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ORIGINAL ARTICLE

Impact of a community-acquired pneumonia care bundle in North East England from 2014 to 2017—A quality improvement project

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Abstract

Objectives: To explore the impact of implementation of Community-Acquired Pneumonia (CAP) quality care bundle.

Setting: Eight acute hospitals in the North East of England and North Cumbria.

Participants: ICD-10 coded CAP aged >18 were identified. A total of 16 201 CAP patients were discharged 2016/2017 (15 707; 2015/2016 and 10 733; 2014/2015).

Outcome measures: Secondary User Service (SUS) data were collected monthly from April 2014 to 2017. Data were pseudonymised and data flows governed by Data Sharing Agreements. CAP measures were based on British Thoracic Society guidance and agreed following clinician consultation. CAP admissions and individual organisational compliance with and impact of, CAP quality bundle measures was explored.

Results: Average length of stay (LOS) was 10.4 days (median 6) 25% >13 days. Crude in-hospital mortality rate was 17.6%, significantly lower (95% CI) than 19.1% in 2015/2016 and 19.3% in 2014/2015. Emergency readmissions within 28 days were 19.7% (19.2%; 2015/2016, 17.9%; 2014/2015). A total of 39.5% of patients received all appropriate care measures. Compliance has improved over time, although not for all hospitals. Most quality measures have higher mortality for those passing measures compared to those failing ($P < .05$ 95% CI). Giving oxygen, had a significantly higher emergency readmission rate, 3.3% higher (95% CI 1.1% to 5.5%). Appropriate antibiotics and recording CURB-65 scores reduced the emergency readmission rates (−2.7% (95% CI −4.5% to −0.8%) −2.6% (95% CI −3.8% to −1.4%), respectively, (P = ns)).

Conclusion: CAP accounts for significant bed days, mortality and readmissions. Although mortality was lower, LOS and readmission rates were not, despite improvements in compliance after implementation of the care bundle. Care bundle use remained sub-optimal.

Abbreviations: CAP, community-acquired pneumonia; HSMR, hospital standardised mortality ratio; ICD-10, International Classification of Diseases, version 10; NCI, not clinically indicated; NHS, National Health Service; ONS, Office for National Statistics; SHMI, summary hospital-level mortality indicator; SUS, secondary user services.

KEYWORDS
community-acquired pneumonia, ICD-10 code, standardised hospital mortality

1 | INTRODUCTION

Community-acquired pneumonia (CAP) is defined as pneumonia acquired outside hospital or health-care facilities. CAP tends to affect older people and is associated with significant morbidity and mortality. Current estimates describe pneumonia as affecting 29 000 people per annum in the United Kingdom with 5%-15% of those hospitalised dying within 30 days of admission. Pneumonia is responsible for more hospital admissions and bed days than any other respiratory condition.[1,2]

The supposition is that CAP care bundles improve the outcomes from pneumonia if widely and systematically implemented.[3,4] In this study, we explore the implementation of CAP quality measures as a mechanism for assessing use and impact of care bundle implementation in acute hospital settings across the whole of the United Kingdom North East and North Cumbria (NENC) geographical region.

The report focuses on process and outcomes, comparing the outcomes for patients over time, against the regional outcomes and based on the type of treatment received, specifically, whether patients passed, failed or were excluded from the pneumonia measures.

2 | METHODOLOGY

2.1 | Setting

This study was conducted across ICD-10 coded CAP patients (Appendix Table A1)

over the age of 18 in eight acute hospitals in the North East of England using a unified database. Secondary User Service (SUS) data were collected by Clarity Informatics Limited from each hospital monthly from April 2014 to 2017. Data were pseudonymised at source and all data flows were governed by Data Sharing Agreements with each trust to ensure appropriate Information Governance.

2.2 | Community-acquired pneumonia quality measures

The seven CAP measures are based on the widely accepted British Thoracic Society guidance[3,4] with details of operational definitions of the measures agreed across all hospitals following consultation with clinicians and nurses from the hospitals via a series of workshops and meetings are as follows;

- CAP-1: Chest X-ray or CT scan of thorax within 4hrs of hospital arrival
- CAP-2: Oxygen assessed within 1hr of hospital arrival
- CAP-3: Oxygen given within 1hr of hospital arrival
- CAP-4: Initial antibiotic received within 4hrs of hospital arrival
- CAP-5: Appropriate initial antibiotic regimen received
- CAP-6: Defines whether a clinical prediction tool (CURB-65 or CRB-65 Score) is recorded
- CAP-7: Critical care advice given if CURB-65 score = 4 or 5 or CRB-65 score = 3 or 4

Clinically appropriate exclusions were applied to the patient population, for example, if a patient was designated as needing palliative care. The measures were agreed and collected initially with three trusts in 2014 with inclusion of a further five trusts in 2015.The care bundle itself was widely accepted as reflecting existing clinical practice, albeit, not consistently delivered quickly. The only measure which involved a change in practice (rather than just increasing the timeliness of existing care) was the routine calculation of a clinical risk prediction tool such as CURB-65 or CRB-65 Score. All the hospitals involved in the project participated in a series of bespoke workshops aimed at educating teams about the bundle and the evidence for its benefits. In addition, teams developed a sticker for the notes that acted as an aid memoire so that all elements of the bundle were completed. These efforts at improvement were shared through the workshops.

2.3 | Outcome measures

We examined three main outcome measures, average length of stay (LOS), crude mortality rate and rate of emergency readmissions within 28 days of discharge.

Length of stay for pneumonia patients is described in days and presented as both mean and median values.

Crude in-hospital mortality rate was determined as the number of patients coded with a discharge method (patient died) or a discharge destination (patient died) divided by the total number of patient spells.[5]

An emergency readmission rate was defined as the number of patients who are readmitted as an emergency, within 28 days of discharge, divided by the total number of live discharges.

2.4 | Process

Initially we considered the overall CAP admissions and compliance with the CAP quality bundle measures as a

whole. We then went onto consider individual organisations and their compliance with the CAP quality bundle measures and then, the impact of the measures and the relationship with outcomes. We defined two scores. The appropriate care score (ACS) was the number of those patients who received all relevant elements of care defined in the bundle and composite process score (CPS) the number of those patients who receive any element of the care defined in the bundle.

2.5 | Patient and public involvement

Patients and members from regional patient support groups were involved in the education workshops. Patients and the public were not involved in the design of the study, its implementation or analysis.

3 | RESULTS

3.1 | CAP prevalence rates

We identified 16 201 pneumonia patients discharged during April-March 2016/2017 for NENC Hospital trusts, this compares to 15 707 and 10 733 patients for the same period for 2015/2016 and 2014/2015, respectively.

The average age for pneumonia patients at NENC Hospital Trusts in 2016/2017 was 73.9 years. Median age was 78 years. Half of all patients were between 67 and 85 years old at discharge with 25% of patients being 85 years or older. The age profile has remained relatively constant over time. The key parameters for pneumonia patients at NENC Hospital Trusts for the 3 years from April 2014 to March 2017 are shown in Figure 1.

The age profile varies across trusts, Newcastle Hospitals having the youngest pneumonia population with an average age of 71.1 years whilst South Tyneside Hospital have the oldest, average age 75.5 years.

3.2 | Outcome measures

Outcomes over time are shown in Table 1.

3.2.1 | Length of stay

The average LOS for pneumonia patients at NENC Hospital Trusts in 2016/2017 was 10.4 days. The median LOS was 6 days. Half of all patients stayed in hospital for between 3 and 13 days, 25% of patients were in hospital for 13 days or longer. The LOS profile for pneumonia patients at NENC Hospital Trusts has remained consistent for the most recent 2 years of the programme and slightly higher than in 2014/2015.

3.2.2 | Mortality

In April-March 2016/2017, the crude mortality rate for Pneumonia patients at NENC trusts was 17.6%, this is significantly lower (95% CI) than the 19.1%in April-March 2015/2016 and 19.3% in April-March 2014/2015.

3.2.3 | Emergency readmissions

In April-March 2016/2017, the rate of emergency readmissions within 28 days for Pneumonia patients at NENC trusts was 19.7%, compared to 19.2% in April-March 2015/2016 and 17.9% in April-March 2014/2015 (Table 1).

3.3 | Quality measures data

For NENC Hospital trusts, from April 2014 to March 2017 compliance with the bundle of quality measures has varied between measures, with lowest compliance for recording of a clinical risk prediction tool (CURB-65 score) at 47.5%, to highest compliance for oxygen assessment within 1 hour of

Population	
Initial Population	42,641
Patients per month	1,184
Final Population (after removals)	40,851
Total bed days	417,047
Average Length of Stay (Days)	10.2
Patient Deaths	7,577
Crude Mortality Rate	18.5%
Emergency Readmissions within 28 days of discharge	6,355
Emergency Readmission rate (% of Live Discharges)	19.1%
Measure Completeness	
Patients marked as Completed	19,919
% Complete	48.8%

FIGURE 1 Summary of key figures for NENC Hospital trusts, from April 2014 to March 2017

TABLE 1 Annual characteristics of discharges and demographics

		Age (years)				Length of stay				Crude Mortality rate		Live discharges	Emergency readmission rate	
Discharge year	Discharges	Mean	Median	Max	IQR	Bed days	Mean	Median	Max	IQR	Deaths (n)	%		Readmissions (n)	%
2014/2015	10 288	73.9	77.0	106	18.8	97 421	9.5	6	162	8	1981	19.3	8307	1485	17.9
2015/2016	14 865	73.4	77.0	106	19.0	156 175	10.5	6	251	10	2837	19.1	12 028	2315	19.2
2016/2017	15 698	73.9	78.0	106	18.0	163 451	10.4	6	1044	10	2759	17.6	12 939	2555	19.7

hospital arrival at 85.5%. Only 39.5% of patients received all appropriate care measures, that is, they received all measures that they were eligible to receive. Overall, bundle measure compliance improved over time, although not for all trusts.

A patient is deemed to have 'passed' a measure if they are eligible for the measure activity and the activity was given within the specified time scales. Figure 2A shows the pass rates for individual NENC Hospital Trusts, for each measure, from April 2014 to March 2017 discharges with Figure 2B showing this over t time.

3.4 | Relationship between compliance with CAP quality measures and outcomes

3.4.1 | Length of stay

Length of stay is a difficult outcome to monitor. Average LOS is heavily influenced by just one or two long stay patients, median LOS is more consistent but rarely identifies differences. We found no statistical difference for LOS across time or with adherence to the CAP measure bundle.

3.4.2 | Mortality

Figure 3 below shows crude mortality rates plotted on a funnel plot for NENC Hospital Trusts, for eligible patients for each pneumonia measure, by pass status, for April 2014 to March 2017 discharges.

The data presented visualises the impact of pass or fail for each measure. Above the mean line represents increased numbers of deaths associated with a measure, below the line represents decreased numbers of deaths. Ideally, passing a measure (green circle) would always be found below the mean and failing a measure (red diamond) would be associated with a figure above the mean. In addition, the data labels are coloured green when the crude mortality rate for patients who pass a measure is lower than for those who fail and where one of those patient groups is significantly (99.8%) different than the mean for all eligible patients. Conversely, the data labels are coloured red when the crude mortality rate for patients who pass is higher than those who fail and one of those patient groups is significantly (99.8%) different than the mean for all eligible patients.

Table 2 below shows the above data in tabular form, showing the difference in the crude mortality rate between eligible patients who pass a measure compared to those who fail, 95% confidence intervals for the differences are included along with Fisher's exact *P* value from a 2-proportion test.

Overall, most measures have higher mortality rates for eligible patients who pass measures compared to those who fail and these differences are statistically significant (95% CI). The exceptions are patients who have CURB-65 or CRB-65

(A)

Measure	Pass	Fail	Compliance Rate
CAP-1: Chest X-ray or CT Scan of Thorax within 4hrs of Hospital Arrival	15,244	3,868	79.8%
CAP-2: Oxygen Assessed within 1hr of Hospital Arrival	11,561	1,967	85.5%
CAP-3: Oxygen given within 1hr of Hospital Arrival	5,208	1,980	72.5%
CAP-4: Initial Antibiotic Received within 4hrs of Hospital Arrival	5,183	2,473	67.7%
CAP-5: Appropriate Antibiotic Received	4,734	2,911	61.9%
CAP-6: CURB-65 Score Recorded	6,216	6,871	47.5%
CAP-7: Critical Care Advice given if CURB-65 Score = 4 or 5	701	1,697	29.2%
ACS: Appropriate Care Score	8,083	12,366	39.5%
CPS: Composite Process Score	48,847	21,767	69.2%

(B)

Measure	2014/15	2015/16	Apr-Jun 2016	Jul-Sep 2016	Oct-Dec 2016	Jan-Mar 2017
CAP-1: Chest X-ray or CT Scan of Thorax within 4hrs of Hospital Arrival	81.0%	76.7%	76.7%	82.9%	84.7%	83.3%
CAP-2: Oxygen Assessed within 1hr of Hospital Arrival	90.5%	79.3%	76.9%	91.5%	92.1%	91.7%
CAP-3: Oxygen Prescribed within 1hr of Hospital Arrival	69.1%	70.1%	68.2%	81.4%	79.5%	81.4%
CAP-4: Initial Antibiotic Received within 4hrs of Hospital Arrival	65.2%	70.1%	61.7%	69.1%	67.8%	69.2%
CAP-5: Appropriate Antibiotic Received	63.6%	68.1%	49.6%	54.5%	60.5%	58.1%
CAP-6: CURB-65 Score Recorded	52.1%	43.6%	49.1%	38.1%	50.3%	52.4%
CAP-7: Critical Care Advice given if CURB-65 Score = 4 or 5	4.8%	99.2%	100.0%	95.1%	100.0%	98.8%
ACS: Appropriate Care Score	45.0%	36.3%	36.6%	35.7%	41.3%	41.7%
CPS: Composite Process Score	66.4%	68.8%	66.1%	70.8%	74.2%	74.4%

FIGURE 2 A, Pass rates by Measure for NENC Hospital Trusts, from April 2014 to Mar 2017 discharges. B, Measure Pass rates over time for NENC Hospital Trusts. The sparkline bars demonstrate the trend of performance for each measure. The dark green denotes the best performance by quarter and the red bar provides the data from the worst performing quarter

score recorded. Mortality is 17.5% for those who fail this measure, mortality is 14.1% for those who pass, therefore, the difference is 3.4% lower (95% CI −4.7% to −2.2%). Eligible patients who receive appropriate antibiotics also show a reduced crude mortality rate but not significantly so.

3.4.3 | Emergency readmissions within 28 days

In order to visualise, by pass status, for April 2014 to March 2017 discharges emergency readmission rates were plotted on a funnel plot for North East trusts, for eligible patients for each pneumonia measure.

For emergency readmissions, oxygen given, has a significantly higher emergency readmission rate for patients who pass the measure compared to those who fail that is, is visualised with the funnel plot as an outlier, 3.3% higher (95% CI 1.1% to 5.5%). Two measures, appropriate antibiotics and CURB-65 score recorded show significantly reduced emergency readmission rates, these are −2.7% (95% CI −4.5% to −0.8%) and −2.6% (95% CI −3.8% to −1.4%), respectively. For all other measures, the differences in readmission rates are not statistically significant.

4 | DISCUSSION

CAP is common and in our study prevalence rose during the period. CAP is also seasonal (with higher rates in winter) and with considerable variation between years dependent up on the epidemiology of microbes circulating in the population. In this study, identification was based on clinical coding in administrative data from a number of different

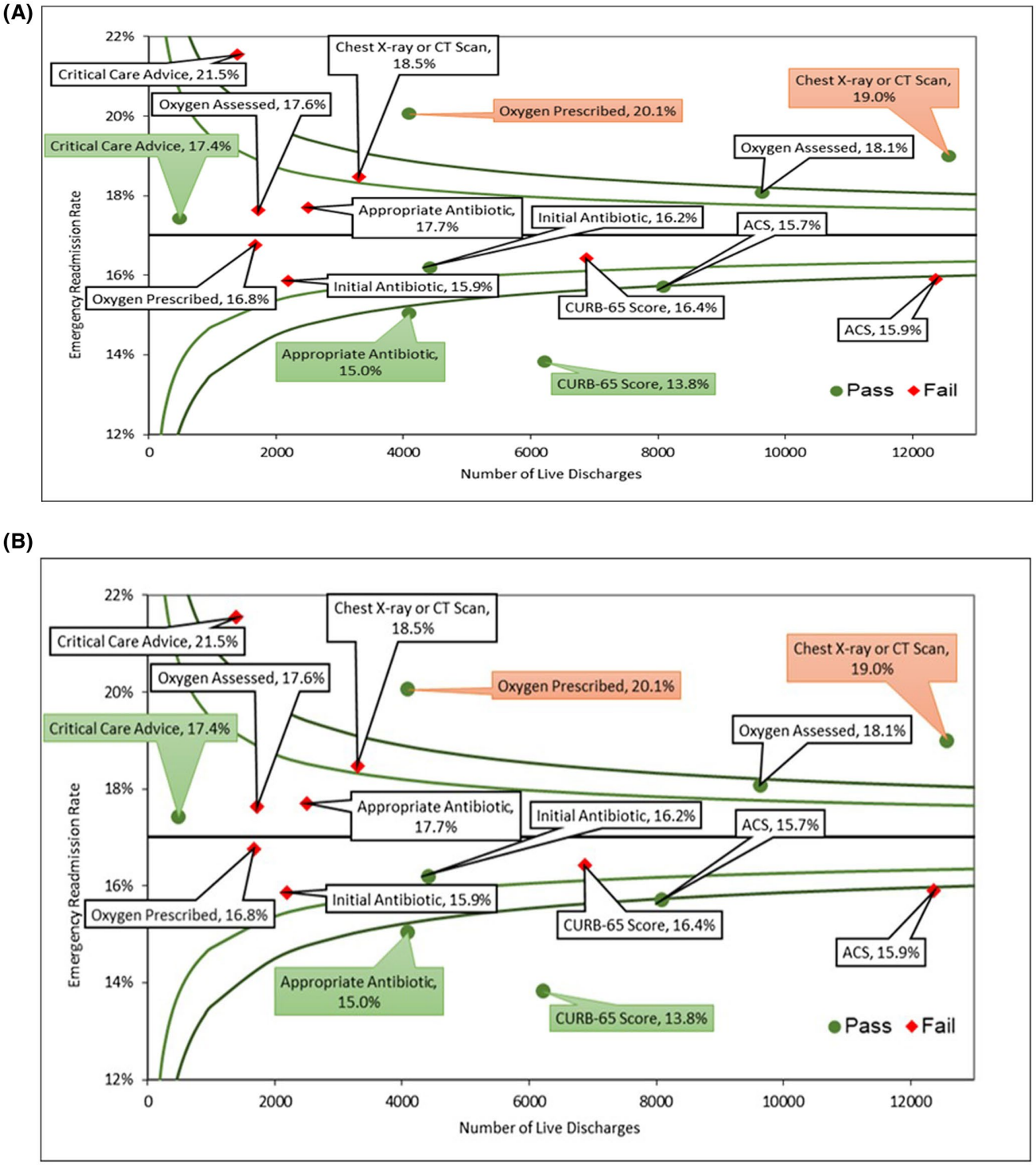

FIGURE 3 Funnel plots by pass status for North East trusts, from April 2014 to March 2017. The data presented visualises the impact of pass or fail for each measure. Above the mean line represents increased numbers of deaths associated with a measure, below the line represents decreased numbers of deaths. Ideally, passing a measure (green circle) would always be found below the mean and failing a measure (red diamond) would be associated with a figure above the mean. In addition, the data labels are coloured green when the crude mortality rate for patients who pass a measure is lower than for those who fail and where one of those patient groups is significantly (99.8%) different than the mean for all eligible patients. In contrast, the data labels are coloured red when the crude mortality rate for patients who pass is higher than those who fail and one of those patient groups is significantly (99.8%) different than the mean for all eligible patients. A, Crude mortality rate; B, Emergency Readmission Rates

TABLE 2 Mortality and readmissions rates according to whether individual components of the CAP quality bundle were passed or failed

		Discharges	Deaths	% Deaths	Diff. pass—Fail	95% LL for Diff.	95% UL for Diff.	Fisher's *P* value	Live discharges	Readmits	% Readmits	Diff. pass—Fail	95% LL for Diff.	95% UL for Diff.	Fisher's *P* value
CAP-1: Chest X-ray or CT scan	Pass	15 244	2670	17.5%					12 574	2390	19.0%				
	Fail	3868	566	14.6%	2.9%	1.6%	4.1%	.000	3302	610	18.5%	0.5%	−1.0%	2.0%	.500
CAP-2: Oxygen Assessed	Pass	11 561	1930	16.7%					9631	1742	18.1%				
	Fail	1967	244	12.4%	4.3%	2.7%	5.9%	.000	1723	304	17.6%	0.4%	−1.5%	2.4%	.683
CAP-3: Oxygen Given	Pass	5208	1120	21.5%					4088	820	20.1%				
	Fail	1980	310	15.7%	5.8%	3.9%	7.8%	.000	1670	280	16.8%	3.3%	1.1%	5.5%	.004
CAP-4: Initial Antibiotic Received	Pass	5183	769	14.8%					4414	715	16.2%				
	Fail	2473	279	11.3%	3.6%	2.0%	5.1%	.000	2194	348	15.9%	0.3%	−1.5%	2.2%	.749
CAP-5: Appropriate Antibiotic Received	Pass	4734	639	13.5%					4095	616	15.0%				
	Fail	2911	408	14.0%	−0.5%	−2.1%	1.1%	.538	2503	443	17.7%	−2.7%	−4.5%	−0.8%	.005
CAP-6: CURB-65 Score Recorded	Pass	6216	874	14.1%					5342	860	16.1%				
	Fail	6871	1202	17.5%	−3.4%	−4.7%	−2.2%	.000	5669	1128	19.9%	−3.8%			
CAP-7; Critical Care Advice Given	Pass	701	219	31.2%					482	84	17.4%				
	Fail	1697	300	17.7%	13.6%	9.7%	17.4%	.000	1397	301	21.5%	−4.1%	−8.1%	−0.1%	.058
ACS: Appropriate Care Score	Pass	8083	1444	17.9%					6639	1270	19.1%				
	Fail	12 366	2054	16.6%	1.3%	0.2%	2.3%	.020	10 312	1966	19.1%	0.1%			

NHS organisations from across a large geographical area in the North of England. Whilst this process is stable variation in identification, documentation and coding are all subject to some variation. CAP is the diagnosis responsible for the highest volume of deaths in the hospital mortality Summary Hospital-level Mortality Indicator (SHMI), it accounts for very significant numbers of bed days, in our study had a 17% readmission rate and is one of the most significant sources of cost and unplanned activity for any NHS hospital. It is, therefore, important that service improvement strategies aim to target this condition to reduce LOS, readmission and mortality rates.

Although mortality was lower in the final year of the project, LOS and readmission rates were not despite improvements in compliance with the care bundle. Use of the care bundle remained suboptimal despite 3 years of effort and whilst some of this may be related to accuracy of documentation and auditing it is likely that the complexity of hospital care systems make it difficult for staff to consistently identify and treat patients with CAP in a timely manner.

A major aim of the programme was to demonstrate that patients have improved outcomes (reduced LOS, mortality and emergency readmissions within 28 days) when they receive appropriate CAP quality care measures. We have looked for variations in outcomes between eligible patients who pass a measure and those who fail.

Overall, most measures have higher mortality rates for eligible patients who pass measures compared to those who fail and these differences are statistically significant (95% CI).

This seems counterintuitive, but could suggest that those with more severe CAP might be recognised and the care bundle complied with whilst less severe CAP is less recognised.

The exceptions are patients who have clinical prediction risk score (CURB-65 or CRB-65) recorded. For patients who pass this measure the crude mortality rate is 3.4% (95% CI −4.7% to −2.2%) lower than for patients who fail the measure suggesting that the use of such tools may raise awareness and led to better outcomes for patients.[6,7] Eligible patients who receive appropriate antibiotics also show a reduced crude mortality rate but not significantly so. There are a range of possible reasons for why crude mortality rates are higher for patients who pass a measure than for those who fail, the most likely is that we are unable to provide an accurate standardisation for severity of pneumonia, complexity, co-morbidity and case mix analysis.

Readmissions show a different picture, oxygen given, has a significantly higher emergency readmission rate for patients who pass the measure compared to those who fail, 3.3% higher (95% CI 1.1% to 5.5%). This may be in keeping with previous studies that suggest that treatments that include oxygen therapy in CAP may affect respiratory drive and as a consequence possibly increase the risk of further events.[8,9] Two measures, appropriate antibiotics and CURB-65 score recorded show reduced emergency readmission rates, these are −2.7% (95% CI −4.5% to −0.8%) and −2.6% (95% CI −3.8% to −1.4%), respectively, which has been noted in previous studies.[10] For all other measures, the differences in readmission rates are not statistically significant.

For average LOS, no statistical significance was found.

It is important to acknowledge any potential limitations to our study. Our data exploring the outcomes is not risk-adjusted and it is not possible to account for random variation or secular trends in case mix between years at this stage. The volume and severity of pneumonia changes from year to year as the prevalence and virulence of causative micro-organisms circulating in the population changes. It is not possible to measure the variation in case-mix in this study. Data using a risk-adjusted measure of mortality based on the Summary Hospital-level Mortality Indicator (SHMI) estimates of predicted mortality would overcome these difficulties.

In conclusion, our study has shown that CAP is common and accounts for significant numbers of bed days, mortality and readmissions. Although mortality was lower in the final year of the project, LOS and readmission rates were not, despite improvements in compliance with the care bundle. Care bundle use remained sub-optimal, which may be related to accuracy of documentation. It is likely that the complexity of hospital care systems make it difficult for staff to consistently identify and treat patients with CAP in a timely manner.

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CONFLICT OF INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

GM was responsible for the original study idea. All authors contributed to the design of the study. LF and MW conducted statistical analysis. AR carried out the thematic coding. All authors contributed to data interpretation. GM, JN and AR drafted the manuscript and all authors read and approved the final manuscript.

DATA AVAILABILITY STATEMENT

The data sets used and/or analysed during the current study are available from the corresponding author on reasonable request.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable. Ethics approval was not sought as the data were collected under normal NHS Clinical Audit arrangements. Only case records were used to obtain data.

CONSENT FOR PUBLICATION

Not applicable.

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APPENDIX

TABLE A1 Clinical ICD-10 Coding used to define community-acquired pneumonia (CAP)

Code	Definition
CAP	
J13	Pneumonia due to *Streptococcus pneumonia*
J14	Pneumonia due to *Haemophilus influenza*
J150	Pneumonia due to *Klebsiella pneumonia*
J151	Pneumonia due to *Pseudomonas*
J152	Pneumonia due to staphylococcus
J153	Pneumonia due to streptococcus, group B
J154	Pneumonia due to other streptococci
J155	Pneumonia due to *Escherichia coli*
J156	Pneumonia due to other aerobic Gram-negative bacteria
J157	Pneumonia due to *Mycoplasma pneumonia*
J158	Other bacterial pneumonia
J159	*Bacterial pneumonia*, unspecified
J160	*Chlamydial pneumonia*
J168	Pneumonia due to other specified infectious organisms
J180	Bronchopneumonia, unspecified
J181	*Lobar pneumonia*, unspecified
J182	*Hypostatic pneumonia*, unspecified
J188	Other pneumonia, organism unspecified
J189	Pneumonia, unspecified
Septicaemia	
A400	Septicaemia due to streptococcus, group A
A401	Septicaemia due to streptococcus, group B
A402	Septicaemia due to streptococcus, group D
A403	Septicaemia due to *Streptococcus pneumonia*
A408	Other streptococcal septicaemia
A409	Streptococcal septicaemia, unspecified
A410	Septicaemia due to *Staphylococcus aureus*
A411	Septicaemia due to other specified staphylococcus
A412	Septicaemia due to unspecified staphylococcus
A413	Septicaemia due to *Haemophilus influenza*
A414	Septicaemia due to anaerobes
A415	Septicaemia due to other Gram-negative organisms
A418	Other specified septicaemia
A419	Septicaemia, unspecified
Respiratory failure	
J960	Acute respiratory failure
J962	Acute and chronic respiratory failure
Cystic fibrosis	
E84.0	Cystic fibrosis with pulmonary manifestations
E84.1	Cystic fibrosis with intestinal manifestations
E84.8	Cystic fibrosis with other manifestations (including combined manifestations)
E84.9	Cystic fibrosis, unspecified