



Clinical study

Pressure ulcer and wounds reporting in NHS hospitals in England part 1: Audit of monitoring systems



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KEYWORDS

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Prevalence;
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Abstract Internationally, health-care systems have attempted to assess the scale of and demonstrate improvement in patient harms. Pressure ulcer (PU) monitoring systems have been introduced across NHS in-patient facilities in England, including the Safety Thermometer (STh) (prevalence), Incident Reporting Systems (IRS) and the Strategic Executive Information System (STEIS) for serious incidents. This is the first of two related papers considering PU monitoring systems across NHS in-patient facilities in England and focusses on a Wound Audit (PUWA) to assess the accuracy of these systems. Part 2 of this work and recommendations are reported pp *-*.

The PUWA was undertaken in line with 'gold-standard' PU prevalence methods in a stratified random sample of NHS Trusts; 24/34 (72.7%) invited NHS Trusts participated, from which 121 randomly selected wards and 2239 patients agreed to participate.

Prevalence of existing PUs: The PUWA identified 160 (7.1%) patients with an existing PU, compared to 105 (4.7%) on STh. STh had a weighted sensitivity of 48.2% (95%CI 35.4%–56.7%) and weighted specificity of 99.0% (95%CI 98.99%–99.01%).

Existing/healed PUs: The PUWA identified 189 (8.4%) patients with an existing/healed PU compared to 135 (6.0%) on IRS. IRS had an unweighted sensitivity of 53.4% (95%CI 46.3%–60.4%) and unweighted specificity of 98.3% (95%CI 97.7%–98.8%). 83 patients had one or more potentially serious PU on PUWA and 8 (9.6%) of these patients were reported on STEIS.

Abbreviations: STh, Safety thermometer; STEIS, Strategic executive information system; SIs, Serious incidents; IRS, Incident reporting systems; PUWA, Pressure ulcer/wound audit; TVS, Tissue viability society; NHS, National health service; PU, Pressure ulcer; CQUIN, Commissioning for quality and innovation; NRLS, National reporting and learning system; CQC, Care quality commission; IAD, Incontinence associated dermatitis; POA, Present on admission; HA, Hospital acquired.

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The results identified high levels of under-reporting for all systems and highlighted data capture challenges, including the use of clinical staff to inform national monitoring systems and the completeness of clinical records for PUs.

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1. Introduction

In efforts to minimise patient harm in health-care systems the measurement of adverse events including pressure ulcers has been undertaken to assess the burden and scale of patient harm and attempt to measure improvement [1–7].

In line with international debate and policy, a number of initiatives have been introduced throughout the NHS in England to facilitate improved care quality and patient safety. They are set against changes to the NHS structure in England, which encompasses two main functions; the first is to commission health services which deliver high quality patient care and improved outcomes and the second is to provide this care [8]. Therefore both commissioners and care providers are important stakeholders for PU monitoring.

The importance of collecting and learning from patient safety incident data was highlighted by ‘An organisation with a memory’ [9] and subsequent implementation publication ‘Building a Safer NHS for patients’ [10], providing the impetus for the National Patient Safety Agency and the National Reporting and Learning System (NRLS) established in 2003 to encourage national reporting of patient safety incidents to facilitate widespread learning and establish priorities for patient safety [11]. Subsequently, an NHS Outcomes Framework was developed to provide national-level accountability for the delivery of outcomes and facilitate quality improvement and includes PUs [12], with operationalization through the Commissioning for Quality and Innovation (CQUIN) framework [13,14] with local target setting for the reduction of avoidable harm.

The policy initiatives have led to the development of data collection systems and quality metrics including: the Safety Thermometer (STh) [15] which includes assessing PU prevalence monthly; Incident Reporting Systems (IRS) to facilitate data reporting to the NRLS [11], and NHS England’s web-based serious incident management system, the Strategic Executive Information System (STEIS) for the reporting of serious incidents (SIs) [16].

The Quality Observatory is an organisation that was set up to enable local benchmarking and the development of metrics [17]. The STh is a nationally co-ordinated measurement tool to support

patient safety improvement in the NHS [15]. While it is a voluntary scheme it is incentivised via CQUINs and most NHS Trusts participate. Data collection is undertaken locally on one specific day of each month by front line nursing teams, for all NHS funded patients. Anonymous data is then uploaded to the national database, providing a point prevalence of existing PUs, which is presented as the percentage of all in-patients with a PU on the STh census date.

IRS’s, using software packages including Datix [18] and Ulysses [19] are locally held databases capturing patient identifiable reported incidents of harm including PUs. Most Trusts routinely upload anonymised IRS data to the NRLS on a monthly basis, though direct reporting to the NRLS can be undertaken [11]. Locally the actual reporting of incidents is encouraged to be undertaken as near to the time of the incident as possible. Incident monitoring data provides either a simple count of the number of PU incidents per month, a measure of the incidence of PUs as a proportion of the number of patients admitted to hospital in that month, or a measure of the number of PUs per 1000 bed days in that month. For SIs there are additional requirements, including reporting the incident to STEIS (without patient or staff names) the NRLS, the Care Quality Commission (CQC) and other bodies as appropriate [16].

There has been a number of difficulties in the definitions (Table 1) and implementation of quality metrics including:

- Interchangeable use of the terms prevalence, incidence and incidents despite their differences.
- Poor coding of pressure ulcers in healthcare records.
- Lack of clear national guidance for the reporting of pressure ulcers (e.g. type of ulcer to be reported, classification system to be used) which has led to inconsistent reporting across the country [20].
- The introduction of the terms ‘Old’ and ‘New’ pressure ulcers in the STh methodology, whereby pressure ulcers present within 72 of admission are classified as ‘Old’.

Table 1 Definitions of data collected on PU monitoring systems.

	Safety thermometer	Incident reporting system/strategic executive information system	Pressure ulcer and wound audit (PUWA)
Classification			
2	✓	As per local Trust policy	✓
3	✓	(see questionnaire results)	✓
4	✓		✓
Unstageable	X		✓
DTI	X		✓
Origin			
Present on admission (POA)	A pressure ulcer that was present when the patient came under your care, or developed within 72 h of admission to your organisation ^a	Recorded at the time of admission as per trusts local classification system ^c	Recorded in the patient's clinical record as category 2, 3, 4, U or DTI at the time of admission
Hospital Acquired (HA)	A pressure ulcer that developed 72 h or more after the patient was admitted to your organisation ^b	Not POA	A pressure ulcer which was not POA
Pressure ulcer data recorded			
Current pressure ulcers	For new and Old the classification of the worst pressure ulcer should be reported.	All data recorded for a patient during their current admission should be recorded, including all classifications of ulcers from all reports listed.	<ul style="list-style-type: none"> • 'Current category' recorded as the category of PU observed at the PUWA skin assessment • 'Worst category' recorded as the worst category^d reported in the patient's clinical records during this admission.
Healed pressure ulcers ^e	N/A		<ul style="list-style-type: none"> • 'Worst category' recorded as the worst category^d reported in the patient's clinical records during this admission.

^a This is the definition for a 'Old' ulcer on the Safety Thermometer.
^b This is the definition for a 'New' ulcer on the Safety Thermometer.
^c Questionnaire responses indicated that only 10 use on admission definition; 12 use within 72 h of admission.
^d Severity of classification from worst to best is 4, 3, Unstageable, DTI, 2.
^e Defined as complete re-epithelialisation in the absence of a scab including normal or erythematous skin.

- Concern regarding inappropriate interpretation and comparisons of data between NHS organisations [20].
- Concern regarding inappropriate interpretation of data by Commissioners in their assessment of Trust performance, with (in some cases) associated financial penalties [21].

The Tissue Viability Society (TVS), therefore agreed to fund a project, supported by the NHS England Safety Team to inform the development of

a standardised approach to pressure ulcer monitoring to underpin implementation of the NHS Outcomes Framework.

2. Aim

The project aimed to assess the accuracy of current PU monitoring systems, against a 'gold standard' Pressure Ulcer/Wound Audit (PUWA) and if appropriate, develop proposals for a standardised approach to PU monitoring. The project comprised

two related pieces of work 1) a PU/Wound Audit and 2) a survey of PU monitoring systems [22] (reported pp *-*). This paper reports the results of the PUWA.

3. Methods

NHS Trusts providing community, secondary and tertiary care in-patient services, who participate in STh data submissions to the Health and Social Care Information Centre (HSCIC), were identified through stratified random sampling. Stratification factors included: STh prevalence rates (i.e. normal range, high and low outliers as defined by the NHS Quality Observatory) taken from the May 2014 STh data; size of in-patient facility (≤ 468 beds, $468 < \text{beds} < 780$, ≥ 780 beds), and geographical location (north: North West, North East, Yorkshire and the Humber, East Midlands, West Midlands, south: South West, South East, London, East of England). The study was conducted on each Trusts STh census date in October 2014.

Assenting NHS Trusts provided a list of all wards and number of beds from which a range of specialities (excluding psychiatric, obstetrics, paediatrics and day case care environments) were randomly selected to participate.

Participating wards were given no prior warning that they would be audited using the PUWA. Following verbal confirmation by the ward that they had completed their STh submission, the nurse in charge was informed about the PUWA. Patients were informed that a national audit study was in progress to check the accuracy of nurses reporting of PUs, and that this involved a visual skin assessment of their pressure area skin sites and looking in their clinical records. They were reassured that their data would remain anonymous and their identity would not be disclosed in the course of the analysis or final report. As such, due to the nature of audits, ethical approval for this study was not required however, verbal consent for skin inspection was obtained in line with usual clinical procedures and care.

The PUWA was conducted using 'gold-standard' PU prevalence methods and included a full skin inspection of all consenting in-patients on the participating wards by two independent qualified clinical members of staff who were blind to the STh submission data. Skin was assessed using the full international PU classification [23], with additional skin status and wound descriptors including the wound type (surgical/traumatic/leg ulcer/dermatological/ischaemic/other) and ulcer type (PU/IAD/Device ulcer/DFU on heel/Combined

PU/IAD) with the origin and current and worst ulcer PU classification (during the current stay) if applicable. A record review was conducted to identify any healed wounds and PU(s) which had been present during their current hospital stay, in addition to the most severe category and the origin of any PUs. The PUWA data collection was designed to obtain data on existing and healed ulcers to use for the assessment of the accuracy of the STh, IRS and STEIS; further data on other wounds were also collected to explore the possibility of misclassification on the monitoring systems. The PUWA data was recorded in an audit booklet and then concealed using an adhesive seal before handing to a third nurse/auditor who then accessed the STh data returns and the IRS and STEIS databases and recorded all incidents reported for the patient's current admission. In order to ensure the correct STh, IRS and STEIS data was obtained, the patients hospital/NHS ID, Date of birth, initials and name of ward were recorded on the front of the booklet; these data were removed prior to transfer to Leeds Institute for Clinical Trials Research (LICTR) in order to maintain anonymity. The hospital name, ward speciality and admission date were also recorded on the booklet. The PUWA data collection was piloted prior to finalising the booklet to ensure it was usable and provided the relevant information for analysis. The assessors, were members of the Tissue Viability Team or ward based expert nurses and experienced in undertaking skin assessment and were given no additional training prior to the audit taking place.

The STh National methodology requires Trusts to record the worst Category of 'Old' and worst Category of 'New' existing PUs using the NPUAP/EPUAP 2009 [23] classification of Category 2–4. 'Old' is defined by the STh [15] as 'a pressure ulcer that was present when the patient came under your care, or developed within 72 h of admission to your organisation' and 'New' as 'a pressure that developed 72 h or more after the patient was admitted to your organisation'. The skin sites affected are not reported and only a maximum of 2 PUs (one per origin) per patient can be reported. Therefore the STh data collected as part of the audit included whether a pressure ulcer was reported on the STh October 2014 submission and, if so, the category for 'old' and/or 'new' ulcers.

The incident reporting systems (IRS and STEIS) were checked and the following data recorded from the patient's current admission: skin site, wound type, PU classification (category 2 or above), and whether the PU was present on

admission (POA). The incident reporting systems may include multiple reports for the same PU and the audit booklet was designed to collect this information.

3.1. Analysis

For all analyses, PUs included all reported ulcers classified as 'PU', 'combined PU/incontinence associated dermatitis (IAD)' or 'device ulcer'. Diabetic foot ulcers or other wounds (e.g. IAD, surgical) are referred to as 'other' wounds. Data summaries and comparisons of the STh data with the PUWA data included only existing PUs, in line with the STh reporting requirements. Data summaries and comparisons of IRS and STEIS data with the PUWA data included both current and healed PUs to reflect the incident data captured by these systems.

The sensitivity of the data source is defined as its ability to report that a PU is present when the patient is confirmed to have a PU via the PUWA data [24]. The specificity of the data source is defined as its ability to report that a PU is not present when the patient is confirmed to not have a PU via the PUWA data [24].

The sensitivity and specificity of the STh and IRS have been estimated in reference to the 'gold standard' PUWA. For the STh, weighted estimates of the sensitivity and specificity for current PUs were calculated using data provided by the NHS Quality Observatory from October 2014 to coincide with the date of the audit. The weighted sensitivity and specificity estimates provide a measure of the accuracy of the STh across the whole of the NHS in England taking into account the stratified sampling approach used and the corresponding likelihood of being reported on the STh submission in October 2014 within each stratum [25].

The estimate of the prevalence of category 2 and above PUs is weighted to take into account the proportion of beds within the corresponding combination of stratification factors from the total population, and the number of patients assessed within our sample for the same combination of stratification factors using October 2014 data provided by the Quality Observatory.

The IRS was assessed using unweighted estimates of the sensitivity and specificity for both current and healed pressure ulcers reported on PUWA. The reason that these estimates are unweighted is because pre-existing information about the probability of being recorded on the IRS is unavailable. Therefore the sensitivity and specificity estimates for the IRS represent the

sample observed in this study rather than across the whole of NHS in England.

3.2. Sample size

The audit sample size calculation is based on patient level data to ensure a direct comparison of the STh with the PUWA. A total of 2614 patients were required to estimate the sensitivity of the STh to within a precision of $\pm 7\%$ (corresponding to the half width of the 95% confidence interval), assuming a true prevalence of category 2 and above PUs of 6.3% [26], sensitivity of 70% (based on local audit work), and 5% significance level. As this is a point prevalence audit there was no requirement to adjust for loss to follow up.

It was acknowledged throughout analysis that data could not be verified with Trusts and, as such, only limited data validation was possible.

4. Results

4.1. PUWA

A total of 34 hospital NHS Trusts in England UK were invited to participate in the project and 24 (70.6%) agreed. From the participating Trusts 121 wards were randomly selected from a range of specialities with a total bed-base of 2468 beds, from which 2239 patients were fully assessed (Fig. 1). The number of patients fully assessed at each Trust ranged from 14 to 174. The length of stay for the current admission could be calculated for 2203 (98.4%) patients; the mean (s.d.) length of stay was 14.7 (22.13) days and ranged from 0 to 286 days with a median of 8 days.

There were 524 (23.4%) in-patients with an existing and/or healed PU or wound, including 154 (6.9%) patients with PU(s), 35 (1.6%) patients with both PU(s) and wound(s) and 335 (14.4%) with wound(s) only (Table 2). The weighted prevalence of existing PUs was 6.6% (95% CI 5.3%–8.0%).

4.2. Safety thermometer

There were 184 patients reported to have one or more existing PUs on the STh and/or PUWA (Fig. 2). The PUWA identified 160 (7.1%) and the STh data return identified 105 (4.7%) patients as having at least one existing pressure ulcer. Of those reported on the PUWA, half (81/160, (50.6%)) were reported on the STh. A further 24 patients identified by the STh as having a PU were not reported by the PUWA, including 10 patients reported as having an 'other'

wound and 14 patients assessed as having no PU or wound on the PUWA.

The weighted sensitivity estimate for the STh was 48.2% (95% CI 35.4%–56.7%) and the weighted specificity estimate was 99.0% (95% CI 99.0%–99.0%). That is, there is a weighted estimate that 48.2% of patients with an existing PU are correctly reported as having a PU and 99.0% of patients without an existing PU are correctly not reported on the STh submission.

Of the 184 patients reported to have one or more existing PU on the PUWA and/or the STh, 129 (70.1%) patients had a POA/'Old' PU and 67 (36.4%) had a HA/'New' PU reported. The levels of under-reporting were more than 44% for both POA (44.2%) and HA (52.2%) ulcers (Table 3). However, 45 (90%) patients with PUs reported as being POA by PUWA were also reported by STh as 'Old', whereas, 16 (64%) reported as having HA PU(s) on PUWA were reported by STh as 'New'. Under-reporting for all Categories of PU were also observed. However, where PUs are reported by both the PUWA and STh, there appears to be an accurate level of reporting of the category of PU in the STh, though numbers are small (Table 3).

4.3. Incident reporting system

A total of 223 patients were reported to have one or more existing/healed PU/incident reported on the PUWA and/or IRS (Fig. 3). The PUWA identified 189 (8.4%) and the IRS data return identified 135 (6.0%) patients as having at least one existing/healed/incident report of pressure ulcer. Of those reported on the PUWA, approximately half (101/189, 53.4%) were reported on the IRS, whilst 34 of the patients reported by IRS were not reported by

the PUWA including 11 patients reported as having an 'other' wound, and 23 assessed as having no existing or healed PU or wound. The number of reports listed for each skin site on the IRS ranged from 1 report to 3 reports.

The IRS has an unweighted sensitivity of 53.4% (95% CI 46.3%–60.4%) and an unweighted specificity of 98.3% (95% CI 97.7%–98.8%). That is, 53.4% of patients with an existing/healed PU were correctly reported on the IRS as having had a PU incident during that hospital admission and 98.3% of patients without an existing/healed PU were correctly not reported as having a PU on the IRS in the population sampled.

The 223 patients with a PU reported on PUWA and/or the IRS had a total of 330 skin sites with a PU reported, of which only 101 (30.6%) were reported on both data sources. There was a slightly higher proportion of under-reporting on IRS for HA PUs (68.0% (51/75)) compared to POA PUs (55.8% (87/156)), whilst there was a high accuracy of reporting for the origin (79.2% (80/101)) for PUs reported on the same skin site by both data sources.

There were high levels of under-reporting on IRS for all PU Categories (Table 4) (67.7% (90/133) Category 2, 45.3% (29/64) Category 3, 60.0% (12/20) Category 4, 43.8% (7/16) Unstageable, 63.6% (7/11) DTI). However, further investigation indicated that where PUs were reported on the same skin site by both data sources (N = 101), there was accurate reporting of category 2–4 PUs recorded on the IRS (83.7% (36/43) Category 2, 60.0% (21/35) Category 3, 75.0% (6/8) Category 4).

Further consideration was given to misclassification of wound types (Table 5). A total of 555 patients had a reported PU or wound on PUWA

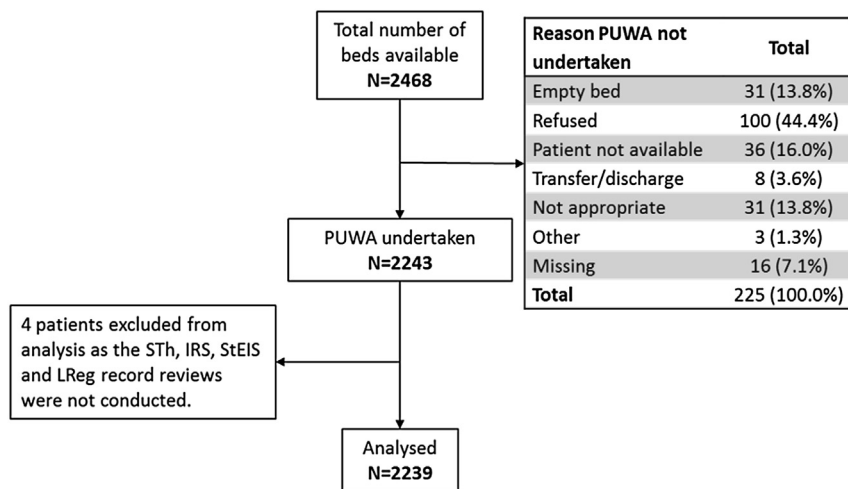


Fig. 1 Participant flow.

Table 2 Data reported on pressure ulcer and wound audit.

Speciality	Total	
Medical	813 (36.3%)	
Surgical	518 (23.1%)	
Rehabilitation/intermediate care	186 (8.3%)	
Orthopaedics and trauma	195 (8.7%)	
Oncology	113 (5.0%)	
Critical care	28 (1.3%)	
Specialist tertiary service	98 (4.4%)	
Cardiology	13 (0.6%)	
Emergency	2 (0.1%)	
Gynaecology	19 (0.8%)	
Haematology	11 (0.5%)	
Spinal Injuries	19 (0.8%)	
Urology	18 (0.8%)	
Other	172 (7.7%)	
Missing	34 (1.5%)	
Total	2239 (100.0%)	
	Existing and/or healed	Existing
Number of patients with PUs	189 (8.4%)	160 (7.1%)
Number of patients with PU and/or wound		
PU(s) only	154 (6.9%)	135 (6.0%)
PU(s) and Wound(s)	35 (1.6%)	25 (1.1%)
Wound(s) only	335 (15.0%)	302 (13.5%)
None reported	1715 (76.6%)	1777 (79.4%)
Number of patients with IAD	110 (4.9%)	91 (4.1%)
Total number of pressure ulcers	250	207
Mean (SD)	1.3 (0.65)	1.3 (0.66)
Median (Range)	1.0 (1.0, 5.0)	1.0 (1.0, 5.0)
Types of pressure ulcers		
PU	225 (53.2%)	187 (90.3%)
Combined PU/IAD	11 (4.4%)	11 (5.3%)
Device Ulcer	14 (5.6%)	9 (4.3%)
Categories of ulcers		
Category 2	133 (53.2%)	105 (50.7%)
Category 3	64 (25.6%)	56 (27.1%)
Category 4	20 (8.0%)	18 (8.7%)
Unstageable	16 (6.4%)	15 (7.2%)
DTI	11 (4.4%)	11 (5.3%)
Missing	6 (2.4%)	2 (1.0%)
Total number of wounds	462	405
Mean (SD)	1.2 (0.56)	1.2 (0.55)
Median (Range)	1.0 (1.0, 6.0)	1.0 (1.0, 5.0)
Types of wounds on 'pressure areas'		
Surgical wound	177 (38.3%)	161 (39.8%)
Traumatic wound	59 (12.8%)	48 (11.9%)
Leg ulcer wound	11 (2.4%)	11 (2.7%)
Dermatological wound	40 (8.7%)	40 (9.9%)
Ischemic wound	2 (0.4%)	2 (0.5%)
IAD	141 (30.5%)	117 (28.9%)
DFU on heel	7 (1.5%)	7 (1.7%)
Other wound	10 (2.2%)	4 (1.0%)
Missing	15 (3.2%)	15 (3.7%)

PU = Pressure ulcer, IAD = Incontinence associated dermatitis, SD = Standard deviation, DTI = Deep tissue injury, DFU = Diabetic foot ulcer.

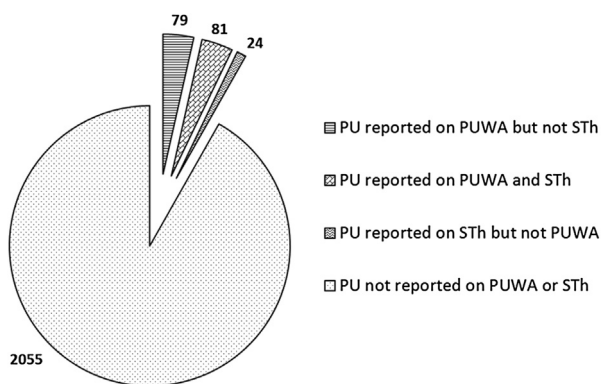


Fig. 2 PU reporting on PUWA and STh (PUWA = Pressure ulcer and wound audit; STh = Safety thermometer).

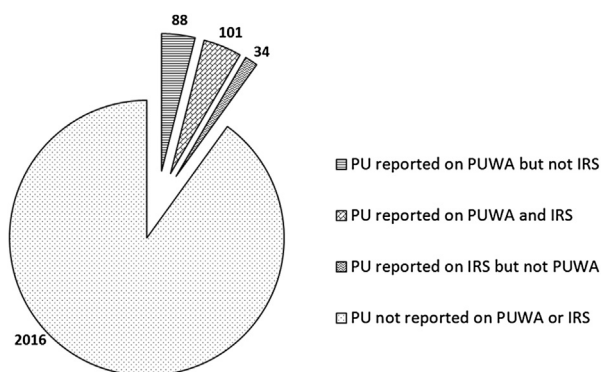


Fig. 3 Data reported on PUWA and IRS (PUWA = Pressure ulcer and wound audit; IRS = Incident reporting system).

and/or IRS, with a total of 810 PUs/wounds. There were greater levels of under-reporting on the IRS for IAD (91.5% (129/141)) and device ulcers (78.6% (11/14)) compared to PUs (56.9% (128/225)) and combined PU/IADs (63.6% (7/11)). It is also noteworthy that the PUWA did not identify 39.5% (64/

162) of PUs and 75.8% (25/33) of IADs reported on the IRS at the corresponding skin site.

4.4. STEIS

Of the 2239 patients assessed as part of the PUWA, 83 had one or more potentially serious incident recorded on the PUWA (defined as a PU classified as category 3, 4, Unstageable or DTI). This included 59 patients with a potentially serious incident POA, 19 with HA, 1 with both POA and HA and 4 where the origin was missing according to PUWA. Of these 83 patients 8 (9.6%) patients were reported on STEIS, including 1 POA, 6 HA and 1 missing (origin as reported on STEIS). In addition, 2 patients with a Category 2 PU and 1 patient with no PU or wound identified on PUWA had an incident reported on STEIS. The maximum number of reports listed for each skin site on STEIS was 1. The low levels of under-reporting to STEIS for all categories of PU are illustrated in Table 6.

5. Discussion

The results of the PUWA add to the wider international debate relating to the use of adverse event metrics data to assess improvement in patient safety and reductions in patient harms. The safety and harm/adverse event literature has previously assessed the level of agreement between raters and shown high levels of agreement in the identification of adverse events (such as medication errors, healthcare-acquired infections, postoperative complications, delayed diagnoses, fall-related injuries, pressure ulcers, etc) from records, but poor reliability in the attribution of the adverse event as preventable and non-preventable [27–32]. Researchers also report difficulty in the interpretation of adverse event data

Table 3 Under reporting and agreement in classification of PUs for the STh vs PUWA.

Category	N (%) not reported on STh		N (%) where ulcer classification agrees (for patients reported on both PUWA and STh)	
	POA	HA	POA	HA
2	28 (53.8%)	24 (72.7%)	20 (83.3%)	7 (77.8%)
3	14 (60.9%)	3 (37.5%)	4 (44.4%)	3 (60.0%)
4	4 (30.8%)	1 (50.0%)	5 (55.6%)	1 (100.0%)
Unstageable	6 (66.7%)	1 (100.0%)	0 (0.0%)	–
DTI	3 (75.0%)	4 (66.7%)	–	–
Category missing	2 (100.0%)	2 (100.0%)	–	–
Total	57 (44.2%)	35 (52.2%)	29 (63.0%)	11 (64.7%)

PU = Pressure ulcer, STh = Safety thermometer, PUWA = Pressure ulcer and wound audit, POA = Present on admission, HA = Hospital acquired, DTI = Deep tissue injury.

Table 4 Categories of pressure ulcer reported on the PUWA and IRS.

	PUWA						DTI	Category Missing	No PU reported	Total
	Category 2	Category 3	Category 4	Unstageable	DTI	Category Missing				
IRS	Category 2 36 (27.1%)	9 (14.1%)	0 (0.0%)	3 (18.8%)	0 (0.0%)	1 (16.7%)	53 (66.3%)	102 (30.9%)		
	Category 3 4 (3.0%)	21 (32.8%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	11 (13.8%)	38 (11.5%)		
	Category 4 1 (0.8%)	1 (1.6%)	6 (30.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (5.0%)	12 (3.6%)		
	Unstageable 0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (25.0%)	3 (27.3%)	0 (0.0%)	5 (6.3%)	12 (3.6%)		
	DTI 0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	1 (1.3%)	2 (0.6%)		
	Category Missing 2 (1.5%)	4 (6.3%)	1 (5.0%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	6 (7.5%)	15 (4.5%)		
	No PU reported 90 (67.7%)	29 (45.3%)	12 (60.0%)	7 (43.8%)	7 (63.6%)	4 (66.7%)	0 (0.0%)	149 (45.2%)		
	Total 133 (100.0%)	64 (100.0%)	20 (100.0%)	16 (100.0%)	11 (100.0%)	6 (100.0%)	80 (100.0%)	330 (100.0%)		

The shaded cells correspond to agreement whilst the bold cells correspond to under-reporting. PU = Pressure ulcer, IRS = Incident reporting system, PUWA = Pressure ulcer and wound audit, DTI = Deep tissue injury.

in terms of changes (or not) over time [1–7] and it has been suggested that studies need to capture specific adverse events that measure the impact of implemented interventions, rather than continuing to rely on broad heterogeneous measures such as adverse events [1].

There is also a wider political agenda to utilise routine clinical data to support improvements in healthcare provision and in healthcare research including clinical trials and quality improvement [33,34]. The policy driver is to maximise the potential use of available data for patient benefit [35] and improve research efficiency and reduce the costs of data capture for research and quality improvement. However, in order to use routine clinical data we need to consider data quality including the completeness and accuracy of the data and their impact on the findings of the research [34]. We need to understand the level of under-reporting in the clinical records, the level of under-recording of clinical coders and the reliability of the data (for example, diagnostic accuracy and classification of disease). Accurate retrieval of adverse events from healthcare records has been explored [1], however there is a question around whether adverse events such as PUs are actually recorded in healthcare records. Our research suggests that the reporting by clinical staff of PU events, including severe PUs, to monitoring systems is not complete and further research is required to understand whether there are similar issues with the level of under reporting in the clinical records.

The results of the PUWA highlight a number of issues important to the challenges of data capture using clinical staff to inform monitoring systems and the completeness of clinical records for one adverse event, pressure ulcers. The results from the PUWA indicate high levels of under reporting of PUs across all existing routine monitoring NHS systems in England including STh, IRS and STEIS at both the patient and skin site level as well as failings in the clinical records. At the patient level, high levels of under-reporting were observed, whereby the PUWA identified patients with PUs not reported on the monitoring systems illustrated by the corresponding estimates of sensitivity. The corresponding estimates of specificity were high, although this is reflecting the nature of specificity as its value depends on the low probability of being reported on the monitoring systems together with the large number of patients confirmed not to have a PU on PUWA [24,36]. It is noteworthy that a clinically significant minority of patients reported on the STh and IRS monitoring systems as having a PU harm were not identified by the PUWA audit

Table 5 Types of wounds reported on the PUWA and IRS.

		PUWA						Total	
		PU	Combined PU/IAD	Device ulcer	IAD	Other wound type*	Ulcer/ wound type Missing	No PU/wound reported	
IRS	PU	89 (39.6%)	3 (27.3%)	1 (7.1%)	5 (3.5%)	0 (0.0%)	0 (0.0%)	64 (65.3%)	162 (20.0%)
	Combined PU/IAD	3 (1.3%)	1 (9.1%)	0 (0.0%)	2 (1.4%)	0 (0.0%)	0 (0.0%)	3 (3.1%)	9 (1.1%)
	Device ulcer	2 (0.9%)	0 (0.0%)	2 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (6.1%)	10 (1.2%)
	IAD	3 (1.3%)	0 (0.0%)	0 (0.0%)	5 (3.5%)	0 (0.0%)	0 (0.0%)	25 (25.5%)	33 (4.1%)
	Ulcer/ wound type missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
	No PU/ wound reported	128 (56.9%)	7 (63.6%)	11 (78.6%)	129 (91.5%)	305 (99.7%)	15 (100.0%)	0 (0.0%)	595 (73.5%)
Total		225 (100.0%)	11 (100.0%)	14 (100.0%)	141 (100.0%)	306 (100.0%)	15 (100.0%)	98 (100.0%)	810 (100.0%)

The shaded cells correspond to agreement whilst the bold cells correspond to under-reporting.

PU = Pressure ulcer, IRS = Incident reporting system, PUWA = Pressure ulcer and wound audit, IAD = Incontinence associated dermatitis.

team. This is of particular concern for the IRS data where 34/135 (25.2%) patients reported as having an ulcer on the IRS were not reported (existing or healed) on the PUWA. This suggests difficulties in identifying pressure ulcer harm from the clinical record and that the submission of an incident report to the IRS is not readily identifiable in the patient record.

There were high levels of under-reporting for all categories of PUs at the skin site level; particularly category 2 PUs. Given the superficial nature of these ulcers, poor recording in clinical records, the potential time delay for the reporting and recording on the monitoring systems and the statistical analysis at skin site level which required both data sources to record the PU at the same skin site, some differences were expected, though not to the extent observed.

The high level of under-reporting of severe, category 3 and 4 ulcers raises concerns on a number of levels. Such ulcers are a serious patient harm, and the lack of awareness of the presence of such harm suggests that local intelligence gathering, handover reports and clinical records do not provide readily available, accurate and accessible information about patient status to the attending clinical team or specialist teams undertaking surveillance of PU harms. This is consistent with research which identified deficits in patient to staff and staff to staff communication of PU status

[37]. Furthermore, the levels of under-reporting on STEIS is not in line with previous suggestions that the majority of organisations report category 3 and 4 ulcers as SIs [20].

The level of under-reporting of IAD and device ulcers on IRS was higher compared to PUs, though the number of device ulcers was small. The proportion of device ulcers reported in the PUWA was smaller than those reported in a previous American study involving an acute medical centre population where device ulcers accounted for 34.5% (39/113) of HA PUs [38]. This can be explained by the inclusion of different patient populations and the inclusion of stage 1 ulcers which accounted for over a third of the device ulcers reported by Black et al. [38].

It is reassuring that where the PUWA and monitoring systems agreed on the presence of a PU, good levels of accuracy of reporting were observed for both the origin (i.e. 'Old'/'New' and POA/HA) of the ulcer and its category. This is consistent with studies of PU classification which demonstrate good inter-rater reliability for the EPUAP (1989), NPUAP (1989) and the NPUAP/EPUAP (2009) classification systems [39]. There were slightly more misclassifications in terms of origin for HA ulcers, potentially reflecting differences in the POA/HA, 'Old'/'New' definitions.

To our knowledge this is the first study to compare national PU monitoring systems. While

Table 6 Patients reported to STEIS by worst category reported on PUWA.

Reported on STEIS	PUWA – worst category							Total
	Category 2	Category 3	Category 4	Unstageable	DTI	Missing	None reported	
Yes	2 (2.0%)	3 (6.8%)	1 (5.3%)	1 (7.7%)	3 (42.9%)	0 (0.0%)	1 (0.0%)	11 (0.5%)
No	100 (98.0%)	41 (93.2%)	18 (94.7%)	12 (92.3%)	4 (57.1%)	4 (100.0%)	2049 (100.0%)	2228 (99.5%)
Total	102 (100.0%)	44 (100.0%)	19 (100.0%)	13 (100.0%)	7 (100.0%)	4 (100.0%)	2050 (100.0%)	2239 (100.0%)

PU = Pressure ulcer, STEIS = Strategic executive information system, PUWA = Pressure ulcer and wound audit, DTI = Deep tissue injury.

the PU prevalence is lower than those reported in previous studies (Pieper 2012) this can be explained by the exclusion of category 1 ulcers; the results are consistent with a recent multi-centre prevalence study undertaken in UK NHS hospitals, which observed a prevalence of 6.3% for category 2 and above ulcers [26,40]. The findings from this part 1 PUWA were considered alongside the part 2 survey of PU monitoring systems (pp *-*) and recommendations were developed and are highlighted in the part 2 publication [22].

A methodology strength is the blinding of those undertaking the PUWA to those obtaining STh, IRS and STEIS information and vice-versa. This required detailed planning and commitment from sufficient numbers of staff with appropriate experience to ensure data collection was accurately undertaken on the STh census day. Even with teams of three (2 conducting PUWA and 1 conducting review of STh, IRS, STEIS data sources) undertaking data collection, it is acknowledged that a fourth independent member of each team would have been advantageous to conduct cross referencing between data sources. This is particularly important given that the PUWA did not identify a clinically important number of PUs (N = 64, 65.3%) and some IADs (N = 25, 25.5%) that were reported on the IRS. There are a number of possible reasons for this including discrepancies between skin sites identified (e.g. right heel identified at PUWA and left heel recorded on IRS); other recording errors (e.g. recording IRS data on incorrect patient PUWA form, though 3 identifiers were used), or difficulties in identifying incident reports made to IRS in the patients clinical record.

Another methodological strength is the inclusion of data relating to patient refusal rates, which are not routinely reported in other prevalence studies. The majority of refusals occurred in 1 Trust which could be related to a lack of experience in undertaking this type of work. These findings could inform the approach used in future studies.

6. Conclusion

Using a robust methodological approach we undertook a PUWA in a stratified random sample of 24 NHS Trusts providing in-patient services for adult patient populations in England to compare current data sources including in-patient STh prevalence data, and incident reporting to the IRS and STEIS. The key finding was high levels of under-reporting for all categories of PUs across all monitoring systems. The results add to the wider international debate relating to the use of adverse event metrics

data to assess improvement in patient safety and reductions in patient harms, highlighting a number of issues including the use of clinical staff to inform national monitoring systems and the completeness of clinical records for case finding of adverse events. Recommendations were developed from this and the complimentary survey of PU monitoring systems and are highlighted in the part 2 publication [22] (reported pp *-*)).

Conflict of interest statement

No conflict of interest has been declared by the author(s).

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References

- [1] Shojania KG, Marang-van de Mheen PJ. Temporal trends in patient safety in the Netherlands: reductions in preventable adverse events or the end of adverse events as a useful metric? *BMJ Qual Saf* 2015 [online first].
- [2] Baines R, Langelaan M, de Bruijne M, Spreeuwenberg P, Wagner C. How effective are patient safety initiatives? A retrospective patient record review study of changes to patient safety over time. *BMJ Qual Saf* 2015;24(9): 561–71.
- [3] Vincent C, Amalberti R. Safety in healthcare is a moving target. *BMJ Qual Saf* 2015 [online first].
- [4] Baines RJ, Langelaan M, de Bruijne MC, Asscheman H, Spreeuwenberg P, van de Steeg L, et al. Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ Qual Saf* 2013; 22(4):290–8.
- [5] Shojania KG, Thomas EJ. Trends in adverse events over time: why are we not improving? *BMJ Qual Saf* 2013;22(4): 273–7.
- [6] Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med* 2010; 363(22):2124–34.
- [7] Tanner J, Padley W, Kiernan M, Leaper D, Norrie P, Baggott R. A benchmark too far: findings from a national survey of surgical site infection surveillance. *J Hosp Infect* 2013;83(2):87–91.
- [8] NHS-England. Understanding the new NHS. London: N. E. Medical Directorate; 2014.
- [9] DH. An organisation with a memory. DH. Norwich: Stationary Office; 2000.
- [10] DH, Building a safer NHS for patients: implementing an organisation with a memory, DH. London: Department of Health.
- [11] NPSA. Seven steps to patient safety: full reference guide. NPSA. London: NPSA; 2004.
- [12] DH. The NHS outcomes framework 2011/12. DH. London: Department of Health; 2010.
- [13] DH. Using the commissioning for quality and Innovation (CQUIN) payment framework for the NHS England. 2008. DH, London.
- [14] DH. Delivering the NHS safety thermometer CQUIN 2012/13; a preliminary guide to delivering 'Harm Free' care. Q. S. C. Team. London: Department of Health; 2012.
- [15] HSCIC. NHS safety thermometer: annual publication, patient harms and harm free care Engalnd. April 2012–March 2014, official statistics. H. a. S. C. I. Centre. HSCIC; 2014.
- [16] NHS-England. Serious incident framework. N. E. P. S. Domain, London. 2015.
- [17] Observatories, N.Q. Quality Observatories, <http://www.qualityobservatory.nhs.uk/> [accessed July 2015].
- [18] Datix. Datix: software for patient safety. 2015. <http://www.datix.co.uk/> [accessed 22.06.15]. Retrieved 22/06/2015.
- [19] Ulysses. Ulysses safeguard healthcare. 2015. <http://www.ulysses.co.uk/safeguard-healthcare/> [accessed 22.06.15]. Retrieved 22/06/2015.
- [20] Dealey C, Chambers T, Beldon P, Benbow M, Fletcher J, Fumaro S, et al. Achieving consensus in pressure ulcer reporting. *J Tissue Viability* 2012;21(3):72–83.
- [21] TVS. Pressure ulcer prevalence monitoring and interpretation of safety thermometer data a briefing paper for commissioners and NHS trusts. 2013. http://tvs.org.uk/wp-content/uploads/2013/05/TVS_PU_Prevalence_Measurement_Safety_Thermometer_Data_ Interpretation1.pdf.
- [22] Coleman S, Smith IL, Nixon J, Wilson L, Brown S. Pressure ulcer and wounds reporting in NHS hospitals in England part 2: survey of monitoring systems. *J Tissue Viability* 2016;25(1):16–25.
- [23] NPUAP/EPUAP. Prevention and treatment of pressure ulcers:clinical practice guideline. Washington DC: National Pressure Ulcer Advisory Panel; 2009.
- [24] Zhou XH, Obuchowski NA, McClish DK. Statistical methods in diagnostic medicine. Hoboken, NJ, USA: John Wiley & Sons, Inc; 2011.
- [25] Begg CB, Greenes RA. Assessment of diagnostic tests when disease verification is subject to selection bias. *Biometrics* 1983;39(1):207–15.
- [26] Briggs M, Collinson M, Wilson L, Rivers C, McGinnis E, Dealey C, et al. The prevalence of pain at pressure areas and pressure ulcers in hospitalised patients. *BMC Nurs* 2013;12(1): 19. <http://www.biomedcentral.com/1472-6955/12/19>.

- [27] Zegers M, de Bruijne MC, Wagner C, Hoonhout LH, Waaijman R, Smits M, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Health Care* 2009;18(4):297–302.
- [28] Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada. *CMAJ* 2004;170(11):1678–86.
- [29] Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S. Adverse events in New Zealand public hospitals I: occurrence and impact. *N Z Med J* 2002;115(1167):U271.
- [30] Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;322(7285):517–9.
- [31] Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 2000;38(3):261–71.
- [32] Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324(6):370–6.
- [33] Wyatt JC. The new NHS information strategy. 2012.
- [34] Cook JA, Collins GS. The rise of big clinical databases. *Br J Surg* 2015;102(2):E93–101.
- [35] DH. The power of information: putting all of us in control of the health and care information we need. D. o. Health. 2012.
- [36] Nixon J, Thorpe H, Barrow H, Phillips A, Andrea Nelson E, Mason SA, et al. Reliability of pressure ulcer classification and diagnosis. *J Adv Nurs* 2005;50(6):613–23.
- [37] Pinkney L, Nixon J, Wilson L, Coleman S, McGinnis E, Stubbs N, et al. Why do patients develop severe pressure ulcers? A retrospective case study. *BMJ Open* 2014;4(1). <http://bmjopen.bmj.com/content/4/1/e004303.full.pdf>.
- [38] Black JM, Cuddigan JE, Walko MA, Didier LA, Lander MJ, Kelpel MR. Medical device related pressure ulcers in hospitalized patients. *Int Wound J* 2010;7(5):358–65.
- [39] NICE. Pressure ulcer prevention: the prevention and management of pressure ulcers in primary and secondary care, Clinical Guideline 179, Methods, evidence and recommendations. National Clinical Guideline Centre; 2014.
- [40] Collinson M. PURPOSE prevalence statistical report: final analysis in the acute trust. CTRU, Leeds Institute of Clinical Trials Research, University of Leeds; 2013.