

# What are the effects of internal audits on quality and safety of hospital care?

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON20561

### Source

NTR

### Brief title

APS study = Audit Patient Safety study

### Health condition

Patient safety, hospital, hospital care, effects, internal audits, internal audit system, auditing

## Sponsors and support

**Primary sponsor:** Radboud University Nijmegen Medical Center

**Source(s) of monetary or material Support:** Radboud University Nijmegen Medical Center

## Intervention

## Outcome measures

### Primary outcome

Complications and adverse events.

### Secondary outcome

1. Patient safety culture;
2. Team Climate;
3. Experiences of patients;
4. Standardized Mortality Rate (SMR);
5. Unintended prolonged hospital stay;
6. Learning effects of health care givers and department leaders.

## Study description

### Background summary

We examine the current internal audits of the Radboud University Nijmegen Medical Centre; are they a valid, reliable and responsive diagnostic instrument to analyze the safety of patient care? And we want to know what the results of the internal audits of the Radboud University Nijmegen Medical Centre are on the safety of patient care in (academic) hospitals. We use a mix method approach (quantitative and qualitative research methods) to measure the effects of internal audits on different levels: patient, professional and department level. To measure the effects of internal audits on patient safety in clinical hospital care we use a before-and-after design. The null hypothesis is that there is no difference of patient safety of healthcare between the measurement before and after the internal audit and between departments with and without an internal audit. The alternative hypothesis is that internal audits improve the patient safety of healthcare in the Radboud University Nijmegen Medical Centre. In this study we perform a determinant analysis to correct statistical for potential confounders. And we also perform a process analysis to explain certain (un)expected effects of internal audits.

This study takes place in the Netherlands.

### Study objective

The objective of this thesis is to get insight into the effects of internal audits on patient safety and on health care professional's behavior in an academic hospital at ward level.

### Study design

Primary outcome:

Complications and adverse events in hospital care are measured by structured retrospective patient record review of hospital admissions 3 months before and 15 months after an internal audit.

Secundairy outcomes:

1. The patient safety culture within a team of health care givers is measured by the Dutch Questionnaire COMPaZ 3 months before and 15 months after an internal audit;
2. The team climate is determined by the Team Climate Inventory 3 months before and 15 months after an internal audit;
3. Patients experiences with hospital care are measured with the Consumer Quality Index of Hospital Admission 3 months before, 9 and 15 months after an internal audit;
- 4.+ 5. The SMR and the data of unintended prolonged hospital stay are derived monthly from the hospital registry database and the national medical registration (LMR);
6. The learning effects of health care givers and department leaders are gathered retrospective by in-depth questionnaires and for this study developed questionnaires.

## **Intervention**

Internal audits.

## **Contacts**

### **Public**

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## **Eligibility criteria**

## Inclusion criteria

The included departments of the Radboud University Nijmegen Medical Centre are:

1. Comprehensive and thus recognizable for other hospitals;
2. Delivering clinical care with basic risks for patient safety;
3. Will be audited between October 2011 and February 2013.

## Exclusion criteria

In this study we exclude the following criteria:

1. The eight 'sub audits' perform by experts (Medication Safety, Hygiene and Infection prevention, ARBO and milieu, Medical Devices, Sterile Medical Aids, Patient-centered, Education and Scientific Research);
2. Departments which facilitating healthcare processes to clinical and outdoor patients, for example Radiotherapy, Operating Rooms and Laboratory Medicine;
3. The safety of outpatients.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-08-2011
Enrollment:	800

Type: Anticipated

## Ethics review

Positive opinion

Date: 12-03-2012

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	NL3192
NTR-old	NTR3343
Other	METC Radboud University Nijmegen Medical Centre : 2011/278
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A