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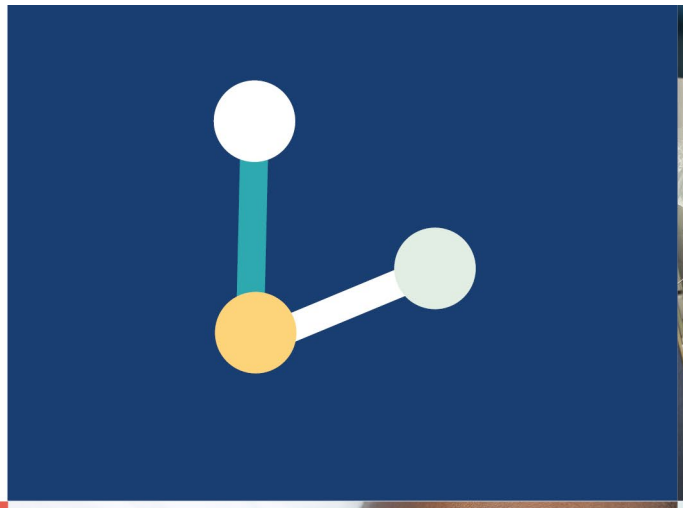
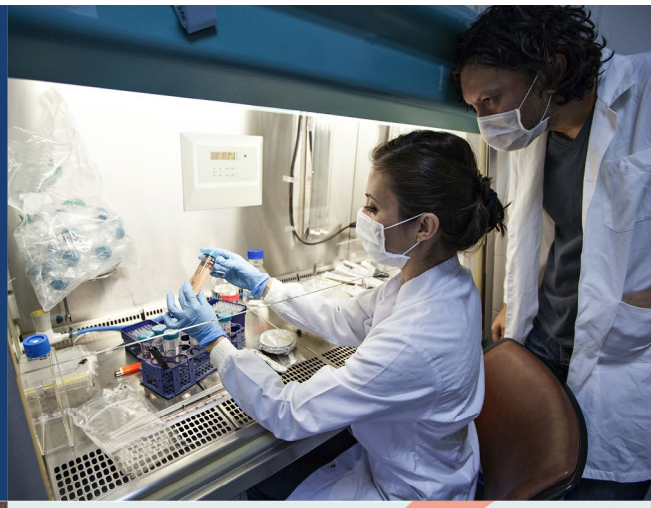
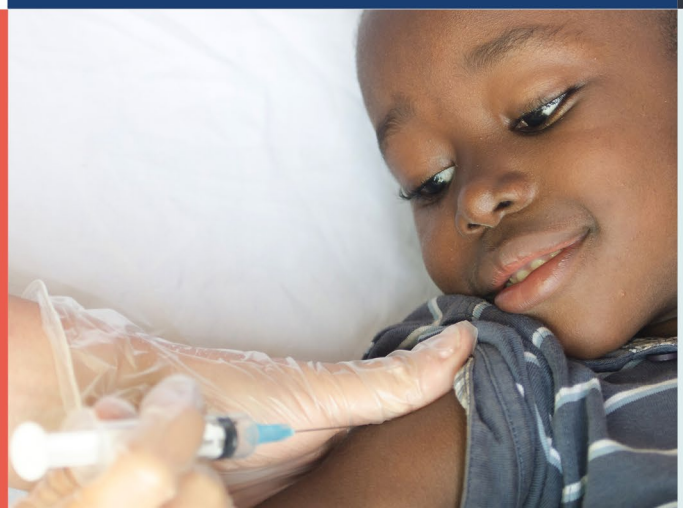
Estimating the potential benefits of a patient safety quality improvement scheme on safer tracheostomy care introduced at scale in NHS hospitals in England

Full Report







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Additional Information:

This study was undertaken by the National Institute for Health Research (NIHR) Applied Research Collaboration Greater Manchester (ARC-GM). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care

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1. Executive Summary

Aim: to estimate the potential impacts of the NHS England Safer Tracheostomy Care Improvement Programme on hospital length of stay, tracheostomy days, ventilator days and days in intensive care.

Data: data on the implementation of key safety interventions in participating NHS hospitals; data on interventions and outcomes from a smaller scale pilot study; data on activity and costs for English NHS hospitals.

Methods: regression analyses of study outcomes and intervention timing using an event study approach.

Results: analyses estimated an average reduction in total hospital length of stay of 33 days per admission 12 months after the introduction of the improvement programme (33.02 days [95% CI -59.17; -6.87]).

Conclusions: participating hospitals successfully implemented most of the key safety interventions in the first 12 months of the programme. Extrapolation of impacts from a smaller pilot study implied potential substantial reductions in length of stay and corresponding resources savings for participating hospitals. Further research is needed to robustly estimate the impact on patient outcomes and hospital costs.

2. Background

Tracheostomies provide artificial airways for approximately 15,000 patients in England and Wales each year (B. McGrath et al., 2015; B. A. McGrath & Wilkinson, 2015a). These patients frequently have significant co-morbidities and care needs that span a range of treatment specialties and locations. However, previous studies have shown defects in tracheostomy care provision in hospital: a combination of inadequate equipment supply, undertrained staff and limited infrastructure result in avoidable harms to patients with corresponding economic consequences for the health system (Cook et al., 2011; B. A. McGrath & Thomas, 2010).

Patients who have tracheostomies are frequently critically ill and have in-hospital mortality reported to be between 25% and 60% (Halum et al., 2012). Whilst much of this is attributable to underlying illness (Shah et al., 2012), up to 30% of patients experience an untoward incident during their stay in hospital. 60-70% of these incidents lead to measurable harm including emergency readmission, prolonged stays in hospital and death (Cook et al., 2011; B. A. McGrath & Thomas, 2010).

The Global Tracheostomy Collaborative (GTC) proposed Quality improvement (QI) strategies designed to mitigate such problems via the improvement of quality and safety of care for patients who have had tracheostomies (McGrath et al. 2017). These strategies comprised of 18 interventions. Between August 2016 and January 2018, 20 hospitals in England participated in the Improving Tracheostomy Care (ITC) programme and implemented a range of interventions at scale based on the GTC quality improvement strategies. The aim of the programme was to pilot the introduction of a QI initiative to improve tracheostomy care at scale in geographically, socioeconomically and demographically diverse hospitals in the National Health Service and evaluate its impact (B. A. McGrath, Wallace, et al., 2020). Evaluations have shown that hospitals that implemented these interventions saw improvements across several quality, safety and efficiency domains including reduced length of stay in hospital, reduced incident severity and reductions in anxiety and depression for patients who had tracheostomies (McGrath et al. 2020). The level of improvement

in these different domains varied across the participant hospitals, as did the specific interventions implemented and their respective tenures.

In 2020, the NHS England Safer Tracheostomy Care Improvement Programme rapidly implemented several of the key interventions from the 20-site Improving Tracheostomy Care programme to 180 hospital sites across England. Implementation occurred during the Covid-19 pandemic, a time where NHS England had significant safety concerns around managing the expected large numbers of new patients requiring tracheostomy in surge locations that were not trained, resourced, or experienced in providing tracheostomy care. Routine and emergency care was anticipated to be delivered by staff drafted from a non-tracheostomy care background. There was insufficient time to replicate the entire range of quality, safety and efficiency-based interventions form the ITC programme (hereafter referred to as the 'pilot') and with the most immediate priority being to ensure patient safety, the key safety elements of the pilot were incorporated into the improvement programme.

The Covid-19 pandemic widely affected the prioritisation of research activities in health care – this included the (hitherto planned) collection of data on the improvement programme for the intended evaluation. Data were not collected on patients who had tracheostomies in participating hospitals, and tracheostomies were not routinely recorded in administrative data sources such as Hospital Episodes Statistics (HES) via the diagnosis or operation code fields. The lack of data creates issues when evaluating the effectiveness and cost-effectiveness of the improvement programme.

The aims of this study are to estimate the potential impacts of the improvement programme in participating hospitals under situations where extrapolations of pilot data are necessary. We do this by answering the following questions:

1. How did the interventions affect hospital outcomes in the pilot programme?

2. What were the estimated benefits from the improvement programme based on when mapped interventions were introduced?

3. Data

We used available data on when the interventions were implemented in participant hospitals in combination with observational data from the original pilot scheme). This allowed us to estimate the benefits of the improvement programme based on extrapolating intervention effects estimated from the pilot sites to participant hospitals under certain assumptions.

3.1 Data from the original pilot programme

We used monthly data at hospital-site level from the pilot. These data are for 20 self-nominating hospital sites in England, Scotland and Wales; include 2,405 patients, and span 30 months from August 2016 to January 2018. The data include information on the number of admissions in which a patient had a tracheostomy; and the four main process measures from which the study outcomes are derived:

- the mean length of stay in hospital per tracheostomy admission;
- the mean days in which a patient had a tracheostomy per tracheostomy admission;
- the mean days spent in an intensive care unit (ICU) per tracheostomy admission;
- and mean days in which a patient received invasive mechanical support (prior to and with a tracheostomy) per tracheostomy admission (ventilator days).

We define a tracheostomy admission as: an in-patient episode requiring a new tracheostomy, or patient admitted with an existing tracheostomy.
Eight of the 20 sites did not have emergency departments, and methodological limitations in data collection in the pilot meant that not all sites collected comprehensive ICU length of stay data or ventilator-days data during a given patient's admission. The data provide a monthly record of whether each of the 20 participant hospitals had introduced any of the eighteen QI interventions (Table 1).

3.2 Data on the introduction of the key interventions for participant hospitals

We used monthly data from the 180 hospitals participating in the improvement programme for the period April 2020 to March 2021. The data record whether (and when) the participating hospitals introduced each (if any) of the four interventions; and these four interventions map to equivalents from the pilot (Table 1). We label the 18 interventions from the pilot in their three domains:

- Organisational efficiency (O1-O6)
- Patient-centred quality of care (Q1-Q7)
- Safety (S1-S5)

These are then mapped to their equivalent four corresponding groups in the data on improvement programme interventions (labelled simply as A, B, C and D) (Table 1). Finally, we used annual hospital-level data from the Secondary Uses Service (SUS) covering hospitals in England for the financial years 2016-17 to 2020-21. SUS is the single, comprehensive data source for health care data in England. SUS data included site-level data on the volume of finished admission episodes, emergency admissions and the number of finished admission episodes comprising male and female patients.

Table 1: Mapping of interventions from the pilot study to the four recorded improvement programme interventions A (standardised care bundles), B (bedhead signs), C (standardised equipment) and D (all other interventions).

Domains and interventions from the pilot study		Equivalent improvement programme interventions
Domain: Organisational efficiency		
O1	Implement a hospital steering group	n/a
O2	Ensure mandatory training for staff caring for tracheostomised patients	**D**
O3	Institute a hospital-wide tracheostomy policy	**D**
O4	Designated tracheostomy cohort wards	**D**
O5	Dedicated tracheostomy coordinator	**D**
O6	Tracheostomy link nurses in relevant wards	**D**
Domain: Patient-centred quality of care interventions		
Q1	Include patient champions	n/a
Q2	Implement Multidisciplinary Tracheostomy Team that sees patients	**D**
Q3	Integrate Speech & Language Therapist (SLTs) in ICU care	**D**
Q4	Involve SLT on Head & Neck wards	**D**
Q5	Involve SLT on general wards	**D**
Q6	Train SLTs to be Fibreoptic Endoscopic Evaluation of Swallow (FEES) proficient	**D**
Q7	Capture patient-level data	n/a
Domain: Safety interventions		
S1	Establish competency standards for staff caring for patients with tracheostomy	**D**
S2	Formalise MDT reviews of adverse incidents with learning	n/a
S3	Standardise bedside and ward area tracheostomy equipment	**C**
S4	Routinely place tracheostomy bedhead signs	**B**
S5	Use standardised tracheostomy care bundles	**A**

Notes: O1, Q1, Q7 and S2 are unmapped interventions

4. Methods

Due to the limitations around data availability previous addressed, we were unable to identify the effect of the programme directly from observed data on patient outcomes in the improvement programme sites. We therefore took a methodological approach which sought to extrapolate findings from the 20 pilot sites to the 180 participant hospitals. Information on the timing of the interventions in the improvement programme sites are matched to estimates of the impacts over time of the interventions from the pilot sites. There are two stages to the approach as set out below.

4.1 Estimating the impact of the interventions over time in the pilot scheme

The first stage of the analysis required estimation of how the mapped interventions (Table 1) affected hospital outcomes in the pilot over time. Estimates from previous evaluations of this scheme only provide average effects which are not sensitive to the timing of the introduction of the specific improvement programme interventions. Information on tracheostomies is not routinely recorded in administrative data, this limits the evaluation as we cannot identify effects using comparator hospitals (that could provide information on what occurred in hospitals in the absence of the interventions). However, the 20 participating hospitals introduced interventions at different points across the duration of the programme – providing a source of within-sample variation, i.e. ‘before and after’ intervention data.

The use of monthly hospital-level data on only 20 sites imposed restrictions on the number of explanatory variables that could be included due the sample size (note that a set of indicators capturing intervention timing also required inclusion in the regression model). In addition to this, the model specification also needed to be simple enough to allow an extrapolation to be performed given the limited recorded information on participant hospitals. These constraints required an intervention definition that was pragmatic and simple and took into consideration relative uptake of the different interventions. We focused on three interventions only because the others were not implemented overall (see Appendix Figures C and D).

We used a binary measure of whether sites had introduced three of the four mapped interventions outlined in Table 1, specifically (A, B and C below):

A. standardised tracheostomy care bundles
B. routinely place tracheostomy bedhead signs
C. standardise bedside and ward area tracheostomy equipment
D. all other interventions *(excluded from binary measure)*

We created a variable measuring time (months) relative to the first month in which all three key mapped interventions were in place. This approach is a modification of an 'event study', which is an approach applied in econometrics to estimate treatment effects when the timing of treatment varies across units (Dobkin et al., 2018; Mason, 2019). In this case, it allowed us to compare the outcomes of sites before and after the introduction of all three of the three key interventions, which is defined as the 'event' in this study.

The key coefficients of interest for this design are those on indicators for each month relative to the introduction of all three key interventions (one month is omitted as the reference period). These coefficients describe the relationship between the outcomes of interest and time prior to and since the introduction of the interventions. (See the appendix for full exposition of the methods including all estimating equations).

We estimated regression analyses using this approach first on the 'level' of the four study outcomes using appropriate count regression methods, and second on the change (in each of) the outcomes relative to the period in which all three interventions were introduced. Using the change in outcomes normalised the distribution of the outcomes such that traditional 'OLS' regression could be used, but also allowed us to estimate a measure that could then be extrapolated using the limited information available on the participant hospitals (i.e. time relative to the introduction of all three key interventions). We used analyses of the change(s) in outcomes as the primary model for estimating intervention effects in the pilot but

checked consistency of these estimates with those from analyses of the level of the outcomes.

4.2 Extrapolating potential impact to the participant sites

The estimated impacts of interventions in the months before and after their introduction were obtained from the regression of the pilot sites. We generated the same measure of time (months) relative to the introduction of all three key mapped interventions for the programme sites over the 12 months from April 2020 to March 2021.

Whilst the above allowed us to estimate levels of change per tracheostomy admission at participant hospitals, we needed to predict the initial expected level of tracheostomy admissions at sites to determine the potential scale of the impact of the improvement programme.

The initial number of tracheostomies was determined by predicting the annualised number of tracheostomy admissions in the pilot sites using hospital-level data on the number of (sex-specific) admissions, emergency admissions and planned admissions. The predicted change in outcomes per tracheostomy admission could therefore be considered alongside the predicted numbers of tracheostomy admissions to illustrate the potential impact of the improvement programmeat scale. Finally, to illustrate the potential impact on costs, we calculated the mean costs per day for a hospital inpatient based on 2019-20 NHS reference costs (NHS England, 2020) and data on admitted patient care activity for 2019-20 (NHS Digital, 2020) (Appendix Table 6).

All analyses were estimated in Stata 14.0 IC; were weighted by the number of admissions per site in each month and used robust standard errors to account for heteroscedasticity.

5. Results

5.1 Analyses of the ITC programme

Overall summary statistics on the number of tracheostomy admissions, study outcomes, and mean patient age for monthly data on hospitals are presented in Table 3. Observations represent a single participating site in a calendar month.

Table 3: Summary statistics for pilot sites

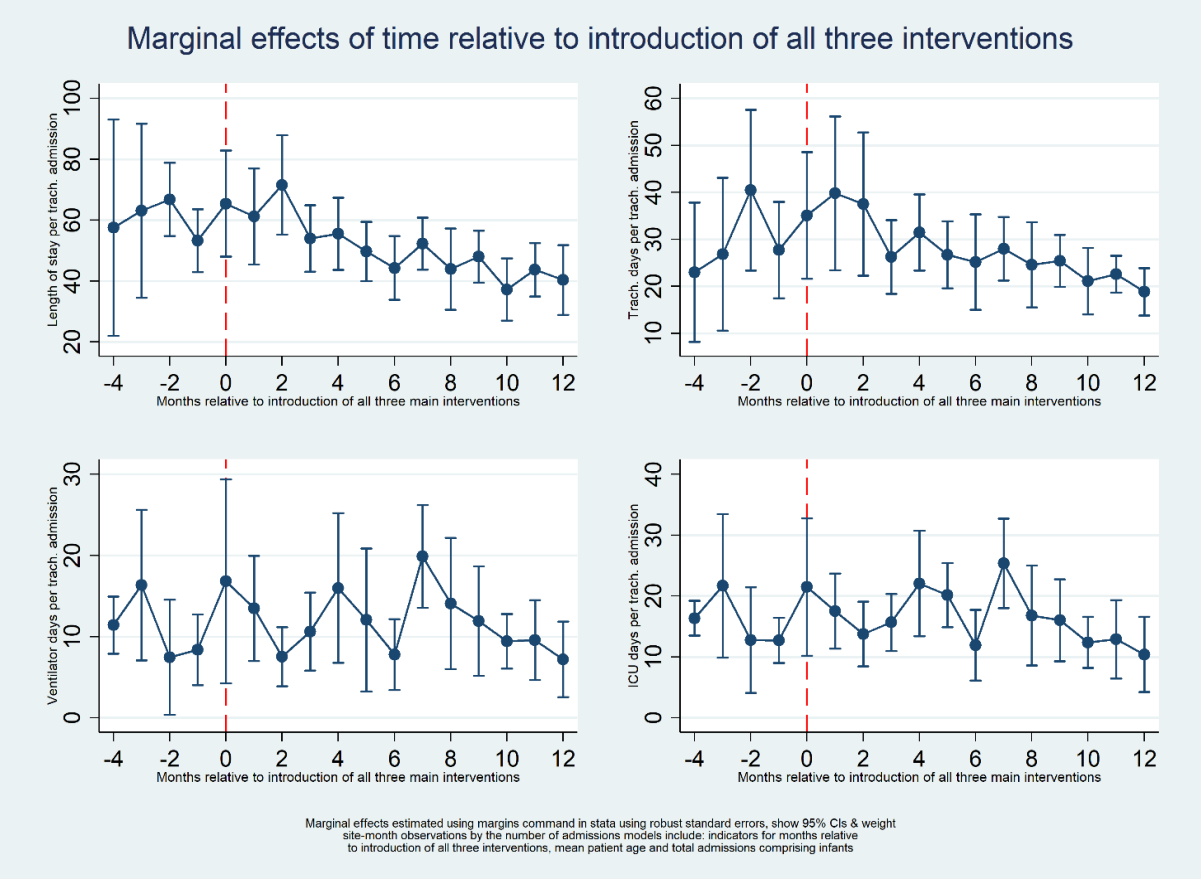
	n	Mean	Median	SD	Min	Max
Tracheostomy admissions (TA)	290	4.98	4.00	4.90	0.00	33.00
LOS per TA	250	51.44	45.71	27.41	1.33	201.00
Tracheostomy days per TA	250	27.57	24.27	18.64	0	131.00
Ventilator days per TA	162	11.58	9.29	11.47	0.00	140.00
ICU days per TA	162	16.20	13.73	12.35	0.00	148.10
Change in LOS per TA relative to r=0	241	-23.30	-18.97	42.96	-121.27	149.00
Change in tracheostomy days per TA relative to r=0	241	-8.97	-3.07	24.50	-93.00	125.00
Change in ventilator days per TA relative to r=0	162	-10.28	0.00	33.31	-133.75	59.00
Change in ICU days per TA relative to r=0	162	-10.29	-0.59	33.53	-136.90	54.63
Patient age	241	53.93	57.38	15.57	0.00	88.00

Notes: r=0 is the period when the hospital had introduced all three key interventions; eight sites did not have emergency departments; data on measure per tracheostomy admission set to missing for months in which there were no tracheostomy admissions; SD=standard deviation; measures 'per admission' and patient age weighted by the number of admissions for a given site in that month

Sites had a mean number of tracheostomy admission per month of 4.98 (median=4.00; SD=4.90), and the mean length of stay for these admissions was 51.44 days (median=45.71; SD=27.41). Patients had a tracheostomy in place for on average 27.57 days (median=23.50; SD=23.63). The mean age of patients for these admissions was 52.98 (median=57.06, SD=18.00).

Appendix Table 2 presents the regression output for estimated effects on the level of the four outcomes indicators for months relative to the introduction of all three key interventions (denoted as 'r=0') [Equation 1 in the Appendix]. We also present the corresponding estimated marginal effects (MEs) to illustrate of the absolute size of effects in Figure 1 and Appendix Table 3.

Figure 1: Predicted values of outcomes and 95% CIs on event time indicators for the (level of the) four outcomes



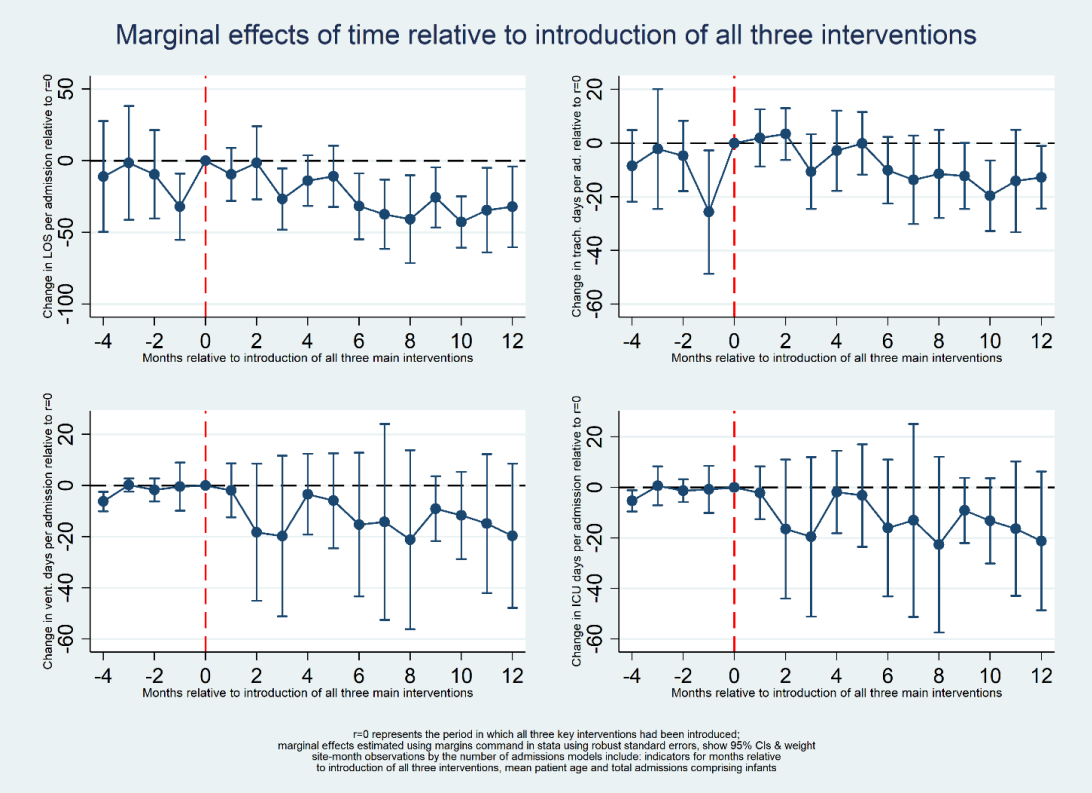
We found that length of stay per tracheostomy admission were estimated to be 65.43 days [95% CI 48.00; 82.86] in the month in which sites had first introduced all three key interventions, reducing to 44.28 days six months after [95% CI 33.81; 54.75], and reducing further to 40.36 days twelve months post-intervention [95% CI 28.90; 51.81] (Figure 1; Appendix Table 3).

The number of days in which a patient had a tracheostomy per admission were estimated at 35.08 days [95% CI 21.62; 48.54] in the month in which sites had first introduced all three key interventions, reducing to 25.13 days six months after [95% CI 14.98; 35.29], and reducing further to 18.83 days twelve months post-intervention [95% CI 13.79; 23.88] (Figure 1; Appendix Table 3).

Ventilator days per tracheostomy admission were estimated to be 16.83 days [95% CI 4.27; 29.39] in the month in which sites had first introduced all three key interventions, reducing to 7.78 days six months after [95% CI 3.42; 12.13], and reducing further to 7.19 days twelve months post-intervention [95% CI 2.54; 11.84] (Figure 1; Appendix Table 3).

ICU days per tracheostomy admission were estimated at 21.49 days [95% CI 10.19; 32.78] in the month in which sites had first introduced all three key interventions, reducing to 11.91 days six months after [95% CI 6.10; 17.71], and reducing further to 10.41 days twelve months post-intervention [95% CI 4.22; 16.60] (Figure 1; Appendix Table 3).

Figure 2: Marginal effects and 95% CIs on event time indicators for the change in outcomes relative to r=0



The results on equivalent analyses of the change in outcomes relative to the first period in which all the key interventions were introduced (r=0) are outlined in Figure 2 and Appendix Table 4 [Equation 2 in the Appendix].

5.2 Extrapolation of effects to the participant sites

Predicted values of the change in outcomes relative to r=0, based on when improvement programme sites introduced all three key interventions, were extrapolated over the first 12 months of the programme as illustrated in Figure 3.

Figure 3: Mean predicted change in outcomes and 95% CIs relative to r=0 over the duration of the improvement programme

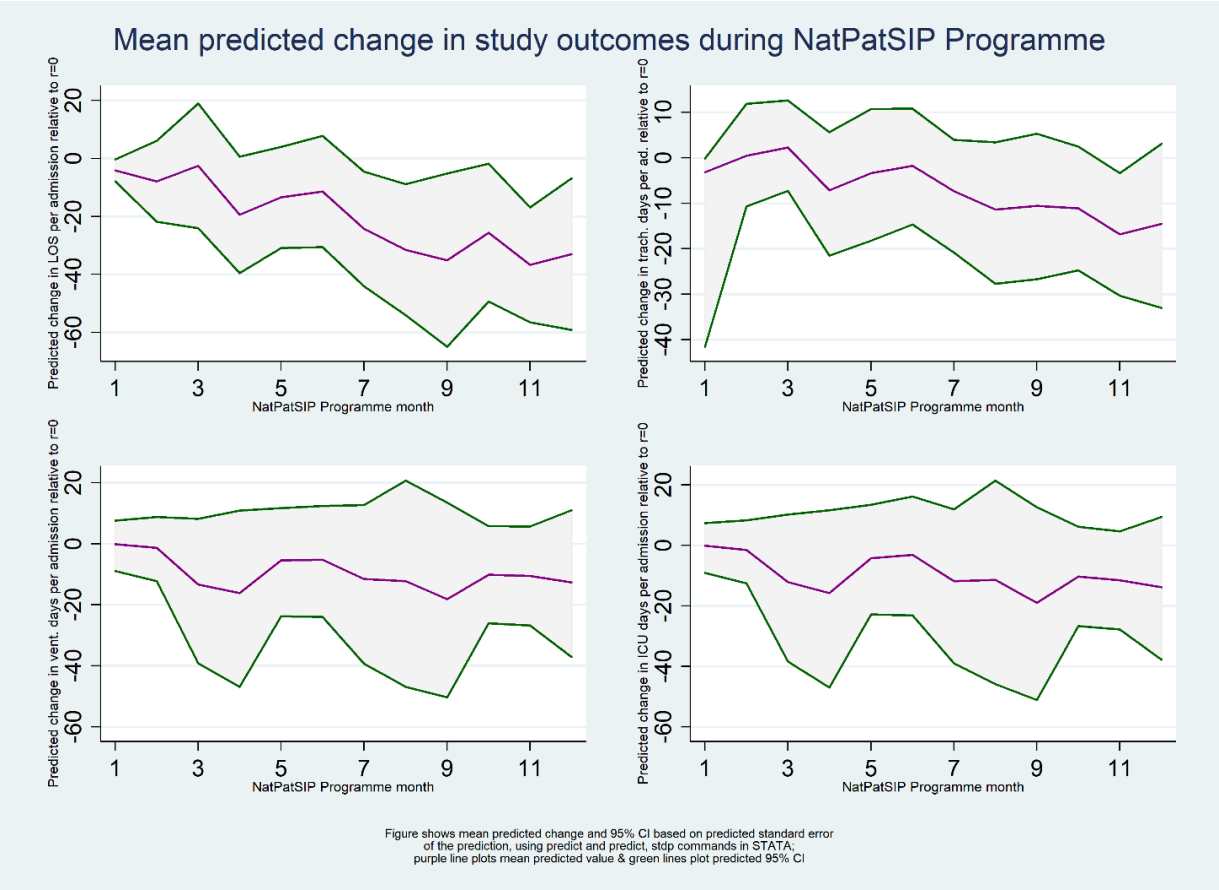


Table 4 outlines the mean predicted values and estimated confidence intervals for participant sites in the 12th month of the programme.

Table 4: Predicted values of change in outcomes after 12 months of the improvement programme

Change per TA after 12 months of programme	Mean predicted change	95% CI	
Total Hospital LOS	-33.02	-59.17	-6.87
Tracheostomy days	-14.52	-33	3.07
Ventilator days	-12.67	-37.04	10.93
ICU days	-13.79	-37.78	9.36

Notes: predictions generated using predict, xb option in stata after estimation of equation (2) for improvement programme sites

Based on information on the when the three key interventions were introduced at participant sites, the mean extrapolated reduction in total hospital length of stay per tracheostomy admission was 33.02 days [95% CI -59.17; -6.87]. Reductions estimated across the other three outcomes were not statistically significant.

Predicted values of annual tracheostomy admissions at programme hospitals were estimated to illustrate the potential scaling of average changes per tracheostomy admission in the overall programme. The mean predicted annual number of tracheostomy admissions in the participant hospitals was 69.63 (median=66.05; SD=21.27); equating to a median number of tracheostomy admissions per month of 5.50.

6. Discussion

6.1 Summary of key findings

We estimated that the original pilot was associated with reductions in average hospital length of stay, tracheostomy days, ICU days and ventilator days per admission over the course of the study based on the time elapsed since the introduction of three key interventions. This is consistent with previous evidence on the original programme effects albeit using different methods (B. A. McGrath, Wallace, et al., 2020). Models were estimated to extrapolate the potential benefits of the improvement programme under the assumption that the changes associated with the time elapsed since the introduction of three key interventions in the original pilot would be replicated. These exhibited reductions in all process metrics examined and an average reduction in total hospital length of stay of 33 days per admission 12 months after the introduction of the programme – corresponding to a potential reduction of over £27,000 per admission (Appendix Table 6).

Scaling our extrapolations suggest that significant resources were saved over the course of the improvement programme: corresponding to a potential saving of over £1.9 million per hospital over 12 months.

6.2 Strengths and limitations

The analyses outlined in this study are subject to several limitations. Many of these limitations relate to issues around data availability that related to the rapid rollout and corresponding lack of data collection during the Covid-19 pandemic. This required a number of practical decisions to be taken in terms of the methodological, but our aim was to provide an estimate of the potential impact of rolling out improvement programme at scale on a number of outcomes relevant to patients and decision-maker and quantify the uncertainty around this estimate and set out the assumptions used to allow an estimated effect to be quantified. Nevertheless, the limitations are set out below.

First, the data from the original pilot were from a small number of hospitals (n=20). Although there were 2,405 patient episodes recorded, not all patients had a comprehensive dataset. This restricted our ability to examine the effect of individual interventions over time, and more generally restricted the capacity of regression analyses to identify statistically significant differences. Second, we were unable to perform a more rigorous, comparative analyses of the impact of the original scheme due to the unavailability of appropriate comparator data as data on tracheostomies are not routinely collected. Third, we were unable to control for the effect of calendar time due to a combination of small sample size and the high degree of correlation between the introductions of the key interventions across sites over time. Many sites introduced interventions quickly and some of the interventions could be expected to influence more than one outcome. Conversely, a focus on tracheostomy care in either program could lead to unmeasured interventions, or groups of interventions occurring together, influencing outcomes. Fourth, we assumed that the effects would be repeated in the participant sites, which imposes strong assumptions on the generalisability of the effect of the interventions.

The two time periods covered by the original pilot project (2016-18) and the improvement programme (2020-21) were very different in that 2020-21 was dominated by COVID-19. The first waves saw critically ill patients requiring invasive ventilation have up to 50% mortality, with survivors requiring prolonged respiratory support and long hospital stays (Grasselli et al., 2020; Huang et al., 2020; Wang et al., 2020; Yang et al., 2020; Young et al., 2020; Zhou et al., 2020) . Around 20% of Intensive Care Unit admissions were still receiving critical care at 28 days, around 8% at 42 days, and around 2% at 56 days (ICNARC, 2020). The predicted or actual requirement for prolonged ventilation is ordinarily an indication for tracheostomy. However, COVID-19 complicates matters in terms of timing and technique, and the pandemic raised important questions regarding balancing the risks not only for patients, but also for staff and for healthcare systems (Williams & McGrath, 2021). Before the pandemic, tracheostomy rates could be expected at around 10-13% of all ventilated ICU admissions in modern healthcare systems, varying with casemix (Bedwell et al., 2019; Blot & Melot, 2005; Fischler et al., 2000; B. A. McGrath & Wilkinson, 2015b; Nathens et al., 2006; Veenith et al., 2008, 2008; Young et al.,

2020). Tracheostomy rates in the pandemic ranged from 16-60% in the UK, Europe and worldwide (Martin-Villares et al., 2021; Queen Elizabeth Hospital Birmingham COVID-19 airway team, 2020; Williams & McGrath, 2021), and were likely double the pre-pandemic baseline rates (Williams & McGrath, 2021). As we learned more about the management of critically ill patients with COVID-19, tracheostomy rates returned to baseline (B. A. McGrath, Brenner, et al., 2020). Although the exact figures are unknown, it is likely that significantly more patients underwent tracheostomy during the improvement programme period than the index ITC program, meaning that the extrapolations presented are based on conservative assumptions regarding volumes of tracheostomies undertaken.

6.3 Implications for future research

This study outlined possible benefits of a scaled QI initiative for tracheostomy care in hospitals in the English NHS. Future studies could exploit improvements in the routine recording of tracheostomy in hospitals by comparing patient outcomes in improvement programme hospitals that have undertaken the QI programme with those experienced by patients in non-participating hospitals. This would markedly further the evidence as to the impact of the QI interventions introduced as part of the original pilot and more recent improvement programme – with potential implications for wider adoption within the NHS and across health systems internationally (Brenner et al., 2020).

6.4 Implications for practice and policy

The improvement programme led to the introduction of a number of QI elements in English NHS hospitals. However, there are a number of areas for further progress including: improvements in routine data collection and centralised analyses to drive care; adoption of the other QI elements from the original scheme that have been shown to have potential to improve care; and expansion to non-English NHS hospitals. These additional changes have the potential to improve on the platform constructed by the improvement programme using evidence on QI strategies for tracheostomy care outlined by the GTC (Brenner et al., 2020).

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8. Appendix

8.1 Methods

We estimated the coefficients on indicator variables for time relative to the event (event time) as follows:

$$y_{it} = a + \sum_{r=j}^{-1} \mu_r + \sum_{r=1}^{J} \mu_r + \varepsilon_{it} \quad (1)$$

where y_{it} is one of four outcome variables for hospital site i in month t; μ_r are coefficients on binary indicators for event time $r = j, .., J$ and ε_{it} is an idiosyncratic error. The coefficients of interest are the pattern on the μ_r dummies which estimate the outcome at a given r relative to the omitted month $(r = 0)$.

We first estimated (1) on the level of the four study outcomes using Poisson regression which is appropriate for the analysis of health care data exhibiting marked skewness/count data properties (see Appendix Figure 1) (Basu & Manning, 2009; Greene, 1997; Manning & Mullahy, 2001). The generalised form (1) was therefore estimated as (A1)

$$Pr(y_{it} = c \mid \kappa) = \frac{\lambda_i^j e^{-\lambda_i}}{y!}; \;\; c = 0, 1, 2.. \quad (A1)$$

where $\kappa = a + \gamma_t + X_{it}\beta + \sum_{r=j}^{J-1} \mu_r + \varepsilon_{it}; \;\; \lambda_i = E[\, y_{it} \mid \kappa \,] = Var[y_{it} \mid \kappa] = e^{\kappa}$.

We then re-estimated the equivalent regression for the cumulative change in each of the four outcomes measured from when each site had introduced all three key interventions (i.e. when event time $r = 0$):

$$\Delta y_{ir} = a + \sum_{r=j}^{-1} \mu_r + \sum_{r=1}^{J} \mu_r + \varepsilon_{it} \quad (2)$$

where

$$\Delta y_{ir} = y_{ir} - y_{ir=0} \quad (3)$$

We did not include fixed effects for chronological time (calendar month) in the analyses due to the high correlation between calendar time and event time in both the ITC and improvement programme hospitals (Appendix Figures 3 & 4). We also omitted mean patient age from (1) and (2) on the basis that this information is unknown in the improvement programme hospitals (and therefore could not be extrapolated), but we examined how the inclusion of patient age affected the estimates in (2) in the appendix:

$$\Delta y_{ir} = a + \sum_{r=j}^{-1} \mu_r + \sum_{r=1}^{J} \mu_r + \beta x_{it} + \varepsilon_{it} \quad (4)$$

where x_{it} is mean patient age for hospital site i in month t.

The estimates on the μ_r coefficients in (2) were then used to generate predicted values of the hospital-level change in outcomes, $\widehat{\Delta y_{ir}}$ for each of the improvement programme sites.

We then used a two-stage approach to summarise an extrapolation of the potential effects of the improvement programme at scale. First, we estimated a simple regression model of the annualised number of tracheostomy admissions in the ITC sites using Poisson regression (written in general form):

$$z_{is} = \alpha + \rho n_{is} + \theta e_{is} + \pi f_{is} + \tau p_{is} + u_{is} \quad (5)$$

where z_{is} represents the number of tracheostomy admissions in hospital i in year s; n_{is} is the number of finished admission episodes in hospital i in year s; e_{is} is the number emergency admissions in hospital i in year s; f_{is} is the number of admissions for female patients in hospital i in year s; p_{is} is the number of planned

admissions in hospital i in year s; and u_{is} is an idiosyncratic error term. The full exposition of (5) is given by (A2):

$$Pr(z_{is} = c \mid \kappa) = \frac{\lambda_i^j e^{-\lambda_i}}{y!};\ \ c = 0, 1, 2.. \tag{A2}$$

where $\kappa = \alpha + \rho n_{is} + \theta e_{is} + \pi f_{is} + u_{is};\ \lambda_i = E[\, z_{is} \mid \kappa\,] = Var[z_{is} \mid \kappa] = e^{\kappa}$.

Estimation of (5) allowed for generating predicted values of the number of tracheostomy admissions in hospital i in year s, $\hat{z}_{is}$, in each of improvement programme sites for the financial year 2020-21 based on the same information on the independent variables in (5) (n_{is}, e_{is} and f_{is}).

Mapping of interventions from the pilot to improvement programme

The pattern of the introduction of the 18 original interventions in the ITC programme over time prior to their mapping to the improvement programme interventions is illustrated more explicitly in Appendix Table 1. Appendix Table 0 shows the equivalent pattern in the mapped interventions S3 (C), S4 (B) and S5 (A) and the binary indicator of the indicating whether all three key mapped interventions (S3, S4 and S5) were in place for both the ITC and improvement programme.

Appendix Table 0: Proportion of programme sites introducing key mapped interventions by project month

Project Month	ITC programme sites				Improvement programme site			
	S3 [C]	S4 [B]	S5 [A]	All 3	S3 [C]	S4 [B]	S5 [A]	All 3
1	1.00	1.00	0.50	0.50	0.78	0.83	0.90	0.72
2	1.00	1.00	0.67	0.67	0.86	0.93	0.97	0.83
3	0.91	1.00	0.73	0.64	0.89	0.96	0.98	0.87
4	0.83	1.00	0.75	0.58	0.89	0.96	0.98	0.87
5	0.79	1.00	0.71	0.57	0.89	0.96	0.98	0.87
6	0.94	0.89	0.89	0.78	0.89	0.96	0.98	0.87
7	0.94	0.89	0.89	0.78	0.92	0.96	0.99	0.90
8	0.94	0.89	0.89	0.78	0.92	0.96	0.99	0.90
9	0.94	0.89	0.89	0.78	0.93	0.97	1.00	0.90
10	0.94	0.89	0.89	0.78	0.93	0.97	1.00	0.90
11	0.94	0.94	0.94	0.89	0.93	0.97	1.00	0.90
12	1.00	0.95	0.95	0.95	0.94	1.00	1.00	0.94
13	1.00	1.00	1.00	1.00	n/a	n/a	n/a	n/a

Note: no information available on NHS hospital sites after month 12; proportion can fall over time due to first/last project month record varying by site.

The corresponding comparisons for the introduction of the interventions in the two programmes - including the fourth ‘all other interventions’ variable - are shown in Appendix Figures 3 and 4.

9. Appendix Tables

Appendix Table 1: Proportion of 20 ITC sites introducing the 18 original interventions by project month

Month	Organisation and Efficiency						Safety					Quality of care						
	O1	O2	O3	O4	O5	O6	S1	S2	S3	S4	S5	Q1	Q2	Q3	Q4	Q5	Q6	Q7
1	0.50	0.00	0.00	1.00	0.00	0.00	0.00	1.00	1.00	1.00	0.50	0.00	0.50	1.00	1.00	1.00	0.50	1.00
2	0.56	0.33	0.33	1.00	0.33	0.11	0.33	1.00	1.00	1.00	0.67	0.00	0.33	0.33	0.33	0.33	0.33	1.00
3	0.64	0.36	0.36	1.00	0.27	0.09	0.36	1.00	0.91	1.00	0.73	0.09	0.36	0.36	0.36	0.36	0.45	1.00
4	0.67	0.42	0.33	1.00	0.25	0.08	0.42	1.00	0.83	1.00	0.75	0.08	0.33	0.33	0.33	0.33	0.42	1.00
5	0.71	0.43	0.36	1.00	0.21	0.14	0.43	1.00	0.79	1.00	0.71	0.07	0.36	0.29	0.29	0.29	0.50	1.00
6	0.72	0.39	0.67	1.00	0.22	0.33	0.44	1.00	0.94	0.89	0.89	0.28	0.44	0.44	0.39	0.39	0.50	1.00
7	0.72	0.39	0.72	1.00	0.22	0.33	0.44	1.00	0.94	0.89	0.89	0.33	0.44	0.50	0.44	0.39	0.50	1.00
8	0.72	0.39	0.72	1.00	0.22	0.33	0.44	1.00	0.94	0.89	0.89	0.33	0.44	0.50	0.44	0.39	0.50	1.00
9	0.72	0.39	0.72	1.00	0.22	0.33	0.44	1.00	0.94	0.89	0.89	0.33	0.44	0.50	0.44	0.39	0.50	1.00
10	0.72	0.39	0.72	1.00	0.22	0.33	0.44	1.00	0.94	0.89	0.89	0.33	0.44	0.50	0.44	0.39	0.50	1.00
11	0.72	0.72	0.83	1.00	0.28	0.61	0.78	1.00	0.94	0.94	0.94	0.78	0.78	0.83	0.72	0.72	0.50	1.00
12	1.00	0.79	0.89	1.00	0.26	0.63	0.84	1.00	1.00	0.95	0.95	0.79	0.84	0.95	0.84	0.84	0.53	1.00
13	1.00	0.84	0.95	1.00	0.26	0.68	0.89	1.00	1.00	1.00	1.00	0.84	0.89	0.95	0.84	0.84	0.53	1.00
14	1.00	0.84	0.95	1.00	0.26	0.68	0.89	1.00	1.00	1.00	1.00	0.84	0.89	0.95	0.84	0.84	0.53	1.00
15	1.00	0.84	1.00	1.00	0.26	0.74	0.89	1.00	1.00	1.00	1.00	0.84	0.95	1.00	0.89	0.84	0.53	1.00
16	1.00	0.80	1.00	1.00	0.30	0.75	0.90	0.95	1.00	1.00	1.00	0.85	0.95	1.00	0.90	0.85	0.50	1.00
17	1.00	0.90	1.00	1.00	0.45	0.85	0.95	0.95	1.00	1.00	1.00	0.95	0.95	1.00	0.95	0.85	0.50	1.00
18	1.00	0.90	1.00	1.00	0.45	0.85	0.95	0.95	1.00	1.00	1.00	0.95	0.95	1.00	0.95	0.85	0.50	1.00
19	1.00	0.90	1.00	1.00	0.45	0.85	0.95	0.95	1.00	1.00	1.00	0.95	0.95	1.00	0.95	0.85	0.50	1.00
20	1.00	0.90	1.00	1.00	0.45	0.85	0.95	0.95	1.00	1.00	1.00	1.00	0.95	1.00	0.95	0.85	0.50	1.00
21	1.00	0.89	1.00	1.00	0.42	0.84	0.95	0.95	1.00	1.00	1.00	1.00	0.95	1.00	0.95	0.84	0.53	1.00
22	1.00	0.89	1.00	1.00	0.42	0.84	0.95	0.95	1.00	1.00	1.00	1.00	0.95	1.00	0.95	0.84	0.53	1.00
23	1.00	1.00	1.00	1.00	0.58	0.84	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.79	1.00
24	1.00	1.00	1.00	1.00	0.58	0.84	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.79	1.00
25	1.00	1.00	1.00	1.00	0.58	0.84	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.79	1.00
26	1.00	1.00	1.00	1.00	0.61	0.83	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.78	1.00
27	1.00	1.00	1.00	1.00	0.63	0.88	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.81	1.00
28	1.00	1.00	1.00	1.00	0.60	0.87	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.80	1.00
29	1.00	1.00	1.00	1.00	0.57	0.86	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.79	1.00

Note: proportion can fall over time due to first/last project month record varying by site

Appendix Table 2: Estimated incident rate ratios (IRRs) and 95% CIs for estimation of model (1)

		LOS per TA			Trach. Days per TA			ICU days per TA			Vent. Days per TA		
		IRR	[95% CI]		IRR	[95% CI]		IRR	[95% CI]		IRR	[95% CI]	
Month relative to r=0 (reference period)	-4	0.879	0.449	1.723	0.656	0.309	1.389	0.761	0.437	1.324	0.679	0.303	1.523
	-3	0.965	0.571	1.630	0.765	0.373	1.568	1.009	0.474	2.150	0.972	0.381	2.481
	-2	1.021	0.740	1.408	1.153	0.651	2.041	0.594	0.252	1.402	0.444	0.133	1.484
	-1	0.814	0.585	1.132	0.790	0.463	1.346	0.592	0.325	1.080	0.498	0.201	1.236
	1	0.935	0.646	1.355	1.134	0.646	1.991	0.816	0.434	1.534	0.801	0.330	1.945
	2	1.094	0.770	1.554	1.069	0.611	1.869	0.641	0.334	1.230	0.447	0.184	1.089
	3	0.825	0.590	1.152	0.748	0.460	1.217	0.730	0.399	1.336	0.630	0.263	1.509
	4	0.848	0.603	1.194	0.897	0.565	1.424	1.026	0.533	1.978	0.950	0.370	2.439
	5	0.759	0.546	1.056	0.761	0.477	1.214	0.938	0.522	1.686	0.717	0.252	2.036
	6	0.677	0.474	0.966	0.716	0.410	1.251	0.554	0.271	1.135	0.462	0.182	1.175
	7	0.799	0.585	1.092	0.797	0.507	1.255	1.181	0.648	2.152	1.182	0.525	2.660
	8	0.671	0.448	1.005	0.701	0.411	1.193	0.783	0.382	1.604	0.837	0.326	2.146
	9	0.734	0.532	1.011	0.724	0.466	1.126	0.746	0.381	1.461	0.708	0.278	1.805
	10	0.568	0.388	0.834	0.602	0.362	1.002	0.577	0.309	1.078	0.561	0.245	1.282
	11	0.668	0.478	0.933	0.644	0.423	0.982	0.601	0.291	1.239	0.569	0.230	1.406
	12	0.617	0.418	0.910	0.537	0.336	0.857	0.485	0.219	1.072	0.427	0.159	1.147
Constant		65.432	50.132	85.403	35.081	23.902	51.490	21.485	12.701	36.342	16.830	7.979	35.501
n		250			250			162			162		

Notes: All models estimated using Poisson regression; weighted by the number of TAs for each site in each month; all models used robust standard errors.

Appendix Table 3: Estimated marginal effects (MEs) and 95% CIs for estimation of model (1)

		LOS per TA			Trach. Days per TA			ICU days per TA			Vent. Days per TA		
		ME	[95% CI]		ME	[95% CI]		ME	[95% CI]		ME	[95% CI]	
Month relative to r=0 (reference period)	-4	57.542	21.990	93.093	23.000	8.155	37.845	16.350	13.503	19.197	11.432	7.912	14.951
	-3	63.114	34.564	91.665	26.829	10.550	43.107	21.681	9.888	33.473	16.355	7.078	25.632
	-2	66.784	54.714	78.854	40.451	23.346	57.556	12.766	4.099	21.433	7.468	0.380	14.556
	-1	53.267	42.902	63.631	27.707	17.452	37.961	12.721	9.009	16.434	8.386	4.037	12.734
	0	65.432	48.004	82.861	35.081	21.620	48.542	21.485	10.192	32.778	16.830	4.268	29.392
	1	61.207	45.442	76.972	39.793	23.428	56.158	17.532	11.405	23.659	13.473	7.000	19.946
	2	71.576	55.227	87.925	37.485	22.235	52.735	13.771	8.466	19.076	7.527	3.880	11.175
	3	53.977	43.067	64.887	26.241	18.400	34.082	15.683	11.005	20.360	10.609	5.812	15.405
	4	55.515	43.625	67.404	31.456	23.321	39.592	22.051	13.392	30.710	15.986	6.768	25.205
	5	49.686	39.995	59.378	26.686	19.556	33.817	20.147	14.898	25.396	12.063	3.259	20.868
	6	44.277	33.805	54.749	25.133	14.980	35.285	11.908	6.104	17.712	7.778	3.424	12.132
	7	52.289	43.795	60.783	27.967	21.208	34.725	25.370	18.027	32.712	19.889	13.563	26.215
	8	43.918	30.581	57.254	24.577	15.499	33.656	16.812	8.601	25.023	14.081	5.989	22.173
	9	48.000	39.436	56.564	25.408	19.854	30.963	16.027	9.310	22.744	11.921	5.202	18.639
	10	37.192	26.962	47.422	21.125	14.059	28.191	12.400	8.221	16.579	9.438	6.086	12.791
	11	43.709	34.916	52.502	22.600	18.676	26.524	12.903	6.475	19.330	9.575	4.677	14.473
	12	40.356	28.899	51.814	18.832	13.787	23.877	10.410	4.220	16.601	7.190	2.540	11.840
n		250			250			162			162		

Notes: ME estimated using margins, predict command in Stata; model VCE: robust; results correspond to equation (1)

Appendix Table 4: Estimated coefficients and 95% CIs for estimation of model (2)

		Change in LOS per TA relative to r=0			Change in trach. days per TA relative to r=0			Change in ICU days per TA relative to r=0			Change in vent. days per TA relative to r=0		
		Coeff.	[95% CI]		Coeff.	[95% CI]		Coeff.	[95% CI]		Coeff.	[95% CI]	
Month relative to r=0 (reference period)	-4	-10.943	-49.628	27.742	-8.507	-21.837	4.823	-5.338	-9.587	-1.089	-6.242	-10.027	-2.457
	-3	-1.487	-41.254	38.280	-2.185	-24.492	20.121	0.670	-7.023	8.363	0.204	-2.348	2.757
	-2	-9.442	-40.278	21.393	-4.746	-17.844	8.352	-1.274	-5.768	3.220	-1.701	-6.174	2.772
	-1	-32.010	-55.077	-8.943	-25.668	-48.688	-2.647	-0.782	-10.118	8.553	-0.387	-9.805	9.031
	1	-9.543	-28.124	9.038	1.927	-8.757	12.612	-2.173	-12.627	8.280	-1.852	-12.410	8.705
	2	-1.437	-26.917	24.044	3.382	-6.258	13.022	-16.502	-44.037	11.033	-18.244	-45.036	8.548
	3	-26.695	-47.980	-5.409	-10.624	-24.564	3.315	-19.541	-51.124	12.041	-19.724	-51.147	11.700
	4	-13.833	-31.518	3.853	-2.812	-17.734	12.110	-1.805	-18.078	14.467	-3.366	-19.161	12.430
	5	-10.877	-32.217	10.462	-0.112	-11.757	11.533	-3.186	-23.508	17.136	-5.898	-24.467	12.672
	6	-31.720	-54.778	-8.662	-10.138	-22.526	2.251	-16.051	-43.103	11.001	-15.234	-43.319	12.850
	7	-37.293	-61.462	-13.124	-13.700	-30.173	2.773	-13.058	-51.218	25.102	-14.199	-52.483	24.085
	8	-40.771	-71.440	-10.102	-11.490	-27.901	4.920	-22.667	-57.396	12.062	-21.144	-56.133	13.845
	9	-25.553	-46.598	-4.509	-12.248	-24.541	0.044	-9.108	-21.992	3.776	-9.066	-21.743	3.612
	10	-42.743	-60.672	-24.814	-19.646	-32.794	-6.498	-13.218	-30.154	3.717	-11.688	-28.723	5.347
	11	-34.454	-63.917	-4.991	-14.157	-33.224	4.911	-16.323	-42.871	10.226	-14.889	-42.078	12.299
	12	-32.062	-60.212	-3.912	-12.733	-24.428	-1.037	-21.211	-48.648	6.227	-19.619	-47.840	8.603
Constant		0.000	0.000	0.000	0.000	.	.	0.000	.	.	0.000	.	.
R-sq.		0.105			0.101			0.057			0.049		
N		241			241			162			162		

Notes: All models estimated using OLS; weighted by the number of TAs for each site in each month; all models used robust standard errors.

Appendix Table 5: Estimates of the relationship between tracheostomy admissions and other measures of hospital activity

	IRR	95% CI	
Finished admission episodes	1.000	1.000	1.000
Emergency admissions	1.000	1.000	1.000
Admissions for females	1.000	1.000	1.000
Planned admissions	1.000	1.000	1.000
Constant	50.592	36.909	69.349
R-sq	0.097		
N	32		

Notes: Model estimated using Poisson regression; robust standard errors

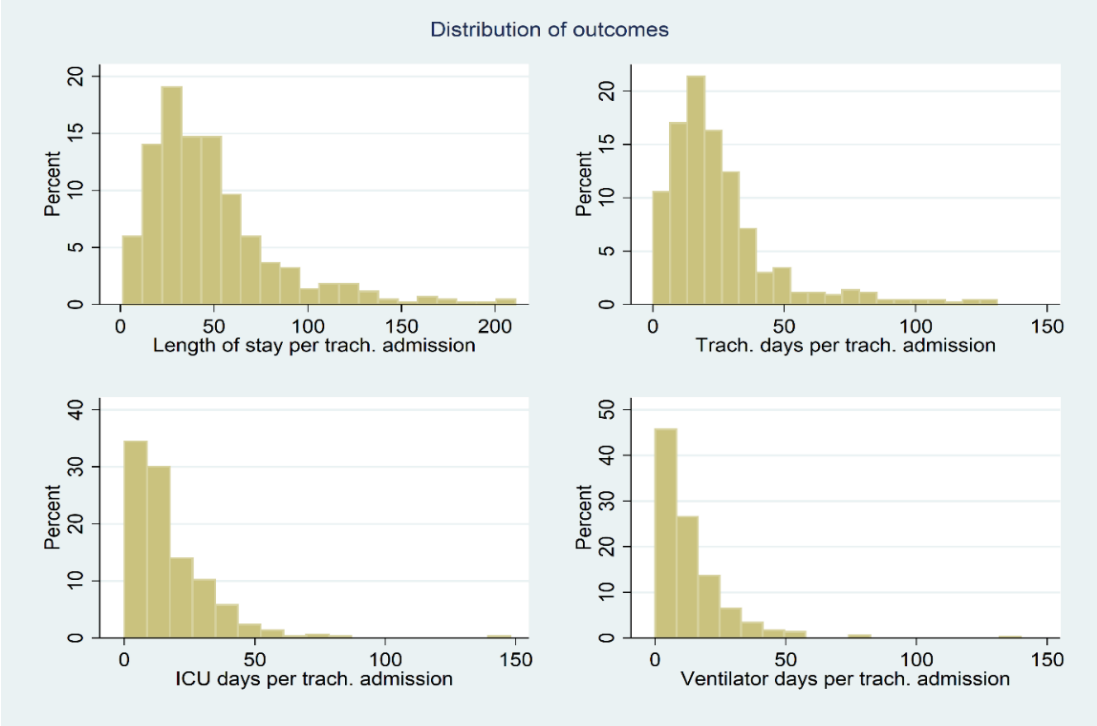
Appendix Table 6: Average NHS inpatient admissions and costs

Admission type	Volume	Average Cost	Total Cost
Elective Inpatients	1,178,525	£4,612	£5,435,357,300
Non Elective Inpatients	3,986,935	£3,519	£14,030,024,265
Mean cost per admission			£3,768
Mean length of stay*			4.5
Mean cost per day			£837

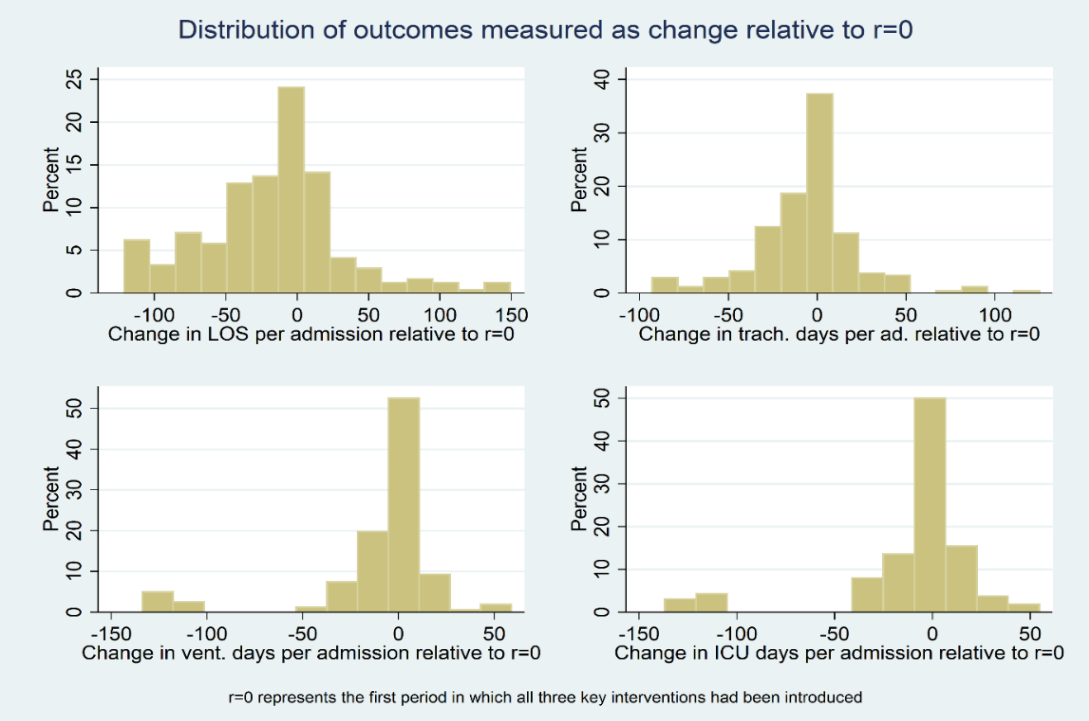
Data from 2019-20 NHS reference costs; *NHS Digital, 2020

10. Appendix Figures

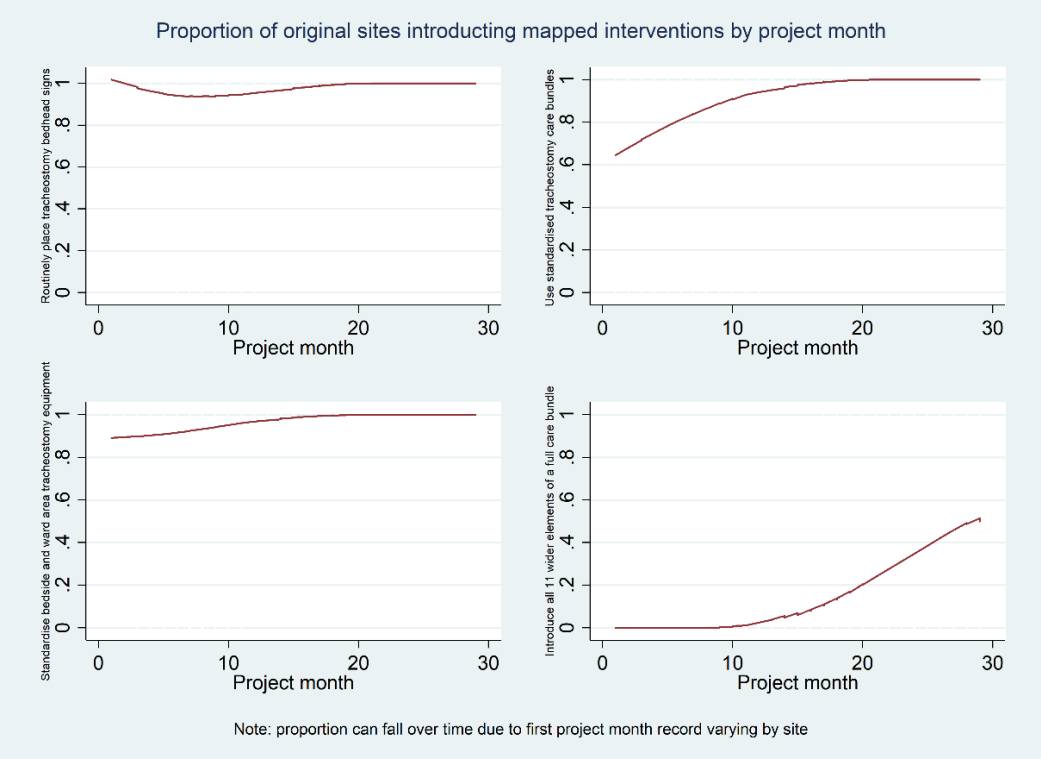
Appendix Figure 1: Distribution of level of the study outcomes



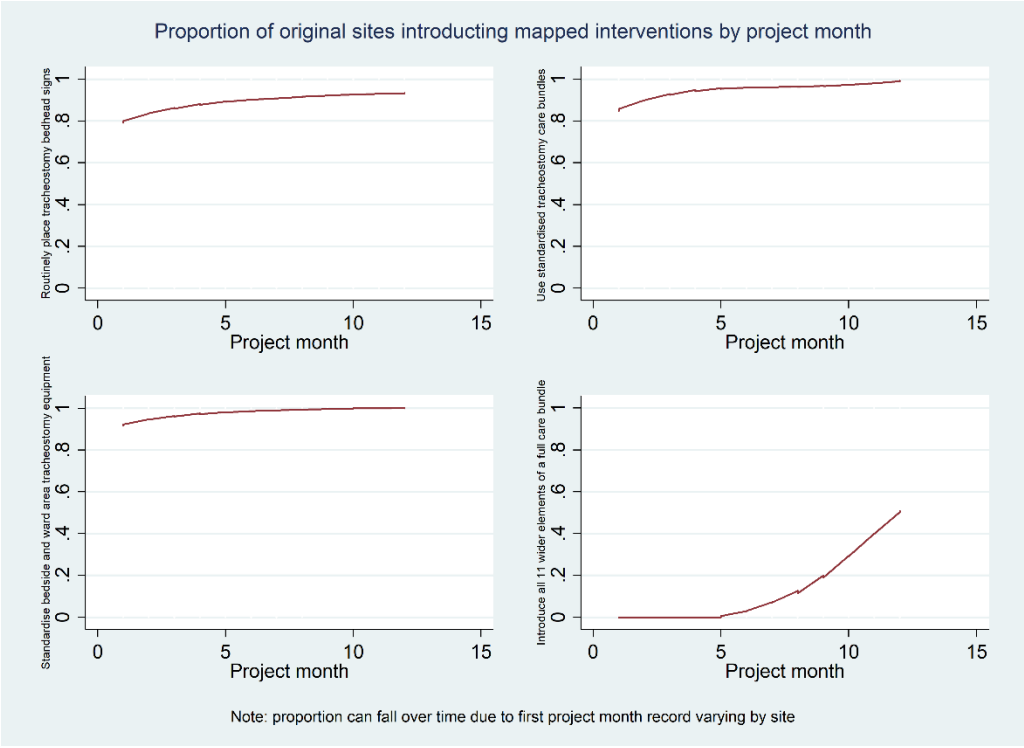
Appendix Figure 2: Distribution of change in outcomes relative to r=0



Appendix Figure 3: Proportion of original ITC study sites introducing mapped interventions by project month



Appendix Figure 4: Proportion of improvement programme sites introducing mapped interventions by project month



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The information in this report is correct at the time of printing.