PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	WHY DO PATIENTS DEVELOP SEVERE PRESSURE ULCERS? A RETROSPECTIVE CASE STUDY
AUTHORS	Keen, Justin; Pinkney, Lisa; Nixon, Jane; Wilson, Lyn; McGinnis, Elizabeth; Stubbs, Nikki; Dealey, Carol; Nelson, E. Andrea; Coleman, Susanne; Patterson, Malcolm

VERSION 1 - REVIEW

REVIEWER	Joke Mintjes HAN university of applied sciences Nijmegen The Netherlands
REVIEW RETURNED	16-Nov-2013

GENERAL COMMENTS	Checklist 1,2. The research question in the abstract is not stated clearly, I suggest to add this sentence from the the introducion" This study focuses on the ways in which the organisational context can influence the development of severe pressure ulcers". Checklist 4. Please clarify in the beginning of the methods section what the settings of the study are, you could refer to table 2. Could you tell how the interviews with the individuals were held, eg open indepth interviews, or using a topic list? In Figure 1 the first text block overwrites an underlying text (on my computer) Interesting paper, nice research. Please accept with the proposed minor revisions.

REVIEWER	Grypdonck, Mqaria Ghent University, dept of Public Health (retired)
REVIEW RETURNED	17-Nov-2013

GENERAL COMMENTS	The study addresses an important problem that is particularly challenging for research: the causes of serious pressure ulcers (pu). The challenge consists in that (fortunately) serious PUs (grade 3-4) are rare. Epidemiological data therefore cannot be used. The authors used a novel approach to this study. They described in detail eight cases and analyzed the data qualitatively through a series of judgments. Each case appears to be richly documented with interviews of patients and staff, and in depth study of records. The authors describe the precautions that were made to avoid bias, at the same time recognizing that this is not entirely possible. They found that in seven of the eight cases organizational factors played a role. They analyzed what these factors were. The article makes a contribution, though limited, to the existing

	literature. The limitation is due to the circularity with which the design is fraught and the impossibility to draw causal inferences. The "subgroup" was asked to select one of five possible explanations for the ulcers. To do this, they need the knowledge that this study intends to produce. Both in the construction of the cases and in the analysis, the researchers are likely to follow known paths. They have to select the data and render them in a specific way to construct the stories of the patients. Existing hypotheses about what could cause PUs to deteriorate instead of to heal are unavoidably at play. It is clear that strong designs are not in order here. The authors took many precautions using both data and researcher triangulation to avoid bias. None the less, the methodology as explained does not provide an explanation, as the authors claim. As in any non-experimental design it is impossible to make a distinction between concurrent and causal events or factors. That serious PUs occur when e.g. patients do not get a proper response to their complaints of pain, does not establish that they are caused by this condition, and, hence, does not indicate that they will disappear if this condition is remediated. The authors are advised to be more accurate in describing the nature of their findings and to discuss also this issue in the discussion section. The study does not show that pressure ulcers are more likely to develop under the indicated circumstances, as there is no comparison made (more likely thus, is not accurate). The occurrence of serious Pus is not explained and at the end of the study we do not understand what processes causes the Pus to aggravate. The authors used a small sample (although they did collect a lot of data) and no reason is given why the sample was limited to eight. I would also like to see why they did not choose a comparative approach in which patients with grade 2 PU were selected of which some got PU grade 3 and others did not. Using the same case study method, I suppose, it would have yielded more strong insights In the discussion the authors conceive of the serious PUs as a safety problem, and use the safety literature to discuss their findings. There is, however, no attention to the difference between most of the safety problems which are tied to an event (perhaps more likely by environmental or organizational conditions) , while serious PUs are seldom tied to one event. For grade 2 or grade 3 PUs to aggravate instead of to heal, often more is involved than one event (if not the number grade 3 PUs would be enormously greater). In describing the analysis, the authors do not indicate how they went about the interpretation of causal attributions which occur readily in people's stories of events while they cannot observe them or do not really know what was the cause. Was this dealt with by comparing the stories? If so, it would be worthwhile to explicate the attention for this problem. If not, it should be addressed in the discussion.

VERSION 1 – AUTHOR RESPONSE

Reviewer - Joke Mintjes
(2) The research question in the abstract is not stated clearly, I suggest to add this sentence from the the introduction - "This study focuses on the ways in which the organisational context can influence the development of severe pressure ulcers".

Agreed. Sentence added as suggested.

(3) Please clarify in the beginning of the methods section what the settings of the study are, you could

refer to table 2. Could you tell how the interviews with the individuals were held, eg open indepth interviews, or using a topic list?

Agreed, and text amended to state settings and nature of interviews.

(4) In Figure 1 the first text block overwrites an underlying text (on my computer).

We have not been able to reproduce this problem, even by sending the Word file between a Windows environment and a Macbook. We would be happy to edit the Figure if copy editors encounter problems.

(5) Interesting paper, nice research.

Thank you!

Reviewer - Grypdonck, Maria
(6) The authors are advised to be more accurate in describing the nature of their findings and to discuss also this issue in the discussion section. The study does not show that pressure ulcers are more likely to develop under the indicated circumstances, as there is no comparison made.

Agreed. This is a particularly helpful comment, as we now appreciate that the text implies that we are making a comparison, but do not spell out what is being compared to what. We have modified the text in a number of places – all change tracked – to avoid the implication.

This said, we *did* make comparisons in the course of the analysis and interpretation. The clinical sub-group made judgements about the nature of the treatment and care that each individual might reasonably have expected to receive, and we compared the main account with the specialist nurse report (based on available clinical notes), where in the latter the nurse indicated departures from national and local protocols. That is, actual care was compared to to what we might term ‘good usual care’. This point has been made clear in the revised text.

(7) The occurrence of serious PUs is not explained and at the end of the study we do not understand what processes caused the PUs to aggravate.

Agreed, and text edited in the Discussion.

(8) The authors used a small sample (although they did collect a lot of data) and no reason is given why the sample was limited to eight.

Agreed, and text added to explain that each account took on average 4 months to prepare. That is, the key issue was one of time and resources.

(9) I would also like to see why they did not choose a comparative approach in which patients with grade 2 PU were selected of which some got PU grade 3 and others did not. Using the same case study method, I suppose, it would have yielded more strong insights.

This is an interesting question, and we partially agree with the view expressed. The principal problem with observing category 2 pressure ulcers prospectively is that, simply by appearing and interviewing an individual, we would almost certainly have influenced the course of events. Specifically, we would have drawn attention to the significance of the pressure ulcer, and would have prompted swift action by the local clinical team. It seems reasonable to predict that few, or none, of the category 2 pressure ulcers would have progressed to category 3 or 4. As a result, we could not have been confident that

we had observed the whole process, from the earliest signs and symptoms to the point where action was (as it turns out, often very belatedly) taken.

The referee nevertheless touches on an important point here, and we have made minor drafting changes in response. We can't say, on the basis of our evidence, whether severe pressure ulcers are an extreme case of category 1 and 2 pressure ulcers, or are qualitatively different. We are aware of the argument – set out particularly clearly by Andrew Hopkins in 'Failure To Learn' – that it is a mistake to assume that there is a single 'triangle of risks'. In a single triangle model of safety, relatively frequent, minor events are at the base of the triangle, with more serious events in the middle. Disasters – category 4 pressure ulcers in our case, but also aviation accidents and explosions at oil refineries – are rare events, sitting at the top of the triangle.

The alternative conceptualisation, used in the aviation industry, is that there is more than one class of risk, and hence more than one 'triangle of risk'. In the case of airlines, for example, there is a clear distinction between individual workplace safety –wearing high viz clothing and so on – and what might be termed process safety, ie safe take off, flight and landing of aircraft.

The empirical point here is that we could not know, at the start of the study, whether pressure ulcers are a 'one triangle problem', with severe pressure ulcers having the same underlying causes as categories 1 or 2. They might turn out to be a 'two triangle problem': the explanations for their development might be different in kind to categories 1 and 2. It was therefore important not to make any assumptions about the nature of the risks involved, and in particular not make the assumption that severe pressure ulcers are 'rare occurrences' of categories 1 and 2.

In addition, we took the view that it would be easier to discriminate between explanations if we were able to collect a large volume of data about a long sequence of events, ie the events that led to the development of a severe pressure ulcer.

Reference: Hopkins A. Failure to learn: the BP Texas City refinery disaster. Sydney: CCH, 2008. Chapter 6.

(10) In the discussion the authors conceive of serious PUs as a safety problem, and use the safety literature to discuss their findings. There is, however, no attention to the difference between most of the safety problems which are tied to an event (perhaps more likely by environmental or organizational conditions) , while serious PUs are seldom tied to one event. For grade 2 or grade 3 PUs to aggravate instead of to heal, often more is involved than one event (if not the number grade 3 PUs would be enormously greater).

We are not sure that we agree with this point. The main thrust of the study was to discriminate between explanations based on a specific event or events on the one hand, and more general systemic failings, identified by the IoM (and others) on the other. (We were also alive to the possibility that there was some other explanation, and to the possibility that clinical staff are not always in a position to intervene, as happened with #8). So, the purpose of the study was to answer the question implied by this comment.

Reason's rightly celebrated Swiss Cheese model has helped many teams around the world, working both in health care and in other sectors. In our study, though, the finding was that there was a sequence of events – analogous to the slices of cheese – in only three of the accounts, whereas the general organisational context contributed to development in 7 of the 8 accounts (see Table 3).

Moreover, our evidence does not support the conclusion that more than one event – a sequence of events – leads to aggravation of a pressure ulcer, for the reason given at the end of (9) above.

(11) In describing the analysis, the authors do not indicate how they went about the interpretation of causal attributions which occur readily in people's stories of events while they cannot observe them or do not really know what was the cause. Was this dealt with by comparing the stories? If so, it would be worthwhile to explicate the attention for this problem. If not, it should be addressed in the discussion.

Agreed. This point is related to (6) and (7) above. Text added to Discussion section.

(12) The literature is not really up to date for a field in which so much is published, but it does not really hamper the quality of the paper.

We have undertaken a literature review (which is not reported here) and found few papers which shed light on the organisational factors – however defined – which contribute to our understanding of the development of severe pressure ulcers. It was the paucity of high quality papers that led us to draw on the wider safety literature. We appreciate that the patient safety literature is growing very fast, but the study design is rooted in classic studies and reports, eg 'To Err Is Human', and the work of Reason, Perrow and Vaughan.