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Imbuing Medical Professionalism in Relation to Safety: A study protocol for a mixed-methods intervention focused on trialling an embedded learning approach that centres on the use of a custom designed board game

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Abstract

Introduction: Healthcare organisations have a responsibility for ensuring that the governance of workplace settings creates a culture that supports good professional practice. Encouraging such a culture needs to start from an understanding of the factors that make it difficult for health professionals to raise issues of concern in relation to patient safety. The focus of this study is to determine whether a customised education intervention with interns and senior house officers (SHOs) can imbue a culture of medical professionalism in relation to patient safety and support junior doctors to raise issues of concern, whilst shaping a culture of responsiveness and learning.

Methods and Analysis: We will use quantitative and qualitative methods to collect data. The sample size will be approximately 200 interns and SHOs across the two hospital sites. Two surveys will be included with one measuring leadership inclusiveness and psychological safety and a second capturing information on safety concerns that participants may have witnessed in their places of work. The PlayDecide embedded learning intervention will be trialled in the middle stage of data collection for both interns and SHOs. A detailed content analysis will be conducted on the surveys to assess any changes in reporting following the PlayDecide intervention. This will be compared with the incident reporting levels and the results of the pre and post intervention leadership inclusiveness and psychological safety survey. Statistical analysis will be conducted using SPSS. Differences will be considered statistically significant at $p<0.05$. Semi-structured interviews using a critical incident technique will be used for the ongoing analysis and evaluation of the project. These will be transcribed, de-identified and coded into themes.

Ethics and Dissemination: The study has been granted ethics approval from University College Dublin (Ref. LS-15-19-Ward-McAuliffe: Imbuing Medical Professionalism in Relation to Safety). The study results will be disseminated through peer-reviewed publications.

Strengths and Limitation of this Study:

- This study will provide useful information for the planning and content of intern and senior house officers programs in teaching hospitals in Ireland and elsewhere.
- The PlayDecide intervention will be developed with key stakeholders within a collaborative framework.
- The core components will be mapped with research and current experiences to enhance its acceptability in practice.
- Key clinical education leads and senior quality and safety staff in both hospital sites will have a central role in ensuring participation, maintaining the momentum of the study, enabling the dissemination workshops and outlining the impact the research will have in practice.
- The principal limitations are that the response rates may vary across hospitals, influenced by the extent to which the research intervention is perceived as relevant and important for junior doctors and the endorsement of the intervention by senior hospital staff.

Introduction

Medical Professionalism is "a set of values, enacted through behaviours and relationships, which underpin the public's trust in doctors"[1]. "New professionalism" refers to the subtle but important evolution in the values and responsibilities that relate to being a good doctor[2]. This evolution has been influenced by changing expectations in the doctor-patient relationship, increasing requirements for doctors to demonstrate ongoing clinical competence and the drive to improve quality and patient safety[3]. Patients' trust in doctors is influenced by: effective communication; respect for autonomy and shared decision-making; maintaining confidentiality; honesty, openness and transparency; raising concerns about patient safety; and maintaining competence and assuring the quality of medical practice[4]. A recent survey of the Irish public revealed that approximately 8 out of 10 were very confident or fairly confident that their doctor would tell them if there had been a mistake/oversight in the course of their care. However, doctors' views about disclosure of errors were mixed: 63% agreed that doctors should disclose all significant medical mistakes, but 85% of doctors surveyed admitted that they had not fully disclosed a mistake to a patient because they were afraid of being sued[5].

This poses a significant challenge particularly as error rates are at an unacceptably high level in healthcare[6]. In 2014 across Ireland there was a total of 53, 108 patient related incidents reported by acute hospitals. These incidents relate directly to on-site incidents reported. On site reporting are incidents reported directly by healthcare locations on the National Incident Management System (NIMS) and excludes incidents reported in the format of a claim to the State Claims Agency[7]. Reviewing the 2012 incidents rates in Ireland the State Claims Agency (SCA) outlined that the reporting rates stood approximately at 2.9 per cent which was considered an under reporting of adverse clinical events especially when compared to other countries reporting adverse event occurrences which were in the range 4-16 per cent[8]. In Ireland the Health Information and Quality Authority (HIQA) have emphasised the importance of a culture of quality and safety that "promotes openness and transparency, teamwork, open and effective communication and a supportive environment within which both service users and providers can raise issues of concern and feel confident that this will not have a negative impact on how they are dealt with"[9]. At the core of this is *speaking up*, that is the act of raising an unethical, incompetent or wrong action or situation that poses a threat to patient safety, with a person who has the power to stop such action/situation[10]. Encouraging such a culture needs to start from an understanding of the factors that make it difficult for doctors and other health professionals to be open about errors. Roland *et al* [11] work in the UK and the USA found that while 19% (UK) and 17% (USA) of doctors were aware of a colleague whom they considered was impaired or incompetent to practice medicine in their hospital or practice only 73% (UK) and 65% (USA) would report that doctor to the hospital, practice, professional society or other relevant authority. The highest reason cited for not reporting was fear of retribution at 34% (UK). This 'culture of silence' was the focus of the Francis Report[12] conducted in the UK as a response to the Mid Staffordshire HHS Foundation Trust Public Inquiry[13], which in turn looked at the 'conditions of appalling care experienced by patients between 2005 and 2008'. The report highlights that staff are often part of a culture of silence where organisations ignore the concerns of staff. The NHS survey, carried out as part of the Francis Report found that >30% of those who raised a concern felt unsafe afterwards with graphic examples outlined within the report of graphic examples of victimisation from those who did raise concerns. Of the sample who did not raise a concern 18% expressed a lack of trust in the system as a reason and 15% blamed fear of victimisation[12].

Within the Irish context, the main reasons given by doctors for not reporting a concern are 44% felt "nothing would happen as a result"; 25% had a "fear of retribution"; and 19% "thought someone else was dealing with the problem"[5]. Duffy's study of healthcare professionals in Ireland also found that almost one-quarter identified fear of litigation as a key barrier to open disclosure following an adverse event[14]. Research by Moore and McAuliffe [15 16] concluded that while 88% of Irish nurses observed an incident of poor care only 70% of nurses reported it. Of the nurses that reported concerns, only 25% were satisfied with the response of the hospital. Amongst those who did not report, the primary reasons given were "not wanting to cause trouble" and "not being sure if it is the right thing to do". Historically the literature has pointed to the perception that junior members of health teams were more likely to undermine rather than build patient safety. In particular, junior doctors are perceived as being categorised as a 'high risk' group bringing little experience, often provided with limited and inadequate supervision and high stress levels[17]. However more recently, the literature points to the strengths of junior doctors with Ibrahim *et al*[18] outlining the potential of cultivating their interest in improving patient care. Bethune *et al*[19] commenting on the Safer Patients Initiative in England[20] argue that doctors in training could have a role in quality improvement if they were adequately equipped and informed. McCarthy *et al* [21] argue that junior doctors are crucial in preventing, reporting and learning from errors, near misses and adverse events.

It is evident from the literature that further work is required to put in place the building blocks to develop a safety culture that supports a culture where interns and SHOs would be supported in speaking up about safety concerns, and senior doctors would be encouraged to respond in a positive manner[22]. This project aims to encourage and support medical graduates to become good doctors. Medical professionalism, as noted above, is a set of values, enacted through behaviours and relationships, which underpin the public's trust in doctors. In this study, we are focussing on professionalism in relation to patient safety. We propose to develop an interactive game that encourages discussion about the important values and behaviours that newly trained doctors (interns) and doctors in their second year (SHOs) need to work on to become good doctors. These issues will be brought to the attention of senior doctors to encourage them to support interns and SHOs by listening to and acting on their concerns, thus shaping a more supportive environment. We envisage that these interactive learning opportunities will encourage doctors to raise issues of concern and will engage doctors and other healthcare professionals in improving the organisation's response to poor

professional practice and safety concerns as well as improving their personal and professional behaviour towards patients, colleagues and their healthcare organisations. This study will measure the effect of this game and associated actions to raise awareness of medical professionalism on the behaviour of doctors and on how concerns about patient safety are raised and responded to by the hospitals they work in. The research will develop and trial an embedded evidence based learning approach that centres on the use of a custom designed serious game to encourage speaking up, as well sharing knowledge and understanding among interns and junior doctors about safety and the importance of discussing and reporting clinical safety concerns within the hospital setting.

Research Design and Methodological Approach

This proposed research design is influenced by an understanding of the on-going work within the national medical intern training curriculum on medical professionalism and the work of the Irish Medical Council, the State Claims Agency and hospitals' quality and safety divisions with medical students, interns and SHOs to raise awareness. Our understanding is that the intern programme on medical professionalism is aimed at shaping the behaviour of interns towards openness and transparency whilst instilling in them a professional obligation to report poor practice and errors in care when they witness them. Instilling a sense of professionalism and obligation may not increase or improve medical professionalism if the interns are working in an environment that does not support such behaviours. A critical element that influences learning and the environment to disclose is leadership. Team leader behaviours have been shown to affect the internal dynamics of a team, in particular, influencing team climate and learning orientation[23 24 25]. If a leader takes an authoritarian, unsupportive, or defensive stance, team members are more likely to feel that speaking up in the team is unsafe. In contrast, if a leader is democratic, supportive, and welcomes questions and challenges, team members are likely to feel greater psychological safety in the team and in their interactions with each other[26].

In a study of nursing leadership and medication errors, Edmondson[27] (1996) found evidence of leadership effects on psychological safety. In some units, nurses described nurse managers as authoritarian and also expressed deep fears about being reprimanded for revealing mistakes. In contrast, nurses in other units felt safe speaking up about errors because their nurse manager had stressed the importance of using this information as a learning tool for the

unit. Nembhard & Edmonton[26], in their work on creating psychological safety for learning within cross-disciplinary teams, found evidence that leader inclusiveness—words and deeds by leaders that invite and appreciate others' contributions—can help to overcome status' inhibiting effects on psychological safety (i.e. the inhibiting effect of the traditional medical hierarchy). They argue that inclusive behaviour on the part of medical leaders may be an essential means of facilitating others' meaningful engagement in team-based quality improvement work because speaking up and reporting errors is more likely to occur when staff feels psychologically safe. Other studies of psychological safety and communication in the health care environment have also highlighted the role of leadership in cultivating a culture of safety but have not articulated the actual practices of leaders that are needed, other than training staff to speak up[28]. Nembhard and Edmonton's research suggests that training leaders to invite team members' comments and to appreciate those comments overtly is as important. We would argue that in the context of reporting of errors and voicing concerns, leaders can demonstrate an overt appreciation of the intern's comments by providing feedback to the intern on how the issue raised has been dealt with and what action is likely to result.

Feedback is one of the fundamental psychological principles of performance management. In the context of reporting and process improvement, Ward *et al.*[29] demonstrated that the level of feedback given to staff on the outcomes of reports made by them in the past had a direct effect on the level of future reporting. The more feedback (on e.g. what had happened their reports, who was currently dealing with them, what the outcomes might be or were, and whether or not and when recommendations would be implemented) that was given to staff the more likely they were to engage with the improvement process in the future. This study will build on these findings to design a learning intervention that targets leaders (senior clinicians) and interns in an attempt to shape a culture of psychological safety.

Design Materials and Methods

This study aims to assess current practice amongst interns and SHOs on reporting and open disclosure in two university hospitals in Ireland. The sample size is expected to be 200 across the two hospital sites. Interns and SHOs rotate into the hospitals each July so the approximate sample size will only be determined when the hospital sites have final numbers. The study will be carried out within the hospital educational and training centres where interns and

SHOs will be attending separate weekly lunchtime seminars. A structured enquiry method[30] will be utilised for the ongoing analysis and evaluation of the project. This method of repeated qualitative interviews with a small sample of key stakeholders in each of the hospitals will allow us to tailor the enquiry to what is relevant to the particular stage of the project. Using this structured approach will allow us to build up a dossier of knowledge about medical professionalism and the challenges of embedding it in each of the hospital cultures. This continuous approach contrasts with the more traditional and widely used end-of-project evaluation and allows the research team to draw inferences about the current status and prospects for the future.

Baseline Data Collection

An initial meeting will take place with Interns and SHOs to explain the study. The following baseline data will be collected in this phase.

Leader inclusiveness and psychological safety.

A brief survey of interns and SHOs will measure leader inclusiveness and psychological safety. Leader inclusiveness refers to the behaviours and attitudes of the clinicians-in-charge. A three-item scale developed and used by Nembhard and Edmonton[26] assesses the extent to which leaders' words and deeds indicate an invitation and appreciation for others as contributing members in a team endeavour. The items on the scale will be adapted for this study. The first two items, 'senior doctors encourage other members of the team to take initiative' and 'senior doctors ask for the input of team members that belong to other professional groups,' were adapted from Shortell *et al*[31] (1991) physician leadership scale. The third item, 'senior doctors do not value the opinion of others equally'' (reverse scored), was developed for the Nembhard and Edmonton study[26]. The level of agreement with each statement (1-strongly disagree, 7-strong agree) is averaged to provide a single perception for each respondent (Chronbach alpha= 0.75).

Psychological safety - five items from Edmondson's[32] psychological safety scale adapted to this context will be used to assess the extent to which respondents felt safe to speak up about issues or ideas regarding their work:

- Members of this team are able to bring up problems and tough issues.

- People in this unit are comfortable checking with each other if they have questions about the right way to do something.
- If you make a mistake on this team, it is often held against you. (reverse scored)
- It is difficult to ask other members of this team for help. (reverse scored)
- Working with members of this team, my unique skills and talents are valued and utilised.

Respondents' agreement (1-strongly disagree, 7-strongly agree) with these items form a single scale (Chronbach alpha=0.73).

Raising Safety Concerns

A cohort of Interns and SHOs will be surveyed weekly over a three month period using a paper based questionnaire method to capture information on safety concerns they may have witnessed in their places of work. This questionnaire will be developed as part of the research project and based upon the Irish Medical Council's eight domains of good professional practice[33]. Information will also be captured on the Interns and SHOs reaction to these events e.g. if and how they reported such events and follow-up action that occurred. A small cohort of Interns and SHOs will also be invited to interview to explore in more depth some of the common themes raised in the surveys.

Incident Reporting Process in the Hospitals

We will work with the risk managers in both hospitals to examine information on events captured by the hospitals incident reporting system before the intervention to serve as a baseline measure for reporting of safety concerns. We will analyse the current methods of reporting and feedback provided by carrying out in-depth interviews with both risk managers. We will also work with the quality and safety teams to identify the actual role of senior clinicians in making changes and improvements as a result of the incident management systems. These insights will inform the development of the PlayDecide game and the dissemination workshops and will be crucial to the success of the project in terms of working with the senior staff to effectively close the loop by responding to any safety concerns that the junior doctors might have.

PlayDecide Learning Intervention

An embedded learning approach that centres on the use of a custom designed game to encourage speaking up, as well as inclusive leadership (words and deeds by leaders that invite and appreciate others' contributions) and responsiveness in the hospital system, will be developed. The aim of a serious game is to educate, train and alter behaviour in a desirable way, such as aiming to increase patient safety[34]. It is either computerised or card based, that merges a video game structure (thus having a specific aim/s) with a non-entertaining purpose in the hope of actively teaching the game players a new piece of information on a specific topic through active engagement such as role-playing and/or discussion. The application of serious games within healthcare is not new. A review by Ricciardi and De Paolis[35] looked at series of serious games that were created within a range of fields such as cardiology, surgery, odontology, nursing, dietitian and diabetes, psychology and first aid, with the latter being the highest number of developed serious games.

PlayDecide is a serious card based game, with a role-playing component to it where each person debates his or her view(s) based on the story card each selected from a selection that looks at a specific theme. The game was created to allow players to discuss controversial issues in a safe environment. The game consists of five different types of cards: story, white, information, challenge and issue cards. Story cards (~12) tell the game player a fictional narrative story of a character based on a real situation on a topic in relations to the main theme such as the experience of a doctor when reporting an incident or the experience of a nurse with a difficult senior staff member. A white card (~12) is a versatile blank card where a participant can write their own story or issue or information or opinion to present to the rest of the group. Information cards (~22) are factual cards that present up to date scientific information about the theme. Challenge cards (~16) are cards used by game players to stir up a conversation when the discussion stalls. Issue cards (~22) exhibit a range of perceptions, questions, and opinions that look at the ethical and implications it has on the overall theme of the game[36].

The game consists of four to eight players, and each game has three phases that take a total of ~80 minutes to play. The first phase takes ~30 minutes where each player picks a story card in turn and summaries each to the group in turn. Similarly, each game player picks two information and issue cards in turn and summaries each. The second phase takes ~30 minutes of discussion among the players. If the discussion stalls, a player can use the challenge card to encourage further discussion. During this time, the group also create clusters that reflect

the themes of the discussion. Each cluster consists of a name, a conclusion, created by an information card, an issue card, a story card and a white card. The third stage takes ~20 minutes where game players discuss four prewritten positions and vote on each of the positions in turn. The group can also devise their own fifth position if any one of the four doesn't encompass their group response[36]. A sub-group of experts from the project steering group will be formed to develop the PlayDecide game which will draw on the information collected in phase one. This group will consist of key stakeholders including representatives from senior medical and nursing staff, risk manager, intern tutors and a patient representative. Membership will be on a voluntary basis. The game when developed will be sent for peer review by two external experts and will be tested by the research team. The game will then be played with interns and SHOs with the aim of encouraging speaking up about clinical safety concerns.

Post Intervention

Raising Safety Concerns and Incident Reporting

The cohort of Interns and SHOs who participated in the PlayDecide intervention will be surveyed weekly to capture information on safety concerns they may have witnessed in their places of work and to whom they reported to. Post intervention information on events captured by the hospitals incident reporting system will also be reviewed with the appointed hospital risk managers for the 6 month post intervention period.

Semi-structured Interviews

Voluntary semi-structured interviews will be undertaken with interns and SHOs. The interview approach will use Flanagan's[37] critical incident technique (CIT). CIT has been described as a systematic, inductive and flexible qualitative research method. It is a methodology for collecting and analysing data with the aim of providing solutions to practical problems[38]. According to Flanagan (1954), observations become fact when a large number of independent observers offer the same descriptions of behaviour. The anonymous interviews will explore participants understanding of an incident and to capture suggestions of what is required to shape a safety culture.

Dissemination Workshops on Leadership and Organisation Responsiveness

Dissemination workshops will be held with senior clinicians and management across both sites to introduce them to the PlayDecide game, to disseminate the information arising from the surveys and the PlayDecide sessions. The workshops will design a system for feedback to the Interns and SHOs on safety concerns they have raised and to promote more inclusive leadership behaviours and organisational responsiveness from this group.

Data Analysis and Data Management

A detailed content analysis will be conducted on the surveys to assess any changes in reporting following the PlayDecide intervention and the dissemination workshops. This will be compared with the incident reporting levels and the results of the pre and post intervention leadership inclusiveness and psychological safety survey. Statistical analysis will be conducted using SPSS (V.20). Differences will be considered statistically significant at $p<0.05$. The interviews will be transcribed de-identified and coded into themes. Themes will be identified based on 'recurrent and distinctive features of participants' accounts, characterising particular perceptions and/or experiences, which the researcher[s] see as relevant to the research questions'[39]. The material coded to each theme will then be re-read and further analysed using NVivo (V10). The most significant themes related to the research objectives regarding their frequency and the emphasis will be reported upon. Data will be stored securely and entered into a password protected anonymised database by the research team. To ensure methodological rigour, the core research team will only have access to the data.

Ethics and Dissemination

The study is based on informed written consent where participation is voluntary and informants will be informed that they can withdraw from the study at any point until the conclusion of the collection of the data. The privacy of the participants will be protected and will be de-identified. All survey data collected will be kept separate from the respondent's names, for anonymity purposes. All data related to the study will be stored on a protected server and can only be accessed by selected members of the research team. The primary issue in this research is that disclosure of errors or concerns about patient safety and quality are properly investigated, upholding the principles of natural justice whilst ensuring no harm occurs as a result of the issue being raised. To ensure this, we will follow the existing policies

and procedures within the sites where the research is taking place. Participants will be advised that if they witness safety concerns that they should bring those to the attention of the risk manager through the incident reporting system. Any intern or SHO, who has been upset by what they witnessed, will also be encouraged to contact the hospital employee assistance programme. Should a situation arise where we are unsure about the ethics, we will seek guidance from the Medical Council. Study results will be disseminated at several partner and research conferences. In addition, study results will be presented to stakeholders outside the academic community. The PlayDecide game and results will be made available online as an open source material.

Discussion

This study will guide the planning and content development of intern and SHO programs in teaching hospitals in Ireland and elsewhere. The PlayDecide intervention will be developed collaboratively with key stakeholders. The core components will be mapped with research and current experiences to enhance its acceptability in practice. The principal limitations are that the response rates may vary across hospitals, influenced by the extent to which the research intervention is perceived as relevant and important for junior doctors and the endorsement of the intervention by senior hospital staff. Key clinical education leads and senior quality and safety staff in both hospital sites will have a central role in ensuring participation, maintaining the momentum of the study, enabling the dissemination workshops and outlining the impact the research will have in practice. Another limitation of the design is that since the surveys will be anonymous, it will be impossible at an individual level to track evolution over time.

The design of this study has significant strengths. Undertaking the proposed study in the two hospital sites will demonstrate that hospital leadership is supporting, prioritising and in particular responding to the issues outlined by the study participants. Collecting the data during hospital based seminars in paper format should result in a high response rate and engagement of the PlayDecide intervention. The games interactive design will provide a unique opportunity for interns and SHOs to discuss safety events and concerns in a safe and supported space which will be facilitated by the research team. Following the dissemination workshops, we anticipate that the findings will also result in recommendations for future best

practice around supporting a safety culture depending on the nature of those recommendations. This may lead to a future study to develop and assess the impact of recommended interventions.

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References

[1] Medical Council. Talking about Good Professional Practice, views on what it means to be a good doctor. Dublin: Medical Council; 2014.
[2] Medical Professionalism Project. Medical Professionalism in the New Millennium: A Physician Charter. *Ann Intern Med* 2002; 136(3):243-246.
[3] Brody H, Doukas D. Professionalism: a framework to guide medical education. Med Educ 2014: 48:980–987.
[4] Irvine D. Patients, professionalism, and revalidation. BMJ 2005: 330(7502):1265-8.
[5] Medical Council. Talking about Good Professional Practice, views on what it means to be a good doctor. Dublin: Medical Council; 2014.
[6] Rafter N, Hickey A, Conroy RM, Condell S, O'Connor P, Vaughan D, Walsh G, Williams DJ. The Irish National Adverse Events (INAES): the frequency and nature of adverse events in Irish hospitals-a retrospective record review study. BMJ Qual and Saf 2016: 0:1-9.
[7] Duffy, A. Data provided from the National Incident Management System by the State Claims Agency 19/08/16.
[8] Oglesby AM. Clinical adverse events notified to the States Claims Agency under the terms of the Clinical Indemnity Scheme. Incidents occurring between 01/01/2012 and 31/12/2012 – Final Report. Dublin: States Claims Agency; 2013.42
[9] Health Information and Quality Authority. National Standards for Safer Better Healthcare. Dublin: Health Information and Quality Authority; 2012.
[10] Firth-Cozen J. Doctors, their wellbeing, and their stress. BMJ 2003; 326:670.
[11] Roland et al. Professional values and reported behaviours of doctors in the USA and UK. BMJ Quality and Safety 2011; 20:515.
[12] Francis R. Freedom to Speak Up. An independent review into creating an open and honest reporting culture in the NHS. London: The Stationery Office; 2015.
[13] Francis, R. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. Executive Summary. London: The Stationery Office; 2013.
[14] Duffy A. An analysis of the culture in Ireland on open disclosure following adverse events

in healthcare. Clinical Risk 2012: 18: 207-223.
[15] Moore L, McAuliffe E. Is inadequate response to whistleblowing perpetuating a culture of silence in hospitals? Clinical Governance: An International Journal. 2010; 15:166-178.
[16] Moore L, McAuliffe E. To report or not to report? Why nurses are reluctant to whistleblow. Clinical Governance: An International Journal. 2012; 14:332-342.
[17] Markwell AL, Wainer Z. The health and wellbeing of junior doctors: insights from a national survey. Medical Journal of Australia. 2009; 191:441.
[18] Ibrahim JE, Jeffcott S, Davis MC, Chadwick L. Recognizing junior doctors' potential contribution to patient safety and health care quality improvement. Journal of Health Organization and Management. 2013; 27:273 – 286.
[19] Bethune R, Roueche A, Hilman T. Is quality of care improving? Improvement efforts need to be targeted at junior doctors. BMJ. 2011; 342:d1323.
[20] Benning A, Ghaleb M, Suokas A, et al. Large scale organisational intervention to improve patient safety in four UK hospitals: mixed method evaluation. BMJ. 2011; 342:d195.
[21] McCarthy SE, O'Boyle CA, O'Shaughnessy A, Walsh G. Online patient safety education programme for junior doctors: is it worthwhile? Irish Journal of Medical Science. 2014
[22] National Patient Safety Foundation. Shining a Light: Safer healthcare through 42 transparency. Boston, MA. National Patient Safety Foundation; 2015.
[23] Baker, R. G., Murray, M., & Tasa, K. (1995). Quality in action: An instrument for assessing organizational culture for quality improvement. Paper presented at the First International Scientific Symposium on Improving Quality and Value in Health Care, Orlando, FL (cited in Nembhard & Edmonston, 2006)
[24] Hult GTM, Hurley RF, Guinipero LC,. Nichols EL. Organizational learning in global purchasing: A model and test of internal users and corporate buyers. Decision Sciences. 2000; 31:293–325.
[25] Zimmerman JE, Shortell SM, Rousseau DM, Duffy J, Gillies RR, Knaus WA, Devers K, Wagner DP, Draper EA. Improving intensive care: Observations based on organizational case studies in nine intensive care units: A prospective, multicenter study. Critical Care Medicine. 1993; 21:1443–1451.
[26] Nembhard IM, Edmondson AC. Making it safe: The effects of leader inclusiveness and professional status on psychological safety and improvement efforts in healthcare teams. Journal of Organizational Behaviour. 2006; 27:941-966.
[27] Edmondson AC. Learning from mistakes is easier said than done: Group and organizational influences on the detection and correction of human error. Journal of Applied Behavioral Science. 1196; 32:5–32.
[28] Leonard MS, Frankel A, Simmonds T, Vega KB. Achieving safe and reliable healthcare: Strategies and solutions. Ann Arbor, MI: Health Administration Press; 2004.
[29] Ward M, McDonald N, Morrison R, Gaynor D, Nugent T. A Performance improvement case study in aircraft maintenance and its implications for hazard identification. Ergonomics, Special Edition: Human Factors in Aviation. 2010; 53:247 – 267.
[30] McDonald N. The Evaluation of Change. Journal of Cognition, Technology & Work. 2014.
[31] Shortell SM, Rousseau DM, Gillies RR, Devers KJ, Simons TL. Organizational assessment in intensive care units (ICUs): Construct development, reliability, and validity of the ICU nurse-physician questionnaire. Medical Care. 199; 29:709–726.
[32] Edmondson A. Psychological safety and learning behavior in work teams. Administrative Science Quarterly. 1999; 44:350–383.
[33] Medical Council. Eight Domains of Good Professional Practice. Dublin: Medical Council; 2010.

[34] Agell L, Soria V, Carrió M. Using role play to debate animal testing. Journal of Biological Education. 2015; 49:3.
[35] Ricciardi F, De Paolis LT. A comprehensive review of serious games in health professions. International Journal of Computer Games Technology. 2014; 1-11.
[36] PlayDecide. FUND Manual; 2010. http://www.playdecide.eu/sites/default/files/instructions/Fund_Manual_4.2.pdf (accessed April 2016).
[37] Flanagan JC. The critical incident technique. Psychological Bulletin. 1954; 51:4.
[38] Kemppainen JK. The critical incident technique and nursing care quality research. Journal of Advanced Nursing. 2000; 32:5.
[39] King N, Horrocks C. Interviews in Qualitative Research. London: SAGE; 2010.

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Imbuing Medical Professionalism in Relation to Safety: A study protocol for a mixed-methods intervention focused on trialling an embedded learning approach that centres on the use of a custom designed board game

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Imbuing Medical Professionalism in Relation to Safety: A study protocol for a mixed-methods intervention focused on trialling an embedded learning approach that centres on the use of a custom designed board game

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Abstract

Introduction: Healthcare organisations have a responsibility for ensuring that the governance of workplace settings creates a culture that supports good professional practice. Encouraging such a culture needs to start from an understanding of the factors that make it difficult for health professionals to raise issues of concern in relation to patient safety. The focus of this study is to determine whether a customised education intervention, developed as part of the study, with interns and senior house officers (SHOs) can imbue a culture of medical professionalism in relation to patient safety and support junior doctors to raise issues of concern, whilst shaping a culture of responsiveness and learning.

Methods and Analysis: We will use quantitative and qualitative methods to collect data. The sample size will be approximately 200 interns and SHOs across the two hospital sites. Two surveys will be included with one measuring leadership inclusiveness and psychological safety and a second capturing information on safety concerns that participants may have witnessed in their places of work. The PlayDecide embedded learning intervention will be developed with key stakeholders. This will be trialled in the middle stage of data collection for both interns and SHOs. A detailed content analysis will be conducted on the surveys to assess any changes in reporting following the PlayDecide intervention. This will be compared with the incident reporting levels and the results of the pre and post intervention leadership inclusiveness and psychological safety survey. Statistical analysis will be conducted using SPSS. Differences will be considered statistically significant at $p<0.05$. Semi-structured interviews using a critical incident technique will be used for the ongoing analysis and evaluation of the project. These will be transcribed, de-identified and coded into themes.

Ethics and Dissemination: The study has been granted ethics approval from University College Dublin (Ref. LS-15-19-Ward-McAuliffe: Imbuing Medical Professionalism in Relation to Safety). The study results will be disseminated through peer-reviewed publications.

Strengths and Limitation of this Study:

- This study will provide useful information for the planning and content of intern and senior house officers programs in teaching hospitals in Ireland and elsewhere.
- The PlayDecide intervention will be developed with key stakeholders within a collaborative framework.
- The PlayDecide intervention will be developed iteratively to draw on the experiences of key stakeholders and will take account of current patient safety research. The core components of the intervention will be mapped onto the above to enhance its acceptability in practice.
- Key clinical education leads and senior quality and safety staff in both hospital sites will have a central role in ensuring participation, maintaining the momentum of the study, enabling the dissemination workshops and outlining the impact the research will have in practice.
- The principal limitations are that the response rates may vary across hospitals, influenced by the extent to which the research intervention is perceived as relevant and important for junior doctors and the endorsement of the intervention by senior hospital staff.

Introduction

The concept and meaning of medical professionalism is changing towards a new professionalism. Medical Professionalism is "a set of values, enacted through behaviours and relationships, which underpin the public's trust in doctors"[1]. "New professionalism" refers to the subtle but important evolution in the values and responsibilities that relate to being a good doctor[2]. This evolution has been influenced by changing expectations in the doctor-patient relationship, increasing requirements for doctors to demonstrate ongoing clinical competence and the drive to improve quality and patient safety[3]. Patients' trust in doctors is influenced by: effective communication; respect for autonomy and shared decision-making; maintaining confidentiality; honesty, openness and transparency; raising concerns about patient safety; and maintaining competence and assuring the quality of medical practice[4]. A recent survey of the Irish public revealed that approximately 8 out of 10 were very confident or fairly confident that their doctor would tell them if there had been a mistake/oversight in the course of their care. A discrepancy in patient trust of doctors and doctors' honesty was identified. Doctors' views about disclosure of errors were mixed: 63% agreed that doctors should disclose all significant medical mistakes, but 85% of doctors surveyed admitted that they had

not fully disclosed a mistake to a patient because they were afraid of being sued[1].

This poses a significant challenge particularly as error rates are at an unacceptably high level in healthcare[5]. In 2014 across Ireland there was a total of 53108 patient safety incidents reported by acute hospitals. These incidents are reported directly by healthcare locations on the National Incident Management System (NIMS) and excludes incidents reported in the format of a claim to the State Claims Agency (SCA)[6]. Reviewing the 2012 incidents rates in Ireland the SCA outlined that the reporting rates stood approximately at 2.9 per cent which was considered an under reporting of adverse clinical events especially when compared to other countries reporting adverse event occurrences which were in the range 4-16 per cent[7]. The Health Information and Quality Authority (HIQA) have emphasised the importance of a culture of quality and safety that "promotes openness and transparency, teamwork, open and effective communication and a supportive environment within which both service users and providers can raise issues of concern and feel confident that this will not have a negative impact on how they are dealt with"[8]. At the core of this is *speaking up*, that is the act of raising an unethical, incompetent or wrong action or situation that poses a threat to patient safety, with a person who has the power to stop such action/situation[9]. Encouraging such a culture needs to start from an understanding of the factors that make it difficult for doctors and other health professionals to be open about errors.

The problems with current incident reporting systems are well described in the literature[10 11 12]. Within the Irish context, the main reasons given by doctors for not reporting a concern are 44% felt "nothing would happen as a result"; 25% had a "fear of retribution"; and 19% "thought someone else was dealing with the problem"**Error! Bookmark not defined.**. Duffy's study of healthcare professionals in Ireland also found that almost one-quarter identified fear of litigation as a key barrier to open disclosure following an adverse event[13]. Research by Moore and McAuliffe [14 15] concluded that while 88% of Irish nurses observed an incident of poor care only 70% of nurses reported it. Of the nurses that reported concerns, only 25% were satisfied with the response of the hospital. Amongst those who did not report, the primary reasons given were "not wanting to cause trouble" and "not being sure if it is the right thing to do". Historically the literature has pointed to the perception that junior members of health teams were more likely to undermine rather than build patient safety. In particular, junior doctors are perceived as being categorised as a 'high risk' group bringing little experience, often provided with limited and inadequate supervision and high stress levels[16]. However

more recently, the literature points to the strengths of junior doctors with Ibrahim *et al*[17] outlining the potential of cultivating their interest in improving patient care. Bethune *et al*[18] commenting on the Safer Patients Initiative in England[19] argue that doctors in training could have a role in quality improvement if they were adequately equipped and informed. McCarthy *et al* [20] argue that junior doctors are crucial in preventing, reporting and learning from errors, near misses and adverse events.

Study Aims and Objectives

This project aims to encourage and support medical graduates to become good doctors. In this study, we are focussing on professionalism in relation to patient safety. We propose to develop an interactive serious game using the PlayDecide framework that encourages discussion about the important values and behaviours that newly trained doctors (interns) and doctors in their second year (SHOs) need to work on to become good doctors. A serious game is a "game in which education (in its various forms) is the primary goal, rather than entertainment"[21]. The application of serious games within healthcare is not new[22].

These issues highlighted from playing the game will be brought to the attention of senior doctors to encourage them to support interns and SHOs by listening to and acting on their concerns, thus shaping a more supportive environment. We envisage that these interactive learning opportunities will encourage doctors to raise issues of concern and will engage doctors and other healthcare professionals in improving the organisation's response to poor professional practice and safety concerns as well as improving their personal and professional behaviour towards patients, colleagues and their healthcare organisations. This study will measure the effect of this game and associated actions to raise awareness of medical professionalism on the behaviour of doctors and on how concerns about patient safety are raised and responded to by the hospitals they work in. The research will develop and trial an embedded evidence based learning approach that centres on the use of a custom designed serious game to encourage speaking up, as well sharing knowledge and understanding among interns and junior doctors about safety and the importance of discussing and reporting clinical safety concerns within the hospital setting (refer to supplementary file 1).

Research Design and Methodological Approach

This proposed research design is influenced by an understanding of the on-going work within

the national medical intern training curriculum on medical professionalism and the work of the Irish Medical Council, the SCA and hospitals' quality and safety divisions with medical students, interns and SHOs to raise awareness. Our understanding is that the intern programme on medical professionalism is aimed at shaping the behaviour of interns towards openness and transparency whilst instilling in them a professional obligation to report poor practice and errors in care when they witness them. Instilling a sense of professionalism and obligation may not increase or improve medical professionalism if the interns are working in an environment that does not support such behaviours. A critical element that influences learning and the environment to disclose is leadership. Team leader behaviours have been shown to affect the internal dynamics of a team, in particular, influencing team climate and learning orientation[23 24 25]. If a leader takes an authoritarian, unsupportive, or defensive stance, team members are more likely to feel that speaking up in the team is unsafe. In contrast, if a leader is democratic, supportive, and welcomes questions and challenges, team members are likely to feel greater psychological safety in the team and in their interactions with each other[26].

In a study of nursing leadership and medication errors, Edmondson[27] (1996) found evidence of leadership effects on psychological safety. In some units, nurses described nurse managers as authoritarian and also expressed deep fears about being reprimanded for revealing mistakes. In contrast, nurses in other units felt safe speaking up about errors because their nurse manager had stressed the importance of using this information as a learning tool for the unit. Nembhard & Edmonton[26], in their work on creating psychological safety for learning within cross-disciplinary teams, found evidence that leader inclusiveness—words and deeds by leaders that invite and appreciate others' contributions—can help to overcome status' inhibiting effects on psychological safety (i.e. the inhibiting effect of the traditional medical hierarchy). They argue that inclusive behaviour on the part of medical leaders may be an essential means of facilitating others' meaningful engagement in team-based quality improvement work because speaking up and reporting errors is more likely to occur when staff feels psychologically safe. Other studies of psychological safety and communication in the health care environment have also highlighted the role of leadership in cultivating a culture of safety but have not articulated the actual practices of leaders that are needed, other than training staff to speak up[28]. Nembhard and Edmonton's research suggests that training leaders to invite team members' comments and to appreciate those comments overtly is as important. We would argue that in the context of reporting of errors and voicing concerns,

leaders can demonstrate an overt appreciation of the intern's comments by providing feedback to the intern on how the issue raised has been dealt with and what action is likely to result.

Feedback is one of the fundamental psychological principles of performance management. In the context of reporting and process improvement, Ward *et al.*[29] demonstrated that the level of feedback given to staff on the outcomes of reports made by them in the past had a direct effect on the level of future reporting. The more feedback (on e.g. what had happened their reports, who was currently dealing with them, what the outcomes might be or were, and whether or not and when recommendations would be implemented) that was given to staff the more likely they were to engage with the improvement process in the future. This study will build on these findings to design a learning intervention that targets leaders (senior clinicians) and interns in an attempt to shape a culture of psychological safety.

Design Materials and Methods

This study aims to assess current practice amongst interns and SHOs on reporting and open disclosure in two university hospitals in Ireland. The sample size is expected to be 200 across the two hospital sites. Interns and SHOs rotate into the hospitals each July so the approximate sample size will only be determined when the hospital sites have final numbers. The study will be carried out within the hospital educational and training centres where interns and SHOs will be attending separate weekly lunchtime seminars. A structured enquiry method[30] will be utilised for the ongoing analysis and evaluation of the project. This method of repeated qualitative interviews with a small sample of key stakeholders in each of the hospitals will allow us to tailor the enquiry to what is relevant to the particular stage of the project. Using this structured approach will allow us to build up a dossier of knowledge about medical professionalism and the challenges of embedding it in each of the hospital cultures. This continuous approach contrasts with the more traditional and widely used end-of-project evaluation and allows the research team to draw inferences about the current status and prospects for the future.

Baseline Data Collection

An initial meeting will take place with Interns and SHOs to explain the study within the two hospital sites. The following baseline data will be collected in this phase.

Leader Inclusiveness and Psychological Safety Questionnaire

A brief survey of interns and SHOs will measure leader inclusiveness and psychological safety. Leader inclusiveness refers to the behaviours and attitudes of the clinicians-in-charge. A three-item scale developed and used by Nembhard and Edmonton[26] assesses the extent to which leaders' words and deeds indicate an invitation and appreciation for others as contributing members in a team endeavour. The items on the scale will be adapted for this study. The first two items, 'senior doctors encourage other members of the team to take initiative' and 'senior doctors ask for the input of team members that belong to other professional groups,' were adapted from Shortell *et al*[31] (1991) physician leadership scale. The third item, 'senior doctors do not value the opinion of others equally'' (reverse scored), was developed for the Nembhard and Edmonton study[26]. The level of agreement with each statement (1-strongly disagree, 7-strong agree) is averaged to provide a single perception for each respondent (Chronbach alpha= 0.75).

Psychological safety - five items from Edmondson's[32] psychological safety scale adapted to this context will be used to assess the extent to which respondents felt safe to speak up about issues or ideas regarding their work:

- Members of this team are able to bring up problems and tough issues.
- People in this unit are comfortable checking with each other if they have questions about the right way to do something.
- If you make a mistake on this team, it is often held against you. (reverse scored)
- It is difficult to ask other members of this team for help. (reverse scored)
- Working with members of this team, my unique skills and talents are valued and utilised.

Respondents' agreement (1-strongly disagree, 7-strongly agree) with these items form a single scale (Chronbach alpha=0.73).

Raising Safety Concerns Questionnaire

A cohort of Interns and SHOs will be surveyed weekly over a three month period using a paper based questionnaire method to capture information on safety concerns they may have witnessed in their places of work. This questionnaire will be developed as part of the research project and based upon the Irish Medical Council's eight domains of good professional

practice[33]. Information will also be captured on the Interns and SHOs reaction to these events e.g. if and how they reported such events and follow-up action that occurred. A small cohort of Interns and SHOs will also be invited to interview to explore in more depth some of the common themes raised in the surveys.

Incident Reporting Process in the Hospitals

We will work with the risk managers in both hospitals to examine information on events captured by the hospitals incident reporting system before the intervention to serve as a baseline measure for reporting of safety concerns. We will analyse the current methods of reporting and feedback provided by carrying out in-depth interviews with both risk managers. We will also work with the quality and safety teams to identify the actual role of senior clinicians in making changes and improvements as a result of the incident management systems. These insights will inform the development of the PlayDecide game and the dissemination workshops and will be crucial to the success of the project in terms of working with the senior staff to effectively close the loop by responding to any safety concerns that the junior doctors might have.

PlayDecide Learning Intervention

An embedded learning approach that centres on the use of a custom designed game to encourage speaking up, as well as inclusive leadership (words and deeds by leaders that invite and appreciate others' contributions) and responsiveness in the hospital system, will be developed. The aim of a serious game is to educate, train and alter behaviour in a desirable way, such as aiming to increase patient safety[34]. It is either computerised or card based, that merges a video game structure (thus having a specific aim/s) with a non-entertaining purpose in the hope of actively teaching the game players a new piece of information on a specific topic through active engagement such as role-playing and/or discussion.

PlayDecide is a serious card based game, with a role-playing component to it where each person debates his or her view(s) based on the story card each selected from a selection that looks at a specific theme. The game was created to allow players to discuss controversial issues in a safe environment. The game consists of five different types of cards: story, white, information, challenge and issue cards. Story cards (~12) tell the game player a fictional narrative story of a character based on a real situation on a topic in relations to the main

theme such as the experience of a doctor when reporting an incident or the experience of a nurse with a difficult senior staff member. A white card (~12) is a versatile blank card where a participant can write their own story or issue or information or opinion to present to the rest of the group. Information cards (~22) are factual cards that present up to date scientific information about the theme. Challenge cards (~16) are cards used by game players to stir up a conversation when the discussion stalls. Issue cards (~22) exhibit a range of perceptions, questions, and opinions that look at the ethical and implications it has on the overall theme of the game[35].

The game consists of four to eight players, and each game has three phases that take a total of ~80 minutes to play. The first phase takes ~30 minutes where each player picks a story card in turn and summaries each to the group in turn. Similarly, each game player picks two information and issue cards in turn and summaries each. The second phase takes ~30 minutes of discussion among the players. If the discussion stalls, a player can use the challenge card to encourage further discussion. During this time, the group also create clusters that reflect the themes of the discussion. Each cluster consists of a name, a conclusion, created by an information card, an issue card, a story card and a white card. The third stage takes ~20 minutes where game players discuss four prewritten positions and vote on each of the positions in turn. The group can also devise their own fifth position if any one of the four does not encompass their group response[36]. A sub-group of experts from the project steering group will be formed to develop the PlayDecide game which will draw on the information collected in phase one. This group will consist of key stakeholders including representatives from senior medical and nursing staff, risk manager, intern tutors and a patient representative. Membership will be on a voluntary basis. The game when developed will be sent for peer review by two external experts and will be tested by the research team. The game will then be played with interns and SHOs with the aim of encouraging speaking up about clinical safety concerns.

Post Intervention

Raising Safety Concerns and Incident Reporting

The cohort of Interns and SHOs who participated in the PlayDecide intervention will be surveyed weekly to capture information on safety concerns they may have witnessed in their

places of work and to whom they reported to. Post intervention information on events captured by the hospitals incident reporting system will also be reviewed with the appointed hospital risk managers for the 6 month post intervention period.

Semi-structured Interviews

Voluntary semi-structured interviews will be undertaken with interns and SHOs. The interview approach will use Flanagan's[36] critical incident technique (CIT). CIT has been described as a systematic, inductive and flexible qualitative research method. It is a methodology for collecting and analysing data with the aim of providing solutions to practical problems[37]. According to Flanagan (1954), observations become fact when a large number of independent observers offer the same descriptions of behaviour. The anonymous interviews will explore participants understanding of an incident and to capture suggestions of what is required to shape a safety culture.

Dissemination Workshops on Leadership and Organisation Responsiveness

Dissemination workshops will be held with senior clinicians and management across both sites to introduce them to the PlayDecide game, to disseminate the information arising from the surveys and the PlayDecide sessions. The workshops will design a system for feedback to the Interns and SHOs on safety concerns they have raised and to promote more inclusive leadership behaviours and organisational responsiveness from this group.

Data Analysis and Data Management

A detailed content analysis will be conducted on the surveys to assess any changes in reporting following the PlayDecide intervention and the dissemination workshops. This will be compared with the incident reporting levels and the results of the pre and post intervention leadership inclusiveness and psychological safety survey. Statistical analysis will be conducted using SPSS (V.20). Differences will be considered statistically significant at $p<0.05$. The interviews will be transcribed de-identified and coded into themes. Themes will be identified based on 'recurrent and distinctive features of participants' accounts, characterising particular perceptions and/or experiences, which the researcher[s] see as relevant to the research questions'[38]. The material coded to each theme will then be re-read and further analysed using NVivo (V10). The most significant themes related to the research objectives regarding their frequency and the emphasis will be reported upon. Data will be

stored securely and entered into a password protected anonymised database by the research team. To ensure methodological rigour, the core research team will only have access to the data.

Ethics and Dissemination

The study is based on informed written consent where participation is voluntary and informants will be informed that they can withdraw from the study at any point until the conclusion of the collection of the data. The privacy of the participants will be protected and will be de-identified. All survey data collected will be kept separate from the respondent's names, for anonymity purposes. All data related to the study will be stored on a protected server and can only be accessed by selected members of the research team. The primary issue in this research is that disclosure of errors or concerns about patient safety and quality are properly investigated, upholding the principles of natural justice whilst ensuring no harm occurs as a result of the issue being raised. To ensure this, we will follow the existing policies and procedures within the sites where the research is taking place. Participants will be advised that if they witness safety concerns that they should bring those to the attention of the risk manager through the incident reporting system. Any intern or SHO, who has been upset by what they witnessed, will also be encouraged to contact the hospital employee assistance programme. Should a situation arise where we are unsure about the ethics, we will seek guidance from the Medical Council. Study results will be disseminated at several partner and research conferences. In addition, study results will be presented to stakeholders outside the academic community. The PlayDecide game and results will be made available online as an open source material.

Discussion

This study will guide the planning and content development of intern and SHO programs in teaching hospitals in Ireland and elsewhere. The PlayDecide intervention will be developed collaboratively with key stakeholders. The core components will be mapped with research and current experiences to enhance its acceptability in practice. The principal limitations are that the response rates may vary across hospitals, influenced by the extent to which the research intervention is perceived as relevant and important for junior doctors and the endorsement of the intervention by senior hospital staff. Key clinical education leads and

senior quality and safety staff in both hospital sites will have a central role in ensuring participation, maintaining the momentum of the study, enabling the dissemination workshops and outlining the impact the research will have in practice. Another limitation of the design is that since the surveys will be anonymous, it will be impossible at an individual level to track evolution over time.

The design of this study has significant strengths. Undertaking the proposed study in the two hospital sites will demonstrate that hospital leadership is supporting, prioritising and in particular responding to the issues outlined by the study participants. Collecting the data during hospital based seminars in paper format should result in a high response rate and engagement of the PlayDecide intervention. The games interactive design will provide a unique opportunity for interns and SHOs to discuss safety events and concerns in a safe and supported space, which will be facilitated by the research team. Following the dissemination workshops, we anticipate that the findings will also result in recommendations for future best practice around supporting a safety culture depending on the nature of those recommendations. This may lead to a future study to develop and assess the impact of recommended interventions.

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References

[1] Medical Council. *Talking about Good Professional Practice, views on what it means to be a good doctor.* Dublin: Medical Council; 2014.
[2] Medical Professionalism Project. Medical Professionalism in the New Millennium: A Physician Charter. *Ann Intern Med* 2002;**136** (3):243-246.
[3] Brody H, Doukas D. Professionalism: a framework to guide medical education. *Med Educ* 2014:**48** (10):980–987.

[4] Irvine D. Patients, professionalism, and revalidation. *BMJ* 2005;**330** (7502):1265-8.
[5] Rafter N, Hickey A, Conroy RM, Condell S, O'Connor P, Vaughan D, Walsh G, Williams DJ. The Irish National Adverse Events (INAES): the frequency and nature of adverse events in Irish hospitals-a retrospective record review study. *BMJ Qual and Saf* 2016:**0** :1-9.
[6] Duffy, A. Data provided from the National Incident Management System by the State Claims Agency 19/08/16.
[7] Oglesby AM. *Clinical adverse events notified to the States Claims Agency under the terms of the Clinical Indemnity Scheme. Incidents occurring between 01/01/2012 and 31/12/2012 – Final Report*. Dublin: States Claims Agency; 2013.
[8] Health Information and Quality Authority. *National Standards for Safer Better Healthcare.* Dublin: Health Information and Quality Authority; 2012.
[9] Firth-Cozen J. Doctors, their wellbeing, and their stress. *BMJ* 2003;**326** (7391):670.
[10] Macrae, C. The problem with incident reporting. *BMJ Quality & Safety* 2016; **25**(2), 71-75
[11] Sujan, M. An organisation without a memory: A qualitative study of hospital staff perceptions on reporting and organisational learning for patient safety. *Reliability Engineering & System Safety*, 2015; 144, 45-52
[12] Anderson, J. E., Kodate, N., Walters, R., & Dodds, A. Can incident reporting improve safety? Healthcare practitioners' views of the effectiveness of incident reporting. International Journal for Quality in Health Care, 2013; **25**(2), 141-150;
[13] Duffy A. An analysis of the culture in Ireland on open disclosure following adverse events in healthcare. *Clinical Risk* 2012:**18** (6): 207-223.
[14] Moore L, McAuliffe E. Is inadequate response to whistleblowing perpetuating a culture of silence in hospitals? *Clinical Governance: An International Journal*. 2010;**15** (3):166-178.
[15] Moore L, McAuliffe E. To report or not to report? Why nurses are reluctant to whistleblow. *Clinical Governance: An International Journal*. 2012;**14** (4):332-342.
[16] Markwell AL, Wainer Z. The health and wellbeing of junior doctors: insights from a national survey. *Medical Journal of Australia.* 2009;**191** (8):441.
[17] Ibrahim JE, Jeffcott S, Davis MC, Chadwick L. Recognizing junior doctors' potential contribution to patient safety and health care quality improvement. *Journal of Health Organization and Management.* 2013;**27** (2):273 – 286.
[18] Bethune R, Roueche A, Hilman T. Is quality of care improving? Improvement efforts need to be targeted at junior doctors. *BMJ.* 2011;**342** :d1323.
[19] Benning A, Ghaleb M, Suokas A, et al. Large scale organisational intervention to improve patient safety in four UK hospitals: mixed method evaluation. *BMJ.* 2011; **342** :d195.
[20] McCarthy SE, O'Boyle CA, O'Shaughnessy A, Walsh G. Online patient safety education programme for junior doctors: is it worthwhile? *Irish Journal of Medical Science*. 2016;**185** (1):51-8.
[21] Michael D, Chen S. *Serious games: games that educate, train and inform*. Boston: Thomson; 2006.
[22] Ricciardi F, De Paolis LT. A comprehensive review of serious games in health professions. *International Journal of Computer Games Technology*. 2014;**9**:1-11.
[23] Baker, R. G., Murray, M., & Tasa, K. (1995). Quality in action: An instrument for assessing organizational culture for quality improvement. Paper presented at the First International Scientific Symposium on Improving Quality and Value in Health Care, Orlando, FL (cited in Nembhard & Edmonston, 2006)
[24] Hult GTM, Hurley RF, Guinipero LC,. Nichols EL. Organizational learning in global purchasing: A model and test of internal users and corporate buyers. *Decision Sciences*. 2000;**31** (2):293–325.
[25] Zimmerman JE, Shortell SM, Rousseau DM, Duffy J, Gillies RR, Knaus WA, Devers K, Wagner DP, Draper EA. Improving intensive care: Observations based on organizational case

studies in nine intensive care units: A prospective, multicenter study. *Critical Care Medicine*. 1993; **21** (10):1443–1451.
[26] Nembhard IM, Edmondson AC. Making it safe: The effects of leader inclusiveness and professional status on psychological safety and improvement efforts in healthcare teams. *Journal of Organizational Behaviour*. 2006;**27** (7):941-966.
[27] Edmondson AC. Learning from mistakes is easier said than done: Group and organizational influences on the detection and correction of human error. *Journal of Applied Behavioral Science*. 1996;**32** (1):5–32.
[28] Leonard MS, Frankel A, Simmonds T, Vega KB. *Achieving safe and reliable healthcare: Strategies and solutions.* Ann Arbor, MI: Health Administration Press; 2004.
[29] Ward M, McDonald N, Morrison R, Gaynor D, Nugent T. A Performance improvement case study in aircraft maintenance and its implications for hazard identification. *Ergonomics, Special Edition: Human Factors in Aviation.* 2010;**53** (2):247 – 267.
[30] McDonald N. The Evaluation of Change. Journal of Cognition, Technology & Work. 2014.
[31] Shortell SM, Rousseau DM, Gillies RR, Devers KJ, Simons TL. Organizational assessment in intensive care units (ICUs): Construct development, reliability, and validity of the ICU nurse-physician questionnaire. *Medical Care*. 199;**29** :709–726.
[32] Edmondson A. Psychological safety and learning behavior in work teams. *Administrative Science Quarterly*. 1999;**44** (2):350–383.
[33] Medical Council. *Eight Domains of Good Professional Practice*. Dublin: Medical Council; 2010.
[34] Agell L, Soria V, Carrió M. Using role play to debate animal testing. *Journal of Biological Education*. 2015;**49** (3):309-21.
[35] PlayDecide. FUND Manual; 2010.
http://www.playdecide.eu/sites/default/files/instructions/Fund_Manual_4.2.pdf [Accessed 14 September 2016].
[36] Flanagan JC. The critical incident technique. *Psychological Bulletin*. 1954;**51** (4):327.
[37] Kemppainen JK. The critical incident technique and nursing care quality research. *Journal of Advanced Nursing*. 2000;**32** (5):1264-71.
[38] King N, Horrocks C. *Interviews in Qualitative Research*. London: SAGE; 2010.