A multicenter before-after study on reducing unnecessary diagnostics through attitude change of the caregivers – The study protocol for the RODEO project

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Abstract

Background Appropriate use of diagnostic laboratory tests is challenging. Estimates of 20% for overutilization and 45% for underutilization have been reported. Introducing effective and sustainable solutions to stimulate optimal use of laboratory testing in clinical practice is a challenge. A recent pilot study from our group, focusing on increasing awareness of appropriate laboratory testing with the aim of changing the mindset of the health care workers, has shown promising results. In the current project we aim to extend this multistep intervention in the departments of Internal Medicine of four large Dutch hospitals. We aim to reduce unnecessary laboratory testing by 5%.

Objectives Our primary objective is to determine the effect of our intervention on diagnostic laboratory test order volume. Our secondary objectives are to determine the effect of our intervention on laboratory expenditure, order volumes and expenditures for other diagnostic modalities and clinical patient outcomes. We will also analyze the barriers and facilitators for implementation of the interventions.

Methods The main interventions of this before and after study will be intensified supervision of residents by experienced physicians regarding test ordering, creating awareness through education and monthly feedback on ordering patterns and changes in (computerized) order entry systems.

Conclusion and discussion In this project we aim to reduce unnecessary diagnostic testing in the Internal Medicine department of four teaching hospitals. Although the main interventions will be similar, each clinic is given the opportunity to place focus on specific facets of the interventions as deemed useful according to the local situation. If effective the study provides a framework for a nationwide initiative for reducing inappropriate laboratory testing.

Keywords: Diagnostic laboratory test; Diagnostic testing; Healthcare quality improvement; Implementation

Word count: 265
Introduction

Over the past decades, a marked rise in healthcare expenses has been observed in Western countries. In the Netherlands, the burden of healthcare on the gross domestic product has increased from 7.9% in 1998 to 10.5% in 2016, corresponding to an increase from approximately 30.9 to 73.7 billion euros. Large part of the total healthcare expenditure consists of hospital care, including diagnostic testing [1, 2]. Volume and consequently costs of performed diagnostic tests are increasing, with earlier studies reporting a doubling rate every five to ten years over the past decades [3].

In 2015, Kobewka et al. [4] reviewed numerous international studies concluding that a considerable proportion of performed (laboratory) tests were unnecessary, i.e. not contributing to patient care. A review addressing the appropriateness of diagnostic laboratory testing, as judged by presence of multiple appropriateness criteria (for example criteria based on testing frequency, choice of test compared to possible alternatives and probability of an abnormal test result), has reported a mean rate of overutilization of approximately one fifth from 1997 to 2012 [5]. Consequently, laboratory testing is often targeted in efforts to reduce healthcare expenditure. Besides the financial impact, overutilization increases the number of false positive results which leads to more, sometimes invasive and potentially harmful tests [6]. Also, excessive blood draw can result in iatrogenic anemia and can lead to less patient friendly practice, for example through painful punctures and unnecessary trips to the hospital [7].

In 2009 a set of multifaceted interventions aimed at reducing test volume and costs was implemented at the Internal Medicine department of the VU university medical center (VUmc). Although these interventions focused mainly on laboratory test reduction, utilization of other diagnostic tools declined too, resulting in a 13% gross reduction in diagnostic expenditure compared to the previous year, thereby saving 350 000 euros. When extrapolating these results, nationwide implementation of these interventions could result in a potential saving of millions of euros, without compromising patient safety.

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In the ‘Reduction of unnecessary diagnostics through attitude change of the caregivers’ (RODEO) project, we will assess the effects of a multifaceted intervention aimed at improving
awareness about (in)appropriate laboratory testing, on the volume and costs of diagnostic testing and clinical outcomes of patients in the Internal Medicine departments of multiple peripheral teaching hospitals during six months. We aim to reduce (unnecessary) diagnostic testing by 5%. Our primary focus will be on laboratory testing, although we will also assess the effects of our intervention on amount and costs of other diagnostics modalities. In addition, we will also assess the sustainability of the interventions during an additional eight month period. We will also analyze the process of implementation of the intervention in the participating hospitals aiming to identify barriers and facilitators of implementation.

This project is a part of the “To do or not to do? Reducing low-value care” program aiming to reduce low value care [8]. The program is initiated by the Dutch Federation of University Medical Centers.
Methods

Study design and setting
This multi-center before-after study will be carried out at the Internal Medicine departments (inpatient, outpatient and emergency department) of Meander Medical Center (Amersfoort), Noordwest Ziekenhuisgroep (Alkmaar and Den Helder), Zaans Medical Center (Zaandam) and Spaarne Gasthuis (Haarlem and Hoofddorp), all teaching hospitals in the Netherlands.

Access to timely data on volume and costs of different diagnostic modalities (laboratory, radiology, microbiology, pathology and nuclear medicine) for the duration of the project and for the three preceding years was a criterion for inclusion. Another criterion for inclusion was consent by the Board of Directors of participating hospitals. Primary approval was obtained by the medical ethical committee of the VU University Medical Center. Subsequently, local approval from the Board of Directors was obtained in participating centers.

De-implementation strategy
The study will consist of three time periods: three to four months pre-intervention, six months intervention and eight months post-intervention.

The study will start at the Internal Medicine department of the Meander Medical Center, Noordwest Ziekenhuisgroep and Zaans Medical Center. After three months, the Internal Medicine department of the Spaarne Gasthuis will start the study. The study will start in August / September 2016 and we expect to finish the study in April 2018.

Before the start of the pre-intervention period, the Internal Medicine department of the participating hospitals will be contacted and informed about the project. Upon inclusion of a department, cooperation agreements will be signed by the principle investigator of the hospital and thereafter a project team consisting of a senior internist (ambassador), internal medicine resident, a business intelligence collaborator and a clinical chemist will be formed.

Pre-intervention period (3-4 months)
During the pre-intervention period, data on volume and costs of diagnostics and on patient outcomes from the previous three years will be collected. Also, data on characteristics of the participating departments such as the numbers and years of experience of residents and supervising physicians, methods and frequency of supervision of residents and characteristics of ordering systems will be collected. The pre-intervention period will start in August or September 2016 at Meander Medical Center, Noordwest Ziekenhuisgroep and Zaans Medical Center and 3 months later at the Spaarne Gasthuis.

Intervention period (6 months)
At the start of the intervention period, a launching conference will take place with all participating departments to further discuss the project, targets and possible measures to reach these targets. We will also assess possible barriers and facilitators for de-implementation.

Upon starting the intervention period, data collected in the pre-intervention period and planned interventions will be presented by each participating department. The main
interventions will be intensified supervision of residents by senior physicians regarding test ordering, creating awareness through education, posters, pocket-cards containing test prices and feedback of ordering patterns and modification in (computerized) order entry systems. The coordinating project team and the local project teams will have monthly meetings to discuss the progress of the interventions, changes in ordering patterns, etc.

Targets for interventions will be determined by the project team from different angles: tests that are known to be frequently overused, tests ordered in high frequency or generating high costs to the department and diagnosis-related groups (DRGs) occurring in high frequency or generating high costs (compared to the benchmark when available).

Each hospital will be given the opportunity to focus on specific facets of the intervention as deemed useful in the local situation, thus ‘tailoring’ their interventions. Examples of activities used are educational sessions on frequently overused tests, revision of standard order panels on laboratory request forms, implementation of time limits for specific laboratory orders, sharing of knowledge between disciplines, pocket-cards listing charges for commonly used tests, revision of guidelines for DRGs deviating negatively from the benchmark, periodic reminders through email, etc.

During the intervention period a conference will be organized in which the project teams will present their results from the first months, exchange experiences and ideas on how to proceed in the remaining months of the project and discuss how to sustain the effects after the active intervention period has been terminated.

The intervention period will start in November or December 2016 at Meander Medical Center, Noordwest Ziekenhuisgroep and Zaans Medical Center and 3 months later at the Spaarne Gasthuis.

Post-intervention period (8 months)
In the post-intervention period the sustainability of the intervention will be analyzed. During this period, a conference will be organized in which the project teams will be asked to present their results and exchange experiences and ideas on how to further sustain the achieved effects. Data on diagnostic volume and costs and patient outcomes will be re-analyzed.

The post-intervention period will start in May or June 2017 at Meander Medical Center, Noordwest Ziekenhuisgroep and Zaans Medical Center and 3 months later at the Spaarne Gasthuis. We expect the post-intervention period to end in December 2017 or January 2018 at Meander Medical Center, Noordwest Ziekenhuisgroep and Zaans Medical Center and in April 2018 at the Spaarne Gasthuis.

Endpoints and data collection
In the RODEO project we aim to reduce the amount (unnecessary) diagnostic laboratory testing. Based on previous experience of our pilot study we decided to aim for a conservative estimate of 5% reduction in total test volume.

Primary endpoint
The primary endpoint is diagnostic laboratory test order volume in the Internal Medicine department (inpatient, outpatient and emergency).

Laboratory test order volume will be assessed as total number of orders for laboratory tests and will be corrected for patient census using ‘weighted patient units’, a measure that will be calculated using the numbers of admissions, in hospital admission days, day care admissions, and number of first outpatient consultations [9, 10]. Order volume and data required for calculation of the number of weighted patient units will be acquired through the Department of Business Intelligence and/or the Department of Clinical Chemistry.

Secondary endpoints
Secondary endpoints are laboratory expenditure, order volumes and expenditure for other diagnostic modalities and clinical patient outcomes.

Laboratory expenditure will be assessed as total expenditure and corrected for patient census. Order volumes and expenditure (if possible) for other diagnostic modalities (radiology, microbiology, pathology and nuclear medicine separately) will be assessed as total number of orders and will also be corrected for patient census.

To ensure a reduction in diagnostic testing does not affect patient outcomes we will take into account clinical patient outcomes before and after the intervention: duration of hospital stay, 30-day readmission rate, rate of repeated outpatient visits relative to first outpatient visits and HbA1c.

Expenditure, order volumes, data required for calculation of the number of weighted patient units and data on clinical outcomes will be acquired through the Department of Business Intelligence and/or the Department of Clinical Chemistry.

Evaluation of barriers and facilitators
An important part of the RODEO project is evaluating barriers and facilitators of implementation of the interventions. To identify these factors, questionnaires (appendix 1) on these topics will be held with each project team during the (pre)intervention period. During the remainder of the project these factors will be discussed during multiple conferences.

Statistical analysis
All statistical analysis will be performed using SPSS Statistics (IBM, USA).

We will assess the volume of diagnostic tests ordered (total volume and volume of laboratory, radiology, microbiology, pathology and nuclear medicine tests separately) during the year after the start of the intervention (i.e. intervention period and post-intervention period) and the preceding years.

We will adjust for patient census by using ‘weighted patient units’, which will be calculated using the following formula:
(10 x number of admissions) + (0.5 x number of patient days) + (3.5 x number of day admissions) + (1.2 x number of first outpatient consultations)

An interrupted time series analysis will be performed to assess the effects of the intervention on test volume. We will use an autoregressive integrated moving average (ARIMA) model to analyze whether the intervention led to a (more profound) change in the number of tests per weighted patient unit after the intervention. We will adjust for seasonal variation.
Discussion

In this protocol we describe the objective, design, de-implementation strategy and endpoints of the RODEO project, aiming to reduce unnecessary diagnostic testing in the Internal Medicine department of 4 large teaching hospitals in the Netherlands.

The approach we will use in our project is derived from an approach previously used in a pilot project within different departments of the VU University Medical Center (VUmc). [1] In this project a senior physician was designated as ‘ambassador’ or ‘local champion’ and was responsible for coordination and implementation of the interventions at the participating department, which consisted mainly of intensified supervision, education and feedback. During this pilot project no modifications were made in the (computerized) order entry system. Although commitment of a supervisor has shown to play a crucial role for the success of the project, the VUmc project identified a prominent role for residents as one of the key success factors. Furthermore, the VUmc study team found the Clinical Chemistry department to play an important role in the pilot project. Therefore, we will appoint a central project team at each participating department consisting of an Internal Medicine supervisor and a resident, a clinical chemist and a collaborator from the department of Business Intelligence.

Although the main interventions will be intensified supervision, creating awareness through education and feedback and changes in (computerized) order entry systems, each hospital will be given the opportunity to place focus on specific facets of the intervention as deemed useful in the local situation. Each clinic thus has the opportunity to ‘tailor’ their intervention as they see fit, which can be considered a strength of our approach. Another strength of our project is the inclusion of 4 relatively large teaching hospitals with 6 locations. A potential limitation of our approach is the non-existence of a control group. Also, it is not possible to determine the effect of individual aspects of this multistep intervention due to the limited time available for this project. Also, we did not include patients in our efforts to reduce laboratory testing.

We expect the study period to end in April 2018. If effective this study provides a framework for a nationwide initiative for reducing inappropriate laboratory testing.
Declarations

Authors’ contribution
RSB, MVB, PWBN and MTB designed the project and drafted the protocol. Funding application was arranged by RSB, MVB, PWBN, MTB, WvS and MK.

Funding statement
This work was supported by the Netherlands Organization for Health Research and Development (ZonMW), grant number 80-83920-98-400. This body has no role in the design of the study and collection, analysis and interpretation of data.

Competing interests
The authors declare that they have no competing interests.

Ethics approval and consent
The project protocol was assessed by the Medical Ethics Review Committee of VU University Medical Center. They determined that the Medical Research Involving Human Subjects Act does not apply to this project and that an official approval by the Medical Ethics Review Committee is not required. Local feasibility is approved by the local ethics committees and Board of Directors in all participating hospitals. Data will be collected anonymously.

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Further acknowledgements:
References
8. Netherlands Federation of University Medical Centers. Doen of Laten? February 8, 2018; Available from: https://www.doenoflaten.nl/.