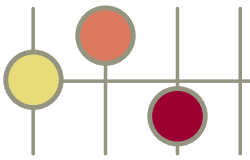
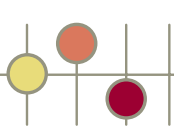


Centre for Reviews and Dissemination

A Systematic Review of Cancer Waiting Time Audits



Promoting the use of research based knowledge

CRD THE UNIVERSITY of York

REPORT 27

A SYSTEMATIC REVIEW OF CANCER WAITING TIME AUDITS

Ruth Lewis
Ros Collins
Adrian Flynn
Michael Emmans Dean
Lindsey Myers
Paul Wilson
Alison Eastwood

Centre for Reviews and Dissemination (CRD)
University of York
YO10 5DD, UK

February 2005

ISBN 1-900640-33 3

This report can be ordered from: Publications Office, Centre for Reviews and Dissemination, University of York, York YO10 5DD. Telephone 01904 321458; Facsimile: 01904 321035: email: crd-pub@york.ac.uk
Price £12.50

The Centre for Reviews and Dissemination is funded by the NHS Executive and the Health Departments of Wales and Northern Ireland. The views expressed in this publication are those of the authors and not necessarily those of the NHS Executive or the Health Departments of Wales or Northern Ireland.

Printed by York Publishing Services Ltd.

Centre for Reviews and Dissemination

The Centre for Reviews and Dissemination (CRD) is a facility commissioned by the NHS Research and Development Division. Its aim is to identify and review the results of good quality health research and to disseminate actively the findings to key decision makers in the NHS and to consumers of health care services. In this way health care professionals and managers can ensure their practice reflects the best available research evidence. The reviews will cover: the effectiveness of care for particular conditions; the effectiveness of health technologies; and evidence on efficient methods of organising and delivering particular types of health care.

Further Information

General Enquiries:	01904 321040
Information Service	01904 321078
Publications:	01904 321458
Fax:	01904 321041
Email:	crd@york.ac.uk

CRD Reports

1. Which way forward for the care of critically ill children? (1995)	£7.50
2. Relationship between volume & quality of health care (1995)	£5.00
4. Undertaking systematic reviews of research on effectiveness. 2nd edition (2001)	£12.50
5. Ethnicity and health (1996)	£12.50
6. Improving access to cost-effectiveness information for health care decision making: the NHS Economic Evaluation Database. (2nd Edition 2001)	£9.50
7. A pilot study of 'Informed Choice' leaflets on positions in labour (1996)	£7.50
8. Concentration and choice in the provision of hospital services (1997)	
Summary Report	£6.00
Part I - Hospital volume and quality of health outcomes	£12.50
Part II - Volume and the scope of activity and hospital costs	£9.50
Part III - Concentration, patient accessibility and utilisation of service	£7.50
Complete set of reports	£30.00
9. Preschool vision screening: results of a systematic review (1997)	£9.50
10. Systematic review of interventions in the treatment and prevention of obesity (1997)	£12.50
11. A systematic review of the effectiveness of interventions for managing childhood nocturnal enuresis (1997)	£12.50
13. Screening for ovarian cancer: a systematic review (1998)	£12.50
14. Women and secure psychiatric services: a literature review (1999)	£12.50
15. Systematic review of the international literature on the epidemiology of mentally disordered offenders (1999)	£12.50
16. Scoping review of literature on the health and care of mentally disordered offenders (1999)	£12.50
17. Therapeutic community effectiveness: community treatment for people with personality disorders and mentally disordered offenders (1999)	£12.50
18. A systematic review of water fluoridation (2000)	£20.00
19. The longevity of dental restorations: a systematic review (2001)	£20.00
20. Informed choice in maternity care: an evaluation of evidence based leaflets (2001)	£20.00
21. Scoping review of the effectiveness of mental health services (2001)	£12.50
22. The effectiveness of interventions used in the treatment/management of chronic fatigue syndrome and/or myalgic encephalomyelitis in adults and children (2002)	£12.50
23. Access to the online evidence base. A survey of the Northern and Yorkshire Region (2003)	£7.50
24. Outcomes measurement in psychiatry (2003)	£12.50
25. Scoping review of sabotage and/or tampering in the NHS (2004)	£12.50
26. Predictors of delay in seeking medical help in patients with suspected heart attack, and interventions to reduce delay: A systematic review (2004)	£12.50

ACKNOWLEDGEMENTS

We would like to thank all the NHS staff that took the time to respond and help us identify potential clinical audits.

We would like to thank Mr Paul Finan (honorary secretary of the ACPGBI in 2003) for allowing us access to electronic databases of abstracts submitted to the ACPGBI conference over the last 2 years; Dr N. H. Cox, Consultant Dermatologist (North Cumbria Acute Hospital Trust), Mike Thompson, Consultant Surgeon (Portsmouth Hospital), and Alastair Johnston (Wandsworth PCT) who assisted us with identifying and obtaining clinical audits.

We also wish to thank members of the advisory panel for their useful advice and constructive comments on the draft protocol and report:

- Mark Baker (Yorkshire Cancer Network)
- Richard Baker (Leicester)
- Jane Barrett (Royal Berkshire Hospital)
- Alastair Johnston (Wandsworth PCT)
- Peter Littlejohns (NICE)
- Clare Morrell (RCN audit)
- Mike Richards (National Cancer Director)
- John Wright (Bradford Hospitals NHS Trust)

CONTENTS

EXECUTIVE SUMMARY

Objective: To assess the implementation and effectiveness of the two-week waiting time policy for cancer referrals and to inform a review of the cancer referral guidelines by NICE.

Design: Systematic review of clinical audits conducted in England and Wales.

Search: Key staff in all NHS Trusts, Strategic Health Authorities, Cancer Networks and relevant professional organisations in England were contacted and asked to provide details of all cancer waiting time audits conducted since 1st April 1999. Searches of the Internet and of a range of electronic databases were also undertaken. Conference proceedings were hand searched.

Selection of studies: Obtained audit reports (sometimes only available as an abstract or slide presentation) were independently assessed for inclusion by two reviewers using pre-defined inclusion criteria. If an audit appeared to be relevant, but it was not possible to confirm this because information was missing, attempts were made to contact the authors.

Main outcome measures: Waiting time to first appointment; GP conformity to guidelines; cancer detection (both cancer rates for populations of referrals and type of referral for populations of cancer patients); appropriateness of type of referral according to hospital clinicians; ability of the guidelines to identify correct referrals (patients meeting guidelines but who had a low suspicion of cancer, or not meeting guidelines but who had a high suspicion of cancer); process of referral (referrals received by hospital within 24 hours and mode of referral).

Results: 241 clinical audits meeting the inclusion criteria were identified. 193 clinical audits were classified as criterion based (i.e. where clinical practice is compared to explicit pre-defined criteria), 36 as non-criterion based (i.e. where practice was not compared to pre-defined criteria), and 12 as research studies. The majority of included studies were poorly reported. Fewer than half (44%) provided sufficient detail on the methods used for the audit to be reproducible.

Under the two-week wait system, there was wide variation in the proportion of site specific cancer referrals that were seen within two weeks, in the proportion of referrals that were found to be in accordance with the symptoms listed in the guidelines, and in the proportion of two-week wait referrals deemed by consultants to warrant an urgent appointment. Less than 20% of included audits provided details outlining any recommended changes to service delivery or how any changes would be implemented. Fewer than 20% of included audits provided details of any plans to re-audit.

Conclusions: Poor reporting can seriously compromise the integrity of the audit process. Audit reports should be written up in sufficient detail to allow the reader to ascertain how the audit was conducted and to assess the validity of the results and how these will be used to improve existing practices and procedures. The methods by which clinical audits of site specific cancers are conducted and reported should be standardised across the NHS.

BACKGROUND

Providing patients with prompt access to specialist cancer services is a major concern of health policy in England and Wales. In its 1997 White Paper *The New NHS Modern and Dependable,* the government gave a commitment that by the end of 2000, everyone with suspected cancer would be able to see a specialist within two weeks of a referral by his or her GP (Department of Health, 1997).

Guidance setting out the necessary action to achieve the two-week waiting time target for breast cancer, to be implementated in April 1999, was issued in December 1998 (Health Service Circular 1998/242). Details on how the two-week waiting time standard was to be achieved for all other suspected cancers was outlined in September 1999 (Health Service Circular 1999/205). The projected roll out for delivery of the two-week wait standard was as follows:

April 2000	Children's cancers, Lung cancer and Leukaemia.
July 2000	Upper and Lower Gastro-intestinal cancers.
October 2000	Gynaecological cancers, Skin cancers, Brain and Central Nervous System.
December 2000	Urological cancers, Head and Neck cancers, Sarcomas and Haematological cancers.

To assist the implementation of the two-week wait standard for these suspected cancers, the Department of Health (DoH) developed and issued guidelines on the appropriate referral of patients with suspected cancers (Department of Health, 2000). The guidelines included pre-specified criteria, developed for each specific cancer site that would help the GP identify those patients requiring urgent assessment by a specialist. The referral guidelines also aimed to help the GP identify those patients requiring a routine referral to hospital, and to help reassure those patients unlikely to have cancer, and who could be appropriately observed in primary care.

To ensure the delivery of the two-week standard, the guidelines indicated that NHS Trusts are expected to monitor and feedback to GPs, via Primary Care Trusts (PCTs), information on the number, timeliness and appropriateness of referrals. All NHS Trusts and Strategic Health Authorities (SHAs) are expected to collate and submit national cancer waiting time datasets (which include data on how many patients are seen within the two-week wait standard) to a national database. The national cancer datasets were developed to ensure consistency of information collection across healthcare boundaries (NHS Executive, 2000a).

In addition to these arrangements for routine monitoring, all NHS Trusts and SHAs have been encouraged to carry out clinical audits of suspected cancer referrals to generate further information. This includes auditing the appropriateness of the referral against the agreed referral criteria, and monitoring the number of patients referred as urgent, the proportion of urgent referrals who are subsequently found to have cancer, and the numbers of routine referrals who are found to have cancer (NHS Executive, 2000b). Audits of cancer referrals have been conducted at a number of NHS trusts, and although some of these audits have been presented at conferences of specialist societies, the findings may not have been published in full.

To inform the ongoing NICE review of the Cancer Referral Guidelines, CRD was commissioned to carry out a systematic review of clinical audits undertaken to assess the implementation and effectiveness of the two-week waiting time policy for cancer referrals. The revised Cancer Referral Guidelines are due to be issued in March 2005. It was hoped that the results of the review would provide valuable information on the impact of the current

referral guidelines as well as show whether the guidelines are having an impact on service delivery.

Although systematic reviews of research studies are now commonplace, a similar approach has rarely been adopted for clinical audit. The review methodology would provide a quantification, classification and assessment of the quality of clinical audits being conducted in England and Wales.

METHODS

Identification of clinical audits

Because many clinical audits are only documented internally, it was unlikely that conventional literature searches of major bibliographic databases would identify many relevant clinical audit reports. Instead, emphasis was shifted to systematically contacting relevant people across the NHS. Although this is much more time consuming, it was felt necessary in order to be as comprehensive as possible in identifying all relevant clinical audits.

A three-stage strategy (described in detail below) was devised and implemented to identify relevant clinical audits. This involved contacting all relevant organisations, and individuals responsible for undertaking or commissioning clinical audits; searching the websites of key organisations; and performing a search of electronic databases (including grey literature databases and those that record abstracts submitted to conferences).

Stage 1

All NHS Trusts and SHAs were contacted via the CRD Single Contact Point (SCP) network. CRD has developed and maintains a network of some 650 key individuals within NHS Trusts and SHAs. Most SCPs have roles and responsibilities connected with clinical audit, effectiveness or governance. These SCPs use their local knowledge and experience to communicate the findings of CRD outputs within their organisation.

A letter was sent to each SCP asking whether they or their organisation had conducted any cancer waiting time audits since 1st April 1999. We asked if they could send us a copy of any audits that had been conducted at their Trust, and also if they knew of any other audits which may be relevant.

Enclosed with each letter was a self-addressed postage-paid sticker to encourage response. Letters were distributed during July 2003.

Reminder letters were sent to non-respondents. These letters also included a request to the SCP that if they were not the appropriate person in their organisation could they pass the letter to the person that was, or give us the details of the most appropriate person to contact.

Reminder letters were distributed to PCTs in September 2003 and to Hospital Trusts in September and October 2003. A combination of telephone calls and emails were also used to follow up non-respondents.

SCPs often informed us that they had either passed the letter on to a colleague or provided details of the most appropriate person to contact. These leads were followed up by a combination of telephone calls, emails and letters.

We did not think that by contacting a single representative in every NHS organisation, we would identify all potential audits. As such, additional contacts were made with a number of key individuals and organisations across the NHS. These included:

- PCT Cancer Leads
- Cancer Service Collaborative (CSC) National Clinical Leads
- Chairs of the Referral Guideline Working Parties
- Cancer Network Managers
- Cancer Network Service Improvement Leads
- Cancer Registry contacts
- Professional Societies (see Appendix 1 for complete list)
- Cancer Screening Services
- Cancer Action Teams

- Relevant Sections of the Department of Health
- Audit Commission
- Commission for Health Improvement
- The Welsh Assembly

Once again, any leads arising from these contacts were followed up by a combination of telephone calls and emails.

Stage 2

During the second stage of our search, we looked at the following Internet sources on the 22nd and 25th of September, 2003.

- NICE (in particular the Clinical Excellence conferences) http://www.nice.org.uk
- Department of Health's cancer web pages http://www.doh.gov.uk.cancer.index.htm
- Modernisation Agency http://www.modern.nhs.uk and its Cancer Services Collaborative (CSC) http://www.modern.nhs.uk.scripts.default.asp?site_id=26&id=5620
- NHS Information Authority http://www.nhsia.nhs.uk.def.home.asp and its Cancer Information Services http://www.nhsia.nhs.uk.cancer.pages and National Clinical Audit Support Programme http://www.nhsia.nhs.uk.phsmi.pages.ncasp.asp?om=m1
- Public Health Observatories http://www.pho.org.uk
- Commission for Health Improvement http://www.chi.nhs.uk
- National electronic Library for Health http://www.nelh.nhs.uk
- National electronic Library for Cancers http://www.nelc.org.uk
- HOWIS: website of NHS Wales http://www.wales.nhs.uk
- Health & Care NI: the official website for Health and Social Care Services in Northern Ireland http://www.n-i.nhs.uk
- Prodigy http://www.prodigy.nhs.uk
- NHS Scotland http://www.show.scot.nhs.uk
- Clinical Governance R&D Unit CGRDU http://www.le.ac.uk.cgrdu and its Journal of Clinical Governance http://www.le.ac.uk.cgrdu.jclingov.html
- Health Service Management Centre Library Catalogue http://www.bham.ac.uk.hsmc.library.opac.index.htm
- RCN Library Catalogue http://rcn-library.rcn.org.uk.uhtbin.webcat
- Royal Society of Medicine Library Catalogue http://www.roysocmed.ac.uk.librar.libcat.htm

We also posted a request for unpublished audits on the following Email discussion lists:

- LIS-HLN@JISCMAIL.AC.UK
- LIS-MEDICAL@JISCMAIL.AC.UK
- CANCER-NURSING-ALLIANCE@JISCMAIL.AC.UK
- GP-UK@JISCMAIL.AC.UK
- HEALTH-SERVICES-RESEARCH@JISCMAIL.AC.UK
- C.H.A.I.N. (Contacts, Help, Advice and Information Network) http://chain.ulcc.ac.uk/chain/chain.htm

Stage 3

During the third stage, we searched the following electronic databases:

- Health Management Information Consortium (HMIC)
- SIGLE
- ISI Proceedings: Science and Technology
- Inside Conferences
- MEDLINE
- EMBASE
- CANCERLIT
- National Research Register
- REFER

The following search strategy was used to capture relevant records. The strategy is shown in a version that will run in the Ovid interface of MEDLINE and was adapted to run on other databases with different interfaces and search options (see Appendix 2).

1. exp Neoplasms/
2. (cancer$ or neoplas$ or oncology$ or malignan$ or tumo?r$ or carcinoma$ or adenocarcinoma$ or sarcoma$).ti,ab.
3. 1 or 2
4. audit$
5. Utilization Review/
6. 4 or 5
7. referral time$.ti,ab.
8. waiting time$.ti,ab.
9. (two week wait$ or 2 week wait$).ti,ab.
10. (two week$ adj2 referral$).ti,ab.
11. urgent referral$.ti,ab.
12. urgent GP referral$.ti,ab.
13. fast track referral$.ti,ab.
14. referral guideline$.ti,ab.
15. (referring adj2 cancer$).ti,ab.
16. cancer referral$.ti,ab.
17. or/7-16
18. 3 and 6 and 17
19. limit 18 to (human and english language and yr=1999-2004)

Screening electronic/database searches for potentially relevant audits
Two reviewers independently assessed the titles (and where possible abstracts) identified by the electronic/database searches for relevance, and if either considered any to be potentially relevant, a full paper copy of the manuscript was obtained.

Additional searches

Conference abstracts
The following published conference proceedings were hand searched:

- The Association of Coloproctology of Great Britain and Ireland (ACPGBI) conference proceedings (published as *Colorectal Disease*) for the three consecutive years 2001 to 2003
- NICE conference proceedings (published as a *Journal of Clinical Excellence*) for the years 2001 and 2002.

We had anecdotal information that the results of some clinical audits conducted in the UK that may be relevant to our review could have been submitted but not necessarily accepted, for presentation at various conferences. In addition to the searches of published conference proceedings via electronic databases and hand searching, we attempted to identify contributions submitted, but not accepted, for relevant conferences by contacting the selection committees. This approach was used for two cancer sites; bladder and colorectal.

We were unable to identify contributions for bladder cancer because of concerns regarding data protection at the relevant professional body. For colorectal cancer, we were able to obtain electronic databases of abstracts submitted to the annual meetings of the ACPGBI conference for the last two years (2002 and 2003).

Assessment of retrieved audits for inclusion

Obtained audit reports (sometimes only available as an abstract or slide presentation) were independently assessed for inclusion by two reviewers using pre-defined inclusion criteria. Any disagreements were discussed and if no agreement was reached a third reviewer was consulted.

If an audit appeared to be relevant, but we were unable to confirm this because information was missing, attempts were made to contact the authors for more information.

Inclusion criteria

Time period when the audit was performed:

The literature search was restricted to clinical audits undertaken within the UK since the introduction of the two-week wait policy. Therefore audits undertaken prior to April 1999 (when the first two-week wait policy was introduced for breast cancer) were excluded. Furthermore, for audits restricted to a specific cancer site, those performed prior to the relevant introduction dates (listed below) were also excluded:

April 2000	Children's cancers, Lung cancer and Leukaemia.
July 2000	Upper and Lower Gastro-intestinal cancers.
October 2000	Gynaecological cancers, Skin cancers, Brain and Central Nervous System cancers.
December 2000	Urological cancers, Head and Neck cancers, Sarcomas and Haematological cancers.

Clinical audits started before but completed after guideline implementation were included if more than 50% of the participants were seen after the implementation of the guidelines.

Peer-review comments on the draft protocol for this review included the suggestion that we should expand our inclusion criteria to incorporate audits conducted prior to the DoH implementation dates, for comparison. We decided that owing to the financial and time constraints of the review, we would be unable to do this.

Study design

Given the number of differing definitions of clinical audit used in the literature, we did not use a strict definition of clinical audit as an inclusion criterion. We have included any study where the authors said that they had conducted an audit. To be considered for inclusion, minimum details of the methodology used had to be reported, which constituted some sort of description of the included participants (which could be as minimal as 'all patients referred between two predefined dates') or a description of the data source.

Any type of evaluation that had been undertaken to measure the effectiveness (including timeliness and appropriateness) of the two-week wait policy was considered.

The only exceptions to this were summary reports of the Cancer Waiting Times Datasets (which includes monitoring data that is routinely collected by all NHS trusts to inform a national database, see Background), which were excluded.

Participants

Patients referred by the GP (both urgently and non-urgently) for suspected cancer (of any type), or patients diagnosed with cancer (of any type).

Intervention

The referral of patients with suspected cancer by the GP (primary care) to the hospital (secondary care) under the two-week wait policy.

Outcomes

All outcome measures were considered, however the principle outcome measures were:

- Waiting time to first appointment
- GP conformity to guidelines
- Cancer detection (to include both cancer rates for populations of referrals and type of referral for populations of cancer patients)

- Appropriateness of type of referral according to the clinician (to include patients who present to hospital with symptoms inconsistent with the referral form/letter)

- The ability of the guidelines to identify correct referrals (those patients that met the guidelines but had a low suspicion of cancer, or did not meet the guidelines but had a high suspicion of cancer)

- Process of referral (referrals received by the hospital within 24 hours and the mode of referral – fax or post/letter or proforma)

Quality assessment

In order to identify existing methods of assessing the quality of clinical audit we carried out an initial broad search of the literature for published checklists. Four relevant references were found, from which an initial comprehensive list of quality criteria was developed (Naylor, 1996; National Institute for Clinical Excellence, 2002; Millard, 2000; Morrell, 1999). We then developed a shorter list (by discussion and consensus), which included components for both generic clinical audit issues and the specifics of measuring cancer-waiting times. This list is presented as part of the data extraction tool in Appendix 3.

Classification of included audits in terms of methodology

For the purpose of this review we have used the definition of clinical audit that has been endorsed by NICE (National Institute for Clinical Excellence, 2002) as the ideal audit methodology, which relates to a criterion-based audit.

The purpose of conducting clinical audit is to ensure that patient care is as good as it can be, or represents optimal care. One of the ways of achieving this is to compare current practice with a predefined standard of care* that describes best practice and gives an indication of how it can be achieved. A standard needs to be based on the best available evidence and is usually developed by those providing the care (or all those involved in the audit) reflecting what they deem to be an acceptable level of care. The process of developing the standards helps to focus everyone's attention on the health care problem, promotes discussion between colleagues and encourages those that are involved to review the relevant medical literature. Comparing current practice against a standard can confirm the existence of problems that may otherwise have remained hidden, and can also help motivate change by highlighting the gulf between current practice and the desired level of care (Crombie, 1993).

A standard is made up of three elements (all of which need to be pre-defined): a criterion, a target, and any exceptions that will be allowed. A criterion is the pre-set cut-off level that distinguishes between adequate and inadequate care; it needs to be clinically relevant, clearly defined and easily measured. If the criterion is not formally stated in advance, deficiencies in care may be overlooked (Crombie, 1993). The target is the proportion of the patients seen who should meet the criterion. If the target is not stated in advance then current practice could be vindicated, whether it be good or bad (Crombie, 1993).

For this review the optimal standard of care is pre-set by the DoH guidelines (and the target is set at 100%); although some included audits may look at other aspects of care not included in the guidelines. However, it is individual NHS trusts that decide which specific audit criteria they will use to measure adherence to these guidelines, and make decisions on which exceptions they will allow.

In order to differentiate studies that the authors have called audit, but do not necessarily meet the definition of clinical audit endorsed by NICE (e.g. non-criterion based audits, reports that describe clinical practice, or before and after research studies) we have classified the included audits/studies as follows: clinical audit (i.e. criterion-based audit), non-criterion based clinical audit (i.e. where practice is not compared to predefined criteria), or research study. See Appendix 4 for a fuller description of the definitions used to classify the studies.

Only audits for which there was documented evidence that pre-defined criteria were used have been classified as criterion-based audit (i.e. audits that report pre-defined criteria either under aims/objectives or in the methodology section, or alternatively, the way that the results have been set out suggests that pre-defined criteria were used, e.g. included in table headings). If the key elements selected from the DoH guidelines that the audit proposed to investigate were not pre-specified in the aims/objectives or methods section of the report then the audit was defined as a non-criterion based audit.

Data extraction strategy

Relevant data from each study were extracted using a pre-defined data extraction tool developed on Microsoft Access™. The tool was piloted using a sample of clinical audits that met our inclusion criteria, and then modified accordingly. Subsequent data extraction was then carried out by one reviewer and checked by a second with discrepancies being resolved by discussion, or if necessary, taken to a third party.

Methods of analysis/synthesis

As each audit will reflect the local circumstances where it was conducted, we decided from the outset that a statistical synthesis of the results of individual audits was unlikely to provide any meaningful results. Therefore, a narrative synthesis was undertaken.

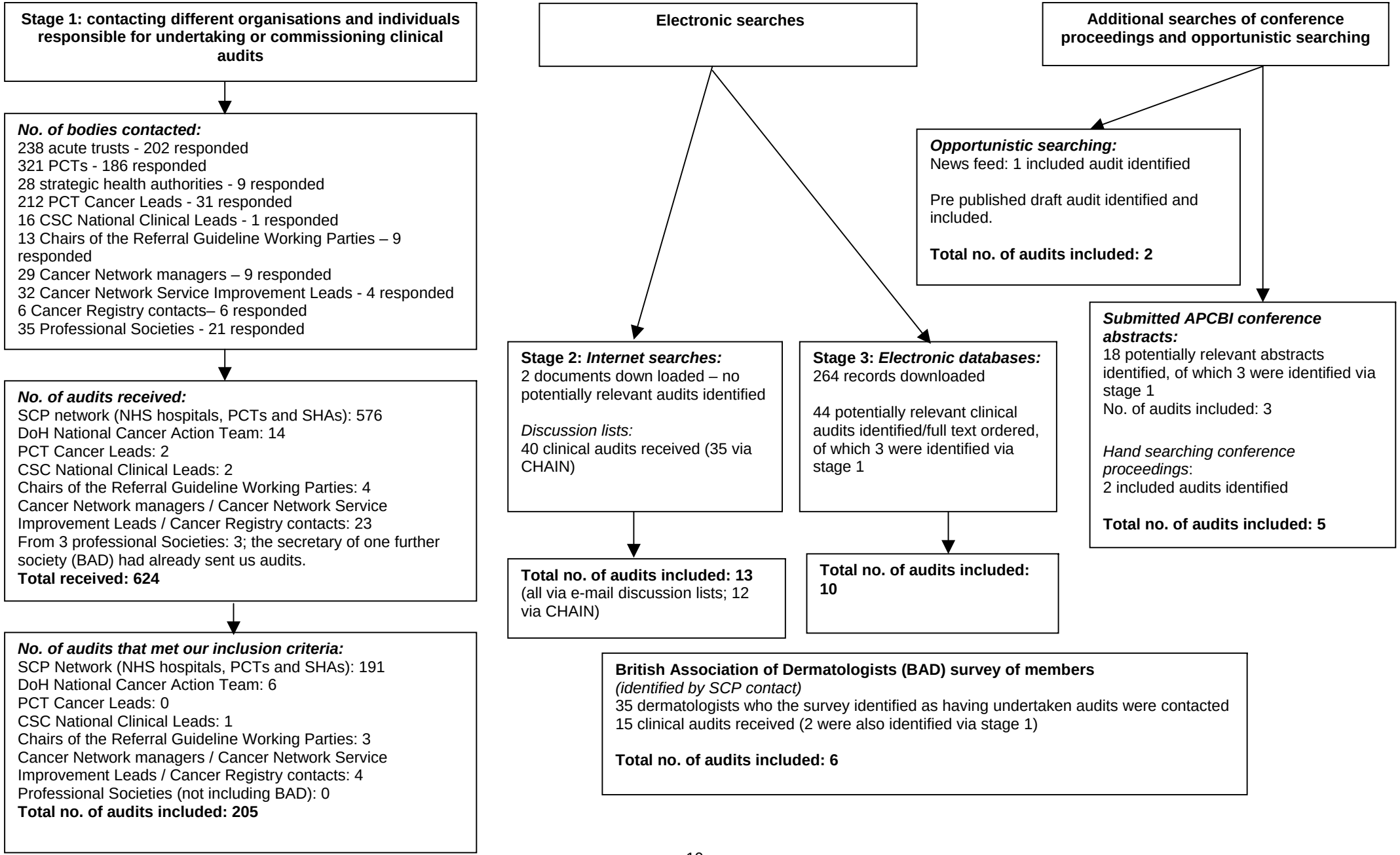
The main results have been presented by cancer site. Each section summarises findings of single site audits and those multiple cancer site audits that reported results separately by cancer site. The findings of clinical audits that examined multiple cancer sites but that did not present separate results for individual cancer sites are presented independently. Finally the findings of both before and after studies and clinical audits that collected data during the time period before and after the introduction of the guidelines (some of which will also have been summarised under individual cancer sites) are discussed.

When reporting findings for two-week wait referrals, included audits have made inconsistent use of the term ‘urgent’. Some audits have differentiated between urgent referrals and two-week wait (or fast track) referrals, some have categorised the terms together and others have used the term urgent referral without specifying which patients are included. Where audits have differentiated between urgent referrals and two-week wait referrals we have only used the data described as two-week wait. Where audits have not differentiated between urgent and two-week wait referrals but appear to be describing two-week wait referrals, we have assumed that the data are in fact describing two-week wait referred patients.

As most included audits were categorised as criterion based, our initial method of categorisation did not turn out to be an effective way of identifying those that would provide the most reliable results. As many of the included audits were only reported in a very brief format, we decided that the results of these might not be very reliable. Therefore alternative criteria were employed to determine which studies would be used to inform the summary of the overall findings. Although we present summary descriptive statistics relating to all the clinical audits that met our inclusion criteria, only the results of audits (and research studies) that were considered to be better reported are discussed in any detail. In other words, only those audits (and research studies) that provide information on how included patients were identified and/or their data source are summarised in any detail. The flow charts showing which included audits met this quality threshold, their study design and population studied, can be found at the beginning of each section.

A summary of all the included audits can be found in Appendix 5 (available on the Internet, http://www.york.ac.uk/inst/crd/waittime.htm).

Figure 1: Results of search strategy used for identifying relevant clinical audits (241 clinical audits were identified that met our inclusion criteria)



GENERAL RESULTS

Identification of relevant clinical audits

We received a total of 624 clinical audits via correspondence with various individuals, which included 576 identified via the SCP network. A summary of the number of clinical audits received and included according to the different searching methodologies is presented in Figure 1. Some of the responses listed in Figure 1 may have been to requests for information made to a different source, which was subsequently passed on/forwarded to other contacts. In many instances several follow-up contacts were necessary before we actually received any audits from some of the hospital trusts, PCTs, SHAs and other contacts. In summary, we contacted 238 acute trusts via letter, of which 202 responded. We contacted 321 PCTs, of which 186 responded. We also sent out letters to 28 SHAs, nine of which responded.

General overview

Two hundred and forty-one clinical audits met the inclusion criteria (WTA 1-241). The number of single and multiple site audits included is given in Table 1.

Table 1: Number of included single and multiple site audits

Cancer site	Number of audits	References
Brain	**1**	WTA 1
Breast	**43**	WTA 2-44
Children's	**1**	WTA 45
Lower GI	**39**	WTA 46-84
Upper GI	**23**	WTA 85-107
Gynaecological	**16**	WTA 108-123
Haematological	**5**	WTA 124-128
Head and Neck	**8**	WTA 129-136
Lung	**15**	WTA 137-151
Sarcoma	**0**	
Skin	**38**	WTA 152-189
Urological	**16**	WTA 190-205
Multiple Sites	**35**	WTA 206-240
Site Not Stated	**1**	WTA 241
Total	**241**	

Two hundred and twenty-one clinical audits were conducted by hospital trusts (149 by general hospitals and 72 by teaching hospitals). Six clinical audits were conducted in primary care and 11 by a cancer network or health authority (this includes three clinical audits that evaluate all the acute trusts in Wales). One further clinical audit was conducted by a professional body, and for the remaining two, it was not stated who conducted the audit.

Using our own classification for methodology (see Appendix 4), 193 clinical audits were classified as criterion based, 36 as non-criterion based clinical audit, and 12 as research studies.

Fifty-seven included all referrals with a suspicion of cancer and 119 included patients referred under the two-week wait rule/urgent referrals. In three audits, the type of referral was either unclear or not stated. Thirty-one audits examined patients diagnosed with cancer and 31 audits looked at both patients referred and those diagnosed with cancer.

Data were collected retrospectively in 133 audits (ten of which had a before and after design), prospectively in 39 audits (five of which were before and after), and partially retrospective and partially prospective in three (all of which were before and after). The direction of the data capture was not stated in 63 audits, one of which was a before and after study. For the remaining three audits, the direction of data capture was not clear from the report. (It should be noted that assumptions on the direction of data collection were

made in some audits, where the information contained in the audit report suggested a direction but this was not explicitly stated.)

Table 2 provides an overview of the quality assessment for all the included audits. The majority of included studies were poorly reported. Fewer than half (44%) provided sufficient detail on methodological aspects for the audit to be reproducible. Less than 20% provided an action plan outlining any recommended changes to service delivery or how any changes would be implemented.

Table 2: Quality of included audits

Quality element	Cancer site													
	Brain	Breast	Children's	Lower GI	Upper GI	Gynaecological	Haematological	Head & Neck	Lung	Sarcoma	Skin	Urological	Multiple	Not Stated
Number of audits	1	43	1	39	23	16	5	8	15	0	38	16	35	1
Involved those providing the service?	1	23	1	18	11	9	4	3	9	0	21	12	18	1
Motive for audit given?	1	34	0	19	9	6	3	3	5	0	18	11	24	1
Clear project plan used?	1	28	0	18	6	7	3	1	5	0	12	5	20	1
Integrity of the population source tested?	0	3	0	0	0	0	2	0	0	0	1	1	6	0
Sample population appropriate?	1	37	0	31	13	12	5	6	10	0	28	13	28	1
Explicit inclusion criteria used?	1	27	0	24	10	7	3	1	6	0	22	6	26	1
Data source checked?	0	5	0	1	0	0	0	0	0	0	0	0	5	1
Data collection tool carefully designed and tested?	0	4	0	3	0	3	0	0	0	0	3	0	3	0
Validity and reliability of data collection considered?	0	3	0	2	0	0	0	0	0	0	0	0	1	0
Time frame justified?	1	4	0	5	3	0	0	0	0	0	7	1	9	0
Process of applying criteria unbiased and robust?	0	4	0	6	0	1	0	0	0	0	1	1	3	0
Adequate data reported	1	29	0	22	8	7	4	4	8	0	19	8	21	1
Data analysed appropriately?	1	27	0	29	14	11	4	4	11	0	26	9	27	1
All patients accounted for?	0	29	0	26	13	5	4	3	5	0	21	9	20	1
Interpretation fair?	1	27	0	26	12	9	3	4	7	0	26	10	29	1
Action plan reported?	0	8	0	9	1	4	3	1	1	0	6	4	7	1
Reaudit planned?	0	5	1	10	1	5	2	2	1	0	10	4	7	0

Overviews of clinical audits meeting quality threshold

A summary of the findings of each included audit can be found in Appendix 6 (available on the Internet, http://www.york.ac.uk/inst/crd/waittime.htm). Although we present descriptive data relating to all included audits, only the findings of audits (and research studies) that reported details on how included patients were identified or gave their data source (n=173) are included in the summaries relating to the main outcome measures. The results of the audits that have not been included were so poorly reported that it was difficult to tell what exactly they related to.

A summary of the results for the main outcome measures across all cancer sites is provided in Tables 3 and 4. However, the following limitations should be borne in mind when interpreting the results presented in these tables.

The small sample size of some of the included audits means that the extent to which the percentage value of the 'sample' represents what is happening for all patients will be seriously compromised.

There is a large variation between the included audits in terms of: their timing (some of which were undertaken shortly after the introduction of the guidelines); the sample size; the type of population examined; the type of sampling method used (many audits included patients seen within a set period of time which differed between audits); and the type of outcomes or audit criteria being evaluated; and how they were measured or investigated.

Assessment of the appropriateness of the referral, and the outcomes relating to the ability of the guidelines to identify correct referrals (patients meeting guidelines but who had a low suspicion of cancer, or not meeting guidelines but who had a high suspicion of cancer) are subjective and were mainly carried out by hospital clinicians.

The reliability with which criteria, such as appropriateness of referral, were applied was not investigated by the vast majority of audits and will most likely vary between different clinicians (and may also vary over time for individual clinicians) and trusts.

Some trusts contributed more than one audit in some analyses, for which similar (or related) findings may be reported.

Table 3 does not include the data from two audits (WTAR 223, 169) relating to the appropriateness of non-two-week wait referrals where it was not clear what constituted 'appropriateness', and as such they could not be incorporated into a single percentage range. It also does not include data from a multiple site audit that did not present separate data for different cancer sites (WTA 227).

One included audit (WTA 19, a single site audit that looked at referrals for breast cancer) reported the proportion of soon, routine, and ungraded GP referrals that met the urgent referral criteria: 23/39 (59%), 7/26 (27%) and 12/62 (19%), respectively. This result is also not included in Table 3.

The proportion of non-two-week wait referrals upgraded by the clinician and two-week wait referrals downgraded by the clinician are also not presented in table 3, as so few audits measured this. Four breast cancer audits reported that 13-32% non-two-week wait referrals were upgraded to two-week wait status by the clinician. One urological cancer audit reported that 0% two-week wait referrals were downgraded and 0% non-two-week wait referrals were upgraded to two-week wait status by the clinician.

The sections that follow summarise the main findings for each cancer site, multiple site audits that could not be included in the sections reporting the results of individual cancer sites, and finally the before and after studies.

Table 3: Summary results across all cancer sites for outcomes related to adherence to guidelines

CANCER SITE (no. of audits included in analyses/no. included in review)**	GP conformity		Appropriateness of type of referral		Ability of the guidelines to identify correct referral	
	Conformity of 2WW referrals to the guidelines (2WWR: audits that included 2WW referrals) (Cancer: audits that included patients diagnosed with cancer)	Non-2WW referrals with symptoms in line with the guidelines (Referrals: audits that included all referrals) (Cancer: audits that included patients diagnosed with cancer)	2WW referrals that warranted urgent referral according to hospital clinician	Clinical symptoms (at 1st appointment) matching 2WW GP referral	2WW referrals that were not in line with the guidelines, but were deemed clinically appropriate	2WW referrals that were in line with the guidelines, but were deemed clinically inappropriate
Brain and CNS (12/12)	2WWR: 0-100% (8 audits)*	-	23-100% (4 audits)*	-	-	22% (1 audit)
Breast (59/72)	2WWR: 65-99% (20 audits)	Cancer: 0% (1 audit)*	18-96% (9 audits)	78% (1 audit)	15-45% (2 audits)	5-17% (2 audits)
Children (9/9)	2WWR: 91-100% (4 audits)*	-	60-100% (4 audits)*	-	-	-
Lower GI (47/71)	2WWR: 53-100% (26 audits)*	Cancer: 29% (1 audit)*	52-74% (6 audits)	33-87% (3 audits)	9-19% (2 audits)	0% (1 audit)
Upper GI (36/54)	2WWR: 76-100% (14 audits)*	Cancer: 100% (1 audit)*	67-96% (5 audits)	59-98% (2 audits)	5-36% (2 audits)	2% (1 audit)
Gynaecological (36/45)	2WWR: 42-100% (19 audits)*	Cancer: 75% (1 audit)*	64-94% (6 audits)	82% (1 audit)	0-25% (2 audits)*	11% (1 audit)
Haematological (21/26)	2WWR: 0-100% (10 audits)*	-	75-100% (5 audits)*	100% (1 audit)*	-	0-26% (2 audits)*
Head and neck (23/30)	2WWR: 0-86% (12 audits)*	Referrals: 35% (1 audit) Cancer: 100% (1 audit)*	36-76% (6 audits)	85% (1 audit)	40-43% (2 audits)*	10% (1 audit)
Lung (33/43)	2WWR: 78-100% (15 audits)	-	87-97% (5 audits)	95% (1 audit)	0-5% (2 audits)*	6% (1 audit)
Sarcomas (10/11)	2WWR: 60-100% (6 audits)*	Cancer: 100% (1 audit)*	67-100% (4 audits)*	-	-	-
Skin (43/59)	2WWR: 9-97% (20 audits)*	-	13-84% (6 audits)	-	1-42% (2 audits)	3% (1 audit)
Urological (34/43)	2WWR: 50-100% (15 audits)* Cancer: 94% (1 audit)	Referrals: 94% (1 audit) Cancer: 48% (1 audit)	78-91% (4 audits)	86% (1 audit)	17% (1 audit)*	-

*Some of the percentages reported are based on a very small number of patients, i.e. <10.
** The audits included in the analyses (and therefore reported in this table) only include those that reported minimal data on how eligible patients were identified or the data source and reported separate results for individual cancer sites.

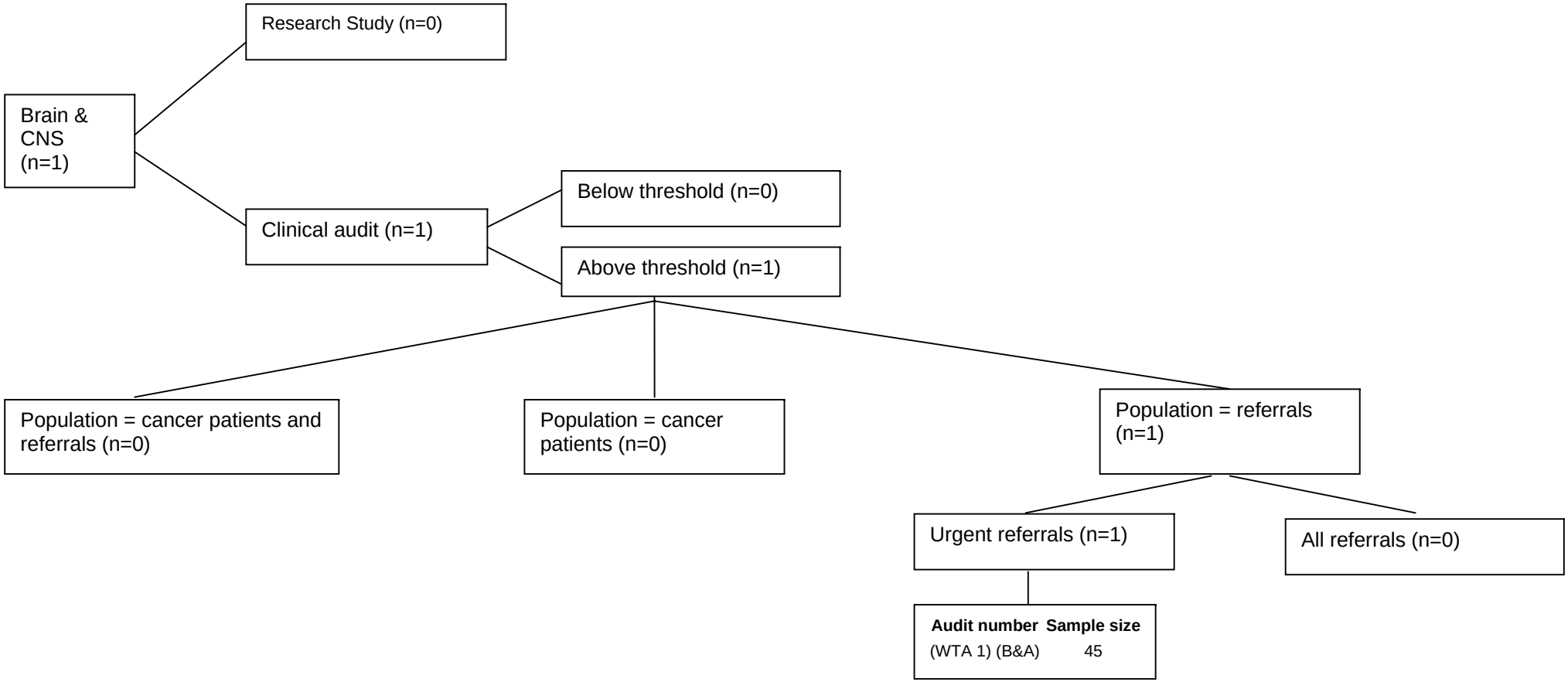
Table 4: Summary results across all cancer sites for cancer related outcomes

CANCER SITE (no. of audits included in analyses/no. included in review)**	Proportion of 2WW referrals among patients diagnosed with cancer	2WW: Cancer detection rates among 2WW referrals Hospital: Cancer detection rates among referrals considered 'urgent' by hospital	Cancer detection rates among non-2WW referrals (not all of which were GP referrals)	Cancer detection rates for 2WW referrals that were in line with the guidelines	Cancer detection rates for 2WW referrals that were not in line with the guidelines
Brain and CNS (12/12)	-	2WWR: 0-15% (8 audits)*	-	-	-
Breast (59/72)	4-83% (9 audits)	2WWR: 0-34% (37 audits) Hospital: 16-50% (3 audits)	Urgent non-2WW: 4-20% (5 audits) Non-urgent: 0-10% (18 audits)	16% (1 audit)	0% (1 audit)
Children (9/9)	-	2WWR: 0% (3 audits)*	-	-	-
Lower GI (47/71)	0-46% (7 audits)*	2WWR: 2-22% (30 audits)	All non-2WW: 9%; Urgent non-2WW: 21% (1 audit) Urgent non-2WW: 14% (1 audit) With 2WW symptoms: 6%; Without 2WW symptoms: 1% (1 audit)	12-21% (2 audits)	0-3% (3 audits)
Upper GI (36/54)	0-40% (9 audits)*	2WWR: 0-30% (23 audits)* Hospital: 5% (1 audit)	Non-urgent: 2% (1 audit)	-	9% (1 audit)
Gynaecological (36/45)	0-34% (8 audits)*	2WWR: 0-25% (18 audits)*	-	15% (1 audit)	0-4% (3 audits)*
Haematological (21/26)	0-25% (3 audits)*	2WWR: 0-75% (10 audits)*	Non-2ww: 19% (1 audit)	25% (1 audit)	-
Head and neck (23/30)	0-25% (4 audits)*	2WWR: 0-18% (14 audits)*	Urgent non-2WW: 1% (1 audit)	-	7-20% (2 audits)*
Lung (33/43)	0-57% (5 audits)*	2WWR: 5-75% (15 audits)*	Non-2WW: 62% (1 audit) Routine: 2% (1 audit)	51% (1 audit)	0-43% (2 audits)*
Sarcomas (10/11)	-	2WWR: 0-20% (7 audits)*	-	-	-
Skin (43/59)	7-44% (6 audits)*	2WWR: 2-36% (23 audits)*	All non-2WW: 25%; Urgent non-2WW: 71% (1 audit)	16% (1 audit)	33% (1 audit)
Urological (34/43)	0-100% (8 audits)*	2WWR: 13-50% (17 audits)*	Non-2WW: 17% (1 audit; all referrals considered urgent by hospital consultant) Routine: 16% (1 audit)	-	0% (1 audit)*

*Some of the percentages reported are based on a very small number of patients, i.e. <10.
** The audits included in the analyses (and therefore reported in this table) only include those that reported minimal data on how eligible patients were identified or the data source and reported separate results for individual cancer sites.

Single site brain and CNS cancer studies

Key: B&A = before and after study



BRAIN AND CNS CANCERS

Overview

12 clinical audits evaluated the referral guidelines for brain and CNS cancers (WTA 1, 206, 207, 209, 210, 212, 229-234).

Eight audits were conducted by a general hospital (WTA 210, 212, 229-234), one in a teaching hospital (WTA 209), and three by a PCT (WTA 1, 206, 207). With the exception of one non-criterion based audit (WTA 207), all were categorised (in terms of the methodology used) as a clinical audit.

All 11 audits that examined a referral population only, included only two-week wait referrals (WTA 1, 206, 207, 209, 210, 229-234). One audit looked at both patients diagnosed with cancer and those being referred (WTA 212).

The data were collected retrospectively in six audits (WTA 1, 206, 209, 210, 212, 230) and prospectively in four audits (WTA 231-234). The direction of data capture was not stated in two audits (WTA 207, 229).

One audit looked exclusively at brain and CNS cancers (single site) and had a sample size of 45 (WTA 1). Eleven audits examined multiple cancer sites but reported separate results for brain and CNS cancers (WTA 206, 207, 209, 210, 212, 229-234), and sample sizes ranged from 1 (WTA 212) to 13 (WTA 233, 234) when only considering brain and CNS cancers.

All 12 audits reported some data on how eligible patients were identified and/or gave the data source. The results of these audits are summarised below.

Outcome measures

Waiting time to first appointment

Four of the multiple site audits reported data on meeting the two-week wait criterion (WTA 209, 210, 233, 234). All four audits examined two-week wait referrals only. The number of two-week-wait referred patients analysed ranged from 4 (WTA 209, 210) to 13 (WTA 233, 234), although the results for one audit (WTA 210) were presented for three brain and CNS cancer patients and one sarcoma patient together. The percentage seen within two-weeks ranged from 1 of 3 available patients (33% (WTA 209)) to 100% (WTA 210, 234).

GP conformity to guidelines

The conformity of the GP referral to the symptoms listed in the guidelines was evaluated by one single site audit in which 30/43 (70%) referrals followed DoH guidelines (WTA 1).

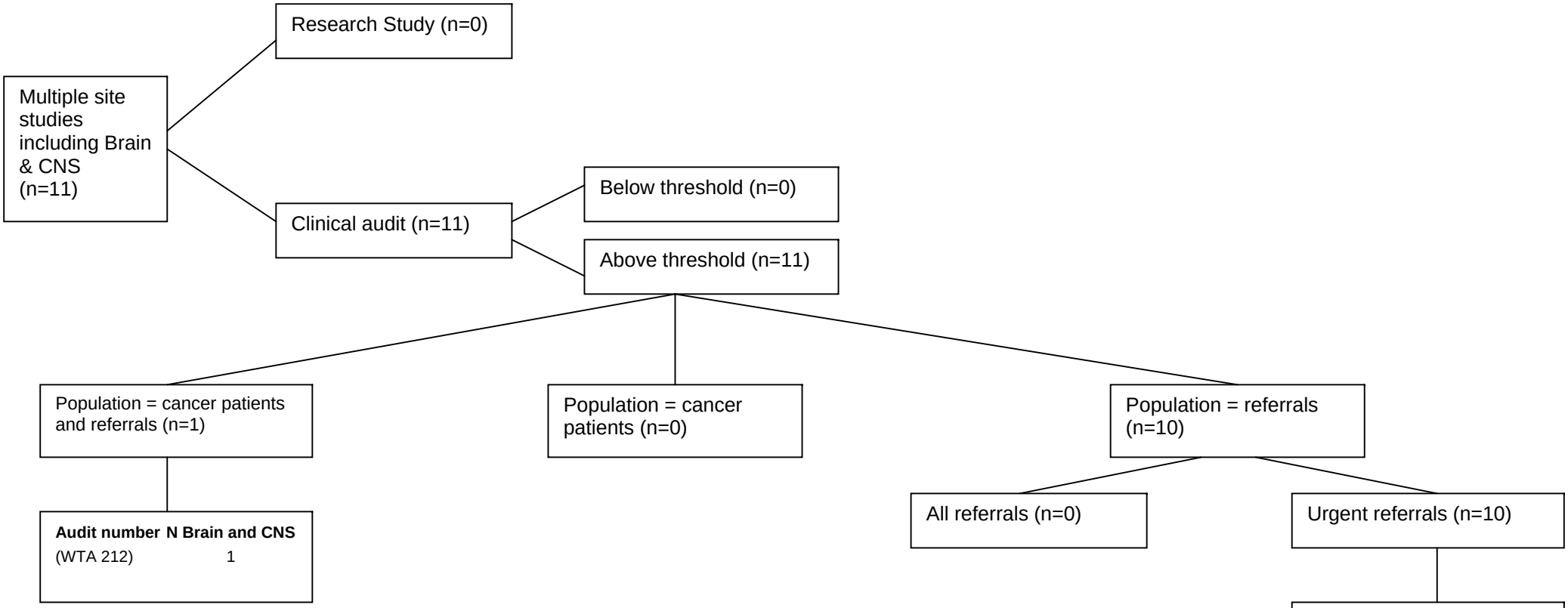
Seven multiple site audits evaluated the conformity of the GP referral to the symptoms listed in the guidelines (WTA 209, 210, 212, 229, 230, 233, 234). With patient numbers analysed ranging from 1 (WTA 212) to 13 (WTA 233, 234), the number of referrals that met the guidelines ranged from 0% (0/1 (WTA 212)) to 100% (2/2 (WTA 230), 4/4 (WTA 210)).

Cancer detection

In the single site audit the cancer detection rate was 4/43 (9%) two-week wait patients (2 astrocytomas, 2 cerebral metastases) (WTA 1). The remainder of patients were diagnosed with chronic daily headache (10), epilepsy (5), migraine (3), demyelination (2), essential tremor (2) and other (17). The audit also reported that during the audit time period, 69 neurological cancers were identified independently of the two-week wait system.

Data on cancer detection rates were reported by seven multiple site audits that examined referral populations and reported data for two-week wait referrals (WTA 206, 209, 210, 212, 231-233). The number of participants referred under the two-week wait rule that were included in the analyses ranged from 1 (WTA 212) to 13 (WTA 233), and the cancer

Multiple site brain and CNS cancer studies



detection rates ranged from 0% (0/1 (WTA 212), 0/2 (WTA 206, 232), 0/3 (WTA 210, 231), 0/4 (WTA 209)) to 15% (2/13 (WTA 233)).

Appropriateness of the type of referral
Four multiple site audits reported the proportion of two-week wait referrals that the clinician assessed as appropriate. The number of patients included in the analyses ranged from 2 (WTA 232) to 13 (WTA 233, 234) and the proportion considered to be appropriate ranged from 23% of 13 (WTA 234) to 100% of 3 (WTA 231).

Ability of guidelines to identify correct referrals
In one multiple site audit the hospital consultant thought that 7/9 (78%) referrals that met the two-week criteria were also clinically appropriate (WTA 229).

Process of referral
Not reported.

Summary

The proportion of brain and CNS patients referred under the two-week wait referral system and seen within two weeks ranged from 33% to 100% (four audits). The proportion of two-week wait referrals that were found to be in accordance with the symptoms listed in the guidelines ranged from 0% to 100% (eight audits).

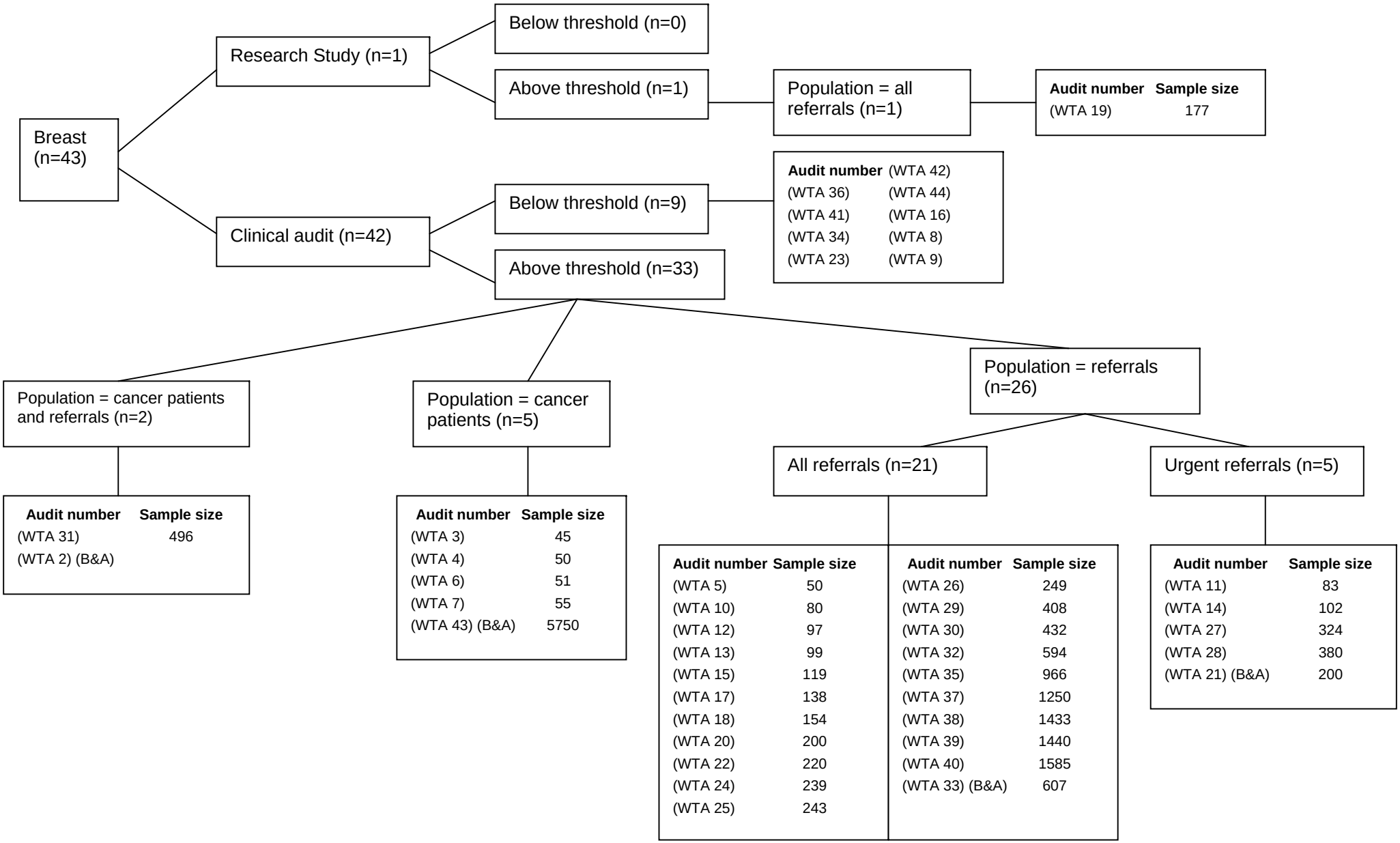
The proportion of patients who were referred under the two-week wait referral system who were subsequently diagnosed with cancer ranged from 0% to 15% (eight audits).

The proportion of two-week wait referrals deemed to be clinically appropriate ranged from 23% to 100% (four audits). The hospital consultant deemed 78% referrals that were in accordance with the two-week guidelines as clinically appropriate (one audit).

All of these results are based upon audits of 13 patients or less.

Single site breast cancer studies

Key: B&A = before and after study



BREAST CANCER

Overview

72 clinical audits evaluated the referral guidelines for breast cancers (WTA 2-44, 206-234).

44 audits were conducted by general hospitals (WTA 3-7, 10-15, 17, 20, 21, 23-25, 28-31, 33, 34, 40, 42, 208, 210-216, 220, 223, 224, 226, 227, 229-234), 12 by teaching hospitals (WTA 2, 8, 9, 16, 36, 37, 41, 209, 217-219, 225), six by cancer networks (WTA 32, 35, 38, 39, 222, 228), five by PCTs (WTA 22, 26, 206, 207, 221), two within health authorities (WTA 18, 27) one was conducted by a cancer registry (WTA 43), one by a professional body (WTA 44), and one did not specify the location (WTA 19).

63 were categorised (in terms of the methodology used) as a clinical audit (WTA 2-6, 8-18, 20-22, 24-40, 42, 43, 206, 208-217, 221-234), eight as a non-criterion based audit (WTA 7, 23, 41, 44, 207, 218-220), and one as a research study (WTA 19).

Of 54 audits that examined a referral population only, 29 evaluated all patients referred to the department or trust (WTA 5, 10, 12, 13, 15, 17-20, 22-26, 29, 30, 32-42, 218, 225), 33 examined two-week wait referrals only (WTA 8, 9, 11, 14, 16, 21, 27, 28, 206, 207, 209-211, 216, 217, 219, 226, 229-234), and for two audits the type of referral was unclear (WTA 44, 228). The patient population of interest included those diagnosed with cancer in nine audits (WTA 3, 4, 6, 7, 43, 208, 221, 224, 227), and nine audits looked at both patients diagnosed with cancer and those being referred (WTA 2, 31, 212-215, 220, 222, 223).

The data were collected retrospectively in 35 audits (WTA 3-7, 12-14, 18, 20, 22, 25, 26, 28, 31, 33, 34, 40, 41, 43, 206, 208-212, 216, 218-220, 224, 226-228, 230) (three of which were retrospective before and after (WTA 33, 43, 218)), prospectively in 22 audits (WTA 2, 10, 15, 17, 19, 21, 23, 24, 27, 29, 30, 32, 35, 37, 42, 44, 221, 225, 231-234) (two of which were prospective before and after (WTA 2, 23) and three partially prospective before and after (WTA 21, 42, 221)). The direction of data capture was not stated or unclear in 15 audits (WTA 8, 9, 11, 16, 36, 38, 39, 207, 213-215, 217, 222, 223, 229).

43 audits looked exclusively at breast cancers (single site) (WTA 2-44) while 29 audits examined multiple cancer sites but reported some results separately for each site (WTA 206-234). The sample size ranged from 45 (WTA 3) to 12,538 (WTA 44) for single site audits and from 23 (WTA 208, 227) to 3,288 (WTA 222) for multiple site audits (when considering breast cancers only). The breast cancer patient sample size was not given in one single site audit (WTA 2) and two multiple site audits (WTA 211, 221).

61 audits (WTA 2-7, 10-15, 17-22, 24-33, 35, 37-40, 43, 206-210, 212-215, 217-234) reported some data on how eligible patients were identified and/or gave the data source, two of these audits were multiple site and did not report any separate results for breast cancer (WTA 221, 225). The results of the remaining 59 audits are summarised below. The other 11 audits were not as well reported (WTA 8, 9, 16, 23, 34, 36, 41, 42, 44, 211, 216) and as such their results are considered to be less reliable. The results of these audits are therefore not discussed further.

Outcome Measures

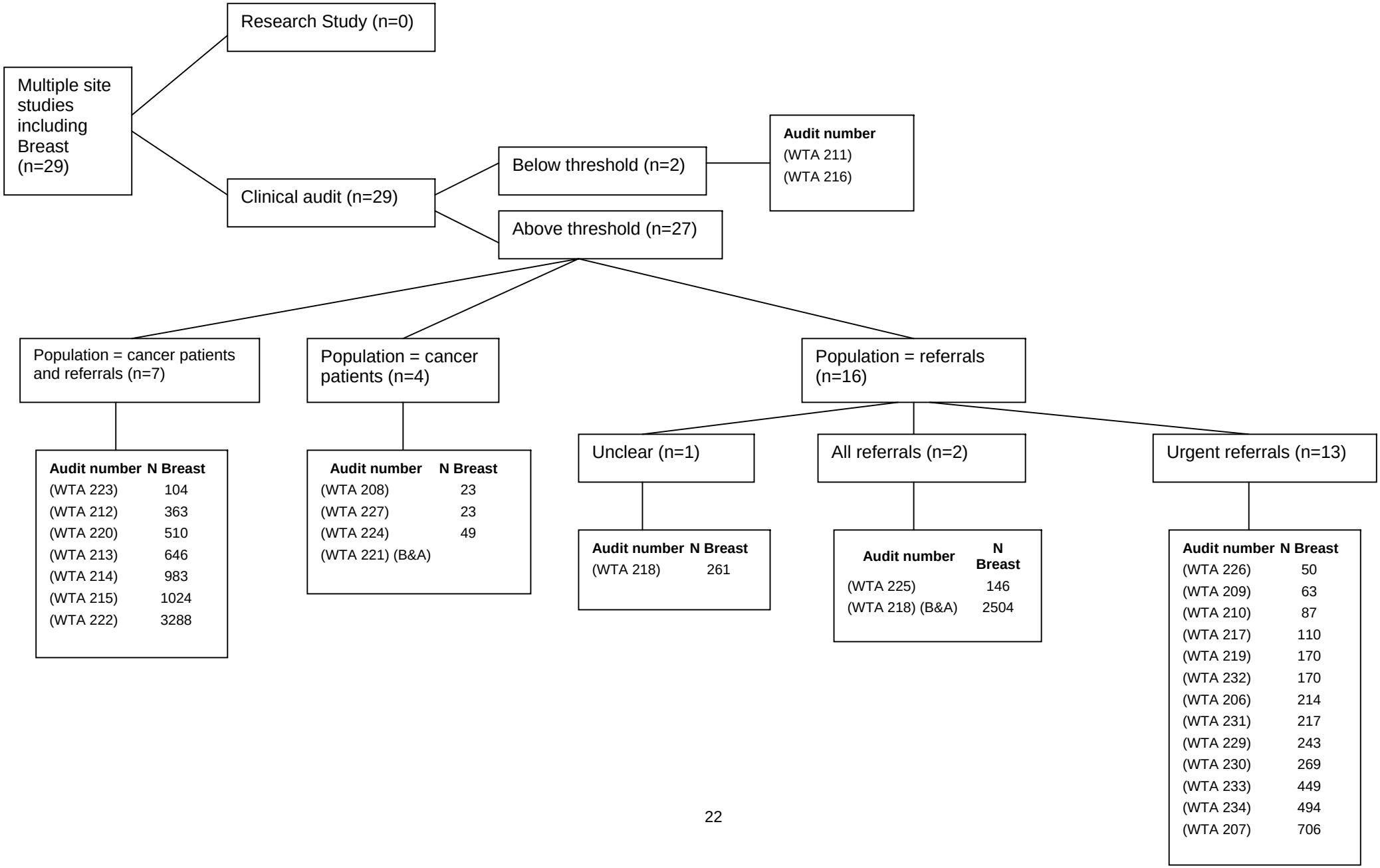
Waiting time to first appointment

Twenty-five single site audits reported data on the proportion of two-week wait referrals that were seen within two weeks. Of the 18 audits looking at a referral population only, 16 looked at all referrals (WTA 5, 10, 12, 13, 15, 17-19, 22, 30, 33, 35, 37-40), and two looked at two-week wait referrals only (WTA 21, 28). Five of the audits examined patients with a diagnosis of breast cancer (WTA 3, 4, 6, 7, 43), while two audits examined mixed populations (referred and cancer-diagnosed) (WTA 2, 31).

According to 17 single site audits (WTA 5, 10, 13, 15, 17-19, 21, 22, 28, 30, 33, 35, 37-40) the number of two-week wait referred patients included in the analyses ranged from 25

Multiple site breast cancer studies

Key: B&A = before and after study



(WTA 15) to 758 (WTA 39) and the percentage seen within two weeks ranged from 13% (6/45 (WTA 18)) to 100% (380/380 (WTA 28); 100/100 (WTA 21)). However, this included two network wide audits (WTA 38, 39) undertaken in Wales, where, unlike the DoH guidelines used in England, it is the hospital that decides on the level of urgency of the referral (not the GP) and the target is 10 working days for the interval between receipt of referral (not date of referral) and first appointment. In addition, for one audit there appeared to be an error in the reporting of this outcome as the number of patients who were seen within 14 days of receipt of referral (3/46) was less than the number of patients that were seen within 14 days of referral date (6/45 (WTA 18)). When excluding this study the percentage seen within 14 days ranged from 67% (60/89 (WTA 33)) to 100% (16 audits). One further audit (WTA 12) that included 62 two-week wait referrals, 24 urgent referrals, and 11 non-urgent referrals reported that 98% of referrals were seen within two weeks. A before-and-after audit found the percentage of patients seen within 14 days dropped from 85% to 67% (WTA 33). Whilst the other before and after audit found that the percentage of patients seen within 14 days rose from 61% to 100% (WTA 21). The two network wide audits reported the percentage of non-urgent referrals that were seen within 10 working days, which ranged from 37% (WTA 38) to 38% (WTA 39), and one audit (WTA 35) reported that 12% of 301 non-urgent referrals were seen within 14 days.

Seven single site audits reported average waiting times for attending an urgent appointment (WTA 10, 19, 30, 33, 35, 38, 39), the average wait ranged from 7 days (WTA 10, 38, 39) to 16 days (WTA 33). The average waiting times for non two-week wait referrals were reported by four single site audits (WTA 19, 35, 38, 39) and ranged from 14 days (WTA 39) to 36 days (WTA 35).

Of two single site audits of mixed populations, one found 100% (of 734 two-week wait referrals) were seen within two weeks (WTA 31) and another (before-and-after) found the percentage of patients seen within 14 days increased from 60% to 87% (WTA 2). However, for this latter audit the actual number of patients that were included was not stated, nor was the source and level of urgency of the referral.

For the five single site audits that looked only at patients diagnosed with cancer (WTA 3, 4, 6, 7, 43), the percentage of patients referred as two-week wait and seen within two weeks ranged from 38% (WTA 4) to 100% (WTA 7) and the number of patients included in the analyses ranged from 24 (WTA 7) to 5750 (WTA 43). One of these audits was a before-and-after audit that found an increase in the percentage seen within two weeks from 66% to 75% (WTA 43). The mean time from the two-week wait referral to first appointment ranged from 9.6 (n=29, (WTA 3)) to 19 (n=34, (WTA 4)) days in three audits (WTA 3, 4, 6). The median wait in one audit (before and after) was 10 days; the median time before the introduction of the guidelines was 11 days (WTA 43).

Eight of the multiple site audits reported data on meeting the two-week wait criterion (WTA 209, 210, 213-215, 219, 227, 234). Four of these audits examined a referral population only (three looked at two-week wait referrals (WTA 209, 210, 219, 234) and one looked at all referrals (WTA 234)), for which the number of two-week wait referred patients analysed ranged from to 57 (WTA 209) to 494 (WTA 234), and the percentage seen within two weeks ranged from 88% (WTA 219) to 100% (WTA 234). Three audits looked at a mixed population (referred and cancer-diagnosed) (WTA 213-215), for which the percentage of cancer patients referred under the two-week wait rule that were seen within two weeks ranged from 76% (22/29 (WTA 213)) to 96% (45/47 (WTA 214)), and the proportion of cancer patients not referred under the two-week wait rule that were seen within two weeks ranged from 13% (7/52 (WTA 214)) to 27% (16/60 (WTA 215)). One audit that only included patients diagnosed with cancer reported that all two-week wait referred patients were offered an appointment within 14 days of referral (WTA 227).

One multiple site audit reported that the average wait, between referral and first appointment, for patients diagnosed with cancer, was 11 days (n=240 (WTA 218)).

GP conformity to guidelines

The conformity of the GP referral to the symptoms listed in the guidelines was evaluated by eight single site audits (WTA 10, 11, 13, 14, 19, 22, 24, 32), with patient numbers ranging from 27 (WTA 13) to 351 (WTA 32). The percentage of two-week wait referrals that met the guidelines ranged from 65% (WTA 10) to 97% (WTA 22). One of these audits (WTA 19) also looked at how many 'soon', routine, or ungraded referrals met the urgent referral criteria, which included 23/39 (59%), 7/26 (27%) and 12/62 (19%), respectively. Two further audits reported data relating to the outcome GP conformity (WTA 28, 242): (WTA 28) reported that 22/380 two-week wait referrals were for patients under 35 years of age; and (WTA 35) reported that where the consultant disagreed with the GP, the disagreement was owing to inappropriate use of GP referral guidelines for 35/63 two-week wait referrals.

Thirteen multiple site audits evaluated the conformity of the GP referral to the symptoms listed in the guidelines, 12 examined a referral population (WTA 207, 209, 210, 217, 222, 223, 226, 228-230, 233, 234) and one looked at patients diagnosed with cancer (WTA 208). The patient numbers ranged from 23 (WTA 208) to 3288 (WTA 222). Twelve audits (WTA 207, 209, 210, 217, 222, 223, 226, 228-234) (that examined a referral population) reported the percentage of two-week wait referrals that met the guidelines, which ranged from 73% (512/706 (WTA 207)) to 99% (265/269 (WTA 230)). Two audits reported the same data for non-urgent referrals: one audit (WTA 223) reported that 20/30 (67%) non-urgent referrals were appropriate, and the second audit (WTA 208) reported that the single routine breast referral was appropriate in that it did not meet the urgent referral guidelines.

Cancer detection

Twenty-four single site audits reported the number of cancers diagnosed in two-week wait referrals (WTA 5, 10, 11, 13-15, 17-20, 22, 24-27, 29, 31-33, 35, 37-40). Twenty of these audits included all referrals (WTA 5, 10, 13, 15, 17-20, 22, 24-26, 29, 32, 33, 35, 37-40), three only included two-week wait referrals (WTA 11, 14, 27) and one included a mixed population (WTA 31). The number of two-week wait referrals that were analysed ranged from 25 (WTA 15) to 758 (WTA 39) and the percentage of patients with a cancer diagnosis ranged from 0% (0/36 (WTA 5)) to 32% (15/47 (WTA 29)) (median 15.5%). However, this included two audits that examined all patients referred to specialist breast cancer teams in Wales, where it is the hospital consultant not the GP that decides on the priority of the referral (WTA 38, 39) (the cancer detection rates for individual trusts ranged from 0% (0/22) to 8% (27/330) (WTA 38) and 0% (0/0) to 45% (5/11) (WTA 39). Furthermore, three of these audits looked at the cancer diagnosis among various 'appointment types', to which each GP referral was allocated by the hospital staff before an appointment was made (WTA 20, 25, 29). The 'appointment type' included in the proportion of cancer diagnoses reported above were those where 'the GP suspected malignancy' or those referred as urgent or fast track by the GP.

Thirteen multiple site audits reported the number of cancers diagnosed in two-week wait referrals (WTA 206, 209, 210, 212, 219, 220, 222, 223, 226, 231-234). Nine of these audits only included two-week wait referral (WTA 206, 209, 210, 219, 226, 231-234) and four included a mixed population (WTA 212, 220, 222, 223). The number of two-week wait referrals that were analysed ranged from 23 (WTA 223) to 3288 (WTA 222) and the percentage of patients with a cancer diagnosis ranged from 11% (WTA 234) to 34% (WTA 212) (median 17%). One of the audits also reported that no cancers were identified among two-week referrals that did not comply with the guidance (20/87 (WTA 210)).

Four single site audits reported cancer detection rates according to the different referral priority given by the hospital clinician (WTA 10, 12, 33, 37). For referrals classified as urgent by hospital clinician, this ranged from 16% (101/622 (WTA 37)) to 50% (10/20 (WTA 10)). This percentage range includes one audit that reported the cancer detection rates among referrals deemed by the hospital clinician to 'warrant an investigation' (WTA 12), and only includes histologically confirmed cancer in another (does not include 2 patients for whom a malignancy was suspected) (WTA 10). This latter audit also reported that of the 20 GP referrals classified as soon by the specialist and the 30 as routine, none were found to have histologically proven cancer, 1/10 classified as non-urgent was diagnosed with cancer (WTA 10). The fourth audit reported that of the 60/288 GP urgent referrals that were

diagnosed with cancer, 58 were categorised as urgent by the consultant staff; 43/51 GP non-urgent referrals with a cancer diagnosis were designated as urgent by the consultant staff (962 GP non-urgent referrals made). The same audit also reported that 8 women subsequently diagnosed with cancer were referred as non-urgent by the GP and classified as non-urgent by the consultant staff; all of which met the DoH referral criteria (WTA 37).

One further single site audit reported that 32/432 GP referrals (urgent, soon and routine) were diagnosed with breast cancer (WTA 30).

Eighteen single site audits reported the number of cancers diagnosed among non-two-week wait referrals (WTA 5, 10, 13, 15, 17-20, 22, 24-26, 29, 32, 37-40). Five of these reported separate data for patients referred as urgent but not two-week wait (WTA 13, 15, 17) or patients who were given an 'appointment type' that meant that they were seen within two weeks (not two-week referrals, but warranted a two-week appointment) (WTA 25, 29). The number of patients included in the analyses ranged from 22 (WTA 15, 17) to 116 (WTA 25) and the percentage of cancers diagnosed ranged from 4% (5/116 (WTA 25)) to 19% (5/26 (WTA 13)). The percentage of cancers diagnosed among non-urgent referrals or those that were ungraded ranged from 0% (1/14 (WTA 5)) to 10% (1/10 (WTA 10)) (median 3%; 18 audits) and the number of patients included in the analyses ranged from 10 (WTA 10) to 1309 (WTA 40). This included two audits that examined all patients referred to a specialist breast cancer team in Wales (WTA 38, 39); the cancer detection rates for individual trusts in one of these audits ranged from 0% (0/22 to 0/330) to 2% (2/93) (WTA 38).

Four single site audits that looked at a patient population of cancer patients reported data on the type of referral (WTA 3, 4, 6, 7). The number of patients included in the analyses ranged from 29 (WTA 3, 6) to 39 (WTA 7). One audit reported that 22/39 (56%) patients were referred as urgent by their GP, 3 were non-urgent GP referrals and the remaining patients were referred via other sources including the breast screening services (WTA 7). In the remaining three audits, when the referrals are received by the trust they are given an appointment type code which includes GPM for those where the GP suspects malignancy and SFT for suspected fast track breast referrals. The percentage of GPM/SFT appointment types ranged from 18% (6/34 (WTA 4)) to 51% (15/29 (WTA 3)).

Six multiple site audits that looked at a patient population of cancer patients reported data on the type of referral (WTA 208, 212, 220, 222-224). The number of patients included in the analyses ranged from 17 (WTA 212) to 1020 (WTA 222) and the percentage of cancers that were detected via the two-week wait system ranged from 4% (WTA 223) to 83% (WTA 208) (median 44.5%).

Appropriateness of the type of referral

The proportion of two-week wait referrals that were judged by the hospital clinician to require a two-week rule appointment was reported by two single site audits (WTA 28, 35). One audit, that examined all referrals as opposed to just two-week wait referrals, reported that the consultant agreed with GP for 232/415 (56%) two-week wait referrals (WTA 35). One audit reported 50/380 (13%) two-week wait referrals were classed as routine by the consultant (8% were not classified (WTA 28)). One further single site audit reported that there was an agreement on appointment priority between the Breast Care Service and GP for 71% of referrals (n=432), of which 70% were referred on a Clinic Referral Form; it was not stated how many were two-week wait referrals though (WTA 30).

Five multiple site audits (WTA 226, 231-234) reported data on the proportion of two-week wait referrals that were considered appropriate by the hospital clinician, which ranged from 38% (19/50 (WTA 226)) to 96% (of 494 referrals (WTA 234)).

Four single site audits (all of which examined all referrals (WTA 15, 22, 26, 35)) reported data on the proportion of GP referrals that were up-graded to two-week wait status by the hospital clinician, which ranged from 13% (WTA 26) to 32% (WTA 22), but the type of referral included in the analyses varied. One audit reported that 6/22 (27%) urgent referrals were upgraded by the hospital consultant to two-week wait status, and that of the 14 patients referred as routine 4 were upgraded to urgent and 8 to soon (WTA 15). One audit

reported that 78/532 (15%) non-urgent or 'not stated' referrals were upgraded by the consultant (WTA 35). One audit (WTA 26) reported that 8/60 (13%) routine referrals were upgraded to 'urgent' (two-week wait status) and one audit (WTA 22) reported that 20 (32%) routine referrals were upgraded to urgent (two-week wait status) by the consultant (actual number of routine referrals not stated).

Five single site audits, all of which examined all referrals, reported information on the referral priority given by the hospital clinician, but did not directly compare the level of agreement between the hospital clinician and GP for each type of referral (WTA 10, 12, 33, 37). One audit reported that of the 97 included referrals (62 of which were two-week wait referrals), 75 were deemed by the hospital clinician to warrant an investigation (WTA 12). One audit reported that 104/308 referrals were classified as urgent by the consultant, where as only 89/308 were referred as urgent by the GP (WTA 33). One audit reported that of the 1250 included referrals, 288 (23%) were coded as urgent by GPs compared with 622 (49%) coded as urgent by the breast unit consultants (WTA 37). One audit reported that of the 80 referrals included in the audit (70 classified as urgent by the GP and 10 as non-urgent), 20 were classified as urgent by the specialist, 20 as soon and 30 as routine (WTA 10). One audit reported that 104/308 GP referrals were categorised as urgent by the consultant as opposed to 89/308 that were actually referred as urgent by the GP (WTA 33).

Two single site audits reported the proportion of patients referred under the two-week wait rule that were considered appropriate based on the patient history or clinical findings, which ranged from 18% (WTA 40) to 51% (WTA 21). Only one audit reported the number of two-week wait referrals (n=276) that were included in the analyses (WTA 40).

The two single site audits that included all patients referred to specialist breast cancer teams in Wales, where it is the hospital surgeon that decides they priority, acknowledged that there appeared to be a high level of inconsistency in surgeon categorisation of 'urgency' in both audits (the proportion of referrals categorised as urgent: 758/1410 (54% (WTA 39)) and 671/1417 (47% (WTA 38)).

Three single site audits reported information on inconsistencies between the GP referral and the patient's presenting symptoms at the hospital clinic. One audit that included 85 two-week wait referrals reported that 16 women (who were less than 50 years of age) had no suspicious features and six women were found to have no palpable lump; hospital staff felt a non-urgent referral would have been appropriate in each case (WTA 24). One audit reported that 39/50 patients had medical symptoms that indicated an urgent referral criteria, where as only 36/50 patients had been referred by the GP as urgent; 12 were 'non-urgent', and the degree of urgency was not stated for 2 (WTA 5). One audit that included new patients referred to any breast clinic in the region reported that 165/855 patients were found to have no abnormality at first clinical assessment, but the authors did not state how many were referred as two-week wait referrals (WTA 35). The same audit also reported the correlation between GP referral criteria and first clinical assessment: 256/524 referred with breast lump; 75/148 persistent mastalgia; and 30/72 asymptomatic nodularities.

One multiple site audit reported that 39/50 (78%) two-week wait referrals had symptoms described by the patients at the clinic matching those highlighted by the GP referral (WTA 226).

One single site audit reported that almost all 30 patients classified as routine by the hospital specialist presented to their GP with painful nodular breast and that in 9 cases the painful nodular breast lesion had disappeared at the time the patient was seen by the specialist (WTA 10).

Ability of guidelines to identify correct referrals

One single site audit reported that all 11 patients referred as two-week wait referrals that were diagnosed with cancer had a referral that was in line with the guidelines; the audit included 83 two-week wait referrals, of which 70 were in line with the guidelines (WTA 11).

For one single site audit, the hospital consultant deemed the referral to be appropriate for 242/292 (83%) patients who were referred in accordance with the guidelines (audit included 351 urgent referrals and 243 routine referrals (WTA 32)).

One multiple site audit found that 3/20 non-compliant two-week wait referrals were considered to be urgent by the hospital clinicians (WTA 210).

One multiple site audit reported that 11/215 (5%) two-week wait referrals that were in line with guidelines were considered clinically inappropriate, and 10/22 (45%) referrals that did not meet the criteria were considered clinically appropriate (WTA 229).

National guidelines for urgent referrals for women age 35 or older with a discrete mass or thickening were compared with local guidance which suggests referral of women with this symptom only if they are aged 50 years or older in one single site audit (WTA 12). The pickup rate was 33% (8/34) using the local criterion compared with 29% (17/58 patients) using the national criterion.

Process of referral
Twelve single site audits reported on the take-up of agreed breast referral forms (WTA 5, 19, 20, 22, 24-26, 29, 30, 35, 37), which ranged from 21% (WTA 37) to 86% (WTA 5). Two audits looked only at the mode of referral for urgent referrals, and found: letter only = 70%, fax only = 19%, letter and fax = 9%, self referral and telephone = 1.7% (WTA 38); and letter = 56%, fax = 43%, telephone = 0.8%, unspecified = 0.5% (WTA 39).

One multiple site audit reported that 81% of urgent breast referrals used the proforma and 95% were faxed (WTA 219).

Six single site audits reported the proportion of two-week wait referrals that were received by the Trust within 24 hours of the GP's decision to refer (WTA 18, 20, 25, 28, 29, 35). The percentage received within 24 hours ranged from 35% (38/109 (WTA 29)) to 96% (366/380 (WTA 28)). Another audit reported that 12% of urgent letter referrals took longer than 5 working days to arrive at the Trust and that the average number of working days between date on GP referral letter and date of receipt by the hospital (urgent letter referrals only, n=426) was 3.2 (median = 3, range 0 to 13 (WTA 39)).

Three multiple site audits reported the proportion of GP two-week wait referrals for breast cancer that were received by the Trust within 24 hours (WTA 206, 210, 219), which ranged from 75% (65/87) to 92% (of 215 two-week wait referral (WTA 206)).

Summary

The proportion of breast referrals under the two-week wait system that were seen within two weeks ranged from 67% to 100% (22 audits) when examining a referral population, and from 38% to 100% (nine audits) when only looking at patients diagnosed with cancer. Conflicting results were reported in before-and-after audits (two increased (one looked at patients diagnosed with cancer), one decreased).

The proportion of two-week wait referrals that were found to be in accordance with the symptoms listed in the guidelines ranged from 65% to 99% (20 audits).

The proportion of patients subsequently diagnosed with cancer after referral under the two-week wait system ranged from 0% to 34% (37 audits). The proportion of patients subsequently diagnosed with cancer after urgent, but not two-week wait, referrals ranged from 4% to 20% (five audits). The proportion of patients subsequently diagnosed with cancer after non-urgent referral ranged from 0% to 10% (18 audits).

When looking at a patient population of cancer patients, the percentage of patients that were referred as two-week wait referrals ranged from 4% to 83% (nine audits).

The proportion of patients whom the hospital clinician deemed to be urgent (should be seen within two weeks) that were subsequently diagnosed with cancer ranged from 16% to 50% (three audits).

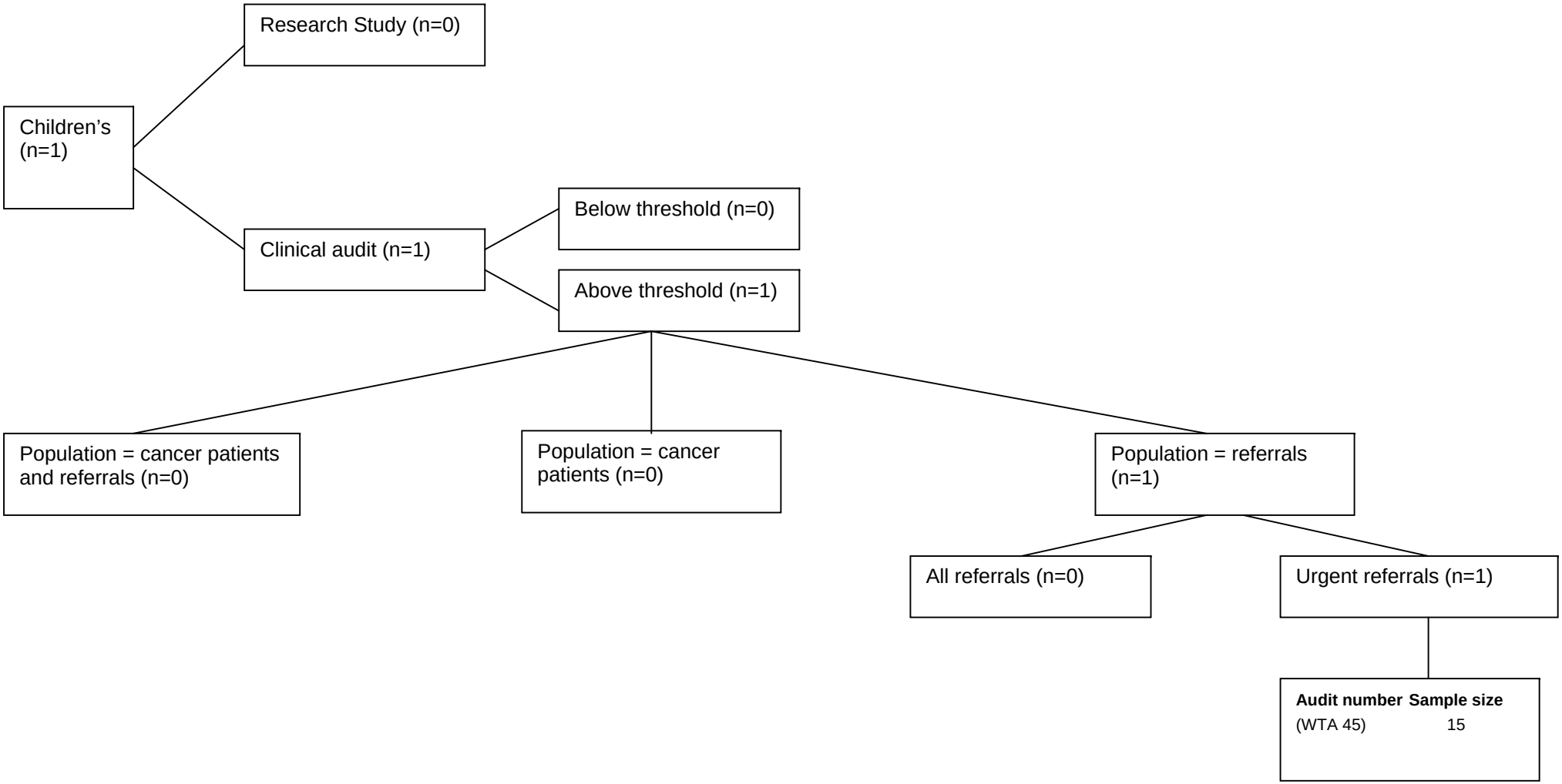
The proportion of two-week wait referrals deemed by the consultant to warrant an urgent appointment (or were considered clinically appropriate) ranged from 18% to 96% (nine audits). The proportion of non-two-week wait referrals that were upgraded by the consultant to two-week wait status ranged from 13% to 32% (four audits), but the type of referral included in the analyses varied.

One audit reported that 78% of two-week wait referrals had symptoms reported by the GP matching those described by the patient at clinic.

The proportion of two-week wait referrals that were in accordance with the guidelines but were considered to be inappropriate by the hospital clinician ranged from 5% to 17% (two audits). 15% to 45% of two-week wait referrals that did not meet the criteria were considered clinically appropriate (two audits).

One audit reported that 16% (11/70) of two-week wait referrals that were in line with guidelines were diagnosed with cancer

Single site children's cancer studies



CHILDREN'S CANCERS

Overview

Nine clinical audits evaluated the referral guidelines for children's cancers (WTA 45, 206, 207, 224, 230-234).

Seven audits were conducted in general hospitals (WTA 45, 224, 230-234) and two in PCTs (WTA 206, 207). With the exception of one non criterion-based audit (WTA 207), all were categorised (in terms of the methodology used) as a clinical audit.

All eight audits that examined a referral population only, included only two-week wait referrals (WTA 45, 206, 207, 230-234). The patient population of interest included those diagnosed with cancer in one audit (WTA 224).

The data were collected retrospectively in four audits (WTA 45, 206, 224, 230) and prospectively in four audits (WTA 231-234). One audit did not specify the direction of data collection (WTA 207).

Eight of the nine audits examined multiple cancer sites but reported some results separately for each site, while one audit looked at children's cancers only (WTA 45). Sample sizes ranged from 1 (WTA 206, 207, 230) (when considering children's cancers only) to 15 (WTA 45).

All nine audits reported some data on how eligible patients were identified and/or gave the data source. The results of these audits are summarised below.

Outcome measures

Waiting time to first appointment

The single site audit reported that all 15 referrals met the two-week rule (WTA 45). The only multiple site audit that evaluated this outcome reported that all 11 children's referrals met the two-week wait rule (WTA 234).

GP conformity to guidelines

The conformity of the GP referral to the symptoms listed in the guidelines was evaluated by the single site audit, which reported only that 'most' of the 15 referrals were appropriate (WTA 45). Four multiple site audits evaluated the conformity of the GP referral to the symptoms listed in the guidelines (WTA 207, 230, 233, 234). With patient numbers ranging from 1 (WTA 207, 230) to 11 (WTA 234), the numbers of referrals that were considered appropriate ranged from 91% (10/11 (WTA 234)) to 100% (1/1 (WTA 207, 230), 2/2 (WTA 233)).

Cancer detection

Three multiple site audits reported cancer detection rates for two-week wait referrals, with no cancers detected in sample sizes of 1 to 5 (WTA 206, 231, 233).

Appropriateness of the type of referral

Four multiple site audits reported the proportion of two-week wait referrals that the clinician assessed as appropriate. The number of patients included in the analyses ranged from 2 (WTA 232, 233) to 11 (WTA 234) and the proportion considered to be appropriate ranged from 60% (3/5 (WTA 231)) to 100% (2/2 (WTA 232, 233)).

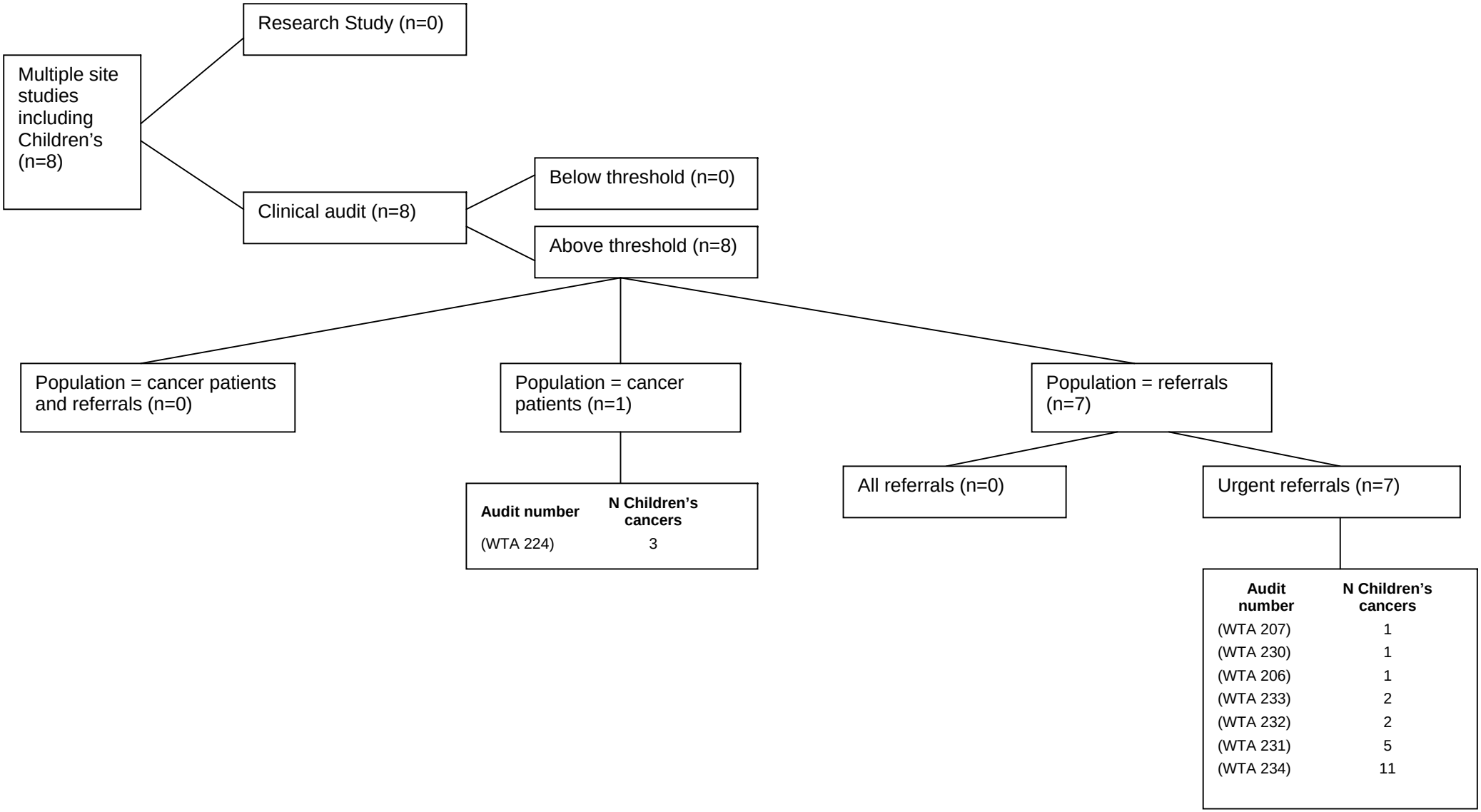
Ability of guidelines to identify correct referrals

Not reported.

Process of referral

Site-specific data on the process of referral was reported by one multiple site audit (WTA 224) that found that 2/3 children were referred on the urgent 14 day proforma.

Multiple site children's cancer studies



Summary

The proportion of patients referred under the two-week wait referral system and seen within two weeks was 100% (two audits). The proportion of two-week wait referrals that were found to be in accordance with the symptoms listed in the guidelines ranged from 91% to 100% (four audits).

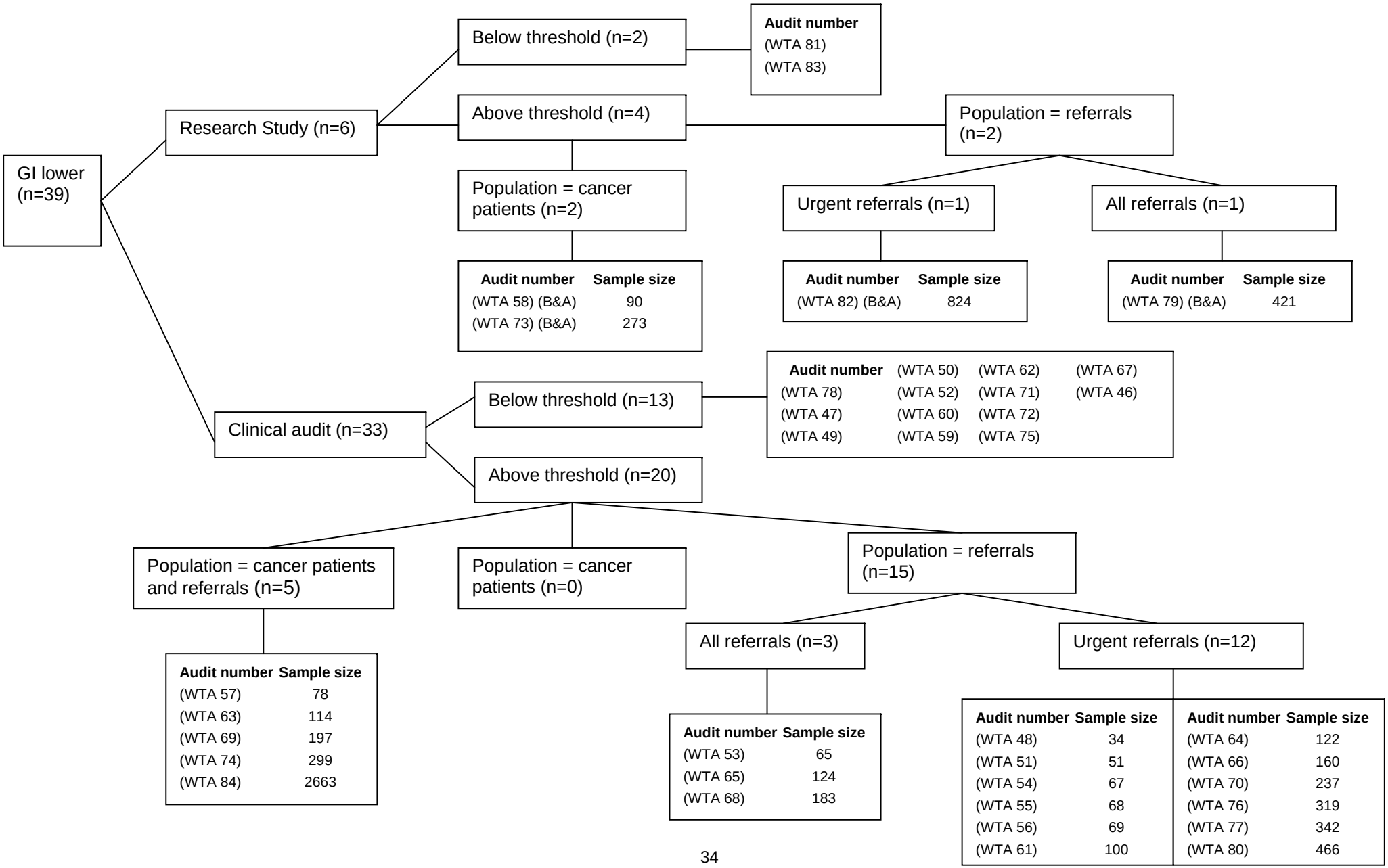
No patient referred under the two-week wait referral system was subsequently diagnosed with cancer (three audits).

The proportion of two-week wait referrals deemed to be clinically appropriate ranged from 60% to 100% (four audits).

All of these results are based upon audits of 15 patients or less.

Single site lower GI cancer studies

Key: B&A = before and after study



LOWER GASTRO-INTESTINAL CANCERS

Overview

Seventy-one clinical audits evaluated the referral guidelines for lower GI cancers (WTA 46-84, 206-219, 222, 223, 225-240).

Fifty-one audits were conducted by a general hospital (WTA 46-48, 51, 53-57, 59-72, 74-79, 83, 84, 208, 210-216, 223, 226, 227, 229-235, 238, 239), 14 by a teaching hospital (WTA 49, 50, 52, 58, 73, 81, 82, 209, 217-219, 225, 236, 237) three within a cancer network (WTA 222, 228, 240), two by a PCT (WTA 206, 207), and one audit was conducted by the Cancer Services Co-ordinating Group (CSCG) and included all acute trusts in Wales (WTA 80).

Fifty-eight were categorised (in terms of the methodology used) as a clinical audit (WTA 47-57, 59-69, 70-72, 74, 76-78, 80, 84, 206, 208-217, 222, 223, 225-234, 236, 237, 239, 240), seven as a non-criterion based audit (WTA 46, 75, 207, 218, 219, 235, 238), and six as a research study (WTA 58, 73, 79, 81-83).

Forty-nine audits evaluated patients that were referred to the department or trust, eight of which examined all referrals (WTA 53, 65, 68, 75, 78, 79, 218, 225) and 41 only included two-week wait referrals (WTA 47-52, 54-56, 59-62, 64, 66, 70-72, 76, 77, 80, 82, 206, 207, 209-211, 216, 217, 219, 226, 229-234, 236, 237, 239, 240). The patient population of interest included those diagnosed with cancer in five audits (WTA 58, 73, 208, 227, 238) and 16 audits looked at a mixed patient population (both patients diagnosed with cancer and those being referred) (WTA 46, 57, 63, 67, 69, 74, 81, 83, 84, 212-215, 222, 223, 235). The population of interest was not clear in one audit (WTA 228).

The data were collected retrospectively in 37 audits (WTA 46, 48, 51-54, 56-60, 62-65, 69, 73, 76, 206, 208-212, 216, 218, 219, 226-228, 230, 235-240) (3 of which had a before and after design (WTA 58, 73, 218)) and prospectively in 15 audits (WTA 55, 66, 68, 74, 75, 78, 79, 82-84, 225, 231-234) (3 of which were before and after (WTA 79, 82, 83)). The direction of the data capture was not stated or unclear in 19 audits (WTA 47, 49, 50, 61, 67, 70-72, 77, 80, 81, 207, 213-215, 217, 222, 223, 229).

Thirty-nine audits (WTA 46-84) (6 of which were categorised as a research study (WTA 58, 73, 79, 81-83)) looked exclusively at lower GI cancers (single site), whilst 32 audits examined multiple cancer sites (WTA 206-219, 222, 223, 225-240).

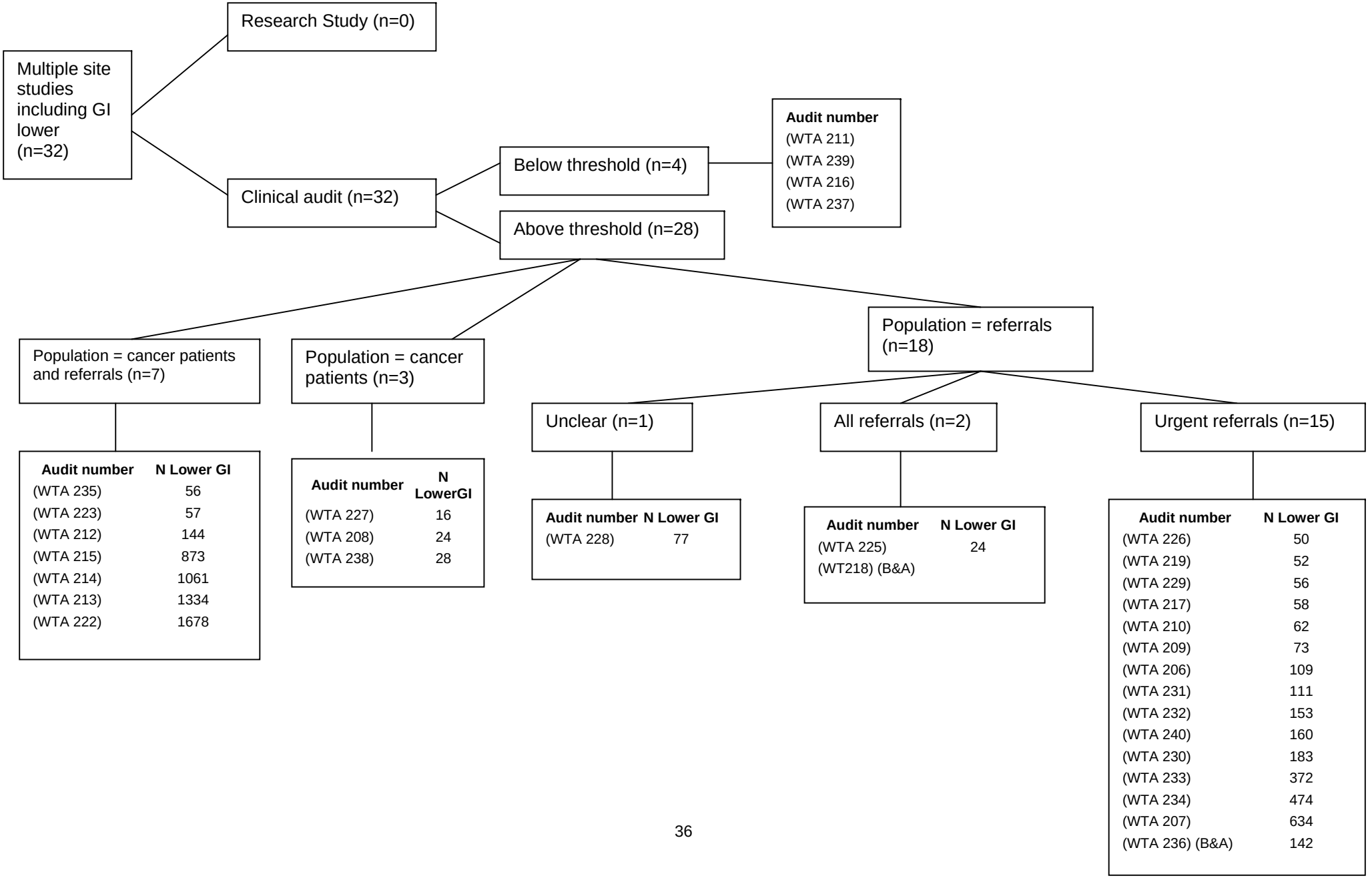
Fifty-two audits reported some data on how eligible patients were identified and/or gave the data source (WTA 48, 51, 53-58, 61, 63-66, 68-70, 73, 74, 76, 77, 79, 80, 82, 84, 206-210, 212-215, 217-219, 222, 223, 225-236, 238, 240). Four of these audits did not report separate data for lower GI cancer (WTA 218, 225, 227, 235). The results of the remaining 48 audits are summarised below. The other 19 audits were not as well reported (WTA 46, 47, 49, 50, 52, 59, 60, 62, 67, 71, 72, 75, 78, 81, 83, 211, 216, 237, 239) and as such their results are considered to be less reliable. The results of these audits are therefore not discussed further.

The sample size ranged from 34 (WTA 48) to 2663 (WTA 84) for the 24 single site audits (4 of which were categorised as a research study) (WTA 48, 51, 53-58, 61, 63-66, 68-70, 73, 74, 76, 77, 79, 80, 82, 84) and from 24 (WTA 208) to 1678 (WTA 177) for the 24 multiple site audits (when only considering lower GI cancers) (WTA 206-210, 212-215, 217, 219, 222, 223, 226, 228-234, 236, 238, 240).

Most of the audits were poorly reported, but three single site audits were identified as being well conducted, having only failed three (WTA 48) or four (WTA 53, 80) of the quality criteria. However, one of these audits only included three patients referred under the two-week wait rule (n=65) (WTA 53). None of the audits demonstrated any major methodological flaw that would render their findings totally unreliable, although the poor reporting means that this cannot be assured.

Multiple site lower GI cancer studies

Key: B&A = before and after study



Results

Waiting time to first appointment

Twelve of the single site audits reported data on meeting the two-week wait criterion (WTA 48, 51, 53, 55, 57, 66, 68-70, 74, 76, 79). Nine of these audits examined a referral population (6 looked at two-week wait referrals only (WTA 48, 51, 55, 66, 70, 76), and 3 looked at all referrals (WTA 53, 68, 79)). Three audits (WTA 57, 69, 74) evaluated both patients referred and those diagnosed with cancer. When excluding one audit (WTA 53) that only included three patients referred under the two-week wait rule (all of which were seen within two weeks) the number of two-week wait referrals that were analysed ranged from 34 (WTA 48) to 319 (WTA 76), and the percentage seen within two weeks ranged from 45% (WTA 68) to 100% (WTA 51, 79).

One further single site audit reported data on how many referrals, that had been deemed 'urgent' by the hospital consultant or deputy (defined as patients at high risk of colorectal cancer based on information given in the GP referral), were seen within two weeks (WTA 80). The audit included 16 multidisciplinary teams in Wales and 15 teams used the Association of Coloproctology guidelines to determine the urgency of referrals. The average waiting time (from the hospital receipt of referral) for patients to be seen for assessment was 30 days (range 0 to 147 days) and 31% of referrals were offered an appointment within 10 working days. For referrals that were made by letter (n=414), the average waiting time (from hospital receipt of referral to first appointment) was 31 working days; 27.3% were offered an appointment within 10 working days. For faxed referrals (n=38), the average waiting time was 9 working days; 66% were offered an appointment within 10 working days. Nine out of 31 (29%) patients subsequently diagnosed with cancer were seen within 10 working days of receipt of referral.

Six multiple site audits that examined a referral population (all included only two-week wait referrals (WTA 209, 210, 219, 234, 236, 240)) reported data on meeting the two-week wait criterion. The number of referrals to the lower GI service that were analysed ranged from 50 (WTA 219) to 474 (WTA 234) and the percentage seen within two weeks ranged from 57% (WTA 209) to 100% (WTA 234). This included non-attenders and cancellations in some of the audits. The time between referral and 1st appointment ranged from 19 to 24 days for the four patients not seen within two weeks in one trust (WTA 210).

Three single site audits (WTA 68, 69, 79) gave an average time (all reported in a different way) to first appointment for non-two-week wait referrals. For urgent (non two-week wait) referrals this included a mean of 37 days (n=24 (WTA 79)); for routine or 'non-urgent' referrals this included a mean of 49 days (n=33 (WTA 79)), a median of 24 weeks (n=42 (WTA 68)), or a median of 25 days (n=20 (WTA 69)). One of these audits reported separate waiting time data for non-two-week wait referrals that were upgraded by the hospital consultant (n=44) to urgent (two-week wait status), which included a median wait of 3 weeks (range 1 to 8 weeks (WTA 68)).

Three of the single site audits that included patients diagnosed with cancer (one of which included a mixed patient population (WTA 57)) reported the average waiting time from referral to first appointment for two-week wait referrals: median 8 days (n=35 (WTA 58)), mean 11 days (n=51 (WTA 73)), and mean 12 days (n=6 (WTA 57)). Patients referred via letter waited an average of 26 days (n=86 (WTA 73)) and patients who did not meet the two-week wait referral criteria waited a median of 28 days (n=10 (WTA 58)). The average wait for non-urgent referrals in one audit was 12 days (n=6 (WTA 57)) and the median wait in another audit was 32 days (n=95 (WTA 74)). One further audit that evaluated all two-week wait referrals and all patients referred to their routine colorectal surgery outpatients (CSOP) clinic, gave the median time to 1st outpatient appointment for those that were diagnosed with cancer; the time to 1st appointment was 12 days (n=65) for two-week wait referrals, 28 days (n=27) for those at high risk of cancer and 26 days (n=12) for those at low risk (WTA 84).

Three multiple site audits examined patients diagnosed with cancer and those referred as two-week wait referrals (WTA 213-215). All three audits were conducted by the same trust. All patients diagnosed with lower GI cancer that were referred as two-week wait referrals

were seen within two weeks, but the number of patients that were included were small (range 5 (WTA 213) to 7 (WTA 215)). The percentage of cancer patients not referred as two-week wait referrals that were seen within two weeks ranged from 20% (WTA 214) to 43% (WTA 215) (number analysed ranged from 56 (WTA 214) to 62 (WTA 213)).

GP conformity to guidelines

The appropriateness of the GP referral according to the symptoms listed in the guidelines was evaluated by 13 single site audits (WTA 48, 53-57, 61, 64, 66, 70, 74, 77, 84). Excluding data from one audit that only included three two-week wait referrals, all of which were appropriate (WTA 53), the percentage of referrals that were considered appropriate ranged from 53% (WTA 74) to 85% (WTA 56). The number of two-week wait referrals included in the analyses ranged from 32 (WTA 48) to 695 (WTA 84).

Fourteen multiple site audits examined whether the GP referrals were in line with the criteria listed in the guidelines (WTA 207, 209, 210, 212, 217, 222, 223, 226, 228-230, 233, 234, 240); three examined more than one patient population (referral population and patients diagnosed with cancer) (WTA 212, 222, 223). The percentage of referrals that were considered appropriate for 13 audits (WTA 207, 209, 210, 212, 217, 222, 223, 226, 228, 229, 233, 234, 240) ranged from 55% (WTA 209) to 91% (WTA 228). The number of two-week wait referrals included in the analyses ranged from 10 (WTA 223) to 634 (WTA 207) for 13 audits and 1678 for one large network wide audit (WTA 222). For one audit, only referrals that were identified as inappropriate by hospital consultants (who were asked to report all referrals that they deemed inappropriate to the audit co-ordinator) were included in the analyses for appropriateness; 181/183 were appropriate (WTA 230).

One multiple site audit that included patients with cancer, reported that 2/7 patients referred as routine met the guidelines for urgent referral (WTA 208). One multiple site audit reported that 32/35 non-urgent referrals were appropriate (WTA 223).

Cancer detection

Cancer rates for populations of referrals:

Data on cancer detection rates were reported by 16 single site audits that examined a referral population (WTA 51, 53-56, 61, 64-66, 68, 70, 76, 77, 79, 80, 82). This included 12 audits that only examined two-week wait referrals (WTA 51, 54-56, 61, 64, 66, 70, 76, 77, 80, 82) and four that evaluated all referrals (WTA 53, 65, 68, 79); one audit did not report separate data for two-week wait referrals (WTA 53) and one audit classified the GP referrals as either ‘routine’ or ‘urgent’ (for the purpose of this review ‘urgent’ referrals have been categorised as two-week wait referrals, but may contain both urgent (non-two-week wait referrals) and two-week wait referrals) (WTA 68). One of the audits reported the proportion of patients with neoplasia (as opposed to cancer), which included adenomatous polyps (WTA 82). It was not stated if any of the other audits either included or excluded neoplastic polyps.

Five further single site audits (WTA 57, 63, 69, 74, 84) that evaluated more than one sample of patients (mixed patient population) reported cancer detection rates. Patient populations included those that were referred (all referrals (WTA 84) or only those referred under the two-week wait system (WTA 57, 63, 69, 84) or as an ‘urgent’ referral (WTA 74)) and those diagnosed with cancer (patients not referred under the two-week wait system, but diagnosed with cancer during the same time period (WTA 57, 69), or all patients diagnosed with cancer irrespective of referral type (WTA 63, 84)). One of these audits actually evaluated three sample populations: all patients diagnosed with cancer (including two-week wait referrals) (n=249, complete records were unavailable for at least 12 patients); all patients referred on the basis of the two-week wait standard (n = 758, 695 included in analyses); and all patients who attended the routine CSOP clinics (n = 1815 (WTA 84)).

Of 18 single site audits (WTA 51, 54-57, 61, 64-66, 68-70, 76, 77, 79, 80, 82, 84) that reported separate data for two-week wait referrals (including 3 that evaluated a mixed population (WTA 57, 69, 84)), the number of participants referred under the two-week wait rule that were included in the analyses ranged from 42 (WTA 68) to 695 (WTA 84), and the cancer detection rates ranged from 6% (4/69 (WTA 56) or 10/160 (WTA 66)) to 19%

(62/335 (WTA 77) or 10/53 (WTA 55)). However, only four audits (WTA 66, 69, 76, 77) reported specific data for colorectal cancer (which is what is reported here) and therefore some of these figures may include other malignancies. The number of participants for whom a cancer diagnosis was not known (including patients still under investigation) or the number still under follow up was only given in four audits (WTA 54, 57, 64, 66). One further audit reported that 26/180 (14%) patients referred as urgent by the GP via a letter were diagnosed with colorectal cancer; 95/180 of the referrals fitted the two-week wait referral criteria (WTA 74). Although this audit was conducted during the appropriate time period for inclusion in the review (guidelines implementation date), the hospital trust conducting the audit had not implemented the guidelines when these GP referrals were made.

Twelve multiple site audits reported cancer detection rates for patients being referred to the lower GI service under the two-week wait rule (WTA 206, 209, 210, 212, 219, 222, 223, 226, 231-234). This ranged from 2% (1/60 (WTA 210)) to 14% (10/73 (WTA 209)), for 11 audits (WTA 206, 209, 210, 219, 222, 223, 226, 231-234). The number of patients included in the analyses ranged from 10 (WTA 226) to 1678 (WTA 222). The remaining audit reported the cancer detection rates for three separate samples, that may not be mutually exclusive (WTA 212), which ranged from 6% (2/33) to 22% (8/37). One audit reported the percentage of patients that had an unknown diagnosis (WTA 226), and one the total number of patients with a non-cancer diagnosis (WTA 223).

In one single site audit, the cancer detection rates for non-two-week wait referrals was 12/137 (9%), and when only considering the 'urgent' referrals the cancer detection rates was 5/24 (21% (WTA 79)). A second audit that included 116 two-week wait referrals and 8 GP referral letters that were deemed to be suspicious of cancer by the consultant reported that one of the patients referred via letter was subsequently diagnosed with cancer (WTA 65).

One single site audit, that examined three sample populations, reported that the diagnostic yield for the routine CSOP clinic was 40/1815 (2%), but not all patients will have been referred with suspected colorectal cancer (WTA 84). The diagnostic yield for those who were found to have symptoms according to the urgent referral criteria (as assessed by the hospital clinicians) was 27/478 (6%); 12/1326 that did not have symptoms according to the criteria were diagnosed with cancer.

Two single site audits (that included all referrals) reported the total number of patients that were diagnosed with cancer: 2/65 (3 patients were referred under the two-week wait rule (WTA 53)) and 4/183 (1 patient was referred under the two-week wait rule (WTA 68)).

The proportion of patients appropriately referred as two-week wait referrals that were subsequently diagnosed with cancer ranged from 12% (18/147 (WTA 70)) to 21% (10/46 (WTA 55)) according to two single site audits.

One multiple site audit that reported a cancer detection rate of 1/60 (2%) also reported that none of the referrals that did not comply with guidelines (26/60) resulted in a diagnosis of cancer (WTA 210).

The proportion of two-week wait referrals that did not comply with the guidelines that were subsequently diagnosed with cancer ranged from 2% (1/63 (WTA 77)) to 3% (3/90 (WTA 70)) according to two single site audits.

Type of referral for populations of cancer patients:
One single site audit that only included patients diagnosed with colorectal cancer reported that 51/137 (37%) patients were referred under the two-week wait rule (WTA 73). One further single site audit that examined two sample populations, one of which included patients diagnosed with cancer, reported that 26/145 (18%) new colorectal cancer patients were referred via the two-week wait system; 24 were found to meet the two-week wait referral guidelines (WTA 74). Although this audit was conducted during the appropriate time period for inclusion (guidelines implementation date), the hospital trust conducting the audit had not implemented the guidelines when the GP referrals were made.

Five multiple site audits (WTA 208, 212, 222, 223, 238) reported the proportion of patients diagnosed with cancer that were referred via the two-week wait system, three of which included a mixed patient population (WTA 212, 222, 223). For lower GI cancer, this ranged from 0% (0/12 (WTA 223)) to 46% (13/28 (WTA 238) or 11/24 (WTA 208)). The number of patients included in the analyses ranged from 7 (WTA 212) to 863 (WTA 222).

Two single site audits that examined a mixed patient population, one of which was patients diagnosed with cancer but not referred under the two-week wait rule, reported that 8/14 (57% (WTA 57)) and 20/56 (36% (WTA 69)) of the patients were referred as routine by their GP. One audit only looked at GP referrals, for which 6/14 (43%) had been given a priority of 'urgent' (WTA 57). For the remaining audit, 36 cancer patients had presented as emergencies or been referred by physicians (WTA 69).

Appropriateness of type of referral
Two single site audits reported data on whether the hospital clinician thought that the GP referral made under the two-week rule actually warranted an urgent two-week wait appointment. One audit found that for 81/119 (68%) the clinician thought that the patient did require a two-week wait appointment (this was not known for a further 3 patients) (WTA 64). One audit that included all patients referred with suspected colorectal cancer reported that 20/42 (48%) 'urgent' referrals were deemed to be 'routine' by the hospital consultant (all included referrals were categorised as either urgent or routine; no distinction was made between urgent and two-week wait referral) (WTA 68). It was not stated how many of these referrals would have met the two-week wait guidelines. The audit that included all patients referred with suspected colorectal cancer also reported that 44/141 (31%) of the routine referrals were upgraded to 'urgent' by the hospital consultant. It was not stated how many of these would have been in accordance with the guidelines (WTA 68). Twenty-two patients were excluded from the audit because: they failed to attend their appointment (n=10), their condition cleared (n=6), they were an inappropriate referral (n=4), or they were seen in other clinics (n=2).

Four multiple site audits (WTA 231-234) reported data on the proportion of two-week wait referrals that were considered appropriate by the hospital clinician, which ranged from 62% (of 111 patients (WTA 231)) to 74% (of 474 patients (WTA 234)).

One single site audit found that 478/1815 (26%) patients attending the routine CSOP clinic had symptoms meeting urgent referral criteria; it was not stated how many were GP referrals (WTA 84).

Two single site audits that examined two-week wait referrals reported data on discrepancies between the GP's assessment and the presentation at the hospital consultation (WTA 51, 54). One audit found that, according to a review of the case notes, the symptoms in clinic did not match the guidelines for 8/60 (13%) patients, whereas the GP referral did not match the guidelines for 12/60 patients (WTA 54). One audit reported that only 17/51 (33%) of the patients were found to have the same symptom as reported by the GP (WTA 51).

One multiple site audit reported that the symptoms described by the patients at the outpatients clinic matched that of the GP referral in 68% of cases (based on 46 Lower GI two-week wait referrals (WTA 226)).

Ability of guidelines to identify correct referrals
Two multiple site audits reported the number of two-week wait referrals that did not meet the referral criteria but were still considered as 'urgent' (clinically appropriate) by the hospital clinician. This ranged from 1/11 (9%; 11/51 referrals were inappropriate and appropriateness not stated for 2 (WTA 229)) to 5/26 (19% (WTA 210)). One audit reported that none of the 40 referrals meeting the guidelines were deemed clinically inappropriate (WTA 229).

Other results
Two-week wait referrals were made using the appropriate form in 24/32 (75%) patients in one single site audit (WTA 48) and 94/100 in another (WTA 61).

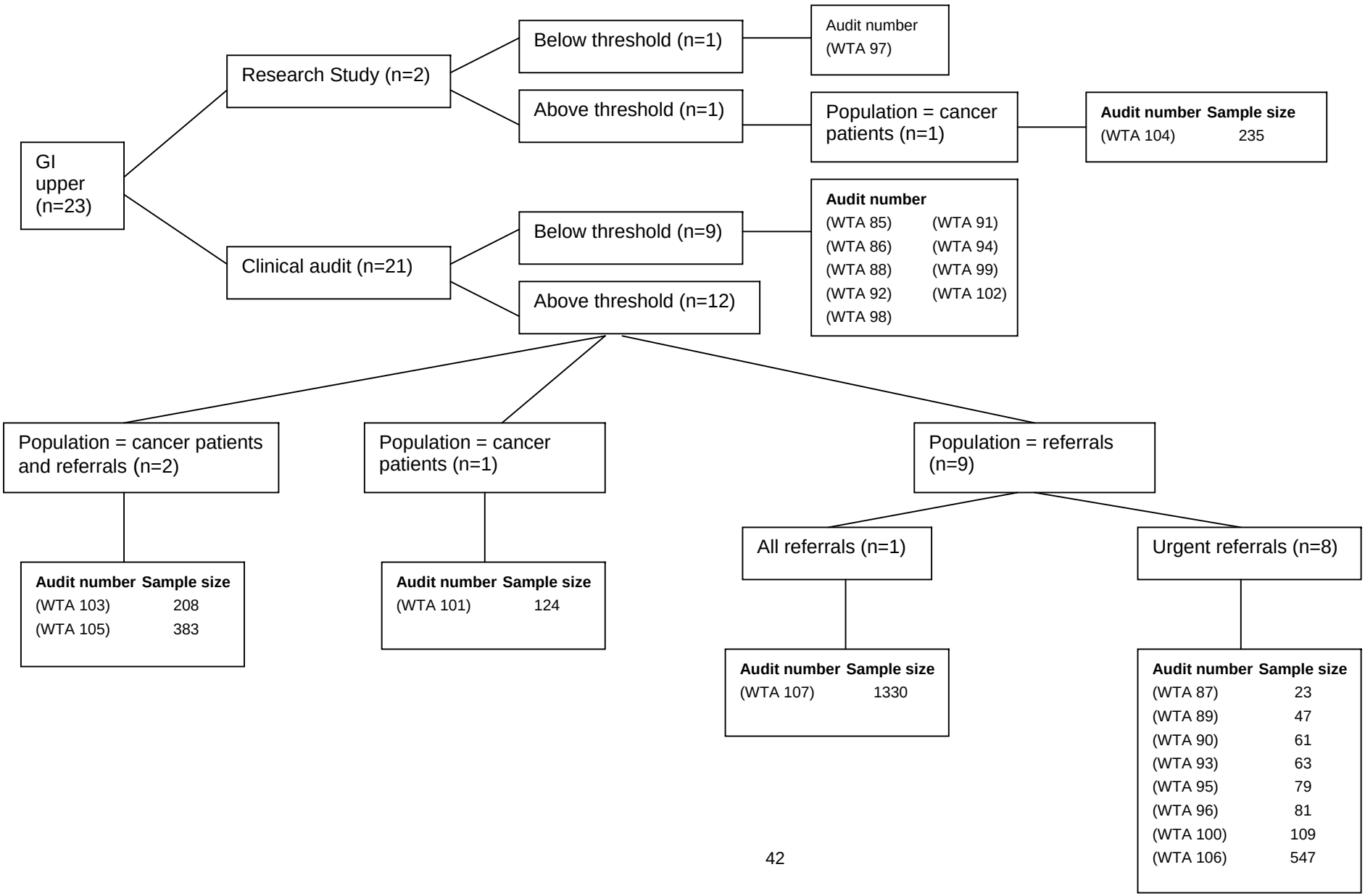
One multiple site audit reported that 88% of the two-week wait referrals (n=52) to the lower GI service were received within 24 hours (WTA 219); 97% were faxed and 97% used the referral proforma. A second multiple site audit reported that 92% of two-week wait referrals were received within 24 hours, and the time taken for those not received within 24 hours ranged from 2 to 6 days (WTA 210).

Summary

When considering audits that examined a referral population, the percentage of patients referred under the two-week wait system and seen within two weeks ranged from 45% to 100% (17 audits; not including one audit n=3). The percentage of two-week wait referrals that were found to be in accordance with the guidelines ranged from 53% to 91% (25 audits; not including one audit n=3). The cancer detection rates among two-week wait referrals ranged from 2% to 14% (30 audits), and for those that were found to be in accordance with the guidelines ranged from 12% to 21% (two audits). The proportion of two-week wait referrals that did not comply with the guidelines that were subsequently diagnosed with cancer ranged from 0% to 3% (3/90) (three audits). The percentage of two-week wait referrals that were judged by the hospital consultant to require a two-week wait appointment ranged from 52% to 74% (six audits). The percentage of patients that had symptoms at outpatient clinic that matched the GP referral ranged from 33% to 87% (three audits). One audit reported that 478/1815 (26%) of patients attending the routine colorectal surgery outpatient clinic had symptoms according to the guidelines and that 27/478 (6%) were subsequently diagnosed with cancer; 12/1326 that did not have symptoms according to criteria were diagnosed with cancer. Two audits looked at whether any two-week wait referrals (that were not in line with the guidelines) warranted an urgent referral (according to the hospital consultant). This ranged from 9% to 19%, and one audit found that 0/40 referrals that met the guidelines were deemed clinically inappropriate by the hospital consultant.

When considering the results of audits that included patients diagnosed with cancer, all two-week wait referrals were seen within two weeks (three audits) and 20% to 43% of non-two-week wait referrals were seen within two weeks (three audits). The percentage of cancer patients that were referred under the two-week wait system ranged from 0 to 46% (seven audits).

Single site upper GI cancer studies



UPPER GASTRO-INTESTINAL CANCERS

Overview

Fifty-four clinical audits evaluated the referral guidelines for upper GI cancers (WTA 85-107, 206-220, 222, 223, 225-227, 229-235, 236, 237-239).

Thirty-six audits were conducted by a general hospital (WTA 87, 89-92, 95-101, 103, 105, 106, 208, 210-216, 220, 223, 226, 227, 229-235, 238, 239), 15 by a teaching hospital (WTA 85, 86, 88, 93, 94, 102, 104, 107, 209, 217-219, 225, 236, 237), one within a cancer network (WTA 222) and two by a PCT (WTA 206, 207). Forty-one audits were categorised (in terms of the methodology used) as a clinical audit (WTA 85-89, 91, 93, 94, 96, 99-103, 105, 107, 206, 208-217, 222, 223, 225-227, 229-234, 236, 237, 239), eleven as a non-criterion based audit (WTA 90, 92, 95, 98, 106, 207, 218-220, 235, 238) and two as a research study (WTA 97, 104).

Thirty-seven audits evaluated patients that were referred to the department or trust, four of which examined all referrals (WTA 102, 107, 218, 225), 33 only included two-week wait referrals (WTA 85-96, 98, 100, 106, 206, 207, 209-211, 216, 217, 219, 226, 229-234, 236, 237, 239). The patient population of interest included those diagnosed with cancer in seven audits (WTA 97, 99, 101, 104, 208, 227, 238) and ten audits looked at both patients diagnosed with cancer and those being referred (WTA 103, 105, 212-215, 220, 222, 223, 235). The data were collected retrospectively in 29 audits (WTA 89-91, 96, 99-101, 103-106, 206, 208-212, 216, 218-220, 226, 227, 230, 235-239) (2 of which had a before and after design (WTA 104, 218)) and prospectively in 7 audits (WTA 93, 107, 225, 231-234). The direction of the data capture was not stated or unclear in 18 audits (WTA 85-88, 92, 94, 95, 97, 98, 102, 207, 213-215, 217, 222, 223, 229) (1 of which had a before and after design (WTA 97)).

Twenty-three audits looked exclusively at upper GI cancers (single site) (WTA 85-107), whilst 31 audits examined multiple cancer sites (WTA 206-220, 222, 223, 225-227, 229-239).

Forty audits reported some data on how eligible patients were identified and/or gave the data source (WTA 87, 89, 90, 93, 95, 96, 100, 101, 103-107, 206-210, 212-215, 217-220, 222, 223, 225-227, 229-236, 238). Four of these audits did not report separate data for upper GI cancers (WTA 218, 225, 227, 235). The results of the remaining 36 audits are summarised below. The other 14 audits were not as well reported (WTA 85, 86, 88, 91, 92, 94, 97-99, 102, 211, 216, 237, 239) and as such their results are considered to be less reliable. The results of these audits are therefore not discussed further.

The sample sizes ranged from 23 (WTA 87) to 1330 (WTA 107) for the thirteen single site audits (WTA 87, 89, 90, 93, 95, 96, 100, 101, 103-107) and 7 (WTA 208) to 995 (WTA 222) for the 23 multiple site audits (when only considering upper GI cancers) (WTA 206-210, 212-215, 217, 219, 220, 222, 223, 226, 229-234, 236, 238).

Outcome measures

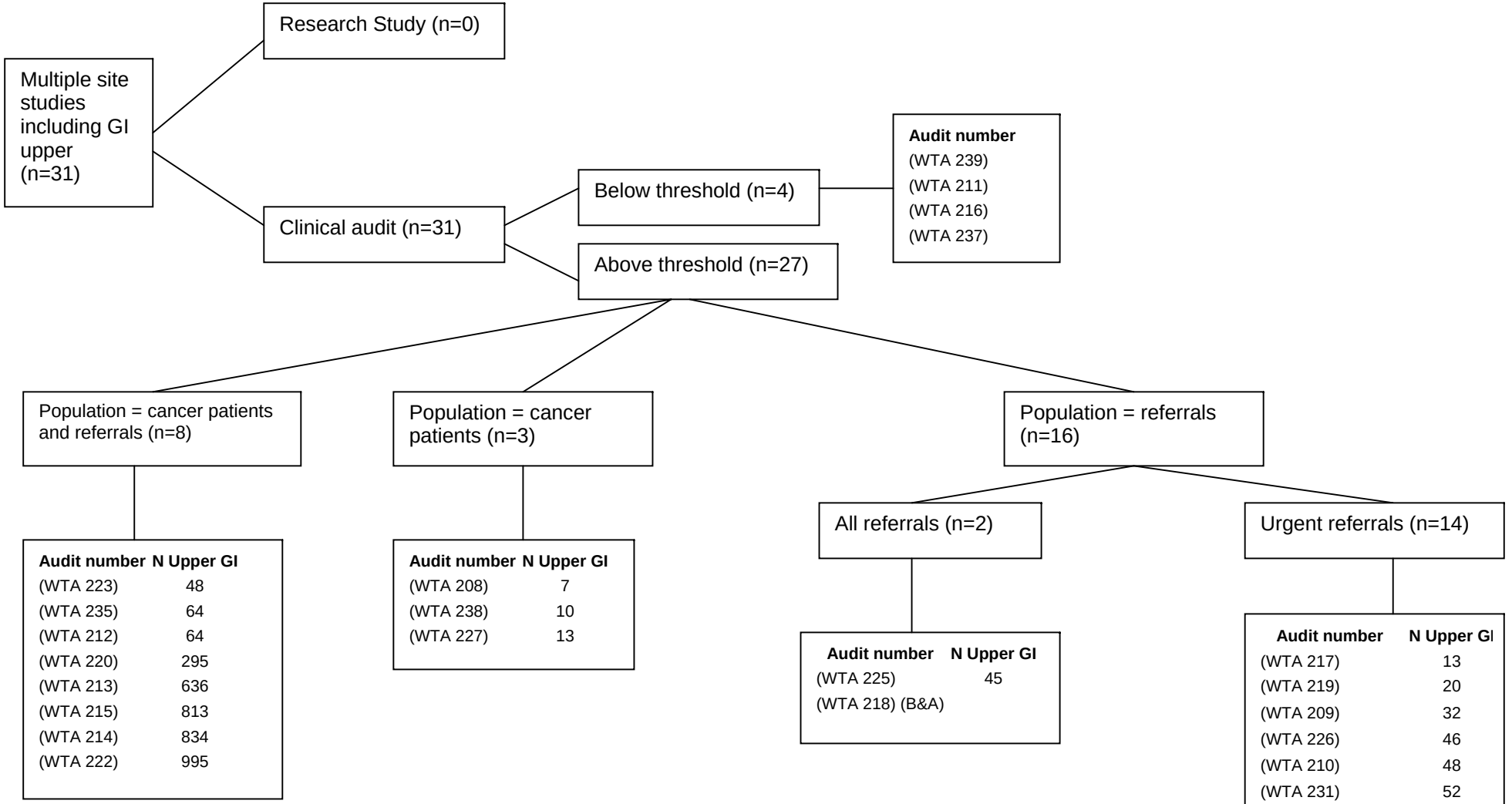
Waiting time to first appointment

Nine of the single site audits reported data on meeting the two-week wait criterion (WTA 87, 89, 90, 93, 95, 103-105, 107). One of these audits (WTA 104) just looked at cancer patients so the results are reported separately. Eight of the multiple site audits reported upper GI site-specific data on meeting the two-week wait criterion (WTA 209, 210, 213-215, 219, 234, 236).

Six of the single site audits examined a referral population only (five looked at only two-week wait referrals (WTA 87, 89, 90, 93, 95) and one looked at all referrals (WTA 107)), and two looked at both referred patients and cancer patients (WTA 103, 105). Five audits reported the number of two-week wait referred patients seen within 14 days of referral

Multiple site upper GI cancer studies

Key: B&A = before and after study



(WTA 87, 89, 93, 95, 103), the number of two-week wait patients that were analysed in these audits ranged from 23 (WTA 87) to 157 (WTA 103) and the percentage seen within two weeks ranged from 75% (WTA 95) to 100% (WTA 87, 93). One of these audits also reported that the mean time from referral to endoscopy was 13 days and that all malignancies identified were in patients who had been seen within two weeks (WTA 95). One audit reported the waiting times for patients who were referred under the two-week wait system and were subsequently diagnosed with cancer (n=26), the mean wait for endoscopy was 7.4 days (range 2 to 12 days), the audit also reported that for patients referred non-urgently but whose symptoms fell within the urgent referral criteria (n=773), the mean wait for endoscopy was 42 days (range 7 to 97 days) (WTA 107). One audit reported that the median time to appointment for two-week wait referred patients (n=307) was 12 days, whilst for non-two-week wait referred patients diagnosed with cancer (n=76) the median wait was 25 days (WTA 105). The final audit examining a referral population reported the median wait to see four individual surgeons; 8 days (range 3 to 21), 4 days (range 1 to 13), 10 days (range 6 to 23) and 11 days (range 9 to 26) (WTA 90).

Five of the multiple site audits examined two-week wait referrals (WTA 209, 210, 219, 234, 236). The number of two-week wait referred patients that were analysed in these five audits ranged from 20 (WTA 219) to 252 (WTA 234). The percentage seen within two weeks ranged from 20% (WTA 209) to 100% (WTA 234).

Three of the multiple site audits reported the proportion of two-week wait referred patients and non-two-week referred patients who were subsequently diagnosed with cancer, who were seen within two weeks of referral (WTA 213-215). The number of two-week wait referred cancer patients analysed ranged from 1 (WTA 213) to 10 (WTA 214) and the proportion seen within two weeks ranged from 0% (WTA 213) to 100% (WTA 214, 215). The number of non-two-week wait referred cancer patients analysed ranged from 36 (WTA 215) to 47 (WTA 213) and the proportion seen within two weeks ranged from 22% (WTA 214) to 28% (WTA 213, 215).

The single site audit that only looked at patients diagnosed with cancer reported the median time from referral to first appointment for patients referred urgently and routinely before and after the introduction of the two-week wait guideline (WTA 104). The median wait for urgent referrals was 15 days before the introduction of the guideline (n=41) compared with 7 days after its introduction (n=41), for routine referrals the median wait was 80 days pre-guideline (n=19) and 44 days post-guideline (n=11), for all patients the median wait was 26 days pre-guideline (n=60) and 8 days post-guideline (n=52), these differences were statistically significant.

GP conformity to guidelines

GP conformity to the referral guidelines was evaluated by three single site audits (WTA 89, 100, 106), with patient numbers ranging from 47 (WTA 89) to 547 (WTA 106). The percentage of two-week wait referrals that were considered to conform to the guidelines ranged from 79% (WTA 89) to 96% (WTA 106).

GP conformity to the referral guidelines was evaluated by 11 multiple site audits (WTA 207, 209, 210, 217, 222, 223, 226, 229, 230, 233, 234), with the number of referred patients ranging from 4 (WTA 223) to 995 (WTA 222). The percentage of two-week wait referrals that were considered to conform to the guidelines ranged from 76% (WTA 210) to 100% (WTA 223); when excluding the audit with only four patients, this ranged from 76% to 97% (WTA 230). One audit also reported the appropriateness of non-two-week wait referrals, 91% (21/23) were appropriate (WTA 223).

In addition, one multiple site audit reported that one upper GI cancer patient had been referred as routine and that this patient had met the guidelines for urgent referral (WTA 208).

Cancer detection

Data on cancer detection rates were reported by ten single site audits that examined a referral population (WTA 87, 89, 90, 93, 95, 100, 103, 105-107). This included nine audits

that examined two-week wait referrals (WTA 87, 89, 90, 93, 95, 100, 103, 105, 106) and one that evaluated all referrals (WTA 107). One of these audits (WTA 103) also examined patients diagnosed with cancer, the results for these patients are presented separately. Of the nine single site audits that examined two-week wait referrals, the number of participants included in the analyses ranged from 20 (WTA 87) to 547 (WTA 106), and the cancer detection rates ranged from 3% (3/105 (WTA 100)) to 30% (6/20 (WTA 87)). One of the audits specified the different types of cancer diagnosed in the 77 patients who were diagnosed with a cancer; there were 30 diagnoses of oesophageal cancer, 11 gastric cancers, 6 pancreatic cancers, 6 colorectal cancers, 2 gallbladder cancers, 4 cholangiocas, 4 lung cancers, 4 non Hodgkins lymphomas, 1 hepatocellular cancer, 1 'GOJ' cancer, 1 renal cancer, 1 laryngeal cancer, 1 abdominal cancer and 5 cancers of unknown primary (WTA 106).

The single site audit that evaluated all referrals reported that 8% of patients coded as urgent by their GP had a diagnosis of cancer and 2% of patients coded non-urgent by their GP had a diagnosis of cancer (WTA 107).

Data on cancer detection rates were reported by 13 multiple site audits that examined referral populations and reported data for two-week wait referrals (WTA 206, 209, 210, 212, 219, 220, 222, 223, 226, 231-234). The number of participants referred under the two-week wait rule that were included in the analyses ranged from 4 (WTA 223) to 995 (WTA 222) and the cancer detection rates ranged from 0% (0/4 (WTA 223), 0/46 (WTA 226)) to 30% (6/20 (WTA 219)).

Three single site audits reported data on type of referral for patients diagnosed with cancer (WTA 101, 105, 243). One single site audit reported that 11% (6/57) of upper GI cancers were identified through the two-week wait route of referral (WTA 103). One audit reported that 28% (29/105) of upper GI cancer patients were referred via the two-week wait route and 72% (76/105) via conventional routes (referral to a clinic, A&E department or direct admission to the ward) (WTA 105). The other audit reported that 39% (47/121) of upper GI cancer patients were referred via the two-week wait route (WTA 101). The others were referred via the jaundice hotline (11%), referred as urgent (10%), emergency admissions (24%), referred as soon (2%), referred as routine (11%), had follow up appointments for other conditions (2%), were private referrals (1%) or transferred from another hospital (1%).

Six multiple site audits that examined patient populations which included patients diagnosed with upper GI cancers reported the route of referral for those patients (WTA 208, 212, 220, 222, 223, 238). The number of patients with cancer included in the analyses ranged from 3 (WTA 212) to 728 (WTA 222) and the proportion that had been referred via the two-week wait referral route ranged from 0% (0/3 (WTA 212)) to 40% (4/10 (WTA 238)). Excluding the three audits with patient samples of ten or less (WTA 208, 212, 238) the proportion of cancer patients who had been referred via the two-week wait referral route ranged from 5% (1/21 (WTA 223)) to 19% (15/78 (WTA 220)).

Appropriateness of the type of referral

One single site audit reported that of 14 patients referred via the two-week wait route, who were not diagnosed with cancer, 3 patients were appropriately referred (according to hospital assessment) and required further investigation whilst 11 patients had symptoms according to the guidelines but were considered inappropriate according to hospital assessment (WTA 87).

Five multiple site audits reported the proportion of referrals considered to be appropriate by the clinician. The number of patients included in the analyses ranged from 46 (WTA 226) to 252 (WTA 234) and the proportion considered to be appropriate ranged from 67% (WTA 232) to 96% (WTA 234).

One single site audit reported that 41% (33/81) of patients who were referred via the two-week wait referral system, did not display symptoms in clinic consistent with those on the GP referral form (WTA 96).

One multiple site audit reported that 98% (45/46) of patients who were referred via the two-week wait referral system, had symptoms in clinic consistent with those on the GP referral form (WTA 226).

One single site audit reported that 81% of patients referred urgently by their GP were coded as urgent by the hospital and 19% were coded non-urgent and that 74% of patients not referred urgently by their GP were coded as urgent by the hospital and 26% were coded non-urgent. The audit went on to report that 5% of patients coded as urgent by the hospital had a diagnosis of cancer and 1% of patients coded as non-urgent by the hospital had a diagnosis of cancer, whilst 8% of patients coded as urgent by their GP had a diagnosis of cancer and 2% of patients coded non-urgent by their GP had a diagnosis of cancer (as reported earlier, under 'cancer detection') (WTA 107).

Ability of guidelines to identify correct referrals
One multiple site audit reported that 5% (1/22) of two-week wait referrals that did not meet the referral criteria were deemed to be clinically appropriate and that 2% (3/128) of referrals meeting the criteria were clinically inappropriate according to the hospital assessment (WTA 229). Another multiple site audit reported that 36% (4/11) of two-week wait referrals that did not meet the referral criteria were deemed to be clinically appropriate and that one two-week wait referred patient who did not meet the referral criteria was subsequently diagnosed with cancer (WTA 210).

Process of referral
The time between the decision to refer and receipt of the referral by the hospital was reported by three multiple site audits (WTA 208, 210, 219). One audit reported that all two-week wait referrals were received in 0-1 days (WTA 208), the others reported that 34/39 (87% (WTA 210)) and 92% (WTA 219) two-week wait referrals were received within 24 hours. The range in time for the five referrals not received within 24 hours was reported in one of the audits, which was 3 to 6 days (WTA 210).

The mode of delivery of the referral was reported in one single site audit (WTA 100); 97 were sent by 'open access', 3 by faxed letter, 1 by posted letter, 1 was a GP admission brought in by ambulance and for 3 patients the mode of referral was not reported (WTA 100).

One single site audit reported that 76/79 referrals used the agreed proforma (WTA 95).

One multiple site audit reported that 94% two-week wait referrals were on the proforma and that 100% were faxed (WTA 219).

Summary
The proportion of patients referred under the two-week wait referral system and seen within two weeks ranged from 20% to 100% (10 audits). The proportion of two-week wait referrals that were found to be in accordance with the symptoms listed in the guidelines ranged from 76% to 97% (13 audits, having excluded one audit with only 4 patients).

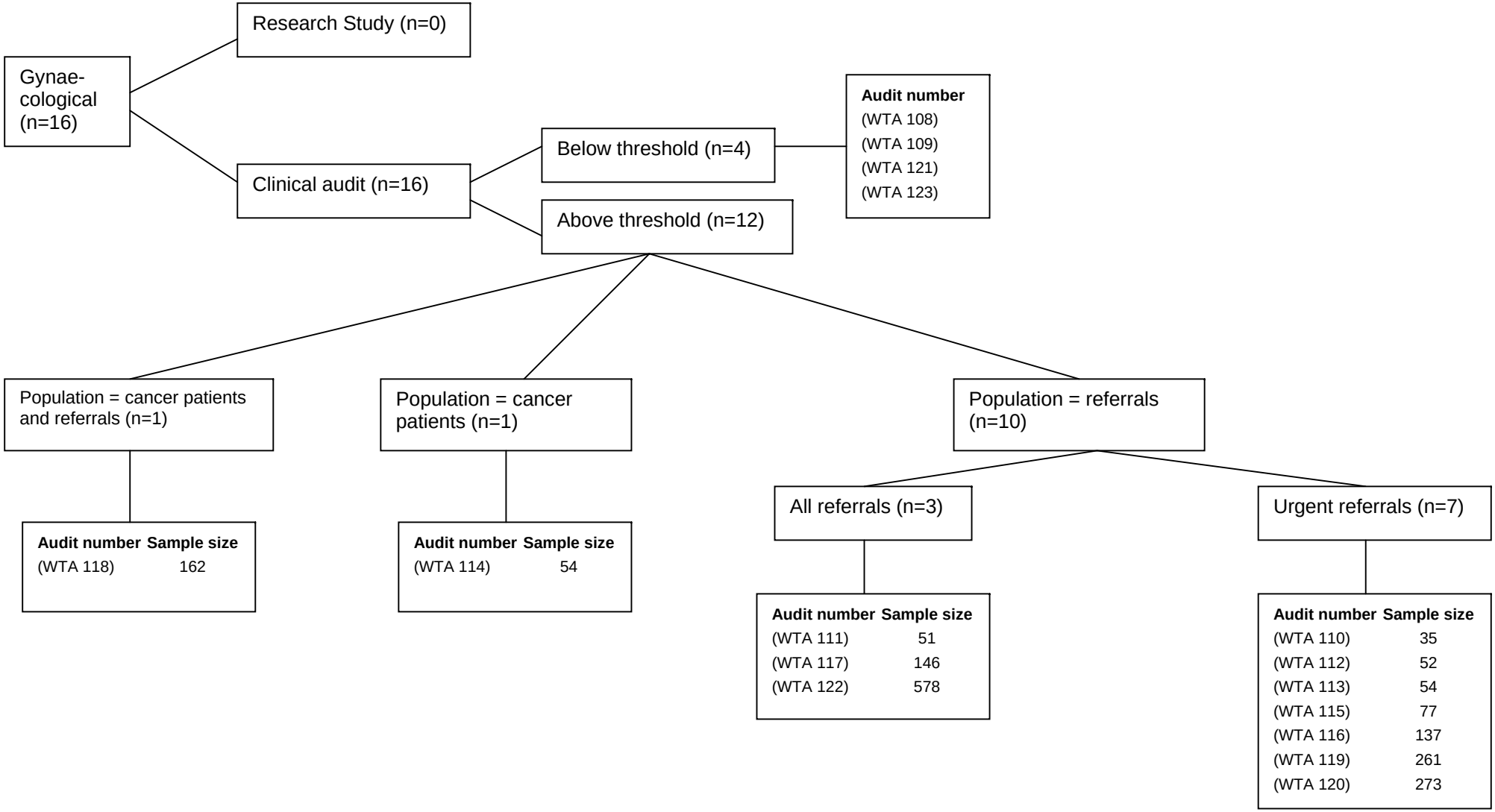
The proportion of patients who were referred under the two-week wait referral system who were subsequently diagnosed with cancer ranged from 0% to 30% (23 audits). The proportion of patients with cancer who had been referred via the two-week wait referral system ranged from 5% to 39% (six audits, having excluded three audits with 10 patients or less).

The proportion of two-week wait referrals deemed to be appropriate by the hospital clinician ranged from 67% to 96% (five audits). The proportion of two-week wait referrals that did not meet the referral criteria but were deemed to be clinically appropriate ranged from 5% to 36% (two audits). The proportion of referrals meeting the criteria that were deemed clinically inappropriate was 2% (1 audit). The cancer detection rate for two-week wait referrals not meeting the guidelines was 9% (1 audit).

The proportion of two-week wait referrals that did not have symptoms in clinic consistent with those on the GP referral form ranged from 2% to 41% (two audits).

The proportion of referrals received by the hospital within one day of the GP's decision to refer ranged from 87% to 100% (three audits).

Single site gynaecological cancer studies



GYNAECOLOGICAL CANCERS

Overview

Forty-five clinical audits evaluated the referral guidelines for gynaecological cancers (WTA 108-123, 206-217, 220-223, 225-234, 238-240).

Thirty-one audits were conducted in general hospitals (WTA 110, 111, 113, 114, 116-120, 122, 123, 208, 210-216, 220, 223, 226, 227, 229-234, 238, 239), seven in teaching hospitals (WTA 108, 109, 112, 121, 209, 217, 225), three by cancer networks (WTA 222, 228, 240), three by PCTs (WTA 206, 207, 221) and one did not specify the location (WTA 115).

Forty-one were categorised (in terms of the methodology used) as a clinical audit (WTA 108-117, 119-123, 206, 208-217, 221-223, 225-234, 239, 240) and four as a non-criterion based audit (WTA 118, 207, 220, 238).

Of 31 audits that examined a referral population only, four audits evaluated all referrals to the department or trust (WTA 111, 117, 122, 225) and 26 included only two-week wait referrals (WTA 108-110, 112, 113, 115, 116, 119-121, 206, 207, 209-211, 216, 217, 226, 229-234, 239, 240). For one audit it was unclear whether the referral population only included urgent referrals or all referrals (WTA 228). The patient population of interest included those diagnosed with cancer in six audits (WTA 114, 123, 208, 221, 227, 238) and eight audits looked at both patients diagnosed with cancer and those being referred (WTA 118, 212-215, 220, 222, 223).

The data were collected retrospectively in 25 audits (WTA 111, 113-116, 118-120, 122, 123, 206, 208-212, 216, 220, 226-228, 230, 238-240) and prospectively in nine audits (WTA 110, 112, 117, 221, 225, 231-234) (1 of which was partially prospective before and after (WTA 221)). The direction of data capture was not stated or unclear in 11 audits (WTA 108, 109, 121, 207, 213-215, 217, 222, 223, 229).

Sixteen audits looked exclusively at gynaecological cancers (single site) (WTA 108-123) while 29 audits examined multiple cancer sites (WTA 206-217, 220-223, 225-234, 238-240). The sample size ranged from 15 (WTA 108, 109) to 578 (WTA 122) for single site audits and from 8 (WTA 208) to 1193 (WTA 214) for multiple site audits (when only considering gynaecological cancers). The gynaecological cancer patient sample sizes were not given in two multiple site audits (WTA 211, 221).

Thirty-eight audits reported some data on how eligible patients were identified and/or gave the data source (WTA 110-120, 122, 206-210, 212-215, 217, 220-223, 225-234, 238, 240). Two of these audits did not report separate data for gynaecological cancer patients (WTA 221, 225). The results of the remaining 36 audits are summarised below. Seven audits were not as well reported (WTA 108, 109, 121, 123, 211, 216, 239) and as such their results are considered to be less reliable. The results of these audits are therefore not discussed further.

Outcome measures

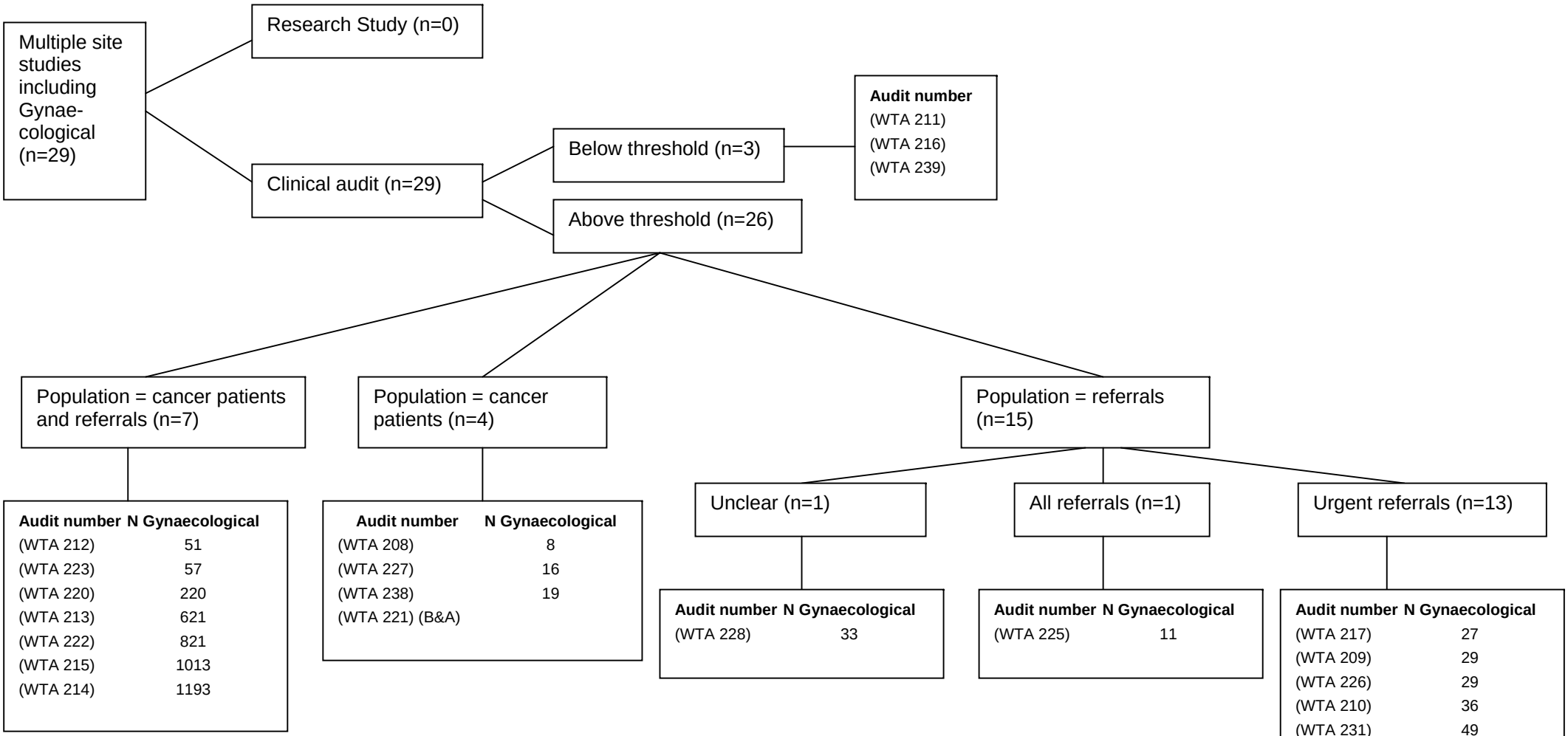
Waiting time to first appointment

Nine of the single site audits reported data on meeting the two-week wait criterion (WTA 110-117, 122). One of these audits (WTA 114) just looked at cancer patients so the results are reported separately. Seven of the multiple site audits reported data on meeting the two-week wait criterion (WTA 209, 210, 213-215, 234, 240).

Five of the single site audits looked at two-week wait referrals only (WTA 110, 112, 113, 115, 116) and three looked at all referrals (WTA 111, 117, 122). For seven of the audits (WTA 110-113, 115, 117, 122) the number of two-week wait referred patients that were analysed ranged from 10 (WTA 111) to 251 (WTA 122) and the percentage seen within two

Muliple site gynaecological cancer studies

Key: B&A = before and after study



weeks ranged from 41% (WTA 112) to 100% (WTA 115). One single site audit reported the median wait between the GP two-week wait referral and the first appointment for each surgeon separately (7 and 11.5 days, range 2 to 23 days) (WTA 116). One single site audit reported that of 93 patients who were not referred by the GP with a suspicion of cancer, but who the consultant classified as urgent, 11% were given an appointment within 14 days (WTA 117).

Four of the multiple site audits examined two-week wait referrals only (WTA 209, 210, 234, 240). The number of two-week wait referred patients analysed ranged from 28 (WTA 209) to 238 (WTA 234). The percentage seen within two weeks ranged from 63% (WTA 209) to 100% (WTA 234).

One single site audit that only looked at patients diagnosed with cancer found that 63% (12/19) patients referred under the two-week wait rule were seen within two weeks (WTA 114).

Three multiple site audits examined patients diagnosed with cancer and those referred as two-week wait referrals (WTA 213-215). All three audits were conducted by the same trust. The proportion of patients diagnosed with gynaecological cancer that were referred as two-week wait referrals and seen within two weeks ranged from 75% (WTA 214) to 100% (WTA 213, 215), but the number of patients that were included were small (range 2 (WTA 213) to 4 (WTA 214)). The percentage of cancer patients not referred as two-week wait referrals that were seen within two weeks ranged from 7% (3/43 (WTA 214)) to 44% (15/34 (WTA 213)).

One multiple site audit that only looked at patients diagnosed with cancer reported that all two-week wait referred patients were offered an appointment within 14 days of referral (WTA 227).

GP conformity to guidelines

The conformity of the GP two-week wait referral to the symptoms listed in the guidelines was evaluated by five single site audits (WTA 110, 111, 115, 119, 120), with two-week wait referred patient numbers ranging from 10 (WTA 111) to 271 (WTA 120). The percentage of referrals that met the guidelines ranged from 42% (WTA 110) to 90% (WTA 111).

Fourteen multiple site audits evaluated the conformity of the GP two-week wait referral to the symptoms listed in the guidelines (WTA 207, 209, 210, 212, 217, 222, 223, 226, 228-230, 233, 234, 240). With patient numbers ranging from 5 (WTA 223) to 821 (WTA 222), the percentage of referrals that met the guidelines ranged from 59% (16/27 (WTA 217)) to 100% (118/118 (WTA 230)).

Two multiple site audits reported the appropriateness of non-two-week wait referrals (WTA 208, 223). One reported that 100% (31/31) were appropriate (WTA 223), the other reported that 3/4 gynaecological cancer patients had been referred as routine and met the guidelines for urgent referral (WTA 208).

Cancer detection

Data on cancer detection rates were reported by seven single site audits that examined a referral population (WTA 111, 115, 116, 118-120, 122). This included five audits that examined two-week wait referrals (WTA 115, 116, 118-120) and two that evaluated all referrals (WTA 111, 122). Of the six single site audits that reported data on two-week wait referrals separately, the number of participants included in the analyses ranged from 77 (WTA 115) to 273 (WTA 120), and the cancer detection rates ranged from 10% (27/261 (WTA 119), 14/137 (WTA 116)) to 25% (WTA 115). The single site audit that evaluated all referrals reported that 4% (2/51) of referrals were diagnosed with cancer (WTA 111).

Data on cancer detection rates were reported by 12 multiple site audits that examined referral populations and reported data for two-week wait referrals (WTA 206, 209, 210, 212, 220, 222, 223, 226, 231-234). The number of participants referred under the two-week wait rule that were included in the analyses ranged from 5 (WTA 223) to 821 (WTA 222)

and the cancer detection rates ranged from 0-12% (0/9, 1/11 and 3/26, all one audit (WTA 212)) to 20% (1/5 (WTA 223)). Excluding the audit with only 5 patients, the cancer detection rates ranged from 0% to 14% (116/821 (WTA 222)).

Two single site audits reported data on the type of referral for patients diagnosed with cancer (WTA 114, 118). One single site audit reported that 24% (13/54) of gynaecological cancers were identified through the two-week wait route of referral (WTA 118). The other audit reported that 34% of gynaecological cancer patients were referred via the two-week wait route, 35% were referred as urgent, 16% as routine and 2% were referred as 'soon' (actual numbers not given) (WTA 114).

Six multiple site audits that examined patient populations which included patients diagnosed with gynaecological cancers reported the route of referral for those patients (WTA 208, 212, 220, 222, 223, 238). The number of patients with cancer included in the analyses ranged from 5 (WTA 212) to 527 (WTA 222) and the proportion that had been referred via the two-week wait referral route ranged from 0% (0/19 (WTA 238), 0/21 (WTA 223)) to 25% (2/8 (WTA 208)). Excluding the two audits with samples of only 5 and 8 patients (WTA 208, 212) the proportion of cancer patients who had been referred via the two-week wait referral route ranged from 0% to 22% (of 527 patients (WTA 222)). One of the audits (WTA 238) stated that 11/12 cervical referrals were using the protocol for smear abnormalities.

Appropriateness of the type of referral
One single site audit reported that the hospital consultant thought that 64% (93/146) of GP referrals referred with a suspicion of cancer actually warranted an urgent appointment (WTA 117).

One single site audit reported that of 110 two-week wait referrals, just under a quarter showed no clinical abnormality (WTA 116).
Five multiple site audits reported the proportion of two-week wait referrals considered to be appropriate by the clinician (WTA 226, 231-234). The number of patients included in the analyses ranged from 28 (WTA 226) to 238 (WTA 234) and the proportion considered to be appropriate ranged from 68% (WTA 226) to 94% (WTA 232).

One multiple site audit reported that 23/28 (82%) of patients who were referred via the two-week wait referral system, had symptoms in clinic consistent with those on the GP referral form (WTA 226).

Ability of guidelines to identify correct referrals
One single site audit reported that 23 cancers were diagnosed in 155 patients (15%) whose two-week wait referrals met the referral criteria, compared with four cancers in 106 (4%) two-week wait referrals that did not meet the referral criteria (WTA 119). One single site audit reported that three of 111 (3%) two-week wait referrals that did not meet criteria were diagnosed with cancer (WTA 120).

One multiple site audit reported that 13/116 (11%) two-week wait referrals meeting the criteria were clinically inappropriate according to the hospital assessment and that 0/8 two-week wait referrals that did not meet the criteria were clinically appropriate (WTA 229). Another multiple site audit reported that 1/4 two-week wait referrals that did not meet the referral criteria were deemed to be clinically appropriate (WTA 210), and that this patient was not subsequently diagnosed with cancer.

Process of referral
The time between the decision to refer and receipt of the referral by the hospital was measured by three single site audits (WTA 112, 113, 115). Sample size, where stated, ranged from 43 (WTA 113) to 52 (WTA 112) patients. The proportion of two-week wait referrals received within 24 hours ranged from 35% (WTA 112) to 100% (WTA 115).

The time between the decision to refer and receipt of the referral by the hospital was reported by one multiple site audit (WTA 210) 35/36 (97%) of two-week wait referrals were received within 24 hours, the other in five days (WTA 210).

One single site audit compared fax referrals seen within two weeks in two hospitals (75%, 50%) with letter referrals (43%, 36%) (WTA 112).

Summary

The proportion of gynaecological patients referred under the two-week wait system and seen within two weeks ranged from 41% to 100% (11 audits). The proportion of two-week wait referrals that were found to be in accordance with the symptoms listed in the guidelines ranged from 42% to 100% (18 audits, having excluded one audit with only 5 patients).

When looking at a population of patients diagnosed with cancer, the proportion of two-week wait referrals seen within two weeks was 63% (one audit, having excluded three audits with only 2 to 4 patients). The percentage of cancer patients not referred as two-week wait referrals that were seen within two weeks ranged from 7% to 44% (three audits).

The proportion of patients who were referred under the two-week wait referral system who were subsequently diagnosed with cancer ranged from 0% to 25% (17 audits, having excluded one audit with only 5 patients). The proportion of patients with cancer who had been referred via the two-week wait referral system ranged from 0% to 34% (six audits, having excluded two audits that included 5 and 8 patients).

The proportion of two-week wait referrals that were deemed to be clinically appropriate ranged from 64% to 94% (six audits).

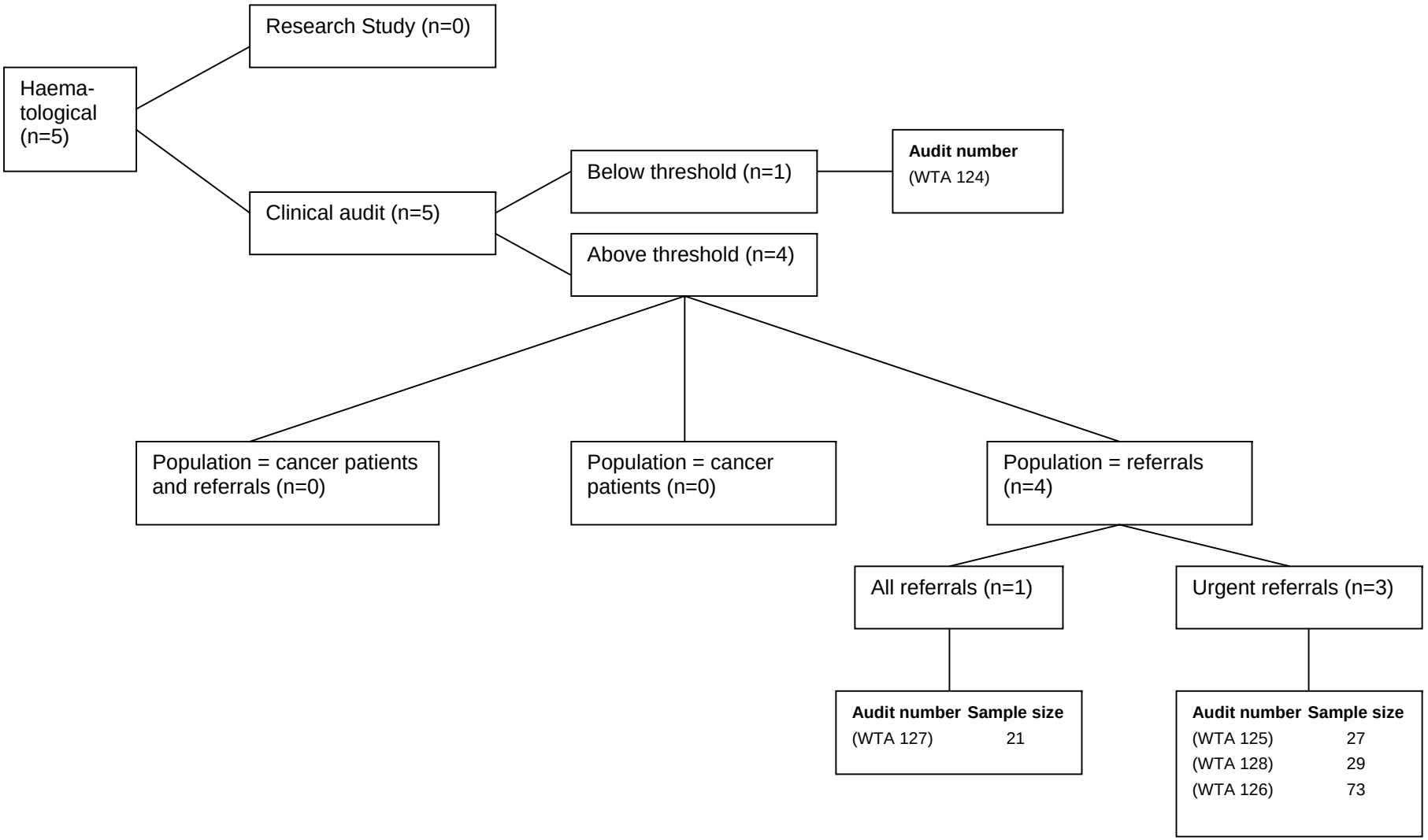
One audit reported that 82% of patients who were referred via the two-week wait referral system, had symptoms in clinic consistent with those on the GP referral form.

One audit reported that 11% of two-week wait referrals meeting the criteria were clinically inappropriate.

The proportion of cancers diagnosed in patients referred via the two-week wait route of referral, but whose referrals did not meet the referral criteria, ranged from 0% to 4% (three audits). One single site audit reported that 15% of patients whose two-week wait referrals met the referral criteria were diagnosed with cancer.

The time interval between the decision to refer and receipt of the referral by the hospital was 24 hours or less for 35% to 100% of patients (four audits).

Single site haematological cancer studies



HAEMATOLOGICAL CANCERS

Overview

Twenty-six clinical audits evaluated the referral guidelines for haematological cancers (WTA 124-128, 206-209, 212-216, 218, 221, 224-227, 229-234).

Sixteen audits were conducted by a general hospital (WTA 125, 208, 212-216, 224, 226, 227, 229-234), seven by teaching hospital (WTA 124, 126-128, 209, 218, 225), and three by a PCT (WTA 206, 207, 221). With the exception of two non-criterion based audits (WTA 207, 218), all were categorised (in terms of the methodology used) as clinical audits.

Of 18 audits that examined a referral population only, three audits evaluated all referrals to the department or trust (WTA 127, 218, 225) and 15 included only two-week wait referrals (WTA 124-126, 128, 206, 207, 209, 216, 226, 229-234). The patient population of interest included those diagnosed with cancer in four audits (WTA 208, 221, 224, 227) and four audits looked at both patients diagnosed with cancer and those being referred (WTA 212-215).

The data were collected retrospectively in 14 audits (WTA 125-128, 206, 208, 209, 212, 216, 218, 224, 226, 227, 230) (including one before-and-after study (WTA 218)), and prospectively in six audits (WTA 221, 225, 231-234) (one of which was partially prospective before and after (WTA 221)). The direction of data capture was not stated in six audits (WTA 124, 207, 213-215, 229).

Five audits looked exclusively at haematological cancers (single site) (WTA 124-128) while 21 audits examined multiple cancer sites but reported some results separately for each site (WTA 206-209, 212-216, 218, 221, 224-227, 229-234). The sample size ranged from 8 (WTA 124) to 73 (WTA 126) for single site audits and from 1 (WTA 208, 224, 227) to 753 (WTA 218) for multiple site audits (when only considering haematological cancers). The haematological cancer patient sample size was not given in one multiple site audit (WTA 221).

Twenty-four audits reported some data on how eligible patients were identified and/or gave the data source (WTA 125-128, 206-209, 212-215, 218, 221, 224-227, 229-234). Three of these audits did not report separate data for haematological cancers (WTA 221, 225, 227). The results of the remaining 21 audits are summarised below. Two audits were not as well reported (WTA 124, 216) and as such their results are considered to be less reliable. The results of these audits are therefore not discussed further.

Outcome measures

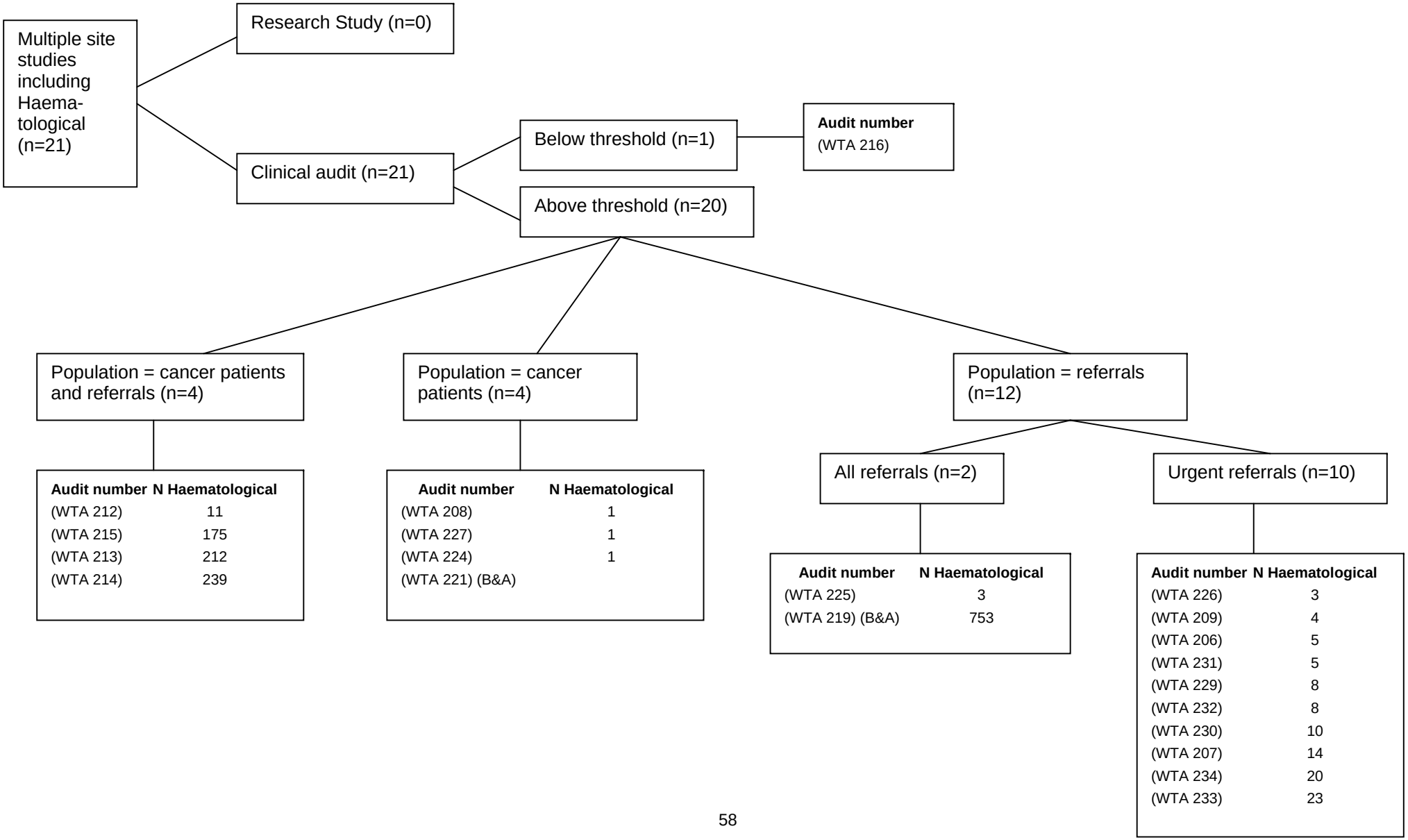
Waiting time to first appointment

Two single site audits reported data on meeting the two-week wait criteria (WTA 126, 128). The number of two-week wait referred patients that were analysed ranged from 29 (WTA 128) to 58 (WTA 126) and the percentage seen within two weeks ranged from 81% (47/58 (WTA 126)) to 93% (27/29 (WTA 128)). The mean time to first appointment was 8 days (range 1 to 35), reported in one audit (WTA 128).

One audit that looked at patients referred by the GP via letter, with symptoms suggestive of cancer (as assessed by the consultant haematologist), reported that 6/18 patients were seen within two weeks, two of whom were subsequently diagnosed with cancer (WTA 127). The mean number of days to first appointment was 24 (range 7 to 74). Audits WTA 127 and 128 were both carried out by the same trust, one looked at patients referred via the two-week wait rule (WTA 128), the other looked at patients referred by the GP via letter, with symptoms suggestive of cancer (as assessed by the consultant haematologist), but do not state that they were referred via the two-week wait rule (WTA 127).

Multiple site haematological cancer studies

Key: B&A = before and after study



Two multiple site audits reported site-specific data on meeting the two-week wait criteria (WTA 209, 234). The number of two-week wait referred patients analysed was 3 in one audit (WTA 209) and 20 in the other (WTA 234). The percentage seen within two weeks to 5 (WTA 214) and the proportion seen within two weeks was 100% in each audit. The number of non-two-week wait referred cancer patients analysed ranged from 46 (WTA 215) to 55 (WTA 213) and the proportion seen within two weeks ranged from 42% (WTA 214) to 47% (WTA 213).

GP conformity to guidelines

The conformity of the GP referral to the symptoms listed in the guidelines was evaluated by three single site audits (WTA 125, 126, 128), with patient numbers analysed ranging from 27 (WTA 125) to 58 (WTA 126). The percentage of referrals that met the guidelines ranged from 74% (20/27 (WTA 125), 43/58 (WTA 126)) to 79% (23/29 (WTA 128)).

Seven multiple site audits evaluated the conformity of the GP referral to the symptoms listed in the guidelines (WTA 207, 209, 226, 229, 230, 233, 234), with patient numbers ranging from 3 (WTA 226) to 23 (WTA 233). The percentage of referrals that met the guidelines ranged from 0% (0/4 (WTA 209)) to 100% (WTA 207, 226). Excluding the audits with only 3 or 4 patients (WTA 209, 226) this ranged from 75% (6/8 (WTA 229)) to 100%.

Cancer detection

Data on cancer detection rates were reported by three single site audits that examined a referral population, including two audits that examined only two-week wait referrals (WTA 126, 128) and one that evaluated non-two week wait referrals (WTA 127). The number of participants referred under the two-week wait rule included in the analyses ranged from 29 (WTA 128) to 58 (WTA 126) and the cancer detection rates ranged from 28% (8/29; 7 were still under review at the time of the audit, but not suspected of having cancer (WTA 128)) to 45% (26/58 (WTA 126)). Four of 21 non-two-week wait referred patients were diagnosed with cancer (WTA 127), five were still under review at the time of the audit, but not suspected of having cancer. In cases where the audits reported specific data for haematological cancers, these are the figures stated. However, where these were not stated, the above cancer detection rates may include cancers of other sites.

Data on cancer detection rates were reported in eight multiple site audits that examined referral populations and reported data for two-week wait referrals (WTA 206, 209, 212, 226, 231-234). The number of participants referred under the two-week wait rule that were included in the analyses ranged from 3 (WTA 226) to 23 (WTA 233) and the cancer detection rates ranged from 0% (WTA 209, 226) to 75% (3/4 (WTA 212)). Excluding the four audits with only 3, 4 or 5 patients (WTA 206, 209, 212, 226), the proportion diagnosed with cancer ranged from 20% (WTA 231) to 39% (WTA 233). One of these audits had two separate samples of patients referred via the two-week wait system for suspected haematological cancer (WTA 212). During the timeframe of their second sample (not included above) there were three two-week wait referrals, with four diagnoses of cancer, therefore, at least one cancer diagnosis must have been referred via the two-week wait system suspected of having a different type of cancer.

Two multiple site audits, each of which included one patient diagnosed with cancer (WTA 208, 224) both reported that the patient was not referred via the two-week wait route. Another multiple site audit, which examined a mixed population, that included 4 haematological cancer patients reported that one of them had been referred via the two-week wait route (WTA 212).

Appropriateness of the type of referral

Five multiple site audits reported data on whether the hospital clinician thought that GP referrals made under the two-week wait rule actually warranted an urgent two-week wait appointment (WTA 226, 231-234). The number of patients analysed ranged from 3 (WTA 226) to 23 (WTA 233) and the proportion deemed appropriate ranged from 75% (6/8 (WTA 232), 15/20 (WTA 234)) to 100% (3/3 (WTA 226)). Excluding the audit with only three patients, the proportion deemed clinically appropriate ranged from 75% to 87% (WTA 233).

One multiple site audit reported that 3/3 patients who were referred via the two-week wait referral system had symptoms in clinic consistent with those on the GP referral form (WTA 226).

Ability of guidelines to identify correct referrals

One single site audit reported that 7/24 patients referred with lymphadenopathy, 2/4 patients referred with hepatosplenomegaly and 0/7 patients referred with bone pain and anaemia and high ESR/plasma viscosity were deemed inappropriate based on the patient's presenting signs and symptoms (WTA 126).

One multiple site audit reported that 6/6 two-week wait referrals that were found to be in line with the guidelines were considered clinically appropriate by the hospital clinician (WTA 229).

One single site audit reported that 25% of appropriate two-week wait referrals (5/20 (WTA 125)) were diagnosed with cancer.

Process of referral

Not reported.

Summary

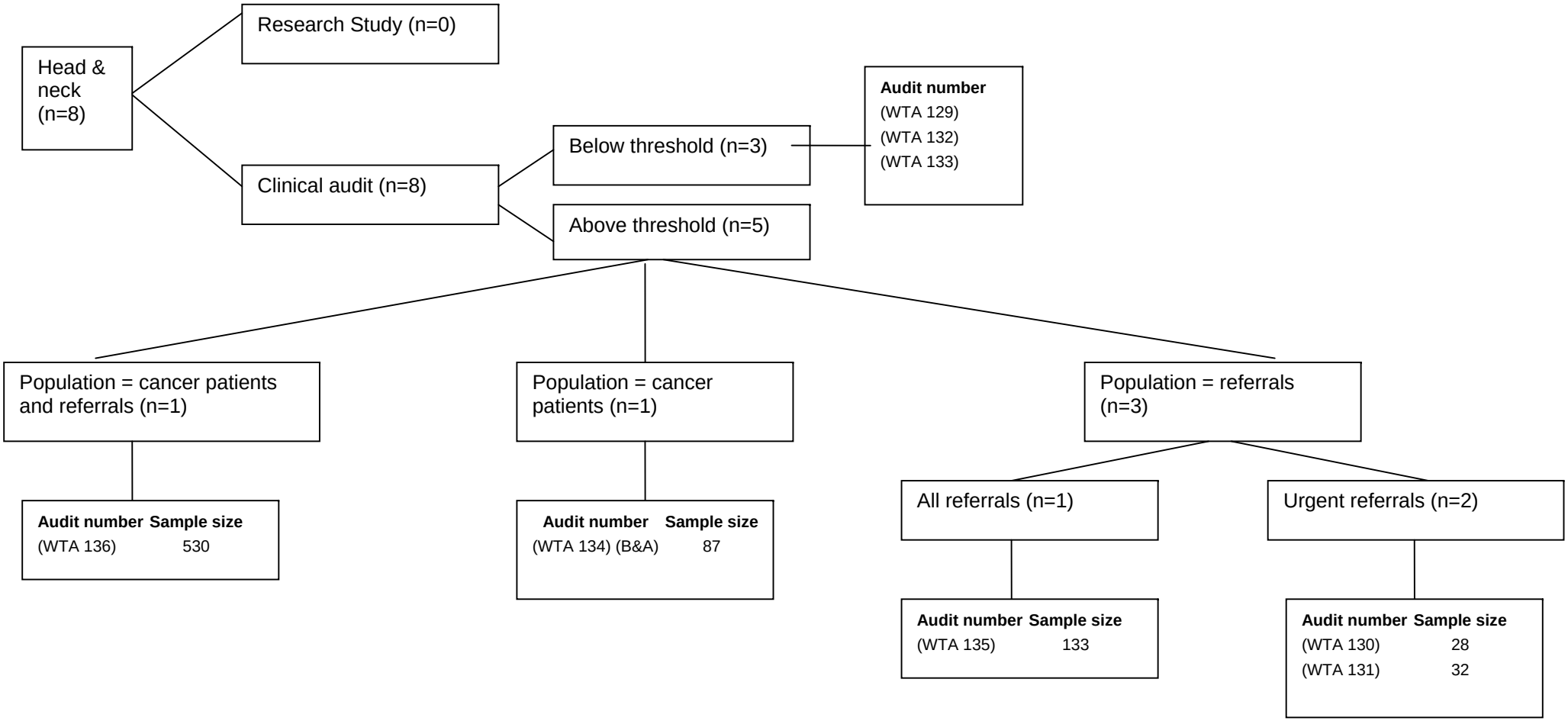
The proportion of haematological cancer patients referred under the two-week wait referral system and seen within two weeks ranged from 81% to 100% (three audits, having excluded one audit with only 3 patients). The proportion of two-week wait referrals that were found to be in accordance with the symptoms listed in the guidelines ranged from 74% to 100% (eight audits, having excluded two audits with only 3 or 4 patients). The proportion of two-week wait referrals deemed to be appropriate by the hospital clinician ranged from 75% to 87% (four audits, having excluded one audit with only 3 patients). The proportion of referrals meeting the criteria that were deemed clinically inappropriate by the hospital clinician was 26% (one audit, have excluded one audit with only 6 patients). One audit reported that all patients who were referred via the two-week wait referral system had symptoms in clinic consistent with those on the GP referral form.

The proportion of cancer patients not referred as two-week wait referrals and seen within two weeks ranged from 42% to 47% (three audits).

The proportion of patients who were referred under the two-week wait referral system who were subsequently diagnosed with cancer ranged from 28% to 45% (six audits, having excluded four audits with only 3, 4 or 5 patients). The cancer detection rate for two-week wait referrals meeting the guidelines was 25% (1 audit). The cancer detection rate for non-two-week wait referrals was 19% (1 audit).

Single site head and neck cancer studies

Key: B&A = before and after study



HEAD AND NECK CANCERS

Overview

Thirty clinical audits evaluated the referral guidelines for cancers of the head and neck (WTA 129-136, 206-217, 223, 225, 226, 229-234, 239).

Twenty-one audits were conducted by a general hospital (WTA 133-136, 208, 210-216, 223, 226, 229-234, 239), seven by a teaching hospital (WTA 129-132, 209, 217, 225) and two by a PCT (WTA 206, 207). Twenty nine were categorised (in terms of the methodology used) as a clinical audit (WTA 129-136, 206, 208-217, 223, 225, 226, 229-234, 239) and one as a non-criterion based audit (WTA 207).

Twenty-one audits evaluated patients that were referred to the department or trust, 19 of which examined two-week wait referrals (WTA 129-132, 206, 207, 209-211, 216, 217, 226, 229-234, 239) and two included all referrals (WTA 135, 225). The patient population of interest included those diagnosed with cancer in two audits (WTA 134, 208) and seven audits looked at both patients diagnosed with cancer and those being referred (WTA 133, 136, 212-215, 223). The data were collected retrospectively in sixteen audits (WTA 130, 131, 133-136, 206, 208-212, 216, 226, 230, 239) (one of which had a before and after design (WTA 134)) and prospectively in five audits (WTA 225, 231-234). The direction of the data capture was not stated or unclear in nine audits (WTA 129, 132, 207, 213-215, 217, 223, 229).

Eight audits looked exclusively at head and neck cancers (single site) (WTA 129-136), whilst 22 audits examined multiple cancer sites (WTA 206-217, 223, 225, 226, 229-234, 239).

Twenty-four audits reported some data on how eligible patients were identified and/or gave the data source (WTA 130, 131, 134-136, 206-210, 212-215, 217, 223, 225, 226, 229-234). The sample size ranged from 28 (WTA 130) to 530 (WTA 211) for five single site audits (WTA 130, 131, 134-136) and from five (WTA 208) to 1186 (WTA 214) for 19 multiple site audits (WTA 206-210, 212-215, 217, 223, 225, 226, 229-234) (when only considering head and neck cancers). One of the audits did not report separate data for head and neck cancers (WTA 225). The results of the remaining 23 audits are summarised below. The other six audits were not as well reported (WTA 129, 132, 133, 211, 216, 239) and as such their results are considered to be less reliable. The results of these audits are therefore not discussed further.

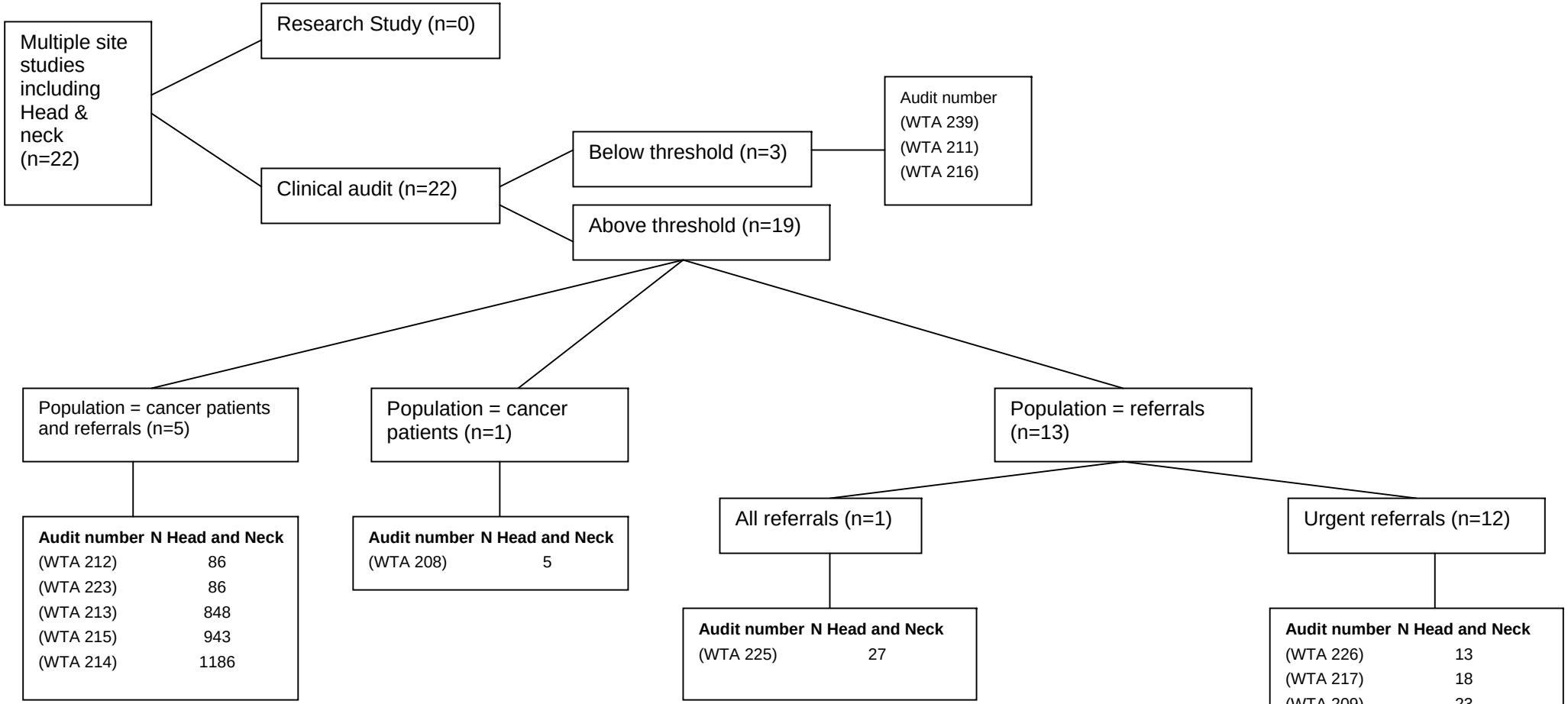
Outcome measures

Waiting time to first appointment

All the single site audits reported data on meeting the two-week wait criterion (WTA 130, 131, 134-136) three of which examined a referral population (2 looked at only two-week wait referrals (WTA 130, 131) and 1 looked at all referrals (WTA 135)). One audit only examined patients diagnosed with cancer (WTA 134) and one audit (WTA 136) evaluated both patients referred and those diagnosed with cancer. This last audit (WTA 136) only reported waiting times for two-week wait referrals that had a subsequent cancer diagnosis (n=31/285).

For the three single site audits that examined a referral population the number of two-week wait referrals that were analysed ranged from 21 (WTA 130) to 50 (WTA 135) and the percentage seen within 2 weeks ranged from 96% (WTA 135) to 100% (WTA 130). One audit reported that the time to 1st appointment for the two patients referred under two-week wait rule not seen within two weeks was 15 and 34 days (WTA 135). The audit also reported that the median time for 48 patients referred by the GP as urgent (not two-week wait referrals) was 29 (range 0 to 120) days.

Multiple site head and neck cancer studies



Audit number	N Head and Neck
(WTA 212)	86
(WTA 223)	86
(WTA 213)	848
(WTA 215)	943
(WTA 214)	1186

Audit number	N Head and Neck
(WTA 208)	5

Audit number	N Head and Neck
(WTA 225)	27

Audit number	N Head and Neck
(WTA 226)	13
(WTA 217)	18
(WTA 209)	23
(WTA 210)	30
(WTA 232)	37
(WTA 231)	42
(WTA 233)	56
(WTA 206)	80
(WTA 230)	92
(WTA 234)	99
(WTA 229)	160
(WTA 207)	257

For the two single site audits that examined patients diagnosed with cancer, of those that were referred as two-week wait referrals the percentage seen within two weeks ranged from 71% (WTA 134) to 100% (WTA 136), but the number of patients included in the analyses were small and ranged from 7 (WTA 134) to 31 (WTA 136). One of these audits also reported that out of the 46 patients diagnosed with cancer referred via any route after the introduction of the two-week wait rule, 18 (39%) were seen within two weeks and that the mean wait was 25 days (range 0 to 170 days) compared with 24/41 (59%) cancer patients referred before the introduction of the two-week wait rule, mean wait 19 days (range 0 to 126 days) (WTA 134). The mean time between the two-week wait referral and appointment for 31 cancer patients was 5.67 days (range 0 to12). The mean time between the GP standard referral and appointment for 32 cancer patients was 22.67 days (range 1 to 77) (WTA 136).

Three multiple site audits that examined two-week wait referrals (WTA 209, 210, 234), reported data on meeting the two-week wait criterion. The number of referrals for suspected head and neck cancer that were analysed ranged from 23 (WTA 209) to 99 (WTA 234) and the percentage seen within two weeks ranged from 70% (WTA 209) to 100% (WTA 234).

Three multiple site audits (from the same trust) that examined more than one sample population (all new cancer patients and all referrals to the cancer clinic) reported the proportion of cancer patients that were seen within two weeks of referral (WTA 213-215). The time interval for all two-week wait referrals, irrespective of final diagnosis was not reported for any of the audits. The numbers of patients diagnosed with cancer and referred as two-week wait referrals were very small and ranged from 2 (WTA 215) to 8 (WTA 214), all of which were seen within two weeks of referral. For those that were not referred as two-week wait referrals, the number analysed ranged from 14 (WTA 213) to 18 (WTA 214) and the percentage seen within two weeks ranged from 11% (WTA 214) to 76% (WTA 215).

GP conformity to guidelines

The appropriateness of the GP referral according to the symptoms listed in the guidelines was evaluated by two single site audits (WTA 131, 135). The percentage that met the guidelines were 70% (WTA 135) to 72% (WTA 131) respectively. However, one of these audits actually reported the number that were deemed to be inappropriate (8/29); referrals that were not in line with the guidelines and those where the patients presenting symptoms did not match those listed in the referral were considered inappropriate and separate results were not provided for both categories (WTA 131). It was not stated how and who assessed the appropriateness of referrals according to the guidelines.

One single site audit that included two-week wait referrals and urgent non-two-week wait referrals reported that 26/74 urgent referrals had symptoms that should have been referred under the two-week wait rule (WTA 135). However, urgent referrals also included A&E and consultant referrals.

Eleven multiple site audits examined whether the GP (two-week wait) referrals were in line with the criteria listed in the guidelines (WTA 207, 209, 210, 212, 217, 223, 226, 229, 230, 233, 234); two examined more than one patient population sample (referral population and patients diagnosed with cancer) (WTA 212, 223). The percentage of referrals that met the guidelines for 10 audits ranged from 57% (WTA 209) to 86% (WTA 212, 233) when excluding one audit that only included one two-week wait referral, which was found to be inappropriate (WTA 223). The number of two-week wait referrals included in the analyses ranged from 13 (WTA 226) to 247 (WTA 207). For one audit, only referrals that were identified as inappropriate by hospital consultants (who were asked to report all audits that they deemed inappropriate to the audit co-ordinator) were included in the analyses for appropriateness; 1/92 were found to be inappropriate (WTA 230). One audit reported that 38/46 non-urgent referrals were appropriate (WTA 223), whilst another reported that one (out of one) cancer patient referred as ‘routine’ had symptoms that met the guidelines for two-week wait referral (WTA 208).

Cancer detection

Cancer rates for populations of referrals:

Four single site audits reported the cancer detection rates among those referred as two-week wait referrals (WTA 130, 131, 135, 136). One of these audits included two sample populations (two-week wait referrals and standard referrals diagnosed with cancer (WTA 136)). The cancer detection rate ranged from 7% (3/45 (WTA 135)) to 18% (4/22 (WTA 130)) and the number of patients included in the analyses ranged from 22 (WTA 130) to 285 (WTA 136). The site of the cancer was given in only two audits: all head and neck in one audit (WTA 136); and 2 head and neck cancers, 1 lung cancer and 2 of unknown type in the other (WTA 131).

Ten multiple site audits reported the cancer detection rates among those referred as two-week wait referrals (for head and neck cancer) (WTA 206, 209, 210, 212, 223, 226, 231-234). However, one audit (that included two population samples (urgent suspected cancer referrals and new cancer diagnoses) only included one head and neck two-week wait referral which did not result in the diagnosis of cancer (WTA 223). For the remaining audits (WTA 206, 209, 212, 226, 231-234) the proportion of cancers detected ranged from 4% (1/23 (WTA 209)) to 17% (5/30 head and neck and thyroid referrals (WTA 210)) and the number analysed ranged from 13 (WTA 226) to 99 (WTA 234).

One single site audit (that included a referral population) reported the cancer detection rate among those that were not referred under the two-week wait rule (WTA 135). The audit, which included both two-week wait referrals and urgent referrals, reported that 1/74 urgent referrals were diagnosed with cancer, but this included A&E and consultant referrals (WTA 135). A second audit that included a review of 530 case notes reported that 52 patients diagnosed with cancer were referred as a standard GP referral and that a further 67 patients who had a cancer diagnosis were referred to the ENT department via another source. However, the patient population of interest was not actually pre-specified and the total number of patients referred as standard by the GP (or non-two-week wait referrals) was not stated (WTA 136).

Type of referral for populations of cancer patients:

One single site audit (before and after design) that examined a patient population consisting of patients diagnosed with cancer reported that 7/46 patients diagnosed with cancer during the year after the introduction of the guidelines were referred on the two-week wait proforma (WTA 134).

Three multiple site audits (WTA 208, 212, 223) reported the proportion of patients diagnosed with cancer that were referred via the two-week wait system, two of which included a mixed patient population (WTA 212, 223). For head and neck cancers, this ranged from 0% (0/39 (WTA 223)) to 25% (1/4 (WTA 212)), but the number of patients included in the analyses was very small for two audits (range 4 (WTA 212) to 5 (WTA 208)).

Appropriateness of type of referral

One single site audit reported data on whether the hospital clinician thought that GP referrals made under the two-week rule actually warranted an urgent two-week wait appointment (WTA 130). Thirty six percent of two-week wait referrals (n=21) were deemed to be appropriate by the hospital consultant.

Six multiple site audits, reported data on whether the hospital clinician thought that GP referrals made under the two-week rule actually warranted an urgent two-week wait appointment (all audits only examined two-week wait referrals) (WTA 209, 226, 231-234). For five of the audits the number of patients included in the analyses ranged from 13 (WTA 226) to 99 (WTA 234) and the proportion considered to be appropriate ranged from 62% (8/13 (WTA 226)) to 76% of 37 (WTA 232) and 76% of 42 (WTA 231). The other audit reported that the reason why five two-week wait referrals were not seen within two weeks was because their urgency status had been down graded by the consultant (WTA 209).

One single site audit reported that some of the two-week wait referrals documented symptoms that did not comply with patient's history in the hospital case notes, but did not report how many (WTA 131).

One multiple site audit reported that 11/13 (85%) patients who were referred via the two-week wait system had symptoms in clinic consistent with those on the GP referral form (WTA 226).

Ability of guidelines to identify correct referrals

One single site audit reported data on the number of two-week wait referrals that did not meet the guidelines that presented with symptoms that were suspicious of cancer (WTA 135). The hospital doctor who examined the case notes, deemed that it was appropriate to treat 6/14 (43%) of the non compliant referrals as two-week wait referrals. One of these six patients was subsequently diagnosed with cancer.

One multiple site audit reported that 13/125 (10%) two-week wait referrals that were found to be in line with the guidelines were considered clinically inappropriate by hospital clinicians (WTA 229).

One multiple site audit reported that 2/5 head and neck and thyroid two-week wait referrals that did not meet the referral criteria were deemed to be clinically appropriate, and that 1/5 patients with a non-compliant referral was diagnosed with cancer (WTA 210).

Process of referral

One single site audit (WTA 131) that included a referral population reported that 7/8 inappropriate two-week wait referrals were made using the Trust's proforma. Another single site audit reported that 46/50 (92%) of two-week wait referrals were received by the trust within 24 hours (WTA 135).

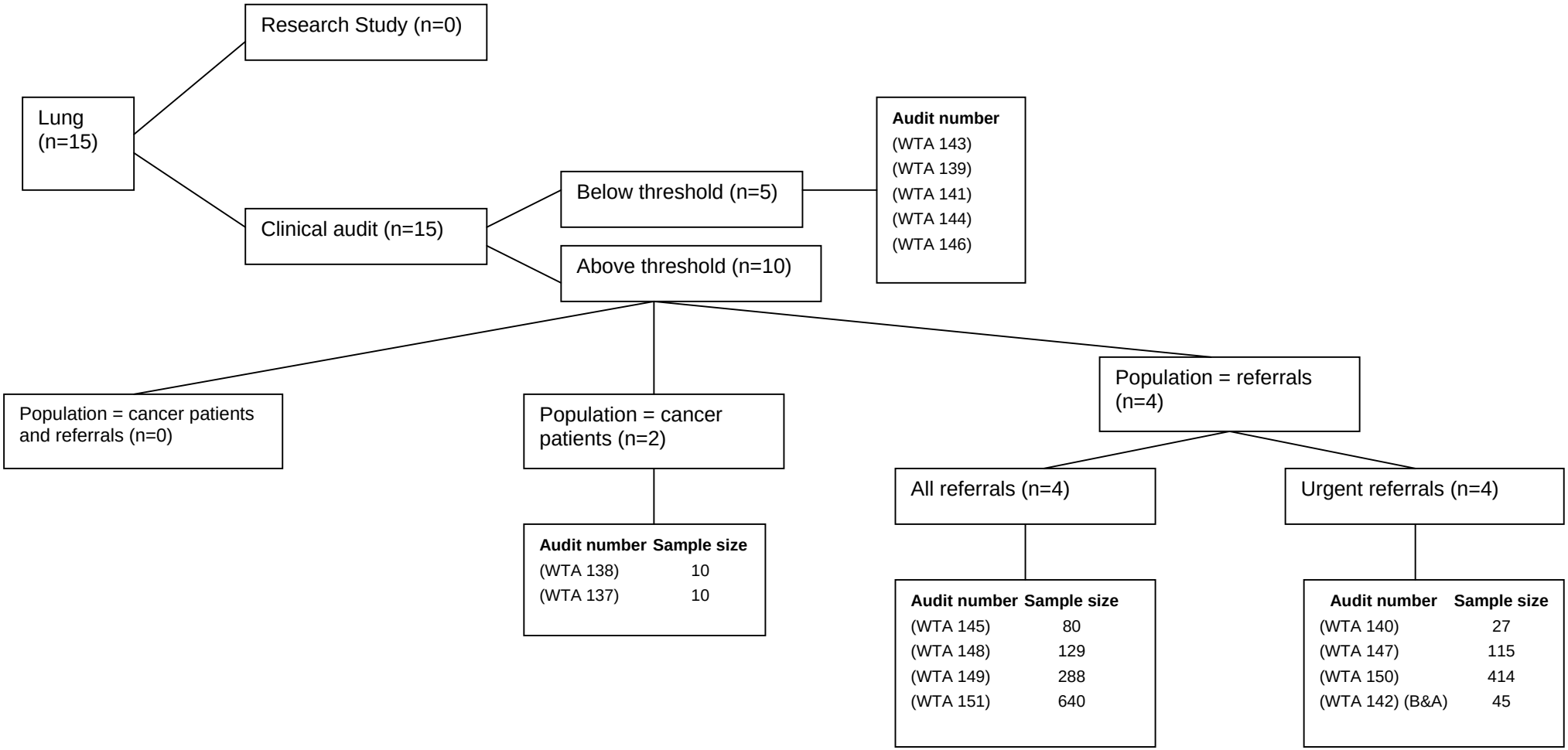
Summary

When considering audits that examined a referral population, the percentage of patients referred under the two-week wait system and seen within two weeks ranged from 70% to 100% (six audits). The percentage of two-week wait referrals that were found to be in accordance with the guidelines ranged from 57% to 86% (12 audits; excluding one audit that only included one two-week wait referral). The cancer detection rates among two-week wait referrals ranged from 4% to 18% (13 audits; excluding one audit that only included one two-week wait referral). The proportion of two-week wait referrals that were considered appropriate by the hospital clinician ranged from 36% to 76% (six audits). The percentage of non-compliant two-week wait referrals that were considered clinically appropriate by the hospital clinician ranged from 40% (2/5) to 43% (6/14) (two audits) and the proportion that were subsequently diagnosed with cancer was 1/5 and 1/14 respectively. One audit reported that 13/125 (10%) two-week wait referrals found to be in line with the guidelines were considered clinically inappropriate by the hospital clinician. One audit reported that 85% of patients who were referred via the two-week wait system had symptoms in clinic consistent with those on the GP referral form.

When considering the results of audits that included patients diagnosed with cancer, the percentage of two-week wait referrals that were seen within 2 weeks was 100% (one audit, having excluded four audits that only included 2 to 8 cancer patients). The percentage of cancer patients that were referred under the two-week wait system ranged from 0% to 15% (two audits, having excluded two audits that only included 4 and 5 cancer patients).

Single site lung cancer studies

Key: B&A = before and after study



LUNG CANCER

Overview

Forty-three clinical audits evaluated the referral guidelines for lung cancers (WTA 137-151, 206-218, 221-223, 225-234, 239, 240).

Twenty-six audits were conducted by a general hospital (WTA 137, 138, 142, 144, 147-150, 208, 210-216, 223, 226, 227, 229-234, 239), 11 by a teaching hospital (WTA 139-141, 143, 145, 146, 151, 209, 217, 218, 225), three within a cancer network (WTA 222, 228, 240) and three by a PCT (WTA 206, 207, 221). Thirty-six audits were categorised (in terms of the methodology used) as a clinical audit (WTA 138-142, 145-149, 206, 208-217, 221-223, 225-234, 239, 240) and seven as a non-criterion based audit (WTA 137, 143, 144, 150, 151, 207, 218).

Thirty-two audits evaluated patients that were referred to the department or trust, seven of which examined all referrals (WTA 143, 145, 148, 149, 151, 218, 225), 24 only included two-week wait referrals (WTA 139-142, 144, 146, 147, 150, 206, 207, 209-211, 216, 217, 226, 229-234, 239, 240), and for one audit the type of referral was unclear (WTA 228). The patient population of interest included those diagnosed with cancer in five audits (WTA 137, 138, 208, 221, 227) and six audits looked at both patients diagnosed with cancer and those being referred (WTA 212-215, 222, 223). The data were collected retrospectively in 22 audits (WTA 137, 140, 142, 145, 147-149, 151, 206, 208-212, 216, 218, 226-228, 230, 239, 240) (one of which had a before and after design (WTA 218)), prospectively in seven audits (WTA 138, 221, 225, 231-234) (one of which was before and after (WTA 221)). The direction of the data capture was not stated or unclear in 14 audits (WTA 139, 141, 143, 144, 146, 150, 207, 213-215, 217, 222, 223, 229).

Fifteen audits looked exclusively at lung cancers (single site) (WTA 137-151), whilst 28 audits examined multiple cancer sites (WTA 206-218, 221-223, 225-234, 239, 240).

Thirty-five audits reported some data on how eligible patients were identified and/or gave the data source (WTA 137, 138, 140, 142, 145, 147-151, 206-210, 212-215, 217, 218, 221-223, 225-234, 240). Two of these audits did not report separate data for lung cancer (WTA 221, 225). The results of the remaining 33 audits are summarised below. The other eight audits were not as well reported (WTA 139, 141, 143, 144, 146, 211, 216, 239) and as such their results are considered to be less reliable. The results of these audits are therefore not discussed further.

The sample sizes ranged from 6 (WTA 138) to 640 (WTA 151) for the ten single site audits (WTA 137, 138, 140, 142, 145, 147-151) and 4 (WTA 227) to 1684 (WTA 218) for the 23 multiple site audits (when only considering lung cancers) (WTA 206-210, 212-215, 217, 218, 222, 223, 226-234, 240).

Outcome measures

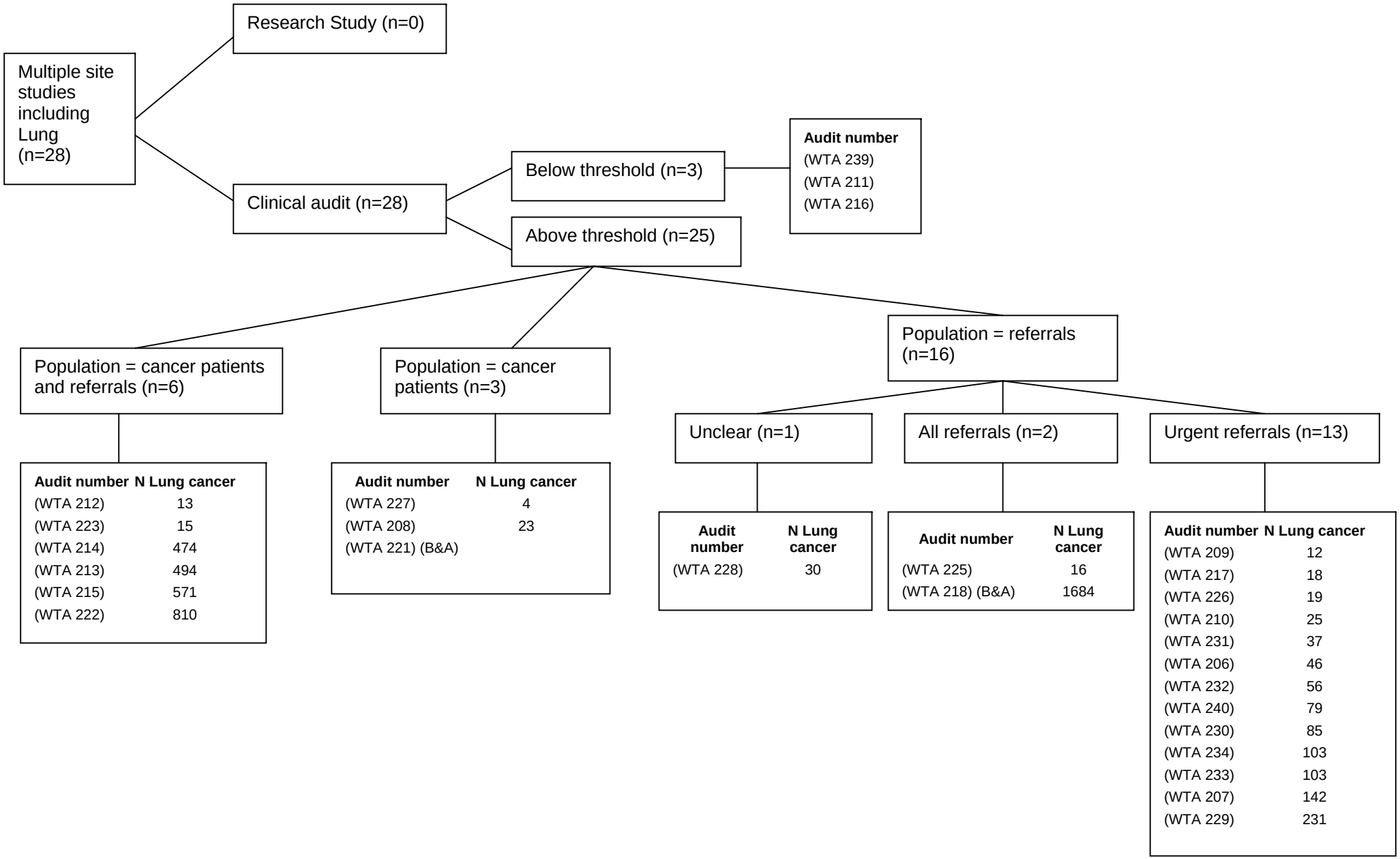
Waiting time to first appointment

Seven of the single site audits reported data on meeting the two-week wait criterion (WTA 137, 138, 140, 142, 145, 148, 149). Two of these audits (WTA 137, 138) just looked at cancer patients so the results are reported separately. Eight of the multiple site audits reported lung cancer site-specific data on meeting the two-week wait criterion (WTA 209, 210, 213-215, 227, 234, 240). One of these audits (WTA 227) just looked at cancer patients so the results are reported separately.

Five of the single site audits examined a referral population only (two looked at only two-week wait referrals (WTA 140, 142) and three looked at all referrals (WTA 145, 148, 149)). Four audits reported the proportion of two-week wait referred patients seen within two weeks (WTA 140, 142, 145, 148); the number of two-week wait referred patients that were analysed ranged from 27 (WTA 140) to 58 (WTA 145) and the percentage seen within two weeks ranged from 78% (WTA 148) to 100% (WTA 140, 145). One single site study

Multiple site lung cancer studies

Key: B&A = before and after study



reported the mean time between the GP referral and the first appointment for two-week wait referrals as 10 days (range 5 to 14 days (WTA 140)), whilst another reported the median time between the GP referral and the first appointment for two-week wait referrals as seven days (range 0 to 85 days (WTA 149)), this audit also reported the proportion of all referrals seen within two weeks as 256/288 (90%).

One single site audit reported the median time between referral and first outpatient appointment for 'non-target referrals', which was seven days (range 0 to 66 days (WTA 149)).

Four of the multiple site audits examined two-week wait referrals (WTA 209, 210, 234, 240). The number of two-week wait referred patients that were analysed ranged from 9 (WTA 209) to 103 (WTA 234). The percentage offered an appointment within two weeks ranged from 96% (WTA 210) to 100% (WTA 209, 234).

Three multiple site audits reported the proportion of two-week wait referred patients and non-two-week referred patients who were subsequently diagnosed with cancer, who were seen within two weeks of referral (WTA 213-215). The number of two-week wait referred cancer patients analysed ranged from 4 (WTA 213) to 19 (WTA 214) and the proportion seen within two weeks ranged from 95% (WTA 214) to 100% (WTA 213, 215). The number of non-two-week wait referred cancer patients analysed ranged from 24 (WTA 214) to 44 (WTA 213) and the proportion seen within two weeks ranged from 42% (WTA 214) to 50% (WTA 213).

One multiple site audit (WTA 218) reported that prior to the two-week wait referral guidelines, referrals (n=833) had an average wait of 48 days, after implementation of the guidelines two-week wait referrals (n=44) had an average wait of seven days and non-two-week wait referrals (n=807) had an average wait of 26 days.

Two single site audits that only looked at patients diagnosed with cancer reported the time from referral to first appointment for four patients referred by their GP (WTA 137) and six patients, five of which were referred by their GP (WTA 138). One found that all patients were seen within seven days (WTA 137) the other found that 5/6 patients were seen within two weeks (WTA 138) (83 to 100%, n=4; 6).

One multiple site audit that only looked at patients diagnosed with cancer reported that all two-week wait referred patients were offered an appointment within 14 days of referral (WTA 227).

GP conformity to guidelines

GP conformity to the referral guidelines was evaluated by three single site audits (WTA 140, 147, 151), with patient numbers ranging from 27 (WTA 140) to 226 (WTA 151). The percentage of referrals that were considered appropriate ranged from 92% (WTA 147) to 100% (WTA 140).

GP conformity to the referral guidelines was evaluated by 13 multiple site audits (WTA 207, 209, 210, 217, 222, 223, 226, 228-230, 233, 234, 240), one of which only looked at non-two-week wait referrals (WTA 223). The number of patients referred via the two-week wait route ranged from 10 (WTA 209) to 810 (WTA 222), the number of patients was not reported for one audit (WTA 228). The percentage of referrals that were considered appropriate ranged from 78% (WTA 217) to 100% (WTA 209, 226, 233, 234). The audit that only reported the appropriateness of non-two-week wait referrals reported that 67% (4/6) were appropriate (WTA 223).

Cancer detection

Data on cancer detection rates were reported by all eight single site audits that examined a referral population (WTA 140, 142, 145, 147-151). This included four audits that only examined two-week wait referrals (WTA 140, 142, 147, 150) and four that evaluated all referrals (WTA 145, 148, 149, 151). One of these audits only reported data for 'appropriately referred' two-week wait referrals, so has been reported separately.

Of the five single site audits that reported separate data for two-week wait referrals (WTA 140, 142, 148-150), the number of participants referred under the two-week wait rule that were included in the analyses ranged from 27 (WTA 140) to 414 (WTA 150), and the cancer detection rates ranged from 41% (11/27 (WTA 140)) to 56% (67/119 (WTA 149)). Two of the audits reported lung cancer detection rates specifically (WTA 140, 150), rather than 'cancer detection rates'. Lung cancer specific detection rates were 33% (9/27 (WTA 140)) and 41% (WTA 150) of two-week wait referrals.

Data on cancer detection rates were reported by 10 multiple site audits that examined referral populations and reported data for two-week wait referrals (WTA 206, 209, 210, 212, 222, 226, 231-234). The number of participants referred under the two-week wait rule that were included in the analyses ranged from 4 (WTA 212) (this audit included two separate samples of two-week wait referred patients; n=4 and 6) to 810 (WTA 222), where stated, and the cancer detection rates ranged from 5% (WTA 231, 232) to 75% (3/4 (WTA 212)). Excluding the audit with patient samples of 4 and 6 (WTA 212), the highest cancer detection rate was 60% (6/10 (WTA 209)).

One single site audit (WTA 149) reported that 104/168 (62%) patients who were 'non-target referrals' were diagnosed with malignant disease, including referrals from A&E, fax, letter, General Medicine and X-ray. Another audit (WTA 148) reported that 2/87 (2%) routine referrals were diagnosed with cancer, discovered four months after referral.

Of the two single site audits that reported cancer detection rates for all patients, not split by mode of referral, one reported that 252/631 (40%) patients were found to have primary lung cancer, 38/631 (6%) were found to have a cancer metastatic to the lungs and 7/631 (1%) were found to have non-lung primaries (WTA 151). The other audit reported that 36/80 (45%) patients referred via two-week wait (n=58), from within secondary care (n=14) or via routine GP referral (n=8) were found to have lung cancer (WTA 145).

Another single site audit reported the proportion of appropriate (met the referral criteria) two-week wait referrals that were subsequently diagnosed with cancer as 51% (48/94 (WTA 147)).

One single site audit that only included two-week wait referrals (WTA 150) reported that 85% of lung cancers were identified through the two-week wait route of referral. Another single site audit (WTA 151) reported that 47% of lung cancers were identified in non-two-week wait patients, however the patient population for this audit included all patients referred to a lung cancer rapid referral clinic, therefore, this may not be representative of other types of clinic included in this review.

Two small single site audits that examined patient populations which only included patients diagnosed with lung cancer reported the route of referral for those patients (WTA 137, 138). In the first study, which included seven patients, four were referred via the GP (57%), stated as 'urgent and faxed', one was under review in the ENT clinic, one was referred from a Chest Physician and one was admitted via A&E (WTA 137). The other study included six patients, five were referred by their GP, though the level of urgency of the referral was not stated (WTA 138), nor is it stated whether any of the patients in either of these two audits had symptoms which are listed in the guidelines for urgent referral.

Four multiple site audits that examined patient populations which included patients diagnosed with lung cancer reported the route of referral for those patients (WTA 208, 212, 222, 223). The proportions of patients with cancer who had been referred via the two-week wait referral route were 0% (0/3 (WTA 212) 0/9 (WTA 223)), 29% of 1013 (WTA 222) and 43% (10/23 (WTA 208)).

Appropriateness of the type of referral

One single site audit reported data on whether the hospital clinician thought that GP referrals made under the two-week rule actually warranted an urgent two-week wait appointment (WTA 150). The audit reported that 45/414 (11%) of referrals were deemed inappropriate by hospital consultants.

Four multiple site audits reported the proportion of two-week wait referrals that the clinician assessed as appropriate (WTA 231-234). The number of patients included in the analyses ranged from 37 (WTA 231) to 103 (WTA 233, 234). The proportion of referrals assessed as appropriate ranged from 87% (WTA 232) to 97% (WTA 233).

One multiple site audit reported that 95% (18/19) of patients who were referred via the two-week wait referral system, had symptoms in clinic consistent with those on the GP referral form (WTA 226).

Ability of guidelines to identify correct referrals
One single site audit reported that 6/14 two-week wait referrals that did not comply with the guidelines were subsequently diagnosed with either a primary or secondary lung cancer (WTA 151).

One multiple site audit reported that 2/39 (5%) two-week wait referrals that did not meet the referral criteria were deemed to be clinically appropriate and that 11/187 (6%) referrals meeting the criteria were clinically inappropriate according to the hospital assessment (WTA 229). Another multiple site audit reported that 0% (0/4) of two-week wait referrals that did not meet the referral criteria were deemed to be clinically appropriate and that none of these patients was subsequently diagnosed with cancer (WTA 210).

Process of referral
The time between the decision to refer and receipt of the referral by the hospital was reported by one single site audit (WTA 148). The time interval was 0 days for 15/27 referrals (all faxes), 1 day for 8 referrals (including three faxes), and one referral each was received in 2 days, 3 days, 4 days and 5 days. Therefore, 85% referrals were received within 1 day of the decision to refer.

The time between the decision to refer and receipt of the referral by the hospital was reported by two multiple site audits (WTA 208, 210). One audit reported that all two-week wait referrals were received in 0-1 days (WTA 208), the other reported that 96% (24/25) of two-week wait referrals were received within 24 hours, the other was received in 13 days (WTA 210).

The mode of delivery of the referral was reported in one single site audit (WTA 150). The audit looked at two timeframes, one in 2000, the other in 2001. In 2000, 48 referrals (38%) were mailed letters, 42 (33%) were faxed letters and 36 (29%) were faxed proformas. In 2001, seven referrals (7%) were mailed letters, 11 (10%) were faxed letters and 88 (83%) were faxed proformas.

Summary

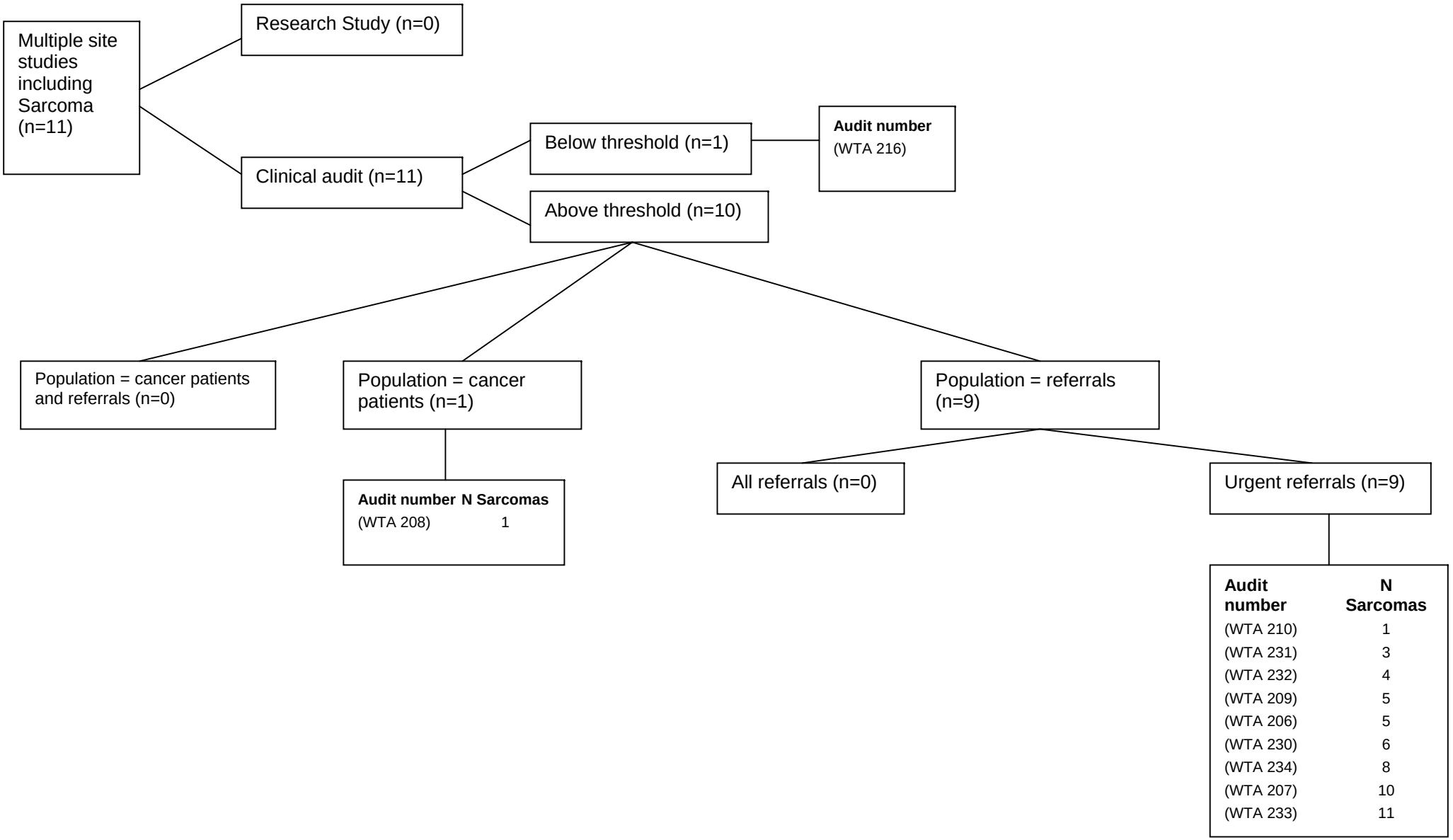
The proportion of patients referred under the two-week wait referral system and seen within two weeks ranged from 78% to 100% (eight audits that examined referred patients). The proportion of cancer patients who were referred under the two-week wait referral system and who were seen within two weeks ranged from 95% to 100% (two audits that examined cancer patients, after excluding three studies with less than 6 patients). The proportion of two-week wait referrals that were found to be in accordance with the symptoms listed in the guidelines ranged from 78% to 100% (15 audits).

The proportion of patients who were referred under the two-week wait referral system who were subsequently diagnosed with cancer ranged from 5% to 60% (14 audits, having excluded one audit with two patient samples of 4 and 6 patients). One audit reported that 51% of two-week wait referrals that met the referral criteria were subsequently diagnosed with cancer. The cancer detection rate among two-week wait referrals that did not meet the guidelines was 43% (one audit, having excluded one audit with only 4 two-week wait referrals that did not meet the guidelines). The proportion of patients with cancer who had been referred via the two-week wait referral system ranged from 0% to 43% (three audits, having excluded two audits with patient samples of 7 or less).

The proportion of two-week wait referrals deemed to be appropriate by the clinician ranged from 87% to 97% (five audits). The proportion of two-week wait referrals that did not meet the referral criteria but were deemed to be clinically appropriate was 5% (one audit, having excluded one audit with only 4 two-week wait referrals that did not meet the guidelines). The proportion of referrals meeting the criteria that were deemed were clinically inappropriate was 6% (1 audit). One audit reported that 95% of patients who were referred via the two-week wait system had symptoms in clinic consistent with those on the GP referral form.

The proportion of referrals received by the hospital within one day of the GP's decision to refer ranged from 85% to 100% (three audits).

Multiple site sarcoma studies



SARCOMA

Overview

Eleven clinical audits evaluated the referral guidelines for sarcomas (WTA 206-210, 216, 230-234).

Eight audits were conducted by a general hospital (WTA 208, 210, 216, 230-234), one by a teaching hospital (WTA 209), and two by a PCT (WTA 206, 207). With the exception of one non-criterion based audit (WTA 207), all were categorised (in terms of the methodology used) as a clinical audit.

All 10 audits that examined a referral population only, included only two-week wait referrals (WTA 206, 207, 209, 210, 216, 230-234). One audit looked at patients diagnosed with cancer (WTA 208).

The data were collected retrospectively in six audits (WTA 206, 208-210, 216, 230), and prospectively in four audits (WTA 231-234). The direction of data capture was not stated in one audit (WTA 207).

All 11 audits examined multiple cancer sites but reported some results separately for each site, and sample sizes ranged from 1 (WTA 208, 210, 216) to 11 (WTA 233) when only considering sarcomas.

Ten audits (WTA 206-210, 230-234) reported some data on how eligible patients were identified and/or gave the data source. The results of these audits are summarised below. One audit was not as well reported (WTA 216) and as such its results are considered to be less reliable. The results of this audit are therefore not discussed further.

Outcome measures

Waiting time to first appointment

Two audits which looked at two-week wait referrals only, reported data on meeting the two-week wait criterion (WTA 209, 234). The number of two-week wait referred sarcoma patients analysed ranged from 5 to 8. The percentage seen within two weeks ranged from 60% (3/5 (WTA 209)) to 100% (8/8 (WTA 234)).

GP conformity to guidelines

Six audits evaluated the conformity of the GP referral to the symptoms listed in the guidelines (WTA 207, 209, 210, 230, 233, 234). With patient numbers ranging from 1 (WTA 210) to 11 (WTA 233), the number of referrals that met the guidelines ranged from 60% (3/5 (WTA 209), 6/10 (WTA 207)) to 100% (WTA 210, 230).

One audit found that the single sarcoma patient met the two-week wait criteria but was referred routinely (WTA 208).

Cancer detection

Data on cancer detection rates were reported by seven audits that examined referral populations and reported data for two-week wait referrals (WTA 206, 209, 210, 216, 231-233). The number of patients referred under the two-week wait rule that were included in the analyses ranged from 1 (WTA 210, 216) to 11 (WTA 233) and the cancer detection rates ranged from 0% (WTA 206, 210, 216, 231, 232) to 20% (1/5 (WTA 209)).

Appropriateness of the type of referral

Four multiple site audits reported the proportion of two-week wait referrals that the clinician assessed as appropriate (WTA 231-234). The number of patients included in the analyses ranged from 3 (WTA 231) to 11 (WTA 233) and the proportion considered to be appropriate ranged from 67% (2/3 (WTA 231)) to 100% (4/4 (WTA 232), 11/11 (WTA 233))

Ability of guidelines to identify correct referrals
Not reported.

Process of referral
One audit found that 1/1 two-week wait sarcoma referrals were received within 24 hours (WTA 210).

Summary

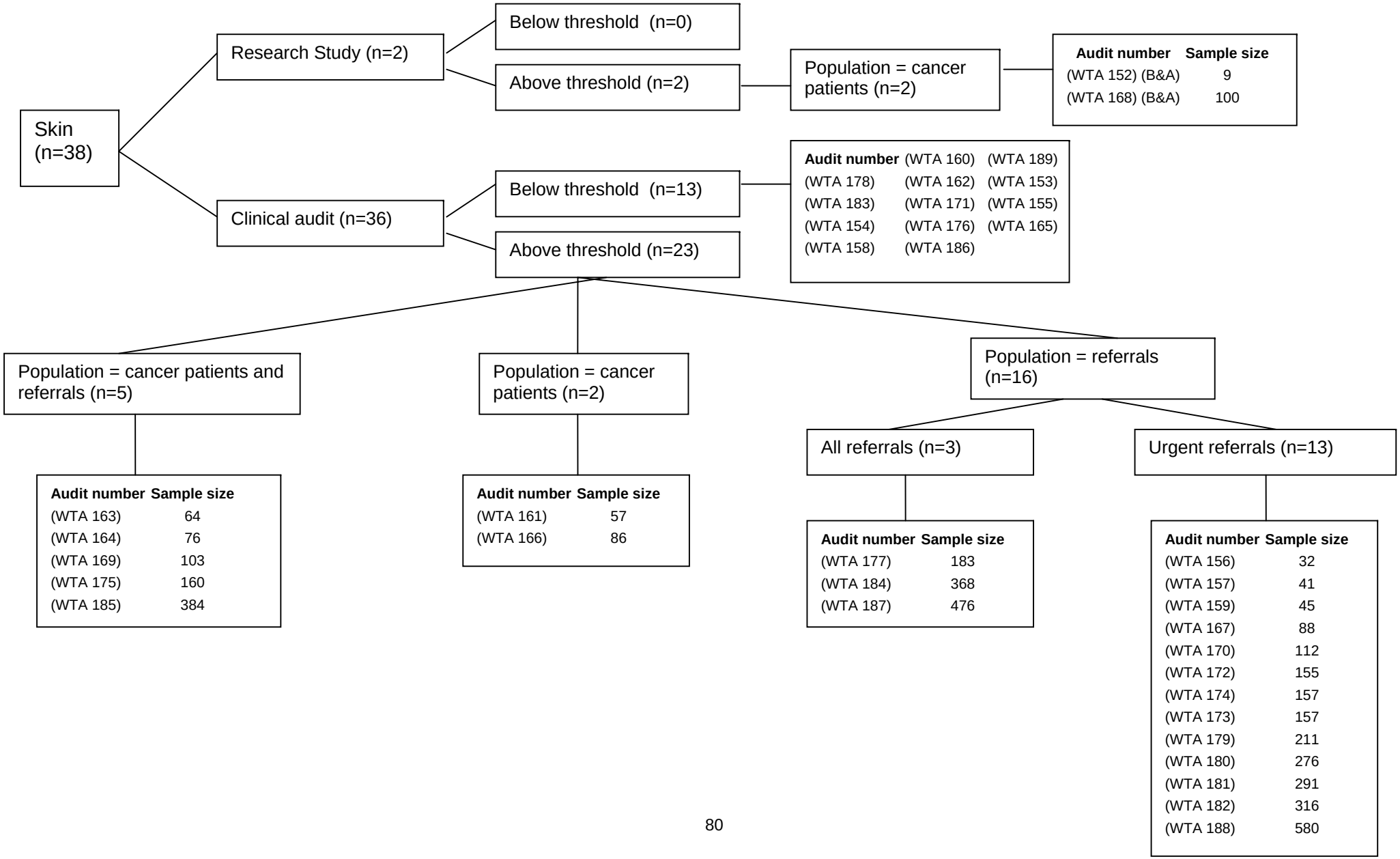
The proportion of two-week wait referrals that were found to be in accordance with the symptoms listed in the guidelines ranged from 60% to 100% (six audits). The proportion of patients referred via the two-week wait system and subsequently diagnosed with cancer ranged from 0% to 20% (seven audits).

The proportion of two-week wait referrals deemed to be appropriate by the hospital clinician ranged from 67% to 100% (four audits).

All of these results are based upon audits of 11 patients or less.

Single site skin cancer studies

Key: B&A = before and after study



SKIN CANCERS

Overview

Fifty-nine clinical audits evaluated the referral guidelines for skin cancers (WTA 152-189, 206, 207, 209-217, 222, 223, 228-234, 239).

Thirty-five audits were conducted by a general hospital (WTA 153, 155-157, 159, 162-166, 168, 169, 172, 175-177, 179-181, 186, 210-216, 223, 229-234, 239), 20 by a teaching hospital (WTA 152, 154, 158, 160, 161, 167, 170, 171, 173, 174, 178, 182-185, 187-189, 209, 217), two by a PCT (WTA 206, 207) and two by a network (WTA 222, 228).

Forty-four were categorised (in terms of the methodology used) as a clinical audit (WTA 154, 156, 158, 159, 161-164, 166, 167, 169, 171, 172, 174-176, 178, 179, 181, 182, 185, 187-189, 206, 209-217, 222, 223, 228-234, 239), 13 as a non-criterion based audit (WTA 153, 155, 157, 160, 165, 170, 173, 177, 180, 183, 184, 186, 207), and two as a research study (WTA 152, 168).

Forty-one audits evaluated patients that were referred to the department or trust, seven of which examined all referrals (WTA 171, 177, 178, 183, 184, 187, 189), 32 only included two-week wait referrals (WTA 154, 156-160, 162, 167, 170, 172-174, 179-182, 186, 188, 206, 207, 209-211, 216, 217, 229-234, 239), and the type of referral was unclear for two audits (WTA 176, 228). The patient population of interest included those diagnosed with cancer in six audits (WTA 152, 153, 155, 161, 166, 168) and 12 audits looked at both patients diagnosed with cancer and those being referred (WTA 163-165, 169, 175, 185, 212-215, 222, 223).

The data were collected retrospectively in 30 audits (WTA 152, 153, 155, 156, 161, 163, 165-169, 174, 175, 178, 180, 181, 183-185, 187, 188, 206, 209-212, 216, 228, 230, 239) (3 of which had a before and after design (WTA 152, 168, 183)) and prospectively in six audits (WTA 159, 189, 231-234). The direction of the data capture was not stated or unclear in 23 audits (WTA 154, 157, 158, 160, 162, 164, 170-173, 176, 177, 179, 182, 186, 207, 213-215, 217, 222, 223, 229).

Thirty-eight audits looked exclusively at skin cancers (single site) (WTA 152-189), whilst 21 audits examined multiple cancer sites but reported some results separately for individual sites (WTA 206, 207, 209-217, 222, 223, 228-234, 239). The sample size ranged from nine (WTA 152) to 610 (WTA 189) for single site audits and from four (WTA 223) to 1677 (WTA 215) for multiple site audits (when only considering skin cancers). The number of skin cancers included in one multiple site audit was not stated (WTA 211).

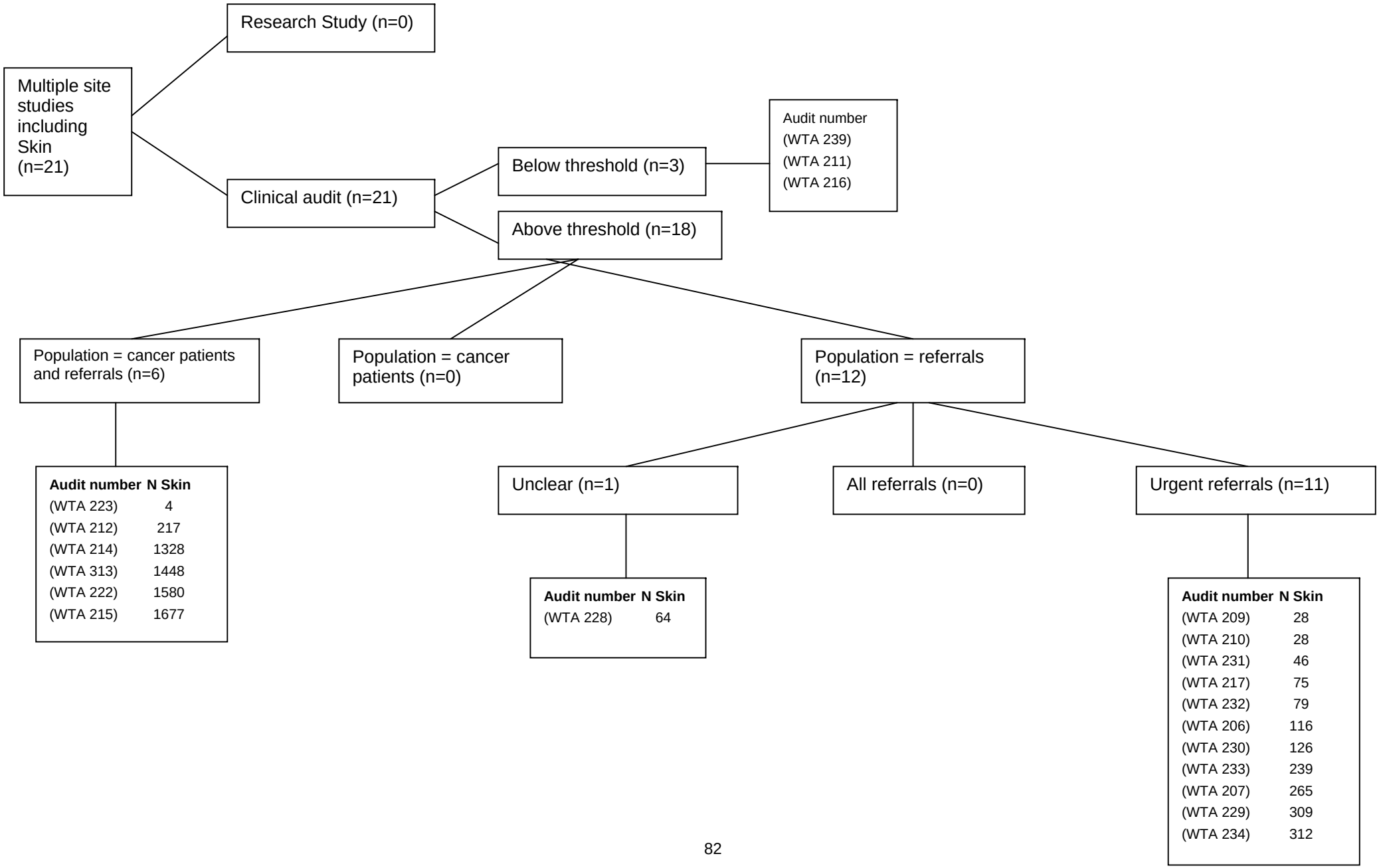
Forty-three audits reported some data on how eligible patients were identified and/or gave the data source (WTA 152, 156, 157, 159, 161, 163, 164, 166-170, 172-175, 177, 179-182, 184, 185, 187, 188, 206, 207, 209, 210, 212-215, 217, 222, 223, 228-234). The results of these audits are summarised below. Twenty-five were single site audits (WTA 152, 156, 157, 159, 161, 163, 164, 166-170, 172-175, 177, 179-182, 184, 185, 187, 188) and 18 were multiple site audits (WTA 206, 207, 209, 210, 212-215, 217, 222, 223, 228-234). The sample size ranged from nine (WTA 152) to 580 (WTA 188) for single site audits and from four (WTA 223) to 1677 (WTA 215) for multiple site audits (when only considering skin cancers). The other 16 audits were not as well reported (WTA 153-155, 158, 160, 162, 165, 171, 176, 178, 183, 186, 189, 211, 216, 239) and as such their results are considered to be less reliable. The results of these audits are therefore not discussed further.

Results

Waiting time to first appointment

Fifteen single site audits reported data on meeting the two-week wait criterion (WTA 156, 163, 164, 166, 168, 170, 172, 174, 179, 181, 182, 184, 185, 187, 188) and seven reported the average waiting time to first appointment (WTA 152, 161, 170, 180, 181, 185, 188). Eleven examined a referral population; nine looked at two-week wait referrals only (WTA

Multiple site skin cancer studies



156, 170, 172, 174, 179-182, 188) and two looked at all referrals (WTA 184, 187). Three audits (WTA 163, 164, 185) evaluated two sample populations (mixed population), which included patients referred under the two-week rule and those diagnosed with cancer during the same time period and four audits (WTA 152, 161, 166, 168) only examined patients diagnosed with cancer.

For twelve of the single site audits that examined a referral population (including mixed population audits) (WTA 156, 163, 164, 170, 172, 174, 179, 182, 184, 185, 187, 188), the number of two-week wait referrals that were analysed ranged from 30 (WTA 156) to 236 (WTA 185) and percentage seen within two weeks ranged from 55% (WTA 188) to 100% (WTA 164). However, one audit (WTA 170) only included appropriately referred patients; one audit (WTA 184) included patients (34%) that were referred with suspected basal cell carcinoma (BCC) as two-week wait referrals (which is not part of the DoH guidelines); and one audit (WTA 185) evaluated the time between the hospital receipt of referral (not GP's decision to refer) and first appointment. Two audits (WTA 172, 188) included cancellations and non-attenders when measuring this criterion and two audits (WTA 156, 174) excluded them. One of these audits (WTA 188) also reported that 12/16 (75%) patients that were subsequently diagnosed with cancer were seen within two weeks (11 had been referred using the skin cancer form). One further audit (WTA 181) found that five out of six trusts reported (via questionnaire) that all patients referred to them via the two-week wait system were seen within two weeks.

Four single site audits that examining a referral population reported the average waiting time to first appointment. For two audits that only included two-week wait referrals, the mean waiting time ranged from 7.7 days (n=75 (WTA 170)) to 15 days (n=215 (WTA 188)). One audit (WTA 180) found that the median time to 1st appointment for the different surgeons ranged from 9 to 14 days (216 two-week wait referrals), and one audit (WTA 181) reported that the average waiting time in six trusts ranged from 6 to 19.4 days.

For two single site audits that examined patients diagnosed with cancer, the percentage seen within two weeks ranged from 61% (43/71 (WTA 168)) to 62% (28/61 (WTA 166)), but it was unclear if all the patients had been referred as two-week wait referrals. One further audit (WTA 152) of cancer patients reported that the average wait to first appointment was 6 days, but only three patients were included in the analyses. One audit (WTA 161) found that the mean wait for faxed referrals was 10 days for malignant melanomas (MM) (n=9) and 7 days for squamous cell carcinomas (SCC) (n=15), and that the mean wait for letter referrals was 29 days for MM (n=13) and 31 days for SCC (n=20). One mixed population audit (WTA 185) reported that the mean time between referral and 1st appointment for patients with MM that were referred by their GP via conventional letter was 40 days (the number of included patients was not stated).

For three multiple site audits (WTA 209, 210, 234) that examined a referral population the percentage of two-week wait referrals seen within two weeks ranged from 59% (WTA 209) to 100% (WTA 210, 234). The number of skin cancer referrals included in the analyses ranged from 27 (WTA 209, 210) to 312 (WTA 234).

Three multiple site audits (from the same trust) that examined more than one sample population (all new cancer patients and all referrals to the cancer clinic) reported the proportion of cancer patients that were seen within two weeks of referral (WTA 213-215). The number of patients diagnosed with cancer and referred as two-week wait referrals were small and ranged from 11 (WTA 215) to 31 (WTA 214), all of which were seen within two weeks of referral for two audits (WTA 213, 214). For one audit 10/11 (91%) were seen within two weeks (WTA 215). For patients diagnosed with cancer that were not referred as two-week wait referrals, the number analysed ranged from 164 (WTA 215) to 214 (WTA 214) and the percentage seen within two weeks ranged from 15% (WTA 213) to 29% (WTA 215). The interval for all two-week wait referrals, irrespective of final diagnosis was not reported for any of the audits.

GP conformity to guidelines

The appropriateness of the GP referral according to the symptoms listed in the guidelines was evaluated by 12 single site audits, six of which looked at two-week wait referrals (WTA 156, 159, 167, 170, 174, 182), four examined a mixed patient population (WTA 164, 169, 175, 185), and two audits only included patients diagnosed with cancer (WTA 152, 166).

The percentage of two-week wait referrals that met the guidelines, according to eight single site audits that included a referral population (WTA 156, 164, 167, 170, 174, 175, 182, 185), varied quite considerably, ranging from 9% (3/32 (WTA 156)) to 96% (151/157 (WTA 174)). However, one of these audits (WTA 175) actually reported the percentage of referrals that was deemed to be inappropriate (68%); one audit (WTA 152) reported the number of referrals that included the tumour size (classed as appropriate for the purpose of this outcome measure); and one audit (WTA 174) reported the proportion of two-week wait referrals for which the GP had included the suspicion of MM or SCC. One further audit (WTA 159) that only looked at two-week wait referrals (n=45) reported that four patients had been excluded because their referral was inappropriate (basal cell carcinoma (BCC) or Bowen's disease).

One single site audit (WTA 169) reported that 89/103 (86%) referrals were made 'with the appropriate degree of urgency', but this sample included 7 'urgent', 5 'soon' and 64 'routine' GP referrals as well as the 27 two-week wait referrals. For referrals that were deemed to have an inappropriate degree of urgency, 64% were given too great a degree of urgency and the remaining 36% were treated with too little urgency.

Of the two single site audits that only included patients diagnosed with cancer, one audit (WTA 166) reported that a clinical diagnosis was not reported in 45/81 referrals (8/81 patients were referred with a different diagnosis than the eventual histological diagnosis), and one audit (WTA 152) reported that the size of the tumour was given in the GP letter for 3/9 patients.

Twelve multiple site audits that examined a referral population evaluated the appropriateness of the GP referral according to the symptoms listed in the guidelines (WTA 207, 209, 210, 212, 217, 222, 223, 228-230, 233, 234) (3 examined a mixed patient population (WTA 212, 222, 223)). The percentage of two-week wait referrals that met the guidelines ranged from 56% (WTA 210) to 97% (WTA 222) with the number of referrals included in the analyses ranging from 4 (WTA 223) to 312 (WTA 234) for 13 audits and 1580 for one large network wide audit (WTA 222) (when excluding this latter audit the appropriateness of referral ranged from 56% to 95% (WTA 230)).

Cancer detection

Cancer rates for populations of referrals:

Data on cancer detection rates were reported by 15 single site audits that examined a referral population (WTA 156, 159, 163, 167, 169, 170, 173, 174, 177, 180-182, 184, 187, 188), two of which examined a mixed patient population (WTA 163, 169).

Thirteen single site audits reported the cancer detection rates (MM or SCC) among those referred as two-week wait referrals (WTA 156, 159, 163, 167, 169, 173, 174, 177, 180-182, 187, 188). The cancer detection rate ranged from 2% (3/160 (WTA 173)) to 33% (9/27 (WTA 169)) and the number of patients included in the analyses ranged from 27 (WTA 169) to 291 (WTA 181) (cancer detection rates ranged between 2% and 12% (25/216 (WTA 180)) in 11 audits (WTA 156, 159, 163, 167, 173, 174, 177, 180-182, 188). In one of these audits (WTA 167) only 46/88 patients had a biopsy (and therefore included in the analysis), one audit (WTA 244) only included faxed referrals, and one audit (WTA 187) included faxed referrals (n=63) and letter referrals that were suggestive of any form of skin cancer (n=306), but only the 41 faxed referrals who received a biopsy have been included in this analysis.

One single site audit (WTA 184) (that examined all referrals) analysed the data per lesion and not by patient. The trust conducting the audit also included BCC in their guidelines. Of the 280 lesions included in the analyses, 24 (9%) MM or SCC were identified (and 86 BCC).

Of the 165 lesions that were referred with suspected MM or SCC, which would have been according to the DoH guidelines, 20 were confirmed as either MM or SCC (12%).

Ten multiple site audits reported the cancer detection rates among those referred as two-week wait referrals (for skin cancer) (WTA 206, 209, 210, 212, 222, 223, 231-234). The proportion of cancers detected ranged from 12% (188/1580 (WTA 222)) to 36% (10/28 (WTA 210)) and the number analysed ranged from 4 (WTA 223) to 1580 (WTA 222) in seven audits (WTA 206, 209, 210, 222, 223, 233, 234). The remaining audit (WTA 212) reported the cancer detection rates for three separate samples that may not be mutually exclusive. The cancer detection rates ranged from 8% (4/51) to 25% (10/40).

One single site audit (WTA 169) (that included a mixed patient population) reported the cancer detection rate among those that were not referred under the two-week wait rule. SCC or MM was identified in 5/7 patients referred as ‘urgent’ by the GP, in 3/5 patients referred as ‘soon’, and 11/64 patients referred as routine.

One single site audit (WTA 169) (that included a mixed patient population) reported that out of the three patients referred under the two-week wait system with suspected BCC (and therefore not within the DoH guidelines), two were later diagnosed with SCC.

Type of referral for populations of cancer patients:
Data on the type of referral for patients diagnosed with cancer were reported by six single site audits (WTA 163, 164, 166, 168, 175, 185), four of which examined a mixed patient population (WTA 163, 164, 175, 185). However, the audits varied in terms of how this process outcome was analysed and the patient population of interest. One audit (WTA 168) reported that 33/77 (43%) cancer patients examined during the latter 21 month period of the audit (after the introduction of yellow fax cancer forms) were referred on 'yellow forms' (presumed to be two-week wait referrals). The audit also reported that 52/77 patients were referred by the GP as 'urgent', 15 as 'soon' and 2 as 'routine'; for the earlier 15-month period 15/23 patients were referred as 'urgent' and 5 as 'soon'. One audit (WTA 175) reported that only 6/42 (14%) patients that had a histological diagnosis of MM were referred as two-week wait referrals, and of the 36 (86%) that were not, 9 were non-two-week wait rule skin referrals, 21 were from other surgical departments, and 6 were direct from GP excisions. One audit (WTA 185) reported that 3/14 (21%) patients with a primary diagnosis of MM were referred via the two-week wait system; 10 were identified in the existing tumour clinic and 1 was a routine referral. Neither of these latter audits looked at the route of referral for SCC. One audit (WTA 163) reported that 2/29 (7%) cancer patients were referred via the faxed protocol (using a skin cancer form) and that 9/29 (31%) were referred by the GP as urgent or to the skin screening clinic. One audit (WTA 166) that evaluated compliance with local guidelines for the management of skin cancer (established since 1995) reported that 56% of referrals had an urgent priority, but it was not stated how many were made according to the two-week wait policy. Fifty-two patients were included in the analyses, of which 2% were referred as soon, 2% as routine, and the referral priority was not stated for 40% (actual patient numbers were not given). One audit that looked at all patients referred via the two-week wait system (n=76) and all patients diagnosed with cancer (during the same period) that were not referred via the two-week wait system found that 14 patients with SCC fitted into this latter category (WTA 164). However, the authors did not give the total number of patients diagnosed with cancer during the audit period.

Although not exactly part of the audit, three further single site audits (WTA 159, 170, 182) that examined a two-week wait referral population also gave the number of cancer patients that were treated by the department within the same time period, as well as how many of them were two-week wait referrals (and thus included in the audit). The number of cancer patients that were referred under the two-week wait system included: 13/167 (8% (WTA 170)); 3/12 (25% (WTA 182)); 3/10 (30% (WTA 159)).

Two multiple site audits (WTA 212, 222) reported the proportion of patients diagnosed with cancer that were referred via the two-week wait system, both of which included a mixed patient population. For skin cancers (excluding BCC), this ranged from 31% (of 604 patients with cancer included in analysis (WTA 222)) to 44% (4/9 (WTA 212)).

Appropriateness of type of referral
Two single site audits (WTA 174, 182) reported data on the assessment of appropriateness of referral by the hospital consultant, both of which included a referral population. One audit (WTA 182) reported that 9/109 (8%) patients referred with suspected MM were considered suspicious of MM by hospital consultants and 13/65 (20%) patients referred with suspected SCC were considered suspicious of SCC by consultants (overall 22/174 (13%) were considered appropriate). The second audit (WTA 174) reported that 151/157 (96%) of GP two-week wait referrals were due to suspected MM (n=103, 68%) or SCC (n=48, 32%), whereas the number of patients suspected of having MM or SCC by the dermatology department was 12 (8%) and 13 (9%), respectively (the dermatologist therefore considered 25/157 (16%) GP referrals to be appropriate).

Four multiple site audits (WTA 231-234) reported data on the proportion of two-week wait referrals that were considered appropriate by the hospital clinician, which ranged from 61% (of 46 patients (WTA 231)) to 84% (of 312 patients (WTA 234)).

Ability of guidelines to identify correct referrals
One single site audit reported 12/75 (16%) referrals that met the guidelines resulted in a cancer diagnosis (WTA 170).

One multiple site audit (WTA 229) reported that 1/116 (1%) two-week wait referrals that did not meet the referral criteria was deemed clinically appropriate by the hospital clinician, and that 5/160 (3%) two-week wait referrals that met the criteria were deemed clinically inappropriate. Another multiple site audit (WTA 210) reported that 5/12 (42%) two-week wait referrals that did not meet the referral criteria were deemed to be clinically appropriate and that four (33%) two-week wait referred patients who did not meet the two-week wait criteria were subsequently diagnosed with cancer.

Process of referral
The mean time from the GP's decision to refer and receipt of referral ranged from 1 (n=207 (WTA 188)) to 2 days (n=3 (WTA 152)) in two single site audits.

One multiple site audit (WTA 210) reported that 26/27 (96%) two-week wait referrals for skin cancer were received by the trust within 24 hours; one GP referral was received within 3 days.

Five single site audits reported data on the method of referral; four (WTA 181, 182, 187) looked at two-week wait referrals and one (WTA 161) examined patients diagnosed with cancer. The findings of the audits were variable. One audit (WTA 181) noted that 95% to 100% of two-week wait referrals were made by fax by all hospitals (n=6) apart from one, where 35% of the referrals were made via standard letter. Another audit (WTA 187) reported that of the 476 referrals made to the rapid lesion assessment clinic, 63 (13%) were faxed and 306 (64%) were made via letter; but this information was not available for 107 (22%) patients. Another audit (WTA 182) reported that 184/185 (99%) urgently referred patients were referred via fax. One single site audit (WTA 161) reported that of the 57 patients diagnosed with SCC or MM, 24 (42%) had been referred via fax and the remainder by letter (58%). The level of urgency of the referral was not stated, but only patients referred to the rapid lesion access clinic were included in the audit. One audit reported that 26/41 (63%) urgent referrals were faxed and 15 posted (WTA 157).

Summary
When considering audits that examined a referral population, the percentage of patients referred under the two-week wait system and seen within two weeks ranged from 55% to 100% (15 audits). The percentage of two-week wait referrals that were found to be in accordance with the guidelines ranged from 9% to 97% (19 audits, excluding one audit with only 4 patients). 63% to 99% of two-week wait/urgent referrals were made by fax (three audits).

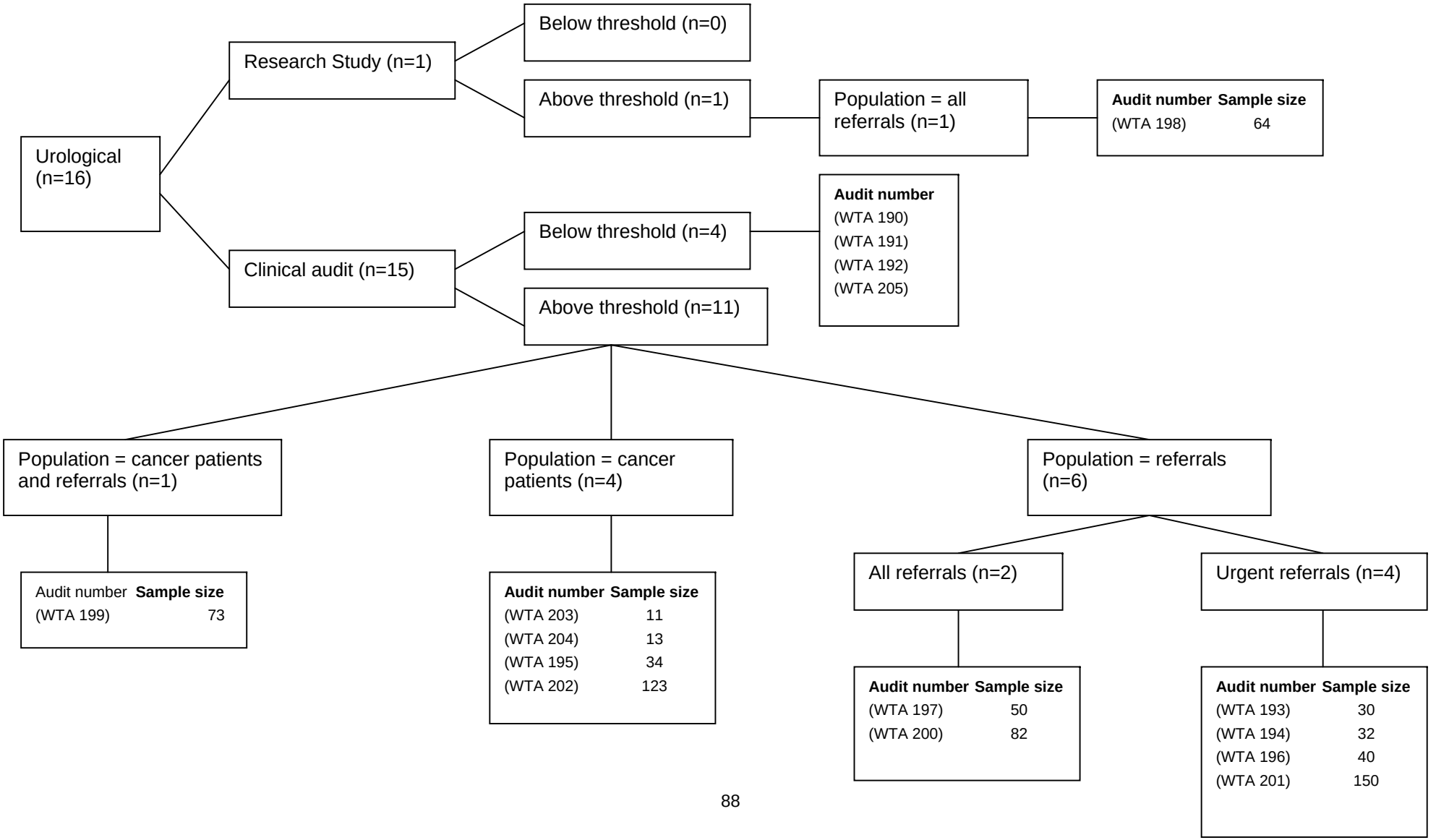
The cancer detection rates among those referred as two-week wait referrals ranged from 2% to 36% (23 audits).

The percentage of two-week wait referrals that were considered appropriate by the hospital consultant ranged from 13% to 84% (six audits).

Two-week wait referrals that did not meet the referral criteria but still deemed to be clinically appropriate by the hospital clinician ranged from 1% (1/116) to 42% (5/12) (two audits). 3% (5/160) of two-week wait referrals that met the criteria were deemed clinically inappropriate (one audit). 33% (4/12) of two-week wait referred patients who did not meet the two-week wait criteria were subsequently diagnosed with cancer (one audit) and 16% (12/75) referrals that met the guidelines resulted in a cancer diagnosis (one audit).

When considering the results of audits that included patients diagnosed with cancer, the percentage seen within two weeks ranged from 61% to 62% (two audits), but it was unclear if all the patients had been referred as two-week wait referrals. 91% to 100% patients that were referred as two-week wait referrals and subsequently diagnosed with cancer were seen within two weeks in three audits conducted by the same trust. The proportion of patients diagnosed with skin cancer that were referred as two-week wait referrals ranged from 7% to 44% (six audits; two audits only considered MM).

Single site urological cancer studies



UROLOGICAL CANCERS

Overview

Forty-three clinical audits evaluated the referral guidelines for urological cancers (WTA 190-217, 221-234, 239).

Thirty audits were conducted by a general hospital (WTA 193-197, 199, 201-205, 208, 210-216, 223, 224, 226, 227, 229-234, 239), eight by a teaching hospital (WTA 190-192, 198, 200, 209, 217, 225), two within a cancer network (WTA 222, 228) and three by a PCT (WTA 206, 207, 221). Forty audits were categorised (in terms of the methodology used) as a clinical audit (WTA 190-197, 200-206, 208-217, 221-234, 239), two as a non-criterion based audit (WTA 199, 207) and one as a research study (WTA 198).

Twenty-eight audits evaluated patients that were referred to the department or trust, four of which examined all referrals (WTA 197, 198, 200, 225), 23 only included two-week wait referrals (WTA 190-194, 196, 201, 205-207, 209-211, 216, 217, 226, 229-234, 239), and for one audit the type of referral was unclear (WTA 228). The patient population of interest included those diagnosed with cancer in eight audits (WTA 195, 202-204, 208, 221, 224, 227) and seven audits looked at both patients diagnosed with cancer and those being referred (WTA 199, 212-215, 222, 223). The data were collected retrospectively in 24 audits (WTA 193-197, 199, 201-206, 208-212, 216, 224, 226-228, 230, 239), prospectively in eight audits (WTA 198, 200, 221, 225, 231-234) (1 of which had a before and after design (WTA 221)). The direction of the data capture was not stated or unclear in 11 audits (WTA 190-192, 207, 213-215, 217, 222, 223, 229).

Sixteen audits looked exclusively at urological cancers (single site) (WTA 190-205), whilst 27 audits examined multiple cancer sites (WTA 206-217, 221-234, 239).

Thirty-six audits reported some data on how eligible patients were identified and/or gave the data source (WTA 193-204, 206-210, 212-215, 217, 221-234). Two of these audits did not report separate data for urological cancer (WTA 221, 225). The results of the remaining 34 audits are summarised below. The other seven audits were not as well reported (WTA 190-192, 205, 211, 216, 239) and as such their results are considered to be less reliable. The results of these audits are therefore not discussed further.

The sample sizes ranged from 11 (WTA 203) to 150 (WTA 201) for the 12 single site audits (WTA 193-204) and 2 (WTA 208) to 1190 (WTA 222) for the 22 multiple site audits (when only considering urological cancers) (WTA 206-210, 212-215, 217, 222-224, 226-234).

Outcome measures

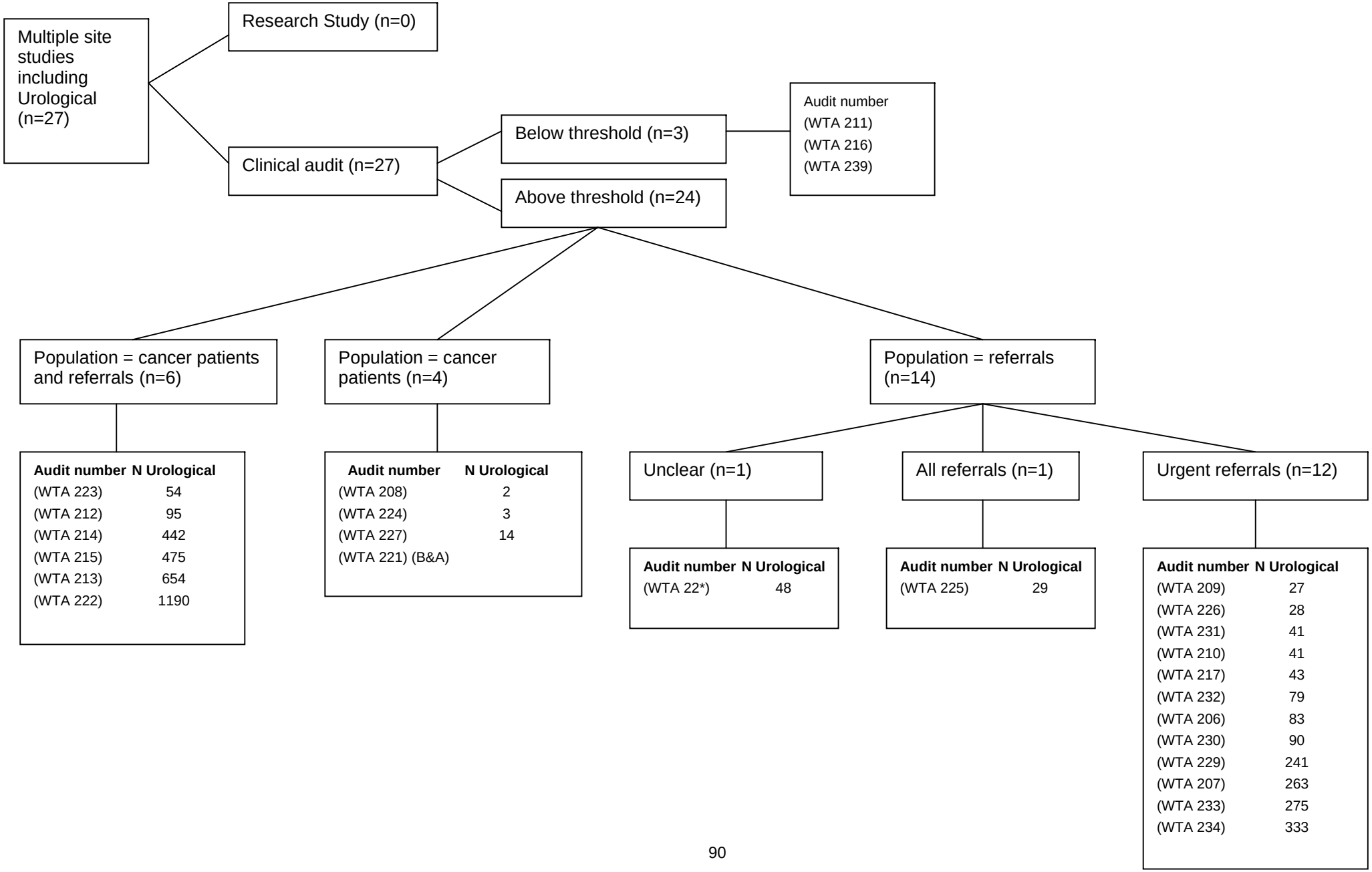
Waiting time to first appointment

Eight of the single site audits reported data on meeting the two-week wait criterion (WTA 196-200, 202-204). Two of these audits (WTA 202, 203) just looked at cancer patients so the results of these audits are reported separately. Seven of the multiple site audits reported data on meeting the two-week wait criterion (WTA 209, 210, 213-215, 227, 234). One of these audits (WTA 227) just looked at cancer patients so the results are reported separately.

Four of the single site audits examined a referral population only (one looked at only two-week wait referrals (WTA 196) and three looked at all referrals (WTA 197, 198, 200)) and one looked at both patients diagnosed with cancer and referrals (WTA 199). Three audits that included a referral population reported the number of two-week wait referred patients seen within 14 days of referral (WTA 196, 197, 199), the number of patients included in their analyses ranged from 3 (WTA 197) to 33 (WTA 196) and the percentage seen within two weeks ranged between 57% (WTA 199) and 100% (WTA 197). One of the audits reported that the median time between receipt of referral and specialist appointment was 14 days (n=30; range 3 to 32 days (WTA 199)) and one of the audits reported that 32/32 two-week wait referred patients received cystoscopy within two weeks, whilst the average time to

Multiple site urological cancer studies

Key: B&A = before and after study



cystoscopy for 32 routinely referred patients was 4.5 weeks (range 2 to 9 weeks (WTA 198)). The other audit, which included patients referred by their GP with a referral 'stating or implying a suspicion of cancer' did not report separate data for those specifically referred as two-week wait referrals (WTA 200). This audit reported that 13% of 82 patients were seen within 14 days and that the median time to appointment was 40 days (range 8 to 97 days). This audit also reported that 0/31 patients referred with suspected haematuria were seen within 14 days.

Three of the multiple site audits examined two-week wait referrals (WTA 209, 210, 234). The number of two-week wait referred patients that were analysed ranged from 26 (WTA 209) to 333 (WTA 234). The percentage seen within two weeks was 30% for one audit (WTA 209) and 100% for the other two (WTA 210, 234).

Three multiple site audits reported the proportion of two-week wait referred patients and non-two-week wait referred patients who were subsequently diagnosed with cancer, who were seen within two weeks of referral (WTA 213-215). The number of two-week wait referred cancer patients analysed ranged from 2 (WTA 213) to 11 (WTA 214) and the proportion seen within two weeks ranged from 45% (WTA 214) to 100% (WTA 213). The number of non-two-week wait referred cancer patients analysed ranged from 53 (WTA 215) to 89 (WTA 213) and the proportion seen within two weeks ranged from 16% (WTA 214) to 42% (WTA 215).

Three single site audits that included patients diagnosed with cancer reported the proportion of two-week wait referred patients seen within two weeks (WTA 199, 202, 203), their sample sizes ranged from 8 (WTA 203) to 47 (WTA 202) and the percentage seen within two weeks ranged from 58% (WTA 199) to 100% (WTA 202, 203). One of these audits (WTA 199) also reported that the average time from referral to first appointment for two-week wait referred patients was 14 days (n=12; range 3 to 32 days) and that 2/9 referrals with no indication of urgency were seen within two weeks, median time between referral and appointment was 20 days (range 12 to 41 days). Another of the audits (WTA 202) also reported the average time from referral to first appointment for all types of referral, incorporating upgrading or downgrading made by the urologist: the median time between referral and first appointment for two-week wait referrals was 9 days for bladder cancer (n=28; range 4 to 14 days), 11 days for renal cancer (n=9; range 1 to 35 days) and 10 days for prostate cancer (n=12; range 0 to 14 days). For urgent referrals the median for bladder cancer was 30 days (n=6; range 14 to 147 days), for renal cancer 39 days (n=5; range 14 to 63 days) and for prostate cancer 49 days (n=11; range 6 to 73 days). For 'soon' referrals the median time between referral and first appointment was 87 days for bladder cancer (n=2; range 60 to 113 days) and 70 days for prostate cancer (n=9; range 22 to 142 days). For routine referrals the median time was 72 days for bladder cancer (n=6; range 15 to 131 days) and 57 days for prostate cancer (n=8; range 36 to 265 days). For other/unmarked referrals the median time was 43 days for bladder cancer (n=5; range 4 to 50 days), 31 days for renal cancer (n=5; range 24 to 57 days) and was 55 days for prostate cancer (n=6; range 28 to 109 days (WTA 202)). Another single site audit that only looked at patients diagnosed with cancer reported that 43% of referrals were seen within 14 days of receipt of referral, although this did not relate specifically to two-week wait referrals. The median time between receipt of referral and specialist appointment was five days (range 0 to 44 days (WTA 204)).

One multiple site audit that only looked at patients diagnosed with cancer reported that all two-week wait referred patients (n=24) were offered an appointment with 14 days of referral, but they did not specify how many of these patients had urological cancers (WTA 227).

GP conformity to guidelines

GP conformity to the referral guidelines was evaluated by three single site audits that examined a referral population only (WTA 193, 196, 197), with patient numbers ranging from 4 (WTA 197) to 33 (WTA 196). The percentage of two-week wait referrals that were considered appropriate ranged from 70% (WTA 193) to 100% (WTA 197); when excluding the audit with only four patients, this ranged from 70% to 88% (WTA 196). One of the audits stated that macroscopic haematuria and testicular swellings were the most common

reasons for referral (WTA 196). One single site audit that examined a population of cancer patients also reported the appropriateness of two-week wait referrals according to the symptoms listed in the guidelines. The number of patients included was 48 and the percentage of two-week wait referrals that were considered appropriate was 45/48 (94%). The audit also reported that 35/73 (48%) non-two-week wait referrals had symptoms that met the two-week wait referral criteria (WTA 202).

Two single site audits reported the symptom each patient was referred for (WTA 194, 201), in one audit 78 patients were referred for haematuria, 19 for testicular swelling, four for renal mass and 33 for elevated PSA (which are all criteria for referral listed in the National Guidelines). Six additional patients were referred for an 'other' symptom, whilst 10 were referred for more than one symptom. The authors state that 24/61 two-week wait referrals that did not result in a diagnosis of cancer were judged to be inappropriate based on the criteria devised by the authors (WTA 201). The other audit reported the reasons for referral to be haematuria for 17 patients, age elevated PSA for eight patients, testicular lump for three patients and renal mass for two patients (which are all criteria for referral listed in the National Guidelines). No reason for referral was given for two patients. The authors state that 78% referrals were deemed appropriate based on the criteria devised by the authors (WTA 194).

GP conformity to the referral guidelines was evaluated by 12 multiple site audits looking at a referral population (WTA 207, 209, 210, 217, 222, 223, 226, 228-230, 233, 234), with the number of two-week wait referrals ranging from 2 (WTA 223) to 1190 (WTA 222), the number of patients was not reported for one audit (WTA 228). The percentage of two-week wait referrals that met the referral guidelines ranged from 50% (WTA 223) to 99% (WTA 222); when excluding the audit with only two patients, this ranged from 83% (WTA 228) to 99%. One audit also reported the appropriateness of non-two-week wait referrals, 94% (34/36) were appropriate (WTA 223).

Cancer detection

Data on cancer detection rates were reported by five single site audits that examined a referral population (WTA 194, 196-198, 201), including three audits that only examined two-week wait referrals (WTA 194, 196, 201) and two that evaluated all referrals (WTA 197, 198), and one single site audit that examined both a referral population and cancer patients (WTA 199). All six audits reported separate data for two-week wait referrals (WTA 194, 196-199, 201), the number of participants referred under the two-week wait rule that were included in the analyses ranged from 4 (WTA 197) to 150 (WTA 201), and the cancer detection rates ranged from 13% (4/32 (WTA 198)) to 40% (12/30 (WTA 199)). Only one audit specified the types of cancer patients were diagnosed with (WTA 199); three patients had bladder cancer, six patients had prostate cancer, one patient had bone metastases, one patient had transitional cell cancer and one patient had renal cancer.

Data on cancer detection rates were reported by 11 multiple site audits that examined referral populations and reported data for two-week wait referrals (WTA 206, 209, 210, 212, 222, 223, 226, 231-234). The number of participants referred under the two-week wait rule that were included in the analyses ranged from 2 (WTA 223) to 1190 (WTA 222), where stated, and the cancer detection rates ranged from 15% (WTA 234) to 50% (1/2 (WTA 223)). Excluding the audit with a patient sample of only two patients (WTA 223), the highest cancer detection rate was 26% (6/23 (WTA 212)).

One single site audit (WTA 198) reported that 5/32 (16%) patients who were referred routinely for frank haematuria were diagnosed with cancer. Another audit (WTA 197) reported that 8/46 (17%) referrals that were either categorised as 'urgent' (n=5) or 'non-urgent GP letter' (n=3), but were not two-week wait referrals, were diagnosed with cancer. The patient population for this audit was new patients referred to the urologists and identified by them as being urgent, therefore, the cancer rates reported are among those considered by the urologists to be urgent.

Three single site audits that examined a patient population that only included patients diagnosed with urological cancers reported the route of referral for those patients (WTA

195, 202, 203). In the first audit, which included 34 patients, five (15%) were referred via the two-week wait route (all were prostate cancers); 10 were referred by the GP as urgent, but not two-week wait (3 bladder cancers, 7 prostate cancers); 12 were referred routinely by the GP (6 bladder cancers, 4 prostate cancers, 1 renal cancer and 1 testicular cancer); three were routine consultant referrals; two were urgent consultant referrals; and two were emergencies (WTA 195). In another audit 8/10 (80%) testicular cancer patients had been referred via the two-week route of referral, one as an emergency and one via another consultant (WTA 203). In the final audit, 28/53 (53%) bladder cancers were referred under the two-week wait route, two as urgent, two as soon, 10 as routine, five were emergency admissions, three by other consultants, one was referred for follow-up and two were unmarked; 8/19 (42%) renal cell cancers were referred via the two-week wait route, two as urgent, one as routine, three were emergency admissions and five were referred by other consultants; 12/51 (24%) prostate cancers were referred via the two-week wait route, four as urgent, two as soon, 18 as routine, five were emergency admissions, four were referred by other consultants and six were unmarked (WTA 202).

Five multiple site audits that examined patient populations which included patients diagnosed with urological cancer reported the route of referral for those patients (WTA 208, 212, 222-224). The number of patients with cancer included in the analyses ranged from 2 (WTA 208) to 1036 (WTA 222) and the proportion who had been referred via the two-week wait referral route ranged from 0% (0/16 (WTA 223) to 100% (2/2 (WTA 208)). Excluding the two audits with patient samples of 2 (WTA 208) and 3 (WTA 224), the highest proportion of cancer patients who had been referred via the two-week route was 31% (4/13 (WTA 212)).

Appropriateness of the type of referral

One single site audit that examined a population of cancer patients (48 were referred as two-week wait referrals, 8 as urgent, 4 as soon, 29 as routine and 34 were non-GP referral) reported data on whether the urologist made changes to the priority of GP referrals. For bladder cancer patients one urgent referral was downgraded to routine, two 'soon' referrals were upgraded to urgent, two routine referrals were upgraded and two were downgraded and one unmarked referral was graded 'soon', for renal cancer no GP referrals were changed and for prostate cancer three routine referrals were upgraded to urgent and one routine referral was upgraded to 'soon' (WTA 202). Overall, none of the non-two-week wait referrals were reported to have been upgraded to two-week wait status and the authors did not report down grading any two-week wait referrals.

Four multiple site audits reported the proportion of two-week wait referrals that the clinician assessed as appropriate. The number of patients included in the analyses ranged from 41 (WTA 231) to 333 (WTA 234) and the proportion considered to be appropriate ranged from 78% (WTA 232) to 91% (WTA 234).

One audit, which examined a population of two-week wait referred patients, reported the proportion of such referrals where the hospital suspected cancer. The hospital suspected cancer for 1/11 bladder cancer referrals, 0/3 kidney cancer referrals, 4/7 prostate cancer referrals and 2/9 testicular cancer referrals (WTA 193).

One multiple site audit reported that 86% (24/28) of patients who were referred via the two-week wait referral system, had symptoms in clinic consistent with those on the GP referral form (WTA 226).

Ability of guidelines to identify correct referrals

One multiple site audit reported that 1/6 two-week wait referrals that did not meet the referral criteria was deemed to be clinically appropriate (WTA 210), and that this patient was not subsequently diagnosed with cancer.

Another multiple site audit reported that 25/28 (89%) two-week wait referrals were considered to be appropriate (had symptoms on proforma that were in line with guidelines) and that 20 patients who did not have malignancy had appropriate two-week wait referrals (WTA 226).

Process of referral
One single site audit reported the proportion of two-week wait referrals received by the hospital within 24 hours, which was 47/48 (98% (WTA 202)).

The time between the decision to refer and receipt of the referral by the hospital was reported by two multiple site audits (WTA 208, 210). One audit reported that all two-week wait referrals were received in 0-1 days (WTA 208), the other reported that 98% (40/41) two-week wait referrals were received within 24 hours, the other was received in 48 hours (WTA 210).

The mode of delivery of the referral was reported in two single site audits (WTA 199, 200). In the first audit the type of referral for those marked two weeks were as follows: trust proforma 53%, GP letter 23%, GP own proforma 13%, not recorded 10%; 50% were faxed and 50% posted (WTA 199). The other audit reported that none of the referrals were on the proforma, three were marked 'see within two weeks', seven were marked 'urgent' and had the possibility of cancer stated, seven had the possibility of cancer stated but were not marked 'urgent', 46 had the possibility of cancer implied and 19 had the possibility of cancer neither stated nor implied; 37% of the referral letters were faxed, the others were mailed.

Two audits reported whether referral proformas were completed correctly; one audit reported that 31% proformas were incorrectly completed (WTA 201), the other reported that 66% proformas were completed correctly (WTA 194).

Summary

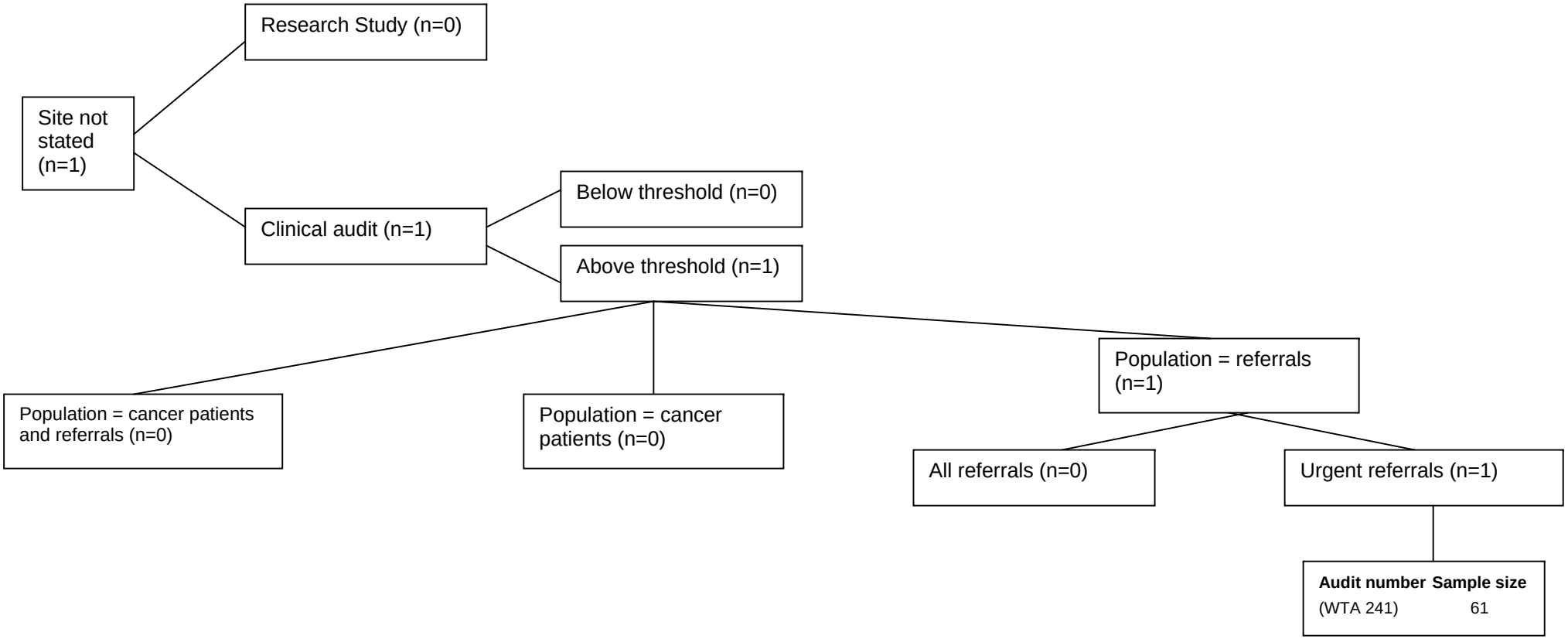
The proportion of patients referred under the two-week wait referral system and seen within two weeks ranged from 30% to 100% (seven audits that examined referred patients). The proportion of cancer patients who were referred under the two-week wait referral system and who were seen within two weeks ranged from 45% to 100% (seven audits that examined cancer patients). The proportion of two-week wait referrals that were found to be in accordance with the symptoms listed in the guidelines ranged from 70% to 99% (13 audits that examined referred patients, having excluded two audits with only 2 or 4 patients). The proportion of cancer patients who were referred under the two-week wait rule and that were in accordance with the symptoms listed in the guidelines was 94% (one audit that examined cancer patients).

The proportion of patients who were referred under the two-week wait referral system who were subsequently diagnosed with cancer ranged from 13% to 40% (15 audits, having excluded two audits with only 2 or 4 urological cancer patients). The proportion of patients with cancer who had been referred via the two-week wait referral system ranged from 0% to 39% (six audits, having excluded two audits with only 2 and 3 urological cancer patients).

The proportion of two-week wait referrals deemed to be appropriate according to the hospital clinician ranged from 78% to 91% (four audits). One audit reported that 1/6 (17%) of two-week wait referrals that did not meet the referral criteria were deemed to be clinically appropriate, none of which were subsequently diagnosed with cancer. One audit reported that 86% of patients who were referred via the two-week wait system had symptoms in clinic consistent with those on the GP referral form.

The proportion of referrals received by the hospital within one day of the GP's decision to refer ranged from 98% to 100% (three audits).

Individual cancer sites not reported



N.B. studies where the cancer site investigated was reported are included in the site specific flow charts.

MULTIPLE SITE AUDITS NOT REPORTED UNDER INDIVIDUAL CANCER SITES

Overview

Twelve multiple site audits that passed our quality threshold (provided some data on how eligible patients were identified and/or gave the data source) reported findings that could not be included in the sections reporting the results of individual cancer sites (WTA 208, 213-215, 221, 225, 227, 230, 235, 236, 238, 241). Three of these audits only report overall results for all included cancer sites (WTA 225, 227, 235 (one audit only looked at gastrointestinal cancers but did not differentiate between upper and lower (WTA 235)). Eight audits (WTA 208, 213-215, 221, 230, 236, 238) reported some findings that were not split according to individual cancer sites. One audit did not report which cancer site/sites were investigated (WTA 241). The sample size ranged from 36 (WTA 221) to 7740 (WTA 215).

Eight audits were conducted in general hospitals (WTA 208, 213-215, 227, 230, 235, 238), three in teaching hospitals (WTA 225, 236, 241), and one by a PCT (WTA 221).

Ten were categorised (in terms of the methodology used) as a clinical audit (WTA 208, 213-215, 221, 225, 227, 230, 236, 241) and two as a non-criterion based audit (WTA 235, 238).

Four audits evaluated patients that were referred to the department or trust, one of which examined all referrals (WTA 225) and three only included two-week wait referrals (WTA 230, 236, 241). The patient population of interest included those diagnosed with cancer in four audits (WTA 208, 221, 227, 238) and four audits looked at more than one patient population; patients referred and patients diagnosed with cancer (mixed patient population) (WTA 213-215, 235).

Results

Waiting time to first appointment

Nine audits reported data on meeting the two-week wait criterion, four of which looked at patients diagnosed with cancer (WTA 208, 221, 227, 238), one looked at two-week wait referrals (WTA 241) and four looked at a mixed patient population (WTA 213-215, 235). Six audits (WTA 208, 213-215, 221, 227) reported the proportion of patients diagnosed with cancer (referred as two-week wait) that were seen within two weeks, which ranged from 70% (14/20 (WTA 221)) to 96% (23/24 (WTA 227) or 44/46 (WTA 208)). One audit reported that of the 90 patients referred as two-week wait referrals, 54 (60%) were seen within two weeks (WTA 235). One audit of cancer patients reported the proportion of all referrals seen within two weeks (14/41 (WTA 238)). One audit of two-week wait referrals reported that 48/61 (79%) were seen within 14 days (WTA 241).

Four audits reported the proportion of patients diagnosed with cancer but not referred via the two-week wait system that were seen within two weeks of referral (WTA 208, 213-215). For three of these audits, the number of patients (referred via other routes) seen within two weeks ranged from 30% (166/390 (WTA 213)) to 51% (195/381 (WTA 215)). The fourth audit reported that 6/7 (86%) urgent (non-two-week wait) referrals were seen within two weeks and 0/15 routine referrals (WTA 208).

Three audits reported the median waiting time to first appointment, all included patients diagnosed with cancer (WTA 208, 227, 238). Two audits split the patients by type of referral: for two-week wait referrals this ranged from 8 (n=24 (WTA 227)) to 9 days (n=46 (WTA 208)). For urgent non two-week wait referrals it ranged from 8 (n=7 (WTA 208)) to 30 days (n=13 (WTA 227)), and for routine referrals it ranged from 38 (n=24 (WTA 227)) to 43 days (n=15 (WTA 208)). One audit also reported that the median time for referrals via other sources (n=27) was 5 days (WTA 208). The other audit reported a median of 25 days for all referrals (WTA 238).

GP conformity to guidelines/appropriateness of type of referral
One audit found that 195/301 (65%) two-week wait referrals were appropriate, based on the information given by the GP in the referral letter (WTA 225). Four of the referrals that did not conform to the guidelines were later deemed to be appropriate, based on the assessment by the hospital clinician. Of those deemed appropriate on reading the referral letter, 52 were considered inappropriate on seeing the patient. The same audit also reported that 59/66 non-two-week wait referrals were deemed to be appropriate based on the information given in the referral letter. The seven patients who should have been referred under the two-week wait system were still deemed to meet the referral criteria according to the hospital clinical assessment. Four of the non-two-week wait referrals that were considered appropriate based on the referral letter were considered inappropriate on seeing the patients at the hospital clinic.
One audit (that only included urgent referrals) reported that of the 50 referrals deemed inappropriate by clinicians, 24 were found to have been in accordance with the DoH guidelines (WTA 230).

Cancer detection
Three audits reported the cancer detection rates for patients referred under the two-week wait system: 3/61 (5% (WTA 241)), 8/90 (9% (WTA 235)) and 32/212 (15% (WTA 236)). However, this latter audit included a further 50 patients with an unconfirmed cancer diagnosis (awaiting results) and the final diagnosis was not known for a further 20 patients (excluding these patients the cancer diagnosis rate is 32/142, 23% (WTA 236)).

Five audits (WTA 208, 213-215, 227) that looked at patients diagnosed with cancer (3 included a mixed patient population (WTA 213-215)) reported the proportions that were referred via the two-week wait system. The number of patients included in the analyses ranged from 87 (WTA 227) to 782 (WTA 214) and the percentage referred under the two-week wait rule ranged from 15% (WTA 215) to 48% (WTA 208). Two of these audits listed the referral mode for non-two-week wait referrals (n=48 (WTA 208) and n=63 (WTA 227)). For one audit (WTA 208) this included 8 GP urgent (non-two-week wait) referrals and 15 routine referrals, and for the second audit (WTA 227) this included 13 GP urgent (non-two-week wait) referrals and 25 routine referrals.

One of the audits that included patients diagnosed with cancer, reported the method of referral for 37 patients with presenting symptoms that were in accordance with the guidelines: 24 were two-week wait referrals and 3 were referred as urgent but not two-week wait (7 were non-GP referrals) (WTA 227). The type of referral was not reported for three patients. A second audit (WTA 208) that looked at patients diagnosed with cancer reported that 8/15 routine referrals had symptoms that were in line with the guidelines for two-week wait referral (colorectal 2/7; gynaecological 3/4; upper GI 1/1; sarcoma 1/1; head and neck 1/1; breast 0/1).

Summary
When only looking at patients diagnosed with cancer, the proportion of patients referred under the two-week wait system that were seen within two weeks ranged from 70% to 96% (six audits), and for those not referred under the two-week wait system ranged from 27% to 51% (four audits).

The cancer detection rates among two-week wait referrals ranged from 5% to 18% (three audits). The percentage of cancer patients that were referred under the two-week wait system ranged from 15% to 48% (five audits).

One audit that included patients diagnosed with cancer reported that 8/15 routine referrals had symptoms that were in line with the guidelines for two-week wait referral. A second audit that also looked at patients diagnosed with cancer reported that of the 37 patients with presenting symptoms that were in line with the guidelines, 24 were referred as two-week wait referrals, 3 as urgent (not two-week wait) and 7 were non-GP referrals (the type of referral was not reported for three patients).

BEFORE AND AFTER AUDITS/STUDIES

Overview

Nineteen audits assessed the impact of the two-week wait policy by comparing clinical practice before and after the implementation of the guidelines (WTA 2, 21, 23, 33, 42, 43, 58, 73, 79, 82, 83, 97, 104, 134, 152, 168, 183, 218, 221).

Seven were categorised (in terms of the methodology used) as a clinical audit (WTA 2, 21, 33, 42, 43, 134, 221), three as a non-criterion based audit (WTA 23, 183, 218), and nine as a research study (WTA 58, 73, 79, 82, 83, 97, 104, 152, 168).

Eight audits evaluated patients that were referred to the department or trust: 6 of which examined all referrals (WTA 23, 33, 42, 79, 183, 218), 2 only included two-week wait referrals (WTA 21, 82). The patient population of interest included those diagnosed with cancer in nine audits (WTA 43, 58, 73, 97, 104, 134, 152, 168, 221) and two audits looked at both patients diagnosed with cancer and those being referred (WTA 2, 83).

The data were collected retrospectively in 10 audits (WTA 33, 43, 58, 73, 104, 134, 152, 168, 183, 218) and prospectively in eight audits (WTA 2, 21, 23, 42, 79, 82, 83, 221) (3 of which were partially prospective before and after (WTA 21, 42, 221)). The direction of the data capture was not stated in one audit (WTA 97).

Seventeen audits looked at a single cancer site (6 breast (WTA 2, 21, 23, 33, 42, 43), 5 lower GI (WTA 58, 73, 79, 82, 83), 3 skin (melanoma and squamous cell) (WTA 152, 168, 183), 2 upper GI (WTA 97, 104), and 1 head & neck (WTA 134)) and two audits examined multiple cancer sites (WTA 218, 221). The sample size ranged from 9 (WTA 152) to 5750 (WTA 43) (number of participants was not stated for one audit (WTA 2)) for single site audits and from 36 (WTA 221) to 13056 (WTA 218) for multiple site audits.

Fourteen audits reported some data on how eligible patients were identified and/or gave the data source, and are therefore considered to represent the most reliable findings; the results of which are summarised below (WTA 2, 21, 33, 43, 58, 73, 79, 82, 104, 134, 152, 168, 218, 221). However, due to the methodology used and poor reporting of the audits the interpretation of the results is limited. Those who analysed the data, in most cases, are likely to have been aware of who were referred prior to the implementation of the guidelines and who were referred after, which could lead to bias. Some of the audits used a post guideline time period during which the guidelines had only just been implemented.

The other five audits were not as well reported (WTA 23, 42, 83, 97, 183) and as such their results are considered to be less reliable. The results of these audits are therefore not discussed further.

Results

Waiting time to first appointment

Twelve audits (WTA 2, 21, 33, 43, 58, 73, 79, 104, 134, 152, 168, 221) compared waiting times to first appointment for patients referred before and after the implementation of the guidelines, two of which looked at both routine and urgent referrals (WTA 33, 79). (One further audit reported information on the average waiting time but the comparisons being made for pre and post data were not useful because for pre guidelines, the mean time was reported for all patients (21 days) and for post guidelines the information was reported separately for cancer patients (11 days) and non-cancer patients (25 days) (WTA 218)). Nine audits (WTA 2, 21, 43, 58, 79, 104, 152, 168, 221) found that a greater number of patients were seen within 14 days (WTA 2, 21, 43, 168, 221) or the average waiting time to first appointment was less (WTA 2, 43, 58, 79, 104, 152) for those that were referred or seen after the implementation of the guidelines. However, one of these audits (that included patients diagnosed with skin cancer) only included three patients that were seen after the implementation of the guidelines (WTA 152). Two of these audits (WTA 21, 79) examined a referral population, six (WTA 43, 58, 104, 152, 168, 221) included patients diagnosed with

cancer, and one audit looked at a mixed patient population (WTA 2). The remaining three audits (WTA 33, 73, 134) (two included patients diagnosed with cancer (WTA 73, 134)) found that patients who were seen prior to the guideline implementation had a shorter wait than those seen after the guidelines were introduced. One audit found that the median wait for patients not meeting the two-week wait criterion increased after the introduction of the guidelines (WTA 58).

GP conformity to guidelines
One audit (WTA 33) found that the urgency of the GP referral was not specified in a greater number of referrals received in 1998 (58%) than those received after the implementation of the guidelines (49%).

Cancer detection
Cancer rates for populations of referrals:
Three audits reported the proportion of patients referred as urgent (or two-week wait referrals) that were subsequently diagnosed with cancer (WTA 33, 79, 82). For one audit the cancer detection rate for urgent referrals was 21% both before (7/34) and after (5/24) the introduction of the guidelines (WTA 79). However, the cancer detection rate for two-week wait referrals in this audit was 15% (11/73), therefore, the cancer detection rate for both urgent and two-week wait referrals together was 16% (16/97) after the introduction of the guidelines, compared with 21% before. A second audit reported that 14/24 (58%) of cancer patients were referred as urgent prior to the guidelines and 16/29 (55%) after the introduction of the guidelines (WTA 33). One audit found that the rate of cancer diagnosed was slightly higher before the introduction of the guidelines (22%) than after (16%), but this difference was not found to be statistically significant (Chi-squared test) (WTA 82).

One audit also compared the proportion of routine referrals that were subsequently diagnosed with cancer, which was found to be marginally higher in those that were referred prior to the guidelines, but the number of included patients was small (WTA 79).

One audit (WTA 82) that compared 420 patients referred under the two-week wait system with 404 patients that were referred for limited colonoscopy prior to the implementation of the guidelines (whose referral met pre-specified criteria) found that a statistically significantly higher proportion of early stage neoplasia (including adenomatous polyps and Dukes' Stage A disease) were seen in the limited colonoscopy group than in the two-week wait group; 71 of 90 as compared with 26 of 69 (Chi-squared P <0.001).

Type of referral for populations of cancer patients:
One audit (WTA 168) reported data on the type of referral for patients diagnosed with cancer (malignant melanoma). In the earlier 15-month period (January 1999 to March 2000) 15/23 patients were referred as 'urgent' and 5 were referred as 'soon'. In the later 21-month period (April 2000 to December 2001) 52/77 patients were referred as 'urgent', 15 as 'soon' and 2 as 'routine' (33 were referred on 'yellow forms'). However, the referral guidelines for skin cancer were introduced by the DoH in October 2000.

Appropriateness of type of referral
One audit reported the proportion of patients that were categorised as urgent by breast specialists as well as the number of patients that were subsequently diagnosed with breast cancer (WTA 33). There was no real difference between the groups (referred in 1998 versus 1999) for either category. The proportion categorised as urgent was 80/299 (27%) in 1998 compared with 104/308 (34%) in 1999. The proportion categorised as urgent and subsequently diagnosed with cancer was 21/24 (88%) in 1998 compared with 27/29 (93%) in 1999.

Other outcome measures
One audit (WTA 104) that compared patients (with upper GI cancer) who were referred during the twelve months before with those referred during the fifteen months after the introduction of the guidelines reported 6-month survival data (urgent referrals: pre 25/41 versus post 19/41; routine referrals: pre 16/19 versus post 9/11).

Summary

Nine out of twelve audits found that a greater number of patients were seen within 14 days or the average waiting time to first appointment was less for those that were referred or seen after the implementation of the guidelines. Two of these audits examined a referral population, six included patients diagnosed with cancer, and one audit looked at a mixed patient population.

Overall there was no real difference in the proportion of patients referred as urgent that were subsequently diagnosed with cancer before and after the implementation of the guidelines (three audits). For one audit, a statistically significantly higher proportion of early disease was seen in the pre-guideline group than in the post-guideline group.

DISCUSSION

Identification of included clinical audits

We were always aware that conventional literature searches would not identify all potentially relevant clinical audits for our review and therefore tried to devise searching methods that would. In the initial stage of our search strategy we attempted to identify and contact all relevant organisations and individuals responsible for undertaking or commissioning audits (see Methods for full details).

We received a very positive response from the NHS to our request for clinical audits made during the initial stage of our search strategy (see Figure 1). An unexpectedly high number of individuals responded on behalf of their NHS organisation with information. We received responses from 85% (n=202) of Hospital Trusts and 54% (n=186) of PCTs in England.

Although the vast majority of audits were obtain by utilising the CRD SCP network, 8% (n=48) of the records identified in Stage 1 were obtained through contact with other individuals and organisations. The summary of the number of clinical audits received via the initial stage of our search strategy is somewhat simplistic because in many instances numerous follow-up contacts were necessary before we actually received any audits. In addition, the number of responses received from various individuals that were contacted does not correspond to the number of clinical audits that we received, or the number of audits conducted by each trust. Some individuals/organisations responded saying that they did not have any relevant audits, some individuals sent us more than one audit, and some contacts sent us numerous audits conducted by other trusts.

There were also instances when we received data about the same audit from multiple sources. Twenty-five audits were received twice (or in some cases three times) from different individual organisations. It was very difficult to identify duplicates, where more than one organisation or individual sent the same audit, as the authors and titles would often change. This was especially true for large-scale audits that involved multiple hospitals or GP practices or for example a health authority wide audit that included more than one hospital trust/PCT. Some of the individuals/organisations contacted sent us audits that were conducted by other trusts, which they were not part of. Some of the NHS Trusts sent us data relating only to their own trust, but did not always make it clear that the audit was also part of an area wide audit.

There were also some instances where the hospital trust responding to our request for information reported that they did not have any relevant audits, yet the local PCT subsequently sent us copies of clinical audit reports conducted by the hospital trust.

Many of the potentially relevant audits that we received were only available in abbreviated form, such as printed slide presentations or a single page of summary statistics. However, some of the audit reports were also accompanied by messages of willingness by various trusts to help with any queries or need for further information. Unfortunately, owing to the time constrains and the sheer number audits that we received we were unable to follow this up in most cases.

Stage 1 of the search strategy has highlighted the logistical difficulties of obtaining information from the NHS, and we cannot be sure that we have identified all potentially relevant clinical audits. Many trusts do not appear to hold a centralised record of what clinical audits have been performed within the trust, which should include those that did not involve the Clinical Audit Department. This was highlighted by the lack of duplication between the audits identified via personal contact with individual NHS hospital trusts and PCTs and those identified via electronic searching (including the search of databases of submitted conference proceedings). Furthermore, in theory, all audits identified via personal contact with members of the British Association of Dermatology should also have been highlighted via personal communication with the hospital trusts.

Setting for included audits

The vast majority of included audits (91%) were conducted in hospital settings (149 by general hospitals and 72 by teaching hospitals). Only six clinical audits were conducted in primary care. The fact that most audits appear to be secondary care led may reflect the fact that the referral guidelines do not explicitly state that primary care organisations should conduct audit. Rather, the referral guidelines state that NHS Trusts should develop clinical audit arrangements with PCTs to feed back information to GPs.

However, in addition to urgent referrals, the guidelines for suspected cancer are supposed to help the GP to identify those patients who require a routine referral to hospital and help reassure patients who are unlikely to have cancer and who can be appropriately observed in primary care. Assessments of whether all patients that should be referred by GPs are being referred would most appropriately be conducted in primary care.

Of those audits that were conducted by PCTs or health authorities, none examined whether all patients that should be referred by GPs (urgent / non-urgent) were being referred.

Quality of included audits

Being able to evaluate the quality of a clinical audit is central to informed decision making. The majority of included audits were poorly reported, with fewer than half (44%) providing sufficient detail on methodological aspects for the audit to be reproducible.

Poor reporting seriously compromises the integrity of the audit process. Many trusts do not appear to write up their audits in full. The reasons why they are not always formally documented may include the fact that clinical audits are often not published, and the audit process may be considered so familiar to those undertaking them that reporting methodological aspects is considered unnecessary. Audit reports should be written up in sufficient detail for a reader (who did not conduct the audit) to be able to ascertain how the audit was conducted.

Most of the included audits, even those available as a full report, did not report on issues such as detailing whether data collection and the population source were checked for accuracy, and details of how compliance with the audit criteria was assessed. Making such information available would allow for a better evaluation of the validity of the results.

It is worth noting that although the referral guidelines indicated that NHS Trusts were encouraged to carry out clinical audits of suspected cancer referrals, no supporting guidance on how best to conduct and report such audits was issued. The actual referral guidelines were vague and unprescriptive, and as a consequence front line health professionals have been left to conduct some form of audit as best they could. The National Clinical Audit Support Programme (NCASP), commissioned by the Healthcare Commission, is currently developing a programme of national clinical audits for breast, colorectal, head and neck and lung cancer treatments; all designed to measure performance against explicit and nationally agreed standards (full details available at: www.nhsia.nhs.uk/ncasp/pages/default.asp). Given the nature and quality of the audits presented in this review, it would seem that the methods by which clinical audits of site specific cancers are conducted and reported should also be standardised across the NHS.

In addition, most included audits chose to examine outcomes relating to the proportion of patients seen within two weeks and cancer detection rates among two-week wait referrals, when data on both of these outcomes are routinely collected as part of the monthly monitoring process. Other outcomes that could be considered pertinent, such as those listed below, were not evaluated by many of the included audits.

- Proportion of non-two-week wait referred patients that had symptoms in line with the guidelines.
- Cancer detection rates for two-week wait referrals that were in line with the guidelines
- Cancer detection rates for two-week wait referrals that were not in line with the guidelines

- Cancer detection rates for non-two-week wait referrals that were in line with the guidelines
- Proportion of two-week wait referrals that were not in line with the guidelines, but were deemed clinically appropriate
- Proportion of two-week wait referrals that were in line with the guidelines, but were deemed clinically inappropriate.

Overall findings of included audits and limitation of the data

There was wide variation in the findings of the included audits for all outcome measures (see Tables 3 and 4, that summarise the overall results of included audits), which seriously limits the interpretation of the summarised overall results. The diversity of the findings is not however, surprising bearing in mind that the included audits varied quite considerably in terms of their timing, sample size, the type of population examined, the type of sampling method used, type of outcomes or audit criteria being evaluated, and how adherence to the guidelines or appropriateness of referrals was assessed.

With the exception of the outcomes of proportion of two-week wait referrals that were seen within two weeks and the proportion of referrals that were found to be in accordance with the symptoms listed in the guidelines (which could in theory be measured by a controlled reproducible method) most of the outcome measures were subjective, and their assessment was mainly carried out by the hospital clinicians who may not be impartial to the findings.

Some of the included audits reported comparative data, for example before and after the introduction of the guidelines or two-week wait referrals versus routine referrals. However, audit data is observational in nature and is subject to numerous biases (Crombie, 1993). As such it can not provide proof that there is a 'real' difference between these comparisons, in other words no definitive comparison can be made between pre and post guideline data or between patients referred under or not under the two-week wait rule.

Are trusts making appropriate use of clinical audit?

As part of the referral guidelines for suspected cancer, the DoH recommended that hospital trusts should systematically evaluate the appropriateness of the referrals they receive against the explicit criteria.

There was wide variation across included audits in the proportion of site specific cancer referrals that were seen within two weeks, in the proportion of referrals that were found to be in accordance with the symptoms listed in the guidelines, and in the proportion of two-week wait referrals deemed by consultants to warrant an urgent appointment.

According to the guidelines, information should be fed back to individual GPs and PCTs on the appropriateness of their referrals. In this review, 70% of included audits provided no details on whether the results were or would be fed back to individual GPs and PCTs.

Where clinical audits indicate the need for changes to the process, procedure or the delivery of services, criterion based audit, as defined by NICE (see Appendix 4), involves ensuring that such changes are implemented and that further monitoring is used to confirm improvement in healthcare delivery.

In this review, less than 20% of included audits provided details of an action plan outlining any recommended changes to service delivery or how any changes would be implemented. Additionally fewer than 20% of included audits reported any plans to re-audit.

It is possible that owing to poor reporting, documentary evidence of action plans exist elsewhere and that any necessary changes to processes and procedures are being acted upon. Making such information available would make it easier for those not directly involved in the audit to assess if and in what ways the audit findings are being acted upon.

CONCLUSIONS

Most included clinical audits were poorly reported and their results demonstrated a wide variation in compliance with the guidelines.

Poor reporting can seriously compromise the integrity of the audit process.

Audit reports should be written up in sufficient detail to allow the reader to ascertain how the audit was conducted and to assess the validity of the results and how these will be used to improve existing practices and procedures.

The methods by which clinical audits of site specific cancers are conducted and reported should be standardised across the NHS.

REFERENCES

Crombie IK, Davies HTO, Abraham SCS, Foley C du V. Audit handbook: improving health care through clinical audit. Chichester: Wiley, 1993.

Department of Health. *The new NHS: modern, dependable.* London: The Stationery Office, 1997.

Department of Health. Referral guidelines for suspected cancer. London: Department of Health, 2000.

Kielhorn A, Graf von der Schulenburg J-M. *The health economics handbook*. 2nd ed. Chester: Adis International Ltd, 2000.

Millard AD. Measuring the quality of clinical audit projects. *Journal of Evaluation in Clinical Practice* 2000;6:359-70.

Morrell C, Harvey G. *The clinical audit handbook: improving the quality of health care*. London: Baillière Tindall, 1999.

National Institute for Clinical Excellence. *Principles for best practice in clinical audit*. Abingdon: Radcliffe Medical Press, 2002.

Naylor CD, Guyatt GH, for the Evidence-Based Medicine Working Group. Users' guides to the medical literature, XI: how to use an article about a clinical utilization review. *JAMA* 1996;275:1435-9.

NHS Executive. Breast cancer waiting times achieving the two-week wait target. *Health Service Circular* (HSC 1998/242) December 1998.

NHS Executive. Cancer waiting times achieving the two week target. *Health Service Circular* (HSC 1999/205) September 1999.

NHS Executive. Referral guidelines for suspected cancer. *Health Service Circular* (HSC 2000/013) April 2000.

NHS Executive. *Cancer information strategy*. London: Department of Health, 2000.

Wilson A, Grimshaw G, Baker R, Thompson J. Differentiating between audit and research: postal survey of health authorities' views. *BMJ* 1999;319(6):1235.

APPENDIX 1

Professional societies and organisations contacted for information

As part of our search strategy to identify relevant clinical audits, we contacted a number of professional societies and organisations for information. Here is a summary of the kind of response we received.

The following societies submitted audits for consideration:

- British Thyroid Association
- British Society of Gastroenterology
- The Royal College of Radiologists

The following societies replied to our request but did not have any audits which they thought were relevant:

- British Gynaecological Cancer Society
- British Thoracic Society
- Royal College of Surgeons of England
- Society for Endocrinology
- British Association of Head & Neck Oncologists
- British Association of Plastic Surgeons
- British Orthopaedic Association
- British Society for Haematology
- Faculty of Dental Surgery
- Royal College of General Practitioners
- Royal College of Obstetricians and Gynaecologists
- Royal College of Ophthalmologists
- Royal College of Paediatrics and Child Health
- Royal College of Pathologists
- Royal College of Radiologists
- The Association of Coloproctology of Great Britain and Ireland
- The Renal Association
- United Kingdom Children's Cancers Study Group

No reply was received from the following bodies:

- Association of Surgeons of Great Britain and Ireland
- British Association for Cancer Research
- British Association of Endocrine Surgeons
- British Association of Oral and Maxillofacial Surgeons
- British Association of Otorhinolaryngologists - Head And Neck Surgeons
- British Association Of Surgical Oncology
- British Association of Urological Surgeons
- British Institute of Radiology (BIR)
- British Oncology Data Managers Association
- British Society for Oral Medicine
- Faculty of General Dental Practitioners
- Royal College of Physicians of London
- The Pancreatic Society of Great Britain and Ireland
- Diagnostics Group DoH

The British Association of Dermatologists informed us that their secretary had previously submitted their relevant audit when contacted as a lead cancer clinician at his local trust. We were unable to contact the Association of Cancer Physicians of the UK.

APPENDIX 2

Detailed searches carried out to inform the review

1. Databases

1a. Health Management Information Consortium (HMIC)

This was searched via the ARC2 WebSPIRS service on 23/09/03. The dates searched were 1999 to 2003/09.

1. cancer* or neoplas* or oncology* or malignan* or tumo?r* or carcinoma* or adenocarcinoma* or sarcoma* *8187 records*
2. audit* *10285 records*
3. referral ADJ time* *5 records*
4. waiting ADJ times* *1052 records*
5. week ADJ wait* *14 records*
6. week* NEAR2 referral* *21 records*
7. urgent ADJ referral* *24 records*
8. urgent ADJ GP ADJ referral* *3 records*
9. fast ADJ track ADJ referral* *1 records*
10. referral* ADJ guideline* *46 records*
11. referring ADJ cancer* *0 records*
12. cancer ADJ referral* *11 records*
13. #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 or #12 *1147 records*
14. #1 and #2 and #13 *13 records*
15. #1 and #2 and #13 and PY:HQ >= 1999 or PY:HMIC >= 1999 *6 records*

Six records were identified.

1b. SIGLE

SIGLE was searched via the ARC2 WebSPIRS service on 23/09/03. The dates searched were 1999 to 2003/06.

1. cancer* or neoplas* or oncology* or malignan* or tumo?r* or carcinoma* or adenocarcinoma* or sarcoma* *5526 records*
2. audit* *3018 records*
3. referral ADJ time* *0 records*
4. waiting ADJ times* *69 records*
5. week ADJ wait* *0 records*
6. week* NEAR2 referral* *0 records*
7. urgent ADJ referral* *0 records*
8. urgent ADJ GP ADJ referral* *0 records*
9. fast ADJ track ADJ referral* *0 records*
10. referral* ADJ guideline* *4 records*
11. referring ADJ cancer* *0 records*
12. cancer ADJ referral* *2 records*
13. #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 or #12 *74 records*
14. #1 and #2 and #13 *1 record*
15. #1 and #2 and #13 and PY:SI >= 1999 *0 records*

No records were identified.

1c. ISI Proceedings: Science and Technology

This database was searched on the ISI Web of Knowledge Internet interface via MIMAS on 24/09/2003. The database was updated on 20 September 2003.

1. TS=cancer* or neoplas* or oncology* or malignan* or tumour* or tumor or carcinoma* or adenocarcinoma* or sarcoma* OR TI=cancer* or neoplas* or oncology* or malignan* or tumour* or tumor or carcinoma* or adenocarcinoma* or sarcoma* OR CF=cancer* or neoplas* or oncology* or malignan* or tumour* or tumor or carcinoma* or adenocarcinoma* or sarcoma* *89224 records*
2. TS=audit* OR TI=audit* OR CF=audit* *6720 records*
3. TS= referral time* OR TI= referral time* OR CF=referral time* *1 record*
4. TS= waiting times* OR TI= waiting times* OR CF= waiting times*
207 records
5. TS= week wait* OR TI= week wait* OR CF=week wait* *2 records*
6. TS=week* SAME referral* OR TI=week* SAME referral* OR CF=week* SAME referral* *15 records*
7. TS= urgent referral* OR TI= urgent referral* OR CF=urgent referral* *1 record*
8. TS= urgent GP referral* OR TI= urgent GP referral* OR CF=urgent GP referral* *0 records*
9. TS= fast track referral* OR TI= fast track referral* OR CF=fast track referral* *0 records*
10. TS= referral* guideline* OR TI= referral* guideline* OR CF=referral* guideline* *4 records*
11. TS= referring cancer* OR TI= referring cancer* OR CF=referring cancer*
0 records
12. TS= cancer referral* OR TI= cancer referral* OR CF=cancer referral*
9 records
13. #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12
235 records
14. #1 and #2 and #13 *2 records*

Two records were identified.

1d. Inside Conferences

Inside Conferences was searched using the Dialog search interface on the 24/09/2003. The search covered the period 1999 to September Week 3 2003.

1. s CT=cancer? or neoplas? or oncology? or malignan? or tumor? or tumour or carcinoma? or adenocarcinoma? or sarcoma? *38410 records*
2. s cancer? or neoplas? or oncology? or malignan? or tumor? or tumour or carcinoma? or adenocarcinoma? or sarcoma? *74892 records*
3. s s1 or s2 *75366 records*
4. s CT=audit? *1657 records*
5. s audit? *6335 records*
6. s s4 or s5 *6495 records*
7. s CT=referralwtime? *0 records*
8. s referralwtime? *1 record*
9. s CT=waitingwtimes? *0 records*
10. s waitingwtimes? *31 records*
11. s CT=weekwwait? *0 records*
12. s weekwwait? *7 records*
13. s CT=week?3nreferral? *0 records*
14. s week?3nreferral? *3 records*
15. s CT=urgentwreferral? *0 records*
16. s urgentwreferral? *0 records*
17. s CT=urgentwGPwreferral? *0 records*
18. s urgentwGPwreferral? *0 records*
19. s CT=fastwtrackwreferral? *0 records*
20. s fastwtrackwreferral? *0 records*
21. s CT=referral?wguideline? *0 records*

22. s referral?wguideline? *2 records*
23. s CT=referringwcancer? *0 records*
24. s referringwcancer? *0 records*
25. s CT=cancerwreferral? *0 records*
26. s cancerwreferral? *4 records*
27. s s7:s26 *45 records*
28. s s27 and s3 *15 records*
29. s s28 and s6 *2 records*
30. s s29.1999:2003 *2 records*
31. s s30.eng *2 records*

Two records were downloaded and saved as file WTAR-dialog65.txt.

1e. MEDLINE

11/12/2003 first search – identified 28 records from Ovid Medline. The search covered the period 1999 to November Week 2 2003. Results in file WTAR-medline-with audit.txt

Database: MEDLINE <1996 to November Week 2 2003>
Search Strategy:
---
1. exp Neoplasms/ *447178 records*
2. (cancer$ or neoplas$ or oncology$ or malignan$ or tumo?r$ or carcinoma$ or adenocarcinoma$ or sarcoma$).ti,ab. *414953 records*
3. 1 or 2 *539168 records*
4. audit$.ti,ab. *19774 records*
5. Utilization Review/ *1993 records*
6. 4 or 5 *21694 records*
7. referral time$.ti,ab. *29 records*
8. waiting time$.ti,ab. *1243 records*
9. (two week wait$ or 2 week wait$).ti,ab. *10 records*
10. (two week$ adj2 referral$).ti,ab. *15 records*
11. urgent referral$.ti,ab. *43 records*
12. urgent GP referral$.ti,ab. *0 records*
13. fast track referral$.ti,ab. *4 records*
14. referral guideline$.ti,ab. *62 records*
15. (referring adj2 cancer$).ti,ab. *18 records*
16. cancer referral$.ti,ab. *47 records*
17 or/7-16 *1451 records*
18 3 and 6 and 17 *34 records*
19 limit 18 to (human and english language and yr=1999-2004) *28 records*

11/12/2003 second search. 195 records were downloaded into WTAR-medline.enl and saved in file WTAR-medline.txt. The search covered the period 1999 to November Week 2 2003.

Database: MEDLINE <1996 to November Week 2 2003>
Search Strategy:
---
1. exp Neoplasms/ *447178 records*
2. (cancer$ or neoplas$ or oncology$ or malignan$ or tumo?r$ or carcinoma$ or adenocarcinoma$ or sarcoma$).ti,ab. *414953 records*
3. 1 or 2 *539168 records*
4. referral time$.ti,ab. *29 records*
5. waiting time$.ti,ab. *1243 records*
6. (two week wait$ or 2 week wait$).ti,ab. *10 records*
7. (two week$ adj2 referral$).ti,ab. *15 records*
8. urgent referral$.ti,ab. *43 records*
9. urgent GP referral$.ti,ab. *0 records*
10. fast track referral$.ti,ab. *4 records*

11. referral guideline$.ti,ab. *62 records*
12. (referring adj2 cancer$).ti,ab. *18 records*
13. cancer referral$.ti,ab. *47 records*
14. or/4-13 *1451 records*
15. 3 and 14 *267 records*
16. limit 15 to (human and english language and yr=1999-2004) *195 records*

After further exploration the final strategy used with MEDLINE, EMBASE and CancerLit was the second MEDLINE search reported above. Identifying thesaurus/keyword terms used to index journal articles received through our correspondence with relevant organisations and individuals, showed that relevant studies did not necessarily include the term 'audit'. A decision was taken not to limit the search by the terms *audit$* or *Utilization Review/* and they were removed from the strategy.

1f. EMBASE

EMBASE was searched via the Ovid interface on the web on 12/12/2003. The dates searched were 1999 to 2003 Week 49.

Search Strategy:

---

1 exp Neoplasms/ *462165 records*
2 (cancer$ or neoplas$ or oncology$ or malignan$ or tumo?r$ or carcinoma$ or adenocarcinoma$ or sarcoma$).ti,ab. *410378 records*
3 1 or 2 *546904 records*
4 referral time$.ti,ab. *26 records*
5 waiting time$.ti,ab. *1084 records*
6 (two week wait$ or 2 week wait$).ti,ab. *15 records*
7 (two week$ adj2 referral$).ti,ab. *10 records*
8 urgent referral$.ti,ab. *38 records*
9 urgent GP referral$.ti,ab. *0 records*
10 fast track referral$.ti,ab. *6 records*
11 referral guideline$.ti,ab. *55 records*
12 (referring adj2 cancer$).ti,ab. *17 records*
13 cancer referral$.ti,ab. *45 records*
14 or/4-13 *1274 records*
15 3 and 14 *254 records*
16 limit 15 to (human and english language and yr=1999-2004) *185 records*

185 records were downloaded and saved in file WTAR-embase.txt.

1g. CancerLit

CancerLit was searched via the SilverPlatter CD-ROM. The dates searched were 1999 to 2002/09.
Note: CancerLit is a closed database, as of 4 April 2003.

15/12/2003 search on the CancerLit CD-ROM (2002/04 - 2002/09) identified 43 records. Results in file WTAR-cancerlit1.txt. Created new Endnote library: WTAR-cancerlit.enl.

Search Strategy:

No.	Records	Request
1	34011	(cancer* or neoplas* or oncology* or malignan* or tumo?r* or carcinoma* or adenocarcinoma* or sarcoma*) in ti,ab
2	2	referral time* in ti,ab
3	41	waiting time* in ti,ab
4	1	(two week? wait* or 2 week? wait*) in ti,ab
5	3	(two week* near referral*) in ti,ab
6	2	urgent referral* in ti,ab

7	0	urgent GP referral* in ti,ab
8	1	fast track referral* in ti,ab
9	2	referral guideline* in ti,ab
10	11	(referring near cancer*) in ti,ab
11	5	cancer referral* in ti,ab
12	65	#2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
13	47	#1 and #12
14	46	#13 and (PY = 1999-2004)
* 15	43	#14 and (LA = "ENGLISH")

15/12/2003 search on the CancerLit CD-ROM (2001 - 2002/03) identified 68 records. The records were downloaded and deduplicated into WTAR-cancerlit.enl. Results in file WTAR-cancerlit2.txt.

Search Strategy:

No.	Records	Request
1	97890	(cancer* or neoplas* or oncology* or malignan* or tumo?r* or carcinoma* or adenocarcinoma* or sarcoma*) in ti,ab
2	3	referral time* in ti,ab
3	71	waiting time* in ti,ab
4	3	(two week? wait* or 2 week? wait*) in ti,ab
5	11	(two week* near referral*) in ti,ab
6	2	urgent referral* in ti,ab
7	0	urgent GP referral* in ti,ab
8	0	fast track referral* in ti,ab
9	4	referral guideline* in ti,ab
10	16	(referring near cancer*) in ti,ab
11	20	cancer referral* in ti,ab
12	117	#2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
13	80	#1 and #12
14	77	#13 and (LA = "ENGLISH")
* 15	68	#14 and (PY = 1999-2004)

15/12/2003 search on the CancerLit CD-ROM (1999 - 2000) identified 43 records. The records were downloaded and deduplicated into WTAR-cancerlit.enl. Results in file WTAR-cancerlit3.txt.

Search Strategy:

No.	Records	Request
1	77584	(cancer* or neoplas* or oncology* or malignan* or tumo?r* or carcinoma* or adenocarcinoma* or sarcoma*) in ti,ab
2	2	referral time* in ti,ab
3	36	waiting time* in ti,ab
4	1	(two week? wait* or 2 week? wait*) in ti,ab
5	1	(two week* near referral*) in ti,ab
6	5	urgent referral* in ti,ab
7	0	urgent GP referral* in ti,ab
8	1	fast track referral* in ti,ab
9	3	referral guideline* in ti,ab
10	10	(referring near cancer*) in ti,ab
11	8	cancer referral* in ti,ab
12	64	#2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
13	46	#1 and #12
14	43	#13 and (LA = "ENGLISH")
* 15	43	#14 and (PY = 1999-2004)

2. Project registers

2a. National Research Register

Issue 3/2003 of the NRR was searched on the Internet.

The search strategy was:

1. cancer* or neoplas* or oncology* or malignan* or tumour* or tumor* or carcinoma* or adenocarcinoma* or sarcoma* *18664 records*
2. audit* *1683 records*
3. referral NEXT time* *3 records*
4. waiting NEXT times* *96 records*
5. week NEXT wait* *6 records*
6. week* NEAR referral* *20 records*
7. urgent NEXT referral* *4 records*
8. urgent NEXT GP NEXT referral* *0 records*
9. fast NEXT track NEXT referral* *0 records*
10. referral* NEXT guideline* *8 records*
11. referring NEXT cancer* *0 records*
12. cancer NEXT referral* *7 records*
13. #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 or #12 *138 records*
14. #1 and #2 and #13 *4 records*

One record of ongoing research was downloaded and saved as file NRR.txt.

2b. ReFER *http://www.doh.gov.uk.research.rd3.information.findings.htm#refer*

The Department of Health's Research Findings electronic Register (ReFeR) was searched on 22/09/2003 using the following search terms:

cancer* and audit*

No relevant research findings were found.

3. Internet

The following Internet sources were searched on 22/09/2003:

- NICE (in particular the Clinical Excellence conferences) http://www.nice.org.uk
- Department of Health's cancer web pages http://www.doh.gov.uk.cancer.index.htm
- Modernisation Agency http://www.modern.nhs.uk and its Cancer Services Collaborative (CSC) http://www.modern.nhs.uk.scripts.default.asp?site_id=26&id=5620
- NHS Information Authority http://www.nhsia.nhs.uk.def.home.asp and its Cancer Information Services http://www.nhsia.nhs.uk.cancer.pages and National Clinical Audit Support Programme http://www.nhsia.nhs.uk.phsmi.pages.ncasp.asp?om=m1
- Public Health Observatories http://www.pho.org.uk
- Commission for Health Improvement http://www.chi.nhs.uk
- National Electronic Library for Health http://www.nelh.nhs.uk
- National electronic Library for Cancers http://www.nelc.org.uk
- HOWIS: website of NHS Wales http://www.wales.nhs.uk
- Health & Care NI: the official website for Health and Social Care Services in Northern Ireland http://www.n-i.nhs.uk

No relevant documents were identified.

- Prodigy http://www.prodigy.nhs.uk
- NHS Scotland http://www.show.scot.nhs.uk

Two relevant documents were identified and downloaded.

The following Internet sources were searched on 25/09/2003:

- Clinical Governance R&D Unit CGRDU http://www.le.ac.uk.cgrdu and its Journal of Clinical Governance http://www.le.ac.uk.cgrdu.jclingov.html
- Health Service Management Centre Library Catalogue http://www.bham.ac.uk.hsmc.library.opac.index.htm
- RCN Library Catalogue http://rcn-library.rcn.org.uk.uhtbin.webcat
- Royal Society of Medicine Library Catalogue http://www.roysocmed.ac.uk.librar.libcat.htm

No relevant documents were identified.

4. Email discussion lists

A request for unpublished audits was posted on the following Email discussion lists:

- LIS-HLN@JISCMAIL.AC.UK
- LIS-MEDICAL@JISCMAIL.AC.UK
- CANCER-NURSING-ALLIANCE@JISCMAIL.AC.UK
- GP-UK@JISCMAIL.AC.UK
- HEALTH-SERVICES-RESEARCH@JISCMAIL.AC.UK
- C.H.A.I.N. (Contacts, Help, Advice and Information Network) http://chain.ulcc.ac.uk/chain/chain.htm

Forty responses were received, 35 of which were from CHAIN.

APPENDIX 3

Data extraction/quality checklist tool for included audits/studies

Study identification
Author: Year: ENL No:

Name of institution:

Type of institution:

Department undertaking the audit:

Cancer site:

Categorisation according to study methodology: *clinical audit, non-criterion based clinical audit, research study, or other*

1. Involvement
Is there any evidence that the project involved or consulted those providing the service?

Who was involved in the audit? In what way were they involved? And at what stages of the audit project were they involved?

2. Aims
Were the reasons for undertaking the audit project clearly and explicitly stated?

What were the aims and objectives of the audit?

3. Project plan
Was a clear plan reported which explicitly set out the methods of the audit well enough for the audit to be repeated, including definition of patients, aspects of care under review and the time period over which criteria apply?

4. Additional process outcomes/audit criteria (other than those relating to the 2-week wait policy)
What additional process outcomes were measured?

Were these process outcomes assessed using pre-specified criteria?
If so, a) what criteria were used? b) how were they developed?

5. Sample
What was the sample/patient population used in the audit?

Sample size

What source(s) was used to identify patients?

Has this source been tested for completeness and accuracy?

Was a random sample or consecutive series used?

Was the sample appropriate, given the aims of the study?
Were explicit inclusion criteria used?

6. Data collection

What was the source of the data?

Was the source of the data checked for accuracy?

Were the data collection tools carefully designed, and piloted or tested before use?

How were the data collected?
e.g. one person extracting the data using a predefined form and then this is checked by another.

Was there consideration of the validity and reliability of data collection, including inter- and intra-rater reliability?

How was the validity and reliability of data collection assessed?

What was the timeframe for the audit?

Was the audit timeframe justified by the authors?

Was the audit data collection prospective or retrospective?

7. Applying the criteria

What process was used for applying the criteria?
e.g. audit assistant deciding which patients fail the criterion and then a clinician going through all the fails, giving reason why some are not true failures.

Was the process of applying the criteria unbiased and therefore likely to yield robust conclusions?

8. Data analysis/report writing

Were adequate data reported?
(i) Did the authors report (in terms of the results) what they set out to analyse?
(ii) Was there enough information provided to follow the process of analysis and assess the author's conclusions?
If the answer to either of these questions is no, then an explanation, if necessary, should be added in the commentary section.

How were the data analysed?
e.g descriptive statistics.

Were data analysed appropriately?
e.g. were the correct statistical analyses used, were the denominators or numerators used for calculating percentages appropriate.

Were all patients accounted for?

Was the interpretation of results fair?

9. Results

What were the results of the audit in relation to two week wait referrals?

- Percentage meeting 2-week target
- Appropriateness of referral
- Related outcomes (e.g. survival)

10. Impact

How were the results communicated to the stakeholders?

Did the project result in an agreed action plan which explicitly set out the changes to services/areas which had been agreed and how they were to be implemented, set a timescale for their implementation, and assign individual responsibility for each change?
Did the project include effective reauditing or plans to undertake one?

11. Cost

What were the approximate direct costs of undertaking the audit project including both clinician and audit staff time costs but excluding minor/negligible costs, overheads and the cost consequences of any changes resulting from the project?

12. Comments

Any additional information that is considered useful, but not covered by the above questions will be reported.

APPENDIX 4

Definitions of different study types (categorisation for methodology)

A strict definition of clinical audit was not used as an inclusion criterion, and therefore any study where the authors stated they had conducted an audit was considered. However, for the purpose of this review, included studies have been classified, according to study methodology, as a clinical audit, non-criterion based clinical audit, research study, or other. The following definitions were used to aid the categorisation of studies.

Clinical audit
There are various definitions for clinical audit, but for the purpose of this review the definition endorsed by the National Institute of Clinical Excellence (NICE) was used as representing the ideal audit methodology, which includes the comparison of care with explicit pre-defined criteria (criterion based audit):

'Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care *against explicit criteria* and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery' (National Institute of Clinical Excellence, 2002).

Audit criteria
Systematically developed statements that can be used to assess specific health care decisions, services and outcomes. They should be clinically relevant, clearly defined and easily measured.

Non-criterion based clinical audit:
Any clinical audit that does not use a set of predefined criteria that define optimal care to measure good practice. Examples include: an audit where cases of poor management or serious adverse events are discussed; or one that simply describes what is happening within a specific clinical setting over a certain period of time.

However, because only clinical audits/studies that evaluated the DoH waiting time policy (which includes pre specified optimal standards of care) have been included in the review it could be argued that all included clinical audits were criterion-based. However, our main reason for categorising the audits was to identify the better quality audits. Therefore, for the purpose of this review, if the authors of the audit did not specify within their objectives, methods or results section the actual element of the two-week wait standard which was being investigated, then it has been categorised as a 'non-criterion based audit'. If, on the other hand, it did pre-specify at least one of the elements of the two-week wait standard (e.g. 100% of two-week wait referrals must be received by the trust within 24 hours of GP decision to refer; or all patients referred under the two-week wait rule must be seen within two weeks of the Trust's receipt of referral), then it was categorised as a 'criterion based audit'.

Research study
Systematic investigation to establish facts or collect information on a subject (Collins English dictionary, 2000).

Differentiating between audit and research
A useful distinction reported by Wilson et al is that of the motivation and objective of the project: audit has the objective of directly improving services against a standard; research may include the objective of defining best practice (Wilson, et al 1999).

Monitoring
'Monitoring' implies keeping track of, regulating or controlling. It can be used in many contexts, such as ongoing measurement of the performance of health services or health professionals; in management, it is the overseeing of input deliveries, work schedules and target outputs. (Kielhorn and Graf von der Schulenburg, 2000).

References

Collins compact English dictionary. Glasgow: Harper Collins, 2000.
Kielhorn A, Graf von der Schulenburg J-M. *The health economics handbook*. 2nd ed. Chester: Adis International Ltd, 2000.

National Institute for Clinical Excellence. *Principles for best practice in clinical audit*. Abingdon: Radcliffe Medical Press, 2002.

Wilson A, Grimshaw G, Baker R, Thompson J. Differentiating between audit and research: postal survey of health authorities' views. *British Medical Journal* 1999;319(6):1235.