PEER REVIEW HISTORY

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ARTICLE DETAILS

<table>
<thead>
<tr>
<th>TITLE (PROVISIONAL)</th>
<th>The Effect of Warning Symbols in Combination with Education on the Frequency of Erroneously Crushing Medication in Nursing Homes – an Uncontrolled Before and After Study</th>
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<td>AUTHORS</td>
<td>van Welie, Steven; Wijma-Vos, Linda; Beerden, Tim; Van Doormaal, Jasperien; Taxis, Katja</td>
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VERSION 1 - REVIEW

<table>
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<tr>
<th>REVIEWER</th>
<th>Quan Zhou</th>
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<tr>
<td>Department of Pharmacy, The Second Affiliated Hospital, School of Medicine, Zhejiang University, PCR</td>
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<tr>
<td>REVIEW RETURNED</td>
<td>27-Apr-2016</td>
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<tr>
<td>GENERAL COMMENTS</td>
<td>This study provides some valuable information to clinicians. It is well designed. However, it needs some minor revision. 1. The authors did not tell the readers why the patients wanted to crush medication themselves. If nasogastric administration is needed, physician will specify during the process of prescribing. Pharmacist will identify the inappropriate orders of medications that could not be crushed. What are the clinical circumstances in which medication to be administered should be crushed? Why did not the physician specify nasogastric administration if the patient indeed needs nasogastric administration. Why did the patients who were not receiving nasogastric administration take medications in the manner of crushing process? If physician prescribes a medication that could not be halved or crushed at a dose of half or 1/3 or 1/5 tablet, pharmacist should find such mistakes.</td>
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<th>REVIEWER</th>
<th>Janet Hoek</th>
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<td>University of Otago, New Zealand</td>
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<tr>
<td>REVIEW RETURNED</td>
<td>29-Apr-2016</td>
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| GENERAL COMMENTS       | I enjoyed reading your interesting and well-written MS, which I think could have important implications for practice in care environments. I offer some suggestions below that I hope will be useful to you.  

First, could you provide more information about how you identified the warning symbols you tested? As you explain, the symbols were both positive and negative (i.e., they advised when medications could and should not be crushed); in many cases, warning symbols are negative (i.e., they discourage behaviour) so I was curious why you decided to use both positive and negative symbols? As a non-pharmacist, I was also interested in the symbol design, which did not have any intuitive connotations for me (though I appreciate the symbols may be more meaningful to people trained in pharmacy). |
To help non-specialists, could you explain how you developed the symbols used? What literature informed your design and did you undertake any pre-testing to assess understanding? Figure 2 suggests the symbols are not particularly large or visually salient, but are simply additional text added to information about the medication (you only explain constraints you faced in your discussion section and this information should ideally come earlier in your MS). Did you consider using colour (green and red are common heuristics that could be useful when delivering go and no-go information)? There is a wide literature on the design and use of warning information and it would be useful to draw on some of this work in your introduction to provide a clearer context for the research you undertook (Friedmann 1988, Chapanis 1994, Braun, Mine et al. 1995, Braun and Silver 1995, Zuckerman and Chaiken 1998, Wogalter, Conzola et al. 2002, Argo and Main 2004, Hoek, Gendall et al. 2011).

You clearly developed a thoughtful education programme but I wondered whether you made any assessment of how many people this reached? You note that 48% attended the lecture, and that you placed posters in wards and provided information via newsletters, but was there any check about how many people who had not attended the lecture saw the other information sources? It might be helpful to others thinking of running similar programmes to know what overall reach you achieved (and whether, in hindsight, you would alter the approach you used to disseminate information)?

I haven’t been involved in observational work of the kind you undertook, but assume your observer was easily able to identify each medication being administered and to differentiate when a patient was receiving multiple drugs? Are there accepted protocols for this sort of observational work? If so, I wonder whether you might allude to how you used these? I’m assuming that any effects of observing nursing staff would have occurred randomly over both waves – perhaps you could comment a little more on this point too?

It was not clear to me how you identified your expected rate of 3% wrong crushed medications or why you expected the intervention to reduce errors by two thirds? Could you explain how you developed these estimates?

You discuss the limitations of your work very thoughtfully but you might comment a little more on future research directions. You have noted the limitations imposed on you by the printing options you had, but if these did not apply, what would you do and how would you suggest others working in this field could extend your findings?

Overall, I think your MS reports on an interesting piece of work; I wish you well with future work in this field.

Possible references

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name
Quan Zhou, Department of Pharmacy, The Second Affiliated Hospital, School of Medicine, Zhejiang University, PCR
This study provides some valuable information to clinicians. It is well designed, however, it needs some minor revision.
1. the authors did not tell the readers why the patients wanted to crush medication themselves. If nasogastric administration is needed, physician will specify during the process of prescribing.
Pharmacists will identify the inappropriate orders of medications that could not be crushed. what are the clinical circumstances in which medication to be administered should be crushed? why did not the physician specify nasogastric administration if the patient indeed needs nasogastric administration.
why did the patients who were not receiving nasogastric administration take medications in the manner of crushing process? If physician prescribes a medication that could not be halved or crushed at a dose of half or 1/3 or 1/5 tablet, pharmacist should find such mistakes.

Authors: Thank you for this comment. As we describe in the discussion section, the physicians have the possibility to document dysphagia in the medical notes and pharmacists will adjust the medication accordingly so medication is supplied that is suitable for administration (i.e. medication which can be crushed or alternative formulations). However, in practice, nurses also sometimes crush medication for patients with swallowing difficulties without this being documented in the notes and physicians may or may not be aware of the dysphagia. This is mainly in cases where these swallowing difficulties are not severe and do not require nasogastric tubes. We have also observed that nurses differ in their approach to patients with dysphagia, i.e. for the same patients, some nurses choose crushing whereas other nurses manage to administer the dosages “uncrushed”. This context would be very interesting to study, but was not the focus of our study.
We have amended the methods section under setting to describe more clearly situations in which crushing of medication took place in the nursing homes as follows:
“In case patients had dysphagia and were prescribed medication they could not swallow, nurses contacted the prescriber or pharmacist, to ask for a suitable alternative formulation (e.g. liquid formulation) or nurses crushed medication.”

Reviewer: 2
Janet Hoek, University of Otago, New Zealand
I enjoyed reading your interesting and well-written MS, which I think could have important implications for practice in care environments. I offer some suggestions below that I hope will be useful to you.
First, could you provide more information about how you identified the warning symbols you tested?
As you explain, the symbols were both positive and negative (i.e., they advised when medications could and should not be crushed); in many cases, warning symbols are negative (i.e., they discourage behaviour) so I was curious why you decided to use both positive and negative symbols? As a non-pharmacist, I was also interested in the symbol design, which did not have any intuitive connotations for me (though I appreciate the symbols may be more meaningful to people trained in pharmacy). To help non-specialists, could you explain how you developed the symbols used? What literature informed your design and did you undertake any pre-testing to assess understanding? Figure 2 suggests the symbols are not particularly large or visually salient, but are simply additional text added to information about the medication (you only explain constraints you faced in your discussion section and this information should ideally come earlier in your MS). Did you consider using colour (green and red are common heuristics that could be useful when delivering go and no-go information)? There is a wide literature on the design and use of warning information and it would be useful to draw on some of this work in your introduction to provide a clearer context for the research you undertook (Friedmann 1988, Chapanis 1994, Braun, Mine et al. 1995, Braun and Silver 1995, Zuckerman and Chaiken 1998, Wogalter, Conzola et al. 2002, Argo and Main 2004, Hoek, Gendall et al. 2011).

Authors: Thank you for the compliments and thanks for these very useful comments and the references which we have included where they fit. We have amended the methods section as follows: “We chose a positive and a negative symbol to give nurses complete information including confirmation which medication they were allowed to crush. This also ensured that medication without a symbol (e.g., medication where suitability of crushing had not been assessed yet) would look different. Technical limitations of the software of the unit dose dispensing system restricted the size and the choice of warning symbols which could be printed on the sachets. Pictograms in the form of pictures as developed by the Pharmacopeial Convention of the United States could not be used.[19] We had to choose relatively simple symbols and could not add any colour.”

Reviewer: You clearly developed a thoughtful education programme but I wondered whether you made any assessment of how many people this reached? You note that 48% attended the lecture, and that you placed posters in wards and provided information via newsletters, but was there any check about how many people who had not attended the lecture saw the other information sources? It might be helpful to others thinking of running similar programmes to know what overall reach you achieved (and whether, in hindsight, you would alter the approach you used to disseminate information)?

Authors: Thanks for this comment, we have expanded the discussion section elaborating on this limitation of our study as follows: “We did not assess the overall proportion of staff we reached with our educational activities. Although, a reasonable number of staff attended the lectures (about 4 members of staff of each study ward, in total 77 out of 160 eligible members of staff, 48%), it remains a challenge to distribute information effectively to all members including part time and temporary staff. In our study, we used relatively traditional ways of disseminating the information on our innovation. Future studies could explore alternative approaches such as social media. Although, we did not assess this as part of our trial, repeated educational efforts are probably necessary for a sustained effect. We also recommend to further develop easy to understand warning symbols/pictograms using colour, e.g., red for not crushing, green for crushing using established guidelines.[30]"

Reviewer: I haven’t been involved in observational work of the kind you undertook, but assume your observer was easily able to identify each medication being administered and to differentiate when a patient was receiving multiple drugs? Are there accepted protocols for this sort of observational work? If so, I wonder whether you might allude to how you used these? I’m assuming that any effects of observing nursing staff would have occurred randomly over both waves – perhaps you could comment a little more on this point too?
Authors: Thanks for this comment, to stress that observation-based data collection is the gold standard to obtain data on medication administration errors, we have added a reference in the methods section supporting this. Furthermore, as a research group, we have ample experience with using this data collection method. We have therefore amended the methods section to address this point as follows:
“In the current study, we have used the same approach as in our previous studies on medication administration errors (e.g., [24]) with essential elements comprising careful training of the observer and a consistent use of the definition of a crushing error.”

Reviewer: It was not clear to me how you identified your expected rate of 3% wrong crushed medications or why you expected the intervention to reduce errors by two thirds? Could you explain how you developed these estimates?

Authors: We have amended the methods section on the sample size as follows: “Based on previous studies of crushing errors [4, 6-9], we assumed a rate of 3% wrongly crushed medication. Although using different interventions, previous studies showed considerable reduction in crushing error rates [6, 9], so we expected to see a 66% reduction by the intervention.” You discuss the limitations of your work very thoughtfully but you might comment a little more on future research directions. You have noted the limitations imposed on you by the printing options you had, but if these did not apply, what would you do and how would you suggest others working in this field could extend your findings?

Authors: Thanks for this comment. We have amended the last part of the discussion (also in response to the comment above) as follows: “In our study, we used relatively traditional ways of disseminating the information on our innovation. Future studies could explore alternative approaches such as social media. Although, we did not assess this as part of our trial, repeated educational efforts are probably necessary for a sustained effect. We also recommend to further develop easy to understand warning symbols/pictograms using colour, e.g., red for not crushing, green for crushing using established guidelines.[30]"

Reviewer: Overall, I think your MS reports on an interesting piece of work; I wish you well with future work in this field.

Authors: Again, many thanks for your helpful comments and for the good wishes!
Effect of warning symbols in combination with education on the frequency of erroneously crushing medication in nursing homes: an uncontrolled before and after study

Steven van Welie, Linda Wijma, Tim Beerden, Jasperien van Doormaal and Katja Taxis

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