RATIONALE FOR A PHARMACIST-LED MEDICATION SAFETY SERVICE

A thesis submitted in partial fulfilment

of the requirements for the award of

Doctorate in Pharmacy

DUSTIN BALZAN

Department of Pharmacy

University of Malta

2018

UNIVERSITY OF MALTA
FACULTY/~~INSTITUTE~~/~~CENTRE~~/~~SCHOOL~~ MEDICINE & SURGERY

DECLARATION OF AUTHENTICITY FOR DOCTORAL STUDENTS

Student's I.D. /Code 229882(M)

Student's Name & Surname DUSTIN BALZAN

Course PHARM D

Title of Dissertation/Thesis

RATIONALE FOR A PHARMACIST-LED MEDICATION SAFETY SERVICE

I hereby declare that I am the legitimate author of this Dissertation/Thesis and that it is my original work.

No portion of this work has been submitted in support of an application for another degree or qualification of this or any other university or institution of higher education.

I hold the University of Malta harmless against any third party claims with regard to copyright violation, breach of confidentiality, defamation and any other third party right infringement.

☐ As a Ph.D. student, as per Regulation 49 of the Doctor of Philosophy Regulations, I accept that my thesis be made publicly available on the University of Malta Institutional Repository.

☑ As a Professional Doctoral student, as per Regulation 54 of the Professional Doctorate Regulations, I accept that my dissertation be made publicly available on the University of Malta Institutional Repository.

☐ As a Doctor of Sacred Theology student, as per Regulation 17 of the Doctor of Sacred Theology Regulations, I accept that my dissertation be made publicly available on the University of Malta Institutional Repository.

☐ As a Doctor of Music student, as per Regulation 24 of the Doctor of Music Regulations, I accept that my dissertation be made publicly available on the University of Malta Institutional Repository.

Signature of Student

29/10/2018
Date

* *Tick applicable paragraph.*

11.06.2015

ABSTRACT

Medication safety is an intrinsic function of hospital quality systems. The aim of the study was to develop a pharmacy-led hospital medication safety service following a psychometric analysis of patient safety attitudes amongst a segment of Mater Dei Hospital staff members. A pre-validated AHRQ questionnaire on patient safety attitudes of staff[1] was distributed amongst a pre-selected cohort of 235 participants from areas including anaesthesia, pharmacy and hospital administration. Results were compared with aggregate data from 680 hospitals in the United States of America who had participated in the same survey during 2016. An internal hospital audit was carried out using an international safety tool designed by the ISMP[2]. Subsequently, a pharmacy-led medication safety service was developed in line with findings.

With a response rate of 45 % (N=105), 36 % of the responses revealed an '*Acceptable*' local patient safety attitude (n=37). Participation in error reporting was low with 52 % not being involved in any reporting (n=55). Eight attitude composite scores exceeded minimum aggregate hospital scores whilst 4 scored below aggregate hospital minima. Findings from the audit together with a Pareto analysis of survey responses, led to the prioritisation of 8 attitude aspects; '*Supervisor expectations promoting patient safety*', '*Management support for patient safety*', '*Overall perceptions on patient safety*', '*Frequency of events reported*', '*Teamwork across units*', '*Staffing*', *'Handoffs and transitions*' and '*Non punitive response to error*'. Interventions were focused on three

[1] Hospital Survey on Patient Safety Culture [Internet]. Rockville, MD: Agency for Healthcare Research and Quality 2007 Dec. Available from: http://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/hospital/index.html [cited March 2017].

[2] ISMP Medication Safety Self Assessment® for High-Alert Medications [Internet]. October 2017. Available from: http://www.ismp.org/selfassessments/SAHAM/ [cited October 2017].

domains impacting the medication use process; drug distribution dynamics, safety improvement of parenteral medicines, and handling of safety alerts.

The study identified how a pharmacist-led medication safety service in the hospital setting can contribute to the identification of priority areas to align local practices to established international targets. The approach developed in this study is now being extended to other areas within the hospital. This study can be used as part of a conventional (Plan-Do-Study-Act) PDSA quality cycle and method transfer is appropriate to other hospitals where medication safety services need to be established or updated.

Keywords:

Safety, Quality, Healthcare, Leadership, Change, Medication-use Process

DEDICATION

I would like to dedicate this work to those who need love.

Those who strive to love, want to change the world but do not know how, or maybe are using more of their time on '*contemplating*' and less on '*being*'... Through research we can reflect the warmth of love to colder places in the dark.

Those who thrive in love, are leaving a lot of good impact; these need encouragement and must remain humble … Through research we keep understanding our limitations and the need to act in spite of.

May this work be a source of inspiration to us all, and encourage us buckle up, remain or get back on the saddle and keep consuming ourselves in a life that will be better for us, those around us and beyond.

ACKNOWLEDGEMENTS

Definite acknowledgements go to Prof. Lilian Azzopardi, Dr. Louise Grech and Prof. Anthony Serracino Inglott for their ardency and for making this possible. At the same time I cannot forget the rest of staff members at the department; academic and non-academic – they have become an important part of my life. Thank you also to Prof. Liberato Camilleri for the incessant help he is giving to all students and professionals who seek his statistical advice.

I would like to express my deepest gratitude to my family, especially my wife Diane, Michaela and Luca, who have accompanied me through the paces of this study opportunity; my parents and aunty Rena for their constant encouragement. I would also like to acknowledge my grandparents, God bless their souls, who have given me a LOT in life.

Sincere thank you to my colleagues especially; Mr. Stephen Falzon, Mr Anthony Cutajar, Mr. Ivan Falzon, Mr. Michael Farrugia, Ms. Carmen Damato, Mr. Walter Busuttil, Dr. David Gatt and Dr. Carmel Abela; my office colleagues, Mario, Ralph Stephanie and Sara; my Doctorate of Pharmacy buddy and work colleague Graziella who has supported me a lot throughout our studies and last but not least thank you to Sonia, Pawlu, Grace and Mario, people who go out of their way to literally take care of us and encourage us in whatever we undertake.

I would also like to thank my colleagues from the Middle East; Osama Tabbara, Rabih Dabliz, Mohammed Siddique, Muhammad Umar Khalid, Nora al-Banyan; Eric Kastango and Michael Freudinger from the US and Alison Beaney from the UK. They inspire and push me forward in Medication Safety.

A thought towards the students at our University who are a reason to be in life; succession planning is a crucial element in quality, and to the patients who represent God in whatever we do to them.

Table of Contents

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

List of Abbreviated Terms

ACCP	American College of Clinical Pharmacy
ACPE	Accreditation Council for Pharmacy Education
ADE	Adverse Drug Events
AHRQ	Agency for Healthcare Research and Quality
AHSP	American Society of Health-System Pharmacists
CCAD	Cleveland Clinic Abu Dhabi
HRO	High Reliability Organisation
ISMP	Institute for Safe Medication Practices
MDH	Mater Dei Hospital
MSO	Medication Safety Officer
PTS	Pneumatic Tube System
SHS	Survey Hospital Score
UIC	University of Illinois, Chicago
UoM	University of Malta

CHAPTER 1 – INTRODUCTION

"That is what alchemists do. They show that,

when we strive to become better than we are,

everything around us becomes better, too."

Paulo Coelho, The Alchemist

1.1 The Medication Safety Service

Evidence asserts that on average, 20% of patients admitted within healthcare establishments experience adverse drug events (ADE) during their hospital stay (Griffin & Resar, 2009). This figure of untoward responses to pharmacotherapy includes both preventable and non-preventable events and reactions. Although not necessarily always the result of systematic flaws or unsafe acts or omissions, injuries with a causal link to a drug effect are events that can be addressed through better control mechanisms such as pharmaco-vigilance (Bos *et al*., 2017). Within the context of this wider view, a hospital's role in safety structures becomes increasingly important. It is documented that between 2001 and 2006, an estimated 250,000 to 500,000 patients died secondary to medical mistakes in the United States of America (US) (Nance, 2008). This was recorded at a time bracket in which passenger deaths aboard major US airlines hit a total of zero. Differences between expectations of harm amongst the aviation and healthcare industry are contrastable.

A thorough understanding of the underlying systematic causes that can lead to such situations is essential to control ADEs. The Institute for Safe Medication Practices (ISMP) in the United States of America and the National Patient Safety Agency (NPSA) in the United Kingdom are leading authors of a wide range of resources addressing these system gaps. On scrutinizing the medication safety pyramid model, it becomes apparent that although the patient is found at the apex of the pyramid, the base is composed of elements including the '*safe culture*', information and influence (Figure 1.1).

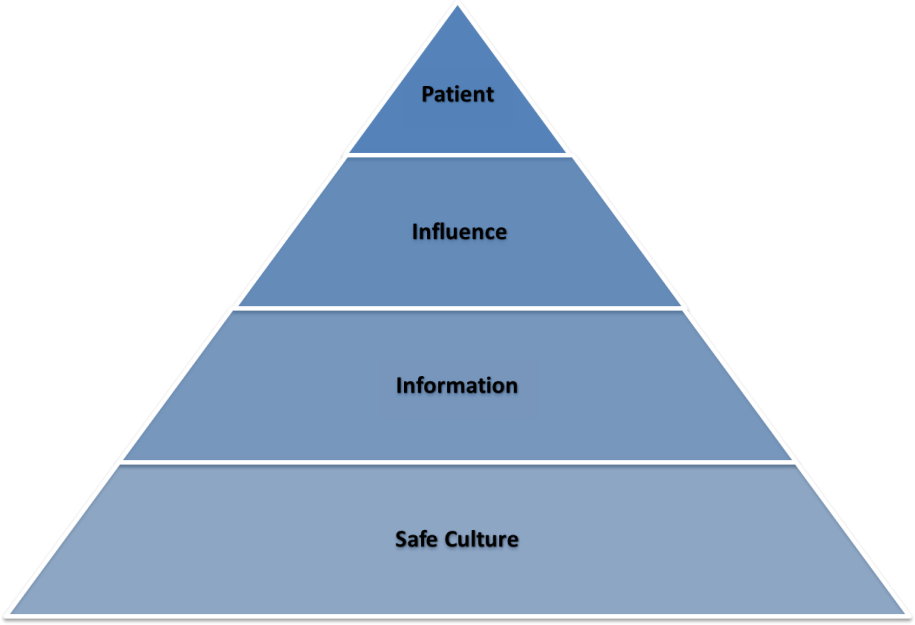


Figure 1.1. The medication safety pyramid

Adapted from Larson, CM, Saine, D, American Society of Health-System Pharmacists. Medication Safety Officer's handbook. Bethesda, MD: American Society of Health-System Pharmacists; 2013.

A successful medication safety program depends on the establishment of a '*safe culture*'. The term 'culture' can be broadly defined as "*the collective programming of the mind that distinguishes the members of one group or category of people from others*" (Hofstede *et al.*, 2010). Literature asserts that the foundation of a successful medication safety program is a dedicated pharmacist leader (Larson and Saine, 2013).

1.2 The Medication Safety Pharmacist

The direct and indirect involvement of pharmacy is warranted wherever and whenever there is a medication use process involved (Figure 1.2)[3]. The primary roles of the medication safety officer (MSO) are to highlight areas of risk and collaborate with healthcare professionals to achieve safety. Through use of evidence-based practice, the MSO sets the professional goalposts whilst utilizing all resources available. This includes staff engagement at all levels, essentially through involvement of vertical and horizontal leadership schemes (Heath, 2010; Sharma, 2010). It is of definite importance that the MSO (and the pharmacy profession) is perceived as an ally rather than a threat (Beardsley *et al.*, 2008). The role of the MSO is to co-ordinate and align the various healthcare professionals responsible for the different sectors of the medication use process across the organization.

Notwithstanding the cultural contexts and constraints, the aim towards a generative culture is to reach as state of "*safety is how we do business here*" (Hudson, 1999). The MSO must contribute towards a vision that is clear for the members of the organisation. This often involves winning the trust of the organisation's decision makers that improved safety and consequently quality will actually save money by reducing waste.

[3] ISMP. (2013). Medication Safety Coordinator. Retrieved November 2013, from http://www.ismp.org/jobline/jobDetails.asp?id=1529&jt=E

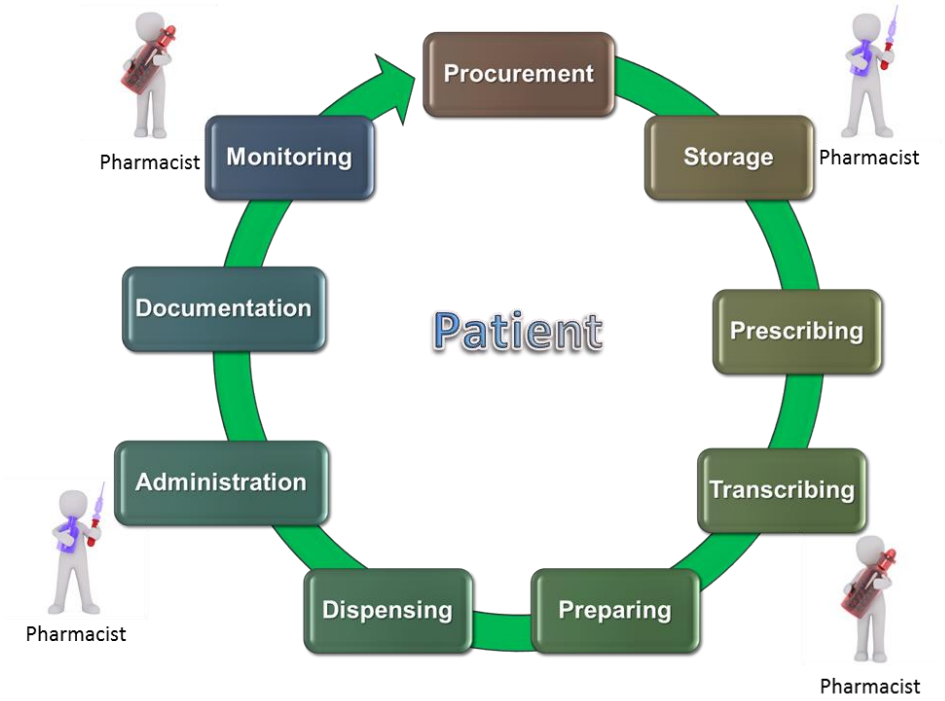


Figure 1.2 Various steps of the medication use process

Constructed from Larson, CM, Saine, D, American Society of Health-System Pharmacists. Medication Safety Officer's handbook. Bethesda, MD: American Society of Health-System Pharmacists; 2013.

There must be an underpinning, decisive element of collaboration. This phenomenon is also equally addressed in the current compilation of practice standards for Clinical Pharmacy, as put together by the American College of Clinical Pharmacy (ACCP), where due emphasis is put on the term 'collaborative' model and approach, shifting the pharmacists' role into one that co-ordinates all aspects of the interdisciplinary '*medication use process*' (ACCP, 2014). This inclination and interest in understanding the business arm of the hospital, is an important buy-in for ensuring patient safety prioritisation. A rapid approach to this is through efficiency in work; short term material wins.

Estimating the cost of harm of one misadventure involving a high alert drug is a good example. Reduction of waste through dose standardisation and process organisation can be another (Pouliquen *et al.*, 2011; Mansfield and Jarrett, 2013). Bringing decision makers closer to the point of action as part of the team is an important actionable goal towards a generative culture.

1.3 Making Patient Safety a Priority

As the importance of economics cannot be understated (Powers, 2014), delays and malfunctions are two main breaches that are highly unacceptable in cultural norms, hence carry a high level of importance. This phenomenon is openly affected by the impacts of cultural schemes like '*uncertainty avoidance,*' elements which can block progression if disregarded (Hofstede, 2010; QU and Yang, 2015). MSOs build up on existing structures, proving that investment in safeguarding safety remains a more profitable option. The level of connectivity offered by today's technology and globalization harmonized a number of acceptable norms amongst a number of countries. Impacts of healthcare's public-private partnership schemes on an international level are often pushing, at times even pulling international hospital accreditation schemes forward; generally with the collateral effects of educating the public on hospital and healthcare expectations. Media influence together with first-hand experience of such schemes can have a behavioural impact; both positive and negative. Use of mechanistic approaches such as Emotional Intelligence (EQ) and other evidence backed strategies are often measures that can make a difference between success and failure – where one wrong move has the potential to unleash movements that can resist further positive change (Kotter, 2012).

Whilst regulatory bodies habitually take note of these safety recommendations, regulation is by nature a more conservative attribute intended at safeguarding and restoring 'peace' through driving practice away from situations known to have caused problems in the past. This phenomenon can tangent away from what is required in driving patient safety up to the generative levels described by the University of Leiden on Safety Culture[4]. Some types of regulatory pressures and conservative schools of thought might at times block or slow down evolutionary processes. It would be typical of high reliability organizations to be particularly attracted to and actually subscribe to experimental improvement; naturally whilst safeguarding the current level in safety and quality of care; but not the '*status quo*'. A clear understanding of this facet is tantamount to a mature process shift towards a culture that generates genuine safety. The establishment of an effective and sustainable change control mechanism is an important aspect to be ensured and periodically updated.

Internally within hospital structures, presenting challenges often take up the macro-cultural and micro-cultural undertones set by the country and in specific context to Mater Dei Hospital; employment within the public sector. Inarguably one cannot deny the impacts of trade unions within hospitals; an important part of the change control mechanism, at times however guided by the '*want*' of the respective employee class, and not necessarily in line with best or recommended practices. As countries can also be affected by socio-political behaviour schemes, it is also a natural consequence that trade unions and other bodies can be likewise impacted by such. This further proves the importance of positive individual attitudes, especially in those with the ability to

[4] Hudson P. Safety Culture – Theory and Practice. Paper Presented at RTO HFM Workshop in Siena. Siena Italy: Leiden University, Centre for Safety Science; 1999. Report No.: RTO MP-032.

influence and drive action. The need for progression in the right direction is key, and the quasi-exclusive importance of intelligent leadership schemes that study ways forward cannot be overlooked. A multifaceted approach has to be rendered suitable for the location in scrutiny; it cannot be installed without tailoring. Periodic re-evaluation of way forward with special attention on identifying and flagging new barriers and means of overcoming them remains an important challenge (Baker, 2001).

1.4 Evolution of Hospital Pharmacy in Malta

The Maltese model of healthcare had been emulating the Anglo-Saxon model for a relatively long period of time since the days of the British rule, as have been many other state organisations. Notwithstanding the achievement of a Republic status in 1974, the Anglo-Saxon influence has been persisting for a significant time, and still is in a number of ways. Malta has joined the European Union in 2004, where a number of European directives intended to harmonise standards came into force. Globalization aided by technological widespread has in the last decade connected the island to a greater set of countries, norms and ideas. The number of countries bearing international accreditation by one of the leading international accreditation firms in the US; Joint Commission International (JCI), is becoming significant, even within Europe (Figure 1.3).

Figure 1.3. Countries having internationally accredited hospitals in line with Joint Commission International (JCI)[5]

Shaded countries depict non-North American countries, in which there are healthcare facilities bearing Joint Commission International (JCI) accreditation at the time of writing.

[5] Archived from URL: https://www.jointcommissioninternational.org/about-jci/jci-accredited-organizations/ [cited January 2018].

This phenomenon is increasing the familiarity and consequent importance of US bodies such as American Society of Health System Pharmacists (ASHP), American College of Clinical Pharmacy (ACCP), Agency for Healthcare Research and Quality (AHRQ) together with the recommendations of the Institute of Safe Medication Practices (ISMP).

Also worth mentioning is the local academic pharmacy influence on the profession. Through collaborative programs including a combination of North American and European influence, the local hospital pharmacist is now exposed to a wider gamut of approaches to the various challenges encountered, especially in the evolving roles and responsibilities of the profession. The notion of world class care is now gaining a deeper level of understanding (Aljadhey *et al*., 2017). The creative way of doing things (as opposed to pre-set ideas and rituals) is challenging the *'status quo'* of a hospital pharmacist from a passive dispenser of medicines to a healthcare professional and scientist who is expected to resort to and work with academia in finding out the best solution of the time – a studied approach.

Target outcomes of healthcare include care improvement, improvement in the health of populations, and cost reduction[6]. International accreditation of hospitals can be regarded as an important tool for positive patient safety evolution. In combination with other instruments, such as market forces and social competition, a pharmacist should study the current scenario and act accordingly (Wachter, 2012).

[6] IHI whitepaper on high impact leadership. Swensen S, Pugh M, McMullan C, Kabcenell A. High-Impact Leadership: Improve Care, Improve the Health of Populations, and Reduce Costs. IHI White Paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2013. (Available at ihi.org)

Also of importance is job satisfaction for the hospital pharmacist, where evidence[7] points out that lack of available opportunities for the pharmacy profession, with diminished opportunities to further studies together with lack of access to timely clinical information can affect the level of pharmacy engagement within a hospital and consequently put patients at harm. As medication errors can occur in any of these three broad domains; prescribing, administration and monitoring, studies assert that prescribing and administration hold the greatest percentage of medication errors (about 40 % each) owing to root causes of inadequate knowledge on selecting the best pharmacotherapy (prescribing), and failures in any of the five rights (administration) whereas issues with transcription carry the rest (20 %). Occurrences, such as for example failures in clinical monitoring, will consequently lead onto errors in selecting the best drug or dose.

By collaborating with other hospital members, pharmacists can offer their expertise in pharmaco-therapeutics in support of a better medication safety profile. This approach further strengthens the importance that the medication use process needs to be seamless and integral. Although the manning of a medication safety service within a hospital does not exclusively require the involvement of pharmacy, the benefit of leading such service by pharmacy has to be understood. Pharmacy can ensure a seamless medication use process, once the professional role of hospital pharmacy is understood better.

[7] Shah A. Pharmacy Intervention in the Medication-use Process - the role of pharmacists in improving patient safety. 2009. Paper produced during an internship with the International Pharmaceutical Federation (FIP) - Den Haag, Netherlands.

1.5 The Setting

The setting of this study is Mater Dei Hospital (MDH), a government owned 900 bedded hospital. The hospital holds a safety alert flagging system for learning (SALearn)[8], as a hospital-wide mechanism through which safety alerts including those of medication nature are channelled. This standard reporting system is both voluntary and anonymous. Attempts were being made to induce legislative changes in protecting safety alerts from being used as evidence in legal confrontations, however as such legislative processes tend to be lengthy, this safety alert flagging system was set-up as a stop-gap move at a time when reporting was being discouraged by constant advise through trade unions. Other previously known barriers to reporting included lack of ergonomic dexterity of reporting structures – as a counter measure, the system brought about options of both manual or online filling, together with options of both electronic or manual submission. There is also a generic e-mail address for communicating alerts together with a mobile pager as alternative channels. Those who choose to disclose their identity, can ask for feedback notifications about the progress on the specific case.

The SALearn system is best regarded as a fluid system under progress, a means to an end. The number of cases received exceeds the established but evolving limited physical capacity of the Patient Safety Group. This limited capacity could at quick judgement suggest a diminished level of institutional acknowledgement on the importance of such a system, however in applying the fair blame approach, instead of

[8] Dalmas M, Azzopardi L, Manduca E, Balzan D, Ward C, Abela C. Launching and Running "SA Learn" - a safety alerting system for Learning at Mater Dei Hospital. In Malta Medical Journal Conference Abstract Book; 2015. p. 58.

blaming administration; one would rather study the systematic reason and hence look at the cultural evolutionary progress in the regard of patient safety. How is patient safety being marketed by professionals?

This approach was launched together with an organisation-wide commitment in ensuring a '*just blame*' approach; a principle which over the recent course of years has been actively maintained and practised throughout the institution. Evidence points out that notwithstanding the positive attributes of such '*just blame*' cultures, individuals tend to retain cynical attitudes (Humm C, 2003). At MDH, the staff's attitude to such reporting was never quantified.

1.6 Aims and Objectives

The aim of the study was to establish a pharmacist-led medication safety service within an interdisciplinary team at Mater Dei Hospital. This gave rise to the research question of "*How can pharmacy align other healthcare providers within ONE cycle, in leading to a positive shift in patient safety?*"

The objectives of the study were to:

1. identify at baseline the patient safety attitudes of hospital staff
2. audit and identify areas for actioning in terms of medication safety
3. develop a medication safety service tailored to meet the identified needs

CHAPTER 2 – METHODOLOGY

"*What's the world's greatest lie?" the boy asked.*

"It's this: that at a certain point in our lives, we lose control of what's happening to us, and our lives become controlled by fate.

That's the world's greatest lie."

Paulo Coelho, The Alchemist

2.1 Study Design

The development of a novel pharmacist-led patient safety service within a healthcare system that is primarily physician-lead, involved a structured approach. This was through acquisition of a baseline metric on patient safety attitudes, identification of other technical attributes and areas of prioritization, followed by the subsequent development of a patient safety service on the identified needs (Figure 2.1). This chapter describes the methodology undertaken to assess patient safety attitudes and identify the prioritization areas warranting the intervention of the pharmacist-led medication safety service within Mater Dei Hospital. The results of the methodology are described in Chapter 3.

Approval for the study was sought from Mater Dei Hospital. Approval was also sought from the Association of Healthcare Research and Quality (AHRQ) for the use of the questionnaire and related statistical package used for analysis and from the Institute of Safe Medicine Practice (ISMP) for the use of the self-audit on safety of high alert medications.

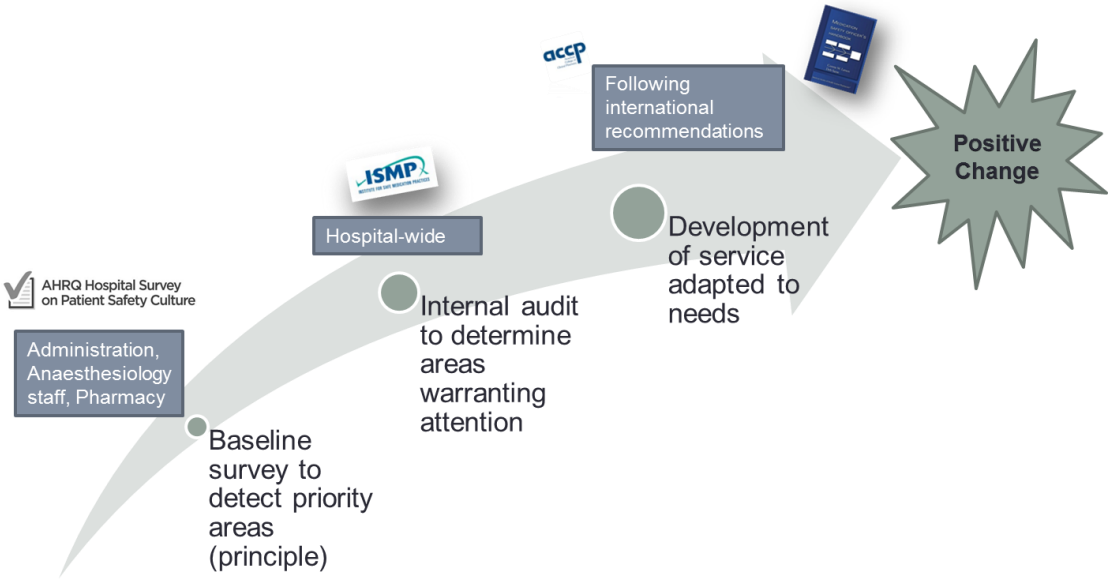


Figure 2.1 Devising a pharmacist-led medication safety service at Mater Dei Hospital

Methodology for developing the service, involved studying the current scenario through baseline AHRQ survey and an ISMP audit tool. This led to the identification and prioritization of areas requiring immediate action through the medication safety service launched.

2.2 Assessing Patient Safety Attributes

A quantitative analysis of the patient safety attitudes was undertaken with the purpose of analysing patient safety attitudes at baseline. Following a recommendation by the Joint Commission (2017), the '*Hospital Survey on Patient Safety Culture*', a tool developed for the Association of Healthcare and Research on Quality (AHRQ)[9] was chosen as the tool to be used for this study (Appendix 1). This AHRQ tool was launched in January 2016 for the Agency for Healthcare Research and Quality (AHRQ) and Medical Errors Workgroup of the Quality Interagency Co-ordination Taskforce (QuIC) by Westat. During its developmental programme, the tool was reviewed by a number of clinical and non-clinical participants together with input from various hospital systems' administrators, professional associations, additional patient safety researchers and the Joint Commission itself. Pilot testing covered more than 1,400 hospital employees from 21 hospitals across the United States of America. The tool consists of 42 items grouped in 12 composite measures together with two individual items; Patient Safety Grade and the Number of Events Reported by Each Respondent during the last year (Table 2.1). It also possesses psychometric properties and can enable hospital-to-hospital comparisons, an element that further explains why this tool was chosen for this study (AHRQ, 2016).

[9] Hospital Survey on Patient Safety Culture [Internet]. Rockville, MD: Agency for Healthcare Research and Quality 2007 Dec. Available from: http://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/hospital/index.html [cited March 2017].

Table 2.1 Items tested by patient safety attitude questionnaire

Individual Items	**Description**	**Number of Questions**
1. Patient Safety Grade	A question probing the respondent's point of view	1
2. Number of Events reported by respondent	A question asking the respondent on the actual number of reports they flagged in the last 12 months	1
Composite items		**Number of Questions**
1. Teamwork Within Units		4
2. Supervisor/Manager Expectations & Actions Promoting Patient Safety		4
3. Organizational Learning – Continuous Improvement		3
4. Management Support for Patient Safety		3
5. Overall Perceptions of Patient Safety		4
6. Feedback and Communication About Error		3
7. Communication Openness		3
8. Frequency of Events Reported		3
9. Teamwork Across Units		4
10. Staffing		4
11. Handoffs and Transitions		4
12. Non-punitive Response to Errors		3

Adapted from Hospital Survey on Patient Safety Culture [Internet]. Rockville, MD: Agency for Healthcare Research and Quality 2007 Dec. Available from: http://www.ahrq.gov/sops/quality-patient safety/patientsafetyculture/hospital/index.html [cited March 2017].

The AHRQ survey consists of these 12 composite items with a maximum of 4 questions each and two individual items testing patient safety grade and number of events reported by respondents. This survey allows comparison of the results obtained with those obtained from 680 US hospitals completing the AHRQ survey in 2016.

2.2.1 Validation

Electronic surveys are usually more ergonomic and cost-effective than paper-based, although the latter methodology can probably be a more suitable option for the more conservative. At the time of writing of this study, MDH was still paper based in relation to clinical duties. Access to computers in some areas especially on wards was also limited so questionnaires were tested for ergonomicity within the local scenario (Norman, 2013). Consequently the paper based version of the AHRQ survey was also offered to participants. An interview-style questionnaire in which the interviewer would visit respondents and capture data was eliminated as an option, in view of noticeable bias by the interviewer and lack of anonymity.

A validation group of thirteen MDH employees from the pharmacy department composed of pharmacists, pharmacy technicians, clerical and security members of staff assembled through convenience sampling, were normalized to fit Gaussian distribution dynamics with respect to age and gender. Each participant was asked to complete two formats of the AHRQ questionnaire:

i. paper version distributed by hand
ii. paperless version, sent electronically

Questionnaire versions were modified for this validation process whereby in the paper format, fields for name and time inclusion were secured and in the paperless version a mandatory field for name and dates was included. Links for paperless version also included a shortened URL and QR code. Participants were allowed to make use of the mobile phone or tablet device for data entry. The paperless version was compiled

using Google forms. This paperless version of the survey was laid out in a simplistic format with a section per each page, enabling the user to go back and alter responses in case of need. Each participant was asked to respond only to questions they felt comfortable at but were urged to complete both questionnaires without copying responses. The time for completion was documented for all filled-in forms.

2.2.2 Participating Cohort

A convenience sample cohort mix of hospital members from both horizontal and vertical structures were identified for participation in the AHRQ questionnaire. Horizontal structures included hospital administration, pharmacy, the patient safety group (PaSQIT), and groups influencing technology. Anaesthesiology members were selected as a vertical test cohort.

Members of the hospital administration included members of the board of directors of the hospital and administrative members involved in key influential roles. The hospital's patient safety group, the PaSQIT, was invited to participate. The PaSQIT was set up to improve patient safety; devised and manages the hospital safety alert system and was deemed important to include in the participating cohort. A member of the group is the hospital's patient safety officer, a clinician who has been tasked a full-time commitment for patient safety. The chairperson of this group is also the deputy chairperson of anaesthesiology. Another group composed of senior people from both professional and administrative backgrounds, with special responsibilities in implementing technological advances within the hospital, was also included in the participating cohort. These individuals were involved in discussions about medication errors and adverse drug events, system failures and technological advances aimed at

improving safety profiles of medication practices such as Computerized Provider Order Entry (CPOE), Clinical Decision Support Systems (CDSS) and other smart technologies such as smart pumps and their inbuilt soft- and hard-stop mechanisms by which to prevent errors. All members of the pharmacy team were invited to participate, pharmacy technicians and pharmacists act on different levels and at different stages of the medication use process and it was deemed important to include both professions.

All operating theatre nurses and anaesthetists working within the anaesthesiology department formed part of the vertical cohort of participants. This group handles a significant proportion of high alert medications, which mediations are often used in clinical situations that are particularly sensitive, e.g. patients being under anaesthesia or having to act in response to complications, in which such members would need to act quickly in response to changing needs. This cohort is particularly conversant with use of electrolytes, parenteral anticoagulants, neuromuscular blockers, narcotics and other anaesthetic agents, including routine administration via the neuraxial route.

2.2.3 AHRQ Survey Administration and Handling

All participants were identified from a staff list. Exclusion criteria included members of staff not on current active employment schemes as in the case of long leave and those who are retired. Target response rate was set at 50 % as recommended by AHRQ[10].

The AHRQ survey was anonymous and no fields were made mandatory. Although from a statistical perspective full anonymity can compromise the acuity of correlations, it was decided that anonymity was a key element in safeguarding the quality of responses within this study, in view of a number of sensitive questions. Participants

[10] AHRQ. Hospital Survey on Patient Safety Culture: User's Guide. Rockville; 2016.

were provided with two versions of the questionnaire, a paper and an electronic version (a URL hyperlink was presented together with a Quick Response (QR) code for users preferring to access questionnaire through a smart device). They were instructed to complete and return only one survey. Surveying techniques followed the instructions specified in the tool's user manual published by AHRQ.

Throughout the survey the first step was to examine each returned survey for problems before responses were assimilated into the dataset for subsequent analysis. Surveys that were either entirely left blank or contained suspicious trends (e.g. consistent scoring patterns throughout) were eliminated. Once a questionnaire was accepted as being valid, it was converted into a standard electronic format. Electronic responses were imported from Google Sheets to MS Excel and paper versions were first entered into the online questionnaire (transcribed) by the researcher. Transcriptions done by the researcher were checked by reading scores backward following data entry. This was a measure against skipping lines with the consequential distortion of correlation between recorded responses and questions proper.

Response rate was calculated with the expression:

$$\frac{Number\ of\ surveys\ returned - incompletes}{Number\ of\ eligible\ staff\ who\ received\ a\ survey}$$

The denominator was obtained from the staff lists used against which the questionnaires were distributed. In anticipation of instances where respondents could mark more than one response per question in the paper version (since most questions made use of a Likert scale), a decision was made to invalidate and nullify such responses as '*no data*.' In the paperless version, this possibility was eliminated

through making such response selection mutually exclusive (only one score could be chosen per section).

This study generated both quantitative and qualitative data. The tool created by AHRQ "*Hospital Data Entry and Analysis Tool*" was obtained from AHRQ and was used to analyse the data generated, using Microsoft Excel ® 2010 platform. Open ended responses were reviewed for any information that could give away the identity of individuals and then in case of aggregates, were tallied and treated descriptively. Any missing data was tackled at this step. Responses that failed acceptance criteria; namely responses being invalid (missing significant parts), lacking demographic information or including choice of same likert score strings (polarised options i.e. excluding neutral option 3) in normally coded and reverse coded items were nullified. The overall score for items within a composite were calculated through the AHRQ provided software package, computing positive and negative responses as percentages.

The twelve composite results were collated and compared intra-cohort (internally within hospital participants) and inter-cohort (comparing MDH hospital against aggregate data from the 680 hospitals). Constituent item level results were then analysed (Pareto analysis) in order to identify those items leading up to 80 % of the total negative scores by this survey. Consequently those composite items having more than two items within this panel, were then shortlisted as '*Important clusters*.' The two individual elements; '*Patient Safety Grade*' and '*Number of Events Reported*' were both analysed and evaluated intra- and inter-cohort. Comments received were also evaluated for common factors.

Composite data obtained was contrasted against the aggregate data from 680 US Hospitals who had carried out the AHRQ survey in 2016. Priority areas were identified from this statistical evaluation, on which the Hospital Medication Service for Mater Dei Hospital was then rolled out.

2.3 ISMP Self-audit Methodology

Subsequent to the AHRQ process, an internal hospital audit on high alert medications was carried out with the aim of identifying the main areas warranting prioritisation for a pharmacist-led medication safety service. The ISMP self-audit tool on the safety of high alert medications for 2017 was chosen[11]. The tool targets the safety use of 11 categories of high alert medications namely:

1. Neuromuscular Blocking Agents
2. Concentrated Electrolytes Injection
3. Magnesium Sulphate Injection
4. Moderate Sedation in Adults and Children, Minimal Sedation in Children
5. Insulin, Subcutaneous and Intravenous
6. Lipid-Based Medications and Conventional Counterparts
7. Anticoagulants
8. Neuraxial Opioids and Local Anaesthetics
9. Opioids
10. Methotrexate for non-oncologic use
11. Chemotherapy (oral and parenteral)

For the purpose of this study, given that the pharmacy was already heavily involved in oncologic and non-oncologic use of chemotherapy including methotrexate use in non-

[11] ISMP Medication Safety Self Assessment® for High-Alert Medications [Internet]. October 2017. Available from: http://www.ismp.org/selfassessments/SAHAM [cited October 2017].

oncologic indications, these two categories were excluded from the exercise which focused on the remaining nine categories of medicines.

Training on the correct use of this ISMP self-audit tool involved the researcher's participation in an international webinar held in October 2017, by ISMP. Presentation material which was disseminated was then used during the focus group undertaking the self-assessment. Key stakeholders intended to form the focus group were identified by the researcher in collaboration with clinical leads. The focus group included the head of pharmacy, clinical chair of anaesthesiology, chairperson of Patient Safety Group (PaSQIT), a Patient Safety Officer, the hospital medical director and nursing director respectively. The focus group members were asked to undertake the ISMP self-audit tool. Subsequently a meeting was held to share and discuss the focus group scoring.

CHAPTER 3 - RESULTS

"Not everything that counts can be counted,

and not everything that can be counted counts"

Albert Einstein

3.1 AHRQ Survey Validation

The validation group consisting of 13 participants were offered a free choice between paper and paperless versions of the questionnaire, simulating the logistical '*goods-to-person*' concept. This was intended to strengthen the ergonomicity and avoiding the anticipated work arounds stemming from lack of comfort in responding to the questionnaire. Instances where individual questions were answered only in one format or invalidated in any way (e.g. more than one response for same question was marked in paper version) were neutralised by removing that question from both questionnaire formats for the correlation test. A *Pearson correlation* test with a one tailed t-test was carried out for each question in the AHRQ survey. Single tailed *p* - values were computed as the direction of incongruence was known where in 12 cases (27 %) the correlation between the two formats was typically weak, as evidenced by respective *p*-values exceeding 0.05. A statistical evaluation involving a t-test of differences between the mean scores obtained for the responses recorded for each question, concluded that there was no statistical difference between the two formats, with respective *p* - values all exceeding 0.05 (Appendix 2).

3.2 Demographics

Out of the 235 questionnaires that were distributed to anaesthesia nurses, anaesthesia physicians, pharmacy staff and members of hospital administration, there were 128 (54%) responses that were returned. Thirty-three responses were rejected because they failed to meet established acceptance criteria for responses leading to 105 valid responses giving a response rate of 45 %. Fourteen questionnaires were returned by

hand to central collection points and the remaining responses were returned electronically. Data was contrasted with aggregate scores based on data from 680 hospitals (N = 447,584 participants) included in the Hospital Survey on Patient Safety Culture 2016 Comparative Database Report. Microsoft Excel 2010 was used as the software package of choice.

Out of the valid questionnaires (N=105), 51 % of participants work in pharmacy, 3 % in anaesthesiology, and 12 % of participants administer their services in other areas of the hospital. Of the disqualified questionnaires, no details were reported as some contained equivalent number scores (polarised) in both positive and reverse coded questions, others contained major missing parts and some contained no demographic data.

Eleven percent of the participants were registered nurses, 20 % were physicians and 32 % pharmacists. There were 25 % group-able under the category of '*others*', of which the majority included pharmacy technicians. Nine percent were members of the administrative stream whilst 3 % chose not to specify. Fifty-five percent of participants work in direct contact with patients as part of their daily work routine, whereas 45 % do not. The most frequent group of respondents (mode) with respect to the number of years working in the hospital was that of 6-10 years, with a relative percentage composition of 39 % of the respondents. This was followed by 29 % who had been working from 1 – 5 years. Twelve percent had been working for 21 years or more, whilst 9 % worked for 16-20 years. Ten percent of the respondents had been working in the hospital for a period between 11 to 15 years.

Thirty seven percent of the participants have been working in their current work area section for 6-10 years, 33 % for 1-5 years, 11 % worked for 11-15 years, 7 % worked for 21 years or more, another 9 % worked for less than a year with only 5 % having been working for 16-20 years in their current area. Most respondents (77 %) worked a weekly quota of 40-59 hours per week, with 12 % of the participants working between 60-99 hours per week. Another 10 % worked between 20 and 39 hours and only 1 % of the participants worked less than 20 hours per week.

With respect to periods spent working in their current specialty or profession, 32 % had been in their professional function for 6-10 years, with 26 % being there for 1-5 years. Thirteen percent had been in the profession for 11 to 15 years whilst 15 % for a period in excess of 21 years. Ten percent had been in the profession for 16-20 years whilst 3 % had been in for less than a year.

3.3 Composite Attributes

In the domain '*Teamwork within units*', 52 % of the respondents replied positively. With respect to *'Supervisor or Manager's Expectations and Actions promoting Patient Safety'*, 55 % of the respondents replied positively.

Forty-eight percent (48 %) of the respondents replied positively with respect to '*Organisational Learning and Continuous Improvement.*' The domain '*Management Support for Patient Safety*' obtained a score of 36 %. A similar score (36%) was obtained for the '*Overall Perceptions of Patient Safety*.'

With respect to '*Feedback and Communication about Error'*, a positive score of 41 % was obtained. In '*Communication Openness*' 46 % of the respondents replied positively. Thirty percent (30 %) of the participants gave a positive response in the aspect of '*Frequency of Events Reported*', with another 33 % reporting positive about '*Teamwork Across Units*'.

A percentage of 27 % responded positively to '*Staffing*' whereas 16 % recorded a positive score with respect to '*Handoffs & Transitions*'. 24 % of the respondents registered a positive response with respect to '*Non-punitive Responses to Error.*'

3.3.1 MDH compared to Survey Hospital Score (SHS)

In comparing MDH results with aggregate data from 680 Hospitals (N = 447,584) (referred to Survey Hospital Score – SHS), using a '*Difference of two proportions z-test*" the difference between the locally obtained values and the mean positive scores in patient safety attributes within SHS were statistically different (Table 3.1). Eight composites; '*Supervisor Expectations and Actions Promoting Patient Safety*' '*Organisational Learning and Continuous Improvement*', 'Teamwork within units', '*Overall Perceptions of Patient Safety*', '*Feedback and Communication about Error*', '*Communication Openness*', '*Staffing*' and '*Non Punitive Responses to Error*,' were equal to or exceeding minimum SHS scores obtained.

Criteria in which positive responses were below SHS Minima include '*Management Support to Patient Safety*', '*Frequency of Events Reported*', '*Teamwork Across Units*' and '*Handoffs and Transitions*' (Table 3.2).

Table 3.1 Patient safety composite scores, tabulated with standard hospital scores (SHS) and whether each attribute was statistically significantly less than mean SHS

Patient Safety Culture Composite	Mater Dei Hospital Score (% Positive Response)	SHS (% Positive Response)	Z-value	p-value*	MDH score less than mean SHS	Difference from SHS mean (% Positive Response)
1. Teamwork Within Units	**52**	**82**	**7.90**	**0.000**	YES	-30
2. Supervisor Expectations and Actions Promoting Patient Safety	**55**	**78**	**5.63**	**0.000**	YES	-23
3. Organisational Learning – Continuous Improvement	**48**	**73**	**5.86**	**0.000**	YES	-25
4. Management Support for Patient Safety	**36**	**72**	**8.17**	**0.000**	YES	-36
5. Overall Perceptions of Patient Safety	**36**	**66**	**6.45**	**0.000**	YES	-30
6. Feedback and Communication about Error	**41**	**68**	**5.94**	**0.000**	YES	-27
7. Communication Openness	**46**	**64**	**3.90**	**0.000**	YES	-18
8. Frequency of Events Reported	**30**	**67**	**7.96**	**0.000**	YES	-37
9. Teamwork Across Units	**33**	**61**	**5.82**	**0.000**	YES	-28
10. Staffing	**27**	**54**	**5.62**	**0.000**	YES	-27
11. Handoffs and Transitions	**16**	**48**	**6.52**	**0.000**	YES	-32
12. Non Punitive Response to Error	**24**	**45**	**4.36**	**0.000**	YES	-21

SHS refers to Survey Hospital Scores – MDH is Mater Dei Hospital

*The result is significant at $p < 0.05$

Table 3.2 Patient safety composite scores, tabulated with Standard Hospital Scores (SHS) and whether each attribute exceeded minimum SHS

Patient Safety Culture Composite	Mater Dei Hospital Score (% Positive Response)	Minimum SHS (% Positive Response)	SHS (% Positive Response)	Maximum SHS (% Positive Response)	Equal to or Exceeding Minimum SHS (Y/N)	Difference From Minimum SHS
1. Teamwork Within Units	**52**	26	**82**	96	**YES**	--
2. Supervisor Expectations and Actions Promoting Patient Safety	**55**	17	**78**	96	**YES**	--
3. Organisational Learning – Continuous Improvement	**48**	15	**73**	93	**YES**	--
4. Management Support for Patient Safety	**36**	39	**72**	96	NO	-3
5. Overall Perceptions of Patient Safety	**36**	36	**66**	90	**YES**	--
6. Feedback and Communication about Error	**41**	17	**68**	89	**YES**	--
7. Communication Openness	**46**	35	**64**	84	**YES**	--
8. Frequency of Events Reported	**30**	43	**67**	94	NO	-13
9. Teamwork Across Units	**33**	34	**61**	91	NO	-1
10. Staffing	**27**	20	**54**	86	**YES**	--
11. Handoffs and Transitions	**16**	22	**48**	80	NO	-6
12. Non Punitive Response to Error	**24**	20	**45**	75	**YES**	--

SHS refers to Survey Hospital Scores – MDH is Mater Dei Hospital

3.3.2 Impact of Working Close to Patients

Members of staff not working in close proximity to patients demonstrate a higher positive response in patient safety attitudes than those cohorts working at bedside. At MDH this difference (24 %) is more pronounced than in SHS hospitals, where difference is less (2 %) (Table 3.3).

3.3.3 Differences between MDH and SHS in Staff Type

From those members of staff who specified their origin in the classes of; administration, physicians, pharmacists and registered nurses, the group that was the closest to the SHS was the pharmacist group, with a difference of 22 %. Administrative staff, physicians, and nurses were all in excess of 30 % difference (less) in their positive responses, compared to the respective members of the SHS (Table 3.4).

Table 3.3 Composite value changes between MDH and SHS for both members of staff with direct interaction with patients *vs.* those without

Patient Safety Culture Composite	MDH With Direct Interaction (% Positive Response)	MDH Without Direct Interaction (% Positive Response)	Difference within MDH (% Positive Response	SHS With Direct Interaction (% Positive Response	SHS Without Direct Interaction (% Positive Response)	Difference within SHS (% Positive Response
1. Teamwork Within Units	39	68	-29	82	82	0
2. Supervisor Expectations and Actions Promoting Patient Safety	40	74	-34	78	81	-3
3. Organisational Learning – Continuous Improvement	31	68	-37	72	74	-2
4. Management Support for Patient Safety	23	53	-30	71	79	-8
5. Overall Perceptions of Patient Safety	21	54	-33	66	69	-3
6. Feedback and Communication about Error	27	57	-30	67	72	-5
7. Communication Openness	33	62	-29	63	67	-4
8. Frequency of Events Reported	20	43	-23	66	69	-3
9. Teamwork Across Units	28	38	-10	61	63	-2
10. Staffing	16	41	-25	54	53	1
11. Handoffs and Transitions	16	14	2	49	43	6
12. Non Punitive Response to Error	20	30	-10	45	49	-4
Average	26	50	-24	65	67	-2

SHS refers to Survey Hospital Scores – MDH is Mater Dei Hospital

Table demonstrates difference in positive scores between staff working in close proximity to patients and those who work away from. At MDH larger differences were obtained, whereas data was more stable within SHS.

Table 3.4 Patient safety composite variations between MDH and SHS, for administration, physicians, pharmacists and nurses

Patient Safety Culture Composite	MDH Admin (% Positive Response)	SHS Admin (% Positive Response)	Difference Admin (% Positive Response)	MDH Physician (% Positive Response)	SHS Physician (% Positive Response)	Difference Physician (% Positive Response)	MDH Pharmacist (% Positive Response)	SHS Pharmacist (% Positive Response)	Difference Pharmacist (% Positive Response)	MDH Nurse (% Positive Response)	SHS Nurse (% Positive Response)	Difference Nurse (% Positive Response)
1. Teamwork Within Units	69	90	-21	39	85	-46	57	83	-26	30	83	-53
2. Supervisor Expectations and Actions Promoting Patient Safety	61	90	-29	36	79	-43	66	81	-15	43	77	-34
3. Organisational Learning – Continuous Improvement	59	84	-25	32	72	-40	55	78	-23	32	72	-40
4. Management Support for Patient Safety	59	86	-27	17	72	-55	42	72	-30	16	66	-50
5. Overall Perceptions of Patient Safety	25	78	-53	18	67	-49	47	69	-22	23	61	-38
6. Feedback and Communication about Error	37	82	-45	24	64	-40	59	71	-12	28	65	-37
7. Communication Openness	52	79	-27	30	67	-37	61	72	-11	26	62	-36
8. Frequency of Events Reported	15	74	-59	23	61	-38	37	59	-22	17	66	-49
9. Teamwork Across Units	43	71	-28	24	62	-38	36	63	-27	28	58	-30
10. Staffing	11	63	-52	19	55	-36	41	62	-21	11	54	-43
11. Handoffs and Transitions	33	52	-19	14	44	-30	9	37	-28	17	49	-32
12. Non Punitive Response to Error	15	65	-50	23	44	-21	33	58	-25	13	45	-32
Average across composites	**40**	**76**	**-36**	**25**	**64**	**-39**	**45**	**67**	**-22**	**24**	**63**	**-39**

SHS refers to Survey Hospital Scores – MDH is Mater Dei Hospital

3.3.4 Impacts of Tenure in Current Position

The percentage scoring to the composite attributes obtained by each band of staff categorised by the tenure in their current position reveals that the highest score was obtained by those in their current role within less than a year, as was the case in SHS.

Variation in recorded scores across the various tenure classes was different in both MDH and SHS. Variation in MDH across the various tenure bands had a standard deviation of 9 whereas variation in SHS across the same bands was within a standard deviation of 2 (Table 3.5).

3.4 Items Making-up a Composite

Pareto analysis of the Negative Percentage Scores obtained by each attribute revealed those items contributing to 80 % of the total negative responses received.

Items composing the various composites were listed. Their respective negative percentage scores were extracted and sorted in descending order. The Pareto study was carried out by calculating the impact of each item on the total negativity scored. It was found that out of the items (n = 42), 67 % (n=28) attributed to 80 % of the total negative responses received (Figure 3.1).

These 67 % were then placed back into their composite categories. Those composite categories having two or more of these short-listed items were then selected as '*important clusters*' (Tables 3.6 and 3.7).

Table 3.5 Composite scores (average values) for both MDH and SHS, categorised by tenure in current position

	Less than 1 year (% Positive Response)	1-5 years (% Positive Response)	6-10 years (% Positive Response)	11-15 years (% Positive Response)	16-20 years (% Positive Response)	21 years or more (% Positive Response)	Average (% Positive Response)	σ (% Positive Response)
Average score MDH	53	33	39	36	27	33	37	**9**
Average score SHS	69	64	63	65	66	67	66	**2**
Difference	**-16**	**-31**	**-24**	**-29**	**-39**	**-34**	**-29**	**8**

SHS refers to Survey Hospital Scores – MDH is Mater Dei Hospital

This table demonstrates the average positive scores of the twelve composite attributes across each tenure band. Standard deviation across the range for both MDH and SHS is computed. Tabulated results show a greater variance (standard deviation) amongst staff cohort tenure bands at MDH.

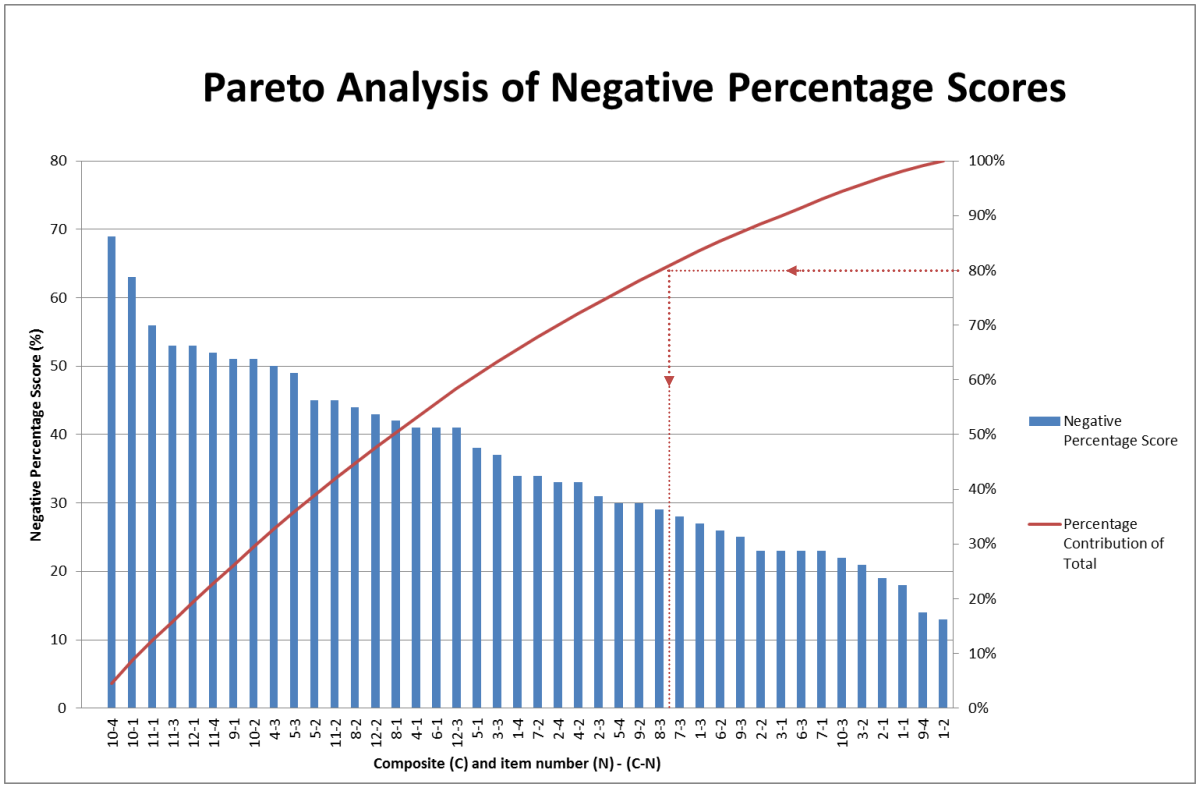


Figure 3.1 Pareto analysis of negative percentage scores

This Pareto Study identifies the codes for items contributing to 80% of the negative scores recorded

Table 3.6 Composites selected on the basis of having more than two items in pareto chart

Patient Safety Culture Composite	Number of items involved in Pareto	Classified as an important cluster? Y/N
1. Teamwork Within Units	1	N
2. Supervisor Expectations and Actions Promoting Patient Safety	2	Y
3. Organisational Learning – Continuous Improvement	1	N
4. Management Support for Patient Safety	3	Y
5. Overall Perceptions of Patient Safety	4	Y
6. Feedback and Communication about Error	1	N
7. Communication Openness	1	N
8. Frequency of Events Reported	3	Y
9. Teamwork Across Units	2	Y
10. Staffing	3	Y
11. Handoffs and Transitions	4	Y
12. Non Punitive Response to Error	3	Y
Number of Composites Selected	**8**	

Table 3.7 Composites and their respective items regarded as '*Important clusters*'

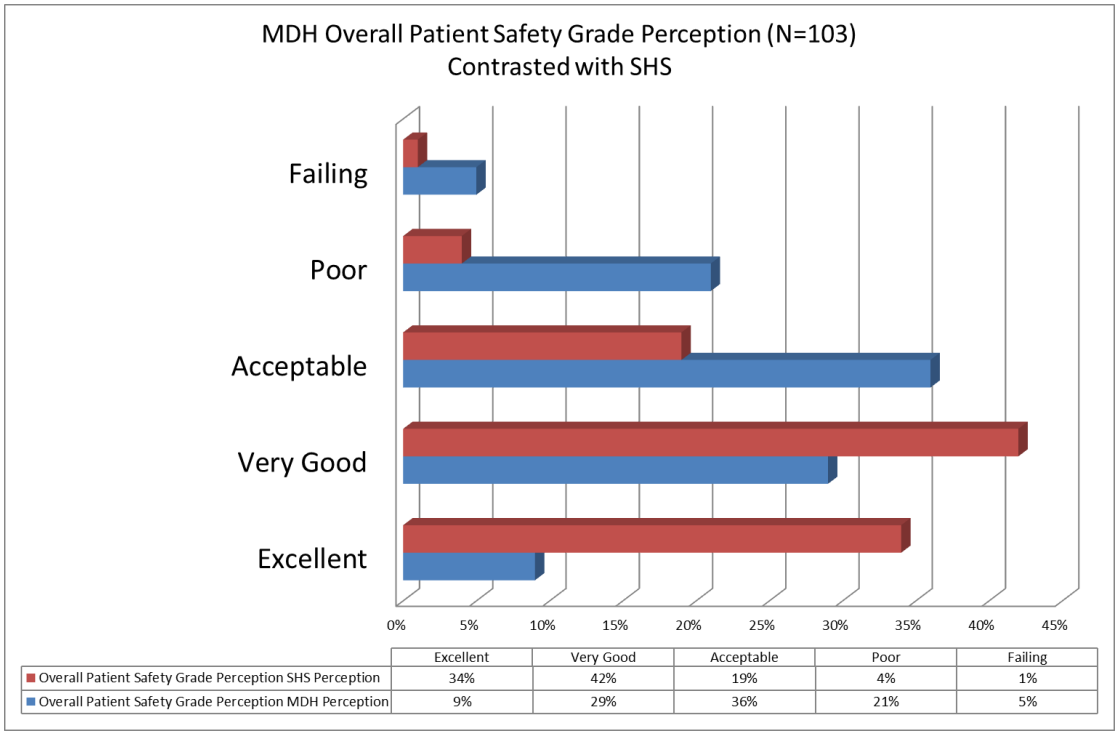
Composite	Items
Composite 2 - Supervisor Expectations and Actions Promoting Patient Safety	Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts. (B3R)
	My supervisor/manager overlooks patient safety problems that happen over and over. (B4R)
Composite 4 - Management Support for Patient Safety	Hospital management provides a work climate that promotes patient safety. (F1)
	The actions of hospital management show that patient safety is a top priority. (F8)
	Hospital management seems interested in patient safety only after an adverse event happens. (F9R)
Composite 5 - Overall Perceptions of Patient Safety	It is just by chance that more serious mistakes don't happen around here. (A10R)
	Patient safety is never sacrificed to get more work done. (A15)
	We have patient safety problems in this unit. (A17R)
	Our procedures and systems are good at preventing errors from happening. (A18)
Composite 8 - Frequency of Events Reported	When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported? (D1)
	When a mistake is made, but has no potential to harm the patient, how often is this reported? (D2)
	When a mistake is made that could harm the patient, but does not, how often is this reported? (D3)
Composite 9 - Teamwork Across Units	Hospital units do not coordinate well with each other. (F2R)
	There is good cooperation among hospital units that need to work together. (F4)
Composite 10 - Staffing	We have enough staff to handle the workload. (A2)
	Staff in this unit work longer hours than is best for patient care. (A5R)
	We work in "crisis mode" trying to do too much, too quickly. (A14R)
Composite 11 – Handoffs and Transitions	Things "fall between the cracks" when transferring patients from one unit to another. (F3R)
	Important patient care information is often lost during shift changes. (F5R)
	Problems often occur in the exchange of information across hospital units. (F7R)
	Shift changes are problematic for patients in this hospital. (F11R)
Composite 12 - Non Punitive Response to Error	Staff feel like their mistakes are held against them. (A8R)
	When an event is reported, it feels like the person is being written up, not the problem. (A12R)
	Staff worry that mistakes they make are kept in their personnel file. (A16R)

3.5 Patient Safety Grade

Thirty six percent of participants (n = 37), represented the most common recorded response; that of an overall '*Acceptable'* Patient Safety Grade. The mode recorded in SHS is '*Very Good*', with 42 % of respondents affirming such observation (Figure 3.2).

Administration members within MDH did not score a higher grade than the other members of the team, as was the case within SHS. Nurses scored a lower grade than other professional cohorts (Table 3.8). Respondents having direct interaction with Patients recorded a lower patient safety grade than those working without direct interaction with Patients. This contrasts with SHS, where respondents working in both systems recorded a similar score (Table 3.9).

Scores obtained from MDH seem to vary more with different tenure levels than do scores obtained at SHS. There are two prominent bi-modal distributions observed at tenure spans 6-10 years and 16-20 years (Table 3.10).



	Excellent	Very Good	Acceptable	Poor	Failing
Overall Patient Safety Grade Perception SHS Perception	34%	42%	19%	4%	1%
Overall Patient Safety Grade Perception MDH Perception	9%	29%	36%	21%	5%

Figure 3.2 Patient safety grade assignment comparison between MDH and SHS

MDH refers to Mater Dei Hospital (blue) and SHS refers to Survey Hospital Score. There were two percent less respondents in this perception test.

Table 3.8 Modal frequency percentage per staffing category in patient safety perception (MDH *vs.* SHS)

Staff Category	Mode - MDH	Mode - SHS
Administration	Acceptable (56 %)	Excellent (47 %)
Pharmacist	Acceptable (36 %)	Very Good (43 %)
Physician	Acceptable (39 %)	Very Good (45 %)
Nurse	Poor (30 %)	Very Good (44 %)

MDH refers to Mater Dei Hospital and SHS refers to Survey Hospital Scores

Table 3.8 demonstrates what the majority of members in each class feel about the Hospital's overall patient safety grade, as compared with same classes within SHS. Results suggest that nurses at Mater Dei Hospital tend to have a low perception, as compared with other classes. Within SHS, nurses tend to have the same opinion as physicians and pharmacists. Administrative members within SHS tend to hold a higher perception of patient safety. Pharmacists and physicians working at MDH share the perception that Patient Safety is '*Acceptable*', as compared to the perception of their counterparts working within SHS, who feel that the perception is '*Very Good*'.

Table 3.9 Modal frequency obtained by staff members in direct contact vs. those in indirect contact with patients (MDH *vs.* SHS)

Staff Category	Mode - MDH	Mode - SHS
With Direct Interaction	Acceptable (42 %)	Very Good (42 %)
Without Direct Interaction	Very Good (37 %)	Very Good (43 %)

MDH refers to Mater Dei Hospital and SHS refers to Survey Hospital Scores

Within SHS, there is no difference in the in the perception of overall Patient Safety between those working in direct contact with patients and those limited to office work.

At Mater Dei Hospital, the difference seems to be more pronounced then in SHS, with those NOT working with direct interaction with patients obtaining a higher score '*Very good*' than those working with direct interaction '*Acceptable*'.

Table 3.10 Modal frequency obtained by staff members at various tenure levels within their current role (MDH *vs.* SHS)

Staff Tenure	Mode - MDH	Mode - SHS
Less than 1 year	Acceptable (63 %)	Very Good (42%)
1-5 years	Acceptable (38 %)	Very Good (42 %)
6-10 years	Very Good-Acceptable (32% -32%)	Very Good (42 %)
11-15 years	Very Good (36%)	Very Good (42 %)
16-20 years	Acceptable-Poor (40% - 40%)	Very Good (42 %)
21 years or more	Very Good (57 %)	Very Good (43 %)

MDH refers to Mater Dei Hospital and SHS refers to Survey Hospital Scores

3.6 Number of Medication Error Events Reported

The majority of participants (52 %) declared that they did not participate in any medication error reporting. Twenty-six percent of participants took part in the reporting of 1-2 events per year whilst 8 % participated in 3-5 events. Fourteen percent of respondents were involved in more than 6 event reports per year (Figure 3.3). Reporting rates at MDH are appreciably close to rates at SHS.

With respect to reporting trends, variations between MDH and SHS staff members were observed in some categories. In the administrative stream, the mode of participants were involved in 6-10 events per year (44 %), this can be contrasted against the mode in SHS admin where the majority of participants from this stream were involved in 0 reports (47 %). As reported by (Figure 3.4), the role of the Pharmacist in medication event reporting is of an incomparable trend as contrasted against SHS hospitals, especially when it comes to reporting more than 11 events per year. Hospital staff in direct contact with patients is in general more likely to participate in event reporting (Table 3.11). Data patterns for MDH are comparable with those of SHS.

In the case of physicians, the majority (50 %) are involved in 1-2 events, with the next band not reporting anything at all (45 %). SHS physicians in their majority do not report (66 %).

Pharmacists at MDH do not report events in their majority, this is highly contrastable with reporting dynamics reported at SHS, where an equi-frequency tri-modal distribution (23 % each) characterises reporting by pharmacists at 0-5 events per year.

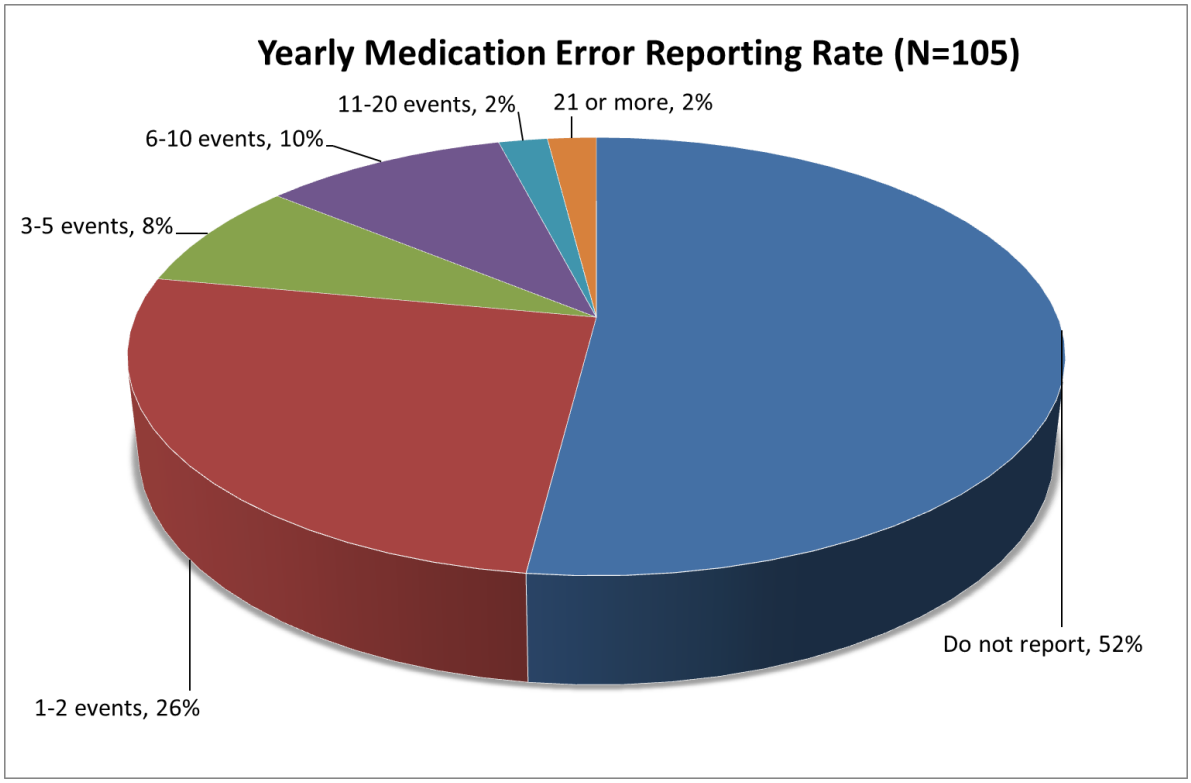
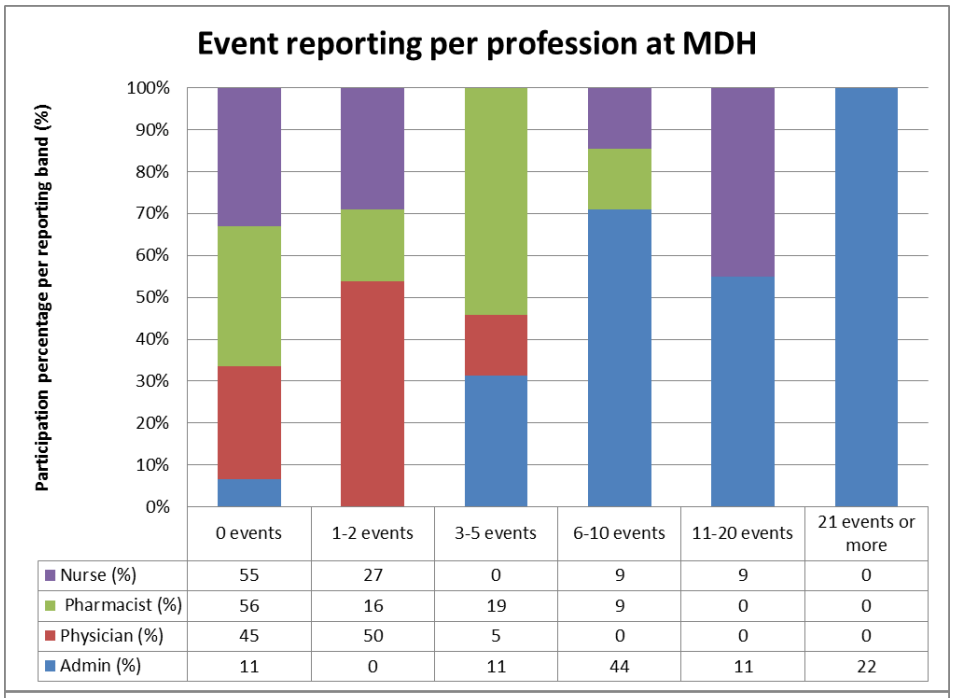


Figure 3.3 Participation in yearly medication error reporting at MDH



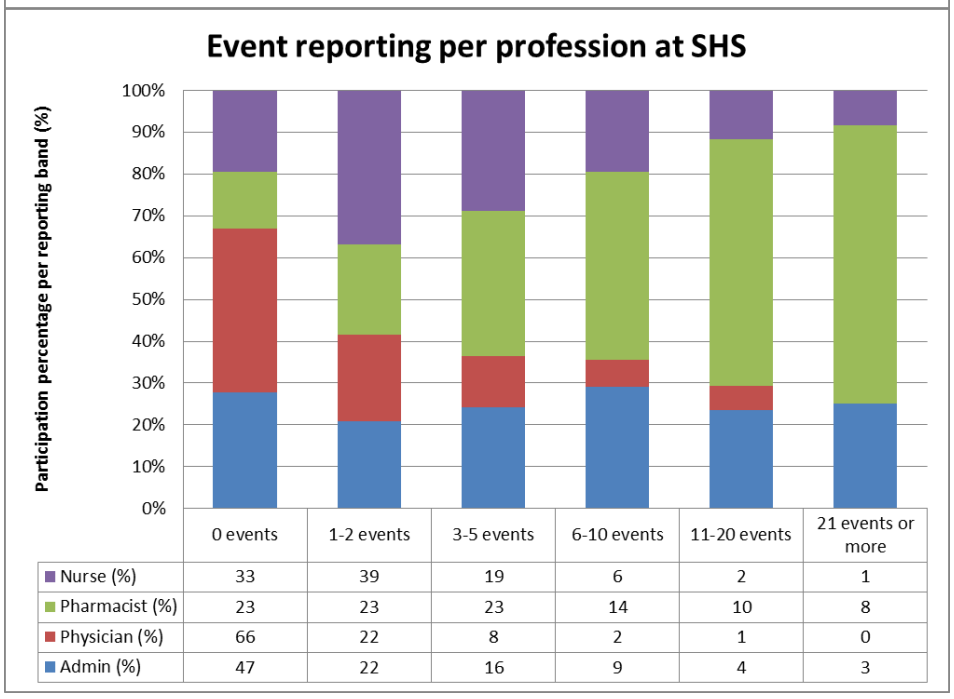


Figure 3.4 Participation of various professional groups in medication error reporting bands at MDH *vs.* SHS

MDH refers to Mater Dei Hospital and SHS refers to Survey Hospital Scores

One can observe the relative decrease in Pharmacist contribution to medication event reporting within MDH as opposed to SHS hospital.

Table 3.11 Event reporting as varied by staff working in direct patient contact *vs.* those not working in direct contact

	With Direct Interaction		Without Direct Interaction	
	MDH (%)	SHS (%)	MDH (%)	SHS (%)
0 events	45	51	62	69
1-2 events	31	30	19	16
3-5 events	7	13	10	8
6-10 events	12	4	7	4
11-20 events	3	2	0	2
21 events or more	2	1	2	1

MDH refers to Mater Dei Hospital and SHS refers to Survey Hospital Scores. Event reporting distribution is reported as a percentage out of a total of 100 % down each column.

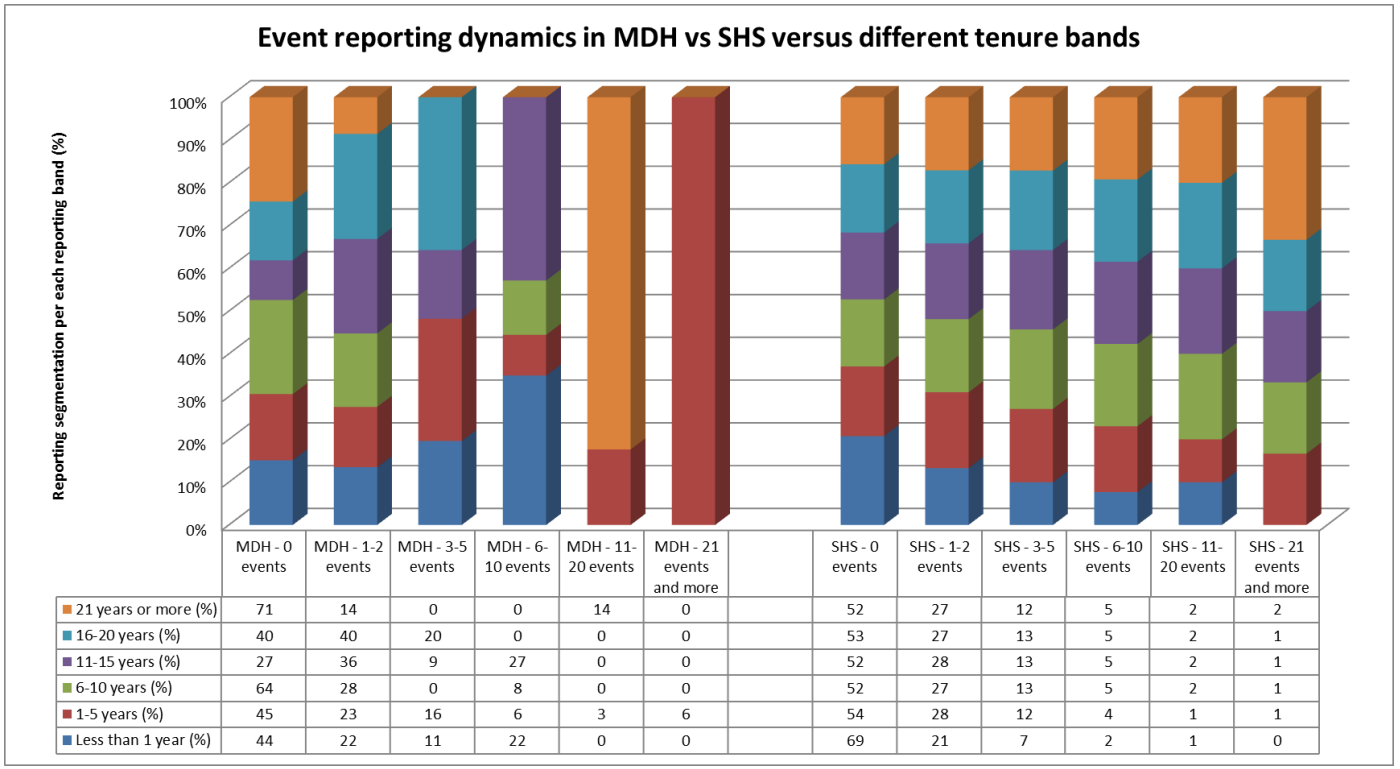
Datasets show that both those working in direct interaction with patients and those working without direct interaction, both hold modes at 0 event reporting during the past year, albeit modes of those working in direct interaction with patients hold weaker percentages in the 0 event category; both MDH and SHS. This concludes that those working in close proximity to the patients tend to report more events than those who do not.

Reporting in nursing is also low with the majority of nurses (55 %) not being involved in any reporting. At SHS, nursing is typically involved into reporting 1-2 events per annum (39 %).

In both MDH and SHS; the mode per each tenure band is normally close to '0' event reporting. At MDH, in the 11-15 year band, there is however a shift away from this dynamic, where the mode is participating in 1-2 events per year. This is duly noticeable with a 'trough' in the number not reporting any event. A noticeable feature is that participation dynamics in such reporting at SHS per each tenure band are however much more reproducible than in those obtained within MDH (Figure 3.5).

Participation in medication error reporting was on the low side. Hospital staff in contact with patients is generally more likely to participate in event reporting. This could be due to factors such as having more visibility to events as they arise. The observation that participation of MDH pharmacists in event reporting is lower as compared to SHS was interpreted in the context that the majority are away from clinical involvement.

On the other hand, the increased involvement of MDH administration in reporting as contrasted with administration bodies of SHS could be due to a hands-on involvement of local administration in the Patient Safety Alert System (SALearn). In these cases both administration members and pharmacists were from the whole hospital, so this data is strongly representative. So devised service, included elements of taking individuals closer to action and creating a sense of ownership in the measure.



	MDH - 0 events	MDH - 1-2 events	MDH - 3-5 events	MDH - 6-10 events	MDH - 11-20 events	MDH - 21 events and more		SHS - 0 events	SHS - 1-2 events	SHS - 3-5 events	SHS - 6-10 events	SHS - 11-20 events	SHS - 21 events and more
21 years or more (%)	71	14	0	0	14	0		52	27	12	5	2	2
16-20 years (%)	40	40	20	0	0	0		53	27	13	5	2	1
11-15 years (%)	27	36	9	27	0	0		52	28	13	5	2	1
6-10 years (%)	64	28	0	8	0	0		52	27	13	5	2	1
1-5 years (%)	45	23	16	6	3	6		54	28	12	4	1	1
Less than 1 year (%)	44	22	11	22	0	0		69	21	7	2	1	0

Figure 3.5 Participation of tenure bands in event reporting (MDH *vs.* SHS)

MDH refers to Mater Dei Hospital and SHS refers to Survey Hospital Scores.

This diagram explains how the trends expressed in SHS are not observable in the MDH situation. This lack of reproducibility can be influenced by the different sample sizes and the different cultural context. Structured patient safety reporting at Mater Dei Hospital is a more recent phenomenon than that within SHS.

3.7 ISMP Audit

The internal audit on high alert medications identified a number of systematic observations that highlighted a number of needs, amongst which the most prominent were:

1. The importance of expanding and continuing trending of patient safety attitudes and related metrics
2. Enhancing Pharmacy's gate keeping role in drug usage within the hospital
3. Increased usage of dedicated drug order sets
4. Reducing unit stocking of high alert medications
5. Standardising and centralising preparation of parenteral medications

3.8 Comments Received

Twenty-four percent of respondents perceived the survey as an important means to air their concerns, with a group of respondents actively stating that this survey carries the potential of improving the current scenario. The number of comments received varied from concerns about staffing to concerns about handovers. Two participants stated that they had been witnessing an improvement in patient safety matters over the years. One respondent stated that the belief that management hovers around the subject and avoids the most evident cause (in his opinion) – staffing, holds him back from reporting. A number of respondents also exhibited a concern that many do not engage in reporting, with one even stating that a potential role for lack of reports is

the lack of feedback the hospital gives to those who report. No one expressed concerns on blame, although one respondent claimed that staff still remains hesitant to reporting.

These anonymous comments were then presented to administration and discussed further. It seems that concerns about staffing are a predominant term and little regard is given to possibilities such as process re-design and improvements, measures that could unlock time pockets and extend the potential of any present capacity, without negatively affecting quality.

3.9 Further Data Analysis

Minimum SHS scores were not exceeded on 4 composite domains; '*Management support to Patient Safety*', '*Frequency of Events Reported*', *'Teamwork across units*' and '*Handoffs or Transitions*', however these were not the only areas that warranted attention. Local sample size induced statistical limitations that have to be kept in context when interpreting results. Although the average SHS scores were not reached; and all scores for the 12 composite values enabled statistical comparison with SHS data, the fact that the sample was not representative of the whole hospital called for a degree of caution to be exercised in data interpretation.

In this perspective, a Pareto study of negative responses (item level) gave a stronger basis for composite item prioritisation. Those individual items leading up to a cumulative 80 % of negative scores obtained were identified and grouped according to their composite. A condition was set that each composite had to include at least two items from such group to be selected. This led to the selection of 8 composites.

1) Supervisor Expectations and Actions Promoting Patient Safety
2) Management Support for Patient Safety
3) Overall Perceptions of Patient Safety
4) Frequency of Events Reported
5) Teamwork Across Units
6) Staffing
7) Handoffs and Transitions
8) Non Punitive Response to Error

The two parallel methodologies (Table 3.12), were then able to identify overlapping priorities, and were conducive to the right level of bias in identifying areas to address. Areas scoring in both methodologies were ranked as 'Tier 1' whereas those featuring positive in only one methodology were classified as 'Tier 2'; the former bearing a higher degree of priority that the latter.

Table 3.12 Prioritization listing of composite attributes using two methods in parallel

Patient Safety Culture Composite	Prioritization using comparison with SHS - Method 1	Prioritization Using Pareto Analysis - Method 2
1. Teamwork Within Units	--	--
2. Supervisor Expectations and Actions Promoting Patient Safety	--	✓
3. Organisational Learning – Continuous Improvement	--	--
4. Management Support for Patient Safety	✓	✓
5. Overall Perceptions of Patient Safety	--	✓
6. Feedback and Communication about Error	--	--
7. Communication Openness	--	--
8. Frequency of Events Reported	✓	✓
9. Teamwork Across Units	✓	✓
10. Staffing	--	✓
11. Handoffs and Transitions	✓	✓
12. Non Punitive Response to Error	--	✓

This table shows the prioritization listing of the composite values when the two methods; method 1, using comparative statistics with international data and method 2, pareto statistics on negative responses without including international data. Both methods identified composite values 4, 8, 9 and 11 as a priority. In setting up the service, components receiving double identification were put in Tier 1 whereas components identified only by pareto analysis were listed as tier 2 priority elements.

CHAPTER 4 - DISCUSSION

"To improve is to change. To be perfect is to change often."

Winston Churchill

4.1 Attitudes

It can be concluded that the patient safety attitude within our hospital's tested cohort, compared with international aggregate data is not exceedingly different.

As responses returned in paper form add up to 13 % (n=14), with nursing being the main group opting for a paper based format, it can be argued that the tested nursing cohort probably lacked direct access to an electronic computer interface; centralised (office based) or decentralised (portable device). The observation that the majority of responses were collected using electronic means also suggests that the hospital is pro-technology. This observed electronic dexterity can be interpreted that easily accessible online systems for data collection are likely to have an edge on paper versions within the sampled hospital population.

The comments field in the survey tool left a good impact as 24 % of the respondents (n=23) used it to leave comments, viewing the latter survey as an '*opportunity*' to register their remarks. A post-test was not applied in close proximity to the baseline because a definite timeline that captures sustainability (18-24 months) needs to be established as a minimum.

The availability of the survey tool and the fact that AHRQ granted the Hospital permission to make hospital wide use of it was a very positive note. The hospital was typically pleased of the fact that the statistical package AHRQ shared was free of charge and that it enabled comparison with hospital aggregate data (defined as SHS in this document). This incentivised the hospital to take such metrics with more vigour; that the hospital chose to commission such a study, proves the hospital's solid

commitment towards improving the safety level from any baseline. Furthermore, the fact that tools like the survey are also free of charge to use further proves that the global incentive towards patient safety optimisation is a reality, notwithstanding the commercialised nature of the industrial realities.

Participation in the ISMP Self-Audit[12] was an important opportunity for the hospital, where a number of participants contributed, with the three main clinical directors of the hospital showing definite interest in the exercise. The availability of thoughtful leaders is expressed as a key for positive gains in patient safety (Wachter, 2012). Apart from hospital (staff) feeling that something concrete was being done, administration was also less concerned that non-useful or rather non-impactful recommendations, often ones which cost a disproportionate amount of resources with no tangible benefits will be recommended. Furthermore, the exercise introduced many to the concept of ISMP. The importance and value of hospital/academic networking was further accentuated. An impactful outcome from this audit was that Pharmacy is now working with anaesthesiology in finding suitable candidate parenteral medications for standardisation and centralised preparation. Also, the importance of technological solutions was presented in clearer context.

This audit was originally intended to be carried out in conjunction with the international participation and submission of data. Participation was not as smooth where participants often opted to be '*chased*' in answering specific responses rather than offering to undertake the whole exercise or modules thereof. This led the whole

[12] ISMP Medication Safety Self Assessment® for High-Alert Medications [Internet]. October 2017. Available from: http://www.ismp.org/selfassessments/SAHAM [cited October 2017].

exercise to be carried out by the author and then any gaps were closed by enquiring pertinent questions to the identified individuals. This was the first exercise of the sort and consequently many were apprehensive about it. Although participation in international data sharing with ISMP was not successfully completed, following the exercise many participating members were then looking forward to prospective participation in future opportunities. Apart from the constant reminder that this was an internal exercise, a proviso that no findings would influence or bring about any measures that induce change processes without substantial evaluation and consultation, was widely communicated with members of staff. The local cultural framework of the Maltese islands, traditionally features strong scores in uncertainty avoidance and power distance. These measures could explain this behavioural mind-set, and for such or similar audits to succeed in the near future, they have to be spearheaded by administrative members holding authority. Excessive discussion can lead some ground members or cliques to fear taking the decision whether to participate or not, and some could do their utmost to jeopardise and eliminate the decision making process. This sharp approach can also eliminate apprehensive concerns and unnecessary fear amongst genuine members who are pro- positive change. Also, conducting such audit as official business gives it more importance as being an intrinsic part of the job, un-connecting any ties from being deciphered as extra work.

From the collective findings of patient safety attitudes and the ISMP self-audit, the medication safety service was oriented towards three main domains (Table 4.1):

Table 4.1 Impact dynamics of chosen measures on each targeted composite attribute

Composite targeted	Medication Distribution	Safety Profile of Aseptic Preparation	Improvement of Safety Alert Flagging
Tier 1			
Management Support for Patient Safety	Improving the process for more accuracy and reproducibility	Move towards centralisation of service together with other measures such as use of oral syringes (avoidance of unintended parenteral administration), filter needles, aseptic technique standardisation demonstrate such support	This approach makes safety matters more prominent and hence facilitates prioritisation
Frequency of Events Reported	Safety alert flagging by pharmacy – driving pharmacy closer to point of action	Standardising processes in a quasi-industrial manner allows for application of non-clinical (industrial) quality system	Measures intended to promote such reporting and establish a baseline reporting rate and turnaround timeframes
Teamwork Across Units	Liaison role of pharmacy within medication use process	Closure of quality gaps (e.g. wrong diluent, wrong technique, contamination) that can lead to therapeutic failures	Collaborative engagement of interdisciplinary staff in problem resolution
Handoffs and Transitions	A seamless system and pharmacy traceability ensures better control	Preparation control and traceability guaranteed. Preparations through such system are back-traceable	Safety alert investigation is more likely to identify flaws in handoffs and transitions, root causes that can be both specific to cases or general across the board
Tier 2			
Supervisor Expectations and Actions Promoting Patient Safety	Organisational commitment in improving the process	Reducing medication preparation at clinical areas send strong message across the board	System diagnostics (rate of reporting/severity) and rate of ADE can provide an important prognostic metric of safety
Overall Perceptions of Patient Safety	Getting pharmacy more involved in the process	Reduction in number of technical options and dilemmas (e.g. compatibility, stability) at clinical level – such decisions taken by technical experts	Increased usage of terms such as '*risk assessment*', '*pharmaco-vigilance*' and '*medication safety*' familiarise hospital stakeholders with such concepts to which they will be able to relate to when encountered
Staffing	More efficient teamwork with previously 'locked' time pockets	Capacity planning for centralised preparation is more robust - industrial approach, reducing time burden on other clinical applications	Staffing requests following a responsible capacity planning exercise are more likely to be honoured
Non Punitive Response to Error	Involvement of interdisciplinary team in resolutions and investigations	Clearer segregation of functions allows for a more rapid systematic understanding – less room for blaming individuals	Such system establishes clearer guidelines of failure taxonomies and culpability assessments

1. Medication Distribution Processes, leading to an increased input of ward Pharmacy, specifically planning service expansion towards operating theatres.

2. Improvement of the safety profile of aseptic preparation of medicines, with the targeted vision of centralizing most aseptic preparatory activities within pharmacy, whilst ameliorating the safety of aseptic processes within clinical environments.

3. Improvement of the safety alert flagging processes, with the clear intent of increasing rate of reporting and preparing the hospital to react better to safety issues in the most correct and timely manner.

Comments received during the survey were shared during patient safety meetings, and amongst members of the administration and staff in general. The greatest subject involved perceptions on staffing, followed by genuine constructive feedback on the safety alert system. Giving members of staff occasions to voice their concerns was an important aspect of this project, as it was more than on one occasion where verbal feedback was received from individuals, where they commented on the tool and declared that they left feedback. Looking at feedback left by respondents, the majority were anaesthetists and personnel from administration. This could infer that different members of staff would prefer different mechanisms of choice through which they would communicate their concerns. Finding the most comfortable and ergonomic mechanisms for the various key stakeholders within the hospital to communicate has to be regarded as an essential step for any organisation, as continuous feedback to any system is a key antidote for any communication failures and mishaps. Work in the

domain of the medication distribution process was a particularly impactful area for marketing the importance of a pharmacy-led service within the hospital. Pharmacy was for a long time being perceived as the entity carrying the sole obligation of supplying and dispensing medicines. Pharmacy is now being asked to join in board meetings where other departments are present, including those meetings on decisions that touch on the subject of medicines even marginally. This can indicate that the wider gamut of the pharmaceutical service spectrum is now being understood. In the hospital the word '*lean*' is also understood more, and the idea of waste is being looked at through a different optic. This has invariably brought about closer work orchestration with members of hospital administration, which members often '*pull*' the need for pharmacy input, and with special emphasis on medication safety. Throughout this campaign, the concept of safety was explained in high resolution – with definite emphasis on costs of mishaps and importance of being proactive and generative. Specific emphasis on concepts such as '*Quality by Design*' are now more readily understood. Perhaps one of the best ways to deliver such information was through explaining concepts when opportunities materialise. The importance of Pharmacy input in therapeutic decisions *vis-à-vis* disease management and international Classification of Diseases (ICD-10) with Disease-Related Groups / Health Related Groups (DRG/HRG) classification schemes was also widely understood, appreciated and seen as an opportunity to standardise approaches.

The importance of pharmaceutical control in the medication use process was further highlighted through the high alert medication audit, where the tool explained the expected roles of pharmacy in appreciable detail. This created the right circumstances

for re-designing drug distribution pathways, challenging the status-quo. This involved considering the potential benefits of technologies enabling closed loop mechanism processes that will enable the eventual realization of the 100 % pharmacist drug order verification, an international patient safety goal. This was useful in preparing the hospital to look towards the future possibilities of establishing a CPOE framework in addition to the conversion of most floor stock to individualized unit doses, consequently improving the medication use process (Davis, 2014).

Coaching materials were distributed amongst various members of the organisation. Lectures were designed with the WHY>HOW >WHAT principle[13] in the sequential order of merit. Lectures connecting the principles and tools of risk management together with the importance of reducing the risk with high alert medications were developed and disseminated in a workshop-like manner to nursing. These lectures were designed to activate the nursing floor on treating high alert medications in a different way from just locking them up in a cupboard.

The concept of change management; and that dynamics of change are by nature an area of expertise that go beyond the asking of people to do things, is becoming a deeply rooted principle. Reference to Lean and Lean six-sigma, Emotional Intelligence (EQ) (Bradberry and Greaves, 2009), and technical terms of quality tools such as Process Validation and Equipment Commissioning are better understood. Risk assessments and patient safety, are also becoming household terms, and will surely become of value in the implementation of projects. The reason behind the underlying

[13] TEDx Talks. YouTube. [Online].; 2009. Available from: https://youtu.be/u4ZoJKF_VuA [cited June 2017].

concept of centralising pharmacy preparation activities (aseptic/non-aseptic compounding) whilst de-centralising Pharmaceutical care services is being understood by many members of staff at different levels. This was a much desired impact in this domain. Through encounters with anaesthesiology and administration, two general attributes these members of staff expect of Pharmacy Mater Dei Hospital Pharmacy are increased presence at ground level together with an increased input of compounded and aseptic preparations. With respect to anaesthesiology this concerned a number of various dosage forms, of which most are used pre- and peri-surgical anaesthesia and which are standardized in dose. Published evidence asserts that a combination of Pharmacy and anaesthesiologist prepared drugs might also carry cost-effective benefits, especially if facility maintenance costs are amortised on other areas of activity (Jelacic *et al*., 2016).

Work towards the improvement in the safety profile of aseptic preparation of medicines involved a mix between internal and external measures; the cornerstone factor being the sustainable centralisation of preparatory activities within pharmacy. The strategy was to create an internal pharmacy structure that could robustly support such a service, whilst at the same time incentivising individuals working within on their future career and expansion. A principal and traditional problem in this domain was that the current workforce is primarily composed of pharmacists, instead of pharmacy technicians (with a ratio approaching 2:1). Over time, this led to a historic role erosion with pharmacists doing a mix between clinical and preparatory work. Furthermore, work distribution was not being planned collaboratively with other clinical professions and members of the compounding unit were feeling that they were understaffed.

Consistent with published literature, this feeling can either be genuine (if there is a transparent capacity planning exercise in place) or it can be a pseudo-impression due to inefficient workflows (systematic influences) that render work inefficient with time pockets that cannot be unlocked (Gregorio *et al.*, 2017). It can also be a mix of the two. Team members were requested to conduct a capacity planning exercise, this doubled up as an important statement that administration wants to address these challenges. A question and answer (Q&A) session was then used in presenting a revision of the exercise with the statement that on completion the exercise would be mutually endorsed by the administration and the group. Published evidence supports these observations and actions in that through optimisation of capacity planning within an aseptic dispensing unit, processes can be streamlined up to a significant degree that even patient waiting times will be improved (Pouliquen *et al.*, 2011). The strategy behind this approach was to mediate the issue from the vantage points of both administration and compounding. Tool used was the capacity exercise plan featured in the latest, most comprehensive guideline book at the time of writing for the UK NHS (NHS Pharmaceutical Quality Assurance Committee, 2016)

The exercise was also used as a means in giving time value and allocations to functions not directly attributable to compounding *per se*. These included activities such as Quality Management and logistics. Opportunity was also being used to attract pharmacy technicians towards technical competencies in aseptic compounding and establishing a new hospital niche for pharmaceutical technologists (a new, establishing professional role with academic MQF 6 and 7 qualifications), with new Quality Management roles and functions. Examples in this regard include remits such as

environmental monitoring and validation. People fulfilling such roles were encouraged to further their studies along the same lines. This was done in achieving a higher level of quality and shaping the evolution of the unit in a re-structured way. This re-structuring is bound to help in inducing new needs and knowledge niches for the prospective pharmaceutical technologist and future curricula, as the role of the pharmaceutical technologist develops further within the hospital environment.

Various work was done with nursing and anaesthesia on understanding critical parts of the aseptic technique. Examples of aspects that were highlighted were the importance of the use of 5 micron filter needles in avoiding Glass Particulate Contamination (GPC), together with the importance of swabbing all outermost surfaces of vials, ampoules and paraphernalia with sterile Isopropyl alcohol before accessing contents. Such events were used to influence educational material, such as hospital newsletters and posters, emulating the approach taken by Marcucci *et al.* (2007), where specific lessons are compiled in one publication, bringing the important lessons to the health care providers.

Active participation in international events and including local members of staff in international networks facilitated measures such as the creation of hospital groups working on the establishment of a ward based workplace instruction documents intended to streamline the preparation of medicines at ward level. On approaching this, there were some initial concerns that pharmacy was contemplating a '*u-turn*' on the set goal of centralising preparation. It was explained that this was being put in place in support of centralisation, in mitigating the concern that centralisation might

induce de-skilling in terms of medicines preparation at bedside. Items such as STAT dosing and short shelf life materials were mentioned as practical examples. Furthermore this short instruction document was intended to accentuate the importance of the parenteral manual; a collation of monographs Pharmacy is working on and which will be implementing throughout 2018[14]. The importance of following through was also re-iterated in an ISMP report following an audit within a number of hospitals in the United Sates[15]. Findings in this US report spanned from syringe re-use on multiple patients, re-entering a vial with used syringe and needle, sharing multi-dose vials between a number of patients and utilisation of source bags or bottles as diluents of choice for a number of patients. These violations were observed in both nursing and physician populations working within those hospitals and included speciality areas such as oncology and anaesthesiology. It was acknowledged that staff competencies in injection safety training must be on-going, where competencies are assessed regularly. The importance of not over-relying on campaigns such as the '*One and Only Campaign*' was expressed, communicating the importance of a deep-level 'multifaceted approach' to both education and surveillance.

This exercise was also useful in advertising the skills of the medicines illustration department as an important part to the interdisciplinary setup. This office was generally being used as a printing press without understanding and appreciating the valued input it could give. Lead members of the infection control unit were also part

[14] Council of Europe. (2016). Resolution CM/Res(2016)2 on good reconstitution practices in health care establishments for medicinal products for parenteral use. Brussels.

[15] ISMP. Institute for Safe Medication Practices Website. [Online].; 2017 Available from: https://www.ismp.org/resources/alarming-survey-results-cdc-unsafe-injection-practices-continue?id=1179 [cited January 2017].

of the focus group and this was positively impactful as the latter are responsible for setting the hospital's standards for aseptic practices at clinical level, and harmonise the Hospital's curricular material on the subject. Curricula and their development in line with changing needs can be an effective means in reducing errors and consequently harm during aseptic preparation of medicines (Dennis, 2015). Members of these focus groups were encouraged to come up with strategic ideas. They were prepared that strategic ideas would then be tested for effectiveness in reaching a vision – of which tools such as Failure Mode Effects Analysis (FMEA) were normally employed. Through this approach, risk management tools were not presented as a task to learn but rather as a solution to a problem, following the WHY>HOW>WHAT logic – making sure that the reason behind every move is clearly understood.

Another impact was the involvement of the set pharmacy led medication safety service in the revision of the treatment charts, where main input was on following international safety recommendations as was the implementation of heparin standardisation; an exercise that gave rise to the first dedicated drug order sets. In the case of heparin, following a TRIZ risk assessment a question and answer (Q&A) training document was compiled together with a set of workplace instructions.

The mechanistic aspects of this approach was to group the important aspects of the medication use process (procurement of right formulation, prescription of right dose, adjustment by monitoring and follow up by pharmacy) and ensure mechanisms by which to maintain control on them. The choice of a question and answer technique was employed in view of its cognitive properties on learning (Adi, 2016). This enabled

the prospective quantification of an important outcome metric[16] : the Percentage of Patients receiving activated partial pro-thrombin time (aPTT) outside protocol limits.

Services were also requested in the domain of reviewing a number of clinical guidelines, of which the establishment of a hospital wide intravenous fluid guideline was a key example.

In the domain of safety alerts and their handling, a crucial aspect was that of clarifying the primary importance of protecting patients from harm, as opposed to the '*fixation*' or '*obsession*' with safety alert logging. Work was done in applying a standardised approach in responding to situations where patients can be harmed. The TRIZ approach was also typically useful within this context.

Statistical evaluation of the set Patient Safety Alert reporting scheme left an appreciable impact on the maturation of what data one should measure. The idea of NOT measuring error rates on their own merit was initially challenged but eventually the importance of improving the metrics in line with rates of reporting and severity mapping was understood. This also laid the way to an increased level of acceptance into establishing rates of Adverse Drug Events (ADE) as a hospital dashboard metric. A technique from Heath (2010) was replicated in that during a patient safety meeting, a number of key influential hospital members were asked if they knew how many errors we were getting and then surprising them by throwing a printed publication on Global trigger tools and the rate of harm (Najjar *et al*., 2013), on the table.

[16] IHI – How to guide – reducing harm through high alert limitations

Re-routing of all medication related safety alerts to pharmacy following central registration was another move to improve the quality of reporting. The establishment of a robust link with Pharmaco-vigilance structures was an important trade off in ensuring that this happens. Quality improvement measures in this regard were also coupled with developmental involvement of areas such as medicines information to increase safety alert flagging, and pharmaceutical technologists to develop solutions that improve workflow logistics through the use of informatics.

In some cases, Pharmacy chose to assemble a multidisciplinary group of hospital members with the remit of conducting a full scale Root Cause Analysis (RCA). This was intended to bring about a greater sensitivity to systematic failures whilst improving the perception of pharmacy. Activity included education sessions in RCA and risk mapping. Training on Root Cause Analysis (RCA) was directed at maximizing the hospital's abilities in handling investigations, with members eventually being in a position of leading sessions. This was done formally during elective meetings and one to one to members who expressed interest. The hospital also requested such individuals to participate in / lead a number of investigations, in which the events were also used in training members in formal RCA and culpability assessment. Active participation in induction lectures on medication safety ensured that lessons learnt in medication safety are disseminated to new members of staff as soon as they join the hospital.

4.2 New Corporate Model

This aspect of practice had its own definite advantages, both intra- and inter-professionally. Within the profession the whole concept of medication safety in a hospital or other healthcare setting had to be redefined as part of this research, where the new role of the medication safety pharmacist in many instances diverts from the hierarchical role assigned by traditional organograms. The new approach developed in this research portrays the pharmacist-led medication safety as a concept, characterized as the tyre and rim of a spoke-laced wheel (Figure 4.1). This tyre would need to morph its type and pressure according to the terrain it is navigating, with the essential dynamic that it faces all the issues, bumps and problems encountered along the way. This epitomizes medication safety as a concept that is ever changing; encountered challenges are also ever-changing and shifting. This prioritizes the importance of characteristics such as '*servant leadership*.' Interconnecting medication safety to administration is an array of spokes, rather flimsy pieces of metal that represent the various sections and their processes. Should the tension within each spoke be too lax, the whole wheel can warp and will suffer, conversely should the tension be excessive, then tension gets pulling hard on both administration and safety, with the risk of snapping and burnout. This explains the importance of making sure that the tension within the wheel spokes is tuned up. At the helm of the interface between the spoke and the hub there are the section line managers of each function. Should something odd happen to one function, slack can be temporarily taken up by other sections, however there would need to be a calculated re-adjustment of tension distribution. On the other side, the unit's administrator is being challenged by both his

own system and also by the axle that transmits the tensions found in other '*wheels*'. Hub lubrication and preventive maintenance are therefore important aspects of any organization planning to keep going for any long period of service life. The vested interest exhibited by one wheel on how the other wheels in the network are doing is a very important strategy that depicts the importance of teamwork across units. Failure in any one area of the hospital is likely to cause ripple effects on other sections and the end goal in general; that of patient safety and efficacy.

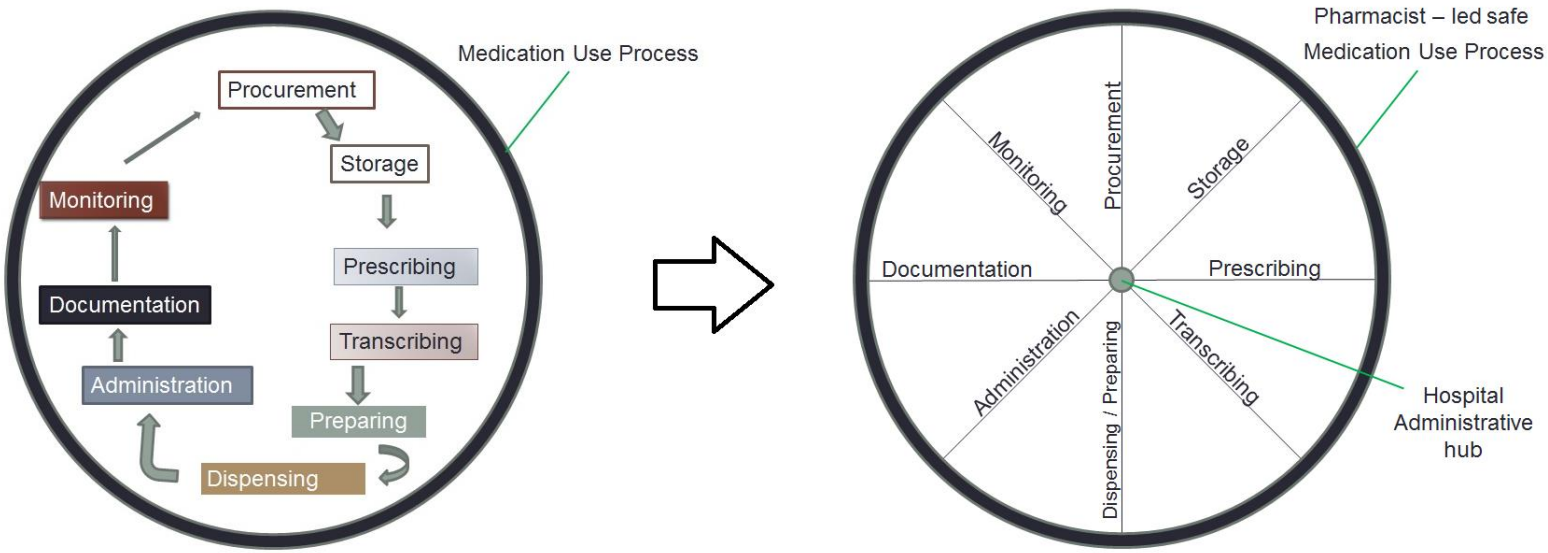


Figure 4.1 Transition from traditional model to a pharmacist-led safe medication use process

A swift wheel is able to negotiate any terrain it is presented with. Medication safety is an intrinsic Quality Assurance function of any hospital. A Pharmacist-Led medication safety service as the tyres and rims of the wheel is to master the ability to read the terrain and work with administration to alter the composition of functions in order to maintain the integrity of the wheel and enable the successful navigation of the terrain. This proves that prioritisation of measures might vary from time to time in the same institution and also transposition of 'measures' from one hospital to the next has to be exercised with caution.

4.3 Reflection

Although measurement of absolute outcomes remain a contentious matter owing to metrological difficulties in data collection and hence usefulness of data, the measurement of other metrics such as patient safety attitudes within an organisation remains important as a process indicator[17]. This study was important in providing an approach that prioritizes measures that can have a positive impact on the patient safety of an organization and quality of healthcare in general. Bodies of evidence state that a '*just*' or '*learning culture*' is more likely to materialize within organisations that involve employees in decision making (Khatri *et al.*, 2009). The definitive impact of a pharmacy-led medication safety pharmacist can only be measured through a continuously accurate and reproducible measurement of ADEs[18].

Consistent with theories of change, any medication safety improvement programme is expected to take its own course of time, especially with respect to awareness and trust. People being led usually support their leader as long as he/she will be the first one to intervene on their behalf. In societies holding a high power distance index (Hofstede *et al*., 2010), a clear realisation of this element can be fundamental in unlocking interaction barriers between a leader and people willing to follow (Sinek, 2014). This element of '*security*' enables individuals within an organisation to act in unison and more decisively. Such elements ward off defensive practices that often block camaraderie, induced by egocentricity. This further expresses the benefits of

[17] The Joint Commission. Sentinel Event Alert Number 57. ; 2017.
[18] Griffin, F., & Resar, R. (2009). IHI Global Trigger Tool for Measuring Adverse Events (Second Edition). IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2009

leadership structures sending a clear message to workers at all levels that they not only understand their problems but also invest time and resources in addressing them. When leadership places people first, gains will be sustainable even though they might come in at a slower rate. Of the various categories of gains, patient safety is one where gains must be sustainable.

An important tactic in extending any new service is through induction; making the service wanted by the right stakeholder group, then waiting for the request. This concept of '*pulling*' rather than '*pushing*' was observed throughout the study. Spending that extra time to '*educate*' hospital members of staff of what they should be expecting from a medication safety officer, and disseminating concrete examples puts the former in a much better and receptive situation. This is an important strategy one has to master especially within the local cultural context, where change might be a more challenging process than other cultures showing a lower uncertainty avoidance index like for example in Scandinavian countries or the United Kingdom.

The Patient Safety Survey[19] is a useful and important tool for tracking improvement in patient safety attitudes over time through a Plan-Do-Study-Act (PDSA) approach (Figure 4.2). Patient safety is a ubiquitous principle and in view of adequate efforts on a global scale the least one can do is to make use of such available resources. The goal

[19] Hospital Survey on Patient Safety Culture [Internet]. Rockville, MD: Agency for Healthcare Research and Quality 2007 Dec. Available from: http://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/hospital/index.html [cited March 2017].

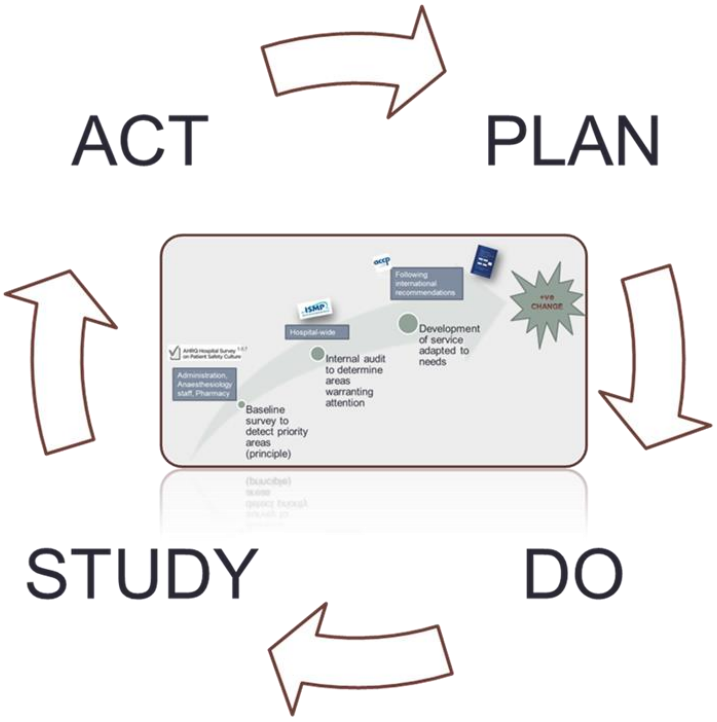


Figure 4.2 The importance of a cyclical approach in patient safety service development

would be to participate in world-wide programs and be a contribution to this global effort. Strengthening professional input with academic ties and involvement generates sustainable resource exchange with the scientific community. In spite of the availability of technological solutions on the market, successful implementation up to the point of measurable benefit faces a number of challenges, most common examples of which include small cohorts of hospitals using them, individuals not being convinced of the technology and complications related to a lack of standardisation (Iacovides *et al*., 2014). This observation strengthens the notion that technological solutions are important tools that are however operated by individuals. Individuals often operate as controlled by their attitudes. The success of health informatics solutions will depend only to a minor degree on the technology and more on the quality of leadership (Harrington *et al*., 2014; Vermeulen *et al.*, 2014). Responsible ways in which tools are used include the belief that tools are a framework through which a system can evolve. Any successful leader would need to keep the attitudes of individuals using them always central, as a priority intervention.

The impact of external factors plays an important role in this and a High Reliability Organization (HRO) has to adapt (step up or down resources) and shift priorities as needs dictate; a good roadmap is crucial (Oster, 2016). These factors will define and re-define the key elements one is to measure. Such measurements are important, but only when seen within the whole context. Measures in patient safety attitudes remain an important metric, where within a clinical context like in other HROs such as the military and high risk civilian activities (Baker, 2001), attitude is crucial. Within such structures, attitude gains prominence as micro-management modalities tend to be too

rigid to enable safety at all times. A prevailing element would be to ensure that members of staff hold a positive attitude on patient safety. Such metrics and behaviour analysis, although only a means to an end are an important element that cannot be overlooked; human beings are very complex systems (Mazzocato, 2011). Especially in cultures typical of Mediterranean climate; cultures exemplified by a high degree of '*power distance*' and '*uncertainty avoidance*' (Hofstede, 2010), good leadership structures that can challenge the '*status quo*' and take the necessary bold steps to a generative culture remain of primary importance.

4.4 Study Limitations

Observed limitations of the study include the following:

- During the validation, the paper questionnaire was generally filled in prior to the paperless version. This could have facilitated the readability of the paperless, however a general feedback response from participants was that they still read every question. Use of mobile phone or tablet device could have impacted on the concentration span as unlike paper, the survey could be more easily completed in a crowded environment.

- Every effort was done to keep surveys anonymous. Whist this was done to increase the quality of results obtained, the fact that questionnaires received were anonymous could not rule out multiple participation. A part of the study took place at times of industrial disputes and no controls were made to ensure that the tools were not used as a tool to strengthen the arguments being launched.

- Participants may have considered other personal experiences outside MDH when completing the survey. Even within the same hospital, microclimate cultures of various areas within the hospital could be appreciably different.

- The survey part of the study was used to capture a baseline metric in the patient safety attitudes. Different participants could have been already exposed to patient safety strategies before the study took place, and that could have impacted on the baseline scores; if they participated in the study.

- Anonymous participation affected participant matching, with definite repercussions on statistical interpretations. This will be a limitation in measuring patient safety attitude changes over time; however the limited statistical power has to be regarded within the full context of other significances, especially measurable ADR patterns (harm indices). Patient safety attitudes remain an important metric that is only a means to an end, and in no way can it be used to describe patient safety progress on its own accord.

- Participants could have influenced each other's responses during survey completion (e.g. by discussing score points). This could reduce statistical power as the recorded responses would be representative of collective responses rather than individual scores.

- A residual response rate (after deleting dubious responses) of 45% (less than 50 %) was ultimately accepted. This decision was made in view of the fact that this exercise was not being used to give an absolute index but rather applied as

a tool to identify priority areas for inclusion in a medication service development programme.

4.5 Recommendations for Future Work

Safety measures in various settings call for approaches tailored to the specific needs of the organization. The approach studied here can be replicated to cover other clinical areas within the hospital and other healthcare institutions. This study approach looked primarily at structures.

In being consistent with the Donabedian triad[20], following successful determination of structures, one should then look at processes and outcomes (Donabedian, 2003). A combination of approaches will ultimately allow one to measure a more reliable metric. Suitable process metrics would include further participation in schemes that test for adherence to standards. Sustainability and reproducibility of safety attitude scores following defined periods (18-24 months) together with studies correlating the various indicators and patient safety attitude metrics can be carried out. As argued by Grossman (2018), caution is to be exercised when one follows metrics and indicators; good quality evidence correlating the metric with the desired outcome must be ascertained before one asserts that any indicator is worth keeping, let alone following. This observation resonates with Lee (2004) in that traditional performance metrics are limited and the dangers of over reliance on them need to be clearly understood. A false sense of security is an important failure in risk management (Ip, 2015).

[20] AHRQ. PSNET - Patient Safety Network. [Online].; 2017 January 4. Available from: https://psnet.ahrq.gov/primers/primer/35/measurement-of-patient-safety [cited January 2018].

With respect to outcome measures indicators, setting up a dashboard consisting of the ADE rate measured by trigger tools is likely to be an appropriate way forward. Keeping the IHI definition of High Impact leadership[21] in context, good outcome measures must be aligned towards the improvement of care, the health of populations and reduction in costs.

The study has explored how a pharmacist-led initiative to mobilise other healthcare providers in establishing and sustaining a medication safety service at MDH. Further work to implement strategies especially with regards to the three key areas identified in this study is the next step forward.

Evaluation of the impact of the pharmacist-led service in medication safety is ongoing research that contributes to improvement and sustainability of the service.

[21] IHI whitepaper on high impact leadership. Swensen S, Pugh M, McMullan C, Kabcenell A. High-Impact Leadership: Improve Care, Improve the Health of Populations, and Reduce Costs. IHI White Paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2013. (Available at ihi.org)

REFERENCES

ACCP. Standards of practice for clinical pharmacists. Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy. 2014;34(8):794-7.

Adi A. Implementing question and answer technique to enhance students' speaking ability at SMP islam paramitha malang. Journal of English Educators Society. 2016;1(1).

Aljadhey H, Alkhani S, Tahir MK. Medication safety officer preparatory course: Outcomes and experiences. Saudi Pharmaceutical Journal. 2017;25(7):1011-4.

Baker A. Crossing the quality chasm: A new health system for the 21st century. BMJ [Internet]. British Medical Journal Publishing Group. 2001;323(7322):1192.

Beardsley RS, Kimberlin CL, Tindall WN. Communication skills in pharmacy practice USA: Lippincott Williams & Wilkins; 2008. 180-195 p.

Bos JM, Bemt PM, Smet PA, Cornelis K. The effect of prescriber education on medication-related patient harm in the hospital: A systematic review. British Journal of Clinical Pharmacology. 2017; 83(5):953-61.

Bradberry T, Greaves J. Emotional intelligence 2.0. San Diego, CA: TalentSmart; 2009. 255 p.

Davis L, Brunetti L, Lee E, Yoon N, Cho S, Suh D. Effects of computerized physician order entry on medication turnaround time and orders requiring pharmacist intervention. Research in Social and Administrative Pharmacy. 2014;10(5):756-67.

Dennis V, Owora A, Kirkpatrick A. Comparison of aseptic compounding errors before and after modified laboratory and introductory pharmacy practice experiences. American Journal of Pharmacy Education. 2015;79(10):1-9.

Donabedian A. An introduction to quality assurance in health care. New York: Oxford University Press; 2003. 46-57 p.

Gregorio J, Cavaco AM, Lapao LV. How to best manage time interaction with patients? Community pharmacist workload and service provision analysis. Research in Social and Administrative Pharmacy. 2017;13(1):133-47.

Grossman DC. Quality of health care for children: The need for a firm foundation of trustworthy evidence. The Journal of the American Medical Association. 2018;319(11):1096.

Harrington L, Hardison VL, Coates J, Wickham V, Norris B, Kane M. Computerized provider order entry (CPOE): Important nontechnical issues and considerations. Nurse Leader. 2014;12(3):54-57.

Heath C. Switch - How to change things when change is hard. 1st ed. Heath D, editor. Toronto: Random House Canada; 2010.

Hofstede GH. Cultures and Organizations: Software of the mind: Intercultural cooperation and its importance for survival. 3rd ed. Hofstede GJ, Minkov M, editors. New York ; London: McGraw-Hill; 2010. 71-82, 187-190 p.

Humm C, Weeks S, Cowell R, John M. Can you trust a no-blame culture? Does our readers panel trust the `no blame' culture of the health services enough to feel

confident about not taking out indemnity insurance? Nursing Standard. 2003;17(19):20.

Iacovides I, Blandford A, Cox A, Franklin B, Lee P, Vincent C. Infusion device standardisation and dose error reduction software. British Journal of Nursing. 2014;23(14):S16.

Ip G. Foolproof - Why safety can be dangerous and how danger makes us safe. 1st ed. London: Headline Publishing Group; 2015. 87-107 p.

Jelacic S, Craddick K, Nair BG, Bounthavong M, Yeung K, Kusulos D, Knutson JA, Somani S, Bowdle A. Relative costs of anesthesiologist prepared, hospital pharmacy prepared and outsourced anesthesia drugs. Journal of Clinical Anesthesia. 2016;36:178-83.

Khatri N, Brown GD, Hicks LL. From a blame culture to a just culture in health care. Health Care Management Review. 2009;34(4):312.

Kotter JP. Leading change. Harvard Business Review Press; 2012. 22-27 p.

Larson CM, Saine D, American Society of Health-System Pharmacists. Medication safety officer's handbook. Bethesda, MD: American Society of Health-System Pharmacists; 2013. 1-43, 243-266 p.

Leape LL. A systems analysis approach to medical error. In Cohen MR, editor. Medication Errors. Washington, D.C.: American Pharmaceutical Association; 1999. p. 2.3-2.8.

Lee F. If Disney ran your hospital : 9 1/2 things you would do differently. Second River Healthcare Press; 2004. 215 p.

Mansfield J, Jarrett S. Using smart pumps to understand and evaluate clinician practice patterns to ensure patient safety. Hospital Pharmacy. 2013;48(11):942-50.

Marcucci L, Martinez EA, Haut ER, Slonim AD, Suarez JI. Avoiding common ICU errors. 1st ed. Brown B, Dernoski NT, editors. Philadelphia: Lippincott Williams & Wilkins; 2007. 145, 369-372 p.

Mazzocato P, Hvitfeldt Forsberg H, von TS. Team behaviors in emergency care: A qualitative study using behavior analysis of what makes team work. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine. 2011;19:70.

Nance JJ. Why Hospitals Should Fly - The ultimate flight plan to patient safety and quality care. 1st ed. Reeder L, Byrnes J, editors. Bozeman: Second River Healthcare; 2008. 25-31 p.

Najjar S, Hamdan M, Euwema MC, Vleugels A, Sermeus W, Massoud R, Vanhaecht K. The global trigger tool shows that one out of seven patients suffers harm in Palestinian hospitals: Challenges for launching a strategic safety plan. International Journal of Quality in Health Care. 2013;25(6):640-7.

Norman D. The design of everyday things. New York: Basic Books; 2013. 116-118 p.

NHS Pharmaceutical Quality Assurance Committee. Quality assurance of aseptic preparation services. 5th ed. Beaney AM, editor. London; Chicago: Pharmaceutical Press; 2016. 34-36 p.

Oster CA, Braaten JS. High reliability organisations. 1st ed. Hall C, editor. Indianapolis: Sigma Theta Tau; 2016. 77 p.

Pouliquen A, Escalup L, Jourdan N, Cottu P, Faure P, Madelaine-Chambrin I. Dose standardisation of anticancer drugs. International Journal of Clinical Pharmacy. 2011;33(2):221-8.

Powers BW, Cassel CK, Jain SH. Ending the cycle of blame in US health care. The Journal of the American Medical Association. 2014;312(20):2091.

Qu WG, Yang Z. The Effect of uncertainty avoidance and social trust on supply chain collaboration. Journal of Business Research. 2015;68(5):911-8.

Sinek S. Leaders Eat Last : Why some teams pull together and others don't. England: Penguin; 2014. 244 p.

Vermeulen KM, Van Doormaal JE, Zaal RJ, Mol PGM, Lenderink AW, Haaijer-Ruskamp F, Kosterink JGW, van DB. Cost-effectiveness of an electronic medication ordering system (CPOE/CDSS) in hospitalized patients. Int Journal of Medical Informatics. 2014; 83(8):572-80.

Wachter RM. Understanding patient safety. New York: McGraw Hill Medical; 2012. 36-48, 263-269 p.

APPENDICES

Appendix 1

AHRQ Survey – Paper Based

Hospital Survey on Patient Safety

Instructions

This survey asks for your opinions about patient safety issues, medical error, and event reporting in your hospital and will take about 10 to 15 minutes to complete.

If you do not wish to answer a question, or if a question does not apply to you, you may leave your answer blank.

- *An **"event"** is defined as any type of error, mistake, incident, accident, or deviation, regardless of whether or not it results in patient harm.*
- ***"Patient safety"** is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of health care delivery.*

SECTION A: Your Work Area/Unit

In this survey, think of your "unit" as the work area, department, or clinical area of the hospital where you spend *most* of your work time or provide *most* of your clinical services.

What is your primary work area or unit in this hospital? Select ONE answer.

- ☐ a. Many different hospital units/No specific unit
- ☐ b. Medicine (non-surgical)
- ☐ c. Surgery
- ☐ d. Obstetrics
- ☐ e. Pediatrics
- ☐ f. Emergency department
- ☐ g. Intensive care unit (any type)
- ☐ h. Psychiatry/mental health
- ☐ i. Rehabilitation
- ☐ j. Pharmacy
- ☐ k. Laboratory
- ☐ l. Radiology
- ☐ m. Anesthesiology
- ☐ n. Other, please specify: _____

Please indicate your agreement or disagreement with the following statements about your work area/unit.

Think about your hospital work area/unit…	**Strongly Disagree** ▼	**Disagree** ▼	**Neither** ▼	**Agree** ▼	**Strongly Agree** ▼
1. People support one another in this unit	☐1	☐2	☐3	☐4	☐5
2. We have enough staff to handle the workload	☐1	☐2	☐3	☐4	☐5
3. When a lot of work needs to be done quickly, we work together as a team to get the work done	☐1	☐2	☐3	☐4	☐5
4. In this unit, people treat each other with respect	☐1	☐2	☐3	☐4	☐5
5. Staff in this unit work longer hours than is best for patient care	☐1	☐2	☐3	☐4	☐5

SECTION A: Your Work Area/Unit (continued)

Think about your hospital work area/unit…	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
6. We are actively doing things to improve patient safety	☐1	☐2	☐3	☐4	☐5
7. We use more agency/temporary staff than is best for patient care	☐1	☐2	☐3	☐4	☐5
8. Staff feel like their mistakes are held against them	☐1	☐2	☐3	☐4	☐5
9. Mistakes have led to positive changes here	☐1	☐2	☐3	☐4	☐5
10. It is just by chance that more serious mistakes don't happen around here	☐1	☐2	☐3	☐4	☐5
11. When one area in this unit gets really busy, others help out	☐1	☐2	☐3	☐4	☐5
12. When an event is reported, it feels like the person is being written up, not the problem	☐1	☐2	☐3	☐4	☐5
13. After we make changes to improve patient safety, we evaluate their effectiveness	☐1	☐2	☐3	☐4	☐5
14. We work in "crisis mode" trying to do too much, too quickly	☐1	☐2	☐3	☐4	☐5
15. Patient safety is never sacrificed to get more work done	☐1	☐2	☐3	☐4	☐5
16. Staff worry that mistakes they make are kept in their personnel file	☐1	☐2	☐3	☐4	☐5
17. We have patient safety problems in this unit	☐1	☐2	☐3	☐4	☐5
18. Our procedures and systems are good at preventing errors from happening	☐1	☐2	☐3	☐4	☐5

SECTION B: Your Supervisor/Manager

Please indicate your agreement or disagreement with the following statements about your immediate supervisor/manager or person to whom you directly report.

	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
1. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	☐1	☐2	☐3	☐4	☐5
2. My supervisor/manager seriously considers staff suggestions for improving patient safety	☐1	☐2	☐3	☐4	☐5
3. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts	☐1	☐2	☐3	☐4	☐5
4. My supervisor/manager overlooks patient safety problems that happen over and over	☐1	☐2	☐3	☐4	☐5

SECTION C: Communications

How often do the following things happen in your work area/unit?

Think about your hospital work area/unit…	**Never** ▼	**Rarely** ▼	**Some-times** ▼	**Most of the time** ▼	**Always** ▼
1. We are given feedback about changes put into place based on event reports	☐1	☐2	☐3	☐4	☐5
2. Staff will freely speak up if they see something that may negatively affect patient care	☐1	☐2	☐3	☐4	☐5
3. We are informed about errors that happen in this unit	☐1	☐2	☐3	☐4	☐5
4. Staff feel free to question the decisions or actions of those with more authority	☐1	☐2	☐3	☐4	☐5
5. In this unit, we discuss ways to prevent errors from happening again	☐1	☐2	☐3	☐4	☐5
6. Staff are afraid to ask questions when something does not seem right	☐1	☐2	☐3	☐4	☐5

SECTION D: Frequency of Events Reported

In your hospital work area/unit, when the following mistakes happen, *how often are they reported?*

	Never ▼	**Rarely** ▼	**Some-times** ▼	**Most of the time** ▼	**Always** ▼
1. When a mistake is made, but is *caught and corrected before affecting the patient*, how often is this reported?	☐1	☐2	☐3	☐4	☐5
2. When a mistake is made, but has *no potential to harm the patient*, how often is this reported?	☐1	☐2	☐3	☐4	☐5
3. When a mistake is made that *could harm the patient*, but does not, how often is this reported?	☐1	☐2	☐3	☐4	☐5

SECTION E: Patient Safety Grade

Please give your work area/unit in this hospital an overall grade on patient safety.

☐	☐	☐	☐	☐
A Excellent	**B** Very Good	**C** Acceptable	**D** Poor	**E** Failing

SECTION F: Your Hospital

Please indicate your agreement or disagreement with the following statements about your hospital.

Think about your hospital…	**Strongly Disagree** ▼	**Disagree** ▼	**Neither** ▼	**Agree** ▼	**Strongly Agree** ▼
1. Hospital management provides a work climate that promotes patient safety	☐1	☐2	☐3	☐4	☐5
2. Hospital units do not coordinate well with each other	☐1	☐2	☐3	☐4	☐5
3. Things “fall between the cracks” when transferring patients from one unit to another	☐1	☐2	☐3	☐4	☐5
4. There is good cooperation among hospital units that need to work together	☐1	☐2	☐3	☐4	☐5

SECTION F: Your Hospital (continued)

Think about your hospital…	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
5. Important patient care information is often lost during shift changes	☐1	☐2	☐3	☐4	☐5
6. It is often unpleasant to work with staff from other hospital units	☐1	☐2	☐3	☐4	☐5
7. Problems often occur in the exchange of information across hospital units.....	☐1	☐2	☐3	☐4	☐5
8. The actions of hospital management show that patient safety is a top priority	☐1	☐2	☐3	☐4	☐5
9. Hospital management seems interested in patient safety only after an adverse event happens.....	☐1	☐2	☐3	☐4	☐5
10. Hospital units work well together to provide the best care for patients	☐1	☐2	☐3	☐4	☐5
11. Shift changes are problematic for patients in this hospital.....	☐1	☐2	☐3	☐4	☐5

SECTION G: Number of Events Reported

In the past 12 months, how many event reports have you filled out and submitted?

- ☐ a. No event reports
- ☐ b. 1 to 2 event reports
- ☐ c. 3 to 5 event reports
- ☐ d. 6 to 10 event reports
- ☐ e. 11 to 20 event reports
- ☐ f. 21 event reports or more

SECTION H: Background Information

This information will help in the analysis of the survey results.

1. How long have you worked in this hospital?

- ☐ a. Less than 1 year
- ☐ b. 1 to 5 years
- ☐ c. 6 to 10 years
- ☐ d. 11 to 15 years
- ☐ e. 16 to 20 years
- ☐ f. 21 years or more

2. How long have you worked in your current hospital work area/unit?

- ☐ a. Less than 1 year
- ☐ b. 1 to 5 years
- ☐ c. 6 to 10 years
- ☐ d. 11 to 15 years
- ☐ e. 16 to 20 years
- ☐ f. 21 years or more

3. Typically, how many hours per week do you work in this hospital?

- ☐ a. Less than 20 hours per week
- ☐ b. 20 to 39 hours per week
- ☐ c. 40 to 59 hours per week
- ☐ d. 60 to 79 hours per week
- ☐ e. 80 to 99 hours per week
- ☐ f. 100 hours per week or more

SECTION H: Background Information (continued)

4. What is your staff position in this hospital? Select ONE answer that best describes your staff position.

- ☐ a. Registered Nurse
- ☐ b. Physician Assistant/Nurse Practitioner
- ☐ c. LVN/LPN
- ☐ d. Patient Care Asst/Hospital Aide/Care Partner
- ☐ e. Attending/Staff Physician
- ☐ f. Resident Physician/Physician in Training
- ☐ g. Pharmacist
- ☐ h. Dietician
- ☐ i. Unit Assistant/Clerk/Secretary
- ☐ j. Respiratory Therapist
- ☐ k. Physical, Occupational, or Speech Therapist
- ☐ l. Technician (e.g., EKG, Lab, Radiology)
- ☐ m. Administration/Management
- ☐ n. Other, please specify:

5. In your staff position, do you typically have direct interaction or contact with patients?

- ☐ a. YES, I typically have direct interaction or contact with patients.
- ☐ b. NO, I typically do NOT have direct interaction or contact with patients.

6. How long have you worked in your current specialty or profession?

- ☐ a. Less than 1 year
- ☐ b. 1 to 5 years
- ☐ c. 6 to 10 years
- ☐ d. 11 to 15 years
- ☐ e. 16 to 20 years
- ☐ f. 21 years or more

SECTION I: Your Comments

Please feel free to write any comments about patient safety, error, or event reporting in your hospital.

THANK YOU FOR COMPLETING THIS SURVEY.

Appendix 2

Validation of AHRQ Survey

Appendix 2

Table 1.1 Pearson correlation between questions in paper vs paperless

Question	Pearson correlation	p-value (one tailed)		Question	Pearson correlation	p-value (one tailed)
A	0.903	0.000		**W**	0.886	0.000
B	0.329	0.148*		**X**	0.731	0.003
C	0.626	0.011		**Y**	0.806	0.000
D	0.911	0.000		**Z**	0.813	0.000
E	0.848	0.000		**A1**	0.893	0.000
F	0.628	0.011		**A2**	0.432	0.070*
G	0.174	0.305*		**A3**	0.737	0.003
H	0.463	0.065*		**A4**	0.687	0.007
I	0.656	0.007		**A5**	0.725	0.004
J	0.240	0.215*		**A6**	0.296	0.163*
K	0.706	0.004		**A7**	0.561	0.023
L	0.592	0.021		**A8**	0.356	0.116*
M	0.870	0.000		**A9**	0.577	0.032
N	0.609	0.014		**A10**	0.554	0.025
O	0.307	0.179*		**A11**	0.469	0.086*
P	0.764	0.001		**A12**	0.511	0.045
Q	0.574	0.025		**A13**	0.353	0.130*
R	0.581	0.019		**A14**	0.839	0.000
S	0.845	0.000		**A15**	0.056	0.432*
T	0.817	0.000		**A16**	0.489	0.045
U	0.860	0.000		**A17**	0.859	0.001
V	0.443	0.086*				

N.B: marked with '*' denote questions obtaining a *p*-value of more than 0.05. In such circumstances (27 % of cases; n= 12), there was no positive correlation between the same questions posed in different media; paper vs paperless.

Table 1.2 Paired t-test of paper vs paperless versions of same questions

Question	Mean	St. Dev	p-Value (2 tailed)	Question	Mean	St. Dev	p-Value (2 tailed)
A	**3.77**	0.927	1.000	**W**	**3.33**	1.073	1.000
	3.77	0.927			**3.33**	1.155	
B	**3.50**	0.798	0.389	**X**	**4.25**	0.754	0.586
	3.75	0.866			**4.15**	0.555	
C	**4.31**	0.630	0.595	**Y**	**3.77**	1.092	1.000
	4.23	0.439			**3.77**	1.166	
D	**3.92**	0.760	1.000	**Z**	**3.54**	1.050	0.673
	3.92	0.954			**3.62**	1.044	
E	**3.00**	1.000	0.588	**A1**	**4.15**	1.144	0.337
	2.92	0.900			**4.00**	1.225	
F	**4.38**	0.650	0.054	**A2**	**2.46**	0.660	0.219
	4.00	0.816			**2.15**	0.899	
G	**2.08**	0.515	0.756	**A3**	**3.67**	1.303	0.220
	2.18	0.874			**3.15**	1.214	
H	**3.08**	0.954	0.586	**A4**	**3.58**	1.084	0.389
	3.17	1.030			**3.15**	1.405	
I	**4.08**	0.277	0.165	**A5**	**3.67**	1.073	1.000
	3.92	0.494			**3.67**	0.778	
J	**2.38**	0.768	0.111	**A6**	**2.23**	0.725	0.794
	2.85	0.801			**2.15**	0.987	
K	**3.85**	0.801	0.673	**A7**	**3.69**	0.630	0.673
	3.92	0.862			**3.77**	0.725	
L	**3.08**	0.900	1.000	**A8**	**2.92**	0.760	0.502
	3.15	0.689			**3.08**	0.641	
M	**3.54**	1.127	0.339	**A9**	**3.42**	0.793	1.000
	3.33	0.985			**3.55**	0.688	
N	**3.54**	0.877	1.000	**A10**	**3.62**	0.768	0.273
	3.54	0.660			**3.38**	0.768	
O	**3.75**	0.754	1.000	**A11**	**3.55**	0.820	0.343
	3.75	0.866			**3.36**	0.674	
P	**3.08**	0.954	0.436	**A12**	**3.00**	0.816	0.503
	2.92	1.038			**3.17**	0.835	
Q	**2.67**	0.985	1.000	**A13**	**3.58**	0.669	0.339
	2.67	1.073			**3.83**	0.835	
R	**3.69**	0.630	1.000	**A14**	**3.69**	0.630	1.000
	3.69	0.630			**3.69**	0.751	
S	**4.42**	0.515	0.339	**A15**	**2.77**	0.725	0.586
	4.46	0.519			**2.83**	0.835	
T	**4.54**	0.519	0.165	**A16**	**3.62**	0.506	0.436
	4.38	0.650			**3.46**	0.776	
U	**2.23**	1.013	0.436	**A17**	**3.45**	0.688	0.168
	2.38	1.325			**3.30**	0.823	
V	**2.58**	1.564	0.518				
	2.08	0.996					

N.B. No statistical difference was found between paper and paperless versions of same questions. Mean and standard deviation per question refer to paper and paperless formats in respective order.