Introduction

Pressure injuries/ulcers (PU) are complex wounds defined as localised damage to the skin and underlying soft tissue, usually over a bony prominence or related to a medical or other device. [1-3] Pressure damage can present as intact skin or an open ulcer and may be painful. The EPUAP, NPIAP and PPPIA state that such injuries can occur as a result of intense and/or prolonged pressure, or pressure in combination with shear, with the tolerance of soft tissue for pressure and shear being affected by microclimate, nutrition, perfusion, comorbidities and condition of the soft tissue. Gefen et al. [4] state that pressure, friction and shear cause tissue deformation, inflammatory oedema and ischaemia that, together, lead to pressure ulceration in bony anatomical sites such as the sacrum, ischium, trochanter and heel.

The burden caused by chronic wounds such as PUs is well established: Guest et al.[5] estimated the total cost of chronic wound management to the National Health Service (NHS) in England to be in excess of £530 million accounting for costs associated with wound dressings, staff visits, and hospitalization, as well as a profound effect on the quality of life of patients and their families. Prescription costs of advanced wound dressings and antimicrobial dressings in primary care in England has been reported to be almost £92 million in the year to July 2018 (based on British National Formulary).[6] (NICE, 2015).

Factors affecting PU incidence

Extant research has focussed on demonstrating clinical benefit of several variables that affect the risk of PU incidence. Bredesen et al. [7] used two cross-sectional data sets obtained from four hospitals in Norway and found that hospital acquired-PUs (HAPUs) were lowest in those hospitals with a strong patient-safety culture. Kayser et al. [8] examined the predictors of category 1 and 2, and more severe category 3, 4 deep tissue and unstageable PUs through a retrospective analysis of the International

Pressure Ulcer Prevalence data between 2011-2016 from a total of 216,626 patient datasets from acute hospitals in the USA. Whilst the prevalence of category 1 and 2 PUs showed an incidence reduction over the analysis period, incidence of more severe PUs remained static. Specific risk factors were also identified as having a greater impact on the development of severe PU; including: hospital stay in the intensive care unit (ICU), ostomies, ambulatory status and faecal management systems. The authors suggested that current strategies for PU may not be adequate to manage those ulcers that are more severe, i.e. category 3 and 4. The subjective variability that is possible from traditional nurse-reported assessment tools to predict PU means that the combination of specific patient-level factors can greatly influence the resulting risk score. Stratifying risk through models that utilise patient electronic records data has the potential to mitigate this variance, providing an objective measure of PU risk. Modelling techniques have been used across a wide range of health care services to predict, estimate and support health care provision and planning; for example, in the prediction of cases of re-hospitalisation, [9] the likelihood of admission to mental health services, [10] and the risk of cardiovascular disease. [11] For PU in particular, modelling techniques present a proactive approach to prevention, informing risk assessment and subsequent clinical decision making. Cramer et al. [12] used an electronic health records based model to predict the incidence of PU in the ICU using data from 50,851 patient admissions to the ICU of Beth Israel Deaconess Medical Center in the USA and found that the model was superior to commonly used scoring systems such as the Braden score as a screening tool for predicting PUs, suggesting machine-learning algorithms are a promising method of identifying those patients most at risk, enabling the adoption of timely interventions to reduce their severity.

Any short- or long-term effects of interventions may in some cases be inferred from direct inspection of data trends. However, changes in responses to specific interventions may be transient, and easily masked by greater underlying seasonality effects, such as fluctuations in number of patients admitted during different months of the year.

PU incidence and recording in Taunton and Somerset

Taunton and Somerset NHS Foundation Trust provides acute health services for a local population of around 340,000 people in a rural area in the South West of England, UK. The trust population includes a higher proportion of residents over 65 years than the national average, and life expectancy is higher than the national average. However, about one in seven children within the Trust catchment area live in low-income families, and one in eight households within the Trust catchment area live in fuel poverty, [13] defined as the necessity to assign in excess of 10% of total household income on heating the home to an adequate level. [14]

The Trust has recorded monthly incidence data of first observations of episode of care PU (category 2 or above) during an episode of care over a 10-year period from 2010; measured as outcomes as part of a quality assurance and improvement audit. In all NHS Trusts, patient safety strategy one of the key principles for effective safety measurement; hence incident reporting is not a measure of actual harm because of its relationship with safety culture. Within the UK all Trusts report category 3 and 4 pressure ulcers, some Trusts also report category 2 PUs. There is always a potential risk of under-reporting when staff are busy or inexperienced.

Interventions implemented by the Trust to reduce incidence during this period were also recorded. Reports are validated by a tissue viability team to ensure accuracy of reporting, as well as to confirm root causes, ensure that the patient was receiving correct care, support with duty of candour, and to ensure that duplicate reports for the same patient were not included.

Data is publicly available in Trust board papers and quality accounts, and local permissions to analyze the data have been obtained.

The aims of this study were:

- To investigate the historical pattern of incidence of episode of care PU in an acute inpatient Trust to increase understanding of the effectiveness of interventions such as procurement of specialized staff and equipment in reducing the incidence rate of PU in patients.

- To use historical data to provide a range for estimates of future incidences.

The following objectives were pursued to achieve these aims:

- To conduct a time-series analysis of smoothed historical PU incidence data to model underlying trends, seasonality effects and the effect of specific interventions

- To investigate series auto-correlation and hence establish a suitable model to derive best estimate future predictions of PU incidence, within an appropriate range of uncertainty.

It is anticipated that the outcomes will be incorporated into the national strategies for benchmarking.

Methods

Observations of category 2 or above (including deep tissue and unstageable) PUs during an episode of care at Taunton and Somerset NHS Foundation Trust were recorded using incident reports from April 2010 to May 2020 inclusive. These reports were used to generate monthly frequencies in all months of the analysis period. Moisture lesions were not included in the count of PU-incidence. Some mucosal injuries were included within the count up to February 2016; however, all such injuries were identified and removed from the data set for the purposes of the current analysis. No patient demographic or health-related data was recorded in this process.

Over the period of analysis, several interventions were implemented which were identified by Trust staff as having the potential to affect incidence rates:

- An increase of 30 hours in specialist nursing support in 2013.

- An investment of 20 pressure re-distributing mattresses and cushions was recorded in December 2015.

- A new full-time specialist tissue viability nurse was employed by the Trust in July 2017.

- A non-mandated online teaching programme to improve prevention rates and identify patients at risk of pressure damage was introduced in 2017; aimed at medical and allied health professionals. However, uptake to this programme was very low, particularly among medical staff.

- A second investment of pressure re-distributing devices (12 turning mattresses) was recorded in April 2018.

Incidence data was represented graphically over the analysis period. Where possible, documented interventions were associated with features in the incidence plot. Time series analysis was conducted on the data to identify and quantify any trends, seasonality or cyclical behaviour, to assess the effect of any interventions implemented during the analysis period; and to specify an appropriate model to predict future observations within confidence limits, by recourse to identification of the extent of autocorrelation within the sequence. The predictive model was an exponentially smoothed model specified from by assessment of the extent of autocorrelation within the series. The fit of the model against extant data was assessed using the R^2 statistic, and used for generation of best estimate predictions with associated 95% confidence limits.

Results

Monthly recorded PU incidence over the period of data collection (April 2010 to May 2020) ranged from 2 to 32 events per month, with a mean monthly frequency of 12.3 (SD 6.60) incidents. The year with the highest mean monthly frequency was reported in 2012 (20.3 incidents per month); and the year with the lowest mean monthly frequency was reported in 2019 (5.08 incidents per month); excluding 2020, for which incomplete data was available at the time of analysis. The monthly average

of all years from 2010 to 2015 was over 10 incidents recorded; the monthly average of all years from 2016 onwards was less than 10 incidents recorded.

PU incidence over the period of data collection was plotted. The plot of the data suggested a linear negative trend with a gradient of -0.0046; i.e. a mean reduction of 0.0046 incidents per month, or 0.055 incidents per year. The plot also indicated some evidence for cyclic, and possibly seasonal behaviour; however, peaks and troughs did not occur at exactly consistent months of the year. Excessive noise was also observed in the data, partially masking any latent effect of the interventions implemented (Figure 1), and reflected by a moderate R^2 value of 0.545 for the trend. A notable value was the value of 13 pressure injuries/ulcers observed during November 2019; outside of expectations arising from the general trend. This point was not aligned with any specific intervention implementation.

Figure 1: Observations of pressure injuries/ulcers (raw frequencies) with fitted linear trend line
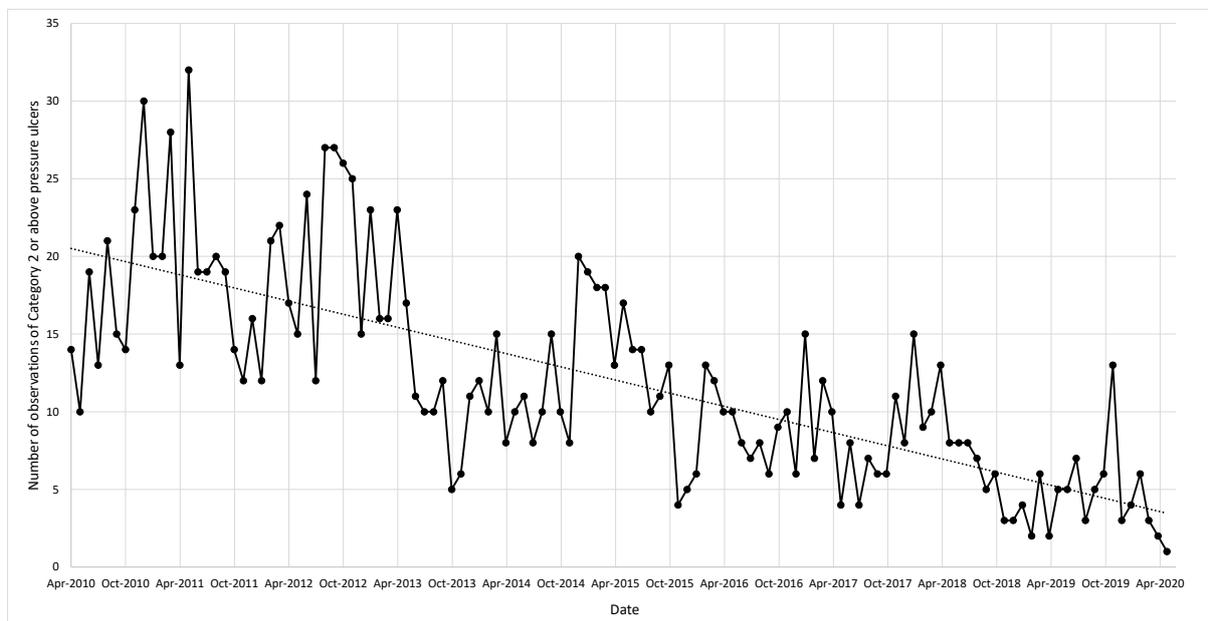
Smoothed data using 5-point moving averages removed much of the noise and stressed the linear trend, which had a similar gradient to the unsmoothed data (-0.0048 incidents per month) but was a considerably better fit to the data (R^2=0.743). A degree of seasonality, which had been less visible in

the unsmoothed plot, was apparent in the smoothed plot, with the majority of localised peak values

occurring in late autumn, winter and early spring (between October and April); consistent with

observations of staff regarding the number and nature of patients admitted during these months.

However, no precise seasonality in the cyclic behaviour was revealed (Figure 2). Outlying values such

as the November 2019 reading were less prominent in the smoothed plot. The documented

interventions implemented between 2013 and 2018 appeared associated with continuous reductions

in incidence, following a near-static period between 2010 and 2013 before which any interventions

designed to reduce PU incidence were implemented.

Figure 2: Observations of pressure injuries/ulcers (5-point moving average) with trend line
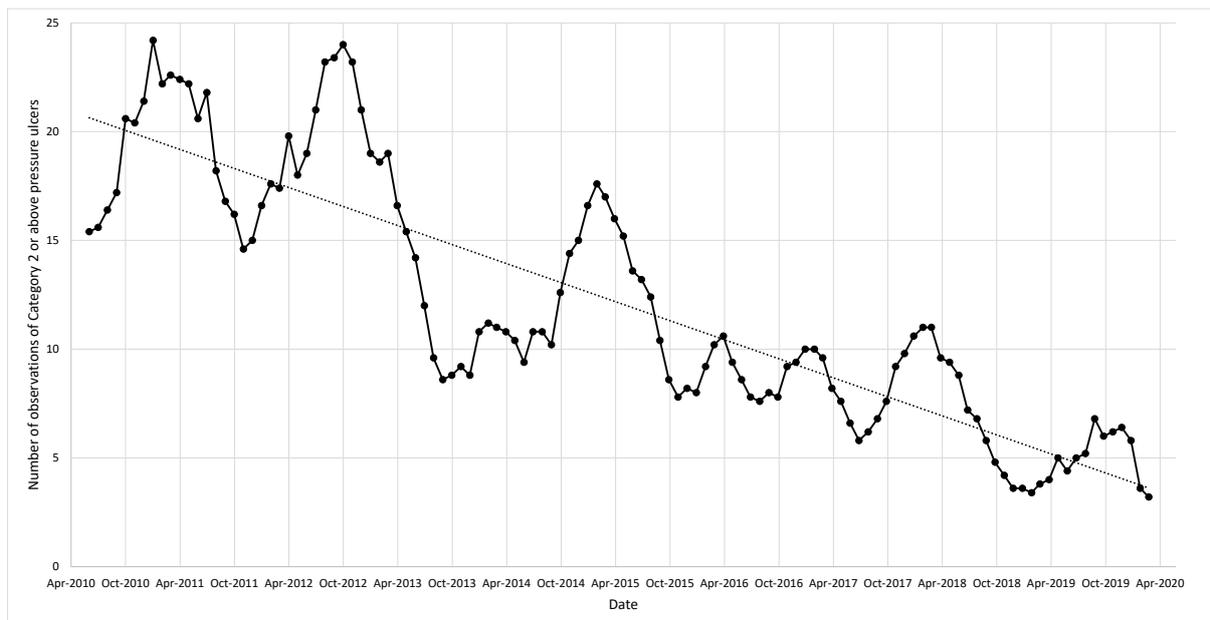
Removing the linear trend using first order differences resulted in a stationary plot with approximate

constant variation, confirming that a linear trend was an appropriate basis for a model. Higher order

differences and differences based on the log transformation did not result in a substantively greater

degree of stationarity or reduced variance. A plot of partial autocorrelation of 1st-order difference

values revealed the series to show moderately strong negative autocorrelation (r=-0.546) at a lag of

1. This is indicative of a "switching" pattern, whereby errors of a given sign (positive or negative) tend

to be followed by error of the opposite sign. Smaller negative values of autocorrelation were also

observed at a lag of 2 (r=-0.303) and at a lag of 12 (representing an annual increment); r=-0.245. Elsewhere negligble autocorrelation was observed (Figure 3).

**Figure 3: partial autocorrelation plot of 1st-order difference data**
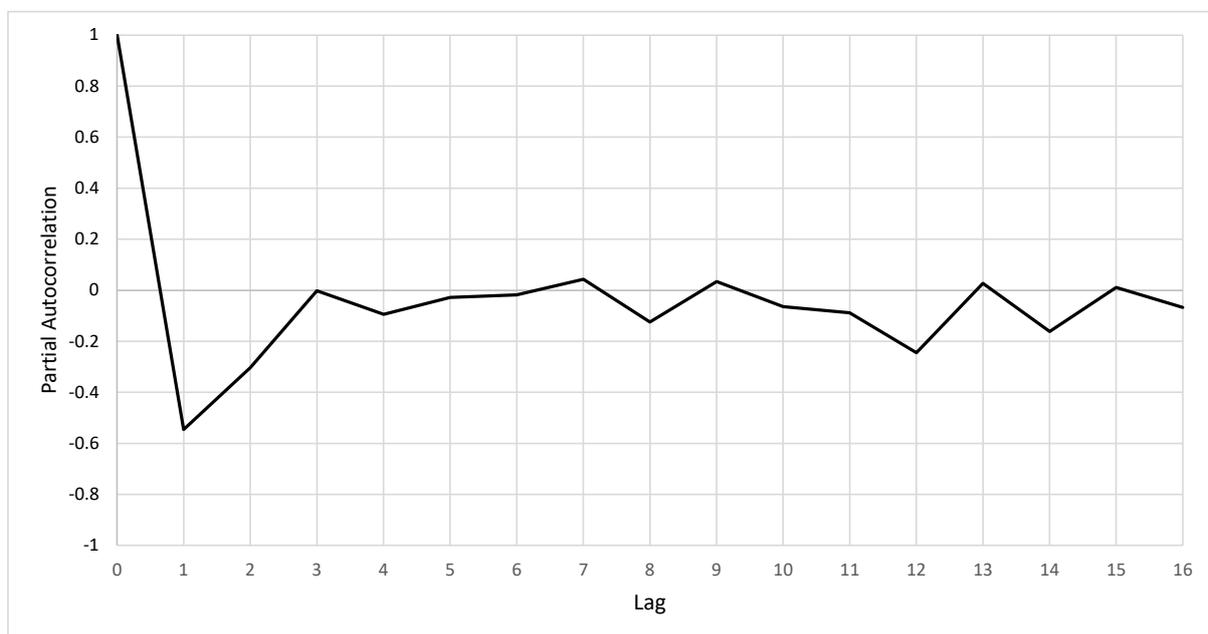
The autocorrelation observed above suggested that an exponential smoothing method would be appropriate for forecasting future values. Inspection of plots (Figures 1, 2) revealed that the magnitude of variation was not constant over the period of analysis, but was approximately proportional to the level of the series, suggesting that the Holt-Winters multiplicative exponential smoothing model may be appropriate for capturing cyclical effects; incorporating the effects of the specific interventions implemented over the analysis period. The Holt-Winters model is appropriate for forecasting data which includes both a trend and seasonal variation. As a triple eponential smoothing technique, it is a member of the family of exponential smoothing methods used to forecast subsequent values using a weighted average of previous values where the weights decay

exponentially from the most recent to the oldest historical value; in other words, the most recently obtained historial data has the greatest influence on future predictions.

The effects of the interventions were assumed to be continuous following the date of implementation. Monthly predictions were requested after May 2020 (the month of the last recorded entry) up to December 2022.

The model was applied to the data, with the fit of the model to recorded values was assessed using the R^2 statistic. The R^2 statistic for the model was 0.610, suggesting a moderately good fit to the data. The model is shown fitted against recorded values in Figure 4.

Figure 4: fitted model and recorded values
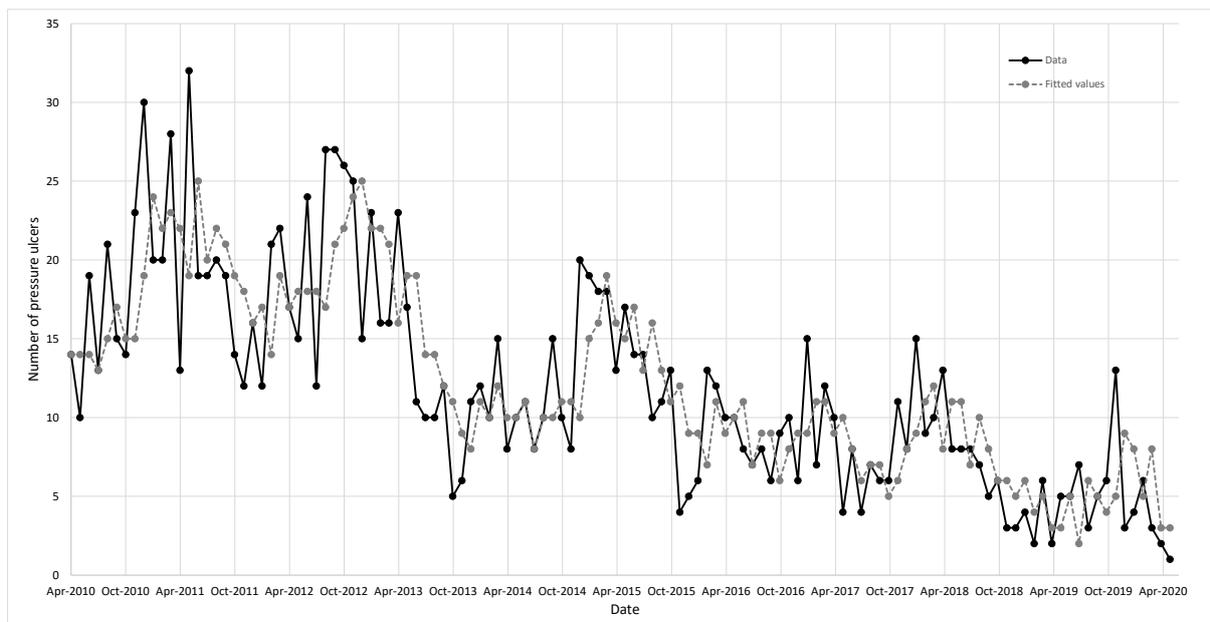
Predictions calculated from this model, with associated 95% confidence intervals (CIs) from June 2020 onwards are summarised in Table 1 below. A lower confidence limit calculated to be negative was taken to be a zero value.

Table 1: predicted values with associated 95% confidence intervals

Month	Predicted observations	95% CI for prediction		Month	Predicted observations	95% CI for prediction
June 2020	4	(0, 12)		October 2021	2	(0, 17)
July 2020	1	(0, 10)		November 2021	3	(0, 18)
August 2020	4	(0, 12)		December 2021	3	(0, 19)
September 2020	3	(0, 13)		January 2022	4	(0,20)
October 2020	2	(0, 12)		February 2022	3	(0,20)
November 2020	3	(0, 13)		March 2022	5	(0,22)
December 2020	3	(0, 14)		April 2022	3	(0,20)
January 2021	4	(0, 16)		May 2022	4	(0,20)
February 2021	3	(0, 15)		June 2022	4	(0,22)
March 2021	5	(0.18)		July 2022	1	(0,19)
April 2021	3	(0, 15)		August 2022	4	(0,22)
May 2021	4	(0, 16)		September 2022	3	(0,22)
June 2021	4	(0, 17)		October 2022	2	(0,21)
July 2021	1	(0, 15)		November 2022	3	(0,22)
August 2021	4	(0, 18)		December 2022	3	(0,22)
September 2021	3	(0, 18)				

Fitted values and predictions are summarised graphically in Figure 5.

Figure 5: Fitted values and predicted values until December 2022
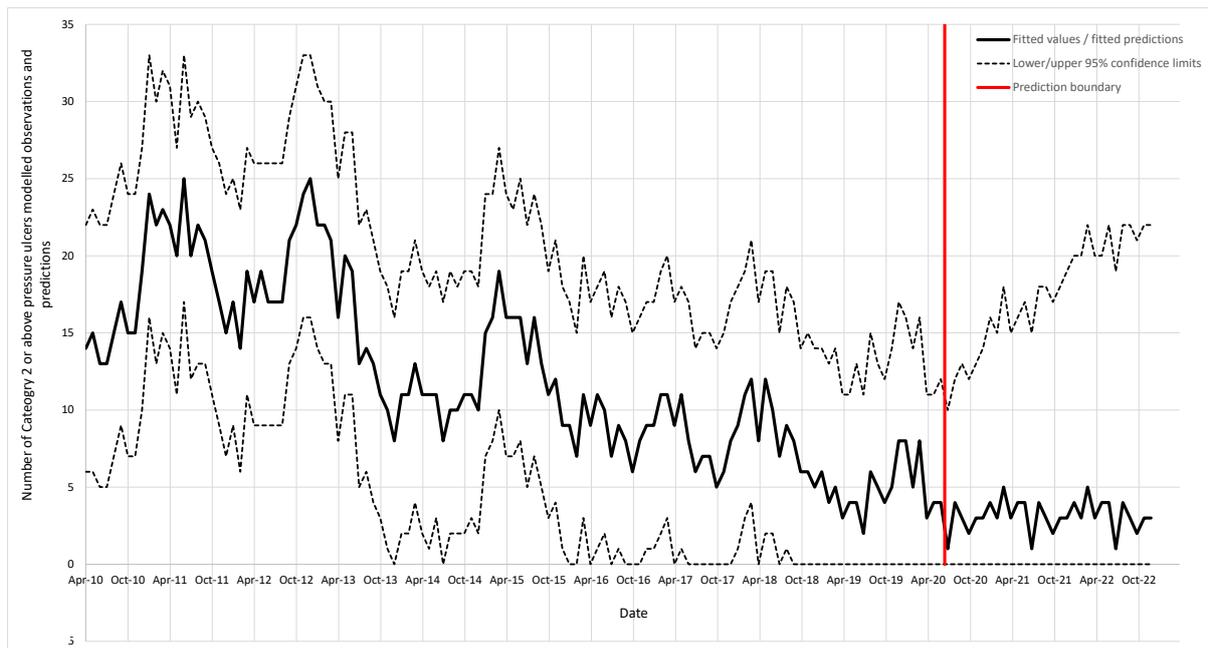
Hence the model predicts at best estimate monthly variation around a near-continuous monotonic trend, continuing the reduction in pressure ulceration occurrence observed in the previous 5 years, with no repeat of the outlying values observed in November 2019. The upper limit for the trend of 22 instances per month represents a return to typical pre-2015 values. The lower limit for the trend is zero.

Discussion

The strongest feature of the time series analysis is a steady decrease in the number of observed pressure injuries/ulcers over time, particularly after 2013; when a series of interventions designed to reduce PU incidence, such as equipment procurement and enrolment of new specialised staff members began to be implemented. Contributions to the observed decreases may also be due to a combination of changes in methodology in validation and improved clinical practice, and other

changes not formally recorded as PU-reducing interventions; in addition to the implementation of specific interventions. The predictions of future incidence continue this downward trend, with no more than 5 incidents per month predicted from March 2021 onwards. However, the uncertainty in the future estimates is wide, reflecting the excessive variation in the data set. It can be stated with a high degree of confidence, however, that immediate future monthly average values are not expected to return to levels observed routinely before 2015.

Obtaining accurate estimates of the incidence and prevalence of PU in both hospital and community settings has historically been difficult, due to a lack of consistency in reporting measures. **Prevalence** of pressure ulceration refers to the proportion of patients who have one or more PUs at or during a period of analysis, whereas **incidence** refers to the proportion or rate of patients, initially free of ulceration, who develop one or more pressure ulcers during the period of analysis. Whilst the current analysis is concerned primarily with incidences, where the duration is known, incidence can be inferred from prevalence data.

Prevalence of PU has been estimated [15] to be between 1.8% to 14%. However, Fletcher & Hall [16] presented unpublished data for May 2018 (taken from the NHS Safety Thermometer) demonstrating rates of 4.5% (all PU) and 0.9% (new PU) among all patients, as measured by the Safety Thermometer, compared with 7% and 1.7% in 2012. [17] They do warn that these figures have been relatively static since 2015, which could be indicative of a slowing down of quality improvement reporting mechanisms.

Estimates of future patterns of incidence of PU during an episode of care can be useful for resource management. However, many authors have observed that several interventions, such as those implemented by Taunton & Somerset NHS Trust over the analysis period can contribute to variability in incidence which would not necessarily be replicated in the future: for example, changes to levels of nurse staffing and facilities, an increase in patient acuity, risk assessment tools variation and other patient-level factors. [18-20] Training more wound care professionals and interdisciplinary wound care

teams, the introduction of a better and efficient system to document prevention and wound data, electronic medical records and, in particular, the introduction of interventions to treat and manage wounds have also been identified by Ebi et al. [21] as factors that may contribute to a reduction in incidence in long term care. In addition, studies have suggested the use of powered active-air-surfaces which seemed to be reducing pressure injury/ulcer incidences although they were found to be less comfortable than standard hospital surfaces. [22] In the current analysis, the effect of past interventions has been modelled: however, it is not possible to account for future events in the predictive component of the model.

The interpretation of historical data trends and their use for prediction of future events may be confounded by the presence of seasonal variation, which has been observed in incidence records of hospital-acquired PU. Patient admission during winter months may be associated with raised incidence of pressure ulceration. During these times, higher numbers of patients are admitted to hospital, for reasons such as falls caused by weather conditions. Moreover, patients admitted during these periods generally have a wider range of co-morbidities including, for example, vascular- and chest issues, pneumonia, seasonal flu, which may be associated with increased pressure injury/ulcer incidence. Studies of data from a survey conducted from 2004 to 2008 showed increased incidence from January to March and reduced incidence from July to September. [23] The same researchers reported that from 2009 to 2011, there was a significant reduction in the magnitude of this seasonality, and only the frequency of incidence in January to March was significantly higher than that in the other months/seasons. However, Baker [24] highlighted that in England in 2019 there were 855,000 cases where a patient waited longer than 4 hours for admission, equating to over one in eight emergency admissions to hospital. This was 33% higher than in 2018, and more than triple the figure for 2014. Additionally the number of 12-hour waits for admission doubled in 2019 compared with 2018: during December 2019 and January 2020 (winter) there were over 2,000 such waits. It is worth noting that the '12-hour wait' category is counted from a decision to admit, and not from the time of arrival. With these prolonged waiting times there is an increased risk to skin integrity and increase in

the risk of pressure injury/ulcer development; as such, it is essential that staff are aware of, and implement interventions to prevent pressure damage as the patient arrives, for example the use of pressure redistributing equipment, regular moving of position; and that the waiting time is clearly articulated to ward staff on transfer.

A finding of note is that the analysis of this audit data identified limited seasonality. While other reported patient events (e.g. falls, and patient mortality) have been observed to show a degree of seasonality, with higher levels of incidence in the winter months, such effects are not immediately obvious in recorded data and are completely absent in corresponding predictions. However, the finding of substantive autocorrelation at low lag values (1, 2) and autocorrelation of smaller effect at a lag of 12 indicate the presence of a trend with concurrent secondary seasonality effects. The cyclical nature of the data recorded up to 2020 is also not immediately apparent in the predicted values.

Individual investigations of case details have revealed no major themes that cross over cases to explain unexpected events such as the high number of cases recorded in November 2019.

Limitations

This study was conducted using data from a single Trust. As such, models and predictions are subject to specific Trust-level factors that may not apply elsewhere. Large levels of variation in reported values have led to an imperfect model fit: the model explains 59% of residual variation. Hence a certain degree of unexplained variation in the data remains. A multi-centre or national study may mitigate the effects of what appears to be clinical variation within a specific individual Trust; possibly due to, for example, staffing levels, skills mix and changes in the numbers of patients and complexity of conditions over time.

The lack of demographic or health-related patient data precludes the possible explanation of a substantive component of variance in the incident data; leading to noisy data and future predictions

of increasing uncertainty: currently beyond about 12 months, the range of uncertainty in predictions becomes too wide to be of immediate practical utility. Modelling limitations also preclude the isolation and quantification of the effects of individual interventions, or to model any graduation in the effectiveness; for example, it might be expected that a new member of staff would require an initial familiarisation period before becoming instrumental in the reduction of PU incidence during an episode of care. Furthermore, the Covid-19 pandemic ongoing at the time may have detrimental implications for PU incidence through diversion of resources.

Conclusions

PU incidence during episodes of care at one acute inpatient NHS Trust has seen a substantive and sustained fall over a 10-year analysis period. There appears to be evidence for long-term benefits of the interventions implemented by the Trust: Figure 2 illustrates that incidence has continued to fall post-2013, after which the majority of interventions were implemented. Notably, incidence levels have continued to reduce in recent years from lower baseline values, where it might be expected that reductions would begin to level off. Indeed, Figure 5 reveals that predictions remain static over the period 2020-22, with no modelled interventions. It may hence be concluded that the interventions implemented by the Trust have been effective in reducing PU incidence by at least comparable, and possibly greater, levels that may have occurred in the absence of interventions. Whilst more specific than the interventions documented by Ebi et al.,[19] the pattern of effect in the current analysis appears to be consistent with earlier findings. The use of data from multiple Trusts may go some way towards eliminating the effects of Trust-specific factors, and this and the utilisation of larger data sets should improve the accuracy and precision of predictions of future events.

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