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Introducing Critical Care Outreach: a ward-randomised trial of phased introduction in a general hospital

Received: 18 July 2003
Accepted: 27 February 2004
Published online: 27 April 2004
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Electronic Supplementary Material
Supplementary material is available in the
online version of this article at [http://
dx.doi.org/10.1007/s00134-004-2268-7](http://dx.doi.org/10.1007/s00134-004-2268-7)

An editorial regarding this article can be
found in the same issue ([http://dx.doi.org/
10.1007/s00134-004-2269-6](http://dx.doi.org/10.1007/s00134-004-2269-6))

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Abstract *Objective:* The purpose of the study was to investigate the effects of introducing a critical care outreach service on in-hospital mortality and length of stay in a general acute hospital. *Design:* A pragmatic ward-randomised trial design was used, with intervention introduced to all wards in sequence. No blinding was possible. *Setting:* Sixteen adult wards in an 800-bed general hospital in the north of England. *Patients and participants:* All admissions to the 16 surgical, medical and elderly care wards during 32-week study period were included (7450 patients in total, of whom 2903 were eligible for the primary comparison). *Interventions:* Essential elements of the Critical Care Outreach service introduced during the study were a nurse-led team of nurses and doctors experienced in critical care, a 24-h service, emphasis on education, support and practical help for ward staff.

Measurements and results: The main

outcome measures were in-hospital mortality and length of stay. Outreach intervention reduced in-hospital mortality compared with control (two-level odds ratio: 0.52 (95% CI 0.32–0.85)). A possible increased length of stay associated with outreach was not fully supported by confirmatory and sensitivity analyses. *Conclusions:* The study suggests outreach reduces mortality in general hospital wards. It may also increase length of stay, but our findings on this are equivocal.

Keywords Critical care · Intensive care · Hospital mortality · Length of stay

Introduction

Following recommendations from the Audit Commission [1] and the Department of Health [2] NHS hospital trusts were invited, in 2000, to bid for funding to establish critical care outreach teams. These are intended to extend critical care skills beyond the intensive care unit (ICU) to all wards in acute hospitals—to identify deteriorating patients, to ensure timely ICU admission or support ward care to avert such admission, to support ICU discharges

and to share critical care skills thus enhancing the skills of the non-specialist work force.

Evidence for the effectiveness of critical care outreach is limited [3, 4, 5]. There is evidence that quality of care before ICU admission may be sub-optimal; that some patients who suffer catastrophic deterioration, including cardiac arrest, have premonitory symptoms and might have improved outcomes with earlier recognition and appropriate management [6, 7, 8, 9, 10, 11]. Attempts to address this have included, in Australia, the Medical

Emergency Team [12, 13] for which there is some evidence of benefit [14] and, in the UK, the Patient At Risk Team [15] which demonstrated reduction in the incidence of cardiopulmonary resuscitation.

Our hospital obtained funding for a Critical Care Outreach Team (CCOT), with a requirement for it to be operational by April 2001. We reviewed the literature and noted that, despite rapid national implementation of this programme, evidence for its benefits was not overwhelming. Once such an intervention has been adopted as standard practice the control conditions essential for good effectiveness studies are no longer available. In our view outreach services should have been introduced to the NHS in the context of a national multi-centre trial, since a definitive study would have required randomisation of a large number of hospitals. Since it was not within our power to achieve this, because a different approach to implementation had been taken at national level, we decided at least to study the impact of introducing this intervention in our own hospital. We designed the study to use the window of opportunity presented by the fact that, during phased introduction of the service to most adult wards in the hospital, control conditions would prevail in wards that had not yet received the intervention.

An application for ethical approval was submitted to York Research Ethics Committee. We were informed that the study should be regarded as auditing the effects of change in the hospital's services and research ethics approval was not required for this.

Methods

Study sample

The study included all patients admitted to 16 acute adult wards of one general hospital over a 32-week period. The length of the study, and consequently the sample size, was determined by the CCOT's prior decision about how to introduce outreach services across the hospital. It was estimated that, in 32 weeks, at least 6000 patients would pass through the study wards, of whom 2300 would be eligible for the primary (matched randomised) analysis. Based on analysis at the individual patient level this would give 80% power for logistic regression to detect a difference at 5% significance level if the two groups had death rates of 5.0 and 8%.

Setting

The hospital is an 800-bed general hospital in the north of England. The 16 study wards had an average of 30 beds each and included eight surgical wards, five medical wards and three elderly medicine wards.

Study design

A pragmatic ward(cluster)-randomised design with phased introduction of intervention was used so that by the end of the study all 16 wards were included (Table 1). In each ward 4 weeks of ward staff training was provided, after which the service was fully operational; thus, the ward moved from control condition to intervention via the training period. Wards were paired, on the basis of professional judgement, according to patients and conditions usually treated, in an attempt to match for overall risk of death or other serious adverse outcomes. Professional judgement was assisted by reference to the number of cardiac arrests reported in each ward. One from each pair of wards was randomised to the earlier phase of outreach introduction. The wards were then divided into four groups, each containing one high-risk and one low-risk pair of wards, with the intention that all four groups would have approx-

Table 1 Outreach service introduction sequence. *SW* surgical ward, *MW* medical ward, *EW* elderly ward

Month	First 4 weeks	Second 4 weeks	Third 4 weeks	Fourth 4 weeks	Fifth 4 weeks	Sixth 4 weeks	Seventh 4 weeks	Eighth 4 weeks
Ward pair								
A1 (SW)	Train	<u>Outreach</u>	<u>Outreach</u>	<u>Outreach</u>	Outreach	Outreach	Outreach	Outreach
H2 (SW)	Train	<u>Outreach</u>	<u>Outreach</u>	<u>Outreach</u>	Outreach	Outreach	Outreach	Outreach
C2 (SW)	CONTROL	Train	<u>OUTREACH</u>	<u>Outreach</u>	<u>Outreach</u>	Outreach	Outreach	Outreach
G1 (SW)	CONTROL	Train	<u>OUTREACH</u>	<u>Outreach</u>	<u>Outreach</u>	Outreach	Outreach	Outreach
B1 (MW)	CONTROL	CONTROL	Train	<u>OUTREACH</u>	<u>OUTREACH</u>	<u>Outreach</u>	Outreach	Outreach
F1 (MW)	CONTROL	CONTROL	Train	<u>OUTREACH</u>	<u>OUTREACH</u>	<u>Outreach</u>	Outreach	Outreach
D2 (MW)	CONTROL	CONTROL	CONTROL	Train	<u>OUTREACH</u>	<u>OUTREACH</u>	<u>OUTREACH</u>	Outreach
E2 (EW)	CONTROL	CONTROL	CONTROL	Train	<u>OUTREACH</u>	<u>OUTREACH</u>	<u>OUTREACH</u>	Outreach
A2 (SW)	Control	<u>CONTROL</u>	<u>CONTROL</u>	<u>CONTROL</u>	Train	OUTREACH	OUTREACH	OUTREACH
H1 (SW)	Control	<u>CONTROL</u>	<u>CONTROL</u>	<u>CONTROL</u>	Train	OUTREACH	OUTREACH	OUTREACH
C1 (SW)	Control	Control	<u>Control</u>	<u>CONTROL</u>	<u>CONTROL</u>	Train	OUTREACH	OUTREACH
G2 (SW)	Control	Control	<u>Control</u>	<u>CONTROL</u>	<u>CONTROL</u>	Train	OUTREACH	OUTREACH
B2 (MW)	Control	Control	Control	<u>Control</u>	<u>Control</u>	<u>CONTROL</u>	Train	OUTREACH
F2 (EW)	Control	Control	Control	<u>Control</u>	<u>Control</u>	<u>CONTROL</u>	Train	OUTREACH
D1 (MW)	Control	Control	Control	Control	<u>Control</u>	<u>Control</u>	<u>Control</u>	Train
E1 (EW)	Control	Control	Control	Control	<u>Control</u>	<u>Control</u>	<u>Control</u>	Train

Ward/month used in model 2 (matched-randomised) indicated by underlined italics and model 3 (before-after) indicated by block capitals

imately equal risk. The order of introduction to the four groups of wards was also randomly determined.

Randomisation was done by D.R. alone, based on ward pairings and risk estimates provided by the rest of the study team.

Intervention

The CCOT was led by a nurse consultant (W.W.) with a team of experienced nurses providing 24-h cover. Critical care medical support was available when required, as judged by the outreach nurses or the ward medical team. Introduction of the service involved a month of training by the CCOT for all nurses and doctors on the ward. In addition to training in care of critically ill patients, this included formal and informal sessions on the use of an in-house “patient at risk” (“PAR”) score (Table is available on journal’s website) to aid identification of patients who might benefit from CCOT attention. This was a simplified version of similar scoring systems described elsewhere [16].

Ward staff used PAR to trigger referral to CCOT and involvement of the admitting team’s consultant. We advised them to view the score as a guide but to seek CCOT involvement in the absence of the requisite score if they were concerned about the patient. The level of CCOT involvement was then determined by discussion with ward staff and the admitting team. As circumstances required, CCOT might support and advise ward staff, remain with the patient and provide individual nursing care on the ward during a crisis period, or facilitate admission to ICU. There was emphasis on sharing skills, on collaboration with the admitting team and on provision of practical “hands on” help to ward staff.

Data collection

Throughout the study period CCOT nurses visited all patients admitted to the 16 wards, within 24 h of admission. Using routinely recorded data they calculated the Simplified Acute Physiology Score II (SAPS II) [17]. This simple scoring system, which allows probability of death to be calculated, used primarily in intensive care has been validated in intermediate care [18] though not in general wards. It was used here as an indicator of patient health status on entry to a ward. The nurses recorded ward number, gender, date of birth, and the patient’s hospital number, for co-ordination with the hospital’s database; from the latter we obtained data on date and mode of discharge or death. Collection of data, including SAPS II, by the CCOT was triggered by admission to a study ward. To ensure accuracy of data entry we performed extensive checks before starting the analysis, including double-checking of SAPS II scores on a 5% random sample of patients.

Analysis

To prepare the dataset for analysis patients were allocated to the first ward to which they were admitted during this spell of inpatient care; thus, patients were allocated to the intervention, training and control groups based on the ward to which they were first admitted, regardless of subsequent ward transfers, if any (intention-to-treat analysis). A very small number of patients were admitted to the hospital more than once during the study period. If these patients passed through at least one of the study wards during both spells of care, they were included more than once in the sample; however, since the different spells may have had different causes, and SAPS II data were collected at the start of each spell, it was appropriate to treat separate spells. The research questions were what effect the intervention would have on (a) the rate of in-hospital deaths, and (b) length of hospital stay.

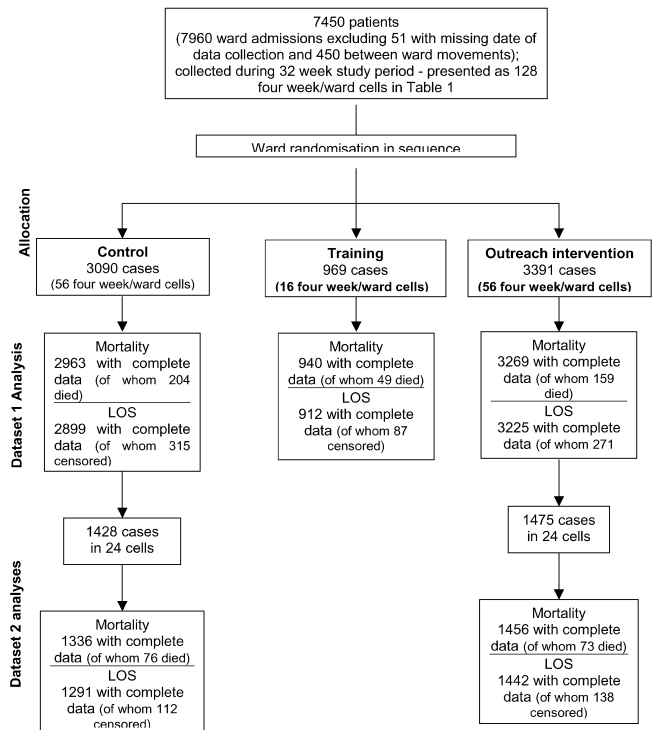


Fig. 1 Patient flow chart. LOS length of stay

We analysed each of the two outcomes using three datasets (Fig. 1).

Dataset 1 (all patients)

All patients were included in the analysis (all ward-month cells in Table 1). Despite using all data, this dataset did not fully utilise the randomised design, as control and outreach were not balanced over either time or ward; however, it did allow comparisons that included the training period.

Dataset 2 (matched randomised)

For each of the randomised pairs of wards there were three consecutive 4-week periods with one ward in control and the other in outreach (shown in italics in Table 1). Dataset 2 was restricted to those blocks. Although this dataset included fewer patients, and did not allow for separate consideration of the training phase of intervention, it utilised the randomisation within ward pairings. This had the advantage of excluding potential bias due to ward characteristics and time trends, as each outreach ward month is balanced by a control in the same month for the other (randomly chosen) member of the ward pair.

Dataset 3 (before–after)

Due to the small number of ward pairs randomised, a third method of focussing the data was used for confirmatory analysis. This dataset included only ward-month cells (indicated by block capitals in Table 1). For each ward, balanced lengths of time in control or outreach intervention condition were included. In this dataset the

randomisation was not utilised but each outreach ward month was balanced by a control in the same ward in a previous month. While this improves the ward balance of the data even compared with Dataset 2, time trends or other study month effects may bias the results.

We used MLwiN 1.10.0007 [19] to perform logistic regression for in-hospital mortality. Results of a one (patient)-level model and a two-level model which takes into account clustering of the data were compared. The one-level model was checked using SPSS-10 (SPSS, Chicago, Ill.). For the two-level model ward month (Table 1) was entered as a random effect with sex, age, logit of SAPS II, ward type (surgical, medical, elderly) and intervention (control, training, outreach) as fixed effects. We adjusted variables so that the intercept would apply to a 62-year-old (mean age) female patient with SAPS II score of 18 admitted to a control surgery ward during the first month (4 weeks) of the study. Sensitivity analyses for in-hospital mortality were performed by exclusion of patients who had stayed less than 2 days or more than 48 days in hospital.

We used SPSS 10 to generate Cox proportional hazard models [20] for length of stay analysis, with sex, age, SAPS II, ward type (surgical, medical, elderly) and intervention (control, training, outreach) entered as explanatory variables. Sensitivity analysis for length of stay was performed by exclusion of patients who had stayed less than 2 days in hospital.

For both mortality and length of stay, study month was used as an additional covariate for datasets 1 and 3, in which it was potentially confounded with the intervention group.

Results

Some key characteristics of patients on admission (age, sex, SAPS II) are shown in Table 2.

Outcome 1: in-hospital mortality

As described above, two-level multivariate logistic regression was performed using three differently focussed datasets. After exclusion of patients with incomplete data, Dataset 1 included 7172 patients and Dataset 2 included 2792 patients. Table 3 shows that the one-level and two-level models gave virtually identical results for Dataset 1, whereas for Dataset 2 the two-level model resulted in a greater estimated advantage of outreach but a 20% wider confidence interval.

Dataset 1 analysis showed that outreach intervention, compared with control, had a significant effect in reducing the chance of death for patients within the intervention wards (two-level odds ratio: 0.70; 95% CI 0.50–0.97). Other variables also made a significant contribution.

Analyzing Dataset 2, the outreach intervention group had an odds ratio of death of 0.52 (95% CI 0.32–0.85) compared with the control group. Analysis using dataset 3 confirmed these findings and are not reported. Sensitivity analyses produced results similar to those presented above.

Outcome 2: length of stay

Cox proportional hazard models were used to assess the impact of CCOT on length of stay (LOS) controlling for the possible influence of other variables. Multi-level modelling was not undertaken for this outcome because of the greater complexity involved in using this technique. The LOS was from study ward admission to discharge from hospital, with censoring of self-discharged or deceased patients. Patients that stayed more than 48 days were treated as if self-discharged on the 48th day. This was done because these were statistical outliers, with length of stay four times the mean. Also, since this hospital sometimes has up to 10% of its beds occupied by patients whose discharge has been delayed by unavailability of alternative care arrangements, it was considered that many of these patients were not true acute hospital patients.

Dataset 1 included 7036 patients for whom all the necessary data were collected (Table 4).

As with the in-hospital mortality analysis, we repeated this analysis using only the matched randomised and before–after data (see above and Table 1), with dataset 2 (matched randomised) the preferred choice as it adjusted for potential bias due to ward characteristics and time trends.

Analysis of LOS using dataset 1 implies that, compared with control, outreach intervention increased patients' mean LOS (hazard ratio: 0.90; 95% CI: 0.84–0.97).

Table 2 Characteristics of patients on admission. *N/A* not applicable

	Control			Training			Outreach		
	Data set 1	Data set 2	Data set 3	Data set 1	Data set 2	Data set 3	Data set 1	Data set 2	Data set 3
Age (mean; 95% CI)	60.5 (59.8–61.2)	57.4 (56.3–58.5)	59.7 (58.7–60.7)	61.0 (59.7–62.3)	N/A	N/A	62.7 (64.3–66.2)	65.2 (64.3–66.2)	59.8 (58.8–60.9)
Male sex (<i>n</i> , %)	1331 (43.4)	611 (43.1)	10	485 (50.3)	N/A	N/A	1745 (51.8)	804 (54.7)	12
SAPS II (25th percentile)	12	8	10	12	N/A	N/A	13	14	12
SAPS II: (median)	19	17	18	18	N/A	N/A	18	20	18
SAPS II: (75th percentile)	24	24	24	24	N/A	N/A	24	26	24
SAPS II: (mean; 95% CI)	18.9 (18.5–19.2)	17.3 (16.8–17.8)	18.4 (18.0–18.9)	18.3 (17.7–18.8)	N/A	N/A	18.7 (18.4–19.0)	19.9 (19.4–20.3)	18.6 (18.1–19.1)

Table 3 Outcome 1: in-hospital mortality; logistic regression

	Data set 1 (patient level)	Data set 1 (two level)	Data set 2: matched randomised (patient level)	Data set 2: matched randomised (two level)
No. of patients included in the analysis	7172 patients of whom 412 died (278 were excluded because of incomplete data)		2792 patients of whom 149 died (111 were excluded because of incomplete data)	
Intercept: odds of death ^a	0.010	0.010	0.010	0.010
Fixed effects: odds ratio (95% CI)				
Patient level:				
SAPS II death probability estimate ^b	3.311 (2.844–3.855)	3.313 (2.844–3.859)	3.734 (2.860–4.874)	3.758 (2.861–4.936)
Age	1.034 (1.022–1.046)	1.034 (1.022–1.046)	1.033 (1.013–1.054)	1.033 (1.013–1.054)
Male gender	1.362 (1.094–1.695)	1.364 (1.095–1.699)	1.540 (1.066–2.226)	1.548 (1.060–2.259)
Ward/month level:				
Medical wards ^c	1.755 (1.355–2.272)	1.759 (1.349–2.292)	2.343 (1.521–3.607)	2.514 (1.473–4.290)
Elderly wards ^c	1.815 (1.298–2.536)	1.816 (1.291–2.556)	1.604 (0.915–2.812)	1.675 (0.859–3.265)
Training group ^d	0.794 (0.550–1.147)	0.793 (0.544–1.159)	N/A	N/A
Outreach group ^d	0.698 (0.505–0.964)	0.695 (0.499–0.969)	0.557 (0.380–0.818)	0.523 (0.322–0.849)
Random effect variance (SE)				
Ward/month	N/A	0.014 (0.042)	N/A	0.161 (0.116)

Data set 1: study month was included in data set 1 analyses as a categorical variable

^a For a female with mean age and mean SAPS II death probability estimate, on a surgical ward in control group

^b SAPS II death probability estimate is the log odds of a variable ranging from 0 to 1 derived from each patient's SAPS II, measured on admission

^c Reference category: surgical wards

^d Reference category: control group

Table 4 Outcome 2: length of stay in hospital; Cox regression

	Data set 1	Data set 2 (matched randomised)	Data set 3 (before–after)
No. of patients included in the analysis	7036 patients of whom 673 censored ^c	2733 patients of whom 250 censored ^d	2855 patients of whom 271 censored ^e
Variables: hazard ratio (95% CI)			
SAPS II score	0.967 (0.962–0.972)	0.967 (0.960–0.975)	0.958 (0.950–0.965)
Age	0.989 (0.987–0.991)	0.988 (0.985–0.992)	0.992 (0.989–0.995)
Male gender	1.083 (1.031–1.139)	1.054 (0.974–1.141)	1.004 (0.928–1.087)
Medical wards ^a	0.760 (0.720–0.802)	0.803 (0.736–0.877)	0.705 (0.642–0.774)
Elderly wards ^a	0.573 (0.512–0.641)	0.627 (0.522–0.753)	0.523 (0.431–0.635)
Training group ^b	0.918 (0.846–0.995)	N/A	N/A
Outreach group ^b	0.905 (0.843–0.972)	0.907 (0.835–0.985)	1.105 (0.979–1.247)

^a Reference category: surgical wards

^b Reference category: control group

^c 414 excluded because of incomplete data

^d 170 excluded because of incomplete data

^e 258 excluded because of incomplete data

SAPS II, ward type, gender and age were also significant influences.

For datasets 2 and 3 the number of patients for whom it was possible to do LOS analysis was reduced from 7036 to 2733 and 2855, respectively. These two analyses produced contradictory findings on LOS. With dataset 3 outreach intervention decreased LOS (hazard ratio: 1.11; 95% CI: 0.98–1.25), but our preferred dataset 2 agreed with the effect shown with dataset 1, indicating that, compared with control, outreach intervention increased mean LOS (hazard ratio: 0.90; 95% CI: 0.84–0.99); however, if allowance for clustering had an effect similar to that in Table 3, wider confidence intervals would pos-

sibly render all three comparisons non-significant. In sensitivity analyses neither dataset 1 nor 2 showed significant difference between control and outreach groups.

Discussion

During phased introduction of a critical care outreach service in one general hospital there was a statistically significant reduction of in-hospital mortality in wards where the service operated compared with those where it did not. Analysis of the data using different methods of focussing the dataset shows this in a consistent manner.

During the course of the study the CCOT nurses were convinced that lives were being saved, and the data support this view.

In relation to LOS our findings are equivocal. Using our preferred analytic model increased length of stay is associated with outreach. This could be consistent with mortality reduction, if sick patients who might previously have died stay longer in hospital than the average uncensored case; however, additional analyses did not provide consistent support for this finding.

The study had weaknesses. The first of these is the major weakness that to do a cluster randomised trial with high enough statistical validity would have required participation of a very large number of hospitals. Confidence intervals were wide, and if our results had been less positive, we might have missed a clinically important improvement. Nevertheless, we think that the consistency of the pattern that emerged in analysis of the mortality data is difficult to ignore or ascribe to pure coincidence. This finding is consistent with the findings of some recent publications. One non-randomised study of critical care outreach reported reduction of emergency admission to intensive wards, shorter length of stay and lower mortality in intensive care [21]. Another non-randomised before-after study found no difference in mortality within ICU, but there was reduction in ICU readmission and increased survival in patients who had been discharged from ICU to other wards [22].

There are other possible weaknesses. There may have been "Hawthorne" effects [23]: carrying out the study was a stimulating experience for all concerned, which may have encouraged dynamic delivery of the intervention, beyond what would be expected of effective implementation outside a research context. Those who delivered the intervention collected much of the data and this is another possible bias, even though someone else undertook data handling and analysis (A.R.). Also, there was only one study site, which limits generalisability.

In an intervention such as this, which has a large educational component, contamination of control wards with the practices being introduced in other nearby wards is a possible problem. This could only have been avoided by randomisation of hospitals rather than wards within

one hospital; however, it seems likely that the effect of such contamination would be to reduce, rather than increase, the size of any effect difference observed between control and intervention wards.

There were practical data collection problems. The SAPS II results were incomplete because the full range of physiological measures is not recorded for all patients and no tests were done specifically for the study. Since more tests were probably available for very ill patients, missing values for patients who would have had low SAPS II scores anyway may not be serious; nevertheless, this is a shortcoming.

The study also had strengths. It was a pragmatic trial, carried out not in a teaching hospital with its additional staff and facilities, but in a general acute hospital. Generalisability is improved by inclusion of elderly care and medical wards as well as surgical ones, and of all patients in those wards.

The study suggests further lines of enquiry. In any similar future work it would be useful to include economic evaluation, omitted here because of the speed with which the study had to be implemented. Since outreach teams have opportunity costs, particularly in diverting skilled nursing staff resources from ICUs, the cost questions are important ones. As well as mortality and length of stay, future studies need to consider issues such as readmission to ICU. Other studies have produced conflicting evidence on the effects of outreach in reducing readmission to ICU [22, 24].

As far as we know there has been no UK study of critical care outreach comparable to this one. It gives considerable support to this method of improving critical care services. If its findings reflect a more general reality, and having a critical care outreach team in a hospital really does save lives, it is important for clinicians and policymakers to ensure that they are established and funded on a secure basis.

Acknowledgements We thank the following people for their support for this study: K. Martin, K. Harrison, H. Paw, G. Cundill, M. Reeder, I. Woods, C. Barr, M. Clubbs, J. Miles, M. Yang, G. Dunn and E. Grant. This work was supported by the York Research Innovation Fund (York Hospitals NHS Trust).

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