

***TOP TIPS FOR THE MANAGEMENT OF  
MISDIAGNOSIS OF CANCER CASES IN A CLINICAL  
NEGLIGENCE CLAIM***

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## **Background Issues**

1. In data published by the Office of National Statistics in 2015, cancer remains the leading cause of death for both men and women in England and Wales, when all types of the disease are combined. As such, cancer accounts for nearly a third of deaths. Rather gloomily, 50% of our generation will likely be diagnosed with cancer during our lifetime.
2. Cancer is also perhaps the disease (or group of diseases) which carries with it the greatest fear factor amongst the population.
3. It is notable that there are over 200 different types of cancer known to develop in any type of cell in the body, each displaying its own distinct symptoms, growing at different rates and varying in each individual case, based upon the patient's physiology, physical and sometimes, psychological history and strength.
4. Against that background, cancer survival rates in the UK are a hot topic. The media have, in recent years, published articles which suggest that Cancer Survival in the UK is the worst anywhere in Europe. Moreover, Cancer Research UK published a report in September 2014 indicating that early diagnosis saves lives, and that late diagnosis of cancers in the UK can explain the poor survival rates in Britain compared with other countries. The same report also suggested that there was extremely wide variation in regional and local practice, accounting for nearly a threefold difference between the best and worst clinical commissioning groups.
5. Such has been the concern about the UK's approach to cancer diagnosis, that league tables for GPs were introduced during 2013, the first set of which appeared to find that more than half are not referring such patients to specialists quickly enough. The national performance data - which covers all 8,000 GP practices in England - enables patients to look up their own surgery, and see how it performs against dozens of indicators about diagnosis and treatment of most of the common diseases and conditions. As recently as September 2016, a voluntary audit for GP practices was launched by a collaboration between the RCGP, Public Health England (PHE), Cancer Research UK and Macmillan. It will collect data on how many cancers have been diagnosed, the types of cancers diagnosed, the number of tests and consultations

GPs use and how many cancers are diagnosed late or early. The review will first look at data from 2014 and then compare this to data from 2015 onwards to build a picture of how diagnosis has changed following the introduction of NICE latest guidance on diagnosing cancer. These will also be compared against the national average.

6. For more than a decade, NHS guidance has stated that patients who visit their family doctor with key signs of cancer should be referred to a specialist within two weeks. Those guidelines have been amended (most recently in 2015) to include a whole raft of additional symptoms worthy of investigation, and a recommendation that GPs are able to request some ‘direct access’ tests urgently – within two weeks or even 48 hours for some rare cancers.
7. It is therefore unsurprising, against that background, that the question of diagnosis in cancer cases is a growing issue for clinical negligence lawyers.
8. The main areas where clinical negligence can affect cancer patients are:
  - Misdiagnosis, including being diagnosed with the wrong type of cancer;
  - Delay in diagnosis – including delayed referral to a specialist or for the carrying out of further tests;
  - Failure to act upon test results;
  - Failure to diagnose- errors made with x-rays, scans and medical records;
  - Incorrect diagnosis including the prescription of the wrong drugs or course of treatment;
  - Surgical errors including the failure to obtain clear margins, and;
  - Failure to monitor and act upon ongoing care and treatment.
9. Of those, delayed diagnosis is by far the most common and as a consequence, this paper will focus upon that issue.

### **Breach of duty**

10. This paper will not go back over the basic building blocks of a professional negligence claim. It presupposes knowledge of the Bolam test as modified by **Bolitho v City and Hackney Health Authority (1998) AC 232**.

11. Many delayed cancer diagnosis claims start with the GP in primary care. The GP is generally the first port of call for the patient reporting symptoms which may be indicative of cancer.
12. In **Ministry of Justice v Cheryl Carter (2010) EWCA Civ 694**, the Claimant who was a prisoner, sought to use the prison doctor, a GP, whom she attended on three occasions complaining of breast pain. On each occasion the breast was palpated but no lump felt. The Claimant was later diagnosed with breast cancer. The Claimant engaged Dr Ross, a GP expert, who stated that by the time of the third presentation, the GP should have become suspicious and made a referral. Dr Cheng, GP engaged by the Trust, considered that where no lump was palpated, no referral was necessary. The Court of Appeal reversed the first instance judgement which found for the Claimant and, they considered, failed properly to apply the Bolam test.
13. In that case, the applicable guidelines stated that where there was no palpable abnormality there was no evidence to support the use of mammography. Equally, a referral pro-forma issued by the relevant trust stated that women with moderate degrees of breast pain who do not have a discrete palpable lesion should have their initial care managed by a GP.
14. The case highlights the extent to which the courts in such claims place reliance upon national and regional guidelines. Those guidelines are expressly intended to ensure a consistent approach throughout the country and to keep standards at a satisfactory level. They are produced by healthcare professionals including NHS staff, academics and members of the healthcare community and are taken to represent a consensus view. In such claims, if it can be proved that there has been a breach of the NICE guidelines, whilst not being probative of negligence (these are guidelines only and there may be cases where there are good reasons for departure from the guidance) it will probably be enough to prove a prima facie case of negligence by the treating GP. It is notable however that more and more cases are being defended upon the basis that it was not negligent to depart from NICE guidance.

15. The current guideline (first produced in 2005, modified in 2011 and substantially in 2015) gives four categories of referral; immediate, very urgent, urgent and non-urgent. Immediate referral is required where symptoms are so bad that nothing but an immediate referral to hospital is adequate – defined as “an acute admission or referral occurring within a few hours, or even more quickly if necessary. Such cases are unlikely to be litigated as it is usually obvious where immediate referral is needed and causation would generally be extremely difficult to establish upon the back of any apparent breach. Non-urgent referrals are also less likely to be litigated as they tend to be used by GPs practising defensive medicine, and to exclude the potentially adverse diagnosis for reassurance and where the cancer is unlikely.

16. Typically urgent referrals are likely to be, and have routinely been, the most contentious area for litigation purposes. The guidelines define urgent referral as a two week referral. Very urgent referral is within 48 hours, and appears largely to be confined to childhood cancers and certain categories of brain and blood cancers.

17. The introduction to the guidelines states:

*“It is generally believed that early diagnosis of cancer is beneficial. However, this is quite difficult to prove scientifically, in part because the natural course of cancer, and of its symptoms, is imperfectly understood. The benefit from earlier diagnosis is usually thought of in terms of survival – with most people considering the chance of surviving their cancer to be higher the earlier it is diagnosed, as the cancer will have had less time to spread. There may be other benefits from expediting diagnosis, such as relief of symptoms.”*

18. The guidelines use a variety of terms to indicate the strength of the recommendations, ranging from “must” to “should” or “offer/consider”. Should is defined as a strong recommendation, where for the vast majority of patients, an intervention will do more good than harm, and be costs effective. Offer or consider are used when NICE are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention and whether or not to have the intervention at all, is more likely to depend upon the patient’s values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing options with the patient.

19. The new guidelines (2015) are much broader than previously and provide almost a checklist of symptoms for which investigations ought to be commenced. The guidelines are separated into thirteen categories organised by the site of the cancer, as follows:

- Lung and pleural cancers
- Upper gastrointestinal cancers
- Lower gastrointestinal cancers
- Breast cancer
- Gynaecological cancers
- Urological cancers
- Skin cancer
- Head and neck cancers
- Brain and central nervous system cancers
- Haematological cancers
- Sarcomas
- Childhood cancers
- Non site specific symptoms

20. A careful consideration of those subcategories will assist in defining the threshold for onward referral or further investigation, including (now) when GPs should directly access further tests.

21. The guidelines then highlight risk factors, which the GP should ask about when taking the patient's history, and symptoms which should cause concern if reported. Equally, the guidelines also have a table of recommendations based upon symptom type.

22. Whilst the guidelines are of the most use in the specific brackets identified, they are of universal application. If one should come across a cancer which is not specifically provided for within the guidelines, they remain helpful in :

- (a) Determining the threshold for urgent referral and whether there is a suspicion of cancer or unexplained symptoms;
- (b) Determining the presence of any "unexplained" symptoms as defined by the guidelines;
- (c) Determining where discussion with a specialist should be considered (ie para 1.16.2 provides that discussion with a specialist should be considered if there

is uncertainty about the interpretation of symptoms and signs, and whether a referral is needed.)

- (d) Determining what the referral letter should include (para 1.16.6) including whether referral is urgent or non-urgent;
- (e) Determining whether review should be considered – ie: for people with any symptom that is associated with an increased risk of cancer, but who do not meet the criteria for referral or other investigative action.

23. As such, the first step in early analysis of most cancer claims, will be a non-expert look at the NICE guidelines, and any pro-forma referral letters or documents utilised in the relevant region, together with a review of the complete medical records. If time is of the essence due to the client's prognosis, attempts should be made through discussion with the proposed defendant and their lawyers to fast track the provision of records.

24. In clinical negligence claims per se, but specifically in cancer claims, a thorough review of the medical records at an early stage is invaluable. In particular, one should pay particular attention to the reporting of symptoms indicated in the guidelines to be characteristic of the cancer which the Claimant has ultimately been proven to have. There should be care taken to identify any missing records as soon as possible. There should also be careful examination and notation of:

- (a) The number of visits reporting such symptoms;
- (b) The quality of the medical notes at those consultations;
- (c) The timeframe between visits, and in particular, the first visit and the Claimant's ultimate diagnosis;
- (d) The extent of any history taken and examination undertaken (including where the Claimant is still alive a comparison between their own description of symptoms and background reported (including specific risk factors such as family history) and those recorded in the records);
- (e) When referral took place;
- (f) What if any, investigations were instigated in primary (and also in secondary) care, how quickly they took place, whether they were directly accessed, the speed with which they were followed up, and how they were followed up;

(g) What information was provided to the Claimant patient about their symptoms and the need for monitoring the same.

25. In terms of assessing the records, it is usually extremely helpful to obtain an early but detailed witness statement from the Claimant (if they are not deceased) or their immediate relative if the Claimant has since died. Such a statement will inform the analysis of the records and help to put them in context, whilst assisting in narrowing the issues from the earliest stage of proceedings.

26. Given that the records can be extensive, it is often worth engaging a specialist company or in house nursing staff to prepare a medical chronology and analysis of the records. That is not to say that such a step is justification for not undertaking a personal review of the documents, but they are often of great assistance when instructing experts, and in identifying any missing documents which need to be chased. Further, where the diagnosis or staging of a cancer is or is likely to be in any doubt, the histopathology samples should be obtained at the earliest opportunity for expert review.

27. The next step is to set about identifying and instructing suitable experts. It is usually worth only instructing an expert on the liability aspects of the case in the first instance, so as to save costs, and help to set the parameters for further experts. However, you have to know also that the Claimant had cancer which was detectable at the alleged date of negligence as plainly, no claim can be sustained upon the basis of a failure to refer for, say, a breast lump which was in fact benign. As such, you are likely to require expert evidence regarding whether the cancer found at ultimate diagnosis was present and detectable at the alleged date of negligence. As such, there will generally be a need for two experts in respect of breach alone, one of which will usually be an oncologist. Plainly, the specialism(s) of the liability expert(s) will be determined by the nature of the failures initially alleged. It is anticipated that (as considered above) many delayed cancer diagnosis claims will at least in part, focus upon primary care and require expert evidence from a GP. If there are additional allegations which appear to arise from the records, such as a failure to report x-rays or scans correctly, or instituting an inappropriate treatment regime, liability reports may then be required from a radiologist and/or an oncologist.



28. Expert selection is critical in most cases, whether dealing with cancer or otherwise. Personal experience of an expert, both on paper and in court is always the best means of choosing one's expert. Asking for the recommendations of colleagues can be invaluable. It is imperative that credible experts are used, and it is therefore always worth trawling recent cases (on lawtel for example) dealing with cancer claims to ascertain which experts have been commended, and found persuasive by the court (specifically in a case dealing with the particular type of cancer with which one is concerned) and perhaps even more importantly, which have been discredited or found wanting. Once initial experts have been selected, they may also be able to assist in recommending additional experts in due course.
29. As always, it is important when instructing experts, to ensure efficient planning. In order to instruct any expert, but particularly given the complexities of cancer claims, the lawyer must first have a clear grasp upon what is required and what the preliminary case is. Forgive me for stating the obvious, but start by making it clear whether you are asking for a report on liability and causation or condition and prognosis or both. The expert should then be provided with a clear copy of all of the medical records, organised logically and in clearly distinguished sections (ie: GP records, records from specific hospitals or timeframes, radiotherapy records, pathology, radiology, drug charts etc). The documents should be clearly paginated without any sections chopped off! If there are documents which have not been obtained or where problems lie in their retrieval, inform the expert in the instruction letter. The documents provided should be listed in an index at the start of the instructions and one should ask the expert to confirm that they have received all of the enclosures and to inform you as soon as possible if they consider any documents to be missing. Any chronology prepared should be included with the instructions as an aid. The expert should also be sent, if at all possible, any early draft of the Claimant's statement, setting out their version of events and key complaints. The expert should be asked to address any concerns regarding inconsistency between the statement and the records and to address how that might affect their view.
30. The instructions must then as always contain a succinct but accurate summary of the key facts as the client and lawyer understand them, the preliminary issues identified

and the key legal tests to be applied, following which the instructions should set out a clear list of questions for the expert to address (with the caveat that anything else they consider to be relevant should also be included). It is in the formation of the questions that preparation and a thoughtful approach to the issue in logical order, is paramount. It is best to begin with general questions and then more specific questions which are phrased in an open ended format to encourage thorough and unbiased answers. By way of example, when instructing a causation (usually oncology) expert in a cancer claim, general questions may include things like:

- (a) Please discuss what outcome would have been expected on the balance of probabilities but for the negligence.
- (b) Describe how that outcome compares with the patient's actual outcome. In other words, on balance how has the alleged negligence altered the clinical outcome?
- (c) If there has been a negligent delay in treatment and if you have not already done so, please consider whether and to what extent that delay has affected the client's clinical outcome.

31. More specific questions may include:

- (a) Describe the precise form of cancer which the patient has acquired as confirmed by histopathological diagnosis;
- (b) Explain the expected natural history of that type of cancer In so doing, please address;
  - i. How long and well do people live with it?
  - ii. What is the likely doubling time or growth rate?
  - iii. Are there any concerns about using doubling times or growth rates and are there any features of this cancer or patient which affect you view?
  - iv. Is it likely that the cancer is amenable to screening – what is the duration of its detectable pre-clinical phase?
- (c) On the balance of probabilities, how advanced or widespread was the cancer at the time when the alleged negligence occurred (ie: what were its likely dimensions, is it likely to have metastasised, was there likely nodal involvement?)

And the list goes on! The expert should be asked to provide literature to support their conclusions, and to highlight any range of literature or alternative views, as well as advising upon the need for additional specialist expert reports (such as histopathology).

32. Once the reports are available, there is little substitute for holding an early conference with one's team of experts to consider the issues in the round and to ensure that all areas of the claim stack up together.

### **Different types of cancers**

33. So far as breach of duty is concerned, the same principles apply across the board, and regardless of which subtype of cancer one is dealing with.
34. However, it is plain that the difficulties of establishing a breach of duty specifically in relation to the timing of ultimate diagnosis, does vary with the type of cancer concerned.
35. It must be remembered that cancer is a highly heterogenous disease. National audit and patient survey data show that the strongest predictor of multiple consultations (and which in turn increase the time from presentation to referral and diagnosis) is tumour site.
36. Between 30% and 50% of patients subsequently diagnosed with multiple myeloma ( a bone marrow/blood borne cancer) or pancreatic, stomach and lung cancer have multiple consultations compared with less than 10% of those subsequently diagnosed with breast cancer or skin cancer (melanoma). Likewise, multiple consultations are higher in patients who turn out to have head and neck cancers. Those differences appear to reflect the "symptom signature" of different cancers. Those where most patients present with fairly specific symptoms such as a palpable breast lump or a visible skin lesion are naturally less associated with multiple consultations. In such cases, where there is a longer period between initial presentation, referral and diagnosis, the prospects of establishing a breach of duty may well be heightened. Likewise, in relation to the follow up from routine cancer screening, such as bowel and cervical cancers.

37. Conversely, many cancers, such as head and neck cancers, which often present with symptoms such as mouth ulcers, sore throat, ear ache, hoarse voice and swelling of the lymph nodes in the neck; lung cancer, which often presents with a persistent cough (often in heavy smokers) and stomach or pancreatic cancers, presenting with abdominal pain, and multiple myeloma, presenting with back pain, tend to undergo additional consultations in primary care before referral and diagnosis. That is unsurprisingly because such symptoms are extremely common in the general population and are frequently associated with a range of benign conditions. Often, it will follow from such presentations that in the absence of red flag symptoms or a strong family history, conservative treatments for routine conditions, allied with a watch and see approach, will be justified. There may also be a higher incidence of investigations undertaken in primary care, which then need to return, and be followed up, before referral occurs.
38. Those differences in signature symptoms and the consequent increase in the reasonable period of time between presentation and referral, will often have a knock on effect upon causation, which is considered further below.

### **Causation**

39. Causation is critical and often the most complicated aspect of a cancer claim. The starting point is the same as any personal injury case. – what would have happened “but for” the negligence. Or to put it another way, what damage flowed from the negligence.
40. There are often a number of stages to causation in a cancer claim. The first is likely to be, had the Claimant been referred for investigations earlier:
- (a) What investigations would have been conducted;
  - (b) What would those investigations likely have identified (and specifically when considering x-rays or scans) would a tumour have been visible;
  - (c) If a tumour had not been visible following investigation, to what extent if at all, would the Claimant have been monitored and rescanned/re-investigated;

- (d) If and when the tumour was visible following investigation, how would it have been staged (ie: how big would the primary tumour have been, how fast was it growing and had it spread);
- (e) If and when the tumour was visible following investigation, what treatment would have been given (surgery, chemotherapy, radiotherapy, and of which type);
- (f) What are the prospects that such treatment would have been curative or led to a markedly better outcome (considering Gregg v Scott issues);
- (g) What would the Claimant's prospects of survival have been (and if the Claimant remains alive, is there a difference in the risk of reoccurrence and early death).

41. If the Claimant has in fact survived in any event and has the same survival prospects and life expectancy, one will need to ascertain the extent of any additional treatment required by reason of any delay, and the extent of any additional pain, suffering and loss of amenity.

42. The starting point for dealing with causation in any cancer claim is to assess the correct team responsible for the Claimant's care, and to ascertain who would have had responsibility for what. Over 95% of cancer cases will be discussed at an appropriately appointed multi-disciplinary team meeting (MDT). The make-up of the MDT will depend upon the type of cancer. For example, an MDT for lung cancer will generally include the following:

- Chest / Respiratory physician - Performs tests such as bronchoscopies and chest x-rays with a view to diagnosing lung cancer. Also, often the doctor who initially coordinates the cancer pathway.
- Oncologist- Provides expertise in the non-surgical treatment of cancer including chemotherapy and radiotherapy.
- Lung Cancer Nurse Specialist (LCNS) - Offers specialist lung cancer information and support to patients and their families.
- Thoracic Surgeon - Performs surgery to the chest, including removal of part or whole lung, staging and symptom management.
- Radiologist - Performs radiological investigations such as CT scans, PET, MRI and bone scans.

- Histopathologist - Examines biopsy samples and other samples to determine the type of cancer
- Palliative Care Team - Specialists in managing symptoms from the disease.

43. For bowel cancer, the MDT will typically include:

- Colorectal surgeon
- Oncologist
- Clinical Nurse Specialist
- Radiologist
- Histopathologist
- Gastroenterologist
- Palliative care team

44. In causative terms, expert evidence from a nursing or palliative care specialist is usually not required (unless of course there are allegations of breach dealing with nursing and which are themselves infrequent and unlikely in most cases to have caused additional injury). However, expert evidence will generally always be needed from:

- (a) An oncologist;
- (b) A radiologist and;
- (c) The specialist surgeon.

45. In lung cancer cases, a chest physician will also generally be required to comment upon the patient's likely diagnosis and treatment management, as well as life expectancy.

46. Psychologists and others may well also be involved in due course. In head and neck cancers, speech and language therapists and dieticians are involved in a patient's care. In breast cancer (and other primarily gender related cancers), reconstructive plastic surgeons will also likely be involved. Such specialisms are usually more relevant to a subsequent assessment of loss and damage rather than causation.

47. Primary evidence will be required from the oncologist as to the staging and prognosis for the cancer at different time points within the case. There are however different categorisations for different cancers. Melanomas may be measured for their Breslow thickness, colorectal cancers have a Dukes stage and for prostate cancer the stage is a measure of the extent of growth or invasion and the Gleason grade is a measure of the aggressiveness of the cancer.
48. The most detailed and common staging system is the Tumour, Node, Metastasis (TNM) system. The size of the tumour is usually measured in centimetres and it is the size of the primary tumour which generally determines its T stage. T1 represents the smallest size and T2, T3 and T4 represent progressively larger tumours depending upon their spread to nearby tissues.
49. At some stage in cancer development, some cancer cells migrate from the primary tumour and spread to the lymph nodes. The nodes may swell and the size of the lymph nodes and / or extent of the spread is categorised by “N” in the TNM scale. N0 represents no lymph node spread with N1, 2 and 3 representing progressively more extensive spread. The T and N categories are different for each cancer type and the definitions of those categories make up a substantial component of oncology text books and are beyond this (in any event legal) talk.
50. The “M” classification stands for metastases or spread to other distant organs. M0 is applicable where there is no such spread and M1 where there is a spread beyond the regional lymph nodes.
51. The TNM combination for any particular tumour is important because it determines the treatment likely to be required and can be translated into a percentage cure rate or average survival time required for arguments on causation. For common cancers such as lung cancer, colon cancer, prostate cancer and breast cancer, the prognosis data are relatively accurate (or considered to be) and can be provided for contemporary UK patients based upon research studies or population databases.

52. The difference in staging can be demonstrated by comparing a T1AN0M0 lung cancer - a primary tumour of less than 2cms with no spread, and a proposed “cure rate” with surgery of around 90% and a T4 N2 M0 lung cancer with a cure rate of less than 20%.
53. For rarer types of cancer the literature may yield only small numbers of reported cases, reducing the accuracy of the outcome statistics, or old studies of patients treated with old technologies. In such cases, the use of a sensible and robust expert is all the more important, as the causation evidence may be rather more controversial.
54. There are other traps for the unwary:
- (a) First, evidence based on patients treated in research studies is often regarded as the best quality but may be subject to the criticism that those entered into the trials usually have a better outcome than the average population, due to selection of only the fittest patients to enter such trials or the better treatments available in university departments compared with smaller cancer centres.
  - (b) The task of determining what the size of the tumour would have been at any date prior to diagnosis, and which is the usually the principal issue for the oncologist, is open to interpretation in the absence of a previous coincidental x-ray or scan on which the tumour was visible but missed as an incidental finding. Absent such comparative radiology, and against which the growth rate of the tumour can be assessed, the retrospective staging of the tumour will depend upon a combination of data on average tumour growth rates (and which vary between types of cancers) and factors specific to the patient and the tumour’s unique characteristics.
  - (c) As a consequence, one must ensure that the chosen oncologist deals with:
    - v. The range of and most recent data on average tumour growth rates for the specific type of cancer in issue;
    - vi. The range of and most recent data on average metastatic growth rates (which frequently vary (usually with faster growth rates) when compared to the primary tumour) specific to the case;
    - vii. Any factors peculiar to biology of the tumour or the patient which might alter the “average”.

There have been instances (and it is always worth doing a further case law trawl as suggested above), where experts (oncologists) have had their evidence found



wanting due to over reliance upon back extrapolation particularly in relation to metastatic growth (rather than primary tumour growth) and the use of online calculators where metastatic disease is present.

55. Even with cancers such as breast cancers where there are well recognised and published studies of doubling times, the experts can usually only give a range of sizes for the tumour at an earlier stage. The greatest difficulties are with less common cancers where there is a lack of data. It is not usually appropriate to use doubling times for similar cancers and one should always check how the oncology expert has reached their conclusion as to the likely size of the tumour. In **McGlone v Greater Glasgow Health Board (2013) COSH 34**, the Claimant's expert used studies to interpolate the size of the Claimant's cervical tumour at the time when it was alleged that diagnosis ought to have been made, but the Court of Session Outer House rejected the evidence which was based upon the VDT of metastatic lung cancers. They also noted the very wide range of doubling times and rejected the notion that the court should simply take the mean time within the range. Nonetheless, the courts have recognised that statistical evidence may be probative of a range of tumour size. Plainly, without reliance upon such data and a willingness to make findings by inference, most delayed cancer diagnosis claims would have to fail!

56. It is equally notable that when seeking to prove a reduced life expectancy following a delay in diagnosis, one should be wary of over-reliance on statistical or epidemiological evidence particularly in the case of rarer cancers or of applying data or evidence regarding one type of cancer to a case involving a different type of cancer.

57. The recent Fatal Accident Act case of **Hague & Rich v Dalzell & Fish [2016] EWHC 2753 (QB)** was a case in which breach of duty was admitted. Had the deceased been referred for investigation of pain and vaginal bleeding, a diagnosis of cervical cancer would have been made and surgery undertaken. The delay was in the order of seven months for treatment and four months in relation to failings on the part of the First and Second defendants. The deceased in that case suffered a further cervical cancer in due course as a result, it appeared, of the growth of residual cancer cells following surgery. She sadly died a year later. Mr Justice Lewis found as fact

that at the time when diagnosis ought to have been made, the tumour would have been stage 1b1. At actual diagnosis, the clinical staging was 1b2 but there was agreement amongst the experts that the tumour "would have been" classed as a 2b tumour on the basis of the MRI scan at that time.

58. The Judge did not accept attempts made by one of the Claimant's experts to use doubling times to interpolate the size and characteristics of the tumour at the time when diagnosis ought to have been made. He quoted from expert evidence as follows: "*...it is inadvisable to use tumour doubling times in this particular tumour because there is no reliable data for the volume doubling time of this tumour or any primary cervical carcinoma growing in situ.*" It was agreed that the particular cancer affecting the deceased was very aggressive and rare. There were only 17 such cases in the literature, the court was advised.

59. The Judge in consequence, also rejected the application of studies on survival chances following treatment for other, more common and less aggressive, kinds of cervical squamous cell carcinomas. He also went further than that and rejected the Claimant's use of statistical evidence to show that the deceased would have been cured with earlier diagnosis and treatment. He observed that "*The figures are intended to show prospectively the likelihood of survival. They are not designed to be applied retrospectively to predict the likelihood of whether any particular individual would have survived if treated by a particular date.*" He commented further that "*the statistics are intended to show likely survival rates for a cohort of people ... [evidence that shows] that just under 95 out of a hundred such patients would be alive after 5 years does not assist in determining whether or not a particular patient will be one of the 95 patients who survive or one of the 5 who do not.*"

60. On the facts, Mr Justice Lewis was persuaded by the expert evidence that "*the tumour in the present case was a highly aggressive, rare form of cancer, namely a sarcomatoid squamous cell carcinoma and that such tumours have a poor prognosis and are likely to recur.*" The Claimants could not persuade him that the deceased would have probably survived more than 5 years on earlier diagnosis.

61. The judgment shows the need to scrutinise the data relied upon. Is it a retrospective study of actual mortality? If, on all the evidence, there is good reason to conclude that the particular patient would have been in the 5% rather than the 95%, then the fact that 95% survive will be irrelevant. Conversely, if there is no such evidence, the fact that 95% survive must be compelling evidence of the likelihood that the particular patient would have survived, assuming that the data is directly relevant to the particular cancer. It does not appear that an argument was run in that case as to whether a loss of life expectancy (in terms of specific years) could be established in the alternative.
62. The specifics of causation and in particular, the likely staging of the cancer and survival prospects at the point of alleged negligence and at defined stages throughout the case, will need to be carefully addressed step by step in an early conference.
63. Once the staging and size of the tumour is assessed, a report will generally be needed from a radiologist to identify the extent to which a tumour of the size supported by one's oncologist or other expert, would have been visible on a plain x-ray and/or a CT scan so as to have mandated further action being taken.
64. Thereafter, the surgical opinion (again specific to the particular type of cancer with which you are dealing) will need to address (in combination with the oncologist) what treatment the Claimant would likely have been offered and with what likely outcome.
65. Further, if there is any doubt as to the classification of a tumour (for example in cases of what were thought to be benign meningiomas which later and swiftly recur as aggressive malignant tumours) there may be a requirement for evidence from a (neuro) pathologist, who will of course, need to review the original specimens taken after surgery.
66. It is therefore plain that such cases are both extremely complex, and require management of an extensive team of experts, whose evidence needs to be pieced together carefully. As a consequence, cancer claims are both fact and labour intensive.

***GREGG v SCOTT AND LIFE EXPECTANCY.***

67. This paper, as an overview, is too broad to take a detailed look at the law on causation. However, it is first necessary to consider the impact of *Gregg v Scott* upon cancer claims. The above case of **Hague & Rich** overlaps with this issue as well as the use of data in assessing tumour size. **Gregg v Scott (2005) UKHL 2** concerned a failure to diagnose cancer, a lymphoma to the left armpit, in a timely manner by the Claimant's treating GP. The negligent delay allowed the cancer to metastasise so that the Claimant's prospects of survival (based upon the expectation of life for another 10 years – the assessment of post treatment survival being measured at 5 and 10 years respectively) were reduced. The claim was pleaded upon the basis that the Claimant's chance of survival was reduced and statistics determined that the delay reduced the prospects of survival from 42% to 25%. It was Mr Gregg's case that he should be able to claim for the loss of that chance.
68. The House of Lords were split 3 to 2 and each law lord gave a different reason for the decision that was made. Ultimately, they decided by a bare majority that to bring a claim one must first prove an injury and the law did not allow for the claim of a loss of chance of survival – either the Claimant can show that he/she would have survived on balance, or not.
69. What however, *Gregg v Scott* does not say is that once an injury has been proved on the balance of probabilities, damages claims cannot be made upon the conventional loss of chance basis.
70. As such, proof of injury must be proved on the balance of probabilities, rather than loss of a chance below 50%, but thereafter, the loss of chance rules apply unfettered.
71. However, as Lord Philips and Baroness Hale both noted there was another way for the Claimant to have presented his case which would have been simpler and allowed for success. That was to prove that the delay in diagnosis had reduced his life expectancy by a specified period which the statistics supported on the balance of probabilities. Instead, Mr Gregg had simply claimed that he would have survived.

72. Such a lost years claim (during life only) was supported by cases such as **JD v Mather (2012) EWHC 3063 (QB)**. In that case, it was found that the Claimant's chances at the date of alleged failure to refer, of surviving a further 10 years were already less than 50 per cent, had the tumour been detected at that time. The principal claim therefore failed on the basis of *Gregg v Scott*. However, on balance of probabilities, the failure to diagnose the tumour earlier had caused the Claimant's life expectancy to be reduced by three years.
73. Clearly damages were not to the same extent as would have been the case had the claim successfully established that but for the negligence, the Claimant did recover damages.
74. By contrast, in **Loretta Oliver v Williams (2013 Med LR 344)**, the Claimant failed to establish a diminution in life expectancy. The Claimant had attended an appointment with her after her symptoms of stomach cramps, bloating and diarrhoea had persisted. The GP decided to have the stool sample analysed. Those results came back as normal. The Claimant returned to see the GP two weeks later. He decided to make an urgent referral to hospital for further investigations. The referral letter was either not received or was lost by the hospital and consequently she did not receive an appointment. Because she did not know about the referral, she did not chase up the appointment. Her symptoms persisted and worsened. She attended the surgery again six months later and saw a different GP who urgently referred her to hospital. The hospital diagnosed the Claimant with ovarian cancer and she underwent surgery. The issue for our purposes (albeit amongst others) was whether the fact that more abnormal tissue was left following surgery in July than would have been left five-and-a-half months earlier, in February, translated into a diminution in life expectancy. Simeon Maskrey QC held that the expert gynaecologists agreed that the five and a half month delay would have made no difference to the staging of the disease or the treatment offered. There was sufficient evidence to conclude on the balance of probabilities that generally the less the volume of cancerous tissue left after surgery the better the prognosis for survival. However, there was no evidence in this case of what proportion of residual cancerous tissue would have been left at the earlier date, as opposed to what was actually left after surgery. Given that the Claimant's expert could not assess the difference in volume of residual material, his estimate of

diminished life expectancy was nothing more than a hunch. Damages were not recoverable for the loss of a chance and the Claimant had to establish that the breach of duty caused or made a material contribution to a measurable degree of loss but she had not done that.

75. Following the redefinition of the law on material contribution in **Sido John v Central Manchester & Manchester Children's University Hospitals NHS Foundation Trust (2016) EWHC 407**, it remains to be seen what impact material contribution arguments may have in delayed cancer claims.

76. Following the John case on the back of **Williams v The Bermuda Hospitals Board [2016] UKPC 4**, in order for a Claimant to succeed he / she must show that:

1. The Defendant has been negligent in its care towards him/her.
2. The negligence has materially contributed to his/h injury.
3. Proving the degree of the contribution on a traditional *but for* basis is a medical impossibility, but the contribution must be more than minimal.

77. Material contribution to risk is insufficient. In circumstances where material contribution to injury can be established, the Claimant ought to recover damages in full in the case of an indivisible injury and in cases of divisible injury, damages for that part of the injury that was attributable to the Defendant's negligence.

78. In **Maytum v Abertawe Bro Morgannwg University Health board (unreported)**, the Claimant was referred urgently by her GP for suspected breast cancer when she was just 31. She had a discrete breast lump for six weeks. A surgeon at the Princess of Wales Hospital downgraded her referral to routine upon the basis that she was under 35 and there were no red flags beyond the presence of the lump. It is interesting to note that this was a case in which the Defendant denied that it was negligent to apply different referral criteria from those recommended in NICE guidelines. As a result of the delay the Claimant's breast cancer was diagnosed and treated five months later than had the referral been urgent. The surgeon did not inform the GP of the downgrade. The claim settled on day four of trial after the evidence of the hospital surgeons. It was agreed that on earlier diagnosis the treatment given would have been exactly the same. The question was however, whether, the Claimant having later

relapsed and developed overt metastases, earlier treatment would have been more effective.

79. The case is interesting for a number of reasons. The use of prognostic tools was expressly dealt with and the experts agreed that the most useful model for assessing likely prognosis in the case was the PREDICT model which the NHS makes available online. The model indicated that in September 2010 when the Claimant ought to have had treatment over 90% of women her age and with her cancer characteristics would have survived for at least 10 years. The corresponding figure from when treatment was actually undertaken was around 80%. Following her relapse, she in fact had a very limited life expectancy. The Defendant's case was that the relapse showed that the Claimant's cancer was unresponsive to treatment and that she would have relapsed at the same time in any event. The Claimant's case was that PREDICT remained valid and that relapse following actual treatment did not establish likely relapse after earlier treatment. During the delay period, the tumour had grown and the number of axillary nodes involved had increased, both of which are adverse prognostic indicators. The mortality rate had just more than doubled during the period of delay (from 10-20%).
80. Plainly, that issue is common to many delay in cancer diagnosis claims. Where the outcome following actual treatment is known, it may well be wrong to categorise them as *Gregg v Scott* cases. Where there has been a relapse, unless that fact wholly undermines the evidence of likely cure on earlier diagnosis, the comparison is between actual outcome after treatment with relapse and limited life expectancy and probable cure on earlier treatment with corresponding likely life expectancy as demonstrated by appropriate modelling.
81. The second relevant consideration arising from this case is whether the delay in diagnosis and treatment could be said to have materially contributed to the distinct injury of relapse and the development of overt metastases. It was argued that even if the cancer had been particularly aggressive, the delay had made a more than minimal contribution to the relapse. The development of overt metastases was an indivisible injury and there were cumulative causes of it, including negligent delay. If the negligent delay caused or materially contributed to the relapse and the relapse

accounts for the reduced life expectancy (or death that has already occurred) then the Claimant may be able to establish causation.

82. Plainly, these cases are complex but there would appear to be no one test of causation applicable to all cancer delay claims. What may apply where prognosis remains favourable after actual treatment may not suit a case where there is a poor prognosis.

83. It is therefore worth considering causation in distinct stages. First, one must look at the likely size of the tumour, and issues with statistical data and the likely treatment differential (as considered above). Thereafter, causation in terms of life expectancy will need to be assessed in steps too:

- (a) Can you establish that but for the alleged negligence, the Claimant would likely have survived (Gregg v Scott) – have prospects of survival dropped from above 50% to below 50%;
- (b) Are there any factors in relation to the claim which makes the predicted survival figures unlikely – ie: the **Hague & Rich** issue – was this a case where the client was likely to fall into the small proportion of people with a poor outcome;
- (c) If you cannot establish likely survival or cure, can you establish that the client's life expectancy has been reduced by a set period (and is that based upon demonstrable evidence – the **Loretta Oliver** issue)
- (d) Is there a material contribution argument specifically where there was a relapse in the client's cancer.

### ***SENSITIVITY***

84. It cannot be overstated how important it is to approach any case, but particularly a cancer claim, with due sensitivity. It is easy to forget that we are dealing with human beings, rather than just a disease or points of academic, medical and legal interest.

85. Many such cases will involve either:

- (a) A Claimant who currently has cancer and is undergoing treatment for it;



- (b) A Claimant who is currently in remission from cancer having undergone surgery and/or chemo/radiotherapy, or;
- (c) The family of the person at the heart of the claim, and who has since died as a consequence of their cancer or treatment associated with it.

86. Every one of those scenarios is fraught with difficulty. In the case of a patient who has died, it can be extremely painful for their nearest and dearest to learn that their loved one would likely have survived and possibly been spared considerable pain and distress in the absence of negligence. It is also difficult to give negative advice where the family may still be grieving and want someone to blame – especially if there has been some breach of duty but an absence of causation. The distinction between those concepts can be hard to take on board. Moreover, even where the claim has legal merit, explaining the often relatively low level of damages that are likely to be awarded following death requires true sensitivity and expectations will need to be effectively and carefully managed from the earliest stage. Clients and families will not want to spend long periods of time and energy (often during already difficult times) dealing with liability and causation only to find out some way down the line that the case may be worth relatively little. It is important to be upfront about the likely value of the claim from the start.

87. It is therefore imperative that the legal team take time to explain the relevant advice gently, with kindness and in straightforward terms which are not hedged about with medical or legal jargon, but also with professionalism and confidence so as to reassure the client(s) that you know what you are talking about. Clients should, as in all cases, be allowed at the earliest stage to tell their story in their own words, and the issues that are important to them, whether or not they prove to be relevant legally, should be taken on board.

88. Equally, where the person with cancer is still alive, it is an inevitable part of the construction of the claim that life expectancy evidence will be required. Being confronted in such stark terms with one's own mortality can be both shocking and potentially detrimental to ongoing treatment. Sometimes, depending upon the Claimant and their (and their families' wishes) such evidence can be given in an

addendum to the main report, and need not therefore be seen by the Claimant (or discussed with them) and that should always be considered carefully.

89. Given the sensitivities of such claims, it is also imperative that consideration is given at the earliest possible stage to the following practical issues:

- (a) Commencing the claim early and if necessary applying for fast track directions, so as to enable requests for interim payments to be made and which might enable the injured party to be made as comfortable as possible (and comforted) during their remaining lifetime;
- (b) Considering the way in which the claim needs to be framed, where there is a likelihood that the living Claimant may die during the litigation process. The risks of undercompensation if settlement is achieved prior to death pitted against the benefits of finality, must be explained carefully and sensitively to the client who already has enough to worry about. Typically, although Defendants may be persuadable otherwise, Claimants have to forego the bereavement award and any services claim continuing after death. A careful calculation has to be made weighing the value of the lost years income claim against the value of the lost dependency claim;
- (c) As a consequence of these issues, consideration should, as always, be given to whether a periodical payments structure would best suit the circumstances of the client and their families, so that the needs of living Claimants and their dependents are appropriately tailored to their needs.

These discussions and decisions will often need to take place at a much earlier stage than in many other catastrophic injury cases.

90. With the above discussion in mind, there are various options available in delayed cancer diagnosis claims where death is anticipated.

- (e) Bring the PI living claim and conclude it as long as the client and the potential dependants under a later FAA claim have full knowledge and understanding of the finality of the claim;
- (f) Bring a living PI claim and stay the claim upon receipt of an interim payment, before converting to a fatals claim giving credit for the interim payment(s) as and when the client dies;

- (g) Wait until the client dies and then bring a FAA claim for the dependants;
- (h) Bring a provisional damages claim for which settlement does not preclude a later FAA claim;
- (i) Bring a living PI claim and resolve some heads of claim (ie: PSLA) but stay the remainder and apply to restore after death with conversion to a FAA claim;
- (j) Resolve the claim with a PPO to continue after death.

91. Which option is suitable in any one case will depend upon a range of factors including the extent to which the Claimant's life expectancy is now limited, whether there are or are likely to be dependants, the confidence in the prognosis, the likely value of any lost years claim as against a potential FAA claim, how amenable the Defendant is, the client's wishes and anxieties, any issues with proof of the attribution of future death to the negligent delay a whether liability is in dispute and therefore the likelihood of interim payments being forthcoming.

92. One must also bear in mind that if settlement is reached including recovery for a protected party in relation to an FAA claim which could not be brought at present because the Claimant is still alive, court approval will still be needed. It is therefore important to consider a strategy for the particular circumstances of each case.

### *QUANTUM.*

93. This paper does not allow for a full consideration of quantum issues in cancer claims. In most regards, the assessment of quantum is exactly the same as any other clinical negligence case, save to note the importance of considering the structure and conduct of the case where the client has a short life expectancy (see above).

94. It is also important, as already stated, to make an early assessment of the likely value of the claim so as to manage expectations effectively.

95. Damages, both special and general, flow from the most careful assessment of causation with which we have already dealt. One must ascertain at the earliest stage

precisely what difference the alleged negligence would have made (and depending upon which test of causation one is able to utilise) to:

- (a) Physical suffering during the delay period and ongoing;
- (b) Treatment required (and any side effects of that given or ought to have been given) particularly chemotherapy and radiotherapy;
- (c) Surgery and the success thereof;
- (d) Future prognosis and life expectancy, and;
- (e) The difference in the client's condition (and capabilities) comparing the actual position and the but for position.

96. General damages are usually rather harder to assess because rarely do they fall within any of the defined JC brackets. There are a wealth of cases in Kemp and Kemp which can assist with quantification, and a common sense assessment of the requisite elements of pain, suffering and loss of amenity for the defined period supported, should be employed.

## **Case study – GP delayed diagnosis**

### **The facts**

It can be assumed that the following facts will be established:

- a. In mid-2005 the Claimant registered the presence of a growth in the right side of his groin.
- b. He went to see his GP for the first time on 16<sup>th</sup> March 2006. The GP observed that the lesion appeared to the Claimant to be growing. It was itchy and bled when scratched.
- c. The GP took the view that it was a seborrheic wart and assured the Claimant that there was nothing for him to worry about.
- d. The Claimant re-attended at the surgery on 16<sup>th</sup> October 2006 and saw a different doctor. This GP considered that the lesion was “huge” with a surface area of 15 x 20mm and thought that it was probably a malignant melanoma. He removed it by curettage and sent it for histology at B hospital.
- e. Dr E histopathologist made macroscopic findings as follows:

“Two portions of skin – smaller is 0.9 x 0.7 x 0.3cm, skin surface is irregular and contains a hyper-pigmented lesion which occupies most of the skin’s surface. The other is 1.5 x 1.0 x 0.5cm - a smooth irregular hyper pigmented lesion.”
- f. Microscopic findings were of ulcerated skin contained a nodular vertical growth phase malignant melanoma. The surface is extensively ulcerated and measures at least 12mm. No evidence of lymphovascular or perineural infiltration. Breslow thickness in better orientated fragments measures 5mm (ie: 5mm depth of cancerous cells) and the Clark level is 4 in this specimen although no subcutaneous fat is included.
- g. On receipt of Dr E’s report, the GP referred the Claimant urgently to B hospital by fax of 23<sup>rd</sup> October 2006. On 30<sup>th</sup> October 2006 the Claimant was seen by Mrs X, a consultant plastic surgeon at the Y hospital which was a specialist referral hospital.
- h. A histopathological report from the Y hospital on 30<sup>th</sup> November 2006 found:
  - Macro – a skin ellipse measuring 65mm x 30mm x 30mm which shows a scarred area on the surface measuring 8mm x 5mm with focal dark

pigmentation). Attached to the skin is a specimen of groin dissection measuring 105mm x 90mm x 30mm. 8 lymph nodes are present in the fat...

- Micro – sections from the skin show a focus of invasive malignant melanoma. The maximum horizontal extent of the focus is 5mm. The Breslow thickness in the excision is 2.8mm (Clark's level IV). This may not be accurate due to previous excision.) There is no evidence of ulceration..two out of eight lymph nodes identified contain metastatic melanoma....

### **The guidelines and findings**

The NICE cancer guidelines for suspected skin cancer from 2005 state that a skin lesion suspected to be melanoma should be urgently referred to a dermatologist and excision in primary care should be avoided. A lesion merits urgent referral if it scores 3 points or more on the following list of seven factors.

#### Major features if the lesion (scores 2 points)

Change in size, irregular shape, irregular colour

#### Minor features if the lesion (scores 1 point)

Largest diameter 7mm or more, inflammation, oozing, change in sensation

The American Joint Committee on Cancer (AJCC) staging system is accepted for staging progression of melanomas. Four predictive factors are used:

- (a) The Breslow thickness of the primary tumour
- (b) Whether the primary tumour has ulcerated
- (c) Whether the cancer has reached one or more of the lymph nodes and if so, whether it is palpable or only detectible under microscope
- (d) Whether there has been metastatic spread.

In March 2006, the Breslow thickness was accepted to be between 3 and 4mm. Ulceration means bleeding and oozing. In March 2006, the lesion bled but did not ooze when scratched. However, the ulcer was accepted to be the site of the malignant

ulceration in March 2006. In October 2006 there was palpable spread to the lymph nodes and in March 2006 there was microscopic lymph node spread. No findings were made as to metastatic spread.

On the basis of the AJCC staging the Claimant was stage 3b in March 2006 which statistically meant chances of survival were less than 50% but around 40%. He was stage 3c in October 2006 which statistically reduced his chances of survival. The difference when considering the median average from the statistics in number of years survived falls from 7.5 years for stage 3b to 4 years for stage 3c.

### **Discussion**

Ignoring limitation issues, imagine that you were presented with the facts and not the medical findings made by the court (this was a real case). Which expert(s) is the Claimant likely to require and what issues should they cover?

Does the Claimant have good prospects on breach of duty and if so, what is the likely date of the breach(es)?

Would it be any different if the Claimant had gone to the GP and not described any growth in the lesion?

Would it make any difference if the Claimant had said that he had tingling or reduced feeling in the lesion area?

Is there a good claim on causation and if so on what basis?

Can he prove that he would have survived but for the breach?

Has he lost years as result of the breach?

Would it be any different if the evidence showed that in March 2006 median chances of survival were 52%?

Would it make any difference if the Claimant had recovered fully from his melanoma but suffered a relapse two years later for which his prospects of survival were 20%?

Would it make a difference if the Claimant's lesion was a rare form of melanoma?