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The research reported in this issue of the journal was commissioned by the HTA programme as project number 06/84/01. The contractual start date was in January 2008. The draft report began editorial review in February 2011 and was accepted for publication in May 2012. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design.The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

What is the value of routinely testing full blood count, electrolytes and urea, and pulmonary function tests before elective surgery in patients with no apparent clinical indication and in subgroups of patients with common comorbidities: a systematic review of the clinical and cost-effective literature

C Czoski-Murray,[1]* M Lloyd Jones,[2] C McCabe,[1] K Claxton,[3] Y Oluboyede,[1] J Roberts,[1] JP Nicholl,[2] A Rees,[2] CS Reilly,[4] D Young[5] and T Fleming[6]

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Background: The evidence base which supported the National Institute for Health and Clinical Excellence (NICE) published Clinical Guideline 3 was limited and 50% was graded as amber. However, the use of tests as part of pre-operative work-up remains a low-cost but high-volume activity within the NHS, with substantial resource implications. The objective of this study was to identify, evaluate and synthesise the published evidence on the clinical effectiveness and cost-effectiveness of the routine use of three tests, full blood counts (FBCs), urea and electrolytes tests (U&Es) and pulmonary function tests, in the pre-operative work-up of otherwise healthy patients undergoing minor or intermediate surgery in the NHS.

Objective: The aims of this study were to estimate the clinical effectiveness and cost-effectiveness of routine pre-operative testing of FBC, electrolytes and renal function and pulmonary function in adult patients classified as American Society of Anaesthesiologists (ASA) grades 1 and 2 undergoing elective minor (grade 1) or intermediate (grade 2) surgical procedures; to compare NICE recommendations with current practice; to evaluate the cost-effectiveness of mandating or withdrawing each of these tests in this patient group; and to identify the expected value of information and whether or not it has value to the NHS in commissioning further primary research into the use of these tests in this group of patients.

Data sources: The following electronic bibliographic databases were searched: (1) BIOSIS; (2) Cumulative Index to Nursing and Allied Health Literature; (3) Cochrane Database of Systematic Reviews; (4) Cochrane Central Register of Controlled Trials; (5) EMBASE; (6) MEDLINE; (7) MEDLINE In-Process & Other Non-Indexed Citations; (8) NHS Database of Abstracts of Reviews of Effects; (9) NBS Health Technology Assessment Database; and (10) Science Citation Index. To identify grey and unpublished literature, the Cochrane

Register of Controlled Trials, National Research Register Archive, National Institute for Health Research Clinical Research Network Portfolio database and the Copernic Meta-search Engine were searched. A large routine data set which recorded the results of tests was obtained from Leeds Teaching Hospitals Trust.

Review methods: A systematic review of the literature was carried out. The searches were undertaken in March to April 2008 and June 2009. Searches were designed to retrieve studies that evaluated the clinical effectiveness and cost-effectiveness of routine pre-operative testing of FBC, electrolytes and renal function and pulmonary function in the above group of patients. A postal survey of current practice in testing patients in this group pre-operatively was undertaken in 2008. An exemplar cost-effectiveness model was constructed to demonstrate what form this would have taken had there been sufficient data. A large routine data set that recorded the results of tests was obtained from Leeds Teaching Hospitals Trust. This was linked to individual patient data with surgical outcomes, and regression models were estimated.

Results: A comprehensive and systematic search of both the clinical effectiveness and cost-effectiveness literature identified a large number of potentially relevant studies. However, when these studies were subjected to detailed review and quality assessment, it became clear that the literature provides no evidence on the clinical effectiveness and cost-effectiveness of these specific tests in the specific patient groups. The postal survey had a 17% response rate. Results reported that in ASA grade 1, patients aged <40 years with no comorbidities undergoing minor surgery did not have routine tests for FBC, electrolytes and renal function and pulmonary function. The results from the regression model showed that the frequency of test use was not consistent with the hypothesis of their routine use. FBC tests were performed in only 58% of patients in the data set and U&E testing was carried out in only 57%.

Limitations: Systematic searches of the clinical effectiveness and cost-effectiveness literature found that there is no evidence on the clinical effectiveness or cost-effectiveness of these tests in this specific clinical context for the NHS. A survey of NHS hospitals found that respondent trusts were implementing current NICE guidance in relation to pre-operative testing generally, and a de novo analysis of routine data on test utilisation and post-operative outcome found that the tests were not be used in routine practice; rather, use was related to an expectation of a more complex clinical case.

The paucity of published evidence is a limitation of this study. The studies included relied on non-UK health-care systems data, which may not be transferable. The inclusion of non-randomised studies is associated with an increased risk of bias and confounding. Scoping work to establish the likely mechanism of action by which tests would impact upon outcomes and resource utilisation established that the cause of an abnormal test result is likely to be a pivotal determinant of the cost-effectiveness of a pre-operative test and therefore evaluations would need to consider tests in the context of the underlying risk of specific clinical problems (i.e. risk guided rather than routine use).

Conclusions: The time of universal utilisation of pre-operative tests for all surgical patients is likely to have passed. The evidence we have identified, though weak, indicates that tests are increasingly utilised in patients in whom there is a reason to consider an underlying raised risk of a clinical abnormality that should be taken into account in their clinical management. It is likely that this strategy has led to substantial resource savings for the NHS, although there is not a published evidence base to establish that this is the case. The total expenditure on pre-operative tests across the NHS remains significant. Evidence on current practice indicates that clinical practice has changed to such a degree that the original research question is no longer relevant to UK practice. Future research on the value of these tests in pre-operative work-up should be couched in terms of the clinical effectiveness and cost-effectiveness in the identification of specific clinical abnormalities in

patients with a known underlying risk. We suggest that undertaking a multicentre study making use of linked, routinely collected data sets would identify the extent and nature of pre-operative testing in this group of patients.

Funding: The National Institute for Health Research Health Technology Assessment programme.

Contents

Glossary

Allodynia Excessive sensitivity to stimuli which does not usually cause pain.

Anterior interosseous syndrome Flexion weakness of the thumb, index finger and sometimes the middle finger, with pronation weakness with flexed elbow; often associated with acute local trauma. (Saeed MA, Gatens PF. Anterior interosseous nerve syndrome: unusual etiologies. *Arch Phys Med Rehabil* 1983;**64**:182.)

Bradycardia Slow heart rate.

Causalgia A persistent burning, shooting pain in a specific peripheral nerve distribution. (Horowitz SH, Horowitz SH. Venipuncture-induced causalgia: anatomic relations of upper extremity superficial veins and nerves, and clinical considerations. *Transfusion* 2000;**40**:1036–40.)

Convulsive syncope Loss of consciousness with tonic–clonic movements.

Diaphoresis Excessive sweating.

Haematocrit The proportion of blood volume occupied by red blood cells.

Hyperpathia Excessive sensitivity to painful stimuli.

Hypotension Abnormally low blood pressure.

Pneumomediastinum Leakage of air into the mediastinum.

Pneumoparotid Enlargement of the parotid gland because of a reflux of pressurised air from the mouth.

Pronation Rotational movement of the forearm at the radioulnar joint without an associated movement at the shoulder. [*Wikipedia Pronation*. Wikipedia. 2009. URL: http://en.wikipedia.org/wiki/Mediastinum (accessed May 2009).]

Syncope Fainting, loss of consciousness.

List of abbreviations

APEC	Anaesthesia Preoperative Evaluation Clinic
ASA	American Society of Anaesthesiologists
CBC	complete blood count
CCSD	Clinical Coding and Schedule Development
CENTRAL	Cochrane Central Register of Controlled Trials
CG3	Clinical Guideline 3
CI	confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
Coags	tests of coagulation
CPM	calcium, phosphate and magnesium
CRD	Centre for Reviews and Dissemination
DARE	Database of Abstracts of Reviews of Effects
ECG	electrocardiography
ECU	European currency unit
EUC	electrolytes, urea and creatinine
EVI	expected value of information
FEV_1	forced expiratory volume in 1 second
FBC	full blood count
G&H	group and hold test
Hb	haemoglobin
HTA	Health Technology Assessment
LFT	liver function test
NHS EED	NHS Economic Evaluation Database
NICE	National Institute for Health and Clinical Excellence
PAC	pre-admission clinic
PAS	patient administration services
PE_{max}	maximum static expiratory
PFT	pulmonary function test
QUOROM	quality of reporting of meta-analyses
RCT	randomised controlled trial
SCI	Science Citation Index
TFT	thyroid function test
UA	urine analysis
U&E	urea and electrolytes test

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has only been used once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure or table legend.

Executive summary

Background

In 2003 the National Institute for Health and Clinical Excellence (NICE) published Clinical Guideline 3, which reviewed the use of routine pre-operative tests prior to routine surgery. Prior to the guideline preparation, a systematic review was undertaken by Munro *et al.* [Munro J, Booth A, Nicholl J. Routine preoperative testing: a systematic review of the evidence. *Health Technol Assess* 1997;**1**(12)] on behalf of the Health Technology Assessment programme in 1997. The guideline development group undertook their own review of the literature. These two reviews defined and updated the purpose of pre-operative testing of apparently healthy patients.

Of the evidence base used to produce the guideline, >50% was graded as amber (i.e. the benefit of the test was unknown). Therefore, despite the existence of some primary research, the evidence on which to base pre-operative testing protocols was inconclusive. Alongside this there has been an increasing awareness of the possibility of subjecting patients to unnecessary tests, and of the issues involved in dealing with the results of tests that may alarm patients but have little clinical significance.

Aims and objectives

The aims of this study were to estimate the clinical effectiveness and cost-effectiveness of routine pre-operative testing of full blood count (FBC), electrolytes and renal function [urea and electrolytes test (U&E)] and pulmonary function [pulmonary function test (PFT)] in adult patients classified as American Society of Anaesthesiologists (ASA) grades 1 and 2 undergoing elective minor (grade 1) or intermediate (grade 2) surgical procedures; to compare NICE recommendations with current practice; to evaluate the cost-effectiveness of mandating or withdrawing each of these tests in this patient group; and to identify the expected value of information. This would determine whether or not there is value to the NHS in commissioning further primary research into the use of these tests in this group of patients.

Methods

Systematic reviews of the literature relating to the clinical effectiveness of routine pre-operative testing of FBC, electrolytes and renal function and pulmonary function in adult patients classified as ASA grades 1 and 2 undergoing elective minor (grade 1) or intermediate (grade 2) surgical procedures, and of the adverse effects of such testing, were carried out. Comprehensive literature searches were undertaken in March to April 2008 and June 2009 to retrieve studies that evaluated the clinical effectiveness of routine pre-operative utilisation of these tests in each of the pre-defined patient/intervention combinations. The searches were not limited by language or location, but were restricted to studies published from 1980 onwards.

Data were extracted by a single reviewer using a customised data extraction form based on that proposed by the NHS Centre for Reviews and Dissemination for studies published in English. Extracted data were checked by a second reviewer and disagreements were resolved by discussion. Quality assessment was performed using a customised tool. Results were presented

in a narrative summary; meta-analysis was not possible because of the diversity of outcome measures used in the different studies.

A systematic review of the cost-effectiveness of the specified pre-operative tests in the above patient group was also undertaken in order to identify papers in which cost-effectiveness of these tests in the pre-defined indications had been modelled. The primary function of the review of cost-effectiveness studies was to inform the development of a de novo cost-effectiveness model. An exemplar cost-effectiveness model was constructed to identify the parameters for which evidence would be required from the published literature.

Routine patient-level data sets of utilisation of pre-operative tests and patient outcomes were identified at the Leeds Teaching Hospitals Trust. These data sets were linked and regression models were used to estimate the impact of routine pre-operative tests on patient outcomes.

Finally, a postal survey of current practice pre-operative testing for the designated patient/procedure combinations was sent to all UK NHS trusts in 2008. The survey was based on the survey undertaken by NICE in 2005.

Results

The systematic literature searches identified a large number of potentially relevant studies of clinical effectiveness. However, when these studies were subjected to detailed review, the evidence base was found to be extremely small: only six observational studies met the review's inclusion criteria, none of which had been conducted in the UK. Five studies assessed the use of both FBCs and U&E; only one study assessed the use of routine PFT. This limited evidence suggests that few apparently healthy patients who undergo routine testing have abnormal test results, and even fewer have both an abnormal result and a consequent change in clinical management.

The systematic review of adverse effects indicated that those most commonly reported in relation to diagnostic venepuncture (pain and bruising, and, more infrequently, vasovagal reactions) are generally not serious. However, nerve injuries may also occur; although these appear to be rare, they are potentially disabling. Adverse events associated with PFT also appear to be unusual. However, male patients with inguinal hernias appear to be at increased risk of incarceration of that hernia.

The systematic literature searches of the cost-effectiveness literature identified a large number of potentially relevant studies. Of 5151 references, only 282 papers were assessed as potentially relevant after review of the title and abstract. Review of the full texts identified eight possible papers, including one full economic evaluation and seven partial economic evaluations. None of these eight papers provides data on the three tests under consideration for the specific patient groups.

The postal survey had a 17% response rate. The majority of responding hospitals were district general hospitals, and they reported that in ASA grade 1 patients aged < 40 years with no comorbidities undergoing minor surgery did not undergo routine tests for FBC, electrolytes and renal function and pulmonary function.

Analysis of the routine data indicated that that frequency of test use is not consistent with the hypothesis of their routine use. FBC tests were performed in only 58% of patients in the data set and U&E tests were carried out in only 57%.

The primary limitation of the studies reported is driven by the paucity of the published evidence. Although we included non-UK studies, we excluded non-English-language studies. These studies may have been relevant to this review although concerns about equivalence of practice with regard to characterisation of patients and clinical response to a given test result between the UK NHS and non-English-speaking health-care systems meant that this would be a substantial assumption. Owing in part to the almost complete absence of randomised data, we included observational studies in the review and studies of this type are associated with an increased risk of bias and confounding.

Conclusions

The paucity of the published evidence combined with the low response rate to the survey on current practice means that conclusions from this study can be made only with great caution. It is clear that there is not a robust evidence base to support the use of these tests in low-risk patients undergoing ASA grade 1 and grade 2 elective surgery. Beyond this, the survey results suggest that current practice has moved on and that the time of universal utilisation of pre-operative tests for all surgical patients has passed. This routine data set provided by Leeds Teaching Hospitals Trust is certainly consistent with this. However, these are data from only one trust.

The analysis of the Leeds Teaching Hospitals Trust routine data indicates that these tests are used in patients in whom there is a reason to consider an underlying raised risk of a clinical abnormality that should be taken into account in their clinical management. Although credible that this strategy has led to substantial resource savings for the NHS, there is no published evidence base to establish that this is the case. The total expenditure on pre-operative tests across the NHS remains significant; however, this may well reflect increasing volumes in surgery in an increasingly comorbid population owing to changing population demographics.

Recommendations for further research

Given the almost complete absence of published evidence on the clinical effectiveness, safety and cost-effectiveness of routine use of these tests in uncomplicated patients undergoing ASA grade 1 and grade 2 procedures, any well-designed research would add to the current state of knowledge. However, to recommend specific research questions it would be necessary for us to have a view as to the value of additional information to decision-makers in the UK NHS. To assess the likely value of such research it would be necessary to have a robust assessment of the current scale of the routine use of these tests in patient/procedure combinations of interest.

The low response rate to our survey, despite significant efforts at follow-up, suggests that this type of survey will not be a satisfactory strategy for scoping the scale of the research opportunity. A systematic identification of routine test databases held by UK NHS trusts is necessary to establish the feasibility of undertaking a multicentre version of the routine data analysis that we report for Leeds Teaching Hospitals Trust.

If feasible, this would allow the identification of the scale of the use of these tests in practice and the degree to which they are being used in otherwise healthy patients, rather than in response to a specific clinical indication. Only once this information is available will it be possible to establish whether or not any further research in this area is required and, if so, which research questions have the greatest potential value to the UK NHS.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1

Introduction

The pre-operative preparation of patients undergoing any surgery involves a multidisciplinary approach. The surgical team assess the appropriateness of the surgery and the anaesthetists assess the patient's fitness for surgery. The development of pre-operative assessment clinics in the last 20 years has seen nursing staff take a key role in the assessment preparation of patients for surgery. Protocols were developed and implemented locally to facilitate the patient care pathway in an environment where skill mix within teams was evolving.

In 2003 the National Institute for Health and Clinical Excellence (NICE) published Clinical Guideline 3 (CG3), which reviewed the use of routine pre-operative tests prior to routine surgery.[1] Prior to the guideline preparation, a systematic review was undertaken by Munro *et al.*[2] on behalf of the Health Technology Assessment (HTA) programme in 1997. The guideline development group undertook its own review of the literature. These two reviews defined and updated the purpose of pre-operative testing of apparently healthy patients.

Of the evidence base used to produce the guideline, >50% was graded as amber (i.e. the benefit of the test was unknown). Therefore, despite the existence of some primary research, the evidence on which to base pre-operative testing protocols was inconclusive. Alongside this there has been an increasing awareness of the possibility of subjecting patients to unnecessary tests, and of the issues involved in dealing with the results of tests that may alarm patients but have little clinical significance.

The OPCECK study, undertaken in 1999[3] by members of this research team, suggested that it was somewhat difficult to attribute pre-operative examination and testing to perioperative and post-operative outcomes for patients. This study was designed to evaluate the performance of appropriately trained nurses and house officers in pre-operative assessment. Both the nurses and doctors were assessed by a clinical fellow in anaesthesia in the areas of clinical examination, history taking and ordering of appropriate tests for the patient. The nurses adhered to test ordering by following local protocols and thus performed far better at this task than junior doctors, who overinvestigated. The outcomes of interest in this study were the correct assessment of the patient, overassessment, underassessment not affecting management and underassessment possibly affecting management. The last was the primary outcome. Patients were followed up to establish if admission and surgery had proceeded as planned. Cancellation of surgery after the assessment clinic for any reason was noted as was the ordering of any additional tests by the surgeon or anaesthetist on admission.

It was difficult in this study to establish the link between patient outcomes and the quality of their pre-operative assessment. Test results were often outwith normal limits but the surgery went ahead anyway as the anaesthetist used his or her clinical judgement to assess the risks to the patient. Linking any change in clinical management resulting from a biochemistry test carried out pre-operatively was problematic.

The NICE review of the evidence that produced the guidelines identified change in clinical management as a result of a pre-operative biochemistry test as an outcome measure.[1] They found that, although some studies reported this as an outcome, they did not refine this further than

delay, cancellation and alteration of treatment. Nor did this include any further explanation of what the change comprised or its impact on patients.[1]

Answering these questions is central to understanding the need for and the impact of pre-operative biochemistry testing on patients who meet the criteria within the guidelines.

Being able to demonstrate that a test was carried out or not carried out as per protocol has little relevance unless the outcomes for patients are improved by these actions. This could be either by avoiding an unnecessary test or by avoiding complications by actions taken on the results of an abnormal test.

Of the 3 million or so surgical procedures carried out in the UK every year, a significant number of patients will be in the category of interest to this review. Although many of these tests are individually cheap, the NHS spends literally millions of pounds each year on tests.

Previous reviews[4,5] were wide-ranging and included a wide range of patients, surgical procedures and tests. By contrast, this review is highly focused in terms of the tests, patients and surgeries under consideration. These are defined below.

The aims of this study

The aims of this study were to:

- undertake a systematic review of the literature of the clinical effectiveness of routine testing of full blood count (FBC), electrolytes and renal function [urea and electrolytes test (U&E)] and pulmonary function [pulmonary function test (PFT)] as part of the pre-operative assessment procedures for patients classified as American Society of Anaesthesiologists (ASA) grades 1 and 2 who are undergoing minor or intermediate procedures
- evaluate the cost-effectiveness of mandating or withdrawing each of these tests from routine pre-operative assessment for patients ASA grades 1 and 2 and minor and intermediate surgery
- compare the evidence with the recommendations in the NICE CG3 and observed practice in NHS hospitals
- identify using modelling techniques the expected value of information (EVI) whether or not there is value in the NHS in commissioning further primary research into the routine use of FBC, U&Es and PFTs in this patient population.

The patient group

The patient group to be considered in this review is those classified as ASA grades 1 and 2 undergoing minor or intermediate surgery. ASA produced guidelines for the classification from one to four according to their health status, comorbidities and, therefore, anaesthetic risk.

The patient group was limited to those undergoing minor or intermediate surgery as defined in the NICE guideline as, for example:

- minor (grade 1): excision of lesion of skin, drainage of breast abscess, etc.
- intermediate (grade 2): primary repair of inguinal hernia, excision of varicose veins of leg, tonsillectomy, knee arthroscopy.

Other minor and intermediate surgical procedures were included in the review and the detailed classification was obtained from Clinical Classification and Schedule Development Group (CCSD) *Schedule of Procedures,* 2005.[6]

The tests

The tests defined in the review are FBC undertaken for:

- known or suspected anaemia
- symptomatic cardiovascular or pulmonary disease
- condition-causing pre-operative blood loss
- bleeding/bruising disease or history of bleeding/bruising disease
- blood disorder (e.g. sickle cell disease, thalassaemia)
- anticoagulant drugs
- chronic disease (e.g. rheumatoid, renal disease).[1]

Urea and electrolytes test (electrolyte, creatinine) for:

- diabetes
- renal disease
- patients taking digoxin, diuretics, steroids, lithum.[1]

Pulmonary function testing for:

- spirometry
- measurement of respiratory mechanics
- measurement of transfer function
- exercise testing
- blood gas analysis.[1]

Comorbidities

This review concentrates on the common comorbidities of cardiovascular, renal and respiratory disease. The scope of the review explicitly excludes diabetes.

Outcomes

The outcomes of interest from the literature were:

- clinical benefit and costs of the tests (primary outcome)
- the chances of finding an abnormal result
- length of stay post-operatively
- post-operative complication rates
- number of operations cancelled due to abnormal test results on the day of operation.

The purpose of routine testing

The main purpose of pre-operative investigation is to provide additional diagnostic and prognostic information to supplement the clinical history of a patient with the aim of:

- providing information that may confirm or question the correctness of the current course of clinical management
- using this information to reduce the possible harm or increase the benefit to patients by altering their clinical management if necessary

- using this information to assess the risk to the patient and opening up the possibility of discussing potential increases of risk with the patient
- predicting post-operative complications
- establishing a baseline measurement for later reference (to refer back to post-operatively); and
- carrying out opportunistic screening that is unrelated to the surgery.[1]

The routine testing of these patients would aim to identify, for example, unexpected anaemia or electrolytes and pulmonary function abnormalities that could impact on their planned anaesthetic or surgical management. By definition, ASA grade 1 and grade 2 patients will have a low incidence of unheralded abnormal tests, and then only a small fraction of these abnormal tests will lead to a measurable change in care. A proportion of the tests will not indicate any disease process, but will simply reflect the outliers in the normal population. The low incidence of abnormal tests makes identification of benefit using a conventional randomised controlled trial (RCT) very difficult.

National Institute for Health and Clinical Excellence guidance

The NICE guideline group set out the best available evidence for undertaking tests and for when these tests would not be necessary. The published evidence was supplemented by additional consensus work with clinical experts. The guideline concluded that there is no evidence to justify the practice of routinely testing patients aged < 50 years who do not present with comorbidities. Only investigations clinically indicated should be carried out.

Abacus survey

The National Institute for Health and Clinical Excellence commissioned Abacus to carry out a survey auditing the implementation of CG3 in 2005.[7] The focus of the survey commissioned by NICE was on the uptake of the guideline and the opinions of the respondents on the usefulness of the guideline, its impact on clinical practice and measure established to undertake internal audit.

We repeated this survey in 2008 with an emphasis on the tests of interest and ASA grade 1 and 2 patients.

How this study has changed from protocol

The paucity of published literature which could be linked to the specific tests and patient group made the building of a cost-effectiveness model problematic. We had proposed undertaking expert elicitation for some model parameters as we expected deficiencies in the evidence base. However, to populate the proposed model would have entailed undertaking expert elicitation for the majority of parameters, including those concerning clinical effectiveness and test performance. The degree of uncertainty that would result from such an undertaking would render such a model unworkable. After extensive discussion within the research team and consultation with external experts, we explored alternative avenues for estimating the clinical effectiveness and cost-effectiveness of routine pre-operative tests. We undertook econometric analyses of routine pre-operative test data held at the Leeds Teaching Hospitals Trust, linked to Hospital Episode Statistics data on outcomes, to estimate the impact of the use of these tests on outcomes.

The econometric work showed that EVI modelling to estimate the cost to the NHS of undertaking further primary research into the value of these tests was not relevant.

Chapter 2

Clinical effectiveness

Methods for reviewing clinical effectiveness

Identification of studies

A comprehensive literature search was performed in March to April 2008. Searches were designed to retrieve studies which evaluated the clinical effectiveness of routine pre-operative testing of FBC, electrolytes and renal function (U&E) and pulmonary function (PFT) in adult patients classified as ASA grades 1 and 2 undergoing elective minor (grade 1) or intermediate (grade 2) surgical procedures.

In addition, relevant citations from retrieved papers were followed up.

Sources searched

The following electronic bibliographic databases were searched:

1. BIOSIS
2. Cumulative Index to Nursing and Allied Health Literature (CINAHL)
3. Cochrane Central Register of Controlled Trials (CENTRAL)
4. EMBASE
5. MEDLINE
6. MEDLINE In-Process & Other Non-Indexed Citations
7. NHS Database of Abstracts of Reviews of Effects (DARE)
8. NHS HTA Database
9. Science Citation Index (SCI).

To identify grey and unpublished literature, the Controlled Clinical Trials database, National Research Register Archive, National Institute for Health Research Clinical Research Network Portfolio database and the Copernic Meta-search Engine were searched.

In an attempt to identify the consequences of not undertaking routine testing, or of false-positive or false-negative test results, further searches were undertaken in June 2008 to retrieve papers which published data on intra- or post-operative adverse events occurring in relevant patients together with information on their test status and/or results.

As few relevant papers were identified by these searches, additional searches were undertaken in April and May 2009 to retrieve papers including information relating to adverse effects associated with commonly used anaesthetics in relation to the patients' test status. In addition to the databases listed above, the following sources were also searched:

- US Food and Drug Administration
- *British National Formulary*
- HTA agencies
- drug companies manufacturing the anaesthetic.

Search strategies

The MEDLINE search strategies are presented in *Appendix 1*. The MEDLINE strategies were adapted for use in the other databases, and these search strategies are available on request.

Search restrictions

The searches were not restricted by date or language.

Inclusion and exclusion criteria

Inclusion criteria

Population

- Adult patients classified as ASA grade 1 or 2 undergoing minor (grade 1) or intermediate (grade 2) surgery (including elective general surgery, day surgery and minor orthopaedic procedures) as classified by the CCSD *Schedule of Procedures,* 2005.[6] It was intended, where possible, to subdivide these into the following subgroups:
  - apparently healthy patients with no clinical indication for testing FBC, electrolytes and renal function and pulmonary function
  - patients with common comorbidities (e.g. respiratory disease, renal disease)
  - patients receiving treatments likely to alter test results (e.g. diuretics).

It was originally planned to limit the population to adults aged 16–60 years. However, because of the paucity of relevant studies which met this inclusion criterion, the population was later extended to include all adult patients.

Intervention

- Routine pre-operative testing of:
  - FBC [including haemoglobin (Hb) concentration, haematocrit, platelet count and white blood cell count]
  - electrolytes and renal function (U&E) (including sodium, potassium, urea and creatinine)
  - pulmonary function test (PFT) (including some or all of spirometry, blood gas analysis, measurement of respiratory mechanics, measurement of transfer function and exercise testing of respiratory system).

Comparator

- No routine pre-operative testing.

Outcomes

- Abnormal test results.
- Changes in management following abnormal test results in patients whose pre-operative clinical examinations were normal.
- Adverse events possibly related to the test result.
- Adverse events probably or possibly caused by the process of testing.
- All-cause mortality.

Setting

- Any country.

Date

- 1980 onwards.

Study type

- RCTs.

- Controlled non-randomised studies (e.g. cohort studies).
- Case–control studies.
- Case series.
- Case reports.
- Systematic reviews.
- Economic evaluations.

Exclusion criteria

The following publication types were excluded from the review:

- animal models
- narrative reviews, editorials and opinions.

Systematic reviews of primary studies were also excluded from the review, but were read in case they led to the identification of additional relevant trials.

In addition, studies were excluded if they were considered methodologically unsound, did not report results in sufficient detail, or reported the use of a package of pre-operative tests from which it was not possible to distinguish the interventions studied in this review.

Sifting

The references identified by the electronic literature searches were sifted in three stages. They were screened for relevance first by title and then by abstract. Those papers which seemed from their abstracts to be relevant were then read in full, as were those for which abstracts were not available. At each step, studies which did not satisfy the inclusion criteria were excluded.

Data extraction strategy

A customised data extraction form based on that proposed by the NHS Centre for Reviews and Dissemination (CRD) was used.[8] Where possible, data were extracted by one reviewer and thoroughly checked by a second reviewer; any disagreements were resolved by discussion. However, with the exception of a study in Hebrew[9] for which a translation was obtained, data from studies which were published in a language other than English were extracted by a single reviewer.

Where available, data relating to the following outcomes were extracted:

- all-cause mortality
- significant abnormal test findings
- change of management
- length of hospital stay
- adverse effects probably or possibly related to the test result
- adverse events probably or possibly caused by the process of testing.

Quality assessment strategy

It was proposed to use criteria based on those proposed by the NHS CRD[8] (see *Appendix 2*) to assess the methodological quality of randomised trials which met the inclusion criteria.

It was proposed to assess the methodological and reporting quality of case series studies which met the inclusion criteria using a customised quality tool that combined generic criteria proposed by the NHS CRD[8] and Chambers *et al.*[10] with review-specific criteria, as follows:

Generic criteria:

- Were patients recruited prospectively?
- Were patients recruited consecutively?
- Were at least 90% of those included at baseline followed up (prospective studies only)?
- Was loss to follow-up reported or explained (prospective studies only)?
- Was follow-up long enough for important events to occur?
- Were outcomes assessed using objective criteria or was blinding used?
- Was an appropriate measure of variability reported?

Review-specific criteria:

- Were the patients' ages and ASA statuses adequately reported?
- Was the operation type and/or risk classification adequately reported?
- Were all operations elective?
- Were all the tests conducted genuinely routine, or might some have been indicated?
- Was a definition of normal or abnormal results provided?

Meta-analysis strategy

It was intended that, where appropriate, meta-analysis would be used to pool results, summary statistics would be derived for each study and a weighted average of the summary statistics would be computed across the studies. In the event, this was not possible because of the diversity of outcome measures used in the different studies.

The statistical calculations were performed using the following software packages:

- Proportions and confidence intervals (CIs) – the confidence interval for proportion calculator produced by Dimension Research (Dimensions Research & Marketing Consultancy, Sharjah, United Arab Emirates).
- The CIs around absolute risk changes – GraphPad software (GraphPad Software Inc., CA, USA).

Results

Quantity and quality of research available

Number of studies of clinical efficacy identified

The electronic literature searches identified 11,953 potentially relevant articles. Of these, four articles related to four studies[9,11–13] which met the review's inclusion criteria (*Figure 1*).

Two additional relevant studies, by Roukema *et al.*[14] and Turnbull and Buck,[15] were identified only from citations.

Number and type of studies included

Six studies[9,11–15] met the inclusion criteria for the review of clinical effectiveness; none was a RCT of pre-operative testing. A pseudo-randomised trial by Roukema *et al.*[14] used year of birth to allocate patients to treatment groups; it studied the effectiveness of pre- and post-operative breathing exercises in preventing pulmonary complications after upper abdominal surgery. However, because all participants underwent pre-operative PFTs, data from the control group could be utilised in the current review as a prospective case series examining the ability of such testing to predict pulmonary complications (see *Quantity of research available*). The remaining five studies were designed as prospective or retrospective case series.[9,11–13,15]

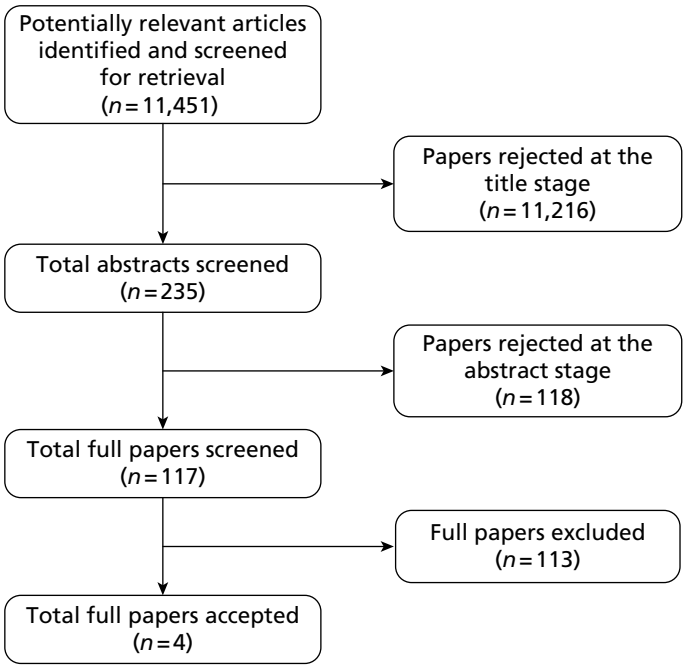

FIGURE 1 Clinical effectiveness: summary of study selection and exclusion (electronic literature searches).

Number and type of studies excluded, with reasons

As may be seen from *Number of studies of clinical efficacy identified*, a substantial number of the references identified by the electronic searches related to studies which did not meet the review's inclusion criteria, and which were therefore excluded during the sifting process. Details are therefore given only of those references which:

- appeared potentially relevant, but could not be obtained
- were excluded after a full reading, if the reason for exclusion is potentially not readily apparent from the full text; or
- might appear from their titles to be particularly pertinent to the subject of the review.

Such references are listed in *Appendix 4*, together with the reasons for their exclusion.

Quantity and quality of research available

Quantity of research available

As noted above, six studies were identified which reported results relating to one or more of the three tests in adult patients in ASA grades 1 and 2 (*Table 1*).[9,11–15] Although Gnocchi *et al.*[11] included in their study patients in ASA grades 1–3, routine testing was performed only in ASA grade 1 patients (tests for patients in ASA grades 2 and 3 were requested according to the conditions identified by, or suspected from, the clinical history and examination). Consequently, only the results relating to ASA grade 1 patients are relevant to, and included in, this review. Roukema *et al.*[14] and Turnbull and Buck[15] did not specify the ASA status of their patients, but described them in terms which strongly suggest that they would appropriately have been categorised as ASA grade 1 or 2; these studies have therefore been included.

The studies related to three surgical specialties:

- general surgery (including cholecystectomy,[15] abdominal surgery,[11] upper abdominal surgery[14] and unspecified 'minor' surgery[9])

- ophthalmology (specifically cataract surgery[12])
- dentistry[13] (see *Table 1*).

Five studies assessed the use of both FBCs and U&Es.[9,11–13,15] Only one study, that by Roukema *et al.*,[14] assessed the use of routine PFTs. The paucity of data relating to routine PFTs reflects the fact that this test is seldom routinely performed in asymptomatic patients; thus, Turnbull and Buck's retrospective review[15] of records relating to 1010 patients found that only three PFTs were performed, in each case in a patient whose history or physical examination had suggested some abnormality of pulmonary function.

Only one study, that by Szmuk *et al.*,[9] specifically met the original criterion that all patients should fall within the 16–60 years age group (see *Table 1*). Of the remainder, the studies by Roukema *et al.*,[14] Tallo *et al.*[12] and Turnbull and Buck[15] did not explicitly state that the study population was limited to adults; however, these studies have been retained as there is no indication that they included children.

As noted in *Number and type of studies included* in this review, data from the control group of Roukema *et al.*'s pseudo-RCT[14] of pre- and post-operative breathing exercises in preventing pulmonary complications after upper abdominal surgery are utilised as a prospective case series examining the ability of routine pre-operative PFTs to predict pulmonary complications.

The remaining studies were designed as case series. Two of these were prospective:

- Gnocchi *et al.*[11] studied all ASA grade 1–3 patients, aged ≥16 years who were scheduled for elective abdominal surgery classified as grade 2 (low risk) or 3 (moderate risk) by the Johns Hopkins Risk Classification System in one hospital in Argentina between 1 September 1995 and 30 April 1998. As noted above, routine testing was undertaken only in patients in ASA grade 1.
- Haug and Reifeis[13] included all ASA grade 1 or 2 patients aged 15–54 years undergoing dental surgery under general anaesthesia or intravenous sedation in one American oral and maxillofacial surgery clinic between 1 February and 30 November 1994.

The remaining three case series were retrospective record reviews:

- Szmuk *et al.*[9] reviewed the records of 300 ASA grade 1 patients aged 18–40 years who had undergone minor elective operations (most commonly hernia repair) in an Israeli public hospital at an unspecified point in time.
- Tallo *et al.*[12] reviewed the records of 1254 patients who had undergone cataract surgery in a single hospital in Brazil between January and December 2005.
- Turnbull and Buck[15] reviewed the records of 1010 otherwise healthy individuals who had undergone cholecystectomy in two Canadian teaching hospitals between 1973 and 1984.

Quality of research available

Quality assessment using the customised tool described in *Quality assessment strategy* suggested that the prospective studies were of higher quality than the retrospective record reviews (for details see *Appendix 5*). However, in some instances this may reflect reporting quality rather than the quality of the study design. So, for example, Szmuk *et al.*[9] and Turnbull and Buck[15] do not specify that the records that they reviewed were those of consecutive patients who met the study's inclusion criteria, although this seems probable. Furthermore, Turnbull and Buck[15] do not make it entirely clear whether or not all the operations were elective. Moreover, as they talk throughout about the number of tests performed, rather than the number of patients tested, it is not wholly clear that each test was performed only once in each patient, nor is it specified that

TABLE 1 Details of included studies of routine pre-operative testing, by alphabetical order of author

Study	Country	Study design	Date of operation	All tests routine	Relevant tests	Number of patients	Age range (mean) (years)	ASA status	Operation type (risk classification)
Gnocchi *et al.* 2000[11]	Argentina	Prospective case series	1 September 1995 to 30 April 1998	Yes	Aged 16–59 years: haemogram Aged ≥60 years: haemogram, plasma creatinine	214	≥16 (ASA grade 1 47.8 ± 19.6; ASA grade 2 61.0 ± 16.5)	1	Abdominal surgery including hernia repair, laparoscopic cholecystectomy and benign proctological surgery (2 or 3)
Haug and Reifeis 1999[13]	USA	Prospective case series	1 February 1994 to 30 November 1994	Yes	FBC, Hb, haematocrit, platelet count, mean corpuscular Hb, mean corpuscular volume, lymphocyte count, mean corpuscular Hb concentration	458 enrolled (GA: 281; i.v. sedation: 177) 380 returned for scheduled procedure (GA: 235; i.v. sedation: 145)	15–54 (23.4)	1 or well-controlled 2	Dental surgery under general anaesthetic or i.v. sedation (Not specified)
Roukema *et al.* 1988[14]	Netherlands	Pseudo-RCT/ prospective case series	No data	Yes	PFT (vital capacity and FEV_1)	84 in control group	≤70; implicitly limited to adults	Not specified; patients described as 'without pre-operative risk factors'	Upper abdominal surgery for benign biliary disease or duodenal ulcer (Not specified)
Szmuk *et al.* 2002[9]	Israel	Retrospective case series	No data	Yes	Determined by the surgeon; included blood count, urea nitrogen, electrolytes	300	18–40	1	Unspecified ('Minor')
Tallo *et al.* 2007[12]	Brazil	Retrospective case series	January 2005 to December 2005	Not clear	Hb, haematocrit, serum sodium, serum potassium, creatinine	1254	Implicitly adult (ASA grades 1–3 68.1 ± 11.6)	1–3; individual patient data provided for all patients suffering adverse events	Cataract surgery (2)
Turnbull and Buck 1987[15]	Canada	Retrospective case series	1973–84	Not clear	Any screening tests received by the patient, including complete blood cell count, sodium, potassium, creatinine, urea	1010	Implicitly adult	Not specified; patients described as 'otherwise healthy' (i.e. apart from the need for cholecystectomy) and as having no other 'active or ongoing disease on admission to hospital'	Cholecystectomy (Not specified)

FEV_1, forced expiratory volume in 1 second; GA, general anaesthetic; i.v. intravenous.

the blood counts and multiphasic screening tests (which included tests for urea and electrolytes) were routinely performed, although this seems likely since, if each test was performed only once in each patient, >98% of patients would have undergone these tests. Turnbull and Buck[15] also failed to provide definitions of normal or abnormal results. Tallo *et al.*[12] also failed to specify whether or not the tests they reported were routine although, again, this seems probable; the very high proportion of patients with at least one abnormal test result suggests that most, if not all, underwent testing (see *Full blood counts*).

Several studies may be biased because of attrition. In the study by Gnocchi *et al.*,[11] 777 patients in ASA grades 1–3 attended an Argentine hospital for pre-operative evaluation, but only 507 (62.3%) returned for surgery; the primary reason why the remaining 270 did not do so was lack of insurance cover for medical expenses. As noted above, Gnocchi *et al.*[11] undertook routine testing only in patients in ASA grade 1, but it is not clear how many of the original 777 patients were assessed as being in grade 1 because test results are presented only for the 214 grade 1 patients who returned to the hospital for a second interview, of whom 210 (98.1%) were deemed to be fit for surgery, but only 139 (66.2%) actually underwent the operation for which they were scheduled; again, the main reason why the remainder did not appeared to be lack of cover for medical expenses. No details were given of the health status of those patients who dropped out at either point in the study compared with those who underwent their scheduled operation, and therefore the study incorporates the potential for systematic bias at both points. Although attrition was lower in Haug and Reifeis' study[13] of patients undergoing dental surgery in the USA, 78 of 458 patients (17%) failed to return on the appointed day. The remaining four studies[9,12,14,15] are less explicit about the pathway from assessment to operation, and the degree of attrition involved; they may also contain a potential for bias, related to financial or other, unknown, factors.

Assessment of clinical effectiveness

Because the included studies had different aims, they did not all report the same data. It has therefore been necessary to summarise each study on its own terms before attempting to compare their findings.

Full blood counts

The prospective case series by Gnocchi *et al.*[11] assessed:

- the prevalence of asymptomatic disease in ASA grade 1 patients
- the frequency of diagnoses which led to the cancellation or postponement of surgery in such patients
- the incidence of perioperative complications in those patients who underwent surgery.

As noted in *Quality of research available*, it is not clear how many ASA grade 1 patients originally entered the study; results are presented only for the 214 who returned to the hospital for a second interview. In addition, it is not clear how many of this 214 were scheduled for grade 2 operations, and how many for grade 3. The number of ASA grade 1 patients with abnormal test results was not reported, although three patients initially classified as ASA grade 1 were reclassified as ASA grade 2 as a result of a diagnosis of hypertension (a reconstruction of the apparent patient flow is represented diagrammatically in *Appendix 6*). Moreover, as published, the results relating to the cancellation or postponement of surgery appear potentially contradictory: on the one hand, four ASA grade 1 patients (1.9%) were said to have had their operations postponed as a consequence of routine testing, but, on the other hand, the authors claimed that no operation was postponed or cancelled because of an unknown disease and stated that, in asymptomatic (i.e. ASA grade 1) patients, routinely requested laboratory tests showed no benefit in terms of either anaesthetic management or the detection of pathologies. All four ASA grade 1 patients whose operations were postponed had severe asymptomatic anaemia (Hb <8 mg/dl).

As noted above, Gnocchi *et al.*[11] found that only 139 of the 210 ASA grade 1 patients deemed fit for surgery (66.2%) actually underwent the operation for which they were scheduled; the reason why the remaining 71 patients did not do so appeared to be lack of cover for medical expenses rather than any medical reason. One hundred and thirty of the 139 who underwent surgery had grade 2 operations; none suffered intraoperative complications and, although four had post-operative complications, a rate of 3.08% (95% CI 0.11% to 6.05%), these complications were considered to be unrelated to the pre-operative tests (two patients had wound infections, one had a haemorrhage from the site of the surgical drain which stopped spontaneously without requiring a blood transfusion and one had a clinical lower limb deep-vein thrombosis). There were no intraoperative or post-operative deaths in ASA grade 1 patients undergoing grade 2 operations.

The other prospective case series, that by Haug and Reifeis,[13] sought to determine whether or not routine laboratory testing affected clinicians' pre-operative evaluation and clinical decision-making. Seven of the 380 patients who returned for their dental procedure had an abnormal test result, a rate of 1.8% (95% CI 0.5% to 3.2%): three had borderline low red blood cell counts, one had borderline low haematocrit, one had a borderline low white blood count and two patients being treated for dentoalveolar abscesses had elevated white blood cell counts. No planned procedures in these patients were postponed, and the authors concluded that the routine laboratory tests had little or no effect on the clinicians' decision-making process.

Szmuk *et al.*[9] evaluated the clinical benefit and cost of routine screening. Only nine patients were found to have abnormal test results, a rate of 3.0% (95% CI 1.1% to 4.9%). All nine had light anaemia (11–12 g), which in each case was attributed to increased menstrual flow and was consonant with the case history or physical examination. No operations were cancelled or delayed as a consequence of the test results. Szmuk *et al.*[9] therefore suggested that blood counts should not be routinely undertaken before minor operations in healthy patients, but should be performed only when indicated by the patient's age, gender, case history and the findings of the physical examination.

Tallo *et al.*[12] sought to determine whether or not pre-operative testing prevented pre- and post-operative adverse events in patients in ASA grades 1–3 undergoing cataract surgery. Seventy-five per cent of these patients had at least one recorded abnormal result on a range of tests, which included fasting blood glucose, electrocardiography (ECG) and chest radiography, as well as Hb, haematocrit, serum sodium, potassium and creatinine. However, only 1.3% had an adverse clinical event which was considered to be related to the anaesthesia or surgery (*Table 2*), and no relationship was observed between abnormal test results and adverse events (chi-squared $p = 0.334$). One hundred and eighty-one patients (14%) were referred to a specialist for pre-operative assessment, of whom 104 were asymptomatic (57.5%; 95% CI 50.3% to 64.7%). Only 20% of these asymptomatic patients underwent any clinical intervention as a consequence of the specialist assessment, compared with 86% of symptomatic patients (*Table 3*). The blood count result was abnormal in only 1 of the 13 patients in ASA grades 1 or 2 who had an adverse clinical event that was considered to be related to the anaesthesia or surgery (*Table 4*).

Turnbull and Buck[15] sought to assess the clinical value of routine pre-operative screening in otherwise healthy patients undergoing cholecystectomy. They reported the number of patients with abnormal results, the number of patients with abnormal results who received clinical interventions consequent on those results and the number of patients who developed a complication relevant to a test – in other words, a complication of which the test was intended to predict an increased risk. Thus, perioperative hypotension or a post-operative Hb concentration < 10.0 g/dl were deemed to be complications relevant to low Hb. The complications relevant to low white blood cell counts were not specified and high white cell counts were not reported as abnormal because of the possibility that they were caused by the patient's cholecystitis.[15]

TABLE 2 Abnormal test results in all ASA grade 1–3 patients undergoing cataract surgery (data from Tallo *et al.*[12])

Patient outcomes	Number	Rate	95% CI
Patients with at least one abnormal test result	936/1254	*74.6%*	*72.2% to 77.1%*
Patients referred for specialist assessment (includes symptomatic and asymptomatic patients)	181/1254	*14.4%*	*12.5% to 16.4%*
Patients who had an adverse clinical event considered to be related to the anaesthesia or surgery	16/1254	*1.3%*	*0.7% to 1.9%*

Data in Roman font were taken directly from the text; data in *italics* were calculated by the reviewer.

TABLE 3 Relationship between presence of symptoms and change of management in ASA grade 1–3 patients undergoing cataract surgery and referred for specialist pre-operative assessment (data from Tallo *et al*.[12])

Patients referred for specialist assessment	Clinical intervention consequent on specialist pre-operative assessment	
	No	Yes
Asymptomatic	83/104 (*79.8%, 95% CI 72.1% to 87.5%*)	21/104 (*20.2%, 95% CI 12.5% to 27.9%*)
Symptomatic	11/77 (*14.3%, 95% CI 6.5% to 22.1%*)	66/77 (*85.7%, 95% CI 77.9% to 93.5%*)

Data in Roman font were taken directly from the text; data in *italics* were calculated by the reviewer.

TABLE 4 Clinical adverse events in ASA grade 1 and 2 patients undergoing cataract surgery (data from Tallo *et al*.[12])

ASA class	Age	Sex	Comorbidities	Abnormal results on relevant tests	Referred for specialist assessment	Change of management	Clinical adverse event
1	52	F	None	No	No	No	Bradycardia
1	76	M	None	No	No	No	Hypertension
2	45	M	None	No	No	No	Hypertension
2	59	M	Diabetes mellitus	No	Yes (endocrinology – fasting blood glucose = 186)	Yes	Hyperglycaemia
2	61	M	None	No	No	No	Bradycardia
2	62	M	None	No	No	No	Bradycardia
2	68	F	Systemic arterial hypertension, diabetes mellitus	No	No	No	Hypertension
2	70	M	Systemic arterial hypertension	No	Cardiology	No	Cerebrovascular accident
2	78	M	Systemic arterial hypertension, diabetes mellitus, chronic renal insufficiency	Creatinine = 2.2	No	No	Hypertension
2	81	F	Diabetes mellitus, hypothyroidism	No	Yes (because of results of ECG and chest radiography; specialty not recorded)	Yes	Bronchospasm
2	81	M	Systemic arterial hypertension	No	No	No	Bronchospasm
2	82	F	None	No	No	No	Acute MI
2	85	F	Systemic arterial hypertension	No	No	No	Bradycardia

F, female; M, male; MI, myocardial infarction.

A total of 1005 complete blood cell counts were undertaken in 1010 patients, but only eight tests were reported as having abnormal results; assuming that each test was undertaken in a different patient, this indicates a rate of 0.8% (95% CI 0.3% to 1.4%). Seven patients had low Hb concentrations (the lowest being 9.9 g/dl); one had a low white cell count (3200/mm^3). Action was taken only in relation to two of the patients with low Hb concentrations [assuming that each test was undertaken in a different patient, this represents a rate of 0.2% (95% CI –0.1% to 0.5%)]. These two patients received pre-operative blood transfusions; despite this, one developed a relevant complication, as did one of the five patients with low Hb who did not receive a transfusion. Rates of relevant complications were therefore substantially higher in patients with abnormal Hb (2/7, 28.6%; 95% CI –4.9% to 62.0%) than in those with normal Hb, 14 of whom had relevant complications [assuming that each test was undertaken in a different patient, the denominator is 998, representing a rate of 1.4% (95% CI 0.7% to 2.1%)]. The one patient with a low white blood cell count did not suffer a relevant complication, although such complications were noted in 110 patients with a normal white blood cell count [assuming that each test was undertaken in a different patient, the denominator is 1004, representing a rate of 11.0% (95% CI 9.0% to 12.9%)] (see *Appendix 7*, *Table 29*). One patient died as a result of a post-operative pulmonary embolus.

The evidence relating to the value of routine pre-operative FBCs for ASA grade 1 or 2 patients undergoing elective minor to intermediate surgery is limited in both quantity and quality, as it is derived from five observational studies: data are available for a total of 1982 patients in ASA grades 1–2 (or equivalent) from the studies by Gnocchi *et al.*,[11] Haug and Reifeis,[13] Szmuk *et al.*[9] and Turnbull and Buck,[15] and a further unspecified number from the study by Tallo *et al.*[12]

As may be seen from the summary in *Table 5*, this limited evidence suggests that the proportion of patients with an abnormal result in any component of the full blood test is low (range 0.8–3.0%), and the proportion with both an abnormal test result and a consequent change in clinical management is lower (range 0–1.9%). No deaths were specifically reported in patients with abnormal test results; Turnbull and Buck[15] reported that one patient died as a consequence of a post-operative pulmonary embolus, but did not state whether or not this patient had an abnormal result on any test.

Electrolytes and renal function (U&Es)

Four studies[9,11,12,15] evaluated the use of tests for electrolytes and renal function. Three of these[9,12,15] assessed such tests in all patients included in the study. However, Gnocchi *et al.*[11] limited routine testing for creatinine to the unspecified number of ASA grade 1 patients in their study who were aged ≥ 60 years; no abnormal results were found in this group.

In the study by Szmuk *et al.*,[9] no patients were said to have abnormal sodium, potassium or creatinine levels. Two patients were found to have slightly high urea nitrogen levels (45–48 mg); these were attributed to mild dehydration which, in both cases, was consonant with the case history or physical examination. As both patients had creatinine levels which were considered normal, with no evidence of any kidney damage, their operations were not cancelled or postponed as a consequence of the abnormal urea nitrogen results.

In the study by Tallo *et al.*,[12] only one patient in ASA grade 1 or 2 suffered a relevant adverse clinical event and had an abnormal U&E result. This was a 78-year-old male with hypertension, diabetes mellitus and chronic renal insufficiency; he had an abnormal creatinine result which had not triggered a specialist referral or a change of clinical management (*Table 6*).

Turnbull and Buck[15] reported that 995 multiphasic screening tests (Sequential Multiple Analysis-12) were undertaken in 1010 patients (*Table 7*). Although 14 patients were said to have

TABLE 5 Abnormal FBC results and their consequences in ASA grade 1–2 (or equivalent) patients undergoing routine pre-operative testing

Study	Number of patients tested	Definition of abnormal result	Number of patients with abnormal results (%; 95% CI)	Number of patients with operation postponed or cancelled because of test result (%; 95% CI)	Number of patients with other change in management because of test result (%)	Number of patients with abnormal test result and related adverse event (%)	Number of deaths in patients with abnormal test result (%)
Any component of FBC							
Gnocchi *et al.* 2000[11]	214	N/A	Not reported	4/214 (*1.9%; 0.1% to 3.7%*)	0	0	0
Haug and Reifeis 1999[13]	380	N/A	7/380 *(1.8%; 0.5% to 3.2%)*	0	0	Not reported; implicitly none	Not reported; implicitly none
Szmuk *et al.* 2002[9]	300	N/A	9 *(3.0%; 1.1% to 4.9%)*[a]	0	Not reported	Not reported; implicitly none	Not reported; implicitly none
Tallo *et al.* 2007[12]	Not clear	N/A	Not reported	Not reported	Not reported	0	0
Turnbull and Buck 1987[15]	1005[b]	N/A	8[c] *(0.8%; 0.3% to 1.4%)*	0	2[d] (*0.2%; –0.1% to 0.5%*)	0	0
Individual components of FBC							
Hb							
Gnocchi *et al.* 2000[11]	214	<8 g/dl	Not reported	4/214 (*1.9%; 0.1% to 3.7%*)	0	0	0
Haug and Reifeis 1999[13]	380	Not specified	3/380 *(0.8%; –0.1 to 1.7%)*	0	0	Not reported; implicitly none	Not reported; implicitly none
Szmuk *et al.* 2002[9]	Records of 300 patients examined. Not clear how many underwent each test	<12 g/dl	9 *(3.0%; 1.1% to 4.9%)*[a]	0	Not reported	Not reported; implicitly none	Not reported; implicitly none
Tallo *et al.* 2007[12]	Not clear	Men <14 mg/dl; women <12 mg/dl	Not reported	Not reported	Not reported	0	0
Turnbull and Buck 1987[15]	1005[b]	Implicitly <10.0 g/dl	7[c] (*0.7%; 0.2% to 1.2%*)	0	2[d] (*0.2%; –0.1% to* 0.5%)	0	0

Study	Number of patients tested	Definition of abnormal result	Number of patients with abnormal results (%; 95% CI)	Number of patients with operation postponed or cancelled because of test result (%; 95% CI)	Number of patients with other change in management because of test result (%)	Number of patients with abnormal test result and related adverse event (%)	Number of deaths in patients with abnormal test result (%)
Haematocrit							
Haug and Reifeis 1999[13]	380	Not specified	1/380 *(0.3%; –0.3% to 0.8%)*	0	0	Not reported; implicitly none	Not reported; implicitly none
Tallo *et al.* 2007[12]	Not clear	Not specified	Not reported	Not reported	Not reported	0	0
Platelet count							
Turnbull and Buck 1987[15]	1005[b]	Abnormal according to 'generally accepted laboratory standards'	0	N/A	N/A	N/A	N/A
White blood cell count							
Haug and Reifeis 1999[13]	380	Not specified	3/380[e] *(0.8%; –0.1% to 1.7%)*	0	0	Not reported; implicitly none	Not reported; implicitly none
Turnbull and Buck 1987[15]	1005[b]	Abnormal according to 'generally accepted laboratory standards'	1 (*0.1%; –0.1% to 1.3%*)	0	1 (*0.1%; –0.1% to 1.3%*)	0	0

N/A, not available.
Data in Roman font were taken directly from the text; data in *italics* were calculated by the reviewer.
a Assuming all 300 patients underwent this test.
b Number of tests performed in 1010 patients.
c Number of abnormal tests.
d Blood transfusion.
e One borderline low, two elevated (the latter two both in patients being treated for dentoalveolar abscesses).

abnormally low potassium levels, the definition of 'abnormal' is not provided and only three were said to be outside 'the traditionally accepted surgical and anaesthetic limits of 3.2 to 5.8 mEq/l (3.2 to 5.8 mmol/dl)'; the lowest value was 3.1 mmol/l. Four of the 14 patients received pre-operative supplementation with potassium; despite this, one of the four suffered post-operative hypokalaemia. None of the patients with low potassium suffered a cardiac complication. Two patients had clinically significantly elevated creatinine (1.8 and 3.2 mg/dl), but no consequent modification of surgical or anaesthetic management was recorded, and there were no relevant complications. Five tests showed abnormal sodium results and one patient had an abnormal urea level, but these abnormalities were said not to be clinically significant. For details, see *Appendix 7*, *Table 30*.

The evidence relating to the value of routine U&Es for ASA grade 1 or 2 patients undergoing elective minor to intermediate surgery is limited in both quantity and quality, being derived from only four observational studies: data are available for a total of 1310 patients in ASA grade 1–2 (or equivalent) from the studies by Szmuk *et al.*[9] and Turnbull and Buck,[15] and a further unspecified number from the studies by Gnocchi *et al.*[11] and Tallo *et al.*[12]

As may be seen from *Table 6*, only one study, that by Szmuk *et al.*,[9] reported the proportion of patients with an abnormal result in any component of the test; this figure was low, at 0.7%, and did not lead to any change in clinical management. No deaths were specifically reported in patients with abnormal test results although, as previously noted, Turnbull and Buck[15] reported that one patient died as a consequence of a post-operative pulmonary embolus, but did not state whether or not this patient had an abnormal result on any test.

Venepuncture: adverse events

Blood samples for FBCs and U&Es are obtained by venepuncture. As none of the included studies reported adverse events relating to this process, additional systematic searches were carried out which were designed to identify studies of adverse events in adults who:

- were comparable in terms of health status with the population included in the review of the clinical effectiveness of routine pre-operative testing [in other words, who either were stated to be ASA grade 1 or 2 or were said to be generally healthy, with no underlying medical conditions or medications (such as anticoagulants) which might influence the incidence of adverse events]; and
- were undergoing simple venepuncture for diagnostic or screening purposes (see *Appendix 8*).

Studies which related to blood donors were excluded because:

- the withdrawal of larger volumes of blood makes it difficult to differentiate between vasovagal reactions and transient relative hypotension due to blood loss[16]
- the use of needles with a larger bore than the 20–22 gauge generally used in blood sampling may increase the risk of injury.[17]

Studies were also excluded if they used more invasive methods of blood collection (cannulation or catheterisation), or collected arterial or capillary rather than venous blood samples.

Case series or case reports were included only if they related to adverse events for which data were not available from larger, higher-quality studies (observational or before-and-after studies).

The searches identified eight relevant articles:

- Observational studies by Galena[16] and Deacon and Abramowitz.[18]

TABLE 6 Abnormal U&E results and their consequences in ASA grade 1–2 (or equivalent) patients undergoing routine pre-operative testing

Study	Number of patients tested	Definition of abnormal result	Number of patients with abnormal results (%; 95% CI)	Number of patients with operation postponed or cancelled because of test result (%; 95% CI)	Number of patients with other change in management because of test result (%)	Number of patients with abnormal test result and related adverse event (%)	Number of deaths in patients with abnormal test result (%)
Any component of U&E							
Gnocchi *et al.* 2000[11]	Not clear[a]	Test was for creatinine only; no definition of abnormal result given	0	N/A	N/A	N/A	0
Szmuk *et al.* 2002[9]	300[b]	N/A	2 (*0.7%; –0.3% to 1.6%*)	0	Not reported	Not reported; implicitly none	Not reported; implicitly none
Tallo *et al.* 2007[12]	Not clear	N/A	Not reported	Not reported	Not reported	1[c]	0
Turnbull and Buck 1987[15]	995[d]	N/A	Not reported	Not reported	Not reported	Not reported	0
Individual components of U&E							
Sodium							
Tallo *et al.* 2007[12]	Not clear	<135 or >145 mmol/l	Not reported	Not reported	Not reported	0	0
Turnbull and Buck 1987[15]	995[d]	Abnormal according to 'generally accepted laboratory standards'	5 *(0.5%; 0.06% to 0.9%)*	0	0	Not reported	0
Potassium							
Tallo *et al.* 2007[12]	Not clear	<3.2 or >5.0 mmol/l	Not reported	Not reported	Not reported	0	0
Turnbull and Buck 1987[15]	995[d]	Abnormal according to 'generally accepted laboratory standards'	14 *(1.4%; 0.7% to 2.1%)*	Not reported	4/995[e] *(0.4%; 0.01% to 0.8%)*	1/995[f] *(0.1%; –0.1% to 0.3%)*	0

continued

TABLE 6 Abnormal U&E results and their consequences in ASA grade 1–2 (or equivalent) patients undergoing routine pre-operative testing (*continued*)

Study	Number of patients tested	Definition of abnormal result	Number of patients with abnormal results (%; 95% CI)	Number of patients with operation postponed or cancelled because of test result (%; 95% CI)	Number of patients with other change in management because of test result (%)	Number of patients with abnormal test result and related adverse event (%)	Number of deaths in patients with abnormal test result (%)
Urea nitrogen							
Szmuk *et al.* 2002[9]	300[a]	<45 mg	2 (*0. 7%; –0.3% to 1.6%*)	0	Not reported	Implicitly none	Implicitly none
Turnbull and Buck 1987[15]	995[d]	Abnormal according to 'generally accepted laboratory standards'	1 *(0.1%; –0.1% to 0.3%)*	0	0	0	0
Creatinine							
Gnocchi *et al.* 2000[11]	Not clear[b]	None given	0	N/A	N/A	N/A	0
Tallo *et al.* 2007[12]	Not clear	>1.0 mg/dl	Not reported	Not reported	Not reported	1[c]	0
Turnbull and Buck 1987[15]	995[d]	Abnormal according to 'generally accepted laboratory standards'	2 *(0.2%; –0.1% to 0.5%)*	0	0	0	0

N/A, not available.
Data in Roman font were taken directly from the text; data in *italics* were calculated by the reviewer.
a Only patients aged ≥ 60 years were tested.
b Assuming all 300 patients underwent this test.
c Hypertension in patient with creatinine of 2.2.
d Number of pre-operative tests.
e Potassium was given pre-operatively.
f Post-operative hypokalaemia in a patient who was supplemented pre-operatively with potassium.

- An uncontrolled before-and-after study by Godwin *et al.*[19]
- Case reports by Nouri *et al.*,[20] Pradhan and Gupta,[21] Saeed and Gatens,[4] Sander *et al.*[22] and Zubairy[23] [for quality of reporting of meta-analyses (QUOROM) diagram, see *Appendix 9*].
- Three additional relevant articles, by Berry and Wallis,[24] Horowitz,[17] and Yuan and Cohen,[25] were identified from citations.

The adverse events identified by these articles fall into three categories:

- vasovagal reactions
- pain and bruising
- more serious nerve injury.

These adverse events are discussed in turn below.

Vasovagal reactions

Vasovagal reactions result from an abnormal reflex stimulation of the vagus nerve. The trigger factors may be emotional or somatic.[26] In most patients, the signs and symptoms (which may include pallor, sweating, nausea, dizziness or light-headedness) are light or moderate and resolve spontaneously. However, some patients experience bradycardia with consequent hypotension, loss of consciousness and, in very severe cases, death.[26]

Because data relating to vasovagal reactions are available from two large observational studies,[16,18] lower-quality studies (case reports and small case series) relating to such adverse events have been excluded.

The larger observational study, that by Galena,[16] recorded adverse effects associated with venepuncture carried out in outpatient settings between October 1988 and April 1991 on 4050 patients who were applying for life insurance. A 20- or 22-gauge needle was used to obtain a maximum of 30 µl of blood from each patient. Delayed reactions were identified using telephone calls made an unspecified length of time after the venepuncture. Potentially serious vasovagal reactions were experienced by 3.4% of patients (*Table 7*); these were significantly more common in men than in women (4.0% vs 1.3%; $p < 0.001$). None of those who experienced convulsive syncope had a previous history of seizure disorder.

Deacon and Abramowitz[18] found lower rates of vasovagal reactions in 3315 adults undergoing venepuncture in three hospital outpatient phlebotomy clinics over a 3-week period, even though 80% had fasted prior to their venepuncture (*Table 8*). Although the rate indicated by the phlebotomists was higher, at 0.9%, than that reported by the patients, it was still substantially lower than the rate of 3.4% reported by Galena.[16]

TABLE 7 Vasovagal reactions in patients undergoing venepuncture in outpatient settings[16]

Complication	Number (%; 95% CI)
Diaphoresis, near syncope	105/4050 (2.6%; *2.1% to 3.1%*)
Syncope	24/4050 (0.6%; *0.4% to 0.8%*)
Convulsive syncope	6/4050 (0.1%; *0.03% to 0.3%*)
Ventricular tachycardia	1/4050 (*0.02%; 0% to 0.1%*)
Total	136/4050 (3.4%; *2.8% to 3.9%*)

Data in Roman font were taken directly from the text; data in *italics* were calculated by the reviewer.

Pain and bruising

Because data relating to pain and bruising are available from one large observational study[16] and one uncontrolled before-and-after study,[19] lower-quality studies (case reports and small case series) relating to such adverse events have been excluded.

In Galena's large observational study,[16] 14.2% of patients reported adverse events related to pain and bruising (*Table 9*). Such adverse effects were significantly more common in women than in men (38.1% vs 7.9%; $p<0.001$), a result which Galena[16] suggested was probably related to narrower veins in women. No cases of local cellulitis or phlebitis were reported.

Godwin *et al.*[19] reported higher overall rates of bruising. This small before-and-after study audited bruising in two groups of 100 consecutive medical and surgical inpatients aged ≥15 years who were not receiving anticoagulants and did not have extensive pre-existing bruises. Venepuncture was performed by phlebotomists using a pre-evacuated tube collection system to take blood from the antecubital fossa. A clean cotton wool ball was then taped to the venepuncture site; the phlebotomist instructed patients in the first group to apply pressure for a few minutes after the venepuncture, but remained with patients in the second group until the bleeding had stopped. The venepuncture site was then assessed 24 hours later. Bruising was less common in the second group (45% vs 25%; $p<0.01$), and such bruises as occurred were also smaller in this group. The difference between the groups was more marked in older patients (*Table 10*) and the investigators suggested that this was perhaps because they were less able than younger patients to apply pressure to the venepuncture site.[19]

Nerve injury

The potentially most serious adverse events associated with venepuncture relate to nerve injury. Such adverse events can have disabling consequences. The only identified publications that report venepuncture-associated nerve injuries sufficiently severe to be brought to medical attention take the form of case reports and one small case series.

TABLE 8 Vasovagal reactions in patients undergoing venepuncture in hospital phlebotomy clinics[18]

Complication	Number (%; 95% CI)
Patient reported feeling very or extremely faint	13/3315 (0.4%; *0.2% to 0.6%*)
Patient reported losing consciousness	7/3315 (0.2%; *0.1% to 0.4%*)
Phlebotomist reported using strategies to manage fainting symptoms[a] with patient	*30/3315* (0.9%; *0.6% to 1.2%*)

Data in Roman font were taken directly from the text; data in *italics* were calculated by the reviewer.
a For example, reclining the patient's chair, asking patients to place their heads between their legs, or using a cold towel.

TABLE 9 Pain and bruising in patients undergoing venepuncture in outpatient settings[16]

Complication	Number (%; 95% CI)
Bruising	416/4050 (10.3%; *9.3% to 11.2%*)
Haematoma	80/4050 (2.0%; *1.6% to 2.4%*)
Pain	80/4050 (2.0%; *1.6% to 2.4%*)
Total	576/4050 (14.2%;, *13.1% to 15.3%*)

Data in Roman font were taken directly from the text; data in *italics* were calculated by the reviewer.

TABLE 10 Bruising after venepuncture, by haemostasis technique and patient age[19]

	Number of patients with bruising (%; 95% CI)	
Patient age (years)	Patient pressure	Phlebotomist pressure
<60	11/37 (30%; *15% to 44%*)	7/42 (17%; *5% to 28%*)
>60	34/63 (54%; *42% to 66%*)	18/58 (31%; *19% to 43%*)
Total	45/100 (45%; *35% to 55%*)	25/100 (25%; *17% to 33%*)

Data in Roman font were taken directly from the text; data in *italics* were calculated by the reviewer.

The case series presented data relating to 11 patients who were referred to a specialist with a particular interest in nerve injuries because of causalgia following routine venepuncture.[17] However, only four of these patients had undergone venepuncture for blood sampling; in the remainder, the venepuncture was for blood donation, insertion of intravenous lines or intravenous medication. A later paper by Horowitz[5] combined data relating to these 11 patients with data from 13 patients who had subsequently been evaluated; this could not be utilised because it presented aggregated data from patients who had undergone venepuncture for blood sampling and patients who had undergone venepuncture for other reasons.

Data relating to the cases identified in the case reports, together with the four relevant patients from Horowitz's case series,[17] are summarised in *Table 11*. They demonstrate that nerve damage consequent on venepuncture can cause long-lasting pain, loss of muscle power and manual dexterity, and may also lead to clinical depression. Two studies specifically stated that a 20-gauge needle was used. In 4 of the 11 cases, venepuncture was specifically said to have been difficult.

The case studies summarised above do not provide any indication of the rate of incidence of nerve injuries related to venepuncture, other than to imply that they were rare. A more specific impression of the incidence rate can be obtained only by considering two studies from blood transfusion centres. In a New Zealand blood transfusion unit performing approximately 80,000 venepunctures a year, Berry and Wallis[24] found that, over a 2-year period, six people suffered injuries to the median nerve or medial and lateral cutaneous nerves which were severe enough for them to seek medical attention – an overall rate of approximately 1 in 25,000 (0.004%). Of those six, only one (noted above) was undergoing venepuncture for diagnostic purposes, using a 20-gauge needle; the remaining five were undergoing venepuncture for blood donation, using a larger 16-gauge needle. As this study gave no indication of the number or proportion of venepunctures undertaken for purposes of diagnosis rather than blood donation, it has not been possible to calculate a rate of nerve injury specific to diagnostic venepuncture; however, it seems likely that it would be lower than the overall rate.

A higher nerve injury rate was reported from a blood donation centre in the USA where nurses routinely reported all donor injuries. Over a 2-year period, 419,000 blood donations were collected using a 16-gauge needle and 66 cases of neurological nerve injury were identified from nursing records – a rate of 1 in 6300 (0.016%).[27] This figure is not directly comparable with the New Zealand figure because it includes cases which were not brought to medical attention, but the data for donors who requested a physician consultation (17 of the 56 individuals with nerve injury for whom follow-up data were available) also indicates a rate of approximately 1 in 25,000 (0.004%) (*Table 12*). This is a conservative estimate: 9 of the 66 donors with nerve injury could not be contacted for telephone follow-up and one was deliberately not contacted because of pending litigation.[27]

TABLE 11 Nerve damage associated with venepuncture

Study	Subject	Purpose and site of venepuncture	Diagnosis	Outcome	Comment
Berry and Wallis 1977[24]	50-year-old woman	Blood grouping; left antecubital fossa	Injury to the medial cutaneous nerve	Pain and swelling in the forearm developed within 24 hours into hyperaesthesia in the whole forearm. A striking improvement was noted 24 hours after treatment with carbamazepine and 3 days later the only symptom was slight pain on moving the arm. Treatment was discontinued after 5 weeks, when the patient had no symptoms except slightly impaired touch sensation in the sensory distribution of the left medial cutaneous nerve	20-gauge needle used
Horowitz 1994[17]	61-year-old woman	Blood sampling; antecubital fossa	Causalgia affecting medial antebrachial cutaneous nerve	Increased symptoms and motor abnormalities of disuse, with joint contracture and psychiatric depression requiring antidepressant medication, observed at 7 years	
Horowitz 1994[17]	61-year-old man	Blood sampling; antecubital fossa	Causalgia affecting lateral antebrachial cutaneous nerve	Increased symptoms and motor abnormalities of disuse, with joint contracture and psychiatric depression requiring antidepressant medication, observed at 4 years	
Horowitz 1994[17]	56-year-old woman	Blood sampling; antecubital fossa	Causalgia affecting medial antebrachial cutaneous nerve	Increased symptoms, with joint contracture and motor abnormalities of disuse, observed at 18 months	
Horowitz 1994[17]	35-year-old man	Blood sampling; wrist	Causalgia affecting superficial radial nerve	The burning pain resolved spontaneously over a 2-week period, but hyperpathia and allodynia in the injured nerve distribution persisted at 2.5 years	
Nouri *et al.* 2000[20]	59-year-old woman	Routine phlebotomy for pre-operative assessment; radial vein	Causalgia affecting radial nerve	Immediate acute pain and numbness; dysaesthesia, hyperaesthesia, allodynia and loss of muscular power still persisted a year later. Following treatment with paroxetine, tramadol and capsaicin (Zacin®, Cephalon) and six nerve blocks, the pain in the arm and forearm was almost completely resolved, and that in the hand and wrist was somewhat reduced	20-gauge needle used. Venepuncture said to be difficult, requiring three attempts
Pradhan and Gupta 1995[21]	32-year-old woman with a minor pyrexial illness	Routine blood testing; cubital vein	Median nerve	Immediate intense pain in whole of left arm persisting on the palmar aspect of the forearm and hand, and accompanied by weakness and tingling. The paraesthesia subsided in 2 months; mild anaesthesia in radial side of palm persisted for 4 months; muscle power returned to normal with physiotherapy, but minimal wasting was still observed after 1 year	Venepuncture said to be very difficult because of non-visibility of veins
Saeed and Gatens 1983[4]	47-year-old man	Pre-operative phlebotomy; cubital vein	Anterior interosseous syndrome	Pain in forearm and inability to flex thumb noted 4 days after surgery. Surgical tendon transfer required 14 months later to enable appropriate movement of the thumb	Venepuncture said to have been very difficult
Sander *et al.* 1998[22]	64-year-old woman	Phlebotomy (purpose not stated); antecubital	Lateral antebrachial cutaneous neuropathy	Acute pain on insertion of needle followed by pain and numbness persisting, with some improvement, for 5 months	

TABLE 11 Nerve damage associated with venepuncture (*continued*)

Study	Subject	Purpose and site of venepuncture	Diagnosis	Outcome	Comment
Yuan and Cohen 1985[25]	31-year-old man	Routine phlebotomy for pre-operative blood tests; cubital vein	Laceration of the lateral antebrachial cutaneous nerve with neuroma formation	Excruciating pain followed by numbness noted during venepuncture, followed by pain and numbness in the forearm persisting for 3 weeks, and resistant to treatment with butazolidin; lidocaine and steroid injection did not produce lasting relief. Surgery was performed on two occasions: the first was ineffective; the second relieved the pain but left permanent numbness. However, motor function was unimpaired	Repeated attempts at venepuncture were required
Zubairy 2002[23]	44-year-old woman	Routine post-operative blood sampling; cubital fossa	Severe anterior interosseus nerve lesion	Loss of function in the thumb and index finger; weakness of pronation. Management was conservative. The first sign of spontaneous recovery was observed at 20 months and normal function at 34 months after the injury	

TABLE 12 Number of blood donors with nerve injury following venepuncture (data from Newman and Waxman[27])

Recovery period	Number of donors with nerve injury and follow-up data ($n=56$) (% of total; 95% CI)	Number requesting physician consultation(s) (% of category, 95% CI)	Number with residual neurological defect[a] (% of category, 95% CI)
<3 days	22 (*39%; 27% to 52%*)	0 (0%)	0 (0%)
3–29 days	17 (*30%; 18% to 42%*)	5 (29%; *8% to 51%*)	0 (0%)
1–3 months	13 (*4%; 0% to 8%*)	8 (62%; *35% to 88%*)	2 (*15%; 0% to 35%*)
3–6 months	2 (*23%; 12% to 34%*)	2 (100%)	1 (50%; *0% to 100%*)
>6 months	2 (*23%; 12% to 34%*)	2 (100%)	1 (50%; *0% to 100%*)

a Mild localised numbness which did not interfere with function.
Data in *italics* were calculated by the reviewer.

In relation to the more common adverse effects associated with venepuncture undertaken for diagnostic or screening purposes in healthy patients, the evidence base is arguably more substantial than that relating to the value of routine pre-operative testing. Vasovagal reactions were reported by two large observational studies, by Galena[16] and Deacon and Abramowitz;[18] these included 7365 individuals. Data relating to pain and bruising from 4250 patients were available from Galena's large observational study[16] and a small before-and-after study by Godwin.[19] Unfortunately, data relating to nerve injuries in patients specifically undergoing venepuncture for diagnostic or screening purposes were available only from case series or case reports.

The adverse events which were most commonly reported were those related to pain and bruising: these affected between 14% and 45% of patients. Vasovagal reactions were rarer, affecting between 0.9% and 3.4%. No incidence data are available relating to nerve injuries; although these injuries are potentially disabling, they appear to be rare, and it seems likely that the incidence rate would be lower than the 0.004% reported in blood donors.

Pulmonary function testing

Only one study, the pseudo-RCT of pre- and post-operative breathing exercises by Roukema *et al.*,[14] provided evidence relating to the benefits of PFTs (*Table 13*). Four of the 84 patients in the

TABLE 13 Abnormal PFT results and their consequences in ASA grade 1–2 (or equivalent) patients undergoing routine pre-operative testinga

Study	Number of patients tested	Definition of abnormal result	Number of patients with abnormal results (%; 95% CI)	Number of patients whose operation postponed or cancelled because of test result (%)	Number of patients with abnormal test result who had a related adverse event (%; 95% CI)	Number of deaths (%)
Roukema *et al.* 1988[14]	84	Vital capacity <75% of normal	4/84 (*4.8%; 0.2% to 9.3%*)	None reported	2/4 (50%; *1% to 99%)*	0

Data in *italics* were calculated by the reviewer.

control group (4.8%; 95% CI 0.2% to 9.3%) had an abnormal result, defined as a vital capacity <75% of normal; these patients also had an abnormal forced expiratory volume in 1 second (FEV_1). Only two of the four patients (50.0%; 95% CI 1.0% to 99.0%) subsequently experienced post-operative pulmonary complications, compared with 48 of the 80 patients with normal vital capacities (60.0%; 95% CI 49.3% to 70.7%), and the investigators therefore concluded that pre-operative PFT had no predictive value.

The evidence relating to the value of routine PFTs for ASA grade 1 or 2 patients undergoing elective minor to intermediate surgery is extremely limited, being restricted to 84 patients in the control arm of a RCT conducted for another purpose.[14] The proportion of patients with an abnormal result was relatively low, at 4.8%, and did not lead to a change in management in any of the patients.

As the included study did not report adverse events relating to PFTs and the clinical effectiveness searches identified only one relevant case report,[28] additional systematic searches were carried out; these were designed specifically to identify studies which reported adverse events associated with PFTs in patients without obvious predisposing health conditions (for the MEDLINE search strategy, see *Appendix 8*). These additional searches identified two relevant articles, by Krasnick[29] and Oliphant *et al.*[30] (for QUOROM diagram, see *Appendix 10*); a further three relevant articles, by Manço *et al.*,[31] Nemet *et al.*[32] and Varkey and Cory,[33] were identified from citations. A seventh paper, reporting a case of short-lived pneumoparotid apparently caused by PFTs, was excluded because the patient had a predisposition to this condition: he could sometimes produce facial swelling intentionally by coughing or blowing forcefully against his closed mouth, and had had bilateral facial swelling after an aeroplane flight.[34]

Krasnick[29] states that the adverse effects of PFTs include dizziness from hyperventilation and vasovagal reactions. However, such adverse events were not reported in the included studies, which reported only potentially more serious adverse events which appeared to be related to increased pressure in the mouth, throat or chest: pneumomediastinum, pneumothorax, subcutaneous emphysema and incarceration of existing inguinal hernia. One study[30] reported an adverse event of a different nature, namely bilateral temporomandibular joint dislocation. The authors noted that, to the best of the their knowledge, this was unique as an adverse effect of PFT: most such dislocations result from wide opening of the mouth, which is not required for PFT (*Table 14*).

The studies summarised above provide little indication of the rate of incidence of adverse events related to PFTs. Four[29,30,32,33] of the six studies were individual case reports; as such, they provide no estimate of the incidence of the adverse events which they report other than to imply that, in the authors' experience, they were unusual. Manço *et al.*[31] reported that pneumomediastinum,

TABLE 14 Pulmonary function testing: adverse events in subjects without obvious predisposing health conditions

Study	Subject	Specific test used	Adverse event	Treatment	Resolution
Krasnick 2001[29]	32-year-old man with upper-chest tightness	Investigational spirometry before and after administration of nebulised levalbuterol hydrochloride	Pneumomediastinum (symptoms severe throat and neck pain and raised vocal pitch)	Apparently none	Symptoms resolved within 36 hours; a chest radiograph 5 days later was normal
Nemet *et al.* 2004[32]	Healthy 22-year-old, non-smoking female volunteer	Repeated FEV_1s performed 'with great vigour' as part of research study	Pneumomediastinum and subcutaneous emphysema	Admitted to hospital overnight and treated with supplemental oxygen	Condition had improved sufficiently by the following day for hospital discharge; a full recovery was made within 2 weeks
Manço *et al.* 1990[31]	Healthy 25-year-old, non-smoking male physician	Standard spirometry, including repeated measurement of PE_{max}, undertaken as part of investigation to establish normal values	Pneumomediastinum, bilateral pneumothorax and subcutaneous emphysema (symptoms discomfort in the neck, mild dysphagia and dysphonia)	Apparently none	Symptoms resolved in about 3 days
Varkey and Kory 1973[33]	Healthy 23-year-old male medical student	FVC undertaken for familiarisation with PFT procedures	Mediastinal and subcutaneous emphysema (symptoms anterior chest pain, dizziness, swollen neck and mild discomfort on swallowing)	Hospital admission for observation, symptomatic treatment for pain	Symptoms subsided completely in the following 5 days
Patel *et al.* 1992[28]	Two male patients (one aged 63 and one aged 80 years) with inguinal hernia	Pre-operative PFT	Incarceration of existing inguinal hernia	Emergency surgery	Uncomplicated recovery; discharged from hospital on the fifth and fourth post-operative day
Oliphant *et al.* 2008[30]	78-year-old man	PFT (purpose not specified)	Bilateral temporomandibular joint dislocation	Supplemental oxygen via nasal cannula; reduction of dislocation under conscious sedation	Discharged with follow-up arranged with a maxillofacial surgeon; PFT repeated uneventfully 6 weeks later

FVC, forced vital capacity.

bilateral pneumothorax and subcutaneous emphysema occurred in 1 of 30 normal subjects in whom repeated measurement of maximum static expiratory (PE_{max}) mouth pressure had been undertaken for research purposes; the remaining 29 subjects suffered no ill effects. However, it seems highly unlikely that the incidence of this complication in normal clinical practice is as high as 1 in 30 as the authors stated that they had not previously observed any complications during extensive use of the technique in normal subjects and patients.[31] Moreover, it is perhaps noteworthy that the subjects of two other case reports were volunteers undertaking PFT for purposes of research[32] or familiarisation:[33] they are likely to have performed the manoeuvres more frequently or more vigorously than would be normal in pre-operative testing. Following their observation that two patients with inguinal hernia developed incarceration in that hernia following routine pre-operative PFT, apparently as a result of the prolonged increase in intra-abdominal pressure caused by forced expiratory spirometry, Patel *et al.*[28] undertook a retrospective review which identified that the remaining six patients with inguinal hernia who were referred for pre-operative spirometry in the same hospital during the same 12-month period did not suffer this adverse event, suggesting an incidence rate of one in four in this particular patient group. They identified no clinical or physiological criteria which differentiated the patients who developed incarceration from those who did not, and therefore concluded that, to prevent this complication, the use of a truss should be considered when undertaking PFT in all male patients with hernias.

Only one of the six studies, that by Patel *et al.*,[28] specifically stated that the adverse effects occurred after routine pre-operative PFT. In the case report by Oliphant *et al.*,[30] the purpose of testing was not clear, while in the case reported by Krasnick[29] it was carried out for investigational purposes. In the remaining three cases, PFT was carried out either for research purposes[31,32] or for familiarisation with the process;[33] it is possible therefore that they were not representative of patients undergoing PFT for routine pre-operative testing. Thus, in the case reported by Manço *et al.*,[31] repeated measurement of PE_{max} mouth pressure was performed in an exercise designed to establish normal values for that laboratory, while Nemet *et al.*[32] reported that the subject performed FEV_1 manoeuvres 'with great vigour', perhaps implicitly greater than usual in clinical practice, and to have continued despite feeling chest pain after the first FEV_1 manoeuvre; she did not report this pain, but ran on a treadmill for 10 minutes before repeating the FEV_1 manoeuvre twice more, by which time the symptoms had increased. Finally, Varkey and Kory[33] reported the case of a healthy 23-year-old male medical student, described as 'most eager to perform as well as possible on the pulmonary function tests', who also continued with the tests despite noticing slight chest pain after the first manoeuvre, and increasing symptoms thereafter. It thus appears possible that, in these three cases, the symptoms may have been caused by particularly energetic performance of the manoeuvres, and exacerbated by continuation with testing despite the existence of those symptoms; such scenarios may not be typical of routine patient testing.

Discussion

The systematic review of the evidence for the clinical effectiveness of routine pre-operative testing in ASA grade 1 or 2 patients undergoing elective surgery has demonstrated the weakness of that evidence base. Despite thorough searching, no relevant RCTs and only six relevant observational studies[9,11–15] were identified; only one[14] of these related to PFTs. Moreover, not all of the observational studies reported the proportion of patients with abnormal test results, and fewer reported the more clinically useful measure, the number of patients whose management was changed as a result of an abnormal test result.

Furthermore, there are concerns that none of the included studies incorporated UK data, and those which were conducted in countries in which health care is funded by private health

insurance, namely Argentina and the USA, incorporate a potential source of bias. As noted in *Quality of research available*, Gnocchi *et al.*[11] state that 270 of the 777 patients in ASA grades 1–3 who attended an Argentine hospital for pre-operative evaluation did not return for surgery (35%; 95% CI 31% to 38%); the primary reason was said to be lack of insurance cover for medical expenses. They do not state how many of the original 777 patients were in grade 1 and therefore scheduled for routine pre-operative testing, but present the results of such testing only for the 214 grade 1 patients who returned to the hospital for a second interview. Of the 210 patients (98%; 95% CI 96% to 100%) who were deemed to be fit for surgery, 71 (34%; 95% CI 27% to 40%) did not undergo the operation for which they were scheduled; again, the main reason appeared to be lack of cover for medical expenses. As no details are given of the health status of the patients who dropped out at either point in the study, compared with those who underwent the scheduled operation, the study incorporates the potential for systematic bias at both points. Although attrition was lower in Haug and Reifeis's study[13] of patients undergoing dental surgery in the USA, 78 of 458 patients (17%; 95% CI 14% to 20%) failed to return on the appointed day; no reasons were given for this. As the other studies are less explicit about the pathway from assessment to operation, they may also contain the potential for bias related to financial or other, unknown, factors.

Chapter 3

Cost-effectiveness

Aim of the cost-effectiveness review

A review of existing literature was undertaken to identify and quality assess all English-language economic evaluations of the routine pre-operative ordering of FBC tests, PFTs and U&Es. This was done in order to:

- assess the quality of published evaluations of these tests that consider both costs and effects simultaneously
- identify and explore the trade-offs involved in undertaking a test to identify a problem that would change the management of the patient, or not undertaking that test and incurring the potential risks to the patient
- explore the uncertainty produced by limitations of empirical data
- identify the areas where further primary research would be most valuable.

Review methods

Identification of studies

A systematic search of the literature to identify evidence on cost-effectiveness of routine pre-operative testing was performed between March and April 2008. Searches were designed to identify cost-effectiveness studied on pre-operative testing of apparently healthy individuals. Pre-operative tests included FBC, electrolytes and renal function (U&E), and pulmonary function (PFT) in the adult patient population, specifically in individuals classified as ASA grade 1 and 2 undergoing elective minor (grade 1) or intermediate (grade 2) surgical procedures.

Search strategy

The search strategy was developed by the Information Resources team at the School of Health and Related Research, University of Sheffield. Additionally, economics filters used by the NHS CRD were used to populate the NHS Economic Evaluation Database (NHS EED) and were adapted to other databases.

The core search strategy used for the review was designed for searching the MEDLINE electronic database, and was adapted as appropriate for all other databases searched, taking into account differences in indexing terms and search syntax for each database. *Appendix 11* provides the search strategies employed.

Databases were searched from their date of inception to the most recent date available at that time. There was no restriction of study by country of origin, date of publication or language.

References were imported into Reference Manager (Thomson ResearchSoft, San Francisco, CA, USA) and then exported into an EndNote (version X2; Thomson Reuters, CA, USA) database, where they were managed.

Sources searched

A range of databases were searched to locate information on economic evaluations of routine pre-operative testing. The aim was to evaluate how relevant studies assessed the cost-effectiveness of the relevant pre-operative tests and the methodology that was adopted.

The following electronic bibliographic databases were searched:

1. MEDLINE
2. MEDLINE In-Process & Other Non-Indexed Citations
3. EMBASE
4. The Cochrane Library (include the CDSR, CENTRAL, NHS EED, NHS HTA and DARE)
5. BIOSIS
6. SCI.

Inclusion criteria

Studies that evaluated the cost-effectiveness, cost–utility or cost–benefit of routine pre-operative testing were eligible for further appraisal as long as they met our abstract selection criteria. More specifically, the analysis had to compare both costs and outcomes of alternative tests and report the results in an incremental basis (e.g. cost per life-year saved or cost per quality-adjusted life-year saved).

Abstract selection criteria:

- *language* – English
- *study stetting* – UK-based study population
- *patient age* – adults (aged 16–60 years)
- *patients* – ASA grade 1 classification (completely fit and healthy) or ASA grade 2 classification (some illness but no effect on normal daily activity)
- *surgical procedures* – minor (grade 1, for example excision of lesion of skin or drainage of breast abscess) or intermediate (grade 2, for example primary repair of inguinal hernia, excision of varicose veins of leg, tonsillectomy or knee arthroscopy)
- *types of procedures* – elective general surgery, day surgery or minor orthopaedic procedures
- *pre-operative tests* – FBC, U&E and PFT (these include the following: some or all of spirometry, blood gas analysis, measurement of respiratory mechanics, measurements of transfer function, exercise testing of the respiratory system; generally, tests that identify unexpected anaemia, electrolyte abnormalities or abnormalities of respiratory function)
- *details of economic evaluation* – resource use/cost and outcome comparison undertaken.

Exclusion criteria

Studies were also excluded if at least one of the three tests under investigation was not carried out (FBC, U&E or PFT). Finally, papers were excluded if the study was carried out on a paediatric or pregnant population.

Papers were initially excluded from further review if the study did not conduct a full economic evaluation, i.e. if there was not an incremental comparison of costs and effects.

However, in addition, economic evaluations that did not contain incremental analysis and partial economic evaluations (e.g. cost analysis) were identified if they satisfied all the other criteria (with the exception of being UK based) in order to extract data that might be used in an economic model.

Identification of relevant data to inform the economic model

Sifting

The sifting of the references identified by the literature searches for relevant papers to the present study was shared between two reviewers (CMc and YO). Both reviewers screened references by title and abstract. Once potentially relevant studies were identified the full manuscripts of those that were not excluded at this stage were obtained for a more detailed appraisal. The screening of full manuscripts was split between the two reviewers. The full papers that were identified as being potentially relevant were shared between the two reviewers for further screening (half of the full manuscripts were assessed by each of the reviewers). Each reviewer selected papers if they met the abstract selection criteria. Abstract selection tables were filled out by the reviewers to identify studies of relevance (see *Appendix 12*). Once references were selected data extraction was undertaken by one of the reviewers (YO) using customised data extraction forms.

Data extraction

Data extraction of the identified references was undertaken by collecting details on specific aspects of the studies that could inform the design and parameterisation of a cost-effectiveness model. The following details were identified in the data extraction form:

- characteristics of studies, type of evaluation and synthesis
  - type of test (FBC, U&E or PFT)
  - interventions (surgery type)
  - study population
  - country
  - duration of study
  - type of model used
  - perspective
  - model assumptions (with regard to outcomes and model construction)
- cost and resource-use data sources
  - unit costs
  - unit cost data sources
  - resource use
  - resource data source
  - currency and currency year
  - discount rate
  - efficacy data and health outcomes/utility efficacy data
  - efficacy data sources
  - health outcomes/utility
  - health outcome data sources
  - discount rate
  - cost-effectiveness ratios
  - total costs
  - total incremental costs
  - total outcome
  - total incremental outcomes
- sensitivity analyses
  - sensitivity analysis methods
  - sensitivity analysis results
- author conclusions.

Further in-depth assessment of studies included

A thorough assessment of the identified references that were selected for data extraction was undertaken. This involved a detailed appraisal of the data that were provided in the studies. Information on the patient population was further assessed to see if clear details regarding the patients' ASA grades were reported and, if so, whether or not it was possible to unpick these data relating to just ASA grade 1 and 2 patients. Additionally, a detailed assessment of the surgical interventions carried out in the studies was undertaken. An evaluation of the data provided in relation to minor or major surgery (as per the definition above) was undertaken. Finally, data regarding the pre-operative tests undertaken in the studies were reviewed to see if they aligned with the tests in question.

Quality assessment of full evaluations included

In order to assess the evidence provided in the studies included in the review, quality assessment of the full economic evaluation included in the review was undertaken. Quality assessment criteria were based on a widely used quality assessment checklist specifically for economic evaluations. The Drummond Checklist[35] was used in order to assess the methodological quality of economic evaluations which met the inclusion criteria. This is a standard checklist for the critical appraisal of economic evaluations and contains a list of questions used to interrogate published studies. An assessment of the evidence provided in the study relating to the cost-effectiveness, cost and utility data reported was undertaken, as well as an assessment of the suitability of this evidence for use in an economic evaluation within the scope of the present study.

No quality assessment was carried out for the partial economic evaluations.

Results

Literature search results

Figure 2 shows the results of the literature search which identified 5151 references in total. Of these, there were 252 duplicated references. Thirty-two references were identified as not being in the English language. Non-English-language references were identified electronically by scanning through the database entries. Two hundred and eighty-two references were identified as relevant from the title and abstract sifting using the abstract selection criteria. Of the 282 full manuscripts that were obtained for further assessment, eight papers[36–43] (one full economic evaluation[36] and seven partial economic evaluations[37–43]) were identified for data extraction.

Full papers excluded

All 282 full papers that were identified as relevant were assessed based on the abstract selection criteria. An abstract selection table was used to log the key characteristic of each paper. Papers were excluded from further detailed assessment and data extraction if they did not fit the inclusion criteria. For example, papers were not included if they were not in the English language or were of studies not carried out in the UK or that did not assess the relevant pre-operative tests. The result of the full paper screening based on the 282 references identified is given in *Table 15*. Manuscripts were excluded if they did not fit one or more of the inclusion criteria. (Characteristics of all the 282 full papers in relation the abstract selection criteria are presented in *Appendix 12*.)

Two hundred and five papers were excluded because they did not provide a full economic evaluation. This was in addition to not assessing the patient population, surgical procedures and pre-operative tests relevant to the current study. A further 39 papers were found not to be in the English language. Seventeen papers were excluded because they did not assess the age range of patients relevant to this study. A further 13 papers did not meet the criteria for the pre-operative tests and the surgical procedures under study.

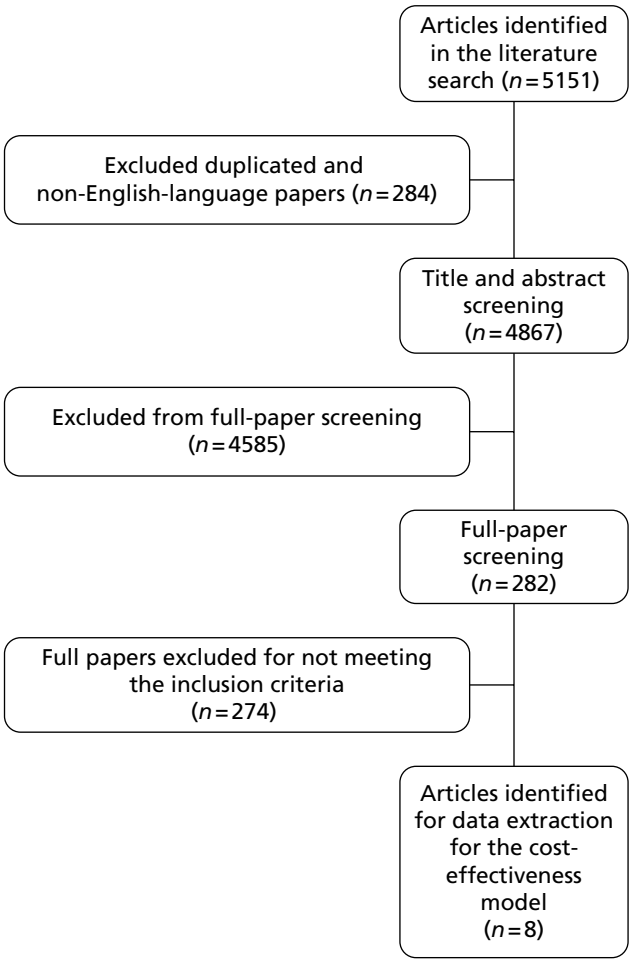

FIGURE 2 Results of cost-effectiveness literature search.

TABLE 15 Results of full paper screening against the abstract selection criteria

Stages		No. of references identified
Manuscripts obtained for more detailed appraisal after title and abstract screening		**282**
Manuscripts excluded from data extraction		
Language – not English	39	
Patients 1 – not aged 16–60 years	17	
Surgical procedures – not minor or intermediate	1	
Tests – not FBC, U&E or PFT	12	
Economic evaluation: not incremental analysis of costs and outcomes and not		
Patients 2 – not ASA grade 1 or 2 classification, or		
Surgical procedures – not minor or intermediate, or		
Tests – not FBC, U&E or PFT	205	
Total no. manuscripts excluded from data extraction		**274**
Manuscripts identified for data extraction		**8**
Full economic evaluations (i.e. report incremental cost-effectiveness ratio)	1	
Partial economic evaluations	7	

Studies identified for inclusion

A final set of eight papers were identified for inclusion in the cost-effectiveness review and data extraction (see *Appendix 13* for data extraction tables). On closer inspection of the data relating to the patient ASA grade, surgical interventions and pre-operative tests performed, it became clear that the studies identified did not provide enough relevant data to inform the model structure or parameterisation of the economic model for any of the three tests currently under study (*Table 16*).

The Lawrence *et al.* study[36] is the only full economic evaluation identified by the literature search. However, the focus of the study is urinalysis (UA), and it does not report results for any of the tests in the scope of the review.

Capdenat Saint-Martin *et al.*[37] assessed the use of a local adaptation of national guidelines combined with active feedback and organisational analysis on the ordering of pre-operative investigations for fit ASA grade 1 patients undergoing surgery in 15 wards in a university hospital in France. Pre-operative tests ordered were assessed over 1 month, before and after the local guideline was employed. The sample population included low-risk patients. The patient population included in the study comprised both children aged < 18 years and adults: pre-intervention, $n = 536$ (47% of the sample were aged < 15 years); post-intervention, $n = 516$ (50% were aged < 15 years). Given that the data were not split by age group, it is not possible to report the findings for the adult population aged 16–60 years independently.

Pre-operative tests assessed included blood typing and screening for unexpected antibodies, Hb, prothrombin time and partial thromboplastin time, platelet count and bleeding time, electrolytes and blood glucose, blood urea nitrogen and creatinine.

Outcome measures reported in the study included the number and type of pre-operative tests ordered within the study period (1 month in 1993 and 1 month in 1994 representing the pre- and post-guideline time periods) and the estimated savings. Mean costs of pre-operative testing were calculated for the two measurement periods, costs were reported in francs, dollars and the European currency unit (ECU – an artificial 'basket' currency that was used by the member states of the European Union as their internal accounting unit at that time).

The study population includes a significant number of patients aged < 15 years. As the current study is concerned with the adult population, this study is not relevant for informing the cost-effectiveness analysis for these tests, as per the scope of the review. The data are presented for the whole sample of patients. There was no subsample analysis that would have enabled the teasing out of data specifically relating to the patient population aged 16–60 years. Additionally, some of the patients underwent emergency surgical procedures. The data for each type of surgery was not presented separately. It was not possible to identify *only* those patients who had minor or intermediate surgery.

The article by Fischer[38] addresses the development and implementation of an Anaesthesia Preoperative Evaluation Clinic (APEC) at a university hospital in the USA. The clinic aimed to provide a service to support physicians in deciding which pre-operative tests their patients might need. All consultations, physical evaluations, educational resources, laboratory and electrocardiographic services, and hospital admissions and registrations were made available in one centralised location. Fischer[38] compared pre-operative tests ordered by surgeons and primary care physicians for a 6-month period before the clinic was introduced in the hospital and the 6-month period that occurred 1 year after the introduction of the clinic when ordering of pre-operative assessments was carried out by the anaesthesiologist. Over a 1-year period in 1995, the APEC evaluated 8972 adult patients (age range was not reported) for surgery and

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TABLE 16 Characteristics of the studies identified for the cost-effectiveness review

Study	Type of evaluation and synthesis	Type of test	Interventions	Study population	Country	Duration of study	Comments
Full economic evaluations							
Lawrence *et al.* 1989[36]	Full cost-effectiveness and cost–benefit analyses	Routine UA	Use of routine UA in the prevention of wound infection for elective clean-wound, non-prosthetic knee procedures. A comparison of routine, or screening, pre-operative UA vs no screening UA for UTI remote from the operative site	Surgical subset of elective, clean wound, intra-articular, non-prosthetic knee procedures not involving osteotomy	USA	Not stated	Insufficient detail given to assume data was limited to ASA grade 1, or adults
Partial economic evaluations							
Capdenat Saint-Martin *et al.* 1998[37]	Not a full economic evaluation – assessed the number and type of pre-operative tests ordered within the study period, the estimated savings and mean cost of pre-operative testing	T/SA, Hb, PT/PTT, Plt/BT, Elec/Glu and BUN/creat	Local adaptation of national guidelines combined with active feedback and organisational analysis	Anaesthetists in 15 surgical wards of Bordeaux University Hospital, Region Aquitain, France	France	1 month in 1993 and 1 month in 1994	ASA grade 1 patients, but includes children and emergency surgery
Fischer 1996[38]	Not a full economic evaluation – total pre- and post-clinic implementation costs were evaluated to assess the cost saving of the introduction of the clinic	CBC, platelets, UA, PT/PTT, general survey panel, electrolytes, renal panel, CXRs and ECGs	APEC	8972 adult patients attending the APEC who were evaluated for surgery and consultation	USA	6-month period pre-APEC and 1-year post APEC	Includes ASA grade 3 and 4 patients. Not enough detail given to grade of surgery
Imasogie *et al.* 2003[39]	Not a full economic evaluation – provides an assessment of cost savings when routine pre-operative testing is discontinued	Includes CBC, electrolytes, creatinine, urea, glucose and ECG	The discontinuation of pre-operative tests in ambulatory cataract surgery – two groups compared: (a) testing group with (b) non-testing group	Consecutive cataract patients' charts were reviewed, during the period of June to September 2000 representing the patients who had routine pre-operative tests (testing group) and June to September 2001 representing the patients who had no routine pre-operative tests (non-testing group)	Canada	4 months	Appears to include any ASA grade

continued

TABLE 16 Characteristics of the studies identified for the cost-effectiveness review (*continued*)

Study	Type of evaluation and synthesis	Type of test	Interventions	Study population	Country	Duration of study	Comments
Johnson and Mortimer 2002[40]	Not a full economic evaluation – a cost-saving analysis was presented in terms of the selective ordering of tests	The medical notes of 100 surgical patients were scrutinised pre-operatively prior to induction of anaesthesia The results of FBC, U&Es/creatinine and random glucose were recorded	Prospective audit of medical notes of patients undergoing elective surgery	100 patients undergoing elective surgical procedures under general anaesthesia	UK	1995–6	ASA status and surgical intervention not reported
Kitz *et al.* 1988[41]	Cost analysis – not full economic evaluation, results present include a cost analysis of operating and recovery room time, staff costs and total costs of pre-operative tests in the two study settings	CBC, UA, ECG, Panel 6 and chest radiogram	Inpatient and ambulatory logs were examined to identify hospital resources used for comparable groups of INPTs and DSU patients undergoing surgical arthroscopy and laparoscopy: level I – visual examination of pelvic viscera; level II –also includes fallopian tube with methylene blue or radio-opaque dye	INPTs and DSU patients undergoing surgical arthroscopy of the knee or diagnostic laparoscopy (ASA grade 1 and 2 patients)	USA	January to June 1984	Limited data, only providing a cost summary
Larocque and Maykut 1994[42]	Not a full economic evaluation – provides unit costs of each of the pre-operative tests employed and a count of each time a test was performed which was compared for the pre- and post-protocol period	CBC, liver profile, chest radiography, electrocardiography and UA	Implementation of a guideline for pre-operative laboratory investigation using retrospective chart audit	Patients operated on including minor surgery and major surgery	Canada	December 1991 to July 1992	Included patients ASA grades 3–5 and major surgery
MacPherson *et al.* 2005[43]	Not a full economic evaluation – the average number of tests per patient and cost of tests per patient were calculated	Coags; CPM; EUC; FBC; G&H; LFT and TFT	Assessment of a protocol-based test ordering system or guideline in the ordering of pathology tests in surgical patients attending PAC	All elective adult surgical patients attending the hospital PAC	Australia	Pre-guideline implementation – Group I (700 individuals attending the PAC between April and June 2002); immediate post-guideline introduction (720 individuals between April and June 2003)	Insufficient detail given to assume data was limited to ASA grade 1, or adults, or grade 1–2 surgery

APEC, Anaesthesia Preoperative Evaluation Clinic; BUN/creat, blood urea nitrogen and creatinine; CBC, complete blood count; Coags, tests of coagulation; CPM, calcium, phosphate and magnesium; DSU, Day Surgery Unit; Elec/Glu, electrolytes and blood glucose; EUC, electrolytes, urea and creatinine; G&H, group and hold test; INPT, inpatient; LFT, liver function test; PAC, pre-admission clinic; Plt/BT, platelet count and bleeding time; PT/PTT, prothrombin time and partial thromboplastin time; T/SA, blood typing and screening for unexpected antibodies; TFT, thyroid function test; UA, urinalysis; UTI, urinary tract infection.

consultation. Patient assessments included ASA grade 1 (12%), grade 2 (29%) and grade 3 (54%). Some patients (< 5%) of ASA grade 4 status were also included in the study. Patients evaluated in the clinic were either undergoing surgery the following day (the authors state approximately 70% of the sample) or undergoing procedures 2–7 days after evaluation (28%). No further details are given about the types of surgery that patients underwent.

The pre-operative tests assessed in the study were as follows: complete blood count (CBC), platelets, UA, general survey panel [renal panel, liver function test (LFT), glucose, calcium, albumin, magnesium and uric acid], electrolytes, renal panel and prothrombin time/partial thromboplastin time. These were recorded as the number of each of the tests carried out between the two time periods.

Outcomes assessed in the study included the number of tests ordered, the number of operating room cancellations and number of delays or adverse patient events. The cost of each test was determined using an in-house system. The total pre- and post-clinic implementation costs were evaluated to assess the cost saving resulting from the introduction of the clinic.

The applicability of this evidence is limited for the purposes of this study. A significant number of patients were ASA grade 3 or grade 4 (just under 60%) and thus outside the scope of the review. Additionally, detailed information regarding surgical procedures was not available; thus, we are unable to identify whether procedures undertaken were minor or intermediate. As a result, the relevance of the results of Fischer[38] to the patients/procedures specified in the scope of the review is unclear.

The study by Imasogie *et al.*[39] aimed to evaluate the potential cost savings accruing when routine pre-operative testing is discontinued in ambulatory cataract surgery patients. The hospital-based study was set in Canada and assessed the introduction of a new policy of discontinuing routine laboratory testing prior to cataract surgery.

The charts of cataract patients were reviewed over a 4-month period prior to (testing group) and after the introduction of the new policy a year later. This provided data on 636 patients in the testing group and 595 patients in the non-testing group.

The pre-operative tests assessed included LFT, ECG, echocardiogram, chest radiography, CBC, INR, partial thromboplastin time, Hb, sickle screen, electrolytes, urea and creatinine (EUC); glucose and cardiac stress test.

Clinical data were collected on ASA grade, past medical history and medications, perioperative events (cancellations, intraoperative hypertension, arrhythmia, hypotension), and post-operative events including unanticipated admission and readmissions.

The costs of individual tests were identified from the hospital finance department. Based on the tests ordered and the cost of each, the total costs of laboratory tests of individual patients were calculated. The outcomes evaluated were perioperative hypertension, hypotension, bradycardia arrhythmias, myocardial ischaemia, myocardial infarction, congestive heart failure, syncope, hypoglycaemia, oxygen saturation of < 90% and airway obstruction.

The authors found that there was no difference in the incidence of pre-operative, intraoperative or post-operative events between the two groups of patients. They found a significant reduction in the number of tests per patient ordered in the non-testing group: 0.4 tests per patient compared with 5.8 tests in the testing group. A 90% reduction in laboratory costs per patient was achieved.

Details of patients' ASA status were not reported in the paper; the authors reported only that these data were collected and that the two groups were not significantly different in terms of ASA status. Although the study provided detailed information on the three tests that are the focus of this study, the lack of information on ASA status, test indication and subsequent treatment and outcomes of treatment, means that generalising from this study to the tightly specified patients in the scope of this review is unlikely to be appropriate.

Johnson and Mortimer[40] carried out a prospective audit of the medical notes of 100 patients (between 1995 and 1996) undergoing elective surgical procedures under general anaesthesia in a teaching hospital in the UK (Manchester Teaching Hospital) in order to determine the value of routine pre-operative screening investigations. These investigations included FBC, U&Es and random glucose. The investigations were performed on all patients presenting for elective surgery.

A total of 773 pre-operative screening investigations were analysed in terms of frequency of abnormalities and whether or not the perioperative management was changed when the result was abnormal. Notes were taken from different specialties (39 vascular, 35 breast and 26 urology), but no further details were given about the surgical operations that were undertaken. The costs of the tests were also examined.

The authors found that 9.1% of test results were abnormal. Perioperative management was altered as a result of only two abnormal results (0.2%). Eight complications occurred perioperatively, none of which could have been predicted by the pre-operative screening tests. A cost analysis was presented using selective ordering of tests.

The study does not give sufficient detail of the patient population or the surgical interventions that were undertaken to assume that the evidence presented is in line with the requirements of the present study. Also, given that the data from the study were derived from one hospital in the UK, generalisability of the results is limited.

The comparison of the use of pre-operative tests, operating and recovery room time for comparable groups of patients receiving inpatient or ambulatory care was undertaken by Kitz *et al.*[41] Hospital costs for the pre-operative tests and for nursing labour costs, based on operating and recovery room times, were also assessed.

Patients undergoing surgical arthroscopy of the knee and diagnostic laparoscopy were included in the study. Diagnostic laparoscopies were divided into two groups: (1) level 1 – visual examination of the pelvic viscera only; and (2) laparoscopy with fallopian tube lavage with methylene blue of radio-opaque dye.

The study utilised inpatient and ambulatory logs to identify patients who underwent inpatient or ambulatory surgical arthroscopy from January to June 1984. Pre-operative tests assessed included CBC, UA, ECG, Panel 6 and chest radiography.

The study provided a cost analysis including the costs of individual laboratory and radiology services. Total hospital costs for the tests were calculated for the inpatients and for the day surgery unit. The study did not aim to assess the cost-effectiveness of the tests or provide a full economic evaluation; for example, no utility data are presented in the study. The evidence is limited for informing the cost-effectiveness model as it provides only a summary of the costs for each of the tests. The costs are based on data from one institution in in the USA. Given that the study was carried out over 20 years ago, the applicability of these costs to the current study setting is extremely limited.

Larocque and Maykut[42] assessed the implementation of guidelines for pre-operative laboratory investigations using a retrospective chart audit. The charts of patients were taken from a Canadian university teaching hospital (between 1991 and 1992).

Patients who had undergone both minor (e.g. cataract extraction, transurethral resection of the prostate) and major (e.g. laparoscopic cholecystectomy, hip arthroplasty, abdominal hysterectomy, breast reduction and radial neck dissection) surgery were included in the study. The study also collected data on the age of patients, any pre-existing conditions, medications, ASA status, type of surgery and type of anaesthesia. Patients in ASA grades 1–5 as well as patients undergoing both minor and major surgery were included. The results were not reported separately for each of the ASA subgroups or combinations thereof.

The outcome measures used in the study included reduction in the number of tests performed and the impact of a reduction in tests on morbidity and mortality.

The study reports the unit cost of each of the pre-operative tests and the number of tests performed. This count was compared for the pre- and post-protocol period. These data are specific to the Canadian teaching hospital in which the study was conducted and thus of limited relevance to a UK analysis. In addition, the study data were reported in an aggregate form (e.g. the total number of investigations), meaning that insufficient detail is available for use in parameterising a UK cost-effectiveness analysis.

MacPherson *et al.*[43] assessed whether or not the introduction of a protocol-based test ordering system (or a guideline) would reduce ordering of inappropriate pathology tests in surgical patients attending a pre-admission clinic (PAC) in a hospital based in Australia. The guideline provided information in two parts: the first contained information about tests to be ordered on the basis of the proposed surgical procedure and the second provided a list of test to be ordered according to a pre-existing medical condition.

The data were obtained from three cohorts of patients attending the PAC over three different time periods: before guideline implementation – group 1 (700 individuals attending the PAC between April and June 2002); immediate post guideline introduction – group 2 (720 individuals between April and June 2003); and the final group (group 3) included individuals attending the PAC clinic the subsequent 3-month period after the introduction of the guideline (763 individuals attending PAC from July to August 2003). The following tests were included in the study: tests of coagulation (Coags), calcium, phosphate and magnesium (CPM), EUC, FBC, group and hold tests (G&Hs), LFTs and thyroid function tests (TFTs).

The study examined the numbers of patients in each group for whom any of eight standard pathology tests had been ordered. The average number of tests per patient (group 1, 2.48; group 2, 1.88; and group 3, 1.91), and cost of tests per patient (group 1, A$42.22; group 2, A$31.89; and group 3, A$33.05) were presented. Further details of the assessment of outcome measures were not given. As with many of the other studies, the usefulness of this study as an information source for a UK cost-effectiveness analysis is limited by the lack of detailed information about the ASA status of patients and surgical interventions undertaken.

Discussion

The systematic review shows the lack of available data involving full economic evaluation of the routine pre-operative ordering of FBC, PFTs and U&Es at present. Only one full economic evaluation was identified.[36] Although we additionally reported seven further partial economic evaluations[37–43] with a view to extracting data that might be used in an economic model, these too provided few data that could be utilised.

Overall, the studies identified were either non-UK based, did not involve ASA grade 1 or 2 patients or did not assess electrolytes and renal function and pulmonary function pre-operative tests. The one cost-effectiveness analysis identified explored the implications of carrying out and not carrying out pre-operative testing; however, it did not include utility-based outcomes, was more than 20 years old and was carried out in the USA. Insufficient evidence was available to construct, or aid construction of, a decision probability model for the three tests.

The seven further partial economic evaluations lacked detailed information about the study population and the surgical interventions. Three studies presented findings of guideline or protocol implementation.[37,42,43] These studies focused on deriving total costs and costs per patient to show the benefits of carrying out a reduced number of routine testing. They did not provide enough detailed cost data to inform the building of an economic model.

The demographics of the patients included in the studies were also problematic. Once again, few details were given; one study[37] included a large proportion of patients aged < 16 years in the analysis and without details of any subanalysis was not applicable to our study setting. Similarly, the ASA grades included in the studies did not fit our criteria, in as much as none of the papers separated the results by ASA grade 1 and ASA grade 2 classes, which are the focus of our study.

There are some limitations to the review that should be noted. The search strategy identified a large number of studies that were not relevant. This may perhaps be the result of utilising broad search terms. However, this was necessary to ensure that relevant studies were not excluded. Additionally, papers that were not in the English language were excluded from the cost-effectiveness review. Some of these papers may have been relevant to the study setting. However, the applicability of non-UK-based studies in informing the model is likely to be limited.

Future studies assessing the cost-effectiveness of pre-operative tests would benefit from providing disaggregate information about the patients' ASA status and the type of surgery proposed, as well as detailed data on any amendments to perioperative management in response to test results, cancellations and delays of operations and perioperative outcomes. The data would allow a better comparison between studies as well helping to characterise the clinical pathway for a cost-effectiveness model.

In terms of data required to reflect the real-world application of the tests, evidence regarding the delivery of tests would be of value in informing an economic model (i.e. delivered in a bundle or in sequence could be a valuable distinction in building an economic model).

Chapter 4

Survey of current practice on pre-operative testing in ASA grade 1 and ASA grade 2

The purpose of the survey was to capture current practice of ordering tests for patients classed as ASA grades 1 and 2 undergoing elective minor or intermediate surgery. To do this we chose to approach hospital-based pre-operative assessment clinics directly. We wanted to obtain as wide a picture as possible from those working in a wide variety of settings. Previously, the Abacus International Survey[7] comprised a paper and online survey. The investigators contacted members of the Royal College of Anaesthetists (RCoA) Pre-operative Assessment Association and the British Anaesthetic & Recovery Nurses Association (BARNA) and requested that they complete their survey which covered all of the recommendations of the clinical guidelines. This audit was commissioned by NICE to gauge the impact of CG3 on clinical practice.

The questionnaire development

We used some of the questions developed by the Abacus survey[7] but excluded those which asked about major surgery and ASA grades above 1 and 2. The questions specifically asked if the indicated tests were carried out routinely. This was to distinguish between those tests that could be considered for the patient in accordance with CG3. We included questions on the testing of patients with common comorbidities of cardiovascular disease, renal disease and respiratory disease. We restricted this to minor and intermediate surgery and for patients aged <60 years as indicated by the briefing document. We also undertook a very brief snapshot of the level of compliance with CG3 in the range of tests presented in CG3 for ASA grades 1 and 2 and minor and intermediate surgery. We did not include any of the questions relating to the respondents' opinion regarding the NICE guidance. We included questions about electronic patient administration services (PAS) including how data from patients results were recorded and whether or not the system differentiated between which pre-operative clinic ordered the test. The original survey[7] included a number of questions specifically about neurosurgery and cardiovascular surgery that we did not include as these questions were poorly answered in the Abacus survey[7] owing to the smaller numbers of centres undertaking this type of surgery. We asked those completing the questionnaire to include a copy of their protocol, if it was locally developed, for use in ASA grade 1 and 2 patients. (See *Appendix 14* for questionnaire.)

Once we had the basic structure we consulted with anaesthetic colleagues locally in Sheffield who had an interest in pre-operative assessment. The short questionnaire was ready to be tested once we had checked the status of the project with the National Research Ethics Service (NRES).

We sent details of the project along with the questionnaire to NRES and it was confirmed that this work was classed as service evaluation and did not require ethics approval. The questionnaire requested details about the professional responsibilities of the person completing it. The respondents were assured of the confidentiality of the responses. We had a code for the hospital trust for monitoring purposes so that reminders were not sent to those who had already returned the questionnaire.

As part of our consultation process on the questionnaire we also asked if our strategy of sending directly to the pre-operative assessment clinics would be appropriate. We were advised that this would be likely to obtain a response from those directly involved on a daily basis in assessing patients and ordering tests according to protocols. In the covering letter we asked if the questionnaire could be passed to other clinics run by different specialties in their hospital if they thought that they were using different protocols. We included additional copies of the questionnaire with pre-paid return envelopes.

In the summer of 2008 we sent out 20 questionnaires to hospitals selected to represent teaching hospitals and district general hospitals. Initially we did not receive any back and sent out reminders. We then received four questionnaires. We reviewed the questionnaires and found that only two had sent a copy of their protocol, which was a copy of the NICE guidance in both cases.

We decided to keep with this strategy and the full survey was sent out to pre-operative assessment clinics in 486 hospitals in England and Wales in the autumn of 2008. These hospitals were identified through internet searches for hospitals that appeared to have a surgical unit. Children's hospitals were excluded. The previous Abacus[7] survey did not report on whether or not their respondents (anaesthetists and pre-operative nurses) worked at the same hospital.

To comply with Welsh-language requirements we asked if the respondents would prefer to have a Welsh-language version available.

The survey results

We did not undertake any statistical analysis and these results presented are descriptive.

From the first mailing of questionnaires, 30 questionnaires were returned. We sent out reminders and a further 53 questionnaires were returned, of which five were blank. This gave a total of 83 questionnaires returned (a response rate of 17%). Twenty-four of these had a protocol attached. All of these protocols were copies of the NICE guidance. It was not possible to compare our low response rate with that of the Abacus study[7] as they were not clear how many potential respondents they contacted. In addition, a number of the questions they asked were skipped by a large number of respondents, which does not allow for comparisons. However, obtaining a high response rate from busy professionals in a clinical setting is always a challenge.

As expected, all those completing the questionnaire were nurses involved in pre-operative assessment, and all were involved in ordering tests. No one completed a questionnaire passed to them by another pre-operative clinic in the same hospital, i.e. no questionnaires named the same hospital more than once.

We included questions on the number of surgical patients and the proportion of minor, intermediate and major surgeries. In addition, we asked for a breakdown of the numbers of patients in ASA grades 1–4. These were so poorly answered that it was obvious that this information was not readily available to the nurses completing the questionnaire. We asked for this information as it could have potentially been of use in the economic model. We have not reported on these results.

The results tables

The tables below are the results from the survey showing the individual responses to the questions on test ordering.

Table 17 shows that there is 100% compliance with the NICE guidance for those aged < 40 years. The older age groups show more variation, particularly with ECG. Where NICE recommends considering undertaking ECG, FBC, U&E, random glucose and UA in patients aged > 40 years,[1] we could perhaps assume that these tests are carried out so frequently in this group as to be classed as routine. However, we did not include a section for tests under consideration which may have limited respondents' choices.

Tables 18 and *19* show the results for patients ASA grade 2 with cardiovascular comorbidity undergoing minor and intermediate surgery. The results are very similar for minor and intermediate surgery. NICE recommends considering FBC and U&E in this group of patients.

Table 20 shows the results for ASA grade 2 patients with respiratory comorbidity.

Table 21 shows the results for ASA grade 2 patients with respiratory comorbidity. Those with respiratory comorbidities are slightly less likely to be considered for U&Es. NICE guidance recommends considering testing U&Es in this patient group.

Tables 22 and *23* show the results for patients with renal comorbidity. NICE recommends U&Es for these patients and to consider FBC.

The types of hospital responding were teaching hospitals ($n = 32$) and district general hospitals ($n = 51$). Slightly more district general hospitals than teaching hospitals responded.

Discussion

In this section of the study we concentrated on finding out if there was still a culture of routine tests for FBC, electrolytes and renal function and pulmonary function in ASA grade 1 and 2 patients undergoing minor and intermediate surgery. Our results show a substantial level of compliance in the reduction of the routine testing of FBC, electrolytes and renal function and pulmonary function in ASA grade 1 and 2 patients. No one reported carrying out PFTs in this patient group.

There was more variation in reporting of tests in patients with comorbidities. NICE guidance recommends that FBC and U&Es be considered for most of these patients with common comorbidities. Our results suggest that in some places these tests may be part of the routine pre-operative work-up. However, the numbers are small and it is equally likely that a clinical judgement is being made whether or not individual patients actually require these tests.

However, we recognise that the ASA grading of patients is likely to be variable and may be subject to grade inflation to enable testing to be carried out within the NICE guidelines. It is possible that there is a degree of familiarity with the guidance in the 7 years since publication and the time of this survey.

There are other considerations including the increasing standardisation of care throughout the NHS and the work of pre-operative assessment clinics. However, we recognise that these do not follow the same structure in each hospital, and indeed some may not have a formal 'clinic' setting.

We attempted to spread our net fairly widely so that we could reach a wider group. However, we recognise that in places where there was no formal pre-operative clinic we could still have failed to reach our intended respondents. We targeted those units with a formal set clinic by addressing

TABLE 17 American Society of Anaesthesiologists grade 1 patients: no comorbidities, minor and intermediate surgery

Age (years)	CXR	ECG	FBC	U&E	Random glucose analysis	UA	PFT
16–40	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
41–60	0 (0%)	15 (18%)	7 (8%)	7 (8%)	0 (0%)	0 (0%)	0 (0%)

TABLE 18 American Society of Anaesthesiologists grade 2 patients: cardiovascular comorbidity, minor surgery

Age (years)	Chest radiography	ECG	Haemostasis	Blood gas analysis	FBC	U&E	Random glucose analysis	UA	PFT
16–40	0 (0%)	83 (100%)	0 (0%)	0 (0%)	7 (8%)	7 (8%)	0 (0%)	0 (0%)	0 (0%)
41–60	0 (0%)	83 (100%)	3 (4%)	0 (0%)	12 (14%)	16 (19%)	0 (0%)	0 (0%)	0 (0%)

TABLE 19 American Society of Anaesthesiologists grade 2 patients: cardiovascular comorbidity, intermediate surgery

Age (years)	Chest radiography	ECG	Haemostasis	Blood gas analysis	FBC	U&E	Random glucose analysis	UA	PFT
16–40	0 (0%)	83 (100%)	0 (0%)	0 (0%)	7 (8%)	16 (19%)	0 (0%)	0 (0%)	0 (0%)
41–60	0 (0%)	83 (100%)	3 (4%)	0 (0%)	12 (14%)	19 (23%)	0 (0%)	0 (0%)	0 (0%)

TABLE 20 American Society of Anaesthesiologists grade 2 patients: respiratory comorbidity, minor surgery

Age (years)	Chest radiography	ECG	Haemostasis	Blood gas analysis	FBC	U&E	Random glucose analysis	UA	PFT
16–40	3 (4%)	15 (18%)	0 (0%)	0 (0%)	7 (8%)	7 (8%)	0 (0%)	0 (0%)	0 (0%)
41–60	14 (16%)	21 (25%)	3 (4%)	0 (0%)	10 (12%)	16 (19%)	0 (0%)	0 (0%)	10 (12%)

TABLE 21 American Society of Anaesthesiologists grade 2 patients: respiratory comorbidity, intermediate surgery

Age (years)	Chest radiography	ECG	Haemostasis	Blood gas analysis	FBC	U&E	Random glucose analysis	UA	PFT
16–40	1 (1%)	15 (18%)	0 (0%)	0 (0%)	7 (8%)	7 (8%)	0 (0%)	0 (0%)	0 (0%)
41–60	14 (16%)	32 (38%)	3 (4%)	0 (0%)	12 (14%)	16 (19%)	0 (0%)	0 (0%)	10 (12%)

TABLE 22 American Society of Anaesthesiologists grade 2 patients: renal comorbidity, minor surgery

Age (years)	Chest radiography	ECG	Haemostasis	Blood gas analysis	FBC	U&E	Random glucose analysis	UA	PFT
16–40	0 (0%)	15 (18%)	0 (0%)	0 (0%)	15 (18%)	83 (100%)	13 (15%)	0 (0%)	0 (0%)
41–60	0 (0%)	21 (25%)	3 (4%)	0 (0%)	21 (25%)	83 (100%)	17 (20%)	0 (0%)	0 (0%)

TABLE 23 American Society of Anaesthesiologists grade 2 patients: renal comorbidity, intermediate surgery

Age (years)	Chest radiography	ECG	Haemostasis	Blood gas analysis	FBC	U&E	Random glucose analysis	UA	PFT
16–40	0 (0%)	15 (18%)	0 (0%)	0 (0%)	15 (18%)	83 (100%)	13 (15%)	0 (0%)	0 (0%)
41–60	0 (0%)	32 (38%)	6 (7%)	0 (0%)	21 (25%)	83 (100%)	17 (20%)	0 (0%)	0 (0%)

the questionnaires to them. We are likely not to have any responses from hospitals relying on trainee medical staff to undertake this role. Our demographics showed that only nurses completed this survey. Other categories of staff may not have seen the questionnaire. As we have shown our response rate was relatively poor and our own local very large trust did not respond as part of the survey. By consulting with our anaesthetic colleagues and with our nursing contacts involved in pre-operative assessment we decided that the responses from nurses would reflect local practice. There was some discussion that nurses would be more aware of any deviations from protocol across the board owing to preferences in testing by senior medical staff.

Undertaking surveys of this kind may be an inefficient method of collecting this kind of information. As part of its guidance, NICE recommends the use of internal audit and the use of routine collected data available through electronic systems. This, of course, disadvantages hospitals with less sophisticated methods of accessing test results.

We did not ask about audit arrangements; in contrast, the Abacus survey[7] in 2005 found that there was relatively poor preparation to undertake audit of the compliance with the guidance.

Chapter 5

Cost-effectiveness of pre-operative testing of full blood count, electrolytes and renal function and pulmonary function in the management of ASA grade 1 and grade 2 surgical patients undergoing minor and intermediate surgery

Introduction

Routine pre-operative testing is a high-volume, low-cost activity within the NHS. The high volume of the tests drives a substantial total budget impact, which means that it is important to establish whether or not the tests are a high-value use of limited NHS resources. The potential savings to the NHS by eliminating these tests if they do not represent good value is significant.

Data on health status on admission, from the National Enquiry into Perioperative Deaths, indicate that, even among the elderly (patients aged ≥ 80 years), patients in categories ASA grades 1 and 2 account for > 50% of all patients.[44]

The aim of this part of the study was to work with clinical experts in the team to construct a decision-analytic modelling framework capable of establishing the value of each of the routinely used pre-operative tests, either individually or in combination, in terms of the incremental costs and outcomes associated with their use for patients in ASA grades 1 and 2, undergoing intermediate or minor surgery. Routine use means use when the test is not clinically indicated on the basis of the patient history or factor identified during the physical examination.

The evaluation considers three tests that historically have been used routinely in all surgeries: FBC, which is used to check for anaemia; U&Es, which checks renal function and sodium levels; and PFT, which assesses lung capacity.

Methods

The first stage in developing a decision-analytic model is to identify the clinical pathway of patients in the scope of the evaluation, the place of the intervention or interventions being evaluated in that clinical pathway and the potential impact of the interventions on the patient pathway.

To do this, we interviewed the consultant anaesthetists within the study team (Charles Reilly and Duncan Young) to map out a representative patient pathway for otherwise healthy (ASA grades 1 and 2) elective minor/intermediate surgery patients and the impact of each of the tests on the clinical pathway. We also asked them to identify appropriate measures of effect for

capturing the impact of the tests, as well as the appropriate time horizon and cycle length for the cost-effectiveness model.

The information obtained was then used to construct a decision tree model with accompanying narrative. This was shared with the consultant anaesthetists for confirmation that it accurately reflected the information they had provided and their expert opinion on the conceptual role of pre-operative tests in this particular indication. The decision tree was then finalised in the light of any further comments.

The finalised decision tree which represented the clinical pathway then provided a framework for identifying the evidence on costs, effectiveness and outcomes required from the systematic literature reviews.

Results

Figure 3 shows a truncated version of the decision tree.

The underlying principle for the use of these routine pre-operative tests is the identification of an asymptomatic condition that could impact on the perioperative and/or post-operative care, prior to surgery in order to allow either an amendment to the care plan, deferring of the procedure to allow the condition to be treated so that the individual is fit for surgery or the cancellation of the surgery if the test results indicate that the balance of risks and benefits of the surgery is no longer positive and treatment of the identified condition is not likely to change the balance of risk and benefits in a relevant time scale.

For each test there is an underlying probability that a patient has the unrecognised condition and a set of test performance characteristics that indicate whether the administration of the test will correctly or incorrectly provide positive or negative results.

Associated with each test result is a clinical strategy based on the measured test result (positive or negative) and each treatment strategy has costs and outcomes associated with it. These differ according to whether the individual is a true-positive, true-negative, false-positive or false-negative. Each pathway has a health state value (utility) associated with it.

The tests operate independently, i.e. the clinical response, costs and outcomes from each test are not dependent on the results of either of the other two tests. However, a positive test result on any one of the tests is a sufficient condition to lead to an operation being delayed.

The proposed cycle length for the model was 1 week and the time horizon for the model was 6 weeks. The cycle length was chosen on the basis of the time it takes for treatments to be initiated and treatment strategies changed. The time horizon was based on the time a clinician would allow for resolution of the types of asymptomatic problems identified by these tests before choosing to cancel the operation. Inevitably there is a substantial element of judgement determining these parameters.

Table 24 reports the parameters required for the construction of the cost-effectiveness model. The evidence for each of the parameters based on the systematic literature reviews reported earlier in this report and national cost databases such as the *NHS Reference Costs 2007/8* is also described in the following chapter (see third column, *Table 27*).[46] There is no evidence in the reported literature for the majority of the parameters required to populate the cost-effectiveness model structure developed.

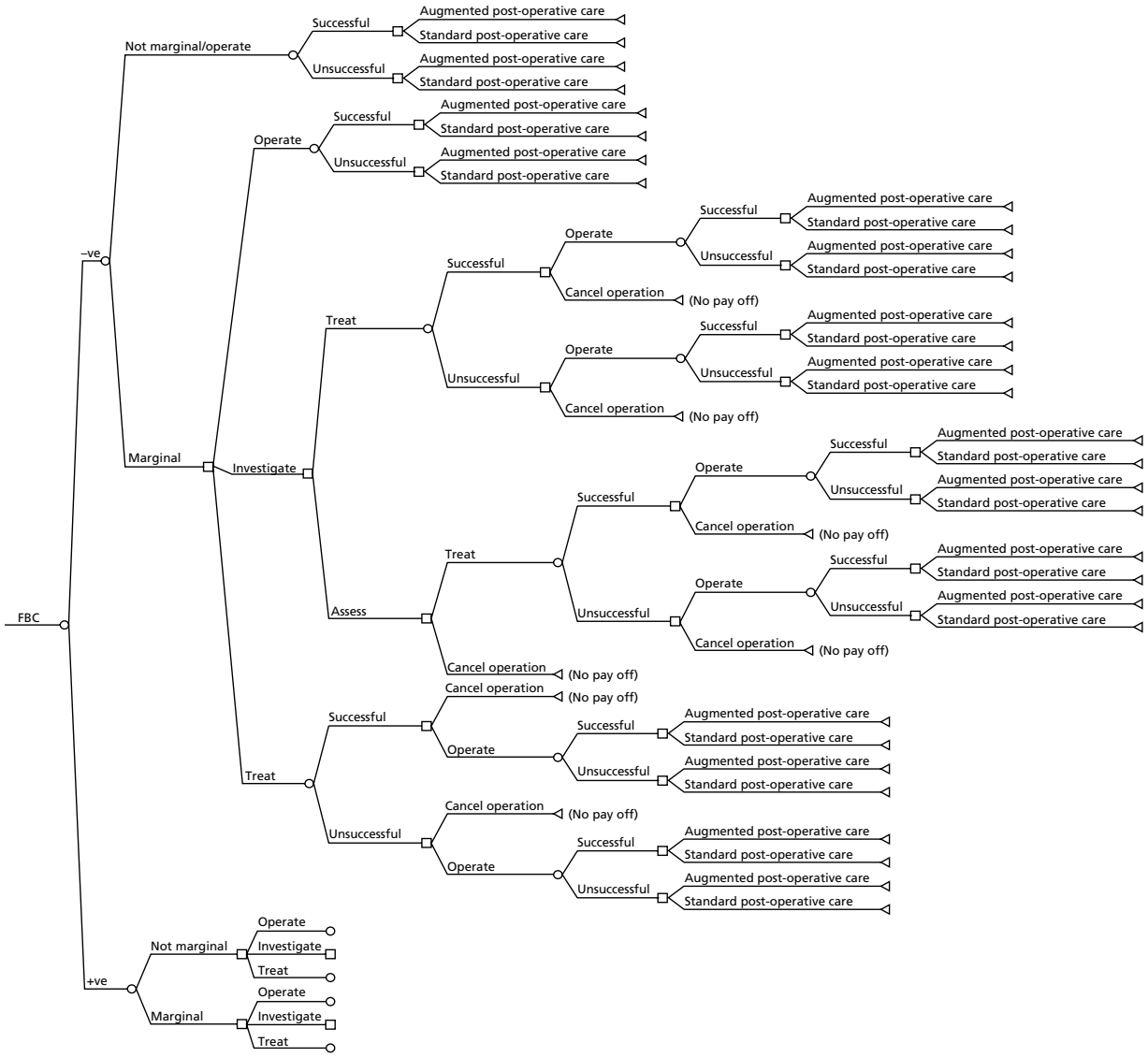

FIGURE 3 Cost-effectiveness of pre-operative test – model structure. Example using FBC. –ve, negative; +ve, positive. Notes: *Assess*: the patient is further assessed given the unclear test result; *Augmented post-operative care*: the post-operative management of the patient is not according to standard care; *Delay operation*: the patient's operation is delayed; *Investigate*: the patient undergoes further investigation to confirm his or her health status; *Marginal*: patient's test result is unclear; *Not marginal*: the patient's test result is not marginal (a clear test result); *Standard post-operative care*: the patient has standard post-operative management; *Successful/unsuccessful*: successful or unsuccessful treatment or operation; *Treat*: the patient is given a treatment if his or her test result is not clearly negative.

Discussion

Conceptually, the role of routine pre-operative tests is easy to describe. However, the evidence base to support the clinical effectiveness of these three tests in any area of surgery is extremely limited. In the context of minor and intermediate surgery for otherwise healthy patients, we could find no published research on their clinical effectiveness. In addition we found no evidence on the test performance characteristics any of the three tests.

Although we had envisaged having to undertake expert elicitation for some parameters owing to a lack of published evidence, to populate the proposed model structure would entail undertaking expert elicitation for the majority of parameters, including those concerning effectiveness and test

TABLE 24 Parameters required for the construction of the cost-effectiveness model

Parameter	Baseline value	Published evidence	Parameter	Baseline value	Published evidence
FBC			***U&E***		
Probability of positive/negative test result	N/A	No	Probability of positive/ negative test	N/A	No
Probability of marginal positive/negative test result	N/A	No	Probability of marginal positive/negative test	N/A	No
Probability of successful/unsuccessful treatment after positive test result	N/A	No	Probability of successful/ unsuccessful treatment after positive test result	N/A	No
Probability of successful/unsuccessful operation	N/A	No	Probability of successful/ unsuccessful operation	N/A	No
PFT					
Probability of positive/negative test result	N/A	No			
Probability of marginal positive/negative test result	N/A	No			
Probability of successful/unsuccessful treatment after positive test result	N/A	No			
Probability of successful/unsuccessful operation	N/A	No			
Costs[45,46]			***Utilities***		
Cost of FBC Test	£6	Yes	Pre-operative utility	N/A	No
Cost of U&E	£4	Yes	Post-operative utilities – successful operation	N/A	No
Cost of PFT	£66	Yes	Post-operative utility – unsuccessful operation	N/A	No
Cost of successful operation[a]	£781–1204	Yes			
Cost of post-test investigation	£225	Yes			
Cost of treatment for conditions identified by pre-operative test[b]	£3.28–71 per month	Yes			
Additional cost of post-operative management[c]	£814–5226	Yes			

a There is a wide range of operations in the minor to intermediate category with a correspondingly wide range of costs. We identified a range of costs that would be used in scenario analyses. The mean of the identified exemplar costs was to be used in the base-case analysis.
b The cost of treating the condition identified by a pre-operative test is clearly dependent on what the condition is. The correct clinical response to a failed PFT can range from being relatively cheap (e.g. respiratory drugs) to extremely expensive (e.g. cardiac surgery). We identified a range of costs to be used in scenario analyses. The base-case analysis would use the least expensive treatment on the basis that otherwise symptomatically healthy patients (ASA grades 1and 2) are unlikely to have the more complex and expensive to treat health problems.
c We assumed the cost of the operation included standard post-operative care. The additional cost is estimated as the difference between the cost of procedures with and without complications in the NHS reference cost for a representative sample of minor and intermediate surgeries.

performance. After extensive discussion within the research team and consultation with external experts we concluded that the results of analyses based on such extensive expert elicitation would lack credibility with the policy and clinical practitioner audiences that the work was designed to inform.

Therefore, we decided to examine alternative avenues for estimating the clinical effectiveness and cost-effectiveness of routine pre-operative tests. Specifically, we would undertake de novo econometric analyses of routine pre-operative test data held at the Leeds Teaching Hospitals Trust, linked to Hospital Episode Statistics data on outcomes, to estimate the impact of the use of

these tests on outcomes. These econometric models could then be linked to cost data to estimate the incremental cost-effectiveness of the tests.

Assuming a robust relationship between the use of these tests and outcomes of surgery could be established, the uncertainty in the parameters in the estimated model would allow simulation modelling to examine the value of further research to reduce that uncertainty, via a simple attribution of a value of health to the modelled outcome.

The econometric modelling is reported in *Chapter 6*.

Chapter 6

Routine pre-operative testing regression analysis report

Introduction

The objective of the study reported in this chapter was to estimate the relationship between the administration of FBC, U&E and PFT and outcomes on otherwise healthy patients undergoing minor or intermediate surgery. The study was undertaken in response to the lack of published evidence on the clinical effectiveness and/or cost-effectiveness of the use of these tests.

We identified a large routine patient-level data set on tests, surgical procedure and outcomes at Leeds Teaching Hospitals Trust and proposed to utilise econometric methods to questions concerning the value of routine testing. Unfortunately, the data set does not report the use of PFTs; therefore, our analysis was constrained to the role of FBC and U&Es.

Methods

An extract was taken from the PAS system of the Leeds Teaching Hospitals NHS Trust for patients admitted for elective surgery in 2008. There were 114,209 records in the full extract, of which 104,021 were for patients aged ≥16 years. Procedure codes were reviewed to identify all minor and intermediate procedures; this left 21,905 unique records. To further simplify the analysis, we eliminated records with more than one hospital episode. This left a sample of 21,792 observations.

By linking the patient's episode to any previous or subsequent episodes recorded in PAS, the following variables were constructed:

- Readmission30Day – the patient was readmitted to Leeds Teaching Hospitals NHS Trust within 30 days.
- Readmission3Month – the patient was readmitted to Leeds Teaching Hospitals NHS Trust within 3 months.
- Readmission12Month – the patient was readmitted to Leeds Teaching Hospitals NHS Trust within 12 months.
- DiedInHospital – the patient died during this episode.
- DiedInHospital30Day – the patient died in Leeds Teaching Hospitals NHS Trust within 30 days.
- DiedInHospital3Month – the patient died in Leeds Teaching Hospitals NHS Trust within 3 months.
- DiedInHospital12Month – the patient died in Leeds Teaching Hospitals NHS Trust within 12 months.
- LengthOfStay – number of days in the episode.

The ASA grade was not recorded in the PAS system. As a proxy for the ASA grade of the patient we calculated both the Charlson score of comorbidity[47] and the total bed-days using any

episodes in the 12 months preceding the operative admission. These variables were labelled as CharlsonScore and PreviousBedDays, respectively.

Using the patient's postcode of residence, the IMD2004 decile was looked up and added to the data set.

A probabilistic record linkage was performed between the PAS extract and an extract from the pathology laboratory results database of the tests performed between 2007 and 2009 (1.4 million records), based on the patient's NHS number, forename, surname, date of birth and gender. This resulted in 997 episodes not being linked to any record in the test result database. This may indicate that either no test had ever been performed for that patient or the degree of agreement between the matching variables was lower than the threshold.

For those episodes where test results were linked, the earliest FBC and U&E preceding the operative episode were returned. Tests more than 60 days prior to the admission were excluded. The following variables were then constructed:

- FBC – the patient had a FBC or not.
- FBCOrderDate – the date the FBC was ordered.
- FBC_DaysBefore – the number of days the FBC was before the episode start.
- FBC_OutsideNormalRange – the test result was outside the normal range.
- U&E – the patient had a U&E or not.
- U&EOrderDate – the date the U&E was ordered.
- U&E_DaysBefore – the number of days the U&E was before the episode start.
- U&E_OutsideNormalRange – the test result was outside the normal range.

Three alternative outcome measures were identified:

- length of stay (continuous in days)
- readmission within 30 days
- hospital mortality.

The key explanatory variables for the analysis were the two dichotomous variables representing whether or not patients had FBCs and U&Es.

In addition, we included a number of pre-specified conditioning variables, specifically:

- age (in years)
- sex (1 = female, 0 = male)
- ethnicity
- socioeconomic status (IMD04 deciles)
- primary diagnosis [Office of Population Census and Surveys: Classification of Interventions and Procedures (OPCS) codes]
- surgical procedure [*International Classification of Diseases*, Tenth Edition (ICD10) codes].

Probit regression models are used to predict the probability of an individual being discharged within 30 days of the procedure, conditioned on a set of individual characteristics. The probit model is

$$P(Y=1 \mid X) = \phi(X'\beta) \qquad \text{[Equation 1]}$$

where P is probability, $Y = 1$ is the observation that an individual is discharged within 30 days of the procedure, X is a vector of explanatory variables which include age, sex, Charlson comorbidity index,[47] ethnicity, socioeconomic status (IMD04), primary diagnosis (OPCS) and surgical procedure (ICD10) and ϕ is the cumulative distribution function of the standard normal distribution. The parameters are estimated by maximum likelihood in Stata version 11 (StataCorp LP, College Station, TX, USA). Models are estimated separately for FBC test and U&E test.

Probit regression models were also used to estimate the likelihood that an individual would receive (a) a FBC or (b) a U&E.

Results

Descriptive statistics for variables included in the analysis are reported in *Table 25*. The first thing to note is that the frequency of test use is not consistent with the hypothesis of their routine use. FBCs were performed in only 58% of patients in the data set and U&Es in only 57%.

Using one outcome, readmission within 30 days, to illustrate the problem, just over 10% of the full sample is readmitted within 30 days. This is 13% if they had FBCs or U&Es but only 8–9% if they did not, which is contrary to our expectations. A probit model for the outcome confirms this. Significant positive coefficients are obtained on the dichotomous variables FBC and U&E suggesting that those who had the tests are more likely to be readmitted within 30 days (*Table 26*).

The main models were estimated for patients with a Charlson score[47] of 0 or 1 and for patients in whom the tests (if carried out) were carried out no more than 30 days prior to admission. However, results are similar if we use tests carried out up to 60 days prior to admission. The results are also similar for an alternative outcome measure (length of stay), with mean length of stay being longer for those in whom tests were performed, again contrary to expectations. It was not possible to investigate the third outcome measure, as hospital 30-day mortality is only 0.1% and 3-month mortality is only 0.4%.

To examine the hypothesis that these tests were not being used routinely, we estimated probit models to predict which patients would undergo FBCs and U&Es. The main explanatory variables are age, sex, Charlson score,[47] OPCS and ICD codes for first procedure and primary diagnosis, race and IMD codes, which proxy for socioeconomic status via the patient's postcode (*Tables 27* and *28*).

There are a large number of statistically significant variables, and, in the case of both FBCs and U&Es, the models correctly predict which patients will be tested in >70% of cases.

Conclusion

The frequencies of the use of the two tests indicate that they are not used routinely for otherwise healthy patients in minor or intermediate surgery. Two sets of probit models confirm this: the first links the use of the tests to a lower probability of being discharged within 30 days of the procedure and the second demonstrates that it is possible to predict quite accurately which patients will receive these tests. Therefore, it appears that clinical practice has changed such that the research question the study was designed to address is no longer relevant.

TABLE 25 Descriptive statistics for variables

Variable	Mean	SD	Min.	Max.
fbc	0.583	0.493	0	1
ue	0.567	0.495	0	1
sex	1.584	0.493	1	2
age	57.031	20.154	15	101
Charlson Score	0.066	0.334	0	6
imd1	0.212	0.409	0	1
imd2	0.108	0.310	0	1
imd3	0.116	0.320	0	1
imd4	0.078	0.268	0	1
imd5	0.092	0.289	0	1
imd6	0.117	0.322	0	1
imd7	0.094	0.291	0	1
imd8	0.064	0.245	0	1
imd9	0.086	0.280	0	1
imd10	0.033	0.178	0	1
race1	0.699	0.459	0	1
race2	0.004	0.060	0	1
race3	0.006	0.080	0	1
race4	0.002	0.048	0	1
race5	0.001	0.026	0	1
race6	0.002	0.039	0	1
race7	0.001	0.033	0	1
race8	0.012	0.109	0	1
race9	0.013	0.113	0	1
race10	0.002	0.045	0	1
race11	0.005	0.071	0	1
race12	0.007	0.083	0	1
race13	0.006	0.076	0	1
race14	0.002	0.047	0	1
race15	0.003	0.052	0	1
race16	0.006	0.080	0	1
race17	0.229	0.420	0	1
opcs1	0.018	0.133	0	1
opcs2	0.036	0.187	0	1
opcs3	0.264	0.441	0	1
opcs4	0.018	0.135	0	1
opcs5	0.033	0.179	0	1
opcs6	0.027	0.163	0	1
opcs7	0.033	0.179	0	1
opcs8	0.019	0.137	0	1
opcs9	0.010	0.099	0	1
opcs10	0.205	0.157	0	1
opcs11	0.017	0.130	0	1
opcs12	0.025	0.404	0	1
opcs13	0.137	0.344	0	1
opcs14	0.039	0.194	0	1
opcs15	0.066	0.248	0	1
opcs16	0.050	0.218	0	1

TABLE 25 Descriptive statistics for variables (*continued*)

Variable	Mean	SD	Min.	Max.
opcs17	0.001	0.032	0	1
icd1	0.001	0.029	0	1
icd2	0.130	0.336	0	1
icd3	0.008	0.086	0	1
icd4	0.017	0.130	0	1
icd5	0.249	0.433	0	1
icd6	0.013	0.114	0	1
icd7	0.016	0.125	0	1
icd8	0.029	0.169	0	1
icd9	0.087	0.281	0	1
icd10	0.021	0.144	0	1
icd11	0.035	0.185	0	1
icd12	0.159	0.365	0	1
icd13	0.040	0.196	0	1
icd14	0.006	0.076	0	1
icd15	0.071	0.257	0	1
icd16	0.020	0.141	0	1
icd17	0.098	0.297	0	1

age, age in years; Charlson Score, Charlson comorbidity index; fbc, dummy variable for FBC test (1 = had test); icd, surgical procedure ICD10 codes, 17 groups (dummy for each group, base = ICD10); imd, socioeconomic status, IMD04 deciles (dummy for each decile, base = IMD1); max., maximum; min., minimum; opcs, primary diagnosis OPCS4 chapter, 17 groups (dummy for each group, base = OPCS1); race, dummies for ethnicity, 17 groups (dummy for each group, base = race1); SD, standard deviation; sex, dummy variable for sex (1 = female); ue, dummy variable for U&E (1 = had test).

TABLE 26 Probit model: FBC and U&E as predictive of 30 day readmission

Independent variable	Coefficient	Standard error	*z*-value	$p>\|z\|$
ue	0.254708	0.074060	3.44	0.001
fbc	0.063463	0.072282	0.88	0.380
age	0.002118	0.001038	2.04	0.041
sex	0.002802	0.038476	0.07	0.942
race2	–0.103160	0.265286	–0.39	0.697
race3	0.156642	0.194972	0.80	0.422
race4	0.132060	0.314043	0.42	0.674
race8	0.010705	0.148053	0.07	0.942
race9	–0.196660	0.162084	–1.21	0.225
race10	0.129890	0.380266	0.34	0.733
race11	–0.273210	0.284263	–0.96	0.336
race12	–0.482300	0.263230	–1.83	0.067
race13	–0.242640	0.256709	–0.95	0.345
race14	0.327621	0.272929	1.20	0.230
race15	–0.375850	0.325198	–1.16	0.248
race16	–0.128960	0.226173	–0.57	0.569
race17	–0.310970	0.040869	–7.61	0.000
opcs41dum2	0.195883	0.261810	0.75	0.454
opcs41dum3	0.465534	0.272863	1.71	0.088
opcs41dum4	–0.524520	0.396648	–1.32	0.186

continued

TABLE 26 Probit model: FBC and U&E as predictive of 30 day readmission (*continued*)

Independent variable	Coefficient	Standard error	*z*-value	$p>\|z\|$
opcs41dum5	0.373183	0.269113	1.39	0.166
opcs41dum6	0.171577	0.270358	0.63	0.526
opcs41dum7	0.719664	0.275405	2.61	0.009
opcs41dum8	0.436592	0.294112	1.48	0.138
opcs41dum9	0.412275	0.402044	1.03	0.305
opcs41dum10	0.848982	0.256433	3.31	0.001
opcs41dum11	0.217559	0.284765	0.76	0.445
opcs41dum12	0.531826	0.273651	1.94	0.052
opcs41dum13	0.273787	0.257670	1.06	0.288
opcs41dum14	–0.126560	0.268081	–0.47	0.637
opcs41dum15	0.823398	0.260753	3.16	0.002
opcs41dum16	–0.024050	0.275910	–0.09	0.931
opcs41dum17	0.434054	0.443554	0.98	0.328
icd101dum2	0.580444	0.559719	1.04	0.300
icd101dum3	0.104997	0.596036	0.18	0.860
icd101dum4	–0.018470	0.617425	–0.03	0.976
icd101dum5	–0.206260	0.565385	–0.36	0.976
icd101dum6	0.779125	0.652997	1.19	0.233
icd101dum7	–0.522250	0.606628	–0.86	0.389
icd101dum8	–0.048780	0.571828	–0.09	0.932
icd101dum9	–0.172280	0.564082	–0.31	0.760
icd101dum10	0.256588	0.572196	0.45	0.654
icd101dum11	–0.281590	0.573682	–0.49	0.624
icd101dum12	–0.110940	0.560829	–0.20	0.843
icd101dum13	–0.210520	0.568083	–0.37	0.711
icd101dum14	0.067331	0.593207	0.11	0.910
icd101dum15	–0.184130	0.562386	–0.33	0.743
icd101dum16	–0.135020	0.562148	–0.24	0.810
cons	–1.842350	0.616409	–2.99	0.003
Probit regression			Number of obs = 11,561	
			LR χ^2 (49) = 840.99	
			Prob > χ^2 = 0.0000	
Log-likelihood = –3669.0966			Pseudo-R^2 = 0.1028	

age, age in years; Charlson Score, Charlson comorbidity index; fbc, dummy variable for FBC test (1 = had test); icd, surgical procedure ICD10 codes, 17 groups (dummy for each group, base = ICD10); imd, socioeconomic status, IMD04 deciles (dummy for each decile, base = IMD1); max., maximum; min., minimum; opcs, primary diagnosis OPCS4 chapter, 17 groups (dummy for each group, base = OPCS1); race, dummies for ethnicity, 17 groups (dummy for each group, base = race1); SD, standard deviation; sex, dummy variable for sex (1 = female); ue, dummy variable for U&E (1 = had test).

TABLE 27 Probit model: likelihood of a FBC

FBC	Coefficient	Standard error	*z*-value	$p>\|z\|$
age	0.013450	0.000577	23.33	0.000
sex	0.106167	0.020416	5.20	0.000
Charlson Score	0.263823	0.029817	8.85	0.000
opcs41dum2	0.670388	0.154974	4.33	0.000
opcs41dum3	–0.143850	0.160748	–0.89	0.371
opcs41dum4	–0.254620	0.188711	–1.35	0.177

TABLE 27 Probit model: likelihood of a FBC (*continued*)

FBC	Coefficient	Standard error	*z*-value	$p>\|z\|$
opcs41dum5	0.020992	0.158024	0.13	0.894
opcs41dum6	–0.066390	0.156711	–0.42	0.672
opcs41dum7	0.629987	0.158717	3.97	0.000
opcs41dum8	0.657884	0.167864	3.92	0.000
opcs41dum9	0.871072	0.204211	4.27	0.000
opcs41dum10	0.285404	0.148939	1.92	0.055
opcs41dum11	0.056132	0.162890	0.34	0.730
opcs41dum12	0.504439	0.160024	3.15	0.002
opcs41dum13	0.544150	0.150607	3.61	0.000
opcs41dum14	–0.066820	0.153476	–0.44	0.663
opcs41dum15	0.461348	0.151350	3.05	0.002
opcs41dum16	0.109387	0.151734	0.72	0.471
opcs41dum17	0.409347	0.320709	1.28	0.202
icd101dum2	0.419199	0.323975	1.29	0.196
icd101dum3	0.571920	0.341416	1.68	0.094
icd101dum4	0.424852	0.355662	1.19	0.232
icd101dum5	0.378974	0.329364	1.15	0.250
icd101dum6	0.835885	0.352417	2.37	0.018
icd101dum7	0.422676	0.342337	1.23	0.217
icd101dum8	0.718548	0.329996	2.18	0.029
icd101dum9	0.651206	0.326306	2.00	0.046
icd101dum10	0.430405	0.329973	1.30	0.192
icd101dum11	0.190715	0.329757	0.58	0.563
icd101dum12	0.537712	0.324084	1.66	0.097
icd101dum13	0.625161	0.327138	1.91	0.056
icd101dum14	0.566180	0.343715	1.65	0.100
icd101dum15	0.384594	0.325289	1.18	0.237
icd101dum16	0.230977	0.331380	0.70	0.486
icd101dum17	0.356863	0.324831	1.10	0.272
race2	–0.057350	0.146366	–0.39	0.695
race3	0.020869	0.110840	0.19	0.851
race4	–0.015280	0.181693	–0.08	0.933
race5	0.270222	0.359077	0.75	0.452
race6	–0.056870	0.219913	–0.26	0.796
race7	0.031166	0.263853	0.12	0.906
race8	0.069126	0.079941	0.86	0.387
race9	0.278117	0.080876	3.44	0.001
race10	0.036855	0.199437	0.18	0.853
race11	0.450421	0.130483	3.45	0.001
race12	–0.027840	0.107624	–0.26	0.796
race13	0.025517	0.117997	0.22	0.829
race14	–0.154780	0.185048	–0.84	0.403
race15	–0.394880	0.171781	–2.30	0.022
race16	0.128506	0.112562	1.14	0.254
race17	–0.308750	0.021965	–14.06	0.000
imd2	–0.099260	0.033301	–2.98	0.003
imd3	–0.142500	0.032641	–4.37	0.000
imd4	–0.133270	0.037335	–3.57	0.000

continued

TABLE 27 Probit model: likelihood of a FBC (*continued*)

FBC	Coefficient	Standard error	*z*-value	$p>\|z\|$
imd5	–0.18264	0.035058	–5.19	0.000
imd6	–0.17627	0.032634	–5.40	0.000
imd7	–0.20314	0.035058	–5.79	0.000
imd8	–0.23122	0.039905	–5.79	0.000
imd9	–0.17274	0.036184	–4.77	0.000
imd10	–0.28820	0.052508	–5.49	0.000
_cons	–1.18645	0.356942	–3.32	0.001
			Number of obs = 21,742	
			LR χ^2(60) = 2074.02	
			Prob > χ^2 = 0.0000	
Log-likelihood = –13,732.975			Pseudo-R^2 = 0.0702	

age, age in years; Charlson Score, Charlson comorbidity index; fbc, dummy variable for FBC test (1 = had test); icd, surgical procedure ICD10 codes, 17 groups (dummy for each group, base = ICD10); imd, socioeconomic status, IMD04 deciles (dummy for each decile, base = IMD1); max., maximum; min., minimum; opcs, primary diagnosis OPCS4 chapter, 17 groups (dummy for each group, base = OPCS1); race, dummies for ethnicity, 17 groups (dummy for each group, base = race1); SD, standard deviation; sex, dummy variable for sex (1 = female); ue, dummy variable for U&E (1 = had test).

TABLE 28 Probit model: likelihood of a U&E

U&E	Coefficient	Standard error	*z*-value	$p>\|z\|$
age	0.022855	0.000594	38.47	0.000
sex	–0.003950	0.020949	–0.19	0.851
Charlson Score	0.284033	0.032064	8.86	0.000
opcs41dum2	0.797629	0.157573	5.06	0.000
opcs41dum3	–0.022990	0.163867	–0.14	0.888
opcs41dum4	–0.170800	0.193337	–0.88	0.377
opcs41dum5	0.114608	0.161157	0.71	0.477
opcs41dum6	–0.068140	0.159945	–0.43	0.670
opcs41dum7	0.831243	0.161683	5.14	0.000
opcs41dum8	0.841626	0.170565	4.93	0.000
opcs41dum9	1.136425	0.209070	5.44	0.000
opcs41dum10	0.466354	0.151633	3.08	0.002
opcs41dum11	0.256710	0.166039	1.55	0.122
opcs41dum12	0.385461	0.161810	2.38	0.017
opcs41dum13	0.171809	0.153065	1.12	0.262
opcs41dum14	0.065127	0.156098	0.42	0.677
opcs41dum15	0.293185	0.154021	3.20	0.001
opcs41dum16	0.221133	0.154649	1.43	0.153
opcs41dum17	0.520082	0.322032	1.62	0.106
icd101dum2	0.045329	0,317082	0.14	0.886
icd101dum3	0.293213	0.335272	0.87	0.382
icd101dum4	0.190669	0.350457	0.54	0.586
icd101dum5	0.109618	0.323055	0.34	0.734
icd101dum6	0.276315	0.348033	0.79	0.427
icd101dum7	–0.149160	0.336500	0.27	0.790
icd101dum8	0.086230	0.323538	0.27	0.790
icd101dum9	0.223007	0.319466	0.70	0.485

TABLE 28 Probit model: likelihood of a U&E (*continued*)

U&E	Coefficient	Standard error	*z*-value	$p>\|z\|$
icd101dum10	0.006708	0.323477	0.02	0.983
icd101dum11	–0.142200	0.323248	–0.44	0.660
icd101dum12	0.006975	0.317239	0.02	0.982
icd101dum13	–0.504150	0.322016	–1.57	0.117
icd101dum14	0.188721	0.338003	0.56	0.577
icd101dum15	–0.015310	0.318523	–0.05	0.962
icd101dum16	–0.142580	0.325056	–0.44	0.661
icd101dum17	–0.043780	0.318076	–0.14	0.891
race2	–0.143600	0.146939	–0.98	0.328
race3	0.147874	0.114834	1.29	0.198
race4	–0.179890	0.199040	–0.90	0.366
race5	0.275862	0.369010	0.75	0.455
race6	0.343529	0.231213	1.49	0.137
race7	0.187172	0.274663	0.68	0.496
race8	–0.052790	0.081704	–0.65	0.518
race9	0.141052	0.079758	1.77	0.077
race10	–0.160120	0.200413	–0.80	0.424
race11	0.118722	0.124858	0.95	0.342
race12	–0.041280	0.110269	–0.37	0.708
race13	0.048866	0.121306	0.40	0.687
race14	–0.281780	0.192301	–1.47	0.143
race15	–0.609830	0.187086	–3.26	0.001
race16	0.046919	0.115946	0.40	0.687
race17	–0.281570	0.022645	–12.43	0.000
imd2	–0.031230	0.034310	–0.91	0.363
imd3	–0.053370	0.033667	–1.59	0.113
imd4	–0.060660	0.038563	–1.57	0.116
imd5	–0.165130	0.036124	–4.57	0.000
imd6	–0.078110	0.033622	–2.32	0.020
imd7	–0.228320	0.035911	–6.36	0.000
imd8	–0.177080	0.041008	–4.32	0.000
imd9	–0.158880	0.037101	–4.28	0.000
imd10	–0.231320	0.053657	–4.31	0.000
_cons	–1.263400	0.351905	–3.59	0.000
			Number of obs = 21,742	
			LR χ^2 (60) = 4056.30	
			Prob > χ^2 = 0.0000	
Log-likelihood = –12,841.233			Pseudo-R^2 = 0.1364	

age, age in years; Charlson Score, Charlson comorbidity index; fbc, dummy variable for FBC test (1 = had test); icd, surgical procedure ICD10 codes, 17 groups (dummy for each group, base = ICD10); imd, socioeconomic status, IMD04 deciles (dummy for each decile, base = IMD1); max., maximum; min., minimum; opcs, primary diagnosis OPCS4 chapter, 17 groups (dummy for each group, base = OPCS1); race, dummies for ethnicity, 17 groups (dummy for each group, base = race1); SD, standard deviation; sex, dummy variable for sex (1 = female); ue, dummy variable for U&E (1 = had test).

It must be noted that these data, although for a large number of observations, are from one trust only (even though that trust consists of a number of hospitals). Although the finding is consistent with the survey findings reported elsewhere in this report, it is quite possible that tests are being use routinely in other NHS hospitals.

It must also be noted that we have been unable to undertake an equivalent analysis for PFTs. Thus, we cannot comment on the use of this test or its impact on the outcome from surgery.

The absence of ASA grade in the data set and deriving this from the Charlson score, although useful, is not the same as having the actual grade recorded by the anaesthetist. Therefore, it is possible that the case mix of the sample of patients included in the data set for the analysis reported in this chapter is more or less diffuse than that specified in the scope of the original study proposal.

A final caveat is that the data set on which the analysis was undertaken is constructed on the basis of a probabilistic linkage of two separate data sets. Although the linkage results were strong, there is a possibility that the test and outcome data do not relate to the same individuals and our findings are spurious.

Chapter 7

Discussion

The original objective of the study reported here was to review the literature on the clinical effectiveness and cost-effectiveness of the routine pre-operative use of three diagnostic tests – FBC, U&E and PFT – in the context of minor and intermediate surgery for otherwise healthy patients, and to synthesise the evidence identified in the context of a de novo cost-effectiveness model.

A comprehensive and systematic search of both the effectiveness and cost-effectiveness literature identified a large number of potentially relevant studies. However, when these studies were subjected to detailed review and quality assessment it became clear that the literature provides no evidence on the effectiveness and cost-effectiveness of these specific tests in the specific patient groups in the context of the UK NHS.

The limitations of the published clinical effectiveness literature – from the perspective of this study – included but were not limited to:

- inadequate reporting of the surgery that patients were being prepared for
- inadequate reporting of the specific tests undertaken and the results of the individual tests
- inadequate reporting of the clinical response to test results; and
- inadequate reporting of the outcomes of the surgery.

These limitations were by and large shared by the published cost-effectiveness literature. In addition, there were almost no studies from the UK NHS, which meant that the estimates of the resource use and cost reported in the identified papers were unlikely to be relevant to the NHS. The studies also failed to report disaggregated information on resource utilisation and cost and focussed on short-term clinical outcomes rather than health outcomes.

The cost-effectiveness literature that was identified did not look at the longer-term outcomes attributable to the use or non-use of these pre-operative tests (i.e. it focused on the difference in the incidence of perioperative complications and the costs associated with these). This is perhaps attributable to the fact that the studies were generally small and investigators quite possibly did not have the resources necessary to undertake longer-term follow-up. It might also be because the relationships between perioperative complications and longer-term health outcomes are insufficiently understood to allow the construction of models to predict these longer-term consequences in the absence of data.

Whatever the reason for the lack of longer-term health outcome data for these pre-operative tests, the literature does not support any robust conclusions about the value of the routine use of these pre-operative tests compared with alternative uses of the limited health-care resources.

In addition to the literature reviews, we repeated a survey of current practice commissioned by NICE as part of their guideline review process in 2005. The results indicate that the degree of uptake of the NICE guidance on pre-operative testing has increased substantially since the original study. The responses suggest that routine pre-operative testing in minor surgery in patients aged < 40 years has all but disappeared from the NHS.[7]

The results of the survey of practice could not be directly verified by this study. However, owing to the lack of published evidence we undertook an additional piece of work, analysing routine testing data from one large teaching hospital trust. The results of this analysis are discussed in more detail below, but they are consistent with the results of the survey and thus may represent a weak validation of these survey results.

The analysis of routine testing and surgical outcome data was not part of the original proposal. However, given the lack of published evidence on the clinical effectiveness and/or cost-effectiveness of these tests, and the importance of the question given the high volumes of pre-operative testing across the NHS as a whole, we deemed it important to exhaust all reasonable avenues of enquiry in pursuit of relevant evidence.

We were fortunate that Leeds Teaching Hospitals Trust had maintained a database of all tests ordered that could be linked, at the individual patient level, to a number of measures of outcome of surgery. This provided a substantial number of observations on which we could estimate regression models. Although the details of the analysis are reported elsewhere, it is worth reiterating that the essence of the work was to estimate the relationship between utilisation of any of the three tests in the pre-operative assessment and the outcomes of surgery in a cohort of otherwise healthy patients undergoing minor or intermediate surgical procedures. It should be noted that we had to approximate the ASA grade 1 and ASA grade 2 score retrospectively. This is not the same as having an original anaesthetist's score, which further increases the uncertainty in the interpretation of the results, as the case mix of the patients in the sample may be more or less diffuse than in the study scope.

If the tests were being used routinely and they were having a positive impact on outcomes, we would expect to see that patients who received the tests were likely to have shorter lengths of stay and more likely to be discharged from hospital by 30 days. The modelled relationships were exactly the opposite of what was expected. Many patients did not undergo any of these tests and those who did were more likely to have longer lengths of stay and less likely to be discharged by 30 days post operation.

In constructing a decision-analytic model for the cost-effectiveness of these tests it became clear that a number of key determinants of the value of these tests were dependent on the specific cause of the abnormal test result. There are multiple potential causes for abnormal tests results for all three tests. The appropriate clinical response, its resource implication and the expected outcomes of the treatment and hence the potential cost-effectiveness of the test are all dependent on the underlying cause. Constructing models for each possible abnormal test/cause combination was outside the scope of this project. However, any future work examining the cost-effectiveness of these tests in pre-operative assessment will have to frame the decision problem in this context if each parameter in the decision problem is going to be clearly specified.

The most defensible conclusion to be drawn from this study is that there is insufficient evidence to support the utilisation of these three tests as part of the routine pre-operative assessment in otherwise healthy patients undergoing minor and intermediate surgery. The survey and analysis of routine data from the Leeds Teaching Hospitals NHS Trust indicate that the time of universal utilisation of these tests in pre-operative assessment may indeed have passed. However, concerns over response rates and the risks of generalising from data on a single trust make this conclusion tentative.

This study raises the question of how to proceed in an evidence-based decision-making context when there is effectively no evidence related to the decision problem. We had originally proposed to address weaknesses in the evidence by using expert elicitation. However, when it became

clear that virtually all of the decision parameters in the decision problem would require expert elicitation, the appropriateness of this strategy became questionable. Challenges associated with establishing who would be the appropriate experts for different parameters in the decision model, how to ensure the representativeness of the sample, and synthesising the evidence provided by different experts on different parameters meant that wholesale elicitation was methodologically questionable and pragmatically beyond the resources of this project.

We considered that establishing a representative sample of experts for the elicitation would be essential if the results of the analysis were to be credible to the medical and decision-making community. However, it would be equally problematic as we are not aware of methods for establishing that the relatively small samples of experts that would be feasible within project resources are representative of such a large community of practitioners. For these reasons, formal elicitation of expert opinion does not appear to offer an analytical solution to the health-care decision-maker's dilemma of how to make an evidence-based decision in the absence of evidence.

Recommendations for further research

The total expenditure on pre-operative tests across the NHS remains significant. Given the almost complete absence of published evidence on the clinical effectiveness, safety and cost-effectiveness of routine use of these tests in uncomplicated patients undergoing ASA grade 1 and 2 procedures, any well-designed research would add to the current state of knowledge. However, to recommend specific research questions it would be necessary for us to have a view as to the value of additional information to decision-makers in the NHS. To assess the likely value of such research it would be necessary to have a robust assessment of the current scale of the routine use of these tests in the patient/procedure combinations of interest.

The low response rate to our survey, despite significant efforts at follow-up, suggests that this type of survey will not be a satisfactory strategy for scoping the scale of the research opportunity. A systematic identification of routine test databases held by NHS trusts is necessary to establish the feasibility of undertaking a multicentre version of the routine data analysis that we report for Leeds Teaching Hospitals Trust.

If feasible, this would allow the identification of the scale of the use of these tests in practice and the degree to which they are being used in otherwise healthy patients, rather than in response to a specific clinical indication. Only once this information is available will it be possible to establish whether or not any further research in this area is required and, if so, which research questions have the greatest potential value to the NHS.

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Contribution of authors

Carolyn Czoski-Murray undertook sections of the reviewing, the survey of current practice and preparation of the report.

Myfanwy Lloyd Jones undertook the systematic review of the clinical effectiveness and the preparation of the report.

Chris McCabe constructed the exemplar cost-effectiveness model and contributed to health economics sections of the draught review.

Karl Claxton provided expert advice in health economics methodology and contributed to the review.

Yemi Oluboyede undertook the cost-effectiveness review and the preparation of the review.

Jenny Roberts undertook the econometric analyses and contributed to the review.

Jon Nicholl provided expert advice and contributed to the report.

Angie Rees undertook the searches and contributed to the report.

Charles Reilly and Duncan Young provided expert advice and both contributed to the report.

Tom Fleming managed the database from Leeds Teaching Hospitals NHS Trust and contributed to the main report.

Helen Light, Leeds Institute of Health Sciences, University of Leeds, provided administrative and clerical support in the formatting of the report.

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Appendix 1

Systematic review of clinical effectiveness: MEDLINE search strategies

Terms for surgery/pre-operative care

1. Surgery/
2. surgery-elective.tw.
3. surgical procedures, elective/or surgical procedures, minor/
4. elective surgery.tw.
5. minor surgery.tw.
6. intermediate surgery.tw.
7. Ambulatory Surgical Procedures/
8. day surgery.tw.
9. asymptomatic.tw.
10. preoperative.tw.
11. pre-operative.tw.
12. pre operative.tw.
13. Ambulatory Care/
14. or/1-13

Terms for routine test

1. Diagnostic Tests, Routine/
2. Preoperative Care/
3. routine test$.tw.
4. routine assessment$.tw.
5. routine investigation$.tw.
6. Clinical Chemistry Tests/
7. Risk Assessment/
8. Blood Cell Count/
9. full blood count.tw.
10. fbc.tw.
11. Hematologic Tests/
12. Urea/
13. Urinalysis/
14. Electrolytes/
15. urine test$.tw.
16. blood test$.tw.
17. u&e.tw.
18. (electrolytes and renal function).tw.
19. Respiratory Function Tests/
20. pulmonary function test$.tw.
21. Spirometry/
22. spirometry.tw.

23. Blood Gas Analysis/
24. blood gas analysis.tw.
25. pft.tw.
26. measurement of respiratory mechanics.tw.
27. measurement of transfer function.tw.
28. Exercise Test/
29. exercise test$.tw.
30. Respiratory System/
31. (42 or 43) and 44
32. h?ematolog$test$.tw.
33. vitalograph.tw.
34. FEV1.tw.
35. Vital Capacity/
36. vital capacit$.tw.
37. transfer function.tw.
38. Pulmonary Diffusing Capacity/
39. diffusing capacit$.tw.
40. dlco.tw.
41. exp Lung Volume Measurements/
42. lung capacit$.tw.
43. cardiopulmonary exercise test$.tw.
44. cpx.tw.
45. maxim$oxygen uptake.tw.
46. V02max.tw.
47. Oxygen Consumption/
48. or/15-41,45,46-61

Adult terms

1. adult/or aged/or middle aged/
2. adult$.tw.

Diagnosis filter from McMaster University

1. sensitiv:.mp.
2. diagnos:.mp.
3. di.fs.
4. or/64-66

For the clinical effectiveness searches, the terms for surgery and pre-operative care were combined with the terms describing the routine test and what they measured/assessed (15–61). These terms were then combined with terms for adults, our target population. Because the tests are used for diagnostic purposes, the search was combined with the McMaster University filter for finding diagnosis studies.

Adverse events search

Adverse events terms

1. Diagnostic Errors/
2. False Negative Reactions/
3. False Positive Reactions/
4. Observer Variation/
5. diagnostic error$.tw.
6. false negative$.tw.
7. false positive$.tw.
8. OR/1-7

The above terms for adverse effects were combined with the surgery and pre-operative care terms, the routine test terms, and the adult terms.

Anaesthetic drug search

Anaesthetic drug terms

1. sevoflurane.af.
2. ultane.af.
3. 28523-86-6.af.
4. desflurane.af.
5. 57041-67-5.af.
6. suprane.af.
7. Propofol/
8. diprivan.af.
9. 2078-54-8.af.
10. rocuronium.af.
11. esmeron.af.
12. 143558-00-3.af.
13. sugammadex.af.
14. bridion.af.
15. organnon25969.af.

The common anaesthetic drug terms were combined with the surgery and pre-operative care terms, the routine test terms and the adult terms.

Appendix 2

Systematic review of clinical effectiveness: quality assessment of randomised controlled trial

Assessment tool based on NHS CRD Report No. 4[8]

Study
Was the method used to assign participants to the treatment groups really random?
What method of assignment was used?
Was the allocation of treatment concealed?
What method was used to conceal treatment allocation?
Was the number of participants who were randomised stated?
Were details of baseline comparability presented?
Was baseline comparability achieved?
Were the eligibility criteria for study entry specified?
Were any co-interventions identified that may influence the outcomes for each group?
Were the outcome assessors blinded to the treatment allocations?
Were the individuals who administered the intervention blinded to the treatment allocation?
Were the participants who received the intervention blinded to the treatment allocation?
Was the success of the blinding procedure assessed?
Were at least 80% of the participants originally included in the randomised process followed up in the final analysis?
Were the reasons for withdrawal stated?
Was an intention-to-treat analysis included?

?, not enough information or not clear; N, no; N/A, not applicable; Y, item addressed.

Appendix 3

Final protocol

Background to the Study

In 2003 NICE published Clinical Guideline 3 which reviewed the use of routine pre-operative tests prior to routine surgery. Prior to the guideline preparation a systematic review by Munro, Booth and Nicholl was undertaken on behalf of the HTA programme in 1997. The guideline development group undertook their own review of the literature. These two reviews defined and updated the purpose of pre-operative testing of apparently healthy patients.

Of the evidence base used to produce the guideline over 50% was graded as amber i.e. the benefit of the test was unknown. Therefore, despite the existence of some primary research, the evidence on which to base pre-operative testing protocols was inconclusive. Alongside this there has been an increasing awareness of the possibility of subjecting patients to unnecessary tests, and of the issues involved in dealing with the results of tests that may alarm patients but have little clinical significance.

The aims of this study

The aims:

- undertake a systematic review of the literature of the clinical effectiveness of routine testing of full blood count (FBC), electrolytes and renal function (U&E), and pulmonary function (PFT) as part of the pre-operative assessment procedures for patients classified as American Association of Anaesthesiologist (ASA) grade 1 and 2 who are undergoing minor or intermediate procedures.
- Evaluate the cost effectiveness of mandating or withdrawing each of these tests from routine pre-operative assessment for patients ASA grade 1 and 2 and minor and intermediate surgery
- Compare the evidence with the recommendations in the NICE Guidance (2003) and observed practice in NHS hospitals
- Identify using modelling techniques the expected value of information (EVI) whether there is value in the NHS in commissioning further primary research into the routine use of FBC, U&Es and PFTs in this patient population.

Search restrictions

The searches will not be restricted by date of language.

Inclusion and exclusion criteria

Inclusion criteria

Population

- Adult patients classified as ASA grade 1 or 2 undergoing minor (grade 1) or intermediate (grade 2) surgery (including elective general surgery, day surgery, and minor orthopaedic procedures) as classified by the CCSD Schedule of Procedures 2005.[1] Where possible, to subdivide these into the following subgroups:
  - Apparently healthy patients with no clinical indication for testing FBC, U&Es and PFTs
  - Patients with common comorbidities (e.g. respiratory disease, renal disease)
  - Patients receiving treatments likely to alter test results (e.g. diuretics).

It was originally planned to limit the population to adults aged 16 to 60. However, because of the paucity of relevant studies which met this inclusion criterion, the population was later extended to include all adult patients.

Intervention

- Routine preoperative testing of:
  - Full blood count (FBC) (including haemoglobin concentration, haematocrit, platelet count, and white blood cell count)
  - Electrolytes and renal function (U&E) (including sodium, potassium, urea, and creatinine)
  - Pulmonary function (PFT) (including some or all of spirometry, blood gas analysis, measurement of respiratory mechanics, measurement of transfer function, and exercise testing of respiratory system)

Comparator

- No routine preoperative testing

Outcomes

- Abnormal test results
- Changes in management following abnormal test results in patients whose preoperative clinical examinations were normal
- Adverse events possibly related to the test result
- Adverse events probably or possibly caused by the process of testing
- All-cause mortality

Setting

- Any country

Date

- 1980 onwards

Study type

- RCTs
- Controlled non-randomised studies (eg cohort studies)
- Case–control studies
- Case series
- Case reports
- Systematic reviews
- Economic evaluations

Exclusion criteria

The following publication types will be excluded from the review:

- Animal models
- Narrative reviews, editorials, opinions.

Sifting

The references identified by the electronic literature searches will be sifted in three stages. Screening for relevance first by title and then by abstract. Those papers which seem from their abstract (or if there is no abstract available) to be relevant will be retrieved and read in full. At each step, studies which do not satisfy the inclusion criteria will be excluded.

Data extraction strategy

A customised data extraction form will be based on those proposed by the NHS Centre for Reviews and Dissemination.[8] Where possible, data will be extracted by one reviewer, and thoroughly checked by a second reviewer; *a*ny disagreements will be resolved by discussion.

Where available, data relating to the following outcomes will be extracted:

- all-cause mortality
- significant abnormal test findings
- change of management
- length of hospital stay
- adverse effects probably or possibly related to the test result
- adverse events probably or possibly caused by the process of testing.

Quality assessment strategy

We propose to assess to use criteria based on those proposed by the NHS Centre for Reviews and Dissemination[8] (see *Appendix 2*) to assess the methodological quality of randomised trials which meet the inclusion criteria.

We will assess the methodological and reporting quality of case series studies which meet the inclusion criteria using a customised quality tool combining generic criteria proposed by the NHS Centre for Reviews and Dissemination[8] and Chambers *et al.*[10] with review-specific criteria, as follows:

- Generic criteria:
  - Were patients recruited prospectively?
  - Were patients recruited consecutively?
  - Were at least 90% of those included at baseline followed up (prospective studies only)?
  - Was loss to follow-up reported or explained (prospective studies only)?
  - Was follow-up long enough for important events to occur?
  - Were outcomes assessed using objective criteria or was blinding used?
  - Was an appropriate measure of variability reported?

- Review-specific criteria:
  - Were the patients' age and ASA status adequately reported?
  - Was the operation type and/or risk classification adequately reported?

- Were all operations elective?
- Were all the tests conducted genuinely routine, or might some have been indicated?
- Was a definition of normal or abnormal results provided?

Meta-analysis strategy

Where appropriate, meta-analysis will be used to pool results, and summary statistics will be derived for each study and a weighted average of the summary statistics be computed across the studies.

The survey

We propose to survey the current protocol use in NHS Trusts in England and Wales to establish if the NICE Guidance is being adhered to. This will be carried out by sending paper questionnaires based on the Abacus study in 2005 to nurses involved in pre operative assessment care.

Economic evaluation

Analysis plan: final protocol

Background

The objective of the study is the value of routinely testing FBC, U&E and PFT in patients with (1) no apparent clinical indication and (2) subgroups with common comorbidities.

The originally proposed approach to construct an economic model based on published literature has not proved possible due to the lack of published evidence on the effectiveness of these tests.

We have identified a large routine patient level data set on tests, surgical procedure and outcomes at Leeds Teaching Hospital Trust with an excess of 1m records. We propose to utilise econometric methods to address the following questions.

1. Having adjusted for patient level characteristics and surgical intervention does not having the tests result in worse outcomes for patients without comorbidities?
2. Having adjusted for patient level characteristics and surgical intervention does not having the tests result in worse outcomes for patients with comorbidities?

Proposed methods

The subset of records for minor and intermediate risk surgical procedures have been identified on the basis of BUPA schedule of procedures. This is consistent with the methods used in our previous work on pre-operative assessment.

The outcomes to be used for these analyses are:

1. Length of stay – continuous in days
2. Readmission within 30 days
3. Hospital mortality

For categorical variables (Readmission within 30 days and Hospital mortality) we will logistic regression models; whilst for the continuous variable (length of stay) we will estimate linear regression models.

The pre-specified conditioning variables in each analysis will be:

- Age –in years
- Sex (1 = female, 0 = male)
- Ethnicity
- socio-economic status – IMD04_decile
- Primary Diagnosis
- Secondary Diagnosis
- Surgical Procedure

The key explanatory variables will be:

- Full Blood Count;
- U&E; and
- Pulmonary function test

These will be entered as dummy variables. We will also enter joint dummy variables for each possible combination of these tests; e.g. FBC and U&E.

The models will be estimated separately for patients with and without comorbidities. Comorbidities will be modelled in two ways. First we will use the presence or absence of a secondary diagnosis as evidence of a comorbidity. Secondly, we will use whether patients had additional tests as a proxy for the presence of a comorbidity. We believe the second measure may be a more sensitive measure for the presence of a comorbidity, although obviously less specific than the recorded secondary diagnosis.

The outputs of these analyses will be six separate models assessing whether the absence of any combination of the three tests is associated with a difference in any of the three measures of outcome. The models will be assessed using standard statistical measures for goodness of fit, specification, and collinearity.

We will report the models in full and whether there is a statistically significant relationship between the absence of any combination of the three tests and length of stay, 30 day re-admission and hospital mortality.

Where the models report a significant relationship we will examine the costs incurred for the tests and the costs associated with the different outcomes in order to assess the likely value of the tests to the NHS. Given the extremely large number of observations available for these analyses, we judge that the absence of statistically significant relationship is sufficient to treat absence of evidence as evidence of absence.

Examining the value of more research

The estimated models can be used to explore the value of information associated with further research into these tests. The standard errors on the model parameters will provide a measure of the uncertainty associated with the relationship between the presence or absence of the test results and patient outcomes. Should we find evidence of a relationship between the routine tests and any of these outcomes, it will be appropriate to examine the value of undertaking further research, such as a prospective randomised controlled trial of these test, to inform future policy.

Using monte carlo simulation it is possible to simulate a distribution for the expected outcomes. The simulated distributions will describe the probability that the use of the routine tests are associated with difference in each of the outcomes and by extension the risk that using the central estimate to guide practice will lead to making the wrong decision. By attaching a value to each of the outcomes, e.g. the cost of a readmission or the value of a statistical life, it will be possible to attribute a value to reducing the risk of making the wrong decision through further research.

Appendix 4

Systematic review of clinical effectiveness: tabulation of excluded studies

Study	Reason for exclusion
Adams *et al.* 1992[48]	Age range 13–80 years; no relevant subgroup analyses
Ajimura *et al.* 2005[49]	No data regarding ASA grade
Alam *et al.* 2003[50]	Age range 4–59 years; no relevant subgroup analyses
Anonymous 1999[51]	Brief summary of an unreferenced Mayo Clinic study
Arieta *et al.* 2004[52]	ASA grades 1–3; no relevant subgroup analyses
Barazzoni *et al.* 1999[53]	Includes children; no relevant subgroup analyses
Billings *et al.* 1993[54]	No data regarding age or ASA grade
Bryson *et al.* 2006[55]	No data regarding age or ASA grade
Cartana *et al.* 1989[56]	No data regarding ASA grade
Desmonts 1993[57]	Nature of surgery not recorded (very poorly reported study)
Diouf *et al.* 1998[58]	Article not available
Dunne *et al.* 2002[59]	ASA grades 1–5; no relevant subgroup analyses
Ebert *et al.* 1997[60]	ASA grades 2–4; no relevant subgroup analyses
Finegan *et al.* 2005[61]	ASA grades 1–4; no relevant subgroup analyses
Fischer 1999[62]	Not research study
Fourcade 1989[63]	ASA grades 1–4; no relevant subgroup analyses
Gallus *et al.* 1973[64]	Major surgery
Golub *et al.* 1992[65]	ASA grades 1–3; no relevant subgroup analyses
Halabe-Cherem *et al.* 1995[66]	Includes major and emergency surgery
Hans *et al.* 2006[67]	Includes major surgery
Johnson *et al.* 1988[68]	No data regarding ASA grade
Johnson *et al.* 2002[69]	No data regarding ASA grade
Kamimura *et al.* 2006[70]	No data regarding ASA grade
Kaplan *et al.* 1985[71]	No data regarding age or ASA grade
Keenan *et al.* 1998[72]	Focus not on specific tests
Kocabas *et al.* 1996[73]	Includes major surgery
Lira *et al.* 2001[74]	ASA grades 1–3; no relevant subgroup analyses
Lira *et al.* 2003[75]	ASA grades 1–3; no relevant subgroup analyses
MacPherson *et al.* 1990[76]	No data regarding ASA grade
Mantha *et al.* 2005[77]	No data regarding ASA grade
McAlister *et al.* 2003[78]	No data regarding ASA grade
McCleane 1990[79]	All ages and ASA grades 1–4; subgroup analyses by ASA grade but not by age
McKee and Scott 1987[80]	No data regarding ASA grade
McKibbin 1996[81]	No data regarding ASA grade
Meguro *et al.* 1996[82]	Article not available
Mignonsin *et al.* 1996[83]	All ages and ASA grades 1–3; subgroup analyses by ASA grade but not by age
Morales-Orozco *et al.* 2005[84]	Article not available
Narr *et al.* 1991[85]	Includes children; no relevant subgroup analyses
Nascimento *et al.* 2004[86]	ASA grades 1–3; no relevant subgroup analyses
Pfaff and van der Linden 1989[87]	No data regarding ASA grade

Study	Reason for exclusion
Philip *et al.* 1997[88]	Article not available; appears to be same study as Philip *et al.* 1999,[89] which did not meet the study inclusion criteria
Roseano *et al.* 2002[90]	ASA grades 2–5; no relevant subgroup analyses; may include emergency surgery
Schein *et al.* 2000[91]	Intervention takes the form of a 'standard battery of medical tests' including electrocardiography and glucose as well as CBC and serum electrolytes, urea nitrogen and creatinine; results reported for the total package, not by individual test
Stephens 2000[92]	Summary of study by Schein *et al.* 2000[91]
Suh *et al.* 1997[93]	Article not available
Velanovich 1991[94]	No data regarding ASA grade
Velanovich 1993[95]	No data regarding ASA grade
Walters and McKibbin 1997[96]	ASA grades 1–3; no relevant subgroup analyses
Wattsman and Davies 1997[97]	ASA grades 1–3; no relevant subgroup analyses
Wittgen *et al.* 1993[98]	Mean ASA grade >2; no relevant subgroup analyses
Wyatt *et al.* 1989[99]	No data regarding age or ASA grade

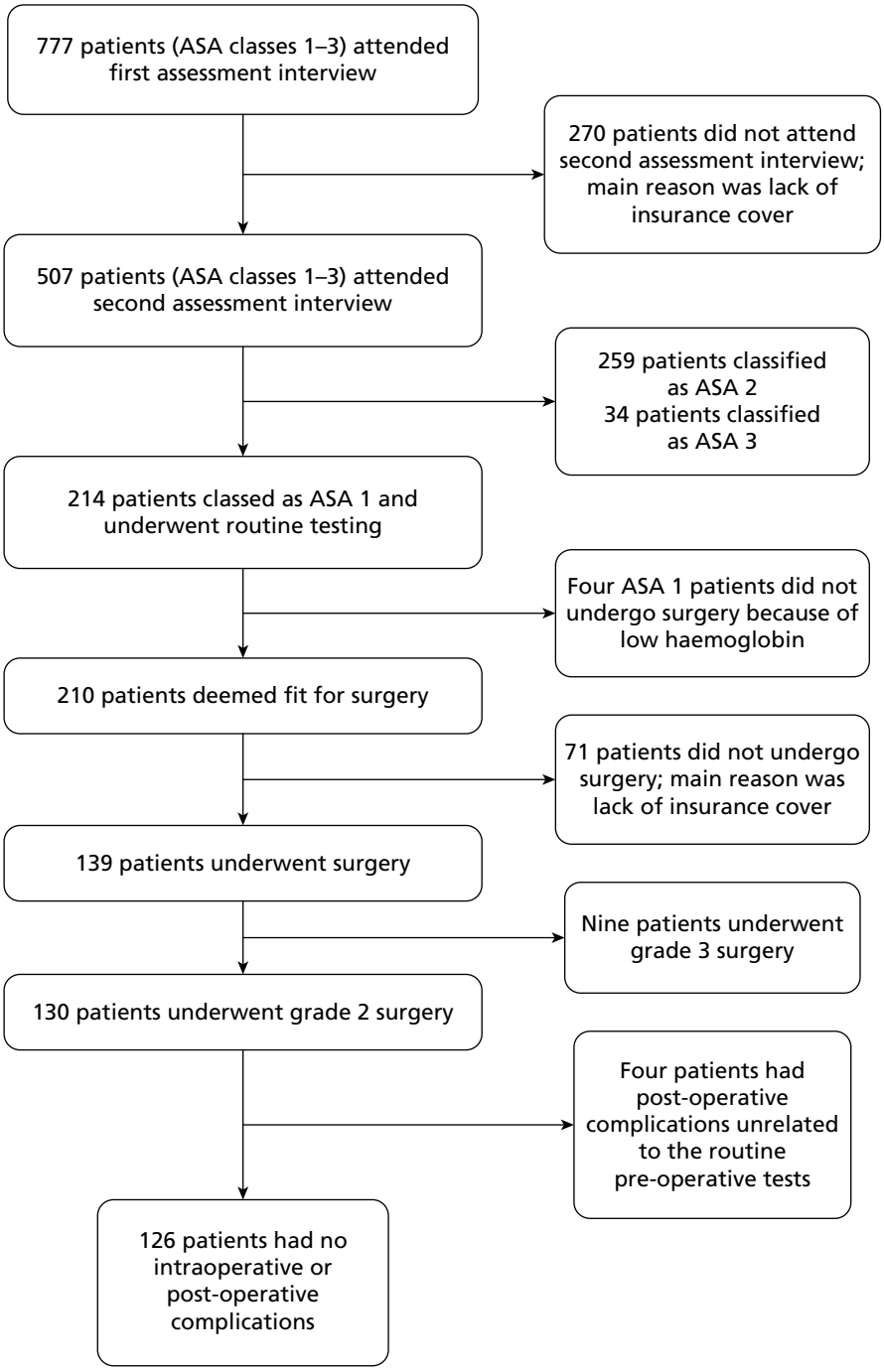
Appendix 5

Systematic review of clinical effectiveness: quality assessment of non-randomised studies

	Study					
Criterion	Gnocchi *et al.*[11]	Haug and Reifeis[13]	Roukema *et al.*[14]	Szmuk *et al.*[9]	Tallo *et al.*[12]	Turnbull and Buck[15]
Prospective recruitment	Yes	Yes	Yes	No	No	No
Consecutive recruitment	Yes	Yes	Yes	Not clear	Yes	Not clear
≥90% followed up	No	No	Yes	Not applicable	No	Not applicable
Loss to follow-up reported or explained	Yes	Yes	Not applicable	Not applicable	Yes	Not applicable
Follow-up long enough	Yes	Yes	Not clear	Yes	Not clear	Not clear
Outcome assessment objective or blinded	Not clear	Yes	Not clear	Yes	Yes	Yes
Measure of variability	Yes	No	No	No	No	No
Age and ASA status reported	Yes	Yes	No	Yes	Yes	Not clear
Operation type and/or risk category adequately reported	Yes	Yes	Yes	Yes	Yes	Yes
All operations elective	Yes	Yes	Yes	Yes	Yes	Not clear
All tests routine	Yes	Yes	Yes	Yes	Not clear	Not clear
Normal/abnormal results defined	No	No	Yes	Yes	Yes	Not clear

Appendix 6

Apparent patient flow in the study by Gnocchi *et al.*[11]



Appendix 7

Turnbull and Buck:[15] summary of relevant pre-operative test results and relevant complications

TABLE 29 Full blood count

Test	Hb	Platelets	White blood cells
No. of abnormal test results	7/1005	0/1005	1/1005
Rate	*0.7%*	*0%*	*0.1%*
95% CI	*0.2% to 1.2%*	Not applicable	*–1.0% to 0.3%*
Patients with relevant complications: total	*16/1010*	37/1010	110/1010
Rate	*1.6%*	*3.7%*	*10. 9%*
95% CI	*0.8% to 2.4%*	*2.5% to 4.8%*	*9.0% to 12.8%*
Patients with relevant complications: normal test result	14/998	37/1005	110/1004
Rate	*1.4%*	*3.7%*	*11.0%*
95% CI	*0. 7% to 2.1%*	*2.5% to 4.8%*	*9.0% to 12.9%*
Patients with relevant complications: abnormal test result	2/7	0	0
Rate	*28.6%*	*0%*	*0%*
95% CI	*–4.9% to 62.0%*	Not applicable	Not applicable
Patients with abnormal test result: action	2/7	Not applicable	0
Rate	*28.6%*	Not applicable	*0%*
95% CI	*–4.9% to 62.0%*	Not applicable	Not applicable
Patients with abnormal test result: no action	5/7	Not applicable	1/1
Rate	*71.4%*	Not applicable	Not applicable
95% CI	*38.0% to 105.0%*	Not applicable	Not applicable
Patients with abnormal test result and relevant complication: action	1/2	Not applicable	Not applicable
Rate	*50%*	Not applicable	Not applicable
95% CI	*–19.3% to 119.3%*	Not applicable	Not applicable
Patients with abnormal test result and relevant complication: no action	1/2	Not applicable	Not applicable
Rate	*50%*	Not applicable	Not applicable
95% CI	*–19.3% to 119.3%*	Not applicable	Not applicable

Data in *italics* were calculated by the reviewer.

TABLE 30 Urea and electrolyte tests

Test	Sodium	Potassium	Creatinine	Urea
No. of abnormal test results	5/995	14/995	2/995	1/995
Rate	*0.5%*	*1.41%*	*0.2%*	*0.1%*
95% CI	*0.1% to 0.9%*	*0.7% to 2.1%*	*–0.1% to 0.5%*	*–0.1% to 0.3%*
Patients with relevant complications: total	1/1010	*21/1010*	0/1010	0/1010
Rate	*0.1%*	*2.08%*	*0%*	*0%*
95% CI	*–0.1% to 0.3%*	*1.2% to 3.0%*	*Not applicable*	*Not applicable*
Patients with relevant complications: normal test result	1/990	20/981	0/993	0/994
Rate	*0.1%*	*2.0%*	*0%*	*0%*
95% CI	*–0.1% to 0.3%*	*1.2% to 2.9%*	*Not applicable*	*Not applicable*
Patients with relevant complications: abnormal test result	0/5	1/14	0/2	0/1
Rate	*0%*	*7.1%*	*0%*	*0%*
95% CI	*Not applicable*	*–6.4% to 20.6%*	*Not applicable*	*Not applicable*
Patients with abnormal test result: action	0/5	4/14	0/2	0/1
Rate	*0%*	*28.6%*	*0%*	*0%*
95% CI	*Not applicable*	*4.9% to 52.2%*	*Not applicable*	*Not applicable*
Patients with abnormal test result: no action	5/5	10/14	2/2	1/1
Rate	*100%*	*71.4%*	*100%*	*100%*
95% CI	*Not applicable*	*47.8% to 95.1%*	*Not applicable*	*Not applicable*
Patients with abnormal test result and relevant complication: action	*Not applicable*	1/4	*Not applicable*	*Not applicable*
Rate	*Not applicable*	*25.0%*	*Not applicable*	*Not applicable*
95% CI	*Not applicable*	*–17.4% to 67.4%*	*Not applicable*	*Not applicable*
Patients with abnormal test result and relevant complication: no action	*Not applicable*		*Not applicable*	*Not applicable*
Rate	*Not applicable*		*Not applicable*	*Not applicable*
95% CI	*Not applicable*		*Not applicable*	*Not applicable*

Data in Roman font were taken directly from the text; data in *italics* were calculated by the reviewer.

Appendix 8

Review of the adverse effects of venepuncture and pulmonary function testing: methods

Identification of studies

Literature searches were performed in August 2009 to retrieve papers on any adverse events associated with the performance of either venepuncture used to obtain samples for blood testing or PFTs.

Sources searched

The following electronic bibliographic databases were searched:

1. BIOSIS
2. CINAHL
3. CDSR
4. CENTRAL
5. EMBASE
6. MEDLINE
7. MEDLINE In-Process & Other Non-Indexed Citations
8. NHS DARE
9. NHS HTA Database
10. SCI.

Search strategies

The MEDLINE search strategies are as follows.

Blood test adverse events search

1. exp Hematologic Tests/ae [Adverse Effects]
2. Blood Specimen Collection/ae [Adverse Effects]
3. Phlebotomy/ae [Adverse Effects] (335)
4. 1 or 2 or 3
5. adult/or aged/or middle aged/
6. adult$.tw.
7. 5 or 6
8. 4 and 7

Pulmonary function test adverse events search

1. exp Respiratory Function Tests/ae [Adverse Effects]
2. adult/or aged/or middle aged/
3. adult$.tw.
4. 2 or 3
5. 1 and 4
6. limit 6 to yr="1999 -Current"

The MEDLINE strategies were adapted for use in the other databases; these search strategies are available on request.

Search restrictions

The searches were not restricted by language. Because of the large number of results retrieved, the PFT adverse effects search was limited to the last 10 years.

Inclusion and exclusion criteria

Inclusion criteria

Population

- Adult patients classified as ASA grade 1 or 2, or otherwise stated to be healthy.

Intervention

- Simple venepuncture for diagnostic or screening purposes.
- Pulmonary function testing.

Outcomes

- Adverse events probably or possibly caused by the process of testing.

Setting

- Any country.

Study type

- RCTs.
- Controlled non-randomised studies (e.g. cohort studies).
- Case–control studies.
- Case series.
- Case reports.
- Systematic reviews.
- Economic evaluations.

Exclusion criteria

As in the systematic review of clinical effectiveness, the following publication types were excluded:

- animal models
- narrative reviews, editorials and opinions.

In addition, studies were excluded if:

- venepuncture was used only to obtain blood donations, or was used both to obtain blood donations and to obtain smaller samples for diagnostic or screening purposes, but no distinction was made between the two uses
- cannulation or catheterisation were used to obtain blood samples
- they related to the collection of arterial or capillary rather than venous blood samples.

Sifting

The same three-stage sifting process was used as was used in the systematic review of clinical effectiveness.

Data extraction strategy

Data were extracted directly to the tables included in the report.

Quality assessment strategy

Because many of the relevant studies took the form of case reports, a formal quality assessment was not undertaken. Larger studies (observational or before-and-after studies) were deemed to be of higher quality than case series or case reports, and the latter were included only if they related to adverse events for which data were not available from the larger studies.

Appendix 9

Review of the adverse effects of venepuncture: quantity of research available

The electronic literature searches identified 466 potentially relevant articles. Of these, eight articles[4,16,18–23] met the review's inclusion criteria (see *Figure 4*).

Three additional relevant articles, by Berry and Wallis,[24] Horowitz[17] and Yuan and Cohen,[25] were identified only from citations.

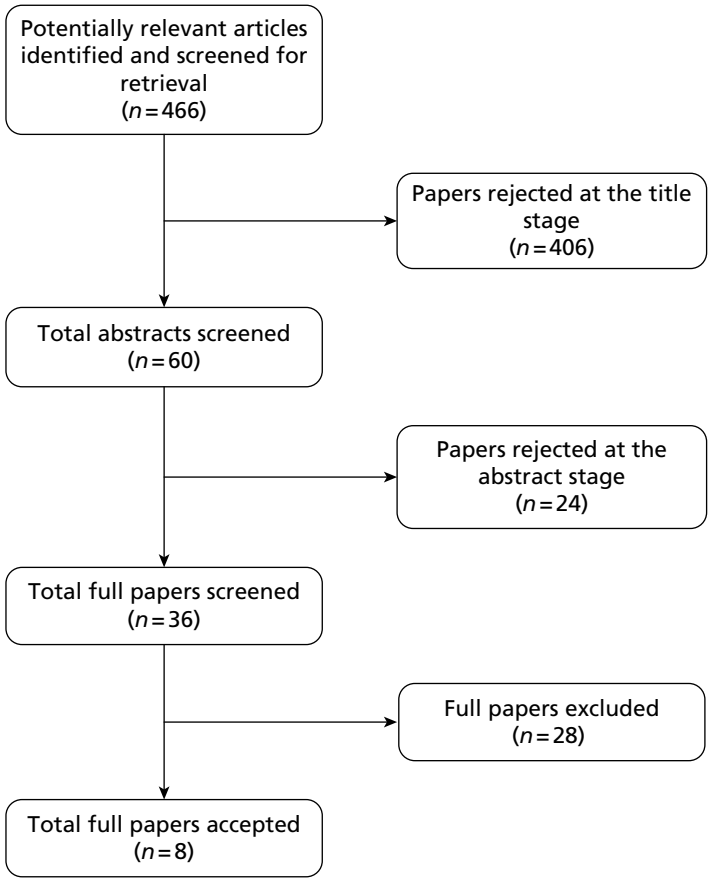


FIGURE 4 Adverse effects of venepuncture: summary of study selection and exclusion (electronic literature searches).

Appendix 10

Review of the adverse effects of pulmonary function testing: quantity of research available

The electronic literature searches identified 396 potentially relevant articles. Of these, two articles[14,28] met the review's inclusion criteria (see *Figure 5*).

Three additional relevant articles, by Manço *et al.*,[31] Nemet *et al.*[32] and Varkey and Cory,[33] were identified only from citations, and a fourth, by Patel *et al.*,[28] was identified by the clinical effectiveness searches.

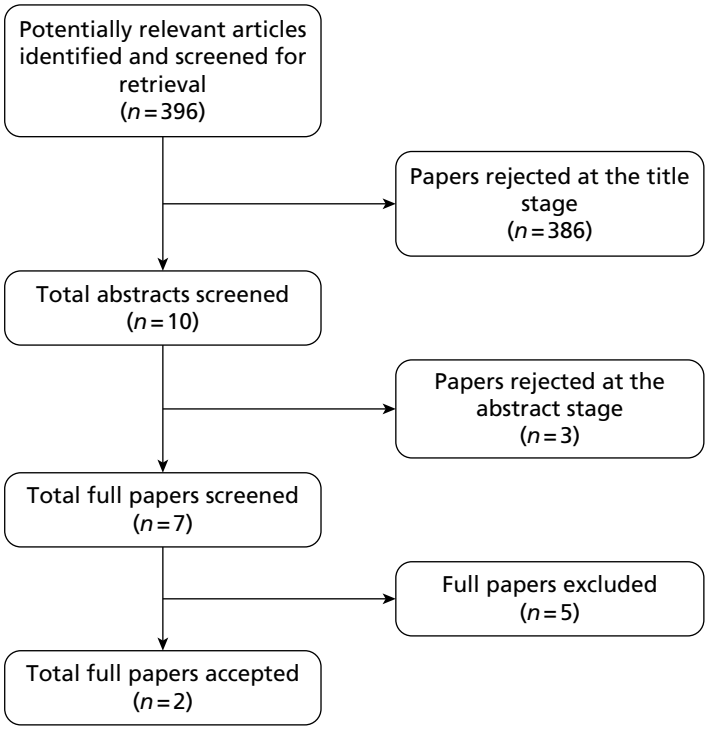


FIGURE 5 Adverse effects of pulmonary function testing: summary of study selection and exclusion (electronic literature searches).

Appendix 11

Search strategies for cost-effectiveness review

MEDLINE/MEDLINE In-Process & Other Non-Indexed Citations – Ovid MEDLINE(R) <1950 to January week 1 2009>

#	Search history	Results
1	Surgery/	27,739
2	surgery-elective.tw.	64
3	Surgical procedures, elective/or surgical procedures, minor/	5914
4	Elective surgery.tw.	4729
5	Minor surgery.tw.	1104
6	Intermediate surgery.tw.	23
7	Ambulatory Surgical Procedures/	8227
8	Day surgery.tw.	1484
9	asymptomatic.tw.	74,729
10	preoperative.tw.	107,611
11	pre-operative.tw.	10,624
12	Pre operative.tw.	10,624
13	Ambulatory Care/	29,659
14	or/1-13	262,897
15	Diagnostic Tests, Routine/	4708
16	Preoperative Care/	40,716
17	Routine test$.tw.	1985
18	Routine assessment$.tw.	749
19	Routine investigation$.tw.	738
20	Clinical Chemistry Tests/	677
21	Risk Assessment/	96,059
22	Blood Cell Count/	17,175
23	Full blood count.tw.	391
24	fbc.tw.	227
25	Hematologic Tests/	3910
26	Urea/	32,935
27	Urinalysis/	2848
28	Electrolytes/	17,466
29	Urine test$.tw.	1538
30	Blood test$.tw.	7113
31	u&e.tw.	451
32	(electrolytes and renal function).tw.	596
33	Respiratory Function Tests/	32,143
34	Pulmonary function test$.tw.	6153
35	Spirometry/	14,322
36	spirometry.tw.	6808
37	Blood Gas Analysis/	17,075
38	Blood gas analysis.tw.	2756

#	Search history	Results
39	pft.tw.	806
40	Measurement of respiratory mechanics.tw.	23
41	Measurement of transfer function.tw.	0
42	Exercise Test/	39,143
43	Exercise test$.tw.	15,186
44	Respiratory System/	10,648
45	(42 or 43) and 44	64
46	h?ematolog$test$.tw.	526
47	vitalograph.tw.	138
48	FEV1.tw.	12,930
49	Vital Capacity/	10,184
50	Vital capacit$.tw.	8648
51	Transfer function.tw.	2623
52	Pulmonary Diffusing Capacity/	2884
53	Diffusing capacit$.tw.	2770
54	dlco.tw.	1275
55	Exp Lung Volume Measurements/	25,821
56	Lung capacit$.tw.	2477
57	Cardiopulmonary exercise test$.tw.	1082
58	cpx.tw.	495
59	maxim$ oxygen uptake.tw.	3356
60	V02max.tw.	21
61	Oxygen Consumption/	80,267
62	or/15-41,45-61	395,740
63	economics/	25,191
64	Exp “costs and cost analysis”/	138,805
65	Economic value of life/	4966
66	Exp economics, hospital/	15,604
67	Exp economics, medical/	11,574
68	economics, nursing/	3775
69	economics, pharmaceutical/	1965
70	Exp models, economic/	6185
71	Exp “fees and charges”/	23,781
72	Exp budgets/	9949
73	ec.fs.	246,405
74	(cost or costs or costed or costly or costing$).tw.	198,747
75	(economic$ or pharmacoeconomic$ or price$ or pricing).tw.	106,075
76	or/63-75	495,837
77	14 and 62 and 76	1480

Bioscience Information Service/Science Citation Index – Web of Knowledge

5
#4 AND #3
Databases=SCI-EXPANDED Timespan=All Years
# 4
TS=(cost* OR economic* OR “fees and charges” OR budget* OR price OR pricing OR pharmacoeconomic* OR pharmaco-economic* OR finance OR finances OR financing OR financial OR fee OR fees OR fiscal OR funding)

Databases=SCI-EXPANDED Timespan=All Years
# 3
#2 AND #1
Databases=SCI-EXPANDED Timespan=All Years
# 2
TS=(routine test* OR routine assessment* OR routine investigation* OR clinical chemistry test* OR blood cell count OR full blood count OR fbc OR hematologic test* OR haematologic test* OR urea OR urinalysis OR electrolytes OR urine test* OR blood test* OR u&e OR respiratory function test* OR pulmonary function test* OR spirometry OR blood gas analysis OR pft OR vitalograph OR FEV1 OR vital capacit* OR transfer function OR pulmonary diffusing capacit* OR dlco OR lung capacit* OR lung volume measurement OR cpx OR oxygen uptake OR V02max OR oxygen consumption OR cardiopulmonary exercise test*)
Databases=SCI-EXPANDED Timespan=All Years
# 1
TS=(surgery OR ambulatory surgical procedures OR asymptomatic OR preoperative OR pre-operative OR pre operative OR ambulatory care)
Databases=SCI-EXPANDED Timespan=All Years

EMBASE – Ovid <1980 to week 4 2009>

1. Surgery/
2. Elective Surgery/
3. elective surgery.tw.
4. minor surgery/
5. minor surgery.tw.
6. intermediate surgery.tw.
7. ambulatory surgery/
8. ambulatory care/
9. day surgery.tw.
10. asymptomatic.tw.
11. preoperative.tw.
12. pre-operative.tw.
13. pre operative.tw.
14. or/1-13
15. diagnostic test/
16. Preoperative Care/
17. routine test$.tw.
18. routine assessment$.tw.
19. routine investigation$.tw.
20. clinical chemistry/
21. risk assessment/
22. blood cell count/
23. full blood count.tw.
24. fbc.tw.
25. blood examination/
26. h?ematolog$ test$.tw.
27. Urea/
28. URINALYSIS/
29. Electrolyte/
30. urine test$.tw.
31. blood test$.tw.

32. u&e.tw.
33. (electrolytes and renal function).tw.
34. lung function test/
35. pulmonary function test$.tw.
36. respiratory function test$.tw.
37. spirometry/
38. spirometry.tw.
39. blood gas analysis/
40. blood gas analysis.tw.
41. pft.tw.
42. measurement of respiratory mechanics.tw.
43. measurement of transfer function.tw.
44. exercise test/
45. exercise test$.tw.
46. respiratory system/
47. 44 or 45
48. 46 and 47
49. vitalograph.tw.
50. FEV1.tw.
51. vital capacity/
52. vital capacit$.tw.
53. transfer function.tw.
54. lung diffusion capacity/
55. diffusing capacit$.tw.
56. dlco.tw.
57. lung volume/
58. lung capacit$.tw.
59. cardiopulmonary exercise test$.tw.
60. cpx.tw.
61. maxim$ oxygen uptake.tw.
62. V02max.tw.
63. oxygen consumption/
64. or/15-43,48-63
65. exp SOCIOECONOMICS/
66. exp "Cost Benefit Analysis"/
67. exp "Cost Effectiveness Analysis"/
68. exp "Cost of Illness"/
69. exp "Cost Control"/
70. exp Economic Aspect/
71. exp Financial Management/
72. exp "Health Care Cost"/
73. exp Health Care Financing/
74. exp Health Economics/
75. exp "Hospital Cost"/
76. (financial or fiscal or finance or funding).tw.
77. exp "Cost Minimization Analysis"/
78. (cost adj estimate$).mp.
79. (cost adj variable$).mp.
80. (unit adj cost$).mp.
81. or/65-80
82. 14 and 64 and 81
83. from 82 keep 1

The Cochrane Library

#1 MeSH descriptor Surgery explode all trees
#2 MeSH descriptor Surgical Procedures, Elective explode all trees
#3 MeSH descriptor Surgical Procedures, Minor explode all trees
#4 (elective surgery):ab or (elective surgery):ti
#5 (minor surgery):ab or (minor surgery):ti
#6 (intermediate surgery):ti,ab
#7 MeSH descriptor Ambulatory Surgical Procedures explode all trees
#8 (day surgery):ti,ab
#9 (asymptomatic):ti,ab
#10 preoperative:ti,ab
#11 pre operative:ti,ab
#12 pre operative:ti,ab
#13 MeSH descriptor Ambulatory Care, this term only
#14 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13)
#15 MeSH descriptor Diagnostic Tests, Routine explode all trees
#16 MeSH descriptor Preoperative Care, this term only
#17 (routine AND (test* OR assessment* OR investigation*)):ti,ab
#18 MeSH descriptor Clinical Chemistry Tests, this term only
#19 MeSH descriptor Risk Assessment, this term only
#20 MeSH descriptor Blood Cell Count, this term only
#21 (full blood count):ti,ab
#22 fbc:ti,ab
#23 MeSH descriptor Hematologic Tests, this term only
#24 (haematology test*):ti,ab
#25 (hematology test*):ti,ab
#26 MeSH descriptor Urea, this term only
#27 MeSH descriptor Urinalysis, this term only
#28 MeSH descriptor Electrolytes, this term only
#29 (urine test*):ti,ab
#30 (blood test*):ti,ab
#31 (u&e):ti,ab
#32 (electrolytes and renal function):ti,ab
#33 MeSH descriptor Respiratory Function Tests, this term only
#34 (pulmonary function test*):ti,ab
#35 MeSH descriptor Spirometry, this term only
#36 (spirometry):ti,ab
#37 MeSH descriptor Blood Gas Analysis, this term only
#38 (blood gas analysis):ti,ab
#39 pft:ti,ab
#40 (measurement of respiratory mechanics):ti,ab
#41 (measurement of transfer function):ti,ab
#42 MeSH descriptor Exercise Test explode all trees
#43 (exercise test*):ti,ab
#44 MeSH descriptor Respiratory System explode all trees
#45 (#42 OR #43)
#46 (#44 AND #45)
#47 (vitalograph):ti,ab
#48 FEV1:ti,ab

#49 MeSH descriptor Vital Capacity, this term only
#50 (vital capacit*):ti,ab
#51 (transfer function):ti,ab
#52 MeSH descriptor Pulmonary Diffusing Capacity explode all trees
#53 (diffusing capacit*):ti,ab
#54 dlco:ti,ab
#55 MeSH descriptor Lung Volume Measurements explode all trees
#56 (lung capacit*):ti,ab
#57 (cardiopulmonary exercise test*):ti,ab
#58 cpx:ti,ab
#59 (maxim* oxygen uptake):ti,ab
#60 V02max:ti,ab
#61 MeSH descriptor Oxygen Consumption, this term only
#62 (#14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61)
#63 (#14 AND #62)

Appendix 12

Excluded studies: cost-effectiveness review

TABLE 31 Excluded references that did not meet the inclusion/exclusion criteria – not in the English language ($n = 39$)

Reference	Population: UK based
Arieta *et al.* 2004[100]	No
Based 1998[101]	No
Binder and Schwarz 2002[102]	No
Christian *et al.* 1988[103]	No
Daher 1996[104]	No
De 1984[105]	
Dempfle 2005[106]	No
Diouf *et al.* 1998[107]	No
Dralle *et al.* 1999[108]	
Eisold 1996[109]	
Hoogbergen 1990[110]	
Hunting 1989[111]	
Irace *et al.* 1990[112]	No
Ise *et al.* 2004[113]	
Junger *et al.* 2002[114]	
Langemeijer 1996[115]	No
Passamonti 2004[116]	No
Persson and Bake 1992[117]	No
Pfaff and Van Der Linden 1989[118]	
Prause 1994[119]	
Raeder 1996[120]	No
Ramschack 1997[121]	
Rassler *et al.* 1994[122]	No
Reingruber *et al.* 1997[123]	No
Ritz *et al.* 1997[124]	No
Roewer and Kehl 2005[125]	No
Rutten *et al.* 1995[126]	No
Sanchez-Alvarez *et al.* 1997[127]	No
Scheidegger 1995[128]	
Schmitt *et al.* 2011[129]	No
Schwilk *et al.* 1993[130]	No
Stohr *et al.* 1998[131]	
Strom *et al.* 1998[132]	
Szmuk *et al.* 2002[9]	No
Van Aken and Rolf 1997[133]	
Van Der 1984[134]	
Van Klei *et al.* 2001[135]	No
Van Melkebeke 2002[136]	No
Vesconi *et al.* 2000[137]	No

TABLE 32 Excluded references that did not meet the inclusion/exclusion criteria – not aged >16 years ($n=17$)

Reference	Patients 1: aged >16 years
Ansermino *et al.* 1999[138]	No
Atwell *et al.* 1973[139]	No
Detsky *et al.* 1987[140]	No
Derkay 2000[141]	No
Dzankic *et al.* 2001[142]	No
Ferrrari 2004[143]	No
Ferrer *et al.* 1994[144]	No
Hoare 1993[145]	2–15 years
Hsia *et al.* 1995[146]	No
Juliana *et al.* 2003[147]	>12 years
Mallick 2006[148]	No
Meneghini *et al.* 1998[149]	No
Parry *et al.* 2005[150]	No
Rossello *et al.* 1980[151]	Patients aged <14 years included
Shah *et al.* 2007[152]	No – includes children (patients aged 5–40 years)
Tornebrandt and Fletcher 1982[153]	No
Wittkugel 2006[154]	No

TABLE 33 Excluded references that did not meet the inclusion/exclusion criteria – not ASA grade 1 or 2 patient population ($n=1$)

Reference	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Abayomi *et al.* 1982[155]	Yes	Yes	Patients with carcinoma of the cervix and endometrium stage 1–4 of the disease	No	FBC, U&E	Yes – cost per positive diagnostic test

TABLE 34 Excluded references that did not meet the inclusion/exclusion criteria – no relevant pre-operative tests ($n = 12$)

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Amberg *et al.* 1982[156]	No	Yes	Not clear if patient population are all adults	Not enough detail to identify ASA status of patients	Not enough detail regarding surgical grade of patients	No – alkaline phosphatase test	Yes
Costamaga *et al.* 1998[157]	No	Yes	Yes	Not clearly stated	Patients who have an endoscopic intervention for the treatment of choledochlithiasis	No	Yes
Edis *et al.* 1978[158]	No	Yes	Yes	No	Surgery for overactive parathyroid glands	No – venous sampling, arteriography	Yes
Erickson and Carlson 1995[159]	No	Yes	Yes	Patients with cholelithiasis	No – laparoscopic cholecystectomy	No – endoscopic retrograde cholangiopancreatography/ endoscopic sphincterotomy	Yes
Hrung *et al.* 1999[160]	No	Yes	Yes	No – patients with suspected breast cancer	No	No – core-needle biopsy or excisional biopsy without pre-operative testing, and magnetic resonance imaging	Yes
Ransom *et al.* 1996[161]	No	Yes	Yes	Unclear about ASA status of patients	No – elective and emergency laparoscopic procedures	No – pre-operative blood type and screen testing	Yes
Roberts 1992[162]	No	Yes				No – allergy blood testing	Yes – based on simulated data
Ruda *et al.* 2006[163]	No	Yes	no	No – patients with negative findings on scans with technetium (^{99m}Tc) sestamibi for sporadic primary hyperparathyroidism	No	No – comparison of pre-operative imaging using ultrasonography; single-photon emission computed tomography with technetium (^{99m}Tc) sestamibi; and control bilateral neck exploration	Yes

continued

TABLE 34 Excluded references that did not meet the inclusion/exclusion criteria – no relevant pre-operative tests ($n = 12$) (*continued*)

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Shaw *et al.* 1997[164]	No	Yes	Yes	No – patients with a history of coronary disease or angina	No – patients about to undergo vascular operations	No – dipyridamole myocardial perfusion imaging, dobutamine echocardiography and cardiac catheterisation before vascular operations	Yes
Sonnenberg and Townsend 1991[165]	No	Yes	Yes	No	Patients with gastrointestinal symptoms who are hospitalised for major elective surgery	No – faecal occult blood testing	Yes
Sonnenberg and Townsend 1992[166]	No	Yes	Yes	Screening for cancer	No	No – faecal occult blood testing	Yes
Weber *et al.* 2002[167]	No	Yes	Yes	No – based on a hypothetical sample of women used in the model. ASA grade of women not provided – included women with stress incontinence symptoms	No – some patients had surgical intervention while others only had a medical intervention	No – two methods of pre-operative assessment in the diagnosis of uncomplicated stress urinary incontinence: basic office assessment Urodynamic testing	Yes
Total	**12**						

TABLE 35 Excluded references that did not meet the inclusion/exclusion criteria – not a full economic evaluation, UK based and no relevant tests or surgical procedure or patient population ($n = 205$)

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Anonymous 1983[168]		Yes	Yes		No		No
Anonymous 1991[169]	No	Yes	Yes	No	General surgery, chest, urology, orthopaedics and gynaecology	FBC, U&E	No – questionnaire survey to attending physicians, total cost of tests in Sweden estimated
Anonymous 1996[170]		Yes	Yes		No		No
Abbott *et al.* 1983[171]		Yes	Yes		Focus is on nurse performance	No	No
Ainley-Walker 1979[172]		Yes	Yes	No			No
Allison and Bromley 1996[173]	No	Yes	Yes	No			No – cost analysis
Alsumait *et al.* 2002[174]	No	Yes	Yes	Not enough detail on ASA grade			No
Archer *et al.* 1993[175]	No	Yes	Yes			No	No
Armstrong *et al.* 2001[176]		Yes	Yes			No	No
Asua and Lopez-Argumedo 2000[177]		Yes	Yes	No			No
Atkins 1994[178]		Yes	Yes	No			No
Bachman *et al.* 1993[179]	No	Yes	Yes	No – included pregnant women		No – screening techniques for detecting asymptotic UTIs	No
Bader 1999[180]	No	Yes	Yes	No		No	No
Bahhady and Underborn 2003[181]	No	Yes	Yes			PFT	No
Barak *et al.* 2006[182]	No	Yes	Yes	No		No	No
Barazzoni *et al.* 2002[183]		Yes	Yes	No	No		No
Bass *et al.* 1995[184]		Yes	Yes	Patients with cataracts	Patients undergoing cataracts surgery	FBC, U&E and PFT	No – frequency of tests reported

continued

TABLE 35 Excluded references that did not meet the inclusion/exclusion criteria – not a full economic evaluation, UK based and no relevant tests or surgical procedure or patient population ($n = 205$) (*continued*)

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Bellan 1994[185]	No	Yes	Yes	No			No
Berger *et al.* 1981[186]	No	Yes	Yes		Patients treated for bladder cancer	No	No
Best *et al.* 2002[187]		Yes	Yes	No			No
Bird *et al.* 1984[188]	No	Yes	Yes			No	No – evaluated shaving procedure for different types of surgery
Blery *et al.* 1983[189]	No	Yes	Yes	No		FBC	No
Blitz *et al.* 2002[190]		Yes	Yes		No	No	No
Blomgren *et al.* 2006[191]	No	Yes	Yes	No		No	No
Boothe and Finegan 1995[192]	No	Yes	Yes	No		No	No
Bushick *et al.* 1989[193]		Yes	Yes	No	No		No
Callaghan *et al.* 1995[194]		Yes	Yes	No			No
Campbell 2006[195]		Yes	Yes	No	No	No	
Campbell *et al.* 1995[196]		Yes	Yes	No	No		No
Caprini 2005[197]		Yes	Yes	No		No	
Carty *et al.* 1997[198]	No	Yes	Yes	Patient ASA status not given	Operation for sporadic primary hyperparathyroidism	No – comparison of single radionuclide imaging technique of ^{99m}Tc-sestamibi and single-photon emission computed tomography imaging	No
Cassidy and Marley 1996[199]		Yes	Yes	No		No	No
Catchlove *et al.* 1979[200]	No	Yes	Yes	No		FBC	No – cost analysis
Chang *et al.* 2000[201]		Yes	Yes	No		No	No
Chu *et al.* 1996[202]		Yes	Yes	No		No	No

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Cirasino *et al.* 2000[203]		Yes	Yes	No	No		No
Clark 2001[204]		Yes	Yes	No		No	No
Clevenger and Tepas 1997[205]		Yes	Yes	No			No
Clinton *et al.* 1986[206]		Yes	Yes	No			No
Cloutier 1995[207]	No	Yes	Yes	No	No	No	No
Clyne and Forlenza 1997[208]		Yes	Yes			No	No
Collier 1998[209]	No	Yes	Yes	No	No	No	No
Collins 2007[210]		Yes	Yes	No		No	No
Collins and Chendrasekhar 1995[211]		Yes	Yes	No			No
Cook and Zitelli 1998[212]		Yes	Yes	No			No
Correa *et al.* 1999[213]		Yes	Yes	No	No	No	No
Crowther *et al.* 2004[214]		Yes	Yes	No			No
Cutler and Leppo 1987[215]		Yes	Yes	No	Coronary artery surgery		No
Daniell *et al.* 1992[216]	No	Yes	Yes	No	Endometrial ablation procedures	No	No
Davenport *et al.* 2005[217]		Yes	Yes		No		No
Davies *et al.* 1994[218]		Yes	Yes		No	No	No
De Nino *et al.* 1997[219]	No	Yes	Yes			No	No

continued

TABLE 35 Excluded references that did not meet the inclusion/exclusion criteria – not a full economic evaluation, UK based and no relevant tests or surgical procedure or patient population ($n = 205$) (*continued*)

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
De *et al.* 1996[220]		Yes	Yes	No	No		No
Degnore and Wilson 1989[221]		Yes	Yes			No	No
Delahunt and Turnbull 1980[222]	No	Yes	Yes	No		FBC, U&E	No – estimate cost saving
Denham and Norman 1998[223]	No	Yes	Yes	Patients with sporadic primary hyperparathyroidism	Surgery under monitored anaesthesia care compared with undirected bilateral exploration	No – (a) standard bilateral exploration and (b) sestamibi-guided limited exploration	No
Devalia *et al.* 2007[224]		Yes	Yes	No	No		No
Dillon *et al.* 2005[225]		Yes	Yes			No	No
Dimakakos *et al.* 1995[226]		Yes	Yes			No	No
Diokno *et al.* 1999[227]		Yes	Yes			No	No
Dix 2003[228]		Yes	Yes		No		No
Doering *et al.* 2000[229]		Yes	Yes	No	No		No
Dorenbusch *et al.* 1995[230]		Yes	Yes	No		No	No – cost analysis
Dublin *et al.* 1997[231]		Yes	Yes	No			No
Dubois *et al.* 1998[232]		Yes	Yes			No	No
D'ugo *et al.* 1997[233]		Yes	Yes	No		No	No
Dyson *et al.* 1992[234]		Yes	Yes	No			No
Eagle 2007[235]	No	Yes	Yes	No	No	No	No
Eckman *et al.* 2003[236]		Yes	Yes			No	No
Einhorn *et al.* 1987[237]	No	Yes	Yes	Patients who have undergone laparotomy for diagnosis of a pelvic mass	Detecting ovarian cancer in an apparently healthy population	Serum markers	No – abstract

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Eiseman *et al.* 1989[238]		Yes	Yes			No	No
Espallargues *et al.* 1996[239]	No	Yes	Yes			Not enough detail on tests	No
Everett 2002[240]		Yes	Yes			No – looking at post-operative nausea and vomiting	Yes
Farrell *et al.* 2003[241]	No	Yes	Yes	No	Pelvic examinations		No – guideline recommendation document
Fattahi *et al.* 2006[242]	No	Yes	Yes	No		Yes	No
Ferrando *et al.* 2005[243]		Yes	Yes		No		No
Finegan *et al.* 2005[244]	No	Yes	Yes	Includes ASA grades 3 and 4 patients	Not clearly defined	Yes	No – reported the total cost of tests ordered, mean number of tests ordered and mean cost of pre-operative testing
Fischer 1999[245]	No	Yes	Yes			No	No
Fischer 1997[246]	No	Yes	Yes	No		No	No
Fischer 1999[247]	No	Yes	Yes	No	No	Yes	No
Harik-Kahn *et al.* 2001[248]	No				No	Lung function	No
Hilibrand and Dina 1998[249]		Yes	Yes	No	No	No	No
Hnatiuk *et al.* 1995[250]		Yes	Yes	Not enough detail on ASA status			No
Hollenbeak *et al.* 2007[251]	No	Yes	Yes	No	No	No	No
Hoeks *et al.* 2007[252]		Yes	Yes	No	No		No
Hollenberg 1999[253]		Yes	Yes	No			No
Horton *et al.* 2006[254]		Yes	Yes		No	No	No
Howard 1997[255]		Yes	Yes	No	No	No	No
Howie *et al.* 1998[256]		Yes	Yes			No	No

continued

TABLE 35 Excluded references that did not meet the inclusion/exclusion criteria – not a full economic evaluation, UK based and no relevant tests or surgical procedure or patient population ($n = 205$) (*continued*)

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Hux 2003[257]	No	Yes	Yes	No		Blood chemistry	Cost analysis
Imasogie 2003[258]	No	Yes	Yes	No			No
Ishaq *et al.* 1997[259]	No	Yes	Yes	Patients undergoing elective non-acute and non-cardiopulmonary surgery		Routine chest radiography	No
Jaffer *et al.* 2005[260]	No	Yes	Yes	Patients undergoing elective non-cardiac surgery	Evaluation of post-operative pulmonary complications after the following surgical procedures: orthopaedic, urologic, neurosurgery, gynaecologic, colorectal or general	FBC, serum chemistries	No – total cost estimates for each patient group
Jang *et al.* 2000[261]		Yes	Yes	No	No	No	No
Johnson *et al.* 1988[262]	No	Yes	Yes	No	Patients undergoing ambulatory surgical procedures	FBC, U&E	No – cost description
Jones and Isaacson 1995[263]		Yes	Yes	No	No	U&E	No
Justice and King 1993[264]		Yes	Yes			No	No
Khandekar 1999[265]	No	Yes	Yes	No	No	No	No
Kitchens 1994[266]	No	Yes	Yes	Not enough detail	Not enough detail	No	Unclear
Lee *et al.* 2004[267]		Yes	Yes	No		No	No
Liberato *et al.* 2007[268]		Yes	Yes	No	No	No	No
Macario *et al.* 1992[269]	No	Yes	Yes	No		FBC, U&E	No – cost analysis
MacPherson 1993[270]	No	Yes	Yes	No		FBC, U&E	No
Mancuso 1996[271]		Yes	Yes		Ambulatory surgery patients	FBC, U&E	No – cost analysis
Mancuso 1999[272]		Yes	Yes	Not enough detail	Not enough detail		No
Mantha *et al.* 2005[273]		Yes	Yes	No			No

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Marcello and Roberts 1996[274]	No	Yes	Yes			FBC, U&E	No
Marton *et al.* 1985[275]	No	Yes	Unclear	Not enough detail given to establish ASA status	No – included in the patients with chronic obstructive pulmonary disease, hypertension, cardiac disease and diabetes	Tests included aminophylline, serum electrolytes, serum digoxin and serum glucose	No
Maurer *et al.* 2004[276]	No	Yes	Yes	No		No	No
McCleane 1988[277]		Yes	Yes			No	No
Morrison and Jacobs 2004[278]		Yes	Yes		Patients undergoing laparoscopic hysterectomy	No – no pre-operative tests discussed	No – cost description but not relevant as study was not concerned with pre-operative tests
Munro *et al.* 1997[279]		Yes	Yes			No	No
Muskett and McGreevy 1986[280]	No	Yes	Yes	No	Patients undergoing a range of surgical procedures	FBC, U&E	No
Nahas 2006[281]	No	Yes	Yes			Serum calcium	No
Nanthakrishnan *et al.* 1989[282]		Yes	Yes			No	No
Naraghi *et al.* 1995[283]		Yes	Yes			No	No
Nardella *et al.* 1995[284]	No	Yes	Yes	No		FBC, U&E	No – cost description
Narr *et al.* 1991[285]	No	Yes	Yes	No		Hb concentration	No – cost analysis
Nelson *et al.* 1987[286]		Yes	Yes	Not enough detail on ASA status		Not enough detail	No – cost analysis
Northup 2004[287]		Yes	Yes	No	No	No	No
Ntia and Okikiolu 1996[288]	No	Yes	Yes	No	No		No
Okelberry 1974[289]		Yes	Yes			No	No
Onder *et al.* 2004[290]	No	Yes	Yes	No	No	No	No

continued

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TABLE 35 Excluded references that did not meet the inclusion/exclusion criteria – not a full economic evaluation, UK based and no relevant tests or surgical procedure or patient population ($n = 205$) (*continued*)

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Oyama *et al.* 2001[291]		Yes	Yes	No	No	PFT	No
Parker *et al.* 2000[292]		Yes	Yes	No		No	No
Parrish 2001[293]	No	Yes	Yes	No	No	No	No
Pasternak and Johns 2005[294]		Yes	Yes	No	No		No
Patel 2000[295]	No	Yes	Yes	No		No	No
Pellikka *et al.* 1995[296]		Yes	Yes			No	No
Peredy and Powers 1997[297]	No	Yes	Yes			No	No
Phipps 1987[298]		Yes	Yes	No		Looks at who delivers tests	No
Poe *et al.* 1988[299]	No	Yes	Yes	No		PFT	No – cost analysis
Pokorny *et al.* 1999[300]	No	Yes	Yes	No	No		No
Pollard and Olson 1999[301]		Yes	Yes			No	No
Pollard *et al.* 1997[302]		Yes	Yes	No	No	No	No
Pollard *et al.* 1996[303]	No	Yes	Yes	Unclear	Unclear	No	No
Popovic *et al.* 1997[304]	No	Yes	Yes	No	No	No	No
Power and Thackray 1999[305]	No	Yes	Yes	No	No	FBC, U&E	No
Putnis *et al.* 2008[306]	No	Yes	Yes	ASA grades 1–3		FBC	No
Qiu 2006[307]		Yes	Yes			No	No
Rabkin and Horne 1979[308]	No	Yes	Yes	ASA status not given	No – elective or emergency operations	No	No
Ransom *et al.* 1995[309]	No	Yes	Yes	No details on ASA grade given	Vaginal hysterectomy	No – pre-operative type-and-screen testing (cross match not full screen)	No

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Raw 2001[310]		Yes	Yes	Not enough detail on ASA status	No		No
Rennie 2004[311]		Yes	Yes			No	No
Reynolds *et al.* 2006[312]		Yes	Yes	Not just ASA grades 1 and 2	Not just minor and intermediate surgery		no
Ricciardi *et al.* 1998[313]	No	Yes	Yes	No		Laboratory tests, Hb, electrolytes, etc.	No – questionnaire used by Swedish study adapted to Italy
Rich 2002[314]		Yes	Yes	No			No
Richie 1990[315]		Yes	Yes	No	No		No
Ridgway *et al.* 1990[316]		Yes	Yes	No	No	No	No
Rink 1993[317]		Yes	Yes		No		No
Roberts *et al.* 1983[318]	Yes	Yes	Yes	Unclear	Unclear	No	No
Robinson *et al.* 2003[319]		Yes	Yes	No	No		No
Roehrborn *et al.* 1986[320]		Yes	Yes			No	No
Roizen 1989[321]	No	Yes	Yes	No		No	No
Roizen 1993[322]	No	Yes	Yes	Not enough detail on ASA status	Vascular surgery		Unclear
Roizen 1994[323]	No	Yes	Yes	No			No – just contains information on when tests are applicable
Roizen 1994[324]	No	Yes	Yes	No			No
Romfh 1989[325]	No	Yes	Yes	No		Blood glucose	No – cost analysis
Russo *et al.* 2007[326]		Yes	Yes	No	No		No
Ryan 2000[327]		Yes	Yes		Orthopaedic surgery	Peak flow, blood pressure, UA	No
Sanders *et al.* 1989[328]	No	Yes	Yes	No	No – total hip replacement surgery	FBC, U&E	Unclear
Sanjay 2004[329]		Yes	Yes	No	No	No	No
Schein 1996[330]		Yes	Yes	No	Cataract surgery		No – description of a forthcoming study

continued

TABLE 35 Excluded references that did not meet the inclusion/exclusion criteria – not a full economic evaluation, UK based and no relevant tests or surgical procedure or patient population ($n = 205$) (*continued*)

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Schroeder 1999[331]		Yes	Yes	No		No	No
Shander *et al.* 2004[332]		Yes	Yes		No		No
Sharaf *et al.* 2004[333]		Yes	Yes		No	No	No
Sheehan *et al.* 2007[334]		Yes	Yes	No	No		No
Sihoe *et al.* 2004[335]		Yes	Yes	No	No		No
Silecchia 2000[336]	No	Yes	Yes	No	No	No	No
Silverstein and Boland 1994[337]		Yes	Yes	No		No	No
Singh *et al.* 1994[338]		Yes	Yes	No			No – letter to editor, comment on a paper
Sinha *et al.* 1997[339]		Yes	Yes	No			No
Smetana and MacPherson 2003[340]	No	Yes	Yes	Not enough detail on ASA status	no		No
Sommerville and Murray 1992[341]	No	Yes	Yes			No	No
Straube *et al.* 2005[342]		Yes	Yes			No	No
Swanson and Scheb 1996[343]		Yes	Yes	No		No	No
Tabas and Vanek 1999[344]		Yes	Yes	No			No
Tait *et al.* 1997[345]		Yes	Yes	No			No
Takemura *et al.* 2002[346]	No	Yes	Yes				No
Takemura *et al.* 2000[347]		Yes	Yes			No	No
Tarazi *et al.* 2000[348]		Yes	Yes	No	No		No
Tawam *et al.* 1996[349]	No	Yes	Yes	No	No		No

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Thompson 1979[350]		Yes	Yes	No		No	No
Thompson *et al.* 1983[351]	No	Yes	Yes	No detail given on patient ASA status	No detail given on the surgical procedures undertaken	No – chest radiography and multichannel blood tests as a screening instrument for chronic obstructive pulmonary disease, tuberculosis, heart disease, and lung cancer in asymptomatic adults – not enough detail given on the set of tests	No
Thue and Sandberg 1994[352]	No	Yes	Yes	No		Blood count	No
Tierney *et al.* 1990[353]	No	Yes	Yes	Not clear	Not clear	Testing physician's knowledge about the costs of screening tests	No
Tigges *et al.* 2004[354]		Yes	Yes			No	No
Turnbull and Buck 1987[15]	No	Yes	Yes	Patients admitted for cholecystectomy	No	FBC, PFT, U&E	No – cost description
Usal *et al.* 1999[355]	No	Yes	Yes	No	No	No	No
Van Der Merwe and Coetzee 1992[356]	No	Yes	Yes	No	No		No
Van Klei *et al.* 2003[357]		Yes	Yes			No	No
Van Klei *et al.* 2001[258]		Yes	Yes			No	No
Van Klei *et al.* 2000[359]		Yes	Yes			No	No
Van Klei *et al.* 2001[360]		Yes	Yes	No			No
Vanzuidewijn *et al.* 1994[361]		Yes	Yes	No	No		No
Velanovich 1993[362]	No	Yes	Yes	No			No
Velanovich 1994[363]	No	Yes	Yes	Not enough detail on ASA status	Elective operations in general, vascular, thoracic, and head and neck surgical services	FBC, U&E	No

continued

TABLE 35 Excluded references that did not meet the inclusion/exclusion criteria – not a full economic evaluation, UK based and no relevant tests or surgical procedure or patient population ($n = 205$) (*continued*)

Reference	Population: UK based?	Language: English?	Patients 1: aged >16 years?	Patients 2: ASA grade 1 or 2 classification?	Surgical procedures: minor or intermediate?	Tests: FBC, U&E or PFT?	Economic evaluation: incremental analysis of costs and outcomes?
Vogt and Henson 1997[364]	No	Yes	Yes	No – includes ASA grade 3 patients	No – not enough detail given to the grade of surgery	Yes	No
Wagner and Moore 1991[365]	No	Yes	Yes	Not enough detail on ASA status		FBC, U&E	No
Walton 1988[366]	Manchester UK	Yes	Yes	Not enough detail on ASA status	Dental surgery patients	FBC	No – cost description
Wattsman 1997[367]	No	Yes	Yes			No	No – cost description
West *et al.* 2000[368]		Yes	Yes	No	No	No	No
Wetchler 1999[369]		Yes	Yes	No			No
Wiencek *et al.* 1987[370]	No	Yes	Yes	No		No	No
Zwack and Derkay 1997[371]		Yes	Yes	No	No	No	No
Total	**205**						

UTI, urinary tract infection.

Appendix 13

Data extraction tables for cost-effectiveness review

TABLE 36 Type of model used

Study	Type of model	Perspective	Model assumptions
Capdenat Saint-Martin *et al.* 1998[37]	N/A	N/A	N/A
Fischer 1996[38]	N/A	N/A	N/A
Imasogie *et al.* 2003[39]	N/A	N/A	N/A
Johnson and Mortimer 2002[40]	N/A	N/A	N/A
Kitz *et al.* 1988[41]	N/A	N/A	N/A
Larocque and Maykut 1994[42]	N/A	N/A	N/A
Lawrence *et al.* 1989[36]	Decision tree	The perspective of the analysis was that of third-party payers	The economic analysis was modified from the definition of a comprehensive evaluation that (1) clinical value or usefulness of the UA is not previously established; (2) clinical outcomes owing to an abnormal UA, other than the possibility of increased risk of wound infection, were not included (e.g. costs and consequences of further evaluation such as intravenous pyelography, cystoscopy, prostatic resection); and (3) the study estimated minimum direct benefits only and did not consider indirect costs or benefits
MacPherson *et al.* 2005[43]	N/A	N/A	N/A

N/A, not applicable

TABLE 37 Cost and resource-use data sources

Study	Cost items	Cost data sources	Resource use	Resource data source	Currency and currency year	Discount rate
Capdenat Saint-Martin *et al.* 1998[37]	Blood typing Hb + platelet count Prothrombin time and partial thromboplastin time Bleeding time Fibrinogen Electrolyte + glucose + urea Hepatic enzymes + chest radiograph + ECG	Not stated	Not stated	Not stated	1993–4 Franks, ECU and US $	Not stated
Fischer 1996[38]	Pre-operative tests assessed in the study: CBC, platelets, US, general survey panel (renal panel, lung function test, glucose, calcium, albumin, magnesium and uric acid), electrolytes, renal panel and prothrombin time/partial thromboplastin time	Not stated	Not stated	Not stated	1994 US $	Not stated
Imasogie *et al.* 2003[39]	Costs of the individual	Ascertained from the hospital finance department	Based on the tests ordered and the cost of each test, total costs of laboratory tests of individual patients were calculated	Ascertained from the hospital finance department	CAN $	Not given
Johnson and Mortimer 2002[40]	Costings for tests Charges being based on a non-emergency basis during the hours of 9.00 a.m. to 4.00 p.m. for NHS patients. These were £3.67 for FBC, £1.62 for U&Es and £1.07 for glucose	Obtained from the hospital pathology department	Not given	Not given	UK £	Not given

Study	Cost items	Cost data sources	Resource use	Resource data source	Currency and currency year	Discount rate
Kitz *et al.* 1988[41]	Pre-operative tests	Within study institution	Nursing labour costs	Within study	Date not stated – assume US $	Not stated
Larocque and Maykut 1994[42]	Cost per test: EUC CAN$4.02; glucose CAN$1.24; liver profile CAN$4.24; chest radiography CAN$30.43	Biochemistry department	N/A	N/A	N/A	N/A
Lawrence *et al.* 1989[36]	(a) Charges for laboratory tests, antibiotics, and professional fees (b) The DRG estimates reimbursement fees for procedures	(a) Teaching hospital of the University of Texas Health Science Centre at San Antonio for 1986 (b) Based on a national urban average of $2967.43, which was not corrected for teaching hospital, area wage index, or disproportionate share of indigent patients. The relative weight of a diagnostic category is applied to this average to obtain the DRG fee	Cost of the hospital day incurred when a planned procedure is postponed due to presence of remote UTI	Estimated with the per diem cost of an average US community hospital bed in 1983 adjusted to 1986 ($461/day) using the consumer price index	All costs are in 1986 US $	Not stated
MacPherson *et al.* 2005[43]	FBC EUC Lung function test Thyroid function test CPM Coags Glucose G&H Unit costs for each test not given	Not stated	None stated	None stated	Australian $	None stated

DRG, Diagnosis Related Group; N/A, not applicable; UTI, urinary tract infection.

TABLE 38 Efficacy data and health outcomes/utility

Study	Efficacy data	Efficacy data sources	Health outcomes/utility	Health outcome data sources	Discount rate
Capdenat Saint-Martin *et al.* 1998[37]	Not stated	Not stated	Perioperative morbidity; patient death	Within study	Not stated
Fischer 1996[38]	Not stated	Not stated	Operating room cancellations and delays or adverse patient events	Within study	Not stated
Imasogie *et al.* 2003[39]	Not stated	Not stated	Perioperative; hypertension, hypotension; bradycardia arrhythmias; myocardial ischaemia; myocardial infarction; congestive heart failure; syncope; hypoglycaemia; oxygen saturation of <90%; and airway obstruction	Not stated	Not stated
Johnson and Mortimer 2002[40]	The numerical value of each result was classed as abnormal when its value fell outside the normal range	Determined by the stated reference range on the hospital blood form (mean ± 2 standard deviations)	Action taken pre-, intra- or post-operatively in consequence of the abnormal result. Complications occurring perioperatively were recorded in detail stating whether or not the pre-operative blood tests were normal	Patient's notes	Not stated
Kitz *et al.* 1988[41]	Not stated	Not stated	Not stated	Not stated	Not stated
Larocque and Maykut 1994[42]	Not stated	Not stated	Mortality or morbidity	Within the study	Not stated
Lawrence *et al.* 1989[36]	(a) Decision tree in figure 1 diagrams the relevant clinical outcomes, with respective probabilities, for elective clean wound knee procedures vis-a-vis the complication of wound infection (b) The base figure of 458,000 procedures annually and the baseline probability estimates for wound infection and its outcomes (shown in figure 1) yield the study results (table 1) (c) Authors estimated that 10% of patients undergoing these procedures would be aged ≥60 years. The 1% increase in risk from UTI, if not prevented, would result in 4.58 additional wound infections in the initial cohort of 458,000 procedures	(a) These probabilities were estimated by the authors (who include an orthopaedic surgeon) after a literature review and after interviews with two other orthopaedic surgeons (b) REF: National Centre for Health Statistics, R. Pokras: Detailed diagnoses and procedures for patients discharged from short-stay hospitals, United States, 1985. Vital and Health Statistica. Series 13, No. 90. DHHS Pub. No. (PHIS) 87–1751. Public Health Service. Washington: U.S. Government Printing Office; April 1987 (c) REF b and Lawrence VA, Kroenke K. 1988	The health outcomes considered were final, one-time only, surgical outcomes. Benefits were prevention of wound infection and its sequelae	Literature and authors knowledge in the area	Not stated
MacPherson *et al.* 2005[43]	None stated	None stated	None stated	None stated	None stated

UTI, urinary tract infection.

TABLE 39 Cost-effectiveness ratios

Study	Total costs	Total incremental costs	Total outcome	Total incremental outcomes	Cost-effectiveness ratios
Capdenat Saint-Martin *et al.* 1998[37]	Annual saving Fr 3.04M	None stated	Perioperative morbidity: $n=11$; patient death: $n=0$	None stated	None stated
Fischer 1996[38]	Total cost per patient – pre intervention US$188.90, post intervention US$76.82	None stated	Operating room cancellations: $n=148$ unexpected cancellations	55% decrease in tests ordered	None stated
Imasogie *et al.* 2003[39]	A potential cost saving of CAN$21,217.70 was possible for the management of 595 patients [(39.67 – 4.01) × 595]; 595 being a hypothetical number of patients in a 4-month period	The cost per patient was CAN$4.01 ± 18.92 in the non-testing group compared with CAN$39.67 ± 19.04, in the testing group A 90% reduction in laboratory costs The cost of tests per patient was reduced from CAN$39.67 to CAN$4.01	Reduction in the proportion of patients referred to the anaesthesia consult clinic to 33% compared with 47% before the guidelines were introduced, but this was not statistically significant	Reduction in the number of tests ordered after the new policy was introduced, from 5.8 tests per patient to 0.4 tests per patient	None stated
Johnson and Mortimer 2002[40]	It is estimated that >£114,000 per year is spent on requests for FBC, U&E/creatinine and random glucose	None stated	64 of 706 (9.1%) results were abnormal. Perioperative management was altered in only two patients (0.3%)	None stated	None stated
Kitz *et al.* 1988[41]	Total hospital costs for the tests – US$1261 (day surgery unit) and US$5893 (inpatients)	None stated	None stated	None stated	None stated
Larocque and Maykut 1994[42]	CAN$93,137.20 total annual saving	Saving CAN$5.20 per patient investigation	Morbidity: 12.6% (pre protocol) and 9.2% (post protocol) Mortality: 0.4% pre protocol and 0% post protocol	None stated	None stated
Lawrence *et al.* 1989[36]	Estimated US$7M on pre-operative UA and associated costs Screening costs: for the cohort of 458,000 procedures, the added cost to the health-care system for routine pre-operative UA is US$6,870,000 or US$28,258,600 if one includes the cost of a hospital day to admit the patient, discover a possible UTI and then postpone the planned procedure	Without routine screening, the cost of treating the additional cases of wound infection is US$13,226 for the baseline risk of 0.01 for wound infection after these procedures Dividing the added costs owing to introduction of a screening programme by the cost of treating the additional infections if UA were not done indicates that the cost of preventing an additional 4.58 infections is 500 times greater than the cost of treating these infections. The net 'benefit' is an approximate deficit of $6,857,000 annually (table 4)	If UTI causes a 1% risk increase wound infection, and if physicians respond appropriately to all abnormal UAs (i.e. treat UTIs pre operatively), then an additional 4.58 wound infections would be prevented	Literature	US$1,500,000 per wound infection prevented. Cost of treating additional cases of wound infection, given no pre-operative urinalysis, is approximately 500-fold less than the cost of screening with routine UA
MacPherson *et al.* 2005[43]	Group 1: AUS$29,549; Group 2: AUS$22,941; Group 3: AUS$25,219	N/A	Test per patient: Group 1: AUS$1742; Group 2: AUS$1356; Group 3: AUS$1483	None stated	None stated

N/A, not applicable; UTI, urinary tract infection.

TABLE 40 Sensitivity analyses

Study	Sensitivity analysis methods	Sensitivity analysis results
Capdenat Saint-Martin *et al.* 1998[37]	N/A	N/A
Fischer 1996[38]	N/A	N/A
Imasogie *et al.* 2003[39]	N/A	N/A
Johnson and Mortimer 2002[40]	N/A	N/A
Kitz *et al.* 1988[41]	N/A	N/A
Larocque and Maykut 1994[42]	N/A	N/A
Lawrence *et al.* 1989[36]	(a) The authors tested the robustness of their results with sensitivity analysis using threshold calculations. In other words, they asked: At what charge for a UA would we break even, i.e. costs would equal benefits? At what charge would it be a toss-up between screening costs and expense of treating additional infections if screening were not done? (b) With a worst-case scenario approach and asking how much would UTI have to increase the risk of wound infection to make it 'worthwhile' to do screening UAs?	(a) With a risk increase of 1%, the break-even point occurs at a charge of US$0.03 per UA (b) The highest estimate of risk increase found in the literature is fivefold, from data seriously flawed by lack of accounting for confounding variables. Using fivefold for the incremental risk imposed by UTI, the threshold cost of US$11.70 at best approaches current charges for a UA
MacPherson *et al.* 2005[43]	N/A	N/A

N/A, not applicable; UTI, urinary tract infection.

TABLE 41 Data extraction for cost-effectiveness review – author conclusions

Study	Author conclusions
Capdenat Saint-Martin *et al.* 1998[37]	The authors found a sharp drop in the number of pre-operative tests ordered by anaesthetists after local adaptation of national guidelines combined with active feedback about their practice and implementation of practice and discussion about organisational changes. Clinical audit is not an appropriate design to establish a causal relation between intervention and effect and caution must be exercised in drawing such conclusions from studies of this type. Nevertheless, they conclude that the changes were profound and coincided not only with feedback of practice but also a radical appraisal of the organisational basis for pre-operative assessment
Fischer 1996[38]	A successful APEC can demonstrate significant clinical advantages, improve quality and value for customers, and provide visible leadership in responding to rapidly changing health-care demands. In 1995, the APEC evaluated 8972 outpatients and to-be-admitted patients. A US$112.09 per patient decrease in pre-operative testing during this year at Stanford has a potential cost-reduction to the hospital of US$1.01M
Imasogie *et al.* 2003[39]	In ambulatory cataract surgery, >90% savings in laboratory costs is possible after elimination of routine tests
Johnson and Mortimer 2002[40]	Over 19,000 operations are performed annually (1995–6) in Wythenshawe Hospital. Using this figure, it is estimated that >£114,000 per year is spent on routine pre-operative blood tests. Our audit did not examine other investigations such as clotting studies, ECGs and chest radiography which are more expensive. We estimate that, in our hospital, elimination of unnecessary screening tests would save approximately £50,000 per annum. Extrapolating this to all acute hospitals in the NHS (approximately 280) could result in cost savings of several million pounds
Kitz *et al.* 1988[41]	Hospital costs for these tests were four times greater for inpatients than for day surgery unit patients. Operating room time was from 20 to 45 minutes longer for INPTs than for DSU patients ($p<0.05$). Recovery room time was from 25 to 52 minutes longer for DSU patients ($p<0.05$). Per patient nursing labour costs paralleled operating and recovery room times. These kinds of analyses are important in identifying opportunities to improve resource use, in assessing institutional costs for surgical care, and in designing strategies that allow institutions and physicians to respond to cost containment pressures
Larocque and Maykut 1994[42]	The observed reduction in the frequency of pre-operative laboratory investigations was attributed to the introduction of the guidelines
Lawrence *et al.* 1989[36]	We estimated that (1) nearly US$7M is spent annually on pre-operative urinalyses and associated costs; (2) given the best estimate of the increase in risk of wound infection attributable to UTI, 4.58 wound infections may be prevented annually, at a cost of US$91,500,000 per wound infection prevented; (3) the cost of treating additional cases of wound infection, given no pre-operative UA, is approximately 500-fold less than the cost of screening with routine UA. We conclude that the routine pre-operative UA is clinically and economically unsound before clean-wound, non-prosthetic knee surgery and probably before other types of clean-wound surgery. For this relatively inexpensive test, aggregate costs are disproportionately high and appear to outweigh clinical benefits. Routine pre-operative UA is clinically and economically unsound before clean wound, non-prosthetic knee surgery and probably before other types of clean-wound surgery. For this relatively inexpensive test, aggregate costs are disproportionately high and appear to outweigh clinical benefits
MacPherson *et al.* 2005[43]	The results of the introduction of the PAC have been significant and sustained since the full implementation of the scheme. The literature is replete with reports from studies that show pathology test ordering is excessive and wasteful

UTI, urinary tract infection.

Appendix 14

Questionnaire

The University Of Sheffield.

This survey has been designed as part of a research project assessing the use of pre-operative testing in NHS hospitals across the UK. The information that you provide will be held as confidential.

1. Your Name_____
2. Job Title_____

A. Your Hospital

3. Name of the hospital in which you work

_____

4. Name of the trust in which you work

_____

5. Does your hospital have a written protocol for pre-operative testing?

Yes ☐ No ☐

If **yes**, we would be very grateful if you could send a copy of your protocol s to:

B. Your Role

7. Does your role involve ordering pre-operative tests indicated in the guideline for patients undergoing elective surgery?

Yes ☐ No ☐

8. Has the NICE guideline No 3: Pre-Operative Tests (2003) been implemented?

Yes ☐ No ☐

C. Clinical Practice

9. Do pre-operative testing protocols differ by surgical speciality at your hospital?

Yes ☐ No ☐

If **yes**, Please indicate why in the space below.

10. Based on the protocol for your trust, please circle yes or no for each of the tests that is indicated.

ASA Grade 1

Surgery Grade	Age	CXR	ECG	Haemostasis	FBC	U+E+Creat	Random Glucose	Urine
One	16-40	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
One	41-60	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
One	61-80	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
One	>80	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Two	16-40	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Two	41-60	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Two	61-80	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Two	>80	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Three	16-40	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Three	41-60	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Three	61-80	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Three	>80	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Four	16-40	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Four	41-60	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Four	61-80	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Four	>80	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N

11. Please do the same for **ASA Grade 2.**

Surgery Grade	Comorbidity	CXR	ECG	FBC	U+E+Creat	Blood Gases	Lung Function	INR / APTT	Liver Function	Random Glucose	Urine
One	Cardiovascular	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
One	Respiratory	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
One	Renal	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Two	Cardiovascular	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Two	Respiratory	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Two	Renal	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N

D. Your Hospital P.A.S system

12. Does your P.A.S system automatically record tests ordered pre-operatively?

Yes ☐ No ☐

13. Does it record the source from which the test was ordered, i.e. which clinic?

Yes ☐ No ☐

14. Does it differentiate between types of pre-operative tests?

Yes ☐ No ☐

15. How easily accessible is this information?

Easy to access ☐ Not easy to access ☐ Don't know ☐

16. Please fill out the following as fully as you can:

a. Number of surgical beds at your hospital _____

b. Number of surgical consultants at your hospital _____

c. Number of surgical patients annually _____

d. What proportion of patients are:

ASA 1 _____

ASA 2 _____

ASA 3 _____

ASA 4 _____

Thank you for your assistance with this questionnaire. If you would like any more information, please contact

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Feedback

The HTA programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (www.hta.ac.uk) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

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