

A CRITIQUE OF THE SCHARR REPORT ON PROSTATE CANCER SCREENING

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.

This point is important for two reasons. Firstly it shows that the SchARR modelling is predicting that there is no benefit to be gained from early diagnosis and treatment in terms of extension of the lives of prostate cancer patients. Secondly it demonstrates that the SchARR conclusions are effectively distorting the outcome of the ERSPC study, which found that up to 31% of prostate cancer patients who would have died in the absence of screening, were still alive at the end of the trial.

¹ Email from Anne Mackie (NSC Director of Programmes) to RJF 17 November 2010.

² Email from Silvia Hummel (SchARR) to RJF, 19 August 2010. See also SchARR report p. 66.

Let us concentrate on the first point. It is hardly surprising that the ScHARR report shows no benefits of prostate cancer screening, since it shows no benefits of early diagnosis and treatment. However, this is a highly controversial stance, and I think that if the ScHARR team want to sustain this conclusion they should undertake to name the oncologists and urologists who suggest that their treatments for prostate cancer have no value and that there is no difference between the outcomes for patients diagnosed at an early stage and those diagnosed with more advanced prostate cancers, when the symptoms become sufficient to drive the patient to see their GP. I suspect that the list of oncologists and urologists who think that their treatments have no value is very short.

The ERSPC results suggest that the lives of 3000 men in the UK would be saved each year by prostate cancer screening. So why do the ScHARR conclusions not reflect this? My understanding is that this difference arises 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 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

³ In the minutes of the 11 October workshop, Jim Chilcott (ScHARR) repeatedly notes the uncertainty of the data used in the ScHARR modelling, for example, “There is considerable uncertainty in terms of both the natural history of prostate cancer and the PSA test” and “The ability to adjust for changes in treatment patterns via modelling is hampered by very poor data collection concerning current treatments”.

with sexual dysfunction. Clearly the results of the Canadian study is a tiny scrap of data based on a limited and untypical 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 concluded that PSA testing reduces the number of deaths from prostate cancer by 56% for men who are screened. Unfortunately, the ScHARR report was written before the Göteborg study was published. However, the ScHARR team expect that the Göteborg data would only make small changes to the conclusions of their report.⁴ Clearly, this should be incorrect because the Göteborg study predicts that screening would save four times as many lives compared to the ERSPC study. However, the results of the Göteborg study are totally neglected in the NSC review of prostate cancer screening.

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.⁵ 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

⁴ Email from Silvia Hummel (ScHARR) to RJF 11 November 2010.

⁵ Email RJF to Silvia Hummel (ScHARR) 27 August 2010; email Silvia Hummel to RJF 10 November 2010.

comprehensible to us.⁶ 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.

⁶ Email from RJF to Anne Mackie (NSC) 20 November 2010.