UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	T Amarnath	**Email address:**	xxxx xxxx
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Role:	**Director of North Derbyshire Bowel cancer screening centre**		

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Yes ☒ **No** ☐

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
221	B. Offer FIT to 50-74 year olds at thresholds below 93 ug/g and decommission (or not start) BS.	I would support option B.
	Improving screening Colonoscopy capacity and quality	Whoever is trained for BS to be trained and upgraded to do colonoscopy. Impose strict criteria for symptomatic referrals to use FiT etc and reduce symptomatic colonoscopy.

		Retrain and transfer symptomatic colonoscopists to screening.
	i. Is the ScHARR model sufficiently robust to support UK policy? -	Yes
	ii. Do the policy recommendations follow from the ScHARR work?	– Probably yes
	iii. Are the policy options feasible? If so how can efforts to deliver either be evidenced? –	Feasible with investment Strict QA , governance and audit as well as cancer & Adenoma detection rates

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	Prof Graham MacKay	**Email address:**	xxxx xxxx
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Yes ☒ **No** ☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
Page 3	Options for consideration	A. Based on the ScHARR model I would support option B - Offer FIT to 50-74 year olds at thresholds below 93 ug/g and decommission (or not start) BS.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	Professor Callum G Fraser	**Email address:**	xxxx xxxx
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Do you consent to your name being published on the UK NSC website alongside your response? Yes			

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
Entire report	General comment.	The report from ScHARR: Optimising Bowel Cancer Screening: Phase 1: Optimising the cost effectiveness of repeated FIT screening and screening strategies combining bowel scope and FIT screening does provide much information of interest to all those involved in bowel screening and concerned with the use of faecal immunochemical tests for haemoglobin (FIT). Note that this response is individual and not on behalf of any organisation. There are a number of minor errors, for example, the use of ug/ml in the second paragraph of 1. Short Summary and on pages 6, 8, 18 and 35 instead of µg Hb/g

		faeces. Moreover, although u is most widely used, µ (Greek micro) is also used and that is correct.
Page 9, conclusions, and elsewhere.	Comment on age range for screening and comment on the preferred option for the future in the NHS BCSP.	I was pleased to see that there was a focus on the age to start bowel screening and that, as per many international and national guidelines and recommendations, as done in the Scottish Bowel Screening Programme and as very much desired by the UK bowel cancer charities, a starting age of 50 years seems favoured. Further, the evidence clearly suggests that a repeated biennial FIT screening strategy would be far more effective and cost effective than a one-off bowel scope and FIT: in consequence, the particular recommendation - **offer FIT to 50-74 year olds at thresholds below 93 µg Hb/g faeces and decommission (or not start) BowelScope** – seems the most cogent to me. Section 19 in document #1 states: Thus, the implications of the ScHARR model are that the services should concentrate on driving FIT sensitivity and colonoscopy capacity up as fast as possible. Who could disagree? Although I am personally unaffected by any decision that is finally reached, I would strongly support this FIT only approach.
4.3	Comment on the use of the data from the NHS BCSP FIT pilot.	My expertise is in laboratory medicine and is concerned with the application of FIT in both screening and assessment of patients presenting in primary care with symptoms of lower bowel disease. Based on this, I agree that, although there are many peer-reviewed publications on the relationship between faecal haemoglobin concentration (f-Hb) threshold (cut-off) and outcome characteristics, the English FIT pilot provides the most appropriate data source for the analyses performed for the report (as in: Moss S, et al. Gut 2017;66:1631-44).

Throughout report – everywhere numerical data on faecal haemoglobin contraptions are given numerically as FITn	General comments on the use of FITn throughout and units to be used.	However, I have a number of concerns regarding the use of the very specific numerical FITn, where n is presumed to be the faecal haemoglobin concentration (f-Hb) threshold (or cut-off) in units of ug/g – which, as above, correctly should be: µg Hb/g faeces – see: Fraser CG, et al. A proposal to standardize reporting units for fecal immunochemical tests for hemoglobin. J Natl Cancer Inst 2012;104:810-4. In addition, the use of FITn has been deprecated by the Expert Working Group on FIT for Screening, Colorectal Cancer Screening Committee, World Endoscopy Organization (see: Allison JE, et al. Comparing fecal immunochemical tests: improved standardization is needed. Gastroenterology 2012;142:422-4). Moreover, throughout the report and especially the appendices, very different sets of FITn are used in the different Tables – why? This makes for more difficult understanding.
Throughout report – everywhere numerical data on faecal haemoglobin contraptions are given numerically as FITn	Comment on the fact that the data in the report were obtained with ONE FIT analytical system and the fact that data on the n of the FITn will not be transferable across different FIT analytical systems.	Firstly, note that the FIT pilot done in England was performed with a single FIT analytical system (OC-Sensor Diana, Eiken Chemical Co., Ltd, Tokyo, Japan). FIT generally use polyclonal antibodies which bind to epitopes on the globin moiety of faecal haemoglobin and thus detect intact haemoglobin and early degradation products. It is vital to note, as very elegantly shown recently by Gies A, et al. Direct comparison of diagnostic performance of 9 quantitative fecal immunochemical tests for colorectal cancer screening. Gastroenterology 2018;154:93-104, that different quantitative FIT give very different clinical outcomes for identical faecal samples at the f-Hb cut-offs recommended by the manufacturers and, very importantly, that this was not corrected by use of identical f-Hb cut-offs in µg Hb/g faeces across the various FIT systems studied. Thus, the n in the FITn cited throughout this ScHARR report are applicable only to

		one only FIT analytical system and, presumably, that might or might not be selected for the NHS BCSP.
Throughout report – everywhere numerical data on faecal haemoglobin contraptions are given numerically as FITn	Comment on the need to use positivity rate in the evaluation and comparison of FIT analytical systems and not FITn.	Secondly, this work of Gies et al and two very recent papers on comparisons of the most commonly used FIT analytical systems, both published in a high-impact, peer-reviewed journal (Grobbee EJ, et al. A randomised comparison of two faecal immunochemical tests in population-based colorectal cancer screening. Gut 2017;66:1975-82, and Passamonti B, et al. A comparative effectiveness trial of two faecal immunochemical tests for haemoglobin (FIT). Assessment of test performance and adherence in a single round of a population-based screening programme for colorectal cancer. Gut 2016 Dec 14. pii: gutjnl-2016-312716 [Epub ahead of print]), quite clearly show that comparison should be done at equal positivity rates and definitely not at equal f-Hb cut-offs. This vital to be adopted approach is also justified in a recent review on strategies for comparisons of FIT (Fraser CG. Comparison of quantitative faecal immunochemical tests for haemoglobin (FIT) for asymptomatic population screening. Transl Cancer Res 2016;5(Suppl 4):S916-9). Very importantly, I advocate that giving the positivity rates achieved along with the various FITn quoted in the ScHARR report and appendices would be most valuable, not just in part as on page 18 in the text (perhaps a very fill table early in the text would suffice?). It is important to note that positivity is not linearly related to f-Hb cut-off, so a single correction factor cannot be applied. Perhaps a graph would also help? Like Figure 20? Ideally, positivity would be added in an additional column to the right of the lists of FITn given in some of the Tables in the Appendices.
Throughout report – everywhere numerical data on faecal haemoglobin	Comment on the fact that FIT analytical systems evolve and results may not be comparable over time as manufacturers	Thirdly, it should be noted that the manufacturers of FIT analytical systems undertake continuous quality improvement and do change some of the variables that can affect the f-Hb results.

contraptions are given numerically as FITn.	“improve” components that can significantly affect outcome data.	For example, the stability of haemoglobin present in a faecal sample is depend on a number of factors, a very important one being the composition of the buffer in the specimen collection device. Note that manufacturers change the composition over time to improve stability (as shown in, for example: Symonds EL, et al. Effect of sample storage temperature and buffer formulation on faecal immunochemical test haemoglobin measurements. J Med Screen 2017;24: 176-181). Data obtained and published in the past, even the recent past, such as in the NHS BCSP pilot, may not be totally applicable to data achieved with the FIT analytical system(s) eventually selected for the NHS BCSP.
Page 37	Retest rate	Note that the “retest” rate will also be different with different FIT analytical systems since some specimen collection devices have merits over others: this is nicely shown in the comparison of two FIT analytical systems by Grobbee et al (citation above).
Limitations 7.2 and Summary	Final comments.	I do not consider that these points influence the main conclusions and the best option documented in the report, namely, that FIT should be offered to 50-74 year olds and BowelScope should be decommissioned (or not begun) seems most cogent: the endoscopy resources thereby liberated should be used to make for as low a f-Hb cut-off as possible (to obtain the desired positivity rate with which the colonoscopy resource can cope). However, I do wonder if the comments on FIT given above – essentially that the numerical data on f-Hb depend on the FIT analytical system used and are not transferrable over system or time – should be detailed in the Limitations section 7.2 of the report. Moreover, it is vital that positivity rather than FITn be considered as the major determinant of the f-Hb eventually applied as the cut-off in the NHS BCSP. In addition, my comments might well be considered for inclusion in the development of phase 2 of the very good work being done by ScHARR on

		Optimising Bowel Cancer Screening.
4.3 Page 17 Paragraph 2	Minor comment on units.	Note that the 100 ng/ml documented in the Italian study cited is equivalent to 20 µg Hb/g faeces.
Page 33 Figure 20 and also Page 36 Table 13	Minor comment on units.	The legends for the x-axes in the components of Figure 20 have mg Hb/g faeces, which should be µg Hb/g faeces. This also holds for the heading in Table 13 on page 36.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

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Role:	**Clinical Director WKMBCSP**		

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Yes

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
Overall	All	I feel the Bowel Scope programme is complex to deliver and arduous for the staff involved. It is also taking up a lot of endoscopy resources but we do not see a large take-up. I believe a better process would be to offer FIT testing instead from the age of 50 obviously with a view to proceeding to colonoscopy for those positive. I am unable to comment on the optimal frequency and cut-off since I think it will take time to identify these optimal values. Perhaps a FIT test at 50 then 55 followed by 2 yearly from 60 as currently with BCSP.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

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Role:	**Retired Consultant Gastroenterologist**		

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Yes X☐ No ☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
	Overall	I am a recently retired Consultant Gastroenterologist and wish to comment upon Bowel Cancer Screening. I have been performing endoscopy for most of my clinical career and was Head of Department for three endoscopy units in the south west during the latter years of my career. I have seen the introduction of, and have implemented, JAG accreditation, the arrival of the BCSP program and recently Bowel Scope. I currently work voluntarily for Bowel Cancer UK as a patient awareness lecturer and in an advisory capacity. An effective Bowel cancer screening program is an essential part of a modern Health

		Service. It should have a significant impact on the outcome of colorectal cancer by detecting and treating the premalignant polyp phase and detecting early/ pre-symptomatic cancer. It must not be at the expense of rapid access to endoscopy for patients with symptoms of colorectal cancer, not impact on follow up of known disease or family history surveillance. I have seen an adverse effect on the ability of endoscopy units to deliver rapid access to symptomatic patients as a result of screening and in particular the current attempts to introduce Bowel Scope screening. I believe that flexible sigmoidoscopy screening was an idea (a good idea thanks to Wendy Atkin) which is now obsolete as medicine progresses. It seems to have been introduced on a political whim with no thought as to the capacity to undertake the program and little thought to it's quality. It will largely be delivered by rapidly trained and inexperienced nurses or technicians. I speak as someone who spent some of my last working months training such Endoscopists and I had to reduce my diagnostic workload as a result. I strongly believe that future developments will transform screening, in particular the development of accurate DNA testing for polyp disease or cancer, as well as population screening for genomic abnormalities such as Lynch syndrome. As a result, I believe that we such maximise our current ability to screen whilst we encourage and wait for these scientific advances. Colorectal cancer is increasing in younger patients and any screening program should start at a younger age, ideally 50 yrs of age. We should also include the identification of patients at risk of Lynch syndrome as part of any screening program. The arrival of the Faecal Immunoglobulin Test (FIT test) has the potential to add a new dimension to the screening process. If the sensitivity is set high enough then it may be able to reliably place negative testing patients in to a low risk category and reduce their screening intervals whilst detecting more polyps and cancers which should increase the yield of screening colonoscopy. Endoscopy capacity is at the heart of the current screening review and whilst efforts are taking place to increase it by Endoscopist training and more efficient use of endoscopy resources, it will be a slow process. In conclusion

		I support the proposal that the Bowel Scope program is scrapped immediately (as per ScHARR) FIT testing should be rolled out nationally as quickly as possible Entry in to the BSCP program should be at aged 50 People testing negative with a sensitive FIT cut-off should be rescreened in 3-5 years The initial BSCP invite should ask patients if they have a family history of Colorectal cancer. It should be possible to devise a follow up questionnaire (perhaps online) which identifies those with possible or probable Lynch syndrome families who could then go straight to colonoscopy or to DNA testing.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

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Role:	Clinical Director		

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Yes x☐ No ☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
Optimising bowel screening: Policy implications for the UK: Page 3 21.i	**i.** Is the ScHARR model sufficiently robust to support UK policy?	The ScHARR model is not sufficiently robust to support UK policy as it takes assumptions from the trial data. There are many uncertainties in the modelling and assumptions which have been used to set the sensitivity threshold for FIT testing and only benefit if capacity for colonoscopy is increased.
Optimising bowel screening: Policy implications for the UK: Page 3 21.ii	**ii.** Do the policy recommendations follow from the ScHARR work?	Yes policy recommendations appear to follow from the ScHARR work.
Optimising bowel screening: Policy implications for the UK: Page 3 21.iii	**iii.** Are the policy options feasible? If so how can efforts to deliver either be evidenced?	Option A: • Roll out of Bowel Scope is a struggle at present due to capacity issues for Acute Trust providers with symptomatic vs screening demand. Therefore it would not be feasible to increase the age range & meet trial uptake level. • Some areas of the UK have rolled Bowel Scope out fully and some have been unable to roll out fully due to lack of endoscopy capacity. • Trial uptake level has not been reached to date due to lack of publicity which screening centres were advised not to undertake in areas where full roll out had not occurred. Requirements for Option A to be feasible: • Defined incentive or target date for full roll out is required for provider sites & guaranteed support from providers and

		their Acute Trusts for the Bowel Scope programme. Advantage of Option A: • No requirement for higher skilled workforce (i.e. accredited screening colonoscopists) as Bowel Scope can be carried out by accredited nurse endoscopists.
Optimising bowel screening: Policy implications for the UK: Page 3 21.iii (continued)		Option B: • Sufficient colonoscopy capacity & higher level of skilled workforce (i.e. screening colonoscopists) would be required, neither of which are currently available. • De-commissioning Bowel Scope: This would have a huge impact on the existing work-force. Increasing capacity to meet this need would require significant increase in workforce and require relaxation of accreditation standards. In addition this option could disrupt the current service. • There are inherent difficulties in de-commissioning an existing service. • Developing Bowel Scope Endoscopists (including the training and accreditation required) for them to reach the level of Screening Colonoscopist would be very difficult to achieve.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

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Role:	Specialty Registrar in Public Health / Screening and Immunisation Lead		

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Yes x **No** ☐

Section and / or page number	Text or issue to which comments relate	Comment
	Use of cost-effectiveness (NMB) as a measure over effectiveness (QALYs) or reduction in CRC incidence or mortality	The authors clearly point out that conclusions and recommendations would be different if the primary measure being used was reduction in CRC incidence or mortality because of the greater benefits in these outcomes which would be achieved from screening older age groups compared to the greatest benefits in terms of QALY's and NMB which would be achieved from screening younger age groups. The authors are clear to report all measures in the results tables for each screening strategy, which clearly show discrepancies between the impacts on

		different measures i.e. CR incidence, mortality, QALY's and NMB. This raises the question about what the goal of the bowel cancer screening programme is? Screening is about achieving the greatest population impact but is that the greatest health benefit from the programme for the cost? Or is it the greatest reduction in CRC incidence and/or mortality?
	Uptake assumptions	The authors highlight the limitation that modelling is based on assumptions about uptake in different age groups due to limited data access/availability of more detailed uptake data. This is an issue, however based on data availability it is accepted that this is best available data at this time to underpin this modelling assumption. The authors completed modelling based on the assumption that FIT uptake will be the same as current gFOBT uptake and that bowel scope uptake in a proposed combined programme would be the same as current uptake. A sensitivity analysis is reported based on the suggestion that bowel scope uptake would increase to that of the pilot (55%) but a similar sensitivity analysis for the expected increase in uptake of FIT compared to gFOBT is not reported. This is despite quoting pilot evidence about how uptake increased in men, among people who have previously declined testing, and among lower socioeconomic groups. This assumption would be important to consider seeing as it could potentially significantly impact capacity.
Results pages 51- 52	NSC proposal 1 – extension of FIT to 50-74years with one-off scope at 58years instead of FIT	The authors state that this combined strategy is cost-effective and effective where 51-65 year olds are screened every two years at FIT161 and where expected endoscopy capacity is 50,000. It is however reported to not be cost-effective under sensitivity analysis where there are lower CRC treatment costs. In addition a combined strategy is not cost-effective for any of the proposed strategies where capacity is expected to be above 50,000. Based on the assumption that 10 bowel scopes and 4 screening referral colonoscopies are equivalent, a repeated FIT screening strategy would be 3 times more effective and 4 times more cost-effective than a one-off bowel scope strategy. This provides clear evidence that NSC proposal 1 – extension of FIT to 50-74yrs with one-off scope at 58yrs instead of FIT is not an option that should be pursued.
	Assumptions on endoscopy	The following assumptions about impacts on capacity have been made in the

	capacity	modelling which seem logical: - Increased detection would lead to an increase in surveillance procedures. This would impact available endoscopy capacity - Capacity would also be impacted by uptake of FIT which is assumed to be same as gFOBT for all ages - No evidence that there would be a change in symptomatic referrals to endoscopy - Sensitivity level of FIT (modelling of different levels done) - Screening interval (modelling of different intervals done) - Eligible screening age (modelling of different age ranges done) Capacity appears to be one of the biggest issues with this programme and we are pleased that it is one of the primary factors being considered as part of this consultation.
Methods – endoscopy capacity pages 20-22	Predicting endoscopy capacity	In summary the authors seem to suggest in the results and conclusions of this document that screening colonoscopy capacity could reasonably increase to 90,000. By when and how is not particularly clear. These conclusions seem to have been drawn based on research conducted previously looking at numbers of non-medical endoscopists trained with projections for 2016 and 2018. In summary this document says current capacity is around 50,000 but 90,000 is achievable. Increasing capacity beyond that currently isn't realistic. Our concern would be about the strategy for increasing endoscopy capacity. The modelling completed to predict the realistic achievement and sustainability of 90,000 is not clear and seems at odds to the current situation in some programmes which are struggling with capacity as a result of recruitment and retention of qualified staff.
Results pages 48-50 (plus further tables in the appendices on page 10 onwards)	FIT strategies	Optimal strategies, in terms of eligible age, screening interval and FIT level, are clearly presented for each capacity level. The tables show the effectiveness, cost-effectiveness, reduction in CRC incidence and reduction in CRC mortality expected based on the model assumptions.

		Optimal strategies based on cost-effectiveness are: 50,000 = 2 yearly 51-64 at FIT 161 (8 tests) 70,000 = 2 yearly 50-70 at FIT 153 (11 tests) 90,000 = 2 yearly 50-74 at FIT 124 (13 tests) Results for capacity over 100,000 are only in the appendices as increases in capacity beyond 90,000 are not expected by the authors. If the primary goal is a cost-effective programme, it is unclear why none of these 3 strategies have been proposed as options in the NSC consultation document.
Appendices pages 11 - 12	NSC proposal 2 – extend FIT to 50-74 years with FIT<93	This isn't actually the recommendation by the authors of the research. The authors recommend 2 yearly screening of 50-74 year olds at FIT 124 as this strategy is deemed to give maximum cost-effectiveness for a capacity of 90,000 which is the highest deemed achievable. The NSC proposal is in fact the most cost-effective outcome given for capacity of 110,000. Whilst the age and interval are the same the sensitivity of the test is higher. One of the primary concerns in bowel cancer screening is capacity. We are therefore concerned on the ability of services to be able to deliver a programme using this screening strategy when it would require an endoscopy capacity level deemed by the authors to not be realistic in the current situation.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

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Role:	**Clinical Director**		

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Yes X **No ☐**

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
All	All	The supporting documents make a very strong case for decommissioning BowelScope (BS) and lowering the FIT start age to 50. This centre strongly supports that view provided: 1. The FIT Hb cut-off is set (as proposed) to meet capacity and adjusted regularly. 2. 2 years notice is given to allow conversion training for current BS screeners to colonoscopy screeners and support for this process is provided. 3. The funding model (e.g. per procedure or per head of the population) is viable. A great concern of many screening centres is that the FOBt service is only

		viable due to support by the BS funding mode - there has been no increase in funding for FOBt screening since 2006 despite large increases in surveillance procedure numbers and inflation of overheads (staffing and costs). A per procedure tariff (which may be different between index and surveillance) would ensure there is no perverse incentive around not increasing uptake rates. 4. Current data on adenoma detection rates in the BS programme are used to inform the models – the data used in the modelling was from early on in the programme and it is likely that adenoma detection rates have increased substantially since then.

UK National Screening Committee
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Consultation comments pro-forma

Name:	xxxx xxxx / xxxx xxxx	**Email address:**	xxxx xxxx / xxxx xxxx
Organisation (if appropriate):	NHS England North (Yorkshire and the Humber)		
Role:	**Public Health Commissioning Lead/ Senior Screening and Immunisation Manager**		

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No ☐ but happy to be contacted for clarity or discussion

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
Covernote/Conclusions/13	But critical to the model assumptions and subsequent policy recommendations is that detection rates and uptake achieved in the trial have not been seen in the English Bowel Cancer Screening programme thus far. There is uncertainty as	This is the most fundamental issue in relation to BS. We know it's effective but uptake is unlikely to be as high as hoped and FIT already has evidence that uptake will be greater.

	to whether BS uptake and detection rates can be increased to the levels reported in the trial, and hence trial reported effectiveness achieved.	
		Modelling – having reviewed all docs from a commissioning point of view the modelling for colons increasing would need to be a holistic discussion with screening and acute trusts. The argument for FIT given there are significant percentages of adenomas detected on both left (as seen under Scope) and right side would be greater than using Scope alone.
Whole pathway approach		What we are picking up is that it would be more worthwhile to focus our commissioning energies on FIT at it's most sensitive which would increase equity to all rather than continuing to progress bowel scope roll out. Would it therefore be sensible to pause bowel scope roll out to take stock of capacity in the system and the holistic pathway? We can then gear up the pathway and implement the more effective method of FIT which is seen to be more accessible and user friendly to patients.
Whole pathway approach		Acknowledgement that the national and local teams will have to work with the whole system (screening and symptomatic) to review capacity of colonoscopies, pathology, radiology and treatment services to understand the pressures and solutions. Bearing in mind the different commissioners for the pathways. It also has an implication on the national training and recruitment agenda due to the current issues with access to all training across the pathway.

UK National Screening Committee
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Consultation comments pro-forma

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Role:	**Programme Manager & Lead Nurse**		

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Yes ☐ **No** ☐

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
2. section 4.4 pages 19-22	General comments about colonoscopy capacity and workforce.	There is no mention of the key performance indicators required by a colonoscopist to become an Accredited Screening Colonoscopist, and perhaps an assumption in the document that all BCSP colonoscopies can be undertaken by any colonoscopist. Bowel Scope endosocopist may only be trained to do flexible sigmoidoscopy, and even if also colonoscopists the majority would not have the required

		lifetime experience and appropriate skills to be eligble to become an accredited screening colonoscopist. All endoscopy units have a finite number of training opportunities as training lists should be capped at 4 symptomatic procedures and if training lists were greatly increased per week this would impact on symptomatic capacity. No training can be undertaken on BCSP lists.
2. Page 60 conclusion	Bowel Scope screening, 3. If bowel scope capacity could be used for undertaking screening referral colonoscopies …..	Not all Bowel Scope lists can be converted to Colonoscopy. Many Screening Centres undertake evening Bowel Scope lists which may not be considered suitable for sedated patients undergoing complex therapeutic procedures, peripheral hospital sites may not undertake colonoscopy.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	**Collated comments from BCSP RAC committee members**	**Email address:**	xxxx xxxx
Organisation (if appropriate):	BCSP research advisory committee		
Role:	**chair**		
Do you consent to your name being published on the UK NSC website alongside your response? **Yes, as "collated comments from BCSP RAC committee members"**			

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
		Our committee's main concern relates to the model & methodology. We make the following observations:
		It seems a high-risk strategy for PHE to base a complete revision of the BCSP based on a single centre's unpublished work. They state that their data is "fairly accurate" when validated against old datasets. We recommend very careful

		stress-testing/validation of that model
		ScHARR mention that this is only phase 1 of their work. It would seem logical to await the more detailed modelling proposed in phase 2
		It would seem sensible to allow other groups access to the model so that they can validate it externally
		ScHARR state that “Validation of surveillance colonoscopies found a significant discrepancy between model predictions and data from the BCSP”. This raises concern about the validity of the model when applied to BCSP data, strengthening the argument for additional work to be undertaken.
		ScHARR mentions that “New data from the BCSP on gFOBT screening is available but is unsuitable for inclusion as the prevalent and incident data available does not include complete screening history information”. We recommend this is addressed – BCSS holds a complete screening history, so this data should be made available to allow further BCSP-specific validation of the model
		Compelling data exists to show that flexi sig screening reduces all-cause mortality – this is almost unique for a screening modality, and should be borne in mind. However, we appreciate that the current option analysis is looking at other cost-related outcome measures
P5	Note that the conclusions reached are based on optimising cost-effectiveness where effectiveness is measured in terms of QALYs gained. If the aim was to optimise QALY gains or CRC incidence/mortality reduction then conclusions would be different.	Given only flexi sig screening has ever been shown to reduce all-cause mortality, how is it possible to model based on life-years gained?
		ScHARR’s work uses modelling methodology. Caution must be given to interpreting this, as it depends on many “best

		guess” assumptions, relating to the natural history of the disease etc. This should be contrasted with the moderate and high quality evidence from RCTs which demonstrate the benefit of specific screening modalities.
		The BOSS uptake rates used may be misleadingly low, due to the programme not being fully rolled out – hence centres have limited publicising the programme
		A more meaningful option analysis might compare a one-off BOSS (with ongoing invitation of initial non-responders to steadily increase compliance) against the optimal FIT screening modality
p13	Around 15% of individuals with positive gFOBT samples turn out to have no abnormality upon further investigation.	THIS MIGHT BE MISLEADING AS MANY OTHERS ARE FALSE POSITIVES TOO (Diverticulosis, haemorrhoids, ETC) - HOW HAVE THEY USED THIS?
P18	(FIG 14)	doesn't give FIT levels on x axis
p29	"polypectomy will always involve a biopsy"	What does this mean? Do they mean histology (cf biopsy)?
p29	Mean number of adenomas requiring Biopsy = 1.9 (based on Winawer)	BCSP data is closer to 1.1-1.2 – significantly different and potentially important. How does this change the modelling?
p36	They use Bressler data of 2% miss rate (indeed then extrapolates this to include high risk adenomas too)	This is an unusually low miss rate – meta-analysis (van Rijn) shows overall figure >20%. What impact does this have on the modelling?
P48 and elsewhere	they model a lifetime CRC incidence reduction of 7.3-9.1% with one-off BOSS; ScHARR's figs are also reflected in table 23 where they state 19% CRCI reduction and 22% CRCM reduction if 100% compliance of BOSS	This seems very different from Atkin’s RCT data: *In per-protocol analyses, adjusting for self-selection bias in the intervention group, incidence of colorectal cancer in people attending screening was reduced by 33% (0·67, 0·60–0·76) and mortality by 43% (0·57, 0·45–0·72).* How is this difference explained? This is important.

	“We note that screening strategies which relax constraints on a constant screening interval and FIT threshold will be considered as part of phase 2.”	So surely we should await phase 2
	They model that FIT will reduce CRC incidence (CRCI reduction of 29% with FIT105 from 50yo)	We are unaware of any real-life evidence to support this, which does cause some concern.
	They quote “However, under the scenario analysis with higher bowel scope test sensitivity from UKFSST”	We just want to check they are not incorrectly assuming the adenoma detection rate methodology used in the Atkin trial is the same as used in the BOSS programme – it is not, so if they have assumed this to be the case they might have erroneously underestimated the impact of BOSS.
	“Under the sensitivity analysis where repeated FIT screens have lower sensitivity it was cost-effective to add bowel scope to each of the repeated FIT screening strategies.”	SO MAYBE THIS SUGGEST THAT IT'S SO NUANCED AS TO BE INADVISABLE TO ACT ON THIS MODELLING ALONE (OF COURSE THE ISSUE WITH BOSS FEASIBILITY IS STILL VALID, ALTHOUGH IS ENDO WORKLOAD BUILT INTO THE ANALYSIS?)
		what impact of BOSS are they assuming on subsequent FIT sensitivity?
table 29	"no screening" has life y and QALY "gain"?	Please can they explain this?
table 30	indicates that they model that gFOB will reduce CRCI by 10.7%	We are unaware of any real-life evidence to support this, which does cause some concern.
table 30	the current COMBO of gFOB + BOSS has fewer screen-detected CRC than gFOB (same strategy) alone	Please can they explain this?
	They have v low screen-detected CRC number for BOSS alone (cf gFOB) - considering both are ?0.1-0.3%? [0.15% by ScHARR data]).	Please can they explain this?
	They model that the optimal age (in terms of cost-effectiveness) for a one-off bowel scope screen is 59. (Note that QALY gain is optimised at a younger	IS THIS SLIGHTLY ODD? GIVEN LONGTERM PROTECTION, AND THE FACT WE'RE FINDING PATHOLOGY AT 55Y, WOULDN'T WE EXPECT THE

	age and incidence and mortality reduction is maximised at an older age.) -	OPPOSITE? Please can they provide a plausible explanation for this?
(p58)	colonoscopy use DECREASES over time	what drives this?
	They state that a limitation of their modelling is "There is a very large degree of uncertainty in the sensitivity to cancer of FIT due to the small sample size. However, the FIT pilot data reflects usage of FIT in a (non-trial) screening setting so we suggest it is the most appropriate data source for this analysis. The result of this is increased uncertainty in model predictions involving FIT."	This seems a highly relevant uncertainty.
	They state "There is considerable uncertainty in how different screening modalities with work when used in combination. This is due to the lack of trial evidence to inform this part of the model. Hence the predictions in relation to combination screening strategies which include bowel scope and FIT should be treated with caution."	This seems a highly relevant uncertainty.
page 3 of the Optimizing cancer screening consultation cover-note	uncertainty as to whether BS uptake and detection rates can be increased to the levels reported in the trial, and hence trial reported effectiveness achieved	The three studies referenced below suggest that the inclusion of two self-referral reminders within the National Health Service bowel scope screening program would increase uptake by ~8–12 percentage-points (estimated by multiplying the proportion of adults not attending an initial appointment [57%] by the proportion of adults attending an appointment following the delivery of the 24-month reminder with either the standard information booklet [14.5%] or the theory-based leaflet [21.5%]), depending on which of the two leaflets were adopted. In both cases this would bring the overall uptake to over 50% (51% and 53%, respectively).' The important point here being that even relatively simple

		interventions which could be adapted to any future modification of the programme could bring uptake much closer to what was seen in the programme. We therefore feel strongly that the option of FIT in combination of bowel scope should not be dismissed as unrealistic based on the difference in actual uptake and of that observed in trials. We do acknowledge that the current evidence is limited to findings from a single centre with a long standing history of carrying out the test. **References**: Kerrison RS, McGregor LM, Counsell N, Marshall S, Prentice A, Isitt J, Rees CJ, von Wagner C (2018) Use of Two Self-referral Reminders and a Theory-Based Leaflet to Increase the Uptake of Flexible Sigmoidoscopy in the English Bowel Scope Screening Program: Results From a Randomized Controlled Trial in London. Annals of Behavioral Medicine Kerrison RS, McGregor LM, Marshall S, Isitt J, Counsell N, Rees CJ, von Wagner C (2017) Improving uptake of flexible sigmoidoscopy screening: a randomized trial of nonparticipant reminders in the English Screening Programme. Endoscopy 49(01): 35-43 Kerrison RS, McGregor LM, Marshall S, Isitt J, Counsell N, Wardle J, von Wagner C (2016) Use of a 12 months' self-referral reminder to facilitate uptake of bowel scope (flexible sigmoidoscopy) screening in previous non-responders: a London-based feasibility study. British journal of cancer 114(7): 751-8
'Implications for UK NSC Recommendations'		In answer to the question posed under 'Options for Consideration' – ii. Do the policy recommendations follow from the ScHARR work?", the short answer is no. Point 18 (p3)

(p3)		This point seems to do little more than suggest Option B is useless; in that (apparently) all efforts should be made to increase colonoscopy capacity to achieve a reduced FIT threshold by the NHS (BCSP workforce/QA support), therefore, rendering any efforts to improve BS useless. The utility of BS is completely based on the (currently unknown) ability of increased capacity for colonoscopy. Effectively, BS is useless if colonoscopy capacity is magically transformed in the very near future – what guarantees were included in the ScHARR report that colonoscopy capacity will definitely be transformed? <u>Point 19 (p3)</u> As any health psychologist knows, intention is not the same as actually performing the behaviour. Although there is the 'intention' services should concentrate on driving FIT sensitivity and colonoscopy capacity up as fast as possible, without actual evidence this is achievable, and then this is not a feasible recommendation. <u>Note</u>: although the Phase 1 Report includes a projection on increasing colonoscopy capacity/training of endoscopists, it does not provide any evidence of where these people will come from, nor who/how will they be funded. On p25 of the Phase 1 report it suggests the number of new trainees could be increased by a factor of five (from 40 in 2016 to 200 in 2018) "*in theory*"…astonishing 'in theory' projections to justify a recommendation is hardly useful to informed decision-making.
Screening starting at age 50		The only apparent justification for starting screening at 50 years of age seems to be:

		1) Previous iterations of the model (presumably undertaken by ScHARR) have used data from Italy (reference 19), which starts screening at 50 years old (p17); and 2) When modelling this single cohort, to allow a fair comparison between screening interventions which commence at different ages, discounting starts at age 50, which is the youngest age at which screening intervention may be first offered (p24) The report does not state the justification for the second point, other than it assists in determining the most cost effective screening strategy for modelling the cohort over a lifetime. Several questions: • What clinical evidence for effectiveness of decreasing the age of screening from 60 to 50 years old was included in the report (and if no evidence, why not); • Why was no sensitivity modelling undertaken to determine relative effectiveness of starting age of 60 in comparison to a starting age of 50 years old?
Informed Choice		Minor and beyond the scope of the present submission, but there is really no indication that the psychosocial or actual practical problems (unnecessary colonoscopies) associated with the increased number of false positives for both the lower threshold and the younger age groups would have on the analysis. Lowering the threshold for FIT will result in changes being made to the information materials associated with invitation (and follow-up) of the programme given the risk of false-positive will increase with each lower threshold (additional to changes in the effectiveness of the lower threshold for detecting CRC, adenomas, etc as well). This will add to cost and service provision of the programme.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	**Collated comments from BCSP RAC committee members**	**Email address:**	xxxx xxxx
Organisation (if appropriate):	BCSP research advisory committee		
Role:	**chair**		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes, as "collated comments from BCSP RAC committee members"

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
P5	Note that the conclusions reached are based on optimising cost-effectiveness where effectiveness is measured in terms of QALYs gained. If the aim was to optimise QALY gains or CRC incidence/mortality reduction then conclusions would be different.	I question whether the correct outcome measure has been used. I would not specify that QALY is a preferred outcome within cost-effectiveness, because we do not expect effect on all-cause death. I would suggest cost per absolute effect on CRC incidence or mortality (cost per prevented cancer/cancer death)

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	xxxx xxxx	**Email address:**	xxxx xxxx
Organisation (if appropriate):	Public Health England		
Role:	Screening and Immunisations Team Thames Valley		
Do you consent to your name being published on the UK NSC website alongside your response? **Yes ☐ No ☐X**			

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
Policy Implications paper Options for consideration	Option A	Para 13: states that uptake rates seen in the clinical trial have not been achieved and it is uncertain as to whether uptake at that level can be achieved therefore this option is neither clinically or cost effective therefore it is our view that this is Not a feasible policy option for bowel screening in in the UK in the long term
	Option B	This option has been shown to be both clinically and cost effective and **is the preferred option**
Optimising Bowel	Do the policy recommendations follow from the	Yes the evidence demonstrates a clear policy direction which

Cancer Screening report	ScHARR work?	is both clinically and cost effective
Pg.9 last paragraph	Are the policy options feasible?	A workforce strategy will be necessary to ensure the additional workforce needed to deliver additional colonoscopies resulting from changes to the programme. The strategy should provide for the current workforce delivering bowel scope to be retrained and redeployed, converting bowel scope work force to colonoscopy workforce where possible.
Pg. 61	Is the ScHARR model sufficiently robust to support UK policy?	Limitations in the analysis in relation to variation in uptake between sub groups have been identified but will be addressed in Phase 2 of the project. Variation in uptake is an issue in the current screening model. Is anticipated that the introduction of FIT will begin to address these. Further evaluation of a new model without bowel scope will be important to show impact on uptake variation in the "real life" context

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	xxxx xxxx	**Email address:**	xxxx xxxx
Organisation (if appropriate):	North of Tyne Screening Centre		
Role:	**Lead Pathologist**		

Do you consent to your name being published on the UK NSC website alongside your response?

No x☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
21	OPTIONS FOR CONSIDERATION	**B.** Offer FIT to 50-74 year olds at thresholds below 93 ug/g and decommission (or not start) BS. I would favour this option. There is a question as to whether capacity and uptake for Bowelscope will ever reach research levels. There are significant pressures with attracting trained staff to be carry out these procedures, for a number of reasons. Likely ongoing staff shortages must be considered.

1	Aim: To publicly consult on whether the evidence presented supports a change to the current tests approved for use in bowel screening programmes. In particular whether an optimal bowel screening programme should use both flexible sigmoidoscopy *and* Faecal Immunochemical Test (FIT).	I understand the rationale behind defining the aim in this way in light of the improvements offered by FIT testing. I wonder if there is not another piece of work required looking at the quality parameters currently used for FOBt bowel screening. I would like to see published data comparing the Scotland and England screening programmes Scotland offers a different model not just with age range. For example colonoscopists have to reach a competent standard, but are not required to pass a screening endoscopic assessment (this requires much effort and deters many endoscopists from supporting the screening programme). Turnaround times for pathology results are 80% at 7 days rather than the 90-95% proposed in newly compiled quality data standards compiled by PHE (noted to still be in draft form only a few days before they come into effect). Why is this? In the English system: The process of reporting incidents using the SAIF from has increased the paperwork for both screening hubs and PHE; does this represent best use of clinical staff's time and resources? I would also like to see more information regarding the rationale behind the quality assurance data required for pathology, especially when applied to bowel scope. Essentially -are the thresholds put in place for screening reliable, reproducible and relevant to the outcomes we want to achieve in the screening programme or do we need a rethink?

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	Dr A.F. Muller	**Email address:**	xxxx xxxx
Organisation (if appropriate):	East Kent Hospitals NHS Trust		
Role:	**Clinical Director Bowel Cancer Screening, East Kent**		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes ☐x No ☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
		Fit testing should replace bowel scope screening
	FIT testing	Fit testing should be used to determine need for FU colonoscopy in the bowel cancer screening programme
		Fit testing should replace guiac testing using the second level of sensitivity in the first instance.

British Society of Gastroenterology response to National Screening Consultation on optimising Bowel Cancer Screening

In response to the consultation the BSG position is that:

1. The UK must do more to improve CRC outcomes and CRC screening should be a core function of NHS endoscopy practice. Resources should be used in a way that maximise patient and population benefit.

2. A harmonised single approach to NHS CRC screening should be developed in contrast to the two current programmes.

3. Bowelscope should be discontinued and FIT screening should be introduced at age 50.

4. FIT screening should be introduced at a level that balances both benefit and deliverability. FIT should be piloted robustly to ensure this. The FIT level should be adjusted over time in line with maximal benefit and in response to capacity of endoscopy services to deliver.

5. Any changes to screening must be deliverable and should not be implemented without adequate resources and training of additional screening colonoscopists.

6. Delivery of screening colonoscopy is different to flexible sigmoidoscopy. Many Bowelscope endoscopists may not be able (or be trainable) to undertake BCSP colonoscopy and utilisation of the existing endoscopic workforce in a new programme is highly unlikely to be straightforward.

7. Due to capacity issues, many current Bowelscope lists are evening lists, and these may not be appropriate for screening colonoscopy. Capacity is not simply about endoscopy and endoscopy nursing, histopathology and wider workforce issues must be considered.

8. Training programmes and expansion of colonoscopy workforce should be targeted to deliver more colonoscopy capacity. Quality of colonoscopy should not be compromised in the interests of expediency. Review of the balance of both specialist and non-specialist clinical commitments by clinicians will be necessary to address the requirement for increased colonoscopy provision.

9. A clear evidence-based strategy for managing surveillance procedures should be developed (BSG currently developing guidelines on surveillance).

10. The screening programme should deliver screening to high risk groups (e.g. Lynch syndrome).

11. Further research should be undertaken to understand how screening might be delivered based upon risk factors other than age

Background

Colorectal Cancer (CRC) outcomes in the UK are suboptimal. CRC diagnosed through the gFOBt based bowel cancer screening programme (BCSP) are earlier stage than those diagnosed in symptomatic populations and patients with screen detected cancers have better outcomes. Over 90% of CRCs are diagnosed outside of the gFOBt BCSP. There is a rising problem of CRC in younger patients and FOBt BCSP is less effective at screening for right sided CRC. BCSP delivers screening based upon age. There is currently no programme for managing high risk groups within the screening programme.

There is clear evidence in clinical trials that flexible sigmoidoscopy screening saves lives and is cost effective. However, the uptake of both gFOBt and Flexible Sigmoidoscopy Screening (Bowelscope) are lower than anticipated from clinical trials; current uptake of Bowelscope is 44%, and of gFOBt is 56%. Bowelscope was introduced without sufficient capacity and workforce within endoscopy services to deliver it. Due to lower uptake and the target age for Bowelscope of 55y it is likely that Bowelscope will have less impact upon CRC mortality than originally projected. Surveillance procedures generated by both Bowelscope and the gFOBt programme place significant additional demands upon endoscopy services.

NHS endoscopy services are under huge pressure, with major capacity issues. The NHS has struggled to deliver Bowelscope screening and it is evident that full roll out is many years away at best and it is probable that this will be impossible to deliver. The presence of 2 screening programmes (gFOBt and Bowelscope) is confusing and inefficient. Faecal Immunochemical testing (FIT) has proven successful within screening programmes and is associated with higher uptake rates.

BSG

The British Society of Gastroenterology (BSG) is an organisation focused on the promotion of gastroenterology within the United Kingdom. It has over three thousand members drawn from the ranks of physicians, surgeons, pathologists, radiologists, scientists, nurses, dietitians, and others interested in the field. Founded in 1937 it has grown from a club to be a major force in British medicine. The BSG is a registered charity. A very high proportion of the BSG's membership will be involved in the provision of both diagnostic and screening endoscopy services as well as wider related elements of training and quality improvement. Our members report significant challenges in the system which must be addressed if optimal outcomes from a screening programme are to be delivered for patients.

Consultation

The current BCSP consultation sets out a model-based approach to underpin discussions regarding future delivery of CRC screening. The model has been subject to critical appraisal but it should be noted that modelling is not always borne out in the real world. It is not a trial and some of the findings of the modelling are not consistent

with current findings in practice e.g. surveillance data. Modelling is dependent upon the data it is based upon and some data in this field are old and may not reflect current practice or experience. Bowelscope screening is not popular for a number of reasons: inadequate capacity and workforce to deliver it; perceived as a 'less than ideal' test with low yield by the workforce delivering the programme. Uptake and yield are lower in the programme than in trials and there is a widely held view that it is not an equivalent quality service to the gFOBt and colonoscopy service which is delivered by BCSP teams.

BSG summary position

The BSG supports the transition from FOBt based colonoscopy and Bowelscope (flexible sigmoidoscopy) screening to a FIT based programme. This must be delivered in a way that is feasible and can be maintained within the capacity and workforce constraints that are evident in the system, with a strong implementation plan that acknowledges them. BSG proposes that a series of meetings of relevant stakeholders and experts should be held to establish the optimal approach for CRC screening based upon a balance of evidence and pragmatic ability to deliver with the workforce available. A collective implementation strategy should then be developed and communicated to the profession.

This response has been actively discussed and prepared in consultation with the Joint Advisory Group on GI Endoscopy (JAG).

Colin Rees
Professor of Gastroenterology
Consultant Gastroenterologist South Tyneside NHS Foundation Trust
Newcastle University

John Anderson
Consultant Gastroenterologist Cheltenham and Gloucester

George Webster
Vice President (Endoscopy) British Society of Gastroenterology
Consultant Gastroenterologist University College London Hospitals

On behalf of British Society of Gastroenterology

Dear all

The RCP is grateful for the opportunity to respond to the above consultation.

We would like to endorse the response submitted by the British Society of Gastroenterology (BSG).

Please note that the RCP registrar has also responded to the consultation in his capacity of Director of the Derbyshire bowel cancer Screening centre.

I would be grateful if you could confirm receipt.

Best wishes

Rochelle Keenaghan | Committee manager
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JAG
Joint Advisory Group on GI Endoscopy

UK National Screening Committee Optimising Bowel Screening Consultation document Response from Joint Advisory Group on GI Endoscopy (JAG)

The UK National Screening Committee published their consultation document setting out some recommendations for the bowel cancer screening programme. The JAG has been asked to comment on this. Comments were sought from all the JAG committee (representing ACP, BSG, RCR, AUGIS, BCSA, RCN). Responses were received from all the major stakeholder representatives.

The following summarises the thoughts of the committee members who responded.

JAG response

The Sheffield School of Health and Related Research (ScHARR) document clearly lays out a thorough evaluation of different models of screening proposed and draws its conclusions which can be assessed by the key stakeholders.

1. We acknowledge the significant benefit that screening has on patient care. However outcomes for bowel cancer are still suboptimal when compared to other countries and there is a need to drive up public awareness and the detection of earlier stage cancers / removal of adenomas.

2. JAG supports the review of screening and planned expansion by improving uptake and efficiency with the aim to refine what we are currently doing in the screening programme.

3. JAG recognises that screening has helped to drive up the standard of all endoscopy in the UK. But we have to also be aware of the strain that many units are under, with pressures on waiting times due to endoscopy capacity (physical space, endoscopists and support staff).

4. There are some concerns regarding the modelling, methodology and validation used by ScHARR. Their model found a significant variation between model predictions and BCSP surveillance data, for example. Much of the natural history modelling, we believe, is based on old data which might be inaccurate due to poor quality colonoscopy at that time. It is felt that more validation work is required using BCSP/contemporary data, before we can be confident of the results.

5. The flexible sigmoidoscopy Bowel Scope programme has not produced as much pathology as the original United Kingdom flexible sigmoidoscopy screening trial (UKFSST) and may be almost impossible to deliver nationally (less than half of eligible people are offered Bowel Scope at present). It therefore does not seem tactically a good use of resource to try to achieve full roll out.

6. On this basis it would appear to be better to change to a Faecal Immunochemical Test (FIT) strategy.
    a. FIT will be more cost effective than Faecal Occult Blood Test (FOBT)

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Registered charity no 210508

b. Early FIT will outperform Bowel Scope by quality-adjusted life-year (QALY) analysis
c. National FIT strategy could be launched everywhere at an appropriate threshold and then as capacity increases FIT threshold could decrease

7. There are challenges for delivery of FIT from age 50. The models compare output based on equivalent endoscopy capacity- rooms and nurses will not be the most difficult bit; Bowel Scope is now delivered by many dedicated BS endoscopists who are not yet colonoscopists. We will need several years to develop enough colonoscopists to provide a comprehensive FIT-colonoscopy service from age 50. In the interim current consultant screening colonoscopists would be required to perform more screening procedures, displacing them from symptomatic lists; colonoscopists could up-skill to become BCS colonoscopists however this will also displace them from symptomatic work which will need to be covered by other endoscopists. This is at a time when Straight to Test pathways are also increasing demand on endoscopy services.

8. Increased need for accredited colonoscopists will put additional demand on JAG to provide:
   a. Upskilling courses
   b. Mentorship training
   c. Pre-accreditation courses
   d. Accreditation assessments
   e. Office administration to support the above

9. **Increased need for symptomatic colonoscopists will put additional demand on JAG to provide:**
   a. **Basic skills colonoscopy courses**
   b. **Polypectomy courses**
   c. **Certification**

10. Given the timescales are unknown we do not know how quickly these training pathways would need to develop capacity. It is likely, however, that the colonoscopy certification demand will come from nurses and other staff groups who are current BowelScope, nurse endoscopists or HEE clinical endoscopists. These groups are likely to have training needs that are significantly different to medical specialty trainees. Given the absence of a rapid training process in colonoscopy the training demand is likely to fall within an already stretched symptomatic service, with an inherent risk to waiting times in these units and the risk that registrar training will be adversely affected.

11. This latter point would raise concern with local and regional trainers and with HEE Postgraduate Deans given that the lack of endoscopy training continues to be a significant challenge to gastroenterology and general surgery training. In addition, this proposed change may cross over with the reduction in specialty training to 4 years - a process that may already threaten colonoscopy training.

12. Units who currently deliver BS often deliver the service in evening sessions. It won't be possible to deliver evening colonoscopy lists which are more likely to be therapeutic and so there will be an increasing need to extend into 7 day service or to build more endoscopy rooms to increase day-time capacity. This has implications for staff recruitment and retention.

13. Demand for the symptomatic service continues to rise year on year. Services typically are planning a 10% capacity increase for the next 3-5 years. Plans are already in place to expand services realistically given the many constraints that exist including financial, workforce availability and facilities. Any additional changes such as increasing screening demand may be met with significant resistance.

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14. Serious consideration needs to be given to the sensitivity level of this test so that there is some 'brake' or control on the potential demand. There is significant concern from within JAG that introduction of this will push endoscopy services over the edge and increase waits seriously on the symptomatic side.

15. **The increasing demand is likely to have an impact on the services' ability to:**
-meet the workforce capacity requirements to provide greatly increased colonoscopy capacity. There is a national shortage of gastroenterologists and there is great difficulty in recruiting.

-attracting new nurses, again a serious national shortage. Time is required to support a new approach, to recruit endoscopy workforce and their training. There is an anticipated need for accelerated training programmes and increased focus on practitioner roles (band 4).

-supply increased kit, decontamination and overall facilities; this will need to be planned for through the usual business planning processes.

- increase use of other tests such as CT Colonography.

16. **Regarding implementation of a new programme,** there needs to be a very clear and timely programme to increase professional and physical capacity in endoscopy units. This is likely to be a 5-10 year strategy involving multiple agencies/organisations i.e. HEE. This will have to be introduced in a staggered way.

17. **JAG is concerned that the proposed plans pose significant** risks relating to the services' ability to meet the standards particularly for waiting times and the workforce. Any increase in colonoscopy demand will have a potentially detrimental effect on the services ability to stay in control and impact on their accreditation.

18. **In summary, the consensus opinion is that although the best option for screening most effectively may be to replace Bowel Scope with FIT screening for** 50-74year olds every 2 years at a lower threshold, JAG anticipates that this will be difficult to deliver whilst new colonoscopists are trained or existing colonoscopists e.g. Gastroenterologists are released from other duties.

A robust plan for transition with the appropriate work force and capacity planning should be put in place before any changes are agreed.

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UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	David Selling	**Email address:**	xxxx xxxx
Organisation (if appropriate):	Joint response from: NHS England - South East (Kent, Surrey and Sussex) PHE Screening and Immunisation Teams for Kent and Medway, Surrey and Sussex		
Role:	Head of Public Health, NHS England - South East (Kent, Surrey and Sussex)		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes x **No ☐**

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
7	Requirement for significant amounts of highly trained people, clinic and hospital time and space	Capacity factors have limited the rate of rollout for bowel scope screening over the first five years to the extent that we now have considerable inequalities in access to this screening test among local populations. The future combination of tests should aim to reduce these inequalities.
11	Use of the maximum available colonoscopy capacity	It would be helpful to understand the detailed assessment and assumptions underlying the national mobilisation plan for this

		capacity, including how introduction of symptomatic FIT may release capacity for screening service use.
13	Uncertainty as to whether BS uptake and detection rates can be increased to the levels reported in the trial, and hence trial reported effectiveness achieved	Locally we have found this uncertainty starting to impact on providers' commitment to delivering previously agreed rollout trajectories. Of particular concern is workforce training – prospective trainees may lack the confidence to start acquiring new skills that may not be required beyond a short timescale. There is therefore a major risk of workforce shortage that needs to be managed within the delivery system – a definite decision within the soonest possible timescale would be helpful.
18	The NHS (and workforce/QA support) run the risk of putting a major amount of time and effort into improving BS in the knowledge that once there is sufficient colonoscopy capacity the best option is to swap BS for FIT.	
21	Options	We have no particular view on what future policy should be and await emergence of the expert and consensus views. Whichever option is chosen, there needs to be clarity about any phasing of the approach to introduction of FIT and (if applicable) decommissioning of BoSS.
General		We would welcome updated national comms in the light of Andrew Lansley MP's recent diagnosis with bowel cancer and public comments linking to non-availability of bowel scope screening which might have detected his condition earlier. This may prompt more widespread queries and concerns.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	Baljit Singh	**Email address:**	xxxx xxxx
Organisation (if appropriate):	ACPGBI		
Role:	**Lead for the ACPGBI FIT Group**		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes ☒ **No** ☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
	Overall comments	**In summary we agree that FIT-colonoscopy from 50 is preferable in terms of coverage, acceptability and cost effectiveness ie option B. An argument can be made to combine FIT with a FBC and ferritin to increase colorectal cancer detection although this would add additional cost and may be impractical.** **The overriding factor determining what level to set the**

		sensitivity for FIT in the screening population is the colonoscopy capacity. The latter could be increased by using FIT for colorectal cancer surveillance. Further colonoscopy capacity will become available by utilising FIT in symptomatic patients who could be investigated by CT colonography and also following the update in the polyp surveillance guidelines. **The key factor for screening is to set a threshold for FIT which is determined by sensitivity so as not to miss a large proportion of colorectal cancers.**

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

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Role:	**Programme Manager**		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes x **No ☐**

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
p.60 2.Optimising Bowel Cancer Screening Phase 1 Report SCHARR	The optimal age for a repeated FIT screening strategy is 50/51 hence it is suggested that the screening start age is reduced compared to what is currently used in the BCSP. The upper screening age varies between 65 and 74, depending on the capacity constraint used	The entry age for access to Bowel Screening should be 50 (which is on a par with Scotland)
p.60 2.Optimising Bowel	It is recommended that the screening interval is kept to 2-	Re-inviting non-attenders should be recommended. There was a trial in North West London where this proved very

Cancer Screening Phase 1 Report SCHARR	yearly screening. However, increased benefits may be obtained my re-inviting non-attenders after a 1 year interval.	successful.
	There is some uncertainty in whether it is cost effective to replace one FIT screen with a one-off bowel scope at age 58/59.	Further study is required for this to be validated. However, the initial FIT screens are likely to identify issues for further investigation if the base start age is 50.
p.2 3. Optimising Bowel Cancer Screening Appendix 1.1	detection rates in the NHS BCSP were significantly lower for HR adenomas and CRC.	Based on the lower detection rates (as identified in the Table on this page) in the lower age ranges – it would make sense to do more less Bowel Scope in 55 year olds and if it is to procedure to undertake the bowel scope in 58 year olds. Linking in with the previous report – should we undertake Bowel Scope at 58 and FIT from 50 (at a rate of 161 or lower if possible?) this would be best case scenario.

UK National Screening Committee
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Consultation comments pro-forma

Name:	Prof. Stephen P. Halloran	**Email address:**	xxxx xxxx
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Role:	**Independent Advisor on CRC Screening – particular expertise in FIT screening**		

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Yes ☒ **No**

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
Optimising bowel screening: Policy implications for the UK	Is the ScHARR model sufficiently robust to support UK policy?	Yes – It provides robust data for initial policy decisions and some guidance for the future evolution of the programme. A FIT-based programme has sound foundations, is a safe and proven screening modality which builds on the established gFOBT programme. FIT is likely to evolve and become even more clinically specific and sensitive for CRC. Research evidence already shows that other population risk markers (many currently recorded on BCSS) can be combined with the

		quantitative FIT and it is likely that we will see additional faecal markers that will add to the sensitivity and possibly the specificity of FIT. No blood markers are currently on the horizon.
Optimising bowel screening: Policy implications for the UK	Do the policy recommendations follow from the ScHARR work?	Yes – The policy recommendations also need to heed the realities of service provision - they did not do so when BS was introduced. RCT evidence for the effectiveness of FS was, and is, unambiguous. For the NSC to endorse the clinical benefit of FS was right but the political pressure to implement it without a thorough pilot has proven an embarrassment. No country has successfully (i.e. with good participation rate and acceptable endoscopy waiting times) implemented both FS and FIT. The ScHARR work provides confidence in the clinical effectiveness of FIT, their data was largely based on the FIT pilot which provided sound data on the practical aspects of FIT implementation within the programme in England.
Optimising bowel screening: Policy implications for the UK	Are the policy options feasible? If so how can efforts to deliver either be evidenced?	The endoscopy resources in England are constrained by both available finance and a skilled workforce. This situation is not unique to the UK! Most countries have a constrained endoscopy resource and those using FIT at a desirable high sensitivity have either poor participation rates or long waiting lists. The quality of endoscopy must be maintained if we are to mitigate against potential harms of screening and maintain public confidence in screening. Quality shortcuts have been proven to lead to 'poor performers' and an embarrassing elevation of interval cancer rates. The Screening Programme in England has made a valiant attempt to rollout out BS but it has proved unexpectedly difficult to recruit / train appropriately skilled endoscopists and perhaps of more significance is that evidence suggests long term retention of staff might prove even more difficult. FIT provides a practical and clinically effective solution which enables the sensitivity and specificity to be adjusted as resources become available, The participation rate in England

		has been shown to be much better than gFOBt and it has reach 73% in the Netherland (a country with a similar health service and philosophy). Whilst a high FIT sensitivity (low threshold) and coverage to 50 – 74 year olds is a realistic objective it needs to be implemented without compromising quality. An implementation plan needs to be developed which gradually extends FIT screening from what is practical in 2018 to what we aspire to and are willing to pay for. A realist assessment of resource and resource development needs to be made - not the remit of ScHARR. Are the policy options for FIT feasible? Yes, but the timescale needs to be realistically assessed and measures adopted to make it happen. Unrealistic goals and timescales wil disenfranchise the public and demoralise service providers.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	xxxx xxxx	**Email address:**	xxxx xxxx
Organisation (if appropriate):	NHS Lothian		
Role:	**PH consultant**		

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Yes ☐ **No x**☐

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
B	Offer FIT to 50-74 year olds at thresholds below 93 ug/g and decommission (or not start) BS.	This appears to be the better option for Scotland given that the BS has not been rolled out across all Boards and uptake for pilot studies has been less than anticipated.
i	Is the ScHARR model sufficiently robust to support UK policy?	The model appears to be sufficiently robust albeit seems to be based mainly on English data therefore application to a Scottish population needs to be considered.

ii	Do the policy recommendations follow from the ScHARR work?	Yes
iv	Are the policy options feasible? If so how can efforts to deliver either be evidenced?	Yes, however the practicality of increasing colonoscopy capacity to that required needs to be explored against current workforce/resource issues

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	xxxx xxxx	**Email address:**	xxxx xxxx
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Role:	**Bowel Cancer Screening Programme Manager – on behalf our service**		

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Yes ☐ **No X**☐

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*

	Issue: If movement to one of the options is to be carried out our preference is that option B would be the ultimate goal. However, we have concerns about the feasibility of this given capacity constraints and achievability of the route/speed of transition	• The paper appears to demonstrate that with a blank sheet of paper and unlimited endoscopy capacity – 2 yearly sensitive FIT testing from 50 -75 years old is a good BCSP programme, however the key issues are capacity and funding. ○ Capacity will be an issue. Many endoscopy units are already full during the week and are working weekends to achieve wait lists. There insufficient colonoscopists available for the workload currently increases in capacity will only exacerbate this issue. Under current accreditation criteria bowel scope capacity (nurse endoscopists who have been trained for flexi sig to do bowel scope) cannot quickly be converted to colonoscopy capacity. Much of the issue with bowel scope roll out has been insufficient capacity as it has been proven it cannot be created quickly. Capacity issues are not limited to colonoscopists – there will also be issues with CTC's, pathologists, endoscopy nurses, SSPs etc. In addition there may be other excess staff who need redeploying as they do not fit the skills/banding mix required for BCSP rather than bowel scope. ○ It is not at all clear how this would be funded – there will need to be a large increase due to increased numbers of procedures. This increase may eventually be released from the cancer pathway but will need to be sourced in the meantime until cancer rates reduce. • In addition ○ It is not wholly clear that the work in the paper is fully robust. There is insufficient detail in some areas. ○ In refining capacity analysis, work needs to be done on surveillance and service protocols too. As follows: ▪ The surveillance numbers outlined look small compared to the proportion of surveillance we are currently seeing ▪ Is the current protocol for 1 and 3 yearly

		surveillance optimal? ▪ Use of sensitive FIT as rule out for symptomatic pathway to free up capacity. • This may show where screening of bowel cancer should aim to be in years to come but the transition path from existing programme will need to be lengthy (10+? years) and very carefully managed. The reducing positivity rates across much of the country could be considered to demonstrate that the existing programme appears to work for many people. A poor transition may provide a worse programme for a period of time.. • Announcing a big bang change without thorough planning and sufficient lead time will result in failure – which ultimately could impact patient care possibly making the programme less effective than it currently is.

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Consultation comments pro-forma

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Role:	**Head of Public Health**		

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Yes ☐ **No** ☐

Section and / or page number	**Comment**
	Please use a new row for each comment and add extra rows as required.
	It is our understanding that both options identified for this consultation present specific implications. We know that it is vital to ensure that the NHS increases the resources and capacity to deliver an effective high quality screening service and that includes ensuring necessary investigations following an abnormal test are available within 14 days and that the full screening service is available to all of the target population. We know that the lack of colonoscopy and pathology capacity are the biggest barriers to implementing the optimal bowel cancer screening programme. Whilst we welcome FIT as a "tool" to save more lives – we have to be realistic that this places a capacity impact onto colonoscopy.

	Within Lancashire & South Cumbria, bowel scope roll out has been massively impacted by endoscopy unit capacity in terms of the physical build/opening hours. We are concerned that FIT colonoscopy lists will be able to simply replace any endoscopy lists created for bowel scope.

UK National Screening Committee
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Consultation comments pro-forma

Name:	Professor Richard Logan, Dr Joanne Morling, Dr Caroline Chapman	**Email address:**	xxxx xxxx / xxxx xxxx / xxxx xxxx
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Role:	**Director, Assistant Director and Manager of the Eastern Hub**		

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Yes x☐ No ☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
All	General comments	We think that a decision to decommission the Bowelscope programme at this time would be premature for the following reasons: 1 There is robust evidence that colorectal cancer screening using flexible sigmoidoscopy is twice as effective in reducing colorectal cancer mortality (28% reduction) as screening using biennial gFOBT (14% reduction, Holme et al. Cochrane Database 2013 issue) Indeed the most recent analysis from the UK trial

		reported a 30% reduction at 17 years (Atkin et al. Lancet 2017). 2 At this time similar evidence for the effectiveness of screening using FIT is lacking. However a recent analysis from a Dutch screening trial using a FIT (mainly OC sensor) found that even at a FIT cut-off of 10ug/g faeces the sensitivity of FIT as assessed by the interval cancer rate was only 77% and at a cut-off of 50ug/g faeces the sensitivity would have been only 56% - a figure not dissimilar to what is currently being achieved with gFOBT in the BCSP. (van der Vlught et al. Gastroenterology 2017). A cut-off of 50ug/g is significantly lower than the proposed cut-offs currently under consideration for the BCSP. 3 It is clear from the above study and others (Digby et al, J Med Screen 2016) that approximately 1 in 4 colorectal cancers have a low propensity to bleed or bleed infrequently particularly in their early stages and consequently will not be readily detectable using a single FIT. The Bowelscope programme offers the opportunity of detecting non-bleeding polyps and preventing some cancers that would be missed by screening with FIT. 4 Uptake of Bowelscope has been greater than many anticipated and as the paper from SCHARR shows uptake is similar in 55yr old men (45%) to that for gFOBT at age 60 (46-47%, Figure 1 p11). Bowelscope offered at age 58 or 60 would be expected to have a greater uptake. 5 Bowelscope has not yet been in operation for 5 years and we have no data yet on its impact on the gFOBT screening programme in terms of subsequent positivity rate, findings at colonoscopy, interval cancer rate and in particular how far the effects of the two programmes might be additive. 6 Screening with FIT of 60-74 yr olds is unlikely to be introduced before 2019 and data on many of the uncertainties alluded to above will become available once FIT screening has been established.

	Health economic report	We would raise significant concerns regarding basing a decision purely on the single health economic analysis provided in the consultation. 1. It is poor practice to use an analysis from a single provider – further analyses should be commissioned 2. The current analyses does not include other optional changes to the programme including e.g. lengthening screening rounds for those with negative colonoscopy; changes in surveillance practice (e.g. FIT). Waiting for the Phase 2 analysis would be very helpful. 3. All costs effectiveness is estimated using the optimised BS uptake of 55% (currently 44%) and therefore unrealistic without significant intervention to raise BS uptake. 4. The analyses are based on maximising net monetary benefit. An outcomes based focus would seem more appropriate, i.e. the most cost-effective way to reach a pre-specified minimal acceptable reduction in CRC incidence/mortality.
	Summary	Both Bowelscope and FIT screening have the potential to be highly effective if optimally implemented. Until such approaches are identified and achieved it is difficult to comment on the direction the programme should take. Earlier screening with the use of FIT, as occurs in other countries is likely to be beneficial, however it is too early to draw any conclusions about the success of Bowelscope. In essence the performance of the tests is currently significantly impacted upon by operational constraints.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

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Role:	**Screening and Immunisation lead, Surrey and Sussex**		

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Yes X☐ No ☐

NB This is an addition to the joint response from PHE/NHSE submitted by David Selling, and concentrates solely on the Options, on which the joint response had no particular view

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
21	Options	The use of 93mg as the FIT threshold surprising, as it is not mentioned in the Executive Summary of the SCHaRR report, and doesn't seem to match any of the analyses of effectiveness in the tables in the appendices. The approach used by SCHaRR is expressed in a very complex document and hard for the layman (in terms of health

		economics) to follow. To ask whether the document is a sound basis for policy is an almost impossible question to answer. However, even taking it at purely face value, there are a number of issues to consider. There seems a difference between SCHARR and NICE in the way QALY thresholds are used. Based on the NMB data published, it seems that most of the options are cost effective in terms willingness to pay at NICE thresholds. On that basis, I think we should be looking for the option which meets the NICE QALY thresholds and gives us the maximum reduction in CRC mortality and CRC incidence. The information in the appendices suggests this as at FIT threshold of 74, which isn't under consideration. Only offering slightly fewer benefits are the reductions provided by BS aged 58, combined with FIT 120 , aged 50-74. It is hard to support the use of a FIT threshold of 93 without seeing the reduction in CRC incidence and mortality associated with it. The closest data in the appendices is a threshold of 94, and this shows a reduction in incidence and mortality less than that achieved by BS aged 58 and FIT 120. Therefore, on the basis that all options meet the NICE thresholds for cost effectiveness, I would support the one which gives the greatest reduction in CRC mortality and incidence, which, reviewing the document as a health economics laymen, appears to be Option A.

UK National Screening Committee
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Consultation comments pro-forma

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Role:	**Colonoscopy Professional Clinical Advisor for South BCSP QA**		

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Yes ☐ **No** ☐

Thank you for giving me the opportunity to respond to this consultation process.

This review is welcomed by the screening fraternity. The main issues going forward appear to relate to the workforce whether we continue with Bowelscope (slow roll out) or switch to FIT only as suggested here.

I will limit my response to my role re QA for the endoscopy part of the service. We currently deliver a high quality service in both gFOBt colonoscopies and Bowelscope. This is partly due to a rigorous accreditation process (with minimum 1000 colonoscopies for each individual undergoing this process) and also through close monitoring of KPIs. Thus, identifying and training a workforce to meet the extra demand associated with a FIT only programme is likely to take some time. Having said that we clearly have not yet identified arobust workforce to completely roll out Bowelscope.

Steve Gore

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
Page number 5,9,20,21,58	Equivalent endoscopy capacity	The Bowelscope workforce is very different to the gFOBt colonoscopy workforse and a significant number of bowelscopists are not and may not wish to be accredited colonoscopists. Also a number of Bowelscope lists take place in community hospitals and it may not be appropriate to undertake screening colonoscopies in some of these units
Page number 12	gFOBt positivity is stable	This appears to have varied across the country and certainly positivity in the South has fallen considerably to ~1% in last 12 months

April 2018

Cancer Research UK response to the UK National Screening Committee consultation: Optimising Bowel Cancer Screening.

Cancer Research UK welcomes the opportunity to respond to this consultation. Bowel cancer is the fourth most common cancer in the UK and around 16,000 people die every year from bowel cancer. Diagnosing bowel cancer at stage I means more than 9 in 10 people survive their bowel cancer for five or more years. But diagnosed at stage IV, fewer than 1 in 10 people survive their bowel cancer for five or more years. The NHS Bowel Cancer Screening Programme is one of the best ways to detect bowel cancer early, when it is easier to treat successfully. Yet, currently around 1 in 10 bowel cancers are detected via this route. We want to see this increase so that fewer people die from bowel cancer.

With the introduction of the Faecal Immunochemical Test (FIT) there is significant potential for the Bowel Cancer Screening Programme to be more effective at diagnosing more cancers earlier and detecting pre-cancerous adenomas. The potential of the screening programme to detect more cancers at an early stage can be improved by lowering the threshold of FIT and/or expanding the age range. We are pleased that the UK National Screening Committee (NSC) is considering ways to optimise the bowel screening programme and reduce the burden of bowel cancer. It is vital, however, that proposed changes are based on the most appropriate and sufficiently robust evidence.

Summary

We do not support either of the policy recommendations in this consultation based on the phase 1 modelling – neither option is acceptable based on the available evidence.
As the authors of the report themselves acknowledge, there are limitations with the model, which overall produces uncertainty in the conclusions. It is entirely possible that the more sophisticated planned phase 2 ScHARR model, with the inclusion of more up to date data, would produce different conclusions and policy recommendations. It is therefore premature to make significant changes to the programme based on the current evidence.

Current capacity constraints should not prevent the NSC from making the best recommendation based on clinical benefit and cost effectiveness. The NSC's role is to advise Government and the NHS on all aspects of screening. It therefore felt inappropriate that capacity constraints featured so strongly in the modelling then used to inform policy options. We appreciate that the NSC is making policy recommendations, which do need to be pragmatic and deliverable. But it is disappointing that the policy recommendations for the most optimal screening programme are being stymied by current endoscopy capacity.

We would prefer the NSC acknowledged resource limitations but provide an ambition based on public health benefit for the NHS to deliver. Any shortfalls undermining the optimisation

of bowel screening should be considered and addressed by the government and NHS when deciding whether to adopt and implement NSC recommendations. Health Education England has introduced a 'workforce impact assessment' in their draft workforce strategy – workforce implications of FIT screening should be encompassed within that, rather than limiting the options considered by the NSC.

We would ultimately like to see the NSC recommend the optimal screening programme for public health benefit, and if necessary, outlining recommendations for more gradual implementation in line with current and projected workforce capacity constraints.

With respect to developing a more robust evidence base on which to make significant policy recommendations we would like to see the timelines and parameters of the phase 2 modelling published as soon as possible. Phase 2 modelling should use the most up to date data available and should offer policy options that are not solely informed by cost-effectiveness.

Is the ScHARR model sufficiently robust to support UK policy?

We do not think it is appropriate to make policy recommendations based on the phase 1 ScHARR modelling because there appear to be several unacceptable limitations with the model, and therefore uncertainties in its predictions. For example, the authors admit there is particular uncertainty around the predictions for surveillance due to the uncertainty around parameters used in the model. Also, the model makes assumptions such as uptake and sensitivity not changing with age, while we know there is evidence that they do. We are therefore unsure whether the model overestimates the benefit in younger ages as a result. Such limitations are stated as being addressed with phase 2 and we would recommend that the ScHARR team consult with those reviewing the surveillance guidance before conducting phase 2 modelling.

In addition, there are limitations with some of the cost estimates data used, particularly on treatment costs. The studies used as a source of treatment costs all have significant limitations. We would not, for example, advise the use of figures from the Incisive Health report, *Saving Lives, Averting Costs* for this type of work. This is critical because the sensitivity analysis itself demonstrates the impact of the uncertainty in costs; showing some scenarios as being cost-saving when using one version of costs, but not when using other versions.

The modelling for whether it is cost-effective to include bowel scope within the programme seems particularly uncertain: "Screening strategies combining bowel scope and FIT were considered. For a repeated FIT screening strategy, whether it is cost effective to replace one FIT screen with one-off bowel scope at age 58 is very uncertain. It depends on the level of screening referral colonoscopies and varies in sensitivity analyses." The selection of a threshold of "below 93 µg/g" for option B assumes that "10 bowel scopes and 4 screening referral colonoscopies are equivalent (based on procedure time)". We would advise further collaboration with colleagues from Health Education England (HEE) and the British Society of Gastroenterologists to validate such assumptions.

Overall, we are not confident that if the phase 1 model were re-calibrated with more recent data, and with less uncertainty in some model values such as costs, that the outcomes and policy recommendations would not be different. Furthermore, the approach for the phase 2 model would seem to be, based on information available to date, significantly more robust and could further change conclusions and recommendations.

We would like to see the phase 2 modelling carried out and published as soon as possible, using the most up to date data available and with re-consideration of estimates for key data such as costs. We understand the screening surveillance guidance is currently being reviewed, so we would recommend that the ScHARR consult with those reviewing the guidance before conducting phase 2 modelling. To help inform policy decisions on how to roll out an optimised bowel screening programme, it would be useful for the modelling to predict results for interim steps for roll out such as, if screening 50-74s is the optimal age range for FIT, is screening 50-74-year olds at a high threshold more or less effective than screening 60-74-year olds at a low threshold, using both cost-effectiveness and clinical benefit as a measure.

We would be keen to encourage transparency with the modelling, and the opportunity for other appropriate teams or experts to have access to the model so that it can be tested under different conditions, or when using alternative perspectives (i.e. mortality benefit).

Do the policy recommendations follow from the ScHARR work?
The policy recommendations proposed would seem to follow from the modelling if the conclusions are based on cost-effectiveness alone. However, as discussed above, we feel that the recommendations are premature and that if the current model was further updated, or phase 2 modelling completed, the outcomes and policy recommendations may be difference. We therefore cannot confidently support either of these recommendations.

Are the policy options feasible? If so how can efforts to deliver either be evidenced?
The policy options suggested are currently not feasible due to endoscopy capacity in the NHS. Cancer Research UK has been campaigning to increase the diagnostic workforce in the NHS. HEE has made some steps to increase capacity but this will take some time to come to fruition. We understand that the current constraints are delaying the introduction of FIT into the bowel screening programme and preventing the test being brought in at an optimal sensitivity level.

Workforce capacity to conduct follow up colonoscopies and pathology should be a key factor for government and the health service when deciding how to implement the optimal programme as recommended by the NSC. But limited capacity should not detract from an ambition to optimise the delivery of the bowel screening programme for clinical gain. Although HEE is coordinating an accelerated training programme to boost clinical endoscopist numbers, these clinical endoscopists are being trained to deliver gastroscopy and flexible sigmoidoscopy, not the colonoscopies required for bowel screening follow up. We need clarity on whether the model considered the cost and staff time of additional training that would allow endoscopists currently trained to conduct flexible sigmoidoscopies

to carry out colonoscopies. This additional training is currently completed through in-house training but Public Health England is investigating creating a transition course for those trained in flexible sigmoidoscopy to deliver colonoscopies. We would recommend having conversations with HEE and British Society of Gastroenterologists on workforce modelling if, as we recommend, capacity is to be considered before conducting phase 2 modelling. If the modelling considers demand and capacity in colonoscopy, this should also be done for the pathology workforce.

About us

Cancer Research UK is the world's largest independent cancer charity dedicated to saving lives through research. It supports research into all aspects of cancer and this is achieved through the work of over 4,000 scientists, doctors and nurses. In 2016/17, we spent £432 million on research in institutes, hospitals and universities across the UK. We receive no funding from the Government for our research and are dependent on fundraising with the public. Cancer Research UK wants to accelerate progress so that three in four people survive their cancer for 10 years or more by 2034.

For more information, please contact Corrie Drumm, Policy Advisor, 020 3469 8609 or corrie.drumm@cancer.org.uk

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

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Role:	**Registrar**		

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Yes ✔ **No** ☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
SECTION 1 Page 5		The document suggests that several options are possible, one of which would result in almost double the number of procedures. In practice the number of endoscopy staff has been a barrier to various forms of expansion in the past.
SECTION 5.3.1. Page 29		There is very little about pathology, and the document almost sidesteps the issue of pathology funding – saying "it

	"Polypectomy will always involve a biopsy. It is unclear whether the NHS reference costs for endoscopy include the pathology costs associated with biopsy". "For the purposes of this analysis we assume that pathology cost will be incurred on top of the procedure costs. The NHS reference cost for histopathology is £29 and this cost has been used in the model for both cancer and adenoma. The mean number of adenomas requiring pathology is assumed to be 1.9 based on data reported from the National Polyp Study by Winawer et al [38]." **Table 5: Endoscopy Costs** **Procedure** / **Cost** / **Code** / **Source** Specialised Screening Practitioner following gFOBT of FIT / £32.50 / 10.4 / Unit Costs of Health and Social Care 2014/15 [35] Specialised Screening Practitioner following BS / £16.25 / 10.4 / Unit Costs of Health and Social Care 2014/15 [35] Diagnostic Colonoscopy / £518 / FZ51Z / NHS Reference Costs 2014/15 [37] Diagnostic Colonoscopy with Biopsy / £600 / FZ52Z / NHS Reference Costs 2014/15 [37] Diagnostic Bowel Scope / £430 / FZ54Z / NHS Reference Costs 2014/15 [37] Diagnostic Bowel Scope with Biopsy / £484 / FZ55Z / NHS Reference Costs 2014/15 [37] Histopathology and / £29 / DAPS02 / NHS Reference	is unclear…". Anecdotally, this is often the Trust financial approach, i.e. hoping pathology will not be noticed and/or that pathology will not notice the extra few 1000 cases as they slowly appear. The wording: "polypectomy will always involve a biopsy" is unlikely to have been written by a histopathologist. The figure of £29 that is then quoted is quite low and its source is not entirely clear, i.e. "NHS reference costs" but with no citation. At the very least, resections would increase if there were an expansion of numbers initially and £29 is certainly not realistic for a resection. With a biopsy rate of around 40-45%, £29 for all pathology costs per endoscopic procedure (compared to £518 for colonoscopy costs for example) still seems low. £29 may cover pathology reporting but not processing and admin etc.

	Histology	Costs 2014/15 [37]	

UK National Screening Committee
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Consultation comments pro-forma

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Role:	Hub Directors & Deputy Director		

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Yes ☒ **No** ☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
Section 4.2, p16 Appendix 1.1, p2	Bowel scope uptake & detection rate	The FS trial was completed 19 years ago and health models have changed considerably. The trial was a much smaller cohort of 40,000 participants with an age range of 55-64 years old and was a research trial, not service led delivery of a screening programme. In practice, the uptake of Bowel scope is low (BCSP data 44%) compared to the FS trial (55%),

		where participants indicated that they were interested in attending screening. We have not been able to replicate either the trial uptake or detection rates in the bowel scope screening programme to date. Considerable health promotion is required to address the low uptake for Bowel scope, and significant resources are required to achieve 100% roll out and, more importantly, 100% local coverage of bowel scope. Bowel scope detection rates are considerably lower than found in the trial. This would suggest that patients are undergoing Bowel scope at the wrong age, and there is general consensus on this point. However, it is unclear if changing the age to 58 would increase the abnormal findings significantly.
Section 4.3, p17 Section 5.3.3, p39	FIT uptake	The results obtained for the London pilot (November 2015 – May 2016) confirmed those observed for the 2014 pilot. This study used the same packaging and instrumentation as the 2014 pilot for the purpose of examining the impact of FIT on uptake in London. Uptake of FIT was even higher than for gFOBt (54.9% vs. 46.4%, OR 1.41, 95% CI 1.36-1.46) compared with the 2014 pilot. The increase in uptake was significantly greater for previous non-responders (FIT 19.6% vs. gFOBt 9.9%, OR 2.21, 95% CI 2.04-2.39) and subjects invited for the first time (53.2% vs. 39.5%, OR 1.74, CI 1.60-1.91). The increase in uptake was higher in males (FIT 52.8% vs. gFOBt 43.1%, OR 1.48, 95% CI 1.40-1.56) than females (56.9% vs. 49.5%, OR 1.35, 95% CI 1.28-1.42). An increase in uptake was observed for all quintiles of deprivation: for the most deprived the uptake for FIT was 47.8% compared with 38.0% for gFOBt (OR 1.50, 95% CI 1.38-1.63).
Section 4.4, p20	Endoscopy capacity	The majority of screening centres are struggling with capacity and workforce issues. Waits for symptomatic and high risk

		surveillance groups are increasing with the result that an endoscopic screening programme targeting an asymptomatic population (with lower detection rates than found in the FS trial) may be at risk of displacing/delaying endoscopic surveillance for high risk groups.
Section 5.3, p28	FIT costs	It is unknown if the FIT costs from the pilot would be same when FIT has been procured nationally as part of the Bowel Cancer Screening Programme.
	Summary	Given the lower than anticipated uptake & detection rates of Bowel scope, option A is not feasible.

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

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Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
	Introduction	The Greater Manchester Screening and Immunisation team is embedded in the Greater Manchester Partnership alongside NHSE colleagues, where we commission screening programmes for our population of 2.8 million people across the 10 local authorities and 10 CCGs of Greater Manchester.

		This consultation response has been drafted by the Greater Manchester Health and Social Care Partnership screening and immunisation team. We have consulted on this response with local authority and CCG partners listed in Appendix 1, and current programme commissioners and providers throughout Greater Manchester.
21 i)	Is the Sheffield school of Health and Related Research (ScHARR) model sufficiently robust to support UK policy?	In general, the use of mathematical modelling is inferior to the use of evidence from pilots or primary research that is explicitly designed to answer a policy question, since it is dependent on assumptions that may not have been rigorously tested. However, we accept that there is a need to make decisions based on modelling in some cases. We do not have the expertise to critique the specific model referred to in this consultation. In Greater Manchester, the gFOBT test has been successful. Its uptake [57%] and adenoma detection rate exceed national minimum standards and are comparable with national data. By contrast, the Bowel Scope (BS) programme has been less successful, with lower uptake even in areas where it is offered to the whole population and lower adenoma detection rates than the pilot. Our data supports a clinical opinion the bowel scope programme has been less effective than initially expected. If the ScHARR model uses data from the BS pilot, we consider that the model is likely to over-estimate the benefits of combining the bowel scope with FIT.

21 ii)	Do the policy recommendations follow from the ScHARR work?	The policy recommendations are logically compatible with the ScHARR work, but there may be alternative recommendations that would be similarly compatible. Removing the bowel scope from the programme will mean that we no longer have a screening approach that can detect tumours/polyps that do not bleed, and it would be important to understand any difference in natural history or patient demographics (including gender) between bleeding and non-bleeding tumours.
21 iii)	Are the policy options feasible? If so, how can efforts to deliver either be evidenced?	
	Common issues	Delivery of either option would result in challenges around Colonoscopy capacity, since both options replace FOBT with a test (FIT) that is likely to drive a higher uptake (particularly for the GM population). The resulting increase in demand for diagnostic colonoscopies will occur in a context in which Greater Manchester (in line with the national experience) is failing to meet the national quality standard for the waiting time for screening colonoscopies in some localities. Creation of extra colonoscopy capacity will take time, and would require careful project management, appropriate funding, a well-designed training pathway (via HEE) and investment in premises, facilities and accreditation for both clinicians and estates.
A	*Option A: Combine BS at trial uptake and quality standards to 58-60 year-olds with a lower sensitivity FIT*	The Greater Manchester roll-out of the bowel scope has been challenging, remains incomplete and currently has low momentum. The current partially-completed roll-out is inequitable, although to a limited extent the availability of the BS in some areas compensates for poor uptake of FOBT. Delivering policy option A would require local screening

		programmes to simultaneously: 1. Support the introduction of a new test (FIT) 2. Continue roll-out of BS 3. Improve the uptake and quality of BS from current levels to trial levels 4. Project manage a capacity increase for Colonoscopy Tasks 2 to 4 are in many ways similar, and would represent competing demands for funding, project management time, screening expertise and clinical staffing. These competing demands would increase overall programme risk. A considerable and unidentified new impetus would be required in order to regain the lost momentum in the current bowel scope roll-out, and to motivate providers to attain trial quality standards.
B	*Option B: Offer FIT to 50-74 year olds at thresholds below 93 ug/g and decommission (or not start) BS.*	Option B has the benefit of removing complexity from the bowel cancer programmes and enabling commissioners and providers to focus on one screening modality. Reaching a threshold of 93ug/g may be feasible with sufficient lead time, funding, and workforce support. The additional consideration in Option B is the need to plan for when to de-commission current BS programmes, and establish re-deployment and re-training arrangements for a highly skilled and valued staff group. It will be essential to do this in such a way that it benefits the upscaling of colonoscopy capacity, but doesn't take out BS in areas where FOBT uptake is low and before FIT is widely available.
	Either option: Implementation considerations and opportunities	
	Considerations	Full implementation of either option will have challenges and

		would need to be phased over several years. Consideration would need to be given to: • Programme funding; to include both capital costs and ongoing costs • Staffing; recruitment, training and retention, with support from HEE • Premises • Estates, Facilities and equipment • Accreditation A key benefit of FIT over gFOBT is the variable threshold. There is an opportunity to set a trajectory towards 93ug/g (Option B) or the appropriate threshold in option A over a number of years, and then enable local areas to vary the threshold between introduction of FIT and the end of the trajectory to reflect current colonoscopy capacity. This would prioritise access to colonoscopy within areas with temporary capacity constraints for those at greatest risk. Similarly, it would be beneficial to phase any extension of the current age range of screening over the period to balance this against lowering the positivity threshold and achieve optimal outcomes throughout the implementation period.
		After consulting with stakeholders, we received feedback that the risk of bowel cancer varies throughout the population, and is 20% higher in smokers, 33% higher in those drinking more than 50 units per week and 70% higher in those with a first-degree relative with bowel cancer. Combining a risk score from these wider risk factors with the numerical FIT test result could have higher predictive value than the FIT result alone. Consideration should be given piloting the use of such a combined risk to determine progression to diagnostic testing
	Opportunities	NICE guidance for the symptomatic colorectal cancer pathway

		supports the use of FIT for symptomatic patients, and GM is currently developing revised pathways to support this, following a trial in Stockport. We would like to explore the possibility of seeking synergies between the development of FIT for screening and symptomatic pathways, including the opportunity to use the same supply chains, laboratories and data systems for both programmes. In Greater Manchester, we estimate that the symptomatic pathway could be equivalent to 10% of volumes in the screening pathway.
	Conclusions	While implementing either option would be challenging, **Option B, using only FIT is preferable** based on the Greater Manchester experience of the existing programmes, and based on the reduced complexity of implementing this option. Consideration should be given to implementation over an ambitious but realistic timescale, should be fully funded and should have a locally variable FIT positivity threshold in the short term, accompanied by a national framework to guide this, in order to prioritise access to colonoscopy capacity.
	References	1. NSC, 2018. Bowel Cancer Screening Consultation Covernote 2. Whyte S. *et al*. 2017 Optimising Bowel Cancer Screening Phase 1: Optimising the cost effectiveness of repeated FIT screening and screening strategies combining bowel scope and FIT screening. University of Sheffield 3. Atkin WS, Edwards R, Kralj-Hans I et al. Once-only flexible sigmoidoscopy screening in prevention of colorectal cancer: a multicentre randomised controlled trial. Lancet; 2010; 375: 1624-33

	Appendix 1	Consultation on this response was conducted with the 10 local authorities, 10 CCGs and the screening programme providers in Greater Manchester. The following organisations asked to be named in support of this response: • Greater Manchester Health & Social Care Partnerhip • Wigan Council • Tameside Council • Trafford Council • Salford City Council & CCG • Stockport Council • Oldham Council • Manchester Health and Care Commmissioning Organisation • Bury Council • Greater Manchester & Eastern Cheshire Strategic Clinical Network

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Optimising bowel cancer screening

Consultation comments pro-forma

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Yes ☒ **No** ☐

Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
Page 9 and page 24	Endoscopy capacity	The report acknowledges that the optimal screening strategy depends on the capacity of endoscopy services within the Bowel Cancer Screening Programme (BCSP), which deliver bowel scope, screening referral colonoscopies, and surveillance colonoscopies. The authors note that '*there is considerable uncertainty in the model predictions of surveillance colonoscopy and capacity for bowel scope and colonoscopy are*

		different' (page 24), and so only considered different numbers of screening referral colonoscopies in their cost-effective analyses. Results were generated for three screening referral colonoscopy capacities: 50,000, 70,000, and 90,000 (colonoscopies per year). The first is just over the current capacity (as of September 2017) within the BCSP (47,000) (although please note that on page 9, it states that the current capacity is 70,000, which we think must be an error?), whilst 90,000 is the optimistic prediction for the end of 2018. We wonder whether there is any evidence that an increase in endoscopy capacity has occurred since the report was published, given that we are now one quarter of the way through 2018? It is important that the level of available screening referral colonoscopies is accurately predicted in the model as it affects which screening strategies are deemed cost-effective. For example, in the base case model, it was cost-effective to replace the FIT screen at age 58/9 with bowel scope at a capacity of 50,000, but not at 70,000 or 90,000. Furthermore, in replacing one round of FIT with bowel scope and thus successfully removing any identified lesions (by bowel scope and by referral colonoscopy for those who needed it), it is highly unlikely that FIT would be necessary for several years after bowel scope, certainly not just two years later, as proposed and modelled. The number of surveillance colonoscopies associated with different screening strategies affects the relative cost-effectiveness of each strategy and so must be accurately estimated. We expect that a strategy based on 8-13 rounds of FIT would generate considerably greater demand for surveillance colonoscopy than a strategy combining fewer FIT rounds with a one-off bowel scope. This expectation is based on the presumption that more people would undergo screening referral colonoscopy and have adenomas detected with the former strategy.
Page 7 and page 43	Endoscopy capacity	In the report, the authors state that '*the model predicted surveillance colonoscopy estimates… should be treated with caution*' (page 7) as they differ by more than two-fold from estimates obtained from BCSP data. Only some of the discrepancy could be explained by the uncertainties in the surveillance model parameters (as discussed on page 43), and so we are concerned that there is something more

		systematically problematic with the model. The surveillance modelling in Phase 2 of the programme will shed light on this matter and we await the results in anticipation.
Page 8, page 24 and page 46	Willingness-to-pay threshold	The authors report to have used two different willingness-to-pay thresholds in the report. A threshold of £13,000 per QALY is mentioned in the methods section (page 24), whereas the executive summary (page 8) and results section (page 46) refer to a threshold of £20,000 per QALY. It is unclear why there is this discrepancy.
Page 32	Adenoma prevalence	In the ScHARR model, estimates for the prevalence of low risk adenomas were 34% at age 55, 37% at age 60, and 39% at age 65. These estimates were taken from the 2011 ScHARR model calibration[1] and were derived from seven autopsy studies. Autopsy studies are an unreliable source of data for estimating adenoma prevalence as people who have died and are subject to autopsies are poor surrogates for living people of the same age. The authors even caution in the 2011 publication that '*there is considerable variation between the prevalence seen in the different autopsy studies'* and that a '*high level of uncertainty was present in the polyp prevalence data due to the age of the studies, geographical differences in populations, and weaknesses in study designs'*.[1] The adenoma prevalence estimates are also considerably higher than those reported in more recent studies of people undergoing screening colonoscopy.[2, 3] We therefore call into question the reliability of the adenoma prevalence estimates. This is an important issue as the sensitivity and specificity estimates for the screening tests were calculated from '*screening detection rates and estimated underlying disease prevalence*' (page 32).
Page 13	Systematic false positivity with gFOBT and FIT screening	Insufficient consideration has been given to the issue of false positive rates with gFOBT and FIT screening. Although the authors acknowledge that *'around 15% of individuals with positive gFOBT samples turn out to have no abnormality upon further investigation'* (page 13), this was based on data from only four screening rounds of the BCSP. These rates might be exacerbated with further rounds of testing. Indeed, evidence suggests that some individuals are particularly susceptible to false positive gFOBTs.[4, 5] The ScHARR report does not consider the potential that systematic false positivity may occur with 8-13 rounds of biennial FIT. If these false-positive individuals are not considered, they would be potentially subjected to excessive colonoscopic examinations adding to the burden in terms of

		endoscopic capacity and putting the patients at unnecessary risk.
Page 15 and Table 28	Overestimation of the effect of gFOBT screening on colorectal cancer incidence and mortality	The ScHARR report estimates that biennial gFOBT screening between the ages 60 and 74 reduces lifetime colorectal cancer incidence and mortality by 10.7% and 16.8% (Table 28), respectively. This is based on the results of a single randomised trial which reported a reduction in colorectal cancer mortality of 13% after 20 years of follow-up (18% when adjusting for non-compliance). No significant reduction in colorectal cancer incidence was seen.[6] The model estimate of a 10.7% reduction in colorectal cancer incidence is therefore surprising. The authors' reasoning is that people undergoing screening within the BCSP are offered up to eight rounds of gFOBT, whereas participants in the trial were only offered three to five gFOBTs. However, in another randomised trial of gFOBT screening, no reduction in colorectal cancer incidence was observed even after nine rounds.[7] Although gFOBT uptake and positivity rates in this trial were similar to in the BCSP, the ScHARR report dismisses this trial: '*It is difficult to use this study as calibration or validation data because the gFOBT protocol used differs from the BCSP in England'* (page 15). Thus, the estimated colorectal cancer incidence reduction figure seems to be based wholly on speculation: '*it seems plausible that gFOBT screening could have an impact on colorectal cancer incidence as FU colonoscopy removes adenomas'* (page 15).
Page 43	Overestimation of the effect of FIT screening on colorectal cancer incidence and mortality	In section 5.6 'Model validation' (page 43), the `long term follow up screening trial data' section describes validation for gFOBT screening and for bowel scope screening but not for FIT screening. The ScHARR report estimates that reductions of 15-29% in colorectal cancer incidence and 18-36% in colorectal cancer mortality can be achieved by biennial FIT screening, depending on the screening age range and FIT threshold used. We are concerned that the cost-effectiveness model is based on these estimates as there is no empirical evidence that biennial FIT reduces long-term colorectal cancer incidence and mortality. Studies on FIT screening have been restricted to evaluating FIT performance only in terms of uptake, positivity rates, diagnostic yield, and diagnostic accuracy for advanced neoplasia at successive screening rounds.[8-16] Furthermore, there is no data on the performance of FIT over more than four rounds, yet the model simulates eight, 11 and 13 FIT rounds. The optimistic estimates of the effect of FIT screening on colorectal cancer incidence and mortality are therefore unfounded. This could

		have an enormous impact on data presented and the conclusions drawn by this report.
Page 44 and page 51	Sensitivity of gFOBT and FIT over repeated screening rounds	In section 5.7 'Sensitivity analyses' (page 44), the report discusses that the base case models assume the same test characteristics for every round of screening and thus that the sensitivity and specificity of FIT are the same in round 13 as in round 1. They state that '*the structure of the model makes it difficult to vary the characteristics for repeated tests*' (page 44). For the base case, it was only cost-effective to replace the FIT screen at age 58/9 with bowel scope at a screening referral colonoscopy capacity of 50,000. However, when the sensitivity of FIT was reduced by 25%, '*it was cost-effective to add bowel scope to each of the repeated FIT screening strategies'* (page 51). The assumptions regarding sensitivity and specificity have a dramatic effect on the conclusions drawn. As the model results are so sensitive to changes in FIT sensitivity, the simple deterministic sensitivity analysis is not satisfactory, particularly as only one other estimate of FIT sensitivity was evaluated. Although the data is limited, there are suggestions that the sensitivity of gFOBT and FIT for advanced colorectal neoplasia decreases in repeat screens.[8, 10-12, 16-19] In fact, when ScHARR modelled gFOBT performance at initial and repeat screens in the English BCSP in 2014, the authors concluded that '*future economic evaluations of gFOBT should not assume equal sensitivities between screening rounds'*.[17] Effort should have been made to further explore the impact of variation in FIT sensitivity over repeated rounds on model predictions (i.e. through probabilistic sensitivity analysis).
Table 23	Underestimation of the effect of bowel scope screening on colorectal cancer incidence and mortality	The ScHARR report estimates that one-off bowel scope screening at age 59 reduces lifetime colorectal cancer incidence and mortality by 8.4% and 9.8%, respectively (Table 23). We believe that this is a significant underestimation and would only occur if the protective effect of bowel scope screening attenuated at a rapid rate. This is not in line with our recently published findings from the UK Flexible Sigmoidoscopy Screening Trial (UKFSST), which demonstrated that once-only bowel scope screening between ages 55 and 64 years reduced colorectal cancer incidence and mortality by 26% and 30%, respectively, an effect consistent over 17 years of follow-up.[20] Smaller reductions in colorectal cancer incidence and mortality are expected in non-trial settings where uptake rates of bowel scope are

		likely to be lower than the 71% achieved in the UKFSST; however, the reductions used in the ScHARR model are likely to have produced underestimations for all cost-effectiveness estimates of screening strategies with bowel scope.
Page 51	Uptake of bowel scope screening	The report has also not given sufficient consideration to the impact of bowel scope uptake rates on cost-effectiveness. In the base case model, using an uptake rate of 44%, it was only cost-effective to replace the FIT screen at age 58/9 with bowel scope at a screening referral colonoscopy capacity of 50,000. However, in the sensitivity analysis '*with higher bowel scope test sensitivity from UKFSST, and higher uptake of 55%*' (page 51), '*it was cost-effective to replace the FIT screen at age 58 with bowel scope at any of the screening referral colonoscopy capacity levels considered'*. The uptake rate of bowel scope therefore strongly influences how optimal a screening strategy appears and should be investigated in greater depth. Although the available data report that bowel scope uptake rate within the BCSP is 44% for the initial roll-out period, the programme has not matured and uptake should increase once the programme rolls out more fully. Furthermore, recent data has shown that bowel scope uptake can be increased if non-screenees are re-invited 12 or 24 months later[21].
Overall conclusions	Termination of FIT screening in older ages	We are concerned about the practicality of several of the proposed screening strategies. The main focus of this report is on maximising cost-effectiveness and that QALY gains are maximised when screening is done at younger ages but incidence and mortality reductions are maximised when screening is done at older ages. Several of the proposed optimal strategies only involve FIT screening up to age 65 or 70 years. It seems illogical to withdraw screening from those aged 71-74 years; these individuals are currently offered gFOBT screening on the basis that it was deemed important to extend the screening age to 74 years due to the high incidence of colorectal cancer in this age bracket.

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Section and / or page number	Text or issue to which comments relate	Comment *Please use a new row for each comment and add extra rows as required.*
P47. 6.2	Under the scenario analysis with higher bowel scope test sensitivity from UKFSST, and higher uptake of 55%, bowel scope was associated with much higher effectiveness and cost effectiveness than FIT20.	See below
6.7	Comparing a one-off FIT20 and a one of bowel scope,	See below

	we see that bowel scope is the most effective but FIT20 is the most cost effective. However under analyses in which bowel scope uptake and/or effectiveness is increased, bowel scope was associated with much higher effectiveness and cost effectiveness than FIT20	
Section 5.3.2 Appx 1.2	**BCSP Bowel Scope** For the bowel scope analysis, data from the NHS BCSP was used. This data includes approximately 240,000 bowel scope procedures undertaken in persons aged 55. The detection rates for age 60 were estimated from this data using the relative detection rates observed in the UKFSST for which we have age categorised data for persons of ages 55-65. For bowel scope screening LR adenomas may be identified at BS or at referral colonoscopy. The NHS BCSP data only contains information about those persons detected with LR adenomas at colonoscopy hence the more detailed UKFSST data was used to supplement this. In both the UKFSST data and the BCSP data the detection rate for LR adenomas at colonoscopy was just over 1% however, the UKFSST data suggests a significant number of LR adenomas (approximately 8%) are also detected at BS (in persons not referred on to colonoscopy). We note that the test characteristics for bowel scope relate to the entire screening episode i.e. 'bowel scope plus index colonoscopy for those who are referred and attend'. The UKFSST is also included here for comparative purposes. For the model base case the BCSP BS data was used as it includes a higher number of bowel scope procedures and is more likely to reflect how the bowel scope screening programme performs in practice. Improvements in bowel scope quality could result in higher HR adenoma and CRC sensitivity as observed in the UKFSST and this was explored within a scenario analysis. Data from the NHS BCSP includes approximately 240,000	ScHARR suggest that bowelscope is under performing compared with FSST I question the accuracy of the ScHARR analysis for bowelscope. We are undertaking the procedure in a younger population. ScHARR did not incorporate data from bcss bowelscope but looked at just those going to colonoscopy and extrapolated**.("it was not possible to compare for LR adenomas")** Bowelscope underperformed in HR adenomas and CRC and ScHARR estimates LR adenomas in "approximately 8%" Bowelscope however is about removing adenomas to prevent cancer rather than detection of cancer or even HR adenomas - and the extrapolation of HR adenoma and CRC data to all adenomas may therefore be biased. One might expect a younger population to have a higher LR adenoma and lower HR adenoma/CRC rate. After all the main difference between a HR adenoma and LR adenoma in size (as well as number, etc) and a 9mm adenoma is LR whilst a 10mm adenoma is HR. Additionally our colonoscopy-removed adenomas are fixed in formalin and I believe measured by a pathologist rather than eyeballed in unit as Wendy's study . The latest bowelscope data I have is across West and east midlands and east of England and shows an adenoma detection rate of 9.57% out of 87912 procedures not including those referred for colonoscopic removal. I would presume this is the LR adenoma rate, which is considerably more than the "approximately 8%" quoted, and when added to the 1.97% HR adenoma rates gives an adenoma detection rate of 11.54% vs overall 10.67% for LR + HR adenomas in FSST for age 55. Bowelscope is therefore outperforming the FSST.

	bowel scope procedures undertaken in persons aged 55. This is a large data set so there is little uncertainty in these detection rates. Compared to the UKFSST detection rates in the NHS BCSP were significantly lower for HR adenomas and CRC. **It was not possible to compare for LR adenomas.** For bowel scope screening LR adenomas may be identified at BS or at referral colonoscopy. The NHS BCSP data only contains information about those persons detected with LR adenomas at colonoscopy hence the more detailed UKFSST data was used to supplement this. In both the UKFSST data and the BCSP data the detection rate for LR adenomas at colonoscopy was just over 1% however, the UKFSST data suggests a significant number of LR adenomas (approximately 8%) are also detected at BS (in persons not referred on to colonoscopy). We note that data on LR adenomas detection rate (including both at BS and at colonoscopy) should be collected to allow comparison between the NHS BCSP and the UKFSST data.	Also uptake : FSST invited 370,000 odd individuals of whom 53% agreed to take part, were randomised and 71% actually attended giving an uptake of 37% to which Bowelscope compares very well. In addition, no health promotion has been allowed for bowelscope on the premise that it is not available for the whole population as yet. In Norfolk, we saw bowelscope uptake rise to 80% following Chris Evans undergoing the procedure on the One Show on BBC 1. It may just take publicity/health promotion to push uptake of bowelscope up from where it is now. The cancer prevention effect of Bowelscope lasts at least 12 years, meaning the number to prevent one cancer will be falling as time goes by, and it is unclear if the ScHARR analysis took this progressive cancer preventative effect into account. A review of bcss bowelscope data (ie from FS not the ensuing colonoscopy) needs to be undertaken before the model can assume that FIT 93 is more cost effective than bowelscope
Appx 1.1	Q3 If bowel scope capacity could be converted to screening referral colonoscopy capacity does this impact on the conclusions? We suppose an endoscopy capacity equivalence of *10 bowel scopes = 4 screening referral colonoscopies*. Two screening strategies with equivalent endoscopy capacity (under this assumption) are compared. We consider a one-off bowel scope screen at age 59. This is associated with a high endoscopy capacity which could also be used to undertake repeated FIT screening with a lower test threshold. Base case analysis (BS sensitivity and uptake from the BCSP) A one-off bowel scope at age 59 (290k bowel scopes, 9k	It is not possible for the foreseeable future to simply convert bowelscope procedures into screening colonoscopies. The accreditation criteria for FOBT colonoscopy are set high and include a lifetime minimum of 1000 colonoscopies. Trainees on average perform 50 per year – indeed colorectal surgery trainees struggle to hit a minimum JAG accreditation of 200 over 7 years of training before CCST. To train the current bowelscope workforce to perform FOBT colonoscopy is likely to be at least 10 years in the future if at all.

	screening referral colonoscopies) is considerably less effective and a cost effective than a repeated FIT74 screening strategy which is associated with 125k screening referral colonoscopies. Such strategies could be considered to have equivalent endoscopy capacity. Hence, if bowel scope capacity could be converted to screening referral colonoscopy capacity instead, it would result in far higher effectiveness and cost-effectiveness to undertake repeated FIT only screening strategies.	
		I worry that the conclusion is going to be to scrap bowelscope in favour of FIT despite concerns about the extrapolation of data vs FSST, but it will be many years down the line before the FIT threshold is reduced to a level that matches the cancer protective effect of bowelscope – in the meantime, we will be in a worse position than at present

UK National Screening Committee
Optimising bowel cancer screening

Consultation comments pro-forma

Name:	xxxx xxxx, xxxx xxxx, xxxx xxxx, xxxx xxxx	**Email address:**	xxxx xxxx
Organisation (if appropriate):			
Role:			

Do you consent to your name being published on the UK NSC website alongside your response?

Yes ☐ **No X**

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required.*
Section 21 (covernote)	B. Offer FIT to 50 – 74 year olds at thresholds below 93 ug/g and decommission BS	To support the age extension of FIT, bowel scope would have to be decommissioned to release relevant capacity.
Short summary – page 5	….reinviting non-attenders after 1 year interval – optimal age for a repeated FIT screening strategy is 50 or 51…	We would need more information to comment as to the capability to do this – presumably this will be covered in phase 2

Model validation, page 7	The surveillance model parameters… significant uncertainty	We will need detailed surveillance predictions to accurately create demand and capacity plans. Phase 2 will enable us respond more realistically as these are the details that affect our business planning which will also identify how we can deliver the predicted service.
conclusions – page 9	one off bowel scope at age 59 less effective than a repeated FIT screening strategy	A repeated FIT screen would be preferable as opposed to a one off bowel scope due to the release of capacity from bowel scope
Endoscopy capacity – page 52	Table 27	As we know we are going ahead with FIT120 – would repeated FIT screening strategy still be more cost effective and how many colonoscopies would this be? Would need relation to local data

Together to stop bowel cancer

Bowel Cancer UK and Beating Bowel Cancer response to the UK National Screening Committee consultation on optimising bowel screening

Introduction

Bowel Cancer UK and Beating Bowel Cancer welcome the opportunity to respond to this consultation on an optimal screening strategy for bowel cancer within the UK. Bowel cancer remains a significant health problem in the UK. Over 41,000 people are diagnosed with the disease each year and 16,000 people die from it. It is the fourth most common cancer and the second biggest cancer killer in the UK. This is despite bowel cancer being preventable, treatable and curable. Evidence shows that the best way to improve survival rates for bowel cancer is by detecting it at the earliest stage when it is more treatable. In fact more than nine in ten people will survive the disease for more than five years if diagnosed at this stage. We know that screening provides the best chance of detecting the disease at this early stage. However the screening programme is currently limited in its ability to achieve the significant stage shift required to drastically improve survival rates for bowel cancer. The challenges that impact its effectiveness are primarily:

- **Uptake**: Participation in screening across the UK varies considerably. In some areas only a third of the eligible population take part.
- **Accuracy**: The current test only looks for the presence of blood in stools and can be affected by diet and medication. This means that it can miss up to 50% of cancers[i].
- **Endoscopy and pathology capacity**: Demand for these services has been increasing over the last few years, but there is a significant lack of capacity to meet this demand.

Summary position

Bowel Cancer UK and Beating Bowel Cancer want to see every eligible person in the UK have access to the best and most effective screening methods. This includes screening from the age of 50 using the faecal immunochemical test (FIT), set at an optimal sensitivity level to enable as many adenomas and early stage cancers to be detected. We would also urge the UK NSC to take into account expanding screening to those at high risk of bowel cancer through genetic conditions, such as Lynch syndrome. In addition to this, the UK NSC should consider the introduction of risk stratification in the bowel cancer screening programme, particularly as the programme has the software to support this, for example, applying different criteria to participants in different episodes or lengthening screening rounds based on an individual's risk. Regardless of the decision made, what is vital to ensure is that the NHS has the resources and capacity to deliver an effective and optimal screening service. A clear, transparent and time-tabled programme of action that is

developed in collaboration with both professional groups and patient representatives must be developed to support this.

Is the ScHARR model sufficiently robust to support UK policy?

We understand that both Cancer Research UK and the British Society of Gastroenterology have raised concerns regarding the modelling used in phase 1, particularly as the model is based on out of data and is not consistent with current findings in practice. The UK NSC must address these concerns in order to ensure that policy recommendations are robustly supported. Phase 2 modelling would be a good opportunity to address these issues. However more detail is required about what this piece of work will involve, as well as the timescale.

Do the policy recommendations follow from the ScHARR work?

It is the understanding of Bowel Cancer UK and Beating Bowel Cancer that although the policy recommendations appear to follow the modelling set out in the consultation document, Cancer Research UK has raised concerns that the modelling itself is not robust enough to support a policy change. We would urge the UK NSC to address this in phase 2.

Are the policy options feasible? If so how can efforts to deliver either be evidenced?

Bowel Cancer UK and Beating Bowel Cancer have the following concerns and recommendations regarding the delivery of an optimal bowel cancer screening programme:

1. Workforce capacity

The aim of the screening programme should be to prevent and detect as many cancers as possible. We are therefore disappointed that the UK NSC has constrained the policy recommendations for the most
optimal screening strategy by taking into account colonoscopy capacity. We absolutely recognise that the biggest constraining factors to implementing an optimal bowel cancer screening programme are a lack of endoscopy and pathology capacity. However, the UK NSC must make decisions based on what's best for the population and what screening strategy presents the best opportunity to prevent bowel cancer and diagnose it early, without the constraints of colonoscopy capacity. Following this, it is up to NHS England, Public Health England, Health Education England and the Department of Health and Social Care to work together, with professional groups and patient representatives, to develop and build a programme of activity to implement this recommendation. This includes setting out what is feasible and by when.

While HEE have taken steps forward to start to address the significant workforce deficits by committing to training 400 clinical endoscopists to undertake additional 450,000 endoscopies a year by 2020, just 48 clinical endoscopists have completed the accelerated training programme. Furthermore these clinical endoscopists are being trained to undertake flexible sigmoidoscopy and/or gastroscopy and while there is potential that this could free up consultant time to carry out more colonoscopy, this has not been evidenced. The Arms-Length Bodies must give due consideration to the appropriate workforce training requirements to support the implementation of an

optimal bowel cancer screening programme. This cannot be developed in isolation of a plan to increase the sensitivity of FIT.

2. Sensitivity of FIT

The introduction of FIT into the screening programme provides us with further opportunity to detect and prevent more cancers. The evidence outlined in the consultation document demonstrates that FIT has clear advantages over the guaiac faecal occult blood test (gFOBT). Based on the strength of this evidence and the clear need to improve survival rates for bowel cancer we would strongly recommend that FIT is introduced as a matter of urgency, particularly as we know that gFOBT can miss as much as 50 per cent of cancers[ii].

We understand and appreciate the impact that a highly sensitive FIT could have on colonoscopy services, particularly as many centres are currently struggling to deal with increasing demand. We would therefore support the introduction of FIT at the same analytical level as the gFOBT of 150 µg Hb/g to ensure a similar positivity yield and therefore minimise the impact on colonoscopy services.

However if the full benefits of FIT are to be achieved then it is essential that plans are put in place to ensure the test can be brought in at a more sensitive level. Estimates show that at a high clinical sensitivity level of around 20 µg Hb/g faeces approximately 7,848 cancers and 22,790 high risk adenomas could be detected, compared to just 3,196 cancers and 3,876 high risk adenomas under the current screening test. Therefore if FIT is to be brought in at a lower sensitivity level, to maintain current positivity rates, there needs to be a clear and planned programme to increase capacity in endoscopy units to ensure the sensitivity can be adjusted to detect more cancers. We know that as screening progresses, round by round, the positivity rate decreases as disease is culled from the population choosing to participate in the screening programme. In this case we would expect the cut-off of faecal haemoglobin concentration to be lowered to fully occupy the available colonoscopy resource. This strategy is a much noted advantage of using quantitative FIT in a bowel cancer screening programme. Not only is FIT more clinically sensitive it is also, according to the UK NSC 2015 Expert Review documents, cost-effective at every sensitivity level. But urgent steps need to be taken to address the significant demand and capacity gap. Without this the potential of FIT will not be fully realised.

Furthermore it is well documented that faecal haemoglobin concentrations rise with age, are higher in men than women, as well as in certain deprivation groups. We would recommend that the UK NSC consider different haemoglobin cut-off concentrations for different patient characteristics, as a way to optimise the sensitivity of FIT for maximum clinical benefit. This should be factored in to phase 2 modelling.

3. Bowel scope screening

Bowel scope screening has been shown to be highly effective – demonstrating once fully rolled out it can prevent a third of bowel cancers and reduce the risk of dying from the disease by more than 40% in those who take up the offer of screening. This benefit has

been shown to last for at least 17 years. Although the implementation of bowel scope has experienced major challenges and the trial results have not been seen in practice, the clear benefits of bowel scope must mean any decision to stop this screening method must be made on robust data. Furthermore there is yet no trial evidence of FIT and bowel scope being used in combination and the implications of this will need to be considered carefully before a decision is made. If bowel scope is discontinued, any additional capacity created must be used to introduce FIT at a more sensitive level. It would not be acceptable for bowel scope to be withdrawn without a timetabled and firm commitment on the optimal use of FIT. This would ensure a less effective programme is not offered in place of bowel scope.

4. High risk groups

Currently, the bowel cancer screening programme only screens healthy individuals age 60-74 every two years. There is no programme for managing high risk groups, such as those with Lynch syndrome, within the programme. Lynch syndrome can increase the lifetime risk of bowel cancer to up to 80%. But research shows that regular colonoscopy screening can help to reduce the risk of dying from bowel cancer by as much as 72% through detecting it early, when it is most treatable and potentially curable. Currently the screening of people with Lynch syndrome is managed by their local hospital but this has led to a postcode lottery across the country, resulting in unacceptable waiting times and poor quality care.

A clinical consensus meeting[iii], organised by Bowel Cancer UK and Beating Bowel Cancer UK, of 10 leading experts in the field of bowel cancer and genetics agreed the BCSP should extend their service to those who have Lynch syndrome so they also receive the same high quality service as the eligible asymptomatic population. This would be the most efficient and effective method to deliver a national screening and surveillance service, utilising existing infrastructure. The BCSP is delivered to a very high standard, has in place robust quality assurance mechanisms for colonoscopy and a good call and recall system. This would help to significantly reduce the vast variation in access, quality and frequency of colonoscopy screening and ensure an efficient, consistent and streamlined approach to the colonoscopic management of people with Lynch syndrome across the country. A precedent has already been set by the NHS Breast Cancer Screening Programme, which routinely tests healthy women for risk of cancer but also manages the screening of those with a known genetic mutation (BRCA 1 or 2) that increases the risk of breast cancer.

About Bowel Cancer UK and Beating Bowel Cancer

Bowel Cancer UK and Beating Bowel Cancer have joined together to stop bowel cancer. We are determined to save lives, improve the quality of life and support all those affected by bowel cancer in the UK. We enable and fund research, provide information and support to patients and their families, educate the public and professionals about the disease and campaign for early diagnosis and best treatment and care for all.

For further information please contact Head of Policy and Campaigns, Asha Kaur, at asha.kaur@bowelcanceruk.org.uk or on 020 7940 1760.

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[i] http://gut.bmj.com/content/gutjnl/early/2011/09/19/gutjnl-2011-300535.full.pdf

[ii] ibid

[iii] https://bowelcancerorguk.s3.amazonaws.com/General%20pdfs/Clinical%20consensus_Lynch%20syndrome_2017_FINAL.pdf