Once again the Federation, with the support of Prostate Action, will be holding an Annual Conference to coincide with our Annual General Meeting for 2011, at which some of the leading names in prostate cancer research and treatment will be speaking. The event will take place on 13th April in the Barnes Wallace Building at the University of Manchester, which is about 5 minutes walk from Manchester Piccadilly Station. To allow people from nearly all parts of the country to get to the Conference, we will start at 11:00am, and we will be done by 4:45pm. Attendance at the event, including lunch, is free to representatives of Member Organisations of the Federation.

The Theme of the event is “Clinical Trials - Hope for the Future”, and we are honoured to have secured the services of four renowned researchers and clinicians: Prof Nick James from Birmingham University, Dr Paul Symonds from Leicester Royal Infirmary, Dr Louise Dickinson from University College London, and Prof Ken Muir, from the University of Warwick. They will be telling us about the latest research in four main areas: treatment of hormone refractory disease, developments in external beam radiotherapy, developments in focal treatments of early stage disease, and risk-based detection.

We do urge member organisations to send a representative to the meeting. Apart from the obvious benefits of hearing from these distinguished speakers, there is some significant business to be discussed and agreed at the AGM which could have far reaching impact for the future of patient support for prostate cancer, and we want to hear your voices. Please use the attached booking form to register to attend.
In August, I received an email from Sandy Tyndale-Biscoe inviting me to a meeting to discuss the Federation’s response to two reports that had been issued by the UK National Screening Committee (NSC). I was particularly interested in the report written by the Sheffield School of Health and Related Research (SchARR) because it was attempting to evaluate the pros and cons of prostate cancer screening based on PSA testing (a subject which is close to the heart of many prostate cancer patients). However, I was immediately troubled because I could not relate the contents of the SchARR report to any of my own experiences as a prostate cancer patient. So I sent an email to the authors asking them to explain a particular aspect of their study. This started a lengthy and often frustrating exchange of emails with both the SchARR team and with the NSC. This exchange of emails was brought to an end by the Director of Programmes of the NSC in November1 even though many of my questions remained open. Personally, I would have preferred to continue that dialogue either by email or by talking directly to the SchARR team. However, since the NSC have prevented this from happening, I was asked by Sandy to write this article for Prostate Matters, setting down the nub of my criticisms.

At first sight, the SchARR report would appear to be very thick and comprehensive. The problems begin when you read through the executive summary, as it becomes clear that its conclusions do not correspond to the findings of the European studies.

Furthermore, the SchARR conclusions seem very remote from the experiences of prostate cancer patients such as ourselves. In such cases, patient experiences are usually dismissed as being ‘anecdotal’ because they are not supported by ‘evidence based research’. That seems questionable when there are hundreds of thousands of prostate cancer patients like ourselves in the UK. However, for present purposes, I am (reluctantly) choosing to set aside patient experiences and to concentrate on examining the SchARR report using on evidence based research, and to challenge the SchARR report on grounds of their choosing.

The SchARR report is based on the ERSPC study which concludes that PSA screening would reduce the number of deaths from prostate cancer by up to 31% for men who are screened. However, on the basis of their modelling, the SchARR report concludes that there is only a small reduction in death from prostate cancer due to prostate cancer screening, and no evidence for lives being extended because of early diagnosis and treatment.2 Thus, there is an acute mismatch between the conclusions of the ERSPC study, which formed the basis of the SchARR study, and the results from the SchARR report. Despite raising the question a number of times, I did not receive an answer from SchARR explaining why this mismatch had occurred.

One example of the SchARR modelling using scraps of data is in its consideration of the disbenefit of sexual dysfunction as a consequence of prostate cancer treatment. In its mathematical modelling, the SchARR report states that the list of oncologists and urologists were entirely correct because the SchARR results are expressed in terms of the whole screened population. In terms of the whole population that would be screened in the UK, 3000 lives represent just a tiny percentage. The problem arises because the SchARR report treats this percentage as though it is not significant, forgetting that, although it is only a tiny percentage it still represents 3000 lives.

There also appears to be a problem with the quality of data so that the SchARR team had to use whatever scraps of data were available.3 Scientifically this would be acceptable so long as the uncertainty in the outcomes of the modelling were studied and reflected the poor quality of some of the input data. However, the SchARR report states most of its conclusions as though they were absolutely correct with no uncertainty. If the quality of some of the input data is as poor as stated by Jim Chilcott (SchARR team), then it follows that the conclusions of the modelling are highly uncertain and it is a shortcoming of the report that these uncertainties are not clearly reflected in the conclusions of the paper.

One example of the SchARR modelling using scraps of data is in its consideration of the disbenefit of sexual dysfunction as a consequence of prostate cancer treatment. In its mathematical modelling, the SchARR report

Continued page 3
Quite literally equates the loss of life of a prostate cancer patient to ten men suffering from sexual dysfunction. This puts a shockingly low value on the life of a prostate cancer patient. This is particularly so when many cases of sexual dysfunction can be resolved by taking tablets such as Viagra or Cialis. So that the SchARR report is effectively equating the life of a prostate cancer patient to a pile of Viagra tablets.

The basis for this aspect of the SchARR modelling is a study of 141 mostly elderly Canadians, 42% of whom were on hormone therapy. These elderly men with severely reduced levels of testosterone were asked such questions as whether they still had erections sufficient for masturbation. Then, after some manipulation of the data, a measure was determined about the loss of quality of life of a prostate cancer patient with sexual dysfunction. Clearly the results of the Canadian study is a tiny scrap of data based on a limited and atypical sample of prostate cancer patients. There are hundreds of thousands of prostate cancer patients in the UK. If you want to know about the side effects of treatment, then ask us!!

The later Göteborg study, which reported just as the SchARR work was finishing, changed everything by concluding that PSA testing reduces the number of deaths from prostate cancer by 56% for men who are screened. NSC and SchARR chose not to factor this significant result into the work. Indeed, the SchARR team expect that the Göteborg data would only make small changes to the conclusions of their report.

I could go on to discuss the way the SchARR report considered risk-based prostate cancer screening, as advocated by the Federation. However, the SchARR report completely omits to consider risk-based screening that would reduce the unnecessary treatment of indolent cancers. This is another very important shortcoming of the SchARR report. Similarly, the NSC review statement neglects to consider risk-based screening.

It is reasonable to ask why patients such as ourselves are able to find such fundamental failures in an academic report written at a prestigious university. The underlying problem is that there was insufficient rigour in the process used to check the validity of the contents of the report before the report was issued. As a result, I was able to find numerical errors in the report. Then the NSC issued the inadequately verified report for peer review, where representatives of the medical profession, patient groups and charities were asked to submit comments over a tightly limited period. This type of peer review is adequate for considering papers on ancient history, for example, where the only things at stake are the reputations of the authors and the publishers. However, the conclusions of the SchARR report have been used as a basis for advising the NHS about screening for prostate cancer, which could potentially save the lives of up to 10,000 men each year in the UK. Therefore the requirement for accuracy and validity in the study should be extremely high. I would suggest that the level of accuracy in the SchARR report should be equivalent to (or exceed), for example, the levels achieved for nuclear reactor safety cases, where very high levels of verification and validation are required commensurate with the risks being considered. It is simply not good enough for the NSC to release inadequately verified documents for peer review when thousands of men's lives each year are being held in the balance.

I have requested that the members of the Federation should have access to the SchARR mathematical modelling so that we can scrutinise it in all of its detail. I also requested that we should be given copies of references in the report which are otherwise not accessible to us. Thirdly, I asked that we should be able to raise questions on aspects of the SchARR report which are obscure and not comprehensible to us. Regrettably, I have not had any response to these requests and this simply reinforces the view that the objective of the NSC is to keep patient groups at arms length and that their peer review process is a sham.
Is The “Overtreatment” Argument Outdated?

By Graham Fulford, Trustee and founder of the Graham Fulford Charitable Trust

One of the reasons frequently given for not supporting a PSA based screening programme is the level of “overtreatment” which will ensue. But is this argument still valid? It might have been 20 years ago when perhaps the old “80/20” rule favoured surgery, but with increasing knowledge and awareness the surgery option is no longer the “market leader”, in fact just the reverse.

It will be seen from the attached table that of the 302 pca cancers jointly found by ourselves and the Kidderminster Prostate Cancer support group out of the first 12,000 or so results followed up from the 15,182 PSA tests carried out to date, only 70, or 23%, have opted for surgery. If anything, the old “80/20” rule has effectively been reversed. Moreover, if one applied the “worst case” scenario of the oft quoted 35% of surgery cases being overtreated this would account for a potential 24 cases, or 8% of the total. But what about the other 92%? Is it fair to penalise them for the “potential”? I deliberately use the word potential because I believe the 35% calculation is probably as out of date as the rest of the statistics quoted in these esteemed but ancient tomes.

Perhaps it was valid when the majority of sufferers were subjected to surgery, but is it now when only 23% of cases have been surgically treated? Possibly not. Moreover the fact that the table of treatments shows 54 cases of “active surveillance” indicates there may be a number of men being, in reality, undertreated.

This isn’t an argument you see expounded very often. The reality is of course, we cannot be sure, but our findings certainly give food for thought and before anybody throws in the old “but yours isn’t a scientifically based trial with a control arm etc.” the fact is it does cover over 15,000 men from all parts of England and from a wide range of socio-economic groups. it is not an insignificant number.

The graphs show one cancer found in the 40-44 age group and eight in the 45-49 age group. These are relatively young men, probably with young families. Roll on “Riskman”. Something has to change! forget the 35,000 cases a year stat everybody trots out. These are only the ones found either because they present with symptoms (and we all know where that will probably lead) or because they were lucky enough to have private medical cover and were “miraculously” found via an “all inclusive” Well Man check which included a PSA test. Funny thing that BUPA still include it as standard in their health checks.

If you would like to view our rolling programme of awareness roadshows, including optional PSA tests, visit: www.grahamfulford.org.uk

To book a new event, please email: gfcharitabletrust@tiscali.co.uk or phone 07831 156071 and help us find the 10,000 prostate cancers that in my opinion really exist. Poor treatment decisions are no excuse for failing to diagnose the condition early. This will only ever improve if the current system is brought to the point of collapse. Hopefully Ken Muir will have good news to report on 13th April re “Riskman” which I’m sure you’re all aware is a patient driven initiative for which The Federation and the groups that have supported it can take great credit. Hopefully a much more accurate test is just around the corner but in the meantime I’m convinced “Riskman” will bring about significant improvements.

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**Age Of Known Cancers**

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<td>37</td>
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**Treatments Selected**

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Richard Firth’s article on pages 2 and 3 dramatically illustrates the problems we face in getting an early detection programme established for prostate cancer. Biased judgements, deliberate mis-use of evidence, questionable value judgements, sloppy research and arrogance all played their part to ensure that the National Screening Committee made the recommendation that the Department of Health wanted to hear.

Well, some of us have had enough of this, and, to mark National Prostate Cancer Awareness Month this March, we will launch a campaign, with widest possible publicity, supported by Max Clifford, no less, to get the process re-opened immediately.

First shot in this campaign will be to send the letter illustrated to everyone we can think of who professes to have at heart the interests of men at risk of prostate cancer, inviting them to sign up to support us. It includes an Annex listing the fundamental flaws in the process that has been followed, much as reported by Richard on page 3, under the following headings: evidence has been ignored that clearly shows the benefits of screening; the decision is based on out of date assumptions about prostate cancer treatment; the decision is based on demonstrably false assumptions about the quality of life impact of prostate cancer detection and treatment; and finally, and most gallingly for us, the report of the decision falsely implied a level of consensus that does not exist.

If you know of any particular individuals that you would like to see targeted by this letter, for example local medical policy makers and clinicians, please email me (see below) with details.
When I joined this great organisation as a Trustee nearly 3 years ago one of my aims was to try to increase the membership to 100 groups representing 10,000 men, and I’m happy to say we are making steady progress. As part of this process I sponsored 2 days of telemarketing during 2010 with a lady who is very experienced and handled the assignment with considerable skill and diplomacy. “The most worthwhile project I’ve ever been involved in” was her comment. This has already yielded about 4 new memberships with more promised. She also carried out a one day follow up exercise before Xmas, paid for by the Federation, and again gave us a free day. I’m delighted to say my fellow Trustees have approved 3 more days to be spread over 2011 so that we don’t lose the valuable momentum gained. Needless to say the Federation is always on the lookout to recruit more or new groups so if you know of anybody at all who might consider joining please encourage them to visit the Federation website. There is a great fact sheet on how to set up a group; first year membership is free and thereafter a mere £1 per active member per annum. Unbelievable value given all the benefits of membership, including the opportunity to apply for a grant of up to £500. I hope we will soon be up to 50 member groups out of the 80 odd groups I believe exist.

So where to after that? It’s generally accepted that 35,000 men are diagnosed each year, so the number of men living with the condition must now exceed 250,000. Surely there is an opportunity to develop new groups nationwide so that these men can have help and support from fellow sufferers? I’m sure with support from us they will soon grow and develop and reach that number anyway. Like most things in life it’s a question of resource i.e. money. I’m sure if we had the funds to do it we could set up an active new group membership drive, touring the country, placing ads and working with health professionals etc. Any thoughts? Perhaps it’s something we could do jointly with Prostate Action? We have a wealth of unparalleled knowledge and experience to call on. Let’s go do it! “Strength in numbers” and “United we stand” and all that!! If you do have any thoughts they would be great to explore at the AGM. In the meantime you can contact me on 07831/156071 or email: gfcharitabletrust@tiscali.co.uk.

The other side of the equation is, I believe, our relationship with health professionals. At the time of my taking on the role of development/recruitment Trustee I suggested that we should also try to recruit “Health Professionals” to be registered with us. This is not just GPs –practice nurses, nurse specialists etc are equally (if not better) placed to understand the needs of patients and the more of them that are aware of the valuable work the support groups do the better. It’s been a slow process but I’ve now got approaching 40 registered and I write to them 3 to 4 times a year with Prostate Matters and various updates which I hope they find of interest.

Until recently I’d had little feedback so wasn’t sure how worthwhile it had been, but the recent “Riskman” mail out of Ken Muir’s questionnaire, to establish the medical profession’s views about a new approach to screening, has been quite revealing. Out of 500 forms despatched to date we’ve had 37 back so far. More are promised and I’m sure we’ll hit Ken’s target of at least 100 for when he makes his pitch for the big funding needed to support the trial. Of these 37 at least 10 (or around 25%) have come back from our “registered” list. One GP even thanked me for “all the information you’ve been sending”, so we are making our mark!

Being a positive sort of chap I had 10,000 registration forms printed originally, so if you do know of any health professional who may be encouraged to register with us please contact me. Let’s at least get to 100 before the AGM! The Federation Trustees have agreed to sponsor a £500 separate telemarketing campaign. This is currently being undertaken by a 53 year old male well experienced in the telemarketing field whose personal circumstances make him perfectly placed to understand the issues surrounding a major cancer and the impact it has on not only the patient’s life but all those around them. Results to date are very encouraging, albeit it’s early days yet. Nick has targeted 40 GP practices in area where he lives. 9 of these have been spoken to and 16 are being followed up. Of the 9, 8 have indicated that they will register. He’s hopeful that at the end of the exercise a conversion rate of at least 25% will be achieved i.e. 10 new registrations. Perhaps even more encouraging one practice has asked Nick and me to give a presentation at one of their regular update meetings to explain what we are all about. I see this as a major breakthrough. Moreover, the Trustees have agreed to invest another £1,000 in this initiative but purely on a “payment by result” basis. The great thing about this route is that costs are controlled. If this initiative is successful, I believe it would represent a major breakthrough in creating awareness and education for GP’s about this insidious disease. It would encourage, them, hopefully, to at least discuss more options with their patients. I would very much welcome your thoughts and feedback, and, of course, assistance with signing up more “Associates”. I look forward to discussing this with you all at the AGM. In the meantime I can be contacted directly as outlined above.
Some two or three years ago, I asked for volunteers to take part in a survey to provide information for a book, with the above title, the purpose of which is to help couples to cope with the effects that prostate disease and its treatments can have on their sex lives. I am very grateful to the brave band of men and their partners who agreed to take part, and completed a questionnaire about the most intimate aspects of their lives. By now, some of them may have begun to wonder whether this book will ever appear. I am happy to say that it will, and sooner rather than later, but I felt that now would be a good time to report progress, and, at the same time, possibly recruit more volunteers. The information so far provided has been invaluable, and could fill a book far bigger than that planned. But it has raised many questions, and some of these could be answered in a revised questionnaire.

The aim of the book is not to tell men what to expect; every man's experience is different. It may, however, help them not to be surprised or worried by what they do experience, and give them hints about how they may overcome the damage that their prostate disease has done. In particular, and above all, we hope it will encourage them to discuss these things with their partners.

The damage that prostate disease and its treatment does to a couple's sex life is in many ways underplayed. It is assumed that the sexual effects of the disease are somehow unimportant and not worth covering in detail, since "prostate disease is an old man's disease" (not so, 15% of one typical support group's members are under 65), and older people are less interested in sex (again, not so). For some time I have felt that there is a crying need for a simple book that describes the sexual effects of prostate cancer and its treatment, from which men may get an idea about what to expect, as well as how to overcome the problems. It should be based on the personal experiences of couples who have been through it.

There are, of course, a few books and pamphlets on the subject, but they are often either depressingly factual or earnest. They tend to concentrate on one aspect, erectile dysfunction, ignoring the fact that the sexual effects of prostate cancer are different for every man, and his partner, and are not confined to erectile dysfunction. For example, loss of ejaculatory function, a key element of sexual pleasure for some men, is almost inevitable with all treatments for prostate cancer. Psychology plays a huge role and prostate illness can itself cause loss of interest in sex, even without the assistance of hormone treatment for those of us unlucky enough to need it. Finally, loss of self-esteem, a well known cause of sexual dysfunction (or, as it appears to the sufferer, inadequacy), can only add to the effects of the physical damage.

So, where have we got to? So far I have had responses from just over 30 men, all anonymous, with, in two thirds of the cases, responses from their partners. Some interesting results already beginning to emerge. One of the most significant is that, of the 50 or so people who have responded, only 3 men reported their sexual lives as fully satisfactory, and of them, in only one case did the partner feel the same. In other words, out of that small sample of 30 couples, only 1 collectively regards their sex life as undamaged. For that particular couple, there is nothing to infer from the treatment (RP followed by RT) that it is any less likely than any other to cause damage.

On the other side of that coin, over half the respondents stated that, since their prostate treatment, their sexual appetite was "not satisfied at all", which rather casts doubt on clinicians' claims of a generally improving situation with regard to the sexual impact of treatment. It is significant that only half of these men would, or could, persuade their wives to involve themselves in the questionnaire. In the sadder of the many sad tales, there is a strong thread of lack of communication between the partners, and there must be a lesson there. We know of cases where the wife has been totally unaware of the libido destroying effects of hormone therapy, and is left hurt, wondering why her husband suddenly shows no interest. It's not just the sex life that's damaged here; it's the whole relationship. Intriguingly, only one couple had sought sexual counselling, which they found very helpful.

A great deal is often claimed about the relative merits, sexual, of the various forms of treatment. In point of fact, it would appear that there is not much to choose in sexual terms when opting for surgery or radiotherapy, and of the two responders who had received treatments that claim reduced sexual impact, brachytherapy and HIFU, both reported poor sexual results.

Where does the book go from here? First of all, I am confident that we will be in a position to publish later this year. However, although there is plenty of material on which to base tales of couples' experiences, it would be good to have a more robust statistics, and for that I am hoping that there may be more couples out there who are prepared to complete the questionnaire. Furthermore, it would be good to have responses from men who have had the less common forms of treatment, e.g. HIFU, Cryotherapy and Brachytherapy.

If you would like to help with this important work, you can download a copy of the survey questionnaire by visiting: www.birchquest.co.uk/6questionnaire.htm
The majority of men with prostate cancer confined to the pelvis are treated by external beam radiotherapy in Leicestershire. Over the last 12 or so years the techniques used to treat patients have become much more sophisticated and effective. Higher doses of radiation delivered to the prostate cancer are more likely to eradicate the tumour. However unless great care is taken, the surrounding organs can be damaged by the radiation treatment. Currently our incidence of side effects is low. Less than 1% of men develop damage resulting in incontinence and severe radiation damage to the bladder or rectum is equally uncommon. About 6% of men develop rectal bleeding due to radiation. About 25% of men develop impotence by two years after radiotherapy. This may be partially due to the radiation treatment and partially due to the hormone treatment that is given along with the radiation. However, changes in the method of delivery of the external beam radiotherapy have enabled us to markedly increase the radiation dose and the prospect of cure. About 12 years ago radiotherapy to the prostate was given through three X-ray beams (one from the front and two from the sides). These X-ray beams were square or rectangular in shape. Of course the prostate is roughly circular. The first development was the use of conformal radiotherapy which can treat irregular shapes such as the circular shaped prostate with a margin of normal tissue around it. This reduced the volume of normal tissue irradiated by almost a half and the incidence of side effects. It allowed us to increase the radiation dose from 60 to 64 Gy and then 70 Gy in seven weeks. When a Medical Research Council trial showed an increase in local control with a dose of 74 compared to 64 Gy we increased our radiation dose to 74 Gy. However, to reduce the chance of side effects we started using intensity modulated radiotherapy (IMRT). Initially patients were treated with quite a simple technique called field-in-field. In most cases we can reduce the dose to critical organs such as the rectum using this technique. However, more sophisticated measures are necessary for some patients. A treatment given to one patient is shown below. This is a man who has cancer of prostate involving the seminal vesicles (the organ that stores sperm that is situated between the prostate and rectum).

The patient’s treatment plan is shown in Figure 1. The seminal vesicles which contain tumour are in pink and the bladder is pale lemon. The seminal vesicles are draped around the rectum. IMRT has been used to reduce the dose to the rectum and this can be seen in way that the isodose lines (areas covered by the same radiation dose – see yellow line) follow the line of the seminal vesicles closely and a full dose is not received within the rectum. Future plans are to start treating patients with either involved lymph nodes or a high risk of lymph node involvement within the pelvis by IMRT.

Running parallel with the development of IMRT has been the development of image guided radiotherapy (IGRT). Imaging systems which are attached to the treatment machine allow the radiation to be directly targeted to the prostate position. This increased accuracy gives greater confidence that the radiation will hit all of the prostate on each treatment and won’t unnecessarily stray into the rectum. By this summer three out of the four treatment machines at Leicester will be able to deliver both IMRT and IGRT, ensuring that as many patients as possible benefit from the advanced technology that is available.