Cancer Research UK response to the UK National Screening Committee consultation: moving from guaiac faecal occult blood test (FOBT) to a faecal immunochemical test for haemoglobin (FIT) in the bowel screening programme - October 2015

Cancer Research UK welcomes the opportunity to respond to this consultation.

Summary
Cancer Research UK supports the adoption of the faecal immunochemical test for haemoglobin (FIT) into the bowel screening programme, as a replacement for the guaiac faecal occult blood test (FOBT). We support the timely replacement of FOBT with FIT because for each month that the introduction of FIT is delayed, around 30 people will miss their opportunity for an earlier diagnosis of their cancer. Early diagnosis is incredibly important as the earlier someone’s cancer is diagnosed, the better their outcomes – for example, regarding bowel cancer, nine out of ten people will survive their cancer for at least ten years if diagnosed at stage one, whereas this drops to just one in ten people when diagnosed at stage four.

Introducing FIT should be prioritised and in an ideal scenario it would be implemented at a low cut-off concentration. However, we understand that current limitations with endoscopy capacity mean a pragmatic approach is more likely to be successful. The introduction of FIT should follow a clearly defined, transparent and monitored timetable for the decrease in cut-off concentration, so we can be sure that the potential of this new technology is realised. This should take into account ongoing programmes of work and commitments from the Department of Health to address endoscopy capacity. Further details and a decrease in cut-off concentration should be included as part of a phased implementation, rather than delaying its introduction.

To ensure a smooth introduction of FIT into the bowel screening programme, the following should be considered:

1. Phased reduction of cut-off concentration
2. Detail on the test itself
3. Processes for subsets of patients – further research
4. Wider changes to the bowel screening programme
5. Cross-border sharing of information

We look forward to working with the National Screening Committee to ensure a smooth implementation process.

1. Phased reduction of cut-off concentration
The cut-off concentration for FIT should be carefully considered to maximise the detection of cancers and advanced adenomas, whilst appreciating the current capacity of endoscopy services. The papers provided through the consultation show that FIT is clearly more effective as it detects more neoplasms. It is also cost-saving compared with FOBT, especially at the lowest cut-off concentration (20ug haemoglobin per gram (Hb/g)). However, endoscopy demand increases as the cut-off is reduced, and current endoscopy capacity prohibits the use of lower cut-offs.
We appreciate that there are ongoing programmes of work to address endoscopy capacity. Whilst these are in progress, it is justifiable that the introduction of FIT is phased in according to a clearly defined, detailed and monitored timetable for reducing the cut-off concentration. The plan for phased introduction of cut-off should be publically available to ensure full accountability of the screening programme. The published timetable to reduce the cut-off concentration must coincide with increases in endoscopy capacity. The Department of Health has stated its ambition for 500,000 extra endoscopies to be delivered by 2020 and we welcome these efforts: as they begin to deliver increases in capacity, this should be reflected in a reduction in the cut-off concentration.

However, further capacity above these extra endoscopies is likely to be needed – as modelling suggests that around 750,000 additional endoscopies (250,000 more than the 500,000 already committed to) will be required over the next five years, without factoring in the decrease in cut-off concentration that is possible with FIT. Effort must be made to address this continuing capacity shortage.

A phased introduction should start in 2016 with a ≤150ug Hb/g threshold. The Independent Cancer Taskforce recommended that roll out should start ‘as soon as possible’. We estimate that the pilot results so far suggest that 150ug Hb/g would detect around 1600 more advanced adenomas every year compared to 180ug Hb/g. 150ug Hb/g has also been chosen in London as their cut-off threshold for their forthcoming pilot. The final ambition for the screening programme should be to maximise effectiveness, and reducing the cut-off concentration to 20ug Hb/g plays an important role in achieving this.

We also believe it is important that consideration is given to how the screening programme can use FIT more smartly, as well as more sensitively, to save more lives. FIT offers potentially much more than a simple binary test, by introducing different thresholds for different groups (e.g. by screening round or gender) there is the potential to concentrate resource where it is most needed. There is also the possibility of using the Hb concentration along with other factors to create a composite risk score. All such approaches would require an evidence base and we encourage the NSC, and the screening programmes, to consider this in planning for future development of the programme and to consider how useful data collection and analysis can be built in.

Detail on the phased introduction:
To ensure the introduction of FIT can be successful, it is important to consider that the transition to FIT will require different technology and organization of resources. The hubs involved in the pilot will already have the required equipment to analyse the kits in place. London will also have access to these analysers as they are conducting a pilot. Other hubs should consider bulk purchasing to increase cost-effectiveness.

The implementation plans, working across Public Health England and NHS England, should consider the following questions to deliver roll-out:
  a. Should invitations be sent initially to specified age groups, people in different screening rounds or with different screening histories i.e. previous non-responders?
b. How to create the right balance of incentives and levers to ensure services provide a high-quality screening, which considers the drive to increase uptake and reduce health inequalities?
c. What is the level of required investment to ensure optimal roll-out?
d. Would the current infrastructure be able to cope with stratification (e.g. by age, gender etc)? If not, what updates or alterations to infrastructure would be required to support stratification?

2. Detail on the test itself
There are many manufacturers producing FIT kits and analysers. The OC-SENSOR system used in the pilot is likely to be the most suitable given its prior use in the England population. Consideration should be made for bulk purchasing across the screening hubs, to ensure the screening programme achieves the best possible value for money through potential discounts.

As demonstrated in the pilot, the collection of one sample leads to advantages in uptake. We therefore recommend that one sample should be collected for each participant. We recognise that collecting multiple samples may have merits, particular with early screening rounds, but the increased uptake because providing just one sample is simpler, remains an advantage that FIT has over FOBT.

3. Processes for subsets of patients – further research
Further research should be conducted to ensure that there are clearly defined processes and sensitivity thresholds in place for management of the following subsets of patients:
  a. Where the result comes in just under the threshold
  b. For those having their first versus a repeat screen
  c. Men/women
  d. Age groups
  e. Different deprivation groups
  f. Whether they have taken part in bowel scope screening
  g. Those with other risk factors, combined with their FIT score to provide a referral

The phased implementation plan should outline how and when these questions can be explored which will not disrupt the introduction of FIT.

Communications, Patient and Public Information
We understand that information has been produced as part of piloting FIT and feel it would be important to have this reviewed and evaluated, ensuring that there is patient and public involvement and engagement during this process. Cancer Research UK would be happy to assist with this.

4. Wider changes to the bowel screening programme
Bowel scope
Although the National Screening Committee are not considering changing other aspects of the programme such as bowel scope, follow-up diagnosis, treatment or surveillance, these should be considered in tandem with the introduction of FIT, as well as cost-effectiveness of these two tests in
This should include consideration of the optimal combination of FIT and bowel scope, including potential changes to the age range, and the screening interval for FIT.

Surveillance will need further attention: as the introduction of FIT will pick up more advanced adenomas, more people will enter surveillance. This will have a big impact on endoscopy capacity.

**Data**
FIT provides a quantitative result: consideration should be made as to the recording, use and communication of this, as it may have clinical utility (in addition to just recording whether someone had a ‘positive or negative’ result according to the cut-off concentration specified at the time). It is also important to continue collecting data on the efficacy of the whole bowel cancer screening programme in combination with bowel scope.

Data from FIT and the bowel cancer screening programme more generally, including coverage, uptake and positivity rate, should be made available in a timely manner. This should be available as an aggregated performance measure to the public, for example as part of the Public Health Outcomes Framework (as cervical and breast are already) as well as in appropriate forms to researchers and analysts.

5. **Cross-border sharing of information**
As Scotland has already announced that it will be implementing FIT, it would be pertinent to ensure that all nations are sharing information which may enable a smooth introduction of FIT to their respective bowel screening programmes.

**About us**
Cancer Research UK is the world’s largest independent cancer charity dedicated to saving lives through research. The charity’s pioneering work has been at the heart of the progress that has already seen survival rates in the UK double in the last forty years. In 2014/15, Cancer Research UK spent £434 million on research in institutes, hospitals and universities across the UK. The charity supports research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses.

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1 Estimated by extrapolating the pilot results to the number of people invited to FOBT bowel screening in England 2012-13 (source: www.publications.parliament.uk/pa/cm201314/cm Hansrd/cm140401/text/140401w0001.htm#140402600015)
2 Bowel Cancer (C18 – C20) Ten-year relative survival rates by diagnosis, Former Anglia Cancer Network, 1996 - 2000
4 Scoping the Future: a evaluation of endoscopy capacity across the NHS in England (2015) Health Services Management Centre at the University of Birmingham and the Strategy Unit at NHS Midlands and Lancashire Commissioning Support Unit, on behalf of Cancer Research UK
6 Lamph, SA; Bennitt, WE; Brannon, CR and Halloran, SP, *Evaluation report: immunochemical faecal occult blood tests* Centre for Evidence-based Purchasing (2009)