patient safety for breast cancer patients, what was the effect on your physical and emotional health as well as your finances?

	No effect	Short-term effect	Long-term effect	Permanent effect
Physical health	☐	☐	☐	☐
Emotional health	☐	☐	☐	☐
Finances	☐	☐	☐	☐

Have your concerns regarding patient safety for breast cancer patients prompted you to consider early retirement?

- [ ] Yes
- [ ] No
- [ ] Other

Have your concerns regarding patient safety for breast cancer patients prompted you to consider working in another country?

- [ ] Yes
- [ ] No
- [ ] Other