The PIVOT Study Protocol

PIVOT: PatIent Views On Testing for cancer (quantitative phase)

1. Team

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2. Aim

To identify a population risk threshold, for investigation of symptomatic cancer

3. Objectives

3.1 To establish whether a susceptible population with symptomatic cancer would choose to be tested at different levels of risk of lung, pancreatic and colorectal cancer.
3.2 To identify the level of sureness attached to responses about whether to be tested or not.
3.3 To identify the relative importance of reasons for choosing to be tested or not.
3.4 To estimate the value a susceptible population places on testing for lung, pancreatic, and colorectal cancer, using willingness-to pay.

4. Background

Most cancer patients present, in the first instance, to primary care. Initial symptoms may indicate cancer, though almost every symptom of cancer has a more common benign possible cause, and this leads to inconsistency over selection of patients for investigation. There is very little evidence about patient's views on testing for cancer and none about how serious symptoms need to be before testing is viewed as desirable.

The PIVOT Study is nested within the DISCOVERY research programme which has the overall aim of understanding and improving diagnostic pathways for cancer. The DISCOVERY programme has three themes: theme 1 (The Symptom Study) is examining later presentation of cancer via a survey and qualitative interviews; theme 2 is examining the risk of symptoms in a number of cancers using the General Practice Research Database and will map pathways between symptom reporting and diagnosis; theme 3 will identify a patient determined risk threshold for cancer investigation (The PIVOT Study) and will model cost-effective investigative pathways culminating in the design and testing of new pathways.

5. Selection of exemplar cancers

Three exemplar cancers (lung, colorectal and pancreatic) have been selected, as each illustrates a different area of diagnostic difficulty. Lung and colorectal cancer are common (lung 47.5 per 100,000; colorectal 44.4 per 100,000), with contrasting 5-year survival rates (lung 6%; colorectal 46%). Lung cancer has a primary care test (the chest X-ray) with good performance characteristics. Patients referred for a chest X-ray can be fast-tracked under the two-week wait rule if cancer is suspected, however fewer than half of diagnosed cases currently take this route.

Colorectal cancer has no specific primary care test and pancreatic cancer has no defined rapid investigative pathway. Pancreas shares many factors with other intra-abdominal cancers, such as ovary,

where non-specific symptoms and the absence of abnormal examination findings contribute to diagnostic delay

6. Design

Questionnaire survey using a touch screen tablet computer. The questionnaire will consist of twelve vignettes (hypothetical scenarios) describing the symptoms of lung, pancreatic and colorectal cancer with risk levels of 1%, 2%, 5% and 10%.

7. Setting and participants

General practice attenders over the age of 40. We aim to survey a total of 1200 patients attending 12 general practices in Bristol and Exeter. Practices will be chosen to ensure a broad representation of urban/rural mix and socio-demographic characteristics. Researchers will recruit patients opportunistically in the waiting area of general practice surgeries at different times of the day and different days of the week. A sample of 1200 patients will provide data on a minimum of 100 responses to each scenario. Patients will not be invited to take part if they are physically or mentally incapable of completing the questionnaire.

8. Methods

We will construct a series of hypothetical scenarios relating to four different levels of risk (1%, 2%, 5%, 10%) for each of the cancers (lung, pancreatic, colorectal), i.e. 12 different scenarios in total. For each scenario, participants will be given evidenced-based information on symptoms, the associated risk of cancer, and details of the appropriate diagnostic test. The scenarios will be developed by an expert panel consisting of members of the programme study team. Each participant surveyed will be presented with a scenario, selected randomly, and asked if, given the information about symptoms and testing procedures, they would choose to have their symptoms investigated. Further questions will identify how sure they are of their decision and the main reason for this response. The content of the scenarios will be reviewed following an initial pilot phase of research. During the pilot phase the study team will also consider the efficacy of the vignettes by comparing them with qualitative interview data conducted as part of theme 1 of the DISCOVERY programme which explores themes around diagnosis and testing for cancer.

If the respondent answers positively, choosing to be tested, we will ask a willingness-to-pay (WTP) question to obtain information on the strength of preference for investigation for each level of risk. The WTP question will be asked using appropriate contextual information to maximise the quality of response, for example, participants may be asked to consider what they might be prepared to give up if they had to pay for the test. The first part of the WTP exercise will present a payment scale for participants to indicate a broad range of values within which their WTP lies. This will be used as a starting point in a bidding exercise to establish a maximum WTP. Final values will fit a geometric series so that smaller values are more precise than larger values. A final question will address participants who refused to offer a valuation to identify the main reason for this.

Participants will be offered the opportunity of completing up to three scenarios, one for each cancer, though they will be given the option of completing only one or two if they prefer.

Further questions will establish participant characteristics including age, sex, household income, ethnicity, employment status, education, personal experience of cancer diagnosis (self or close family member) and accessibility of nearest hospital.

9. Data

Data for analysis will comprise:

Variable	**Categories**
date of completion	dd/mm/yyyy
day of week	M/T/W/Th/F
time of day	am/pm
site ID	BS1, BS2 … BS6 & EX1, EX2 … EX6
researcher ID	RB1, RB2, RE1, RE2
level of response (1st,2nd or 3rd)	1/2/3
age	40-49/50-59/60-69/70-79/80+
sex	male/ female
household income	<£10k/£10k-£25k/£25k-£40k/£40k-£75k/>£75k
ethnicity	white british/white other/mixed/asian or asian british/black or black british/chinese/other
employment status	retired/unemployed, seeking work/unemployed unable to work/working part time/working full time
highest qualification	none/GCSE O-level, CSE/C&G or equivalent/A-level or equivalent/undergraduate degree/postgraduate degree or professional qualification
ever diagnosed with cancer?	yes/no
family member diagnosed with cancer?	yes/not that I know of
convenience of nearest main hospital	very convenient/quite convenient/quite inconvenient/very inconvenient/
travel time to nearest main hospital	<½ hour/½ - 1 hour/1-2 hours/2-3 hours/>3 hours
choose to be tested now?	yes/no
sureness	very sure/fairly sure/unsure
main reason for yes (to be revised in line with qualitative findings)	peace of mind/early detection/want to take advantage of a test if it is offered/ family would want it/worthwhile at my age
main reason for no (to be revised in line with qualitative findings)	Low risk of cancer/rather not know/time consuming/don't like the sound of the test/difficulty in getting to the hospital/treatment would not help
Willingness-to-pay (if yes to testing): payment scale	£1-£100/£101-£300/£301-700/£700+
willingness-to-pay (if yes to testing): bidding	£6/£25/£56/£87/£100/£110/£155/£224/£270/£300/ £320/£398/£503/£620/£700/£752/£895/£1000

main reason for £0 wtp	I cannot afford anything extra/I do not believe I should pay for healthcare/It is too difficult to put a value on health care

We will hold no patient identifiable data.

10. Analysis

We will use regression techniques to establish a population level of risk for each cancer above which investigation is preferred to watchful waiting. The information on participant characteristics will indicate differences of attitude across sub-groups, for example, whether age or sex has a bearing on the decision. The subsequent data on surety and willingness-to-pay will indicate the strength of the preferences and the validity of the results.

11. Outputs and benefits

This project should answer a key question in cancer diagnostics: at what level of risk does a susceptible population believe rapid investigation for possible cancer is warranted? This output will feed into the DISCOVERY programme's overall output of improving diagnostic pathways for cancer.

The methodological approach of the willingness-to-pay is, to our knowledge, novel in a number of aspects, which will be of interest to the research community. Use of a touch screen tablet computer allows greater flexibility than a paper questionnaire and allows random selection of scenarios ensuring that an even number of each of the 12 are completed and that each participant completes no more than one for each cancer. The flexibility also allows for a bidding approach to the willingness-to-pay part of the study which is quick and easy to administer. In addition, by using a payment scale to establish the starting point of the bidding for each participant separately, we will be minimising the effect of 'starting point bias'.

12. Timescale

2011	
January – March	Develop questionnaire
April / May	RAs appointed in Exeter and Bristol
May – July	Recruit practices
July	Refine the questionnaire using data from the qualitative phase
August	Pilot the questionnaire and refine further
September – March (2012)	Data collection
2012	
April – Oct	Data analysis
Nov – Mar (2013)	Dissemination – write papers and present results at conferences