

I-PASS handover system: a decade of evidence demands action

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In this issue of *BMJ Quality and Safety*, Jorro-Barón and colleagues¹ report the findings of a stepped-wedge cluster randomised trial (SW-CRT) to evaluate the implementation of the I-PASS handover system among six paediatric intensive care units (PICUs) at five Argentinian hospitals between July 2018 and May 2019. According to the authors, prior to the intervention there were complaints that handovers were ‘...lengthy, disorganized, ...participants experienced problems with interruptions, distractions, and ... senior professionals had problems accepting dissent’.

Adverse events were assessed by two independent reviewers using the Global Assessment of Pediatric Patient Safety instrument. Study results demonstrated significantly improved handover compliance in the intervention group, validating Kirkpatrick Level 3 (behavioural change)² effectiveness of the training initiative. Notably, however, on the primary outcome there were no differences between control and intervention groups regarding preventable adverse events per 1000 days of hospitalisation (control 60.4 (37.5–97.4) vs intervention 60.4 (33.2–109.9), $p=0.998$, risk ratio: 1.0 (0.74–1.34)). Regarding balancing measures, there was no observed difference in the ‘full-shift’ handover duration (control 35.7 min (29.6–41.8); intervention 34.7 min (26.5–42.1), $p=0.490$), although more time was spent on individual patient handovers in the intervention period (7.29 min (5.77–8.81); control 5.96 min (4.69–7.23); $p=0.001$). From the provider perspective, preintervention and postintervention Agency for Healthcare Research and Quality (AHRQ) safety culture surveys did not show significant differences in their responses to communication-focused questions before and after the intervention.

Thus, consistent with all previous studies, I-PASS was implemented successfully and handover quality improved. However, is the lack of association of I-PASS implementation with clinical outcomes and adverse events in this study a concern? To answer this question, it is necessary to review the origins of I-PASS more than a decade ago and its continually expanding evidence base.

HEALTHCARE HAS A HANDOVER PROBLEM

Handovers are among the most vulnerable reoccurring processes in healthcare. In the AHRQ safety culture survey,³ the handovers and transitions of care domain is consistently among the lowest scoring, and handover and communication issues are among the most common cause of Joint Commission Sentinel Events and the subject of Joint Commission Sentinel Event Alert Issue 58.⁴ A study by CRICO Strategies found that communication issues were a factor in 30% of 23 658 malpractice claims filed from 2009 to 2013, accounting for \$1.7 billion in incurred losses.⁵ The importance of handovers and care transitions for trainees is specifically discussed in a Clinical Learning Environment Review Issue Brief published by the Accreditation Council for Graduate Medical Education (ACGME),⁶ and Section VI.E.3 (Transitions of Care) of the ACGME Common Program Requirements (Residency) addresses the requirement for residents to be taught and to use structured handovers.⁷

Both the numbers of handovers and handover-related problems have increased in contemporary practice because of greater patient complexity and the expanding number and types of providers involved in a typical patient’s care. Further, in teaching institutions, resident work-hour restrictions have resulted



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in the need for complex coverage schemes. Off-hours care is often provided by ‘cross-covering’, ‘float’ or ‘moonlighting’ practitioners who are responsible for numerous unfamiliar patients during their shifts, thus imposing an even greater need for effective handovers. The net effect of all these changes may be inconsistent, fragmented care resulting from suboptimal handovers from one provider, service or hospital to another, with resulting medical errors (often of omission) and adverse events.

STRUCTURED, STANDARDISED HANDOVERS

These serious vulnerabilities have led to pleas for more consistent, structured and standardised handovers.^{8–11} In addition to their use in routine shift-to-shift provider sign-off, these may be of particular value in the high-risk transfers of critically ill patients, such as from operating rooms to postoperative care units and ICUs^{12–16}; admissions to a surgery unit¹⁷; management of trauma patients^{18–20}; ICU to general ward transfers^{21 22}; night and weekend coverage of large services, many of whose patients are unfamiliar to the physician receiving the handover^{23–28}; and end-of-rotation resident transitions.^{29–31}

Given these considerations, standardised handovers, often involving mnemonic devices, have been widely advocated and studied in the past several decades, though many lack rigorous evaluation and few if any showed demonstrable associations with outcomes.^{32 33} Further, although some individual hospitals, units and services have implemented their own idiosyncratic handover systems, this does not solve the issue of handover inconsistency between different care delivery sites. A basic, common framework that could be customised to individual use cases would clearly be preferable.

THE I-PASS SYSTEM

Responding to these concerns, the I-PASS Study Group was initiated in 2009 and the I-PASS Institute in 2016. Although numerous other systems are available, since its pilot studies a decade ago,^{34 35} I-PASS has emerged as the dominant system in healthcare for structured, standardised handovers. This system is specifically designed for healthcare applications; it is based on adult educational principles and simple to use; it has been extensively validated in the peer-reviewed literature encompassing studies at multiple institutions in the USA and internationally^{34–40}; and extensive training materials are available to assist programmes in implementation.^{39 41–45} Ideally, this system is implemented hospital-wide, which addresses the issue of cross-unit and cross-service transfers.

I-PASS includes five major elements regarded as important for every handover—illness severity, patient summary, action list, situation awareness/contingency planning and synthesis by receiver. The first three of these elements are often included in

non-structured handovers, although not necessarily in a specific sequence or format. The last two I-PASS elements—situational awareness/contingency planning and synthesis—have not historically been included in typical handover practice. The former assures that any anticipated problems are conveyed from the handover giver to the incoming provider and that appropriate responses to these issues are discussed. Synthesis is closed-loop communication, with brief read-back of the handover information by the receiver to assure their accurate comprehension, followed by an opportunity for questions and discussion. This read-back of mission-critical communications is standard operating practice in other high-reliability settings such as aviation, the military and nuclear power. It is essential to establishing a shared mental model of the current state and any potential concerns. However, other than in I-PASS, it is quite uncommon in healthcare, with the potential exception of confirming verbal or telephonic orders.

I-PASS VALIDATION

In an initial study of I-PASS handover implementation by residents on two general inpatient paediatric units at Boston Children’s Hospital,³⁴ written handovers were more comprehensive and had fewer omissions of key data, and mean time spent on verbal handover sessions did not change significantly (32.3 min vs 33.2 min). Medical errors and adverse events were ascertained prospectively by research nurse reviewers and independent physician investigators. Following I-PASS implementation, preventable adverse events decreased from 3.3 (95% CI 1.7 to 4.8) to 1.5 (95% CI 0.51 to 2.4) per 100 admissions ($p=0.04$), and medical error rates decreased significantly from 33.8 per 100 admissions (95% CI 27.3 to 40.3) to 18.3 per 100 admissions (95% CI 14.7 to 21.9; $p<0.001$). A commentary by Horwitz⁴⁶ noted that this was ‘...by far the most comprehensive study of the direct effects of handoff interventions on outcomes within the context of existing work-hour regulations and is the first to demonstrate an associated significant decrease in medical errors on a large scale’, while also noting limitations including its uncontrolled, ‘before and after’ design, confounding by secular changes, Hawthorne effects and inability to blind the nurses collecting adverse event data.

The more expansive, landmark I-PASS study was conducted by Starmer and colleagues³⁷ among nine paediatric hospitals and 10 740 patient admissions between January 2011 and May 2013. Handover quality was evaluated, and medical errors and adverse events were ascertained by active surveillance, including on-site nurse review of medical records, orders, formal incident reports, nursing reports and daily medical error reports from residents. Independent physician investigators classified occurrences as adverse events, near misses or exclusions, and

they subclassified adverse events as preventable or non-preventable. Results revealed a 23% reduction in medical errors from the preintervention to the postintervention period (24.5 vs 18.8 per 100 admissions, $p < 0.001$) and a 30% reduction in preventable adverse events (4.7 vs 3.3 events per 100 admissions, $p < 0.001$). Inclusion of prespecified elements in written and verbal handovers increased significantly, and there was no significant change in handover time per patient (2.4 vs 2.5 min; $p = 0.55$).

Subsequent investigations in other institutions have replicated many of the findings of the original I-PASS studies, with higher postintervention inclusion rates of critical handover elements; fewer mistakes or omissions; greater provider satisfaction with handover organisation and information conveyed; unchanged or shorter handoff times; and decreased handover interruptions (probably reflecting greater attention to the importance of the handover process).^{36 40 47–50} In a mentored implementation study conducted in 2015–2016 among 16 hospitals (five community hospitals, 11 academic centres and multiple specialties), handover quality improved, and there was a provider-reported 27% reduction in adverse events.³⁸ Among nurses at Boston Children's Hospital, I-PASS implementation was associated with significant decreases in handover-related care failures.⁴⁰

In recognition of its achievements in improving healthcare quality, the I-PASS Study Group was awarded the 2016 John M Eisenberg Award for Patient Safety and Quality by the National Quality Forum and the Joint Commission.

THE CHALLENGE OF LINKING HANDOVERS TO CLINICAL OUTCOMES AND EVENTS

Although investigations from many centres, including the report of Jorro-Barrón and colleagues,¹ have now confirmed that I-PASS can be readily assimilated and used by clinicians, most of these have either not rigorously assessed adverse events, medical errors and other clinical outcomes (Kirkpatrick Level 4 evaluation) or have failed to demonstrate significant postintervention improvements in these clinical outcomes. Why is this, and should current or potential I-PASS users be concerned?

With regard to the first question, there are practical considerations that complicate the rigorous study of clinical outcome improvements associated with I-PASS (or any other handover system). Notwithstanding the importance of effective communications, these are only one of many provider processes and hospital systems, not to mention the overall hospital quality and safety culture, that impact a patient's clinical outcome. In most hospitals, a diverse portfolio of quality and safety improvement initiatives are always being conducted. Disentangling and isolating the effects of any one specific intervention, such as I-PASS handovers, is challenging if not impossible. At a minimum, it requires real-time,

prospective monitoring by trained nurse or physician reviewers as in the original I-PASS studies, a research design which realistically is unlikely to be reproduced. Ideally, the study design would also include blinding of the study period (control or intervention) and blinding of observers, the former of which is virtually impossible for this type of intervention.

Further, if other provider processes and hospital systems are functioning at a high level, they may partially offset the impact of suboptimal communications and make it even more challenging to demonstrate significant improvements. The current study of Jorro-Barón and colleagues,¹ which uses PICUs as the unit of analysis, illustrates this concept. PICUs are typically among the most compulsive, detail-oriented units in any hospital, even if they may have nominally 'non-standardized' handovers.

STUDY DESIGN: THE SW-CRT

In an attempt to address the limitations of some previous studies, Parent and colleagues⁵¹ studied eight medical and surgical ICUs across two academic tertiary teaching hospitals using an SW-CRT design. Clinician self-assessment of having been inadequately prepared for their shift because of a poor-quality handoff decreased from 35 of 343 handoffs (10.2%) in the control arm to 53 of 740 handoffs (7.2%) postintervention (OR 0.19; 95% CI 0.03 to 0.74; $p = 0.03$). 'Last-minute', early morning order writing decreased, and handover duration increased but not significantly (+5.5 min; 95% CI 0.34 to 9.39; $p = 0.30$). As in the current study of Jorro-Barón and colleagues,¹ who also employed an SW-CRT, there were no associated changes in clinical outcomes such as ICU length of stay, duration of mechanical ventilation or necessity for reintubation. The authors comment that given high baseline quality of care in these ICUs, it was not surprising that there were no changes in outcomes.

An SW-CRT is generally considered a rigorous study design as it includes cluster randomisation. However, though novel and increasingly popular, this approach is complex and may sometimes add confusion rather than clarity.^{52–57} Its major appeal is that all clusters will at some point, in a random and sequential fashion, transition from control to intervention condition. For an intervention that is perceived by participants as having more potential for good than harm, this may enhance cluster recruitment. It may also make it possible to conduct a randomised study in scenarios where pragmatic considerations, such as the inability to conduct interventions simultaneously across numerous clusters, may make a parallel randomised study (or any study) infeasible.

However, as acknowledged even by its proponents, the added practical and statistical complexity of SW-CRTs often makes them more challenging to properly implement, and compared with traditional parallel cluster randomised trials they may be more prone to biases.^{53–57} A Consolidated Standards of Reporting Trials extension has been specifically developed in response to

these concerns.⁵⁵ Unique design and analytical considerations include the number of clusters, sequences and periods; clusters per sequence; and cluster-period sizes.^{55 56} Concerns include recruitment and selection biases; proper accounting for secular trends in outcomes (ie, because of the sequential rather than simultaneous nature of the SW-CRT design, observations from the intervention condition occur on average at a later calendar time, so that the intervention effect may be confounded by an underlying time trend); accounting for repeated measures on participants and clusters in sample size calculations and analyses (ie, data are not independent); possible time-varying treatment effects; and the potential for within-cluster contamination of observations obtained under the control or intervention condition.^{52–56}

Regarding contamination, a secular trend may be responsible if, for example, institutional activities focused on improving patient outcomes include a general emphasis on communications. There might also be more direct contamination of the intervention among clusters waiting to be crossed over, as described in the context of the *Matching Michigan* programme.⁵⁸ Participating in a trial and awareness of being observed may change the behaviour of participants. For example, in the handover intervention of Jorro-Barón and colleagues,¹ some providers in a control condition cluster may, because they are aware of the interest in handovers, begin to implement more standardised practices before the formal shift to the intervention condition. This potentially dilutes any subsequent impact of the intervention by virtue of what could be considered either a Hawthorne effect or a local secular trend, in either case leading to generally better handovers in the preintervention period. Some SW-CRTs include a transition period without any observations to allow for sufficient time to implement the intervention,^{53 59} thereby creating more contrast. Finally, because of sometimes prolonged PICU length of stay and regularly scheduled resident rotations on and off a unit or service, some patients and providers might overlap the transition from control to intervention state and contribute observations to both, while others will be limited to one or the other. This possibility is not clearly defined by the authors of the current study, but seems unlikely to have had a major statistical effect.

DO WE NEED MORE EVIDENCE?

From an implementation science perspective, handovers are a deeply flawed healthcare process with the demonstrated potential to harm patients. A new tool—I-PASS—has been developed which can be easily and economically taught and subsequently applied by virtually any provider, and many resources are available to assist in implementation.⁴⁵ It has few, if any, unintended negative consequences to patients or providers and has been associated in at least two extensive and well-conducted (although non-randomised) trials with dramatic reductions in medical errors and adverse events. Notably,

these were conducted at a time when there was much less emphasis on and awareness of handover systems, including I-PASS. Thus, there was much greater separation between control and intervention states than would be possible today.

Returning to the question posed at the beginning of this commentary, is the inability to demonstrate a favourable impact on clinical outcomes in studies other than those of the developers^{34 35} a reason to question the value of I-PASS? For the reasons discussed above, I think not. In his classic 2008 article,⁶⁰ ‘The Science of Improvement’, Dr Don Berwick recounts the transformational development of sophisticated statistical analyses in healthcare, of which the randomised clinical trial is the paradigm. While in many instances randomised controlled trials have been invaluable in scientifically affirming or rejecting the utility of specific treatments or interventions, their limitations are more obvious in interventions involving complex social and behavioural change. Berwick illustrates this challenge with the example of hospital rapid response teams, whose benefit was challenged by the results of a large cluster randomised trial. His comments regarding that conflict are equally applicable to the current challenge of demonstrating the impact of standardised handovers on clinical outcomes:

These critics refused to accept as evidence the large, positive, accumulating experience of many hospitals that were adapting rapid response for their own use, such as children’s hospitals. How can accumulating local reports of effectiveness of improvement interventions, such as rapid response systems, be reconciled with contrary findings from formal trials with their own varying imperfections? The reasons for this apparent gap between science and experience lie deep in epistemology. The introduction of rapid response systems in hospitals is a complex, multicomponent intervention—essentially a process of social change. The effectiveness of these systems is sensitive to an array of influences: leadership, changing environments, details of implementation, organizational history, and much more. In such complex terrain, the RCT is an impoverished way to learn. Critics who use it as a truth standard in this context are incorrect.

Having personally observed the value of I-PASS, as well as the devastating consequences of inadequate handovers, I vote with Dr Berwick. The evidence for effectiveness is overwhelming and the need for action is urgent—all that is lacking is the will to implement.

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