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BMJ Open Impact of a treatment escalation/limitation plan on non-beneficial interventions and harms in patients during their last admission before in-hospital death, using the Structured Judgment Review Method

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ABSTRACT

Objectives To assess the effect of using a treatment escalation/limitation plan (TELP) on the frequency of harms in 300 patients who died following admission to hospital.

Design A retrospective case note review of 300 unselected, consecutive deaths comprising: (1) patients with a TELP in addition to a do-not-attempt cardiopulmonary resuscitation order (DNACPR); (2) those with DNACPR only; and (3) those with neither. Patient deaths were classified retrospectively as ‘expected’ or ‘unexpected’ using the Gold Standard Framework Prognostic Indicator Guidance.

Setting Medical, surgical and intensive care units of a district general hospital.

Outcomes The primary outcome was the between-group difference in rates of harms, non-beneficial interventions (NBIs) and clinical ‘problems’ identified using the Structured Judgement Review Method.

Results 289 case records were evaluable. 155 had a TELP and DNACPR (54%); 113 had DNACPR only (39%); 21 had neither (7%). 247 deaths (86%) were ‘expected’. Among patients with ‘expected’ deaths and using the TELP/DNACPR as controls (incidence rate ratio (IRR)=1.00), the IRRs were: for harms, 2.99 (DNACPR only) and 4.00 (neither TELP nor DNACPR) ($p<0.001$ for both); for NBIs, the corresponding IRRs were 2.23 (DNACPR only) and 2.20 (neither) ($p<0.001$ and $p<0.005$, respectively); for ‘problems’, 2.30 (DNACPR only) and 2.76 (neither) ($p<0.001$ for both). The rates of harms, NBIs and ‘problems’ were significantly lower in the group with a TELP/DNACPR compared with ‘DNACPR only’ and ‘neither’: harms (per 1000 bed days) 17.1, 76.9 ($p<0.001$) and 197.8 ($p<0.001$) respectively; NBIs: 27.4, 92.1 ($p<0.001$) and 172.4 ($p<0.001$); and ‘problems’: 42.3, 146.2 ($p<0.01$) and 333.3 ($p<0.001$).

Conclusions The use of a TELP was associated with a significant reduction in harms, NBIs and ‘problems’ in patients admitted acutely and who subsequently died, especially if they were likely to be in the last year of life.

Strengths and limitations of this study

- Gold Standards Framework criteria and the Structured Judgement Review Method were used to evaluate the context of each patient’s illness and the important outcomes of clinical decision making and treatment.
- Our study adds to existing evidence regarding the advantages of treatment escalation/limitation plans in patients who are critically ill and potentially nearing the end of life.
- Case note reviews were unavoidably unblinded, and reviewer bias was possible in determining the key outcome measures.
- The study did not include patients who survived critical illness and this may limit the generalisability of the study conclusions.

INTRODUCTION

Around 30% of patients admitted to acute hospitals in Scotland are in the last year of life, and nearly 10% die during the index admission.¹ In all, nearly 30 000 patients die in Scottish hospitals per annum, representing just over half of all deaths.² However, treating hospital patients who are on an end-of-life trajectory in the same way as those who have a reversible cause for their illness may not only be futile³ but also harmful and costly.^{4,5}

Unrealistic societal expectations and professional incentives often drive a ‘fix it’ approach to treating acute illness that disregards context and prognosis. The pressures to do so are multiple, powerful and entrenched.⁶ As a consequence, non-beneficial interventions (NBIs) are commonplace. For example, in patients admitted with fracture neck of femur, many of whom are in

the last year of life, in-hospital mortality is significant (5%–15%) and often related to preoperative comorbidities. The ‘fix it’ approach to managing the fracture (an intervention that is almost always appropriate) is often applied to post-operative complications (sometimes inappropriate).⁷

In a recent systematic review comprising data from 38 studies in 1.2 million patients, Cardona-Morrell *et al* reported that between 31% and 38% of major medical interventions were non-beneficial in patients in the last year of life.⁸ Further, whether treatments are beneficial or not, all treatments are associated with risks, and a proportion will eventually culminate in harm. Harms include not only physical but also psychological and spiritual elements. NBIs can perpetuate illusions of recovery, are wasteful of resources and often have a negative impact on families⁵ and professional staff as well as patients.⁹

Avoiding inappropriate overinvestigation and over-treatment, as well as undertreatment of palliative care needs, is key to delivering better care.¹⁰ These concepts are central to Realistic Medicine¹¹ and Choosing Wisely.¹² One well-established method of avoiding a futile and potentially harmful intervention is the do-not-attempt cardiopulmonary resuscitation order (DNACPR). This addresses the inappropriateness of CPR in the context of an expected natural death. Although the scope of DNACPR is on the face of it limited to one particular intervention, evidence has emerged that its use is unintentionally broader. Some health professionals as well as members of the public interpret ‘DNACPR’ as a surrogate for withholding other treatments.^{13 14} The difficulties associated with DNACPR highlight the need for a more appropriate tool that facilitates personalised treatment escalation/limitation decisions and communicates them effectively.

Treatment escalation/limitation plans (TELPs) have been developed to minimise the risk of harm by setting individualised boundaries for treatment in the event of deterioration in the patient’s clinical status. They facilitate the avoidance of treatments that are ‘futile, burdensome or contrary to a patient’s wishes’. A TELP also addresses the issue of discontinuity of care that often adversely influences patient management at times of acute deterioration. The TELP is a communication tool that summarises goals as well as limitations of treatment for patients who are unstable or nearing the end of life. The goals of care, including resuscitation status, are based on assessing a patient’s diagnosis(es) and their illness trajectory, the reversibility of acute deterioration and the patient’s preferences and wishes. A completed TELP is filed at the front of the patient’s notes for ease of access, particularly for staff working out of hours and at weekends.

Various TELPs are being used in the UK^{14 15} and a national version is being developed.^{14 16} Among the first was the Universal Form of Treatment Options (UFTO) developed by Fritz and Fuld.¹⁷ These authors reported that using the UFTO was associated with a significant

reduction in medical harms, notably those that contributed to death, compared with using DNACPR alone.

AIMS

The aim of the present study was to evaluate the effect of a TELP on harms, NBIs and ‘problems’,^{18 19} in patients during their last admission leading to in-hospital death. These were identified using the Structured Judgement Review Method (SJRM) and based on reviewers’ judgements about treatment/care considered to be poor or very poor or had the potential to have a negative impact on patient safety.¹⁸

METHODS

The study compared the frequency of harms, NBIs and clinical ‘problems’^{18 19} in 300 consecutive patients who were admitted acutely and subsequently died in University Hospital, Hairmyres, between February and May 2017. Patients were included regardless of their age and preadmission clinical status. Patients who died in the emergency department were excluded.

Cases were allocated to one of three groups:

Group 1: those who had both a DNACPR and a TELP.

Group 2: those who had a DNACPR only.

Group 3: those with neither a DNACPR nor a TELP.

The decision to use either a TELP or a DNACPR order was at the discretion of the clinical teams responsible for each patient’s care and was not obligatory. In each case, the DNACPR/TELP was initiated by the lead consultant or was required to be endorsed by him/her within 24 hours.

Group allocation was determined by examining each patient’s clinical record and checking for DNACPR and TELP completion.

Reviewers assessed whether each patient’s death was ‘expected’ or ‘unexpected’ using a modification of the Gold Standard Framework (GSF) Prognostic Indicator Guidance (PIG).²⁰ The PIG is based on the General Medical Council (UK) 2010 definition of patients ‘likely to die within the next 12 months’. The criteria used to identify an ‘expected’ death are listed in [table 1](#). However, only two of the three recommended triggers were used: the ‘Surprise Question’ was considered inappropriate in a retrospective mortality case note review.

Study end-points

Detailed case note review was undertaken to identify specific clinical ‘problems’, using an adaptation of the SJRM used in the National Mortality Case Record Review Programme¹⁸ (see online supplementary appendix A and [table 2](#) (column 2, ‘Examples’)).

For each identified ‘problem’, the reviewers then judged whether it was associated with NBIs and/or whether harms had occurred (answering either yes, no or possibly). NBI was defined as a treatment undertaken or continued with the intention of stabilising or reversing

Table 1 Gold Standard Framework Prognostic Indicator Guidance criteria

Gold Standard Framework Prognostic Indicators for an 'expected' death	<ul style="list-style-type: none"> ▶ Acute life-threatening conditions presenting as sudden catastrophic events (death likely within a few hours or days). ▶ Advanced, progressive, incurable conditions that suggest a life expectancy of 12 months or less. ▶ General frailty with or without declining performance status that suggest a life expectancy of 12 months or less. ▶ Existing conditions that confer an increased risk of dying from acute deterioration in their health.
Triggers	<ul style="list-style-type: none"> ▶ The Surprise Question: 'Would you be surprised if this patient were to die in the next few months, weeks, days'? (This trigger was not used in the context of a retrospective review). ▶ General indicators of decline—deterioration, increasing need or choice for no further active care. ▶ Specific indicators related to principal medical diagnoses (outlined in the Guidance document).

the patient's clinical status but failing to do so. These did not include comfort measures. A harm was defined as an identifiable event resulting from treatment overuse or underuse, or where the potential benefits of an intervention were significantly outweighed by detriment.

Qualitative assessment of each case was undertaken using comments sections in the data collection form (see online supplementary appendix A). Data collection was approved by the NHS Lanarkshire Quality Improvement department.

Case reviewers and quality control

The principal authors (CJL and DRT) were assisted by two co-reviewers (HKO and AR) who had previous experience with mortality casenote reviews. Independent duplicate reviews were undertaken for 20% of cases. Kappa scores for inter-rater agreement were calculated. If there were any important disagreements, these were discussed and resolved prior to final analysis.

Outcomes and statistical analyses

The primary outcome measure was medical harms. The secondary outcomes were NBIs and SJRM 'problems'.

Analyses were undertaken to determine whether there was a significant difference in the rates of harms between the three study groups. The secondary outcomes were analysed similarly. Chi-squared tests were used to test differences in proportions. Models were fitted using Poisson regression to test the difference in rates. The coefficients of Poisson regression are logs of the incidence rate ratios (IRRs). The group comprising patients who had both a TELP and DNACPR was used as the control group. The models were fitted first with the groups as independent variables, and then again with adjustments for sex, age, ward location, 'expected'/'unexpected' death and time from admission to death.

Power calculation and ethical approval

Online statistical software was used to generate a power calculation. Given an α of 0.05, a sample of 98 patients per group was needed to provide 80% power to detect an absolute difference of 30% between each group.

As this study comprised a retrospective case note review, ethics committee approval was not required. All data were anonymised.

Treatment escalation/limitation plan

The TELP used in NHS Lanarkshire hospitals (known locally as the Hospital Anticipatory Care Plan) is provided in online supplementary appendix B. The TELP was introduced across all acute medical, surgical, intensive care and Care of the Elderly units in University Hospital Hairmyres during 2015. Training and education included one-to-one coaching sessions (provided by DRT) to all relevant consultants on the topics of futility, medical harms and prognostic conversations as well as using the TELP. A specific training video was widely distributed to trainee doctors and nursing staff.²¹

Patient and public involvement

Patients and members of the public were not involved in the design of this study.

RESULTS

In total, there were 301 consecutive deaths (6.5% of 4604 admissions during the specified period). Full hospital records were available for 289. Duplicate reviews were undertaken in 60 cases. The inter-rater agreement (Kappa score) was 0.74 for reviewer 1 versus 2, 0.78 for reviewer 1 versus 3 and 0.85 for reviewer 1 versus 4.

Of the 289 deaths, 145 were men and 144 women (table 3). Their mean age at death was 78.3 years (range 29–100). Seventy-four per cent of deaths occurred in medical areas, 18% in surgical areas and 8% in the intensive care or high dependency units. The mean time to death following admission was 15.3 days (range 1–225). Using GSF criteria,²⁰ 247 deaths (85.5%) were retrospectively deemed to have been 'expected'.

In all, 155 patients (53%) had both a TELP and a DNACPR order, 113 (40%) had a DNACPR order only and 21 patients (7%) had neither.

In patients with 'expected' deaths, the TELP was endorsed a mean of 11.3 days (SD 19.4) after admission and 7.9 days (SD 10.7) prior to death. DNACPR was documented on average 5.5 days (SD 11.1) after admission and 11.5 days (SD 19.6) prior to death.

The frequencies and rates of harms, NBIs and clinical 'problems' for each of the three study groups are shown in table 4. The IRR for harms comparing patients who had

Table 2 Rate of individual clinical ‘problems’ (per 1000 patient days) in 247 patients with ‘expected’ deaths (using Gold Standard Framework²⁰) in University Hospital, Hairmyres during their last hospital admission prior to death, categorised using an adaptation of the Structured Judgement Review Method¹⁸

Description of clinical ‘problem’ using structured judgement review		Examples	All patients	TELP and DNACPR	DNACPR only	Neither TELP nor DNACPR
1	Assessment, investigation or diagnosis	An arterial blood gas taken that did not result in a change in management. A delay in making a diagnosis or missing one altogether.	12.5	6.7	25.2*	34.8*
2	Medication/ intravenous fluids/ electrolytes/ oxygen	Intravenous fluids given when they were not indicated/required. Side effects arising from unnecessary intravenous antibiotic therapy.	19.5	12.6	33.9*	58.0*
3	Treatment and management plan	Escalation in level of a patient’s care when they were dying. Ambiguity regarding whether the patient was for active or palliative care.	21.3	11.5	40.0*	92.8*
4	Palliative or end-of-life care	Documentation of end-of-life symptoms, for example, breathlessness, without evidence of these being treated. Documentation of psychological, social or spiritual distress without evidence of it being addressed.	15.8	7.8	33.9*	34.8*
5	Operation/invasive procedure	An operation carried out shortly before the patient died which had little or no potential for benefit. Placement of central venous line which did not benefit the patient.	2.8	1.1	4.35*	34.8*
6	Clinical monitoring	Delay in recognising or reacting to evidence of a deteriorating patient (Early Warning Score). Monitoring continued and acted on when it was fully recognised that the patient was dying.	4.5	2.2	8.7*	23.2*
7	Resuscitation following a cardiac or respiratory arrest	CPR carried out when there was no chance of success. Inappropriate ICU admission following an arrest.	2.8	0.4	4.3*	58.0*
8	Any other type not fitting the categories above	Patient coerced into receiving treatment against their wishes. Distress experienced by family members/loved ones as a result of inappropriate care.	5.0	3.3	8.7*	11.6*

*P values all <0.01 for between-group comparisons using TELP/DNACPR group as controls.

CPR, cardiopulmonary resuscitation; DNACPR, do-not-attempt cardiopulmonary resuscitation; ICU, intensive care unit; TELP, treatment escalation/limitation plan.

both a TELP and DNACPR (IRR=1.00) and those with DNACPR only was 2.77 (95% CI 1.96 to 3.92, $p<0.001$). The corresponding value for those with neither TELP nor DNACPR was 2.61 (95% CI 1.50 to 4.55, $p<0.001$). For NBIs, the IRR for DNACPR only was 1.98 (95% CI 1.48 to 2.64) and 1.44 (95% CI 0.83 to 2.50) for neither. The corresponding values for ‘problems’ were 2.04 (95% CI 1.62 to 2.58) for DNACPR only and 1.78 (95% CI 1.19 to 2.68) ($p<0.001$ and $p<0.001$, respectively) for neither. Further analyses excluding ‘unexpected’ deaths showed

similar results: the IRRs were 2.99 (95% CI 2.10 to 4.28) (DNACPR only) and 4.01 (95% CI 2.30 to 6.99) (neither) for harms ($p<0.001$ for both); 2.23 (95% CI 1.66 to 3.00) and 2.20 (95% CI 1.26 to 3.83) for NBIs ($p<0.001$ and $p<0.005$, respectively); and 2.30 (95% CI 1.82 to 2.91) and 2.76 (95% CI 1.84 to 4.15) for ‘problems’ ($p<0.001$ for both).

Adjustments for age, sex, ward location and ‘expected’/‘unexpected’ death (as determined retrospectively using GSF) did not substantially change the results. When

Table 3 Patient demographics

	All	TELP+DNACPR	DNACPR only	Neither
Number of patients	289	155	113	21
Mean age at time of death (years, range)	78.6 (29–100)	79.7 (49–100)	78.1 (44–98)	73.1 (29–96)
Male	145 (50.1%)	73 (47.1%)	58 (51.3%)	14 (66.7%)
Female	144 (49.9%)	82 (52.9%)	55 (48.7%)	7 (33.3 %)
Location				
Medical	216 (74.0%)	124 (79.8%)	83 (73.4%)	11 (52.3%)
Surgical	51 (18.0%)	28 (18.2%)	15 (13.3%)	7 (33.3 %)
ICU	22 (8.0%)	3 (2.0%)	15 (13.3%)	3 (14.3%)
Length of hospital stay (days (SD))	15.3 (21.0)	18.7 (24.8)	12.5 (15.3)	5.5 (5.5)
‘Expected’ death*	247 (85.5%)	141 (91.0%)	93 (82.3%)	13 (51.9%)
‘Unexpected’ death*	42 (14.5%)	14 (9.0%)	20 (17.7%)	8 (38.1%)

*based on Gold Standard Framework criteria²⁰ applied retrospectively
 DNACPR, do-not-attempt cardiopulmonary resuscitation; ICU, intensive care unit; TELP, treatment escalation/limitation plan.

the time between admission and death was taken into account in the Poisson regression models, the differences between the three groups increased.

Data for each of the individual problem categories are shown in [table 2](#). There were significant between-group differences in each of the eight domains.

DISCUSSION

In this study, we demonstrated that the use of a TELP in addition to a standard DNACPR order was associated with a reduced frequency of harms especially in patients judged to be nearing the end of life, compared with using a DNACPR alone.

Avoiding treatment overuse (as well as underuse) is an important dimension in achieving optimum care for all patients, irrespective of their clinical status.²² Our study indicated that this goal can be facilitated using a TELP: there were significantly fewer instances of NBI when a TELP was used ([table 4](#)). Treatment underuse was explored indirectly using the Structured Judgement Review Method. Undertreatment of a patient’s palliative care needs in the two groups without a TELP was a frequent reason for there being a ‘problem’ ([table 2](#), item 4).²³

Quality of care in critically ill patients who subsequently die is influenced by many complex factors. The apparent benefits of using the TELP is not simply explained on the basis of cause and effect. Perhaps a TELP helps to reduce the perception of uncertainty that often leads clinicians to make inappropriate decisions in critical illness. Anecdotally, the TELP appears to act as a permission-giving prompt in favour of modified care including earlier palliative treatments in patients who are approaching the end of life.

Using the GSF PIG,²⁰ we identified retrospectively that 86% of 289 patients in the study could reasonably be considered to have been on an end-of-life trajectory.

This equated to 5% of all admissions. The GSF PIG has been recently validated in a hospital-based population.²⁴ The tool is largely based on assessing preadmission comorbidities, illness trajectory and performance status. Although 93% of our cases had a documented DNACPR, suggesting that prognostic elements were considered at least in part by most clinicians, the fact that the mean time from admission to DNACPR completion for patients with ‘expected’ death was 5.5 days indicates that recognition of the patient’s illness trajectory and prognosis was delayed. Learning to identify patients who may be in the last year of life is an important skill that needs to be more consistently applied in the acute setting.

Similarly, TELPs were completed in only 53% of the cases. The timing of TELP completion was delayed even further: the mean time from admission was 11.3 days. Ideally, both DNACPR and TELP should be completed concurrently and at an early stage during a hospital admission. Clinicians frequently cite uncertainty as the reason for not doing so. However, the fact that 86% of patients had an ‘expected’ death based on preadmission criteria provides evidence that both DNACPR and a TELP are needed and should be completed sooner rather than later.

The use of TELPs is still relatively new—in contrast to DNACPR which has been widely used over a long interval. Our TELP was introduced across the three major NHS Lanarkshire hospitals in 2015. An extensive education and awareness programme during 2016/7 has focused not just on pro forma development²¹ but on coaching and mentoring consultant clinicians with an emphasis on identifying futility,^{7 25} avoiding treatment overuse²² and non-beneficial treatments,⁸ and harms reduction as key background reasons for using the TELP. That programme also focused on ‘prognostic conversations’ to facilitate shared decision-making. Discussion with patients/family members is a key element in preparing any TELP and is

Table 4 Harms, non-beneficial interventions and clinical 'problems' (as judged using the Structured Judgement Review Method¹⁸) in 289 patients during their last hospital admission prior to death

	Harms				Non-beneficial interventions				Clinical problems			
	TELP+DNACPR	DNACPR only	Neither TELP nor DNACPR	Neither TELP nor DNACPR	TELP+DNACPR	DNACPR only	Neither TELP nor DNACPR	Neither TELP nor DNACPR	TELP+DNACPR	DNACPR only	Neither TELP nor DNACPR	Neither TELP nor DNACPR
All patients (n=289)												
Patients (n)	155	113	21	21	155	113	21	21	155	113	21	21
Events (n)	48	97	17	15	77	111	15	15	120	179	29	29
Rate per 100 admissions	31.0	85.8†	81.0†	71.4*	49.7	98.2*	71.4*	71.4*	77.4	158.4*	138.2*	138.2*
Rate per 1000 bed days	16.7	68.8*	147.8*	130.4*	26.7	78.8*	130.4*	130.4*	41.6	127.0*	252.2*	252.2*
Patients with 'expected' deaths (n=247)												
Patients (n)	141	93	13	13	141	93	13	13	141	93	13	13
Events (n)	46	91	17	15	74	109	15	15	114	173	29	29
Rate per 100 admissions	32.6	97.8*	130.8*	115.4*	52.5	117.2*	115.4*	115.4*	80.9	186.0*	223.1*	223.1*
Rate per 1000 bed days	17.1	76.9*	197.8*	172.4*	27.4	92.1*	172.4*	172.4*	42.3	146.2*	333.3*	333.3*

The group with both a TELP and a DNACPR are regarded as the control group. Where the rate of events per 100 admissions is >100, then this implies more than one event per admission.

*P<0.001; †P0.002.

DNACPR, do-not-attempt cardiopulmonary resuscitation; GSF, Gold Standard Framework; TELP, treatment escalation/limitation plan.

highlighted in the TELP that we use (see online supplementary appendix B).

Our study provides data to support the original work of Fritz *et al.*¹⁷ In that study, the reduction in harms achieved using the UFTO was 37% for the rate per 1000 patient days. This compares with 77% in the present study. The methodologies differ between the studies. In the study by Fritz *et al.*, the Global Trigger Tool was used to identify harms,^{26 27} whereas we used the SJRM.¹⁸ The nature and threshold for harms identification may be different between the two methods, but the overall pattern of outcomes and conclusions are similar.

In an important review, Fritz has emphasised that discussions and decisions about resuscitation should incorporate broader goals of care and proceed towards a TELP.¹³ We agree, and our findings strongly support this recommendation. Although particularly useful in patients identified to be on an end-of-life trajectory, the TELP tool should be used to guide the management of clinical deterioration in *any* patient with critical illness. The scope of a TELP encompasses a broad range of intervention options rather than just a single one such as CPR. The availability of a TELP encourages earlier, more meaningful conversations with patients and their families, and also facilitates improved levels of communication between on-call staff out-of-hours and at handovers.²⁸

Our study has several weaknesses. Given the nature of the hospital record review process, it was not possible to blind reviewers as to whether a patient had a TELP, a DNACPR order or neither, given that this information was always referred to in patients' notes. Two of the authors (CJL and DRT) have been extensively involved with the development and implementation of the TELP. We accept that these reviewers may have been biased towards finding problems in the group of patients who did not have a TELP. We attempted to mitigate this by cross-checking data obtained by all four reviewers and the inter-rater correlations were high (κ values 0.74 to 0.85.) Our study was retrospective and based in a single centre during late winter and spring. Seasonal factors, notably workloads and bed availability may have resulted in delayed recognition of prognosis or actioning of a TELP. It did not address the effectiveness of the TELP in critically ill patients who were subsequently discharged from hospital. Obtaining data in this group would enable assessment of whether the benefits of the TELP are more generalisable.

In conclusion, our study provides evidence that anticipatory planning for patients who are critically ill, and in particular the use of a TELP to communicate such a plan, is an important contributor to reducing harms in hospital. The mechanism whereby a TELP plays a part in medical decision-making is complex but includes a reduction in clinicians choosing NBIs. The process of identifying the illness trajectory, setting agreed goals of treatment and using an appropriate communication tool to ensure continuity of care was often late rather than timely in the care of critically ill or dying patients

in our hospital. Considering and discussing these issues on admission to hospital and using a TELP earlier during admission to hospital have the potential to contribute to improved patient care. The outcome of studies including the development of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) tool will be important.¹⁶

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Contributors CJL contributed to the design of the study, evaluated case records, coordinated data analysis and wrote the manuscript. JNC was responsible for data management. GPH provided statistical advice and conducted data analysis. HKO evaluated case records. AR evaluated case records. DRT designed the TELP, designed the study, evaluated case records and wrote the manuscript.

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