Improving patient safety through standardised handoff in internal medicine

Submission date	Recruitment status	Prospectively registered
04/12/2023	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	Statistical analysis plan
05/03/2024	Completed	Results
Last Edited	Condition category	Individual participant data
12/07/2024	Other	Record updated in last year

Plain English summary of protocol

Background and study aims

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.

Therefore, the objective of this study is to assess the impact of a pragmatic implementation of the I-PASS-handoff bundle in an acute internal medicine ward 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

Who can participate?

Internal medicine resident physicians and patients hospitalised on the internal medicine ward.

What does the study involve?

The intervention includes an evidence-based package of best practices (the I-PASS-handoff bundle) created to reduce communication failures during patient handoffs. 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.

All residents working on the internal medicine ward will participate and patient data on adverse events will be collected before and after the implementation of the intervention.

What are the possible benefits and risks of participating?

There is no foreseeable risk to resident physicians. There may be a small risk to patients, since the overal medical treatment can be affected by the intervention, although, we believe not

negatively. There may, however, be a possible benefit to patients from improved information flow and, therefore, a possible reduction in preventable harm. Benefits to resident physicians may be an improved information transfer and safety attitude.

Where is the study run from?
Cantonal Hospital of Baden, Canton Aargau (Switzerland)

When is the study starting and how long is it expected to run for? July 2022 to September 2024

Who is funding the study? Swiss Society of General Internal Medicine (SSGIM)

Who is the main contact? Fabian Brennecke, f.brennecke@gmx.ch

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Improving Patient Safety through Standardised Handoff in Internal Medicine: protocol for a prepost quality improvement study in a general internal medicine ward to prevent adverse events

Acronym

IPASS-IM

Study objectives

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, the staff, and the hospital.

Ethics approval required

Ethics approval not required

Ethics approval(s)

A clarification of responsibility has been submitted to the local ethics committee and the ethics committee has determined that the study does not need prior approval (Req-2023-00501).

Study design

Single-centre interventional pre-post quality improvement study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Improving patient safety

Interventions

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

The intervention applies to resident physicians working at the study site and includes the following:

- 1. An oral presentation on I-PASS and the importance of safe and accurate handover and documentation
- 2. A 30-minute online learning tool aimed at resident physicians explaining the I-PASS mnemonic and each item as well as its implications for daily practice
- 3. Two short 30-minute in-person handover training with a focus on applying the I-PASS mnemonic and the importance of accurate, concise handover
- 4. A pocket card with a QR-Code to access valuable resources for training
- 5. Mandatory application of the I-PASS mnemonic in the daily documentation process
- 6. Focussed weekly to bi-weekly feedback on handover and documentation practices

As the study is designed as a pre-post quality intervention, there will be no prespecified end date of the intervention, as it is planned to be an ongoing quality improvement effort. Accordingly, there is no direct control intervention.

Intervention Type

Behavioural

Primary outcome(s)

Rate of adverse events per 1000 patient days collected using the Global Trigger Tool (GTT), a validated chart review tool to identify triggers frequently associated with adverse events. The electronic health record (EHR) from all patients admitted and discharged from the internal medicine wards, who have previously consented to the use of medical data for scientific purposes, will be screened during a a prespecified period within the pre- and post-implementation phase. Any triggers that have occurred within the time from admission to discharge including a 30-day post-discharge period will be investigated for evidence of adverse events.

Key secondary outcome(s))

- 1. Rate of preventable adverse events per 1000 patient days collected using the Global Trigger Tool (GTT) within the time from admission to discharge including a 30-day post-discharge period
- 2. Overall length of stay (LoS) measured using admission and discharge dates from the EHR at admission and discharge
- 3. Staff satisfaction with a structured handoff process measured using a survey at 2 weeks before the implementation of the pilot phase and 6 months after the pilot phase
- 4. Safety culture measured using the Safety Attitudes Questionnaire at 2 weeks before the implementation of the pilot phase and 6 months after the pilot phase

Completion date

30/09/2024

Eligibility

Key inclusion criteria

- 1. Age >18 years
- 2. Patients discharged from the Department of Internal Medicine

Participant type(s)

Patient, Health professional

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Key exclusion criteria

- 1. Patient admitted to the wards with a purely palliative care plan and death within 24 hours of admission
- 2. Patients who were predominately hospitalised and treated in any surgical unit (>50% of the overall length of stay)
- 3. Patients who do not have a signed general consent form or who have refused their general consent

Date of first enrolment

01/12/2023

Date of final enrolment

31/05/2024

Locations

Countries of recruitment

Switzerland

Study participating centre Kantonsspital Baden

Im Ergel 1 Baden Switzerland 5404

Sponsor information

Organisation

Cantonal Hospital of Baden, Canton Aargau

Funder(s)

Funder type

Research organisation

Funder Name

Swiss Society of General Internal Medicine (SSGIM)

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes