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Correct venous blood specimen collection for increased patient safety

Submission date
05/04/2013

Recruitment status
No longer recruiting

Registration date
30/04/2013

Overall study status
Completed

Last Edited
30/04/2013

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Venous blood specimen collection (VBSC) is one of the most common procedures within health care and errors in VBSC increase the risk of patient harm. VBSC is a practical task and has to be performed by evidence-based guidelines. A number of studies suggest that most of the errors within laboratory testing including VBSC are linked to the pre-analytical phase i.e. before the sample is analyzed in the laboratory. The preanalytical phase includes for example patient preparation, patient identification, test request management, test tube labeling, specimen collection, specimen handling, and information search. Common pre-analytical errors include mistakes in patient identification, test-request management, test-tube labeling, time of patient rest, time of venous stasis, sample handling, and information search. Examples of consequences of pre-analytical errors are missed or delayed diagnosis, delay in care, and unnecessary work of time. Within Sweden the National Board of Health and Welfare in 2008 stated that 11.9% of all avoidably injuries were caused by diagnostic errors and of that 8.3% caused default or delayed diagnosis. Haemolysis, a common reason for specimen rejection and renewed sampling, is also most often caused by pre-analytical errors. In Sweden the general performance of VBSC is described in an instruction manual for health care staff. The methods for VBSC can vary and change over time, therefore educational programs within this area is important as well as increased knowledge about information search procedures to ensure patient safety and reduce risk due to VBSC errors. The demand for an educational intervention program arose after our reports of sub-standard VBSC guideline adherence earlier 2007. So, an educational program focused on VBSC was implemented in a County Council of North Sweden. No study, as far as we know, has performed or evaluated VBSC interventions. Haemolysis index as well as questionnaire could assess the effect of an intervention and identify near misses within the preanalytical phase. Thereby it is possible to evaluate interventions and compare the performance by PHCs, departments and down to the individual level.

In summary, this study will increase knowledge and gain future insights for performing VBSC interventions. Such knowledge will hopefully improve patient safety for example by decreasing the delay of diagnosis. Hopefully, this studies also will stimulate the use of HI and questionnaire instruments for evaluation of preanalytical practices. To be able to evaluate interventions will increase the opportunity to reform and develop more effective interventions and thereby improve VBSC and reduce costs.

Aims

The overall aim of this thesis is to develop instruments and to evaluate an educational-program in venous blood specimen collection practices.
The specific aims for each study are;
1) To test a recently developed questionnaire on self-reported venous blood sampling practices for validity and reliability
2) To monitor the percentage of haemolysed venous blood specimens of 11 primary health cares (PHCs) before and after the large-scale intervention to assess possible improvements of VBSC practices.
3) To evaluate the impact of a short but large-scale educational intervention program on phlebotomists' adherence to VBSC guidelines.

Who can participate?
Primary health care phlebotomists participating in the survey 2007.

What does the study involve?
Two groups were created. One group underwent the VBSC educational intervention program including compulsory studies before education, attendance at two oral lectures and participants responded to six randomly chosen examination questions. The other group worked under normal circumstances. After the educational intervention the quality of blood samples was assessed by haemolysis index. Six month after the educational intervention the self-reported questionnaire answers was assessed.

What are the possible benefits and risks of participating?
Benefits for the participants are increased knowledge of VBSC, personnel get attention and a daily practice lift as important, all participants get the same information.
No risks recognized.

Where is the study run from?
Primary health care centres in Västerbottens and Västernorrlands County Council, Sweden.

When is the study starting and how long is it expected to run for?
The study started in January 2007 and ran until December 2011.

Who is funding the study?
Västerbottens County Council, ALF Funding for research, development and education.

What is the main contact?
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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
Impact of a short large-scale educational intervention program on venous blood specimen collection practices

Study objectives
Our hypothesis was that an educational intervention program would improve phlebotomists' venous blood specimen collection performance and increase their adherence to guidelines.

Further reading:
Follow up study: Bölenius K, Söderberg J, Hultdin J, Lindkvist M, Brulin C, Grankvist K: Minor improvement of venous blood specimen collection practices in primary health care after a large-scale educational intervention. Clinical Chemistry and Laboratory Medicine 2013, 51:303-310.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board, Department of Medical Research, Umeå, Sweden. Date approval: 15/08/2006

Study design
Follow-up (haemolysis index) and an intervention-study (controlled evaluation), both with a before-after approach

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Venous blood specimen collection practices

Interventions
The demand for an educational intervention program arose after our reports of sub-standard venous blood specimen collection guideline adherence. The Västerbotten County Council executive board therefore gave permission for an educaional intervention program comprising all venous blood specimen collection personnel, provided it would be cheap and have minor interference with daily healthcare work (n=2171). Given these restricted premises, laboratory instructors with experience of teaching developed a large-scale educational intervention program regarding pre-analytical practices including a specific lecture of venous blood specimen collection guideline practices. The focus was on implementation of venous blood specimen collection guidelines (according to the National handbook for healthcare almost identical to the CLSI H3-A6 guidelines) and local directives. During the lecture, emphasis was put on how to avoid haemolysis as well. The large-scale educational intervention program included three parts: 1) compulsory studies of the national venous blood specimen collection guidelines before education: 2) compulsory attendance at two oral lectures: 3) participants were to respond adequately to six written examination questions (randomly chosen from a bank with 24 questions) addressing education content. One of the two lectures included information of local pre-analytical errors, general VBSC practices, patient identification procedures, information search procedures, and practices important to avoid haemolysis. The second lecture addressed collection of microbiological specimens. Eight to 89 VBSC personnel participated in each lecture session. One-third of the IG (n=27) participated through live internet link. All participants passing the examination received a competency certificate valid for four years.

The total duration was in total 3 hours for the individual phlebotomist.

The control group answered the questionnaire at the first opportunity 2007 and then worked after normal routine. The control group responded to their follow-up at the same time as the first from the intervention group responded to its questionnaire.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The validated venous blood specimen collection questionnaire including questions about background characteristics, patient identification, specimen collection, sample storage, information search procedures, test request management, and test-tube labelling.

Secondary outcome measures

Low-level haemolysis. Haemolysis reflects a blood specimen quality and is used in a follow-up study.

Overall study start date
01/01/2007

Completion date
01/07/2011

Eligibility

Key inclusion criteria
Inclusion criteria for both groups were set to phlebotomists working at PHCs and having answered questionnaire in 2007.
Intervention group: Male and female, age range 28-65
Control group: age range 38-70

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Intervention group (n=84), Control group (n=79)

Key exclusion criteria
Questions and items with missing answers were excluded from the analysis

Date of first enrolment
01/01/2007

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
Sweden

Study participating centre
Medical Biosciences, Clinical Chemistry
Umeå
Sweden
901 87

Sponsor information

Organisation
Umeå University (Sweden)

Sponsor details
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Sponsor type
University/education

Website
http://www.umu.se

ROR
https://ror.org/05kb8h459

Funder(s)

Funder type
Government

Funder Name
Västerbottens County Council, Umeå (Sweden) - Research and education

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