

Direct Access to Diagnostic Tests for Cancer

Best Practice Referral Pathways for General Practitioners

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Introduction

For 2009 the number of people diagnosed with cancer in England was 264,679 (1). This number will continue to rise as the population ages. However, five year survival rates for many cancers have improved and there are currently about 1.8 million people living with or after cancer in England (2). As well as improved treatments, this increase in survival rates could also be attributed to the commitment of those working in primary and specialist care to provide timely access to diagnosis and treatment. In particular general practitioners (GPs) are able to urgently refer suspected cancer patients to rapid access clinics, where they will be seen by a specialist within two weeks. This is outlined in the National Institute for Health and Clinical Excellence (NICE) referral guidelines for suspected cancer, which recommend the specific symptoms and criteria required for referral (3).

However, cancer outcomes in England are lower than the best outcomes in Europe (4). The Government estimates that 5,000 lives would be saved each year if England was to achieve cancer survival rates at the European average (5). Significant numbers of patients continue to be diagnosed at a late stage, greatly inhibiting their chances of survival. *Improving Outcomes: A Strategy for Cancer* (IOSC) (January 2011) therefore sets out a commitment to achieve earlier diagnosis. In the majority of cases the GP is the first medical professional to see a patient with symptoms suspicious of cancer and so the Department of Health (DH) has committed additional funding to support direct access for GPs to diagnostic tests that can help them diagnose or exclude cancer earlier.

In particular, the following priority areas have been identified in cases where the urgent GP referral for suspected cancer (i.e. two week urgent referral pathway) is not appropriate but a patient's symptoms still require investigation. As highlighted in the Operating Framework for the NHS in England 2011/2012, commissioners and local providers will want to consider the four priority areas for diagnostics for improving earlier diagnosis of cancer (6):

- Non-obstetric ultrasound: to support diagnosis of ovarian cancer
- Chest X-ray: to support diagnosis of lung cancer
- Flexible-sigmoidoscopy: to support the diagnosis of colorectal cancer
- Brain MRI: to support diagnosis of brain cancer

The Operating Framework for the NHS in England for 2012/13 subsequently sets out the expectation for less than 1 per cent of patients to wait longer than six weeks for a diagnostic test (6).

Statement of purpose

This guide covers the process for direct referral by GPs to specific diagnostic tests for the assessment of particular symptoms where cancer may be suspected but the urgent GP referral (two week wait) process is not applicable. It deals specifically with the circumstances and symptoms which may warrant such referrals. It does not extend into the patient pathway beyond the diagnostic testing stage. It is written for the benefit of all health care professionals across primary and secondary care and to inform those who both provide and commission services. It forms part of the broader programme to support the implementation of direct access to diagnostics. To support providers and commissioners in the delivery of direct access pathways, the NHS Improvement diagnostics team have also developed best practice diagnostic pathways for each of the four areas – ovarian, lung, bowel and brain cancers. Other strands include support for data collection and consideration of tariffs.

Background

The Cancer Diagnostics Advisory Board, chaired by Professor Sir Mike Richards, the National Cancer Director, was established to provide expert and clinical advice on improving access to cancer diagnostics. To speed up patient access to diagnostics, the Board examined the possibility of increasing direct access to diagnostics tests by GPs across different cancer types. The Board chose to prioritise the four areas identified following consideration of data on present arrangements. These data included a diagnostics baselining exercise carried out by the DH Knowledge and Intelligence Team and a GP questionnaire relating to present and preferred access to diagnostics. The Board's decision was also determined by whether providing direct access for different cancer types would expedite diagnosis.

The Board has commissioned this guide to aid GPs in determining which patients would be suitable for direct referral to local services providing these diagnostic tests. To support this work, the Department of Health has undertaken baseline assessments to determine the current referral routes used by GPs and the numbers of patients diagnosed by differing referral routes. Central to the plans outlined in *Improving Outcomes: A Strategy for Cancer* is an investment of more than £450 million over four years to achieve earlier diagnosis. This money will go towards raising awareness of the signs and symptoms of cancer, in addition to funding increased GP access to diagnostic tests and more testing and treatment in secondary care.

This guide has been compiled by a working group on behalf the Cancer Diagnostics Advisory Board that included representatives from primary care, radiology and NICE. A lead clinical expert supported the development of each of the clinical pathways for investigation and opinion was sought more widely from clinical experts as appropriate. Members of the working group have looked to existing evidence-based guidelines such as NICE referral guidelines (which are currently being reviewed) and the 7th edition of the Royal College of Radiologists referral guidelines: *Making the best use of clinical radiology* (7). It has aimed to complement this with evidence from research including the significant primary care research that has evolved over the past five years, for example the CAPER programme (8). The authors have also used expert opinion including the Royal College of General Practitioners, the Royal College of Radiologists and the Royal College of Pathologists. See Annex for membership of the working group and full acknowledgements.

This guide recognises that sending patients for diagnostics testing is not inconsequential. Coincidental findings will occur which will impact both on the individual patient and on health resources. GPs will need to bear this in mind when considering referral of patients for diagnostic testing and may wish to discuss these risks with their patient. We would of course also expect GPs to use their clinical judgement in referring patients, as well as be mindful that data from the national cancer patient experience 2010 survey has shown that young people and certain BME groups have more visits to the GP before referral for cancer.

Non-obstetric ultrasound

Although often referred to as the silent killer, recent evidence has shown that patients with ovarian cancer present to GPs with symptoms that if investigated earlier would allow earlier diagnosis. Recently published NICE guidance (10) has updated and clarified the symptoms which would warrant further investigation by GPs. This guide aims to contextualize and supplement these existing NICE guidelines, highlighting patients who, although not suitable for an urgent GP referral for suspected cancer, should be investigated.

Chest X-ray

Although direct access to chest X-ray services for GPs is already available, data shows a variability in requests for chest X-rays across the country and many people with lung cancer continue to be diagnosed at a late stage. This guide aims to raise awareness of the symptomatic indications that warrant urgent chest X-ray, as set out in the NICE Referral guidelines for suspected cancer (3), and to lower the threshold for GPs when deciding to request a chest X-ray for their patient.

Flexible-sigmoidoscopy

Emergency presentations for colorectal cancer remain high (25%), with a further 26% diagnosed through the urgent GP (two week wait) referral process (29). It is recognised that earlier diagnosis of cancers, particularly colorectal cancer, can significantly increase chances of survival. The availability of direct access to flexible-sigmoidoscopy for GPs is currently variable. This guide outlines the symptoms and circumstances which warrant direct referral for flexible-sigmoidoscopy, in particular for patients who do not meet current NICE urgent referral criteria but whose symptoms place them at higher risk of colorectal cancer than the rest of the population. It is hoped that faster access to diagnostics for this group of patients will aid earlier diagnosis and in turn improve survival rates.

Brain MRI

58% of people with a brain tumour present to health professionals as an emergency in casualty. Only 1% are diagnosed following an urgent referral for suspected cancer from their GP (29). In some areas of the country urgent referral processes for brain cancer do not exist and many areas do not currently have direct access to MRI brain.

The DH is committed to introducing direct access to brain MRI for GPs. This guide aims to raise awareness of the symptomatic indications that may warrant urgent referral for specialist review and indications where referral for direct access to MRI brain may be appropriate. The guide further suggests that GPs may wish to initiate a direct referral for MRI brain at the same time as initiating an urgent referral service (two week wait) for patients with suspected brain cancer, depending on local arrangements. It is hoped that this will benefit patients through facilitating a faster diagnosis.

Clinical pathways

1. Non-obstetric ultrasound scan

1.1. Ovarian cancer

Ovarian cancer accounts for one in 25 cases of female cancer (1). 3453 women died from ovarian cancer in 2009, making it the leading cause of gynaecological cancer (1). Relative five year survival estimates (based on survival probabilities observed during 2000-01) for ovarian cancer in England and Wales was 34% (11). Survival is significantly higher in those patients diagnosed earlier (13).

Survival rates for ovarian cancer remain lower than the European average. Earlier diagnosis could improve survival outcome (14). At present only 26% of cases are diagnosed through the two-week urgent referral pathway with 29% by emergency presentation (29). The significantly lower survival rates for ovarian cancer observed in England are generally attributed to later diagnosis, with as many as 70% of ovarian cancers already at an advanced stage (FIGO Stage III or IV) at the time of diagnosis, making them more difficult to treat (15).

Historically ovarian cancer was known as the silent killer but recent studies have shown the majority of women with ovarian cancer, even those with early stage disease, have symptoms prior to diagnosis (16) and there is increasing evidence that symptoms may be present for a year or more (17). Ovarian cancer is particularly difficult to diagnose on clinical grounds as the presentation may be with vague, non-specific abdominal symptoms (10), but there is accumulating evidence that women with ovarian cancer experience specific symptoms more frequently, more severely and more persistently than women who were found not to have the disease (18), (19), (20), (21).

1.2. Diagnosis

NICE has recently published guidelines on the recognition and initial management of ovarian cancer (10). These guidelines have generated considerable debate in primary care, gynaecological oncology and pathology communities. During the development of the material within this document representatives from all those communities together with NICE have collaborated. There is an acknowledgement as to the limitations of the evidence base from which the NICE guidelines were derived together with an appreciation and acceptance of their underpinning rationale as a strategy to reduce the time taken to reach a diagnosis. All disciplines are working to support the implementation of this guide whilst further research is ongoing to contribute to the future evidence base.

The working group's recommendations are given below. Included are some suggested clarifications based on discussion with experts which should aid GPs further in determining whether to refer patients. This is followed by information on the estimated predictive risks of symptoms associated with ovarian cancer.

1.2.1 and 1.2.2 NICE guidance

1.2.1 Patients warranting referral under the two week wait

Refer the woman urgently if physical examination identifies ascites and/or a pelvic or abdominal mass (which is not obviously uterine fibroids).

1.2.2 Patients who may benefit from a direct GP referral for test

Carry out tests in primary care if a woman (especially if 50 or over) reports having any of the following symptoms on a persistent or frequent basis – particularly more than 12 times per month:

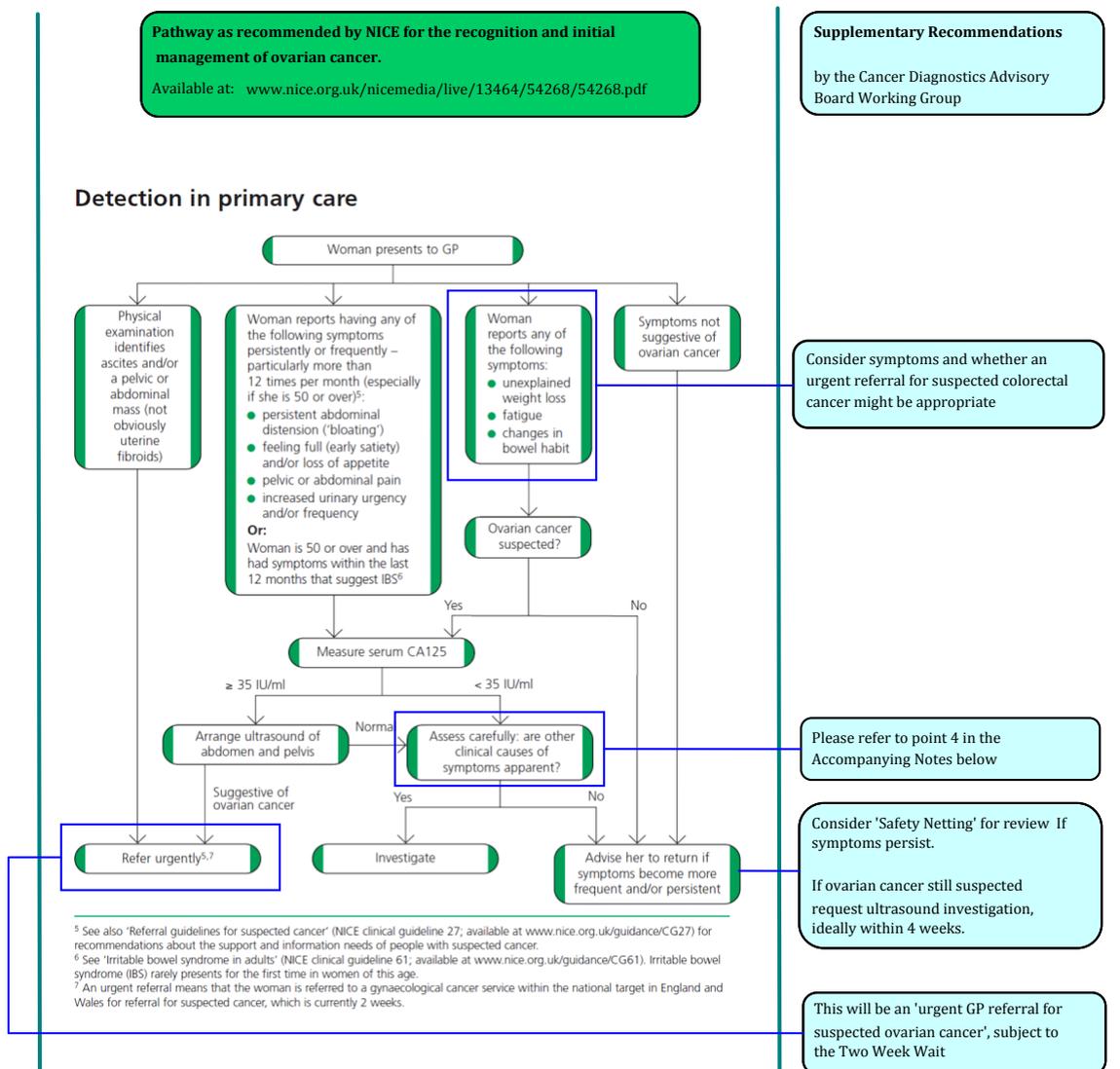
- Persistent abdominal distension (women often refer to this as 'bloating')
- Feeling full (early satiety) and/or loss of appetite
- Pelvic or abdominal pain
- Increased urinary urgency and/or frequency.

Consider carrying out tests in primary care if a woman reports unexplained weight loss, fatigue or changes in bowel habit (though colorectal cancer is a more common malignant cause).

Advise any woman who is not suspected of having ovarian cancer to reconsult with her GP if her symptoms become more frequent and/or persistent.

Carry out appropriate tests for ovarian cancer in any woman of 50 or over who has experienced symptoms within the last 12 months that suggest irritable bowel syndrome (IBS), as IBS rarely presents for the first time in women of this age.

Figure 1 Detection in primary care



Accompanying notes

1. This pathway is based on the premise that clinical examination is undertaken at the outset. CA125 in this context is only applicable to women where examination is unremarkable.
2. If CA125 >35 IU/ml, then arrange an urgent pelvic ultrasound examination (US) within 2 weeks, ideally a trans-abdominal / trans-vaginal ultrasound scan (TA/TV US).
3. If US suggests ovarian cancer refer urgently for suspected cancer (two week wait referral).
4. NICE recommend the following management for any woman with a CA125 above threshold and a normal ultrasound:
 - Assess her carefully for other clinical causes of her symptoms and investigate if appropriate

- If no other clinical cause is apparent, advise her to return to her GP if her symptoms become frequent or persistent.
5. CA125 below threshold does not exclude ovarian cancer in symptomatic women. If CA125 below threshold, then organise review of patient at 6 weeks. Ensure appropriate safety netting for reattendance if symptomatic. If there are still concerns regarding possibility of ovarian cancer (and having considered any more likely diagnosis) arrange US, ideally within 4 weeks.
 6. Ensure safety netting advice regards reattendance at any subsequent time if symptoms recur/persist.
 7. Specific symptom diaries may be helpful to support accurate reporting of symptoms.

1.2.3 The predictive risks of symptoms suggestive of ovarian cancer

The following table highlights the risk of ovarian cancer associated with certain symptoms estimated from primary care based studies, where they have been performed. It is assumed that the patient is over 50 years of age (or has a high risk of cancer from, for example, a strong family history of cancer); the patient has a primary complaint of one or more symptoms; and there is no obvious alternative diagnosis. This information may help to support decisions as to whether to refer a patient.

Table 1. The risk of ovarian cancer associated with certain symptoms

Symptom	Approximate risk of cancer (22)	Does this meet urgent GP (two week) referral criteria for suspected cancer?	Suggested investigation	Notes
Pelvic or abdominal mass or ascites	Unknown, but likely to be very high	Yes	For two week wait referral	
Abdominal distension	2.4%	Not in 2005 guidance, but listed as a possible symptom of ovarian cancer in 2011 guidance	CA125	If CA125 >35 IU/ml, then arrange pelvic ultrasound within 2 weeks If the ultrasound suggests ovarian cancer, for two week wait referral If CA125 below threshold then arrange a review of the patient at 6 weeks. If still concerns regards possibility of ovarian cancer arrange ultrasound within 4 weeks
Unexplained pelvic or abdominal pain	0.3%			
Difficulty eating or early satiety	Unknown, but low			
Increased urinary frequency	0.2%			
Multiple or repeated symptoms (two or more of the above)	As a rough rule, add up the figures above. Combination excluding abdominal distension are rarely above 1%			Multiple symptoms strongly suggest measurement of CA125
Note: Distension means increasing/persistent swelling of the abdomen ('up and up') and bloating intermittent swelling ('up and down'). Women do not necessarily use these terms in the same way, so this needs clarification. Bloating is of much lower risk (17).				

2. Chest X-ray

2.1. Lung cancer

In 2009 there were over 33,000 new cases of lung cancer in England. More than 28,000 died from the condition in England in 2009, more than from breast and colorectal combined – and lung cancer is now the leading cause of cancer death in women (1). The incidence of lung cancer in those under age 40 is rare but incidence rises sharply with age. 87% of cases occur in people over 60 (1).

Lung cancer continues to be diagnosed at a late stage – The National Lung Cancer Audit showed that in 2010 70% of cases were stages IIIB or IV at the time of diagnosis. In 2007 about 40% of cases were diagnosed via emergency admission and 22% of lung cancer cases were referred through the two-week urgent referral pathway (29). Outcomes are significantly worse for those diagnosed following an emergency presentation.

It is believed that patients present late due to a lack of awareness of the symptoms that are characteristic of lung cancer. NICE (2011) has highlighted the need for coordinated campaigning to raise public awareness.

2.2. Diagnosis

Chest radiography (CXR) is advocated as the best first line test for suspected lung cancer (MBUR-7). NICE 2005 guidelines describe high-risk symptom patterns warranting CXR. GP access to chest X-ray is already freely available, however, the threshold for requesting CXR is variable and the rationale for this guide is to link evidence-based clinical features associated with higher probability of lung cancer with earlier CXR. Including these features in the chest X-ray request will enable a more helpful radiological report leading to earlier diagnoses of lung cancer.

The high-risk symptom patterns warranting a chest X-ray highlighted by NICE are given below. This is followed by information on the estimated predictive risks of symptoms associated with cancer.

2.2.1. Patients requiring referral

Immediate referral (emergency admission if necessary)

- Signs of superior vena caval obstruction (swelling of the face and/or neck with fixed elevation of jugular venous pressure)
- Stridor
- Massive haemoptysis.

Patients requiring referral under the two week wait rule

- Persistent haemoptysis in smokers or ex-smokers who are aged 40 years and older;

- A chest x-ray or chest CT scan suggestive of lung cancer (including pleural effusion and slowly resolving consolidation) (NICE lung cancer 2011); and
- A normal chest x-ray where there is a high suspicion of lung cancer.

2.2.2. Patients who may benefit from a direct GP referral for chest X-ray

Patients who present with the symptoms below may benefit from direct chest X-ray referral the report should be returned ideally within one working day.

- Haemoptysis
- Unexplained persistent (over 3 weeks):
 - Cough with or without any of the following
 - Dyspnoea
 - Loss of weight/appetite
 - Underlying chronic respiratory problems with unexpected changes in existing symptoms
 - Chest pain (non-cardiac) / shoulder pain (with no obvious cause)
 - Hoarseness
- Chest signs
- Features suggestive of metastasis from lung cancer
- Other signs: finger clubbing, cervical lymphadenopathy
- Worsening spirometry.

Accompanying notes

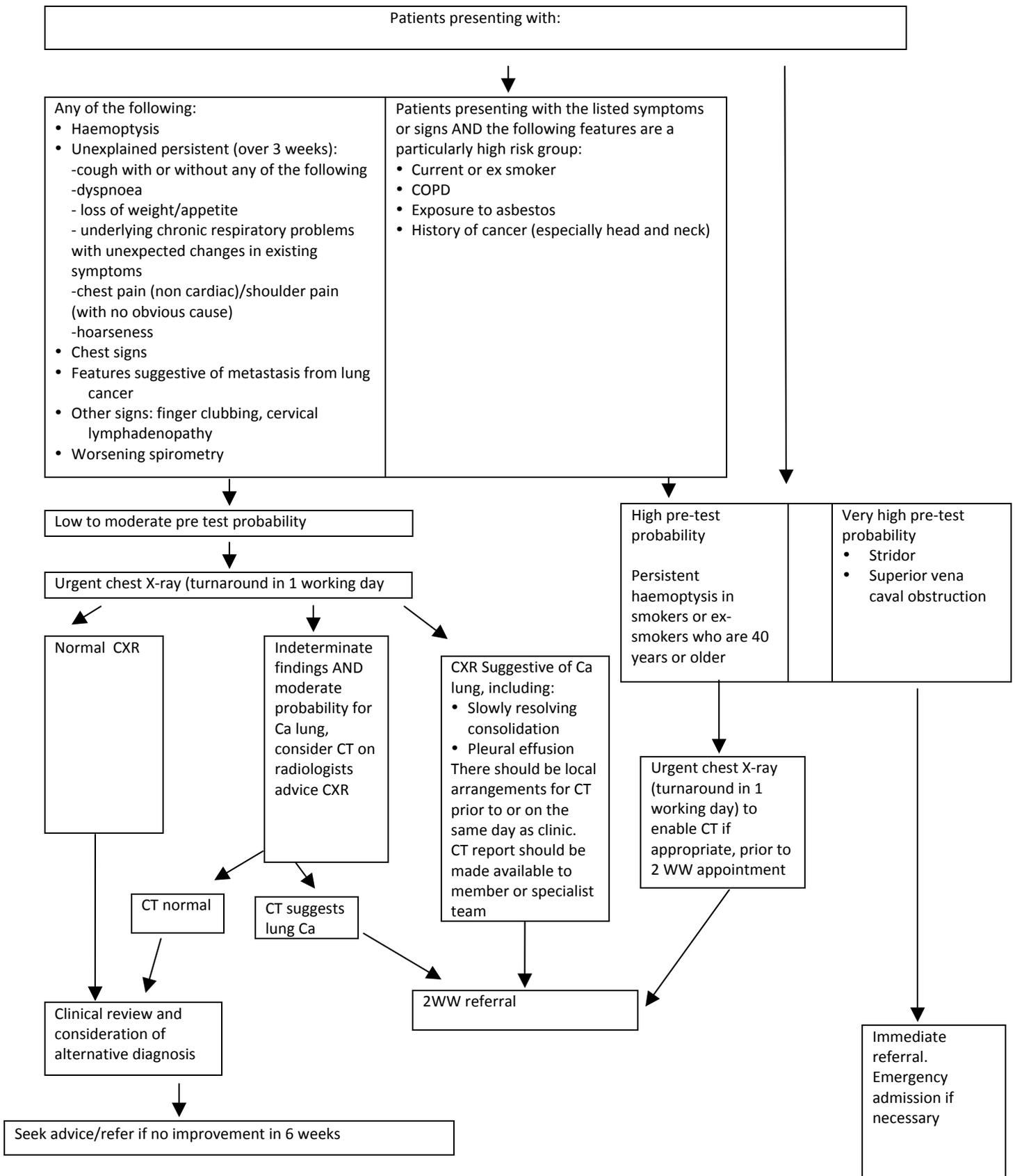
1. Providing appropriate concise clinical information for the CXR request (possibly on a bespoke request form) will aid estimation of pre-test probability of significant pathology.
2. Although NICE 2005 guidance does not explicitly set an age limit for referral for CXR, consider the low incidence of lung cancer under age 40.
3. In symptomatic patients, the large majority of CXRs will be abnormal, but *a normal CXR does not exclude a diagnosis of lung cancer*.
4. Patients with a moderate pre-test probability of lung cancer and an indeterminate CXR may need chest CT according to the reporting radiologist's advice. Guidance from NICE states: "If a chest X-ray or chest computed tomography (CT) scan suggests lung cancer (including pleural effusion and slowly resolving consolidation), patients should be offered an urgent referral to a member of the lung cancer multidisciplinary team (MDT), usually a chest physician". There are many examples around the country where abnormal CXRs automatically trigger either a referral to a rapid access lung cancer clinic or a CT scan.
5. Any concerns regarding the very low radiation dose of CXR or repeated CXR should be taken in context with the important diagnostic information available from this test. The

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CXR effective dose is 0.015mSv (7), which equates to 2.5 days of background radiation and less than a one in a million risk of developing fatal cancer.

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Figure 2 Flow chart for lung cancer



2.2.3. The predictive risks of symptoms suggestive of cancer

The following tables highlight the risk of lung cancer associated with certain symptoms estimated from primary care based studies, where they have been performed. It is assumed that the patient is over 40 years of age (or has a high risk of cancer from, for example, a strong family history of cancer). The patient has a primary complaint of one or more symptoms, and there is no obvious alternative diagnosis. This information may help to support decisions as to whether to refer a patient.

Here, the threshold is lower for requesting a CXR to investigate symptom profiles not selected by NICE.

Table 2. The risk of lung cancer: Smokers or ex-smokers with many years of smoking

Symptom	Approximate risk of cancer (24)	Does this meet two week referral criteria?	Suggested investigation
Superior vena cava obstruction or stridor	Unknown, but likely to be very high	These presentations require an urgent or emergency referral	
Haemoptysis	4.5%	Yes	CXR. Consider referral if persistent, even if X-ray normal
Chest pain (non-cardiac)	1.3%	Yes, but after 3 weeks	CXR should be offered earlier, particularly if the patient describes their cough or dyspnoea as unusual for them (25)
Dyspnoea	1.2%		
Cough	0.9%		
Loss of weight / loss of appetite	2.1%	No	CXR should be an early test, unless other cancers more likely
Fatigue	0.8%	No	CXR if other chest symptoms
Multiple or repeated symptoms (two or more of the above)	As a rough rule, you can add up the figures above	No	CXR

Table 3. The risk of lung cancer: Non-smokers, including ex-smokers with a short smoking career (5 cigarette packs/years)

Symptom	Approximate risk of cancer (24)	Does this meet two week referral criteria?	Suggested investigation	Notes
Superior vena cava obstruction or stridor	Unknown, but likely to be very high	These presentations require urgent or emergency hospital referral		
Haemoptysis	2.4%	Yes	CXR. Consider referral if persistent, even if X-ray normal	
Chest pain (non-cardiac)	0.8%	No	CXR if symptoms have not resolved within three weeks	
Dyspnoea	0.7%			
Cough	0.4%			
Loss of weight / loss of appetite	1.1%	No	CXR should be an early test, unless other cancers more likely	
Fatigue	0.4%	No	For CXR only if other chest symptoms	
Multiple or repeated symptoms (two or more of the above)	As a rough rule, you can add up the figures above	No	CXR unless clear alternative diagnosis. Re-attendance with continued symptoms generally warrants CXR unless clear alternative diagnosis	

3. Flexible-sigmoidoscopy

3.1. Colorectal cancer

Between 1971 and 2008, incidence rates for colorectal cancer have increased by 33% for men and 12% for women. In 2008, colorectal cancer accounted for 14% of all new cancer diagnoses in men (57 new cases per 100,000 population) and 12% in women in England (37 new cases per 100,000) (26), (27).

5-year survival rates from cancer of the colon and cancer of the rectum are calculated separately. For colon cancer, the five-year survival rate for men is 52% and for women 54% (diagnosed between 2004 and 2008 and followed up to 2009). For cancer of the rectum, the five-year survival for men is 54% and for women 57% (diagnosed between 2004 and 2008 and followed up to 2009) (28).

Colorectal cancer is most commonly diagnosed in those aged 60 and over. Cases are highest in those aged between 70-79 for men and in those aged 85 and over for women. For a number of these symptoms associated with colorectal cancer, the risk of achieving a firm diagnosis varies with age (12).

25% of patients diagnosed with colorectal cancer present through an emergency presentation, 26% are diagnosed through an urgent two-week referral and 24% are diagnosed through a GP referral not completed through an urgent two-week wait referral (29).

The NHS bowel cancer screening programme was introduced in 2006 for men and women in their 60s and achieved national coverage by 2010. The age inclusion criteria is being extended to men and women up to their 75th birthday (those aged over can self-refer), and piloting of flexible-sigmoidoscopy screening for everyone aged around 55 will begin in autumn 2012.

3.2. Diagnosis

The 2005 NICE guidelines highlight criteria for 'high risk' patients who should be referred under an urgent two-week wait (3).

Nevertheless, it is known that only 50% of colorectal cancers ever have this 'high-risk' symptom pattern that would qualify for an urgent NICE referral with the remaining 50% having no obvious symptom complex (24). These patients take longer to be diagnosed and also have a worse mortality (30). As such, detecting cancer early in these patients will yield most benefit.

3.2.1. Patients warranting referral under an urgent two-week wait

NICE 2005 guidelines outline that an urgent referral to be seen within 2 weeks should be made for (3):

- Patients aged 40 years and older reporting rectal bleeding with a change of bowel habit towards looser stools and/or increased stool frequency persisting for 6 weeks or more

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- Patients aged 60 years and older, with rectal bleeding persisting for 6 weeks or more without a change in bowel habit and without anal symptoms
- Patients aged 60 years and older, with a change in bowel habit to looser stools and/or more frequent stools persisting for 6 weeks or more without rectal bleeding
- Patients presenting with a right lower abdominal mass consistent with involvement of the large bowel, irrespective of age
- In patients presenting with a palpable rectal mass (intraluminal and not pelvic), irrespective of age
- In men of any age with unexplained iron deficiency anaemia and a haemoglobin of <11g/100 ml
- In non-menstruating women with unexplained iron deficiency anaemia and a haemoglobin of <10g/100 ml.

NB: NICE guidance further outlines that GPs should consider urgently referring patients of any age presenting with iron deficiency anaemia for gastroscopy or specialist review (31).

3.2.2. Patients who may benefit from direct access

Patients who may benefit from a direct GP referral for flexible sigmoidoscopy

Patients presenting with the following symptoms that may be suggestive of cancer may benefit from further investigation with endoscopy to help establish a cause for their symptoms. These patients may be referred directly for flexible-sigmoidoscopy or to a one-stop clinic where available:

- Patients aged 40 years and older with unexplained rectal bleeding persisting for at least 6 weeks
- Patients aged 55 years and older presenting with rectal bleeding of any duration.

The Cancer Diagnostics Advisory Board is fully aware that in many areas services are already in place that would support direct access to flexible-sigmoidoscopy for patients with all cause symptomatology. Commissioners may wish to continue or consider extending access to these patients where local decision makers feel it preferable and capacity would allow. In such circumstances, the following criteria are suggested:

- Patients aged up to 55 years with persistent or intermittent rectal bleeding for at least 6 weeks
- Patients aged 55 years and older presenting with rectal bleeding of any duration.

3.2.3. Patients with changes of bowel habit

NICE already suggests urgent referral for:

- Patients aged 60 years and older, with a change in bowel habit to looser stools and/or more frequent stools persisting for 6 weeks or more without rectal bleeding.

It is now suggested that the following group of patients are referred for specialist opinion to determine appropriate investigation:

- Patients aged 40 years and older with a change in bowel habit to loose or more frequent stools for at least 6 weeks.

3.2.4. Patients with iron-deficiency anaemia

Patients with iron-deficiency anaemia, but with haemoglobin values above the NICE threshold of 10g/dl (women) and 11g/dl (men) still have an increased risk of colorectal cancer (32). If there is no alternative explanation for the iron-deficiency anaemia, investigation by gastroenterology is warranted especially in with the haemoglobin values near the NICE threshold.

3.2.5. The predictive risks of symptoms suggestive of colorectal cancer

Direct access will prove most useful for those patients presenting to primary care who have symptoms of 'low' to 'moderate' risk.

The following table highlights the risk of colorectal cancer associated with certain symptoms estimated from primary care based studies. It is assumed that the patient is over 40 years of age (or has a high risk of cancer from, for example, a strong family history of cancer), the patient has a primary complaint of one or more symptoms and there is no obvious alternative diagnosis. This information may help to support decisions as to whether to refer a patient.

Table 4. Risk of colorectal cancer associated with certain symptoms

Symptom	Approximate risk of cancer	Does this meet two week referral criteria?	Suggested investigation
Rectal or abdominal mass	Unknown, but likely to be very high	Yes, regardless of the patients' age	These patients should be referred urgently for suspected cancer (two week wait)
Rectal bleeding	Varies by age (12), from 0.5% in those under 60 years, to 4.5% (males) or 2.8% (females) in those over 80 (33), (34), (35)		Urgent referral for suspected cancer for NICE qualifying patients. Consider direct referral for flexible - sigmoidoscopy for: i) all patients aged over 55 with rectal bleeding of any duration; or ii) all patients aged over 40 with rectal bleeding for at least 6 weeks
Diarrhoea	Varies by age (12)	Yes, if present for 6 weeks in patients aged over 60	Consider referral to specialist in those aged over 40 if present for at least 6 weeks with no obvious cause
Anaemia without an alternative cause	Risk increases with age and severity	Yes, if iron deficient and Hb <11g/dl in males, or <10g/dl in females of any age	Urgent referral for suspected cancer for NICE qualifying patients Consider referral to specialist Also consider urgent referral for gastroscopy
Multiple or repeated symptoms (two or more of the above).	As a rough rule, add up the figures above, assuming each of diarrhoea and anaemia, insufficient to meet the NICE threshold, to have a risk of 1%. Most combinations of symptoms will have a risk >2%	No	Consider referral to specialist

Common gastrointestinal symptoms

Abdominal pain, weight loss and constipation are common symptoms encountered in primary care and may be due to a wide range of pathologies. For example, though rare for first time presentation in patients aged over 50, irritable bowel syndrome is a common condition that can present with abdominal pain. Inflammatory bowel disease is another condition that can present with both weight loss and abdominal pain. Finally, unintentional weight loss as a sole symptom may be appropriate for urgent referral under a two-week wait if suspecting upper gastrointestinal cancer.

As such, when presented with patients with these common symptoms, GPs will wish to consider a range of cancer and non-cancer related causes and request further investigations where they deem appropriate. Additionally, it is possible that no obvious cause will be found for some patients presenting with these symptoms.

Furthermore, the chance of diagnosing cancer in patients with these symptoms increases if the symptom described presents in association with other abdominal symptoms. In these patients, referral for consideration of further investigations including endoscopy or urgent referral may be warranted. The following table highlights the risk of colorectal cancer associated with these symptoms estimated from primary care based studies, where they have been performed. It is assumed that the patient is over 40 years of age.

Table 5. Risk of colorectal cancer associated with other symptoms

Symptom	Approximate risk of cancer	Does this meet two week wait referral criteria?	Suggested investigation
Abdominal pain without a clear cause	1.1% (24)	No	Consider referral to specialist those aged over 40, particularly if present with other symptoms, especially if the pain is new or different from previously experienced pain
Loss of weight	1.2% (24)	No	Consider referral to specialist in those aged over 40, particularly if present with other symptoms
Constipation	Low risk of less than 1% in all ages	No	Consider referral to specialist in those aged over 40, particularly if present with other symptoms

Accompanying notes

1. Considering best practice in obtaining a diagnosis in patients with gastrointestinal symptoms

For patients where direct access to flexi-sigmoidoscopy has been suggested according to the guidance above, a referral for direct access flexible-sigmoidoscopy should ideally result in a consultation with a healthcare professional who performs the investigation, conducts a clinical evaluation, and who makes recommendations on further management.

As such, GPs will wish to consider what constitutes best practice when instigating a referral for further evaluation of symptoms. An ideal process may include referral to a one-stop direct access clinic that can exclude cancer as a cause of symptoms but also allows sufficient clinical space for further evaluation of symptoms and treatment where appropriate.

2. CT-colonography is now recognised as an alternative to lower GI endoscopy in the frail elderly. Barium enema is no longer recommended (36).

3. Faecal occult blood testing

The NHS bowel cancer screening programme in England is based around the use of faecal occult blood testing (FOB) in asymptomatic men and women. Faecal occult blood testing is only a suitable investigation as part of a population-based screening programme for colorectal cancer. It is not recommended in the primary care setting for symptomatic patients.

4. NICE colorectal cancer guideline and consultation

In November 2011, NICE published a new clinical guideline for use in NHS England on 'Colorectal cancer: The diagnosis and management of colorectal cancer' (9). NICE are also currently consulting on a draft colorectal cancer quality standard.

4. Brain Magnetic Resonance Imaging (MRI)

4.1. Brain cancer

Brain cancer is amongst the top 20 most common cancers diagnosed each year in both men and women. In 2009, brain tumours accounted for 3,137 deaths in England, approximately 2% of all cancer deaths (1). The 5 year survival rate from brain cancer was approximately 16% for both men and women diagnosed between 2004-2008 and followed up to 2009 (28).

Due to changes in the methods of data collection and coding as well as newer, more sophisticated methods to diagnose brain cancer such as CT and MRI, it is difficult accurately to assess trends of brain cancer over time. However, the incidence of some types of brain cancer such as gliomas in elderly patients is thought to be increasing (37).

Males are more likely to suffer from brain cancer. Overall, the number of new cases for the whole population was approximately 8 per 100,000 in 2007 in England, with a crude diagnosis rate in males of 9 per 100,000 and in women of 7 per 100,000. 72% of people with a brain tumour present over the age of 50 (38). The incidence is highest in those aged between 60-80 for men and for women. After 80 years of age, the incidence appears to decrease; however, this may be due to the methods used in data collection.

58% of brain tumours are presently diagnosed via an emergency presentation, with only 1% of patients diagnosed following an urgent GP referral for suspected cancer (two week wait) (29).

4.2. Diagnosis

MRI scanning has become an increasingly important and widespread imaging tool since its introduction to the NHS. Together with CT scanning, its introduction has led to the increased and earlier diagnosis of brain cancer in patients.

This guide aims to raise awareness of the symptomatic indications that warrant urgent referral for specialist review and where a direct referral to MRI brain in tandem may benefit patients through achieving a faster diagnosis. Additionally, this guide will help GPs consider circumstances where a direct referral for MRI brain alone may be appropriate and most useful.

4.2.1. Headache – a common complaint

Headache is an extremely frequent symptom encountered in primary care with an estimated consultation rate of 4.4 per 100 patients (39). Of these patients, 3% are referred to secondary care for further assessment.

70% of patients with a brain tumour will experience a headache during their illness at some time (40). Despite this, the risk of headache being associated with a brain tumour is low and is estimated to be around 0.09% (39). Several of the non-headache symptoms and signs of brain cancer are subtle, so selection of patients for direct investigation is particularly dependent upon the GP's experience and intuition. It should be noted however that brain tumours are less common than colorectal, ovarian or lung cancers (41). If a practitioner can make a diagnosis of primary headache then imaging for reassurance is not indicated. This is supported by RCR

guidelines. Imaging is not usually useful for isolated headache without abnormal neurological features.

As always, an accurate history and examination can significantly contribute to the clarity of diagnosis. The British Association for the Study of Headache (BASH) have published a useful guide on the diagnosis and management of headaches (42).

If investigation for headache is undertaken and significant pathology has been excluded, there will be a necessity to continue to follow up and treat appropriately.

4.2.2. Patients warranting referral under the two week wait

The table below outlines the symptoms warranting an urgent referral for suspected cancer (to a two week wait service) as highlighted in NICE 2005 guidelines (3). This is supplemented by accompanying information suggesting how direct access to MRI brain scanning may be of benefit to the three different cohorts of patients identified in the NICE guidelines.

It is important to remember that patients presenting with drowsiness or vomiting may need immediate referral to Accident and Emergency and further management in an appropriate neuroscience unit. Patients presenting with seizures may also require emergency admission and / or urgent referral to an epilepsy service.

Table 6. Symptoms warranting urgent referral for suspected cancer (for a two week wait service)

<p><u>NICE 2005 suggested urgent referral criteria for 2 week wait (3)</u></p> <ul style="list-style-type: none"> • Patients with symptoms related to the central nervous system including: <ul style="list-style-type: none"> ○ progressive neurological deficit ○ new-onset seizures ○ headaches ○ mental changes ○ cranial nerve palsy ○ unilateral sensorineural deafness¹ • Patients with headaches of recent onset accompanied by features suggestive of raised intracranial pressure, for example: <ul style="list-style-type: none"> ○ vomiting ○ drowsiness ○ posture-related headache ○ pulse-synchronous tinnitus ○ or by other focal or non-focal neurological symptoms, for example: <ul style="list-style-type: none"> ○ blackout ○ change in personality ○ change in memory • Patients with a new, qualitatively different, unexplained headache that becomes progressively severe • Patients with suspected recent-onset seizures • Patient with a history of cancer accompanied with symptoms as described above 	<p><u>How direct access may benefit patients</u></p> <p>NICE 2005 guidelines also state that if rapid access to scanning is available, this should also be considered as an alternative to urgent referral</p> <p>For this cohort of patients where urgent referral is recommended, GPs may wish to refer patients direct for MRI brain in addition to a referral for specialist review</p> <p>This would benefit patients by reducing time taken in achieving a diagnosis with results available by the time of urgent review with the appropriate specialist</p> <ol style="list-style-type: none"> 1. Examination should include checking fundi for papilloedema. If headache is suspicious of raised intracranial pressure and there is doubt regarding presence or absence of papilloedema urgent assessment by optometrist could be undertaken depending on local arrangements 2. If fever, drowsiness, neck stiffness or concern re CNS infection, thrombosis or sub-arachnoid haemorrhage contact neurological services same day
<p><u>NICE suggests consideration of referral in patients with rapid progression of:</u></p> <ul style="list-style-type: none"> • Sub acute focal neurological deficit • Unexplained cognitive impairment, behavioural disturbance or slowness, or a combination of these • Personality changes confirmed by a witness and for which there is no reasonable explanation even in the absence of the other symptoms and signs of a brain tumour 	<p><u>How direct access may benefit patients</u></p> <p>For this cohort of patients where consideration for urgent referral is recommended, GPs may wish to proceed direct to MRI brain</p> <p>This may also be accompanied by an urgent referral for specialist review or GPs may wish to wait for the MRI scan result before deciding the most appropriate for specialist review</p> <ol style="list-style-type: none"> 1. Examination should include checking fundi for papilloedema. If headache is suspicious of raised intracranial pressure and there is doubt regarding presence or absence of papilloedema urgent assessment by optometrist could be undertaken depending on local arrangements 2. If fever, drowsiness, neck stiffness or concern re CNS infection, thrombosis or sub-arachnoid haemorrhage contact neurological services same day
<p><u>NICE non-urgent referral or discussion with a specialist. These are patients presenting with:</u></p> <ul style="list-style-type: none"> • Unexplained headaches of recent onset present for at least 1 month and not accompanied by features suggestive of raised intracranial pressure 	<p><u>How direct access may benefit patients</u></p> <p>For this cohort of patients where non-urgent referral for specialist review is recommended, MRI brain may be suitable as an alternative to this referral as part of the initial management plan</p> <p>GPs may wish to refer these patients for specialist review depending on the results of the MRI brain scan</p>

¹ Professional opinion is that this should be confined to patient to recent onset of unilateral sensorineural deafness

4.2.3. Additional groups of patients where direct access MRI brain may be of benefit

GPs may also wish to consider direct referral for MRI brain in patients presenting with the following symptoms that have been highlighted as warning symptoms in BASH, MBUR-7 and primary care based literature and do not appear in current NICE 2005 guidelines.

Table 7. Additional groups of patients where direct access MRI brain may be of benefit

New onset headache in patients aged over 50	Consider direct referral for MRI brain Excluding patients where a primary diagnosis is made i.e. migraine, tension headache, cluster headache, trigeminal neuralgia and importantly temporal arteritis and MRI would not be helpful unless resistant to treatment (40), (42)
Headache causing patients to wake from sleep (40), (7)	Consider direct referral for MRI brain
New headache in a patient with a history of immunocompromisation (42), (7)	Consider direct referral for MRI brain
Headaches that have been present for some time but have changed significantly, particularly with a rapid increase in frequency (40)	Consider direct referral for MRI brain

4.2.4. The predictive risks of symptoms suggestive of brain cancer

The following table highlights the risk of cancer associated with certain symptoms estimated from primary care based studies, where they have been performed. It is assumed that the patient is over 50 years of age (or has a high risk of cancer from, for example, a strong family history of cancer). The patient has a primary complaint of one or more symptoms, and there is no obvious alternative diagnosis. This information may help to support decisions as to whether to refer a patient.

Table 8. Risk of brain cancer associated with certain symptoms

Cohort	Symptom	Approximate risk of cancer	Suggested investigation and notes
NICE suggested urgent referral criteria for 2 week wait	New, qualitatively different, unexplained headache that becomes progressively severe	0.1% unless additional symptoms	NICE 2005 guidelines state that if rapid access to scanning is available, this should also be considered as an alternative to urgent referral
	New onset seizures	1.2%, rising to 2.3% in over 60s	For this cohort of patients where urgent referral is recommended, GPs may wish to refer patients direct for MRI brain in addition to a referral for specialist review
	Patients with a previous history of cancer with the above symptoms		This would benefit patients by reducing time taken in achieving a diagnosis with results available by the time of urgent review with the appropriate specialist
NICE suggested consideration of urgent referral for 2 week wait	Sub acute focal neurological deficit	Unknown, except for focal neurological deficit, 0.03%	For this cohort of patients where consideration for urgent referral is recommended, GPs may wish to proceed direct to MRI brain
	Unexplained personality change		
	Unexplained cognitive loss	Will be higher in patients with a previous cancer	This may also be accompanied by an urgent referral for specialist review or GPs may wish to wait for the MRI scan result before deciding upon the most appropriate referral for specialist review
NICE non-urgent referral or discussion with a specialist	New onset headache	0.1% unless additional symptoms	Consider direct referral for MRI brain in patients with headache present for at least 1 month and not accompanied by features suggestive of raised intracranial pressure

Note: It is likely that multiple symptoms carry a higher risk of brain cancer, though there is insufficient evidence to be certain.

Accompanying notes

1. A ‘normal’ scan

A normal investigation does not preclude the need for ongoing follow up, monitoring and further investigation. Furthermore, a seemingly ‘normal’ MRI scan may in certain instances provide false reassurance in patients who have neurological pathology that MRI scanning is unable to detect.

CT head remains the investigation of choice for investigation of a subarachnoid haemorrhage (7).

2. Suitability of MRI

It must be recognised that some patients, approximately 10% (43), (44), may be either unsuitable or unable to tolerate MRI scanning. These include patients with pacemakers in-situ or those with severe claustrophobia. In these patients, a CT scan may be an appropriate alternative investigation, though GPs will wish to consider the potential radiation exposure associated with CT scans.

3. Incidental findings

The identification of incidental pathology is a well recognised and potentially significant outcome for patients who undergo MRI scanning. It is estimated that between 3-10% of scans (45) (46) (47) may yield abnormalities in otherwise healthy individuals. This may impact on these patients in a number of ways including further investigations and the potential impact on health insurance premiums.

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As incidental findings are not an infrequent result of MRI scanning, patients should have prior counselling and information to make them aware of the potential for such findings as a consequence of their investigation.

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