Prostate cancer litigation in the NHS

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The threat of medical litigation continues to grow; however, within services for prostate cancer there have been no studies quantifying this observation. In this paper the authors looked at the past 12 years of both successful and unsuccessful claims for compensation, with the aim of identifying the reasons for litigation and highlight any areas that could be addressed by the urological community.

In the United Kingdom, levels of litigation in the NHS have not reached those endured by our colleagues in the USA. However, patient expectations continue to increase and, when these are not met, compensation claims are met by the ever-expanding market for litigation. In 2013, the number of successful claims in the NHS hit record levels, an increase of 23% from 2012. Since then, successful claims have fallen and in 2015 there was a 7% reduction from the previous year. However, from 2004 the number of unsuccessful claims that were resolved without payment of damages has continued to grow year on year. Urology makes up a relatively small proportion of litigation claims in the NHS, accounting for around 3% of costs in 2015/16 (Figure 1). The largest proportion of claims is from orthopaedic surgery, accident and emergency and obstetrics.

We conducted a study to quantify litigation claims made by patients with prostate cancer in an effort to ascertain the reasons for both successful and unsuccessful claims, and their relative costs. If the medical profession aspires to reduce litigation and patient dissatisfaction, one of the first steps required is to identify the topography of the current situation. This will facilitate meaningful analysis and subsequent changes to current services, with the aim to improve both patient care and reduce litigation costs. These costs are not only financial, but also professional and personal.

The negative aspects for the patient are clear because only where dissatisfaction exists is a claim born. However, we must not forget the clinicians involved in patient care – many of whom find the toll of investigation taxing on their mental and physical health. Litigation claims have also been shown to affect clinical decision-making – often resulting in the practice of overly defensive medicine, with over-investigation and unnecessary invasive procedures. This was examined in a recent study by Bourne et al, who demonstrated that of those doctors who experienced a past complaint, 23.2% subsequently
‘suggested invasive procedures against professional judgement’. This can further increase the chance of litigation in a self-fulfilling vicious cycle of damaging consequences, as the balance between under-diagnosis/treatment and over-investigation/treatment tips away from the optimum.

The study
An application under the Freedom of Information Act was submitted to the NHS Litigation Authority (NHSLA), requesting information regarding all litigation cases in the UK involving prostate cancer from 2005–2017. The NHSLA is a not-for-profit part of the NHS that provides indemnity cover for legal claims against the NHS, assists the NHS with risk management, shares lessons from claims, and provides other legal and professional services for its members. It is thereby involved in dealing with all claims against the NHS. The key-phrase ‘prostate cancer’ was used to highlight all successful and unsuccessful cases over the time period. We then analysed this data by looking at the total number of cases (both successful and unsuccessful), the relative costs of claims, and whether litigation in prostate cancer increased over the time period assessed. Finally, we wanted to analyse and categorise the claims into those used in previous literature for medical litigation to see which aspect of care resulted in a claim for compensation.

Study findings
There were a total of 63 successful litigation claims between 2005–2017, costing the NHS £5,370,504. Of this total, £2,809,004 was paid out to patients, with legal fees accounting for the remainder.

Per year there was an average of 5.25 successful and 4.18 unsuccessful cases, and the number of claims was found to slowly increase over time. From 2005–2008, there was an average of 7 cases (4.33 successful, 2.67 unsuccessful); from 2008–2011, an average of 8 cases (4.67 successful, 3.33 unsuccessful); from 2011–2014, an average of 10.67 cases (7 successful, 3.67 unsuccessful); and from 2014–2017, an average of 11.67 cases (5 successful, 6.67 unsuccessful). The general trend is shown in Figure 2, while the costs associated with the claims are shown in Table 1.

The majority of successful cases were for delays in diagnosis (62%), with an average payment to the patient of £19,597. Six of the successful claims (9.5%) were for operative complications, and these had an average payment to the

![Figure 2. The number of prostate cancer related claims per year 2005–2017](image)

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of unsuccessful claims</th>
<th>Number of successful claims</th>
<th>Total payment to patients (£)</th>
<th>Average payment to patients (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005–2006</td>
<td>3</td>
<td>5</td>
<td>66,250</td>
<td>13,250</td>
</tr>
<tr>
<td>2006–2007</td>
<td>2</td>
<td>4</td>
<td>50,334</td>
<td>12,584</td>
</tr>
<tr>
<td>2007–2008</td>
<td>3</td>
<td>4</td>
<td>172,500</td>
<td>43,125</td>
</tr>
<tr>
<td>2008–2009</td>
<td>3</td>
<td>5</td>
<td>629,025</td>
<td>125,805</td>
</tr>
<tr>
<td>2009–2010</td>
<td>5</td>
<td>4</td>
<td>175,253</td>
<td>43,813</td>
</tr>
<tr>
<td>2010–2011</td>
<td>2</td>
<td>5</td>
<td>46,200</td>
<td>9,240</td>
</tr>
<tr>
<td>2011–2012</td>
<td>4</td>
<td>8</td>
<td>380,592</td>
<td>47,574</td>
</tr>
<tr>
<td>2012–2013</td>
<td>3</td>
<td>6</td>
<td>330,000</td>
<td>55,000</td>
</tr>
<tr>
<td>2013–2014</td>
<td>4</td>
<td>7</td>
<td>711,000</td>
<td>101,571</td>
</tr>
<tr>
<td>2014–2015</td>
<td>7</td>
<td>6</td>
<td>83,150</td>
<td>13,858</td>
</tr>
<tr>
<td>2015–2016</td>
<td>6</td>
<td>2</td>
<td>18,800</td>
<td>9,400</td>
</tr>
<tr>
<td>2016–2017</td>
<td>7</td>
<td>7</td>
<td>145,900</td>
<td>20,843</td>
</tr>
</tbody>
</table>

Table 1. Successful prostate cancer related claims and damages paid per year
patient of £187 717. Six of the successful claimants (9.5%) suffered what was deemed to be unnecessary surgical treatment for their cancer – and this had an average payment of £188 500 (Table 2).

### Delays in diagnosis

This study is an up-to-date assessment of litigation in prostate cancer, and is therefore relevant to urologists and those working in the prostate cancer pathway.

Identifying areas of potential discontent is of interest for a number of reasons. Delays in diagnosis and treatment, complications and inappropriate or unnecessary treatment are sometimes unavoidable, but are important to patients because of potential or actual harm, with increased risks for morbidity and mortality. Litigation claims are extremely stressful for clinicians, their families and their colleagues. Claims or complaints can be viewed as a challenge to our competence and there are significant impacts on both personal and professional wellbeing.

The vast majority of successful and unsuccessful claims were related to perceived delays in diagnosis. In clinically significant disease, delayed diagnosis and treatment can lead to missed opportunities for treatment intended to cure, prolong or improve quality of life. Unfortunately, the level of detail provided by the NHSLA is limited, and so it is difficult to draw any meaningful conclusions as to why delayed diagnosis was so frequent. It is also impossible to determine whether these were a result of logistical failure or clinical judgement. One conclusion we can make is that secondary care is responsible for these delays, as primary care litigation is not covered by the NHSLA.

Examples of the level of information provided include:

- Failure to carry out a request for PSA levels in a blood test resulting in delayed diagnosis of prostate cancer
- Failure to act upon abnormal PSA result leading to delay in diagnosis and treatment of prostate cancer
- Alleged failure in communication regarding need for follow-up biopsy as part of surveillance, resulting in a delay in diagnosis of developing prostate cancer, which was inoperable when identified.

The basis of a successful claim for delayed diagnosis is that the patient has potentially missed out on potential curative, or life-prolonging treatment. However, the clinical importance of delayed diagnosis in prostate cancer is very difficult to evaluate. For example, it is notoriously difficult to quantify the impact of the delay on survival or mortality, especially when we factor in a lack of information regarding timing of delays, grade and stage of cancer, etc.

It has been suggested that focusing on three areas can reduce delays in diagnosis:5

- Patient education - by increasing exposure and awareness of prostate disease, patients are informed when to seek medical attention and therefore achieve a reduction in the time between onset of symptoms and urological assessment.
- Primary care education - by improving knowledge about when to refer or investigate, we can reduce delays in referral times and delays prior to investigation results.3
- Systems management - by focusing on the patient journey in relation to referral times, fast track pathways, and the optimisation of investigations, results and subsequent management.5

### Consequences for doctors

The personal consequences for doctors following litigation are often ignored. In fact, clinicians with current or recent complaints have been shown to have a 17% rate of moderate/severe depression compared to those with no complaints (9.5%), with a 2.08 times (95% CI 1.61 to 2.68) higher chance of reporting thoughts of self-harm or suicidal ideation.3 These are distressing numbers, and although the General Medical Council is now trying to rectify this through the introduction of ‘The Doctor Support Service’, these interventions are yet to be evaluated.

As mentioned in the introduction, litagative claims can adversely affect patient care, as well as adding to the financial burden on the NHS.

Litigation investigations are associated with a loss of empathy, burnout and an increased chance of taking time off work – with 27% of doctors with complaints spending more than a month off work.3,6 Of interest, Bourne et al showed that 84.7% of doctors with a recent complaint reported changing the way they practised medicine as a result, with 72.7% of doctors changing their practice after observing a colleague with an experience of a complaint.3 This change of practice resulted in

<table>
<thead>
<tr>
<th>Table 2. Successful prostate cancer related claims by category</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Delayed diagnosis and treatment</td>
</tr>
<tr>
<td>Inappropriate surgical treatment</td>
</tr>
<tr>
<td>Inappropriate medical treatment</td>
</tr>
<tr>
<td>Surgical complication</td>
</tr>
<tr>
<td>Nursing care</td>
</tr>
<tr>
<td>Unclear cause</td>
</tr>
</tbody>
</table>
23% of those surveyed suggesting invasive procedures against their professional judgement, and 14% more likely to abandon a procedure at an earlier stage. This may carry a paradoxical consequence, as 10 of the successful claims were completed for the harm and side-effects caused by over-diagnosis and over-treatment. We have listed some examples of transcripts provided from the NHSLA to illustrate the detail of these claims:

- ‘Negligent treatment of prostate cancer caused unnecessary pain and suffering’
- ‘Alleged delay in diagnosis of prostate cancer and inappropriate prostate surgery’
- ‘Misdiagnosis of prostate cancer - underwent radical prostatectomy unnecessarily’
- ‘Diagnosis of prostate cancer made, resulting in radical prostatectomy. Subsequent re-examination of specimens confirmed no cancer present. Patient now suffers incontinence and impairment of sexual function.’
- ‘Misdiagnosis of prostate cancer. Underwent unnecessary radiation treatment.’

**Dangers of over-treatment**
The balance between early detection with subsequent reduction in advanced disease and disease-specific mortality, versus unnecessary side-effects from over-treatment, is particularly delicate and varies greatly depending on patient preference. In the literature, over-diagnosis is classified as an epidemiological or clinical phenomenon, but as the definition differs among different authors it has been difficult to evaluate. Most studies consider over-treatment as the proportion of biopsies that met criteria for insignificant disease, or the proportion of radical prostatectomy specimens that contained organ-confined, low-grade and low-volume disease. Subjecting patients to multiple prostate biopsies has been shown to increase their chance of undergoing prostatectomy with consequent insignificant level of disease (organ-confined with negative margins, Gleason score six or less and less than 10% estimated volume). Resnick et al showed that the risk for patients undergoing radical prostatectomy for insignificant disease was 31.1%, 43.8% and 46.8% in those undergoing one, two and three-plus prostate biopsies, respectively. Conversely, the risk of significant disease was found to be 64.6%, 53% and 52%, respectively.

Despite fluctuations in the number of cases in prostate cancer, the general trend over the 12-year period shows increasing numbers. In 2015–2016, across the NHS (all specialties) there was actually a 4.6% reduction in the number of claims, but the financial provision for claims has increased by £2.5 billion, reflecting increased levels of legal fees, damages and costs.

With the aim of reducing costs and promoting sound clinical practice, the NHSLA has provided £18.7 million to financially reward trusts that demonstrate improvements in patient safety (with a focus on human factors and safety culture). We are yet to see a response from this incentive, and whether the current trend can be curbed remains to be seen.

Limitations of this study are that we were unable to identify the claims that were settled out of court by the NHSLA, as well as the claims that are discontinued because the claimant is advised that a successful claim is unlikely in court. Finally, NHSLA data is collected only for claims management and not for risk management or research purposes. The detail required for case descriptions is therefore inadequate and inconsistent.

**Conclusions**
Both societal expectation and patient awareness of litigation continue to grow. As a result, doctors must adapt and acquire new skills to manage these expectations effectively. This study highlights the need for a careful, honest interaction with patients.

With improved diagnostics in prostate cancer, we can perhaps reduce litigation by improving accuracy in differentiating clinically significant and insignificant disease. These include pre-biopsy MRI, measurement of PSA velocity, and...
genetic variants\textsuperscript{11} and tissue-based risk stratification tests,\textsuperscript{12} among others.

In the year to March 2016, the NHSLA in England paid out £1.49 billion in claims for clinical negligence, a rise of 27\% on the previous year (Figure 3). There are concerns that much of the increased payout falls into the hands of no-win, no-fee lawyers. The NHSLA have reported that in 2015–16, of payouts of £100 000 or less, 55\% of all compensation went to the hands of solicitors.\textsuperscript{7} The rising percentage of payouts claimed by the legal teams has not gone unnoticed, and there are plans to introduce a cap on the fee claimed; however, this has been resisted and we await its formal introduction.

Declarations of interests: none declared

References