THE DETECTION & TREATMENT OF BREAST CANCER & CLAIMS FOR LOSS OF LIFE EXPECTANCY IN CLINICAL NEGLIGENCE CASES

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Reports relating to the detection and treatment of breast cancer in the UK have hit the headlines twice in the last month spawning a good deal of editorial comment and public debate.

The publication in October 2012 of a report commissioned jointly by the Department of Health and Cancer Research UK weighing the risks and benefits of mammographic screening was followed within days by wide reporting of the Medical Practitioners Tribunal Service's interim suspension of breast surgeon Ian Paterson, pending investigation of allegations that he has deviated from national and local guidelines to the possible detriment of more than 1,000 women.

This paper briefly outlines salient factors from these events for the clinical negligence practitioner as well as drawing attention to a relevant first instance decision in the case of *JD v Mather* [2012] EWHC 3063 which provides an example of how the courts might apply *Gregg v Scott* [2005] 2 AC 176, HL to claims for loss of expectation of life.

Breast screening

The Breast Cancer Screening Programmes in the UK currently invite women aged 50- 70 years for screening mammography every 3 years. From its inception, there has been a debate about the benefit (reduction in mortality) and harm (over diagnosis and treatment) of the breast screening programme.

It is known that mammographic screening detects some cancers that would not have become clinically apparent during a woman's lifetime were it not for the screening. Neither the woman nor the doctor, however, can know whether the detected cancer is one which could be fatal or which would, in the absence of screening, have remained asymptomatic and undetected. Notably, the distinction is not as easy as determining whether the cancer is ductal carcinoma in situ (DCIS) or is invasive at time of diagnosis as DCIS is associated with subsequent development of invasive breast cancer after wide local excision in a percentage of cases.

Thus screening results in a clinical and ethical dilemma. On one hand, the benefit of early identification of cancer and the consequent decrease in mortality needs to be considered. On the other hand, there is the risk of women receiving surgical, radiological and medical intervention for cancers which would, left untreated, prove harmless.

With this background in mind, Cancer Research UK and the Department of Health jointly commissioned an independent review into the benefits of breast cancer screening and the report was published in October 2012.

The panel involved noted that randomised control trials from which mortality estimates in a non-screened population could be taken had many limitations; not least that they pre-dated significant advances in the treatment of breast cancer. Nevertheless, the panel estimated that an invitation to screening delivers about a 20% reduction in breast cancer mortality i.e. about 1,300 deaths per year.

The panel acknowledged that it was even more difficult to measure the frequency of over diagnosis but referred to three randomised control trials. The best estimate, albeit from a paucity of reliable data, was that for every 10,000 women invited to screening every year, 681 are diagnosed with cancer of which 129 will represent over diagnosis and 43 deaths will be prevented.

The panel did not consider that the improvement in the treatment for breast cancer was a reason for stopping screening and concluded that the screening program *"confers significant benefit and should continue".* They also noted, however, that it was important to communicate the risks and potential benefits to women so that they could make informed decisions.

Following publication of the report, the press coverage has tended to focus on the negative aspects of the report with headlines referring to screening, *"harming thousands"* and *"causing more harm than previously thought".* The NHS has responded to the media coverage and emphasised that, despite the injuries and distress associated with over diagnosis, the panel concluded that screening conferred significant benefit.

For the time being, therefore, it is clear that breast screening is here to stay and treatment arising from "over diagnosis" will generally be a non negligent complication of the screening harm/ benefit analysis.

It is understood, however, that the information provided to women as part of the breast cancer screening process is currently being reviewed as clear communication of the harms and benefits to women to enable them to make informed choices is regarded as being of the utmost importance in the context of a modern health system.

Mr Ian Paterson

The Background:

On 29th October 2012, Mr Ian Paterson, a Consultant Breast Surgeon employed by the Heart of England NHS Foundation appeared before the MPTS (Medical Practitioners Tribunal Service, formerly the judicial arm of the General Medical Council) and was suspended from the medical register pending a full investigation by the GMC in to his practice. He faces allegations that he performed up to 1,150 "*unnecessary, inappropriate or unregulated operations*".

In summary, it is alleged that whilst in his NHS practice, Mr Paterson performed incomplete mastectomies which he described as "*cleavage sparing mastectomies*". This involved leaving in situ some breast tissue in order for an improved cosmetic result to be achieved. This was contrary to guidance and is considered by some experts to give rise to a heightened risk of recurrent disease. Moreover, as a result of some breast tissue and on occasions some tumour being left in situ, some women are likely to have undergone radiotherapy which they would have avoided if they had undergone a full mastectomy. All patients who underwent the "cleavage sparing" mastectomies were recalled by the hospital. It is understood that some are now undergoing regular monitoring whilst others have had further surgery.

Further, whilst in private practice, it is alleged that Mr Patterson performed unnecessary lumpectomies. The question arises as to whether this was a non-negligent outcome caused by inevitable over diagnosis in any screening process. However, if the allegation is that there was a failure to perform pre-operative biopsies, this would suggest that surgery was being undertaken in the absence of any malignancy and such a defence would be unavailable to the surgeon.

Civil Claims:

It is reported that that there are in excess of a 100 civil claims currently being pursued arising out of Mr Paterson's treatment.

Breach of Duty:
Expert evidence relating to breach of duty will inevitably focus on any deviation in Mr Paterson's practice from the local and national guidelines. However, practitioners would be well advised to remember that guidelines are only guidance and that proof of any deviation is not the full answer to an allegation of negligence. The question remains: in the circumstances of each case (e.g. the stage, grade and position of this tumour; the age and health of this woman) was the decision to deviate from usual practice clinically justified? This will involve a consideration of both *Bolam v Friern Hospital Management Committee* [1957] 1 W.L.R. 582 and *Bolitho (Deceased) v City and Hackney HA* [1998] A.C. 232. In addition, there are likely to be questions as to the consenting process – was each patient aware that the procedure was not a full mastectomy and was outside of relevant guidelines? What procedure would the patient have chosen if properly consented?

Causation:
Where breach of duty can be established, it is quite likely that there will be a claim for:

- Unnecessary or additional treatment, sometimes including radiotherapy and surgery and
- Additional distress, sometimes causing psychological injuries.

The Claimant's advisors should also investigate with the experts the possibility of further serious consequences, asking:

- What if any complications have arisen from the additional treatment?
- In relation to the cleavage sparing mastectomies:
    - What physical consequences have there been of surgery in irradiated tissue where that surgery would otherwise have preceded radiotherapy?
    - What impact, if any, has the negligence had on the Claimant's prospects of survival?

Survival:

It may well be that in the vast majority of cases, the treatment has not caused any worsening of the patient's prognosis either because the tumour was fully excised in any event and/or because revised treatment has taken place in good time. However, there may be cases where the prognosis has been altered and this will require careful investigation.

The Heart of England NHS Trust state their views as to this on their website as follows:

We regret that we are currently unable to advise definitively upon whether patients who underwent a CSM (cleavage sparing mastectomy) are at statistically greater risk of recurrence than if they had gone a full mastectomy, as there is no published data available.

A Claimant should not be advised to await such data – if it is ever published it will relate to a limited cohort of women and in any event it will, at best, be inconclusive for many years to come. The answer must largely depend upon the position, stage and grade of the tumour, the length of time since diagnosis and surgery and upon whether there has been any spread or recurrence of the disease since the treatment. The assessment of risk will depend upon careful analysis of medical notes as well as statistical evidence with the relevant experts.

When considering this question, the clinical negligence practitioner will of course consider it in the context of the House of Lords decision in the case of *Gregg v Scott* – i.e. can it be established that as a result of the negligence the Claimant's prospects of survival have fallen from above to below 50%.

However, it is worth reminding oneself that where such prospects cannot be demonstrated, the Claimant may still have a claim for loss of life expectancy where the staging of the cancer has increased as a result of the negligence. This possibility was raised and left open by Baroness Hale in her judgment in *Gregg v Scott* at paragraphs 206 -207 and has recently been applied in a first instance decision reported on Lawtel; *JD v Melanie Mather* [2012] EWHC 3063.

In *JD v Melanie Mather,* the Claimant's primary case was that but for a delayed diagnosis of a malignant melanoma in his groin, he would have received treatment giving him a better than 50% chance of survival whereas his prospects of survival were now very poor. Bean J found that even following a prompt diagnosis, the prospects of survival would have fallen below 50% and the principal claim therefore failed. Nevertheless, taking in to account statistical evidence as to the median life expectancies of (a) patients with tumours of the stage the Claimant's would have been if promptly diagnosed and of (b) patients with tumours of the stage at the Claimant's actual diagnosis, Bean J accepted the Claimant's expert evidence that the negligence had caused a *loss of expectation of life* of 3 years.

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