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Clinical Investigation

CLINICAL INVESTIGATION

Improving tracheostomy care in the United Kingdom: results of a guided quality improvement programme in 20 diverse hospitals†

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Abstract

Background: Inconsistent and poorly coordinated systems of tracheostomy care commonly result in frustrations, delays, and harm. Quality improvement strategies described by exemplar hospitals of the Global Tracheostomy Collaborative have potential to mitigate such problems. This 3 yr guided implementation programme investigated interventions designed to improve the quality and safety of tracheostomy care.

Methods: The programme management team guided the implementation of 18 interventions over three phases (baseline/implementation/evaluation). Mixed-methods interviews, focus groups, and Hospital Anxiety and Depression Scale questionnaires defined outcome measures, with patient-level databases tracking and benchmarking process metrics. Appreciative inquiry, interviews, and Normalisation Measure Development questionnaires explored change barriers and enablers.

Results: All sites implemented at least 16/18 interventions, with the magnitude of some improvements linked to staff engagement (1536 questionnaires from 1019 staff), and 2405 admissions (1868 ICU/high-dependency unit; 7.3% children) were prospectively captured. Median stay was 50 hospital days, 23 ICU days, and 28 tracheostomy days. Incident severity score reduced significantly (n=606; P<0.01). There were significant reductions in ICU (−;0.25 days month^{-1}), ventilator (−;0.11 days month^{-1}), tracheostomy (−;0.35 days month^{-1}), and hospital (−;0.78 days month^{-1}) days (all P<0.01). Time to first vocalisation and first oral intake both decreased by 7 days (n=733; P<0.01). Anxiety decreased by 44% (from 35.9% to 20.0%), and depression decreased by 55% (from 38.7% to 18.3%) (n=385; both P<0.01). Independent economic analysis demonstrated £33 251 savings per patient, with projected annual UK National Health Service savings of £275 million.

Conclusions: This guided improvement programme for tracheostomy patients significantly improved the quality and safety of care, contributing rich qualitative improvement data. Patient-centred outcomes were improved along with significant efficiency and cost savings across diverse UK hospitals.

Clinical trial registration: IRAS-ID-206955; REC-Ref-16/LO/1196; NIHR Portfolio CPMS ID 31544.

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Editor's key points

- Systems of tracheostomy care are inconsistent and poorly coordinated, resulting in variable quality of care.
- A 3 yr guided implementation of the Global Tracheostomy Collaborative investigated interventions designed to improve quality and safety of tracheostomy care.
- Management-team-guided implementation of 18 interventions over three phases in 20 sites representing the diversity of the UK National Health Service was assessed using quality metrics, interviews, focus groups, and questionnaires.
- There were significant reductions in; ICU days; ventilator days; tracheostomy days and hospital length of stay. Time to first vocalisation and first oral intake both decreased, anxiety and depression decreased, and cost of care decreased significantly.
- It was possible to improve the quality and safety of tracheostomy care in a socio-economically, geographically, and operationally diverse group of hospitals participating in a dedicated, guided quality improvement programme.

Tracheostomies act as artificial airways for around 15 000 patients in England and Wales annually.[1–4] Patients often have significant co-morbidities, with medical needs that cross traditional specialty working boundaries and locations. These patients are dependent on competent, knowledgeable staff to keep them safe. Landmark studies consistently highlight failings in tracheostomy care provision in hospital, demonstrating how inadequate staff training, deficient equipment provision, and lack of necessary infrastructure lead to avoidable patient harm, morbidity, and mortality.[2,5–7] Patients who undergo tracheostomy are often critically ill and have in-hospital mortality reported from 25% to 60%, with most of this mortality attributed to underlying illness.[8,9] However, up to 30% of tracheostomy patients experience an untoward incident during their hospital stay. Measurable harm occurs in 60–70% of such incidents, including hospital or ICU (re) admission, prolonged in-patient stays, hypoxic brain injury, and death.[6,7] Delays in care are common because of the variety and complexity of services accessed by tracheostomised patients.[10]

Single hospitals or teams have previously reported success in improving outcomes, demonstrating that many problems in tracheostomy patients are amenable to prospective quality improvement (QI) strategies.[11–15] To coordinate resources and strategies for such solutions at scale, groups, such as the UK National Tracheostomy Safety Project (NTSP) (www.tracheostomy.org.uk) and the Global Tracheostomy Collaborative (GTC; www.globaltrach.org), have emerged, providing approaches to improve care.

The GTC is a global community of healthcare institutions, teams, and individuals focused on collaborating to implement or expand upon best practices that can improve the quality or safety of care.[16] Multidisciplinary teams include members from the diverse specialties involved in tracheostomy care, and emphasise the central roles for patients, families, and carers in decision-making and iterative improvement processes.[17] The GTC key drivers for improvement are described elsewhere,[11,18] but briefly, comprise.

(i) Multidisciplinary care: an institution-level multidisciplinary committee and a multidisciplinary 'tracheostomy team' that meet and see patients regularly
(ii) Standardisation of care: planned protocols or care pathways
(iii) Broad staff education
(iv) Patient and family involvement
(v) Patient-level data: to track changes, benchmark, and drive improvements

To date, only small-scale evaluations of adopting the GTC drivers for improvement and associated interventions have been reported from individual sites or clusters of sites. Whilst a four-site UK implementation programme positively impacted care, it remained unclear whether these interventions could have a similar impact on patient outcomes at scale.[12] These patient outcomes include several widely used QI metrics, such as mortality, adverse events, length of stay (LOS), and cost, and also patient-centred measures most relevant to tracheostomy patients, such as time to first vocalisation, time to first oral intake, and measures of anxiety and depression. The aims of this study were to conduct a large-scale demonstration programme in geographically, demographically, and socio-economically diverse hospitals in the UK's public National Health Service (NHS); to refine existing interventions and evaluate their impact on safety and variation in care; and to understand the contextual implementation challenges for delivering reliable and sustainable change in patient outcomes. This study is also intended to share methods the readers can adapt to their own hospital and clinical practice. The Improving Tracheostomy Care programme's key objectives were to partner 20 UK hospitals, identifying leaders and champions from healthcare staff and patients; to rapidly implement GTC/NTSP resources by creating a change culture; to create a national collaborative environment for tracheostomy QI; and to describe and evaluate the experiences of patients and staff.

Methods

Study oversight

This investigator-initiated, multicentre, unblinded observational study was (competitively) funded by The Health Foundation, in partnership with the Royal College of Anaesthetists, the NTSP, and the GTC. As part of the grant award, independent improvement consultancy was provided by Springfield Consultancy and independent economic evaluation by the University of East Anglia Health Economics Consulting. The study was designed by the authors and overseen by a representative steering committee.

Ethical considerations

The GTC has sought extensive advice in complying with country-specific Ethics Committee (Institutional Review Board) guidelines to fulfil its purpose as a QI collaborative. There were clear additional aims for the Improving Tracheostomy Care programme beyond the QI Collaborative, with detailed questioning, interviews, and qualitative data collection from NHS patients and staff. National Research Ethics Committee approval was granted on July 11, 2016 (IRAS Project

ID 206955; REC Ref 16/LO/1196), subsequently adopted onto the National Institute for Health Research Portfolio (CPMS ID 31544).

Site selection

We identified and contacted the 44 potential UK hospitals from those with prior active engagement with either the NTSP or the GTC. The first 20 sites that indicated a positive interest and multidisciplinary commitment to participating in the programme, along with appropriate research capability and capacity, were included. These 20 self-nominating sites represented the diverse nature of NHS hospitals, geographically, structurally, and organisationally. Specifically, the hospitals spanned England, Wales, and Scotland, and included adult and paediatric district general and tertiary services with a range of tracheostomy services.

Interventions

The participating sites were grouped geographically, with study setup staggered over 3 months. An initial site visit by the study team profiled existing tracheostomy services and infrastructure. High-level executive engagement and support were secured, and local tracheostomy multidisciplinary teams and leaders were identified, supported, and developed. Interventions to improve care were identified from existing local practices, other participating sites, and the wider GTC community, or were newly developed to meet specific needs. Interventions were selected and prioritised by consensus processes previously described.[19] Eighteen interventions were selected and grouped into themes addressing patient safety, patient-focused quality of care, and organisational efficiency (Table 1). There was no funding available for sites to develop or implement new interventions or services, although many developed internal business cases for new staff roles during the course of the programme, supported by data generated by the project. The GTC membership for all hospitals was paid for by the programme along with funding for tracheostomy Train the Trainer and provider courses via the Advanced Life Support Group (www.alsg.org) based on NTSP guidelines.[17,18,20,21] Sites participated in 6-monthly themed national meetings and workshops with invited tracheostomy and QI expertise offering guidance on the content (tracheostomy care) and implementation (QI) elements of the programme. Additional GTC webinars, meetings, and forums were provided, along with peer support and guidance from fellow participants and the management team to promote a learning community around best practices. For example, if a particular site did not have an existing tracheostomy policy, competency standards, or educational programme, other sites were asked to provide not only their resources, but an explanation of how these resources had been developed and implemented. All meetings included strong patient and family representation. The number of interventions considered as 'fully implemented' (site representatives' opinion) was captured 6-monthly, so constructing aggregate implementation scores by site, intervention, and time.

Data collection: patient level

Patient-level data were entered by local staff into the GTC-specific Research Electronic Data Capture (REDCap) database.[19,22] Under the Memoranda of Understanding and Data Sharing Agreements, anonymous exports were provided for pooled analysis, with additional linked patient data made available from locally submitted critical care minimum data sets (CCMDS) and local patient safety incident reporting. Sites were provided with data entry templates and examples, and regular feedback was provided to encourage comprehensive data capture.

Recorded patient safety incidents were anonymised for site and date, and then classified independently by three authors (AO, BC, and BAM). A previously described harm score was applied,[12] summarised as 0 (no/minor physiological change; green), 1 (temporary harm; yellow), 2 (temporary harm with increased length of critical care or hospital stay; orange), 3 (permanent harm; red), 4 (intervention needed to sustain life;

Table 1 Interventions undertaken by sites, grouped into themes. MDT, Multidisciplinary team.

- Organisational efficiency (six items)
  - O1 Implement a hospital steering group
  - O2 Ensure mandatory training for staff caring for tracheostomised patients
  - O3 Institute a hospital-wide tracheostomy policy
  - O4 Designated tracheostomy cohort wards
  - O5 Dedicated tracheostomy coordinator
  - O6 Tracheostomy link nurses in relevant wards
- Patient-centred quality of care interventions (seven items)
  - Q1 Include patient champions
  - Q2 Implement multidisciplinary tracheostomy team that sees patients
  - Q3 Integrate speech and language therapists (SLTs) in ICU care
  - Q4 Involve SLTs on head and neck wards
  - Q5 Involve SLTs on general wards
  - Q6 Train SLTs to be fibreoptic endoscopic evaluation of swallowing proficient
  - Q7 Capture patient-level data (Research Electronic Data Capture database)
- Safety interventions (five items)
  - S1 Establish competency standards for staff caring for patients with tracheostomy
  - S2 Formalise MDT reviews of adverse incidents with learning
  - S3 Standardise bedside and ward area tracheostomy equipment
  - S4 Routinely place tracheostomy bedhead signs
  - S5 Use standardised tracheostomy care bundles

dark red), and reaction may have caused or contributed to death (black).

Each adult site was asked to recruit 10–20 patients or their families/carers, capturing experiences of tracheostomy care at three distinct phases: baseline (months 0–10), implementation (11–22), and evaluation (23–30) using Hospital Anxiety and Depression Scale (HADS) questionnaires. Hospital Anxiety and Depression Scale consists of 14 questions scored 0–3, with seven questions each focusing separately on anxiety and depression.[20,23] Total scores of ≤7 are considered 'no case' (for depression/anxiety) in each category, 8–10 'borderline', and ≥11 'cases'. A free text field was included. Unstructured interviews conducted by local staff guided by templates were offered to patient participants, both providing more qualitative narrative accounts. Hospital Anxiety and Depression Scale is a standard questionnaire, validated for use by patients and families for assessing anxiety and depression.

Data collection: staff

Additionally, 10–20 front-line staff and site leads from all sites per phase completed the Normalisation Measure Development (NoMAD) 'engagement' questionnaires, appreciative inquiry forms, and semi-structured interviews. Normalisation Measure Development is based on the normalisation process theory and proposes four constructs (coherence, cognitive participation, collective action, and reflexive monitoring) addressing different aspects of implementing new practices.[21,24] Answers are scored on a 5-point Likert scale bounded by 'strongly agree' (score 5) through to 'strongly disagree' (score 1). Staff could repeat surveys, but different staff were encouraged to participate, representing 'snapshots' of opinions. Appreciative inquiry takes an action research approach that offers insight into positive and negative aspects of past, current, and future practices and staff barriers and enablers. Appreciative inquiry forms and interview questions are detailed elsewhere.[19]

Analysis

Data were pooled anonymously into Microsoft Excel (Microsoft, Redmond, WA, USA), grouped by site, admission month (hence phase), and other discriminators. Simple descriptive statistics with mean (standard deviation) or median (interquartile range) values are reported as appropriate. Non-parametric linear regression investigated relationships between outcome and predictor variables, with confidence intervals (CIs) for slopes based upon Kendall's t constructed using StatsDirect 3.1.22 (StatsDirect Ltd, Birkenhead, UK). Cuzick's test identified trends in duration of care metrics.

After Month 30, an additional 60 days of data collection occurred for LOS. Patients not completing their hospital stay at this point had their LOS truncated. Sensitivity analyses investigated the impact: firstly, removing patients admitted during the first and last months, and secondly, removing patients with truncated LOS. Analysis of variance (ANOVA) and Kruskal–Wallis H-tests were used to examine differences between groups using SPSS 22.0 (IBM Corp., Armonk, NY, USA). Fisher's exact test was used, where data could be summarised into contingency tables. Cronbach's alpha (SPSS) evaluated the reliability and consistency of the HADS and NoMAD tools in this setting, with an alpha of >0.80 representing good reliability.

For qualitative interviews and appreciative inquiry, thematic analysis was performed to identify, investigate, and report themes from the transcripts.[22,25] Narratives were initially read line by line and coded into categories, without formal validation or double coding. Evaluation of large volumes of text was supported by NVivo 11 (QSR International, Melbourne, Australia), a qualitative data analysis software tool for coding and analysis of unstructured text. Codes were merged to develop themes representing participant experiences and perceptions.

Economic evaluation

Independent health economic evaluation was conducted to examine the cost minimisation associated with the implementation of the improvement strategies. The model specifically considered bed days and days of specific ICU organ support (CCMDS). Resource use was valued using the 2017/2018 NHS national schedule of reference cost.[26] Costs were calculated for neonatal ICU days for infants, paediatric ICU days for children, adult ICU days, and relevant ward days. The cost of care was calculated for each period (baseline, implementation, and evaluation) and the incremental costs reported.

Results

Interventions

Sites had different baseline profiles with different interventions in place (Figs 1–3). Most sites took 12 months to start implementing substantial numbers of interventions. All sites made significant changes, with a median of nine new interventions per site (range: 4–13). Variation between sites in the number of implemented interventions reduced from a maximum difference of nine to two items over the programme. Sites had most difficulty implementing hospital-wide tracheostomy coordinators (eight sites unsuccessful) and ward-level tracheostomy link nurses (contact points between ward and hospital-wide specialist services; three sites unsuccessful). Patient champions (Q1) and patient-level data collection (Q7) were least likely to be implemented at baseline (two sites). Safety interventions appeared easiest to implement (group mean implementation score: 89), followed by organisational (72.5) then quality interventions (71). A total of 371 staff attended national Train the Trainer days over the programme, supported by 4000 local tracheostomy half-day training places.

Patient-level data

Hospital admissions were recorded from August 1, 2016 (Month 0) to January 31, 2018 (Month 30). Patient-level data were submitted from all sites with 2405 discrete patient admissions captured in the final combined database. A total of 1868 patients (77.7%) were admitted to ICU or high-dependency unit during their hospital stay, with detailed CCMDS data available for 1080. A total of 584 patients (24.3%) were admitted with existing tracheostomies, and 177 patients (7.3%) were <16 yr old (Table 2).

A total of 727 patient safety incidents were reported, with 26 considered non-clinical, leaving 701 incidents in 657 patients (27.3% of all patients), and 58 patients experienced multiple incidents. Table 3 describes the incident categories,

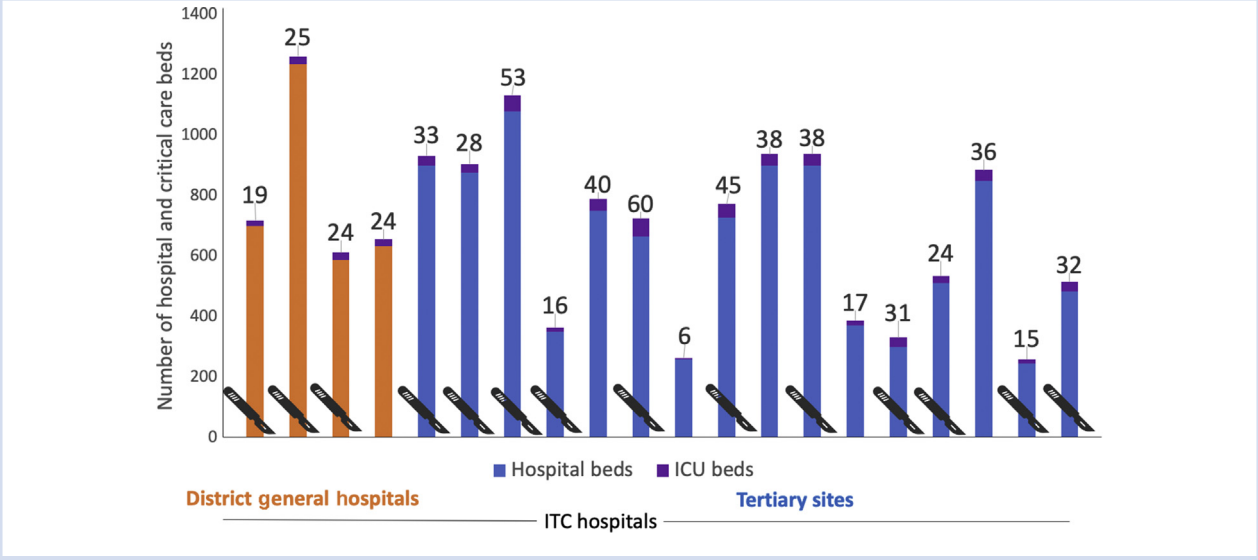

Fig 1. Baseline characteristics of participating Improving Tracheostomy Care (ITC) sites (anonymised). Bar height represents total number of hospital beds, with the top portion and number indicating the total number of critical care beds at that site. The scalpel icon indicates on-site head and neck surgical services.

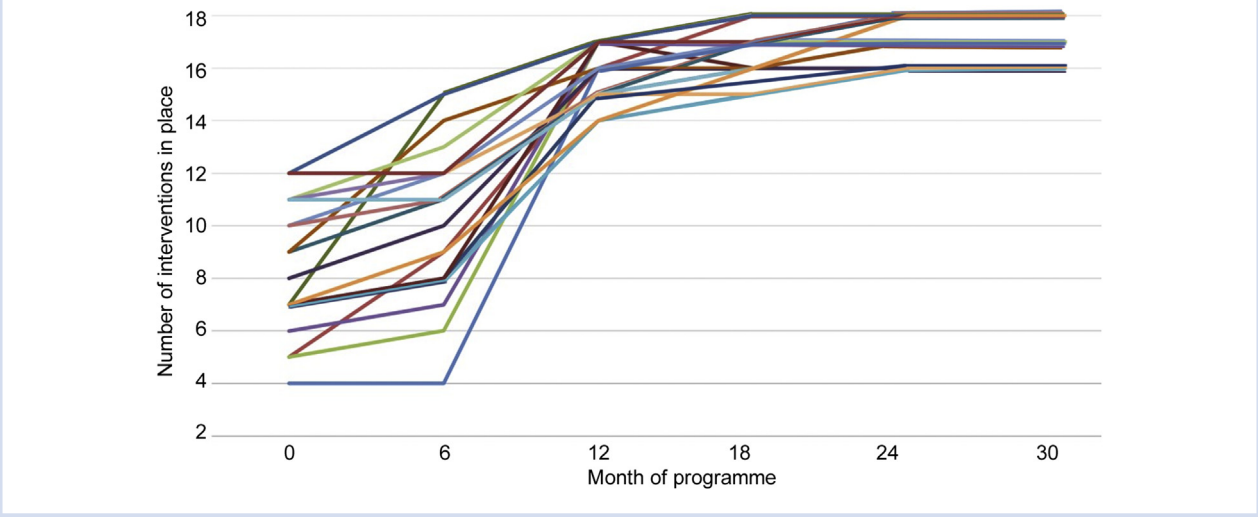

Fig 2. Total count of interventions implemented by individual sites (each represented by a different coloured line) at 6-monthly intervals throughout the program.

most commonly accidental decannulation (18.4%), tube obstruction (10.4%), skin breakdown (7.8%), and bleeding (7.3%). There was a significant reduction over time in the severity score assigned to incidents by the blinded assessors in the 606 incidents reported with sufficient detail to assign a harm score (linear regression slope: −0.044 [95% CI: −0.034 to −0.055]; ANOVA $P<0.001$; Fig. 3). Essentially, incidents occurred throughout, but significantly fewer severe incidents occurred later in the programme, with significantly less harm as a result. Significantly more incidents occurred in paediatric admissions (47.5%) *vs* adult admissions (24.9%; $P<0.001$). More patients experienced more than one incident in the paediatric group (17.9% *vs* 7.2%; $P<0.001$).

The primary driver of cost reduction was the significant reduction in ICU and hospital LOS associated with the guided improvement programme. Considering all patients, there were significant reductions in tracheostomy time (equating to 0.35 days month^{-1} of the programme; $P<0.001$), total hospital LOS (0.8 days; $P<0.001$), ICU LOS (0.25 days; $P<0.001$), and ICU ventilator days (0.1 days; $P=0.002$) (Fig. 4). These significant trends remained when sensitivity analyses were performed: firstly, removing 10 and 85 patients from the first and last

Table 2 Patient descriptive statistics across the three phases. N/A, data not available.

Descriptive statistics		Baseline	Intervention	Evaluation
n	2405 participants	656 participants	1178 participants	571 participants
Ethnicity	Caucasian	76.7%	78.9%	76.7
	African American	4.0%	3.7%	4.0
	Asian	7.3%	7.3%	9.5
	Other	1.2 %	1.3%	1.6
	N/A	10.8%	8.8%	8.2
Age (yr)	Average	50.1	51.1	50.8
	Minimum	0.0	0.0	0.0
	Maximum	93.0	93.0	99.0
Sex	Male	60.2%	63.02%	61.8%
	Female	34.6%	33.82%	35.6%
	N/A	5.2%	3.22%	2.6%
Patient Category	Adult	91.0%	93.2%	92.5%
	Pediatric	8.7%	6.5%	7.2%
	N/A	0.3%	0.3%	0.3%
Tracheostomy planned before to admission	Planned	9.0%	11.5%	10.9%
	Not Planned	8.2%	9.0%	10.7%
	N/A	82.8%	79.5%	78.5%
Existing tracheostomy present at admission	Yes	25.9%	22.6%	25.9%
	No	74.1%	77.4%	74.1%
	N/A	0.0%	0.0%	0.0%
Patient admitted to ICU	Yes	78.8%	79.1%	73.4%
	No	21.2%	20.5%	25.9%
	N/A	0%	0.3%	0.7%
Patient survived to hospital discharge	Yes	581.6%	81.8%	71.8%
	No	16.3%	14.2%	14.2%
	N/A	2.1%	4.0%	14.0%

months, respectively; secondly, removing the 33 patients in whom the final LOS was truncated.

The greatest LOS reductions were seen between the intervention and evaluation phases, mirroring the uptake of interventions and reflecting the time taken to establish new systems and treatment pathways. For the whole data set, incremental costs between the baseline and evaluation periods translate into a cost saving per admission of £33 251 (£20 305 from ICU; £12 946 from wards). These cost savings do not account for GTC membership (£5000 GBP per year), or the costs of new services, equipment, staff time for the program, or staff posts, which varied considerably between sites.

A total of 385 consenting patients completed a HADS questionnaire after an in-patient admission (baseline, n=142; implementation, n=128; and evaluation, n=114). There was a 44.3% reduction in anxiety prevalence (decreasing from 54.2% to 37.4%; P=0.008) and a 52.7% reduction in depression prevalence (decreasing from 38.7% to 18.3%; P<0.001; Table 4). For the anxiety construct, 373 complete cases were analysed, producing a Cronbach's alpha of 0.86. For depression, 363 complete cases produced an alpha of 0.83. This represents good reliability of the HADS questionnaire in our setting.

Patients highlighted communication and oral nutritional intake as key areas of their care journey during baseline data collection, areas that the programme's interventions could be expected to influence.[26,27] Communication and nutritional metrics were available for 733 patient admissions (REDCap and additional local data). Time to cuff deflation decreased significantly over the three phases from a median of 17 to 10 days (n=477; P<0.001). Time to first use of a speaking valve with a ventilator decreased significantly from a median of 14 to 7 days (n=199; P=0.037), with clinically meaningful (but not statistically significant) reductions in time to speaking valve use with spontaneous ventilation (from 19 to 12 days; n=204; P=0.77). Time to first oral intake decreased significantly over the course of the programme (from 26 to 9 days; n=168; P<0.001).

Staff data

At baseline, 204 appreciative inquiry forms (36 from leads and 168 from front-line staff) described quality concerns themed around harm, variation in practices, adequacy of training, and safe staffing levels.[19] Themes evolved during implementation (122 forms; 17 leads/105 front line) and evaluation phases (125 forms; 18 leads/107 front line) describing positive improvements in education and training attendance, new collaborations resulting in better coordination of care, standardising or introducing new equipment or processes, the utility and more effective use of tracheostomy-specific data, a perception of fewer patient safety incidents, the delivery of patient-centred care, and involvement of patients and families. Data collection burdens remained a prominent theme throughout.

Data were the dominant theme arising from 37 baseline site lead interviews, emphasising both opportunity and collection burdens. Concerns around staff training, resources, and the challenges of multidisciplinary relationships were also prominent with excitement around engaging in QI and raising the profile of tracheostomy care. Themes later evolved (from 22 lead interviews) demonstrating continued motivation supported by early local achievements, the enabling effect of the collaborative programme, and rich testimony for the value

Table 3 Frequency of incidents occurring in patient groups. Individual patients may experience multiple incidents. HCP, Healthcare professionals.

	Adult (*n*=2228; 93%)	Paediatric (*n*=177; 7%)	Total (*n*=2405; 100%)	All incidents (%)
All incidents reported (incident count)	625	102	727	100
Clinical incident reported (incident count)	619	82	701	96.4
At least one incident reported (patient count)	554/2228 (24.9%)	84/177 (47.5%)	638/2405 (26.5%)	
				All clinical incidents (%)
Accidental decannulation	105/619 (17.0%)	24/82 (29.3%)	129/701	18.4
Tracheostomy tube obstruction	36/619 (5.8%)	37/82 (45.1%)	73/701	10.4
Skin breakdown at tracheostomy site	47/619 (7.6%)	8/82 (9.8%)	55/701	7.8
Significant bleeding from tracheostomy (>10 ml fresh red blood)	50/619 (8.1%)	1/82 (1.2%)	51/701	7.3
Failed decannulation (within 72 h)	42/619 (6.8%)	4/82 (4.9%)	46/701	6.6
Local skin or stoma infection/ inflammation	45/619 (7.3%)	1/82 (1.2%)	46/701	6.6
Air leak	41/619 (6.6%)	2/82 (2.4%)	43/701	6.1
Laryngectomy patient: inadequate identification/ provision	36/619 (5.8%)	0	36/701	5.1
Communication between HCPs	30/619 (4.8%)	1/82 (1.2%)	31/701	4.4
Delay in care	28/619 (4.5%)	0	28/701	4.0
Tracheal injury (at insertion or later)	18/619 (2.9%)	0	18/701	2.6
Infrastructure: no suitable bed	7/619 (1.1%)	0	7/701	1.0
Infrastructure: staff knowledge	6/619 (1.0%)	0	6/701	0.9
Tracheo-oesophageal fistula	6/619 (1.0%)	0	6/701	0.9
Granuloma	1/619 (0.2%)	4/82 (4.9%)	5/701	0.7
Infrastructure: inadequate bedside equipment	5/619 (0.8%)	0	5/701	0.7
Loss of airway	5/619 (0.8%)	0	5/701	0.7
One-way valve used with cuff inflated	3/619 (0.5%)	0	3/701	0.4
Chemical injury	2/619 (0.3%)	0	2/701	0.3
Tracheo-cutaneous fistula	2/619 (0.3%)	0	2/701	0.3
Illicit drug use by patient	1/619 (0.2%)	0	1/701	0.1
Moving and handling (fall)	1/619 (0.2%)	0	1/701	0.1
Tube adjustment	1/619 (0.2%)	0	1/701	0.1
Insufficient details to classify further	103/619 (16.6%)	0	103/701	14.7

of the programme in sharing strategies and driving improvements.

A total of 1019 unique participants (61.8% front line) completed 1536 NoMAD forms, with over half declaring 3–10 yr experience caring for patients with tracheostomies. Supplementary Fig 2 shows that the overall mean construct scores increased significantly over the programme by a mean difference of 0.26 (P=0.02). Stratifying sites into quintiles of aggregate NoMAD scores demonstrated significant differences in the rates of change in incident severity scores over the first 12

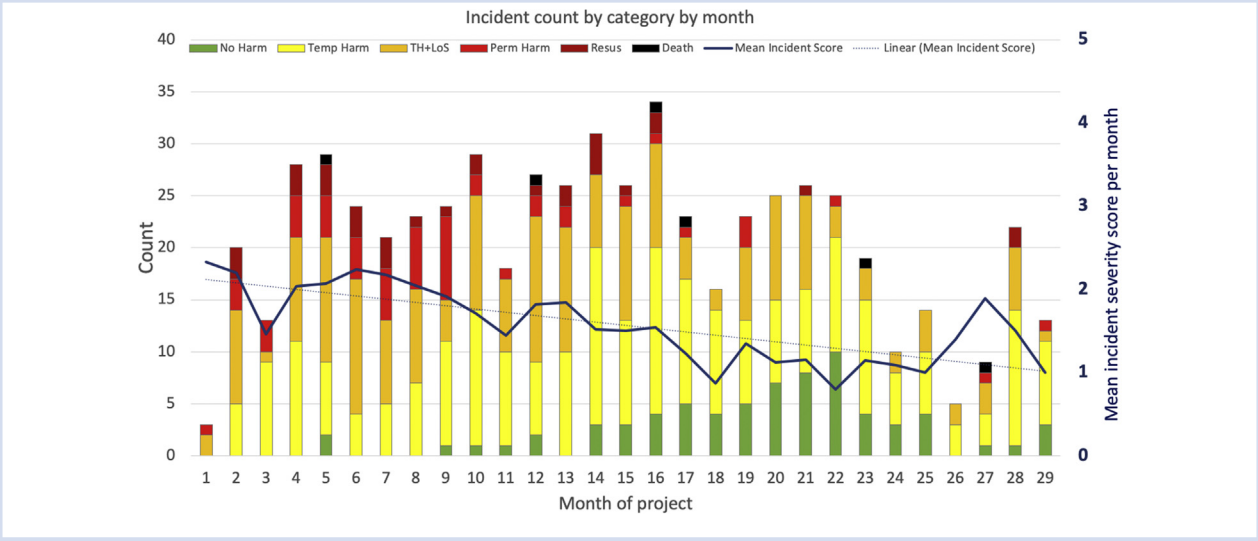

Fig 3. Incident categories by month of program. Solid line represents mean incident severity score. Broken line represents linear regression line. Regression Equation: $y = -0.044x + 2.215$ (ANOVA $p<0.01$, 95% CI for slope = −0.034 to −0.055). Categories: No Harm; Temp(orary) harm; Temporary Harm with increased length of stay (TH+LoS); Perm(anent) Harm; Resus(citation) required; Death.

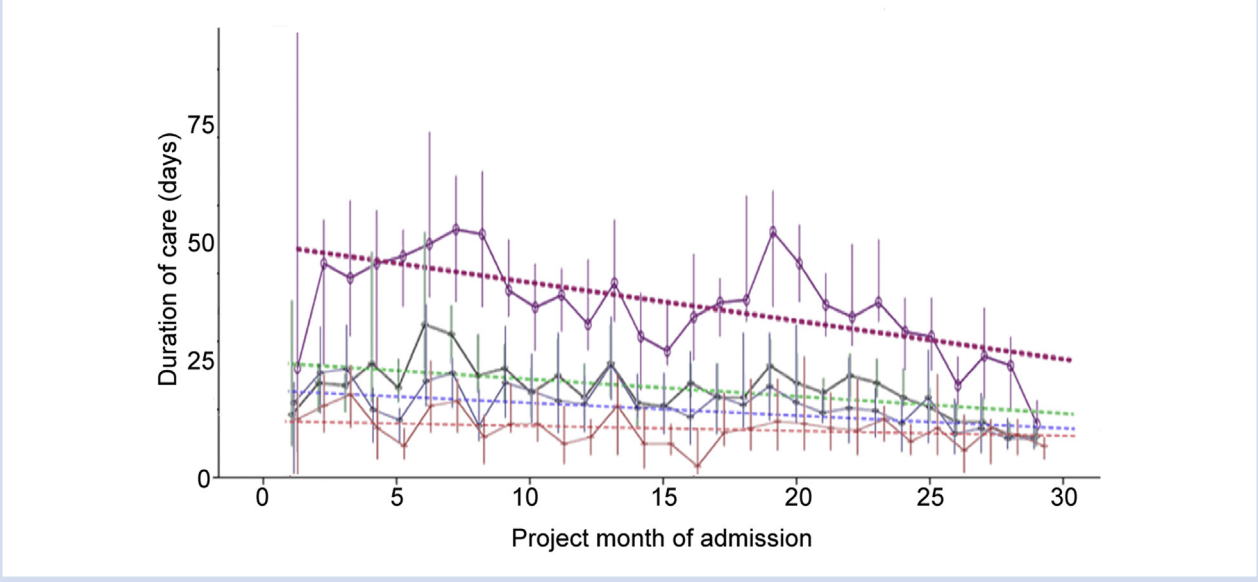

Fig 4. Duration of care metrics. Monthly median (marker) with inter-quartile range (error bars). Significance of the slopes are indicated by Cuzick's test for trend (all $p<0.01$). The slope of the trend line and 95% confidence intervals calculated by non-parametric linear regression: Hospital length of stay (purple) −0.78 (−1.14 to −0.42); Tracheostomy days (green) −0.35 (−0.59 to −0.15); ICU length of stay (blue) −0.25 (−0.25 to −0.24); Ventilator days (orange) −0.11 (−0.11 to −0.11).

months of the programme: slope coefficient −0.08 (a monthly reduction in incident severity) for the highest scoring (most engaged) quintile *vs* 0.02 (no reduction) for the lowest. There was good reliability for the four constructs (question groups) of the NoMAD questionnaire (coherence α=0.81; cognitive participation α=0.85; collective action α=0.80; reflexive monitoring α=0.77; general questions α=0.81). When analysing all questions pooled together, α=0.92. This represents good-to-excellent reliability for NoMAD in this setting.[27,28]

Discussion

This comprehensive programme showed that it is possible to improve the quality and safety of tracheostomy care in a socio-economically, geographically, and operationally diverse group

Table 4 Breakdown of anxiety and depression cases over the three phases of the programme from the Hospital Anxiety and Depression Scale questionnaires (n=385).

		Phase of programme							
		Baseline		Implementation		Evaluation		Change (baseline to evaluation)	
		Count	Phase (%)	Count	Phase (%)	Count	Phase (%)	Change (%)	Fisher's exact P-value
Anxiety classification	No anxiety case	65	45.8	53	41.4	72	62.6	Reduction in anxiety cases	
	Borderline anxiety	26	18.3	35	27.3	20	17.4	44.3% reduction (from 54.2% to 37.4%)	<0.01
	Anxiety case	51	35.9	40	31.3	23	20.0		
Depression classification	No depression case	63	44.4	69	53.9	81	70.4	Reduction in depression cases	
	Borderline depression	24	16.9	22	17.2	13	11.3	52.7% reduction (from 38.7% to 18.3%)	<0.01
	Depression case	55	38.7	37	28.9	21	18.3		

of UK NHS hospitals participating in a dedicated, guided QI programme. The views of patients and their families were actively sought and acted upon, designing, adopting, and delivering innovative resources.[17,26,27] Whilst difficulties were captured, meaningful change and improvements occurred at all sites (at different rates), reducing psychological distress associated with poor or less patient-focused care. As expected, QIs led to organisational efficiencies, with motivated multidisciplinary teams acting proactively, decannulating patients appropriately and earlier, and reducing tracheostomy days and ICU and hospital LOS. Qualitative data suggesting that the lower ICU admission rates observed towards the end of the programme were primarily related to upskilling of non-critical care locations and increasing staff confidence admitting or discharging to these locations.[12,29,30] Our mixed-methods research has captured a rich knowledge base for enabling change in this complex field, which will be invaluable for future research and QIs.

Amongst interventions that appear most difficult to implement were a dedicated tracheostomy coordinator, link nurses on relevant wards, speech and language therapists (SLTs) able to perform fibreoptic endoscopic evaluation of swallowing, and patient champions. These organisational interventions had been shown by hospitals outside of the Improving Tracheostomy Care group to be effective methods of coordinating care, delivering efficient and effective proactive management.[13–15,31–37] However, dedicated posts typically take 6–12 months to arrange and recruit to, perhaps longer to fund, and qualified and equipped SLTs take time to train.[37,38] Commencing new services and embedding into practice can take years. Finding a suitable patient champion can also take time, and the inclusion of a relevant patient in the team can be an unfamiliar experience to some, leading to barriers.[11,39] Patient champions engaged in a number of core activities, including education, advocacy, strategy, and review of local materials (such as policies, information leaflets, care plans, and care bundles), to ensure that all interventions remained as relevant and patient focused as possible. Realising this value, all sites embedded patient champions by the end of the programme, many of whom attended site lead meetings and actively participated in the group.

This programme addressed a breadth of improvements aimed primarily at improving patient safety and patient experience, which realised the anticipated associated improvements in organisational performance and, therefore, costs. This study was designed to build on the successes of smaller studies of tracheostomy QI in single sites and hospital clusters, but scaling up such initiatives does not guarantee success. The recent Enhanced Peri-Operative Care for High-risk patients (EPOCH) study implemented a complex QI programme for emergency laparotomy care in 93 UK hospitals,[40] comprising 37 component interventions, building on an evidence base of arguably weak, small-scale before-and-after study designs, similar to the methodologies of many of the studies underpinning this tracheostomy programme. Whilst similarities exist between the findings of this study and EPOCH (high perceived data burden, limited staff time, and limited resources dedicated to change management, in a complex patient population with around 20% 90 day mortality), our study was able to influence care; reduce variation; and positively impact upon safety, quality, and process measures. The smaller scale of the tracheostomy QI programme and the self-selecting motivated cohort of hospital sites likely contributed to our positive outcomes. The national picture for tracheostomy care at baseline is also complex, fragmented, and with unacceptably high rates of preventable harm and a lack of patient focus,[2] meaning that there may be more scope for positive change than the more evolved pathways of laparotomy care.

Whilst the majority of the site multidisciplinary teams expected to have knowledge of all tracheostomy in-patients, it is highly likely that not all admissions were recorded and comprehensive outcome data were not collected for all. However, our pre-planned sensitivity analyses did not affect the observed reductions in duration of care metrics. The data burden for staff was perceived as high. To commend this programme to the wider NHS and beyond, we recommend that contemporaneous electronic data capture systems that integrate with existing NHS systems are explored to ease burdens on staff.

Whilst this programme has answered many questions, it has also identified many potential areas for future research. Further investigations should evaluate the impact of combinations of interventions on key outcomes; develop balanced score cards (providing a 'dashboard' of progress); develop ease impact matrices (guiding sites in balancing the difficulty of

implementing a particular intervention with its potential impact); and continually develop resources for patients, families, and staff wishing to embark on tracheostomy QI. The sites participating in this programme were motivated, engaged, and interested in tracheostomy care. This may not be the case in future sites, although this in itself may offer greater potential for improvement. We propose that future sites that are initially less engaged with improvement efforts may benefit from a tailored programme starting with easy-to-implement interventions (e.g. bedhead signs) before building towards more difficult/complex interventions (such as multidisciplinary ward rounds). Our study did not measure the sustainability of change and impact beyond the programme, but continued membership of the GTC will provide quarterly feedback and benchmarking to participating sites. This data tracking and feedback may help drive and sustain improvements.

This programme is the first to demonstrate significant improvements in outcome measures developed in partnership with adult and paediatric tracheostomy patients at this scale. Improvements were seen at all sites in the domains of quality, safety, and resultant organisational efficiency, translating into significant potential cost savings of around £275 million per year for the wider NHS. Importantly, we have learned what to do, how, and when, contributing rich and deep new knowledge around making changes in the NHS. We believe that these results will have a meaningful impact in the NHS and beyond.

Authors' contributions

Study concept/design: BAM, SW, JL, BB, MF, TLF, TC, AN, DWR
Analysis and interpretation: BAM, SW, JL, BB, BC, AO, MF, TLF
Drafting and revisions: all authors

Declarations of interest

The authors declare that they have no conflicts of interest. For transparency, the following authors serve in varying capacities within the Global Tracheostomy Collaborative: DWR is the Founder and President; Erin Ward, MJB, AN, and TC serve as the Board of Directors; and BAM and JL serve as committee members. BAM is also the Chair of the UK National Tracheostomy Safety Project; European Lead of the Global Tracheostomy Collaborative; and National Clinical Advisor for Tracheostomy, NHS England.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2020.04.064.

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