

Frequently Asked Questions

March 2013

1. What is a Cancer Decision Support Tool?

Cancer Decision Support (CDS) tools are an aid to clinical decision-making, to assist GPs in their decisions about whether or not to refer or request further diagnostic investigation, in patients where they believe there is a risk of cancer. The tools in this project display the risk of a patient having a specific type of cancer; founded on analysis of an historic population cohort and their risk of having cancer based on a range of factors including symptoms, medical history and demographic data.

2. What is the Cancer Decision Support Tools project?

The plan is to support GPs in using an electronic cancer decision support tool based on two risk calculators for cancer: the Risk Assessment Tool (RAT), developed by Professor Willie Hamilton and QCancer developed by Professor Julia Hippisley-Cox.

Macmillan is coordinating a first phase from March 2013 for six months, which will aim to test these cancer decision support tools in clinical practice and address any issues. This will ensure the development of valuable cancer decision support tools in electronic form, with firm evidence for their impact, and ensure they work across primary and secondary care as valid and defensible reasons for referral. Cancer Research UK has been asked to coordinate the evaluation of this project.

The tool will focus in phase one on lung, colorectal, pancreatic, oesophago-gastric, and ovarian cancers. Macmillan's GP advisor community feel that these are the cancers which most lend themselves to such a tool, and which would most benefit patients who are diagnosed earlier.

3. Who is involved in the project?

Macmillan is leading this project, which supports, the wider National Awareness and Early Diagnosis Initiative (NAEDI). This helps ensure alignment with other projects to promote earlier diagnosis of cancer, including the Department of Health's (DH) cancer awareness campaigns. Cancer Research UK, who are responsible for coordinating the evaluation of some of the NAEDI initiatives this year, are working to define the evaluation metrics and data collection methods for this project. The project has funding and oversight from the DH. Regionally, the project will be supported by your Cancer Network, who will co-ordinate recruitment of Practices and develop a local approach to training based on the core training documents and videos produced by Macmillan.

4. Why are we undertaking this project?

England has relatively poor survival rates for cancer which has been linked to more advanced stage at diagnosis and to delays occurring between the onset of symptoms and the start of treatment. Later diagnosis may be due to late presentation, delays within primary care or delays following referral to secondary care services. An average GP will see seven or eight new cases of cancer (excluding non-melanoma skin cancer) each year but will see hundreds, or possibly, thousands, of patients with symptoms that could possibly be due to

cancer. Cancer decision support tools have been developed to help GPs identify the one patient with cancer among the many who do not.

5. How does the cancer decision support tool work?

The tool runs alongside the electronic system that runs at your practice. We have worked with developers to ensure that the tool can be installed and used in conjunction with all current IT providers. There are three functions to the tool: *The symptom checker; the prompt* and the *population risk stratification* function.

The symptom checker allows the GP to record a patient's additional and/or repeat symptoms during the consultation. For this to work, the GP must already think that the person in front of them has symptoms that raise some concerns of cancer, and want to use the tool as an aid to clinical judgement in deciding a course of action. The symptom checker uses symptomatic read codes to calculate a % risk score for that patient based on the symptoms they are presenting with as well as taking into consideration relevant read coded data and demography for the previous 12 months.

The prompt function part of the tool calculates a patient's risk score by accessing demographic information about the patient via their patient record, relevant tests and read-coded symptomatic information from the previous 12 months to calculate a risk score in the form of a pop up prompt when the patient's record is accessed. If a risk of over 2% is calculated for any of the 5 tumour sites we are piloting, a prompt will appear in the top right of the screen. If there is a risk of over 2% for more than one tumour site then all relevant values will be displayed, sorted high to low. This function is useful for GPs in consultation where perhaps the likelihood of cancer is not immediately apparent for example where a patient has seen a number of different GPs, or the symptoms displayed are rather non-specific. In order for the tool to drive the prompt function the patient must have relevant read-coded data within their patient record.

The Population risk stratification function allows the practice to see a list of patients for whom a risk has been calculated. It can be sorted by risk so that, for example, the practice manager could see the patients for whom the risks appear highest based on the information recorded in the clinical record.

6. How should the cancer decision support tool be used?

The tool can be used as a reminder to GPs to consider the likelihood of an individual patient having specific types of cancer. The tool is used to support the GP in considering whether further investigations or referral would be appropriate. It is an aid to clinical decision-making.

7. What do the risk values in the tool mean?

The risk values in the tool are the proportion of those people within the original study population with the listed characteristics and/or symptoms who have that cancer type.

8. Will using the cancer decision support tool raise patient anxiety of the probability of having cancer?

These tools are designed only as an aid for GPs and GPs will be expected to exercise their own judgement about how they use these tools in the consultation setting. However, some GPs have reported that a discussion about the level of

risk can be useful as part of the consultation with patients about their symptoms. However people have different perceptions of risk and for some it may increase their anxiety. Other NAEDI activities are helping us understand patient and public views of cancer and the implications for awareness and early diagnosis.

9. What is the role of practice managers in this project?

Practice managers will have a brief role at the outset of the project, in order that the software can be loaded remotely onto the Practice's computers. They might also be involved in providing a small amount of initial information on the Practice and its GPs, such as the GP IT system used, the list size, and number of GPs.

10. What does the tool actually look like?

This project will use an IT-based tool which is integrated into your everyday GP IT system. The tool has three facets: firstly, the tool calculates a risk of having a specific type of cancer for every patient seen in consultation. If the risk is above a certain level, a prompt will appear on screen letting the GP know that the patient might warrant a referral or investigation for a suspected cancer. Secondly, a symptom checker can be called up, which allows the GP to enter relevant symptoms, and calculate a risk. Thirdly, a risk stratification function can be used which will show calculated risk levels of all registered patients on a Practice's list.

Participating GPs are encouraged to use all of these facets during the project. It is intended that the tool will be immediately useful in practice, and not too time-consuming or burdensome.

11. Why is the project focused on an IT solution?

This project focuses on an IT-based solution, because feedback from GPs suggested that this would be a useful way in which they could access a CDS tool. We are building in functionality for a greater number of tumour sites, which lends itself to an IT solution. This approach also allows us to draw on the historic READ-coded records held within a GP IT system, enhancing the power of the tool.

12. Will I be able to use a desk based tool?

We do not want to stop GPs from using anything they already find effective. However, for the benefit of this evaluation, if your Practice falls within one of the pilot sites then only the IT version will be made available to you by your cancer network during 2012/13. This is to ensure that during the 6 month testing phase the evaluation is as robust as possible. If you are already using a desk based tool then we would encourage you to adopt the IT solution but this will be your decision.

13. Won't I find the prompts intrusive?

Feedback from our previous pilot of an IT-based tool suggested that there is a balance to be struck in determining the threshold at which prompts appear, and whether certain cases should be excluded from the prompt function. During this project we have the chance to make amendments, based on feedback. As well as initial careful consideration of how best to approach prompts for each tumour site, we will during the project, if necessary, adjust the level at which prompts appear to ensure they are useful and appropriate.

14. Will the tool work on my GP IT system?

We have agreed to build this tool during the testing phase, on BMJ Informatica software. Any GP Practice which holds a BMJ Informatica licence will see the CDS tool built into their existing software. Almost all other GP Practices will also be able to participate, as we have secured agreement with the major native GP IT providers that they will host the CDS tool as a software add-on. The add-on will start up automatically when you turn on your computer, and will run unobtrusively in the background.

15. Will the population risk stratification function be able to include specific high risk population groups?

The population risk stratification function allows users to sort by column. This will include columns for those identified as having high, medium and low risk values as calculated by the CDS tool. At this stage the columns do not reflect more nuanced information on the identification of high risk population groups. However, development of this software is an iterative process, and this is something that could be added at a later stage.

16. What national discussions have been held with secondary care regarding the potential for increased levels of referral and diagnostic activity?

It is hard to tell what impact the CDS tool will have on levels of referral and diagnostic activity, indeed this is one of the things we seek to measure as part of the project. Our best guide in this currently is the previous desk-based RAT pilot. Evaluation of this pilot found that a total of 2593 RATs (1160 lung, 1433 colorectal) were completed. Compared with the preceding 6 months, there were 292 more chest X-rays, 104 extra 2-week chest clinic appointments, and 47 additional diagnoses of lung cancer. For suspected colorectal cancer, there were 304 more 2-week referrals, 270 more colonoscopies, and 10 more cancers identified. RATs appeared to help GPs in their selection of patients for cancer investigation. Users reported that RATs helped to confirm a need for investigation as well as allowing reassurance when investigation was not needed.

The evaluation of the current project will be interested in the use of diagnostics, and referral rates. It's clear that if the tool is to be successful it needs buy-in from secondary care, with that in mind the Department of Health will be writing to secondary care providers endorsing the project and asking for co-operation. Clinical and project leads from each of the participating cancer networks will also want to consider how they have these discussions locally.

17. How will data be captured for evaluation?

CR- UK is coordinating the evaluation of this project. This will consist of a quantitative and qualitative element. Evaluation is an important component of this project, with the findings informing any future roll-out of the cancer decision support tools. We therefore very much value the input of participating GPs, though this will be kept to a minimum.

The intention is to draw wherever possible on standard routinely collected datasets, particularly in terms of measuring impact on investigations and referrals. In addition, functionality is being built into the tool to provide pseudo-anonymised data on use of the tools throughout the project. These data will be used to inform quantitative evaluation, and mean that we can collect data for evaluation without asking for direct input from participating GPs.

There will be a small number of specific questions for participating GPs to complete at the time of using the CDS tool, so we can gain insight into how GPs are using the tools and how they affect decision-making. Some qualitative information will be collected to further explore how the tools are used in practice and how they might be improved. In order to do this a small sample of participating GPs will be asked to volunteer some additional time to take part in a telephone interview lasting less than an hour.

18. What does signing up to capturing pseudo-anonymised data mean for GPs?

In terms of active engagement and additional workload, signing up to data capture will not have an impact on participating GPs. What GPs are agreeing to, is that they are happy for certain of their demographic characteristics such as gender and length of practice, to be captured in an aggregated, pseudo-anonymised form and used as part of our evaluation. One of the areas of focus for the evaluation is determining how these tools are accepted into practice, who uses them and how. These data will be invaluable in enhancing our understanding in this area.

19. What data will you collect as part of the evaluation?

We are still finalising our evaluation approach. At this point, we're proposing to collect for each patient an anonymised readout of their date of presentation, age, sex, signs/symptoms, and risk score. In addition, we want to collect some information about the GP (collected once, at the beginning), as well as GP responses about whether the score was higher/lower/the same as they had thought, how they were managing the patient, and whether they would have referred/investigated if they hadn't used the tool (collected through a small on-screen tickbox, completion of which each time will be optional though strongly encouraged).

20. How do these tools relate to NICE referral guidelines?

These tools are designed to pick up those 'low risk but not no risk' patients who sometimes fall outside the parameters of existing NICE guidance. Some secondary care buy-in to the tool is necessary, as per FAQ 15.

21. What evidence already exists for the use of cancer decision support tools in primary care?

This work builds on previous pilots of cancer decision support tools; such as the NCAT-led desk-based lung and colorectal tool, and Macmillan's IT-based lung and colorectal tool. Learning from the evaluation¹ of these pilots is being used to inform the way in which this project is being approached. The project itself is accompanied by a comprehensive evaluation, which will enable us to further build the evidence base for the use of these tools.

22. Has the project been ethically approved?

As this project can be defined as "Service Evaluation" according to National Research ethics definitions, ethics approval is not required. Ethical approval will

¹ A summary of the evaluation of the NCAT pilot can be found here: <http://ncat.nhs.uk/sites/default/files/RAT%20pilot%20final%20report.pdf>. A summary of the evaluation of the Macmillan pilot can be found here: http://www.macmillan.org.uk/Aboutus/Healthprofessionals/Primary_care_cancer_leads/Resources.aspx.

be sought if required from the research organisation undertaking qualitative interviews as part of the evaluation.

23. Is the CDS tool compatible with Phoenix System One?

The tool has been designed to work with all GP systems including System One. The version 3 Read code database has been integrated into the tool thus allowing the CDS to run perfectly normally without any interference.

24. What is process for the tool to be installed at a Practice?

You will be given a phone number to call BMJ Informatica. Within that call they will ask a few questions so when the installation process begins it will quick and simple. BMJ will need to know:

- What date they can remotely install the tool.
- Who can assist BMJ with the installation? (This involves being at the chosen work station and reading a code to BMJ so they can remotely install the tool).
- If the PCT has locked down the surgery then they will need to be informed previous to the install date to allow BMJ Informatica access to the site.
- A list of users who require the tool and access to their machine.

25. Does the installation affect the Practice?

The remote installation does not affect the Practice in any way. The installation can also be done anytime throughout the day in accordance to the Practice wishes.

26. What happens if the Practice changes their GP IT system?

This is solved very easily. All the Practice need to do is call BMJ Informatica and they will remotely change the tool with no affect to the surgery.

27. Do all members of the Practice need to have the tool installed?

Only the staff members that require the tool will have it installed on their workstation or user account.

28. Can anyone in the Practice use the tool?

This pilot is focussing on evaluating the usability and functionality of the tool from the perspective of GPs. We ask that during the pilot, only GPs use the tool. This is so that we can effectively compare and contrast the data that we collect as part of the evaluation. Depending on the recommendations of the pilot (post August 2013) we would hope to roll out the tool more widely and would anticipate that other practice team members would also be able to use the tool within consultations (e.g. Practice Nurses).

29. How long will training take to complete?

The way that training is delivered by networks will vary. Some will use protected learning time or plenary events, others will engage with individual practices either in person or on the 'phone.

Macmillan will develop a range of written and video-based training materials for cancer networks to use with their local practices. Time taken to undertake training will depend on the method of delivery used by the network. GPs will need to commit between one and two hours as a general guide.

Training materials will also be available online at the Macmillan website for the duration of the project, and Macmillan will run a webcast session to enable those GPs who couldn't make network training to access facilitated online training.

30. What will the training cover?

Training will cover three main areas of focus:

- i. General information about cancer decision support tools, how they work and how GPs should use them in practice.
- ii. Background information on the RAT and QCancer, how they were developed and how they calculate scores.
- iii. Detailed walk through of the IT, for each of the three ways in which the tool works.

31. Why are we concentrating on these tumour sites?

The decision to focus on these five tumour sites was taken by Macmillan's GP Advisor team; as the sites which would most benefit from early diagnosis, that are challenging for GPs to deal with in terms of symptomatic presentation, that are mostly not currently a focus for established NHS Screening programmes, and that offer the greatest chance of earlier diagnosis for the largest number of patients.

32. What happens after phase one of this project?

After phase one and its evaluation, if the findings are favourable these tools will be rolled out in a wholesale manner. If further controlled refinement and testing is needed, then Macmillan will lead on this work.

Macmillan is taking steps so that, if tools are to be rolled out wholesale, they will be available on a number of native IT providers as well as continuing to be available as part of the BMJ Informatica iCAP software.

33. Will I be able to use both QCancer and RAT?

Following much discussion, the Clinical Reference Group has agreed that each practice will be exposed to one algorithm for the six month duration of the project. This will be organised on a Cancer Network/CCG basis, with participating areas allocated to one of two groups. Practices falling within one group will be exposed to one algorithm, and practices in the other group to the other algorithm.

The allocation of the Networks/CCGs to the two groups has taken into account local health profile data and numbers of practices recruited per area, to achieve a reasonable balance between the two.

34. Will GPs/practices know which algorithm they are being exposed to?

Yes, this information will be provided in the training. The algorithm the score derives from will also be clear at the time the tool is used.

35. Why have practices been allocated on a Network/CCG rather than practice level?

If budget and resource permit, there is an intention to use data held centrally in the Cancer Waiting Times database to look at any impact on urgent referrals for suspected cancer and conversion and detection rates, to complement the data collected at the time the tools are used. This will be much easier if all involved practices within one Network are exposed to the same algorithm.

36. Why will practices only be exposed to one algorithm for the six month duration of the project?

There are a number of things which have been taken into account when arriving at this decision. In terms of implementation, it is easier if practices are exposed to scores from one algorithm for the duration of the project, rather than switching them half way through.

From an evaluation point of view, previous work has suggested that use of the tools may decay over time. If tools are switched half way through the project, it may not be possible to properly assess this process and see it play out in practice. Part of the evaluation is also interested in how the tools have been used in practice, any barriers to use, and how they may be improved, with data collected through qualitative interviews at the end of the project. It will be difficult to know which feedback relates to which tool if GPs have been exposed to both.

37. What are the medico-legal implications of using this tool? Is the % risk score entered in the patient record?

This tool is intended as an aid to clinical decision-making, to reinforce and inform clinical opinion. GPs are not compelled to act on the basis of the scores displayed, but are merely able to consider the score, if useful, in deciding a course of action for a patient. All of the information that is driving the risk calculations is already present in the patient's notes. Previous pilots of both desk-based and IT based RATs have not led to medico-legal issues.

Risk scores for patients are not entered into the patient record at any point; the only amendment that is made to patient records is if symptoms have been entered when using the symptom checker then a READ code for this symptom can be added to the patient's notes.

38. What proof is there of the tools' efficacy?

Both QCancer and RAT have a weight of evidence behind them. Peer-reviewed articles on RAT have appeared in a range of publications including the British Medical Journal, and the British Journal of Cancer. Peer-reviewed articles on QCancer have appeared in a range of publications including the British Journal of General Practice, the British Medical Journal, the British Journal of Cancer, and the European Journal of Cancer Care.

39. At what % risk level will prompts appear?

Both RAT and QCancer can calculate % risk scores from below 1% to a high level of probability. However, one of the main things we've learned from our previous pilot of an electronic version of the RAT, is that it's important to set prompts at the right level to be effective for clinicians to use. Too low, and an element of 'prompt fatigue' can creep in, too high and the aim of a tool designed to identify patients at 'low risk but not no risk' becomes compromised.

Our clinical reference group, which brings together opinion from a range of tool developers, academic GPs and Macmillan GP Advisors, has agreed that risks of 2% and over will generate a prompt. For each tumour site we will consider whether particular patient groups should have defined prompt thresholds or exclusions. For example, in our previous pilot we found we needed to consider

how best to handle the patient cohort with COPD within the prompt facility for lung cancer.

40. What safeguards to BMJ/Informatica have in place with regard Information Governance?

All Informatica software is developed in compliance with the NHS standard ISB 0129. Clinicians are involved in reviewing software (including audits) to ensure risks are minimised and a panel of GP beta testers also test software prior to release to practices. For further information please see **Appendix A**.

41. Will the tool run in real time on the GP IT system?

Any information entered during consultation will be updated onto a patient's record during the practices' scheduled system updates. These are usually scheduled to happen overnight. All data entered/captured within consultations during the day will be updated within the scheduled system update. So, whilst information entered on the symptom checker will change the score 'live' in front of you, if you enter information in the patient's notes you will not generate new prompts or see changes in the risk stratification scores until the system has updated overnight.

42. Does the tool link to other patient management systems (eg. Choose and book)?

No. To help us capture information about the clinician's experience of using the tool, and to help inform the evaluation, there is a section within the symptom checker function that allows the clinician to tick relevant information about tests that they have recommended. The tool is a standalone function that does not interact with any other patient or clinical management systems that may be in place. Clinicians will still need to book/schedule tests in the usual way, as per their practice protocol.

43. What is the threshold for smoking status?

Heavy smoker: 20 > cigarettes per day

Moderate smoker: 10>19 cigarettes per day

Light smoker: <10 cigarettes per day

Appendix A



IG Audit+.docx

Macmillan Cancer Risk Calculators

The Macmillan Cancer Risk Calculators are based on BMJ Informatica's iCAP/Audit+ technology and this document should be read in conjunction with the document covering Audit+.

The Cancer Risk Calculators are implemented as audits within Audit+ with some modifications to the user interface to accommodate the requirements of those reviewing the project. Some of the changes alter the data that is collected to enable the user experience and patient experience to be measured. This experience data is stored in the Audit+ database and transmitted along with risk score data and symptom data to BMJ Informatica servers hosted on N3 in a secure datacentre. None of this data can be related back to an individual patient as no patient identifying information is sent with this data. Cancer Research UK who are evaluating the project will download this data to help them with their evaluation.

Audit+

Audit+ is the basic product which underlies all the other BMJ Informatica products except Frontdesk. The other products introduce some variation and additional complexity which is dealt with in the specific documents for those products.

The overarching principle that all BMJ Informatica products adhere to is that as much processing as possible is done on the practice system so that only data that is specified to be sent outside the practice actually leaves the practice. In the standard default case no patient identifiable data leaves the practice and only numerical data is sent (this process is similar to the way QOF achievement reports are made to the QMAS system).

Practices with a local server or using hosted Vision

The diagram in appendix A illustrates the processes and flows when Audit+ is installed in a practice with a local server or a practice using a hosted Vision system (EMIS web requires different data flows which are discussed later).

Audit+ consists of a server component (which may be installed on the practice clinical system server or another machine) and a client component which is installed on user's workstations. The server component (everything inside the grey box on the diagram) should be included in the practices backup process however only limited amounts of historical data are retained within Audit+ and all patient data is refreshed nightly. The software is upgraded via the internet with messages being sent to users to show an upgrade is available. The server component upgrade requires user intervention to start the process to ensure this occurs at a time convenient to the practice. Once the server component has been upgraded (which normally takes less than 10 minutes) the client component is upgraded automatically when a user logs into the software.

To obtain data from the practice clinical system Audit+ uses a clinical data adapter which is specific to the clinical system in use. This connects to the clinical system via the API or other approved method and extracts patient level data. The data adapter converts this raw data into a generic data stream which it passes to the audit analysis engine. This process enables the different data structures and coding systems in use in clinical systems to be processed in a consistent manner.

The data analysis engine takes the data from the data stream and analyses it in accordance with the audits installed in Audit+. The results of the analysis, which include patient identifiable data, are stored in the Audit+ database. Patient data that does not appear in the results of the analysis is not stored.

Users at the practice can access the results of an analysis via the client component of Audit+. This login can be password protected or can be associated with the user's windows logon at the discretion of the practice. Users can see lists of patients and the data that the audit has found. They may also (depending on the audit specification) see prompts when looking at a patient's record. These prompts enable data to be added back to the patient record to improve data quality and patient care.

An analysis is scheduled to run every night to update the Audit+ database and it is this overnight analysis which triggers any data transmission (ad hoc analyses which the practice may run do not trigger any data transmission). Data can be sent from the practice at two points; from the analysis engine and from the Audit+ database via the Output Aggregator. The default setup where Audit+ installations are associated with an Audit Central installation at PCT or CCG level is that after every analysis the numerical results are transmitted to Audit Central over N3. This data is just numerical and conveys information like numbers of patients with a particular condition, the numbers of patients with a condition who have had a specified blood test. No patient identifiable information is sent, only the practice can see which patients have been selected by the audit.

If non-numeric, patient identifiable data is required it can be transmitted from the analysis engine over N3 to a secure repository as defined by the customer. The data to be transmitted is defined by the audit and only the data specified is transmitted, all other data remains in the practice. The practice retains control over this transmission and can turn it off if they wish.

Practices using EMIS web

EMIS web uses a central hosted database and its different architecture requires a different approach to other systems. The data flows are illustrated in Appendix B.

In the case of EMIS web Audit+ is installed within the practice network (it cannot be installed in the EMIS web data centre) so all the data processing and transmission from the practice is unchanged. The difference is that the data stream comes from a remote system rather than the practice database.

To supply the data stream EMIS web transmits patient data across the N3 network to the iCAP Central Server. This stores the data in a holding database until it is collected by the iCAP agent installed on the practice network. The iCAP agent downloads the practice data to a cache within the practice network. This cache is then analysed by the iCAP/Audit+ analysis engine in the same way as for practices with a local server.

Testing

All BMJ Informatica software (including audits) is tested in house (this includes review by clinicians), and by a panel of GP beta testers before release to customers. Software is developed in accordance with the NHS standard ISB 0129 for clinical safety. In addition BMJ Informatica works with iSOFT/CSC and NHS Connecting for Health to develop and test QOF rulesets each year prior to their release to other clinical suppliers.

FAQs

Q: Does BMJ Informatica have any information security accreditation?

A: Yes we are accredited to ISO 27001.

Q: What happens if an audit needs to be changed for some reason?

A: We can make changes to audits and deploy them automatically to practices using them without any practice intervention needed.

Q: What are the security arrangements for iCAP Central?

A: iCAP central is hosted in a secure data centre approved for connection to the N3 network. The data centre has a secondary backup centre should there be problems with the primary centre.



