



National
Cancer
Screening
Service

Recommendations for a
colorectal cancer screening
programme in Ireland

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Letter of submission and executive summary

03 December 2008

Ms Mary Harney, TD
Minister for Health and Children
Department of Health and Children
Hawkins House
Dublin 2



National
Cancer
Screening
Service

Dear Minister Harney,

The Board of the National Cancer Screening Service (NCSS) wishes to thank you for your request for advice on the development of a national colorectal cancer screening programme.

In April 2007, the NCSS established the Expert Advisory Group on Colorectal Cancer Screening. The Expert Group, chaired by Professor Niall O'Higgins presented its final report to the Board of the NCSS in October 2008. I am pleased to enclose the Expert Group's final report, the report of the International Validation Panel and the NCSS business implementation plan for your consideration.

As you are aware colorectal cancer is an important health problem in Europe. Each year over 380,000 persons are newly diagnosed with colorectal cancer. About half of these patients die of the disease making colorectal cancer the second leading cause of cancer deaths in Europe. Almost one million people suffering from colorectal cancer are going through cost-intensive treatments putting a huge burden on the health budgets of individual member states.

- In Ireland colorectal cancer is the second most commonly diagnosed cancer among both men and women. Each year approximately 1,900 new cases of colorectal cancer occur, 1,070 in men and 830 in women.
- Colorectal cancer is the second most common fatal cancer among men and women in Ireland. Approximately 930 people die from colorectal cancer each year in Ireland, 525 men and 405 women.
- Over the last 15 years the number of cases of colorectal cancer has risen by approximately 20% in both sexes. By 2020 the number of new cases of colorectal cancer diagnosed each year in Ireland is projected to increase by 79% in men and 56% in women. This projected growth is attributable to an increasing and ageing population.
- Ireland has the highest mortality rate for colorectal cancer in Western Europe and according to GLOBOCAN 2002 had the fourth highest mortality rate amongst men worldwide.

The Board has concluded that a strong case exists for the implementation of a population-based screening programme. Several European countries have already implemented colorectal cancer screening programmes.

- England has chosen to implement biennial faecal occult blood testing (FOBT) for all those aged between 60 and 69 years by 2010.
- Scotland is currently screening those aged between 50 and 74 years.
- Wales has also begun screening all those aged between 60 and 69 years.
- Northern Ireland aims to begin screening by the end of 2009.
- National population-based programmes also exist in Finland, France, Italy and Poland.
- Regional based screening in advance of a national programme is underway in Portugal, Slovenia, Sweden and Spain.
- In Germany, although not population-based, annual FOBT testing is offered for those aged between 50 and 54 years and colonoscopy for those aged between 55 and 65 years.
- Austria offers 10 yearly colonoscopy from age 50.

The Board has given due consideration to the report of the NCSS Expert Advisory Group on Colorectal Cancer Screening and the report of the International Validation Panel.

- It is the Board's recommendation that the immunochemical faecal occult blood test (iFOBT) which operates on an automated testing platform, should be the primary screening tool for a population-based colorectal cancer screening programme in Ireland. This will be the first international population-based screening programme for colorectal cancer that utilises this technology as the primary screening tool.
- Individuals aged 55-74 years should be invited to participate in the screening programme.
- Biennial screening is the recommended screening interval.
- Persons with a positive result from the primary screening test should be offered a total colonoscopy.
- When a screen-detected cancer is diagnosed the screening process should continue until the end of primary treatment, after which time the patient should join the symptomatic service for clinical follow-up.

In developing a business implementation plan a number of assumptions were made that included an eligible population of 700,000, a 60% response rate to invitation to screening and a FOBt positivity rate of 6%. The number of individuals aged 55-74 years who will present for colonoscopy will be 25,200. Therefore there will be invitations for 12,600 screening colonoscopies per year. With the uptake for colonoscopy for iFOBt positive individuals likely to be 90%, it is estimated that there will be a requirement for 11,340 colonoscopies per annum arising from primary screening.

It is the Board's recommendation that four screening centres, each with two endoscopy suites, will be initially required to provide the necessary 11-12,000 colonoscopies per year for immediate national implementation of a population-based screening programme. It is recommended that these screening centres should be designed, equipped and operate discretely from the symptomatic service. Screening colonoscopy centres should be located in association with a designated cancer centre and form part of the cancer networks so that ancillary facilities of a symptomatic service can be available. Additional consultant medical staff, specialist nurses and radiographers, administrative and technical staff will be required.

Based on our previous experience in the implementation of BreastCheck and CervicalCheck it is estimated that it would take a minimum two year lead in period from approval to the commencement of screening. The preparatory costs in accordance with this timetable would be €1 million in year one and €6 million in year two. The operating costs in the first full year of operation are estimated at €15 million. In addition to the total operating costs the capital cost estimate for developing four screening centres is estimated at €13-€14 million.

In framing its recommendations the Board has also carefully considered the inherent linkages that exist between a population-based screening programme and symptomatic [non-screening] colonoscopy services. It is estimated that approximately 10% of all colonoscopy activity is ultimately related to cancer diagnosis. There is realistic concern about the potential impact of increased colorectal cancer screening activity on demand for symptomatic colonoscopy services. Consideration of total colonoscopy capacity has strongly shaped the planning of colorectal cancer screening programmes in other countries including Finland, England and Wales. The experience from BreastCheck is that a fully operational screening programme increases the demand by those outside the screening age range for symptomatic services. Lengthy waiting lists already exist for colonoscopy procedures in Ireland and increased screening without increased capacity can only be expected to exacerbate this situation. The Board recognises that there is a need to design a screening programme which is compatible and consistent with best practice and where the demand for other colonoscopy services is not excessively impacted.

In that context the opportunity presents itself to address both the requirements for screening and deficits in symptomatic colonoscopy services by developing an eight colonoscopy centre model, **managed by the NCSS**, based on a 50% utilisation by the screening service and a 50% utilisation for symptomatic purposes, on the basis of equity of access based on clinical need alone. From a population screening perspective this would provide the desirable objective of having the screening locations more widely distributed and therefore more accessible. From a symptomatic service perspective it would have the advantage that deficits in the symptomatic services would be addressed in tandem with and parallel to the development of a screening service. However, the fundamental principle that a screening programme operates separately from colonoscopy services for patients with symptomatic gastrointestinal complaints must remain.

In the event that the eight centre concept is selected as the desired model the Board believes that priority should be given to the development of the four 'screening only' centres giving rise to the possibility of the phased implementation of the eight centre combined model.

The estimated operating costs presented for the screening service would ultimately be distributed among eight as opposed to four centres. There would however be additional costs related to developing and enhancing symptomatic services operating from these centres. It is anticipated that these additional costs would range from €8-€15 million operational costs per annum. There would also be additional capital costs of €6.5-€14 million. Our aim would be to minimise additional costs by enhancing existing expertise and services already available, thereby achieving economies of scale through the integration of existing clinical infrastructures that meet international endoscopy QA standards, the efficient use of existing resources and injection of additional resources where necessary. This would require an evaluation exercise similar to that conducted by the NCSS in relation to colposcopy services for CervicalCheck and the methodology employed is readily transferable.

The European Guidelines for Quality Assurance in Colorectal Cancer Screening are nearing completion and are due to be published in 2009. It is now an opportune time for the NCSS to establish a QA committee to oversee and develop a concurrent QA framework for a national colorectal screening programme in Ireland. The Board has identified this workstream as one of the key priority activities for 2009 to ensure the potential for the delivery of a population-based colorectal screening programme in 2011. There are already well established EU guideline subgroups with whom the NCSS Colorectal QA Committee can now effectively and efficiently collaborate. In our view it is critical that the NCSS is an active participant in these international collaborations to ensure that the reports from the NCSS Expert Advisory Group on Colorectal Cancer Screening can be interpreted and amended appropriately in the context of new and emerging clinical and scientific developments. This will ensure that the business implementation plan can be adjusted in a timely fashion in accordance with international best practice.

The NCSS commissioned HIQA to undertake a health technology assessment (HTA) on colorectal screening in October 2007. The HTA commenced in February 2008. The aim in commissioning this work was to supplement the clinical advice of the NCSS Expert Advisory Group on Colorectal Cancer with detailed information on the resource implications and cost-effectiveness of screening. It is our expectation, based on knowledge of similar work conducted in other jurisdictions, that a population-based screening programme for colorectal cancer will be cost-effective. We are submitting this report in advance of the HTA because it is clear from clinical best practice that an immunochemical faecal occult blood test should be the primary screening tool for a population-based screening programme and because there is a delay in the finalisation of the HTA report which is not now anticipated for completion until early 2009.

As you are aware, on 02 December 2003 the Health Ministers of the European Union unanimously adopted a recommendation on cancer screening. The EU Council Recommendation set out the fundamental principles of best practice in the early detection of cancer. More specifically the report of The National Cancer Forum (2006), recommended that a colorectal cancer programme be established that encompassed population-based screening, utilising faecal occult blood testing (FOBT), and a coherent programme for the investigation and treatment of people with symptoms suggestive of colorectal cancer.

The Board believes that the business implementation plan and the options presented contain the mechanism by which Ireland can now establish a truly world class screening programme for colorectal cancer and meet the aspirations set out in the EU Council Recommendation and the Report of The National Cancer Forum (2006).

In summary the Board is recommending:

- An immunochemical faecal occult blood test (iFOBT) that operates on an automated testing platform as the primary screening tool for a population-based colorectal screening programme.
- A target population for screening of all men and women aged 55 and 74 years with a screening interval of two years.
- Total colonoscopy to be offered to those individuals who test positive with the iFOBT.
- A four centre – screening only model – with operational costs of €15 million in the first full year of operation and a capital outlay of €14-€15 million or;
- An eight centre – combined model – with operational costs ranging from €23-€30 million in the first full year of operation and a capital outlay ranging from €20-€29 million.

In order to continue its work in this area the Board therefore seeks a mandate to:

- Undertake a detailed study of existing symptomatic endoscopy services to enable us to refine cost estimates for the eight centre model and maximise efficiencies in the delivery of a population-based screening programme.
- Identify potential screening centre sites in consultation with the National Cancer Control Programme.
- Establish an NCSS colorectal screening QA committee with EU linkages.
- Develop and implement training programmes in consultation with the appropriate professional bodies to meet workforce development needs of the screening programme.
- Develop the appropriate IT software and infrastructure to support a colorectal screening programme building on the base of existing NCSS IT platforms.
- Work with consumer groups and key stakeholders to undertake a comprehensive market research programme to develop the best means of maximising acceptance of this screening programme.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Tony O'Brien', with a horizontal line above and below the text.

Mr Tony O'Brien
Chief Executive Officer
For and on behalf of
The National Cancer Screening Service Board

About the National Cancer Screening Service

The National Cancer Screening Service Board was established by the Minister for Health and Children in January 2007. The establishment followed the launch of 'A Strategy for Cancer Control in Ireland 2006' which advocates a comprehensive cancer control policy programme in Ireland by the Cancer Control Forum and the Department of Health and Children.

The Strategy set out recommendations regarding prevention, screening, detection, treatment and management of cancer in Ireland in coming years and recommended the establishment of a National Cancer Screening Service Board.

Governance of BreastCheck – The National Breast Screening Programme and the former Irish Cervical Screening Programme (ICSP) Phase One was transferred to the Board of The National Cancer Screening Service (NCSS) on its establishment. The NCSS has been responsible for the establishment of CervicalCheck – The National Cervical Screening Programme.

The functions of The National Cancer Screening Service are as follows:

- To carry out or arrange to carry out a national breast screening service for the early diagnosis and primary treatment of breast cancer in women;
- To carry out or arrange to carry out a national cervical cancer screening service for the early diagnosis and primary treatment of cervical cancer in women and;
- To advise on the benefits of carrying out other cancer screening programmes where a population health benefit can be demonstrated;
- To advise the Minister, from time to time, on health technologies, including vaccines, relating to the prevention of cervical cancer; and
- To implement special measures to promote participation in its programmes by disadvantaged people.

Since its establishment The National Cancer Screening Service has aimed to maximise expertise across screening programmes and improve efficiency by developing a single governance model for cancer screening.

The mandate of the Board of the NCSS also includes a policy, development and advice role. This has related initially to formulating this proposal for a national, population-based colorectal screening programme. In addition, the Board has established an Expert Group on Hereditary Cancer Risk comprising of experts in the areas of breast cancer, colorectal cancer, cancer epidemiology and medical genetics.

At the request of the Minister for Health and Children, the Board of the NCSS undertook a thorough review of the role of HPV vaccines in the prevention and control of cervical cancer. The Board is also empowered to provide advice to the Minister for Health and Children relating to other screening developments.

On its establishment, Dr Sheelah Ryan, former Chairperson of the National Breast Screening Board was appointed as Chairperson of the Board and Mr Tony O'Brien was appointed as Chief Executive Officer of the National Cancer Screening Service.

The Board, appointed by the Minister for Health and Children, consists of 12 members.

Members of the Board of the National Cancer Screening Service

Dr. Sheelah Ryan, Chairperson

Dr Grainne Flannelly

Dr Marie Laffoy

Ms Edel Moloney

Mr Jack Murray

Dr Ailis Ni Riain

Dr Ann O'Doherty (appointed June 08)

Professor Martin O'Donoghue

Professor Niall O'Higgins (until June 08)

Dr Donal Ormond

Mr Eamonn Ryan

Professor Frank Sullivan

Dr Jane Wilde

Mr Tony O'Brien, Chief Executive Officer

Ms Majella Byrne, Secretary to the Board & Head of Corporate Services

SECTION 1

Final report of the NCSS Expert Advisory Group on Colorectal Cancer Screening

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Membership

- Professor Niall O’Higgins, Chairperson
- Dr Helen Fenlon, Consultant Radiologist, BreastCheck & Mater Misericordiae University Hospital
- Dr Michael Flynn, GP & Irish College of General Practitioners - RIP
- Dr Padraic MacMathuna, Consultant Gastroenterologist, Mater Misericordiae University Hospital
- Ms Ann Murphy, Clinical Nurse Specialist, Cork University Hospital
- Professor Diarmuid O’Donoghue, Consultant Gastroenterologist St. Vincent’s University Hospital & University College Dublin
- Professor Colm O’Moráin, Professor of Medicine, Consultant Gastroenterologist AMNCH & Trinity College Dublin
- Professor Ronan O’Connell, Professor of Surgery, University College Dublin
- Professor Conor O’Keane, Consultant Pathologist, Mater Misericordiae University Hospital

Members of the Expert Group who contributed to the First Report and are now members of the HTA Evaluation Team

- Dr Linda Sharpe, Epidemiologist, National Cancer Registry Ireland
- Professor Anthony Staines, Professor of Health Systems Research, Dublin City University

Ex-Officio members

- Dr Sheelah Ryan, Chairperson, National Cancer Screening Service Board
- Mr Tony O’Brien, Chief Executive Officer, National Cancer Screening Service
- Dr Alan Smith, Consultant in Public Health Medicine, National Cancer Screening Service

Acknowledgements

- Mr Patrick Cafferty, Planning and Risk Manager, National Cancer Screening Service

Foreword

The purpose of a screening programme for cancer is to save lives, through the prevention of premature deaths from the condition being screened. Screening means the investigation of people who have no symptoms of the disease. The expectation is that potentially fatal conditions can be detected before they cause symptoms and at a stage when they can be effectively treated and cured.

Abundant evidence from all around the globe indicates that deaths from colorectal cancer, a common and potentially fatal condition in men and women, can be prevented by high-quality screening.

In April 2007, the National Cancer Screening Service Board established an expert advisory group to study the medical and scientific evidence concerning screening for colorectal cancer and to make recommendations to the Board about the potential benefits of introducing a population-based screening programme for this condition in Ireland.

The Group, representing Medical Consultant Specialists, Public Health Consultants and Epidemiologists, General Practitioners, Nursing and administrative experts from the National Cancer Screening Service, met on many occasions and completed an extensive evaluation of current evidence on the subject.

As Chairman of the Group, it is with pleasure that I acknowledge with appreciation the voluntary contributions, in time and in expertise, of the members of this Group in the preparation of this report. Their experience and knowledge has ensured that this report contains the best available information on the subject. Each member contributed significantly to the work of the group.

In addition to his membership of the group, we were most fortunate to have available the skills, abilities and experience of Dr Alan Smith, Consultant in Public Health Medicine, who advised and guided the Group at many stages during its deliberations.

It is with great sadness that we record the death of one of the members of the group, Dr Michael Flynn, who died after a short illness. A former President of the Irish College of General Practitioners, he was responsible for many innovations in Irish medicine. He contributed to the work of the Expert Group by his extensive knowledge of medicine and his deep concern for patients.

A first report of the Expert Advisory Group was presented to the Board in December 2007. An independent peer review of the report was sought from an international panel of experts on colorectal cancer screening - Professor Wendy Atkin and Professor Robert Steele from the UK, Professor Jean Faivre from France and Professor Michael O'Brien from the USA. This review process took place in Dublin in August 2008.

Our final report has applied the advice of the peer reviewers and reflects current standards of care. The recommendations form the basis of an up-to-date, effective and quality assured programme for colorectal cancer screening in Ireland.

Following our firm recommendations to the Board of the National Cancer Screening Service in this, our final report, it is essential that a Health Technology Assessment (HTA) be completed so that the cost-effectiveness of the proposed screening programme can be measured - information that will be of considerable value to the Minister for Health and Children and to the Government. The HTA is being conducted at present and the results should be available by the end of 2008.

The recommendations in this report apply to the population at average risk for colorectal cancer. We are confident that the proposals are in keeping with the best current evidence and that, when implemented, will undoubtedly reduce the number of deaths from colorectal cancer in Ireland. We submit this report to the Board of the National Cancer Screening Service with the recommendation that a national screening programme for colorectal cancer be established by 01 January 2011.

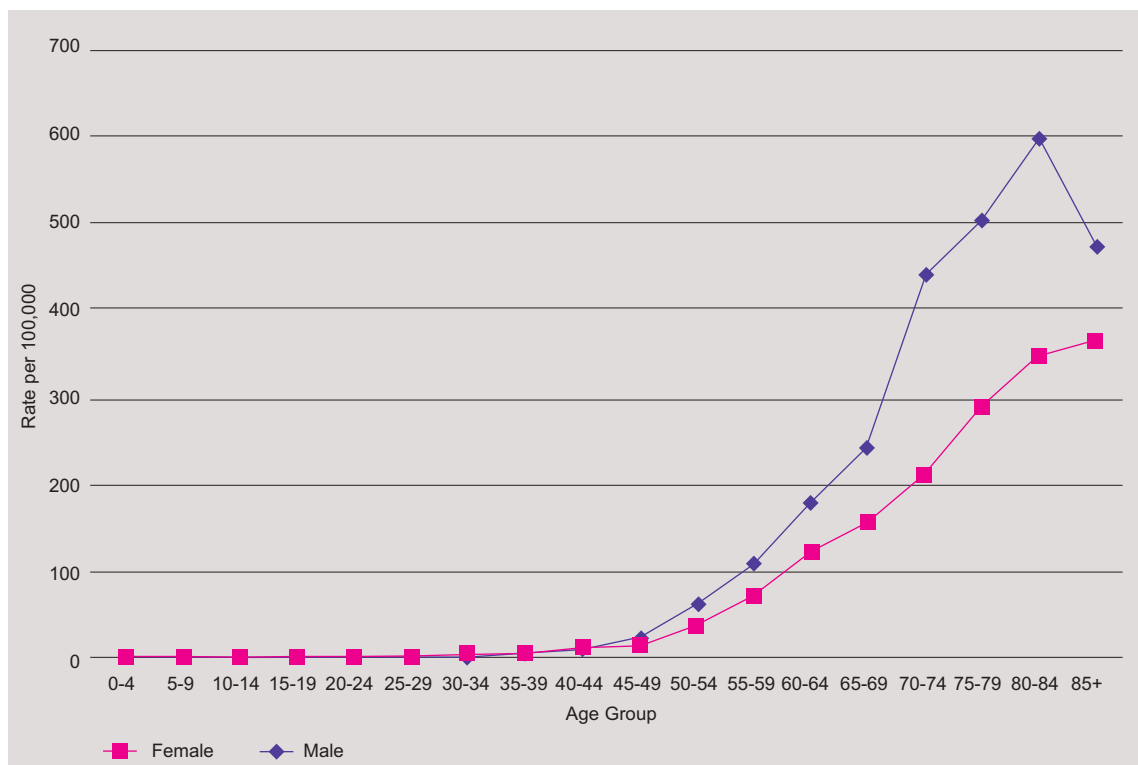
Professor Niall O'Higgins
Chairman
Expert Advisory Group on Colorectal Cancer Screening

October 2008

1. Epidemiology

- 1.1 In Ireland, colorectal cancer is the second most commonly diagnosed cancer among men and women in Ireland. Approximately 1,900 new case of colorectal cancer are diagnosed each year, with more cases in men than women (1,070 versus 830).
- 1.2 The burden of the disease in the population is growing. In the interval between the early 1990s and 2004/05 the number of cases rose by approximately 20% in both sexes. The National Cancer Registry, Ireland has projected that by 2020 the number of new cases of colorectal cancer diagnosed each year in Ireland will increase by 79% in men and 56% in women. This projected growth is due predominantly to an increasing and ageing population.
- 1.3 Colorectal cancer incidence rates generally increase with increasing age. Around a fifth of cases occur in the 55-64 year age group, a third of cases in the 65-74 year age group and a third (or more) of cases in those over 75 years (Figure 1).

Figure 1 Age specific incidence rates 2005



- 1.4 Many hundreds of patients suffering from colorectal cancer go through expensive treatment that places a huge burden on health budgets each year.
- 1.5 Approximately 500 men and 400 women die from colorectal cancer each year making it the second most common cause of cancer death in Ireland. The number of deaths has remained relatively constant over the last decade. Ireland now has colorectal cancer incidence rates higher than the EU average and according to GLOBOCAN 2002 the 4th highest mortality rate amongst men and the 15th highest mortality rates amongst women.
- 1.6 In summary, Ireland has a high incidence of colorectal cancer leading to mortality rates that are amongst the highest in the world. Cases of colorectal cancer are preventable or curable through screening and the detection of pre-cancerous disease or early cancer.

2. Screening test recommendation

- 2.1 It is recommended that an immunochemical faecal occult blood test (iFOBt) that operates on an automated testing platform be adopted as the primary screening tool for a population-based colorectal screening programme.
- 2.2 The iFOBt has a number of advantages over the guaiac based faecal occult blood test (gFOBt) when compared against World Health Organisation (WHO) criteria for an ideal faecal occult blood test (Table 1).

Table 1 The ideal faecal occult blood test-guaiac versus immunochemical

WHO Criteria ¹	Guaiac	Immunochemical
Convenient without need to attend a physician	Yes	Yes
Readily organisable	Yes	Yes
Acceptable with easy and simple faecal sampling	Yes	Yes
Specific for intestinal bleeding	No	Yes
Applicable to population-based screening	Yes	Yes
Amenable to strict quality assurance (QA) methods and objective analysis	No	Yes

- 2.3 Compared to gFOBt the iFOBt is a test that;
- i. is specific for human haemoglobin and not subject to interference by diet and drugs;
 - ii. is selective for intestinal bleeding;
 - iii. has reported higher participation/acceptability rates with relatively simple faecal sampling;
 - iv. involves the sampling of one or two consecutive stools rather than three;
 - v. has comparable or superior performance characteristics (sensitivity, specificity);

1 World Health Organisation & World Organisation of Digestive Endoscopy. Am J Gastroenterology 2002;97:2499-2507

- vi. has the option of an automated testing platform option which is more amenable to a rigorous quality assurance (QA) programme and allows for a high throughput of samples and the measurement of a quantitative objective endpoint based on haemoglobin concentration;
- vii. facilitates the centralisation of all colorectal screening at a single central laboratory.

2.4 Although the only population-based randomised controlled trial (RCT) evidence to show a reduction in colorectal cancer mortality from screening is in relation to the use of gFOBt the conclusion from current published evidence is that the impact of iFOBt is likely to be greater than that of gFOBt. The screening process is simpler, involves the objective measurement of a quantitative end point, studies report higher participation rates and superior test performance. Higher cancer and pre-cancer detection rates can therefore be anticipated.

3. Screening pathway recommendation

- 3.1 It is recommended that the target population for a screening programme should be between 55 and 74 years of age with a screening interval of two years.
 - 3.1.1 There are approximately 670,000 individuals in this age range (Central Statistics Office, Census 2006)
- 3.2 As outlined in 2.1 the use of an iFOBt that operates on an automated testing platform is recommended.
- 3.3 It is recommended that total colonoscopy should be offered to those individuals who test positive with the iFOBt.
- 3.4 It is recommended, subject to strict QA referral protocols, that CT colonography be used as the supplementary screening test in the event of an incomplete colonoscopy and where a repeat colonoscopy is unlikely to be successful. Incomplete colonoscopy can occur as a result of inadequate bowel preparation or for anatomical reasons.
 - 3.4.1 In exceptional circumstances, where clinically appropriate, barium enema may need to be considered as an additional option.
- 3.5 It is recommended that when a screen detected cancer is diagnosed the screening process continues up until the end of primary treatment after which time the patient joins the symptomatic service for clinical follow-up.
 - 3.5.1 Surgery remains the definitive primary treatment for localised colorectal cancer.
 - 3.5.2 Pre or post-operative radiotherapy should be considered as a primary treatment option in patients with operable rectal cancer.

4. Service planning

4.1 Table 2 summarises the key assumptions in current service planning figures presented here.

Table 2 Service planning assumptions

Assumption	Value
Target population	700,000
Uptake	60%
iFOBT positivity	6%
Colonoscopy acceptance	90%
Colonoscopy outcome- <i>Normal</i>	50%
Colonoscopy outcome- <i>Polyp</i>	40%
Colonoscopy outcome- <i>Cancer</i>	10%

4.2 A national screening programme will issue approximately 350,000 invitations each year of a two yearly screening cycle.

4.3 The assumed uptake will result in the receipt and processing of approximately 210,000 completed iFOBT kits each year.

4.4 The assumed iFOBT positivity and colonoscopy acceptance will result in 11,340 colonoscopies being performed each year from primary screening.

4.4.1 There will be 5,662 normal colonoscopies.

4.4.2 There will be 4,530 'polyp detected' colonoscopies.

4.4.3 There will be 1,134 cancers detected.

4.5 It is recommended that a screening centre should be designed, equipped and operate separately from the symptomatic service. Screening colonoscopy centres should be located in association with a designated cancer centre so that ancillary facilities of a symptomatic service can be available. Interference of symptomatic services by screening colonoscopies should not be permitted. The development of a colorectal screening service should be associated with a parallel system of improvement of services for symptomatic patients.

- 4.5.1 The BreastCheck model of operation has proven to be successful, delivers a truly world class service and should be replicated.
- 4.5.2 Screening centres located in association with a colorectal cancer centre will ensure that full multidisciplinary team expertise and facilities are available if and when required e.g. CT colonography, emergency surgery.
- 4.6 It is recommended that four screening centres, each with two endoscopy suites, will be initially required to provide the necessary 11-12,000 colonoscopies per year for immediate national implementation of a population-based screening programme (based on the service planning assumptions presented in Table 2).
 - 4.6.1 Screening centres should operate at least 48 weeks per year.
 - 4.6.2 Screening centres should have opening hours that facilitate maximum participation amongst the eligible target population i.e. outside routine 9-5 working day.

5. Management of the screen detected polyp

- 5.1 Adenomatous polyps are the most frequent neoplasm found during colorectal screening and it is the removal of these lesions that has been shown to reduce the risk of developing colorectal cancer and advanced adenomas.
- 5.2 To reduce the risk of a future colorectal cancer, patients with adenomas are usually placed into a surveillance programme of periodic colonoscopy to remove missed synchronous and new metachronous adenomas and cancers.
- 5.3 Several studies have shown that the risk of a subsequent colorectal carcinoma is related to the characteristics of previously removed adenomas at the first/baseline colonoscopy and include three or more adenomas, high grade dysplasia or villous features on histology and size ≥ 1 cm.
- 5.4 Risk stratification can markedly reduce the intensity of follow-up in a substantial proportion of patients so that colonoscopy resources can be more appropriately shifted from surveillance to screening and diagnosis.
- 5.5 It must be acknowledged that the management of the screen detected polyp, specifically the appropriate interval for repeat colonoscopy and ultimately a return to a population-based screening programme, is a continually developing and evolving field. Surveillance recommendations are likely to change over time toward a more conservative approach in terms of surveillance intervals.

- 5.6 In the interim the Expert Group recommends the adoption of the UK ‘Surveillance Guidelines after removal of colorectal adenomatous polyps’ which have been approved by the Association of Coloproctology of Great Britain and Ireland (ACPGBI).
- 5.7 It is recommended that those diagnosed with low risk, intermediate risk or high risk polyps should leave the screening programme and be followed up (with surveillance colonoscopies) in the symptomatic service.
- 5.8 Emerging research suggests that a more conservative approach in terms of surveillance intervals is warranted. This suggests an interval of five years for those with intermediate risk and within three years for the first surveillance colonoscopy for those with high risk.
- 5.8.1 It is recommended that the future QA structure underpinning the programme should monitor developments in this area and make recommendations accordingly.

6. Colonoscopy training and accreditation

- 6.1 It is recommended that for a population-based screening programme, screening colonoscopy should be carried out only by Consultants who are specifically trained in colonoscopy and accredited by an official training body in Ireland. Potential endoscopists are likely to fall into the following three categories:
 - 6.1.1 Newly appointed Consultant Gastroenterologists.
 - 6.1.2 Consultant Gastroenterologists (currently in practice).
 - 6.1.3 Consultant Colorectal (Specialist) Surgeons performing greater than 200 complete colonoscopies per annum.
- 6.2 Other Consultants wishing to participate as a screening endoscopist would have to be accredited by an accreditation body/mechanism representing the Irish Society for Gastroenterologists and the Royal College of Surgeons in Ireland.
- 6.3 It is recommended that the performance of screening endoscopists should be continually measured against appropriate and agreed performance indicators under a comprehensive QA structure for the programme.

7. Hereditary risk cancer - colorectal cancer

- 7.1 The majority of colorectal cancers occur in individuals without any identifiable risk factors. The NCSS Expert Advisory Group on Colorectal Cancer Screening has focused on this population.
- 7.2 As cancer in high risk groups frequently occurs outside the age range recommended for population screening (Section 3.1), a programme to detect cancers in individuals with risk factors will also be required to ensure a comprehensive programme of colorectal cancer screening.
- 7.2.1 Approximately 25% of patients have identifiable risk factors predisposing to colorectal cancer including:
- Family history of colorectal or adenoma under 60 years.
 - Previous history of colorectal carcinoma or adenoma.
 - Chronic ulcerative colitis or Crohn's disease.
 - Familial adenomatous polyposis.
 - Hereditary non-polyposis colorectal cancer.
 - Juvenile polyposis.
- 7.3 The NCSS has now established an Expert Group on Hereditary Cancer Risk. This group, that includes experts in the areas of colorectal cancer, cancer epidemiology and medical genetics, will review and evaluate international evidence regarding best practice in screening for a hereditary colorectal cancer risk.
- 7.4 It is anticipated that the Expert Group on Hereditary Cancer Risk will submit their report in 2009 to the Board of the National Cancer Screening Service on the organisation and development of an integrated cancer control and screening service for those with an inherited pre-disposition to colorectal cancer.

SECTION 2

Report of the International Validation Panel

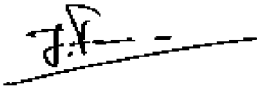
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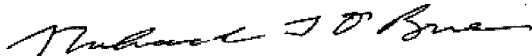
Members of International Validation Panel



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Scotland
UK

1. Introduction

Colorectal cancer is the second most common malignant tumour in Europe both in incidence and mortality. In Europe more than 400,000 cases of colorectal cancer are diagnosed annually and 212,000 people die from the condition. Although the five year survival rates are improving, more than 50% of those affected die of the disease.

In Ireland, colorectal cancer is the second most commonly diagnosed cancer among men and women. Each year approximately 1,900 new case of colorectal cancer are diagnosed. Over the last 15 years the number of cases has risen by approximately 20% in both sexes. By 2020 the number of new cases of colorectal cancer diagnosed each year in Ireland is projected to increase by 79% in men and 56% in women². In Ireland, approximately 900 people die from colorectal cancer each year making it the second most common cause of cancer death in Ireland. The number of deaths has remained relatively constant over the last 10-15 years.

The Minister for Health and Children requested the Board of the National Cancer Screening Service to examine the case for a national colorectal cancer screening programme. In April 2007, the National Cancer Screening Service established the Expert Advisory Group on Colorectal Cancer Screening. The Expert Group, chaired by Professor Niall O'Higgins, presented its first (interim) report to the Board of the NCSS in December 2007 and intends to submit its second and final report in October 2008.

Following a request from the National Cancer Screening Service we agreed to participate in an external peer-review of the first (interim) report of the Expert Advisory Group on Colorectal Cancer Screening. This process took place on 06-07 August 2008 and the format is outlined in Appendix 1. Our recommendations are presented here.

2 National Cancer Registry Ireland

2. Recommendations

2.1 Proposed screening test

We note that the Expert Group has examined five options for a primary screening tool; an immunochemical faecal occult blood test (iFOBT); a guaiac based faecal occult blood test (gFOBT); flexible sigmoidoscopy, colonoscopy and CT colonography.

- ***We agree with the NCSS Expert Group's recommendation of the iFOBT test as the screening tool of choice for a population-based screening programme.***

The iFOBT has a number of advantages over the gFOBT that includes:

- o The option of an automated testing platform which is more amenable to a rigorous quality assurance (QA) programme.
 - o A high throughput of samples and the measurement of a quantitative objective endpoint based on haemoglobin concentration.
 - o The facilitation of centralisation of all screening at a single central laboratory.
 - o Reported higher participation/acceptability rates with easy and simple faecal sampling without a need for diet and drug restrictions.
 - o Selectivity for intestinal bleeding.
 - o Comparable or better sensitivity and specificity performance characteristics.
- ***We are not in a position to recommend a specific iFOBT test but suggest that this is done by means of a tendering process that would address the specific scientific and operational needs of a national programme.***
 - ***We agree with the NCSS Expert Group's opinion that there is insufficient evidence to recommend the use of flexible sigmoidoscopy, colonoscopy or CT colonography as the primary screening tool for a population-based screening programme.***

2.2 Proposed screening process

We note that the Expert Group has recommended the following;

- o Target population aged 55-74years
 - o Biennial screening
 - o Participation target of 60%+
 - o An iFOBt test operating on an automated testing platform
 - o Colonoscopy to be offered to those with a single positive iFOBt
 - o CT colonography to be utilised as a supplementary screening test
 - o The screening process will continue up to and including primary treatment
-
- ***We agree with the NCSS Expert Group's recommendation of biennial screening of a target population aged 55-74. We understand that a Health Technology Assessment due for completion by the end of 2008, will provide useful cost effectiveness profiles of screening different age groups to inform a controlled incremental roll-out of a national programme.***
 - ***An initial participation rate of 50% is probably more realistic but a 60% target could be an overall programme goal.***
 - ***We agree with the NCSS Expert Group's recommendation of an iFOBt test that operates on an automated testing platform. While there is some evidence to support a recommendation of a single sample iFOBt test as part of the screening pathway, a final decision (e.g. single versus two samples), informed by ongoing international research, need not be made until closer to the establishment of a national programme.***
 - ***Ongoing monitoring and evaluation of a screening programme is essential for quality assurance purposes and service planning to inform a controlled incremental roll out of a national programme. It is recommended that a monitoring and evaluation group is established for this purpose and a series of key performance indicators developed in order to facilitate the process. Key performance indicators have been developed in the UK and other European countries and could be adapted for use in Ireland.***
 - ***A positive iFOBt will necessitate communication from the programme with the individual to explain the options available to them. This communication should take the form of a letter offering them either a telephone or face to face appointment with a health professional.***

- ***Clear protocols should be developed to manage all eventualities arising from a positive iFOBT including refusal of colonoscopy and incomplete or inadequate colonoscopy.***
- ***A colonoscopy should only be repeated if inadequate bowel preparation is the principal factor in a failed colonoscopy and the individual has consented.***
- ***We agree with the NCSS Expert Group's recommendation of CT colonography as a supplementary screening test if inadequate bowel preparation has been ruled out as a contributing factor and if it is felt that a repeat colonoscopy is unlikely to be successful for either technical or medical reasons. Strict referral protocols should be developed to govern this management pathway.***
- ***We would suggest that barium enema should be considered, where clinically appropriate, as an additional option if/when CT colonography is not available.***

We note the background briefing on the operation of BreastCheck and the fundamental principle that has been adopted by the NCSS that a screening pathway is complete at the end of primary treatment. We note that in the context of colorectal screening this includes surgery and pre/post operative radiotherapy

- ***We accept the rationale and would support the position that the Expert Group has adopted in terms of including primary treatment for colorectal cancer as part of the screening pathway.***
- ***We would recommend that all treatment regimens are managed via effective governance structures, are protocol driven and are consistent with international best practice.***
- ***We would recommend that adjuvant chemotherapy treatment, while not a part of the screening pathway per se, also needs to be similarly managed under the wider National Cancer Control Programme.***

2.3 Service planning

We note the background briefing on the operation of BreastCheck and CervicalCheck and in particular the methods that are employed to build a population register for a national screening programme.

We note the background briefing on the concept of the operation of BreastCheck and the current demands being made of symptomatic endoscopy services in Ireland.

- ***We would agree with the plan outlined for the NCSS to act as the central point for a national screening programme with responsibilities that would include the population register, invitation letters and iFOBT distribution, ICT, communication/educational materials and co-ordinating referral appointments.***
- ***There is considerable expertise and readily available documentation that could be adapted from the UK and other European screening programmes to inform, amongst others, the development of invitation letters and educational and screening promotion material.***
- ***It is our opinion that primary care will play a critically important role in promoting the screening programme and improving participation rates. Therefore it is of paramount importance that primary care physicians and their relevant professional bodies are included in policy development and are kept informed on progress in implementing a national programme.***
- ***We support the NCSS Expert Group's recommendation of independent screening centres for a population-based colorectal screening programme on the basis of the success of the BreastCheck model in Ireland.***
- ***Based on an iFOBT positivity rate of 6% it would appear that four independent screening centres, each with two endoscopy suites, should provide sufficient capacity for a national screening programme.***
- ***Feasibility, logistics, capacity and expertise are the primary factors that should influence the selection of screening centres.***
- ***Screening centres would need to operate outside of the routine Monday-Friday 9am-5pm working week to facilitate maximum participation amongst the eligible target population.***
- ***It is not possible at this point to predict the numbers of surveillance colonoscopies that will be generated by a national screening programme (ongoing research will inform this aspect) but it would seem reasonable to include these as part of the workload for a 'stand alone' screening centre.***

- *There is considerable merit in developing a pathology reference centre as part of a national colorectal screening programme to develop specific pathological expertise, standardised reporting criteria and reporting templates. Multi-disciplinary team (MDT) meetings will play a critical part in the appropriate management of difficult polyp pathology.*
- *In the context of an iFOBT test operating on an automated testing platform we support the NCSS Expert Group's recommendation of a single central laboratory to process samples.*
- *The designated laboratory should be internationally accredited and managed via appropriate internal and external QA governance structures*
- *Clinical management protocols will need to be developed for occurrences of rare lesions found on colonoscopy e.g. a very large adenoma. International best practice and available expertise should determine the clinical management e.g. tertiary referral for specialist endoscopic mucosal resection or referral for surgery.*

2.4 Surveillance colonoscopy

- *The management of the screen detected polyp is a continually developing research field and consensus recommendations are likely to change over time toward a more conservative approach in terms of surveillance intervals.*
- *We would advise that the NCSS Expert Group adopts a single management algorithm for the screen detected polyp for the national programme. In that context the UK 'Surveillance guidelines after removal of colorectal adenomatous polyps' and approved by the Association of Coloproctology of Great Britain and Ireland (ACPGBI) would seem appropriate.*
- *It is difficult to predict the exact percentage of those undergoing colonoscopy likely to require surveillance until there is an indication of the positivity rate of different polyp pathology arising from colonoscopy following a positive iFOBT in a national programme.*
- *At this point in time our expert opinion is that 20-30% of those undergoing colonoscopy are likely to require surveillance colonoscopies.*
- *Surveillance colonoscopies won't be a significant up-front workload for the screening programme but eventually (year three onwards) it will have a large impact and the programme must have sufficient in built capacity and contingency.*

2.5 Colonoscopy capacity, training and accreditation

We note the background briefing on the comprehensive Specialist Registrar (SpR) training programme in Ireland and the requirement of a Certificate of Completion of Specialist Training (CCST) for specialist registration with the Medical Council of Ireland.

We note the background briefing on the employment arrangements of Consultants associated with BreastCheck.

- ***We agree with the NCSS Expert Group's recommendation that screening colonoscopy should be carried out by individuals who are specifically trained in colonoscopy and accredited by an official training body.***
- ***The NCSS Expert Group's recommendation should ensure that the appointment of newly qualified medical endoscopists to the screening programme is of the highest international standard.***
- ***We would recommend that the NCSS Expert Group consider an appropriate accreditation mechanism for currently registered/practicing medical endoscopists who have not graduated from a formal SpR training programme before their participation in a national screening programme.***
- ***We would recommend that the performance of screening endoscopists should be continually measured against appropriate and agreed performance indicators under a comprehensive QA programme.***
- ***We would agree that the BreastCheck model of employment for Consultants has the potential to be an attractive employment opportunity for appointment to a national screening programme.***
- ***We are not in a position to recommend specific numbers but we agree with the NCSS Expert Group's outline of the staffing requirements for a screening centre.***

Appendix 1

International Validation Panel National Colorectal Cancer Screening Agenda

Wednesday 06 August 2008	
9:30 am-10.00 am	National Cancer Control Programme Mr Tony O'Brien, CEO National Cancer Screening Service (NCSS)
10:00 am-10.15 am	NCSS Expert Advisory Group on Colorectal Cancer Screening Prof. Niall O'Higgins, Chair, NCSS Expert Advisory Group on Colorectal Cancer Screening
10:15 am – 10:30 am	Epidemiology of colorectal cancer in Ireland Dr Alan Smith, Consultant in Public Health Medicine, NCSS
10.30 am – 10.45 am	The proposed screening test *
10:45m to 11:00 am	Break
11:00 am to 12:15 pm	The proposed screening test ctd *
12:15 pm to 1:00 pm	The proposed screening process *
1:00 pm to 2:15 pm	Lunch
2:15 pm to 3:00 pm	Service planning *
3:00pm to 4:00 pm	Surveillance of the screen detected polyp *
4:00pm to 4:15 pm	Break
4.15 pm to 5:00 pm	Colonoscopy capacity/training *

Thursday 07 August 2008

9:00 am to 11:00 am	Private session for Validation Panel
11:00 am to 11:15 am	Break
11:15 am to 1:00 pm	<ul style="list-style-type: none">- Follow up discussion- Review of issues- Finalisation of Validation Panel conclusions- Wrap up
1:00 pm to 2:00 pm	Lunch

* Format: Short presentation followed by round table discussion

SECTION 3

Colorectal cancer screening in Ireland – business implementation plan

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Executive summary

1.1 Background

- The purpose of screening is to reduce cancer deaths and to improve the quality of life of people found to have cancer.
- It is of utmost importance that a screening programme attains the highest level of quality and quality assurance measures should be incorporated into every stage of the process.
- Colorectal cancer is the second most commonly diagnosed cancer among both men and women in Ireland.
- Each year approximately 1,900 new cases of colorectal cancer occur, 1,070 in men and 830 in women.
- Colorectal cancer is the second most common fatal cancer among men and women in Ireland.
- Approximately 930 people die from colorectal cancer each year in Ireland, 525 men and 405 women.
- Colorectal cancer incidence rates generally increase with increasing age.
- The incidence of colorectal cancer in Ireland is higher than the EU average.
- Ireland has the highest mortality rate for colorectal cancer in Western Europe and according to GLOBOCAN 2002 has the fourth highest mortality rate amongst men worldwide. Women in Ireland have the 15th highest mortality rate worldwide.
- As the incidence of colorectal cancer is increasing and survival rates are improving in an Irish context, a population-based cancer screening programme has the potential to decrease incidence and reduce mortality.
- Screening for colorectal cancer involves the testing of individuals who have no symptoms of the disease.
- A screening programme for colorectal cancer would have a favourable impact on mortality because of;
 - the close association between early stage at diagnosis and long-term survival;
 - the fact that most cancers have a benign phase (adenoma/polyp) before becoming malignant;
 - the long time taken for most adenomas to be transformed into cancers;
 - the relatively long time that established cancers are present before they cause symptoms.

- The screening service requires significant additional organisational structures and systems and should not interfere with the symptomatic service for people with gastrointestinal complaints.
- It is recommended that an immunochemical faecal occult blood test (iFOBt) that operates on an automated testing platform be adopted as the primary screening tool for a population-based colorectal screening programme.
- Persons with an abnormal result from the primary screening test should be offered further investigation as part of the screening process.
- Total colonoscopy is the recommended procedure for people who test positive with the iFOBt.
- The colonoscopy should aim at examining the entire colon to the caecum which should be verified by photographic confirmation in over 90% of cases.
- Colonoscopy should be carried out only by individuals who have received specific training and accreditation in colonoscopy.
- In up to 10% of people the colonoscopy may be inadequate or incomplete for either technical or anatomical reasons and CT colonography is recommended for such individuals as part of the screening process.
- The additional demand for colonoscopy and CT colonography services generated by a national screening programme should be separate from the symptomatic endoscopy service.
- Additional consultant medical staff (Gastroenterologists, Colorectal Surgeons, Anaesthetists, Radiologists, Pathologists), Specialist Nurses and Radiographers, Administrative and Technical Staff will be necessary in a national screening programme.
- When a screen-detected cancer is diagnosed it is recommended that the screening process continue until the end of primary treatment, after which time the patient joins the symptomatic service for clinical follow-up.
- As the incidence of colorectal cancer is relatively low before the age of 50 years and increases progressively with age, the initial target age group for a screening programme should be between 55 and 74 years.
- The programme should aim for a participation rate of 60% amongst the target population.
- 60% uptake would mean approximately 420,000 individuals in the 55-74 age range presenting for screening.
- Biennial screening is the recommended screening interval.

- Quality assurance measures, being an integral component of screening, must apply to the administrative, organisational, technical, clinical, surgical, laboratory and epidemiological aspects of the programme. These measures must involve audit systems amenable to internal and external quality review.
- It will be essential that procedures for evaluation and monitoring are built into any programme established in Ireland. An important element of this will be ensuring that the IT systems enable monitoring of performance and linkage with other external data sources (e.g. cancer registrations, death certification etc.).

1.2 Recommendations

- The purpose of this initiative is to develop a national screening programme for colorectal cancer. The programme will be characterised by common standards and protocols, centralised and regional recruitment, bulk purchasing of testing, regional endoscopy provision, follow-up and outcome reporting.
- The programme will be modelled on the existing successful screening programmes in breast and cervical cancer. It will make use of existing expertise and infrastructure available by partnering with them and achieving economies of scale through the integration of infrastructure and the efficient use of resources wherever possible.
- After analysing medical evidence and international best practices, the National Cancer Screening Service Expert Advisory Group on Colorectal Cancer Screening has put forward the following recommendations.
 - a. Utilisation of the immunochemical faecal occult blood test (iFOBt).
 - b. Full colonoscopy as follow-up of iFOBt positive individuals.
 - c. Target age for a screening should be between 55 and 74 years.
 - d. Biennial screening.
 - e. CT colonography be made available for incomplete or inadequate examinations.
 - f. Colonoscopy services generated by a national screening programme should have a separate operational structure from the symptomatic service.
 - g. Colonoscopy facilities that would include two endoscopy rooms on site.
 - h. Colonoscopy screening centres located in association with hospital services equipped with the facilities and expertise needed to deal with any urgent difficulty or complication that may arise.
 - i. Fully trained and accredited staff in accordance with the programmes QA governance structure.

- j. Colorectal cancer should be prevented by removal of adenomatous polyps in the pre-malignant phase and be treated expertly in a multidisciplinary setting.
 - k. When a screen detected cancer is diagnosed it is recommended that the screening process continue until the end of primary treatment, after which time the patient joins the symptomatic service for clinical follow-up.
- Key components of the screening process will be evaluated in accordance with the programme’s quality assurance (QA) governance structure, including amongst others: participation rates; proportion ineligible for colonoscopy; positivity rate to screening, sensitivity, specificity and positive predictive value of screening; uptake of colonoscopy; yield of cancers and adenomatous polyps; time required for each step of the process; costs of the process; acceptability of the information provided; quality of communications with specialists, GPs and patients; data integrity and laboratory functioning.
 - A summary of projected costs is presented in Table 1 assuming a two year lead-in period from approval to the commencement of screening. The operating costs in the first full year of operation are estimated at €15.2 million.

Table 1 Projected costs

Total operational costs	Year 1 €	Year 2 €	Year 3 €
Total direct operating costs	735,000	2,412,270	13,800,709
Contingency @10%	73,500	241,227	1,380,070
Net operating cost	808,500	2,653,497	15,180,779
One time only costs	250,000	3,481,000	65,000
Total operating costs	1,058,500	6,134,497	15,245,779

- In addition to the total operating costs listed in Table 1 the capital cost estimate for four screening centres is estimated at between **€13-14 million** (excluding any land purchase, planning and development fees, decanting costs, internal management and disruption costs, insurance costs and tender price inflation and deflation).

2. Problem statement

2.1 Epidemiology of colorectal cancer

Each year worldwide an estimated one million new cases of colorectal cancer are diagnosed and more than half a million people die from the disease ⁽¹⁾. Colorectal cancer is the second most commonly diagnosed cancer among both men and women in Ireland ⁽²⁾. Each year approximately 1,900 new cases of colorectal cancer occur, 1,070 in men and 830 in women. The burden of the disease in the population is growing. Between 1994-1996 and 2003-2005 the number of cases rose by approximately 20% in both sexes. This growth is almost entirely a consequence of population increases and ageing.

Colorectal cancer incidence rates generally increase with increasing age. Only around 12-13% of cases present in those aged under 50. Around one fifth of cases occur in the 55-64 age group and another 26% in women and 33% in men are diagnosed in those aged 65-74 years. One third of cases in men and more than 40% in women are diagnosed in those aged 75 and older; this reflects the greater proportion of older women in the population.

By 2020, the number of new cases of colorectal cancer diagnosed each year in Ireland is projected to increase by 79% in men and 56% in women, compared to the incidence in 1998-2002 ⁽³⁾. This projected growth is a result of a combination of demographic changes and underlying trends in incidence.

Approximately 930 people die from colorectal cancer each year in Ireland, 525 men and 405 women. Taking men and women together, this makes colorectal cancer the second most common fatal cancer in Ireland ⁽²⁾. Similar trends have been seen over the past two-three decades in many developed countries.

Ireland ranks in the upper quartile of countries as regards incidence of colorectal cancer. For both sexes in Ireland, incidence rates are higher than the European Union average ⁽⁵⁾. As regards mortality the picture is more serious. According to the 2002 GLOBOCAN estimates, Ireland has the fourth highest mortality rate for colorectal cancer among men worldwide; the mortality rate for men exceeds that in most other European countries and those in the USA and Canada. Women in Ireland have the 15th highest mortality rate worldwide ^(4, 6).

Relative survival at five years after diagnosis for patients diagnosed in Ireland during 1994-2001 is estimated to be 49.2% overall and 48.1% for men and 50.7% for women ⁽⁷⁾. Survival rates have been increasing slowly over time. In Ireland, five year relative survival rose from 47.7% for patients diagnosed in 1994-1997 to 51.0% for those diagnosed in 1998-2001. This improvement was still evident after adjustment for age, stage and other variables. Survival of colorectal cancer patients diagnosed in Ireland in 1995-99 was somewhat lower than the European average of 53.8% at five years ⁽⁸⁾. The highest survival is seen in the Nordic countries and the countries of central

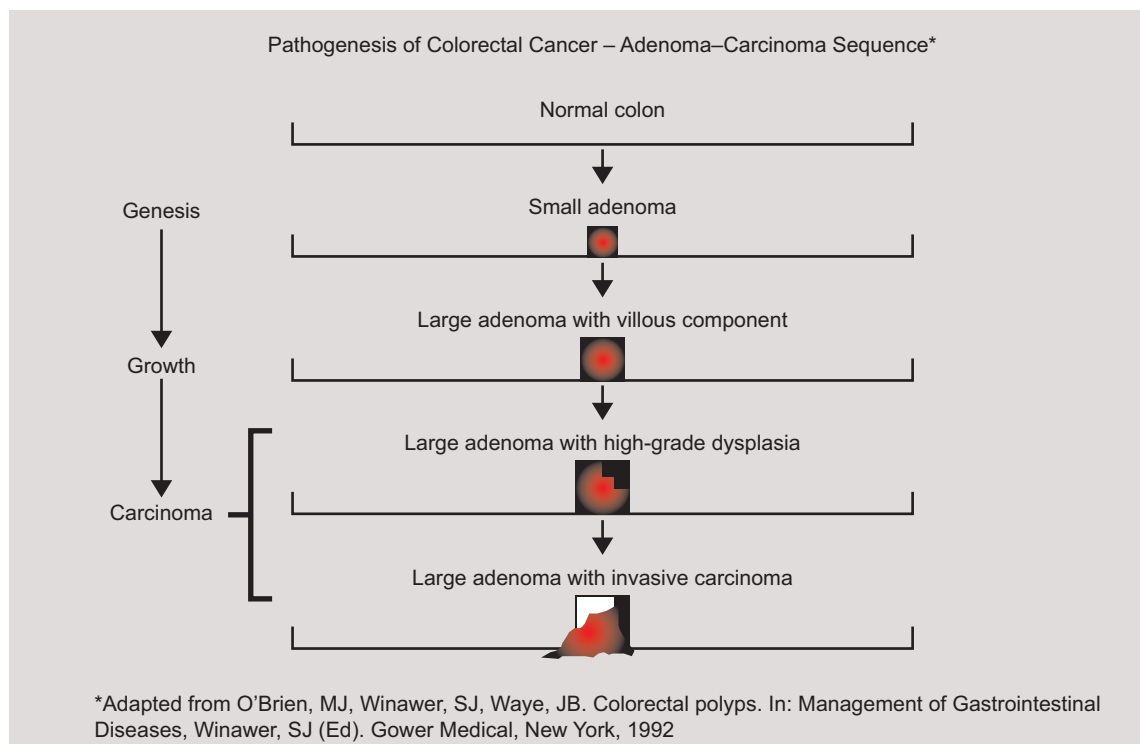
Europe (Switzerland, Netherlands, France and Germany). Patients in Ireland, the UK, Spain and Portugal have intermediate survival, while those in Eastern Europe have the lowest survival. Of those cases diagnosed in Ireland in 1998-2001, 7.3% were stage I, 15.7% stage II, 14.3% stage III and 21.6% stage IV ^(2,7). For 41.1% of cases full staging information was not available (i.e. one or more of Tumour, Node, Metastasis (T N M) was unknown/not recorded).

2.2 Pathogenesis of colorectal cancer

The molecular events underlying colorectal cancer offer insight into this cancer. A stepwise accumulation of somatic mutations underlies sporadic cases while germline mutations are responsible for the inherited syndromes. The risk factors are both environmental and genetic. The presentation of colorectal carcinoma follows one of three patterns: sporadic, inherited, and familial.

- Sporadic disease with no family history accounts for approximately 75% of all colorectal cancer. It is most common in persons older than 50 years of age. Dietary and environmental factors may be contributory.
- About 5% of patients have an inherited predisposition to colorectal cancer.
- The third and least well understood pattern is known as 'familial'. Up to 15-20% of cases fall into this category. Affected patients have a family history but the pattern is not one of the inherited syndromes. Individuals from these families are at increased risk although the risk is not as high as with the inherited syndromes.

Figure 1 Pathogenesis of colorectal cancer



3. Potential to screen for colorectal cancer

Colorectal cancer screening programmes have been or are about to be introduced in many countries. The UK government plans to have a faecal occult blood (FOB)-based screening programme in place for the all those aged between 60 and 69 years in England by 2010 and in Scotland the arrangements are to screen those aged between 50 and 74 years. In France it is expected that the programme will have been extended nationally to all 95 departments within a year for people aged 50 to 74 years and a nationwide programme covering the same age range is in place in Finland. Other European countries have regional programmes in place.

In the report of The National Cancer Forum in 2006, a recommendation was made that a colorectal cancer programme be established to encompass;

- (i) population-based screening utilising faecal occult blood testing (FOBT);
- (ii) screening for those considered to be at particularly high-risk for developing the disease and;
- (iii) a coherent programme for the investigation and treatment of people with symptoms suggestive of colorectal cancer.

The purpose of screening is to reduce cancer deaths and to improve the quality of life of people found to have cancer. Screening for disease involves the investigation of people who believe themselves to be free from and not affected by the condition. Screening for cancer therefore means the testing of individuals who have no symptoms of the disease. Any screening service involving the examination of people who are apparently well, requires additional organisational structures and systems to those needed for people with symptoms or medical complaints, for whom established systems are primarily intended.

4. Colonoscopy service capacity in Ireland

There is justifiable concern about the potential impact of increased colorectal cancer screening activity on demand for colonoscopy services. Consideration of colonoscopy capacity has strongly shaped the planning of colorectal cancer screening programmes in other countries including Finland, England and Wales. Lengthy waiting lists currently exist for symptomatic colonoscopy services in Ireland and increased screening without increased capacity in this sector can only be expected to exacerbate this situation. There is thus a need to design a screening programme which is compatible and consistent with good practice and where the demand for symptomatic colonoscopy services is not excessively impacted.

Assuming the eligible population is 700,000, a 60% response rate to screening and a positive iFOBT rate of 6%, the numbers presenting for colonoscopy will be 25,200 for those aged 55 to 74 years. This suggests that, in a biennial screening arrangement, there will be invitations for 12,600 screening colonoscopies per year. With the uptake for colonoscopy for iFOBT positive individuals likely to be 90%, it is estimated that there will be a requirement for 11,340 colonoscopies per annum arising from primary screening.

The essential principle in the conduct of a screening programme is the aim of the highest possible standard at every stage of the process. The process of a national screening programme is initiated and established by the State and not by the citizen or the patient. Hence the State is obliged to ensure, in as far as is possible, that the programme reaches the recognised international standards for quality at each stage of the process.

Screening colonoscopy should therefore be carried out by individuals who are specifically trained in colonoscopy and accredited by an official training body or an accreditation body/mechanism representing the Irish Society for Gastroenterology and the Royal College of Surgeons in Ireland.

5. Feasibility analysis

A prerequisite for the consideration of a screening programme is that the targeted disease should be an important health problem. Colorectal cancer is clearly a significant burden on our health services.

The iFOBt is readily available and increasing the laboratory capacity to perform this test will be straightforward.

Endoscopy capacity is more problematic and waiting lists exist for the provision of these services. It is clear that there is currently insufficient capacity to meet the demands of a fully implemented screening programme. Thus, full implementation will be impacted by system capacity and new approaches will be needed to make best use of existing capacity.

6. Financial implications

Many factors operate in arriving at a decision concerning public health spending. Considerations such as the medical and epidemiological appropriateness of the proposed service, inequalities and disparities in access or delivery of existing programmes, priorities in the public health system and the overall feasibility and safety of an intervention are some important issues involved in the process.

7. Programme plan

7.1 Barriers

The primary barrier to a full programme is likely to be the capacity for colonoscopy services. Special provisions will be needed for the support of adequate appropriately trained clinical staff to do colonoscopies. Development of clinical practice guidelines will be undertaken as part of the development of an overall QA programme and will draw from the expanding evidence-based literature and from other programmes, including collaborative efforts with international stakeholders.

7.2 Milestones and timelines

Activity	Q1 Year 1	Q2 Year 1	Q3 Year 1	Q4 Year 1	Q1 Year 2	Q2 Year 2	Q3 Year 2	Q4 Year 2	Q1 Year 3
Recruit programme manager	√								
Recruit support staff	√								
Programme plan development	√								
Establish QA Advisory Committee and recruit programme leaders	√								
Identify test sites		√							
Test laboratory implementation		√							
National education and materials preparation		√							
IT system business plan development		√							
Evaluation plan			√						
Identify eligible subjects; identify most appropriate form of invite to participate; screening and follow-up				√					
Recruit clinical staff					√				
Local education and publicity						√			
Screening commences									√

√=Activity start

7.3 Priority activity 2009

The European Guidelines for Quality Assurance in Colorectal Cancer Screening are nearing completion (personal communication: European Commission, Budapest, October 2008). The first quarter of 2009 will see finalisation of chapters. The second quarter of 2009 will see sign-off. The third quarter of 2009 will see their publication.

It is now an opportune time for the CEO of the NCSS to establish a QA Committee to oversee and develop a QA framework for a national colorectal programme. There are already well established EU guideline subgroups (epidemiology, laboratory, pathology, surgery and polyp surveillance) with whom an NCSS QA Committee could collaborate. There are a number of rapidly developing issues within these subgroups that are highly relevant to an Irish programme (including the appropriate number of stool samples for iFOBt, iFOBt cut-off thresholds, surveillance of screen-detected polyps). It is critical that the NCSS is an active participant in these discussions to ensure that the reports from the NCSS Expert Group on Colorectal Cancer Screening can be interpreted in the context of new and emerging clinical and scientific developments. This will ensure that the business implementation plan presented here can be adjusted in accordance with international best practice.

8. Detailed description

8.1. Process

Individuals between the ages of 55 and 74 will be invited to participate in screening using the iFOBT.

Assuming an eligible population of approximately 700,000, a 60% response rate to screening and a positive iFOBT rate of 6%, the number presenting for colonoscopy will be 25,200 for those aged 55-74 years. This suggests that, in a biennial screening arrangement, there will be invitations for 12,600 screening colonoscopies per year. With the uptake for colonoscopy for iFOBT positive individuals likely to be 90%, it is estimated that there will be a requirement for 11,340 colonoscopies per annum arising from primary screening (Figure 3).

Screening centres should be located in association with a designated cancer centre so that the ancillary facilities of a symptomatic service can be available. Screening colonoscopy requires dedicated facilities and additional medical, nursing and administrative staff. The screening unit should be designed, staffed and operate discretely from the symptomatic service. The activity of the screening centre should not interfere with the work of the symptomatic service or vice versa. The current symptomatic services for patients with gastrointestinal complaints lack the personnel, facilities and equipment to allow them to cope with the additional burden of screening since the symptomatic workload is currently stretched to maximum capacity. Some centres are not able to deal efficiently and speedily with the needs of symptomatic patients.

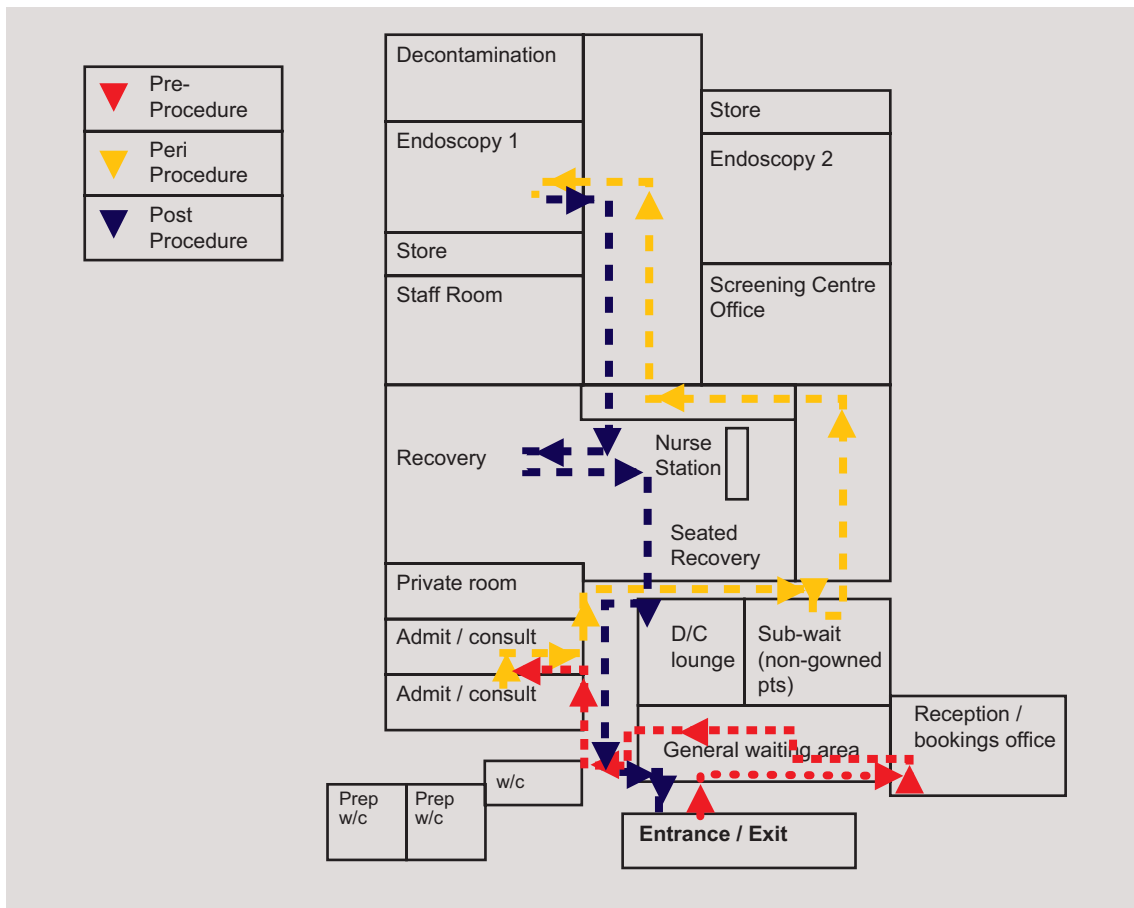
A CT scanner should be available at the adjacent clinical facility and arrangements should be in place for co-ownership/use of the CT scanner between the screening and the symptomatic services. Additional capacity will be needed to establish this arrangement. When a cancer, or other condition requiring in-patient treatment is diagnosed, such investigation and treatment as the patient needs should be carried out by the members of the screening team and the patient should remain in the care of the screening service until such primary treatment has been completed. After this treatment the patient should join the symptomatic service for follow-up. It is essential that the high quality of care demanded by a screening programme be matched by a similar level of care in the symptomatic service. The hospital providing facilities to accommodate a screening centre must also provide a specific number of beds and surgical operating-theatre time for patients requiring in-patient care and surgical treatment.

Each designated colorectal cancer screening centre should have two endoscopy rooms dedicated to screening colonoscopy. Each room should be able to process at a minimum eight to 10 colonoscopy examinations per day or in a five day working week,

80 to 100 per week. The provision of screening centres should be on the basis of clinical best practice, equity and quality assurance. As a result, there will be a minimal initial requirement for at least four centres geographically dispersed throughout the country within close proximity of cancer centres in order to accommodate the anticipated demand for 11,340 colonoscopies. It is very likely that additional numbers of screening centres will be required to maximise participation amongst the eligible population and to ensure national coverage. This issue will be an immediate priority for the programme QA Committee and the Executive Management Team.

An example of a screening centre floor plan which has been used for capital cost estimates is presented in Figure 2.

Figure 2 Example of screening unit floor plan



Ref: UK Joint Advisory Group on GI Endoscopy (JAG)

The UK Joint Advisory Group on GI Endoscopy (JAG) has also issued draft guidance on staffing levels and skill mix appropriate for the provision of a safe endoscopy service (see Table 2 and Table 3).

Table 2 Staffing levels and skill mix for an endoscopy service

	Support staff	Extra recovery nurse	Screening centre manager	Total WTE
One room	5	1	1	6
Two rooms	10 (5x2)	1	1	12
Three rooms	15 (5x3)	0	1	16
Four rooms	20 (5x4)	1 (HCA)	1	22

Ref: UK Joint Advisory Group on GI Endoscopy (JAG)

The recommendation from the NCCS Expert Advisory Group is that each screening centre should have two endoscopy rooms in operation.

Table 3 Endoscopy skill mix - two rooms in operation

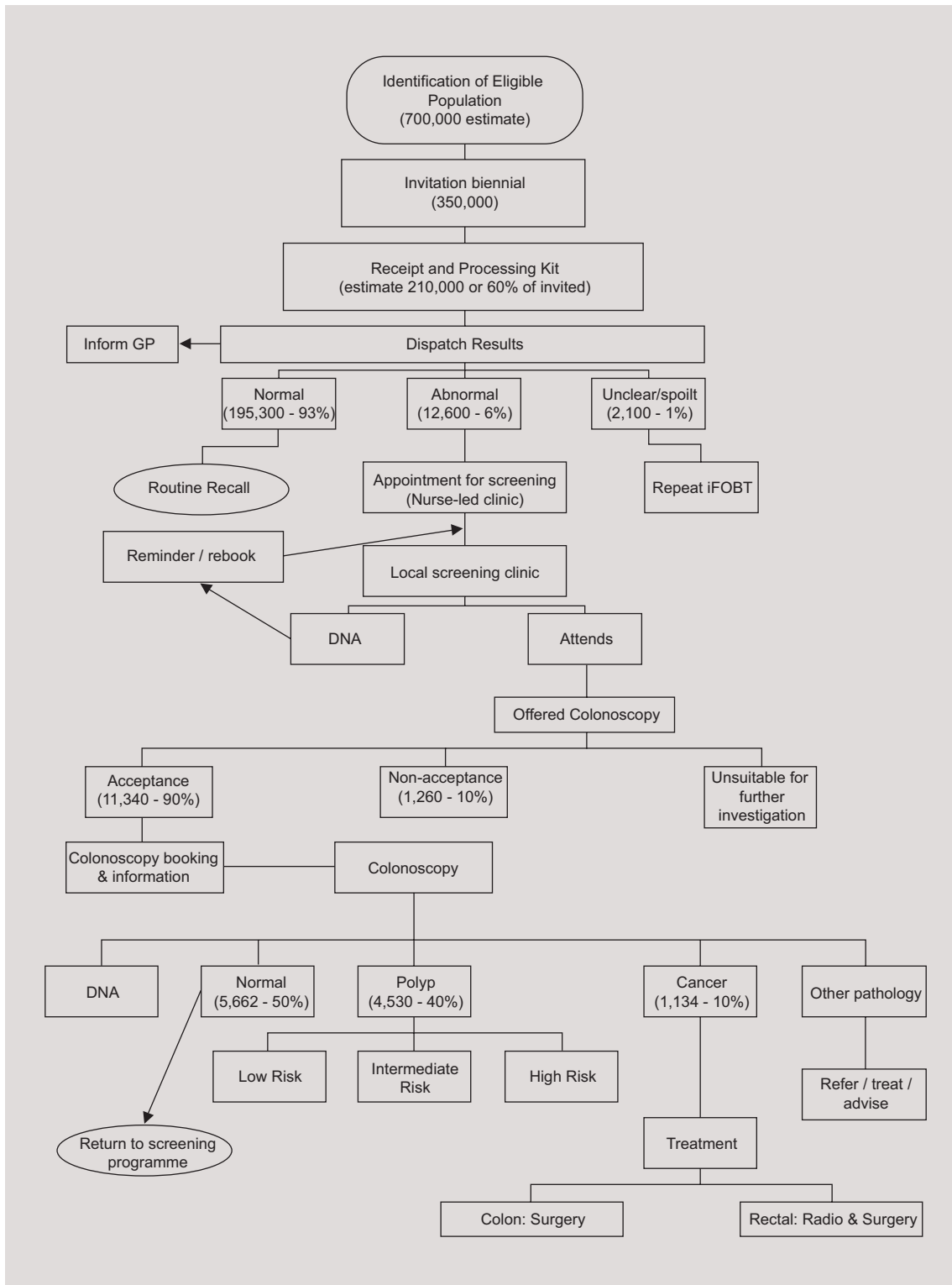
Room	Number of staff	Staffing
Admit/consult	1	Registered Nurse (RN)
Endoscopy room	2	RN and Health Care Assistant (HCA)
Decontamination	1	HCA
Recovery	2	RN and HCA

Ref: UK Joint Advisory Group on GI Endoscopy (JAG)

In the NHS Bowel Cancer Screening Programme (personal communication: NHS Bowel Cancer Screening Southern Programme Hub, Surrey Screening Centre, October 2008) a typical endoscopy session is structured as follows:

- Total duration: 3-3.5 hours.
- Total endoscopies: Four (allowing 45 minutes per patient).
- During an actual colonoscopy there are typically four people in the room; the endoscopist and two qualified staff assisting while a fourth person acts as a 'runner'.
- The patient is generally accompanied at the screening centre by their 'specialist screening nurse' the person with whom they've been in contact with following a positive screening test result, explanation of next steps etc. This person generally acts as a mentor, advocate, and programme data administrator.

Figure 3 Colorectal cancer screening programme overview



The final report of the NCSS Expert Advisory Group currently recommends that those diagnosed with low, intermediate or high risk polyps should leave the screening programme and be followed up with surveillance colonoscopies in the symptomatic service. It is being proposed in the draft EU QA Guidelines that the purpose of surveillance should not be to detect cancers but to prevent the development of cancer i.e. if surveillance colonoscopy is picking up interval cancers/adenomas then it is possible that there was an error with either the initial programme colonoscopy (missed lesions) or the length of the surveillance intervals themselves (personal communication: European Commission, Budapest, October 2008). There is potential to use this new concept as a QA measure for the screening programme itself. Retaining data control on these individuals would only be possible if surveillance colonoscopies remained under the colorectal screening programme. This issue will be an immediate priority for the programme QA Committee and the Executive Management Team.

8.2 Objectives

Several objectives are being addressed in order to assist in planning, development, evaluation and refinement of the programme structure and service delivery model to guide programme planning. These include:

- To demonstrate an integrated programme of invitation, testing, colonoscopy and pathological diagnosis with good communications and quality control.
- To develop educational and information materials for participants and an information line.
- Identification and development of invitation process and delivery of test kits.
- To assess participation rates in each component of the programme.
- To measure time to completion of the process.
- To measure detection rate of relevant pathology.
- To assess costs of each component of the programme.

8.3 Description

The implementation of the programme will require the development of the programme infrastructure and the establishment of processes and standard operating procedures.

The programme will be responsible for patient recruitment, iFOBT kit performance and colonoscopy referral service. Eligible people aged 55 to 74 years will be identified from the central population registry and sent an invitation including explanatory information. The programme will test the options of sending a test kit with the invitation, compared to providing it after a response, and proceed with the better option based on participation rates and costs. After using the kit, the patient will post (pre-paid) the completed kit to the programme. Tests will be analysed by the programme at a single central laboratory. After interpretation, the results will be returned electronically to the screening programme. Test results and recommendations will be transmitted directly to the patient and to the general practitioner (GP) nominated by the patient for their clinical records. All data will be captured by the screening programme database, which will maintain a longitudinal record for each activity.

Those testing positive will be referred for colonoscopy. Upon referral to the screening centre, a pre-assessment will be arranged either by telephone or in person. Both options will be examined. At that visit, the procedure will be explained, eligibility confirmed, and the consent process initiated. Information will be provided on necessary preparation and the colonoscopy appointment booked. At the colonoscopy appointment the patient will meet the endoscopist and the consent process will be concluded. Results of the endoscopy will be entered into the information system for transmittal to the screening programme. Cancers and clinically significant polyps will be biopsied during the colonoscopy and forwarded to a laboratory for interpretation. For colonoscopy and pathology elements, a synoptic reporting form will be used. Throughout this process, data will be collected at each step and this will be used to generate written reports for transmission to GPs. This form will be electronically transmitted to the screening programme database from which reports will be generated.

A number of activities will be evaluated, including (not an exhaustive list): best method of invitation; participation rates; proportion identified at a higher risk; proportion ineligible for colonoscopy; positivity rate to screening and the predictive value and true and false positive rates of screening; uptake of recommended procedures; yield of cancers and pre-cancers; time required for each step of the process; costs of the process; effectiveness of the information provided; communications with specialists, GPs, and patients; data integrity and functioning of the laboratory systems.

8.4 Client recruitment

In the months prior to the official public launch, a comprehensive media campaign will be initiated throughout the country. Additionally, preparatory work will be done with local stakeholders and key opinion leaders in order to inform and recruit hard to reach groups and people of varied ethnicity. Particular attention will be paid to geographical issues in rural/remote areas.

8.5 iFOBT

Immunochemical faecal sampling kits will be purchased in bulk after the completion of a tender process, assembled with instructions and mailed to screening participants. The collection kit components are stable and not subject to any postal restrictions.

8.6 Transportation of samples

Completed test kits will be returned to a central laboratory by post. Screening participants will be instructed to post their samples (pre-paid envelope) to a central laboratory location.

8.7 Laboratory and reporting of test results

The testing will be carried out at a central processing and receiving laboratory. The screening programme database will receive test results electronically from the Laboratory Information System (LIS). Business processes already exist within the NCSS to accommodate electronic transfers of data. In addition to the programme database development and purchase of the instrument interface there will be some additional work required to define fields to be transferred from the LIS and to test that the interface is working correctly. Once established the NCSS ICT Department will be responsible for ongoing functioning of the interface.

8.8 Colonoscopy services

Colonoscopy clinics will be designed and designated for colorectal cancer screening. At present, screening colonoscopies are performed in the same manner as diagnostic colonoscopies. A screening colonoscopy is performed on an individual who is healthy and asymptomatic. Experience from the English Bowel Cancer Screening Programme (personal communication: NHS Bowel Cancer Screening Southern Programme Hub, Surrey Screening Centre, October 2008) has revealed that although they are a healthier population, screening colonoscopies have a high therapeutic procedure requirement e.g. multiple polyp removal.

The designated centres will each need to have an endoscopy system to facilitate the collection of data and the transfer of requisite data to the screening programme.

Patients will be assessed prior to the colonoscopy. As the majority of screening participants will be healthy, asymptomatic individuals, abnormal findings should be few. Individuals, for example, with bleeding disorders, on anticoagulants, or significant heart disease will be managed in accordance with best clinical practice. An experienced and appropriately accredited endoscopist who fulfils criteria outlined by the screening programme to ensure safety and quality control will perform the colonoscopy. Adherence to QA endoscopy standards will be continually monitored.

8.9 Pathology and reporting

All pathology specimens received from colonoscopy will be sent to an accredited laboratory. Experience with other screening programmes has demonstrated that uniformity and consistency (quality assurance) are best maintained by centralisation of pathology services. There is considerable merit in developing a pathology reference centre to develop specific pathological expertise, standardised reporting criteria and reporting templates. A centralised case repository will also provide easy access to collected material for research and teaching purposes.

8.10 Information system

Currently the NCSS is building a new population registry system, for use by all cancer screening programmes. However, there will be a need to develop a system to facilitate clinical history, call/recall linkages with the laboratory reporting system for iFOBT results and utilise appropriate technology for the direct import of colonoscopy and pathology reports.

8.11 Financial summary

Table 4 summarises the estimated one-time operating costs, recurring operating costs, labour and non-labour costs, diagnostic and clinical support services impacts, and total costs for the first three years of operation beginning 01 January 2009. In developing this proposal and budget several assumptions have been made which are outlined below.

The following costs are included in the budget presented in Table 4:

- Administration costs of the programme, including market research, screening promotion, advertising, invitation letters, evaluation etc.
- The cost of the iFOBt kit and testing.
- Colonoscopy equipment for four screening centres.
- Disposables associated with a colonoscopy (forceps, snares, brushes etc.).
- A central information and communication system.
- Interfaces between screening centre, IT systems and NCSS central office.
- Professional costs associated with colonoscopy procedures.
- Professional costs associated with treatment of identified lesions/cancers.

A number of additional assumptions have been made that include the use of a 3% inflation figure per year for all non-staffing expenses. Staffing calculations also assume a salary increase of 3% per year.

Table 4 Financial summary

One time only operational cost	Year 1 €	Year 2 €	Year 3 €
Office equipment, computers, printers	0	50,000	5,000
IMIT interface and population programme	250,000	25,000	10,000
Colonoscopy equipment (per centre 2 pentax Hi Line Systems, 2 diathermy) x 4 centres	0	2,694,000	25,000
Special clean station sinks (1 x 4 centres)	0	12,000	0
Colonoscopy computer systems (€75,000 x 4 centres)	0	300,000	25,000
Colonoscopy room furnishings (x 4)		400,000	0
Total one-time costs	250,000	3,481,000	65,000

Operational cost

(a) Labour

Staffing category	Year 1 €	Year 2 €	Year 3 €
Management / admin total	€0	€2,002,270	€2,719,013
Medical / dental total	€0	€0	€3,215,687
Nursing total	€0	€0	€1,855,236
Other patient and client care	€0	€0	€882,504
Health and social care professionals	€0	€0	€143,969
Total staffing	€0	€2,002,270	€8,816,409

(b) Non-labour

Category	Year 1 €	Year 2 €	Year 3 €
Quality assurance infrastructure	250,000	50,000	50,000
Communication & market research	100,000	150,000	450,000
Clinical research	50,000	50,000	50,000
Recruitment & training	50,000	75,000	50,000
Legal & professional fees	250,000	50,000	25,000
Administrative expenses	25,000	25,000	25,000
Travel and accommodation	10,000	10,000	10,000
Letter printing & dissemination (1million per year)	0	0	1,000,000
Kits, lab reagents, disposables, envelope, stamp (€3.75 per kit)	0	0	787,500
Processing (disseminate kit, receive kit, process kit, send out results). Estimate of €10 per test	0	0	2,100,000
Disposable biopsy forceps (€12 each x 5,000 annual)	0	0	60,000
Disposable polypectomy snare (€18 each x 5000 annual)	0	0	90,000
Disposable brushes for cleaning scopes (€295.79 brushes box of 50 x 15,000)	0	0	88,800
Maintenance for Pentax (8 systems – 2 per centre 10% of purchase price)	0	0	168,000
Maintenance for computer application	0	0	30,000
Total non-labour	735,000	410,000	4,984,300

Table 5 Summary of total operational costs

Total operational costs	Year 1 €	Year 2 €	Year 3 €
Total direct operating costs	735,000	2,412,270	13,800,709
Contingency @10%	73,500	241,227	1,380,070
Net operating cost	808,500	2,653,497	15,180,779
One time only costs	250,000	3,481,000	65,000
Total operating costs	1,058,500	6,134,497	15,245,779

In addition to the one time and recurring operating costs Table 5 summarises the capital outlay for four screening centres.

Table 6 Capital cost estimates

Capital cost	Year 1 €	Year 2 €	Year 3 €
Building cost site 1	2.8m	0	0
Building cost site 2	2.8m	0	0
Building cost site 3	2.8m	0	0
Building cost site 4	2.8m	0	0
Professional fees	1.8-2.8m		
	0	0	
Total operating costs	13-14m	0	0

These costs do not include other potential related costs that might include land purchase, planning and development fees, decanting costs, internal management and disruption costs, insurance costs and tender price inflation and deflation.

8.12 Financial risk considerations

There are a number of financial risks that need to be considered as the screening programme proceeds in the context of a changing health care system, including a heightened awareness of the need for screening and preventive measures as health strategies successfully take hold at a population level. These risks, their probability, impact and mitigation strategies are summarised as follows.

Risk 1: The proposed programme could underestimate incremental demand for screening services in the eligible target population as education and communication strategies take effect. This would increase the screening numbers with commensurate additional positive iFOBTs identified, plus additional colonoscopies, laboratory and pathology services.

Probability: Low

Impact: Medium

Mitigation strategy: The demand for screening and follow-up services will be monitored closely during the ongoing evaluation and modifications will be made as necessary. Over the long-term, as more colorectal cancers are prevented or detected early with a successful screening programme, there will be a commensurate reduction in treatment costs.

Risk 2: The proposed programme could underestimate the actual positivity rate for iFOBTs, resulting in additional required colonoscopies and placing further demand on the health system for these and follow-up laboratory and pathology services.

Probability: Low

Impact: Low

Mitigation strategy: Positivity rates will be monitored closely during the on going evaluation and modifications will be made as necessary. The iFOBT offers the additional option of an automated testing platform. Ultimately with feedback of programme results and data on detection rates of cancers and adenomas the threshold for a positive test can be adjusted to achieve the most appropriate balance between sensitivity, specificity and colonoscopy capacity

Risk 3: iFOBT costs could over time, exceed budgeted amount as technology changes.

Probability: Low

Impact: Low

Mitigation strategy: iFOBT kits will be put to tender to minimise costs. It is anticipated that costs over the long-term will be successfully negotiated through contractual arrangements with vendors.

Risk 4: Colonoscopy costs for the programme over time will exceed the amounts available within appropriations.

Probability: Low

Impact: Medium

Mitigation strategy: This is not expected to occur. However, all aspects related to the cost of colonoscopies will be carefully reviewed as part of the planning.

8.13 Governance and operations

The programme will be integrated into the existing NCSS operational environment, which involves a shared management and support services structure. This structure is supported by centralised ICT for information technology and through a Service Level Agreement for contracted laboratory services.

8.14 Operational challenges and mitigation strategies

Pre-assessments and follow-up visits will be conducted as part of the screening programme. This could change the work scope and flow in the screening centre. The programme will issue results and follow-up letters. In order to undertake this, the creation of information systems to manage this process is key. The information system will include components for data input, reporting, patient management and outcome analysis.

8.15 Evaluation framework

There are a number of ways to evaluate programmes. The evaluation framework will emphasise two aspects – monitoring and impact. Monitoring evaluation will assess the screening process and outcomes to facilitate refinement of the programme. Included will be issues such as whether the target population was reached; if initial objectives were met; screening centre comparisons; and fine-tuning the operational pathways and processes. A systems analysis approach with particular attention paid to component analysis will be put in place. Impact evaluation will include assessment of whether the programme has been implemented according to the business plan; if the objectives were met; if there are any unintended consequences, and whether differences in implementation between the sites affected screening outcomes. An objectives-based approach will be used. Both quantitative and qualitative methods, including patient and physician focus groups will be incorporated. This is important in order to continually identify ways to improve effectiveness, efficiency and efficacy to inform the controlled implementation of the programme.

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