Welcome to the first newsletter for the ProtecT study. We have written the newsletter to update you on the ProtecT study and to thank you for your ongoing support.

**Current Progress**

The ProtecT study is now running across the UK. There are nine centres where men can take part in ProtecT, with a hospital in each area co-ordinating activities:

- Bristol, Southmead Hospital
- Newcastle, Freeman Hospital
- Sheffield, Royal Hallamshire Hospital
- Birmingham, Queen Elizabeth Hospital
- Cardiff, University Hospital of Wales
- Edinburgh, Western General Hospital
- Cambridge, Addenbrokes Hospital
- Leicester, Leicester General Hospital
- Leeds, St James Hospital


So far, over 30,000 men have had a PSA test at a Prostate Check Clinic, and there over 500 men in the ProtecT study with localised prostate cancer. The numbers are increasing as more men are invited to take part in the study. Some men in Sheffield, Newcastle and Bristol are already in their third year of helping the study.
What does the ProtecT study involve?

- All men like yourself who have been diagnosed with localised prostate cancer will have a treatment within ProtecT decided by randomisation or selection.
- The research nurses at your centre will invite you to attend the hospital each year to see how you are getting along.
- The ProtecT research centre at the University of Bristol, Department of Social Medicine will send you a questionnaire each year, after an initial one at six months.
- Lucy Brindle, a specialist interviewer from the ProtecT research team in Bristol may ask to interview some men to get more detailed views.

Why is it so important to carry on taking part?

- The ProtecT study cannot exist without your support.
- It is very important that you continue to visit the research nurses and complete the annual questionnaires as these results will help determine which is the best treatment for localised prostate cancer in the future.
- Please complete the questionnaires and come for the annual visit even if you think nothing has changed over the last 12 months.

What happens to the information from the questionnaires and hospital visits?

- All the questionnaires are brought securely to the research centre in Bristol and entered into a specialised ProtecT study research database.
- Andrea Wilson leads a team of secretaries in the research centre who are responsible for entering the questionnaire data.
- We are very careful to keep your data confidential at all times.
- The questionnaire data are used only by the Protect research team and are not passed on to your GP or anyone else.

What is new or coming up in the near future?

- **Diet Diaries.** To gain further information and understanding of the lifestyles of men with localised prostate cancer, ProtecT has introduced a diet diary for men to complete when they enter the study. Men already participating in the study will not be asked to complete this diary.

- **Health economic questionnaire.** Although there are already some questions about the costs incurred to treat prostate cancer it is necessary to gain more in-depth information. It is expected that between January and June 2004, some men participating in ProtecT, and their partners may be asked to complete an additional health economic questionnaire to assist us in gathering this information.
Are there any results from the study yet?

- The ProtecT study is a large and important study which will inform the NHS how best to treat localised prostate cancer
- The study will be running for many years before the final results are given to the NHS and published in the major medical journals
- Some of the early findings about taking part in the ProtecT study have been published


Notes

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This is my life...as a ProtecT study co-ordinating nurse

My life as a ProtecT team member began in 1999 when the feasibility study commenced to find out whether a main trial was possible. At that time I was the Lead nurse in Sheffield. In 2001, when the main study began, I became the co-ordinating lead nurse. The aim of my role is to assist with the smooth running of the study and to ensure that new centres have adequate training and support.

One of the main roles I have is to establish new ProtecT centres. This month it was Leeds. On September the 1st, I visited a practice that was interested in being involved in the study and arranged to meet the practice staff to answer any questions or concerns they had. I met with the practice manager and 3 GP partners and am happy to report, they were all very enthusiastic and agreed to take part in the study.

My visit to Leeds continued with my participation on an interview panel to appoint ProtecT research nurses for this new centre. Another success - two nurses employed. To ensure everything is set up for them, I visited Leeds again later in the month to order and check equipment, and stock the office. Recruitment of men into the study at Leeds will start soon....

Back at Sheffield, one of the nurses, Irene Sharkey, commenced maternity leave (I’m pleased to say we now have our second ProtecT baby in Sheffield, with a third on the way!). Obviously, whilst she’s away recruitment must continue at the same pace. Therefore, we’ve seconded Michael Slator to Irene’s job for 6 months. I spent time with Michael training and supporting him at the GP Prostate check clinics. He took to it straight away and I believe he’s already mentioned to Irene that she can extend her maternity leave if she wants to!

I have also been assisting with the practicalities of incorporating one of the Trial Steering Committee’s recommendations – recruiting younger men (aged 45-49) to the study. We will initially conduct a pilot study in Sheffield and report our findings to the overseeing committees, which ensure that the study is being conducted in the best way – taking into account any new evidence as it becomes available. We will begin recruiting men in this age group during the autumn.

Since we will be recruiting over 100,000 men into the study we have the opportunity to collect blood samples for future research into prostate cancer. They are stored in large freezers at –80 °C. The way in which samples have been collected, processed, stored and catalogued has changed over the 4 years we have been recruiting men. I have been busy organising the logistics of incorporating these changes.

Apart from this, much of my time during September has been spent tied to the keyboard of my computer. How I envy the speed others appear to type! As the study protocol has been updated recently other documents required amendments to reflect these changes.

Over the 4 years that I have been involved in the study there have been many challenges. The study has evolved and grown to become one of the largest male health studies in the country. What hasn’t changed however is the teamwork and commitment from everyone involved. There’s a long way to go before we get the answers to our questions, but I see no sign of our enthusiasm waning. Personally, my favourite aspects of my job are when I have the opportunity to help out with clinics. This is because I am reminded of why we are doing the study in the first place. The public and your support has been phenomenal.
Who funds the ProtecT study?

- The Health Technology Assessment (HTA) Programme which is funded by the Department of Health (http://www.doh.gov.uk)
- The ProtecT study is a flagship study of the HTA and formed part of a major meeting in London in October to highlight the achievements of the HTA research for the NHS
- The HTA website is [http://www.hta.nhsweb.nhs.uk](http://www.hta.nhsweb.nhs.uk). The NCCHTA has responsibility for managing, providing support to, and developing the HTA programme as a whole:

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Where can I find out more information about the ProtecT study?

- You can contact the ProtecT information centre,
  - Email: info-protect@bristol.ac.uk

- You can contact the study coordinator Dr Athene Lane who is based in Bristol,
  - Tel: 0117 9287335
  - Email: Athene.Lane@bristol.ac.uk
  - Fax: 0117 9287365

- You can contact the lead research nurse at your local centre:
  - Bristol: Liz Salter (0117 9595080)
  - Newcastle: Teresa Lennon (0191 2231461)
  - Sheffield: Joanne Howson (0114 2712791)
  - Birmingham: Claire Plum (0121 6272992)
  - Cardiff: Mandy Jones (02920 748408)
  - Edinburgh: Norma Lyons (0131 5372433)
  - Cambridge: Phillipa Herbert (01223 596225)
  - Leicester: Sue Bonnington (0116 2584375)
  - Leeds: Christie Walker (0113 20655491)

We are constructing a ProtecT website, please look out for the launch in future newsletters.

Once again a very big thank you from the ProtecT study team.
We are extremely grateful for your support.