National Institute for Health and Care Excellence

Final

Chapter 3 Paramedics with enhanced competencies

Emergency and acute medical care in over 16s: service delivery and organisation

NICE guideline 82

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Figure 7: Number referred to primary care – quasi-experimental study

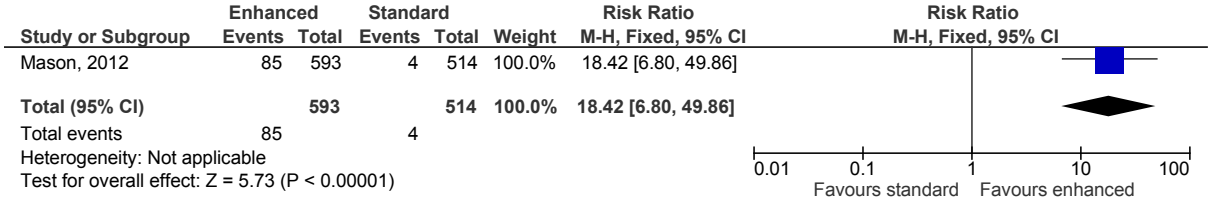
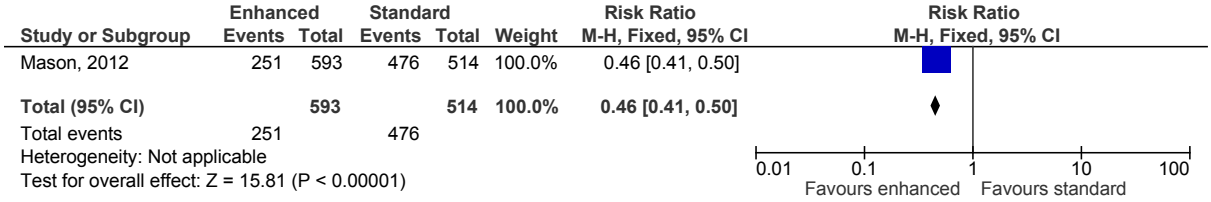


Figure 8: Number referred to hospital (ED or direct admission to a hospital ward) – quasi-experimental study



Appendix D: Clinical evidence tables

Study	**Mason 2007[28]**
Study type	RCT (cluster randomised controlled trial).
Number of studies (number of participants)	1 (n=3018; 56 clusters).
Countries and setting	Conducted in England; setting: large urban area.
Line of therapy	1st line.
Duration of study	Intervention time: intervention + follow-up (3 days and 28 days after the incident).
Method of assessment of guideline condition	Adequate method of assessment/diagnosis.
Stratum	Overall.
Subgroup analysis within study	Not applicable.
Inclusion criteria	Patients aged 60 and above were eligible for inclusion when the call to the ambulance service originated from a Sheffield postcode between 8am and 8pm, with a presenting complaint that fell within the scope of practice of the paramedic practitioners.
Exclusion criteria	Not reported.
Recruitment/selection of patients	Patients were recruited from 1 September 2003 to 26 September 2004. During each week, a paramedic practitioner based in the ambulance control room identified eligible calls by the presenting complaint and notified a paramedic practitioner in the community (during intervention weeks) or in the emergency department (during control weeks). All identified patients were approached face to face either in the community or in the emergency department for written consent to follow-up. To avoid unnecessary burden on participants, patients who had more than one eligible episode were recruited only for their first episode.
Age, gender and ethnicity	Age: mean (SD): 82.6 (8.3). Gender (Females): 2192 (72.6%) Ethnicity: not reported.
Further population details	Presenting complaint Fall: 2682 (88.9%) Haemorrhage: 171 (5.7%) Acute medical condition: 164 (5.4)
Indirectness of population	No indirectness.
Interventions	(n=1549) Intervention 1: the paramedic practitioner service being active (intervention). A paramedic practitioner based

	in the ambulance control room identified eligible calls by the presenting complaint and notified a paramedic practitioner in the community (during intervention weeks). (n=1469) Intervention 2: the paramedic practitioner service being inactive (control), when the standard 999 service was available. During inactive weeks, the paramedic practitioners were removed from operational duties within the ambulance service and undertook research duties including obtaining patients' consent and follow-up.
Funding	Academic or government funding
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PARAMEDIC PRACTITIONER IN THE COMMUNITY (DURING INTERVENTION WEEKS) VERSUS PARAMEDIC PRACTITIONER IN THE EMERGENCY DEPARTMENT (DURING CONTROL WEEKS). Protocol outcome 1: Number of hospital admissions - Actual outcome: Hospital admission 0-28 days: Group 1: 626/1549, Group 2: 683/1469;. Risk of bias: All domain - high, Selection - low, Blinding - high, Incomplete outcome data - low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness Protocol outcome 2: Re-contact rate - - Actual outcome: ED attendance (0-28 days): Group 1: 970/1549, Group 2: 1286/1469; Risk of bias: All domain - high, Selection - low, Blinding - high, Incomplete outcome data - low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness Protocol outcome 3: Patient satisfaction - Actual outcome: Very satisfied with care; Group 1: 656/1549, Group 2: 528/1469; Risk of bias: All domain - high, Selection - low, Blinding - high, Incomplete outcome data - low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness Protocol outcome 4: Mortality - Actual outcome: Mortality at 28 days; Group 1: 68/1549, Group 2: 74/1469; Risk of bias: All domain - high, Selection - low, Blinding - high, Incomplete outcome data - low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Quality of life; Conveyance(carriage) rates; Number of patients seeking further contacts after initial assessment by paramedic (GP, 999, ED or 111) OR Re-contact rates within 7 days; Adverse events; Number of hospital admissions; Staff satisfaction.

Study	**Mason 2008[29]**
Study type	RCT (cluster-randomised controlled trial).

Number of studies (number of participants)	1 (n=3018 in the study, n= 2,025 analysed). This study is part of the study Mason 2007. The study analysed patient who went on to have an unplanned ED attendance in the 7 days after discharge from care at the index episode.
Countries and setting	Conducted in UK; setting: large urban area.
Line of therapy	1st line.
Duration of study	Intervention time: Intervention + follow-up.
Method of assessment of guideline condition	Adequate method of assessment/diagnosis.
Stratum	Overall.
Subgroup analysis within study	Not applicable.
Inclusion criteria	Patients were eligible for inclusion into the trial if they presented to the emergency medical services (EMS) with a call originating from a UK Sheffield zip code between September 1, 2003 and September 26, 2004; the call was made between 08:00 and 20:00 hours; the patient was aged 60 years or over; and they had a presenting complaint that fell within the scope of practice of the paramedic practitioners (PPs) working within the scheme.
Exclusion criteria	Not reported.
Recruitment/selection of patients	During each week, a PP based in the EMS control room identified calls eligible for PP assessment by presenting complaint and notified a PP in the community (intervention weeks) or in the ED (control weeks). All identified patients were approached face-to-face for written consent to follow-up. Patients who had more than 1 eligible episode during the trial period were recruited for their first episode only. Subsequent episodes were logged, but patients were not re-recruited for trial purposes.
Age, gender and ethnicity	Age: mean (SD): 82.6 (8.3). Gender (Females): 2192 (72.6%). Ethnicity: not reported.
Further population details	Presenting complaint Fall: 2682 (88.9%) Haemorrhage: 171 (5.7%) Acute medical condition: 164 (5.4)
Indirectness of population	No indirectness.
Interventions	(n=1549) Intervention 1: the paramedic practitioner service being active (intervention). A paramedic practitioner based in the ambulance control room identified eligible calls by the presenting complaint and notified a paramedic practitioner in the community (during intervention weeks). (n=1469) Intervention 2: the paramedic practitioner service being inactive (control) when the standard 999 service was available. During inactive weeks, the paramedic practitioners were removed from operational duties within the

	ambulance service, and undertook research duties including obtaining patients' consent and follow-up.
Funding	Academic or government funding.
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PARAMEDIC PRACTITIONER IN THE COMMUNITY (DURING INTERVENTION WEEKS) VERSUS PARAMEDIC PRACTITIONER IN THE EMERGENCY DEPARTMENT (DURING CONTROL WEEKS) Protocol outcome 1: Re-contact rate - Actual outcome: Unplanned emergency department attendance; Group 1: 133/1118, Group 2: 86/907; Risk of bias: All domain - very high, Selection - low, Blinding - high, Incomplete outcome data - low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: serious indirectness	
Protocol outcomes not reported by the study	Mortality; Quality of life; Conveyance(carriage) rates; Number of patients seeking further contacts after initial assessment by paramedic (GP, 999, ED, 111) OR Re-contact rates within 7 days; Patient and/or carer satisfaction; Adverse events; Number of hospital admissions; Staff satisfaction.

Study	**Mason 2012[31]**
Study type	Quasi experimental intervention trial.
Number of studies (number of participants)	1 (n=5525); Ambulance service only (n=1107).
Countries and setting	Conducted in the UK; setting: emergency and urgent care.
Line of therapy	1st line
Duration of study	Intervention time: intervention +follow-up.
Method of assessment of guideline condition	Adequate method of assessment/diagnosis.
Stratum	Overall.
Subgroup analysis within study	Not applicable.
Inclusion criteria	All patients presenting with urgent or emergency complaints that were eligible to be seen by the ECPs and presented to either the intervention or control services between May 2006 and August 2007 were included in the trial. The patients ECPs were eligible to see were determined by the setting in which they operated and local protocols developed by individual services.
Exclusion criteria	Not reported.

Recruitment/selection of patients	Not reported.
Age, gender and ethnicity	Age: mean (SD): 49.4 (30.8). Gender (males): 981 (41.6%) Ethnicity: not reported.
Further population details	Not reported.
Indirectness of population	30% of the population were children or trauma patients.
Interventions	Overall: (n=2363) Intervention 1: Five matched pairs of intervention Emergency Care Practitioners (ECP): ambulance, care home, minor injury unit, urgent care centre and GP out-of-hours. The services included: ECPs working as single responder to 999 calls, ECPs responding to direct calls to service from nursing and residential homes, ECPs working in a minor injury unit based in a shopping centre, ECPs working in a GP led primary care out of hours (OOHs) service, ECP led 24 hour Urgent Care Centre based in a community hospital, ECPs working alongside nurse practitioners in a walk-in-centre (WIC) and ECPs working alongside nurse practitioner in a minor's clinic in an emergency department (ED). (n=3162) Intervention 2: control. Usual care services. The services included: Ambulances crewed by standard paramedic/technician response responding to 999 calls, ambulance crewed by standard paramedic/technician response responding to 999 calls from nursing and residential homes, emergency nurse practitioners working in minor injury unit based in community hospital, GPs led out of hours (OOHs) primary care service, nurse led 24 hour casualty based in a small infirmary, nurse practitioner led walk-in centre (WIC) and nurse practitioner led minor clinic within an emergency department (ED). Ambulance service: (n=593) Intervention 1: Emergency Care Practitioner working as a single responder to ambulance service '999' calls. (n=514) Intervention 2: Standard paramedic/technician ambulance responding to ambulance service '999' calls.
Funding	Academic or government funding.
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: Protocol outcome 1: Number of hospital admissions: - Actual outcome: Referred to hospital (ED referral or direct admission to hospital ward): Group 1: 251/593, Group 2: 476/514; Risk of bias: All domain - very high, Selection - high, Blinding - high, Incomplete outcome data - low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: serious indirectness	

Protocol outcome 1: Number of patients seeking further contacts after initial assessment by paramedic (GP, 999, ED, 111) Or Re-contact rates within 7 days) - Actual outcome: Referred to primary care; Group 1: 85/593, Group 2: 4/514; Risk of bias: All domain - very high, Selection - high, Blinding - high, Incomplete outcome data - low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: serious indirectness	
Protocol outcomes not reported by the study	Mortality; Quality of life; Conveyance (carriage) rates; Adverse events; Staff satisfaction.

Appendix E: Economic evidence tables

Study	Dixon 2009[16]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA (health outcome: QALYs) **Study design:** cluster randomised controlled trial with randomisation at the level of the service where weeks were allocated randomly to either the intervention or the control. Dispatch and patient recruitment were undertaken by a paramedic practitioner (see also Mason 2007[28] and Mason 2008[29] in the clinical review). **Approach to analysis:** economic evaluation alongside the clinical trial, with within-trial analysis of resource use, costs and QALYs**.** Complete-case analysis used as the base case. **Perspective:** UK NHS **Follow-up**: 28 days **Treatment effect duration**[(a)]**:** 28 days	**Population:** Elderly patients (> 60 years) with a presenting complaint that fell within the scope of practice of the paramedic practitioner (PP) working within the scheme. **Cohort settings:** Mean age: NR Male: NR **Intervention 1: (n= 1549)** Usual care where Paramedic practitioner (PP) scheme was inactive and standard 999-service in operation. This meant that the paramedic practitioner is removed from operational duties within the ambulance service. The PP based in the ambulance control room identifies the calls eligible for PP assessment and refer them to a PP based in the ED for follow-up. **Intervention 2: (n=1469)** PP scheme active, with the PP attending to calls from patients presenting with complaints within the PP scope of practice, which includes presentations with falls, lacerations, epistaxis, minor burns and foreign bodies. The additional skills they possessed included local anaesthetic	**Total costs (mean per patient) for complete case analysis:** Intervention 1: NR Intervention 2: NR Incremental (2−1):- £680 (95% CI: NR; p=NR) **Total costs (mean per patient):** Intervention 1: £2,641 Intervention 2: £2,102 Incremental (2−1):- £551 (95% CI: -£1,170 to £67; p=NR) **Currency & cost year:** 2004 UK pounds. **Cost components incorporated:** Training, PP time, other emergency responders' time, ED visits, inpatient admissions, social care assessment, primary and community care costs, and nursing/residential	**QALYs (mean per patient) for complete case analysis:** Intervention 1: NR Intervention 2: NR Incremental (2−1): -0.0003 (95% CI: NR; p=NR) **QALYs (mean per patient):** Intervention 1: 0.039 Intervention 2: 0.038 Incremental (2−1): -0.001 (95% CI: -0.003 to +0.000; p=NR)	**ICER (Intervention 1 versus Intervention 2):** £2,266,667 per QALY gained (da)[(b)] 95% CI: NR Probability Intervention 2 cost-effective (£20K threshold): > 95% **Analysis of uncertainty:** Sensitivity analysis using higher unit cost for PP time showed that the incremental cost saving reduced to £92. Another sensitivity analysis using multiple imputations to address the problem of missing data resulted in a reduction of the probability that the intervention is cost effective at £20,000 per QALY gained threshold to 73%, with the incremental cost saving reduced to £162.

Discounting: Costs: n/a; Outcomes: n/a	techniques, wound care, suturing, neurological, cardiovascular and respiratory system examination and protocol-led dispensing. The PP based in the ambulance control room identifies the calls eligible for PP assessment and refer them to a PP based in the community.	care costs.		
Data sources				
Health outcomes: clinical data relating to the initial episode were collected from the hospital patient administration system (PAS data) and ED and ambulance records. Follow-up data were collected from patients using the EQ-5D questionnaire at 28 days. **Quality-of-life weights:** the EQ-5D UK tariff was used to as the source of QoL weights. **Cost sources:** Both local and national sources were used for cost data including NHS reference costs, PSSRU Sheffield teaching hospital and South Yorkshire ambulance service records.				
Comments				
Source of funding: public funding body (Health foundation) **Applicability and limitations:** There is some uncertainty regarding the applicability of the costs and resource use from 2004 to current NHS context. Some social care costs were also included which means that the perspective is not strictly NHS and PSS. Estimates of effectiveness are based on a single RCT so by definition is not reflective of the whole body of evidence in this area. Baseline data on quality of life were assumed equal and not actually measured in the study. Large percentage of missing data which may reduce the power of the analysis to detect differences. Limited number of sensitivity analyses was presented.				
Overall applicability[(c)]: partially applicable **Overall quality[(d)]:** minor limitations				

Abbreviations: 95% CI: 95% confidence interval; CUA: cost–utility analysis; da: deterministic analysis; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; NR: not reported; PP: paramedic practitioner; QALYs: quality-adjusted life years.

(a) For studies where the time horizon is longer than the treatment duration, an assumption needs to be made about the continuation of the study effect. For example, does a difference in utility between groups during treatment continue beyond the end of treatment and if so for how long.

(b) Calculated by NGC. Intervention 2 is less costly and less effective.

(c) Directly applicable/Partially applicable/Not applicable.

(d) Minor limitations/Potentially serious limitations/Very serious limitations.

Appendix F: GRADE tables

Table 7: Clinical evidence profile: enhanced versus standard - RCT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Enhanced versus standard - RCT	Control	Relative (95% CI)	Absolute		
Mortality at 28 days												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	None	68/1549 (4.4%)	5%	RR 0.87 (0.63 to 1.2)	6 fewer per 1000 (from 19 fewer to 10 more)	⊕⊕OO LOW	CRITICAL
Number of hospital admissions (0-28 days)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	None	626/1549 (40.4%)	46.5%	RR 0.87 (0.8 to 0.94)	60 fewer per 1000 (from 28 fewer to 93 fewer)	⊕⊕⊕O MODERATE	IMPORTANT
ED attendance (0-28 days)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	None	970/1549 (62.6%)	87.5%	RR 0.72 (0.69 to 0.75)	245 fewer per 1000 (from 219 fewer to 271 fewer)	⊕⊕⊕O MODERATE	IMPORTANT
Unplanned emergency department attendance												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	None	133/1118 (11.9%)	9.5%	RR 1.25 (0.97 to 1.62)	24 more per 1000 (from 3 fewer to 59 more)	⊕⊕OO LOW	IMPORTANT
Patient satisfaction - very satisfied with care												

1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	None	656/1549 (42.3%)	35.9%	RR 1.18 (1.08 to 1.29)	65 more per 1000 (from 29 more to 104 more)	⊕⊕OO LOW	CRITICAL

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
2 Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs.

Table 8: Clinical evidence profile: enhanced versus standard – Non-randomised study (Quasi-experimental study)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Enhanced versus standard - NRS**	**Control**	**Relative (95% CI)**	**Absolute**		
Number referred to hospital (ED or direct admission to a hospital ward)												
1	observational studies	very serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	251/593 (42.3%)	92.6%	RR 0.46 (0.41 to 0.5)	500 fewer per 1000 (from 463 fewer to 546 fewer)	⊕OOO VERY LOW	IMPORTANT
Number referred to primary care												
1	observational studies	very serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	85/593 (14.3%)	0.8%	RR 18.42 (6.8 to 49.86)	139 more per 1000 (from 46 more to 391 more)	⊕OOO VERY LOW	IMPORTANT

1. *All non-randomised studies automatically downgraded due to selection bias. Studies may be further downgraded by 1 increment if other factors suggest additional high risk of bias, or 2 increments if other factors suggest additional very high risk of bias.*

2 Downgraded by 1 increment as outcome is indirect.

Appendix G: Excluded clinical studies

Table 9: Studies excluded from the clinical review

Reference	Reason for exclusion
Angelache 1987[3]	No data presented. Foreign language paper. Not a relevant population – pregnant women.
Anon 1995[1]	Unable to locate.
Anon 2014A[2]	No data which can be analysed.
Arreolarisa 2000[4]	No relevant outcomes. Not a relevant population – trauma patients.
Arreolarisa 2007[5]	Population does not match protocol – trauma patients.
Barr 2011[6]	Not appropriate study design – magazine article.
Brown 2011[7]	Not appropriate study design – article. No data presented.
Caffrey 2014[8]	Not appropriate study design – literature review.
Campbell 2008[9]	Not a relevant intervention – paramedics administering drugs in the Emergency department.
Cantor 2012[10]	Not relevant – looks at hospital transfer of MI patients. No control group.
Clarke 2014[11]	No control group. No relevant outcomes.
Cooper 2007[14]	Not relevant intervention – leadership skills. No relevant outcomes
Cooper 2004[13]	Not appropriate study design – qualitative study.
Cooper 2009[15]	Not appropriate study design – literature review
Dixon 2009[16]	Cost effectiveness from the Mason RCTs.
Dyson 2014[17]	Systematic review looking at experience rather than enhanced competencies.
Evans 2014[18]	Systematic review with inadequate quality assessment or studies.
Filatova 1974[19]	Not a relevant population – study conducted in Russia. Foreign language paper.
Frandsen 1991[20]	Observational study n<500.
Gilovan 1987[21]	Not a relevant population – study conducted in Romania. Foreign language paper.
Gray 2008A[22]	Not about competencies of staff, about differences in outcomes for elderly patients and people with breathing difficulties.
Haynes 1999[23]	No relevant outcomes.
Nicholl 1998[33]	Population does not match protocol – serious trauma patients.
Jayamaran 2014[24]	Population does not match protocol – trauma patients.
Lemay 2006[25]	Not a relevant comparison, about ACP's using STEMI tool.
Lewis 1979[26]	US study. Not relevant for UK context as do not have a physician on ambulance.
Mason 2006[27]	Not appropriate study design – non-comparative.
Mason 2007A[30]	Observational study, n<250. No multivariate analysis.
Mitchell 1997[32]	Observational study n<500. No multivariate analysis.
Ohara 2012[34]	No relevant outcomes. Reviewed case notes and developed a quality and safety care score which is only outcome.
Rowley 1987[35]	Not a relevant comparison, not standard paramedic.
Sanghavi 2015[36]	Not relevant to the UK.
Smith 2013[37]	Not relevant. Laboratory study.

Reference	Reason for exclusion
Spoor 1977[38]	Unable to locate
Spoor 1981[39]	No relevant outcomes.
Stiell 2007[40]	Not relevant to the UK.
Sukumuran 2005[41]	Population does not match protocol – trauma patients.
Tohira 2014[42]	Unable to locate.
Wright 1985[43]	Not relevant. Costs of training and description of training.

Appendix H: Excluded economic studies

Table 10: Studies excluded from the economic review

Reference	Reason for exclusion
Mason 2007A[30]	This study was assessed as partially applicable with very serious limitations. The study is conducted in 3 settings, only 1 of which is applicable to the current review (999 setting). It is not clear whether the usual care provided in the 999 setting is by paramedics with standard competencies. Additionally, ECPs in the study could have a background as a paramedic or nurse or other health care professional, with differences in training costs and subsequent incremental costs. There is some uncertainty regarding the applicability of the costs and resource use from 2004 to current NHS context. EQ-5D is reported to have been used but no detailed data on QALYs are provided. The study also has serious limitations as it is an observational study with limited adjustment for confounders. Estimates of effectiveness are from 1 study, so by definition, do not reflect all evidence in this area. Very limited data is presented for the cost analysis with no information on nature or quantities of resources used and their unit costs. The source of unit costs for the health services used, other than personnel time, is not clear. The authors reported that cost data were available only for 56 patients, so the cost analysis is not sufficiently powered. Only a difference in cost is reported with no details of how this estimate was arrived at. Sensitivity analysis is reported.