New Blood Test to Radically Reduce Unnecessary Invasive Procedures for Bowel Cancer Suspects

The Lymphocyte Genome Sensitivity Test is a new blood test being developed by Oncascan Limited. One promising application is to use it to triage suspect bowel cancer patients. If they score lower than a determined threshold they will not have either cancer or potentially harmful polyps and can safely avoid an endoscopic investigation. The practical performance of the test is currently being studied on a trial cohort of bowel cancer GP referrals.

Background

Colonoscopy is used to detect bowel cancer and allows the removal of pre-cancerous polyps, but it is invasive, painful, time consuming, expensive and carries some risk. The often indistinct reasons for referral (eg change of bowel habit, bloating, noticing blood in faeces) results in a high number - around 70% - of false positives; ie patients who do not actually need colonoscopy. Clinicians are keen to reduce this proportion in order to benefit patients. This initiative is intended to safely identify many of the false positive cases with a cost effective blood test and thus reduce investigation by colonoscopy.

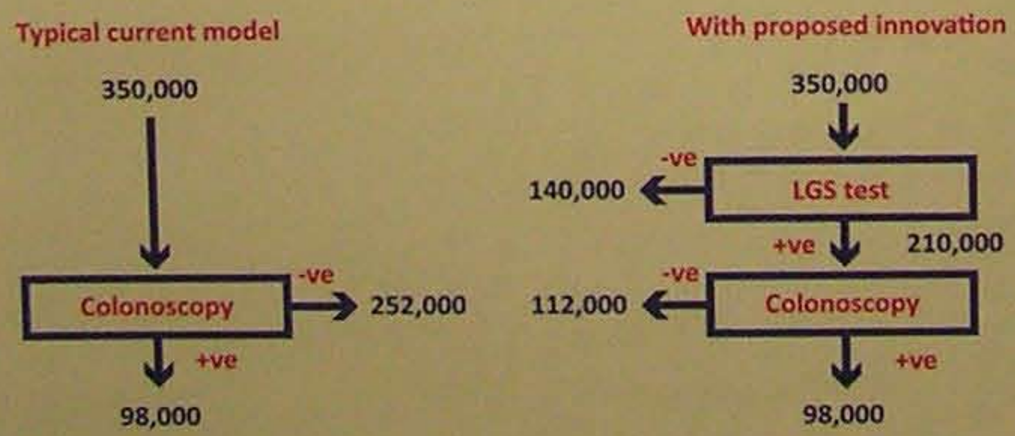
In England, NICE have estimated that there are some 250,000 unnecessary colonoscopies carried out each year. This translates to some 6 million per annum globally. Potential patient benefits and healthcare provider savings are therefore very considerable.

The LGS Test

The patented Lymphocyte Genome Sensitivity ("LGS") test uses the increased sensitivity to ultra-violet ("UV") induced DNA damage of lymphocytes from cancer patients to distinguish between those with and without cancer. It works by using a device that exposes blood cells to UV radiation and then quantitatively assessing DNA damage, all in a controlled and reproducible manner.

Diagnosis Pathway Innovation

The proposed innovation is to carry out an LGS blood test on each suspect bowel cancer patient referred by their GP for specialist investigation. Currently nearly all such referrals, assuming they are suitable, will undergo a colonoscopy. In future a significant proportion need not have this procedure but without missing any candidates who would benefit by having cancer diagnosed or polyps removed.



Innovation annual saving = 140,000 fewer colonosocopies with the same diagnostic outcome

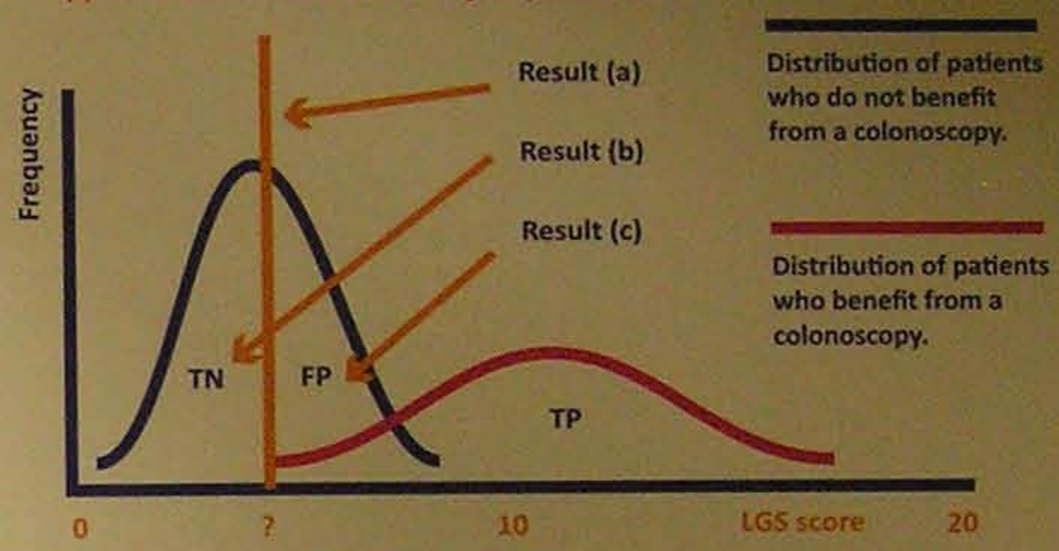
Figures above are annual patient numbers for England. The 98,000 shown as +ve include not just bowel cancer cases identified but those who have polyps removed. The latter is about three times the former.

Current Study

Encouraged by early results, Oncascan Limited, which has licensed the exclusive worldwide rights to the LGS test, is now carrying out an evaluation, funded largely by SBRI Healthcare, to investigate the performance of the LGS test on a cohort of referrals for suspect colorectal cancer. Specifically the study is designed to identify the criterion value below which there are no false negatives. This will allow the benefits of the LGS test to be quantified and justify the investment needed to develop an automated instrument to carry out the assay at scale.

Results

The study is designed to provide the following information:
(a) What is the criterion value for which there are no false negatives?
(b) At this criterion value what is the true negative rate?
(c) At this criterion value what is the false positive rate?



Anticipated outcome:

FN = 0%	By definition
TN = 40%	Approx expectation
FP = 32%	Approx expectation
TP = 28%	Approx expectation

"Unnecessary" colonoscopies = TN + FP = 72%

"Unnecessary" colonoscopies avoided = TN / (TN + FP) = 56%

Study Funding

Oncascan Limited was awarded an SBRI Healthcare development contract for this study. This work was commissioned and funded by NHS England. The views expressed in this publication are those of the authors and not necessarily that of the funding partners.

Collaboration and Investment

Oncascan expects to realise the full potential of the LGS Test together with technical and commercial partners. Significant investment will also be required. Accordingly we would welcome discussions with prospective collaborators and shareholders.

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