Delayed diagnosis of cancer

Thematic review

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Executive summary

Delayed diagnosis of cancer: Thematic review **presents the findings of a project at the National Patient Safety Agency (NPSA) which was designed to explore issues of patient safety around delayed diagnosis of cancer, and provide the NHS with potential solutions.**

Three main methods were used in this project:
- Literature review (English language publications since the year 2000);
- Review of incidents reported to the NPSA's National Reporting and Learning System (NRLS);
- Consultation with stakeholders (focus groups, discussions and presentations).

Additionally, consideration was given to other sources of patient safety data such as complaints, litigation and audits.

National Reporting and Learning System (NRLS) analysis

During one year (June 2007 to May 2008) around 1,650 patient safety incidents were reported to the NRLS relating to actual or potential delayed cancer diagnosis. This will be an underestimate of the total number of incidents because of the reporting bias inherent in voluntary reporting systems, especially in primary care where the level of reporting is very low (constituting only 0.4% of all patient safety incidents reported nationally). With approximately 294,000 people diagnosed with cancer in the UK per year, this represents a small but nonetheless important issue.

Of the patient safety incidents reported to the NRLS, 508 were considered in detail. Of these, 89 (17%) were reported as resulting in death (2), severe harm (25) or moderate harm (62). However, degree of harm was very difficult to assess because the consequences of any delay in cancer diagnosis may not be known.

Detail of the estimated length of delay was available for 150 of these patient safety incidents. In 37 (25%) cases the delay was less than one month, with 56 (37%) showing delays of 1-3 months and 57 (38%) showing delays of more than three months, with a maximum delay of up to three years.

The site of the primary tumour was indicated in 294 patient safety incident reports. The most common tumour group was gynaecological (17%), followed by skin (16%), urological (15%), breast (12%), lower GI (10%) and lung (9%).

The types of patient safety incident were classified as relating to:
- Diagnostics (53%)
  - Pathology (41%)
  - Radiology (12%)
- Communication (26%)
- Cancellations (15%)
- Clinical assessment (5%)
- Waiting lists (<1%)

Patient safety incidents relating to pathology were broken down into those occurring pre-laboratory (47%), in-laboratory (44%) and post-laboratory (9%). Pre-laboratory problems included incorrect labelling, poor preservation of specimens and transport issues. In-laboratory problems included reporting delays, reporting errors and processing errors.

Post-laboratory problems were primarily related to results not being communicated or acted upon by clinical teams.

Patient safety incidents relating to radiology were primarily concerned with failures in the communication of results and reporting delay. Communication problems related to the communication of accurate and relevant patient information in a timely fashion, referrals and communication of results. Diagnostic and communication problems highlighted deficiencies in processes to ensure action is taken to track investigations and act on results. Cancellations of surgery and procedures due to inadequate preparation and clinic appointments were also seen to cause delays.

Although failures in clinical assessment was seen in only 5% of cases in this review, that is probably a reflection of reporting culture. Data from other sources was used to demonstrate this concern more accurately.

Consultation with stakeholders

Consultation with stakeholders took the form of two focus group events (one in Manchester, one in London), involving 50 participants recruited through Cancer Networks (including patients, carers, healthcare professionals and commissioners), direct discussions with Cancer Network representatives and feedback from presentations at two national early diagnosis meetings. Key issues from these workshops and discussions included:

- doctor-patient communication, for example patients not feeling that GPs were listening to them;
- poor communication between care settings;
- poor clinical assessment and management, with guidelines not being followed;
- cultural issues – patients adopting a passive role and not feeling empowered to challenge health professionals;
- lack of a patient safety culture in primary care.

Additional sources of information

Three additional sources of information on delays were reviewed and related primarily to primary care:

- A report from the Medical Defence Union (2003). This showed that more than half the claims settled against GPs were for delayed diagnosis. The major risk area was cancer.
- An analysis of 1,000 cases of delayed or missed diagnosis published by the Medical Protection Society. Again, cancer formed the largest category.
- Reports from the Scottish Primary Care Cancer Group analysing 4,181 cases of cancer diagnosed in 2006 and 2007 and 7,430 between 2007 and 2008. These reports provide data on average patient delays and GP delays by tumour type.

Recommendations

This report makes five broad recommendations (described in detail from page 36):

1. Development of an accessible diagnostic tool for use in primary care.
2. Identify, review and disseminate good practice in the process of ordering, managing and tracking tests and test results.
3. Review and develop methods for empowering patients who may be on a cancer diagnostic pathway.
4. Develop a model for stronger leadership and improved patient safety reporting and learning, including Significant Event Audit (SEA), at a local and national level.
5. Develop indicators of delayed diagnosis for routine monitoring.

1. Introduction and background

The National Patient Safety Agency (NPSA) began a programme of work in 2007 to improve patient safety in cancer. The programme consists of three main areas: radiotherapy, chemotherapy and delayed diagnosis.[1]

This review forms part of the NPSA's work on the theme of delayed diagnosis, and aims to:

- scope the patient safety issues related to delayed diagnosis of cancer;
- identify potential solutions for delayed diagnosis of cancer;
- develop patient safety recommendations for earlier diagnosis of cancer;
- make recommendations for improvement to practitioners and policy makers.

Every year around 294,000 people in the UK will be diagnosed with cancer and around 155,000 will die from the disease.[2] It is the leading cause of mortality in people under the age of 75.[3]

Cancer mortality and late diagnosis

Outcomes for people with cancer are improving in the UK. In England, cancer mortality in people under 75 years of age fell by over 17% between 1996 and 2005; equating to approximately 60,000 lives saved over this period. Wales also reports 'real improvements in cancer survival'.[4] However, although there may be difficulties in interpreting cancer data between countries because of differing data coverage and collection methods, there are concerns that outcomes in the UK are not as good as many other European countries[5] or North America. The EUROCARE-4 cancer survey showed that the UK ranked 9th for male cancer mortality rates (where first equals lowest rates), and 22nd for female cancer mortality rates, compared with 27 other European countries.[6]

Although treatment availability, quality of care, screening programmes and the effectiveness of public health initiatives are among the factors likely to be implicated in survival rates, late or missed diagnosis has been suggested as a major contributor to the UK's ranking.[3] Cancers are diagnosed at a more advanced stage in the UK compared with other European countries: in the National Cancer Research Institute 2008 conference public lecture, Professor Michel Coleman noted that, by taking out of the EUROCARE statistics all women who die within a year of diagnosis of breast cancer (since their cancer was likely to have been diagnosed at an advanced stage), survival rates in the UK fall into line with the European average.[7] The implication is that late diagnoses are responsible for the lower UK figures.

Cancer survival is an important issue but delayed diagnosis can also have a negative effect on quality of life, with the use of more toxic treatments when cancer is diagnosed at an advanced stage and an increase in psychological distress.[8]

Cancer strategies in England and Wales

Cancer Services in Wales[9] was published in 1996 and represented Wales' first national cancer plan. *Designed to Tackle Cancer in Wales*[10] was published at the end of 2006 with the aim of improving cancer care in Wales. It presented a three year strategic framework for improvement, and a vision for 2015 in which early detection and improved access to diagnosis were highlighted as priorities. Reducing the delay to diagnosis was specifically underlined as a necessity if outcomes in Wales are to be improved.

The NHS Cancer Plan[11] for England was published at the end of 2000 and set out a comprehensive 10 year strategy to improve prevention, screening, early diagnosis and treatment

for cancer. The *Cancer Reform Strategy (CRS)*[3] was published at the end of 2007 to build upon the achievements of the *NHS Cancer Plan* and set the direction for the next five years. Early diagnosis of cancer was highlighted as one of the most significant challenges to be addressed.

National Awareness and Early Diagnosis Initiative (NAEDI)

The National Awareness and Early Diagnosis Initiative (NAEDI) was announced in the CRS and launched formally in November 2008. NAEDI is led jointly by the Department of Health (DH) and Cancer Research UK.[12]

NAEDI works across nine areas of activity:
- Measuring public awareness of cancer
- Promoting earlier presentation
- Reducing primary care delay
- Key messages
- Review of the evidence base
- International comparisons
- New research
- Diagnostics
- Health economics

The NPSA programme of work on late diagnoses of cancer informs the NAEDI steering group. This project excluded the other workstreams already covered by NAEDI, including public awareness of symptoms and the national audit of cancer diagnosis in primary care led by the Royal College of General Practitioners (RCGP).[13]

What is meant by delayed diagnosis of cancer?

What constitutes a delayed diagnosis and the effect of that delay is a complex and much debated issue in cancer. Cancer diagnoses are made on screening, as incidental findings and following the presentation of an individual with symptoms to a healthcare practitioner. A delay in diagnosis can occur for many reasons. For example: when an individual does not attend for screening; when the screening service does not diagnose the cancer or initiate a treatment pathway; when an incidental finding is not appropriately acted upon; when an individual does not recognise a symptom of cancer; when an individual with symptoms does not seek healthcare advice or when a healthcare practitioner or system fails to detect a cancer or initiate a treatment pathway. For this project, a working definition of the concept of delayed diagnosis was developed:

Delayed diagnosis in cancer is when someone who has cancer:
- is not investigated or referred for investigation; *or*
- having been investigated, is not diagnosed at the time of the investigation; *or*
- is diagnosed incorrectly; *or*
- where a positive test result or diagnosis is not communicated effectively to a clinician with the ability to act on the information; *or*
- where a positive test result or diagnosis is not acted upon and treatment commenced as appropriate.

Delays may occur at different stages of the cancer diagnostic journey and have been commonly defined as being either patient focused or healthcare provider focused.[14] One of the most influential models for describing delay was proposed by Andersen et al. in 1995.[15] This model of 'total patient delay' described six stages from the individual detecting signs and symptoms, through to beginning treatment. A number of types of delay were posited in this model:

- Appraisal   – delay in symptom interpretation
- Illness   – delay in decision to seek medical attention
- Behavioural – delay in making an appointment
- Scheduling   – delay in time from making appointment to being seen
- Treatment   – delay in receiving treatment

In Andersen's model, the emphasis is on 'patient delay' rather than delays which occur later in the pathway; four stages of the delay are attributable to the patient and only the fifth stage is attributable to healthcare providers. Indeed, research has tended to focus on delays attributable to patients and, as a result, delay is often ascribed to patients because that is where there is evidence. Yet this conclusion may be an artefact of the research focus; delays further along the pathway are likely to be significant, have been underestimated and under researched.[16]

Some studies have defined a series of delays that relate not only to patients, but also to providers in primary and secondary care. Hansen et al. describe three overall categories of delay in the cancer diagnostic pathway:[17]

- Patient delay;
- Doctor delay – primarily seen as primary care practitioner delay;
- System delay – primarily seen as hospital or secondary care delay.

These overall categories are further broken down and graphically portrayed in Figure 1:
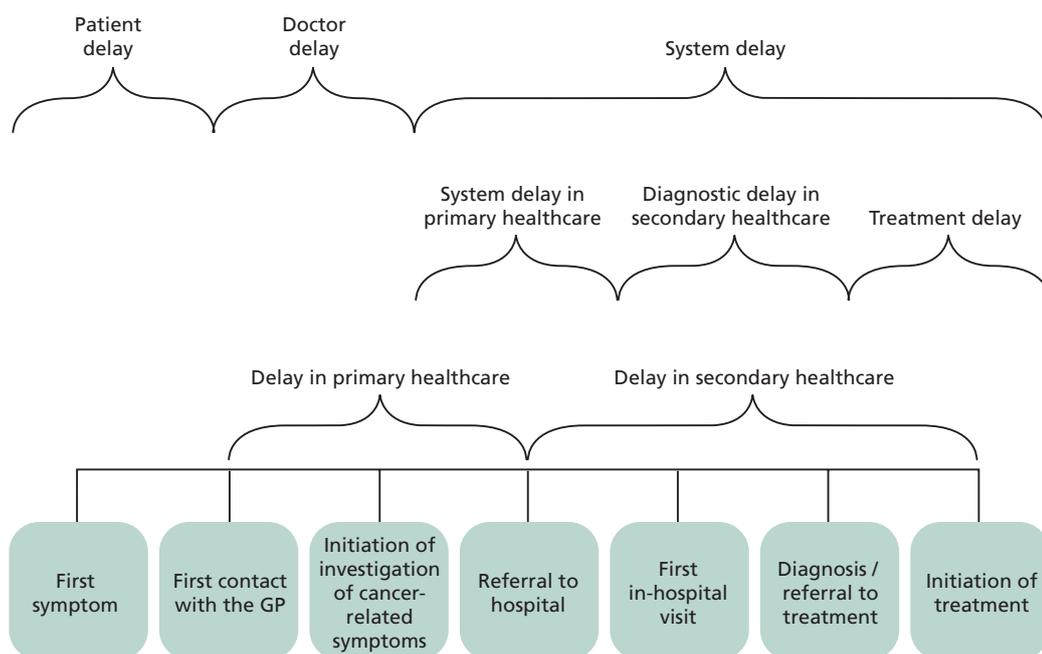
Figure 1: Categorisation of diagnostic delay

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BMC Health Serv Res 2008; 8: 49.

This NPSA review uses Hansen's model as an analytical framework to understand risks to patient safety in the diagnostic pathway. Hansen et al. use the term 'doctor delay' to represent healthcare practitioner delays in primary care. The term healthcare practitioner will be used in this review to encompass the many practitioners that are involved in giving healthcare advice and assessment in the UK, such as dentists, nurses, opticians, pharmacists etc. It is worth noting that diagnosis is a process that can be complex, and will include detection of malignancy, defining of primary site and tumour type, together with the extent of the disease or stage. Diagnostic testing and work-up can include biochemistry, histopathology and imaging, as well as surgical interventions that may also be definitive treatments. Individuals with cancer will present to primary care practitioners and directly to secondary care.

2. Methods

Three main methods were employed in this review project:
1. **A focused literature review: to provide updated evidence on causes of, and solutions to, late diagnosis.**
2. **A systematic interrogation of the NPSA's National Reporting and Learning System (NRLS): to identify patient safety incidents in relation to delayed or missed cancer diagnoses.**
3. **Consultation with stakeholders: to improve our understanding of what goes wrong, what works, and what improvements could be made to support early diagnosis.**

Other relevant sources of information, where reports of patient safety incidents might be received and recorded, such as the NHS Litigation Authority, the Medical Defence Union (MDU) and the Medical Protection Society (MPS), were also considered.

Focused review of the literature

A focused review of literature to September 2008 was undertaken to identify factors contributing to delayed diagnosis of cancers, the various types of cancer involved and any models, tools or approaches developed to improve cancer diagnosis. The initial literature search was limited to research published in the English language since the year 2000, which saw the publication of the *NHS Cancer Plan* and significant changes in cancer services (although it is recognised that papers published in 2000 represent data collected prior to that date).[11] Peer-reviewed published literature, web-based publications and some of the 'grey' literature, such as conference proceedings, dissertations, clinical trial registrations, guidelines and protocols, were also reviewed.

Review of incidents reported to the National Reporting and Learning System (NRLS)

The NPSA's NRLS holds a unique data set to help understand provider and system delays to diagnosing cancer. The NRLS is a voluntary reporting system to collect and learn from patient safety incidents. A patient safety incident is defined as:

"Any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care".[18]

Patient safety incidents are reported by individual NHS staff through local trust risk management systems and web based e-forms. Patients and carers can also report directly through an open access e-form. The NRLS was set up in 2003 and there are now more than three million incident reports on the database.

Local risk management systems remain the dominant route for submitting reports to the NRLS; the proportion of reports submitted through this route has not dropped below 98% since 2004. Generally speaking, the local reporting culture is more established in acute and mental health hospitals than in primary care; even within primary care, general practices are much less likely to report incidents than community services.

The NRLS is a confidential reporting system and the individual reports are not investigated or verified by the NPSA. Since these incidents are self-reported they are not necessarily

representative of the NHS across England and Wales and therefore need interpreting with care. In particular, it may not be appropriate to use these figures for describing the actual level of occurrence for incident types, as voluntary systems are known to be inherently biased.

Of particular importance here is the lack of reporting culture in primary care compared with acute hospitals, which means that any analysis will show only a small proportion of incidents in primary care, and from general practice in particular. Nevertheless, the findings do represent actual events and problems that have occurred. It is also important to note that not all people diagnosed with cancer come through the urgent GP referral route; patients are also referred through routine non-cancer pathways and referrals within secondary care.

Using lessons learnt from a preliminary data analysis, a full search of the NRLS was undertaken for patient safety incidents occurring between 1 June 2007 and 31 May 2008 using a range of search terms.[19] By making the search terms inclusive it was anticipated that a significant number of the incidents identified would not be relevant. However, if any of the search terms were removed, relevant incidents were lost. A random sample (n=1,500) of the total number of patient safety incidents (n=4,855) was, therefore, analysed in detail to ascertain relevance as follows:

- **Diagnostic delay:** patient safety incidents indicating a definite or probable delay in diagnosing cancer or potential cancer;
- **High risk:** patient safety incidents representing a risk of delay to cancer diagnosis but without enough details to confirm an actual diagnostic delay;
- **Not relevant or unclear:** patient safety incidents not indicating a diagnostic delay and/ or cancer.

A separate search on the phrase 'two week wait/delay' was also undertaken. This returned relevant reports that would not have been identified in the main search and are referred to throughout this analysis.

Consultation with stakeholders

Members of Cancer Networks in England and Wales were invited to regional focus groups facilitated by the project team. The aims of the focus groups were to:

- develop an understanding of the issues associated with late diagnosis;
- generate illustrative examples of problems and issues in the local diagnostic pathway;
- work with cancer specialists regionally to identify and test out ways to improve early diagnosis and patient safety reporting around late diagnosis;
- generate examples of good practice, tools, and improved processes, including better data sources and data capture, that could be generalised and/or shared nationally to improve patient safety in cancer.

Additionally, the project team presented early findings, facilitated workshops and listened to participants at national events, including the NAEDI launch and the 10th annual Britain Against Cancer conference.[20] Finally, national leaders in cancer were consulted in focused discussions.

3. Findings from the literature review

The literature on delay in cancer diagnosis is extensive. While it was not within the scope of this thematic review to provide a complete systematic review of the existing literature, an overview of different areas researched on delay in cancer diagnosis and key findings was collated.

The aim of this overview was to direct and enhance the consultation with stakeholders, complement the findings from the NRLS data and provide an indication of how and where risks were most likely to occur along the cancer diagnostic pathway. In addition, the literature highlights risks of delay in relation to varying tumour sites/tumour groups, although there is evidence to suggest that some cancers have been studied more extensively than others.[21] This section sets out the key findings of the NPSA literature review and will be presented following Hansen's model of patient delay, practitioner delay and system delay, as discussed in section 1.

Patient delay

Patient delay is generally defined as the length of time an individual will be aware of symptoms before seeking healthcare practitioner advice. Most of the literature reviewed focused on patient delay in the diagnostic journey and highlighted the following risk factors:

- symptom recognition and interpretation;
- psychological factors;
- socio-demographic and ethnicity factors.

Symptom recognition and interpretation

The manner in which individuals interpret and label their symptoms has been shown to influence help-seeking behaviour in a wide range of illnesses including cancer. It has been suggested that symptom recognition accounts for at least 60% of the total delay in cancer treatment in women with breast and gynaecological cancer.[22] Vague or non-specific symptoms are more likely to be attributed to everyday explanations such as indigestion, old age or the menopause.[23] For example, in a study of oral and pharyngeal cancers, Brouha et al. found that most patients attributed their pharyngeal cancer to a common cold or infection and their oral cancer to an infection or dental problems.[24] However, well recognised specific symptoms are more likely to lead to prompt recognition of serious illness.[24] For example, a survey of 996 women concerning breast cancer knowledge showed that a painless breast lump was widely recognised as a significant symptom, but non-lump breast symptoms were less likely to be attributed to breast cancer.[25]

Individuals who do not identify symptoms as cancer are more likely to delay seeking healthcare advice than those who do.[26,27] A population-based study of breast cancer patients found that just over half of the patients delayed seeking a doctor's advice for more than a month because they considered their symptoms to be harmless.[28] In another example, 53% of the patients found to have oral cancer waited 31 days before seeking help from a healthcare practitioner, and 39% waited more than three months because they attributed the symptoms to minor, self correcting conditions.[29]

Psychological and behavioural factors

A link has been suggested between psychological factors and help-seeking behaviour in healthcare. Cancer can be associated with pain, suffering and death.[24] In a Cancer Research UK

survey in 2007, cancer was shown to be the number one fear; topping the list over Alzheimer's disease, heart attacks and terrorism.[30]

In several studies, fear and anxiety have been shown to impact on patient delay.[24,28,31] In a qualitative literature review by Smith et al., fear of cancer and fear of embarrassment were identified as key factors contributing to delay in patient presentation to a healthcare practitioner.[23] The anxiety associated with recognising a potential cancer symptom has also been shown to result in delayed presentation.[32]

Guilt and fear of medical judgement were considered by Tromp et al. as two psychological factors that might explain patient delay in patients who drank five or more alcoholic drinks per day.[33] However, Brouha et al. found no relationship between smoking and alcohol consumption and patient delay in oral and pharyngeal cancer.[24]

Socio-demographic and ethnicity factors

Research on the relationship between socio-demographic factors and patient delay has shown mixed results. For example, Brouha et al. found no association between marital status, living situation (alone or with family), education or income, and patient delay for oral or pharyngeal cancer.[24] A systematic review of 54 studies looking at delays in the diagnosis of colorectal cancer found little evidence that age, gender or socio-economic status had an effect on patient delay.[32] Hansen et al. found that women who were employed and those who smoked experienced longer patient delay than women who were retired and those who did not smoke, but demonstrated no specific socio-economic predictors for patient delay in men.[17]

Age was identified as an important socio-demographic factor, being older has been cited as a factor leading to delay patient.[34,29] In breast cancer, older women are not only more at risk of developing the disease, but have also been shown to have poorer knowledge about breast cancer risks and symptoms and are more likely to delay presentation to a healthcare provider.[26] However, the previously held view that the elderly under-consult and are less likely to seek help for symptoms that are not causing pain or disrupting functionality, was dismissed by a review in 1985.[35]

Research examining the impact of cultural and ethnic factors on patient delay has identified how such factors may contribute to late presentation of cancer. Breast cancer examination can be difficult for religious Muslim women; Islamic laws prohibit nudity and self exposure in front of any man other than one's husband. Lack of availability of female doctors was seen as a deterrent for Muslim women accessing breast screening services.[36] Following culturally tailored interventions for Israeli-Arab women, marked improvements were found in the number of women who presented for breast cancer screening.[37]

Healthcare practitioner or provider delay

This is the interval between first consultation with a healthcare provider and referral for diagnostic tests or specialist assessment. Some authors refer to this phase of delay as primary care delay or delay in general practice. When assessing potential delays on the diagnostic pathway, healthcare provider delay is under-estimated and under-researched. Some of the factors contributing to provider or practitioner delay include:

* symptom misattribution;
* no examination or investigation of malignancy;
* co-morbidity;
* patient characteristics.

In the systematic review by Mitchell et al., healthcare provider delay related to initial misdiagnosis and insufficient examination by the practitioner, was the most commonly occurring theme associated with delay in referral.[32]

A study of women subsequently diagnosed with ovarian cancer reported that GPs did not investigate their symptoms thoroughly or alternatively attributed their symptoms to a non-cancer cause and treat accordingly.[16] In a separate study of 132 women with ovarian cancer who were surveyed by the charity Target Ovarian Cancer, over 60% experienced difficulties with diagnosis and over a third visited their GP with symptoms between three and five times. Almost two-thirds of the women expressed a concern that the GP had not taken their issues seriously.[38] Inconclusive or false negative test results have also been seen as factors causing delays.[32]

Data from the *National Survey of NHS Patients: Cancer* found that patients who did not see their GP prior to diagnosis (those attending screening, presenting to A&E or secondary care) had shorter delays in all six cancer groups studied, than those who did see their GP.[39] Co-morbidity may contribute to delay with GPs attributing the symptoms to the existing disease. In a study of lung cancer, co-morbidity delayed the diagnosis in just over 20% of patients.[40] However, co-morbidity has also been shown to prompt earlier referrals[41] while having no impact for others.[42]

Patient characteristics have also been identified as having some influence on provider delay. Hanson et al. found that men experienced longer doctor delays, and women with a larger household fortune experienced the shortest delay.[17] The Mitchel et al. review of colorectal cancer delay found that older people, those from higher social classes and higher socio-economic groups were referred more quickly, although the findings were inconclusive regarding gender.[32]

System delay

System delay refers to the interval between referral and definite diagnosis or treatment. This includes waiting times for tests in secondary care, further investigations of symptoms in secondary or specialist care, and administration. It is under-researched but there is evidence to suggest that, even with improved diagnostic and treatment pathways in cancer, there are still problems with:

- waiting times for tests;
- waiting times for non-urgent referrals;
- administrative delays for follow up (leading to increased patient delays).

Both the DH and the Welsh Assembly Government (WAG) have strong commitments to ensure that patients with suspected cancer are seen by a specialist within two weeks.[10,11] However, not all patients with cancer are referred for further tests or consultations.

In the Bjerager et al. study of diagnostic delay for lung cancer patients in primary care, waiting times for tests was highlighted as a key reason for delay. This system delay ranged from one to 57 days, with a median of 14 days, and was due mainly to waiting times for chest x-rays (some of which were conducted in primary care, median delay was longer for tests carried out in secondary care). The lack of explicit follow-up appointments were also shown in this study to have prolonged the delay for 11% of lung cancer patients who waited for up to seven months to consult their GP again.[41]

Davies et al. used clinical audits, qualitative data from patients and feedback from GPs to identify possible delays in referral for colorectal cancer patients. The analysis revealed problems with communication, information and support about diagnosis, with most delays occurring in secondary care, often after non-urgent referrals. Implementing referral guidelines and developing a faxable urgent referral pro forma along with educational meetings reduced average waiting times.[43]

Tumour site

Much of the research identified related to specific tumour sites; delays to diagnosis may have different consequences depending on tumour site. Delayed presentation of symptomatic breast cancer of three months or more is associated with lower survival rates. Richards et al. reported that patients with a delay of three months or more had a 12% lower five year survival than those without delay.[44] Colorectal cancer survival rates vary according to the stage of disease at diagnosis: the 90% five year survival rate for early cancers falls to 15% for advanced tumours.[45] Patients whose initial symptoms of tongue and glottic cancer were overlooked by their GPs were at significantly increased risk of death at three years compared with patients initially referred or followed-up.[46] However, delays between referral and diagnosis may not always be associated with a poorer prognosis.[47]

Different cancers have different referral routes, which will have important implications for how delay in diagnosis is mitigated. Barratt et al. examined the route to diagnosis for individuals with lung cancer. They found that only 28% followed the urgent cancer referral pathway. While 68% were referred to outpatients, less than half were referred to a respiratory department. More than a fifth were admitted as an emergency, having previously described a lung cancer symptom to their doctor. While the interval from first symptom to referral was similar across the different pathways, the referral to diagnosis interval was significantly longer in patients misdirected to other outpatient departments (66 days) than those sent to respiratory clinics (29 days) or admitted as an emergency (16 days).[48]

Childhood cancers

There appears to be less research specifically on delay in childhood cancers. While delays tend to be shorter for children, there are nonetheless specific problems for children and young people in getting a diagnosis, especially at the point of healthcare practitioner delay. Findings from a survey conducted at the annual Teenage Cancer Trust 'Find your Sense of Tumour' conference for teenagers and young people with cancer reported in the CRS[3], revealed that over a third of young people visited their GP with cancer symptoms five times before being referred to a specialist. Despite the fact that no age data was provided for the teenagers and young people surveyed, this finding is in line with evidence to suggest that younger children have less delay than older children.[49]

In addition to factors such as age, the literature suggests that the two main issues that contribute to delayed diagnosis in children and young people are misattribution of symptoms and the role of parents (and the relationships between doctors and parents). Timely diagnosis of cancer in children is difficult due to misinterpretation of symptoms by patients, parents and healthcare practitioners alike. Both parent delay in seeking healthcare advice and practitioner delay in diagnosis has been related to uncommon clinical presentation of symptoms, but symptom misattribution by healthcare provider caused longer delays.[50] For example, another study by the same authors found a median patient delay of nine days, but a median healthcare provider delay of 30 days (ranging up to 69 days).[50]

A qualitative study of parents of children and young people found that parents recognised something was wrong with their child, despite early symptoms often being vague, partly because of changes in their child's behaviour and mood. Yet they felt doctors tended to discount their views and fail to see the seriousness of the child's symptoms. In some cases disputes opened up between parents and doctors.[51]

4. Findings from the National Reporting and Learning System (NRLS)

Overview

A total of 4,855 patient safety incidents from the NRLS meeting our search criteria were identified for the 12 month period 1 June 2007 to 31 May 2008. A computer-generated random sample of 1,500 incidents were individually reviewed. A detailed analysis of the data was carried out.[19]

The project team regrouped the incidents as follows:
- Group 1 (diagnostic delay): 388 reports (26%)
- Group 2 (high risk of diagnostic delay): 120 reports (8%)
- Group 3 (not relevant): 992 reports (66%)

Group 3 incidents were excluded from the analysis. They included reports where it was clear that the investigation or abnormality was not related to cancer; where the mention of the oncology team was irrelevant to the incident; or where the incident concerned cancer treatment or palliative care rather than diagnosis.

Incidents from groups 1 and 2 were included in the analysis. These amounted to a total of 508 incidents. Extrapolating from the random sample[52] suggests that:

Between 1 June 2007 and 31 May 2008 there were approximately 1,650 patient safety incidents reported to the NRLS relating to actual or potential delayed diagnosis.

Groups 1 and 2 were differentiated in this final report because some aspects of the patient safety incident reports in group 2 meant that it was not possible to be certain the incidents constituted delays in diagnosis.

There is a fine line between groups 1 and 2; all are patient safety incidents that have the potential to put patient safety at risk. Many of the patient safety incidents in the high risk group were not in group 1 simply because there was not enough information in the report to establish whether a delay had actually happened.

Note: The examples in the following boxes represent text taken from the incident reports. They have been altered to remove identifiable data, grammar and spelling has been corrected and shorthand elaborated on to aid understanding, but they essentially remain the words of the individual making the report.

Group 1 represents actual delays, as illustrated by the example in box 1:

Box 1: Specimen unable to be processed in pathology (Group 1: diagnostic delay)

> *Breast core specimens were left in the faxitron machine after x-ray and not put in the specimen pot for sending to Pathology. This resulted in a delay of almost 24hrs before pathology received the specimen. The specimen had 'dried out ' and was unable to be processed; therefore the diagnosis is inadequate and the patient will need another biopsy.*

Examples from Group 2 are shown in boxes 2 and 3:

> *MRI request received in MR dated 10th January. Patient sent appointment date for 27th February. Patient rang the breast team to say she knew nothing about having an MRI. Following enquiries by the breast cancer nurse it was discovered that the appointment was intended for another patient*

The incident in box 2 presents a risk of diagnostic delay to the patient who should have received the appointment letter. However, there was no way of knowing whether there was a delay or whether in fact the correct patient was sent a timely appointment (or indeed could have had the original appointment).

> *Trus (transrectal ultrasound) biopsy specimen incorrectly labelled with another patient's name and number*

Similarly, the patient safety incident in box 3 describes a mis-labelled specimen. The wrong label was spotted and reported as a patient safety incident; however, it is not known whether the correct patient's specimen was received at the laboratory and dealt with appropriately. Nevertheless, there is a risk that the specimen was not matched up with the correct patient resulting in a diagnostic delay.

Length of delay and degree of harm

Detail of the length of delay was provided in only 150 of the incident reports. However, where data were available, diagnostic delays ranged from one day to over two years. It is likely, although not inevitable, that longer delays will cause greater harm. Figure 2 shows the estimated length of delay where an indication was provided:
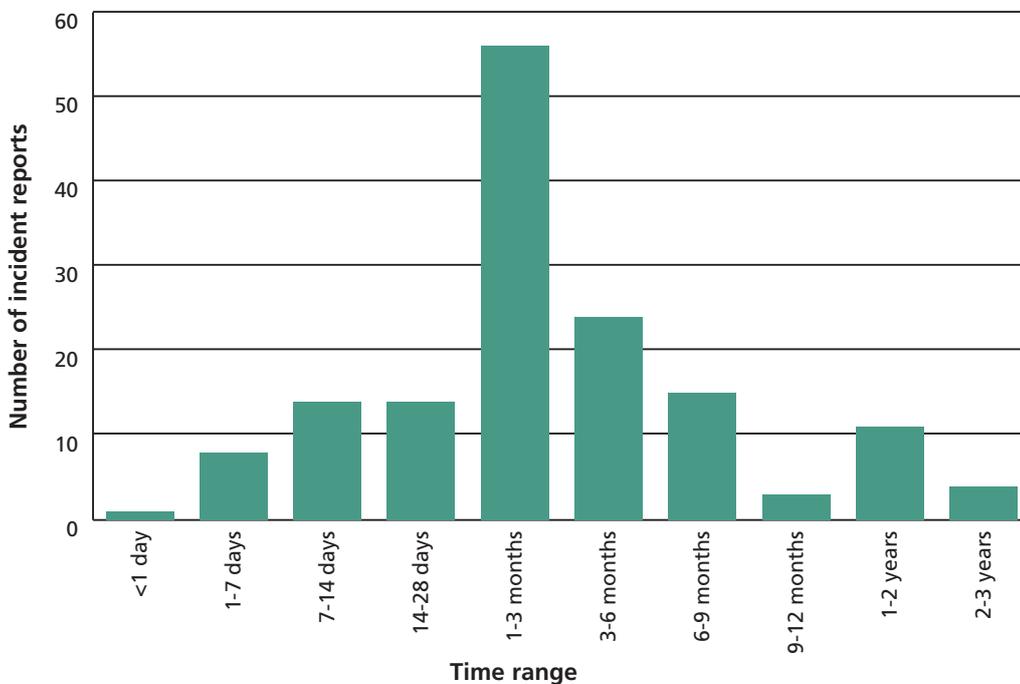
Figure 2: Estimated delay where indicated (150 of the 508 incidents relating to actual or potential delay in cancer diagnosis: a random sample of NRLS data from 1 June 2007 to 31 May 2008)

The degree of harm caused by the patient safety incident is estimated by the person reporting the incident. Most patient safety incidents reported to the NRLS are described as causing little or no harm, which is consistent with the data reviewed for this report, as shown in table 1. There were 331 incidents described as 'no harm' and a further 88 as 'low harm'. Twenty-five incidents were described as severe harm with an additional two resulting in death. The deaths and severe harms were in group 1 (diagnostic delay) and represented 7% of those incidents.

Table 1: Degree of harm (random sample of NRLS data from 1 June 2007 to 31 March 2008 relating to an actual or potential delay in cancer diagnosis)

	Percentage of incidents (number in sample)	
Death	<1%	(2)
Severe harm	5%	(25)
Moderate harm	12%	(62)
Low harm	17%	(88)
No harm	65%	(331)
Total	100%	(508)

Examples of incidents resulting in severe and moderate harm are shown in boxes 4 and 5:

Box 4: An incident reported as severe harm

> *A lady was referred urgently by the general practitioner to a consultant dermatologist in August 2006. She was seen in November 2006, diagnosed with a "sebaceous cyst" and referred on to a general surgeon. Nothing happened and the general surgeon was not aware of the referral. The general practitioner then referred again in July 2007 to the breast clinic. The patient was seen in 5 days and diagnosed with a 4.3cm invasive ductal carcinoma, grade 2. The specialist said there were no features of a sebaceous cyst whatsoever and reported that this was a significant delay in this lady's diagnosis of around 12 months.*

Box 5: An incident reported as moderate harm

> *A 76-year old patient experienced a 6 month delay in the diagnosis of melanoma to the foot, resulting in what was described as 'moderate harm'. The person had been referred from community podiatry with a non-healing right heel ulcer. Reviewed by two medical consultants who both agreed on diagnosis and treatment for diabetic foot ulcer. After a few visits the ulcer remained non-healing. Patient was then referred to a dermatologist who initially agreed with the diagnosis. However, on the second review of the patient in dermatology clinic, the dermatologist biopsied the wound and diagnosed melanoma.*

It is worth noting that it is likely to be difficult to predict degree of harm on an incident report that is completed before the outcome of investigations and treatments are known (see box 6). In cancer cases, the person may be in an advanced stage of the disease before the error comes to light or the error may lead to an increased risk of cancer recurrence. Further, some types of 'harm' are not considered as severe, because they are not life-threatening or disabling, despite resulting in notable emotional and/or physical distress (see box 7).

Box 6: An incident reported as no harm without knowledge of further test results

> *A barium enema was requested by clinic last year and was carried out on this person in October 2006. The result was not sent to the surgeon's office nor was it made available until August 2007. The patient was recalled immediately and, on further investigation, has been found to have a stricturing lesion which may be malignant.*

Box 7: Examples of incidents where disease consequences are unknown but likely to cause emotional distress and reported as no harm

> - *The patient's operation was cancelled due to lack of theatre staff. The patient and family were upset and enquiring about the risk of cancer spreading.*
> - *There was a delay in the patient receiving a follow-up appointment after vulval biopsy. Treatment has been delayed as a result.*

Patient group and tumour site

Age, gender or tumour site were not provided on all patient safety incident reports in the NRLS. Age was not provided in 185 (36%) cases but, where it was provided, all ages were represented in the data, with a fairly even distribution between the ages of 36 and 85 years. A small group of incidents were reported as involving children and young people under the age of 18 (n=18), including three babies under the age of one year, although sometimes the free text did not match up with the age range listed. The largest groups implicated were the 56 to 65 year olds and 66 to 75 year olds (figure 3).
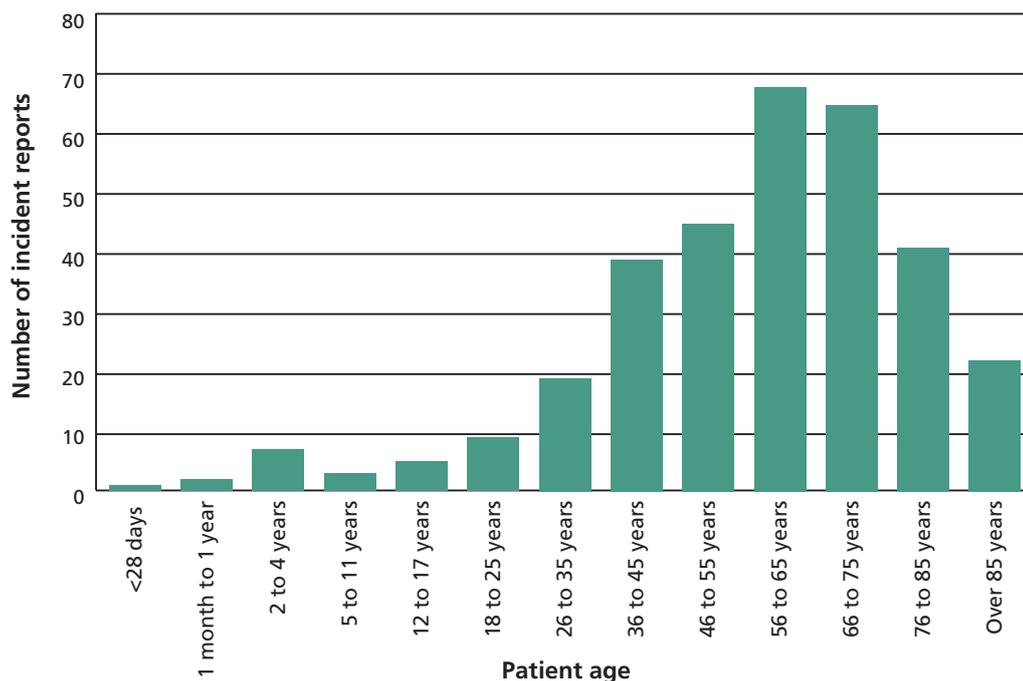
Figure 3. Incident report by age range (326 of the 508 incidents relating to actual or potential delay in cancer diagnosis: a random sample of NRLS data from 1 June 2007 to 31 May 2008)

Gender was included in 330 of the incident reports and was listed as 185 female and 148 male.

In 214 incidents there was no indication of tumour site, but where available the data showed that a range of tumour sites were affected, as shown in table 2. The three most frequently cited tumour sites/groups were gynaecological, skin and urological.

Table 2: Tumour sites where indicated as reported in incidents of actual or potential delay in cancer diagnosis: random sample of NRLS data from 1 June to 31 May 2008 (due to rounding down of percentages they may not all add up to 100%)

Tumour site	Group 1: Diagnostic delay (%)	Group 2: High risk (%)	Total (%)
Gynaecological	36 (9)	15 (12)	51 (10)
Skin	34 (9)	12 (10)	46 (9)
Urological	35 (9)	9 (7)	44 (9)
Breast	23 (6)	13 (11)	36 (7)
Lower gastrointestinal	26 (7)	3 (2)	29 (6)
Lung	23 (6)	3 (2)	26 (5)
Head and neck	18 (5)	1 (<1)	19 (4)
Brain and central nervous system	12 (3)	2 (2)	14 (3)
Upper gastrointestinal	9 (2)	4 (3)	13 (3)
Haematological	10 (3)	1 (<1)	11 (2)
Bone and sarcoma	4(1)	0 (0)	4 (<1)
Other	1 (<1)	0 (0)	1 (<1)
Unknown	157 (40)	57 (47)	214 (42)
Total	**388 (100)**	**120 (100)**	**508 (100)**

NRLS incident types

Because of the inherent reporting bias of the NRLS, almost all of the reported incidents occurred at the point of 'system delay', primarily secondary care. The qualitative analysis of the free text identified several types of incident within this part of the diagnostic pathway where diagnostic delays, or the risk of delay, occurred. These are summarised in table 3:

Table 3: Types of incident in order of frequency as reported in incidents of actual or potential delay in cancer diagnosis: random sample of NRLS data from 1 June to 31 May 2008

Settings or aspects of the pathway	Group 1: Diagnostic delay (%)	Group 2: High risk (%)	Total (%)
Diagnostics	208 (54)	62 (52)	270 (53)
Pathology	149 (38)	58 (48)	207 (41)
Radiology	59 (15)	4 (3)	63 (12)
Communication	84 (22)	48 (40)	132 (26)
Cancellations	65 (17)	10 (8)	75(15)
Clinical assessment	27 (7)	0 (0)	27 (5)
Test waiting list	2 (<1)	0 (0)	2 (<1)
Unknown	2 (<1)	0 (0)	2 (<1)
Total	**388 (100)**	**120 (100)**	**508 (100)**

All categories of incident were analysed in further detail.

Diagnostics

Pathology

Pathology, primarily histopathology, was the largest category of patient safety incident reported in the random sample. It should be remembered that the search terms were designed to find patient safety incidents regarding diagnostic tests that could be associated with cancer, for example biopsy. When considering 'pathology', this report includes incidents related to the complete patient pathway, from the ordering of a test to the taking of a sample, transporting and processing the sample, to the result being acted upon. Table 4 presents a breakdown of a more detailed analysis of these incidents:

	Group 1: Diagnostic delay (%)	Group 2: High risk (%)	Total (%)
Pre-lab problems	62 (42)	31 (53)	93 (45)
In-lab problems	72 (48)	23 (40)	95 (46)
Post-lab problems	15 (10)	3 (5)	18 (9)
Unclear	0 (0)	1 (2)	1 (<1)
Total	**149 (100)**	**58 (100)**	**207 (100)**

Table 4: Breakdown of pathology (primarily histopathology) incidents as reported in a random sample of NRLS data from 1 June 2007 to 31 May 2008 concerning incidents of actual or potential delay in cancer diagnosis

Pre-laboratory incidents (almost half the total number of pathology incidents) included problems with:
- taking samples;
- labelling;
- preserving samples;
- arrival in the laboratory (either delayed or not at all).

Looking separately at patient safety incidents related to 'two week waits', there were incidents where samples were not correctly labelled as urgent and were consequently delayed beyond the two-week time period.

Box 8: Examples of pre-laboratory incidents as reported in a random sample of NRLS data from 1 June 2007 to 31 May 2008 concerning incidents of actual or potential delay in cancer diagnosis

Taking samples: A patient attending for an urgent cancer referral had their pathology results delayed after lab reported receiving an empty specimen pot.

Labelling: A batch of 5 breast biopsies was sent to the histopathology lab. A labelling / numbering error occurred which caused the biopsies from part of one case to be given the lab number of one of the other cases. The error was noted in the lab. Although the investigation identified the blocks most likely to have been affected by the error, DNA testing was requested on all the blocks to confirm. The 5 patients were called to clinic to have blood samples taken to act as reference samples for the DNA testing. The DNA tests… confirmed the expected outcome; only two cases had been affected by the error. These cases were relabelled with the correct numbers and the slides submitted to the pathologist for reporting. The outcome is that five patients had a delay in receiving their biopsy result.

Preserving samples: A patient underwent a mastectomy on 7th August - the time taken on the request card was indicated as 14.30hrs. The specimen was not received in Cellular Pathology until 09.00hrs on 8th August. As a result the specimen was extremely poorly fixed and the preservation of the tumour very poor. This will hinder accurate diagnosis regarding histological grade and may make hormone receptor status impossible to assess.

Arrival in the laboratory: A urine sample was sent on this patient by taxi along with a pleural fluid sample on another patient (for) leukaemia diagnosis….at 11.40. The section rang at 16:00 …to say that the sample had not arrived.

Incidents occurring in the laboratory (46% of the total) included reporting delays of weeks or months or errors in reporting where malignancies were erroneously reported as benign. Processing errors were also noted. Box 9 provides examples:

Box 9: Examples of incidents in the laboratory as reported in a random sample of NRLS data from 1 June 2007 to 31 May 2008 concerning incidents of actual or potential delay in cancer diagnosis

Reporting delay: Tissue sent to the lab on 16th June was not reported until 28th August. The patient in meantime has died. The diagnosis was cancer.

Reporting error: Report on breast core biopsy for Patient A erroneously reported as no evidence of malignancy as pathologist confused slides from this case with another case of Patient B. The error was not detected at the multidisciplinary team meeting because the cases had only just been reported prior to the meeting. This resulted in Patient B with a benign breast condition receiving a malignant diagnosis and subsequently undergoing a wide local excision. Meanwhile, Patient A with malignant breast disease received a benign diagnosis initially and then needed an additional biopsy later to achieve the correct diagnosis.

Processing error: There was a processing malfunction which affected all the biopsies processed overnight …. This particular case was a cervical biopsy. A full report could not be issued. A repeat biopsy was suggested if clinically appropriate.

Post-laboratory incidents included failure to review the results and/or appropriately act upon the result.

The consultant… approached me… to inform me that a biopsy that I had carried out had been filed in this patient's notes. The findings show a basal cell carcinoma. The consultant's concern was that the pathology form had been filed in the notes and there was no evidence that the results had been looked at by a doctor.

Patient attended for 3 month appointment post prostate surgery…Biopsies showed cancer of the prostate but patient unaware and thought that after this length of time everything was ok. Very distressed. Apology and explanation given. Histology sent to secretary for filing…, not signed. Patient given treatment and investigation options…

Box 10: Examples of post-laboratory incidents reported in a random sample of NRLS data from 1 June 2007 to 31 May 2008 concerning incidents of actual or potential delay in cancer diagnosis

Radiology

Radiology issues accounted for 59 diagnostic delays and a further four where the risk of delay was high. These reports were primarily concerned with failures in communication of abnormal results, reporting delay and reporting error. Examples are shown in box 11:

Failure in acting upon abnormal results: *This lady was initially seen in February with post-menopausal bleeding, thought to be a urethral caruncle. However, the ultrasound scan showed endometrial thickness of 6.6mm. Further follow up was not arranged. The lady was found to have cancer of the endometrium in October.*

Report not sent: *The patient was referred to out-patients with epileptic seizures. The patient was seen on 21st September. An MRI took place beginning of October and was reported the next day as a malignant brain tumour. The report was not relayed to the clinician or GP. The GP enquired beginning of November and was given the result. The GP faxed an urgent referral to the specialist. Meanwhile, the patient developed bad headaches as a result of tumour growth and required an emergency admission and surgery.*

Delay in reporting: *Chest x-ray suggesting lung cancer on film obtained on the 1st November 2007. Reported on 24th November 2007. Delivered on 1st February 2008.*

Box 11: Examples of radiology incidents as reported in a random sample of NRLS data from 1 June 2007 to 31 May 2008 concerning incidents of actual or potential delay in cancer diagnosis

There were two incidents specifically concerning the Picture Archives and Communications System (PACS), which is a relatively new system that enables images such as x-rays and scans to be stored electronically and viewed on screens. The system is being rolled out over a three year period from 2007 and it may take some time before related patient safety incidents start being reported. The two incidents are shown in box 12:

- *An earlier examination was reported instead of the current one. This happened because PACS changes the screen on which the current exam is being displayed, at random. This would have led to the patient not being treated for his cancer.*
- *Patient has an attendance for a CT (computerised tomography) Biopsy. It has not been processed (or cancelled) and yet there are not images on PACS.*

Box 12: Examples of incidents concerning the use of PACS in radiology as reported in a random sample of NRLS data from 1 June 2007 to 31 May 2008 concerning incidents of actual or potential delay in cancer diagnosis

Communication

Communication incidents accounted for around a fifth of the sample. A further breakdown is shown in table 5:

	Group 1: Diagnostic delay (%)	Group 2: High risk (%)	Total (%)
Follow up communication problems	31 (37)	2 (4)	33 (25)
Appointment miscommunication	26 (31)	2 (4)	28 (21)
Referral communication problems	16 (19)	1 (2)	17 (13)
Accuracy of information	8 (10)	43 (90)	51 (39)
Other	3 (3)	0 (0)	3 (2)
Total	**84 (100)**	**48 (100)**	**132 (100)**

Incidents in this category related to the systems in place to ensure the communication of accurate and relevant patient information, referrals, booking of appointments and follow up of patients. These are largely administrative tasks and illustrate the need for robust processes to be in place to ensure failures do not occur. Many of these processes should be in place as part of national cancer standards.

Examples are provided in box 13:

Follow up:
- *A 28 year old woman was seen in out patients on 5th October as a new patient. No notes were available so the consulting doctor took notes on a pad and asked the secretary to make up a set of notes. The doctor ordered a biopsy, the results of which showed CIN3. A letter was dictated and this was left with the secretary to type and make a follow up appointment. The GP contacted the doctor on 9th June the following year to ask whether the patient had had any treatment; when the doctor investigated, it emerged the patient had not been seen since the OPA.*
- *Patient had skin biopsy taken February 2006. Results showed further appointment and treatment necessary. Letter dictated by Consultant dated March 2006 stated further appointment would be made. No further appointment or follow up actually arranged. Error noted when patient was re- referred by GP in July 2007, with recurrence of basal cell carcinoma at left temple.*

Referral:
- *On tracking a set of patient notes, I discovered a referral letter from a GP for another patient in her case notes. The second patient is a lady with metastatic cervical cancer and had been referred as an emergency.*
- *Patients wife contacted department as awaiting date from …and had not heard anything. Notes traced to consultant desk. Patient seen in clinic 22nd June, letter typed 4th July. Letter found in pile of unsigned correspondence, consultant away on holiday from 7th July for two weeks. Who was going to sign letter and send? How long would it be sat on desk unless patient phoned? 37 year old with probable cancer of the rectum.*

Inevitably, there is some potential overlap between communication and other categories but, if the incident was primarily about communication, it was categorised here; for example, some reports categorised as communication issues came from pathology settings where actions were not taken in response to a report. Similarly, some reports were about cancellations, but if the

problem was about communication of the cancellation, or for example, communication of the urgency of the required test, then the report was categorised under communication.

Communication was also the most commonly seen failure in the 'two week wait' search, with 15 of the 30 patient safety incidents linked to the process of referral and communication of results, as shown in box 14:

Communication between primary and secondary care and between clinicians: *I returned from holiday on Monday 4th September to find 5 two week wait patient forms left on my desk. Messages were left on the fax front sheet stating ' sorry, tried to call but no answer, I have left a message on your answer machine'. Hospital numbers had been faxed through on 28th August and had appointment target dates of 7th Sept.*

Communication between departments in secondary care: *Patient with weight loss seen as two week referral on 26th April. Referred to dietician and for urgent CT scan. Scan performed on 4th May and patient reviewed by dietician on 23rd May. Scan result and notes not brought to my attention until 25th October. This is an unacceptable delay and posed a serious risk to the patient.*

Communication about patient's status: *Patient was booked onto Urology clinic on 2nd Jan under the two week wait rule. The clinic was cancelled due to sickness of the consultant but it was not identified that this patient was on a 14 day target and he was therefore not rebooked onto an appropriate clinic.*

Box 14: Examples of incidents relating to communication in the 'two week wait' data search of incidents reported to the NRLS from 1 June 2007 to 31 May 2008 concerning incidents of actual or potential delay in cancer diagnosis

Cancellations

Despite targets for reducing cancellation of surgery, cancellations were the third most important theme in this dataset. A common problem was the need to cancel procedures because of a lack of beds, or (particularly with children) a lack of a specialist service. Other problems included clinics cancelled due to staff absence and lack of available, working equipment to carry out procedures. Some reports indicated poor planning and preparation for investigations.

Examples included not ensuring the availability of specialist staff, poor communication when booking investigations and ensuring other staff or the patient were aware of the importance of the appointment and/or requirements for adequate preparation for the procedure.

Examples are provided in box 15:

Lack of specialist anaesthetist: *One year old child presented with concerns over intracranial pathology and possible cerebral tumour. We were unable to carry out an MRI scan due to the inability to provide anaesthesia.*

Poor preparation: *The patient was supposed to have been prepared for a PET (positron emission tomography) scan arranged urgently. This meant Nil By Mouth (NBM) before the procedure. On arrival the scan had to be cancelled as the patient had been given lunch on the ward, despite nursing staff being aware of the NBM requirement. The scan was vital to this patient's management regarding surgery for a brain tumour. The patient will now have to wait a further week for the PET to be rescheduled.*

Poor preparation/lack of suitable equipment: *Patient came to theatre for laparoscopy and lymph node biopsy. There were no 30 degree scopes available to carry out the procedure safely, therefore the lymph node biopsy was not performed. Patient woken up and the surgeon informed.*

Clinic cancellations: *Four patients returning to clinic for results had appointment on 8th Feb cancelled….Rebooked for weeks or months later i.e. 23rd May clinic reduced – non urgent patient left on, cancer patient removed. Three other patients involved.*

Box 15: Examples of incidents relating to cancellations as reported in a random sample of NRLS data from 1 June 2007 to 31 May 2008 concerning incidents of actual or potential delay in cancer diagnosis

Clinical assessment and other incidents

Other categories of incidents were in the minority, accounting for less than 10%, but were nonetheless important.

Notably, errors at the point of clinical assessment accounted for 7% of the actual delays. These reports referred to cases where the clinician missed a diagnosis of cancer; examples are shown in box 16. This type of incident may be reported less frequently by clinical staff. All of these incidents took place in secondary healthcare services, but this is most likely to be an artefact of the reporting culture rather than an implication that such errors do not occur in primary care settings.

Box 16: Examples of incidents relating to clinical assessments as reported in a random sample of NRLS data from 1 June 2007 to 31 May 2008 concerning incidents of actual or potential delay in cancer diagnosis

- *A young woman presented in A&E (accident and emergency) with a fit, confusion and headache. She had already been seen at another hospital and discharged. She was found by A&E to have a brain tumour.*
- *This patient was moved from the Medical Assessment Unit after being seen by an F2 doctor only, without any senior review. The patient came in following a fall, and the doctor examined her knee. However it has now been noted that the patient has bleeding per rectum, abdominal mass and atrial fibrillation.*
- *A diagnosis of oral cancer was missed by two clinicians - one in October and one in November. Staff member informed mid December.*

Other reports included two incidents where waiting times were breached and two where no details were provided.

5. Findings from workshops

Two focus group events were held, one in Manchester and one in London.[53] Participants were recruited through Cancer Networks. A total of 50 people participated in the events, including patients, carers, general practitioners (GPs), public health specialists, Cancer Network directors, nurses, cancer specialists, service improvement directors and commissioners.

Participants were invited to prepare vignettes recounting diagnostic delays from their own experience. During the workshops these vignettes were explored using the principles of Root Cause Analysis[54] to gain a better understanding of where and how things go wrong and to pinpoint areas for improvement.

In addition to the specially planned events, the preliminary findings of the NRLS analysis were presented at the NAEDI launch, the Britain Against Cancer conference and to individual Cancer Networks. Feedback from these meetings is also included with the analysis.

The findings focused mainly on primary and secondary care delays in the pathway. The most frequent message heard was that some patients go to their GP several times with the same symptoms that are not fully investigated. There are several issues underlying this problem, as well as others that were raised. These issues often overlapped, but were categorised into themes:
- communication;
- clinical assessment and management;
- cultural issues.

Communication

Communication was an important, multifaceted theme that arose during the meetings. Most communication issues were raised about doctor-patient communication. However, communication between care settings and communication between systems was also mentioned.

Doctor-patient communication

"I knew something was wrong. I know my body better than they do." Event participant

Patients and carers commented that the consultation with GPs felt too short, and they had limited opportunity within the time available to discuss all their concerns. Furthermore, they felt that GPs did not always listen to them. One participant felt her GP was too quick to dismiss her symptoms as menopausal or 'neurotic'. Box 17 provides a further example from the focus groups:

Note: Quotes are taken from comments made during the focus group events held by the NPSA in 2008 to explain the issues around delayed diagnosis of cancer. All names have been changed in the following examples to protect anonymity.

"Alice", a woman in her early 60s, returned to her GP several times with abdominal discomfort and other symptoms. She felt he did not listen to her, that he found her a 'nuisance'. She eventually consulted a private practitioner, whom she felt took her seriously. She described this practitioner as a partner in her care. The private practitioner arranged for a series of tests. Alice disclosed that when she was finally given a diagnosis of ovarian cancer, she had actually thanked the consultant for the diagnosis, because she felt vindicated.

Box 17: An older woman who did not feel listened to

It was not only listening skills but other communication skills, including questioning skills, which were raised in the focus groups. If patients do not realise they have a symptom or sign that might be unusual or important, they will not necessarily mention it, even though it might be critical in making a diagnosis. Unless GPs ask the right questions, these critical symptoms can be missed. This is supported by the literature around diagnosis where obtaining critical information improves diagnostic accuracy.[55]

Non-verbal communication (especially repeated attendances at the practice) was also mentioned as an important indicator. It was suggested in the focus groups that sometimes GPs did not notice or take action when patients' behaviour changed. A patient might start to attend the practice frequently after having attended infrequently in the past; this could be a sign of a persistent set of symptoms that was not being adequately treated. There were several examples of patients going to their GP on several occasions with the same symptoms but not getting the right advice/action, as illustrated in box 18:

Box 18: A person who started to attend frequently with the same set of symptoms

"Vernon" was 75. His wife had died and he had poor social networks. He had rarely visited his GP in the past but he started to attend frequently with aches and pains and stiffness. The GP assumed Vernon was depressed. He was not signposted to any other services. One year later he was diagnosed with prostate cancer with bony metastasis.

Conversely there were also examples where GPs did recognise unusual behaviours in their patients and acted, as shown in box 19. In these cases, the GPs usually had a relationship with the patient, could recognise that the pattern of attendance or the type of complaints had changed, and were able to act rapidly and effectively. This could be compromised in group practices where patients saw different GPs each time, or where patients saw locums, resulting in discontinuity of care.

Box 19: A GP recognises unusual pattern of attendance and complaint

Dr "Patel" saw Mrs "Martin", whom she knew well, in early January. Mrs Martin complained of nausea and vomiting, which Dr Patel and Mrs Martin attributed to Christmas and New Year excess. Three weeks later Mrs Martin returned, having lost three quarters of a stone. She was still vomiting and her abdomen was tender. Dr Patel ordered an urgent ultrasound scan and blood tests. Mrs Martin was diagnosed with a small bowel tumour.

In such situations, the relationship between GP and patient seemed to be important. On the other hand, there were occasions where patients found seeing a locum or a different doctor beneficial. The new doctor saw patients' stories with a fresh eye, which meant they were sometimes able to make a diagnosis of cancer that had been missed in previous consultations. The notion that a 'second opinion' can be beneficial despite the risk of discontinuity of care has been recognised in the literature.[56]

Communication between care settings and systems

A number of examples were raised where communication had failed between care settings. Most commonly, there were communication problems when patients attended Accident and Emergency, with tests being carried out in the hospital and not communicated in a timely way to the GP, or even the attendance not being communicated. This could result in serious events being missed by the GP. Communication between primary care and secondary care were considered especially important in diagnostics, where tests are commonly ordered in primary care but carried out in secondary care. Effective mechanisms for tracking results was not established in all practices and issues such as results being returned to the non-referring GP, or to a group of GPs, had the potential to cause delays.

There were also communication problems and lack of co-ordination *within* the primary care setting. Box 20 describes an example of where communication broke down between various departments:

"Roisin" went to the practice nurse with a lump on her vulva. The practice nurse examined the lump and stated that it was probably a cyst, but no tests were ordered. Roisin returned several times to the nurse as the lump became larger and more painful. The nurse did not escalate the problem up to the GP. Roisin then had several GP appointments but she did not see the same GP each time. She also saw different gynaecologists and went to A&E. After 15 months' delay, Roisin was finally diagnosed with vulval cancer.

Box 20: Communication problems across a number of settings

A group of communication issues came from secondary care providers. They sometimes felt they did not have adequate information from primary care when first seeing a patient. Some clinicians called for standardised referral forms to aid the diagnostic process. It was also noted that, at the multidisciplinary team (MDT) milestone, if a patient comes with late stage disease the patient is regarded as a 'late presentation' – implying that the delay lies with the patient rather than the system. This is not helped by the problem of not having details routinely recorded about the care pathway into and through primary care. A possible audit of late stage presentation to MDT would be hampered by the lack of information available on the care pathway.

Clinical assessment and management

Clinical assessment is closely linked to good communication and there were examples where doctor-patient communication problems resulted in poor clinical management. However, there were also more concrete issues relating to routine procedures and processes.

For instance, guidelines and policy recommendations were not always acted on, could feel overwhelming in volume (described as a 'plethora' by one practitioner), and sometimes resulted in confusion if they contrasted with national campaigns: all of these factors contributed to examples of delays. The example in box 21 describes a situation where the GP did not follow guidelines:

"Alaia" went to the GP with a suspect skin mole. The GP was young, and new to the practice. He was not a designated skin GP. Contrary to the guidelines, he decided to excise the lesion – using 'cut and burn' - and he disposed of the material. However, he did refer the patient to hospital. The dermatologist eventually diagnosed melanoma but the diagnosis was delayed because the GP was not able to send a sample.

Box 21: GP not following guidelines

It also emerged in discussions that practitioners were not always sure how to respond when the patient did not fit a particular set of guidelines or expectations. Examples were raised with childhood cancers, in particular, where practitioners did not expect to see cancer symptoms, and also in other age groups where cancer was not expected, as shown in box 22:

"Paulette" was 29 years old. She had recently given birth and was breastfeeding. She went to her GP with a breast lump. The GP assumed the problem was mastitis and did not refer her to the breast clinic. Paulette returned twice more to the GP as the lump did not go away. When she was finally diagnosed, she had advanced breast cancer with extensive spread.

Box 22: Patient much younger than expected so guidelines not followed

Unusual or rare cancers were also difficult for practitioners to identify, although there were concerns when patients returned time and again with persistent symptoms and many of the examples showed that they were not investigated for possible cancer.

Clinical assessment was also sometimes hampered by test ordering and results. Practitioners described being falsely reassured after ordering tests which came back negative. This might be because they had not tested for the relevant disease or because the test was not sensitive enough or the results were equivocal. Receiving negative, or false negative results, has been cited in the literature as a cause of delay.[33] Further, some tests ordered as urgent or emergency were reported as still taking too long; one GP gave an example of an emergency scan taking three weeks.

Cultural issues

A common theme in the focus groups and discussions was the culture of the doctor-patient relationship in which the patient tends to assume a passive 'patient' role. This concept was first described more than 50 years ago by Talcott Parsons but still appears to be relevant.[57] Despite persistent symptoms, which do not get better, patients return again and again to their GP without feeling that their symptoms have been addressed; they rarely complain or ask for a second opinion. If a test result does not come through they tend not to ask about it and may not realise the testing process has failed. For example, GPs can tell patients they will be contacted if the result of a test is problematic, so if they are not contacted, the patient assumes nothing is wrong, despite continuing to experience symptoms. One patient commented that if she had not had a supportive partner she would not have persisted in seeking help. Another finally refused to continue with her own doctor and sought help in the private sector, as shown in box 23:

Box 23: From 'passive' to 'active' patient

> *Mrs "Ahmed" was a 76 year old lady who attended her GP in May with difficulty swallowing. She returned three more times, without her symptoms getting better. She went to see her dentist, who needed to fit new dentures. In October she returned to the GP having lost a stone and a half. Mrs Ahmed had a gastroscopy, carried out by a nurse, which did not show any abnormalities. She was then referred to a gastroenterologist but she refused to go, based on the results of the gastroscopy. Instead she consulted a private Ear Nose and Throat specialist. In November she was diagnosed with end stage oral cancer.*

The passive patient role can often be reinforced by GPs and practice staff; patients are not empowered to challenge or to be experts in their own condition. Box 24 gives an example that shows how the system supports the culture:

Box 24: The passive patient culture

> *Mr "Rossi" had been seen by the haematologist at the local hospital. He was informed by the hospital when the GP should have his results. He went along to the surgery to check whether they had been received. The receptionist said she could not see any results but that in any case, they would not be able to divulge results to Mr Rossi without written proof of consent from the hospital that Mr Rossi could see his results. Mr Rossi explained he would like to see his GP as he was worried he might have leukaemia. The receptionist could not offer an appointment for a week and suggest that Mr Rossi should fax the hospital to ask them to speed up the results. Three days later, Mr Rossi was able to see his GP due to a cancellation. After the consultation, the GP contacted the hospital then rang Mr Rossi with the news that he had chronic lymphatic leukaemia.*

Leadership, organisational culture and patient safety

The other issue that became apparent was the culture of patient safety in primary care. The focus group participants discussed the need to improve patient safety culture amongst GPs. Examples included deviation from established guidelines, failure to fast-track patients at risk, and not regarding incidents such as the examples in this report as patient safety incidents which offer an opportunity for widespread learning. In the workshops there was a call for patient safety data to be collected in a consistent manner.

Meanwhile, some of the Cancer Networks reported that there was no primary care lead in their Network. Although three years of funding was provided to set up these posts following the *NHS Cancer Plan*, the posts have not necessarily been sustained.

6. Primary care perspective

This section considers the key issues in primary care in relation to delays in the diagnostic pathway, including what is known about delays in primary care, the perspective of GPs and what improvements need to occur.

The generic issue of missed diagnoses in primary care

Diagnostic delay is an issue that is recognised to be important by GPs.[58] Figures from the MDU in 2003[59] show that more than half the claims settled against GPs were for delayed diagnosis. The major risk area was cancer with tumour types as follows:

- breast (22%)
- bowel (14%)
- cervix (13%)
- skin (8%)
- brain (7%)
- lymphoma (5%)

The MDU identified the reasons for delay as:

- failure to examine the patient properly;
- inadequate follow-up arrangements;
- lack of appropriate investigations;
- reports misfiled in notes (usually kept in paper files);
- dysfunctional communication between healthcare staff and between healthcare staff and patients;
- incomplete or inadequate record keeping, and failure to refer or ambiguous prioritisation of referral.

Published data from the MPS regarding general practice negligence claims also highlights the problems of delayed or misdiagnosis, with cancer forming the largest category in this 1,000 case analysis.[60] The three main cancers sites were gynaecological, digestive organs and breast.

## What are the key issues in cancer diagnosis in primary care?

The Scottish Primary Care Cancer Group reports on cancer diagnosis give significant insight into the primary care component in the cancer pathway.[61,62] These reports involved analysis of 4,181 cases of cancer diagnosed between 2006 and 2007, and 7,430 between 2007 and 2008. This project offers the most detailed analyses available to date in the UK. It is important to note that fast track electronic referral was not introduced in Scotland until 2006.

The findings of the reports are summarised as:

- Patients with head and neck cancer took the longest time to present (median 30 days). Patients with melanoma and colorectal cancer also presented comparatively late (median 26 days and 21 days).

- Patients with bladder cancer, leukaemia, cervical cancer and breast cancer took the shortest time to present from first noticing a sign or symptom.
- There was wide variation between practices in the time taken for patients to be referred to hospital. Patients with breast cancer and melanoma were referred quickly whereas, for other tumour groups (notably lung and prostate), patients spent longer in the primary care part of the journey.
- Even when cancer was suspected patients were not always fast tracked. The report emphasised the importance of implementing referral guidelines and enforcing fast track schemes. It would appear that practices interpreted the guidelines differently.
- Patients with non-specific symptoms and/or co-morbidity caused particular difficulty.
- Level of GP engagement with the national audit was high with GPs showing evidence of reflection and being open about the issue.
- There were differences between practices even in the same health board and between tumour types.
- A significant number of cancers were diagnosed outside of the fast track system. The report called for improvements in routine care and referrals.
- The report highlights the importance of prompt access to investigations in primary care.
- The report's success suggested that a national process of data collation and synthesis across a region/district is worth considering.

Figure 4: Data from the first Scottish Primary Care Group report showing the average number of days delay in cancer diagnosis in primary care. This shows that patients have symptoms for a significant period of time before seeking help and that there can be considerable delay in referral, particularly for some tumour types.
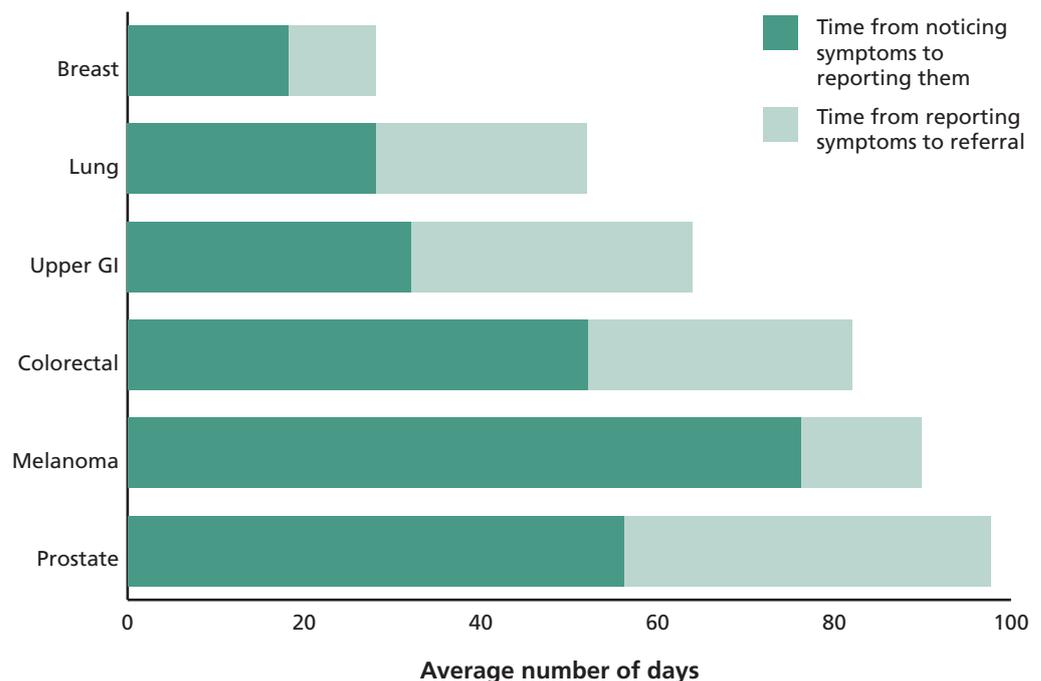
The primary care patient pathway

The primary care patient pathway can be described as:

1. **Health seeking behaviour:** patient with symptoms or concern – decision to seek assistance from primary care;
2. **Access:** appointment with GP or practice nurse;
3. **Clinical assessment:** evaluation of symptoms, use of guidelines and shared decision making;
4. **Test ordering:** access and management of tests – blood tests/ imaging;
5. **Follow up with results;**
6. **Referral to secondary care:**
   a. missed referral;
   b. inappropriate prioritisation of urgency;
7. **Assessment in secondary care.**

Figure 5 provides a graphical overview of the pathway. Because of lack of systematic data, particularly from primary care, it is not possible with absolute certainty to define levels of risk along the pathway.
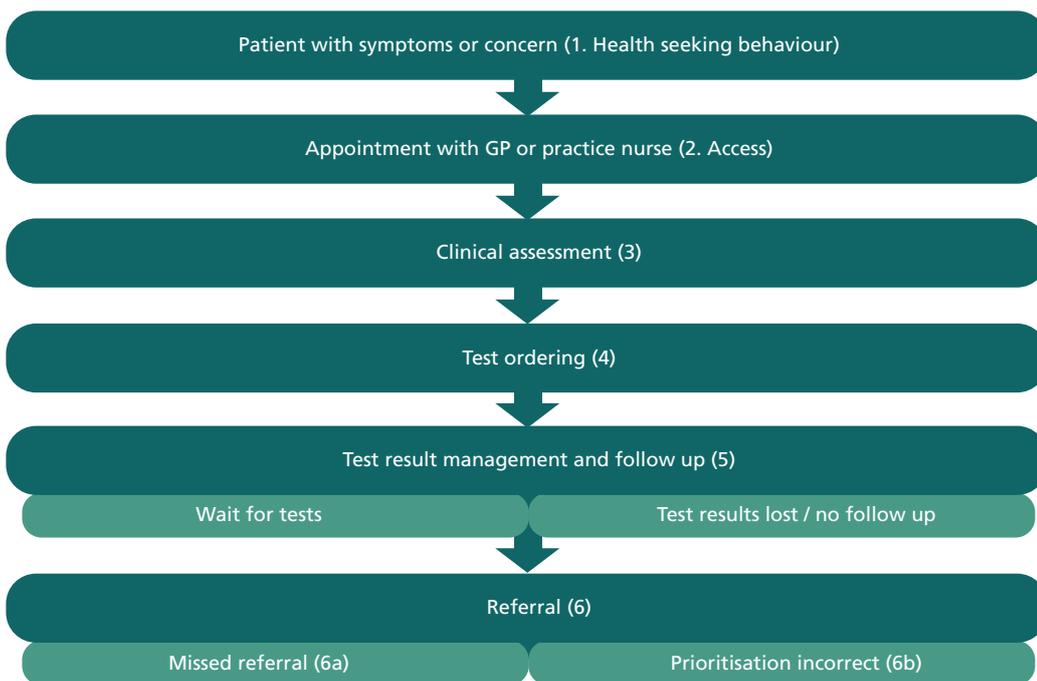

Figure 5: Primary care patient pathway

An adult patient was diagnosed with Iron deficiency anaemia. Given parenteral Iron. No other investigations. Still iron deficient six weeks later. Referred by letter to general surgical outpatients. Seen three weeks later. Patient had bowel cancer and in retrospect had met criteria for fast tract lower GI referral. (Case from a Cancer Network Audit)

Box 25: Example of stages 3 and 6b of the primary care patient pathway

Incident reporting in primary care

General practice contributes only 0.4% of all patient safety incidents reported nationally. GPs have their own system of reporting called Significant Event Audit (SEA). This technique is widely practised and is part of the Quality and Outcomes Framework (QOF) of the General Medical Services (GMS) contract, where primary care teams have to undertake a review of 12 events, including new cancer diagnoses, over three years. The technique has many strengths, particularly its educational ethos. However, there is a wide variation in the quality of SEA, no systematic sharing of learning and low levels of reporting into local and national systems. A major issue is

the use of differing terminology (critical incidents, significant event, serious untoward incident (SUI), adverse event) despite attempts at defining a common language.

There is a need for greater standardisation, use of agreed and accessible terminology and improvement in the practice of SEA. The Scottish Audits show levels of participation in national audits can be high and provide significant opportunity for learning. This was achieved through an agreed designated enhanced service (DES) specification as part of the GP contract.

In October 2008 the RCGP and the NPSA published guidance on significant event auditing.[63]

Box 26: Detailed perspectives from GPs: reflections for learning (Scottish Primary Care Cancer Group)

- *Perhaps if my colleague had done a PR (rectal) examination at the initial contact the rectal tumour would have been identified and the pathway for this patient may have then been faster. (rectal cancer)*
- *With hindsight the patient should have been referred sooner and more urgently for further investigation by myself. (bladder cancer)*
- *My colleague said he would refer in December but referral was not made. Patient contacted the practice again in February. We have since looked into our system for sending referrals. (lymphoma)*
- *Patient presented with weight loss and suggestion of pelvic mass. Urgent pelvic ultra sound scan requested, but four weeks later patient had to be admitted with ascites (abnormal build up of fluid in the abdomen). Management of the developing ascites might have been made easier had we been able to get the scan (and hence diagnosis) earlier. (ovarian cancer)*

Nature of general practice and difference with secondary care

GPs are not complacent and recognise that cancer is a leading cause of concern to the public, and that prompt diagnosis is an important issue to patients and doctors.[60]

Making an accurate diagnosis can sometimes be difficult in primary care because of non-specific symptoms at presentation. Latest figures available show that just over 300 million consultations took place in general practice in England in 2008.[64] Many patients will have co-morbidity which can make the evaluation of symptoms such as tiredness, which can indicate cancer, complex. Diagnosis can be challenging and this can be source of conflict between primary and secondary care. The positive predictive value of a symptom or a test is dependent on the prevalence of a condition in a setting. For example, most patients with a cough in general practice will not have lung cancer, whereas the probability of lung cancer in patients with a cough attending a specialist respiratory clinic is higher. As prevalence falls, the number of false positives increases, which results in a lower predictive value.[65]

GPs refer thousands of individuals with cancer every year through the two week fast track scheme, but they investigate and assess many more patients who do not have cancer. The assessment of a classic 'textbook' presentation of cancer is relatively straightforward. However, the more usual and difficult scenario is the patient with vague symptoms with co-morbidity. Frequently, clinical encounters are inconclusive without it being possible to make an accurate diagnosis. Whilst greater vigilance is needed, it has been stated that it is important not to routinely over-investigate or make inappropriate referrals.

The distinction between the task of a generalist and a hospital specialist is essential for understanding the diagnoses in general practice.[66]

The role of the GP is to:
- tolerate uncertainty;
- explore probability; and
- marginalise danger.

The role of the hospital specialist is to:
- reduce uncertainty;
- explore possibility; and
- marginalise error.

This distinction is essential to consider when developing solutions, for example, the use of more formal methods of diagnosis, such as probabilities of signs and symptoms, and use thresholds for investigation and referral.[67]

The changing nature of general practice means there are additional providers and practitioners where patients can enter the system, for example, walk-in centres. These have the potential to increase access but also the potential for fragmentation of care.

7. Summary and recommendations

Summary of findings, discussion and conclusions

This review has presented an analysis of incidents related to diagnostic delay in cancer reported to the NPSA's NRLS. Analysis of a sample of patient safety incidents suggested there were more than 132 incidents a month concerning a delayed or potential for delayed diagnosis of cancer between 1 June 2007 and 31 May 2008.

The analysis of the NRLS sample demonstrated patient safety incidents that primarily occurred in secondary care. Combining this with a focused review of the literature and consultation with a range of stakeholders revealed a range of safety concerns and risks along the cancer diagnostic pathway.

Patient delay

Most of the published literature focused on the delay in patients seeking help. Patient delay was not an area covered by the NRLS or that featured heavily in the consultation exercise, but two themes were nonetheless significant.

Firstly, the literature suggests that one of the most important reasons for patient delay is symptom misattribution. This has a major impact on delayed diagnosis: people who do not identify their symptoms as possible symptoms of cancer are more likely to delay going to the doctor. The consultation exercise found examples where a critical symptom (such as change in bowel habit) may seem unremarkable for the patient.

Secondly, the evidence also points to fear as being an inhibitor to people seeking help for a possible cancer.

Both of these themes have implications for patient safety in terms of improving public information and also for working with primary care to improve doctor and patient awareness of relevant symptoms. Older people may be particularly affected by patient delay and activity to increase awareness might be best targeted to people in older age groups.

Doctor / provider delay

There is some research on doctor or provider delay. This usually, but not always, refers to primary care. Only a small proportion of patient safety incidents are reported to the NRLS from primary care and this is an indicator of one of the patient safety concerns: that there continues to be a need to increase reporting from primary care.

The material gained through the workshops resonated with the findings reported in the research literature. One important overall theme in both the literature and from the consultation was repeated attendance on the part of some patients with the same symptoms, and GPs misattributing those symptoms to another condition. Underpinning this theme were the linked issues of doctor-patient communication and a tendency for patients to accept the lack of diagnosis or symptom resolution without complaint: the 'passive patient' role.

A lack of adherence to guidelines and problems when patients did not fit expectations, especially when they were out of the expected age range for cancers, was seen in the literature and the workshops. The literature suggests that there are also specific issues facing young people and children, and that communication between doctors and parents makes an important

contribution to delays in diagnosis. The NRLS revealed a small group of incidents affecting young people with cancer; however, these were all events that took place in secondary care.

System delay

Nearly all of the NRLS data related to diagnostic delays in secondary care, with some at the interface between primary and secondary care. The top three categories were patient safety incidents that occurred in the context of diagnostics, primarily histopathology, delays due to a variety of communication issues, and cancellations.

At least a third of the patient safety incidents reviewed resulted in reported harm to patients, including death and serious harm. Problems included: samples not being delivered safely to the laboratory; errors within the laboratory; administration problems leading to patients being misinformed of results or not sent appointments; and cancellations of procedures due to lack of availability of staff or equipment or inadequate preparation for the procedure. Incidents involving diagnostic services accounted for over half of the reports in the NRLS. Problems between secondary and primary care included GPs not being informed of results and GPs alerting secondary care providers of a problem by making contact to find out what had happened to their patient's test – albeit several months after the test was ordered.

Recommendations and next steps

As this report demonstrates, there is scope for improving the diagnosis of cancer. Many of the issues highlighted will be taken forward through NAEDI and wider improvements in the NHS through the *High Quality Care for All: Next Stage Review* (NSR).[68] This includes strategies for greater patient involvement and empowerment, more responsive primary and community care including better models of care, quality metrics, stronger commissioning and proposals for leadership. The NSR also places quality as the organising principle of the NHS. Provider quality, including those in primary care, should become more consistent and responsive through proposals for quality accounts and registration with the Care Quality Commission (CQC).

During this project, five key patient safety areas have been identified. Two of these recommendations are straightforward and are already being taken forward. The remaining three recommendations are complex and need collaborative approaches and embedding within existing quality improvement workstreams.

Key patient safety area 1: Recognition of cancer in primary care

This project suggests that there is a need to improve support for primary care professionals in diagnosing cancer earlier. Clinical diagnostic errors or delays are often considered as failures linked to skills and training but, in keeping with our understanding of patient safety, there are system fixes that can decrease their frequency. Support is needed to give GPs better, easy to use tools to evaluate signs and symptoms and for practices to improve their systems. Collaboration with the RCGP will establish how this is best undertaken in line with other initiatives currently being developed, including the national primary care audit of cancer diagnosis. Computer-based decision support systems have been developed but are not currently in widespread use. Symptom misattribution and communication issues in primary care were important factors raised in consultations and in the literature. Existing referral guidelines for cancer diagnosis were published by the National Institute for Health and Clinical Excellence (NICE) in 2005.[69] In the consultation exercise, there was a call for these to be updated, and presented in a new way with further development of diagnostic tools.

> ### Recommendation 1: An accessible diagnostic tool for use in primary care.
> The NPSA is working with partners such as the RCGP and the National Cancer Action Team to adapt cancer referral guidelines.

Key patient safety area 2: Test ordering, processing and tracking of results

This project found a number of problems with diagnostic testing – from poor preparation and processing of tests, through to failures in communicating results and cancellations. All of these problems increased the risk of error and potential delay in diagnosis. Delay may not be recognised because of an apparent lack of accountability and audit of the system 'as a whole' together with significant 'hand over' of responsibility along the pathway. NHS providers should have in place robust clinical risk management protocols to ensure a safe system for the management of test results using electronic processes. Guidance documents have been produced in relation to radiology results, including an NPSA Safer Practice Notice and the communication of unexpected radiology results have been addressed in cancer peer review.[70, 71]

Recommendation 2: Identify, review and disseminate current good practice in the process of ordering, managing and tracking tests and test results.

Reviewing good practice in primary and secondary care, for example, using computer-based systems for following patients along the cancer diagnostic pathway, would serve to:

- identify areas of good practice which could be shared nationally and be the basis of new agreed national standards;
- identify data requirements and computer-based systems for improvements to be standardised and measured, locally and nationally.

These systems would need to be able to deal efficiently and effectively with test results, detect overdue and missing results, register the issuing of amended or supplementary reports and highlight if significant results are expected. Connecting for Health are taking forward this recommendation in collaboration with other partner organisations.

Key patient safety area 3: Empowering patients

The workstreams underway as part of NAEDI are key to addressing some of the issues found in this review. In particular, promoting awareness and encouraging early presentation will be essential in tackling patient delay, which featured strongly in the literature. However, there was evidence in this review that patients can get stuck in the diagnostic pathway in primary or secondary care. Colleagues participating in the workshops were keen to see the development of ways of enabling patients to overcome some of these barriers and take more control of their own safety.

Recommendation 3: Review and develop methods for empowering patients on a cancer diagnostic pathway.

The aim would be to help patients ensure they are kept informed, can ask for a second opinion if they wish and are enabled to follow up test results relating to their own care. Methods could include:

- Patients being given an information card whenever test results are outstanding. The card would outline what tests have been performed, when the results are expected and who to contact if a result has not been communicated to them, together with what to do if the result is negative but symptoms persist;
- Posters in GP surgeries and outpatient clinics designed to positively to encourage patients to ask questions;
- Exploring the concept of 'three strikes and you are in' approach where patients who remain undiagnosed after three consultations with persisting symptoms are referred.

All partner organisations, including the RCGP and their Patient Partnership Group, Cancer Networks, service users and cancer charities are asked to consider existing models and approaches which might exist in other areas of care but which could be adapted for use in cancer pathways.

Key patient safety area 4: Improving patient safety culture in diagnostic delay

The starting point is to recognise late diagnosis as a patient safety issue and focus on improving leadership and organisational learning culture in primary and secondary care. Good quality communication between practitioners, particularly across interfaces, and between practitioners and patients is essential. Very few patient safety incidents are reported to the NRLS from primary care. Despite SEA being part of QOF, there is no compulsion for SEAs to deal with patient safety incidents, nor for action to be taken locally to collate SEAs to enable learning and development. Opportunities exist for GPs through appraisal to consider any case of delayed diagnosis and to show learning and change. Cancer Networks are not routinely informed of patient safety incidents in relation to cancer which have occurred within their Network. Mechanisms that exist for national learning in patient safety are not embedded in the Cancer Network learning and development structure.

Recommendation 4: Develop a model for stronger leadership and improved patient safety reporting and learning, including SEA, at a local and national level.

- Primary care commissioners should consider setting out requirements for better data collection at primary care level, including undertaking and sharing of SEA on all diagnostic delays, and specific quality outcomes to be achieved in line with local need.
- Patient safety leads in Strategic Health Authorities and Local Health Boards working with Cancer Networks should include leadership and reporting in their local patient safety strategy.
- Primary Care Trusts and Local Health Boards should encourage practices to report diagnostic delays, perhaps through a designated enhanced service (DES), or by sharing SEAs, with metrics of delay in number of days (patient, doctor and system) and mechanisms for feedback including appraisal schemes for GPs.
- The NPSA will continue to work to improve reporting to the NRLS, including from primary care, through developments including an eform specifically tailored to GPs and through building specialist learning portals within Patient Safety Direct,[72] and by the development of a national standardised proforma for undertaking SEA.

Key patient safety area 5: Improve understanding of delayed diagnosis

Late presentation to the MDT is often assumed to be a result of patient delay. This review has found that there are many other parts of the pathway where delay can take place. Late presentation to the MDT, therefore, presents an opportunity to understand more about what has happened to each patient and whether there are patterns of patient safety errors that increase the risk of late diagnosis locally that could be corrected.

Recommendation 5: To improve routine monitoring of delayed diagnosis.

- Organisations should review systems their cancer MDTs have in place to identify, report and investigate delays (whether attributable to patient, doctor and/or system) for referral to an appropriate cancer specialist team.
- The process would be initiated by the cancer MDT but would need to involve primary care, other disciplines (for example, non-cancer specialists who have been involved in the patient's care), and managers. The aim would be for teams to identify cases meriting review and to identify what could be improved for future patients.

The NPSA provides aggregate Root Cause Analysis tools which can be helpful for such investigations.

Summary

In summary, this review has highlighted a number of issues that contribute to delay in the diagnosis of cancer. The data from the NRLS and consultation exercise focused mainly on delays at primary care and secondary care, and the interface between the two. A series of practical recommendations based on collaboration with clinicians, patients and national and local cancer leaders have been made.

There is considerable scope for improvements in practice. Change will require a multifaceted approach using existing enablers such as commissioning. Factors more likely to lead to improvements include greater patient empowerment, stronger clinical leadership, local processes that engage clinicians using systematic monitoring of delay indicators, education and training, particularly in use of clinical guidelines, and the promotion of improved safety culture towards learning organisations.

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