Assessing the accuracy of routinely collected data and their potential use in pressure ulcer trials

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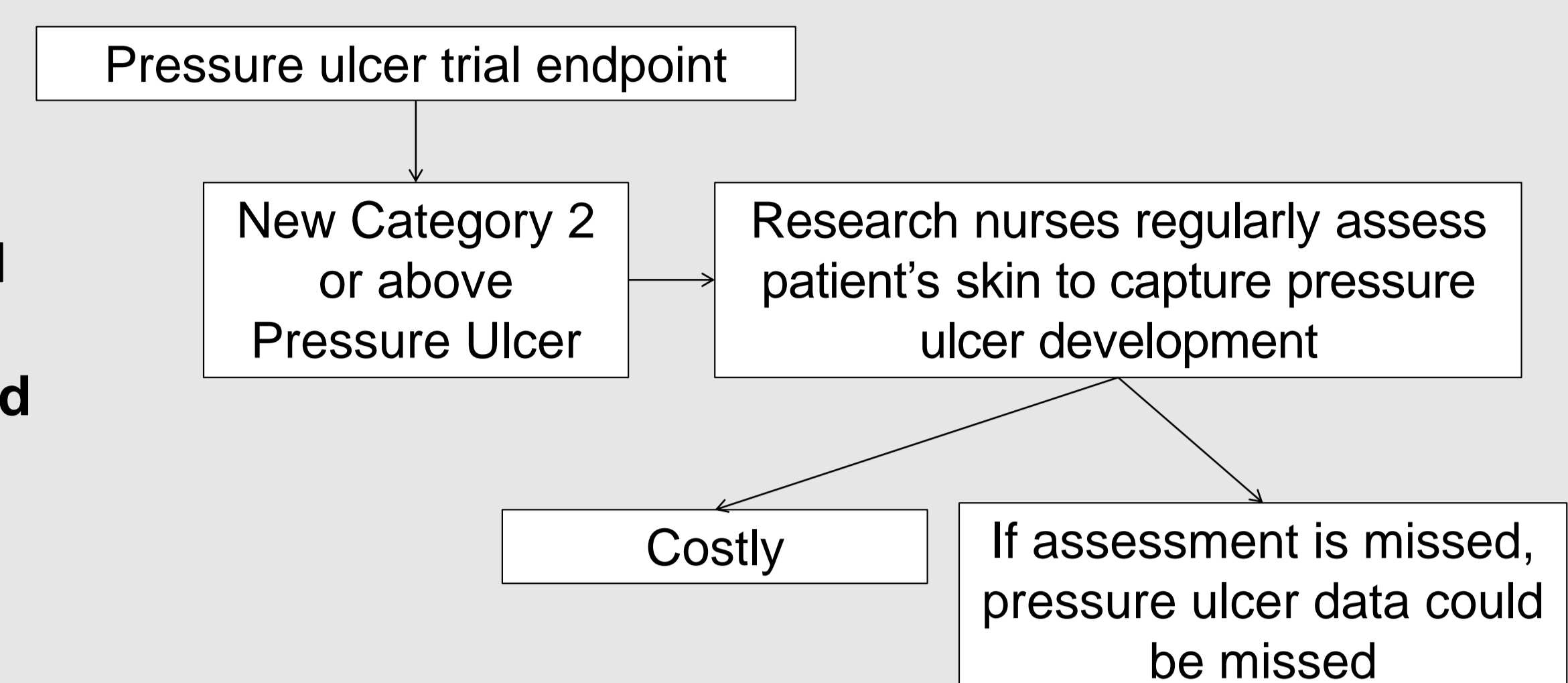
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Background

In the absence of electronic records, current adverse event (AE) reporting relies on staff reporting an AE to an electronic system; for pressure ulcer monitoring, systems have been introduced in the English NHS including;

- Safety Thermometer (STh)
- Incident Reporting Systems (IRS) (e.g. Datix/Ulysses)
- Strategic Executive Information System (STEIS) for the reporting of Serious Incidents Requiring Investigation (SIRI).

Wealth of routinely collected pressure ulcer data that could theoretically be utilised for pressure ulcer research.

Concerns about inconsistencies in the local implementation of these systems and over-interpretation of data, prompted the Tissue Viability Society (TVS) to fund a project, supported by NHS England, to assess the accuracy of pressure ulcer monitoring in England.

Pressure ulcer trial endpoint → New Category 2 or above Pressure Ulcer → Research nurses regularly assess patient's skin to capture pressure ulcer development → Costly / If assessment is missed, pressure ulcer data could be missed

Project Design

Gold Standard:
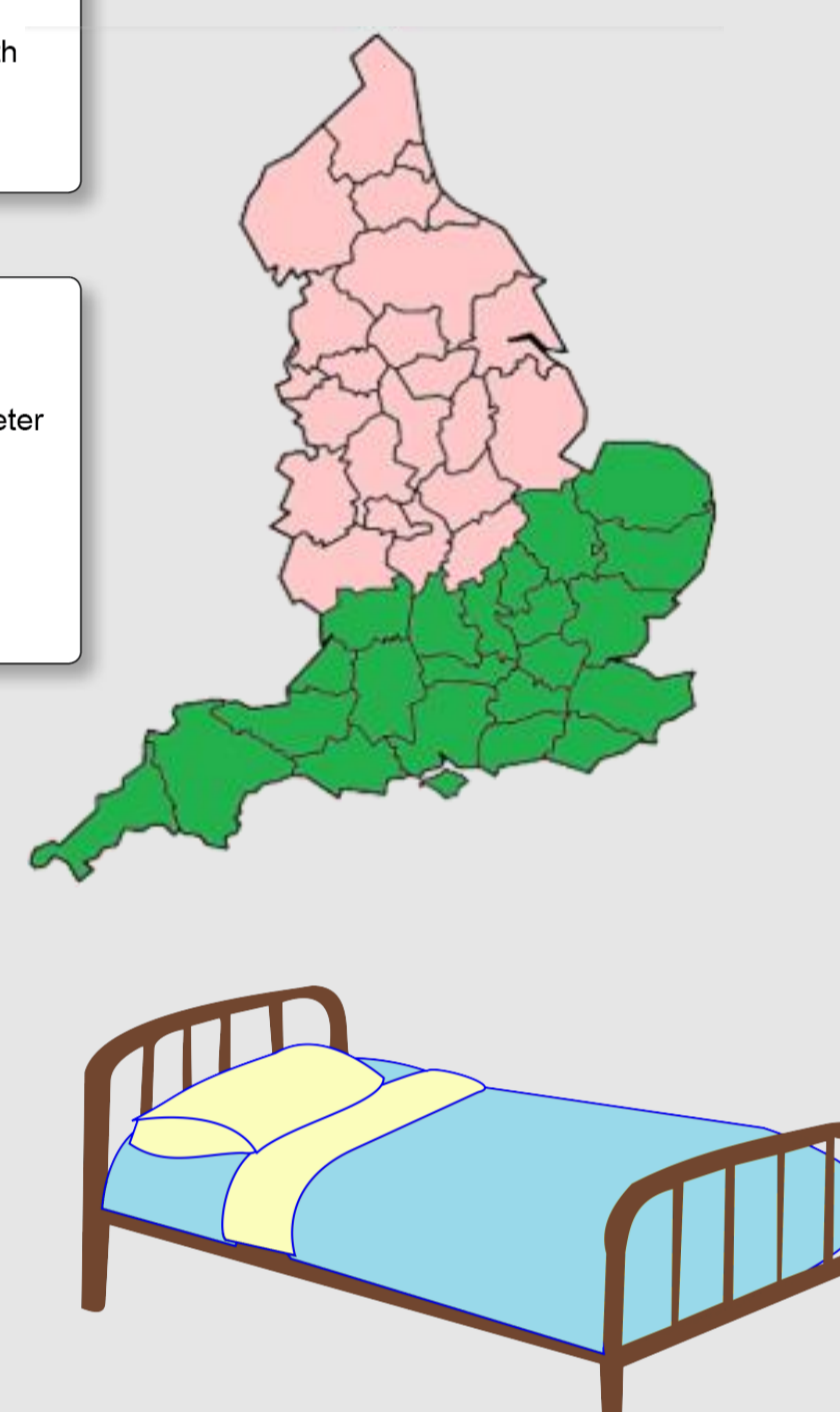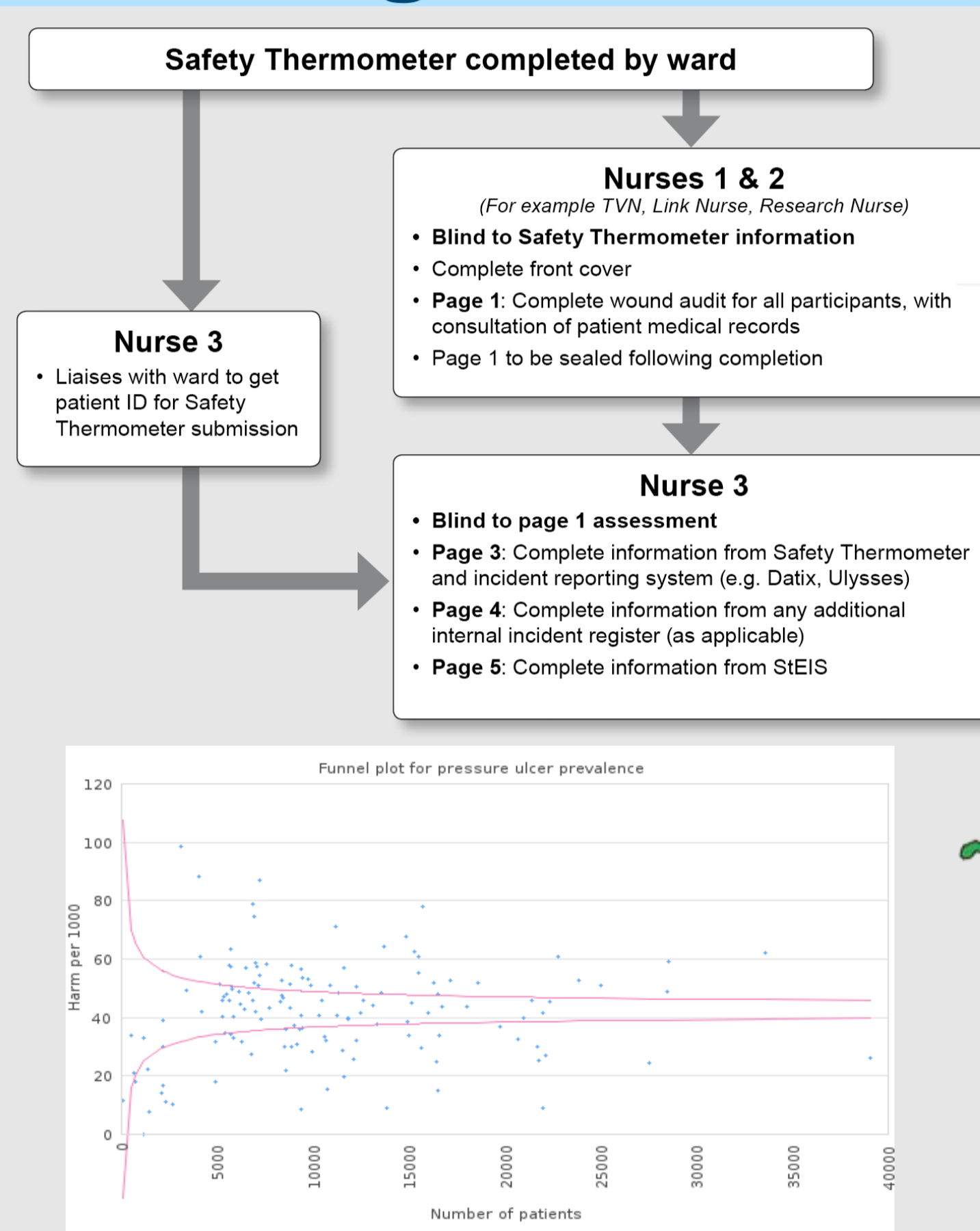Audit conducted in line with 'gold standard' pressure ulcer prevalence methods

Sample:
Stratified random sample of Trusts

Stratification factors:
- Geographical location (North/South)
- Size of Trust (Small/Medium/Large based on number of beds)
- STh Outlier status in May 2014 (Low outlier/Normal/High outlier)

A qualitative survey was also conducted to elicit information about local practice and implementation of monitoring systems

Safety Thermometer completed by ward

Nurses 1 & 2
(For example TVN, Link Nurse, Research Nurse)
- Blind to Safety Thermometer information
- Complete front cover
- Page 1: Complete wound audit for all participants, with consultation of patient medical records
- Page 1 to be sealed following completion

Nurse 3
- Liaises with ward to get patient ID for Safety Thermometer submission

Nurse 3
- Blind to page 1 assessment
- Page 3: Complete information from Safety Thermometer and incident reporting system (e.g. Datix, Ulysses)
- Page 4: Complete information from any additional internal incident register (as applicable)
- Page 5: Complete information from StEIS

Funnel plot for pressure ulcer prevalence

Sample size

Based on patient level data to ensure a direct comparison of the STh data with the audit data

Assumptions:
- Prevalence of Category 2 and above Pressure ulcers of 6.3% [1]
- Sensitivity of 70% based on local audit work in one Trust
- 5% significance level
- No drop out

Sample size of 2614 evaluable patients required to estimate STh submission sensitivity and specificty with 95% confidence intervals of widths +/- 7% and +/- 0.02%, respectively.

Analysis

Weighted sensitivity and specificity were estimated using Safety Thermometer data provided by NHS England. An example of the method for calculating sensitivity is provided here using Begg and Greene's paper [2]. Let

$$R = \begin{cases} 1, & \text{If on the Safety Thermometer} \\ 0, & \text{Otherwise} \end{cases}$$

$$D = \begin{cases} 1, & \text{If patient has a PU on the wound audit} \\ 0, & \text{Otherwise} \end{cases}$$

$$V = \begin{cases} 1, & \text{If patient was assessed in the TVS audit} \\ 0, & \text{Otherwise} \end{cases}$$

X = strata with the number of strata ranging from $i = 1$ to $i = 18$

Then for each strata, i, we have:

From stratified random sample			
	$D = 1$	$D = 0$	
$R = 1$	a_i	b_i	$a_i + b_i$
$R = 0$	c_i	d_i	$c_i + d_i$
	$a_i + c_i$	$b_i + d_i$	

From the NHS data (i.e. sampling frame)	
$R = 1$	e_i
$R = 0$	f_i
	$e_i + f_i$

Let $T = \sum_{i=1}^{18}(e_i + f_i)$.

Assuming that participant selection does not depend on disease status we have, from

Bayes Theorem: $Sensitivity = Pr(R = 1|D = 1) = \dfrac{\sum_{i=1}^{18}\left(\frac{e_i a_i}{a_i + b_i}\right)}{\sum_{i=1}^{18}\left[\left(\frac{e_i a_i}{a_i + b_i}\right) + \left(\frac{f_i c_i}{c_i + d_i}\right)\right]}$

Note that if our sample was the same as our entire sampling frame then $e_i = a_i + b_i$ and $f_i = c_i + d_i$ which reduces our sensitivity calculation down to $\dfrac{\sum_{i=1}^{18} a_i}{\sum_{i=1}^{18}(a_i + c_i)} = \dfrac{A}{A+C}$ (i.e. unweighted sensitivity)

The data provided by the NHS has the following structure:

Strata	Trust	PU prevalence (according to STh)	No. of beds
1	1	q_1	m_1
1	2	q_2	m_2
1	3	q_3	m_3
2	4	q_4	m_4
2	5	q_5	m_5
3	6	q_6	m_6
3	7	q_7	m_7

Therefore, for each strata, i, $e_i = \sum_j q_j m_j$ and $f_i = \sum_j (m_j - q_j m_j)$ where j corresponds to Trust.

Results

- Data was received for 2239 patients, from 24 NHS Trusts providing in-patient services for adult populations in England.
- Weighted prevalence of existing pressure ulcers was 6.6% (95% CI 5.3% to 8.0%)

Reporting System	Sensitivity (95% CI)	Specificity (95% CI)
STh (weighted estimates)	48.2% (35.4%-56.7%)	99.0% (99.0%-99.0%)
IRS (unweighted estimates)	53.4% (46.3% to 60.4%)	98.3% (97.7% to 98.8%)

- Of the 2239 patients 83 had one or more potentially serious pressure ulcer and 8 (9.6%) were reported on STEIS.

Discussion

Using a robust methodological approach we undertook an audit and survey to compare current data sources including in-patient STh data, IRS and STEIS. Two key findings were:

- High levels of under-reporting for all systems
- The adoption of different definitions and variation in data collection and validation processes which preclude Trust-to-Trust comparisons of pressure ulcer prevalence and incident rates.

This indicates that, at present, _current routine data sources for pressure ulcer monitoring are inadequate for identifying outcomes in pressure ulcer research_.

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 [3].

We did not assess the accuracy of individual patient level notes; further work is required to assess the reliability of hand written records and/or accuracy of electronic records when they are introduced more widely in the NHS

References

1. Briggs, M., et al., _The prevalence of pain at pressure areas and pressure ulcers in hospitalised patients_ http://www.biomedcentral.com/1472-6955/12/19. BMC Nurs, 2013. 12(1): p. 19.

2. Begg, C.B. and R.A. Greenes, _Assessment of diagnostic tests when disease verification is subject to selection bias._ Biometrics, 1983. 39(1): p. 207-15.

3. Shojania, K.G. and P.J. Marang-van de Mheen, _Temporal trends in patient safety in the Netherlands: reductions in preventable adverse events or the end of adverse events as a useful metric?_ BMJ Quality & Safety, 2015

Acknowledgements