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Military Operating Room of the Future

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Human Factors; Handoffs; Handover; Communication; Teamwork; Trauma; Cardiac Surgery; Patient Safety; Improvement; Systems Analysis

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1. INTRODUCTION

Effective handoffs of care are critical for maintaining safety and avoiding communication problems in acute care. This program of work examined the entire trauma pathway, to include multiple handoff types, in multiple phases of care, and explores multiple dimensions of intervention. We have taken a broad approach to problem definition and early analysis, using incident reports, observation and classification of flow disruptions along the trauma pathway, process mapping, interviews and direct observation. We have found the most important factors to be related to task and teamwork, and have been able to demonstrate redesigns of handoffs to provide better defined processes that also improve teamwork. We also identified situations in which patients can deteriorate, and tested a secure smartphone information display and messaging system, that employed user-centered design to improve situational awareness and teamwork in a simulated trauma setting.

2. KEYWORDS

Human Factors; Handoffs; Handover; Communication; Teamwork; Trauma; Cardiac Surgery; Patient Safety; Improvement; Systems Analysis;

3. OVERALL PROJECT SUMMARY

General Introduction

They serve several purposes, including transfer of information, transfer of responsibility, identifying deviations from normal, revealing problems, social interaction, distributing knowledge, and reinforcing values. Transitions in trauma care, like other forms of handoffs, are vulnerable to systems problems and human errors. This project took a mixed-methods approach to understanding, modeling, and improving handoffs in trauma and other acute care scenarios. Developing interventions through a human-centered model of care, we were able to examine improvements associated with technology, training, environment and task redesign.

This program of work examined the entire trauma pathway, to include multiple handoff types, in multiple phases of care, and uses multiple dimensions of intervention. 12 studies were conducted, grouped into categories of systems analysis (4 studies), pre surgery handoffs (2 studies), post surgery handoffs (3 studies), deterioration (2 studies), and technology development (1 study). The systems analysis developed a range of process maps, analyzed clinician interviews, explored incidents associated with handoffs, and flow disruptions in handoffs over the course of trauma care. We examined pre surgery handoffs from the Emergency Department (ED) to Imaging, and transfers from the ED and other locations into the Surgical Intensive Care Unit (SICU). Post surgery handoffs examined were the Post Anesthetic Care Unit (PACU), the Cardiac Surgery Intensive Care Unit (CSICU), and in Congenital Heart Surgery(CHS). Studies in deterioration explored the relationship between mortality and changes in vital signs from EMS to ED transfer, and the parameters that predict failure to rescue deteriorating patients. Finally, we tested and developed a smartphone app to assist in communications, handoffs, teamwork and delivering better care.

For ease of reading, this section summarizes those studies. Later sections provide more detail of those individual studies. The challenge was how to appropriately identify opportunities for improvement, to test them, and to make such innovations sustain.
General Methods
The complex and variable nature of handoffs required several different approaches to data collection. Fundamentally, this was a pseudo-ethnographic research and quality improvement program, with the research team working closely (and sometimes within) the care teams to understand the challenges they face from a realist viewpoint. Interventions were developed with the input and assistance of the care teams, and implemented using Plan-Do-Study-Act (PDSA) cycles. To guide the research, interviews were conducted to understand the challenges involved in handoffs, their purpose, and the perceived components of success. We also analyzed previously reported incidents, and observed some of our own. Trauma databases were used to explore the role of handoffs on deterioration and failure-to-rescue. More than two hundred handoffs of different types were studied through direct observation, using either relatively unstructured qualitative observations of flow disruptions, or more structured observations of technology, information and teamwork. Self reporting forms were used where we could not reasonably conduct observations. Finally, we used in simulation and in situ simulation to evaluate different approaches to handoffs, using video observation and structured debriefings to elicit required data. The areas, studies and methods are summarized in table 1.

Table 1: Summary of Studies and Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Pre-Arrival/ Arrival</th>
<th>Pre OR</th>
<th>Post-Op / ICU</th>
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<tr>
<td>Direct Observation</td>
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<td>Direct Observation</td>
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<td>Pre-communication</td>
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<td>Flow Disruptions</td>
<td>Information Equipment Teamwork</td>
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<td>Handoff Quality</td>
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<td>Unexpected Events</td>
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<td>Process Measures</td>
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<td>Smartphone App</td>
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<td>CT Checklist</td>
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<td>Outcome Measures</td>
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<td>Simulation performance</td>
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<td>Teamwork</td>
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General Findings
The key research accomplishments are:

- Detailed mapping of handoffs along the trauma pathway and other high-risk analogue handoffs within a hospital, revealing a complex handoff “ecosystem” and a structure upon which to define handoff properties and designs.
- An analysis of the disruptions during transitions and handoffs along the trauma pathway showing that:
  - Many patients experience some disruption during care transition
  - Co-ordination problems are dominant causes
  - The sicker, more at risk patient experience more problems.
- An analysis of hospital incident reports of handoffs, revealing that task and teamwork causes are dominant
- The deployment of observational methods to measure specific types of handoffs and transitions, exploring the relationship between task and teamwork.
- A statistical model of the relationship between tasks, teamwork and process in transitions from OR to PACU and ICU.
- Measurement of the reliability of handoffs to surgical ICU.
- Development and evaluation of three interventions that validate this approach
- Development of a teamwork and communication app to improve handoffs, information provision and teamwork across the trauma pathway and beyond.

General Discussion
Our analysis of flow disruptions, process maps, and direct observations suggest that it is the high risk, less frequent handoffs that created the greatest problems. Handoffs to ICU involve an entire change in care team, happen with the sickest patients, and are relatively unstructured. In terms of improvement, process and teamwork improvements offer the best solution, as indicated by interviews, flow disruption analysis, and direct observation of interactions between teamwork and process.

As a model of high acuity handoffs and direct admissions to ICU, we focused interventions on cardiac patients transferring from the OR. Working within the CSICU allowed us to observe with reliable frequency these types of handoffs. By expanding the concept of handoff from the traditional mnemonic (e.g. SBAR), to incorporated process redesign, checklists, teamwork, and training, we demonstrated that encouraging the optimal task, team and technology interactions will produce measurable improvements in the handoff process.

General Conclusions
Phase II of the Operating Room of the Future program has built a unique set of knowledge around handoffs in high risk patients. We have taken a broad approach to problem definition and early analysis, using incident reports, observation and classification of flow disruptions along the trauma pathway, process mapping, interviews and direct observation. We have found the most important factors to be related to task and teamwork, and have been able to demonstrate redesigns of handoffs to provide better defined processes that also improve teamwork. We also identified situations in which patients can deteriorate, and tested a secure smartphone information display and messaging system, that employed user-centered design to improve situational awareness and teamwork in a simulated trauma setting.
Systems Analysis

Introduction
A range of models exist for describing the complex relationship between systems components but generally they acknowledge that people; tasks; equipment; tools and aspects of the organization all interact to produce either successful or unsuccessful processes and outcomes. In order to understand the different types of handoff and the context in which those handoffs happen, we first examined the systems of work in which these handoffs are embedded. This required a mapping of the process, interviews with staff, analysis of incidents associated with handoffs, and direct observation and analysis of flow disruptions.

Study 1: Process Mapping
Through detailed considerations, patient shadowing, and discussing the process with clinicians in different parts of the hospital, we investigated how patients move around the hospital, which identified areas and methods for subsequent detailed study of specific handoffs. Our observations and assessments considered six key areas of the handoff process, of which 1-4 were eventually studied.

1. Emergency Department (ED) to Imaging (CT)
2. Admission to the Surgical Intensive Care Unit (SICU)
3. Operating Room (OR) to the Post Anesthesia Care Unit (PACU)
4. OR to the Cardiac Surgical Intensive Care Unit (CSICU)
5. Step-down Handoffs from ICU to Ward
6. Shift-to-shift handoffs

A further mapping process also allowed us to superimpose human-centered considerations that typify each different handoff. Considering the function of each handoff, there were three types.

- Type 1: Care Process Handoff. Required: decision making, resource management and co-ordination
- Type 2: Team Transfer Handoff. Required: equipment transfer, teamwork processes, information handoff
- Type 3: Care Continuity Handoff: Required: maintains situation awareness and shared decision making

Type 1 handoffs – typified by decision making in the ED and CT – are moments at which the care of the patient and their treatment pathway change rapidly, based on the use of dynamic changing resources, and requiring the team (some of whom may be new to that patient) to agree on a decision and co-ordinate the response to ensure the appropriate follow-through. Type 2 handoffs – typified by transfers from surgery – are where the transfer of the patient is both physical and between teams, requiring continuity of information and care between the teams. With these handoffs, the care pathway should be clear, and the patient relatively stable, so the dynamic decision making component is not required, and can be more easily structured. Type 2 handoffs are where we hypothesize will be the greatest need for precise information transfer to better identify deteriorating patients. Type 3 handoffs – typified by within-unit handoffs – require the maintenance of patient care over a longer period, requiring the continual updating of patient information and strategic shared decision making to move the patient through their care to discharge. All three handoffs are qualitatively different, and so have different requirements. Finally, we mapped in detail processes for the ED to Imaging transfer process (figure 4), admission to ICU (figure 5), and for step-down from ICU to ward care (figure 6). All three processes are typified by a non-linear sequence of multiple communications, largely by telephone, prior to the physical movement of the patient.
Figure 2: Handoffs and Information Flow along the Trauma Care Pathway

1. EMS contacts ED
2. MICN
   a. takes the call
   b. records the details
   c. sends out a tannoy
   d. pages the team
   e. puts the information in on the whiteboard
   f. provisionally briefs the team
3. Trauma resident conducts briefing with ED Docs and Nurses
4. Patient arrives
5. EMT briefs team
6. Primary and secondary surveys
7. ED Nurse liaises with CT
8. ED nurse liaises with OR
9. Trauma team liaise with x-ray technicians
10. Patient moved to CT
    a. ED team accompany patient to CT
    b. ED team update radiographer
11. Patient moved to ED
    a. Handover to ED docs & nurses
12. Patient moved to OR: Handoff to OR team
13. Patient moved to ICU: Handoff to ICU team
14. Patient moved to floor: Handoff to floor nurses
Figure 3: Handoff process map and typical types.

Figure 4: Process for transfer of patient from ED to Imaging.
Figure 5: Process for admission of patient from the OR to ICU

Figure 6: ICU to Ward Step-Down Handoff Process
Study 2: Interviews
In order to understand from the provider point of view those generic skills and system configurations that differentiate between good and bad handoffs, semi-structured interviews were conducted with staff. For this we worked with Madigan Army Medical Center, where a series of interview and focus groups were conducted with a total of 113 staff (15 ICU Nurses, Attendings & Residents; 3 respiratory technicians; 34 anesthesia providers; 4 blood bank staff; 8 ED staff; 8 general surgery residents, and 40 OR staff). We recorded 67 individual comments and perspectives that were then classed into several categories. First, we considered the reported purposes of handoff that featured in the comments. Next, the process considerations, and finally, we classified comments according to the SEIPS model of human factors (Figure 7).

Overall, we found that a good handoff is defined by the transfer of information, responsibility, and the shared planning of future care. This is influenced by: clear leadership & role definition, face-to-face communication, and a standard template and process to follow. We concluded that an improved handoff process could include

- Face to face handoffs with both physicians and nurses
- Structured process: including notification of patient prior to arrival, standardized information handoff, agree a plan for ongoing care
- Training, role definition, clear transfer of accountability
- Technologies – computer systems, whiteboard, paper

This supported our underlying hypothesis that handoffs have a range of systems components allowing improvements on several dimensions.

\[Figure 7: Results from provider interviews\]
Study 3: Incident Analysis
To understand more about injuries relating to handoffs, we analyzed 19 hospital incidents associated with handoffs (figure 8). These data were accessed via MIDAS, the patient safety incident reporting system at Cedars-Sinai. Of the 54 handoff defects indentified, 52% were attributed evenly to either team or task (14 in each category). Though care needs to be taken with hindsight bias when examining these data, this provided further weight to our approach of measuring process, teamwork and information flow in handoffs.

During our research, we had the opportunity to observe a sequence of failures in handoff from ED to ICU that further illustrated how minor incidents occur and how they might escalate to more serious situations:

- A 72 year old demented patient in the ED required major emergent surgery that would typically require a direct ICU admission post op
- Intraoperative discussion between anesthesia, surgery and nursing suggested that the patient required minimal operative repair and therefore was going to need an ICU bed but could recover in the PACU
- The PACU notified the ICU charge nurse that a patient who was presently in the OR needed to be admitted directly to the ICU based upon the assumed case
- The ICU charge RN asked that bed reservation be called so a bed can be assigned to the patient, and then to call back as is standard procedure.
- The anesthesiologist communicated with the ICU MD via a phone call providing the patient’s name and suggested that more information would be provided at the end of the case.
- Patient was extubated post-op as the surgery was less extensive than expected
- The patient was transported to the PACU as per anesthesia and surgery’s request but then diverted to the SICU based on preoperative planning
- The patient arrived in the ICU with no updated handoff between the MDs or the RNs. The charge nurse and accepting nurse were at the bedside to evaluate the patient and receive a report. However, the transferring PACU RN stated that she knew “nothing” about the patient.
- The accepting nurse assessed the patient, noted that he appeared altered and in respiratory distress and immediately informed the ICU MD who came to the bedside.
- The ICU immediately intubated the patient although his unidentified baseline dimension likely contributed to the respiratory distress.

Figure 8: Results of incident database analysis

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- The ICU immediately intubated the patient although his unidentified baseline dimension likely contributed to the respiratory distress.
Study 4: Flow Disruption Analysis

The direct observation of process failures provides a valuable perspective on the mismatches between system and human, intent and action. Flow disruptions are intraoperative problems that cause deviations from the optimal course of care and provide the identification of a broad range of system problems. The detailed behavioral analysis this data affords lends itself to substantial post-hoc analysis that allows feedback and system improvement. The significance of flow disruptions lies in their ability to provide a hitherto unavailable perspective on the quality and efficiency of the system\textsuperscript{11}. Observational studies focusing on flow disruptions allow for a systematic, quantitative and replicable assessment of the relations between the surgical environment, processes and outcomes\textsuperscript{12}. In phase one, we found that flow disruptions for trauma patients occurred at a rate of approximately 9 per hour, with coordination and communication issues accounting for over half the flow disruptions\textsuperscript{13}. We used this flow disruption data to understand more about care transitions and handoffs during initial trauma care.

A total of 160 patients were studied, and a total of 351 care transitions were observed (mean 2.2 ± 0.09 per patient). Of these patients, 68 (42.5\%) experienced at least one disrupted transition during their care, with a mean of 0.66 ± 0.15 flow disruptions per patient and 0.31 ± 0.07 flow disruptions per transition. We used this flow disruption data to examine where patients most frequently transition from and to, and the flow disruptions associated with those transitions. Examples of flow disruptions in handoffs included:

- Transport monitor had no charge
- Elevator went down instead of up on the way to the surgical suite from the preop area.
- Team had to wait in hallway because CT wasn’t ready
- Began transport without the nurse. Had to stop and wait in the hall and wait for the nurse to catch up.
- Bed hit another bed in the congested hallway
- Resident forgot to bring documentation, and there was a delay while they turned around to get it
Mapping the transitions of care by patient (figure 10) shows that 81.8% of patients were assessed and transferred to imaging for further diagnostics, with 72.4% of patients arriving back in the ED following imaging assessment to await further consultation or discharge assessment. 9.4% of patients return to the ED and then are transferred to the ICU or OR. Sicker, time-pressured, and more at risk patients are more likely to experience problems. Thus, reducing the number of transitions and improving co-ordination in transitions along the trauma pathway may reduce risks and improve efficiency.

The majority of flow disruptions in this study (53%) were related to coordination problems (figure 11), such as where CT was already occupied; the nurses in pre-op did not have the correct paperwork; the patient was taken to the wrong room; or critical team members were missing when needed. There is a small additive effect where multiple transitions equate to a higher number of flow disruption transitions per patient and the number of flow disruptions per transition reduces slightly as patients experience one, two or three transitions. The data also demonstrates “high risk” and “low risk” patient experiences. Whenever a patient goes directly to the OR, or when a patient needs immediate admission to ICU, there is a higher risk of transition disruptions than when they go to the floor, discharge, or a holding area having first been to CT. In high risk transitions 40% of patients experience two or more transition flow disruptions during their care, as opposed to 13% for the low risk transition patients. It is the sicker, more urgent patients who are more likely to experience these non-standard transitions, and in doing so experience more flow disruptions.

**Figure 10: Observed flow disruptions during trauma care transitions**

![Diagram of trauma care transitions](image-url)
Discussion

This process demonstrated a number of key issues that helped focus our subsequent work. First, patients move frequently and rapidly between care teams and locations. These movements are a complex orchestration of people, equipment information and organization. Transfers involve multiple phone calls, face to face communications, IT systems, forms, and people of different specialties. These processes are regularly problematic, which can create more serious situations, especially for sicker or more high risk patients who need to be transferred faster and with less problems.

Handoffs take many forms and serve different purposes. They are the transfer of responsibility and information, the closure of old plans and the instigation of new plans. They may require physical movement of patients and equipment, and they may require the transfer of responsibility to a new team. They may require both at once. This confirmed that handoffs have a range of systemic components that might influence performance. Good teamwork in particular is the key to a good handoff, but teamwork exists within a complex organizational, professional and socio-cultural environment. It also illustrated how handoff is not necessarily a one-off information transfer but a dynamic part of ongoing care. The effects of a poor handoff might be felt hours, days or possibly weeks afterwards.

These differences between handoff types required handoff-specific measurement strategies. In essence, it was necessary to develop a different way to assess each handoff. Some handoffs are regular, predictable and frequent. Others are irregular, variable and infrequent. Some can be understood through unobtrusive direct observation of face-to-face interactions. Others happen asynchronously or over the telephone (requiring an invasive observation method). Our subsequent approach therefore explored several of the highest risk areas of handoffs. Patients are transferred to and from the imaging facility frequently, so these transitions needed to be studied in more detail. However, they are perhaps the least risky, with transfers between ED and ICU higher risk and still relatively frequent, and transfers from OR to ICU less frequent, but of higher complexity and higher risk. First, we explored pre-surgery handoffs, based on the findings from our flow disruption analysis. We examined issues in the transfer of trauma patients from ED to imaging and from trauma service to ICU. Next, we explored post-surgery handoffs from OR to PACU/ICU in high-risk surgeries. We were not confident of achieving a high sample size in trauma care, so elected to study cardiac surgery, which is amongst the highest risk of all surgeries. Finally, we explored handoffs and deterioration in pre-arrival care and subsequently across the course of the care delivered.
Pre-Surgery Handoffs

Introduction

The initial systems analysis provided two pre-surgery areas for handoff. The first was in examining the transfer of patients from ED to the ICU. This had been identified as potentially high risk handoff in the interviews, confirmed in the flow disruption and incident analysis. As a Type two handoff (physical and team transition), this automatically made it potentially risky. However, given the irregularity of this type of transfer, we needed to consider a method other than direct observation for the assessment of the handoff.

The other area for focus was in the transfer from ED to imaging, which was relatively low risk Type one handoff (a change in location but not care team), was experienced by four fifths of trauma patients. However, the flow disruption analysis had shown it to be problematic, and there was already considerable previous data exploring problems in imaging. This generated the hypothesis that improvements might be possible with a checklist intervention. For trauma care, these handoffs are critical, since they will be the first change in the care team. Thus, the transfer of patient, equipment and critical care information for these patients from one team to the next is a particularly important part of care.

Study 5: Transfers to the Surgical Intensive Care Unit

This study examined the process of informing about arrival of the patient; the handoff itself; and later effects. Since these handoffs are irregular to identify and thus challenging to observe, we adopted a self-report methodology. Though reliant on perceptions, it has generated valuable data upon which it will be possible to generate steps toward an intervention.

The data was gathered at three levels in the SICU: the receiving nurse, the charge nurse, and the resident physician. The full data collection sheet can be found in Appendix 3, and consisted of a series of questions exploring pre-operative communications, the completeness of the handoff (and the items handed off) and whether subsequently patients had been sicker than expected. Forms were distributed to the team following an introduction at a weekly unit meeting, with a surgical resident and research nurse following up to ensure that the reports had been completed successfully.

From the RN data we received 74 self reports. In 93% of cases the communication prior to patient arrival was timely and appropriate. For the handoff itself, in 85% of cases the report was felt to be complete, with 92% +/- 4% of 13 information items reliably reported (Figure 12). However, in one case only the patient’s name was reported. In another, the wrong dosage was indicated. From the charge nurse data, a total of 68 handoffs were reported. For those, in about one-quarter of patients (26%) there was no communication between charge nurse and doctor. The admission process from the ED would appear to be the least reliable (figure 13). 34% of patients were reported as sicker than expected, and in 18% of patients something unexpected happened. While this may not directly indicate flaws in the system, it suggests that expectations (or situation awareness) might be significantly reduced in these cases. Finally, of the 79 physician handoff self reports, 68% of physicians felt that patient acceptance to the unit had been properly communicated. 16% patients were admitted where ICU admission was felt to be inappropriate, with handoffs inappropriate in 12% of cases. In comparison with the charge nurse, 9% patients were sicker than expected, and 5% had unexpected events associated with their care.
Figure 12: Information handoffs (SICU Nurse)

Reliability of admission communications

% of SICU patients

Figure 13: Charge nurse self reports
Study 6: Improving ED to Imaging Transfer with a Checklist

A checklist was developed for improving patients admission into CT. This is based on concerns information, team and process during transition to CT, and especially in ensuring appropriate preparedness for CT scanning. 81% of trauma patients visit the CT scanner. We had found that this transfer process was fraught, and created many delays, especially in coordinating the team and the complex components required for this task. For example, we found that some patients can be delayed in the corridor waiting for the scanner to become available; and some are not appropriately prepared early for the removal of metal objects (especially earrings) from their person. We also found flow disruptions in CT due to patients who move and we may be able to more adequately prepare for them for their time in scanning. We thus instigated a CT checklist to aid in the transfer of patients from ED to CT (figure 14).

Figure 14: CT Imaging Checklist

Observers waited in the ED, and responded immediately to the trauma pager, going directly to the trauma bay to observe the team, according to a structured observation process (Appendix 3). The process was evaluated by adding up the number of tasks completed before and after arrival in CT from the key list of required tasks (Patient on monitor; transport bag present; additional pain meds available; CT orders entered; metallic items removed; arm band placed; scanner assigned). Teamwork was measured on a scale of 1-5 for 6 dimensions (Leadership, Cooperation, Communication, Assessment, Situation Awareness). Finally, time data were also measured at different points in the process.

41 cases were studied. We measured a significant improvement in process (p=0.02), and teamwork (p=0.0001), but with an increase in the preparation time in CT (p=0.024). This can be seen in figure 15. Despite positive these results, the CT checklist was not sustained after the research team left. However, following an incident where a patient’s airway was not fully secured, which may have contributed to deterioration and other complications, the concept was re-instituted with a new and simplified version of the checklist (figure 16)
Figure 15: CT checklist results
**ED/Trauma CT Safety Communication Check List**

**CT:**
- [ ] Is CT scanner ready?
- [ ] Have orders been placed for planned imaging studies?

**Blood/Fluids/Access:**
- [ ] Does patient have adequate IV access?
- [ ] Does patient need additional IVF/blood for use in CT?

**Airway:**
- [ ] Is airway patent?

**Meds: Sedation/analgesics/antiemetics:**
- [ ] Does patient need sedation/analgesics/antiemetics at this time?
- [ ] What meds do we anticipate needing in CT?

ED RN Scribe/Leader ______________________________

Trauma Chief ______________________________

This form is part of a Quality Improvement project aimed at improving safety during transport of Trauma patients to and from CT. The component area called out and the form is to be signed by the primary Trauma nurse and Trauma Chief prior to the patient leaving the ED for CT, attesting that the components of the check list were discussed and agreed to. All members of the treatment team are encouraged to voice their concerns over patient safety before and during transport.

Figure 16: ED to CT Transfer Checklist Version 2
Discussion
The pre-surgery handoffs studied were typified by physical patient movement, with (admission to ICU) or without (ED to Imaging) a transfer of responsibility. We found that for both types of handoffs there was a perception that handoffs were generally effective, with some small defects. In our observations and measurements, we found inconsistencies and weaknesses that individually were inconsequential, but that were observed to have down-stream impact on teamwork, communication and quality of care. In both, we also noted instances where these otherwise minor or innocuous problems had concatenated to acutely threaten patient safety.

For the ICU, treatment details are sometimes omitted from nurse reports, while the charge nurses found up to one third of patients are sicker than expected, while one in ten physicians find something similar. For CT, several items improved performance, and the subsequent re-introduction of the checklist following a serious event emphasized this. Experimentally, we established the relationship between teamwork, technology and process. Interventions are possible, but can be challenging if the perception is otherwise positive. When an opportunity for improvement arises, working with the ED and trauma teams it was possible to redesign the process several times. As has been found before, sustainability is the fundamental challenge.

In the next set of studies we focused on clinical areas that did recognize improvements were needed, and later we explored the potential for information technology implementations to assist in sustainability.
Post-Surgery Handoffs

Introduction
Handoffs from surgery to ICU are some of the most critical in the hospital. Patients are frequently unstable – or at least have some risk of instability following their operation – are usually receiving a number of medications, are frequently on other means of life support, and are usually semi- or unconscious. These handoffs constitute a complete change in care team from one that has spent at least several hours with the patient (the surgical team) to the postsurgical or ICU teams who have never before seen that patient. Even the physical transfer of the patient carries risks.

Previous studies in post-surgery handoffs describe four stages:

1. Pre-handoff (before the patient arrives). It is important to know when the patient is going to arrive? (<30 mins and >2 mins warning), what sort of condition will they be in, and how to set up the room (vent settings, pumps, drips, lines, support technology).

2. Technology transfer. Sick, complex patients require complex equipment, monitoring, drugs and other technological support. Technology needs to be configured swiftly and reliably. The technology in a handoff from the cardiac surgery OR is usually: Ventilator, BIS & Cables, Urimeter, Bair Hugger, IV Pole + C-clamp, 3x suction (vent, chest, gastric), 6x Monitor Cables (EKG, Sats, BP, 3x pressure monitoring cables), 3x Garbage (Regular, bio material, pharmacy waste). Occasional additions include: CCO SWAN Catheter monitor and cable, LA pressure line cable, Extra infusion pump, Ventricular Assist Devices.

3. Information handoff. The information handoff is perhaps the most critical component, and is largely unstructured. SBAR, a popular handoff mnemonic, is not sufficient to guide the complexity of information for these patients. We need to consider who hands over information and when, what information is really important (patient details, surgical procedure), what can be obtained from the IT systems and what needs to be transferred verbally.

4. Discussion and Plan. The final component to strengthen the process is to discuss and agree a plan for the care of the patient and establish a shared mental model of the next stages of care. This should involve at least one OR physician and one ICU physician and nurse, but preferably all. We need to consider what should be discussed? (E.g. Bloods/ fluids/ pain/ antibiotics/ feeding/ lines/ drains/ monitoring), and what contingencies to plan for (E.g. monitoring, extubation, expectation).

![Handoff process from OR to ICU](image)

Study 7: OR to Post-Operative Care
Our initial study in post-operative care was chosen to contrast a high risk and a lower risk Type 2 handoff, using the same measurement methods, in order to understand the relative efficacy of each. By examining process and teamwork it would help us to understand not only the relationship between the two in these types of handoffs, but the effects of the different levels of risk.
Using direct observation methods of process, task and teamwork, we observed 32 handoffs from the OR to PACU, and 26 handoffs from OR to CSICU using the same data collection template. This direct observation method collects data on patient information (6 items – name, age, history, allergies, diagnosis, procedure, current state), anesthetic information (intraoperative course, bloods, meds, vitals, fluids, pain relief, lines, post-op investigations), surgical information (intraoperative course, blood loss, number of drains, DVT prophylaxis, antibiotics, feeding plan), and on the physical tasks (set up of monitors, pumps, lines, fluid bags, drains). Teamwork was measured on a scale of 1-5 for 6 dimensions (Leadership, Cooperation, Communication, Assessment, Situation Awareness). These data are shown in figure 18.

Analysis of these data demonstrates interactions between the teamwork measures and the information transfer. Using a linear multiple regression using total information transfer process completion as the outcome measure, we found that there is a correlation with Leadership (p= 0.0084), Cooperation (p= 0.0002), Communication (p= 0.0089), task completion (p= 0.0017), and PACU vs ICU (p= 0.0072). Essentially, information transfer is significantly better in the CSICU, but independent of location, is also better if the equipment is set up beforehand and if teamwork is effective. Perhaps most powerfully, this model predicts 61% of the variation in information transfer.

Figure 18: PACU and SCICU handoff data
Study 8: OR to Adult Cardiac ICU

Recognizing that the Cardiac ICU patients provided an model for high-risk, complex patients where handoffs are important for ongoing care, we focused on this group for a second set of observations. Adapting these methods specifically for cardiac surgery, we collected data from 40 handoffs from the OR to CSICU. The direct observation method collected data on patient information (7 items – name, age, history, allergies, diagnosis, procedure, current state), anesthetic information (intraoperative course, bloods, meds, vitals, fluids, pain relief, lines, post-op investigations), surgical information (intraoperative course, blood loss, number of drains, DVT prophylaxis, antibiotics, feeding plan), and on the physical tasks (set up of monitors, pumps, lines, fluid bags, drains). Teamwork was measured on a scale of 1-5 for 5 dimensions (Leadership, Cooperation, Communication, Assessment, Situation Awareness).

Mean duration was 7.13 minutes ± 0.74, mean equipment transfer success (from 13 items) is 75% ± 7%, the mean number of people involved is 7, with the mean information transfer (from a total of 25 items) is 57% ± 5%, and mean teamwork score of 17.0 (out of 30). On average, less than 60% of the total number of information items were handed off. Patient name is mentioned only 29% of the time; and allergy status only 37% of the time; plan for pain relief 50% of the time; and post-operative investigations 12% of the time. Data are shown in figure 19. Analyzing the data in a linear regression demonstrates that this success of information transfer is proportional to handoff duration (p=0.048), and teamwork score (p=0.0017), with the relationship defined as:

% Info Transferred = 25% + 2% per minute duration + 1% per Teamwork score

To explore the association between handoffs, complications and outcomes we also examined length of stay in relation to information handoff and teamwork score (figure 20). This proved inconclusive.
Intervention Development

Our aim was to construct a generic template for improvement that could be adapted for different scenarios. The intervention consisted of a new process, consisting of new preparation, communication and teamwork components. It was implemented through three tools: (i) a clearly presented and laminated process (ii) a set of checklists to assist in the information transfer and (iii) laminated role cards to assist in teamwork definition. Considerable efforts were directed to develop the checklists in a multi-disciplinary team, consisting of anesthesiologists, surgeons, ICU specialists, cardiologists and nurses.

Protocols were documented and updated into an easy-to-use form as the interventions are developed and tested. The protocol for preparation of patient arrival in ICU is shown below. We then worked with the clinicians to establish appropriately clear and usable documentation that assisted clarity and sustainability (figure 21).

a) Cardiac Anesthesiologist/Fellow/resident: will complete the handoff sheet in the OR prior to transfer to CSICU
b) A phone call (or text) to the CSICU charge nurse (Voalte phone 33471) will be made by the Cardiac Anesthesiologist with the following information:
   i. Estimated time of arrival
   ii. Patient Acuity: High or Low
   iii. Whether the patient has one or more of the following devices:
       PA line, LA line, CRRT, IABP, ECMO, any other MCS device
   iv. Whether the patient is on a ventilator or extubated.
c) Prior to leaving the OR, the Attending Cardiac surgeon will review the handoff sheet in order to make sure that there is agreement on all the parameters listed
d) Upon arrival in the CSICU the handoff report will be given based on the items listed on the handoff sheet
e) Once handoff if complete and the scripted content has been covered thoroughly, any questions answered etc., the handoff sheet will remain at the bedside as a reference point.

Figure 20: Length of stay in relation to information and teamwork in post-surgical handoffs
The most problematic component of the intervention was in developing a better method for communicating between OR and ICU prior to transfer. A smartphone solution platform was being used at CSMC, which offered a solution for the need to warn and prepare the Charge Nurse for the arrival of the patient. However, this solution (known as the Voalte phone system) was found to be unreliable, with calls not getting through. A work-around was developed for the smartphone to forward the call to the ICU phone when the Charge Nurse’s Voalte phone was not answered.

The transfer information aids are shown in figures 22 and 23, and demonstrate extensive changes, including more comprehensive ventilation settings, more lines and drains, more drug types with "tall man" lettering, more details on blood products, pace makers, and the addition of an anesthesia end time box to assist in glucose management.

---

**Figure 21: Protocol for pre-admission**

- **PRE ADMISSION PROCEDURE**
  - **1. SET UP EQUIPMENT**
    - Ventilator
    - EKG & Cables
    - IV Pole & Collarm
    - 3x suction (trach, chest, gastro)
    - 6x Monitor Cables
    - EKG, Sat, BP, 3x pressure monitoring
    - 3x Garbage
  - **2. SERVE ETO OR**
    - Appropriate tray & gowns
    - Sterilizer with cables
    - Newborn, Unstable or Complex Patient
    - Bed Warmer
    - Epinephrine
    - Calcium Chloride
  - **3. DOCUMENTATION**
    - Obtain computerized emergency medications sheet
    - Review & P
    - Review standards of care for the procedure
  - **4. COMMUNICATION**
    - Discuss with OR team
    - Complete OR Pump Report
    - Inform: Attending
    - Resident
    - Secondary Nurse
    - Charge Nurse
    - Respiratory
Figure 22: Information Aid for Transfer of Adult Cardiac Patients from OR to CSICU – Early Draft

Figure 23: Information Aid for Transfer of Cardiac Patients from OR to ICU – Final Draft
Results of the Intervention
The handoff protocol achieved 90-95% compliance, and was generally well received, though some surgeons did not actively participate or become engaged in the process. Comparing results before and after the intervention, anesthetic information, surgical information and total information are significantly improved; as are all aspects of teamwork aside from situational awareness. Duration was slightly, but non-significantly longer in the post intervention group (9.00 mins ± 1.2) than in the pre intervention group (7.13 mins ± 0.7).

Study 9: OR to Congenital Cardiac ICU
Congenital cardiac surgery is high risk team endeavor where teamwork and process have been found to impact patient outcomes and failure-to-rescue directly[18]. Our previous work in handoffs in this area had implemented checklists, process re-design, and specific teamwork processes (a structured briefing, discussion and agreed plan). This lead to a fundamental improvement in our handoff process that has since provided a framework for a number of other studies[19]-[23]. We sought to build on this success in a new congenital heart service to examine the use of simulation and workspace layout, as well as previously successful interventions.

Working with the congenital heart surgery team, we initially conducted observations and interviews, mapping out the process (figure 25), and engaging staff in the need to improve handoffs. Weekly handoff improvement staff meetings began, to define and review the process, then to adapt it based on experience of the previous week. This lead to the development of the transfer form (figure 26), which was similar to the adult cardiac format, with specifics designed for congenital surgery. Off-line simulation and in-situ simulations (in an ICU bay) were conducted to understand the technology, teamwork and information transfer requirements and pitfalls. This identified several micro-process changes to the task, the requirement for different equipment to allow smoother technology transfer, and also identified workspace layout challenges.

The photo in Figure 27 illustrates how vital signs monitors could be obscured from sight in ICU rooms by the configuration of the stands. With two stands– which are not uncommon, particularly amongst the sickest patients – this problem can be exacerbated (right photograph). Not only is the monitor not visible from all except a limited point on the right of the room, but the nursing workstation is cramped and the ventilator on the left is extremely close to the bathroom door. This is a classic ergonomic design problem which had the potential to contribute to a range of unrecognized complications. Improved vision for monitoring was resolved inexpensively and effectively by working through a range of potential solutions through in-situ simulations, and working with the estates management team to change the monitor arm to allow greater clearance for the monitor from the infusion bags.
Figure 25: Congenital Heart Surgery Handoff Processes

Figure 26: Information Aid for Transfer of Congenital Heart Patients from OR to PICU
This was evaluated in two distinct phases of care. GROUP 1 were cared for prior to establishing the handoff process, and GROUP 2 were cared for in the CHPICU after the new handoff process was introduced. 29 patients were included in the study, 15 in GROUP 1, and 14 in GROUP 2. We recorded whether an organized team huddle occurred, and through direct observation, flow disruptions in 5 categories (organization, team, patient, equipment, communication), were scored, giving a process score from zero to 5. We also scored clinical disruptions in 5 categories (vitals, bleeding, general clinical, respiratory, and drugs), giving a treatment score from zero to 5. Finally, we gathered patient treatment concerns after 6 hours of care (defined as stable or unstable), and then scored the change over 24 hrs (defined as better, the same, or worse).
21 (72%) patients had a proceduralized team handoff, while 8 did not follow a recognized procedure (4 in both groups). The proceduralized handoffs helped to identify communication discrepancies in 1 out of 10 cases (10%) in GROUP 1 and 7 out of 11 cases (63%) patients in GROUP 2. Time to complete the handoff was significantly less in GROUP 2 (mean = 22.5 mins± 8.0, median = 20 min), compared to GROUP 1 (mean = 38.1± 11.9, median = 37.5 min), p=0.007. There was also a halving in flow disruptions (Mean Gp1= 1.5, mean Gp2 = 0.86, p=0.19) and treatment problems (Mean Gp1= 0.8, mean Gp2 = 0.33, p=0.04) following the implementation of the process. In both groups, equipment problems were frequent causes of disruption, with organizational problems substantially reduced in group 2 (50% of Gp1 cases to Gp2 7% of cases). Vitals and respiratory problems were substantially reduced in Gp 2(36% vs 7%; 21% vs 0%). However, stability in the 6hr and 24hr periods was unchanged.

**Discussion: Post-Surgery Handoffs**

A structured handoff process improves detection of missing information, reduces handoff duration, flow disruptions and clinical disruption. Information transfer is dependent teamwork and process (if the equipment is set up beforehand). This observation was replicated several times in these studies. Workspace issues may also play a part, especially in the location of the handoffs (PACU, CSICU, PICU) and the environment (room and equipment layout).

The key components were to ensure that only the vital handoff items are on the sheet, and that it can fit on two sides of normal sized paper. We conducted several development and engagement cycles with both the adult and congenital cardiac services. This allowed us to conduct the development in parallel to benefit from cross-pollination of ideas, and to ensure that consistent formats are developed, while the high risks, regularity, and complexity of cardiac patients provide the ability to model the handoff process. In particular, it gave us the ability to examine multiple high-risk care transitions with more frequency than would have been available in trauma care alone. It also allowed us to apply team, task, and technology models to these care transitions to study them with greater statistical power than would have been available to us with trauma patients. The extension to pediatric cardiac surgery has served both as a comparator to consider the components of translation between surgeries, at an equivalent or higher level of risk and complexity. This has allowed us to more rapidly understand and develop our interventions than would have been possible in trauma care alone, while still allowing us to translate our findings back into trauma care toward the end of the project.

This is an important result alone, but also suggests that ensuring equipment setup and better teamwork might lead to improved information transfer in these type 2 handoffs.

Developing a team handoff process is important in reducing the variability of care and responding to deterioration and other patient treatment demands. This can be achieved through adapting tasks and processes, forms and checklists, teamwork, workspace and both treatment-related technologies (such as infusion pumps) and information management technologies.
Deterioration

Introduction

Unexpected patient deterioration is a serious and frequent problem for healthcare teams. While ICU outreach, or rapid response teams have helped to ensure better responses, there has been little progress in developing better methods to avoid or identify sick patients. From a different perspective, to reduce unnecessary complications associated with deterioration, it is beneficial to improve the identification of deterioration as well as the response once deterioration is identified. To develop a better means to identify deterioration requires either an improvement in the diagnostic information available, or an improvement in expectation. If a patient is expected to be at risk of deterioration, they are much more likely to be identified earlier in their deterioration than a patient who is assumed otherwise to be well.

In our Phase one studies, we noted that improving expectation of the nature of an arriving trauma case – through the pre-arrival display of vital signs and mechanism of injury – combined with a briefing that also improved teamwork, process and treatment expectations, contributed to a reduced time in the ED and shorter length of stay. We also noted the inadequacy of the handoff from EMS to ED. Thus, to examine deterioration along the trauma pathway, we first studied the nature and type of injury for patients arriving via EMS and arriving in the ICU, in relation to their eventual outcome. Next, we examined the difference between EMS and ED vital signs as a predictor of deterioration. Finally, we used the concept of „failure to rescue“ (ie. the failure to appropriately treat deterioration) to examine the predisposing factors to deterioration along the trauma pathway.

Study 10: Predictors of Mortality in Trauma Care

The National Trauma Database (NTDB) contains a range of fields that can be used to explore the effects of various system and patient parameters on patient outcomes. We identified 2,541 patients within this database who had received trauma care between 2009-2011. Cases were stratified according to ICD-9 code, with available data on admission heart rate, oxygen saturation, systolic blood pressure, initial hematocrit, ICU length of stay, and Outcome. We used this data to examine the relationship between injury and outcome, and to examine initial vital signs in relation to outcome.

The relationship between ICD-9 injury and mortality is found in figure 29, which demonstrates that head and pelvic injuries offer the greatest threats to mortality, with chest and abdomen injuries less fatal, and face injuries the least fatal. Examining the predictivity of vital signs, we found that fatal chest injuries have lower initial heart rate, systolic blood pressure, and oxygen saturation. Fatality with abdominal injuries and bony chest injuries are also characterized by initially lower systolic blood pressure (figure 30).

Next, we selected patients who had been treated by the Cedars Sinai trauma service from August 2011 to November 2012, which was a total of 1577 patients, of whom 1507 lived (95%). We then conducted a more detailed analysis of specific items related to the change in vital signs from the EMS in the field to the ED. By examining the change between initial field and initial ED measures of systolic blood pressure, pulse rate, respiration rate, oxygen saturation and GCS, were able to examine the deterioration during this initial period (figure 31). The predictive p-values are found in table 2. These encouraging results allowed us to build a multi-variable model that incorporates all these parameters into a single predictive model. Significant factors are age (Chi^2=18.07, Odds Ratio=1.04, p<0.0001), change in Glasgow Coma Scale (Chi^2=3.09, Odds Ratio=1.19, p=0.0482), change in systolic blood pressure (Chi^2=9.97, Odds Ratio=1.029, p=0.0016), and change in Oxygen saturation (Chi^2=5.50, Odds Ratio=1.05, p=0.0190). The ROC curve is shown in figure 32.
Figure 29: Injury type and mortality

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<td>97.9</td>
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<tr>
<td>Chest</td>
<td>74.4</td>
<td>97.4</td>
</tr>
<tr>
<td>Chest - bony injury</td>
<td>98.3</td>
<td>98.3</td>
</tr>
<tr>
<td>Face</td>
<td>99.0</td>
<td>98.1</td>
</tr>
<tr>
<td>Head</td>
<td>98.4</td>
<td>97.9</td>
</tr>
<tr>
<td>Pelvic</td>
<td>NA</td>
<td>99.8</td>
</tr>
</tbody>
</table>

Figure 30: Injury type and vital signs in relation to mortality.
<table>
<thead>
<tr>
<th></th>
<th>In Field</th>
<th>In ED</th>
<th>Difference (Absolute)</th>
<th>Difference (Modulus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic Blood Pressure</td>
<td>0.09</td>
<td>0.73</td>
<td>0.11</td>
<td>0.0003</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>0.49</td>
<td>0.07</td>
<td>0.27</td>
<td>0.013</td>
</tr>
<tr>
<td>Respiratory Rate</td>
<td>0.05</td>
<td>&lt;0.0001</td>
<td>0.90</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>02 Saturation</td>
<td>0.020</td>
<td>0.079</td>
<td>0.11</td>
<td>0.004</td>
</tr>
<tr>
<td>GCS</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>0.004</td>
<td>0.09</td>
</tr>
</tbody>
</table>

Table 2: Predictors of mortality

Figure 31: Means and 95%CI for parameters associated with subsequent death
Study 11: In hospital failure-to-rescue

We examined failure to rescue (FTR), defined as mortality following the development of an in-hospital complication. The factors associated with increased risk of FTR following trauma are largely unknown.

The National Trauma Databank (NTDB) datasets 2007-2011 were queried. Exclusions were: Age < 16 yr, deaths in the ED, patients with any body region abbreviated injury scale (AIS) of 6, injury severity score (ISS) of 75, hospital length of stay (LOS) < 24 hours, mechanism other than blunt or penetrating, admission to centers reporting < 80% of AIS and/or <20% of comorbidities and/or < 200 subjects in the NTDB. All patients with any reported complication were then selected and those who survived (non-FTR) were compared to those who did not (FTR). A forward logistic regression model was utilized to identify predictor of FTR. The risk of FTR was also examined within age groups and number of complications.

Of 3,313,117 eligible patients, 218,986 (6.6%) met inclusion criteria and had at least one complication developed during the in-hospital stay. Of those, 201,358 (91.2%) survived (non-FTR) and 17,628 (8.8%) did not (FTR). Compared to non-FTR patients, FTR patients were more likely to be in the age groups 65 to 89 yr and ≥ 90 yr (49.4% vs. 29.0%, p<0.01 and 4.2% vs. 1.2%, p<0.01 respectively), more likely to require an ICU admission (89.6% vs. 56.3, p<0.01) and mechanical ventilation (MV) (73.4% vs. 32.1%, p<0.01).

A forward logistic regression identified 22 variables as predictors of FTR. Of those, age 65 to 89 (y) was the strongest predictor (AOR [95% CI]: 6.58 [6.11, 7.08], p<0.01), followed by the need for MV (AOR [95% CI]: 2.99 [2.81, 3.17], p<0.01) and an ICU admission (AOR [95% CI]: 2.61 [2.40, 2.84], p<0.01). The AUC for the model was 0.852. Using age group 16 to 45 (y) as the reference group, the adjusted risk for FTR increased with increasing age in a stepwise fashion: AOR (95% CI): 1.94 (1.80, 2.09) for age group 46 to 65 yr, 6.78 (6.19, 7.42) for the age group 66 to 89 yr and 27.58 (21.81, 34.87) for the age group ≥ 90 yr (all p<0.01). The same applied for the number of complications; the adjusted risk of FTR increased in a stepwise fashion with increasing number of complications.
Discussion

We found a range of contextual, patient and process parameters that predict clinical deterioration and failure-to-rescue in trauma patients. Though only having scratched the surface of what might be possible, this is encouraging for being able to identify at-risk patients.

Studies in deterioration and failure-to-rescue are complex and remain challenging to observe simply because they form a small sub-set of the overall clinical population. Without an ability to collect detailed performance – often only obtainable via direct observation – it is challenging to examine the individual, team and system contributions to these events. However, our work has already demonstrated from a number of indirect observations that physiological stability can be assisted in high risk patients through the consideration of process, team, technology, and environmental parameters.

Clearly, given the challenges in responding to the detailed and interacting parameters that predict deterioration and FTR, developing technology to support this process was of vital importance and huge potential value. This was explored in the final set of studies.
Technology Support

Introduction
Mobile communications displaying the critical information would allow even earlier building of situation awareness and team cohesion and thus provide better handoffs. Originating from our work in phase 1, we continued the development of a Smartphone application that assists in the early management of trauma patient information. We recognized the value and existing uses of text and photos to communicate about patient care, and became interested in the ways in which our teamwork, communication and patient management interventions could be supported and sustained with well designed smart phone technology. Teamwork can be enhanced through the distribution of information to a smart phone, coupled with the ability to provide information on a constantly updating electronic whiteboard. The provision of this information to OR, CT, and other specialist services geographically distributed in the hospital. Together, this would substantially enhance the ability for clinicians to predict and respond quickly and appropriately to the sickest patients. As well as providing a better response for individual patients and better teamwork, this would also ensure better use of hospital resources. The awareness of the huge range of physicians, nurses and other specialists involved would be improved. This would encourage the delivery of timely, appropriate, error-free care to the patient. A modular approach, coupled with the integration of wider information sources, and designed with a human-centered understanding of decision making could further enhance team performance not only in the initially assessment phase, but right through CT and OR care to ICU admission and beyond.

Figure 34: Trauma 360 app screens

This simple mobile platform allows a further range of enhancements that might considerably aid in subsequent patient care, and go well beyond the initial purposes of enhancing communication, and information distribution. Like the flight management system in a modern aircraft, this presented an opportunity to investigate a „system of
systems” that provides patient-centered communication, sensor integration, real-time remote access to dynamic patient information, diagnostic support, process management, care planning, and hand-off tools. Theoretically, this could improve communication amongst team members and across the hospital system (such as CT, OR or ICU). It would improve integration of care processes and diagnostics, encourage adherence to best practice, and quality & safety processes. It would support handoffs and team member changes, while supporting diversity of patients, patient-centered care, and the complexity of healthcare delivery, reducing deterioration and improving response.

**Study 12: Development of a coordination and communication trauma app**

As part of our ongoing work to develop smartphone systems to assist in the delivery of care and reduce error and flow disruptions, we instigated two simulation sessions for demonstration and evaluation of the trauma360 app. Scenarios were selected and designed by a faculty consisting of surgeons, trauma specialists, simulation specialists, and human factors specialists. The trauma teams consisted of four practicing residents, and four experienced ED nurses, with a trauma attending acting as part of the research and simulation team, to prompt the residents were necessary. For one simulation session, an ED fire was simulated with an indoor smoke machine which was hidden from view and triggered after approximately 10 minutes.

The simulation sessions started with a briefing about goals and aims, which included downloading of the Trauma 360 app and basic instruction in its use. There was then a familiarization with the simulation equipment and dummy, following which the trauma team were sent to disparate locations of the simulation center to await the trauma call. This represented disparate hospital locations from which the trauma team arrive. Upon paging, and (in the app use condition, app paging), the team arrived in the simulated ED and conducted a briefing. After 5 minutes, the simulated patient (a Gaumard Simulation Dummy) arrived and the simulation began properly. Completion was at the moment the simulated patient was moved out of the ED, as if to go to imaging (or, in the case of the fire scenario, as if to be evacuated). A debriefing was conducted after a short rest, which consisted of guided discussion on technical, teamwork, and technology related learning points and issues that had arisen in the simulation. A video recording was made that allowed the participants to review their own performance. As part of the debriefing, the team were asked to complete a NASA TLX (Task-Load Index) to assess overall perceived workload during the simulation.

The simulations were extremely successful, and served as a formative test of the utility and usability of the trauma 360 app for encouraging communication, improved handoffs and increased adherence to trauma protocols and checklists. Participants reported that it was a valuable experience for all involved, and benefitted from a competent leader and previous experience in simulation. They found the Trauma 360 app to be helpful for displaying when a patient is expected, and the vital signs, and expressed how much they missed not having this information (the usual standard of care) when it was not available. The large screen display of that information was useful, and the team suggested additional functionality, including an integrated checklist with specific care protocols to aid in decision making and optimal care. The results of the workload rating are found in figure 36, which suggest that though workload was slightly higher with the app, these differences were non-significant, whereas there was a significant reduction in distractions.
Figure 35: Photographs of simulation session 2. Clockwise from top left: the simulated patient arrives in the simulated ED; the manikin is prepared by a simulation technician; the trauma team ventilate the patient; the simulation team treat the patient; a fire breaks out in the trauma bay; the team assess the patient; the prepared simulation space.
Discussion

New technology is introduced into healthcare everyday with little consideration of the impact on the clinical user. This can have an impact on patient care. We aimed to understand the impact of this new technology, before being introduced into the real environment.

The trauma 360 app was useful, easily useable and well liked by the trauma and ED nursing team. It allowed them to prepare better for the incoming patient, which provided better expectation and improved handoffs. This suggests that further development of the Trauma 360 would be warranted. To fully benefit, future simulations should include a broader array of simulated services and roles – such as MICN, EMS, ER Attending-Resident, OR, CT, Pharmacy/Blood Bank, At-Home Specialist/Surgeon. This could be facilitated by designating different areas, within the flexible simulation space, to represent the different points of the care continuum, such as CT, Surgery and ICU.

In the future, we will seek to develop an even more robust “human-centered” application that i) integrates and distributes a range of patient information to clinicians, ii) allows patient-centered communication management iii) supports clinical decision making and iv) accounts for teamwork requirements and information system constraints. This should include enriched decision support and embed it into the app such that information is provided at the right time, in the right way, precisely where it is needed - at the point of care. Continued funding would support simulation and live trials to test the utility of this app in a wide range of military and civilian environments and other acute illnesses such as ruptured aortic aneurysms, stroke and acute myocardial infarction.

Figure 36: NASA Task Load Index subjective workload ratings.
4. KEY RESEARCH ACCOMPLISHMENTS

Study 1, which generated process maps for a range of handoffs found may different types, with several synchronous and asynchronous communication methods. We summarized handoffs into type 1 (location change, team constant) and type two (location and team both changed). In study 2 we interviewed providers, who emphasized transfer of responsibility and information transmission, with teamwork being essential for good handoffs. Study 3 analyzed incident data, and found that task and team factors predisposed to these events, in part due to the complex sequence of communication tasks required for effective handoff. In study 4, we observed several hundred flow disruptions during trauma handoffs, over half of which were attributed to communication, and which affected the higher risk, more urgent patients the most. This combination of studies demonstrated the task and team complexity, variability and criticality of high risk handoffs.

Looking at pre-surgery handoffs, study 5 suggested that while there was a general consensus that handoffs in the surgical ICU were acceptable, there were nonetheless gaps and weaknesses in the process. Communication was complicated by the number of phone calls which were needed to complete the full process, but were not always completed. Moreover, between 10% and 30% of patients were sicker than expected following the handoff. A simple checklist intervention for transferring patients to imaging seemed to have benefits in study 6, and after initially being unsustained, was redesigned, re-implemented, and sustained following a salient incident that would have been originally presented. This work illustrated that though relatively low risk handoffs, critical safety and performance improvements were possible. Sustainability depends on the perception of need amongst the staff, which for these handoffs was generally low.

Study 7 explored handoffs from the OR to the PACU and Cardiac ICUs through direct observation, measuring the information handed off, the time of each handoff, and teamwork on a 5 point, 5 dimension scale. We found that information transfer is significantly better in the CSCIU, but also better if the equipment is set up beforehand and if co-operation, communication and leadership are effective. In study 8 we examined the Cardiac ICU data further, finding a relationship between information transfer, teamwork and handoff duration, but not with outcomes. We then developed an intervention of role definition, process development, and information transfer. This achieved approximately 90% compliance, information transfer was improved, as were all teamwork scores. This was further examined in congenital heart surgery in Study 9. As part of a similar checklist and task-based intervention, we also improved the ICU workspace to provide better views of the monitors, improving situational awareness.

In order to explore patient deterioration, study 10 explored predictors of mortality in trauma care, finding that as well as being able to predict outcomes from injury type, we were also able to build a multi-variable model that related changes in physiological measurements between pre-hospital EMS and ED with mortality rate. Study 11 then explored failure-to-rescue in hospital, demonstrating complications and ages as a predictor. Finally, study 12 examined, in simulation, the use of a smart phone app to assist in communication across the trauma pathway from pre-hospital to ED trauma care. This demonstrated positive effects on performance and has subsequently been developed into a fully deployable software solution.

5. CONCLUSION

Handoffs can be improved, and deterioration reduced by:

- Considering the purpose, requirements and process of handoff
- Facilitating the transitions of the highest risk patients
- Use of checklists, task designs, and teamwork training
- Optimizing the relationship between information transfer, team skills, and time available for the handoff.
- Improving the working environment to ensure availability of monitoring information and patient data.
- Considering particular patient risk factors for deterioration and planning for such events.
- Supporting situational awareness, decision making, teamwork and communication through the use of carefully designed and integrated software on mobile and fixed platforms.
6. PUBLICATIONS, ABSTRACTS AND PRESENTATIONS

This details all the academic products that this research supported, either through direct publication of findings, or through opportunity collaborations with other human factors and handoffs researchers.

**Lay Press**


Liz Stinson. How Designers Are Reinventing Trauma Care to Save Soldiers” Lives. Wired. 07/25/14. [http://wrd.cm/1omkIr3](http://wrd.cm/1omkIr3)

**Peer-Reviewed Scientific Journals**


**Invited Articles**


**Abstracts**


Maghen N; Behringer E; Weber A; Arabia F; DeCastro M; Wiegmann D; Catchpole, K.. (2014). Improving the transfer of critical patient information from OR to Cardiac Surgical ICU (CSICU): Observational Analysis of present practice. Western Anesthesia Residents Conference. Critical Care Medicine 42 (12), A1557. Won Third place out of >100 for best research.


Presentations


K. Catchpole. Task, Team and Technology Integration in Surgical Care. Invited oral presentation at the 2013 Symposium on Human Factors and Ergonomics in Health Care, March 11-13, 2013, Baltimore, Maryland, USA


*A. Gangi, K. Catchpole, R. Blocker, D. Wiegmann, B. Gewertz, J. Blaha, E.J. Ley. Time To Prepare Impacts Emergency Department Efficiency And Flow Disruptions.Quick Shot Presentation at the 8th Annual Academic Surgical Congress, February 5-7, 2013 in New Orleans, LA.


7. INVENTIONS, PATENTS AND LICENSES

Nothing to report.

8. REPORTABLE OUTCOMES

- The most comprehensive assessment of multiple handoffs across a health system ever conducted.
- Comprehensive process mapping of transitions of care
Detailed analysis of flow disruptions in trauma care handoffs
Clear demonstration of the relationship between task, team and process in handoffs
Development of a simple emergency department to imaging transfer checklist
Development of checklist interventions to improve transfer from operating room to ICU
Identification of process and patient features associated with deterioration and failure-to-rescue
Development of a smartphone app to improve communication from emergency medical services to trauma team, and within the trauma team.

9. OTHER ACHIEVEMENTS
- Development of a smartphone application to improve communication from emergency medical services to trauma team, and within the trauma team.
- Development and deployment of a purpose-designed research simulation facility

10. REFERENCES


## APPENDIX 1: Studies against tasks

<table>
<thead>
<tr>
<th>Task</th>
<th>Aim 3 Studies</th>
<th>Aim 4 Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Process mapping of current state of communication and data transfer</td>
<td>Study 1</td>
</tr>
<tr>
<td>B</td>
<td>Data collection on process deviations</td>
<td>Studies 2, 3 and 4</td>
</tr>
<tr>
<td>C</td>
<td>Analysis and items categorized</td>
<td>Studies 2, 3 and 4</td>
</tr>
<tr>
<td>D</td>
<td>Prospective data collection</td>
<td>Study 2, 10 and 11</td>
</tr>
<tr>
<td>E</td>
<td>Root cause analysis</td>
<td>Studies 4-9</td>
</tr>
<tr>
<td>F</td>
<td>Feedback to current stakeholders</td>
<td>Study 3</td>
</tr>
<tr>
<td>G</td>
<td>Identify areas of high priority/high impact/high risk</td>
<td>Studies 4-9</td>
</tr>
<tr>
<td>H</td>
<td>Design potential interventions</td>
<td>Studies 10-11</td>
</tr>
<tr>
<td>I</td>
<td>Develop protocols</td>
<td></td>
</tr>
<tr>
<td>J</td>
<td>Tests of change in simulation</td>
<td>Study 12</td>
</tr>
<tr>
<td>K</td>
<td>Successful interventions tested and refined at CSMC and partners</td>
<td>Studies 6,8,9,12</td>
</tr>
<tr>
<td>L</td>
<td>Findings disseminated as best practices</td>
<td></td>
</tr>
</tbody>
</table>
## APPENDIX 2: Data Collection Methods

**ED to Imaging Data Collection Template**

### Data

<table>
<thead>
<tr>
<th>Observation Time</th>
<th>Database ID</th>
<th>First Discussion of CT</th>
<th>Time of ED Order</th>
<th>Time of CT Ready</th>
<th>Time of ED Arrival</th>
<th>Time of CT Arrival</th>
</tr>
</thead>
<tbody>
<tr>
<td>[209] [200] [Code Brain]</td>
<td>[209] [200] [Code Brain]</td>
<td>[209] [200] [Code Brain]</td>
<td>[209] [200] [Code Brain]</td>
<td>[209] [200] [Code Brain]</td>
<td>[209] [200] [Code Brain]</td>
<td>[209] [200] [Code Brain]</td>
</tr>
</tbody>
</table>

### Patient/Team Preparedness

<table>
<thead>
<tr>
<th>Preparedness</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient on Monitor</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Transport Bag</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Additional Pain Meds</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>CT Order Executed</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Remove Metallic Items</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Arm Bands Placed</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Scaler Attached</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Time of CT Scanning

<table>
<thead>
<tr>
<th>Start Time/End Time</th>
<th>[209] [200] [Code Brain]</th>
<th>[209] [200] [Code Brain]</th>
<th>[209] [200] [Code Brain]</th>
<th>[209] [200] [Code Brain]</th>
<th>[209] [200] [Code Brain]</th>
<th>[209] [200] [Code Brain]</th>
</tr>
</thead>
</table>

### Leadership

<table>
<thead>
<tr>
<th>Leadership</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clearly defined team leader. Good Time management, all tasks completed, non-hierarchical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processed, but sometimes not completed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identity of team leader not clear.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

### Cooperation and Resource Management

<table>
<thead>
<tr>
<th>Cooperation and Resource Management</th>
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<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>All team members clearly identified and perform all designated tasks.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identify all members not clear, some do not perform assigned tasks.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unable to determine identity of team members.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Communication and Interaction

<table>
<thead>
<tr>
<th>Communication and Interaction</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear communication with team leader. Tasks and responsibilities clear.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication not divided. All team members are aware of their responsibilities.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underutilized or redundant communication across different levels.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Assessment and Decision Making

<table>
<thead>
<tr>
<th>Assessment and Decision Making</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment of patient outcome and all major tasks complete.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 and 2 survey answers and/or incomplete.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Situation Awareness/Coping with Stress

<table>
<thead>
<tr>
<th>Situation Awareness/Coping with Stress</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unchanged findings or distractions did not disrupt daily workflow.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unchanged findings or distractions did not disrupt task completion.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unchanged findings or disruptions completely upset daily workflow and task completion not anticipated.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. Did you receive notification about patient admission?  YES  NO
   a. If not, did another RN?  YES  NO
2. Was it communicated that patient was "accepted"?  YES  NO
   a. How was it communicated?
      i. ICU Team to Charge RN
      ii. Staff RN to ICU team
      iii. Other
3. Who called who for report?
   a. ICU RN called RN to obtain report?
   b. RN called ICU RN to obtain report?
4. How many attempts were made?
5. Was report obtained in a timely manner? (within one hour)  YES  NO
6. Did you receive an appropriate handoff?  YES  NO
   a. Phone/fax to fax
   b. RN/RN
7. Do you feel your handoff report was complete?  YES  NO
8. Please answer if the following was discussed in handoff:

<table>
<thead>
<tr>
<th>Patient name</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical History</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergy Issues</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient current condition</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Were the orders complete when patient arrived to ICU?  YES  NO
10. Did the Doctor communicate about patient admission?  YES  NO
11. Was ICU admission appropriate?  YES  NO
12. Was patient sicker than communicated?  YES  NO
   a. Did anything unexpected happen with this patient?  YES  NO

COMMENTS: (If more space is needed please comment next to question or on the back of the form)

*Appropriate handoff you received the key information needed to care for the patient.
**Please provide details for any "No" answers.
| Charge RN | DAY SHIFT or NIGHT SHIFT (please circle one) | Date: __________
|-----------|---------------------------------------------|------------------
| 1. Did you receive notification about patient admission? | YES | NO |
| a. if not, did another RN? | YES | NO |
| 2. Where is the patient coming from? | O/R/PACU | ED | Other: ________ |
| 3. Was it communicated that patient was "expected"? | YES | NO |
| a. How was it communicated? | i. SCU Team to Charge RN | ii. Staff RN to SCU Team | iii. Other |
| 4. Did the Doctor communicate about patient admission? | YES | NO |
| 5. Was ICU admission appropriate? | YES | NO |
| 6. Was patient sicker than communicated or expected? (which) | YES | NO |
| a. Did anything unexpected happen with this patient? | YES | NO |
| 7. Did you notify? | YES | NO |

**Please provide details for any "No" answers in comments box**

**COMMENTS:**

---

*Appropriate handoff: you received the key information needed to care for the patient.*
## OR to ICU Handoff Data Collection Template

### Information

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<tr>
<td>Age</td>
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<tr>
<td>Medical History</td>
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<tr>
<td>Allergy Status</td>
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<tr>
<td>Diagnosis</td>
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<tr>
<td>Name of procedure</td>
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<td></td>
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<tr>
<td>Patient current condition</td>
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### Anesthetic information:

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<tbody>
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<td></td>
<td></td>
</tr>
<tr>
<td>Blood transfusion (had/needs), location of blood bags</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Relevant medications patient received in theatre</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Plan for monitoring (vitals parameter range and action)</td>
<td></td>
<td></td>
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<tr>
<td>Plan for intravenous fluids</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Plan for pain relief</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plan for lines, eg. Central venous, arterial</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Postoperative investigations, eg Hb, Cxray</td>
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### Surgical information:

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<tr>
<td>Number of drains and plan</td>
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<tr>
<td>Feeding plan</td>
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### Tasks

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<tr>
<td>Monitors and alarms set up before handover</td>
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<tr>
<td>Pump ready before the handover</td>
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<tr>
<td>Lines arranged and set up</td>
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<td></td>
</tr>
<tr>
<td>Urine bag located appropriately</td>
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</tr>
<tr>
<td>Drains located safely</td>
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### Patient-specific tasks:

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<tbody>
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<td></td>
</tr>
<tr>
<td>Patient well covered</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Patient having good pain relief</td>
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### Teamwork:

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<tr>
<td>Cooperation</td>
<td>0 1 2 3 4 5 6</td>
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<td>Communication</td>
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<tr>
<td>Assessment</td>
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<td></td>
</tr>
<tr>
<td>Situation</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 3: Selected Published Papers

Association for Academic Surgery

Flow disruptions in trauma care handoffs

Ken R. Catchpole, PhD, Alexandra Gangi, MD, Renaldo C. Blocker, PhD, Eric J. Ley, MD, Jennifer Blaha, MBA, Bruce L. Gewertz, MD, and Douglas A. Wiegmann, PhD

Department of Surgery, Cedars-Sinai Medical Center, Los Angeles, California
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Trauma
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Disruptions

ABSTRACT

Background: Effective handoffs of care are critical for maintaining patient safety and avoiding communication problems. Using the flow disruption observation technique, we examined transitions of care along the trauma pathway. We hypothesized that more transitions would lead to more disruptions, and that different pathways would have different numbers of disruptions.

Methods: We trained observers to identify flow disruptions, and then followed 181 patients from arrival in the emergency department (ED) to the completion of care using a specially formatted PC tablet. We mapped each patient’s journey and recorded and classified flow disruptions during transition periods into seven categories.

Results: Mapping the transitions of care shows that approximately four of five patients were assessed in the ED, transferred to imaging for further diagnostics, and then returned to the ED. There was a mean of 2.2 ± 0.09 transitions per patient, a mean of 0.66 ± 0.15 flow disruptions per patient, and 0.31 ± 0.07 flow disruptions per transition. Most of these (53%) were related to coordination problems. Although disruptions did not rise with more transitions, patients who were directly to the operating room or needed direct admission to intensive care unit were significantly more likely (P < 0.0028) to experience flow disruptions than those who took other, less expedited pathways.

Conclusions: Transitions in trauma care are vulnerable to systems problems and human errors. Coordination problems predominate as the cause. Sicker, time-pressured, and more at-risk patients are more likely to experience problems. Safety practices used in motor racing and other industries might be applied to address these problems.

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1. Introduction

Patient care transitions—for example, changes in patients’ locations, care teams, or both—are often critical times that can be associated with medical errors [1,2]. As a consequence, it has been recognized that effective handoffs of care are necessary for maintaining safety [3]. There has been considerable interest in examining shift-to-shift handoffs and handoffs from the emergency department (ED) to the receiving team [4–6], but no studies have examined the subsequent transitions experienced by this vulnerable but heterogeneous group of patients who may be extremely sick and are at risk of...
rapid and unexpected deterioration. In contrast to other studies that consider care transitions in terms of fixed handovers with standard information [7,8], ED patients may follow diverse treatment paths and are frequently moved to several other locations within the hospital, such as the imaging suite, the intensive care unit, or the operating room (OR). Because such transfers are often carried out under time and resource pressure by different teams, this activity requires a range of support and monitoring equipment, documentation, communication, and coordination activities to ensure that the process is executed smoothly.

The concept of flow disruptions (FD) [9]—defined as deviations from the natural progression of a procedure that potentially compromise safety or efficiency—has previously been used to identify safety concerns in high-risk procedures [10]. They provide both quantitative measures and qualitative detail about the weaknesses in health care systems and processes that create inefficiency and risk. When validated, such specific data can be used for systems diagnosis and improvement. This technique is particularly useful where the structure and organization of processes is highly variable and heterogeneous [11].

We aimed to analyze flow disruptions during the care transitions that patients experience during trauma care. We hypothesized that more disruptions would lead to more disruptions and that different pathways would have different disruptions.

2. Methods

This was a post hoc analysis of a prospectively collected data set [Lei et al., unpublished data; Shokhed et al., unpublished data] obtained through direct observation during August, September, October, and November of 2 successive years. Observers followed 181 patients trauma-activated patients through the care process at an 878-bed tertiary Level I metropolitan nonprofit academic medical center from the time the patient arrived in the ED until the patient was admitted either to the OR, intensive care unit (ICU), or floor; held for further assessment in the ED, or discharged. The Cedars-Sinai Institutional Review Board reviewed and approved the study.

Researchers covered all day and night shifts apart from 2 AM to 8 AM. We used a specially adapted tablet-PC data collection tool to record timings, transitions, and FDs, which observers categorized in real time according to type of FD; the phase in which the FD occurred (ED, Imaging, OR, OR; Transition); and a free-text description. Each entry was also time-stamped automatically by the software. A comprehensive tutorial ensured that the observers—who derived from medical and human factors backgrounds—were able to properly identify and categorize FD. To ensure equivalence, one researcher (RS) examined each FD post hoc, to exclude those that were not relevant or did not have clinical or process significance.

We analyzed each patient’s record according to the specific care pathway that was taken. We tabulated the frequency with which different pathways were used and the number of transitions associated with each pathway. Although patients undergoing operations eventually were transferred to either the postanesthesia care units or the intensive care unit (ICU), in these surgical patients we did not include observations beyond the OR in the analysis, because these transitions were viewed as distinct from those directly associated with initial trauma care. As well, patients evaluated and discharged from the ED did not experience a physical transition and so were excluded from further analysis.

We derived two basic performance measurements: the total number of transition FDs per patient, from which we derived the number of FDs per transition per patient (i.e., the first figure divided by the total number of transitions experienced by that particular patient).

We then examined the transitions that were the highest risk by calculating the mean number of FDs per transition for each of the 10 patient pathways that were identified in the initial pathway mapping (this allowed us to classify patients into “high-risk transition” and “low-risk transition” groups). Given the heterogeneity of the patient pathways and the relatively low numbers of FD transitions encountered, we used nonparametric statistics for inferential statistics. We used the Mann-Whitney U-test to compare mean numbers of FDs between high risk and low risk. In the final analysis, the chi-square statistic compared the frequency of disruptions between the high-risk and low-risk groups. We performed all statistical calculations using JMP®9.0.2 (SAS Institute Inc, Cary, NC).

3. Results

We observed a total of 181 patients; 81.8% were transferred to imaging, with 88.5% of those patients (72.3% of the total) then returning to the ED, to be held either for further consultation, for discharge, or for onward transition to the OR, ICU, or the floor (Fig. 1). We excluded 21 patients from further analysis, including 19 who were immediately discharged and did not experience a transition and two additional patients who had extraordinary experiences (one patient experienced six FDs in transitioning from ED to imaging back to ED, then to the floor; and another experienced eight FDs during a single transition from the ED directly to the OR). These cases were considered statistical outliers, because most patients experienced zero to four FDs per case.

The remaining 160 patients experienced a total of 351 transitions, with 28% occurring in the ED, 15% in the OR, and 6% in the ICU. The most frequent transitions were patient transfers between the ED and the OR (30%), followed by transfers between the ED and the ICU (20%). The remaining transitions were distributed as follows: 15% from the OR to the ICU, 10% from the ICU to the OR, and 5% from the OR to the ICU.

Most FDs (53%) were related to coordination problems (Fig. 2, such as when computed tomography was already occupied, the nurses on the preoperative staff did not have the correct paperwork, the patient was taken to the wrong room, or critical team members were missing when needed). There is a small additive effect where multiple transitions equate to a higher number of FDs per patient (Fig. 1, bottom panel), and the number of FDs per transition reduces slightly as patients experience one, two, or three transitions (Fig. 3, top panel). No differences were observed to be significant.
The distribution of results suggests that there are clear high-risk and low-risk patient experiences (Fig. 4). Whenever a patient goes directly to the OR, or when a patient needs immediate admission to ICU, there is a higher risk of transition disruptions than when patients go to the floor or discharge, or a holding area after having first been to the computed tomography. Wilcoxon signed-ranks test confirmed a significant difference ($z = 3.22; p = 0.0015$) in the number of FEs per transition between high- and low-risk transitions. In high-risk transitions, 40% of patients experienced two or more transition FEs during their care, as opposed to 12% for low-risk transition patients (Table 1). This clearly coincides with higher-level trauma: Sicker, more urgent patients more likely experience these nonstandard transitions, and in doing so, they experience more FEs. Using the overall number of FEs per patient and examining the frequencies of patients with zero, one, or two transitions (to guard against type I error, given the lower sample in the high-risk group), we found a statistically significant chi-square statistic ($11.7, p = 0.0028$), which confirmed that there was a significant difference between the number of transition FEs in low-risk transition and high-risk transition groups.

4. Discussion

We have demonstrated three key principles associated with care transitions in one trauma service. First, the vast majority of disruptions during trauma transitions derive from coordination issues. Second, successive handoffs do not necessarily increase the number of transition FEs. Finally, some patient pathways are at a demonstrably higher risk of transition FEs. Patients who are taken directly to the OR or need immediate ICU care are far more likely to experience multiple disruptions during care transitions than are those who follow a more standard and less time-pressured pathway. In essence, the sickest patients who need the most rapid and specialized treatment are most at risk from coordination and other problems during their transitions to different care teams and locations.

By and large, about one in every two high-risk transitions experiences a disruption, compared with about one in every five low-risk transitions. Clearly, this is partly an effect of patient complexity and time pressure. In particular, sick patients may need to be moved quickly, which increases the chances of errors or omissions during the transition. There is
presumably also an effect of familiarity. After initial assessment in ED, nearly three quarters of patients go to imaging, and then return to the ED. The cases that do not follow this route are the ones most prone to disruptions. Thus, the need to conduct complex transitions with sick patients, under time pressure, using a non-routine pathway, leads to distinct coordination challenges that result in these disruptions. The implications for mass casualty events are potentially more severe, because these high-risk pathways are likely to be frequently used with patients with a higher degree of uncertainty and more severe injuries, with a higher ED workload, and with a limited number of available staff and equipment [12]. All of this further illustrates the value of employing these methods under such considerations, simulations, or assessments. 

Coordination fails just when you need it to work the best. These findings contrast with most published handoff investigations, in which the emphasis has been on the standardization of discrete handoff processes to improve communication of information. Clearly, the non-routine transitions with sequences that are less discrete and normalized across patients are more at risk of coordination problems. There is therefore a need to consider how to enhance coordination in urgent, time-pressed, non-routine transitions. In a previous study, a multidimensional handoff process was implemented for high-risk surgery patients, based on practices in aviation and motor racing [13,14]. Improved handoff performance was demonstrated.

Table 2 illustrates how a similar approach might be applied here. Operationalizing these adaptations would involve several stages of development, testing, and modification [15]. Consistent application might be furthered by use of context-
sensitive information technology tools to manage the process, information, and communication with the many care venues (imaging, OR, and the ICU) [56,17]. We are currently exploring the former and developing the latter, and hope to implement a range of changes over the coming months, to potentially include checklists, process simplification, teamwork improvements, and careful application of information technology.

Transitions from the ED are among the most complex handoffs in health care, with a highly variegated population of patients and care givers. This study supports our belief that there need to be more thorough examinations of such under-appreciated risk situations. That said, this was a relatively small sample within a single hospital. It is not clear whether these results would generalize to a wider population. Also, we were unable to study patients who were transferred from the OR to ICU because of the limitations of observation and the dataset. Furthermore, in this study, we evaluated only FIs; we did not examine teamwork, the communication of information, or the working environment, all of which are frequently the focus of other published handoff work; nor were we able to study whether any adverse events arose from our observations.

5. Conclusions
Transitions of care for trauma patients are prone to disruptions. Coordination problems predominate as the cause. It is the sicker, more time-pressured, more risk patients who are more likely to experience disruptions; direct transitions to the OR or ICU are associated with higher numbers of disruptions. System-based solutions, reflecting lessons learned in other industries, may be helpful.

Acknowledgments
This project is part of the Cedars-Sinai OR30 initiative, funded by the Department of Defense, Telemedicine and Advanced Technology Research Center Grant W81XWH-10-1-0139, which seeks to reengineer teamwork and technology for 21st-century trauma care. The authors thank the other project contributors: Ray Chu, MD, Heidi Hotz, RN, Steven Rudd, MD, Ben Starnes, MD, Robert M. Rush, MD, Bill Taggart, BS, Cathy Karl, MBA, Richard Karl, MD, Eduardo Salas, PhD, Sacha Duff, MS, Shannon Weber, RN, Brittany Dixon, Elena Fornenchko, Jean-Philippe Chouvat, Mark Pauken, Tracy Exesso, and Cynthia Huang, and all of the ED and trauma staff who allowed the authors to observe them at work.

REFERENCES


A Human Factors Subsystems Approach to Trauma Care

Ken Catchpole, PhD, Eric Ley, MD, Doog Wiegmann, PhD, Jennifer Blaha, MBA, Daniel Shouhed, MD, Alexandra Gang, MD, Renaker Blocker, PhD, Richard Karl, MD, Cathy Karl, MBA, Bill Taggart, BS, Benjamin Starnes, MD, Bruce Gewertz, MD

IMPERATIVITY A physician-centered approach to systems design is fundamental to ameliorating the causes of many errors, inefficiencies, and reliability problems.

OBJECTIVE To use human factors engineering to redesign the trauma process based on previously identified impediments to care related to coordination problems, communication failures, and equipment issues.

DESIGN, SETTING, AND PARTICIPANTS This study used an interrupted time series design to collect historically controlled data via prospective direct observation by trained observers. We studied patients from a level I trauma center from August 1 through October 31, 2011, and August 1 through October 31, 2012.

INTERVENTIONS A range of potential solutions based on previous observations, trauma team engagement, and iterative cycles identified the most promising subsystem interventions (headsets, equipment storage, medication packs, whiteboard, prebriefing, and teamwork training). Five of the 6 subsystem interventions were successfully deployed. Communication headsets were found to be unsuitable in simulation.

MAIN OUTCOMES AND MEASURES The primary outcome measure was flow disruptions, with treatment time and length of stay as secondary outcome measures.

RESULTS A total of 86 patients were observed before the intervention and 120 after the intervention. Flow disruptions increased if the patient had undergone computed tomography (CT) ($F_{2000} = 20.0, P < .001$) and had been to the operating room ($F_{2000} = 6.31, P < .01$), with an interaction among the intervention, trauma level, and CT ($F_{2000} = 6.50, P = .01$). For total treatment time, there was an effect of the intervention ($F_{2000} = 217, P < .001$), whether the patient had undergone CT ($F_{2000} = 43.0, P < .001$), and whether the patient had been to the operating room ($F_{2000} = 85.8, P < .001$), with an interaction among the intervention, trauma level, and CT ($F_{2000} = 15.1, P < .001$), reflecting a 20- to 30-minute reduction in time in the emergency department. Length of stay was reduced significantly for patients with major mortality risk ($P = .01$) from a median of 8 to 5 days.

CONCLUSIONS AND RELEVANCE Deployment of complex subsystem interventions based on detailed human factors engineering and a systems analysis of the provision of trauma care resulted in reduced flow disruptions, treatment time, and length of stay.
Application of human factors engineering principles in trauma care may reduce flow disruptions (FDs), treatment time, and length of stay. In health care, unintentional harm is frequent and often caused by faulty systems that allow errors to perpetuate, permitting injury to occur. Rather than focusing solely on who made an error, a systems analysis of how, when, where, and why errors occur provides a window through which it is possible to understand the weaknesses of the modern health care provision process. As with many other specialties, trauma care benefits from studies of safety, quality, efficiency, and error.

Human factors engineering is based on the principle that system performance and human well-being can be improved through an integrated approach to individual skills, teamwork, equipment, task, environment, and organizational design. Considerable evidence supports improving work systems through interventions such as checklists, briefings, standardized care pathways, formal protocols, team resource management training, and technological development to improve teamwork, shared knowledge, workflow, and outcomes. The greatest successes are usually achieved by involving physicians, nurses, and other practitioners in the process of developing improvements and by designing systems around human needs. This person-centered approach to systems design is fundamental to ameliorating the causes of many errors, inefficiencies, and reliability problems.

Previous studies have sought to use human factors engineering to redesign the trauma process using a multidisciplinary team of experts in process improvement, human factors research, and trauma care. To identify key areas for improvement of our trauma system, Blocker et al. and Catchpole et al. previously conducted process mapping, interviews, safety culture questionnaires, and direct observation of FDs and process timings. Flow disruptions are defined as "deviations from the natural progression of an operation thereby potentially compromising the safety of the operation" and have been empirically linked with surgical errors. The study of FDs has helped identify systems problems in a variety of other long-term care clinical settings. Within our trauma system, the most common FDs were coordination problems, communication failures, and equipment issues, with significantly higher numbers and rates of disruption in the computed tomography (CT) imaging room and the operating room (OR). These FDs were observed most often in more seriously injured patients.

This total systems analysis, combined with theoretical and practical expertise, generated a range of task-, team-, environment-, and equipment-related solutions. We hypothesized that each could be individually effective and together would reduce FDs, reduce treatment time within the first hour of patient care, and reduce length of stay.
geons and 8 or more residents. Because teams were comprised of an ad hoc group and rarely the same, the number of different teams observed was at least 12 within the core trauma team, with many more permutations when taking into consideration the supporting ED and technician members.

To assess interrater reliability, 11 trauma patients had 2 observers, whose responses were compared using a Cronbach a test. Data were obtained from the University Healthcare Consortium database for all trauma patients during the preintervention and postintervention phases.

**Design and Deployment of Interventions:**
Analysis of FDs suggested that communication and coordination, leadership and teamwork, patient factors, and equipment issues could benefit from targeted interventions. Data gathered from interviews found that coordination and protocol deviations were common causes of frustration; interviewees expressed some confusion over leadership. The FDs, particularly in the form of superfluous noise, reduced the amount of information transferred among team members. Role confusion was reported, especially with task sharing and leadership between the ED and trauma staff.

Having collected and analyzed the FD data, a multidisciplinary team that consisted of 8 physicians (including E.L., B.E., A.G., and D.S.), 6 human factors scientists (including K.C., J.W., and R.B.), 3 nurses, and 2 health care improvement experts (including J.B.) was brought together for one and a half days to define problems and identify solutions. The main problem areas were identified, and a range of potential solutions to each were generated. Then, a short list was generated based on practical considerations or the projected time needed for implementation. This short list was framed within the components of the Systems Engineering in Patient Safety human factors model, which also assisted in down-selection, to ensure coverage of task, team, environment, and technology. After the meeting, members of the ED and trauma teams were invited to discuss the short list and be involved in the studies. As implementation moved forward, we used small, iterative plan-do-study-act cycles to develop each intervention to a level where it was practical and deliverable. We then developed effectiveness and uptake measures, followed by full deployment of the interventions from May 1 through September 30, 2012. Figure 1 illustrates the general process by which the interventions were developed, with the rationale and implementation strategy in eTable 1 in the Supplement.

Observational measures of the uptake of each subintervention were used to gauge the effectiveness of the whiteboard, prebriefing, and teamwork behaviors (eTable 1 and eTable 2 in the Supplement). Sixty-nine patients in the postintervention phase were studied with an additional observer who used an observation template that collected a range of measures to ascertain the use of these interventions. For the other interventions, appropriate evaluation methods were chosen to demonstrate effectiveness or uptake. All intervention evaluation metrics are summarized in eTable 2 in the Supplement.

**Statistical Analysis**
All data were positively skewed so means (SDs) and medians (ranges) were calculated. For statistical analysis, the log-transformation function was used, which generated a more appropriate distribution for parametric analysis. The main observational data (treatment times and FDs) were studied in stepwise multivariable linear regression models, which took into account intervention period, trauma level (high or low), whether the patient had been to the CT imaging room and the OR, and interaction among the intervention, trauma level, and CT imaging room. For patient outcome data (length of stay and intensive care unit stay), separate before-and-after comparisons were made with Kruskal-Wallis tests for each risk of mortality estimate (minor, moderate, major or extreme, as defined in the University Healthcare Consortium database).
Results

Deployment of Subsystem interventions
Five of the 6 subsystem interventions were deployed. All deployed interventions were measured as being effectively used to some degree, although reliability differed. All intervention evaluation metrics are summarized in eTable 2 in the Supplement. The equipment storage standardization provided time and movement benefits. Although the transport medication pack was rarely used, the presence of the guidance provided extra benefits. The whiteboard was used and completed in a timely manner in 70% of cases and usually had all key information documented. There was not always sufficient time to conduct a pretrauma briefing, and the variable amount of time available to the team was a clear limitation, but anecdotal subjective views were positive. The teamwork training was well received and resulted in significant improvements in observed teamwork and explicit teamwork behaviors.

Direct Observation Sampling
In the preintervention phase, 85 patients were observed. In the postintervention phase, 120 patients were observed (from which the 69 patients used for effectiveness evaluation were also taken). The samples, results, and statistical modeling are provided in eTables 3, 4, and 5 in the Supplement. The 11 dual-observed patients had a Cronbach α of 0.846, indicating good internal consistency.

For FDs in high-acuity patients, there is a reduction in mean, median, and range. The FDs in lower-acuity patients had a reduction in range. Taking the log of the FD total to address skewness, FDs (r = 0.31) increased if the patient had been to the CT imaging room \((F_{\text{med}} = 20.0, P \leq .001)\) and the OR \((F_{\text{med}} = 69.1, P \leq .001)\), with an interaction among the intervention, trauma level, and CT \((F_{\text{med}} = 6.50, P < .01)\). This finding reflects the particular benefit for high-acuity patients undergoing CT (Figure 2).

For total treatment time, there was a significant effect of the intervention \((F_{\text{med}} = 21.7, P < .001)\) if the patient went to the CT imaging room \((F_{\text{med}} = 43.0, P < .001)\) or the OR \((F_{\text{med}} = 84.8, P < .001)\), with a significant interaction among the trauma level, CT, and the intervention \((F_{\text{med}} = 11.1, P < .001)\). Figure 3 shows a mean 20- to 30-minute reduction in time spent in the ED.

Discussion

Interventions based on detailed human factors engineering and systems analysis of trauma care provision led to measured benefits, including reduced TIs, treatment time, and length of stay. We built on previous single-intervention studies by implementing a combination of interventions to address several problems from multiple perspectives. Improvements were designed to address the broad range of barriers to effective care identified by our prior systems analysis. Physician-centered considerations and iterative approaches were brought to all the interventions developed to engage and adapt our solutions to

Figure 4. Length of Stay × Risk of Mortality

Error bars indicate 95% CIs.
local requirements and system complexity. Although many studies have attempted change of multiple dimensions, and even fewer have evaluated improvement and the greater whole. For example, in 2 particularly well-regarded studies, the multiple intervention dimensions used have only emerged subsequent to the main findings, which has resulted in replication problems. To our knowledge, although teamwork-level human factors studies in trauma care about, this comprehensive systems-level human factors analysis and intervention has never been previously attempted in trauma care.

Given that the reductions in FDs did not suggest a strong effect size, the reduction in ED time and the length-of-stay effects are perhaps more surprising. This length of stay was not compared with a nontreatment control group, and we were unable to track individual patients through their entire care and thus were unable to directly relate outcomes to our study population. However, there are a number of reasons to consider this outcome as a result of some importance. First, we were careful to select similar periods and similar patient populations. Second, although all interventions were not used all the time, it is likely that they were deployed in the trauma patients we did not directly observe in similar proportions. For example, the teamwork training presumably benefited all trauma patients, not just those we observed, whereas the briefing was well received and the whiteboard was used independently of our studied patients. Third, our process changes were most beneficial for the higher-risk patients, as evidenced in the length-of-stay and FD findings. Finally, the reduction in ED time is a reflection of the well-observed value in the provision of early effective trauma care. We suspect that this time benefit is associated with the small reduction in FDs and further additional interventional benefits that were not directly measured. For example, when teamwork, communication, and coordination are improved, we might expect improved decision making, faster response to CT and OR procedures, and better ability to provide more effective and timely care rather than simply the avoidance of FDs.

It is worth noting that a proportion of FDs may be advantageous (eg, there may be a coordination advantage in minor pauses or timeouts) and that skilled teams are able to use such pauses to prevent adverse effects on patients. This context also provides further support for the strength of the time and length-of-stay effects over the reduction in FDs themselves. Thus, although a multisite controlled study would be needed to confirm these results, we believe the present results are sufficient to indicate the value of such an endeavor.

We also measured the effectiveness and uptake of all our subsystem interventions, affording extra detail regarding the mechanism and replicability of overall effects. Although not all subsystem interventions were used all the time, most were used effectively most of the time. This variation in use is a realistic part of system function and suggests that the present study is a conservative estimate of the benefits of this type of whole systems approach if greater reliability can be achieved. In this analysis, we did not test the contribution of the interventions individually, instead seeking to examine the overall effect of the combination because the evidence for each was sufficient alone, whereas no studies, to our knowledge, have examined multidimensional human factors interventions. The subsystems approach is an example of how improvements that address multiple dimensions of team (training), task (briefing), equipment (medical transport packs), and environment (equipment storage standardization) may be more effective than focusing on one dimension. In particular, the typical focus in health care improvement or training and other methods of direct behavioral change are limited but frequently deployed even though other system considerations might also offer performance benefits. As a final note, although our approach afforded a complex systems analysis and an expert team, the underlying themes of our interventions that emerged were simplification, teamwork, and integration and management of information.

This study was not masked because the interventions were overt. Observers were not masked to the interventions but had not been extensively involved in their development and implementation, and in some cases they may have been unaware (only R.B. was part of the project team). The observer who recorded the effects of the interventions was more involved with the interventions and thus aware of the changes that had been made but was not directly involved in their generation or implementation and was provided with a strictly structured set of items to score. We also cannot ignore the Hawthorne effect. However, the presence of observers was largely unobtrusive and identical in the preintervention and postintervention phases. In addition, previous experiences suggest that their influence, at least in the OR, does not preclude the observation of system problems. In terms of sampling, there was a difference in the overall sample sizes in the preintervention and postintervention phases, although we have high-acuity patients, in whom the most benefits were observed, there is near parity (sample sizes of 74 and 69 in the preintervention and postintervention phases, respectively).

Conclusions

This is the first study, to our knowledge, to objectively examine the effects of multiple subsystem interventions in trauma care. The detailed study of the trauma system and the collection of data prospectively were central in guiding us toward the largest improvement opportunities. By reviewing hospital policy documentation, we mapped the process and conducted interviews and focus groups with a broad range of physicians to discover their impressions of the problems. Using the human factors and systems performance improvement methods, we collected data on the entire trauma process. Through a combination of statistical analysis and multidisciplinary consensus, we identified key aspects of process, workplace modification, teamwork, technology, and information management that would benefit from reengineering. By piecing together all the collected data elements, we were able to target our interventions to have the greatest positive effect on the process. These interventions were developed, integrated, and evaluated for their relevance and effectiveness. This early study
Research

Original Investigation

in a complex field suggests benefits in reduced FDSs, reduced treatment time, and the potential for reduced length of stay.

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Toward the modelling of safety violations in healthcare systems

Ken Catchpole

ABSTRACT
When frontline staff do not adhere to policies, protocols, or checklists, managers often regard these violations as indicating poor practice or even negligence. More often than not, however, these policy and protocol violations reflect the efforts of well intentioned professionals to carry out their work efficiently in the face of systems poorly designed to meet the diverse demands of patient care. Thus, non-compliance with institutional policies and protocols often signals a systems problem, rather than a people problem, and can be influenced among other things by training, competing goals, context, process, location, case complexity, individual beliefs, the direct or indirect influence of others, job pressure, flexibility, rule definition, and clinician-centred design. Three candidates are considered for developing a model of safety behaviour and decision making. The dynamic safety model helps to understand the relationship between systems design and human performance. The theory of planned behaviour suggests that intention is a function of attitudes, social norms and perceived behavioural control. The naturalistic decision making paradigm posits that decisions are based on a wider view of multiple patients, expertise, systems complexity, behavioural intention, individual beliefs and current understanding of the system. Understanding and predicting behavioural safety decisions could help us to encourage compliance to current processes and to design better future interventions.

COMPLIANCE AND VIOLATIONS IN COMPLEX SYSTEMS
Patient safety research initially focused on understanding the true extent and sources of errors, typified by case-note review, direct observation studies and implementation of basic quality improvement systems. Eventually this moved towards quantitative methodologies and then to use of theoretical models and more recently, several major evidence-based safety innovations. Reliable implementation of these new ways of working has been more difficult. Violations—failures to follow rules, processes and guidelines—are still frequent and quality improvements are not always apparent. Compliance to hand hygiene protocols may be observed as low as 2% in the operating room; mask discipline can be extremely variable; equipment counts can be disruptive and ineffective; distractions are frequent...
Viewpoint

deep vein thrombosis prophylaxis is notoriously variable,\textsuperscript{24, 25} checklists and timeouts may be used sporadically,\textsuperscript{26} with considerable variation in their uptake.\textsuperscript{27} Though the reader is directed towards detailed considerations of error and violations,\textsuperscript{28} five types of violation are often discussed:

- erroneous violations—due to a lack of understanding or inexperience;
- exceptional violations—when unusual circumstances require an unusual response;
- situational violations—when the environment makes adherence difficult;
- routine violations—when a shortcut is taken regularly;
- optimising violations—when there is a desire to improve a work situation.

Rather than being deliberate negligence of poor practice, work in other industries illustrates that rules and procedures constitute fragile safety barriers, and violations usually reflect good intentions to complete work efficiently, even if the behaviours are eventually misguided and unsafe. Thus, the apparent simplicity of safer processes belies the complexity of their implementation within the healthcare system.\textsuperscript{31}

Questions of safety must be framed within an understanding of the relationship between people and systems of work. Errors are frequent, accidents normal,\textsuperscript{32} and are predisposed by deficiencies within systems which may promote the wrong behaviours and allow errors to perpetuate to catastrophe.\textsuperscript{7} Indeed rather than being a hazard, people create safety in complex systems by providing the flexibility to function, despite the risks of errors in an uncertain, time pressured resource-constrained world.\textsuperscript{7} Under financial and workload pressures, accepted ways of working can migrate toward unsafe boundaries\textsuperscript{33} through shortcuts and lowered accepted standards. Efficiency and throughput issues can create difficult working environments,\textsuperscript{34} where manager and clinician dash over the need to trade organisational goals (eg, efficiency) for safety goals for individual patients. New processes or checks need to be trained and implemented, which can add time, financial and managerial pressures to the system, with the monitoring of these requirements further increasing overhead cost.\textsuperscript{33} Effective implementation processes incorporate hands-on leadership, frontline decision making, dedicated resources, local modification and feedback.\textsuperscript{35} Sometimes, the implementation of guidelines is hindered by organisational constraints.\textsuperscript{36} Sometimes people are simply unaware of their deviations.\textsuperscript{7} Thus, in the same way that errors cannot necessarily be avoided through ‘trying harder’, seeing violations of safety processes as purely due to individual will does not account for the systemic pressures upon the individuals delivering care.

SYSTEMS MODELS OF COMPLIANCE

A range of models and techniques are available to help us understand how the systems of work affect behaviour. The system of surgery has been examined in detail by several groups who have been able to observe the effects on behaviour and operative course of different configurations, specialties, distractions, disruptions and unintentional outcomes.\textsuperscript{37} These interactions can be complex but demonstrably influence outcomes.\textsuperscript{8} Models exist for describing the complex relationship between systems components\textsuperscript{13} and but generally they acknowledge that people, tasks, equipment, tools and aspects of the organisation all interact to produce either successful or unsuccessful processes. From an organisational perspective, the dynamic safety model\textsuperscript{39} provides a framework examining organisational tendencies toward or away from unacceptable workload, economic failure and safety, thus allowing the qualitative consideration and potential quantification of high-level organisational issues.

Systemic predisposition to error—that is, how workplaces can create the opportunity for people to make and perpetuate mistakes—needs to be mediated by an understanding of individual behaviour and responsibility. A systematic review of violations across a range of industries (including, but not limited to, healthcare) suggests worker centred design, training, competing goals and rule definition, as predictors as well as individual characteristics.\textsuperscript{40} For example, in medication administration, violations may be influenced by context, process and hospital location.\textsuperscript{41} Anaesthesiologists’ decisions to follow or deviate from guidelines are influenced by the beliefs they hold about the consequences of their actions, the direct or indirect influence of others, and the presence of factors that encourage or facilitate particular courses of action.\textsuperscript{42} Compliance can be observably influenced by case complexity and job pressure.\textsuperscript{43} Despite the focus on an evidence base, a systematic review of the use of guidelines finds that flexibility of recommendations to local context and concise recommendations are also important aspects of adherence.\textsuperscript{44} Systemic ambiguities which discourage a clear understanding of how things ‘should’ work may be particularly useful in understanding healthcare violations.\textsuperscript{45}

BEHAVIOURAL MODELS OF COMPLIANCE

Improving safety is also about achieving behavioural change, which is influenced by knowledge, beliefs, decision processes, context and social influences.\textsuperscript{46} In fact, the use of procedures and processes may be viewed as counteracting the use of expertise and common sense,\textsuperscript{47} and thus senior staff can often be the trigger for violation that leads to a migration within the system as a whole.\textsuperscript{48} Indeed, even exceptional violations can eventually become accepted practice.\textsuperscript{49} Rule violations may also give the violators an impression of power.\textsuperscript{50} This is reflected in the different attitudes to rules that doctors and nurses share,\textsuperscript{15} and in the cognitive dissonance apparent in the responses of surgeons to the surgical safety checklist,
with a higher proportion stating they would like the checklist used during their care than believed it improved safety, improved communication and prevented errors. The challenge is to encourage clinicians to make the right decisions that protect each patient they care for, above the financial, social and workload pressures from the higher echelons of the organisation, their peers, legal systems and even professional organisations.

At the ‘sharp end’ of the organisation, possibly the most influential theory in health psychology for understanding individual behavioural intention has been the theory of planned behaviour. In addition to generic health-related behaviours such as smoking, drug taking and dieting, it has been applied to hand hygiene prediction and venipuncture. In its simplest form, the theory can be expressed as the mathematical function in box 1. This has been the basis for the Technology Acceptance Model which is not without its critics, but illustrates how, with sufficient understanding, compliance and violation might be modelled. If we consider some broad analogies—when perceived behavioural control might relate to implementation processes and organisational pressure; social norms might be examined through teamwork and concepts of professional standards; and attitudes might be measured through consideration of evidence bases, prior experience and knowledge—then it may be possible to build a model of how the nature of change, systems design, and individual and professional influences can lead to violation decisions. However, the precise parameters, the nature of the model and their relationship would need to be defined through observation and experimentation.

NATURALISTIC DECISION MAKING

Compliance is a classic systems problem, with initial violations predisposed to at the organisational or managerial level, and perpetuated through a range of measurable socio-technical parameters. The naturalistic decision making paradigm helps us to understand how human decision making is mediated by this organisational and environmental context. It posits that decisions are usually made in uncertainty, under time pressure, with ill-defined goals, and are based on expertise, pattern matching or recognition of a given situation, and are thus nonlinear, non-analytical and not necessarily logical, rational or based on risk/benefit considerations. Naturalistic decision making has been extremely influential in the human factors science of decision making, especially to understand and improve tactical decisions in military operations and is beginning to be used in healthcare.

Direct observation in the emergency department found that only about 45% of the decisions were planned, with the rest being opportunistic or forced by interruptions. Moreover, decisions were not being made about individual patients alone, but their care within the wider view of the ED as a whole, and situational factors that defined the local, immediate demands for resources. Indeed, these different goal-directed behaviours can have an interfering influence on the performance of evidence-based behaviour. Thus, it is becoming apparent in healthcare systems, as in other industries, that the decision to adhere to guidelines, processes or safety procedures is not necessarily logical, linear and evidence-based, but on a wider view of multiple patients, expertise, systems complexity, behavioural intention, individual beliefs and current understanding of the system.

SUMMARY

Behavioural change and violation reduction are keystones of the safety movement, but the mechanisms have been infrequently described and even less frequently quantified. It is in the quantification that we may be able to achieve robust scientific evidence, and a greater ability to predict and balance throughput, cost and safety. Though a great many approaches to human decision making and violations exist, the models selected here take different but complimentary perspectives. The Systems Engineering Initiative for Patient Safety (SEIPS) model examines the broad influences of behaviour upon systems, and lends itself to multi-parameter measurement through direct observation, but may not directly address or predict individual behavioural outcomes. It might therefore provide a useful way to quantify the context of a system. The theory of planned behaviour and the technology acceptance model is quantifiable from a behavioural approach, but may be oversimplified and does not address the broad array of behavioural determinants of SEIPS. Finally, the dynamic safety model and naturalistic decision making paradigm, though largely qualitative, make the links between system and person, directly acknowledging the systemic tradeoffs between safety and efficiency that need to be made every day. They may therefore provide a framework in which systems context and individual behaviour might be brought together in a

Box 1 Theory of planned behaviour expressed as a testable model

Behavioural intention = (W^3)A\beta b + e + (W^3)SN + (n + m) + (W^3)

PBC (c + p)

Aβ: attitude towards behaviour (b): strength of each belief (e): evaluation of the outcome or attribute
SN: social norm (n): strength of each normative belief + (m): motivation to comply with the referent
PBC: perceived behavioural control (c): strength of control belief + (p): perceived power of control factor
W: empirically derived weight/coeficient
quantifiable form. Whether that is possible remains to be seen. Clearly this is a complex challenge.

Within a framework that recognises behaviours arise from systems of work,13 organisations are under a range of pressures,34 and that decisions need to be understood from a naturalistic point of view,43 it is possible to explore these relationships from a quantitative and qualitative perspective. The immediate utility would be in developing quantitative models that describe the influence of organisation, context, tasks and tools on systems safety behaviour. The longer-term benefit would be in understanding the mechanisms of safety change and the prediction of successful or unsuccessful interventions. This would provide a better understanding of how we can improve the safety of patients within complex and increasingly pressured healthcare organisations. It may be the piece of the puzzle we are missing.

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Competing interests Dr Catchpole is an Associate Editor for BMJ Quality and Safety. He has received honoraria from a variety of healthcare improvement organisations for speaking about human factors, behavioural safety and quality improvement in complex systems, but has no competing interests.

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Interventions employed to improve intrahospital handover: a systematic review

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ABSTRACT

Background Modern medical care requires numerous patient handovers, and handover error is recognised as a potential hazard in patient care, and the information error rate has been estimated as 15%. While accurate, reliable handover is essential to high quality care, uncertainty exists as to how intrahospital handover can be improved. This systematic review aims to evaluate the effectiveness of interventions aimed at improving the quality and/ or safety of the intrahospital handover process.

Methods We searched for articles on handover improvement interventions in EMBASE, MEDLINE, HMIc and CINAH between January 2002 and July 2012. We considered studies of staff knowledge and skills, staff behavioural change, process change or patient outcomes.

Results 33 potentially relevant papers were identified from which 29 papers were selected for inclusion (two randomised controlled trials and 27 uncontrolled studies). Most studies addressed shift change handover and used a median of three outcome measures, but there was no outcome measure common to all. Poor study design and inconsistent reporting methods made it difficult to reach definitive conclusions.

Information transfer was improved in most relevant studies, while clinical outcomes improvement was reported in only two of 10 studies. No difference was noted in the likelihood of success across four types of intervention.

Conclusions The current literature does not confirm that any methodology reliably improves the outcomes of clinical handover, although information transfer may be increased. Better study design and consistency of the terminology used to describe handover and its improvement are urgently required.

INTRODUCTION

The practice of modern medicine relies upon increasingly complex work environments and supporting processes. One process central to the delivery of safe care is handover (handoff). Clinical handover has been defined as ‘the transfer of professional responsibility and accountability for some or all aspects of care for a patient, or group of patients, to another person or professional group on a temporary or permanent basis.’ The publication of healthcare-derived error reports prompted significant changes both in the delivery of care and how clinicians view error. Following the introduction of reduced working hours, the number of shift handovers in Europe and the USA has increased by up to 40%, and handover between doctors has become formalised. It has been estimated that an average inpatient will require 24 handovers during their hospital stay, and that 1.6 million handovers occur in the USA per year. The safety benefit derived from shorter working weeks should be viewed in the context of the additional risks associated with an estimated 13% error rate derived from handover.

Handover failures typically contribute to a cascade of failures involved in adverse outcomes, rather than being sole causes, making the estimation and investigation of handover-derived harm difficult. Common consequences of handover failures, such as near misses and delays in care, are difficult to assess for their overall contribution to potential harm.

Handover can be viewed simply as a human interaction where information is sent, received and processed. However, this process receives multiple inputs relating to the core healthcare tasks of prescribing; investigation requests; receiving and interpreting results; ensuring continuity of care; and delivery of patient advice. It is therefore possible to nest
**Systematic review**

This human-to-human interaction within a wider system of work which requires the examination of the action and interaction of technology, environment, tasks and the organisation surrounding the handover. Recognition of the potential risks of handover errors has led many researchers to attempt to improve it using a range of methods, both simple and multi-component. Interventions generally target information transfer directly, individual behaviour or the wider system. Approaches have included process standardisation; training and education; changes to the physical environment; use of technology; explicit signalling of accountability transfer; and others. The diversity of methods used to evaluate the results has been even greater, but can be grouped as dealing with patient outcome, staff satisfaction, compliance with protocols, time taken for handover and information transfer (eg, completeness or accuracy of information transfer).

Uncertainty remains as to the most effective method for improving intrahospital handover. This systematic review aims to evaluate interventions which have been developed to improve the quality and/or safety of the hospital handover process with a view to enabling hospital practitioners and researchers to focus on refining the most effective interventions.

**METHODS**

**Scope of review**

We wished to be inclusive of studies of attempts to improve all types of handover within hospital settings. We therefore developed a search strategy based on the PICO question. In [POPULATION] groups of clinical staff handing over information about patients under their care, do [INTERVENTION; systematic intentional interventions] compared to [COMPARISON; no intervention] improve [OUTCOMES; patient outcome, staff satisfaction, time taken or information transfer]? Inclusion criteria for studies comprised: (a) includes an intervention developed with the intent of improving handover quality and/or safety (b) set within an intrahospital environment (c) uses both preintervention and post intervention assessment (d) assesses any of knowledge and skills of staff, time taken for handover or related tasks, staff behavioural change or patient outcomes.

The protocol was registered with an international database of prospectively registered systematic reviews, PROSPERO (registration number: CRD42012001993).

**Search strategy**

We searched EMBASE, MEDLINE, HMIC and CINAHL for papers published in English between January 2002 and July 2012, using a search strategy based on the terms below. Synonyms of handover, inter-hospital and intervention were used thus:
study could achieve was reduced from the original 27 to 20.

In a similar fashion, we adopted a modification of a recognised guideline to evaluate intervention transferability. The Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines were developed in 2009 to promote standardised reporting of healthcare quality improvement interventions. \(^{18}\) For the purposes of this review, Q8, Q9a, Q9b, Q9c, Q14a, Q16b and Q16c were used to critique the included papers on the reporting of their intervention. We also recorded whether there was a specific mention of the SQUIRE guidelines.

RESULTS

A total of 29 studies were identified for inclusion in this review. The search of EMBASE, MEDLINE, HMIC and CINAHL provided a total of 631 citations and following de-duplication 437 papers remained (figure 1). Of these, 329 were excluded after abstract review as not matching the inclusion criteria. The full text of the 108 remaining citations was reviewed in more detail; 79 of these did not meet the inclusion criteria and were excluded. The remaining 29 papers met the inclusion criteria (figure 1) and are displayed in the summary table (see online supplementary table S1).

The study designs of the included studies included: two randomised control trials (RCTs);\(^{19,20}\) one preintervention/postintervention controlled trials;\(^{21,25}\) 25 pre-intervention/postintervention uncontrolled trials;\(^{22-46}\) and one Pan-Do-Check-Act design.

A total of 11759 handovers were included in studies which gave this information, with a median of 103 handovers per study. Ten studies\(^{19,21,26,27,31,32,39,41,44,46}\) gave no information on the number of handovers they included (see online supplementary table S1).

Study duration

Of those studies which gave information on the length of time for each study component, the median length of time (days) for preintervention data collection was 28 (range 4–224), for intervention was 28 (range 1–252), the gap between intervention and the commencement of postintervention data collection was 10.5 (range 9–365) and the postintervention data collection period was 28 (range 4–224). Seven studies gave no information on any component of their study design timeline\(^{34-37,41-43}\) and 14 gave no information on one or more study timeline components.\(^{19,21,23,25,29-32,39,40,45-47}\)

Study environments

The majority of the studies (22) were performed in one ward environment.\(^{20-41}\) Four studies were performed in more than one environment\(^{19,44,45,46}\) and three gave no detail on the study environment.\(^{42,44}\)

Improvement strategies

The included studies took varied approaches to handover improvements. Fifteen studies were monocomponent interventions.\(^{19,21,22,27,31,34,37,44,46}\) and the remainder contained two or more components. Seven studies shared an intervention component: two interventions used the SIGNOUT mnemonic\(^{20,44}\) and five used the SBAR mnemonic in its original\(^{41,42,47}\) or slightly adapted format.\(^{43}\)

Outcome measures

The studies evaluated their interventions using a total of 82 discrete outcome measures, each study using between one and five measures (median of three). Since there was no prior classification system available, we developed a simple pragmatic classification to allow us to consider studies with similar outcome focus together. Based on the measures in the papers chosen for inclusion, we chose to group study outcome measures, as relating to: Information
transfer, Staff satisfaction, Handover duration, Clinical outcomes and Compliance with handover protocol. Two studies evaluated their interventions with two outcome measures, six used three, one study used four, and one used five outcome measures. There were no primary outcome measures in common between all the studies (see online supplementary table S2).

The studies are presented in online supplementary table S3 and online supplementary appendix by type of intervention—information system, person or wider system—and if a study contained a component from more than one category, the study is represented twice.

Seventeen studies reported a statistically significant change in at least one of their outcome measures, while 10 did not. Improvements in information transfer were the most commonly reported successes, being found in more than half of the studies examining this, and staff satisfaction was the next most commonly improved in 35% of studies—a similar proportion to those reporting improvements in time taken and compliance with protocols. Of studies which attempted to evaluate changes in patient outcome, only two of 19 reported a significant benefit with one study reporting a 12% decrease in adverse events (need for cardiopulmonary resuscitation (CPR), extracorporeal membrane oxygenation (ECMO) and acidosis) (p < 0.001) and the other study reporting a significant reduction in length of stay (p = 0.047). There was no obvious difference between the success rates of multi and monocircuit interventions, and none of our defined categories (standardisation tools, team training approaches or quality improvement programmes) seemed to be clearly associated with a better chance of a positive outcome.

There were two RCTs in the study selection, and we considered these separately. One focused on the use of a computerised reporting system to speed up handover, and found that it achieved this aim without apparently increasing the risks of adverse events or care errors. The method of randomisation was poorly described and the concealment of treatment allocation was not clear. Although the senior assessor who judged whether clinical errors had occurred was blinded to treatment group, the data supplied to this clinician apparently came from the residents under study and therefore unblinded, resulting in a high risk of bias. The other RCT evaluated the benefit of supervisor feedback on handover performance among internal medicine residents, but suffered from similar defects in randomisation and blinding of assessors. This study reported significant improvement in compliance with the protocol but also suffered from a high risk of bias.
The quality score of the included studies according to the modified D&C checklist ranged from 1 to 17, with the median score of 9, IQ (7.5, 12). There was no statistical difference in the median D&C score of positive and negative studies (Mann–Whitney U test p = 0.248).

**DISCUSSION**

**Our findings in context**

We embarked on this review from the viewpoint that handover is important, frequently the focus for improvement studies and difficult to characterise. Failures in handover can produce a wide variety of untoward outcomes ranging from lack of event awareness, to loss of significance, and to dropping or lacking information required to perform tasks. In medicine, the serious consequences which can ensue are well recognised, as is the disparate and unsatisfactory nature of handover processes in many settings. This explains the large number of studies devoted to improving handover processes. Unfortunately, this review shows that the poor quality of most studies leaves us unable to draw many firm conclusions about how handover may be optimised. We found that the large majority of published studies are small, uncontrolled, unblinded before/after comparisons, and often with a short or undefined follow-up period. The only outcome category which was apparently improved in more than 50% of studies which looked at it was information transfer. Time taken for the process, compliance with protocol and staff satisfaction were all improved in a minority of studies, while clinical outcome improvements were reported in only two of 10 studies. This does not exclude the possibility that the positive findings in some of these studies were valid, but the lack of strong trends and the poor study designs mean that we cannot have much confidence in this. At present, it appears that information transfer is the aspect of handover in which interventions most readily show change whether this results in any beneficial outcomes beyond better recording of data is however unclear.

**Information transfer**

It seems rational to use information transfer as a key outcome measure for evaluating handover since reliable transfer of information is the principal purpose of formal handover. However, we need to consider carefully what we wish to know about information transfer in order to measure it effectively. We suggest that the functional value of a handover session can be effectively measured by evaluating three aspects of information transfer—completeness, accuracy and organisation. The last of these is essential to ensure that the most important data are not obscured by other items and are easy to identify because the information is presented in a structured way. However, we recognise that other taxonomies for describing information transfer may also be valid, for example, that proposed by Paterson and Wears or by Pezzolesi et al, and that ultimately empirical trials will determine whether our suggestion proves the most useful.

**The need for a taxonomy**

Another major problem identified by the review is the lack of any common language or taxonomy for describing or classifying handovers, improvement methods or types of outcome. Other fields of study have found this a major handicap to progress and we therefore recommend that attempts are made to harmonise terminology and definitions. This would greatly assist others trying to repeat the work. However, the problem is the great heterogeneity of handover settings and types which exist in healthcare. To develop a taxonomy which can adequately describe all of these is challenging, and arguably to consider them all together as we have done may be inappropriate, depending on the question posed. If an agreed taxonomy existed, it would have helped us to make more sense of the literature by allowing us to identify whether there were subgroups where the literature findings allowed us to hypothesise (and the data available would allow no more than this) that certain intervention types were particularly valuable.

We nevertheless suggest that handovers themselves require a template for describing them which covers setting, personnel, means of information transfer, standardisation of procedure, feedback and summarisation, task allocation and recording. We have used a four-category classification to divide the approaches to improvement reported in the studies we found, but feel further improvements to this could be made. However, for the present we recommend the classification of outcomes into measures of staff satisfaction, information transfer, protocol compliance and clinical outcome. Not only did this deal with all the papers in the current study in a satisfactory manner, but it lends itself readily to analysis of the data using the Kirkpatrick four level evaluation model for training and educational interventions.

**Need for improved study design and reporting standards**

The evidence we found in this review has to be regarded as very unreliable because the studies were of poor design and therefore susceptible to bias from multiple sources. This was reflected in the low scores on the modified D&C scale used. Secular trends may give a false impression of improvement caused by interventions; observers may find it very difficult to avoid bias in assessing subjective endpoints; and short follow-up periods can give an unrealistic impression of impact if they capture a fleeting improvement in performance which quickly fades. The two randomised studies should be less susceptible to bias but their unusual design, the lack of clinically relevant...
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endpoints and the lack of true blinding decrease their internal validity significantly. Generally speaking, the transferability of the studies in this review was also low, as reflected in the scoring using the SQUIRE guidelines.

Limitations
The limitations of our own study were partly a consequence of the problems of the literature we studied. A more comprehensive search not restricted by language, date range or a search of the ‘grey literature’ might have yielded further studies, but it seems unlikely that this would have improved the overall quality or reduced the heterogeneity of the studies. An example of the heterogeneity was the duration of the study periods, which varied by a factor of at least 50 for each component of the study. These two aspects of the literature, heterogeneity and poor quality, were the principal causes of our inability to reach strong conclusions. Our initial hypothesis was very broad, and perhaps we might have achieved more insights into the literature had we focused on a smaller and less heterogeneous subgroup of handover types. Any such restriction would of course have affected the applicability of our findings. We felt it was important to assess the quality of study design and reporting in these studies, since the generally poor level of scientific rigour in these areas is such an important contributor to the difficulty in reaching definitive conclusions from this literature at present. We used modifications of the SQUIRE and DIS checklist to study transferability and validity, respectively. Our modifications were designed to allow evaluation of an enormously heterogeneous and often poorly described group of studies. Several questions in both checklists were not appropriate for evaluation of studies of handover of the types included in our search, either because they were entirely irrelevant or because they were partially irrelevant and attempting to answer them would increase rather than decrease uncertainty in the evaluation of the studies. We recognise that the truncated evaluations we used have not been fully validated, but we feel the logic used in producing them means that they are more likely to be both valid and discriminatory than the use of the full versions of the tools involved. Further work could verify this hypothesis; at present, we have to accept that our quality and transferability assessments should be considered with caution.

Recommendations
We recommend that future studies of handover improvement should use a standardised taxonomy to describe the key aspects of handover, although we recognise that handovers are so heterogeneous that it is unlikely that any individual study will need to record data about every aspect. We include a proposal for a framework on which such a template could be constructed (see online supplementary table S4) and strongly suggest that this is adopted for future study designs.

We strongly recommend that the standards of study design and reporting for handover intervention research are strengthened by adoption of some basic desiderata of clinical research. Researchers should consider using a control group not subject to contamination by the intervention, use standard definitions of terms to describe the handover, measure the intervention and the outcomes, and employ blinded observers or hard objective endpoints, as well as a realistic and specified duration of follow-up. As a consequence of this review, we would recommend that a consensus is reached on a core standardised handover assessment method. This would enable inter-intervention comparison and aid the development of a strong evidence base as to which improvement methods are of benefit. We would recommend that some form of information transfer assessment should be included in this method, but that consideration should be given to including an outcome from each of the four categories we identified. We would also recommend that future interventional trials follow the SQUIRE reporting guidelines which would enable future researchers and clinicians to repeat their findings and the dissemination of improved safety processes between institutions.

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