



Why do patients develop severe pressure ulcers?

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3 **WHY DO PATIENTS DEVELOP SEVERE PRESSURE ULCERS?**
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5 **A RETROSPECTIVE OBSERVATIONAL STUDY**
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10 **ABSTRACT**

11 *Background:*

12 Severe pressure ulcers are important indicators of failures in the organisation and delivery
13 of treatment and care. We have a good understanding of patient risk factors, but a poor
14 understanding of the role played by the organisational context in their development.
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17 *Methods:*

18 The study was undertaken in six sites in Yorkshire, England. A retrospective case study
19 design was used. Data were collected from a range of sources, including interviews with
20 individuals with severe pressure ulcers and staff, and clinical notes, and used to construct
21 accounts of eight individuals who developed severe pressure ulcers. Sequential and
22 iterative review, involving reviewers with different backgrounds, were used to validate the
23 accounts and to identify explanations for the events observed.
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31 *Results:*

32 Four accounts indicated that specific actions by clinicians contributed to the development of
33 severe pressure ulcers. But seven of the eight – including the four – indicated that they
34 were more likely to develop in organisational contexts where, (i) clinicians failed to listen
35 and respond to patients' or carers' observations about their risks or the quality of their
36 treatment and care, (ii) clinicians failed to recognise and respond to clear signs that a
37 patient had a pressure ulcer or was at risk of developing one and, (iii) services were not
38 effectively co-ordinated.
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45 *Conclusions:*

46 The accounts, taken together, could only be partially explained in terms of specific events,
47 or sequences of events. The findings support the conclusion that there was general
48 acceptance of sub-optimal clinical practices in seven of the eight accounts in the contexts
49 where patients developed severe pressure ulcers.
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3 Article Summary
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5 Strengths and limitations of this study
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- 7 • This study contributes to our understanding of a poorly understood process, the
8 development of a severe pressure ulcer
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- 10 • Few previous studies have explicitly sought to discriminate between psychological
11 and broader organisational explanations for adverse events in health care settings
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- 13 • The diversity of patients who develop severe pressure ulcers, and of the settings
14 where they occur, raises a risk of sampling bias
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- 16 • The retrospective study design brings with it a risk of hindsight bias
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INTRODUCTION

The European Pressure Ulcer Advisory Panel/ National Pressure Ulcer Advisory Panel (EPUAP/NPUAP) defines a pressure ulcer as, “localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.” [1] Pressure ulcers are a significant source of pain and distress for the individuals who develop them [2]. In recent years the importance of severe pressure ulcers as indicators of poor quality and safety of health services has been recognised. Category 2 ulcers or above, as rated on the EPUAP/NPUAP 1-4 scale, are classed as reportable incidents in official guidelines in the National Health Service (NHS) in England. [3] Category 3 and 4 ulcers are widely termed severe pressure ulcers, and have to be reported as serious untoward incidents. [4] Pressure ulcers are also one of four patient safety indicators in a new NHS monitoring tool. [5]

There are two distinct ways of thinking about patients’ risks of developing pressure ulcers. The first is based on the assumption that all PU risks are associated with patients’ health status or their behaviour. The implication is that clinicians should focus on identifying patients who are at risk, assess the nature and scale of their risks, and design clinical interventions to reduce them. We have a good understanding of patient risk factors. [6] The second way of thinking starts from a different assumption, which is that the quality of treatment and care can also influence patients’ risks of developing pressure ulcers. Patients who are at risk are more likely to develop them in settings where quality of care is poor. The events at Mid Staffordshire NHS Foundation Trust, where at one point dozens of PUs were being reported every month, help to underline the significance of this point. [7]

We currently have a relatively poor understanding of the ways in which the wider organisational context contributes to their prevention or development. A small number of studies have indicated that it plays a role, but the nature and significance of that role remains to be elucidated. [8] This study focuses on the ways in which the organisational context can influence the development of severe pressure ulcers. It focuses on identifying the best explanation for their development, using explanations derived from the patient

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3 safety literature, which advances both psychological and sociological explanations for errors
4 and adverse events [9].
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8 **METHODS**

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10 Severe pressure ulcers occur relatively rarely, and can develop in a wide range of settings,
11 and it is not currently possible to predict who will develop them and who will not. [6] As a
12 result it is not practical to study their development prospectively. It is, though, possible to
13 reconstruct the events that lead to the development severe pressure ulcers retrospectively.
14 We undertook a retrospective case study, where severe pressure ulcers were end-points,
15 and also indicators of adverse outcomes of treatment and care. A process tracing case
16 study method was used, focusing on the experiences of eight individuals. [10]
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24 *Primary Data Collection*

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26 Research Ethics Committee approval and local research governance approvals from six study
27 sites in Yorkshire, England, were obtained. Participants were sampled purposively, in order
28 to maximise the diversity of individuals and the contexts in which they developed severe
29 pressure ulcers. Sampling was also pragmatic: individuals who had developed a Category 3
30 or 4 pressure ulcer were identified by members of the local tissue viability nurse teams.
31 Consent to participate was obtained from patients, and where appropriate also from their
32 main carers.
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41 Data were collected by a field researcher with a non-clinical background from five sources,
42 namely interviews with individuals who had developed a severe pressure ulcer (and where
43 relevant also their main carers), interviews with clinical and other staff who had been
44 involved in their care, clinical records, other documents relevant to the account such as
45 critical incident reports, and relevant local policy documents, eg on assessment of risks of
46 skin breakdown (Figure 1, Stage 1). Interviews with clinical and other staff are listed in
47 Table 1. 70 interviews in total were conducted across the eight accounts. The site principal
48 investigator, who in each case was a nurse with a specialist interest in tissue viability,
49 collated patient notes in a parallel exercise, following current practice in the NHS in England
50 for root cause analyses.
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Figure 1: Analysis and Review of Individual Accounts

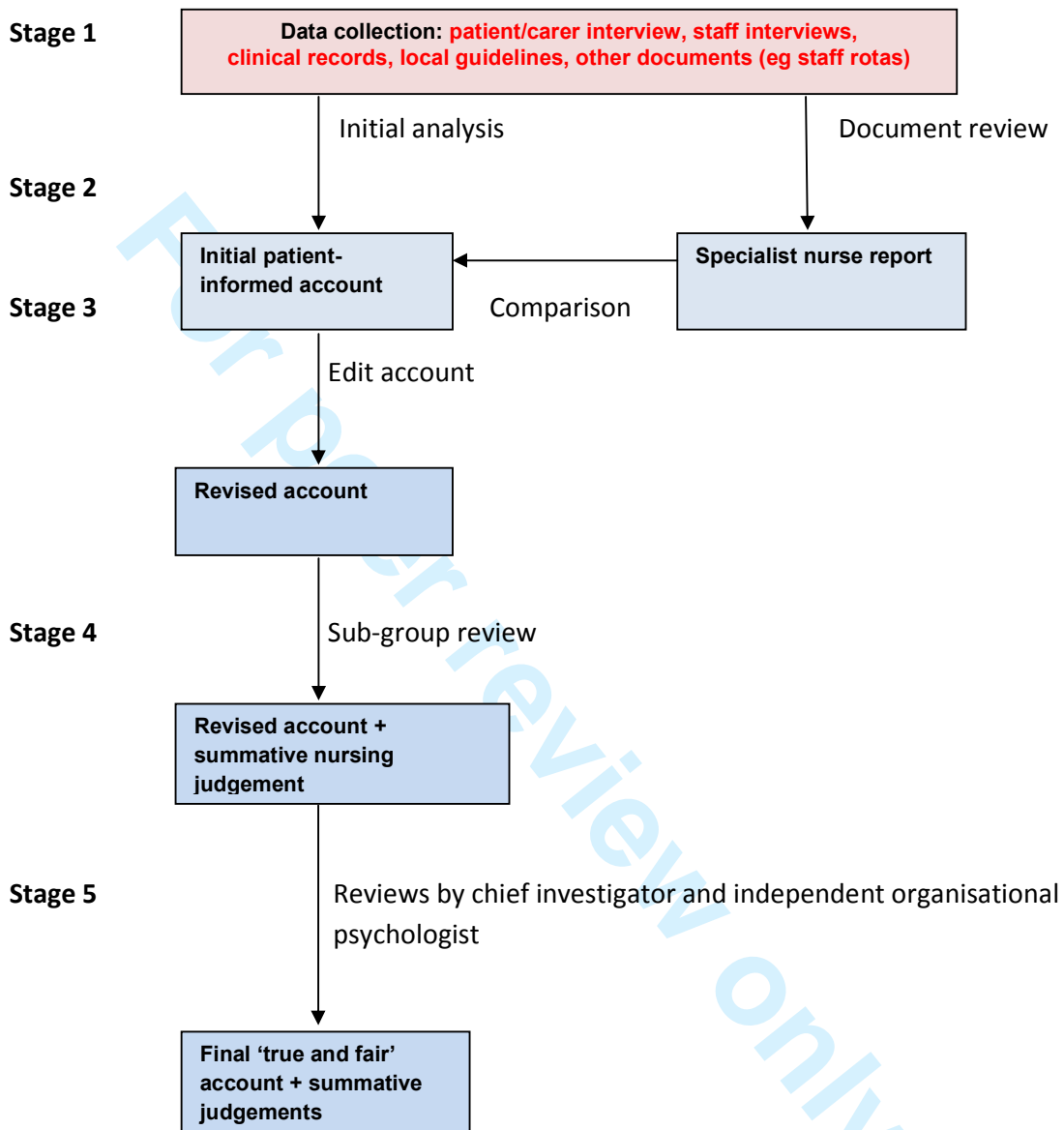


Table 1: Number of People Interviewed by Account

Account	Individual	Carer	Viability Nurse	Tissue	District nurse	Nurse	Health/home	Consultant	Junior doctor	Physiotherapis	Occupational	Ward clerk	Liaison nurses	Ward	Quality	Total
1	1	1	2			2	2	1		1	1	1	1	1		14
2	1		1			2	3	1	1	1		1		1		12
3	1		1			2		1		1					1	7
4	1	1	1		1	1	1			1						7
5	1	1	2		2	3	1							1	1	12
6	1		1			2	1	1						1		7
7	1	1	1		1	2	2									8
8	1	1	1													3

Development of Retrospective Accounts

The initial accounts each had two components. The first consisted of verbatim passages of the patient/carer interview, which captured their explanations of the events that led to their severe pressure ulcers. Second, a Microsoft Access database was created for each account, and used to organise decisions and actions into a chronological sequence, with patient and carer data in one column, other interview data in a second and records and other documentary sources in a third (see Figure 1, Stage 2). The presentation of data in parallel columns made it possible to identify consistencies and inconsistencies between different data sources, and also the 'strength' of evidence available about each event, reflected in the number and quality of sources. Data from the two components were used to identify a provisional timeline of events for each account.

A tissue viability nurse specialist from the relevant study site undertook a parallel review, based solely on available patient records and on other available documentation, including local guidelines and critical incident reports (ie not including the patient/carer interview).

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3 The method followed the guidance for reviews of critical incidents in the NHS in England.
4 The nurse wrote a report, identifying key decisions and actions in chronological order,
5 including departures from local guidelines. The field researcher and tissue viability nurse
6 specialist then met and compared their accounts, identifying consistencies and
7 inconsistencies, eg actions that the nurse judged as important, that were not included in the
8 initial patient-driven account. Timelines were revised in the light of additional facts or
9 insights generated (Stage 3).

16 17 *Refinement of the Accounts*

18 The subsequent stages of the analysis were designed to minimise some of the risks of bias
19 known to be associated with retrospective analysis, notably hindsight bias, through review
20 of each account by researchers with different backgrounds. The initial summaries of each
21 account were reviewed by a sub-group of nursing members of the research team; one
22 independent hospital-based and one independent community-based tissue viability nurse
23 specialist, and one of the Co-Chief Investigators (Stage 4).

24 The accounts were analysed in two ways. First, they were used to identify any errors – in
25 the opinion of the sub-group – made in the decisions and actions recorded in each account.
26 Each point was checked by going back to primary data sources. This produced an account
27 that could be deemed to be ‘true and fair’. Second, drawing on Yin’s strategy for
28 discriminating between hypotheses in case studies, [11] clinical sub-groups were asked to
29 select one or more of five explanations for the events portrayed in an account. The five
30 explanations were that a severe pressure ulcer:

- 31 1. Could not have been avoided;
- 32 2. Developed following an isolated mistake made by a clinician;
- 33 3. Developed following a sequence of unconnected errors;
- 34 4. Developed in an organisational context that made development more likely;
- 35 5. Developed for another reason, not covered by the first four.

36 The first explanation captures a situation where clinical staff did everything that might
37 reasonably have been expected. The second reflects the dominant assumption in the

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3 patient safety literature, and is supported by some evidence about pressure ulcer
4 development. [12,13] The third is a version of Reason's 'Swiss Cheese' model, and again has
5 some support in the pressure ulcer literature. [14-17] The fourth, which also has some
6 support in the pressure ulcer literature, focuses on the role of the organisational context,
7 highlighted in the Institute of Medicine's report, *To Err Is Human*. [18-21] The fifth
8 explanation is a logical extension to the first four, retaining the possibility of a novel
9 explanation.

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17 The revised accounts and explanations were reviewed by the non-clinical Co-Chief
18 Investigator and then by an organisational psychologist who had not been involved in the
19 earlier stages (Stage 5). The reviews focused on the coherence of each account, ie the
20 extent to which the patient's explanation and/or the nurses' judgements made sense of the
21 available evidence. In the final step in the analysis, the eight accounts were analysed
22 inductively, in order to identify themes that were common across the accounts. [22]
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29 RESULTS

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31 The study demonstrates that it is possible to develop detailed retrospective accounts of
32 events, and to use them to judge which of five possible explanations best fits the available
33 evidence. The large volumes of data collected and included in the timeline appear to have
34 minimised problems that might have arisen as a result of 'missing data'. The iterative
35 review process, involving reviewers with different backgrounds, appears to have minimised
36 the risks of mis-interpretation. As we note in the Discussion, though, the results may still be
37 subject to a number of biases.
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45 The eight individuals were selected, in part, to maximise diversity (see Table 2). There were,
46 therefore, marked differences in their personal characteristics and in their treatment and
47 care. They were all, though, at high risk of developing pressure ulcers, or of existing
48 pressure ulcers deteriorating. Different explanations were offered by those interviewed for
49 the development of severe pressure ulcers. For example, in a number of accounts some
50 staff interviewed blamed patients, on the basis that they had not complied with advice on
51 managing their risks, eg shifting position regularly. But patients themselves, in the same
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accounts, pointed to specific actions or omissions – failure to be turned regularly overnight, to provide a specialised mattress, or to respond to patients' comments about their own risks.

Table 2: Individuals and settings

Account	Individual	Setting
1	38 year old woman with paraplegia	Acute hospital, surgical ward
2	65 year old woman with long-term chronic neurological condition and undiagnosed infection	Acute hospital, medical ward
3	75 year old man with multiple chronic health problems and acute infection	Community hospital, rehabilitation ward
4	37 year old woman with long-term degenerative congenital neurological condition	At home
5	90 year old man with multiple chronic health problems and undiagnosed acute illness	Acute hospital, surgical ward
6	39 year old woman in hospital for acute undiagnosed post-operative surgical complications	Acute hospital, surgical ward
7	65 year old man with quadriplegia	At home, respite care and acute hospital
8	89 year old woman who fell at home	At home

Elimination of hypotheses

The diverse group of individuals all had the same outcome, a severe pressure ulcer. In one account (#8) development was judged to be unavoidable, because the individual concerned developed a severe pressure ulcer in her own home, before any health professional saw her. The other seven accounts were deemed to involve avoidable severe pressure ulcers, both in the specialist nurse reports and the reviews by the clinical sub-group, on the basis that there was clear evidence of departures from the care that the patient might reasonably have expected to receive. The second and third hypotheses were causal in nature: in one account (#3) there was a single precipitating event, and there was a sequence of precipitating events in three others (#2, #4 and #6). In each of the four cases, though,

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3 reviewers judged that, while specific events played a role, they provided only part of the
4 explanation. In these cases, and in the three remaining ones – seven of the eight - the
5 clinical sub-group and subsequent reviewers all judged that the organisational context made
6 development of a severe pressure ulcer more likely (see Table 3). None of the eight
7 accounts, in the view of the clinical sub-group or subsequent reviewers, supported an
8 alternative explanation.
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Table 3: Summative judgements by account

Account	Unavoidable	Single/isolated event	Sequence of events	Environment made development more likely	Other explanation
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4			•	•	
5				•	
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The organisational context

The next step was to understand how the organisational context made the development of severe pressure ulcers more likely. Inductive analysis of the eight accounts led to the identification of three main themes. First, the 'voices' of the individuals who developed severe pressure ulcers were not heard by staff. As noted above the individuals themselves behaved differently, and had different relationships with clinical staff, but failures to heed information were evident in several accounts. For example, there were examples of patients making repeated appeals for pain and discomfort to be addressed, and expressing concerns about their own wellbeing, which were not heeded over periods of hours or even days. In some instances these appeals seem to have been dismissed by staff: that is, they were heard but not taken seriously. Patients were also blamed for the development of their pressure ulcers, on the basis that they did not comply with instructions they were given, and branded as 'difficult' - even when they had cognitive impairments.

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3 Second, there were failures to recognise and act on warning signs. Risk assessments were
4 not undertaken when they should have been, in some cases only being undertaken several
5 days after admission to an acute hospital ward. Evidence of pre-existing clinical risks in
6 records was not acted upon in six of the seven patients where the environment was judged
7 to have made development more likely. Action was not taken promptly when overt
8 evidence – including the presence of a Category 2 pressure ulcer - was identified.
9 Conversely, there was evidence of poor documentation, so that adherence with patients'
10 care plans was not recorded, and in some instances direct evidence of skin redness or a
11 pressure ulcer was not recorded. Some healthcare assistants, who provided direct care,
12 observed that they lacked the appropriate training to identify and record risks, or were not
13 allowed to record them.
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24 Third, there were co-ordination failures, between patients, carers and staff, staff in the
25 same setting, between staff in different settings in the same organisation (eg two wards),
26 and between staff in different organisations. Sometimes this was manifested as inter-
27 professional communication failure, and in some cases there was poor communication
28 between the same professional groups in two locations. One example of the latter came in
29 a post-operative setting, where risks were not properly communicated between the
30 anaesthetic recovery unit and the post-operative ward. In other accounts records were not
31 moved with an individual, so that key information was not available in a new setting. It
32 would be possible to interpret these points as clear evidence of failures by individuals or
33 teams. But there is a corollary to this point: nurses and healthcare assistants, in particular,
34 could find themselves working in conditions where they had limited information about
35 individuals and their risks, eg where patients had unknown diagnosis, or where records had
36 not travelled with the patient from another location. It is possible, therefore, that individual
37 members of staff behaved reasonably in the contexts in which they found themselves. The
38 problems observed could be attributed to weaknesses in the overall co-ordination of
39 treatment and care.
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54 DISCUSSION

55 This study sought to explain why patients develop severe pressure ulcers, by reconstructing
56 events retrospectively, and then discriminating between alternative explanations for their
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3 development. The principal explanation is that severe pressure ulcers are more likely to
4 develop in organisational contexts characterised by one or more of, (i) clinicians failing to
5 listen to patients' or carers' observations about their risks or the quality of their treatment
6 and care, (ii) clinicians failing to recognise and respond to clear signs that a patient had a
7 pressure ulcer or was at risk of developing one, and, (iii) services not being effectively co-
8 ordinated. These can all be interpreted as failures in the governance of the services in the
9 settings studied. In four of the accounts it was possible to identify specific, or causal,
10 precipitating events, but these events occurred in problematic contexts.
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19 As noted in the Methods section, the study was designed in significant part in order to
20 minimise biases in the data collection and analysis in a retrospective, observational study.
21 This study suggests that a novel method, based on tracing back the course of events
22 retrospectively from a known outcome, can be used to reconstruct key events. The
23 resulting accounts can be subjected to detailed review, and used to discriminate between
24 alternative explanations for those events, and in the process preserve the 'voices' of the
25 individuals affected. This said, it is important to stress that there are a number of sources of
26 bias, starting with selection bias: while the sampling strategy maximised diversity, the eight
27 accounts are of individuals who were willing and able to consent to participate. The initial
28 presentation of the timelines, and the backgrounds of the analysts and reviewers, are also
29 potential sources of bias. A study team with different clinical or disciplinary backgrounds
30 might have arrived at different judgements: for example, a team with backgrounds in
31 human factors psychology might have placed greater weight on single events or sequences
32 of events. There is also a risk, using a retrospective design, of hindsight bias, particularly in
33 reviewers assuming that staff must have known more than they actually did, and should
34 therefore have acted differently [23]. The sequential and iterative review process has, we
35 hope, served to minimise these biases, but we cannot say that they have been eliminated.
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50 We can interpret our findings in the context of the patient safety literature. Reason [17]
51 points out that investigations of accidents, across many industries, have changed
52 significantly over the last fifty years. An early focus on equipment failure gave way, in the
53 1970's and 1980's, to a focus on human error, and then more recently to accounts that
54 focused on systems and cultural issues. In spite of this, many patient safety studies today
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3 focus on causal explanations, based either on patient characteristics or errors made by
4 individual clinicians. These were represented by the second and third explanations.
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6 Relatively few focus on the wider organisational context, represented by the fourth
7 explanation. [11] The findings reported here only partially support the second or third
8 explanation. Only one patient was deemed to have an unavoidable severe pressure ulcer –
9 because service providers were unaware of a fall at home – supporting the first explanation,
10 and there was no support for a fifth, alternative, explanation. The overall findings are,
11 though, consistent with explanations that emphasise systems and culture.
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19 In the literature on the role of the organisational context on patient safety, explanations
20 tend to emphasise *either* systems or culture. The study results suggest that, for people who
21 developed severe pressure ulcers, *both* were important. In relation to systems-based
22 explanations, the evidence about the poor co-ordination of services is broadly consistent
23 with the arguments in *To Err Is Human*, namely that many safety failures are essentially
24 system failures. [21] Drawing on the work of Perrow and others, the Institute argued that
25 accidents are more likely in systems that are inherently complex – having many
26 interconnected elements. [23] The findings in this study supported the observation that
27 there were co-ordination failures between services that were loosely coupled with one
28 another, ie generally run independently of one another, but needing to co-ordinate with
29 one another. For example, there were communication failures between wards at times
30 when there were major ward re-organisations, so that key information was not passed on.
31 Similarly, one of the community-based accounts revealed that the individual was in receipt
32 of a hospital service that community staff were unaware of, and hence could not take into
33 account in risk assessment or care planning.
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47 At the same time, the failures to listen properly to patients – and even dismiss their
48 concerns - and to act when there was a superficial pressure ulcer present, emphasise the
49 importance of prevailing cultural norms. The evidence suggests that the environments
50 where severe pressure ulcers developed were ones where staff were under time pressure,
51 where there were problematic relationships between staff groups, and where staff were
52 defensive, and prepared to attribute failures to colleagues or to the ‘difficult’ behaviour of
53 patients. Clinicians adopted risky work routines that were not appropriate for the vulnerable
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3 patients that were in their care. Severe pressure ulcers developed in contexts where there
4 was normalisation of deviance, a phenomenon where risky practices become the norm in a
5 work setting, and staff either don't recognise the extent of the risks they are taking, or are
6 aware of them but underestimate them 24]. This resonates with wider concerns about the
7 culture in parts of the NHS in England, where staff can be defensive and quick to blame
8 others, rather than being open and prepared to learn from adverse events [6].
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Contributorship Statement

JN and JK conceived and designed the study initially. The study design was developed iteratively over a period of months by CD, JK, EM, JN, LP, NS. LP undertook primary data collection. Additional data were collected and collated by EM, NS, LW. JK drafted the article and revised it critically on the basis of comments from the other authors. All authors were formally involved in the analysis and interpretation of the findings. Co-authors will give final approval of the version to be published.

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Competing

No competing interests

Data Sharing Statement

No data

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WHY DO PATIENTS DEVELOP SEVERE PRESSURE ULCERS? A RETROSPECTIVE OBSERVATIONAL STUDY

ABSTRACT

Background:

Severe pressure ulcers are important indicators of failures in the organisation and delivery of treatment and care. We have a good understanding of patient risk factors, but a poor understanding of the role played by the organisational context in their development.

Methods:

The study was undertaken in six sites in Yorkshire, England. A retrospective case study design was used. Data were collected from a range of sources, including interviews with individuals with severe pressure ulcers and staff, and clinical notes, and used to construct accounts of eight individuals who developed severe pressure ulcers. Sequential and iterative review, involving reviewers with different backgrounds, were used to validate the accounts and to identify explanations for the events observed.

Results:

Four accounts indicated that specific actions by clinicians contributed to the development of severe pressure ulcers. But seven of the eight – including the four – indicated that they were more likely to develop in organisational contexts where, (i) clinicians failed to listen and respond to patients' or carers' observations about their risks or the quality of their treatment and care, (ii) clinicians failed to recognise and respond to clear signs that a patient had a pressure ulcer or was at risk of developing one and, (iii) services were not effectively co-ordinated.

Conclusions:

The accounts, taken together, could only be partially explained in terms of specific events, or sequences of events. The findings support the conclusion that there was general acceptance of sub-optimal clinical practices in seven of the eight accounts in the contexts where patients developed severe pressure ulcers.

Article Summary

Strengths and limitations of this study

- This study contributes to our understanding of a poorly understood process, the development of a severe pressure ulcer
- Few previous studies have explicitly sought to discriminate between psychological and broader organisational explanations for adverse events in health care settings
- The diversity of patients who develop severe pressure ulcers, and of the settings where they occur, raises a risk of sampling bias
- The retrospective study design brings with it a risk of hindsight bias

INTRODUCTION

The European Pressure Ulcer Advisory Panel/ National Pressure Ulcer Advisory Panel (EPUAP/NPUAP) defines a pressure ulcer as, “localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.” [1] Pressure ulcers are a significant source of pain and distress for the individuals who develop them [2]. In recent years the importance of severe pressure ulcers as indicators of poor quality and safety of health services has been recognised. Category 2 ulcers or above, as rated on the EPUAP/NPUAP 1-4 scale, are classed as reportable incidents in official guidelines in the National Health Service (NHS) in England. [3] Category 3 and 4 ulcers are widely termed severe pressure ulcers, and have to be reported as serious untoward incidents. [4] Pressure ulcers are also one of four patient safety indicators in a new NHS monitoring tool. [5]

There are two distinct ways of thinking about patients’ risks of developing pressure ulcers. The first is based on the assumption that all PU risks are associated with patients’ health status or their behaviour. The implication is that clinicians should focus on identifying patients who are at risk, assess the nature and scale of their risks, and design clinical interventions to reduce them. We have a good understanding of patient risk factors. [6] The second way of thinking starts from a different assumption, which is that the quality of treatment and care can also influence patients’ risks of developing pressure ulcers. Patients who are at risk are more likely to develop them in settings where quality of care is poor. The events at Mid Staffordshire NHS Foundation Trust, where at one point dozens of PUs were being reported every month, help to underline the significance of this point. [7]

We currently have a relatively poor understanding of the ways in which the wider organisational context contributes to their prevention or development. A small number of studies have indicated that it plays a role, but the nature and significance of that role remains to be elucidated. [8] This study focuses on the ways in which the organisational context can influence the development of severe pressure ulcers. It focuses on identifying the best explanation for their development, using explanations derived from the patient

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3 safety literature, which advances both psychological and sociological explanations for errors
4 and adverse events [9].
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8 **METHODS**

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10 Severe pressure ulcers occur relatively rarely, and can develop in a wide range of settings,
11 and it is not currently possible to predict who will develop them and who will not. [6] As a
12 result it is not practical to study their development prospectively. It is, though, possible to
13 reconstruct the events that lead to the development severe pressure ulcers retrospectively.
14 We undertook a retrospective case study, where severe pressure ulcers were end-points,
15 and also indicators of adverse outcomes of treatment and care. A process tracing case
16 study method was used, focusing on the experiences of eight individuals. [10]
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24 *Primary Data Collection*

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26 Research Ethics Committee approval and local research governance approvals from six study
27 sites in Yorkshire, England, were obtained. Participants were sampled purposively, in order
28 to maximise the diversity of individuals and the contexts in which they developed severe
29 pressure ulcers. Sampling was also pragmatic: individuals who had developed a Category 3
30 or 4 pressure ulcer were identified by members of the local tissue viability nurse teams.
31 Consent to participate was obtained from patients, and where appropriate also from their
32 main carers.
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41 Data were collected by a field researcher with a non-clinical background from five sources,
42 namely interviews with individuals who had developed a severe pressure ulcer (and where
43 relevant also their main carers), interviews with clinical and other staff who had been
44 involved in their care, clinical records, other documents relevant to the account such as
45 critical incident reports, and relevant local policy documents, eg on assessment of risks of
46 skin breakdown (Figure 1, Stage 1). Interviews with clinical and other staff are listed in
47 Table 1. 70 interviews in total were conducted across the eight accounts. The site principal
48 investigator, who in each case was a nurse with a specialist interest in tissue viability,
49 collated patient notes in a parallel exercise, following current practice in the NHS in England
50 for root cause analyses.
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Figure 1: Analysis and Review of Individual Accounts

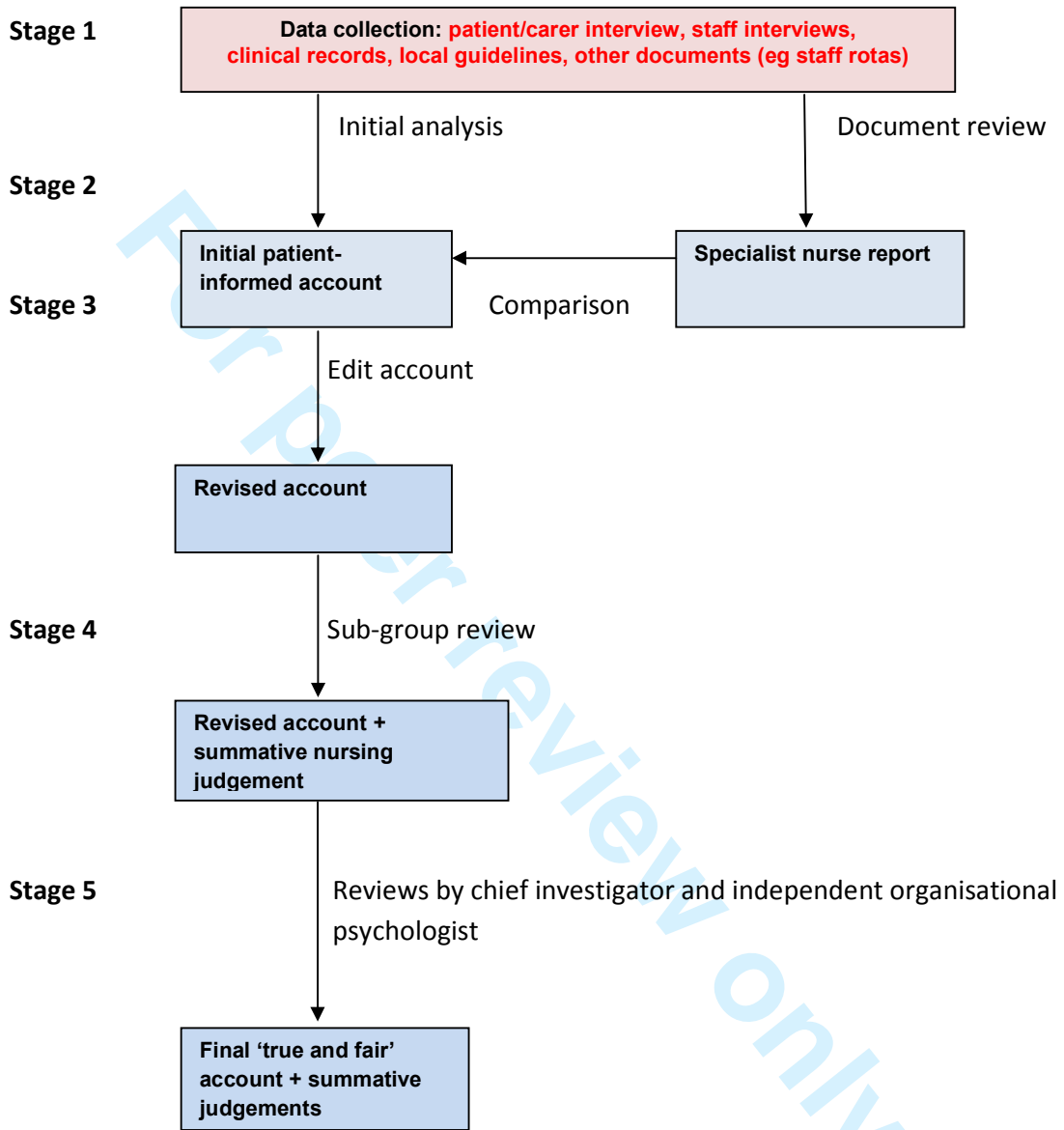


Table 1: Number of People Interviewed by Account

Account	Individual	Carer	Viability Nurse	Tissue	District nurse	Nurse	Health/home	Consultant	Junior doctor	Physiotherapis	Occupational	Ward clerk	Liaison nurses	Ward	Quality	Total
1	1	1	2			2	2	1		1	1	1	1	1		14
2	1		1			2	3	1	1	1		1		1		12
3	1		1			2		1		1					1	7
4	1	1	1		1	1	1			1						7
5	1	1	2		2	3	1							1	1	12
6	1		1			2	1	1						1		7
7	1	1	1		1	2	2									8
8	1	1	1													3

Development of Retrospective Accounts

The initial accounts each had two components. The first consisted of verbatim passages of the patient/carer interview, which captured their explanations of the events that led to their severe pressure ulcers. Second, a Microsoft Access database was created for each account, and used to organise decisions and actions into a chronological sequence, with patient and carer data in one column, other interview data in a second and records and other documentary sources in a third (see Figure 1, Stage 2). The presentation of data in parallel columns made it possible to identify consistencies and inconsistencies between different data sources, and also the 'strength' of evidence available about each event, reflected in the number and quality of sources. Data from the two components were used to identify a provisional timeline of events for each account.

A tissue viability nurse specialist from the relevant study site undertook a parallel review, based solely on available patient records and on other available documentation, including local guidelines and critical incident reports (ie not including the patient/carer interview).

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3 The method followed the guidance for reviews of critical incidents in the NHS in England.
4 The nurse wrote a report, identifying key decisions and actions in chronological order,
5 including departures from local guidelines. The field researcher and tissue viability nurse
6 specialist then met and compared their accounts, identifying consistencies and
7 inconsistencies, eg actions that the nurse judged as important, that were not included in the
8 initial patient-driven account. Timelines were revised in the light of additional facts or
9 insights generated (Stage 3).

16 17 *Refinement of the Accounts*

18 The subsequent stages of the analysis were designed to minimise some of the risks of bias
19 known to be associated with retrospective analysis, notably hindsight bias, through review
20 of each account by researchers with different backgrounds. The initial summaries of each
21 account were reviewed by a sub-group of nursing members of the research team; one
22 independent hospital-based and one independent community-based tissue viability nurse
23 specialist, and one of the Co-Chief Investigators (Stage 4).

24 The accounts were analysed in two ways. First, they were used to identify any errors – in
25 the opinion of the sub-group – made in the decisions and actions recorded in each account.
26 Each point was checked by going back to primary data sources. This produced an account
27 that could be deemed to be ‘true and fair’. Second, drawing on Yin’s strategy for
28 discriminating between hypotheses in case studies, [11] clinical sub-groups were asked to
29 select one or more of five explanations for the events portrayed in an account. **The five
30 explanations were that a severe pressure ulcer:**

- 31 1. Could not have been avoided;
- 32 2. Developed following an isolated mistake made by a clinician;
- 33 3. Developed following a sequence of unconnected errors;
- 34 4. Developed in an organisational context that made development more likely;
- 35 5. Developed for another reason, not covered by the first four.

36 The first explanation captures a situation where clinical staff did everything that might
37 reasonably have been expected. The second reflects the dominant assumption in the

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3 patient safety literature, and is supported by some evidence about pressure ulcer
4 development. [12,13] The third is a version of Reason's 'Swiss Cheese' model, and again has
5 some support in the pressure ulcer literature. [14-17] The fourth, which also has some
6 support in the pressure ulcer literature, focuses on the role of the organisational context,
7 highlighted in the Institute of Medicine's report, *To Err Is Human*. [18-21] The fifth
8 explanation is a logical extension to the first four, retaining the possibility of a novel
9 explanation.

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17 The revised accounts and explanations were reviewed by the non-clinical Co-Chief
18 Investigator and then by an organisational psychologist who had not been involved in the
19 earlier stages (Stage 5). The reviews focused on the coherence of each account, ie the
20 extent to which the patient's explanation and/or the nurses' judgements made sense of the
21 available evidence. In the final step in the analysis, the eight accounts were analysed
22 inductively, in order to identify themes that were common across the accounts. [22]

23 24 25 26 27 28 29 **RESULTS**

30
31 The study demonstrates that it is possible to develop detailed retrospective accounts of
32 events, and to use them to judge which of five possible explanations best fits the available
33 evidence. The large volumes of data collected and included in the timeline appear to have
34 minimised problems that might have arisen as a result of 'missing data'. The iterative
35 review process, involving reviewers with different backgrounds, appears to have minimised
36 the risks of mis-interpretation. As we note in the Discussion, though, the results may still be
37 subject to a number of biases.

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45 The eight individuals were selected, in part, to maximise diversity (see Table 2). There were,
46 therefore, marked differences in their personal characteristics and in their treatment and
47 care. They were all, though, at high risk of developing pressure ulcers, or of existing
48 pressure ulcers deteriorating. Different explanations were offered by those interviewed for
49 the development of severe pressure ulcers. For example, in a number of accounts some
50 staff interviewed blamed patients, on the basis that they had not complied with advice on
51 managing their risks, eg shifting position regularly. But patients themselves, in the same
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accounts, pointed to specific actions or omissions – failure to be turned regularly overnight, to provide a specialised mattress, or to respond to patients' comments about their own risks.

Table 2: Individuals and settings

Account	Individual	Setting
1	38 year old woman with paraplegia	Acute hospital, surgical ward
2	65 year old woman with long-term chronic neurological condition and undiagnosed infection	Acute hospital, medical ward
3	75 year old man with multiple chronic health problems and acute infection	Community hospital, rehabilitation ward
4	37 year old woman with long-term degenerative congenital neurological condition	At home
5	90 year old man with multiple chronic health problems and undiagnosed acute illness	Acute hospital, surgical ward
6	39 year old woman in hospital for acute undiagnosed post-operative surgical complications	Acute hospital, surgical ward
7	65 year old man with quadriplegia	At home, respite care and acute hospital
8	89 year old woman who fell at home	At home

Elimination of hypotheses

The diverse group of individuals all had the same outcome, a severe pressure ulcer. In one account (#8) development was judged to be unavoidable, because the individual concerned developed a severe pressure ulcer in her own home, before any health professional saw her. The other seven accounts were deemed to involve avoidable severe pressure ulcers, both in the specialist nurse reports and the reviews by the clinical sub-group, on the basis that there was clear evidence of departures from the care that the patient might reasonably have expected to receive. **The second and third hypotheses were causal in nature: in one account (#3) there was a single precipitating event, and there was a sequence of precipitating events in three others (#2, #4 and #6). In each of the four cases, though,**

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3 reviewers judged that, while specific events played a role, they provided only part of the
4 explanation. In these cases, and in the three remaining ones – seven of the eight - the
5 clinical sub-group and subsequent reviewers all judged that the organisational context made
6 development of a severe pressure ulcer more likely (see Table 3). None of the eight
7 accounts, in the view of the clinical sub-group or subsequent reviewers, supported an
8 alternative explanation.
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Table 3: Summative judgements by account

Account	Unavoidable	Single/isolated event	Sequence of events	Environment made development more likely	Other explanation
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4			•	•	
5				•	
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7				•	
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The organisational context

The next step was to understand how the organisational context made the development of severe pressure ulcers more likely. Inductive analysis of the eight accounts led to the identification of three main themes. First, the 'voices' of the individuals who developed severe pressure ulcers were not heard by staff. As noted above the individuals themselves behaved differently, and had different relationships with clinical staff, but failures to heed information were evident in several accounts. For example, there were examples of patients making repeated appeals for pain and discomfort to be addressed, and expressing concerns about their own wellbeing, which were not heeded over periods of hours or even days. In some instances these appeals seem to have been dismissed by staff: that is, they were heard but not taken seriously. Patients were also blamed for the development of their pressure ulcers, on the basis that they did not comply with instructions they were given, and branded as 'difficult' - even when they had cognitive impairments.

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3 Second, there were failures to recognise and act on warning signs. Risk assessments were
4 not undertaken when they should have been, in some cases only being undertaken several
5 days after admission to an acute hospital ward. Evidence of pre-existing clinical risks in
6 records was not acted upon in six of the seven patients where the environment was judged
7 to have made development more likely. Action was not taken promptly when overt
8 evidence – including the presence of a Category 2 pressure ulcer - was identified.
9 Conversely, there was evidence of poor documentation, so that adherence with patients'
10 care plans was not recorded, and in some instances direct evidence of skin redness or a
11 pressure ulcer was not recorded. Some healthcare assistants, who provided direct care,
12 observed that they lacked the appropriate training to identify and record risks, or were not
13 allowed to record them.
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24 Third, there were co-ordination failures, between patients, carers and staff, staff in the
25 same setting, between staff in different settings in the same organisation (eg two wards),
26 and between staff in different organisations. Sometimes this was manifested as inter-
27 professional communication failure, and in some cases there was poor communication
28 between the same professional groups in two locations. One example of the latter came in
29 a post-operative setting, where risks were not properly communicated between the
30 anaesthetic recovery unit and the post-operative ward. In other accounts records were not
31 moved with an individual, so that key information was not available in a new setting. It
32 would be possible to interpret these points as clear evidence of failures by individuals or
33 teams. But there is a corollary to this point: nurses and healthcare assistants, in particular,
34 could find themselves working in conditions where they had limited information about
35 individuals and their risks, eg where patients had unknown diagnosis, or where records had
36 not travelled with the patient from another location. It is possible, therefore, that individual
37 members of staff behaved reasonably in the contexts in which they found themselves. The
38 problems observed could be attributed to weaknesses in the overall co-ordination of
39 treatment and care.
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54 DISCUSSION

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56 This study sought to explain why patients develop severe pressure ulcers, by reconstructing
57 events retrospectively, and then discriminating between alternative explanations for their
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3 **development.** The principal explanation is that severe pressure ulcers are more likely to
4 develop in organisational contexts characterised by one or more of, (i) clinicians failing to
5 listen to patients' or carers' observations about their risks or the quality of their treatment
6 and care, (ii) clinicians failing to recognise and respond to clear signs that a patient had a
7 pressure ulcer or was at risk of developing one, and, (iii) services not being effectively co-
8 ordinated. These can all be interpreted as failures in the governance of the services in the
9 settings studied. **In four of the accounts it was possible to identify specific, or causal,**
10 **precipitating events, but these events occurred in problematic contexts.**
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19 As noted in the Methods section, the study was designed in significant part in order to
20 minimise biases in the data collection and analysis **in a retrospective, observational study.**
21 This study suggests that a novel method, based on tracing back the course of events
22 retrospectively from a known outcome, can be used to reconstruct key events. The
23 resulting accounts can be subjected to detailed review, and used to discriminate between
24 alternative explanations for those events, and in the process preserve the 'voices' of the
25 individuals affected. This said, it is important to stress that there are a number of sources of
26 bias, starting with selection bias: while the sampling strategy maximised diversity, the eight
27 accounts are of individuals who were willing and able to consent to participate. The initial
28 presentation of the timelines, and the backgrounds of the analysts and reviewers, are also
29 potential sources of bias. A study team with different clinical or disciplinary backgrounds
30 might have arrived at different judgements: for example, a team with backgrounds in
31 human factors psychology might have placed greater weight on single events or sequences
32 of events. There is also a risk, using a retrospective design, of hindsight bias, particularly in
33 reviewers assuming that staff must have known more than they actually did, and should
34 therefore have acted differently [23]. The sequential and iterative review process has, we
35 hope, served to minimise these biases, but we cannot say that they have been eliminated.
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50 We can interpret our findings in the context of the patient safety literature. Reason [17]
51 points out that investigations of accidents, across many industries, have changed
52 significantly over the last fifty years. An early focus on equipment failure gave way, in the
53 1970's and 1980's, to a focus on human error, and then more recently to accounts that
54 focused on systems and cultural issues. In spite of this, many patient safety studies today
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3 focus on causal explanations, based either on patient characteristics or errors made by
4 individual clinicians. These were represented by the second and third explanations.
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6 Relatively few focus on the wider organisational context, represented by the fourth
7 explanation. [11] The findings reported here only partially support the second or third
8 explanation. Only one patient was deemed to have an unavoidable severe pressure ulcer –
9 because service providers were unaware of a fall at home – supporting the first explanation,
10 and there was no support for a fifth, alternative, explanation. The overall findings are,
11 though, consistent with explanations that emphasise systems and culture.
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19 In the literature on the role of the organisational context on patient safety, explanations
20 tend to emphasise *either* systems or culture. The study results suggest that, for people who
21 developed severe pressure ulcers, *both* were important. In relation to systems-based
22 explanations, the evidence about the poor co-ordination of services is broadly consistent
23 with the arguments in *To Err Is Human*, namely that many safety failures are essentially
24 system failures. [21] Drawing on the work of Perrow and others, the Institute argued that
25 accidents are more likely in systems that are inherently complex – having many
26 interconnected elements. [23] The findings in this study supported the observation that
27 there were co-ordination failures between services that were loosely coupled with one
28 another, ie generally run independently of one another, but needing to co-ordinate with
29 one another. For example, there were communication failures between wards at times
30 when there were major ward re-organisations, so that key information was not passed on.
31 Similarly, one of the community-based accounts revealed that the individual was in receipt
32 of a hospital service that community staff were unaware of, and hence could not take into
33 account in risk assessment or care planning.
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47 At the same time, the failures to listen properly to patients – and even dismiss their
48 concerns - and to act when there was a superficial pressure ulcer present, emphasise the
49 importance of prevailing cultural norms. The evidence suggests that the environments
50 where severe pressure ulcers developed were ones where staff were under time pressure,
51 where there were problematic relationships between staff groups, and where staff were
52 defensive, and prepared to attribute failures to colleagues or to the ‘difficult’ behaviour of
53 patients. Clinicians adopted risky work routines that were not appropriate for the vulnerable
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3 patients that were in their care. Severe pressure ulcers developed in contexts where there
4 was normalisation of deviance, a phenomenon where risky practices become the norm in a
5 work setting, and staff either don't recognise the extent of the risks they are taking, or are
6 aware of them but underestimate them 24]. This resonates with wider concerns about the
7 culture in parts of the NHS in England, where staff can be defensive and quick to blame
8 others, rather than being open and prepared to learn from adverse events [6].
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SQUIRE Guidelines
(Standards for Quality Improvement Reporting Excellence)
Final revision – 4-29-08

- These guidelines provide a framework for reporting formal, planned studies designed to assess the nature and effectiveness of interventions to improve the quality and safety of care.
- It may not be possible to include information about every numbered guideline item in reports of original formal studies, but authors should at least consider every item in writing their reports.
- Although each major section (i.e., Introduction, Methods, Results, and Discussion) of a published original study generally contains some information about the numbered items within that section, information about items from one section (for example, the Introduction) is often also needed in other sections (for example, the Discussion).

<i>Text section; Item number and name</i>	<i>Section or Item description</i>
<u>Title and abstract</u>	<i>Did you provide clear and accurate information for finding, indexing, and scanning your paper?</i>
1. Title	<ul style="list-style-type: none"> a. Indicates the article concerns the improvement of quality (broadly defined to include the safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of care) b. States the specific aim of the intervention c. Specifies the study method used (for example, “A qualitative study,” or “A randomized cluster trial”)
2. Abstract	Summarizes precisely all key information from various sections of the text using the abstract format of the intended publication
<u>Introduction</u>	<i>Why did you start?</i>
3. Background Knowledge	Provides a brief, non-selective summary of current knowledge of the care problem being addressed, and characteristics of organizations in which it occurs
4. Local problem	Describes the nature and severity of the specific local problem or system dysfunction that was addressed
5. Intended improvement	<ul style="list-style-type: none"> a. Describes the specific aim (changes/improvements in care processes and patient outcomes) of the proposed intervention b. Specifies who (champions, supporters) and what (events, observations) triggered the decision to make changes, and why now (timing)
6. Study question	States precisely the primary improvement-related question and any secondary questions that the study of the intervention was designed to answer
<u>Methods</u>	<i>What did you do?</i>
7. Ethical issues	Describes ethical aspects of implementing and studying the improvement, such as privacy concerns, protection of participants’ physical well-being, and potential author conflicts of interest, and how ethical concerns were addressed
8. Setting	Specifies how elements of the local care environment considered most likely to influence change/improvement in the involved site or sites were identified and characterized
9. Planning the intervention	<ul style="list-style-type: none"> a. Describes the intervention and its component parts in sufficient detail that others could reproduce it b. Indicates main factors that contributed to choice of the specific intervention (for example, analysis of causes of dysfunction; matching relevant improvement experience of others with the local situation)

Text section; Item number and name	Section or Item description
Planning the intervention (continued)	c. Outlines initial plans for how the intervention was to be implemented: e.g., <i>what</i> was to be done (initial steps; functions to be accomplished by those steps; how tests of change would be used to modify intervention), and <i>by whom</i> (intended roles, qualifications, and training of staff)
10. Planning the study of the intervention	a. Outlines plans for assessing how well the intervention was implemented (dose or intensity of exposure) b. Describes mechanisms by which intervention components were expected to cause changes, and plans for testing whether those mechanisms were effective c. Identifies the study design (for example, observational, quasi-experimental, experimental) chosen for measuring impact of the intervention on primary and secondary outcomes, if applicable d. Explains plans for implementing essential aspects of the chosen study design, as described in publication guidelines for specific designs, if applicable (see, for example, www.equator-network.org) e. Describes aspects of the study design that specifically concerned internal validity (integrity of the data) and external validity (generalizability)
11. Methods of evaluation	a. Describes instruments and procedures (qualitative, quantitative, or mixed) used to assess a) the effectiveness of implementation, b) the contributions of intervention components and context factors to effectiveness of the intervention, and c) primary and secondary outcomes b. Reports efforts to validate and test reliability of assessment instruments c. Explains methods used to assure data quality and adequacy (for example, blinding; repeating measurements and data extraction; training in data collection; collection of sufficient baseline measurements)
12. Analysis	a. Provides details of qualitative and quantitative (statistical) methods used to draw inferences from the data b. Aligns unit of analysis with level at which the intervention was implemented, if applicable c. Specifies degree of variability expected in implementation, change expected in primary outcome (effect size), and ability of study design (including size) to detect such effects d. Describes analytic methods used to demonstrate effects of time as a variable (for example, statistical process control)
Results	<i>What did you find?</i>
13. Outcomes	a) Nature of setting and improvement intervention i. Characterizes relevant elements of setting or settings (for example, geography, physical resources, organizational culture, history of change efforts), and structures and patterns of care (for example, staffing, leadership) that provided context for the intervention ii. Explains the actual course of the intervention (for example, sequence of steps, events or phases; type and number of participants at key points), preferably using a time-line diagram or flow chart iii. Documents degree of success in implementing intervention components iv. Describes how and why the initial plan evolved, and the most important lessons learned from that evolution, particularly the effects of internal feedback from tests of change (reflexiveness) b) Changes in processes of care and patient outcomes associated with the intervention i. Presents data on changes observed in the care delivery process ii. Presents data on changes observed in measures of patient outcome (for example, morbidity, mortality, function, patient/staff satisfaction, service utilization, cost, care disparities)

<i>Text section; Item number and name</i>	<i>Section or Item description</i>
Outcomes (continued)	<ul style="list-style-type: none"> iii. Considers benefits, harms, unexpected results, problems, failures iv. Presents evidence regarding the strength of association between observed changes/improvements and intervention components/context factors v. Includes summary of missing data for intervention and outcomes
<u>Discussion</u>	<i>What do the findings mean?</i>
14. Summary	<ul style="list-style-type: none"> a. Summarizes the most important successes and difficulties in implementing intervention components, and main changes observed in care delivery and clinical outcomes b. Highlights the study's particular strengths
15. Relation to other evidence	Compares and contrasts study results with relevant findings of others, drawing on broad review of the literature; use of a summary table may be helpful in building on existing evidence
16. Limitations	<ul style="list-style-type: none"> a. Considers possible sources of confounding, bias, or imprecision in design, measurement, and analysis that might have affected study outcomes (internal validity) b. Explores factors that could affect generalizability (external validity), for example: representativeness of participants; effectiveness of implementation; dose-response effects; features of local care setting c. Addresses likelihood that observed gains may weaken over time, and describes plans, if any, for monitoring and maintaining improvement; explicitly states if such planning was not done d. Reviews efforts made to minimize and adjust for study limitations e. Assesses the effect of study limitations on interpretation and application of results
17. Interpretation	<ul style="list-style-type: none"> a. Explores possible reasons for differences between observed and expected outcomes b. Draws inferences consistent with the strength of the data about causal mechanisms and size of observed changes, paying particular attention to components of the intervention and context factors that helped determine the intervention's effectiveness (or lack thereof), and types of settings in which this intervention is most likely to be effective c. Suggests steps that might be modified to improve future performance d. Reviews issues of opportunity cost and actual financial cost of the intervention
18. Conclusions	<ul style="list-style-type: none"> a. Considers overall practical usefulness of the intervention b. Suggests implications of this report for further studies of improvement interventions
<u>Other information</u>	<i>Were other factors relevant to conduct and interpretation of the study?</i>
19. Funding	Describes funding sources, if any, and role of funding organization in design, implementation, interpretation, and publication of study



**WHY DO PATIENTS DEVELOP SEVERE PRESSURE ULCERS?
A RETROSPECTIVE CASE STUDY**

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3 **WHY DO PATIENTS DEVELOP SEVERE PRESSURE ULCERS?**
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5 **A RETROSPECTIVE CASE STUDY**
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3 **WHY DO PATIENTS DEVELOP SEVERE PRESSURE ULCERS?**
4 **A RETROSPECTIVE CASE STUDY**
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10 **ABSTRACT**

11 *Background:*

12 Severe pressure ulcers are important indicators of failures in the organisation and delivery
13 of treatment and care. We have a good understanding of patient risk factors, but a poor
14 understanding of the role played by the organisational context in their development. This
15 study focuses on the ways in which the organisational context can influence the
16 development of severe pressure ulcers.
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22 *Methods:*

23 The study was undertaken in six sites in Yorkshire, England. A retrospective case study
24 design was used. Data were collected from a range of sources, including interviews with
25 individuals with severe pressure ulcers and staff, and clinical notes, and used to construct
26 accounts of eight individuals who developed severe pressure ulcers. Sequential and
27 iterative review, involving reviewers with different backgrounds, were used to validate the
28 accounts and to identify explanations for the events observed.
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35 *Results:*

36 Four accounts indicated that specific actions by clinicians contributed to the development of
37 severe pressure ulcers. But seven of the eight accounts indicated that they developed in
38 organisational contexts where, (i) clinicians failed to listen and respond to patients' or carers'
39 observations about their risks or the quality of their treatment and care, (ii) clinicians failed
40 to recognise and respond to clear signs that a patient had a pressure ulcer or was at risk of
41 developing one and, (iii) services were not effectively co-ordinated.
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48 *Conclusions:*

49 Patient accounts could only be partially explained in terms of specific events, or sequences
50 of events. The findings support the conclusion that there was general acceptance of sub-
51 optimal clinical practices in seven of the eight contexts where patients developed severe
52 pressure ulcers.
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3 Article Summary
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5 Strengths and limitations of this study
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- 7 • This study contributes to our understanding of a poorly understood process, the
8 development of a severe pressure ulcer
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- 10 • Few previous studies have explicitly sought to discriminate between psychological
11 and broader organisational explanations for adverse events in health care settings
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- 13 • The diversity of patients who develop severe pressure ulcers, and of the settings
14 where they occur, raises a risk of sampling bias
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- 16 • The retrospective study design brings with it a risk of hindsight bias
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INTRODUCTION

The European Pressure Ulcer Advisory Panel/ National Pressure Ulcer Advisory Panel (EPUAP/NPUAP) defines a pressure ulcer as, “localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.” [1] Pressure ulcers are a significant source of pain and distress for the individuals who develop them. [2] In recent years the importance of severe pressure ulcers as indicators of poor quality and safety of health services has been recognised. Category 2 ulcers or above, as rated on the EPUAP/NPUAP 1-4 scale, are classed as reportable incidents in official guidelines in the National Health Service (NHS) in England. [3] Category 3 and 4 ulcers (which involve injury deep into the skin, muscle or bone) are widely termed severe pressure ulcers, and have to be reported as serious untoward incidents. [4] Pressure ulcers are also one of four patient safety indicators in a new NHS monitoring tool. [5]

There are two distinct ways of thinking about patients’ risks of developing pressure ulcers. The first is based on the assumption that all PU risks are associated with patients’ health status or their behaviour. The implication is that clinicians should focus on identifying patients who are at risk, assess the nature and scale of their risks, and design clinical interventions to reduce them. We have a good understanding of patient risk factors. [6] The second way of thinking starts from a different assumption, which is that the quality of treatment and care can also influence patients’ risks of developing pressure ulcers. Patients who are at risk are more likely to develop them in settings where quality of care is poor. The events at Mid Staffordshire NHS Foundation Trust, where at one point dozens of PUs were being reported every month, help to underline the significance of this point. [7]

We currently have a relatively poor understanding of the ways in which the wider organisational context contributes to their prevention or development. A small number of studies have indicated that it plays a role, but the nature and significance of that role remains to be elucidated. [8] This study focuses on the ways in which the organisational context can influence the development of severe pressure ulcers. It focuses on identifying the best explanation for their development, using explanations derived from the patient

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3 safety literature, which advances both psychological and sociological explanations for errors
4 and adverse events [9].
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8 **METHODS**

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10 Severe pressure ulcers occur relatively rarely, and can develop in a wide range of settings,
11 and it is not currently possible to predict who will develop them and who will not. [6] It was
12 not therefore practical to study their development prospectively. If, for example, we had
13 prospectively identified patients with category 2 ulcers, in order to evaluate differences
14 between those that developed a category 3 or 4 ulcer and those that did not, our presence
15 would have drawn attention to the significance of the pressure ulcers. It is likely to have
16 prompted swift action by the local clinical team, and it seems reasonable to predict that few,
17 or even none, of the category 2 pressure ulcers would have progressed to category 3 or 4.
18 As a result, we would have biased our observations, possibly substantially, and could not
19 have been confident that we had observed the whole development process, from the
20 earliest signs and symptoms to the point where action was taken. It was, though, possible
21 to reconstruct the events that lead to the development severe pressure ulcers
22 retrospectively. We undertook a retrospective case study, where severe pressure ulcers
23 were end-points, and also indicators of adverse outcomes of treatment and care. A process
24 tracing case study method was used, focusing on the experiences of eight individuals in
25 Yorkshire, England. [10] Each account took, on average, four months to create, from the
26 initial interview with an individual to the signing off of a detailed account of the
27 development of that individuals' severe pressure ulcer.
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34 *Primary Data Collection*

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36 Research Ethics Committee approval and local research governance approvals from six study
37 sites, were obtained. Participants were sampled purposively, in order to maximise the
38 diversity of individuals and the contexts in which they developed severe pressure ulcers.
39 The settings included patients' own homes, acute hospital medical and surgical wards, a
40 community hospital and a nursing home during a period of respite care. Sampling was also
41 pragmatic: individuals who had developed a Category 3 or 4 pressure ulcer were identified
42 by members of the local tissue viability nurse teams. Consent to participate was obtained
43 from patients, and where appropriate also from their main carers.
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52 Data were collected by a field researcher with a non-clinical background from five sources,
53 namely interviews with individuals who had developed a severe pressure ulcer (and where
54 relevant also their main carers), interviews with clinical and other staff who had been
55 involved in their care, clinical records, other documents relevant to the account such as
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3 critical incident reports, and relevant local policy documents, eg on assessment of risks of
4 skin breakdown (Figure 1, Stage 1). Interviews were open-ended and in-depth, and are listed
5 in Table 1. 70 interviews in total were conducted across the eight accounts. The site
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8 principal investigator, who in each case was a nurse with a specialist interest in tissue
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10 viability, collated patient notes in a parallel exercise, following current practice in the NHS in
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12 England for root cause analyses.
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Table 1: Number of People Interviewed by Account

Account	Individual	Carer	Viability Nurse	Tissue	District nurse	Nurse	Health/home care assistant	Consultant	Junior doctor	Physiotherapist	Occupational Therapist	Ward clerk	Liaison nurses	Ward Manager	Quality assurance mgr.	Total
1	1	1	2			2	2	1		1	1	1	1	1		14
2	1		1			2	3	1	1	1		1		1		12
3	1		1			2		1		1					1	7
4	1	1	1		1	1	1			1						7
5	1	1	2		2	3	1							1	1	12
6	1		1			2	1	1						1		7
7	1	1	1		1	2	2									8
8	1	1	1													3

Development of Retrospective Accounts

The initial accounts each had two components. The first consisted of verbatim passages of the patient/carer interview, which captured their explanations of the events that led to their severe pressure ulcers. Second, a Microsoft Access database was created for each account, and used to organise decisions and actions into a chronological sequence, with patient and carer data in one column, other interview data in a second and records and other documentary sources in a third (see Figure 1, Stage 2). The presentation of data in parallel columns made it possible to identify consistencies and inconsistencies between different data sources, and also the 'strength' of evidence available about each event, reflected in the number and quality of sources. Data from the two components were used to identify a provisional timeline of events for each account.

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3 A tissue viability nurse specialist from the relevant study site undertook a parallel review,
4 based solely on available patient records and on other available documentation, including
5 local guidelines and critical incident reports (ie not including the patient/carer interview).
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7 The method followed the guidance for reviews of critical incidents in the NHS in England.
8
9 The nurse wrote a report, identifying key decisions and actions in chronological order,
10 including departures from local guidelines. The field researcher and tissue viability nurse
11 specialist then met and compared their accounts, identifying consistencies and
12 inconsistencies, eg actions that the nurse judged as important, that were not included in the
13 initial patient-driven account. Timelines were revised in the light of additional facts or
14 insights generated (Stage 3).
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22 *Refinement of the Accounts*

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24 The subsequent stages of the analysis were designed to minimise some of the risks of bias
25 known to be associated with retrospective analysis, notably hindsight bias, through review
26 of each account by researchers with different backgrounds. The initial summaries of each
27 account were reviewed by a sub-group of nursing members of the research team; one
28 independent hospital-based and one independent community-based tissue viability nurse
29 specialist, and one of the Co-Chief Investigators (Stage 4).
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37 The accounts were analysed in two ways. First, they were used to identify any errors – in
38 the opinion of the sub-group – made in the decisions and actions recorded in each account.
39 The specialist nurse reports, in particular, were important in helping to identify decisions
40 made and actions taken, and hence provided an evidential basis for identifying errors of
41 omission or commission. Each point was checked by going back to primary data sources.
42 This produced an account that could be deemed to be ‘true and fair’. On the basis of the
43 account the clinical sub-group made expert judgements about departures from the
44 treatment and care that each individual might reasonably have expected to receive. These
45 departures – such as failures to undertake proper risk assessments or to act when there
46 were clear signs of skin redness or a category 1 ulcer – were possible precipitating, or
47 contributing, events in the development of each severe pressure ulcer. Second, drawing on
48 Yin’s strategy for discriminating between hypotheses in case studies, [11] clinical sub-groups
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3 were asked to select one or more of five explanations for the events portrayed in an
4 account. The five explanations were that a severe pressure ulcer:

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8 1. Could not have been avoided;
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10 2. Developed following an isolated mistake made by a clinician;
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12 3. Developed following a sequence of unconnected errors;
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14 4. The organisational context made development more likely; ;
15
16 5. Developed for another reason, not covered by the first four.
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19 The first explanation captures a situation where clinical staff did everything that might
20 reasonably have been expected. The second reflects the dominant assumption in the
21 patient safety literature, and is supported by some evidence about pressure ulcer
22 development. [12,13] The third is a version of Reason's 'Swiss Cheese' model, and again has
23 some support in the pressure ulcer literature. [14-17] The fourth, which also has some
24 support in the pressure ulcer literature, focuses on the role of the organisational context,
25 highlighted in the Institute of Medicine's report, *To Err Is Human*. [18-21] The implicit
26 assumption underpinning this explanation is that sub-optimal treatment and care are
27 provided, compared with the overall treatment and care that an individual might reasonably
28 expect to receive, as judged by the clinical sub-group and subsequent reviewers. The fifth
29 explanation is a logical extension to the first four, retaining the possibility of a novel
30 explanation.
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42 The revised accounts and explanations were reviewed by the non-clinical Co-Chief
43 Investigator and then by an organisational psychologist who had not been involved in the
44 earlier stages (Stage 5). The reviews focused on the coherence of each account, ie the
45 extent to which the patient's explanation and/or the nurses' judgements made sense of the
46 available evidence. In the final step in the analysis, the eight accounts were analysed
47 inductively, in order to identify themes that were common across the accounts. [22]
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53 54 **RESULTS**

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56 The study demonstrates that it is possible to develop detailed retrospective accounts of
57 events, and to use them to judge which of five possible explanations best fits the available
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evidence. The large volumes of data collected and included in the timeline appear to have minimised problems that might have arisen as a result of 'missing data'. The iterative review process, involving reviewers with different backgrounds, appears to have minimised the risks of mis-interpretation. As we note in the Discussion, though, the results may still be subject to a number of biases.

The eight individuals were selected, in part, to maximise diversity (see Table 2). There were, therefore, marked differences in their personal characteristics and in their treatment and care. They were all, though, at high risk of developing pressure ulcers, or of existing pressure ulcers deteriorating. Different explanations were offered by those interviewed for the development of severe pressure ulcers. For example, in a number of accounts some staff interviewed blamed patients, on the basis that they had not complied with advice on managing their risks, eg shifting position regularly. But patients themselves, in the same accounts, pointed to specific actions or omissions – failure to be turned regularly overnight, to provide a specialised mattress, or to respond to patients' comments about their own risks.

Table 2: Individuals and settings

Account	Individual	Setting
1	38 year old woman with paraplegia	Acute hospital, surgical ward
2	65 year old woman with long-term chronic neurological condition and undiagnosed infection	Acute hospital, medical ward
3	75 year old man with multiple chronic health problems and acute infection	Community hospital, rehabilitation ward
4	37 year old woman with long-term degenerative congenital neurological condition	At home
5	90 year old man with multiple chronic health problems and undiagnosed acute illness	Acute hospital, surgical ward
6	39 year old woman in hospital for acute undiagnosed post-operative surgical complications	Acute hospital, surgical ward
7	65 year old man with	At home, respite care and

	quadriplegia	acute hospital
8	89 year old woman who fell at home	At home

Elimination of hypotheses

The diverse group of individuals all had the same outcome, a severe pressure ulcer. In one account (#8) development was judged to be unavoidable, because the individual concerned developed a severe pressure ulcer in her own home, before any health professional saw her. The other seven accounts were deemed to involve avoidable severe pressure ulcers, both in the specialist nurse reports and the reviews by the clinical sub-group, on the basis that there was clear evidence of departures from the care that the patient might reasonably have expected to receive. The second and third hypotheses were causal in nature: in one account (#3) there was a single precipitating event, and there was a sequence of precipitating events in three others (#2, #4 and #6). In each of the four cases, though, reviewers judged that, while specific events played a role, they provided only part of the explanation. In these cases, and in the three remaining ones – seven of the eight - the clinical sub-group and subsequent reviewers all judged that the organisational context made development of a severe pressure ulcer more likely, compared with the overall treatment and care that the individual might reasonably have expected to receive (see Table 3). None of the eight accounts, in the view of the clinical sub-group or subsequent reviewers, supported an alternative explanation.

Table 3: Summative judgements by account

Account	Unavoidable	Single/isolated event	Sequence of events	Environment made development more likely	Other explanation
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4			•	•	
5				•	
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The organisational context

The next step was to understand how the organisational context contributed to the development of severe pressure ulcers. Inductive analysis of the eight accounts led to the identification of three main themes. First, the 'voices' of the individuals who developed severe pressure ulcers were not heard by staff. As noted above the individuals themselves behaved differently, and had different relationships with clinical staff, but failures to heed information were evident in several accounts. For example, there were examples of patients making repeated appeals for pain and discomfort to be addressed, and expressing concerns about their own wellbeing, which were not heeded over periods of hours or even days. In some instances these appeals seem to have been dismissed by staff: that is, they were heard but not taken seriously. Patients were also blamed for the development of their pressure ulcers, on the basis that they did not comply with instructions they were given, and branded as 'difficult' - even when they had cognitive impairments.

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3 Second, there were failures to recognise and act on warning signs. Risk assessments were
4 not undertaken when they should have been, in some cases only being undertaken several
5 days after admission to an acute hospital ward. Evidence of pre-existing clinical risks in
6 records was not acted upon in six of the seven patients where the environment was judged
7 to have contributed to development. Action was not taken promptly when overt evidence –
8 including the presence of a Category 2 pressure ulcer - was identified. Conversely, there
9 was evidence of poor documentation, so that adherence with patients' care plans was not
10 recorded, and in some instances direct evidence of skin redness or a pressure ulcer was not
11 recorded. Some healthcare assistants, who provided direct care, observed that they lacked
12 the appropriate training to identify and record risks, or were not allowed to record them.
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22 Third, there were co-ordination failures, between patients, carers and staff, staff in the
23 same setting, between staff in different settings in the same organisation (eg two wards),
24 and between staff in different organisations. Sometimes this was manifested as inter-
25 professional communication failure, and in some cases there was poor communication
26 between the same professional groups in two locations. One example of the latter came in
27 a post-operative setting, where risks were not properly communicated between the
28 anaesthetic recovery unit and the post-operative ward. In other accounts records were not
29 moved with an individual, so that key information was not available in a new setting. It
30 would be possible to interpret these points as clear evidence of failures by individuals or
31 teams. But there is a corollary to this point: nurses and healthcare assistants, in particular,
32 could find themselves working in conditions where they had limited information about
33 individuals and their risks, eg where patients had unknown diagnosis, or where records had
34 not travelled with the patient from another location. It is possible, therefore, that individual
35 members of staff behaved reasonably in the contexts in which they found themselves. The
36 problems observed could be attributed to weaknesses in the overall co-ordination of
37 treatment and care.
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52 **DISCUSSION**

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54 This study sought to explain why patients develop severe pressure ulcers, by reconstructing
55 events retrospectively, and then discriminating between alternative explanations for their
56 development. The principal explanation is that severe pressure ulcers developed in
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3 organisational contexts where there were failures in the overall governance of services.
4 Specifically, they were characterised by one or more of, (i) clinicians failing to listen to
5 patients' or carers' observations about their risks or the quality of their treatment and care,
6 (ii) clinicians failing to recognise and respond to clear signs that a patient had a pressure
7 ulcer or was at risk of developing one, and, (iii) services not being effectively co-ordinated.
8 In four of the accounts it was possible to identify specific, or causal, precipitating events, but
9 in each case these events occurred in organisational contexts where there were more
10 general governance problems
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19 As noted in the Methods section, the study was designed in significant part in order to
20 minimise biases in the data collection and analysis in a retrospective, observational study.
21 This study suggests that a novel method, based on tracing back the course of events
22 retrospectively from a known outcome, can be used to reconstruct key events. The
23 resulting accounts can be subjected to detailed review, and used to discriminate between
24 alternative explanations for those events, and in the process preserve the 'voices' of the
25 individuals affected. This said, it is important to stress that there are a number of sources of
26 bias, starting with selection bias: while the sampling strategy maximised diversity, the eight
27 accounts are of individuals who were willing and able to consent to participate. The initial
28 presentation of the timelines, and the backgrounds of the analysts and reviewers, are also
29 potential sources of bias. A study team with different clinical or disciplinary backgrounds
30 might have arrived at different judgements: for example, a team with backgrounds in
31 human factors psychology might have placed greater weight on single events or sequences
32 of events. There is also a risk, using a retrospective design, of hindsight bias, particularly in
33 reviewers assuming that staff must have known more than they actually did, and should
34 therefore have acted differently [23]. The sequential and iterative review process has, we
35 hope, served to minimise these biases, but we cannot say that they have been eliminated.
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50 We can interpret our findings in the context of the patient safety literature. Reason [17]
51 points out that investigations of accidents, across many industries, have changed
52 significantly over the last fifty years. An early focus on equipment failure gave way, in the
53 1970's and 1980's, to a focus on human error, and then more recently to accounts that
54 focused on systems and cultural issues. In spite of this, many patient safety studies today
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3 focus on causal explanations, based either on patient characteristics or errors made by
4 individual clinicians. These were represented by the second and third explanations.
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6 Relatively few focus on the wider organisational context, represented by the fourth
7 explanation. [11] The findings reported here only partially support the second or third
8 explanation. Only one patient was deemed to have an unavoidable severe pressure ulcer –
9 because service providers were unaware of a fall at home – supporting the first explanation,
10 and there was no support for a fifth, alternative, explanation. The overall findings are,
11 though, consistent with explanations that emphasise systems and culture.
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19 In the literature on the role of the organisational context on patient safety, explanations
20 tend to emphasise *either* systems or culture. The findings suggest that, for people who
21 developed severe pressure ulcers, *both* were important. In relation to systems-based
22 explanations, the evidence about the poor co-ordination of services is broadly consistent
23 with the arguments in *To Err Is Human*, namely that many safety failures are essentially
24 system failures. [21] Drawing on the work of Perrow and others, the Institute argued that
25 accidents are more likely in systems that are inherently complex – having many
26 interconnected elements. [23] The findings in this study supported the observation that
27 there were co-ordination failures between services that were loosely coupled with one
28 another, ie generally run independently of one another, but needing to co-ordinate with
29 one another. For example, there were communication failures between wards at times
30 when there were major ward re-organisations, so that key information was not passed on.
31 Similarly, one of the community-based accounts revealed that the individual was in receipt
32 of a hospital service that community staff were unaware of, and hence could not take into
33 account in risk assessment or care planning.
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47 At the same time, the failures to listen properly to patients – and even dismiss their
48 concerns - and to act when there was a superficial pressure ulcer present, emphasise the
49 importance of prevailing cultural norms. The evidence suggests that the environments
50 where severe pressure ulcers developed were ones where staff were under time pressure,
51 where there were problematic relationships between staff groups, and where staff were
52 defensive, and prepared to attribute failures to colleagues or to the 'difficult' behaviour of
53 patients. This takes us away from a causal explanation, linking clinical actions to the
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3 development of severe pressure ulcers, to one where the explanation is that prevailing
4 norms substantially influenced the decisions and actions of individuals, which in turn led to
5 the errors of commission and omission described above. Clinicians adopted risky work
6 routines that were not appropriate for the vulnerable patients that were in their care.
7
8 Severe pressure ulcers developed in contexts where there was normalisation of deviance, a
9 phenomenon where risky practices become the norm in a work setting, and staff either
10 don't recognise the extent of the risks they are taking, or are aware of them but
11 underestimate them.[24] This resonates with wider concerns about the culture in parts of
12 the NHS in England, where staff can be defensive and quick to blame others, rather than
13 being open and prepared to learn from adverse events [6].
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Figure legend

Figure 1: Analysis and Review of Individual Accounts

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Contributorship Statement

JN and JK conceived and designed the study initially. The study design was developed iteratively over a period of months by CD, JK, EM, JN, LP, NS. LP undertook primary data collection. Additional data were collected and collated by EM, NS, LW. JK drafted the article and revised it critically on the basis of comments from the other authors. All authors were formally involved in the analysis and interpretation of the findings. Co-authors will give final approval of the version to be published.

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Competing

No competing interests

Data Sharing Statement

There are no additional data available from the study.

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WHY DO PATIENTS DEVELOP SEVERE PRESSURE ULCERS?

A RETROSPECTIVE CASE STUDY

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Key words: pressure ulcer – patient safety – case study – retrospective study

Word Count excluding Figure, Tables etc: 4529

WHY DO PATIENTS DEVELOP SEVERE PRESSURE ULCERS?

A RETROSPECTIVE ~~CASE~~OBSERVATIONAL STUDY

ABSTRACT

Background:

Severe pressure ulcers are important indicators of failures in the organisation and delivery of treatment and care. We have a good understanding of patient risk factors, but a poor understanding of the role played by the organisational context in their development. [This study focuses on the ways in which the organisational context can influence the development of severe pressure ulcers.](#)

Methods:

The study was undertaken in six sites in Yorkshire, England. A retrospective case study design was used. Data were collected from a range of sources, including interviews with individuals with severe pressure ulcers and staff, and clinical notes, and used to construct accounts of eight individuals who developed severe pressure ulcers. Sequential and iterative review, involving reviewers with different backgrounds, were used to validate the accounts and to identify explanations for the events observed.

Results:

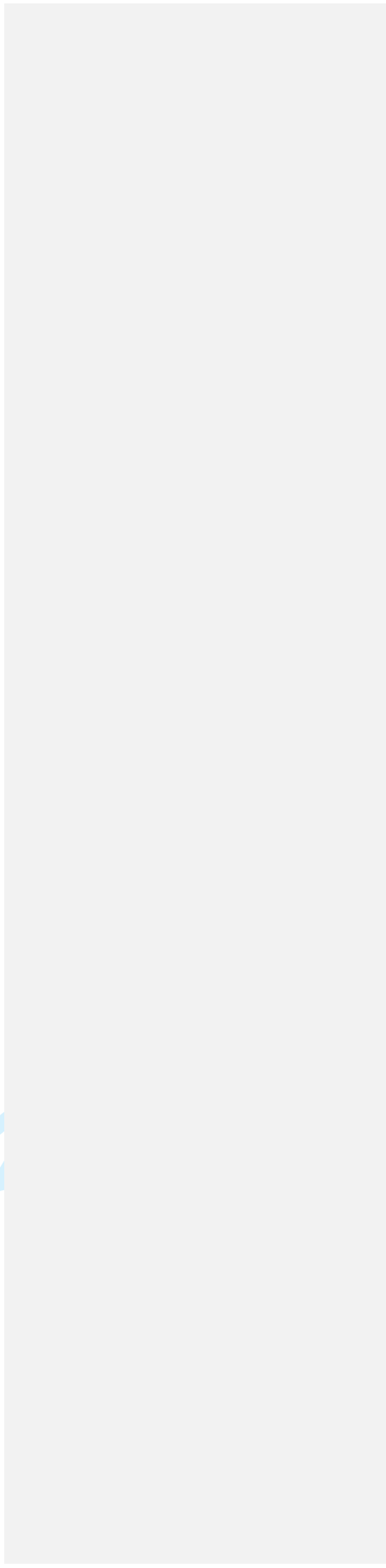
Four accounts indicated that specific actions by clinicians contributed to the development of severe pressure ulcers. But seven of the eight ~~accounts—including the four—~~ indicated that they ~~were more likely to develop~~ ed in organisational contexts where, (i) clinicians failed to listen and respond to patients' or carers' observations about their risks or the quality of their treatment and care, (ii) clinicians failed to recognise and respond to clear signs that a patient had a pressure ulcer or was at risk of developing one and, (iii) services were not effectively co-ordinated.

Conclusions:

~~The Patient~~ accounts, ~~taken together,~~ could only be partially explained in terms of specific events, or sequences of events. The findings support the conclusion that there was general acceptance of sub-optimal clinical practices in seven of the eight ~~accounts in the~~ contexts where patients developed severe pressure ulcers.

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For peer review only



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7 Article Summary

8 Strengths and limitations of this study

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10 • This study contributes to our understanding of a poorly understood process, the
11 development of a severe pressure ulcer
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13 • Few previous studies have explicitly sought to discriminate between psychological
14 and broader organisational explanations for adverse events in health care settings
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16 • The diversity of patients who develop severe pressure ulcers, and of the settings
17 where they occur, raises a risk of sampling bias
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19 • The retrospective study design brings with it a risk of hindsight bias
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- This study contributes to our understanding of a poorly understood process, the development of a severe pressure ulcer
 - Few previous studies have explicitly sought to discriminate between psychological and broader organisational explanations for adverse events in health care settings
 - The diversity of patients who develop severe pressure ulcers, and of the settings where they occur, raises a risk of sampling bias
 - The retrospective study design brings with it a risk of hindsight bias

INTRODUCTION

The European Pressure Ulcer Advisory Panel/ National Pressure Ulcer Advisory Panel (EPUAP/NPUAP) defines a pressure ulcer as, “localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.” [1] Pressure ulcers are a significant source of pain and distress for the individuals who develop them. [2] In recent years the importance of severe pressure ulcers as indicators of poor quality and safety of health services has been recognised. Category 2 ulcers or above, as rated on the EPUAP/NPUAP 1-4 scale, are classed as reportable incidents in official guidelines in the National Health Service (NHS) in England. [3] Category 3 and 4 ulcers (which involve injury deep into the skin, muscle or bone) are widely termed severe pressure ulcers, and have to be reported as serious untoward incidents. [4] Pressure ulcers are also one of four patient safety indicators in a new NHS monitoring tool. [5]

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There are two distinct ways of thinking about patients’ risks of developing pressure ulcers. The first is based on the assumption that all PU risks are associated with patients’ health status or their behaviour. The implication is that clinicians should focus on identifying patients who are at risk, assess the nature and scale of their risks, and design clinical interventions to reduce them. We have a good understanding of patient risk factors. [6] The second way of thinking starts from a different assumption, which is that the quality of treatment and care can also influence patients’ risks of developing pressure ulcers. Patients who are at risk are more likely to develop them in settings where quality of care is poor. The events at Mid Staffordshire NHS Foundation Trust, where at one point dozens of PUs were being reported every month, help to underline the significance of this point. [7]

We currently have a relatively poor understanding of the ways in which the wider organisational context contributes to their prevention or development. A small number of studies have indicated that it plays a role, but the nature and significance of that role remains to be elucidated. [8] This study focuses on the ways in which the organisational context can influence the development of severe pressure ulcers. It focuses on identifying the best explanation for their development, using explanations derived from the patient

safety literature, which advances both psychological and sociological explanations for errors and adverse events [9].

METHODS

Severe pressure ulcers occur relatively rarely, and can develop in a wide range of settings, and it is not currently possible to predict who will develop them and who will not. [6] It was As a result it is not therefore practical to study their development prospectively. If, for example, we had prospectively identified patients with category 2 ulcers, in order to evaluate differences between those that developed in a category 3 or 4 ulcer and those that did not, our presence would have drawn attention to the significance of the pressure ulcers. It is likely to have prompted swift action by the local clinical team, and it seems reasonable to predict that few, or even none, of the category 2 pressure ulcers would have progressed to category 3 or 4. As a result, we would have biased our observations, possibly substantially, and could not have been confident that we had observed the whole development process, from the earliest signs and symptoms to the point where action was taken. It was, though, possible to reconstruct the events that lead to the development severe pressure ulcers retrospectively. We undertook a retrospective case study, where severe pressure ulcers were end-points, and also indicators of adverse outcomes of treatment and care. A process tracing case study method was used, focusing on the experiences of eight individuals in Yorkshire, England. [10] Each account took, on average, four months to create, from the initial interview with an individual to the signing off of a detailed account of the development of that individuals' severe pressure ulcer.

Primary Data Collection

Research Ethics Committee approval and local research governance approvals from six study sites in Yorkshire, England, were obtained. Participants were sampled purposively, in order to maximise the diversity of individuals and the contexts in which they developed severe pressure ulcers. The settings included patients' own homes, acute hospital medical and surgical wards, a community hospital and a nursing home during a period of respite care.

Sampling was also pragmatic: individuals who had developed a Category 3 or 4 pressure ulcer were identified by members of the local tissue viability nurse teams. Consent to participate was obtained from patients, and where appropriate also from their main carers.

Data were collected by a field researcher with a non-clinical background from five sources, namely interviews with individuals who had developed a severe pressure ulcer (and where relevant also their main carers), interviews with clinical and other staff who had been involved in their care, clinical records, other documents relevant to the account such as

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7 critical incident reports, and relevant local policy documents, eg on assessment of risks of
8 skin breakdown (Figure 1, Stage 1).—Interviews ~~with individuals and with clinical and other~~
9 ~~staff~~ were open-ended and in-depth, and are listed in Table 1. 70 interviews in total were
10 conducted across the eight accounts. The site principal investigator, who in each case was a
11 nurse with a specialist interest in tissue viability, collated patient notes in a parallel exercise,
12 following current practice in the NHS in England for root cause analyses.
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Figure 1: Analysis and Review of Individual Accounts

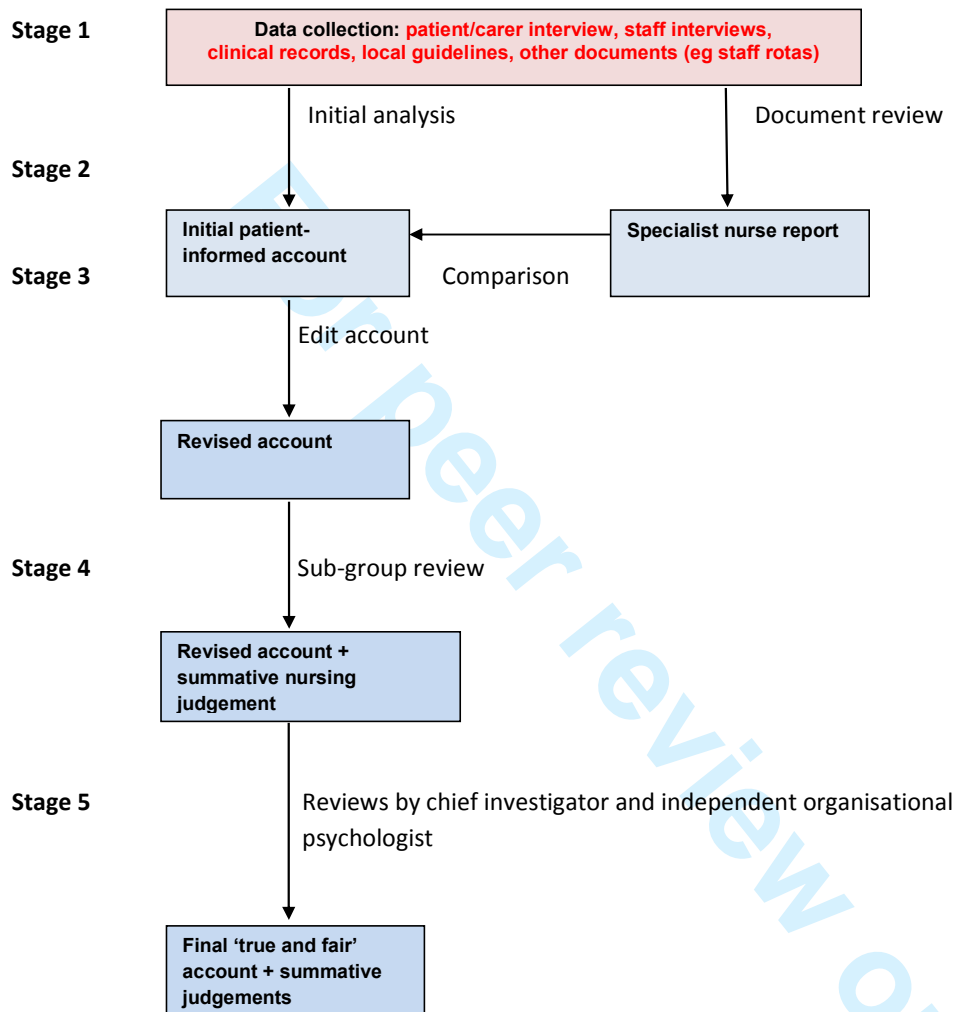


Table 1: Number of People Interviewed by Account

Account	Individual	Carer	Viability Nurse	Tissue	District nurse	Nurse	Health/home care assistant	Consultant	Junior doctor	Physiotherapist	Occupational Therapist	Ward clerk	Liaison nurses	Ward Manager	Quality assurance mgr.	Total
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Development of Retrospective Accounts

The initial accounts each had two components. The first consisted of verbatim passages of the patient/carer interview, which captured their explanations of the events that led to their severe pressure ulcers. Second, a Microsoft Access database was created for each account, and used to organise decisions and actions into a chronological sequence, with patient and carer data in one column, other interview data in a second and records and other documentary sources in a third (see Figure 1, Stage 2). The presentation of data in parallel columns made it possible to identify consistencies and inconsistencies between different data sources, and also the 'strength' of evidence available about each event, reflected in the number and quality of sources. Data from the two components were used to identify a provisional timeline of events for each account.

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7 A tissue viability nurse specialist from the relevant study site undertook a parallel review,
8 based solely on available patient records and on other available documentation, including
9 local guidelines and critical incident reports (ie not including the patient/carer interview).
10 The method followed the guidance for reviews of critical incidents in the NHS in England.
11 The nurse wrote a report, identifying key decisions and actions in chronological order,
12 including departures from local guidelines. The field researcher and tissue viability nurse
13 specialist then met and compared their accounts, identifying consistencies and
14 inconsistencies, eg actions that the nurse judged as important, that were not included in the
15 initial patient-driven account. Timelines were revised in the light of additional facts or
16 insights generated (Stage 3).
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23 *Refinement of the Accounts*

24 The subsequent stages of the analysis were designed to minimise some of the risks of bias
25 known to be associated with retrospective analysis, notably hindsight bias, through review
26 of each account by researchers with different backgrounds. The initial summaries of each
27 account were reviewed by a sub-group of nursing members of the research team; one
28 independent hospital-based and one independent community-based tissue viability nurse
29 specialist, and one of the Co-Chief Investigators (Stage 4).
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35 The accounts were analysed in two ways. First, they were used to identify any errors – in
36 the opinion of the sub-group – made in the decisions and actions recorded in each account.

37 [The specialist nurse reports, in particular, were important in helping to identify decisions
38 made and actions taken, and hence provided an evidential basis for identifying errors of
39 omission or commission.](#) Each point was checked by going back to primary data sources.

40 This produced an account that could be deemed to be ‘true and fair’. [On the basis of the
41 account the clinical sub-group made expert judgements about departures from the
42 treatment and care that each individual might reasonably have expected to receive. These
43 departures – such as failures to undertake proper risk assessments or to act when there
44 were clear signs of skin redness or a category 1 ulcer – were possible precipitating, or
45 contributing, events in the development of each severe pressure ulcer.](#) Second, drawing on
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53 Yin’s strategy for discriminating between hypotheses in case studies, [11] clinical sub-groups
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7 were asked to select one or more of five explanations for the events portrayed in an
8 account. The five explanations were that a severe pressure ulcer:
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- 10 1. Could not have been avoided;
- 11 2. Developed following an isolated mistake made by a clinician;
- 12 3. Developed following a sequence of unconnected errors;
- 13 4. ~~Developed in an~~The-organisational context made development more likely; that made
14 development more likely;
- 15 5. Developed for another reason, not covered by the first four.

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22 The first explanation captures a situation where clinical staff did everything that might
23 reasonably have been expected. The second reflects the dominant assumption in the
24 patient safety literature, and is supported by some evidence about pressure ulcer
25 development. [12,13] The third is a version of Reason's 'Swiss Cheese' model, and again has
26 some support in the pressure ulcer literature. [14-17] The fourth, which also has some
27 support in the pressure ulcer literature, focuses on the role of the organisational context,
28 highlighted in the Institute of Medicine's report, *To Err Is Human*. [18-21] The implicit
29 assumption underpinning this explanation is that sub-optimal treatment and re care are
30 provided, compared with the overall treatment and care that an individual might reasonably
31 expect to receive, as judged by the clinical sub-group and subsequent reviewers.—The fifth
32 explanation is a logical extension to the first four, retaining the possibility of a novel
33 explanation.
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42 The revised accounts and explanations were reviewed by the non-clinical Co-Chief
43 Investigator and then by an organisational psychologist who had not been involved in the
44 earlier stages (Stage 5). The reviews focused on the coherence of each account, ie the
45 extent to which the patient's explanation and/or the nurses' judgements made sense of the
46 available evidence. In the final step in the analysis, the eight accounts were analysed
47 inductively, in order to identify themes that were common across the accounts. [22]
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52 RESULTS

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The study demonstrates that it is possible to develop detailed retrospective accounts of events, and to use them to judge which of five possible explanations best fits the available evidence. The large volumes of data collected and included in the timeline appear to have minimised problems that might have arisen as a result of 'missing data'. The iterative review process, involving reviewers with different backgrounds, appears to have minimised the risks of mis-interpretation. As we note in the Discussion, though, the results may still be subject to a number of biases.

The eight individuals were selected, in part, to maximise diversity (see Table 2). There were, therefore, marked differences in their personal characteristics and in their treatment and care. They were all, though, at high risk of developing pressure ulcers, or of existing pressure ulcers deteriorating. Different explanations were offered by those interviewed for the development of severe pressure ulcers. For example, in a number of accounts some staff interviewed blamed patients, on the basis that they had not complied with advice on managing their risks, eg shifting position regularly. But patients themselves, in the same accounts, pointed to specific actions or omissions – failure to be turned regularly overnight, to provide a specialised mattress, or to respond to patients' comments about their own risks.

Table 2: Individuals and settings

Account	Individual	Setting
1	38 year old woman with paraplegia	Acute hospital, surgical ward
2	65 year old woman with long-term chronic neurological condition and undiagnosed infection	Acute hospital, medical ward
3	75 year old man with multiple chronic health problems and acute infection	Community hospital, rehabilitation ward
4	37 year old woman with long-term degenerative congenital neurological condition	At home
5	90 year old man with multiple chronic health problems and undiagnosed acute illness	Acute hospital, surgical ward
6	39 year old woman in hospital for acute undiagnosed post-	Acute hospital, surgical ward

	operative surgical complications	
7	65 year old man with quadriplegia	At home, respite care and acute hospital
8	89 year old woman who fell at home	At home

Elimination of hypotheses

The diverse group of individuals all had the same outcome, a severe pressure ulcer. In one account (#8) development was judged to be unavoidable, because the individual concerned developed a severe pressure ulcer in her own home, before any health professional saw her.

The other seven accounts were deemed to involve avoidable severe pressure ulcers, both in the specialist nurse reports and the reviews by the clinical sub-group, on the basis that there was clear evidence of departures from the care that the patient might reasonably have expected to receive. The second and third hypotheses were causal in nature: in one account (#3) there was a single precipitating event, and there was a sequence of precipitating events in three others (#2, #4 and #6). In each of the four cases, though, reviewers judged that, while specific events played a role, they provided only part of the explanation. In these cases, and in the three remaining ones – seven of the eight - the clinical sub-group and subsequent reviewers all judged that the organisational context made development of a severe pressure ulcer more likely, [compared with the overall treatment and care that the individual might reasonably have expected to receive](#) (see Table 3). None of the eight accounts, in the view of the clinical sub-group or subsequent reviewers, supported an alternative explanation.

Table 3: Summative judgements by account

Account	Unavoidable	Single/isolated event	Sequence of events	Environment made development more likely	Other explanation
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4			•	•	
5				•	
6			•	•	
7				•	
8	•				

The organisational context

The next step was to understand how the organisational context [contributed to](#) made the development of severe pressure ulcers [more likely](#). Inductive analysis of the eight accounts led to the identification of three main themes. First, the 'voices' of the individuals who developed severe pressure ulcers were not heard by staff. As noted above the individuals themselves behaved differently, and had different relationships with clinical staff, but failures to heed information were evident in several accounts. For example, there were examples of patients making repeated appeals for pain and discomfort to be addressed, and expressing concerns about their own wellbeing, which were not heeded over periods of hours or even days. In some instances these appeals seem to have been dismissed by staff: that is, they were heard but not taken seriously. Patients were also blamed for the development of their pressure ulcers, on the basis that they did not comply with instructions they were given, and branded as 'difficult' - even when they had cognitive impairments.

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7 Second, there were failures to recognise and act on warning signs. Risk assessments were
8 not undertaken when they should have been, in some cases only being undertaken several
9 days after admission to an acute hospital ward. Evidence of pre-existing clinical risks in
10 records was not acted upon in six of the seven patients where the environment was judged
11 to have ~~contributed to~~ development ~~more likely~~. Action was not taken promptly when
12 overt evidence – including the presence of a Category 2 pressure ulcer - was identified.
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14 Conversely, there was evidence of poor documentation, so that adherence with patients'
15 care plans was not recorded, and in some instances direct evidence of skin redness or a
16 pressure ulcer was not recorded. Some healthcare assistants, who provided direct care,
17 observed that they lacked the appropriate training to identify and record risks, or were not
18 allowed to record them.
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25 Third, there were co-ordination failures, between patients, carers and staff, staff in the
26 same setting, between staff in different settings in the same organisation (eg two wards),
27 and between staff in different organisations. Sometimes this was manifested as inter-
28 professional communication failure, and in some cases there was poor communication
29 between the same professional groups in two locations. One example of the latter came in
30 a post-operative setting, where risks were not properly communicated between the
31 anaesthetic recovery unit and the post-operative ward. In other accounts records were not
32 moved with an individual, so that key information was not available in a new setting. It
33 would be possible to interpret these points as clear evidence of failures by individuals or
34 teams. But there is a corollary to this point: nurses and healthcare assistants, in particular,
35 could find themselves working in conditions where they had limited information about
36 individuals and their risks, eg where patients had unknown diagnosis, or where records had
37 not travelled with the patient from another location. It is possible, therefore, that individual
38 members of staff behaved reasonably in the contexts in which they found themselves. The
39 problems observed could be attributed to weaknesses in the overall co-ordination of
40 treatment and care.
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51 DISCUSSION

52 This study sought to explain why patients develop severe pressure ulcers, by reconstructing
53 events retrospectively, and then discriminating between alternative explanations for their
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7 development. The principal explanation is that severe pressure ulcers are more likely to
8 develop in organisational contexts where there were failures in the overall governance of
9 services. Specifically, they were characterised by one or more of, (i) clinicians failing to
10 listen to patients' or carers' observations about their risks or the quality of their treatment
11 and care, (ii) clinicians failing to recognise and respond to clear signs that a patient had a
12 pressure ulcer or was at risk of developing one, and, (iii) services not being effectively co-
13 ordinated. ~~These can all be interpreted as failures in the governance of the services in the~~
14 ~~settings studied.~~ In four of the accounts it was possible to identify specific, or causal,
15 precipitating events, but in each case these events occurred in organisational problematic
16 contexts where there were more general governance problems.
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24 As noted in the Methods section, the study was designed in significant part in order to
25 minimise biases in the data collection and analysis in a retrospective, observational study.
26 This study suggests that a novel method, based on tracing back the course of events
27 retrospectively from a known outcome, can be used to reconstruct key events. The
28 resulting accounts can be subjected to detailed review, and used to discriminate between
29 alternative explanations for those events, and in the process preserve the 'voices' of the
30 individuals affected. This said, it is important to stress that there are a number of sources of
31 bias, starting with selection bias: while the sampling strategy maximised diversity, the eight
32 accounts are of individuals who were willing and able to consent to participate. The initial
33 presentation of the timelines, and the backgrounds of the analysts and reviewers, are also
34 potential sources of bias. A study team with different clinical or disciplinary backgrounds
35 might have arrived at different judgements: for example, a team with backgrounds in
36 human factors psychology might have placed greater weight on single events or sequences
37 of events. There is also a risk, using a retrospective design, of hindsight bias, particularly in
38 reviewers assuming that staff must have known more than they actually did, and should
39 therefore have acted differently [23]. The sequential and iterative review process has, we
40 hope, served to minimise these biases, but we cannot say that they have been eliminated.
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51 We can interpret our findings in the context of the patient safety literature. Reason [17]
52 points out that investigations of accidents, across many industries, have changed
53 significantly over the last fifty years. An early focus on equipment failure gave way, in the
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7 1970's and 1980's, to a focus on human error, and then more recently to accounts that
8 focused on systems and cultural issues. In spite of this, many patient safety studies today
9 focus on causal explanations, based either on patient characteristics or errors made by
10 individual clinicians. These were represented by the second and third explanations.
11 Relatively few focus on the wider organisational context, represented by the fourth
12 explanation. [11] The findings reported here only partially support the second or third
13 explanation. Only one patient was deemed to have an unavoidable severe pressure ulcer –
14 because service providers were unaware of a fall at home – supporting the first explanation,
15 and there was no support for a fifth, alternative, explanation. The overall findings are,
16 though, consistent with explanations that emphasise systems and culture.
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24 In the literature on the role of the organisational context on patient safety, explanations
25 tend to emphasise *either* systems or culture. The [study results findings](#) suggest that, for
26 people who developed severe pressure ulcers, *both* were important. In relation to systems-
27 based explanations, the evidence about the poor co-ordination of services is broadly
28 consistent with the arguments in *To Err Is Human*, namely that many safety failures are
29 essentially system failures. [21] Drawing on the work of Perrow and others, the Institute
30 argued that accidents are more likely in systems that are inherently complex – having many
31 interconnected elements. [23] The findings in this study supported the observation that
32 there were co-ordination failures between services that were loosely coupled with one
33 another, ie generally run independently of one another, but needing to co-ordinate with
34 one another. For example, there were communication failures between wards at times
35 when there were major ward re-organisations, so that key information was not passed on.
36 Similarly, one of the community-based accounts revealed that the individual was in receipt
37 of a hospital service that community staff were unaware of, and hence could not take into
38 account in risk assessment or care planning.
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48 At the same time, the failures to listen properly to patients – and even dismiss their
49 concerns - and to act when there was a superficial pressure ulcer present, emphasise the
50 importance of prevailing cultural norms. The evidence suggests that the environments
51 where severe pressure ulcers developed were ones where staff were under time pressure,
52 where there were problematic relationships between staff groups, and where staff were
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7 defensive, and prepared to attribute failures to colleagues or to the 'difficult' behaviour of
8 patients. This takes us away from a causal explanation, linking clinical actions to the
9 development of severe pressure ulcers, to one where the explanation is that prevailing
10 norms substantially influenced the decisions and actions of individuals, which in turn led to
11 the errors of commission and omission described above. Clinicians adopted risky work
12 routines that were not appropriate for the vulnerable patients that were in their care.
13 Severe pressure ulcers developed in contexts where there was normalisation of deviance, a
14 phenomenon where risky practices become the norm in a work setting, and staff either
15 don't recognise the extent of the risks they are taking, or are aware of them but
16 underestimate them.^[24] This resonates with wider concerns about the culture in parts of
17 the NHS in England, where staff can be defensive and quick to blame others, rather than
18 being open and prepared to learn from adverse events [6].
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Contributorship Statement

JN and JK conceived and designed the study initially. The study design was developed iteratively over a period of months by CD, JK, EM, JN, LP, NS. LP undertook primary data collection. Additional data were collected and collated by EM, NS, LW. JK drafted the article and revised it critically on the basis of comments from the other authors. All authors were formally involved in the analysis and interpretation of the findings. Co-authors will give final approval of the version to be published.

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Competing

No competing interests

Data Sharing Statement

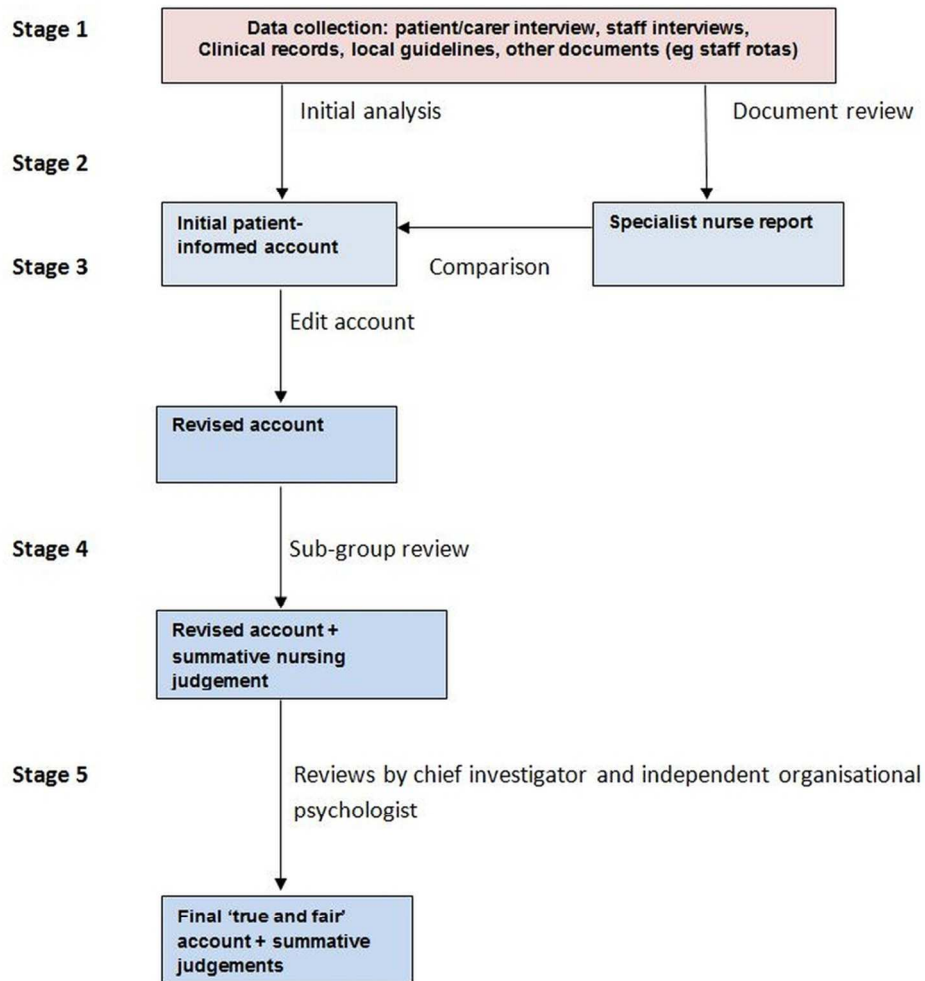
No data

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SQUIRE Guidelines
(Standards for Quality Improvement Reporting Excellence)
Final revision – 4-29-08

- These guidelines provide a framework for reporting formal, planned studies designed to assess the nature and effectiveness of interventions to improve the quality and safety of care.
- It may not be possible to include information about every numbered guideline item in reports of original formal studies, but authors should at least consider every item in writing their reports.
- Although each major section (i.e., Introduction, Methods, Results, and Discussion) of a published original study generally contains some information about the numbered items within that section, information about items from one section (for example, the Introduction) is often also needed in other sections (for example, the Discussion).

<i>Text section; Item number and name</i>	<i>Section or Item description</i>
<u>Title and abstract</u>	<i>Did you provide clear and accurate information for finding, indexing, and scanning your paper?</i>
1. Title	<ul style="list-style-type: none"> a. Indicates the article concerns the improvement of quality (broadly defined to include the safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of care) b. States the specific aim of the intervention c. Specifies the study method used (for example, “A qualitative study,” or “A randomized cluster trial”)
2. Abstract	Summarizes precisely all key information from various sections of the text using the abstract format of the intended publication
<u>Introduction</u>	<i>Why did you start?</i>
3. Background Knowledge	Provides a brief, non-selective summary of current knowledge of the care problem being addressed, and characteristics of organizations in which it occurs
4. Local problem	Describes the nature and severity of the specific local problem or system dysfunction that was addressed
5. Intended improvement	<ul style="list-style-type: none"> a. Describes the specific aim (changes/improvements in care processes and patient outcomes) of the proposed intervention b. Specifies who (champions, supporters) and what (events, observations) triggered the decision to make changes, and why now (timing)
6. Study question	States precisely the primary improvement-related question and any secondary questions that the study of the intervention was designed to answer
<u>Methods</u>	<i>What did you do?</i>
7. Ethical issues	Describes ethical aspects of implementing and studying the improvement, such as privacy concerns, protection of participants’ physical well-being, and potential author conflicts of interest, and how ethical concerns were addressed
8. Setting	Specifies how elements of the local care environment considered most likely to influence change/improvement in the involved site or sites were identified and characterized
9. Planning the intervention	<ul style="list-style-type: none"> a. Describes the intervention and its component parts in sufficient detail that others could reproduce it b. Indicates main factors that contributed to choice of the specific intervention (for example, analysis of causes of dysfunction; matching relevant improvement experience of others with the local situation)

Text section; Item number and name	Section or Item description
Planning the intervention (continued)	c. Outlines initial plans for how the intervention was to be implemented: e.g., <i>what</i> was to be done (initial steps; functions to be accomplished by those steps; how tests of change would be used to modify intervention), and <i>by whom</i> (intended roles, qualifications, and training of staff)
10. Planning the study of the intervention	<p>a. Outlines plans for assessing how well the intervention was implemented (dose or intensity of exposure)</p> <p>b. Describes mechanisms by which intervention components were expected to cause changes, and plans for testing whether those mechanisms were effective</p> <p>c. Identifies the study design (for example, observational, quasi-experimental, experimental) chosen for measuring impact of the intervention on primary and secondary outcomes, if applicable</p> <p>d. Explains plans for implementing essential aspects of the chosen study design, as described in publication guidelines for specific designs, if applicable (see, for example, www.equator-network.org)</p> <p>e. Describes aspects of the study design that specifically concerned internal validity (integrity of the data) and external validity (generalizability)</p>
11. Methods of evaluation	<p>a. Describes instruments and procedures (qualitative, quantitative, or mixed) used to assess a) the effectiveness of implementation, b) the contributions of intervention components and context factors to effectiveness of the intervention, and c) primary and secondary outcomes</p> <p>b. Reports efforts to validate and test reliability of assessment instruments</p> <p>c. Explains methods used to assure data quality and adequacy (for example, blinding; repeating measurements and data extraction; training in data collection; collection of sufficient baseline measurements)</p>
12. Analysis	<p>a. Provides details of qualitative and quantitative (statistical) methods used to draw inferences from the data</p> <p>b. Aligns unit of analysis with level at which the intervention was implemented, if applicable</p> <p>c. Specifies degree of variability expected in implementation, change expected in primary outcome (effect size), and ability of study design (including size) to detect such effects</p> <p>d. Describes analytic methods used to demonstrate effects of time as a variable (for example, statistical process control)</p>
Results	<i>What did you find?</i>
13. Outcomes	<p>a) Nature of setting and improvement intervention</p> <p>i. Characterizes relevant elements of setting or settings (for example, geography, physical resources, organizational culture, history of change efforts), and structures and patterns of care (for example, staffing, leadership) that provided context for the intervention</p> <p>ii. Explains the actual course of the intervention (for example, sequence of steps, events or phases; type and number of participants at key points), preferably using a time-line diagram or flow chart</p> <p>iii. Documents degree of success in implementing intervention components</p> <p>iv. Describes how and why the initial plan evolved, and the most important lessons learned from that evolution, particularly the effects of internal feedback from tests of change (reflexiveness)</p> <p>b) Changes in processes of care and patient outcomes associated with the intervention</p> <p>i. Presents data on changes observed in the care delivery process</p> <p>ii. Presents data on changes observed in measures of patient outcome (for example, morbidity, mortality, function, patient/staff satisfaction, service utilization, cost, care disparities)</p>

<i>Text section; Item number and name</i>	<i>Section or Item description</i>
Outcomes (continued)	<ul style="list-style-type: none"> iii. Considers benefits, harms, unexpected results, problems, failures iv. Presents evidence regarding the strength of association between observed changes/improvements and intervention components/context factors v. Includes summary of missing data for intervention and outcomes
<u>Discussion</u>	<i>What do the findings mean?</i>
14. Summary	<ul style="list-style-type: none"> a. Summarizes the most important successes and difficulties in implementing intervention components, and main changes observed in care delivery and clinical outcomes b. Highlights the study's particular strengths
15. Relation to other evidence	Compares and contrasts study results with relevant findings of others, drawing on broad review of the literature; use of a summary table may be helpful in building on existing evidence
16. Limitations	<ul style="list-style-type: none"> a. Considers possible sources of confounding, bias, or imprecision in design, measurement, and analysis that might have affected study outcomes (internal validity) b. Explores factors that could affect generalizability (external validity), for example: representativeness of participants; effectiveness of implementation; dose-response effects; features of local care setting c. Addresses likelihood that observed gains may weaken over time, and describes plans, if any, for monitoring and maintaining improvement; explicitly states if such planning was not done d. Reviews efforts made to minimize and adjust for study limitations e. Assesses the effect of study limitations on interpretation and application of results
17. Interpretation	<ul style="list-style-type: none"> a. Explores possible reasons for differences between observed and expected outcomes b. Draws inferences consistent with the strength of the data about causal mechanisms and size of observed changes, paying particular attention to components of the intervention and context factors that helped determine the intervention's effectiveness (or lack thereof), and types of settings in which this intervention is most likely to be effective c. Suggests steps that might be modified to improve future performance d. Reviews issues of opportunity cost and actual financial cost of the intervention
18. Conclusions	<ul style="list-style-type: none"> a. Considers overall practical usefulness of the intervention b. Suggests implications of this report for further studies of improvement interventions
<u>Other information</u>	<i>Were other factors relevant to conduct and interpretation of the study?</i>
19. Funding	Describes funding sources, if any, and role of funding organization in design, implementation, interpretation, and publication of study