

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Validation of a survey tool to assess the patient safety attitudes of pharmacy students
<b>AUTHORS</b>	Walpola, Ramesh; Fois, Romano; Carter, Stephen; McLachlan, Andrew; Chen, Timothy

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Mingming Zhang Chinese Cochrane Center Chian
<b>REVIEW RETURNED</b>	02-Jun-2015

<b>GENERAL COMMENTS</b>	<ol style="list-style-type: none"> <li>1. The information presented in the background section is interesting but it is not providing anything new to the reader. I would encourage the authors to provide more information on studies that have already been conducted and what they showed of survey tools that measure patient safety attitude of health care student?</li> <li>2. Could you please provide further information on how the pharmacy students were selected for inclusion? How was the students selected within the first and second year?</li> <li>3. A test–retest reliability should be conducted to assess the reproducibility of the questionnaire</li> <li>4. How was the survey response rates calculated?</li> <li>5. How to identified a survey was valid?</li> <li>6. How to deal with the missing value?</li> <li>7. Did participants provide written consent to undertake the survey?</li> <li>8. Did you have any inclusion/exclusion criteria's for participants?</li> </ol>
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<b>REVIEWER</b>	Andrew Carson-Stevens Cardiff University, Wales University of British Columbia, Canada
<b>REVIEW RETURNED</b>	13-Jun-2015

<b>GENERAL COMMENTS</b>	<p>Abstract: Introduction missing;</p> <p>Introduction: The introduction would benefit from being framed from an evaluation of education perspective, where the modification of an existing survey to assess patient safety attitudes as an outcome measure for course evaluation. Highlighting existing literature, and where relevant the paucities that exist in research and development to date would strengthen the introduction considerable.</p> <p>Highlighting that WHO recognise patient safety education is important although unclear why there is specific mention of the Australian Patient Safety Education Framework here. The link with</p>
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	<p>the final sentence could be strengthened by raising the issue around evaluation of patient safety educational efforts. In addition, throughout the introduction, a more thorough and critical appraisal of studies that have evaluated patient safety educational interventions would also reassure me that the authors are appropriately identifying gaps in the literature in terms of evaluation and the need to develop suitable outcome metrics. This would also set up a stronger discussion of findings in relation to their key findings and relationships with existing literature. The 'so what' &amp; 'now what' of which might be best considered in terms of the levels of learning available from evaluation of educational interventions and determining what concepts work in which contexts (Parry, Carson-Stevens et al., 2013).</p> <p>Para 3 (line 40-43); the acknowledgement of curricular innovation at the University of Sydney might be more appropriate in the method section.</p> <p>Why specifically choose the version by Madigosky et al and not any variation presumably refs 10-15? Has this tool been used in evaluation of educational programmes? Critically appraise why this tool and not others.</p> <p>Minor issues: Line 20/21: reference needed</p> <p>Methods: This section would benefit from describing the development process (i.e. modification) of the survey tool prior to description of who the survey was tested on. The authors might consider 'survey development' and 'survey piloting' as sub-headings to make the development and testing process clearer.</p> <p>State reference number for Ethics Committee approval.</p> <p>Please describe the clinical experience / training of year 1 and 2 students; what are the notable differences that one might need to consider (if any) for interpretation of results purposes, and the underlying hypothesis for choosing these two groups.</p> <p>Describe the process for deciding on what survey items should be modified – any consensus seeking methods used? construct validation by educators at the university?</p> <p>Were there any additions made to the survey; if not, why?</p> <p>Justify why definitions of patient safety, error, and incident were those defined by the Australian Commission, instead of those within the WHO International Classification for Patient Safety. Presumably adaptation for local context / aim to encourage buy-in?</p> <p>What was the process of face validation; which methods were used (focus group?, cognitive interviewing?), how many were included in this phase, and how as feedback gathered and analysed from this group?</p> <p>How did you determine the cut off for retention at 0.25 – presumably as method in previous studies?</p> <p>Explain in plain english the terms 'model parsimony', 'RMSEA' to</p>
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	<p>measure absolute fit, and comparative fit index, and any other statistical jargon, since most readers will not follow this, and be clear about the rationale for their use and what they indicate in terms of validation. This will make the paper more accessible.</p> <p><b>Results</b>          Could the following point be raised in the discussion – "However, as most students that are engaged in employment in pharmacy are undertaking non-clinical roles (19.7% vs 8.6%), it is unlikely that current employment will influence junior students' responses to the survey questions."? The discussion of the formal, informal and hidden curriculum might be pertinent here.</p> <p>A more structured discussion could be useful; suggest consideration of some key headings: main findings, relationship with the literature, implications for stakeholder groups, strengths and limitations, conclusion.</p> <p>"robust two-staged analytical method, involving EFA followed by CFA, was used to assess the reliability and validity of the survey tool." -- highlight this as a strength of your study in the relevant section.</p> <p>I would encourage the authors to reflect on the implications of survey tools like this have for both summative and theory-driven formative evaluations of educational interventions (see Parry, Carson-Stevens et al., 2013) and the kind of learning they can be generated to inform future design (development, testing) of educational interventions using improvement methods.</p> <p>Conclusion needs more consideration of implications for educators and evaluators.</p>
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### VERSION 1 – AUTHOR RESPONSE

Reviewer 1: Mingming Zhang

1. The information presented in the background section is interesting but it is not providing anything new to the reader. I would encourage the authors to provide more information on studies that have already been conducted and what they showed of survey tools that measure patient safety attitude of health care student?

The introduction has now been restructured and includes more information about previously used survey tools and the justification for the need for a validated survey tool for pharmacy students that evaluates patient safety attitudes and values.

2. Could you please provide further information on how the pharmacy students were selected for inclusion? How was the students selected within the first and second year?

There were no specific inclusion and exclusion criteria for the study – the study was open to all students enrolled in the first and second years of the BPharm degree at the University of Sydney. We have now emphasised this in the methods section:

“All students enrolled in the first and second years of the BPharm degree at the University of Sydney were invited to participate.”

3. A test–retest reliability should be conducted to assess the reproducibility of the questionnaire

We thank the reviewer for their comment. We were unable to assess test-retest reliability and have now acknowledged this as a limitation in the discussion.

“In addition, despite test-retest reliability not being performed, conducting a CFA on data collected at the same time ensured a form of reliability...”

4. How was the survey response rates calculated?

The survey response rates were calculated by dividing the number of completed surveys received by the number of students enrolled in the first and second years of the BPharm program at the University of Sydney.

This has been described in the methods section as follows:

“The survey response rate was calculated by dividing the total number of surveys completed by the number of students enrolled in each year group.”

5. How did you identify if a survey was valid?

We are not entirely clear what the reviewer is asking here – all fully completed surveys received were included in the study (see response below).

6. How did you deal with missing values?

We received very few surveys which contained missing responses for any of the items (a total of 2 surveys). These were excluded from the analyses, bringing the total number of surveys to 446.

7. Did participants provide written consent to undertake the survey?

All students were provided with a participant information sheet prior to formally participating in the study. There was no obligation to participate in the study and written consent was considered as the completion and return of the survey.

8. Did you have any inclusion/exclusion criteria's for participants?

Please see our response above to the reviewer's second question.

Reviewer 2: Andrew Carson-Stevens

Abstract: Introduction missing;

We confirm that a short background/introductory statement is included in the abstract:

“Patient safety education is a key strategy to minimise this harm, and is increasingly being introduced into junior pharmacy curricula. However, currently there is no valid and reliable survey tool to measure

the patient safety attitudes of pharmacy students.”

Introduction: The introduction would benefit from being framed from an evaluation of education perspective, where the modification of an existing survey to assess patient safety attitudes as an outcome measure for course evaluation. Highlighting existing literature, and where relevant the paucities that exist in research and development to date would strengthen the introduction considerable.

The introduction has been rewritten and framed from an evaluation perspective as suggested, highlighting the importance of assessing patient safety attitudes as part of evaluating educational programs . References to current paucities in the literature have also been added and highlight the need for a validated survey to measure pharmacy students’ patient safety attitudes.

Highlighting that WHO recognise patient safety education is important although unclear why there is specific mention of the Australian Patient Safety Education Framework here. The link with the final sentence could be strengthened by raising the issue around evaluation of patient safety educational efforts. In addition, throughout the introduction, a more thorough and critical appraisal of studies that have evaluated patient safety educational interventions would also reassure me that the authors are appropriately identifying gaps in the literature in terms of evaluation and the need to develop suitable outcome metrics. This would also set up a stronger discussion of findings in relation to their key findings and relationships with existing literature. The ‘so what’ & ‘now what’ of which might be best considered in terms of the levels of learning available from evaluation of educational interventions and determining what concepts work in which contexts (Parry, Carson-Stevens et al., 2013).

We have now removed the reference to the Australian Patient Safety Education Framework. We have also included more detail about why there is a need to develop a validated survey tool for evaluating pharmacy student attitudes.

Para 3 (line 40-43); the acknowledgement of curricular innovation at the University of Sydney might be more appropriate in the method section.

As suggested, the reference to curricular innovation at The University of Sydney has now been removed from the introduction.

Why specifically choose the version by Madigosky et al and not any variation presumably refs 10-15? Has this tool been used in evaluation of educational programmes? Critically appraise why this tool and not others.

We chose to use the tool developed by Madigosky et al. as it is the most widely adapted and validated patient safety education evaluation tool. We have now included more information in the introduction detailing this and why the tool developed by Madigosky et al. was selected for used in this study:

“The most widely adapted and validated tool is the Patient Safety/Medical Fallibility Survey, originally developed by Madigosky et al. for use in medical students.[12] Previous studies among pharmacy students have focused on evaluating knowledge and beliefs to patient safety using unvalidated survey tools,[9 10] and attitudes to patient safety have been largely unstudied.”

In addition, greater information about the modification process in this study has been included in the methods section.

Minor issues:

Line 20/21: reference needed

We have now included the following reference: : “Marriott JL, Nation RL, Roller L, et al. Pharmacy education in the context of Australian practice. Am J Pharm Educ 2008;72(6)”

Methods:

This section would benefit from describing the development process (i.e. modification) of the survey tool prior to description of who the survey was tested on. The authors might consider ‘survey development’ and ‘survey piloting’ as sub-headings to make the development and testing process clearer.

The methods section has been now amended to include more information on the development of the survey for our use. Subheadings have now also been included to improve the clarity of this process.

State reference number for Ethics Committee approval.

The Ethics Committee project approval number: 2013/219 has been added.

Please describe the clinical experience / training of year 1 and 2 students; what are the notable differences that one might need to consider (if any) for interpretation of results purposes, and the underlying hypothesis for choosing these two groups.

The methods section has been updated to include details of year 1 and year 2 students’ clinical experience:

“As both year groups would have completed an introductory pharmacy practice unit of study and introductory clinical placements (four hours) at the time of survey completion, it was hypothesised that these two groups of students would have the most comparable clinical experience and be suitable participants in the validation of the survey instrument.”

Under the “Analysis” section of the methods, the methodology to investigate the potential differences between year groups is stated with the actual differences reported as part of the results.

Describe the process for deciding on what survey items should be modified – any consensus seeking methods used? Construct validation by educators at the university?

The methods now contain more information about the modification of the survey and the items added or removed. Due to the original survey being developed for medical students, items were modified, similarly to other health disciplines, changing the term ‘medical practitioner’ to ‘pharmacist or medical practitioner’. The addition of new survey items or exclusion of original survey items have now also described as has how consensus was achieved.

Were there any additions made to the survey; if not, why?

More information about the modification of the survey and the addition of items has been included.

“In addition, two questions to evaluate attitudes towards questioning more senior health care professionals, one question on patients’ role in healthcare and one question on peer learning were added.”

Justify why definitions of patient safety, error, and incident were those defined by the Australian Commission, instead of those within the WHO International Classification for Patient Safety. Presumably adaptation for local context / aim to encourage buy-in?

Terminology consistent with the Australian Commission was used in order to make the survey relevant to Australian health care setting. We have now included more information describing the rationale for inclusion of the Australian Commission's definitions and the face validation process:

"Pharmacy academics also perceived that due to junior pharmacy students' limited clinical experience, definitions of "Patient Safety", "Error" and "Incident" should be included in the pretext to the survey. The student group were provided with terms defined by a range of healthcare organisations. As a result, the definitions used by Australian Commission for Safety and Quality in Healthcare were selected due to both the perceived ease of understanding and perceived contextual relevance to junior pharmacy students."

What was the process of face validation; which methods were used (focus group?, cognitive interviewing?), how many were included in this phase, and how as feedback gathered and analysed from this group?

A new subheading relating to face validation is now included in the methods section, with greater detail provided about the process used:

"The face validity of the survey instrument was assessed through focus groups among three populations: 5 pharmacy academics, 5 practising pharmacists and 7 pharmacy student representatives. Based on feedback from the three groups, one of the original questions relating to uncertainty in healthcare was considered ambiguous and was removed from the final survey tool. Pharmacy academics also perceived that due to junior pharmacy students' limited clinical experience, definitions of "Patient Safety", "Error" and "Incident" should be included in the pretext to the survey. The student group were provided with terms defined by a range of healthcare organisations. As a result, the definitions used by the Australian Commission for Safety and Quality in Healthcare were selected due to both the perceived ease of understanding and perceived contextual relevance to junior students. The final survey was approved in a subsequent focus group."

How did you determine the cut off for retention at 0.25 – presumably as method in previous studies?

A literature search was conducted to determine an acceptable cut-off value for factor retention. Among homogenous samples it has been suggested that a cut-off value of 0.25 is acceptable to decide on factors which should be retained in a model (Tabachnick and Fidell). We have now referenced this in the methods section.

Explain in plain english the terms 'model parsimony', 'RMSEA' to measure absolute fit, and comparative fit index, and any other statistical jargon, since most readers will not follow this, and be clear about the rationale for their use and what they indicate in terms of validation. This will make the paper more accessible.

We have now simplified the language describing the statistics involved in confirmatory factor analysis in the methods section:

"To evaluate the goodness of fit of the model, a number of fit statistics were examined. Firstly, the Chi Square statistic was used to evaluate model parsimony (i.e. that the model accomplishes a desired level of explanation with as few variables and relationships between variables as possible). In addition, root mean-square error of approximation (RMSEA) was used to evaluate absolute fit (a

measure of how well the data fits the proposed model) and the Comparative Fit Index (CFI) was used to evaluate the comparative fit (a measure of how well the data fits a model where relationships exist between the survey items compared to a model where no relationships exist)."

## Results

Could the following point be raised in the discussion – "However, as most students that are engaged in employment in pharmacy are undertaking non-clinical roles (19.7% vs 8.6%), it is unlikely that current employment will influence junior students' responses to the survey questions."? The discussion of the formal, informal and hidden curriculum might be pertinent here.

We thank the reviewer for their comment. One of the key assumptions in performing a CFA is that similar samples are compared. As a result, the authors feel that it is important to note that this assumption has been satisfied earlier on in the results section of the paper.

The survey's relevance to the formal, informal and hidden curriculum is also now included in the discussion as part of the "Implications for stakeholders" section of the discussion.

A more structured discussion could be useful; suggest consideration of some key headings: main findings, relationship with the literature, implications for stakeholder groups, strengths and limitations, conclusion.

Key headings have now been added to the discussion as suggested.

"robust two-staged analytical method, involving EFA followed by CFA, was used to assess the reliability and validity of the survey tool." -- highlight this as a strength of your study in the relevant section.

We have highlighted the robustness of our methodology as a key strength of our study in the "Strengths and Limitations" section of the discussion:

"Furthermore, the relatively large sample size obtained (N=446) allowed for a rigorous analytical approach to be undertaken, enabling both EFA and CFA to be performed with sufficient sample sizes for validation of the survey tool."

I would encourage the authors to reflect on the implications of survey tools like this have for both summative and theory-driven formative evaluations of educational interventions (see Parry, Carson-Stevens et al., 2013) and the kind of learning they can be generated to inform future design (development, testing) of educational interventions using improvement methods.

We thank the reviewer for their suggestion. Additional information about the implication of the survey tool has been provided in the new "Implications for stakeholders" section of the discussion.

"The use of this survey tool provides a number of benefits for educators. Given that the literature identifies a significant need to provide more training to pharmacy and other healthcare students on all aspects of patient safety, it is crucial that pharmacy schools have a mechanism for evaluating the impact of these programs.[25 38-40] It is noteworthy that current patient safety programs for pharmacy students often include elements of identifying, understanding, reporting, managing and communicating risk. The underlying attitudes leading to the practice of these positive safety behaviours can all be evaluated using the survey tool. In addition, there are a number of potential benefits which may arise through the repeated use of this tool throughout a student's degree program. Firstly, it will provide a means to evaluate the longitudinal effect of patient safety education interventions and changes in students' attitudes. It can also be used to measure the effect of the

informal and hidden curricula on students' patient safety attitudes, which is particularly important as students commence experiential learning placements and as more students engage in casual employment in assistance roles. Thus the evaluation of these changes can provide useful information about the educational needs of students through their degrees and when additional and more targeted interventions will need to be provided."

Conclusion needs more consideration of implications for educators and evaluators.

We have now revised our conclusion to emphasise the implications for educators and evaluators:

"This study has demonstrated the validity of a tool to evaluate the attitudes of pharmacy students across a number of patient safety areas. Given that there is growing recognition of the need to educate pharmacy students in patient safety concepts, this survey can be used by pharmacy schools to evaluate the underlying dimensions of students' patient safety attitudes, which have direct effects on the manner in which students practice. Through the use of this tool, pharmacy schools will be able to further develop and tailor their patient safety training to better suit students' educational needs."

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Andrew Carson-Stevens Patient Safety Research Lead, Wales Primary and Emergency Care Research Centre, Cardiff University, UK  Visiting Professor, Department of Family Practice, University of British Columbia, Canada
<b>REVIEW RETURNED</b>	24-Jul-2015
<b>GENERAL COMMENTS</b>	All original comments have been addressed.