Welcome to the second newsletter for the ProtecT study. We have written this newsletter to update you on the study and to thank you for your continuing support. We hope you enjoy reading it!

**Background**

The ProtecT study is a research project taking place in nine parts of the UK (Birmingham, Bristol, Cambridge, Cardiff, Edinburgh, Leeds, Leicester, Newcastle and Sheffield). The study aims to evaluate treatments for localised prostate cancer. It is comparing surgery (radical prostatectomy), radiotherapy (radical conformal) and active monitoring (monitoring with regular check-ups).

**Current Progress**

The ProtecT study has been running across the UK since 1999. There are nine centres where men can take part in ProtecT, with a hospital in each area co-ordinating activities:

- **Birmingham** - Queen Elizabeth Hospital
- **Bristol** - Southmead Hospital
- **Cambridge** - Addenbrooke’s Hospital
- **Cardiff** - University Hospital of Wales
- **Edinburgh** - Western General Hospital
- **Leeds** - St James Hospital
- **Leicester** - Leicester General Hospital
- **Newcastle** - Freeman Hospital
- **Sheffield** - Royal Hallamshire Hospital
We have made considerable progress since the study began. All nine centres are now fully involved in the study. Sheffield, Newcastle and Bristol started in 1999. Birmingham, Cardiff and Edinburgh started in 2002, and Cambridge, Leicester and Leeds started in 2003.

**Current numbers of men participating in the ProtecT study**

- Between 2001 and 2006, we expect to invite around 200,000 men across the UK to take part in the ProtecT study. By the end of this summer, we had invited over 80,000 men.
- To date, almost 45,000 men have had a PSA test at a Prostate Check Clinic, and there are nearly 800 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 fourth year of helping the study.
- The average age of the men in the ProtecT study is 59 years, ranging from 50 to 69.
- The study will recruit until May 2006, but follow-up will continue for 10-15 years.

**What are the aims of the ProtecT study?**

Prostate cancer is a serious health problem. There are 15,000 new cases in the UK every year. We do not know enough about the relative benefits of each of the three standard treatments to be able to advise men which treatment to have. The ProtecT study aims to investigate the following issues:

- Prostate cancer history and pathway during follow-up
- Impacts of the three treatments
- General health
- Quality of life
- Cost implications for the NHS and participants

The ProtecT study is a randomised controlled trial (RCT). This means that we discuss with participants whether they are willing to have their treatment decided by a process called randomisation. Randomisation means that they have an equal chance of having any of the three treatments. This produces comparable groups of patients and provides results of the highest scientific quality.
How did I become involved in the ProtecT study?

- We are working closely with GP surgeries in Birmingham, Bristol, Cambridge, Cardiff, Edinburgh, Leeds, Leicester, Newcastle and Sheffield, which have been randomly selected to take part in the study. Random selection ensures that we obtain a wide sample of men.
- Kerry Avery, a Research Associate in Bristol, contacted your GP to invite your GP surgery to participate.
- Your GP then wrote to all men aged between 50 and 69 years in your surgery, including yourself, to ask if you would like to take part in the study by inviting you to attend a Prostate Check Clinic and have a PSA test. Men in this age group are at risk of developing prostate cancer and may benefit from being investigated. A pilot study is also being carried out including men aged 45 to 49 years to see if they would attend and benefit.

What does the ProtecT study involve?

- All men like you 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.

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.
- We are very careful to keep your data confidential at all times.
- The questionnaire data are used only by the Protect research team and will not be passed on to your GP or anyone else without your consent.

What is new?

- **Health economic questionnaire.** Some men participating in ProtecT, and their partners, are being asked to complete an additional health economic questionnaire to assist us in gathering information about the costs incurred to treat prostate cancer, including your own costs.
- **Diet Diaries** - To gain further understanding of the lifestyles of men with localised prostate cancer, ProtecT has introduced a seven-day diet diary for men to complete when they enter the study. Men are asked to complete a diary of everything that eat or drink over a seven-day period. This adds more detailed information to the diet and lifestyle questionnaire most men have completed. Some men already participating in the study may also be asked to complete this diary.
Who oversees the ProtecT study?

The study is overseen by an independent Trial Steering Committee and a Data Monitoring and Safety Committee.

The **Trial Steering Committee** comprises a number of experts from the USA and Europe. This committee meets regularly to review the progress and conduct of the study.

*From left to right: Professor Fritz Schröder, The Netherlands; Dr Athene Lane, ProtecT co-ordinator; Mr Peter Holding, ProtecT co-ordinating nurse; Mr Stephen Lemon, funding body representative; Professor Jenny Donovan, ProtecT Principal Investigator; Professor Tim Peters, ProtecT Principal Statistician; Professor Peter Albertsen, USA; Dr Mary Robinson, ProtecT Lead Uro-pathologist; Professor David Neal, ProtecT Principal Investigator; Dr Jan Adolfsso, Sweden Professor Michael Baum, Chair of the TSC; Professor Stephen Frankel, CAP Principal Investigator; Ms Teresa Lennon, ProtecT co-ordinating nurse; Professor Kent Woods, Deputy Chair of the TSC; Professor Tom Walley, funding body Director; Professor David Dearnaley, London; Professor Freddie Hamdy, ProtecT Principal Investigator; Professor Malcolm Mason, ProtecT Lead oncologist.*

The **Data Monitoring and Safety Committee** comprises a number of experts from around the UK, including urologists, oncologists, social scientists and statisticians, and is responsible for reviewing issues related to the safety and ethics of the study and for undertaking analysis of the study data.
Are there any results from the study yet?

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


Who funds the ProtecT study?

- The Health Technology Assessment (HTA) Programme, which is funded by the Department of Health [www.doh.gov.uk](http://www.doh.gov.uk).

- The HTA website is [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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A WEEK IN THE LIFE OF… Sue Bonnington, a ProtecT study Lead Research Nurse from the Leicester General Hospital

Monday: Today we had our end of year review meeting, where the Lead Investigators for the study, Freddie Hamdy, Jenny Donovan and Athene Lane, visit new centres after they have been recruiting for a year in order to review their progress and ensure they are maintaining the high standards expected in this study. It is a tense time for my team and I, but we were all very relieved to hear that we are doing very well and that they were pleased with our progress. Sadly, our celebrations are overshadowed by the news that Jo Bowtell, our secretary, is leaving us to work in her family’s hotel business. Jo will be greatly missed and will be difficult to replace.

Tuesday: Back to business as usual after the excitement of yesterday. I have a meeting with the practice manager of a new GP practice in Hinckley, who is interested in participating in ProtecT. This first meeting is an opportunity for me to explain to the practice about the ProtecT study and, more importantly, to answer any questions and concerns they may have about taking part. Managed to get myself lost on the one-way system on the way and very nearly missed the meeting. However, it went very well and I have arranged a further meeting with the GPs to discuss the preparation of the list of eligible men from their practice…managed to get back to the office without getting lost this time!!

Wednesday: This morning is spent in the office organising a replacement for our secretary. This process can take several months, so I need to get the ball rolling as soon as possible. I have already had several people show an interest in applying, which is very encouraging. I have a Prostate Check Clinic this afternoon at a GP surgery in Earl Shilton. We have been going to this surgery for nearly a year now and are coming to the end of the list of men to see at the clinic. All the staff and doctors have made us feel very welcome and we will all feel sad to leave.

Thursday: Today is Urology Outpatients day. I have several new patients on the clinic list who are being seen for their diagnosis appointments. Mr Kockelbergh, the Urology Consultant and Local Investigator for the study, will see them and decide if they will be eligible to continue in the study. If they are, I will arrange to see the men for an information appointment to discuss their diagnosis and treatment options in more detail. Two of the men seen today are eligible for the study and I have booked appointments to see them next week. The other patients require further investigations, so I will see them when they come back to clinic after they are completed. The clinic actually finishes on time (a rare event!), which has given me time to go back to the office and complete the paperwork from today’s appointments.

Friday: A chance to catch up with general office work and answer my e-mail messages this morning. I have an information appointment this afternoon with a new patient who was diagnosed last week. I spent several hours with this man and his wife talking about his diagnosis and treatment, and answering their questions. They are keen to continue with the study and the man has agreed to be randomised to his treatment, saying that it took the dilemma away from him trying to decide the treatment himself. He was allocated to have Radiotherapy, which he was happy to accept.

Well, that’s the end of my week, not quite as exciting as “Bridget Jones’ Diary” - for one thing Colin Firth didn’t come and sweep me off my feet, but one can still dream! I’m off home now to walk my dog Molly and have a belated celebratory glass of wine.
Where can I find out more information about the ProtecT study?

- We are pleased to say that we have recently launched our new website:
  - Please visit the website at www.epi.bris.ac.uk/protect
  - Click on ‘Taking Part’, especially designed to give you more detailed information
  - User name = part, password = protect to access the information sheets
  - Click on ‘Study Newsletter’ to see the first issue of the newsletter.

- 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: info-protect@bristol.ac.uk
  - Fax: 0117 9287292

- You can contact the lead research nurse at your local centre:
  - Birmingham: Claire Plumb (0121 6272992)
  - Bristol: Liz Salter (0117 9505050 ext 2690)
  - Cambridge: Phillipa Herbert (01223 596225)
  - Cardiff: Mandy Jones (02920 748408)
  - Edinburgh: Norma Lyons (0131 5372433)
  - Leeds: Debbie Cooper (0113 2065491)
  - Leicester: Sue Bonnington (0116 2588316)
  - Newcastle: Teresa Lennon (0191 2231461)
  - Sheffield: Joanne Howson (0114 2712791)

What if I move?

- If this happens, it is very important that you let us know where you are moving. This is so that we can keep in touch with you during the course of the study.

- Please tell your ProtecT research nurse when you attend for your appointment or contact them on the above telephone numbers or write to the ProtecT study, Canynge Hall, University of Bristol, Whiteladies Road, Bristol BS8 2PR.

Keeping you informed

We hope you found this newsletter interesting and informative. We hope to send you a newsletter every year to keep you up to date with the progress of the ProtecT study.

We’d be happy to hear your comments or any ideas for anything you’d like to see in the next issue.

Last, but certainly not least, we’d like to say a very big thank you to you from the ProtecT study team. We are extremely grateful for your continuing support.