Information sheet:
PATIENT Medical Notes Review & Quality of Life Questionnaire

We are inviting you to take part in a research project called: Electronic Risk Assessment for Cancer (ERICA) led by Professor Willie Hamilton at the University of Exeter Medical School.

Please read this information to help you decide if you would like to take part in the study.

What is this research about?
The UK is not as good as other countries in diagnosing cancer early. A team led by researchers at the University of Exeter has developed new electronic risk assessment tools (otherwise known as eRATs) to help GPs identify possible cancer. The eRATs sit in GP's computer system; they go off when a patient reports a symptom with at least a 2% chance of a possible cancer. This means that the eRATs alert GPs to patients who may be at a very low risk. However, an eRAT prompt doesn't necessarily mean that the GP is concerned that a patient actually has cancer. It simply alerts the GP to think about the possibility. The GP will use their clinical knowledge to decide the best course of action for the patient. We are studying how good eRATs are in helping GPs to catch cancer sooner. In the ERICA study some GP surgeries will have the eRATs installed on their computer system; other GP surgeries won't.

We are contacting you because at a recent visit to your GP you reported some symptoms which either triggered an eRAT or would have triggered an eRAT if they were being used in your GP surgery. It is important to note that the symptoms you reported are likely to be explained by an illness other than cancer. Because you are receiving this letter does not mean that you have cancer.

As researchers, we do not know why you went to see your GP, or know how your GP has chosen to manage your care. If your GP has access to eRATs we do not know how much they used the tool. So, it is important for the research for us to learn about the care you may be receiving and how this is affecting your quality of life.

More specifically like to know two things:

1) How eRATs affect use of GP or hospital services. For example, do patients from a GP surgery that have eRATs see their GP more or have more tests and investigations than patients from practices that do not use eRATs?

2) How patient's quality of life changes after they have been to see their GP and reported symptoms that caused the eRATs to fire.

What does taking part involve?

So that we can answer the questions above we would like to ask your permission to: 1) review your medical records or 2) review your medical records and send you a short questionnaire at two points in time. You do not have to agree to either of these activities. If you would like to agree to just one of the activities then that is fine as well.

If you agree to the research team looking at your medical records, we will go to your GP surgery in a few weeks' time and look at the NHS services you have used over a two month period. We will start looking from the point you visited your GP and reported symptoms that either caused (or would have caused) the eRAT to fire.

If you agree to complete the questionnaires, we will send them to you in the post along with a pre-paid envelope for you to return them to the research team free of charge. You can complete the questionnaires in your own time. The first questionnaire will focus on your quality of life and ask you 5 questions. It should take you less than 5 minutes to complete. The second questionnaire, sent to you by post three months after the first, will contain the same quality of life questions and a few additional questions asking if you have used any more specialised NHS services. It should take you less than 10 minutes to complete.

Do I have to take part?

No. Participation is entirely voluntary. If you do take part in the study you will be asked to sign a consent form. On the consent form you will be able to agree to either having your medical notes reviewed, or having your medical notes reviewed and completing the questionnaires. You are always free to withdraw at any time. You do not have to give a reason for withdrawing. If you do withdraw any information that you have already given will remain part of the study.

What are the benefits or advantages of taking part?

Although you would not receive any money for taking part, participating in research like this helps to improve future patient care. This research is exploring whether the eRATs are effective in catching cancers earlier, and therefore may potentially save lives. By taking part in this research you will help us to understand whether the eRATs are a useful tool, how they might impact on patients' quality of life, and how they might impact the NHS services that individuals go on to use.

What are the risks or disadvantages of taking part?
You will be asked to give up about 15 minutes of your time in total. We do not envisage any serious risks in taking part in the study. However, given the subject matter, we recognise that some emotions may arise and you may have some concerns about possible cancer. If you are concerned about your health our research team can provide contact information for the patient advice and liaison service (PALS). You should also feel free to contact your GP to discuss any health concerns that you have.

What if there is a problem?
If you are unhappy about any aspect of the study then please contact the researcher or trial manager (details given below) who will address your issues. You can also contact Ms Pam Baxter at Exeter University who specialises in making sure that research studies are run appropriately. Pam's contact details are:

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Will my participation be kept confidential?
Yes. Only researchers within the ERICA trial and selected staff at your GP surgery (e.g., your GP and a staff manager) will know of your participation in the study. Any data collected will be anonymised. Personal data will be stored securely at the University of Exeter Medical School where only members of the ERICA research team will have access to identifiable data.

For the purposes of this study we will also use consent to protect your confidentiality and provide you with choice in your participation. All information collected in this study will be kept strictly confidential and stored either on an encrypted password protected computer, or in a locked cabinet at the University, which can only be accessed by the researcher (and research supervisors). You will be allocated a unique participant number, which will ensure the information from your medical notes/questionnaire responses will be protected and cannot be identified by anyone else. Any personally identifiable information will be stored separately and securely from information obtained from the research.

How will my data be used?
Your responses to our questions will be used to inform the main study question: how useful are risk assessment tools in the clinical setting and what is the impact on the NHS? Your anonymous answers to questionnaires and any NHS services you have used will be analysed along with lots of other patients. We will report findings for groups of patients. No individual level data will be reported. The group level data will be used for educational purposes, in research reports, research presentations or for publication.

Access to personal data will be restricted to the ERICA research team. Names and participant details will not be passed to any third parties and no named individuals will be included in the write up of the results.

What will happen to my data after the study?
We will retain your questionnaire data and/or notes review data for the purposes of future research or for educational purposes. Within the next five years, your anonymised data may be made available to third parties for research purposes only – providing those parties have received approvals from an independent ethical review committee. Your personal identifying data will be kept for 5 years under secure conditions on University of Exeter servers. Data will be collected and retained in accordance with the UK Data Protection Act 2018, and managed in accordance with the trial-specific standard operating procedure for data management.

You will be allocated a unique study ID or pseudonym and the information linking your ID to your personal information (i.e. your notes review data and your questionnaire data) will be kept separately and securely at the University of Exeter.

How will the results of the research study be used?
Once the study is complete, the results will be written up and published in scientific journals and presented at national and international academic conferences. If you would like a copy of any publication or a summary of the results, please let the researcher know.

Note on data processing
Due to recent regulatory changes in the way that data is processed (General Data Protection Regulation 2018 and the Data Protection Act 2018) the University of Exeter's lawful basis to process personal data for the purposes of carrying out research is termed as a 'task in the public interest'. The University will endeavour to be transparent about its processing of your personal data and this information sheet

should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection. If you have any concerns about how the data is controlled and managed for this study then you can contact Pam Baxter, Senior Research Governance Officer, whose details are above.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Ethical approval and review

This project has been granted ethical approval by London – City & East Research Ethics Committee (REC Ref: 19/LO/0615).

The Patient Advice and Liaison Service (PALS). For your nearest PALS service please contact either your GP surgery for details or access them via this link: *https://www.nhs.uk/Service-Search/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363*

Thank you for reading this information

If you would like to take part or have any further questions, please contact:

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