ISRCTN45427977 https://doi.org/10.1186/ISRCTN45427977

Laboratory tests order communication system optimization: a randomised controlled trial

Submission date 15/04/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/05/2014	**Overall study status** Completed	
Last Edited 22/02/2017	**Condition category** Other	

Plain English summary of protocol

Background and study aims
When inefficiently designed software is combined with a non-evidence based medical practice, the result can be disastrous, leading to patient harm, significant impact to quality of life and damage to the health system due to unnecessary costs. The aim of this study is to compare the effects of modifying the electronic health record ordering communication system, by changing the basic shortcut menu and adding a clinical decision support system.

Who can participate
All the doctors working in the Western Oporto Group of Health Centers (except the Health Center where the researchers work).

What does the study involve
This study involved a modification of tests ordering system software. Doctors are randomly allocated to one of two groups: group 1 (system as it is now) or group 2 (a modified version of the electronic health record ordering communication system).

What are the possible benefits and risks of participating?
For group 1 participants, benefits include the use of a more complete software solution with a decision support tool and the risk is the difficulty to adapt to a new version of the system.

Where is the study run from?
Western Oporto Group of Health Centers (Portugal)

When is the study starting and how long is it expected to run for?
January 2012 to September 2012

Who is funding the study?
Astrazeneca Portugal Foundation's 2010 program for support of research

Who is the main contact?
Dr Carlos Martins

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of order communication system optimization in the prescription of unnecessary laboratory tests: a randomised controlled trial

Study objectives
Will the optimization of the ordering communication system, by changing a shortcut menu and adding a clinical decision support system based on the integration of the United States Preventive Services Task Force recommendations, improve the profile of laboratory tests prescription and reduce the prescription of unnecessary laboratory tests?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern Regional Health Administration Medical Ethics Committee, 17/06/2011, ref: 56/201

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Laboratory tests prescription

Interventions
The control group continued to use the usual version of the EHR software (SAM). The intervention group used a modified version of the software (SAM modified) installed in each server. The modification of the SAM consisted of two principal changes:

1. Basic shortcut menu changes, including changes to the composition of the basic menu set of diagnostic laboratory tests, with withdrawals (uric acid, serum protein electrophoresis, sedimentation rate, and electrocardiogram and lung X-ray tests) and additions (HDL cholesterol, faecal occult blood test, triglycerides, Pap smear and mammography tests)
2. Addition of an evidence-based decision support

We added traffic light based coloured dots according to the USPSTF recommendations, and an additional information box containing the summary of the USPSTF recommendation and a link to the integral recommendation at the USPSTF website.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary outcomes were chosen to assess the impact of our intervention in the number of diagnostic and laboratory tests prescribed by physicians including four different perspectives:

1. Impact on the number of the prescriptions of diagnostic and laboratory tests that were withdrawn from the basic menu
2. Impact on the number of the prescriptions of diagnostic and laboratory tests that were added to the basic menu
3. Impact on the number of the prescriptions of diagnostic and laboratory tests that were marked with green dots (USPSTF recommendations grade A and B)
4. Impact on the number of prescriptions of diagnostic and laboratory tests that were marked with red dots (USPSTF recommendations grade D)

Prospective monthly monitoring and data collection occurred until 31/01/2013. To allow a pre-post analysis in both groups, a retrospective monthly data collection of both control and intervention groups was also performed between 01/12/2011 and 31/05/2012.

Secondary outcome measures
1. Monthly number of family physicians prescribing
2. Monthly number of face-to-face consultations made
3. Monthly number of each diagnostic
4. Laboratory test prescribed

Prospective monthly monitoring and data collection occurred until 31/01/2013. To allow a pre-post analysis in both groups, a retrospective monthly data collection of both control and intervention groups was also performed between 01/12/2011 and 31/05/2012.

Overall study start date
01/01/2012

Completion date
30/09/2012

Eligibility

Key inclusion criteria
All family physicians working and prescribing diagnostic and laboratory tests in the Western Oporto group of health centers (except those where the authors worked)

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
9 computer servers, 14 health centers, 117 family physicians

Key exclusion criteria
Family physicians working in the same health center as the researchers

Date of first enrolment
01/01/2012

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
Portugal

Study participating centre
Faculdade de Medicina da Universidade do Porto
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Sponsor information

Organisation
AstraZeneca HealthCare Foundation (Portugal)

Sponsor details
AstraZeneca Produtos Farmacêuticos, Lda
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Sponsor type
Charity

ROR
https://ror.org/05mt63e64

Funder(s)

Funder type
Charity

Funder Name
AstraZeneca HealthCare Foundation (Portugal)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/02/2017		Yes	No