

BMJ Open 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, while 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 preintervention and postintervention leadership inclusiveness and psychological safety survey. Statistical analysis will be conducted using SPSS. Differences will be considered statistically significant at $p < 0.05$. Semistructured 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

Strengths and limitations of this study

- This study will provide useful information for the planning and content of intern and senior house officers programmes 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.

results will be disseminated through peer-reviewed publications.

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 the 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 53 108 patient safety incidents reported by acute hospitals. These incidents are reported directly by healthcare locations on the National Incident Management System 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% which was considered an under-reporting of adverse clinical events, especially when compared with other countries reporting adverse event occurrences which were in the range 4%–16%.⁷ The Health Information and Quality Authority 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.^{10–12} 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.¹³ Research by Moore and McAuliffe^{14 15} concluded that while 88% of Irish nurses observed an incident of poor care, only 70% of the nurses reported it. Of the nurses that reported concerns, only 25% were satisfied with the response of the hospital. Among 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 England¹⁹ 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 (senior house officers (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 as 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 online supplementary file 1).

RESEARCH DESIGN AND METHODOLOGICAL APPROACH

This proposed research design is influenced by an understanding of the ongoing 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 while 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.^{23–25} 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, Edmondson²⁷ (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 and Edmondson,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 are more likely to occur when staff feels psychologically safe. Other studies of psychological safety and communication in the healthcare 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 Edmondson'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 to 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 among 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 method³⁰ will be used 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 Edmondson²⁶ 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 physician leadership scale. The third item, 'senior doctors do not value the opinion of others equally' (reverse scored), was developed for the Nembhard and Edmondson 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's³² 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 used.

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 3-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 on 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 for example, 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 speaking up about 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 relation 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 and look at the ethical implications they have 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 min to play. The first phase takes ~30 min 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 min 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 min 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 subgroup 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, quality and safety clinical lead, 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.

POSTINTERVENTION

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 them to. Postintervention information on events captured by the hospitals incident reporting system will also be reviewed with the appointed hospital risk managers for the 6-month postintervention period.

Semistructured interviews

Voluntary semistructured interviews will be undertaken with interns and SHOs. The interview approach will use Flanagan's³⁶ 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,³⁶ 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 preintervention and postintervention 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 on. 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 while 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 programmes 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.

Contributors All the authors have made significant intellectual or practical contributions. MW, EM, AD, UG, UC, CH, NM and KE conceived the project and procured project funding. MW and ÉNS are managing the project including data collection with assistance from CK. ÉNS, EM, CK and MW drafted the manuscript and all authors read, edited and approved the final manuscript.

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