

## Research papers

# Patient involvement in national clinical guidelines: the NICE guidelines on referral for suspected cancer

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### ABSTRACT

There is a general agreement that guidelines should assist decision making by patients. However, there is less agreement on how this can be achieved. In this article, the recently published guidelines on referral for suspected cancer are used to illustrate some of the approaches adopted by the National Institute for Health and Clinical Excellence (NICE) in

England Wales. It is argued that considerable progress has been made in recent years on ways of promoting patient involvement through guidelines, although some problems remain to be resolved before genuine involvement is achieved.

**Keywords:** guidelines, NICE, patient involvement

## Introduction

Guidelines have been defined as ‘systematically developed statements to assist practitioner and patient decision making’.<sup>1</sup> This definition has become widely accepted and has imposed on guideline developers the duty of producing guidelines that promote patient involvement, and perhaps even the concept of the patient as the source of control.<sup>2</sup> In the UK, considerable progress has been made in methods of guideline development, first by the Scottish Intercollegiate Guideline Network (SIGN) and more recently by the National Institute for Health and Clinical Excellence (NICE).<sup>3,4</sup> This article will focus on guidelines produced by NICE, which contain recommendations on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales. They are based on best available evidence, but an extensive consultation process is involved in their development. This includes not only the deliberations of a guideline development group that is composed of professionals and representatives of patient and carer groups, but also external, national, open consultation with registered stakeholders. The stakeholders include professional, commercial, and patient and carer organisations. Each guideline takes up to two years to develop. NICE has established several national collaborating centres (NCCs) to help develop the clinical guidelines, and these are the NCCs for acute care, cancer, chronic

conditions, mental health, nursing and supportive care, primary care, and women’s and children’s health. The guideline for referral for suspected cancer was developed by the NCC for primary care. Each guideline is published in four versions. There is the full guideline which contains all the recommendations plus details of the methods used and the underpinning evidence. There is also the NICE guideline, which presents the recommendations from the full version in a format focused on implementation for healthcare workers; this is supplemented by the quick reference guide which summarises the recommendations in a format useful for the end user. Finally, there is a version for the public that is written for people without specialist medical knowledge. To date, 34 guidelines have been published by NICE and 40 are under development.

## Guideline development

Patient involvement in guideline development is achieved in several ways. The first approach is to ensure wide consultation from the start. This involves agreement of the scope, following consultation with stakeholders who include patient organisations. Once the scope of the guideline has been confirmed, the

guideline group is formed. Each guideline development group includes at least two representatives of patients and carers, and this was the case with the guideline on referral for suspected cancer. That guideline group also included health professionals (general practitioners, a surgeon, public health physician, nurse, clinical psychologist and others), plus the technical team who service the group with evidence reviews and methodological support.

The role of the patient and carer representatives on the guideline group includes contributing their own experience and perspective to the deliberations of the group. They also have a wider role however, in that they present an opportunity for the health professionals to talk within the group to non-clinical individuals about the recommendations. Of course there is often an element of explanation in this, but there is

also an element of learning on the part of the health professionals. Health professionals develop a better understanding of the patient perspective. Having observed this dialogue take place in guideline development groups, I am convinced that it is a critically important ingredient to producing guidelines that promote the involvement of patients in their care.

## The recommendations

The impact of patient involvement in guideline development can be illustrated by the recommendations in the referral guidelines for suspected cancer. The recommendations for breast cancer are shown in Box 1.

### Box 1 Breast cancer

Refer a patient who presents with symptoms suggestive of breast cancer to a team specialising in the management of breast cancer.

In general:

- convey optimism about the effectiveness of breast cancer treatments and survival of breast cancer patients
- discuss the information and support needs of your patient and respond sensitively
- encourage all patients, including women over 50 years old, to be breast aware.

Always take the patient's history into account. For example, it may be appropriate, in discussion with a specialist, to agree referral within a few days in a patient who reports a lump or a symptom that has been present for several months.

#### Urgent referral

Refer urgently patients:

- of any age with a discrete, hard lump with fixation, with or without skin tethering
- who are female, aged 30 years and older with a discrete lump that persists after their next period, or presents after menopause
- who are female, aged younger than 30 years:
  - with a lump that enlarges
  - with a lump that is fixed and hard
  - in whom there are other reasons for concern such as family history
  - of any age, with previous breast cancer, who present with a further lump or suspicious symptoms
  - with unilateral eczematous skin or nipple change that does not respond to topical treatment
  - with nipple distortion of recent onset
  - with spontaneous unilateral bloody nipple discharge
- who are male, aged 50 years and older with a unilateral, firm subareolar mass with or without nipple distortion or associated skin changes.

#### Non-urgent referral

Consider non-urgent referral in:

- women aged younger than 30 years with a lump
- patients with breast pain and no palpable abnormality, when initial treatment fails and/or with unexplained persistent symptoms. (Use of mammography in these patients is not recommended.)

#### Investigations

In patients presenting with symptoms and/or signs suggestive of breast cancer, investigation prior to referral is not recommended.

The initial recommendations are general and include conveying optimism about the effectiveness of breast cancer treatments and survival, discussing the information and support needs of the patient, and encouraging all women aged over 50 years to be breast aware. Of course, the recommendations also include clear statements about when cancer should be suspected and the patient referred, but they go further in requiring the health professional to consider the concerns and needs of the patient.

The way in which these recommendations for the health professional are transformed into information for the patient with suspected cancer and their carers is shown by the abstract taken from the information for the public version of the referral for suspected cancer guidelines relating to breast cancer, and included in Box 2.<sup>3</sup>

The preparation of the information for patients from the guideline recommendations is undertaken by skilled editors. They consult with the patient representatives of the guideline group, with the aim of producing information that is readily understood. The information is published in a small booklet, and in the case of the referral guidelines for suspected cancer, the booklet is 55 pages long. In addition to repeating the recommendations in an understandable form, the information includes background information about the types of cancer and what the patient can expect from the GP. The underlying principle is that by providing more information, the patient, if they wish, can be more involved in decisions about their care.

The proportion of patients who will refer to the information booklet is difficult to predict. Although

## Box 2 Breast cancer

Breast cancer is cancer of the breasts and can occur in men as well as women. A patient with symptoms of breast cancer should be referred by the general practitioner (GP) to a team specialising in breast cancer.

Your GP should explain that treatments for breast cancer are very effective and help many people survive. The GP should be sensitive towards patients being referred for suspected cancer and discuss any specific information and support needs the patient may have.

The GP should encourage all patients, including women over 50 years old, to be breast aware. This should help avoid delays in people coming forward with symptoms. The GP should take a patient's history into account when making decisions about referral. For example, the GP might talk to a specialist and arrange referral for patients reporting a lump or other symptom that has been present for several months.

### Urgent referral

Urgent referral should be made in patients:

- of any age with a separate, distinct, hard lump that is fixed, with or without dimpling of the skin (sometimes called skin tethering)
- aged 30 years and older with a separate, distinct lump that is still present after their next period, or occurs after the menopause
- aged younger than 30 years with a lump that is growing or has other features linked with cancer (such as being fixed and hard), or other factors such as family history
- of any age, who have had breast cancer before, and have a new lump or other suspicious symptoms
- with eczema on one breast or a nipple change that does not get better when treated
- with a recent change in nipple shape
- with a bloody discharge from one nipple
- who are male, aged 50 years and older with a firm lump in one breast with or without a change in nipple shape or skin changes

### Non-urgent referral

Harmless lumps in people under 30 years of age are very common. Patients under 30 with a lump should be referred non-urgently by the GP.

The GP should also make a non-urgent referral for patients with breast pain and no other symptoms, when the first treatment that the GP offers doesn't work. A non-urgent referral should also be made if there are any unexplained persistent symptoms.

### Tests

Where patients have symptoms suggestive of breast cancer, NICE recommends that tests should not be carried out before referral to a specialist.

the booklet is available from the NICE website, it may not be readily available at all times in all practices, and in any case a proportion of patients will not want to look at a booklet, want only selected information, not speak English, or have other problems in reading. Therefore, the booklet is only part of the process of patient involvement that flows from guidelines.

## Support and information needs

Another way in which the completed guidelines seek to promote patient involvement is the inclusion of a set of recommendations specifically concerned with

the support and information needs for people with suspected cancer (Box 3).

The underlying research evidence on the support and information needs of people who are being referred with suspected cancer is very limited. The guideline group drew on the limited evidence available and their own expertise to produce the recommendations included in Box 3. These are recommendations for health professionals, and they centre on the involvement of the patient, taking account of their needs, circumstances, and preferences. Patients need information in order to be involved. Support also plays a part in promoting involvement through ensuring that the professional understands the patient's circumstances and preferences. It is very likely that programmes to implement the guidelines will focus on

### Box 3 Support and information needs of people with suspected cancer

#### Support

- Ensure patients are able to consult a primary healthcare professional of the same sex, if preferred.
- Discuss with patients (and carers as appropriate) their preferences for being involved in decision making about referral options and further investigations (including risks and benefits).
- Normally tell adults that they are being referred to a cancer service, but if appropriate provide reassurance that most people who are referred will not turn out to have a diagnosis of cancer.
- Follow current advice on communicating with patients and/or their carers and breaking bad news.
- Assess the patient's need for continuing support while waiting for their referral appointment. Invite the patient to contact you again.
- Consider the information and support needs of patients and the people who care for them.
- Take into account personal circumstances, such as age, family or work responsibilities, isolation, or other health or social issues.
- Provide culturally appropriate care.
- Be aware that men may have similar support needs, with the patient's agreement.

#### Information

- Promote awareness of key presenting features of cancer.
- Be willing and able to give patients information on the possible diagnosis (both benign and malignant).
- Information should cover:
  - where patients are being referred to
  - how long they will have to wait for the appointment
  - how to obtain further information about the type of cancer suspected or help prior to the specialist appointment
  - who will they be seen by
  - what to expect from the service they will be attending
  - what type of tests will be carried out, and what will happen during diagnostic procedures
  - how long it will take to get a diagnosis or test results
  - whether they can take someone with them to the appointment
  - other sources of support, including those for minority reports.
- Have information available in a variety of formats on both local and national sources of support.
- In situations where diagnosis or referral has been delayed, or there is a significant compromise of the doctor/patient relationship, take care to assess the information and support needs of the patient, parents and/or carers, and make sure these needs are met. Give the patient an opportunity to consult another primary healthcare professional if they want to.
- In children and young people, discuss the referral decision and any information needs with the parents or carers (and the patient, if appropriate).

the recommendations about the symptoms and signs that indicate the need for urgent referral under the two week wait scheme. However, the guideline group would encourage primary care organisations who are promoting implementation of the guidelines to pay attention to the support and information needs recommendations as well. These flow from the involvement of patients in the development of the guideline and therefore deserve the close attention of health professionals.

## Discussion

The Bristol Inquiry's first recommendation was that health professionals in the NHS should provide care on the basis of partnership with patients (Box 4).<sup>6</sup> This recommendation is echoed in *The NHS Plan* of 2000 for services to be built around the needs and preferences of patients.<sup>7</sup> Through involvement of patients in guideline development groups and the formal consultation processes that take place during guideline development, supported by the inclusion of recommendations specifically concerned with patients' preferences and needs, and the provision of guidelines in a format specifically for patients, NICE guidelines are contributing to the creation of an NHS culture which values patient involvement. Of course, there is more to be done. Methods of direct consultation with

patients rather than through the intermediary of patients' groups would be a useful next step. Thought should also be given to more effective ways of getting information to patients or potential patients about the content of guidelines. This is far from simple, but over a period of time it may be possible to present information in formats that make the education of the public by NICE an accepted feature of care in England and Wales. Furthermore, guidelines are but one of many activities to promote patient involvement. The creation of the health service that is genuinely responsive, and designed in accordance with patients' preferences and needs, will take a considerable time.

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## CONFLICTS OF INTEREST

None.

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### Box 4 Partnership: involving patients (Bristol Inquiry<sup>6</sup>)

- In a patient-centred healthcare service patients must be involved, wherever possible, in decisions about their treatment and care.
- The education and training of all healthcare professionals should be imbued with the idea of partnership between the healthcare professional and the patient.
- The notion of partnership between the healthcare professional and the patient, whereby the patient and the professional meet as equals with different expertise, must be adopted by healthcare professionals in all parts of the NHS, including healthcare professionals in hospitals.