Improving Patient Safety through Standardised Handoff in Internal Medicine: protocol for a pre-post quality improvement study in general internal medicine wards to prevent adverse events

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Abstract

INTRODUCTION Medical errors are a serious cause of adverse events and can arise from poor communication between health care professionals. Patient handoffs are one major risk factor for miscommunication, information loss, and thus, resulting in adverse events and patient harm. Standardized handoff has been shown to reduce preventable adverse events in paediatric care units.

METHODS AND ANALYSIS In a pre and post quality improvement study in an general internal medicine wards of a secondary acute care teaching hospital, we will assess the effects of the introduction of an evidence-based package of best practices (the I-PASS-handoff bundle). The I-PASS handoff bundle has been validated in the paediatric setting and has been shown to reduce adverse events due to medical errors through handoffs. The bundle consists of three components: (1) A mnemonic, (2) Communications, teamwork and handoff skills training, and (3) an ongoing process and culture change campaign.

The primary endpoint is the incidence of preventable adverse events. Secondary endpoints will be the overall AE rate and Length of Stay (LOS). Preventable AEs will be subcategorized into diagnostic, and therapeutic AE. We will use surveys, interviews, and monitoring to evaluate team culture and staff satisfaction.

REGISTRATION The study was registered at the ISRCTN registry (ISRCTN49330740).

ETHICS AND DISSEMINATION The local ethics committee has approved a clarification of responsibility and deemed this quality improvement study to not require formal approval. Dissemination plans include delivering events for stakeholders, presenting at conferences and producing articles for open access publications.

1 # Article Summary

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Role of sponsor {5c}	None

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Introduction

Medical errors during inpatient care pose a threat to patient safety and are a serious public health problem (1) A medical error is an act of omission or commission in planning or execution that contributes or could contribute to patient harm and is thus, a preventable adverse event (AE) that requires additional monitoring, treatment or hospitalization (1,2). In-hospital AEs are frequent; a meta-analysis published in 2019 reported an overall AE incidence of 12%, half of which were deemed preventable (3). Recent single-center studies conducted in Swiss hospitals found similar or even greater AE rates (4,5). A recent chart review study from the US confirms high adverse events rates, with little progress being made in the last decades (6). Furthermore, AEs contribute substantially to the cost of healthcare (7), not only by their nature of requiring additional medical resources but also due to malpractice cases (8).

Major contributors to AEs are errors in care management and/or coordination. According to the sentinel event report by the Joint Commission, published in 2021, 46% of errors involve failures in care management (9). Care coordination involves deliberately organizing patient care activities and sharing information among all healthcare providers to achieve more effective care (10) The Institute of Medicine (IOM) identified care coordination as a key strategy to improve the effectiveness, safety, and efficiency of the healthcare system (11) Examples of care coordination approaches include teamwork, establishing accountability and agreeing on responsibility, communication, sharing knowledge, assessing patient preferences, and creating a proactive care plan. Although many care coordination approaches address the transition of patients from a hospital to outpatient care or coordination of care within networks, the same principles apply during inpatient treatment in a continuum of care (12)

The World Health Organisation recommended standardized handoffs to reduce miscommunication (13,14). However, the adoption of such standardized tools and studies on their effectiveness are limited (15,16). The I-PASS-handoff bundle is a validated intervention designed to facilitate and standardise existing handoff procedures to include key items needed to minimise communication errors that was developed in the paediatric setting (17) In a multicentre prospective intervention study a relative reduction of 23% in the overall rate of medical errors and of 30% of pAE was observed (18). Potential mechanisms for the reduction in pAE are reductions of omissions of crucial information during handoff as well as improved teamwork and safety culture (19)

However, as the I-PASS-handoff bundle has been developed in paediatric hospitals, investigations concerning its utility and impact on patient safety outcomes in other disciplines of medicine and internal medicine are scarce (20). A recent multicentre prospective effectiveness implementation study, which included 16 internal medicine clinics, showed a clear reduction in adverse events (21). In this study, the number of AE was based on reports of residents which were not validated further. Furthermore, the study showed that a large-scale introduction of the I-PASS-handoff bundle requires substantial changes to existing processes (22). Hence, objective data concerning the effect of the I-PASS-handoff bundle on patient safety in other settings and countries as well as the feasibility of implementation is still needed.

Objectives

Therefore, the objective of this study is to assess the impact of a pragmatic implementation of the I-PASS-handoff bundle in acute internal medicine wards on patient-relevant outcomes and team culture.

The specific aims are to:

1) improve handoffs and reduce the number of preventable and non-preventable adverse events (AE) related to communication breakdown and inadequate handoffs..
2) evaluate the adherence and acceptance of a standardized handoff among internal medicine residents and assess barriers and facilitators for the implementation and change in culture.
3) improve team culture, communication, and staff satisfaction

We hypothesize that a standardized handoff will not only reduce patient-relevant outcomes but also improve satisfaction, communication, and team culture for residents and other healthcare professionals on the wards. If a standardized handoff can be successfully implemented, we expect a substantial benefit for the patient, staff, and the hospital.

Methods

Design

We will conduct a pre- and post-quality improvement study to assess the impact of the introduction of the I-PASS handoff bundle on patient safety outcomes for three to six months before and after the introduction of the I-PASS handoff bundle, or until the estimated sample size is reached. The implementation phase of the I-PASS handoff bundle started in September 2023 with a 4-month transition period. The study was planned according to the recommendations for before and after studies without control groups (23) and the protocol is written in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Checklist (24).

Trial Registration

The study was registered at the ISRCTN registry (ISRCTN49330740) on March 5th 2024.

Definitions

Several terms and definitions for error, adverse events, and preventable adverse events have been used. In this study, we will use the following definitions:

Medical error was defined as an act of omission or commission in planning or execution that contributes or could contribute to an unintended result (1) The majority of errors do not cause harm (i.e., are silent) but reflect faulty processes. Examples of medical errors are delays or omissions in diagnostic workup or therapy, as well as inappropriate or wrong diagnostic or therapeutic decisions, e.g., prescription errors.

Adverse events (AE) were defined as harm resulting from medical management rather than the underlying disease (1,2,25).

Preventability of adverse events (AE) are defined as AEs that result from medical errors. Preventability itself requires an assessment of the nature of the event and the medical management, which might have caused the event, by experienced clinicians (2).

Study setting

The study will be conducted at and by the team of the Division of General Internal Medicine (IM) of the Cantonal Hospital Baden in Baden (KSB), Switzerland. The KSB provides 24-hour services for a population of 350’000. Although the department has specialists from all fields, including a large oncology and nephrology unit, the leading treatment team for hospitalized patients consists of internal medicine residents and attending physicians. Thus, the Department is responsible for the training of a

substantial number of general internal medicine residents of different levels of experience (first to last year of residency).

Although handoff procedures do not only occur within the department itself but also between different departments (e.g. emergency room, internal medicine wards, intermediate care units, ICU & primary care providers), we mainly focused on handoff procedures within the department of IM, because a wide-scale implementation of a standardised handoff process would have needed resources that were unavailable at the time of the study development.

Current handoff procedures in the department of IM

At any given time, roughly 120 to 135 patients are hospitalized in the department of IM. During a weekday dayshift (i.e. Monday through Friday), one resident cares for 8 to 10 patients, meaning that of the 64 general internal medicine residents, approximately 14 residents work the day shift, together with about 8-12 attending physicians. On weekends (i.e. Saturday and Sunday), three residents and one attending physician care for all hospitalized patients during the dayshift. On late- and nightshifts (Monday through Sunday), one resident provides additional care if necessary, and an attending is on call working at the emergency department (ED).

Residents document the current care plan inside the electronic medical record (EMR). This documentation contains the most vital information, including an updated current and past medical history, as well as an action list guiding care coordination and therapy. All internal medicine residents and attendings, as well as specialists, have access to this care plan. The clarity, content and structure of this care plan varies due to the complexity of the patient and various other factors, including the training level of residents as well as time constraints. This heterogeneity had been previously identified

by resident physicians as an issue regarding effective patient care, as the varying degrees with which handoff had been documented could increase the residents perceived workload due to a necessity to review patient files more thoroughly.

During care transitions (i.e. between shifts), residents provide unstandardised verbal handoff, if deemed necessary. Handoff procedures to residents on the weekends consist of a written handoff of varying content and clarity within the EMR, as well as a verbal handoff of some of the patients during a Friday afternoon report. Handoff between residents in various other instances (e.g. off-days, sick days, planned rotations etc.) is also unstandardised and subject to large variations of its contents and clarity. Handoff between attendings is also unstandardised and subject to perceived necessity.

Intervention

We will introduce the I-PASS-handoff bundle to all physicians working in the department of IM. Current intradepartmental handoff procedures and documentation processes will be standardised and adapted to reflect key components of effective handoff procedures, outlined by the bundle (26).

The bundle, which was developed in paediatric hospitals through an iterative process from 2010 through 2014, consists of three components:

1) IPASS mnemonic for standardized verbal and written handoff communications: **I**llness severity, **P**atient summary, **A**ction list, **S**ituation awareness and contingency planning, and **S**ynthesis by the receiver.
2) Communications, teamwork, and handoff skills training: Didactic workshop, role play, computer module, faculty development program.

3) Ongoing process and culture change campaign led by clinical and administrative facility leadership.

The conceptual model of the IPASS bundle that may be more effective than other standardized handoff approaches is based on closed-loop communication including a synthesis of the receiver (**Error! Reference source not found.**). The receiver confirms the handoff and provides feedback. Report giver and receiver review documentation to supplement the verbal handoff. The active participation of the receiver facilitates a more comprehensive and efficient information transfer. Furthermore, the structured communication and documentation of the patient's illness severity and contingency plans may also play an important role in improving patient safety through anticipatory thinking.

Implementation Timeline

Between July 2022 and January 2023, the study protocol and the implementation procedures have been developed within the research group. Stakeholder interviews with residents have been performed to assess general awareness and motivation for the project. Implementation and training will be guided by the mentored implementation guide (26) designed by the SHM I-PASS Coordinating Council, and adapted to the needs and demands of our clinic (see **Error! Reference source not found.**).

Between February and July 2023, stakeholder dialogue was used to finalize training plans and implementation. Between July and September 2023, an e-learning course was completed by residents and attendings working in the internal medicine wards. Peer assessments and feedback were used to improve procedures and learning material to address previously identified issues concerning training that have been deemed crucial to implementing a standardised handoff protocol (16,27,28).

In September 2023, I-PASS was introduced in all internal medicine wards in a stepwise fashion. This included the following:

- Adoption of the I-PASS mnemonic to structure documentation and handoff processes
- Encouraging residents to communicate vital information such as illness severity and contingency plans clearly and concisely to nursing staff
- Resident training workshop in communication and handoff that reflects vital information contained within the I-PASS mnemonic
- Development of a badge card with the I-PASS mnemonic on one side and a QR-code link to an I-PASS resource site

During a four-month transition period from September through December, unit-level training and monitoring with feedback was conducted. Stakeholder feedback will be used to further improve procedures and satisfaction.

In December 2023, I-PASS went live on all internal medicine wards. New staff starting work after the implementation will be taught individually in smaller groups and given the learning materials, to ensure adherence to the I-PASS-handoff-bundle. Attending physicians as well as individual residents will act as “I-PASS champions” and monitor adherence and provide feedback. After the implementation, a strategy to ensure sustainability will be developed.

Primary and secondary outcomes of interest

The study aims to investigate the following outcomes:

<u>Primary outcome:</u>

- Overall rate of preventable adverse events (pAE)

Secondary outcomes:

- Overall rate of adverse events (AE)
- Length of Stay (LoS)
- Staff satisfaction with a structured handoff process
- Safety culture

Patient Selection and Eligibility

Data from hospitalized patients in the internal medicine wards during the pre and post-intervention period will be included in this analysis. The eligibility criteria are as follows:

Inclusion criteria:

- Age >18 years
- Patients discharged from the department of IM

Exclusion criteria

- Patient admitted to the wards with a purely palliative care plan and death within 24 hours of admission
- Patients who were predominately hospitalised and treated in any surgical unit (>50% of the overall LoS)

We anticipate that completeness of documentation will not be an issue since documentation standards within the clinic are extremely rigorous. Patients who were admitted to a surgical ward, but were subsequently transferred to an internal medicine ward have to be hospitalized in any internal medicine ward for more than 50% of their entire LoS; any event occurring during treatment by the surgical staff will not be considered for further analysis.

Sample size & feasibility

The sample size calculation was based on a study evaluating AEs using the GTT in a comparable setting.(5) The study will be powered to detect a reduction of 30% in the overall number of pAE and is based on the following assumptions: (1) the pAE rate in the department of internal medicine is similar to the pAE rate reported in an academic hospital in Switzerland (5), and (2) the reduction in pAE is similar to the one reported by the I-PASS study group (18) We therefore, estimated that the data of 694 admissions (347 before and 347 after the intervention) are required to have 80% power to detect a 30% reduction in the rate of pAE, assuming a 2-sided α error of .05.

To achieve the estimated sample size we expect that a period of 3-6 months will be sufficient, based on the number of admissions in the year 2022, which totalled 6'411 patients. We will evaluate records from all patients who were hospitalized on given due dates. Due dates will be spaced two weeks apart. To correct for potential seasonal bias, patient records from the preintervention period will be collected exactly one year prior.

Data acquisition

<u>Patient demographics and AE</u>

All data regarding patient information will be gathered through the review of the electronic health record (EHR), anonymized and transferred into a REDCap database. Potential AE will be identified by reviewing the EHR. Identification of AE will be done using the Global Trigger Tool (GTT)(29), a chart review tool developed by the Institute for Healthcare Improvement. The GTT describes how the EHR should be reviewed to identify prespecified triggers, that have varying likelihoods of detecting adverse events (5). Within the GTT handbook, an adverse event is classified as such when it causes harm to the patient; harm is defined as meeting the criteria for the categories E-I

defined by the taxonomy of medical errors by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)(30):

- Category E: temporary harm to the patient and required intervention
- Category F: temporary harm to the patient requiring initial or prolonged hospitalisation
- Category G: permanent patient harm
- Category H: intervention required to sustain life
- Category I: Death

During primary screening, all patient harm (irrespective of the correlation to medical management) will be evaluated and event reports of patient harm will be generated. Based on the nature of the event and the available documentation we will decide whether the event was certainly due to medical management (and therefore an AE), or whether it was due to the underlying condition (and therefore not an AE), or whether it is uncertain. In a secondary screening, event reports with uncertainty about the association with the medical management will be further evaluated. Preventability will be assessed using a four-point scale ranging from 1-4 (very likely unpreventable (1), likely unpreventable (2), likely preventable (3) and very likely preventable (4)). We will assess interrater agreement in a subset of 5% of identified AEs. Preventable AEs are defined as AEs with a score of ≥3 by both reviewers. Disagreement between the ratings will be discussed between the reviewers and resolved with consensus or by third-party mediation (MW or DS).

We will collect information on patient's demographics, type (emergency vs. elective) of hospital admission, the wards patients were treated on, comorbidities based on ICD-10 codes, transfer to intermediate or intensive care units, length of hospital stay, number of different residents responsible for the treatment, and death during

hospitalization. The LoS will be reported in full days and assessed by the dates of admission to and the date of discharge from the internal medicine ward. In addition, we calculated the Charlson and Elixhauser comorbidity indexes, both validated measures to predict mortality in patients with multiple comorbidities.

Adherence and acceptance of a standardized handoff, staff satisfaction and team culture

We will investigate teamwork, culture and staff satisfaction in units using validated instruments. The teamwork scale of the safety attitudes questionnaire has been used in similar studies in Switzerland and seems well suited for the current study (31,32). This will also include an assessment of satisfaction in residents and attendings by anonymized online surveys after the roll-out and at 6 months.

Blinding

The investigators identifying and assessing adverse events were not blinded, as it was not possible to obfuscate the data collection time period.

Analysis plan

We will summarize continuous variables with means, standard deviations and T-scores. Dichotomous variables will be summarized with percentages. Clinical characteristics and outcomes of cases in the pre- and post-implementation period will be compared using the Student's t-test, Wilcoxon rank sum test, or chi-squared test, as appropriate.

We will compare the incidence rates of medical errors and preventable AE and length of stay by using poisson regression models in the pre- and post-intervention group. For the statistical analysis the software application R will be used.

Trial status

At the time of submission, the primary data regarding adverse events has been collected. Interviews with participating resident physicians are pending and data analysis is ongoing.

Patient and Public Involvement

There was no involvement of patients or the public.

Declarations

Ethics approval

According to the Swiss laws on human subject research, Swiss regulations, and according to the ethical committee (Ethikkommission Nordwestschweiz, Req-2023-00501), this quality improvement project was exempt from ethical approval. The study complied with international standards including the declaration of Helsinki and good clinical practice.

Availability of data materials and Consent for publication

Dissemination plans include delivering events for stakeholders, presenting at conferences and producing articles for open access publications. The final dataset will be published in a data repository. All authors have agreed to the publication plan

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Authors contribution & Conflicts of Interest

FB & MW contributed in equal parts to the writing of the rough draft of the manuscript. UH, JR and LA provided expert opinion on statistical methodology and development of

the study procedures. DS provided the scientific rationale and was responsible for supervision and coordination of the manuscript. The authors declare no conflict of interest.

Statement on the use of Artificial Intelligence (AI)

The software Grammarly (v.1.2.165.1647) was used as a spell-check. No further AI software was used in the writing of this manuscript.

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Discussion

Because of various challenges such as regulatory changes, economic pressure, and the COVID-19 pandemic, the continuum of care is threatened by staff shortage, staff fatigue and absenteeism. Physicians increasingly report high burnout scores and being overwhelmed with work which reduced quality of care and thus may potentially result in increased numbers of AE. In Switzerland, a reduction in working hours for residents resulted in shorter individual workdays but also in an increase in daily shifts increasing the number of handoffs between residents. The number of physicians, that are involved in care coordination has been increasing, in part due to an increase in resident and attending physicians working part-time, as well as an increased involvement of various specialists. Care coordination, therefore, encompasses care transition and with it transition of information between various providers on all levels.

During inpatient care, patient handoff is a necessity. Information has to be delivered from one healthcare professional to the next. Insufficient handoff increases the risk of

lost or incomplete information, which may result in an AE through diagnostic or therapeutic delays and errors (33). A systematic review of studies on missed tests in hospitalized patients showed that between 1 and 75% of test results were not followed up with potential detrimental safety implications (34). Further, the main barriers to early detection and timely management of severe sepsis included poorly coordinated handovers and communication breakdowns to address the urgency a septic patient needed.(35) Hence, expanding care teams increase the risk of information loss(27) and therefore the risk of harm, since miscommunication is assessed to be a root cause of a substantial amount of preventable AE (9,18,36).

Therefore, actions to improve care coordination and effective handoff are an important area to improve diagnostic and therapeutic quality and the effectiveness of care in acute medicine wards. Although the World Health Organisation (WHO) suggested as early as 2007 to adopt standardised handoffs to reduce miscommunication (13,14), adoption of such standardized tools and studies on their effectiveness are limited (15,16)

In this quality improvement project, the introduction of a standardized handoff bundle, the I-PASS handoff bundle, will be introduced into acute general internal medicine wards. The I-PASS-handoff bundle is a validated intervention designed to facilitate and standardise existing handoff procedures to include key items needed to minimise communication errors (17). In the paediatric stetting, the bundle has been shown to improve patient safety with a relative reduction of 23% in the overall rate of medical errors and of 30% of pAE (18) Potential mechanisms for the reduction in pAE are reductions of omissions of crucial information during handoff as well as improved teamwork and safety culture (19).

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