Third evaluation of the National Patient Safety Program in Dutch hospitals: A Safety-II approach using FRAM analysis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22124

Source
NTR

Brief title
TBA

Health condition

Screening frailty for older patients, double checking injectable medication administration and performing medication reconciliation at discharge.

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Ministry of Health, Wellbeing and Sports

Intervention

Outcome measures

Primary outcome

The primary outcomes are:
1. A process evaluation of the different care processes by comparing the Work-as-Done vs.

the Work-As-Imagined according to the FRAM method.
2. A qualitative description of whether the FRAM intervention has provided healthcare professionals with more insight into the different care processes and whether team reflection has stimulated behavioral change among healthcare professionals and substantive changes in the process.
3. A quantitative description of team learning and behavior change by quantifying the proposed and implemented changes of the care process and protocols.

Secondary outcome

The secondary outcomes are:
1. Employee resilience among healthcare professionals and compliance of several Safety Indicators (SIs). Employee resilience will be measured using the EmpRes scale, a nine-item scale.
2. Compliance will be measured by collecting the following SIs:
- Percentage of discharged patients of 18 years and older where medication reconciliation at discharge was performed.
- Percentage of patients of 70 years and older who are screened for frailty.
- Percentage of high-risk medication administrations in which a second check during administration was correctly performed.
3. A process evaluation will be conducted using the COM-B model. One month after a wedge has ended, the contact person of the ward will be interviewed to evaluate the process. These interviews will be analyzed with the help of the 'behaviour change wheel’ and 3 essential conditions of the COM-B model: Capability, Opportunity, Motivation.

Study description

Background summary

Within this research project, we will examine the effect of the Functional Resonance Analysis Method (FRAM) as an intervention to help healthcare professionals gain visual insight into three healthcare processes: screening frailty of older patients, double checking injectable medication administration and performing medication reconciliation at discharge. For each process, we will first map out how the process would ideally be performed (work-as-imagined) based on guidelines. Secondly, we will interview healthcare professionals involved in the process to determine how the processes are done in practice (work-as-done). During a feedback meeting with healthcare professionals from each participating ward, the work-as-done model versus the work-as-imagined model will be discussed. Healthcare professionals will be invited to explore the findings and discuss the causes and implications for their workflow. During this feedback meeting, the main focus will be on organizational learning, rather than (non-)adherence to guidelines. The FRAM intervention aims to help healthcare professionals to gain more insight into the variability in these particular healthcare processes. Nursing wards of internal medicine, surgery, cardiology and orthopedics and ICUs from 19 Dutch hospitals will be included in the study. We will use a stepped wedge design, allowing

all participating wards to eventually be exposed to the intervention. The primary outcomes are 1)an evaluation of the different care processes by comparing the Work-as-Done vs. the Work-As-Imagined, 2) a qualitative description of whether the intervention has provided healthcare professionals with more insight into the healthcare processes and whether team reflection has stimulated behavioral change among healthcare professionals and substantive changes in the process, and 3) a quantitative description of team learning and behavior change by quantifying the proposed and implemented changes of the care process and protocols. The secondary outcomes will provide quantitative insight into the effects of the intervention on daily practice. These outcomes are employee resilience, compliance with several safety indicators (SIs) related to the observed healthcare processes and a process evaluation.

Study objective

By using FRAM, healthcare professionals will gain more insight into the variability of the healthcare processes, which leads to improved compliance with the selected safety indicators.

Study design

A stepped wedge design will be used, meaning that every two months two to three wards per theme will receive the intervention. After ten months, all wards will have received the intervention. Employee resilience will be measured at baseline level and at the end of the data collection period. The safety indicators will be collected every two months in all participating wards.

Intervention

The FRAM intervention includes:
- FRAM interviews with healthcare professionals,
- a feedback meeting with healthcare providers of the participating ward to discuss WAI and WAD,
- an interview with the contact person of each ward to evaluate the implementation process of the FRAM.

Contacts

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Eligibility criteria

Inclusion criteria

All Dutch hospitals are invited to participate in the study. Specific wards are eligible for participation within each theme:
- Frail older patients: internal medicine and surgery wards.
- High-risk medication: ICUs and internal medicine and surgery wards.
- Medication reconciliation: cardiology and orthopedics wards.

Exclusion criteria

Hospitals that are undergoing drastic changes (mergers, implementation electronic health record system, etc.) are not eligible for participation.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2020
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	16-07-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8778
Other	METc VUmc : 2019.571

Study results

Summary results
We aim to publish our results in a peer reviewed journal.