Appendix D: Clinical evidence tables

Study	Emlet 2012[34]
Study type	Non-randomised comparative study
Number of studies (number of participants)	(n=820)
Countries and setting	Conducted in USA; Setting: Intensive care unit (mixed medical and surgical)
Line of therapy	Not applicable
Duration of study	Intervention time: 8 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Not reported
Exclusion criteria	Not reported
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Other: Not reported. Gender (M:F): Not reported. Ethnicity: Not reported
Further population details	1. Critical care patients: Critical care patients (mixed medical-surgical unit). 2. Frail elderly: Not applicable/Not stated/Unclear 3. Speciality/profession: Inter-professional handover (19 fellows in a Multidisciplinary Critical Care Training Programme; ICU nurses).
Indirectness of population	No indirectness
Interventions	(n=431) Intervention 1: Structured (planned framework as defined by the study) between healthcare professionals between shifts in acute settings - this will include (i) set times of the day, (ii) using a structured template/proforma for the handover (iii) recording the information in written or electronic form. The intervention schedule consisted of 12-hour shifts with 1 hour overlap between day and night shifts to allow for a 30 minute structured sign-out while walking through the ICU. The intervention schedule was designed with best evidence for circadian-based shift scheduling design; forward cycling shifts with short strings of nights. Sign-out curriculum and clinical cases were developed from Agency for Healthcare Research and Quality Patient Safety Web resources, Veterans Administration Patient Safety Web resources, and previously published papers. Prior to the beginning of intervention period, the 4 fellows were given a 2 hour interactive workshop on structured sign out and expectations, and also given special

Study	Emlet 2012[34]
	access to a feature called sign-out in the electronic medical record so that information could be saved securely and sign-out lists could be generated to assist in communication. Only fellows during the intervention periods had access to the sign-out feature in the electronic medical record. This 2 hour session reviewed content and structure of a problem-orientated sign-out with anticipatory guidance, expectations for sign-out while walking through the unit, and hands on instruction on how to create and print sign-out list. Weekly monitoring was performed by electronic survey of fellows during intervention blocks requesting feedback on quality and if sign-out was given as instructed: verbally, face-to-face while walking through ICU with printed, computer-generated sign-out lists. Directed feedback (positive or negative) was given bimonthly. Duration was 32 weeks (periods alternated between 4 and 8 week blocks of time). Concurrent medication/care: Shift scheduling. Comments: number of participants= number of admissions. (n=389) Intervention 2: Normal handover - Routine unstructured handover. The control schedule consisted of an overnight call every fourth night, where the total continuous hours worked during call was not >30 hours. No education on sign-out was provided during call periods, and no quality assurance of sign-out was monitored. Usual practice consisted of a brief verbal description of patients to the fellow on call with handwritten notes at the fellow's discretion. Duration was 32 weeks (periods alternated between 4 and 8 week blocks of time). Concurrent medication/care: none.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: STRUCTURED HANDOVER versus ROUTINE UNSTRUCTURED HANDOVER

Protocol outcome 1: Mortality
- Actual outcome: Mortality at 8 months; Group 1: 26/431, Group 2: 33/389; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Single centre study, small sample size, non-randomised design; Indirectness of outcome: Serious indirectness, Comments: Intervention also comprised shift scheduling

Protocol outcome 2: Avoidable adverse events (prescribing errors (errors of omission or commission) cardiopulmonary resuscitation, unplanned admission to intensive care, delayed or missed investigations, delayed or missed treatments)
- Actual outcome: Readmission <48 hours at 8 months; Group 1: 21/431, Group 2: 14/389; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Single centre study, small sample size, non-randomised design; Indirectness of outcome: Serious indirectness, Comments: Intervention also comprised shift scheduling
Protocol outcome 3: Patient and/or carer satisfaction
- Protocol outcome 3: Patient and/or carer satisfaction

Study	Emlet 2012[34]
- Actual outcome: Family satisfaction score at 8 months. Group 1: 24 (15, 41), Group 2: 22 (15, 39). Minimum and maximum scores are in brackets. At the time of study the Critical Care Family Needs Index was the only previously validated survey to measure family needs. The Critical Care Family Needs Index is scored such that a minimum value of 18 would denote that family needs were met, whereas a maximum value of 57 would denote that family needs were not met. Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Single centre study, small sample size, non-randomised design; Indirectness of outcome: Serious indirectness, Comments: Intervention also comprised shift scheduling Protocol outcome 4: Length of stay - Actual outcome: ICU length of stay at 8 months; Group 1: mean 5.65 days (SD 8.7); n=431, Group 2: mean 8.43 days (SD 17.2); n=389; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Single centre study, small sample size, non-randomised design; Indirectness of outcome: Serious indirectness, Comments: Intervention also comprised shift scheduling Protocol outcome 5: Staff satisfaction - Actual outcome: Final vote- attending at 8 months; Group 1: 6/11, Group 2: 2/11; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Single centre study, small sample size, non-randomised design; Indirectness of outcome: Serious indirectness, Comments: Intervention also comprised shift scheduling - Actual outcome: Final vote- fellows at 8 months; Group 1: 6/16, Group 2: 7/16; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Single centre study, small sample size, non-randomised design; Indirectness of outcome: Serious indirectness, Comments: Intervention also comprised shift scheduling - Actual outcome: Final vote- nurses at 8 months; Group 1: 22/30, Group 2: 2/30; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Single centre study, small sample size, non-randomised design; Indirectness of outcome: Serious indirectness, Comments: Intervention also comprised shift scheduling	
Protocol outcomes not reported by the study	Quality of life.

Study	Coon 2015[20]
Study type	Before and after study.
Number of studies (number of participants)	(n=261)
Countries and setting	Conducted in USA; Setting: Neurosciences ICU.
Line of therapy	Not applicable.
Duration of study	Intervention + follow up: 6 months.
Method of assessment of guideline condition	Adequate method of assessment/diagnosis.
Stratum	Overall.

Study	Coon 2015[20]
Subgroup analysis within study	Not applicable.
Inclusion criteria	Not reported.
Exclusion criteria	Not reported.
Recruitment/selection of patients	Consecutive patients.
Age, gender and ethnicity	Age - Mean (range): Pre-implementation: 65 (24-77), Post-implementation: 63 (23-84). Gender (M:F): Pre-implementation: 55F; Post-implementation: 70F. Ethnicity: not reported.
Further population details	1. Critical care patients: Critical care patients (Neurointensive ICU). 2. Frail elderly: Not applicable/Not stated/Unclear. 3. Speciality/profession: Profession-specific handover (Physicians).
Indirectness of population	No indirectness
Interventions	(n=131) Intervention 1: Structured (planned framework as defined by the study) between healthcare professionals between shifts in acute settings - this will include (i) set times of the day, (ii) using a structured template/proforma for the handover (iii) recording the information in written or electronic form. Creation of an ICU documentation checklist, including details on: medication reconciliation, urinary catheter, prophylaxis, vitals/cares, consults and follow-up. Duration: 3 months. Concurrent medication/care: none. (n=130) Intervention 2: Normal handover - Routine unstructured handover. Pre implementation handover. Duration: 3 months. Concurrent medication/care: none
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: THIS WILL INCLUDE (I) SET TIMES OF THE DAY, (II) USING A STRUCTURED TEMPLATE / PROFORMA FOR THE HANDOVER (III) RECORDING THE INFORMATION IN WRITTEN OR ELECTRONIC FORM versus ROUTINE UNSTRUCTURED HANDOVER

Protocol outcome 1: Avoidable adverse events (prescribing errors (errors of omission or commission) cardiopulmonary resuscitation, unplanned admission to intensive care, delayed or missed investigations, delayed or missed treatments) at Define
- Actual outcome: ICU readmissions at 6 months; Group 1: 5/131, Group 2: 4/130; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - before and after study; incomplete reporting of results; Indirectness of outcome: No indirectness
- Actual outcome: Rapid response team calls at 6 months; Group 1: 4/131, Group 2: 2/130; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - before and after study; incomplete reporting of results; Indirectness of outcome

Study	Coon 2015[20]
Protocol outcomes not reported by the study	Mortality; Quality of life; Patient and/ or carer satisfaction; Length of stay; Staff satisfaction.

Study	Gonzalo 2014[42]
Study type	Before and after study.
Number of studies (number of participants)	(n= not reported).
Countries and setting	Conducted in USA; Setting: Academic medical centre.
Line of therapy	Not applicable.
Duration of study	Intervention + follow up: 1 year.
Method of assessment of guideline condition	Method of assessment/diagnosis not stated.
Stratum	Overall.
Subgroup analysis within study	Not applicable.
Inclusion criteria	An electronic handoff tool (eSignout) was added to the pre-existing ED dashboard functionality that included (i) standardised fields for ED-based physician and nursing manual entry of sign out information, (ii) an automated page to the recipient ward-based physician send by the ED-based physician through the dashboard once the sign out information is ready for review and (iii) ability for the recipient ward-based physician to either electronically 'accept' the patient using the eSignout tool.
Exclusion criteria	N/A
Recruitment/selection of patients	Not reported.
Age, gender and ethnicity	Age: Not reported. Gender (M:F):42:38 (before implementation); 880:508 (following implementation). Ethnicity: Not reported.
Further population details	1. Critical care patients; 2. Frail elderly; 3. Speciality/profession.
Indirectness of population	No indirectness.
Interventions	(n=1388) Intervention 1: Electronic-based handover - using electronic means to conduct the structured handover. eSignout was added to the pre-existing ED dashboard functionality that included (i) standardised fields for ED-based physician and nursing manual entry of sign out information, (ii) an automated page to the recipient ward-based physician send by the ED-based physician through the dashboard once the sign out information is ready for review and (iii) ability for the recipient ward-based physician to either electronically 'accept' the patient using the eSignout tool (thereby commencing the patient transfer from ED to medicine ward) or, alternatively, to automatically page the sending ED-based physician for verbal communication if eSignout information was believed insufficient or requiring

Study	Gonzalo 2014[42]
	clarification. Following verbal communication, the ward-based physician would then electronically 'accept' the patient via eSignout, initiating the patient transfer. Duration: 1 year. Concurrent medication/care: Not reported. Comments: number of participants is number of surveys. (n=80) Intervention 2: Normal handover - routine unstructured handover. Verbal communication between sending ED-based physician and recipient ward-based physician mandatory prior to patient transfer. Duration: unclear. Concurrent medication/care: not reported. Comments: number of participants is number of surveys.
Funding	Funding not stated.
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: USING ELECTRONIC MEANS TO CONDUCT THE STRUCTURED HANDOVER versus ROUTINE UNSTRUCTURED HANDOVER. Protocol outcome 1: Staff satisfaction. - Actual outcome: The overall sign-out process at 1 year; Group 1: mean 6.25 (SD 1.91); n=1058, Group 2: Group 2: mean 6.08 (SD 2.20); n= 78 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Before and after study; differential missing data rate between groups.; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality; Avoidable adverse events (prescribing errors [errors of omission or commission] cardiopulmonary resuscitation, unplanned admission to intensive care, delayed or missed investigations or delayed or missed treatments); Quality of life; Patient and/or carer satisfaction; Length of stay.

Study	Graham 2013[46]
Study type	Before and after study.
Number of studies (number of participants)	(n=period 1: 39 night shifts, ~2700 handoffs. Period 4: 19 night shifts, ~1300 handoffs).
Countries and setting	Conducted in USA; Setting: urban teaching hospital.
Line of therapy	Not applicable.
Duration of study	Intervention time: 1 year.
Method of assessment of guideline condition	Method of assessment/diagnosis not stated.
Stratum	Overall.
Subgroup analysis within study	Not applicable.
Inclusion criteria	Define.

Study	Graham 2013[46]
Exclusion criteria	Define.
Recruitment/selection of patients	Not reported.
Age, gender and ethnicity	Age - Mean (SD): Period 1: 26.9 (1.6); Period 4: 27.2 (1.1). Gender (M:F): Period 1:68%F; Period 3: 39%F. Ethnicity: not reported.
Further population details	1. Critical care patients; 2. Frail elderly; 3. Speciality/profession.
Extra comments	Period 1 was baseline (no interventions). Period 2 in the study was after the implementation of shift scheduling alone. Period 3 was after shift scheduling and the electronic template in place, but a few months before Period 4, which was with shift scheduling and the electronic template in place (1 year after baseline). The analysis is therefore between periods 1 and 4.
Indirectness of population	No indirectness.
Interventions	(n=19) Intervention 1: Electronic-based handover - using electronic means to conduct the structured handover. An electronic template was created for the handoff that linked to the hospital's clinical information system and provided cues for appropriate content, including a summary assessment of the patient, past medical history, current medication list, active problems, current clinical status at the time of handoff, 'contingency planning' where the primary team provided anticipatory guidance for events that were likely to occur overnight, and a task list to be completed during the overnight shift. Duration: unclear. Concurrent medication/care: prior to the implementation of the electronic template, the shift model was altered to facilitate face to face verbal communication between the primary and night time coverage physicians. By asking the night float teams to arrive 1.5 hours earlier, and requiring the primary teams to remain in the hospital until their arrival, the intermediary handoff was removed. Comments: number of participants is number of shifts represented. The intervention is represented by the term 'period 4' in the study. (n=39) Intervention 2: Normal handover - routine unstructured handover. At baseline, day to night handoff was a 'double handoff' whereby the primary physicians handed off to an intermediary physician, so that they could leave the hospital earlier and preserve duty hour limits. A second handoff occurred between the intermediary and night-time coverage physician when the night shift began. The written handoff used a simple free text box linked to each of the patients in the hospital's clinical information system, with no structure for content. Duration: unclear. Concurrent medication/care: none. Comments: Number of participants is number of shifts represented. The routine unstructured handover is represented by the term 'period 1' in the study.
Funding	Other (Health Resources and Services Administration training grant; Midcareer Investigator Award in Patient-Orientated Research from the National Institute on Aging (K24AG035075); Harvard Catalyst (NIH Award #ULI RR

Study	Graham 2013[46]
	025758) and financial contributions from Harvard University and its affiliated academic health care centres.).
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: USING ELECTRONIC MEANS TO CONDUCT THE STRUCTURED HANDOVER versus ROUTINE UNSTRUCTURED HANDOVER Protocol outcome 1: Avoidable adverse events (prescribing errors (errors of omission or commission) cardiopulmonary resuscitation, unplanned admission to intensive care, delayed or missed investigations, delayed or missed treatments) at Define. - Actual outcome: Critical data omissions at 1 year; Group 1: 0/19, Group 2: 23/39; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Crossover - Low, Comments - Before and after study; survey responses used for outcome reporting; intervention also incluuded shift scheduling; Indirectness of outcome: No indirectness - Actual outcome: Near misses at 1 year; Group 1: 0/19, Group 2: 9/39; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Crossover - Low, Comments - Before and after study; survey responses used for outcome reporting; intervention also incluuded shift scheduling; Indirectness of outcome: No indirectness - Actual outcome: Adverse events at 1 year; Group 1: 0/19, Group 2: 4/39; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Crossover - Low, Comments - Before and after study; survey responses used for outcome reporting; intervention also incluuded shift scheduling; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality; Quality of life; Patient and/or carer satisfaction; Length of stay; Staff satisfaction.

Study	Kerr 2016[58]
Study type	Before and after study.
Number of studies (number of participants)	1 (n=not reported).
Countries and setting	Conducted in Australia; Setting: Mixed adult and paediatric ED of a teaching hospital in Melbourne, Australia.
Line of therapy	Not applicable.
Duration of study	Other: 5 day pre-implementation phase and 5 day post-implementation phase
Method of assessment of guideline condition	Method of assessment/diagnosis not stated.
Stratum	Overall.
Subgroup analysis within study	Not applicable.
Inclusion criteria	Not reported.
Exclusion criteria	Not reported.
Recruitment/selection of patients	Review of ED patient records and direct observation.
Age, gender and ethnicity	Age - Other: Gender (M:F): Not reported. Ethnicity: Not reported.
Further population details	1. Critical care patients: Not applicable/Not stated/Unclear.

Study	Kerr 2016[58]
	2. Frail elderly: Not applicable/Not stated/Unclear. 3. Speciality/profession: profession-specific handover (nurse handover).
Indirectness of population	Serious indirectness: Mixed adult and paediatric ED.
Interventions	(n=151) Intervention 1: Structured (planned framework as defined by the study) between healthcare professionals between shifts in acute settings - this will include (i) set times of the day, (ii) Using a structured template/proforma for the handover (iii) recording the information in written or electronic form. Structured nursing handover based on the ISBAR (identify, situation, background, assessment, recommendations) handover approach, modified to address deficits in nursing care practice in the ED. Key features: systematic, conducted at the bedside, involvement of patients/relatives, viewing of charts during handover, preliminary group handover for general information about unstable patients, notepads providing prompts about nursing care needs, treatment and disposition plan and important care elements (medication chart, vital signs, fluid balance). Duration: 5 days. Concurrent medication/care: not reported. (n=128) Intervention 2: Normal handover - Routine unstructured handover. Handover undertaken in an enclosed area located away from the clinical area, carried out by the nurse in charge of the outgoing shift to those on the incoming shift; generally occurring 3 times a day. Duration: 5 days. Concurrent medication/care: not reported.
Funding	Other (Nurses Board of Victoria Legacy Limited fund).
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: THIS WILL INCLUDE (I) SET TIMES OF THE DAY, (II) USING A STRUCTURED TEMPLATE / PROFORMA FOR THE HANDOVER (III) RECORDING THE INFORMATION IN WRITTEN OR ELECTRONIC FORM versus ROUTINE UNSTRUCTURED HANDOVER Protocol outcome 1: Avoidable adverse events (prescribing errors (errors of omission or commission) cardiopulmonary resuscitation, unplanned admission to intensive care, delayed or missed investigations, delayed or missed treatments) - Actual outcome: medications administered as prescribed at 5 days; Group 1: 149/151, Group 2: 125/128; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality; Quality of life; Patient/carer satisfaction; Length of stay; Staff satisfaction.

Study	Zou 2016[127]
Study type	Before and after study.
Number of studies (number of participants)	1 (n=3933)
Countries and setting	Conducted in China; Setting: Medical unit of a tertiary general hospital in China.
Line of therapy	Not applicable.

Study	Zou 2016[127]
Duration of study	Other: 1 year pre-intervention and 1 year post-intervention.
Method of assessment of guideline condition	Unclear method of assessment/diagnosis: not reported.
Stratum	Overall: N/A.
Subgroup analysis within study	Not applicable.
Inclusion criteria	Not reported.
Exclusion criteria	Not reported
Recruitment/selection of patients	Unclear.
Age, gender and ethnicity	Age - --: Not reported. Gender (M:F): Not reported. Ethnicity: Not reported.
Further population details	1. Critical care patients: Not applicable/Not stated/Unclear. 2. Frail elderly: Not applicable/Not stated/Unclear. 3. Speciality/profession: profession-specific handover.
Extra comments	Admissions included patients with gastroenterological and endocrinological diseases such as pancreatitis, gastrointestinal bleeding, cirrhosis, liver cancer and diabetes.
Indirectness of population	No indirectness: no indirectness.
Interventions	(n=1970) Intervention 1: Structured (planned framework as defined by the study) between healthcare professionals between shifts in acute settings - this will include (i) set times of the day, (ii) using a structured template/proforma for the handover (iii) recording the information in written or electronic form. Standard nursing handover form including patient name, medical record number, diagnosis, signs/symptoms, abnormal test results, care plan 'to do' tasks, scheduled tests/procedures, fall risk, oxygen therapy and catheter. Oral report given by outgoing nurses at nursing station, then bedside handoffs. Head nurse supervised each handoff process. Duration October 2012 - September 2013. Concurrent medication/care: Not reported. (n=1963) Intervention 2: Normal handover - Routine unstructured handover. Verbal nursing handoffs at the nursing station at shift change time; occasionally bedside handoffs for critical patients; information transferred was incomplete and unsystematic. Duration October 2013 - September 2014. Concurrent medication/care: Not reported.
Funding	Funding not stated.

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: THIS WILL INCLUDE (I) SET TIMES OF THE DAY, (II) USING A STRUCTURED TEMPLATE / PROFORMA FOR THE HANDOVER (III) RECORDING THE INFORMATION IN WRITTEN OR ELECTRONIC FORM versus ROUTINE UNSTRUCTURED HANDOVER

Protocol outcome 1: Avoidable adverse events (prescribing errors (errors of omission or commission) cardiopulmonary resuscitation, unplanned admission to intensive

Study	Zou 2016[127]
care, delayed or missed investigations, delayed or missed treatments). - Actual outcome: Handoffs related errors at 1 year; Group 1: 5/1970, Group 2: 53/1963; Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Mortality; Quality of life; Patient/carer satisfaction; Length of stay; Staff satisfaction.