

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	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
AUTHORS	Ward, Marie; McAuliffe, Eilish; Ní Shé, Éidín; Duffy, Ann; Geary, Una; Cunningham, Una; Holland, Catherine; McDonald, Nick; Egan, Karen; Korpos, Christian

VERSION 1 - REVIEW

REVIEWER	Mark Sujan University of Warwick, UK
REVIEW RETURNED	25-Sep-2016

GENERAL COMMENTS	<p>This paper describes a research protocol, where the aim of the research is to develop and to evaluate an intervention based on a game targeted at improving junior and middle grade doctors' feeling of psychological safety, and hence their ability to speak up about patient safety concerns.</p> <p>The problems with incident reporting and the prevalence of a culture of fear and blame have been widely documented in the literature, and therefore this research addresses an important issue. The use of a game as an educational intervention is interesting, and if successful could be adopted easily throughout the health service.</p> <p>The introduction provides a good overview of the motivation to this project. It is somewhat long, and certain sections might be shortened in order to make space for other issues that could be addressed earlier in the paper. More specifically:</p> <p>(1) the problems with incident reporting are well known, and the description could be shortened with reference to the literature (e.g. Macrae, C. (2016). The problem with incident reporting. <i>BMJ Quality & Safety</i>, 25(2), 71-75; Anderson, J. E., Kodate, N., Walters, R., & Dodds, A. (2013). Can incident reporting improve safety? <i>Healthcare practitioners' views of the effectiveness of incident reporting. International journal for quality in health care</i>, 25(2), 141-150; Sujan, M. (2015). An organisation without a memory: A qualitative study of hospital staff perceptions on reporting and organisational learning for patient safety. <i>Reliability Engineering & System Safety</i>, 144, 45-52.)</p> <p>(2) Some background to the nature of the intervention (i.e. the use of games) might be helpful in the introduction because at present there is no mention of this early on.</p> <p>(3) The aims and objectives should be stated clearly either in the introduction or in a separate section.</p> <p>Methods: the research design currently suffers from two</p>
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	<p>weaknesses that could be improved upon easily in a minor revision:</p> <p>(1) More explicit statement of aims and objectives (see last comment above)</p> <p>(2) More explicit mapping of the proposed methods to these objectives, along with a justification for why the methods have been chosen.</p> <p>(3) Further detail in the description of the methods, for example: how questionnaires will be developed; how the educational intervention will be delivered in practice; how the evidence gathered through the different methods will be synthesised.</p> <p>The development of the game includes a multi-disciplinary group. One might argue that interventions aimed at changing culture work best when they are aimed at such multi-disciplinary groups. It is not quite clear why within this project the intervention is aimed only at junior and middle grade doctors, and why other roles such as allied health professionals, nurses, and non-medical senior clinicians are excluded. Similarly, why consultants and managers are excluded. Could the intervention be expanded to include a broader range of roles?</p> <p>Good luck with your research!</p>
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REVIEWER	<p>Pernilla Ulfvengren KTH Royal Institute of Technology Sweden</p> <p>I have collaborated with Nick McDonald and Marie Ward in Aviation research but not been part of this research.</p>
REVIEW RETURNED	05-Mar-2017

GENERAL COMMENTS	<p>Very well written paper that with minor revisions should be accepted. Title could be more clear on that this work is developing a framework and methodology</p> <p>Fore example: Towards New Medical professionalism - Developing of a study protocol/methodology for an embeeded Learning approach including serious games</p> <p>The paper could use a figure of the process describing the logic from theory and identifying factors blocking relevant aspects of transparancy, trust etc. as well as from the theories of leadership in teamwork. Then how the game and Learning interventions will contribute to the expected result of increased understanding of what to report and why.</p> <p>I was confused by the tempus used since it was not clear from the start that this was before studies and that the actual interventions had not begun. Make this more explicit in purpose of paper?</p> <p>In section Strenght and weaknesses it could be clearer what is Strengths and Weaknesses.</p> <p>3rd bullet talks of core components...of what?</p> <p>Introduction starts abrupt. Perhaps write something like : The concept and meaning of medical professionalism is changing towards a new professionalism...</p> <p>Page 3 line 46 suggests to add: a discrepancy in patient trust of doctors and doctors' honesty...was identified...</p> <p>Page 2 line 1-7 Logic unclear between the stated problem on trust to error rates and then wrong in numbers? 53, 108 patients?? 53108 patients?</p>
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	<p>Page 5 line 3-6 Identify factors explaining why they do not “speak up”?</p> <p>Page 6 Why is not section under heading research design and methodological approach part of the previous. Discussing the relation of various theoretical backgrounds complied to the logic of your study? More factors than in previous study identified and could be discussed in figure suggested for relations between lack of “speaking up” as well as leadership theoris on wording etc. Then make a summary and “model” in the end of page 7 before research materials (rename as research design here?)</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

(1) the problems with incident reporting are well known, and the description could be shortened with reference to the literature (e.g. Macrae, C. (2016). The problem with incident reporting. *BMJ Quality & Safety*, 25(2), 71-75; Anderson, J. E., Kodate, N., Walters, R., & Dodds, A. (2013). Can incident reporting improve safety? *Healthcare practitioners' views of the effectiveness of incident reporting. International journal for quality in health care*, 25(2), 141-150; Sujan, M. (2015). An organisation without a memory: A qualitative study of hospital staff perceptions on reporting and organisational learning for patient safety. *Reliability Engineering & System Safety*, 144, 45-52.)

- Thank you these papers have been included and introduction has been amended and shortened.

(2) Some background to the nature of the intervention (i.e. the use of games) might be helpful in the introduction because at present there is no mention of this early on.

- This has been included in study aims and objectives

(3) The aims and objectives should be stated clearly either in the introduction or in a separate section.

- We have added in a separate section with aims and objectives

Methods: the research design currently suffers from two weaknesses that could be improved upon easily in a minor revision:

(1) More explicit statement of aims and objectives (see last comment above)

- As above

(2) More explicit mapping of the proposed methods to these objectives, along with a justification for why the methods have been chosen.

- This is noted in Research design and methodological approach.

(3) Further detail in the description of the methods, for example: how questionnaires will be developed; how the educational intervention will be delivered in practice; how the evidence gathered through the different methods will be synthesised.

- Leader Inclusiveness and Psychological Safety-Amended to include Questionnaire
- Raising Safety Concerns-Amended to include- Questionnaire
- Data synthesis is outlined in data analysis and data management.
- Data collection delivery is outlined in Design materials and methods that states: The study will be carried out within the hospital educational and training centres where interns and SHOs will be attending separate weekly lunchtime seminars.

The development of the game includes a multi-disciplinary group. One might argue that interventions aimed at changing culture work best when they are aimed at such multi-disciplinary groups. It is not

quite clear why within this project the intervention is aimed only at junior and middle grade doctors, and why other roles such as allied health professionals, nurses, and non-medical senior clinicians are excluded. Similarly, why consultants and managers are excluded. Could the intervention be expanded to include a broader range of roles?

- Thank you for this comment we had initially proposed playing the game within multidisciplinary teams however our funders the Medical Council explicitly requested that the game be played with junior doctors. We expect following implementation of this study with junior doctors that a second phase of the study could include MDT teams. Within The paper on page 5 reference is made from the recent literature of the potential role doctors in training could have a role in quality improvement if they were adequately equipped and informed.

Reviewer: 2

Title could be more clear on that this work is developing a framework and methodology
Fore example: Towards New Medical professionalism - Developing of a study protocol/methodology for an embedded Learning approach including serious games

- The focus of this project is to develop and trail an embedded learning approach to improving speaking up among junior doctors and to develop organisational responsive to this speaking up. This paper outlines the study protocol for carrying out the research.

The paper could use a figure of the process describing the logic from theory and identifying factors blocking relevant aspects of transparency, trust etc. as well as from the theories of leadership in teamwork. Then how the game and Learning interventions will contribute to the expected result of increased understanding of what to report and why.

- The PlayDecide intervention will be collaboratively designed with key stakeholders as part of this study. It is a good idea to include a figure representing how the different components of the game will address our core research question and this is something we will do when we publish the results of the study. In the meantime we have included a table clearly outlining the pre and post intervention measures and the intervention components.

I was confused by the tempus used since it was not clear from the start that this was before studies and that the actual interventions had not begun. Make this more explicit in purpose of paper?

- Yes this will be assigned as a 'Study Protocol' paper.

In section Strength and weaknesses it could be clearer what is Strengths and Weaknesses.

3rd bullet talks of core components...of what?

- PlayDecide Game added

Introduction starts abrupt. Perhaps write something like : The concept and meaning of medical professionalism is changing towards a new professionalism...

- This has been amended.

Page 3 line 46 suggests to add: a discrepancy in patient trust of doctors and doctors' honesty....was identified...

- This has been added

Page 2 line 1-7 Logic unclear between the stated problem on trust to error rates and then wrong in numbers? 53, 108 patients?? 53108 patients?

- Amended to: In 2014 across Ireland there was a total of 53108 patient safety related incidents reported by acute hospitals.

Page 5 line 3-6 Identify factors explaining why they do not "speak up"?

- The factors have been identified in the section above: 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....

Page 6 Why is not section under heading research design and methodological approach part of the previous. Discussing the relation of various theoretical backgrounds complied to the logic of your study? More factors than in previous study identified and could be discussed in figure suggested for relations between lack of “speaking up” as well as leadership theoris on wording etc.

Then make a summary and “model” in the end of page 7 before research materials (rename as research design here?)

- Yes as we said above a figure / model is a good idea to represent the complexities of the behaviours that we are trying to impact on with the core components of the game. This figure / model will come in later papers presenting our findings. For the moment we include a simple diagram outlining the pre and post intervention measures and the intervention components.

VERSION 2 – REVIEW

REVIEWER	Mark Sujan Warwick University, UK
REVIEW RETURNED	16-May-2017

GENERAL COMMENTS	<p>I reviewed the original draft, and I am happy with the revisions made by the authors in response to my earlier suggestions.</p> <p>The paper addresses an important topic (engaging junior medical staff in patient safety), which continues to present a stubborn problem. The findings of the research should be useful to medical educators and risk managers.</p>
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REVIEWER	Pernilla Ulfvengren KTH Royal Institute of Technolog, Sweden
REVIEW RETURNED	12-Jun-2017

GENERAL COMMENTS	<p>The Review template in BMJopen assumes that a study has been performed.</p> <p>It is difficult to apply this to an article that explains a planned study, which is not yet performed, hence has no results or conclusions to discuss, or to assess how conclusions drawn are coherent to the results and methods.</p> <p>Therefor N/A is used in several criteria for Review.</p> <p>It would have been possible I suppose to write this paper as the study being the development of this planned intervention where the method of this development was clearly described rather than framing the study of itnerest in the paper being th planned one. It would adress more on how the researchers came up with this design. WS-meetings, barinstorming, discussions, collective experiences from earlier research interventions etc. A method section for this would clearly explain the choice and selections for Components in the intervention. Then results would have been the described planned intervention and methodology and discussion on this development and arguments for its proposed success in actually</p>
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carrying out this study.

But It is a carefully written article with thorough descriptions of the planned study and I have reviewed is as this and tried to apply the criteria and advice that it is accepted for what it is.I am looking forward to the results after the developed study protocol has been applied!