Title of the study: The effect of evidence-based order sets within a CPOE (computerized physician order entry) system on the quantity and quality of laboratory test ordering in family practice: a cluster randomized trial

Funding: Federal Health Care Knowledge Centre (KCE), Administratief Centrum Botanique (Doorbuilding), Boulevard du Jardin Botanique 55, B-1000 Brussel

Research facility: Academic Center For Primary Care, KU Leuven, Kapucijnenvooer 33, Blok J – Bus 7001, 3000 Leuven

Ethics committee: *EC Onderzoek UZ / KU Leuven*

I Necessary information for your decision to participate

Introduction

You are being invited to take part in a comparative clinical study. With this study we want to investigate the influence a computerized system, designed to avoid unnecessary laboratory tests, on the laboratory test orders by physicians. This means that the laboratory test order you have been offered was either prescribed in the usual manner, in accordance with the conditions of good medical practice or through this computerized system. This systems is designed to improve care, however this does not mean that physicians not using this intervention offer bad care.

We are simply asking you whether we can collect data from your medical records to be able to combine them with those of other patients receiving the same treatment and to process them statistically for research purposes.

Apart from a few questionnaires we may ask you to complete, no additional diagnostic or monitoring procedure will be proposed.

Before you agree to take part in this study, we invite you to take note of its implications in terms of organisation, possible risks and benefits, to allow you to make a decision with full awareness of the implications. This is known as giving "informed consent".

Please read these few pages of information carefully and ask any questions you want to the investigator or his/her representative.

There are 3 parts to this document: the information essential to your decision, your written consent and supplementary information (appendices) detailing certain aspects of the basic information.

If you take part in this study, you should be aware that:

- The treatment offered to you by the investigator in accordance with current recommendations will not be altered if you take part in the study.
- This clinical study is being conducted after having been reviewed by an ethics committees.
- Your participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. Even after having signed this document, you can stop taking part by informing the investigator.
- The data collected on this occasion are confidential and your anonymity is guaranteed during publication of the results.
- Insurance has been taken out in case you should suffer any damage in connection with your participation in this clinical study.
- You may contact the investigator or a member of his/her team at any time should you need any additional information.

Further information about your "Rights as a participant in a clinical study" can be found in section III.

Objectives and course of the study

This clinical study has been organised to study the effects of a computerized system on the laboratory test ordering by general physicians.

We are inviting you to take part in this clinical study because your doctor has ordered laboratory tests for you within the context of your clinical situation.

This clinical study is to include around 300 general practitioners (GPs) and 12 600 patients in Belgium.

Your participation in the study will last around 9 months, during which we will ask your doctor to send us information related to your treatment, to the progression of your clinical situation, the results of the ordered laboratory tests, and the results of additional tests which may have been ordered.

It is possible that you will be contacted by an independent researcher to complete a telephone questionnaire. In this case, a report form will be generated by the software system in which your identity will be made known to the independent researcher who will be taking the interview. Once all the data has been entered in to the report form, they will be coded. The research facility will not know your identity at any moment.

Description of risks and benefits

As indicated above, neither the treatment that has been proposed or the diagnostic and monitoring procedures for your clinical situation go beyond good medical practice. No risk, in terms of health, can be linked to your participation in this study.

Similarly, you should not expect any personal benefits as a result of taking part in the study. Know only that your participation will allow us to better understand the influence of a clinical decision support service on the laboratory orders by your physician and thus to offer better treatments in the future.

Withdrawal of consent

Your participation is voluntary and you are entitled to withdraw your consent to take part in the study for any reason, without having to justify your decision.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which you withdraw will be retained. No new data may be sent to the sponsor.

If you take part in this study, we ask you:

- To cooperate fully in the smooth running of this study.
- Not to conceal anything such as information relating to your state of health, the medication you are taking or the symptoms you are experiencing.
- To inform your doctor if you are asked to take part in another study to discuss with him/her the possibility of taking part in this study and to see whether you should then stop taking part in the present study.
- To accept the possible need for investigator/GP contact for the gathering of additional information if appropriate

Contact

If you need further information, but also if you have problems or concerns, you can contact the investigator (Delvaux Nicolas) or a member of his/her research team (De Burghgrave Tine) on the following telephone number (016/37 72 76).

If you have any questions relating to your rights as a participant in a clinical study, you can contact the patient rights ombudsman[a] of UZ / KU Leuven.

II Informed consent

Participant

I declare that I have been informed of the nature of the study, its purpose, its duration, the possible side effects and what is expected of me. I have taken note of the information document and the appendices to this document.

I have had sufficient time to think about it and discuss it with a person of my choice (GP, relative).

I have had the opportunity to ask any questions that came to mind and have obtained a favourable response to my questions.

I understand that data about me will be collected throughout my participation in this study and that the investigator and the sponsor of the study will guarantee the confidentiality of these data.

I agree to my personal data being processed as described in the section dealing with confidentiality guarantees (page x/y). I also consent to these data being transferred to and processed in countries other than Belgium.

I agree to the research data collected for the purposes of this study being processed at a later date provided this processing is limited to the context of the present study (better understanding of the disease and its treatment).

I agree to my GP or other specialists in charge of my health being contacted if required to obtain additional information about my health.

I have received a copy of the information to the participant and the informed consent form.

Surname, first name, date and signature of the volunteer

_____

Witness/Interpreter

I was present during the entire process of informing the patient and I confirm that the information on the objectives and procedures of the study was adequately provided, that the participant (or his/her legal representative) apparently understood the study and that consent to participate in the study was freely given.

Surname, first name and qualification of the witness/interpreter:

Date and signature of the witness/interpreter.

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Collaborating GP

I, the undersigned, _____ GP, confirm that I have verbally provided the necessary information about the study and have given the participant a copy of the information document.

I confirm that no pressure was applied to persuade the patient to agree to take part in the study and that I am willing to answer any additional questions if required.

I confirm that I operate in accordance with the ethical principles set out in the latest version of the "Helsinki Declaration", the "Good Clinical Practices" and the Belgian Law of 7 May 2004 related to experiments on humans.

Surname, first name, date and signature of the investigator's representative

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Surname, first name, date and signature of the investigator

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III Supplementary information

Supplementary information on the organisation of the study

The study will not require any additional contacts with investigators. All the data will be collected through your GP, your medical record and the laboratory. It is possible that you will be contacted by phone at the end of the trial about 1 year from now. This research assistant will conduct a telephone interview on your current medical situation and any additional investigations that were performed after the laboratory test that was taken today. Finally, it is possible that additional coded information will be requested from other institutions such as RIZIV-INAMI or the Intermutualistisch College regarding care you received and its cost.

Supplementary information on the protection and rights of the participant in a clinical study

Ethics Committee

This study has been reviewed by the ethics committee of UZ / KU Leuven, which has issued a favourable opinion. It is the task of the Ethics Committees to protect people who take part in a clinical trial. They make sure that your rights as a patient and as a participant in a clinical study are respected, that based on current knowledge, the study is scientifically relevant and ethical.

You should not under any circumstances take the favourable opinion of the ethics committee as an incentive to take part in this study.

Voluntary participation

Before signing, do not hesitate to ask any questions you feel are appropriate. Take the time to discuss matters with a trusted person if you so wish.

Your participation in the study is voluntary and must remain free of any coercion: this means that you have the right not to take part in the study or to withdraw without giving a reason, even if you previously agreed to take part. Your decision will not affect your relationship with the investigator or the quality of your future therapeutic care.

If you agree to take part in this study, you will sign the informed consent form. The investigator will also sign this form to confirm that he/she has provided you with the necessary information about the study. You will receive a copy of the form.

Costs associated with your participation

The sponsor has arranged to compensate the hospital for the time devoted to the study by the investigator and his/her team. You will not receive any compensation for your participation in this study. Furthermore, the study will not involve any additional costs for you.

Guarantee of confidentiality

Your participation in the study means that you agree to the investigator collecting data about you and to the study sponsor using these data for research purposes and in connection with scientific and medical publications.

You are entitled to ask the research facility what data are being collected about you and what is their use in connection with the study. This data concerns your current clinical situation but also some of your background, the results of examinations carried out within the context of care of your health in accordance with current standards. You have the right to inspect these data and correct them if they are incorrect[b].

This means that he/she undertakes not only never to reveal your name in the context of a publication or conference but also that he/she will encode your data before sending them to the manager of the database of collected data. The Scientific Institute for Public Health (WIV-ISP) is responsible for guaranteeing the safety and security of your data. When sending your medical data to the WIV-ISP, your identity is anonymised using a complicated encryption. Your identity can be made known again if additional information is necessary, but the research team will never know your name. If you are contacted by phone for additional information, this will be done by an independent person who is bound by professional secrecy and who will have no further access to your medical data after the interview.

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b These rights are guaranteed by the Law of 8 December 1992 on the protection of privacy in relation to the processing of personal data and by the Law of 22 August 2002 on patient rights.

Your GP will be the only one to be able to establish a link between the data transmitted throughout the study and your medical records[c].

The personal data transmitted will not contain any combination of elements that might despite everything allow you to be identified[d].

For the study data manager designated by the sponsor, the data transmitted will not allow you to be identified. The latter is responsible for collecting the data gathered by all investigators taking part in the study, processing them and protecting them in accordance with the requirements of the Belgian law on the protection of privacy.

To verify the quality of the study, it is possible that your medical records will be examined by third parties (ethics committee, representatives of the study sponsor, external auditors). In any event, this may only take place under the responsibility of the investigator or of one of his/her colleagues and by persons subject to the obligation of professional secrecy.

These (encoded) data will be able to be sent to Belgian or other regulatory authorities, to the relevant ethics committees, to other doctors and/or to organisations working in collaboration with the sponsor.

They will also be able to be sent to other sites of the sponsor in Belgium and in other countries where the standards in terms of the protection of personal data may be different or less stringent[e].

Your consent to take part in this study therefore also implies your consent to the use of your encoded medical data for the purposes described in this information form and to their transmission to the aforementioned people and authorities.

The sponsor undertakes only to use the data collected within the context of the study in which you are taking part.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which you withdraw will be retained. No new data may be sent to the sponsor.

Insurance

In an observational study, the only possible risk would be a flaw in the measures taken to protect the confidentiality of the private information about you. Even without fault, the sponsor accepts responsibility for damage caused to the participant (or his/her dependants) and linked directly or indirectly to participation in this study. In this context, the sponsor has taken out an insurance contract (Amlin Europe NV, through mediation of Vanbreda Risks & Benefits NV, contract number 299.053.700, contact details: Vanbreda Risk & Benefits NV, Plantin en Moretuslei 297, 2140 Antwerp, tel +32 3 217 6767)[f].

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[c] For clinical studies, the law requires this link with your records to be retained for 20 years.

d The database containing the results of the study will therefore not contain any combination of elements such as your initials, your gender and your full date of birth (dd/mm/yyyy).

e The sponsor then undertakes to respect the constraints of the European Directive and the Belgian legislation on the protection of privacy.

[f] In accordance with Article 29 of the Belgian Law related to experiments on humans (7 May 2004)