



University
of Glasgow

Souter, Vivienne Louise (2000) Clinical audit to improve the management of infertile couples in Scotland. MD thesis.

<http://theses.gla.ac.uk/6939/>

Copyright and moral rights for this thesis are retained by the author

A copy can be downloaded for personal non-commercial research or study, without prior permission or charge

This thesis cannot be reproduced or quoted extensively from without first obtaining permission in writing from the Author

The content must not be changed in any way or sold commercially in any format or medium without the formal permission of the Author

When referring to this work, full bibliographic details including the author, title, awarding institution and date of the thesis must be given

Clinical Audit to Improve the Management of Infertile Couples in Scotland

MD Thesis

University of Glasgow

September 2000

Dr Vivienne Louise Souter

Royal Infirmary of Edinburgh

This thesis is based on original work performed by Dr Vivienne Souter and has not been submitted for a degree at any other university. The literature review, development of the criteria for good quality care, questionnaire development, collation of results, data analysis and composition of the thesis were all undertaken by the author. The site visits, training of audit assistants and extraction of data from general practice case notes were undertaken by the author with help from Dr Gillian Penney. Data extraction from the hospital case notes was performed by non-medical audit assistants and data entry was performed by Mrs Elaine Stirton, the project secretary. Dr Jane Hopton, Research Psychologist gave advice on the psychological aspects of the study.

Dr Vivienne L. Souter

Clinical Audit to Improve the Management of Infertile Couples in Scotland

Summary

Aims:

1. To review the literature on clinical audit: its history, methodology and role in the current National Health Service (NHS) Clinical Effectiveness initiative.
2. To describe and discuss one national clinical audit exercise, the Gynaecology Audit Project in Scotland (GAPS) audit of the investigation and initial management of infertility.

Audit methods

Agreement of audit criteria

Audit criteria (22 relating to care provided by gynaecologists and 12 relating to care by general practitioners) were developed using a combination of literature review and panel discussion. The literature review comprised a systematic search of the MEDLINE and EMBASE databases for infertility publications over the past 20 years and drew particularly on six guideline documents recently published by authoritative national bodies. The audit criteria were modified during discussion by a panel comprising specialist and generalist gynaecologists, general practitioners and a health economist. The criteria were validated by means of consensus surveys of all 168 consultant/senior registrar gynaecologists in Scotland (response, 157/168, 94%) and of a representative sample of 500 general practitioners (response, 414/500, 83%).

Measurement of clinicians' reported practice

In addition to seeking consensus views on the suggested audit criteria, the questionnaire surveys outlined above sought information on clinicians' reported practice in relation to the same topic areas.

Measurement of actual practice

Care provided by *general practitioners* was assessed by review of the general practitioner referral letters in the hospital records of women with infertility attending out patient clinics in 12 representative Scottish hospitals. 1241 referral letters were available for review during the first audit period in 1996 and 892 during 1997. In addition, the general practice records of 75 infertile women managed in 25 volunteer general practices throughout Scotland were reviewed.

Care provided by *hospital gynaecologists* was assessed by review of the full case records. 1510 records were reviewed during 1996, and 1080 during 1997.

Measurement of patient satisfaction and experience

Patients' views on their care were assessed by a postal questionnaire survey of those women whose case records were reviewed. In 1996, 806/1510 (53%) responded and in 1997, 533/1080 (49%) responded.

Feedback of audit results and recommendations

The findings of the 1996 audit period, along with recommendations for changes in practice, were fed back to participating clinicians by distribution of a

comprehensive feedback report to all consultant and senior registrar gynaecologists and an abbreviated report to all general practice principals. In addition, presentations were given at postgraduate meetings in four participating hospitals and at five national or international specialty based meetings. Principal findings have also been published in two journals (see Appendices 10 and 11).

Principal Results

Care by general practitioners

The review of referral letters revealed that less than half of couples have basic tests of confirmation of ovulation and semen analysis performed in primary care. Conversely, up to a fifth of women with regular menses undergo unnecessary and expensive endocrine investigations. Between the two audit periods, significant, but modest, improvements occurred in the proportion of couples where the male partner was examined and had semen analysis performed and where the woman's rubella status was checked.

Care by gynaecologists

Between the two audit periods, significant changes in line with nine of the agreed audit criteria were demonstrable. Two significant changes contrary to the agreed criteria also occurred.

Patient satisfaction and experience

The patient survey indicated that 87% of women were satisfied with their care. However, over a third (39%) had never been asked to bring their partner to the clinic; 86% felt they had not been given enough help with emotional aspects of infertility; only a third had been given any written information and 78% expressed a wish for more written information.

Conclusions

Clinical audit remains a cornerstone of national strategies to promote more uniform standards of high quality, evidence-based care. The GAPS Infertility Audit demonstrated the feasibility of conducting a national audit exercise encompassing patient management in both primary and secondary care settings. Modest changes in the process of care and in patients' experience were demonstrable. The modest extent of change confirms the view that audit and feedback may not be the most effective means of promoting improvements in practice. Further research is needed to determine obstacles to change and the most effective ways of overcoming them.

CONTENTS

TABLES AND FIGURES

1 INTRODUCTION

- 1.1 OBJECTIVES
- 1.2 INTRODUCTION TO INFERTILITY
- 1.3 THE HISTORY OF AUDIT
- 1.4 AUDIT METHODOLOGY

2 METHODS

- 2.1 DEVELOPING STANDARDS FOR AUDIT
- 2.2 MEASURING PRACTICE
- 2.3 DISSEMINATION OF THE RESULTS
- 2.4 RE-AUDITING

3 RESULTS

- 3.1 REVIEW OF THE LITERATURE RELATING TO THE DIAGNOSIS AND INITIAL MANAGEMENT OF INFERTILITY
- 3.2 THE CONSENSUS SURVEY AND REPORTED PRACTICE
- 3.3 THE HOSPITAL CASE NOTE REVIEW
- 3.4 INFORMATION RELATING TO PRIMARY CARE ALONE
- 3.5 THE PATIENT SATISFACTION SURVEYS
- 3.6 A SURVEY OF PSYCHOLOGICAL HEALTH IN WOMEN WITH INFERTILITY

4 DISCUSSION

- 4.1 DISCUSSION OF THE METHODOLOGY
- 4.2 DISCUSSION OF THE RESULTS
- 4.3 DISCUSSION OF THE PROJECT OVERALL
- 4.4 THE WIDER CLINICAL EFFECTIVENESS INITIATIVE AND THE ROLE OF AUDIT WITHIN THIS

5 CONCLUSIONS

APPENDICES

TABLES AND FIGURES

- Table 1** Scottish Intercollegiate Guideline Network (SIGN) Grading of evidence.
- Table 2** SIGN Grading of recommendations based on the strength of evidence.
- Table 3** Suggested criteria for good quality care in *hospital practice*.
- Table 4** Suggested criteria for good quality care in *general practice*.
- Table 5** Summary of the results of the consensus survey of gynaecologists.
- Table 6** Criteria with scientific evidence and stronger consensus among clinicians.
- Table 7** Criteria with scientific evidence but with weaker consensus among clinicians.
- Table 8** Criteria lacking scientific evidence but with stronger consensus among clinicians.
- Table 9** Criteria lacking scientific evidence and with weaker consensus among clinicians.
- Table 10** Criteria that were rejected by clinicians in the consensus survey.
- Table 11** Practices where there were significant changes in care in line with the suggested criteria for good quality care between the two rounds of audit.
- Table 12** Practices where there were no significant changes in care and those where there were significant changes away from the suggested criteria for good quality care, between the two rounds of audit.
- Table 13** Results of the postal questionnaire survey of general practitioners.
- Table 14** The percentage of cases where information from the *general practice case notes* suggested that the criterion for good quality care had been met.
- Table 15** The percentage of cases where information from the *general practice referral letter* in the hospital case notes suggested that the criterion for good quality care had been met.
- Table 16** Comparison of the general practice letters for *new referrals* between the first and second rounds of audit.

- Table 17** Responses from female partners to specific questions about the attitude of the doctor at their most recent clinic visit.
- Table 18** The overall rank given to each of five suggested aspects of care in the patient satisfaction survey of female partners.
- Table 19** The five commonest subjects of written comments made by female responders in the patient satisfaction questionnaire.
- Table 20** Written suggestions made by female partners as to how the service could be improved.
- Table 21** Selected quotes from responders illustrating some of the commonest themes among the written comments in the female partner satisfaction questionnaire.
- Table 22** Comparison of the responses to the patient satisfaction questionnaire between the first and second rounds of audit.
- Table 23** Comparison of the male and female responses to questions about the doctor's attitude in the patient satisfaction questionnaires.
- Table 24** The percentage of responders and non-responders in each diagnostic category in the survey of psychological health and the mean GHQ-12 score for each diagnostic category.
- Table 25** Mean scores for items of the SF-36 from Jenkinson et al. [84] and the results from the present study for different age groups.
- Table 26** Mean scores for the GHQ-12 and the three selected items of the SF-36 in those patients who answered "yes" or "no" to the question "At this point in time would you take up an offer to speak to an infertility counsellor?"
- Table 27** Summary of published studies using standard psychological instruments to measure psychological well being in women undergoing infertility investigation and treatment
- Figure 1** A summary of the development of audit since 1989
- Figure 2** The Audit Cycle

ACKNOWLEDGEMENTS

I would like to thank Dr Gillian Penney for her support and advice throughout the project and the Clinical Resource and Audit Group (CRAG) of the Scottish Office Department of Health for funding of the Gynaecology Audit Project in Scotland (GAPS).

1 INTRODUCTION

1.1 OBJECTIVES

Medical research, education and improving patient care have long been, at least ostensibly, venerated by the medical profession. Paradoxically therefore, there has until recently been little in the way of systematic quality assurance incorporated into medical care. In the past decade there has been a dramatic change in the assessment of what is "good medical care" and medical audit has been central to this. This thesis aims to explore audit methodology and its role in improving clinical effectiveness in relation to a national audit of the investigation and initial management of infertility in Scotland.

The objectives of the thesis are:

1. To review the literature on medical audit, its history, methodology and its role in the quest to improve the quality of medical care in general, and in the NHS Management Executive's Clinical Effectiveness Initiative, in particular.
2. To review the literature relating to the diagnosis and initial management of infertility.
3. To describe and discuss the Gynaecology Audit Project in Scotland (GAPS) audit of the investigation and initial management of infertility.

1.2 INTRODUCTION TO INFERTILITY

Infertility as a Topic for Audit

The Epidemiology of Infertility

Scientific Developments over the Past 50 years

Infertility as a Topic for Audit

Infertility is a common problem affecting an estimated 1 in 10 couples at some point during their reproductive lives.[1] Clinical practices are known to vary widely among different centres [2,3] and surveys of patient satisfaction have highlighted inadequacies in the service from the consumers' perspective.[4,5] In recent years the term "infertility" has to some extent become synonymous with expensive and ground-breaking assisted reproductive techniques, while the initial steps in the management of this condition have received less attention. Assisted reproductive techniques (ART) are closely monitored and regulated through the Human Fertilisation and Embryology Authority (HFEA) but this is not the case for infertility management that falls out with ART. These factors, as well as the considerable resource implications, identify the investigation and initial management of infertility as a topic worthy of medical audit.

The Epidemiology of Infertility

Infertility is defined as the failure to achieve a pregnancy after one year of unprotected intercourse and is estimated to affect between 8% and 15% of couples at some point during their reproductive lives.[1] It is uncertain as to whether the prevalence of infertility is increasing. The birth rate in Scotland is certainly falling. Between 1976 and 1995, there was a 13% fall in the birth rate, which is now the lowest since records began.[6] How much of this is due to a voluntary reduction in childbearing is unknown. What is certain, however, is that couples are more likely to seek medical help with infertility than they were in the past.[7]

A number of factors make it seem likely that the prevalence of infertility is increasing. Fecundity falls as the female partner's age increases over 30 years and there is no doubt that women are delaying having their first child in comparison to their mothers and grandmothers. In Scotland the mean age of women giving birth to their first child has risen from 23.1 years in 1976 to 25.7 years in 1995.[6] In the same time period, there has been a 28% reduction in the rate of first births to women under 25 years, and an increase of 150% in mothers of 30 years and over giving birth.[6] This has accompanied a change in the role of women within society in general. Factors that have been instrumental in these changes include the availability of reliable contraception, particularly the oral contraceptive pill, and legal termination of pregnancy.

There has been a concurrent increase in the prevalence of sexually transmitted diseases and, in particular, chlamydia trachomatis. Chlamydia is clearly linked with tubal damage, ectopic pregnancy and subsequently compromised fertility.[8,9] The fertility of the male partner may also be falling and there is fairly convincing, if still controversial, evidence that the quality of semen in the UK is deteriorating.[10] This has been accompanied by a significant increase in the incidence of cancer of the testis which is now the commonest malignancy in young men in this country.[11]

It would seem probable, therefore, that there has been a real increase in the prevalence of infertility and certain that there has been a shift in the attitude of

society to this problem. With our growing power to restrict our fertility, we are becoming more demanding about manipulating it. Paradoxically, the advent of reliable birth control and legal termination of pregnancy have resulted in fewer babies available to infertile couples for adoption.

These factors have struck at the heart of human life: our ability to reproduce. Infertility has become a huge medical, scientific, public and ethical topic with many of the issues being debated in a public forum. Patients are better informed than they have ever been and are demanding high standards

Scientific Developments over the Past 50 years

It is incredible to think that it was only 50 years ago that it was first observed that ovulation occurs in the middle of the menstrual cycle.[12] Since then, remarkable steps have been made in the understanding of reproductive physiology and the development of infertility investigations and therapeutic options. These include the introduction of ovulation induction agents in the 1960's, the use of bromocriptine for hyperprolactinaemia, laparoscopy, the first successful In Vitro Fertilisation (IVF) pregnancy in the 1970's and the further development and widespread use of assisted reproductive techniques and embryo storage in the 1980's.[12] More recent developments include micromanipulation techniques particularly intracytoplasmic sperm injection (ICSI) and pre-implantation genetic diagnosis following embryo biopsy.[13,14] These techniques have been accompanied by a whole new realm of ethical dilemmas which have taxed the HFEA and captured the imagination of the public at large.[15]

1.3 THE HISTORY OF MEDICAL AUDIT

Confidential Enquiry into Maternal Deaths

The Development of Audit in the United States

Growing Audit Philosophy in the UK: Catalysts for Change

The Government's Commitment to Audit

"Working for Patients" 1989

Medical Audit; Scottish Working Paper 2

Executive Letters 1993-1996

The CASPE Reports

"Promoting Clinical Effectiveness"

"Clinical Audit in the NHS"

"Clinical Guidelines"

"Thirty First Report of the Public Accounts Committee"

The Role of the Royal Colleges

The British Medical Association

The Response of the medical Profession

National Audit Initiatives

Clinical Resource and Audit Group (CRAG)

Scottish Clinical Audit Resource Centre (SCARC)

The National Centre for Clinical Audit

Eli Lilly National Audit Centre

The Kings Fund

Background to Gynaecology Audit Project in Scotland (GAPS)

The turning point for medical audit came in 1989 with the publication of the government white paper: *Working for Patients*.^[16] This outlined the need for audit and introduced, essentially for the first time, the concept of medical audit as an integral part of the National Health Service (NHS) and essential component of every doctor's job.

The paper defined medical audit as "a systematic, critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome for the patient". "Working for patients" marked a major shift in the philosophy behind the NHS in general, and established "audit" as one of the main components of the proposed reforms. Medical audit itself, however, was *not* a new idea.

Confidential Enquiry into Maternal Deaths

Probably one of the first, and best known, audits in the United Kingdom (UK) is the Confidential Enquiry into Maternal Deaths. Three-yearly reports have been produced in England and Wales since 1952. In Northern Ireland these have been published every four years since 1956. Similar reports were published in Scotland at varying intervals between 1965 and 1985 but included perinatal as well as maternal deaths. Since 1985 Scotland, England, Wales and Northern Ireland have joined together to produce triennial reports of maternal deaths only.

The Enquiry is based on a multidisciplinary, peer review approach involving anaesthetists and pathologists as well as obstetricians. The report attempts to identify the reasons for all maternal deaths in the UK and any aspects of care that were substandard. It goes on to make recommendations on the basis of its findings. It is, as indicated by its title, confidential as regards the patients, hospitals and staff involved. Although co-operation from clinicians in providing the necessary information is not mandatory, only a minority fail to provide the clinical data for what are often sensitive cases. Of the 323 maternal deaths known to the most recent Enquiry, completed forms were received for 320 cases.^[17]

Between 1973 and 1987 the maternal mortality rate in England and Wales fell from 20 to 10 per 100,000 maternities and has remained stable since. Hypertensive disorders and thrombosis and thromboembolism, have stubbornly persisted as the commonest causes of death and, even in the most recent report, care was considered to be substandard in 41% of cases.^[17] The Confidential Enquiry has probably contributed to the reduction in maternal deaths but social, economic, demographic and legislative changes, as well as advances in medical science must also have been instrumental.

The Report encompasses one outcome only, mortality and gives no information about long term morbidity or 'near misses'. What it has done, however, is to pave the way for other similar enquires such as the Confidential Enquiry into Peri Operative Deaths (CEPOD) and the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI).

The Development of Audit in the United States of America

The need for standardisation and audit of medical care has been long recognised in the USA. In 1913 the American College of Surgeons was established and hospital standardisation was one of its main aims.[18] Four years later, a Hospital Standardisation Programme was instituted with funding from the Carnegie Foundation.[18] Criteria were drawn up against which to measure hospital performance. Of the initial 692 hospitals, each with 100 beds or more that were surveyed, only 89 met the standards. The numbers were made public but the list of hospitals was destroyed to keep it from the press! In time, however, many more hospitals did achieve the five principles which were drawn up by the American College of Surgeons and known as the 'Minimum Standard'.

In 1950, the Standardisation Programme was replaced by the Joint Commission on Accreditation of Hospitals and, in 1965, legislation was introduced, in the form of the Medicare Act, to ensure that only those hospitals which met the standards set by the Joint Commission were eligible for Medicare.[18]

In the 1970's, the Joint Commission began to promote medical audit and quality assurance in a much more structured and systematic manner. In 1972, the Professional Standards Review Organisation (PSRO) was legislated for and medical audit was made a requirement of this.[19] Unfortunately, however, the introduction of mandatory legal requirements for hospital standards as opposed to voluntary accreditation, has not been without problems. Its aim was to make doctors responsible for cost-containment and quality of care but in reality, although insurance payments could be denied if care was deemed to be inappropriate, the federal government had little power to deal with quality issues. To some extent it has become a minimum paper exercise and the aim of improving the quality of care has not been realised.

A decade later the PSRO was replaced by the Peer-Review Organisation (PRO) programme which was set up to monitor the implementation of the Medicare prospective-payment system. The function of the PRO in improving the quality of care overall has never been formally evaluated and, once again, the power of the body to impose changes by imposing sanctions is limited.

In 1985 the Joint Commission Board of Commissioners set up a quality assurance initiative with greater emphasis on improving clinical care and included the use of clinical performance indicators. The main thrust of the initiative was to incorporate severity-adjusted clinical performance measures and improve the approach to evaluating organisational performance.[20] As a result of the reimbursement arrangements for medical care in the USA, large amounts of detailed information about patients are held on computer but, despite this, the cost of the initiative has been prohibitive.[21] Although it was greeted with support in general from physicians [20,22] it has failed to achieve its anticipated impact.[20]

In 1989, further legislation in the form of the Omnibus Budget Reconciliation Act resulted in the establishment of the Agency for Health Care Policy and Research. The Agency was formed primarily to develop and maintain guidelines and to establish measures of care.[23] Unfortunately this has failed to produce consistently robust guidelines and new approaches to quality assurance are afoot.[24]

The USA has led the way in quality assurance measures in health care but the success of this endeavour is unclear. There are, however, particular problems associated with the funding of its health care system which include the incentives for reimbursement of medical care, pressure to contain costs and professional

liability. While quality assurance initiatives have increased public accountability they have had negative effects on care including overuse of hospital procedures. One of the fundamental problems with the PSRO was that it concentrated on issues of structure and function rather than more sensitive measures of quality. Numerical representations obtained through monitoring are not always good measures of quality and, although they may identify potential problems, they are certainly not sufficient to comprehensively assess care. The structure of the PSRO was determined nationally but implementation was left to local initiatives and doctors themselves participated little in evaluating quality and improving areas where deficiencies were identified. Parameters of clinical performance need careful interpretation or they may result in misleading conclusions. In particular, the results need to be adjusted for patient variables. Outcome measures represent a difficult area and interpretation is impossible without severity measures. While some outcomes are easily assessed (e.g. mortality) others, such as quality of life, are more difficult to quantify. What is certain is that monitoring standards costs money. Twenty percent of the total cost of health care in the USA is expended on administration [25] and it can be of no comfort to Medicare and Medicaid that there is little evidence that these quality initiatives have resulted in cost savings. Between 1972 and 1980, the PSRO was estimated to have cost 1 billion dollars [23] and it has been mooted to cost 1.8 dollars for every 1 dollar saved.[19] The USA stands as a salutary lesson of the problems of medical audit when it is imposed from out with the profession and when its primary concern is cost saving as opposed to improvement in the quality of care.

Growing Audit Philosophy in the U.K.: Catalysts for Change

In the UK in the 1970's, there was a growing recognition of the need for medical audit. Audit began to feature in the medical literature and was highlighted by some of the professional colleges including the Royal College of Radiologists and the Royal College of General Practitioners.[26,27]

There was however, very little headway made until the late 1980's and early 1990's. This is reflected in the number of Medline citations over this time period. Between 1976 and 1979 there were no references to "medical audit" as a keyword as compared to the period between 1992 and 1996 when there were 1604 references to "medical audit" and a staggering 4952 to "quality assurance". The gradual realisation of the need for audit from within the profession was reinforced by the emergence of external pressures that are discussed below.

The Government's Commitment to Audit

"Working for Patients" 1989 {876}

The White Paper "Working for Patients"[16] marked the Government's commitment to audit and major changes in the Health Service. It introduced the concept of independent Hospital Trusts, increasing integration of the Health Service with the Private Sector, service contracts and a change in the structure of management bringing it much more along commercial lines established in industry. It outlined greater accountability for consultants and the power of managers to influence the use of resources.

Medical audit was "probably the least controversial of the NHS Reforms".[28] The strategy for change within the Health Service, however, became inextricably linked to the Government's plans for medical audit which were also made explicit in "Working for Patients".

The impetus for the White Paper came from the increasing demand for resources within the NHS in the 1980's and the recognition of wide variations in practices and costs among different health care providers. The Government had introduced general management into the NHS in 1984 and this had highlighted the need for improvements in the delivery of health care.

The Paper's stated objectives were summarised as: "to give patients, wherever they live in the UK, better health care and greater choice of the services available" and "greater satisfaction and rewards for those working in the NHS who successfully respond to local needs and preferences".

In the chapter relating to "The Work of Hospital Consultants" it outlined its aim to "see all hospital doctors taking part in... medical audit" within two years. While emphasis was placed upon medical leadership of audit and the need for peer review, the role of managers in agreeing topics for audit and being party to the findings of audit was made clear. The Paper enumerated the Government's commitment to the involvement of the medical Royal Colleges and the inclusion of audit as an essential element of medical training. Eight Working Papers relating to the implementation of "Working for Patients" were published in England. Six were published in Scotland detailing the proposed path north of the border.

Medical Audit; Scottish Working Paper 2 [29]

This paper re-iterated many of the points made in the National White Paper, in particular the philosophy of audit as an integral part of the clinician's role and an essential component of training of junior staff. It stressed the need for confidentiality surrounding the identity of doctors and patients but that general

results should be made known to managers. The methodology and form of the audit were felt to be something that should be decided at a local level. The authors of the Working Paper recognised that this was an area that needed more work but that a comprehensive set of outcome measures for health should be developed.

In practical terms it called for each Health Board to set up a Medical Audit Advisory Committee which was to be headed by a senior clinician and include representatives of the major medical specialties and management. The aim of these Committees was to promote and help initiate local audit, monitor audit activity and detail a programme of interventions to be audited in the following year. The Committees were also expected to produce an annual report of the audit activities in their area.

In 1990/91, the Department of Health allocated £26 million for medical audit: £24 million to Health Authorities and £2 million to the Royal Colleges and other National Organisations including the Kings Fund.

Since "Working for Patients" [16] and the subsequent Working Paper No.6 "Medical Audit"[30] the Government has strengthened its commitment to clinical audit and other quality initiatives including clinical guidelines and evidence based practice.[31,32] Selected landmarks in this process are discussed in the following section.

Executive Letters 1993-96

Between 1993 and 1996 a number of letters relating to audit have been produced by the Management Executive of the NHS. Some of the most relevant letters are summarised below:

April 1993 EL(93)34 [33] Clinical Audit in the HCHS: Allocation of Funds 1993/94
This announced the funding for medical and nursing audit for the next year and asked Regional Health Authorities to include audit in contracting of health services.

July 1993 EL(93)59 [34] Meeting and Improving Standards in health care - A Policy Statement on the Development of Clinical Audit
Stated the Government's commitment to multi-professional audit.

November 1993 EL(93)104 [35] Clinical Audit in HCHS: Funding for 1994/95 and Beyond
Heralded a change in the funding of audit such that it would be in general funding for Regional Health Authorities (RHA) save for a central fund to finance the audit programmes of the Royal Colleges and selected national projects. It stipulated that costs for audit should be included in contracts from 1994/95.

February 1994 EL(94)20 February 1994 [36] Clinical Audit 1994/95 and Beyond
Gave guidance on costing of audit in contracts.

October 1995 EL(95)103 [37] The New health Authorities and the clinical Audit Initiative: Outline of Planned Monitoring Arrangements
Enumerated the accountability of the new Health Authorities for the development and monitoring of clinical audit. Announced a national audit information centre.

February 1996 EL(96)16 [38] Arrangements for Clinical Audit in Primary Health Care

Outlined plans for funding and further developing clinical audit in primary care including audit across the boundaries of primary and secondary care.

The CASPE Reports

In 1993 the Department of Health commissioned CASPE (Clinical Accountability Service Planning and Evaluation) Research to perform a number of studies evaluating the development and impact of clinical audit.[39-45] Findings from two of these reports, "The Audit Activities of the Medical Royal colleges and their Faculties in England" [41] and "The development of Audit: findings of a national survey of commissioning authorities in England"[42], are discussed elsewhere in this Introduction.

"Promoting Clinical Effectiveness: A framework for action in and through the NHS 1996"[32]

This report was particularly aimed at Chief Executives of Health Authorities and NHS Trusts, although it was relevant to all healthcare professionals. Its emphasis was upon effectiveness and more specifically cost effectiveness. It set a three pronged attack: *Inform, Change and Monitor*.

The section entitled *Inform* outlined the need to inform decision makers, including doctors patients and managers, about the most effective and cost effective interventions. It discussed a number of existing sources and some new initiatives and these will be discussed more fully later in this chapter. It outlined the potential for national quality indicators as a means of comparison between health care providers.

It envisaged doctors, patients and managers once again being the instigators of *Change*. The need for cost effectiveness issues being built into contracts and policy-making was recognised, as was a need for urgent research into changing the behaviour of individuals and organisations. Clinical audit, guidelines and education were identified as the key mechanisms for this.

Local and national audit, outcome indicators and comparative data sets were discussed as a means of addressing the third area: to *Monitor* these changes.

"Clinical Audit in the NHS; Using Clinical Audit in the NHS a Position Statement 1996"[46]

In 1996 the NHS Executive published "Clinical Audit in the NHS; Using Clinical Audit in the NHS a Position Statement". This defined clinical audit as "a clinically led initiative which seeks to improve the quality and outcome of patient care through structured peer review whereby clinicians examine their practices and results against agreed standards and modify their practice where indicated".

The use of the term *clinical* audit signified a move away from solely *medical* audit towards a multidisciplinary approach within the health service. The document described the Government's goals of increasing the contribution of patients' experiences to the findings of audit, moving towards a multi-professional approach, addressing issues across the interfaces between primary, secondary and tertiary care, including audit in both under graduate and post graduate education and promoting a stronger evidence base for audit projects.

It was recognised that, as yet, not all clinicians were participating in audit and that there was a need to foster an atmosphere to encourage all to do so. Health

professionals, it said, “need to feel it (*audit*) provides a safe environment for discussing sensitive details about their professional practice without the fear of provoking management sanction or civil litigation”. The report stressed the need for educational facilities (including access to the Cochrane Library within every hospital) and protected audit time. Although the definition of clinical audit did not include any mention of audit being used to reduced costs, the NHS Executive did encourage topics where cost effectiveness could be audited.

“Clinical Guidelines: Using clinical guidelines to improve patient care within the NHS 1996”[31]

Later in 1996 the NHS Executive produced “Clinical Guidelines: Using clinical guidelines to improve patient care within the NHS” and this will be discussed in the section on guidelines.

Thirty-First Report from the Committee of Public Accounts 1996

In the same year, however, the Public Accounts Committee (PAC) cast major doubts over the benefits and costs of clinical audit in England saying “it remains difficult to determine the precise impact..... on the quality of patient care and to assess the return on the substantial investment of time and money”. The NHS Executive responded swiftly and defensively commissioning more work into the evaluation and monitoring of audit, while conceding that there will be “important lessons to be learnt in assessing the value of clinical audit”. [46]

The PAC was also critical of the time it took to set up the National Clinical Audit Centre and expressed concern about effective dissemination of audit results and avoiding duplication of projects. The Report noted that “the Executive do not at present intend to make the data about quality of care gathered through clinical audit available to patients. We consider that the local reporting of quality indicators, suitably anonymised and interpreted, would be of great value in informing local action and public choice”. The NHS Management Executive pledged to pilot a scheme evaluating indicators of the quality of care and make such information available for patients by 1998. [46]

The Role of the Medical Royal Colleges and in Particular, the Royal College of Obstetricians and Gynaecologists

The Government recognised at an early stage the need to involve the Royal Colleges in order to promote acceptance of medical audit amongst the medical profession as a whole. [16] As well as ring-fenced funds allocated on a regional basis to health care providers, the Department of Health provided money directly to the twelve medical Royal Colleges to develop audit activities. Between 1989 and 1994 this amounted to £5,907,111; £301,907 of which was allocated directly to the Royal College of Obstetricians and Gynaecologists (RCOG). [47] The Department of Health provided little in the way of direction as to how this money should be spent, advice about methodology or the topics that would be most relevant to audit.

The Royal College of Physicians had a pre-existing audit committee but for the majority of Colleges the first step was to set up such a committee. The RCOG Audit Committee was established in 1991. Unlike some of the other committees, it was multi-professional, had an attendance rate of 80-90% from its members and continued to meet approximately four times per year until it was superseded by the Clinical Effectiveness and Standards Board in 1999. [47]

In 1990 the RCOG circulated Interim Guidelines on Medical Audit with suggestions for audit topics in Obstetrics and Gynaecology.[48] A year later, in common with seven of the other Colleges, the RCOG set up a Medical Audit Unit. The Unit aimed to “support and encourage medical or clinical audit (as opposed to financial audit or audit of training)” and set out five key areas it planned to focus on: prenatal diagnosis, fetal and infant outcomes, identification of low risk in obstetrics, dysfunctional uterine haemorrhage and infertility. It has subsequently circulated members of the RCOG with seven Bulletins outlining its aims, information on audits co-ordinated by the RCOG, and guidance on how and what to audit in obstetrics and gynaecology. The Unit has set up a database of successful audits and audit protocols and offers advice to clinicians setting up their own audit projects. In addition it has co-ordinated a number of multi centre audits: MISTLETOE (Minimally Invasive Surgical Techniques, Laser, Endothermal Or Endoresection), VALUE (Vaginal Abdominal or Laparoscopic Uterine Excision), an audit of antenatal care and an audit of the impact of Clinical Guidelines in Colposcopy in improving patient care.

Nine years after the inception of the RCOG Audit Unit, however, it remains difficult to evaluate the impact of the Audit Unit nor its audit projects or guidelines. There is no doubt that the RCOG Audit Unit promoted audit in the specialty, but whether this has led to improvements in patient care is unknown. As with the other Royal Colleges, the Department of Health must wonder whether this has been a cost effective use of resources. Indeed the funding of the Unit has been re-evaluated and it has been discontinued in its original form.

In 1994 the Department of Health commissioned an independent research consultancy (CASPE Research) to undertake an evaluation of the development, progress and impact of audit in the Hospital and Community Health Services (HCHS). As part of this, the role and responsibilities of the medical Royal Colleges and their Faculties in the development of audit was assessed. The report concluded that funding of the audit activities of the Royal Colleges by the Department of Health was appropriate and that a framework for audit had been developed by all the Colleges.[41] It did, however, highlight problems. The guidance given to the Colleges as to how the money should be spent was inadequate and some of the Colleges were unclear about the objectives of it. The topics which should be addressed in large scale audits and the planning of these was unclear. There was little in the way of evaluation of the effectiveness of audit nor clinical practice guidelines. There was also inadequate emphasis on educational aspects of audit. The report recommended that the Colleges should support audit activities rather than actually carry out audits, adopt a multi-professional approach, communicate more effectively with the Department of Health and the rest of the NHS and include more emphasis on the educational aspects of audit.

The British Medical Association

The British Medical Association (BMA) has supported the Government’s move towards audit from the outset and was involved in the decision making as regards the contents of Working Paper 6 (Medical Audit) [30] which accompanied Working for Patients.[16] It set up a Working Group into Quality and published a number of editorials and a series of articles about clinical audit. These formed the basis of a British Medical Journal book “Audit in Action”. [49] In 1992, the BMJ Publishing

Group produced the first edition of the journal "Quality in Health Care" and subsequently established another journal aimed at improving the quality of care, "Evidence Based Medicine," in 1995.

The Response of the Medical Profession

The Government's commitment to audit expressed in "Working for Patients" was not echoed throughout the medical establishment and there are a number of explanations for this. The dictionary definition of "audit" is: "an official examination of accounts to see that they are in order" [50] and the Government made it clear that "the quest for value for money must be an essential element" of the work of the NHS. This association with money was reinforced by the concurrent changes in the structure of the NHS and moves to improve efficiency. "Working for patients" proclaimed that audit *must* be undertaken but it did not suggest any specific methodology, nor areas of the service which should be addressed, nor any evidence that audit would improve the National Health Service. Not surprisingly, many already over stretched doctors were suspicious, unconvinced and unenthusiastic. The fact that audit was now being imposed upon the profession was the source of even greater resentment.

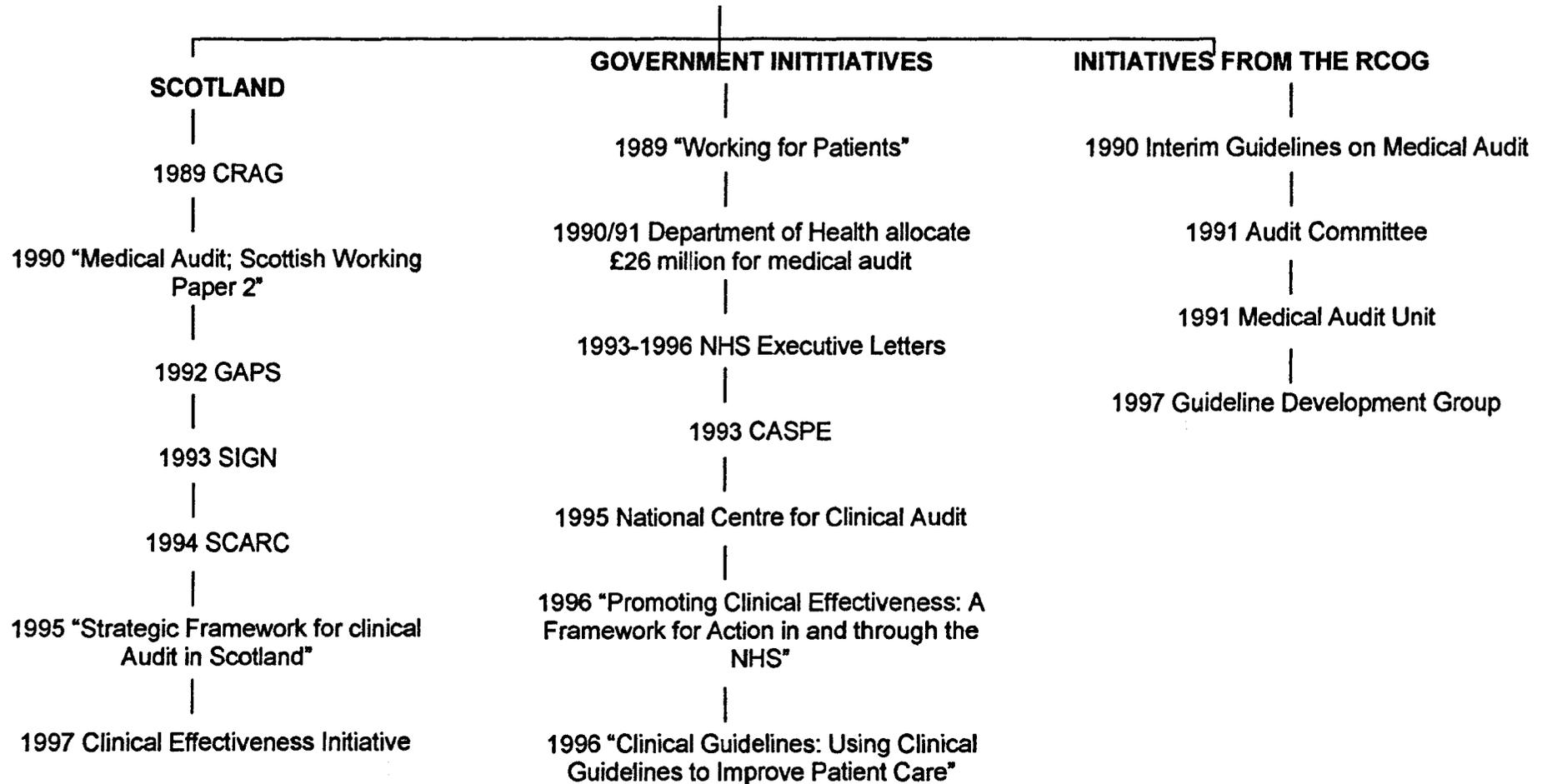
However, even before 1989, audit was seen as a threat towards the Medical Profession, challenging its professional integrity and potentially undermining its traditional power base.[51,52] As far back as 1972, Sir Richard Doll expressed concerns about the monitoring of doctors' activities, reflecting a deep rooted resistance to outside interference in the workings of the medical profession and concern about the misinterpretation and misuse of such information: "formal reviews of the outcome of practice can create seriously wrong impressions unless they are conducted with statistical wisdom, and they can hardly be expected to encourage the development of mutual trust and confidence".[53] He also voiced doubts about the ability of such monitoring to genuinely improve care: "we must insist that the object of monitoring is not only to see whether a plan is being carried out but also that the effect of the plan is good".[53]

Twenty years later, a postal survey of Staffordshire general practitioners showed a major shift in attitude towards auditing care.[54] Most responders felt compelled to undertake audit but found it time consuming and in need of more resources. Female general practitioners, those with smaller practice lists and those who had been involved with audit for the longest were the most positive in their attitude to it. However, concerns about the value of "monitoring" the activities of doctors remained, only 53% of the general practitioners surveyed believing that audit would improve the health of the population.

In contrast, Webb et al. found 65% of the general practitioners they surveyed were convinced of the ability of audit to improve patient care although in many cases the skills and resources (both in terms of time, money and staffing) were lacking.[55] The success of the Government's move towards audit depended on professional attitudes.[53] A decade down the line, most doctors do participate in medical audit and many do so enthusiastically.[43] The strength of feeling of opposition to audit was probably, in many cases, overestimated.[53]

A summary of relevant events in the development of audit since 1989 is shown in Figure 1.

Figure 1: A SUMMARY OF THE DEVELOPMENT OF AUDIT SINCE 1989



National Audit Initiatives

Clinical Resource and Audit Group (CRAG)

In Scotland the infrastructure for audit has been led by the Clinical Resource and Audit Group of the Scottish Office which was set up in 1989 in response to "Working for Patients". CRAG was formed from a pre-existing group called the "Clinical Resource Use Group" (CRUG) with the addition of a post graduate dean, a regional advisor in general practice and an extra nurse. CRUG had aimed to identify examples of effective use of clinical resources and disseminate these standards through Chief Administrative Medical Officers (CAMO's). The aim of CRAG at its inception, was to implement audit in Scotland and with this in mind four sub committees (for Medical, Nursing, Dental and Pharmaceutical Audit) were set up between 1989 and 1991. In 1990 a National Projects Committee was also established to allocate clinical audit funds and oversee *national* audit projects. It aimed to encourage audit projects in particular areas and evaluate the implementation of guidelines. The audit subcommittees have subsequently amalgamated and, since 1993, the focus has been very much on multi-professional audit.

In 1995, CRAG published the "Strategic Framework for Clinical Audit in Scotland"* which made more explicit the vision for audit which had been set out in the Scottish Working Paper 2 - "Medical Audit".[29] It re-iterated the responsibility and accountability of Health Boards for the delivery of an audit strategy. It set target for directorates and general practices to produce a yearly rolling programme of audit topics and stressed the need for multi-professional audit especially that spanning the interfaces between primary, secondary and tertiary care. The particular difficulties of establishing audit in primary care and the community were, however, recognised.

The three national priority areas specified in the Common Core Work Programme: Mental Health, Cancer and Cerebro-Vascular Disease were highlighted for audit projects.

The Report identified the need to implement change on the basis of audit results and the link between audit and guidelines. The role of audit in purchasing and the monitoring of contracts was also discussed. The Report restated the importance of patient and staff confidentiality in audit and recommended that individual audits should include a systematic assessment of patients' views. Interestingly, however, unlike the Confidential Enquiry into Maternal Deaths, there was the suggestion that the results may not be protected from public scrutiny and the reported stated that "The confidentiality of clinical staff and hospitals is important but must not take precedence over patient interests".

A Clinical Outcomes Working Group has also been set up under the auspices of CRAG and has published yearly reports. The fifth and most recent of these presented 15 outcome indicators from three broad categories: Maternal and Child Health, Cancer Survival and Emergency Admission Rates after Surgery.[56] The data were obtained from Scottish Morbidity Record (SMR) forms and standardised for age, sex, socio-economic background and prior morbidity. The indicators directly relating to obstetrics and gynaecology were: percentage of first births carried out by caesarean section; percentage of women whose second delivery was vaginal when their first delivery had been by caesarean section; percentage of live births admitted to a neonatal unit for 48 hours or less; percentage of live births admitted to a neonatal unit for more than 48 hours; dilatation and curettage (D&C) as a percentage of elective gynaecological

admissions in women under 40 years; percentage of terminations of pregnancy at under nine weeks carried out by medical methods; survival from cancer of the ovary and percentage of patients readmitted as emergencies within 28 days of discharge following an elective hysterectomy. The reasons underlying differences between different trusts or health boards can be speculated upon but the indicators are crude measures and more detailed investigation would be needed to identify specific factors.

Scottish Clinical Audit Resource Centre SCARC

In 1994 CRAG funded the Scottish Clinical Audit Resource Centre (SCARC) at Glasgow University. The Centre provides information and library services, runs educational courses relating to audit and maintains a database of Scottish Audit projects. SCARC has an important role to play in the dissemination of the results of audit in Scotland.

Scottish Intercollegiate Guidelines Network (SIGN)

SIGN was established in 1993 and produced its first report in 1995: "Clinical Guidelines. Criteria for Critical Appraisal for National Use".[57] This defined a rigorous methodology for clinical practice guidelines based on a system for categorising the strength of evidence supporting guidelines following systematic review of the medical literature. The ideal, or Level Ia evidence, would be based on the meta-analysis of randomised controlled trials and the least strong, Level IV, where the evidence is obtained from expert reports or consensus opinion (Table 1). SIGN's Report on guideline development recognised, however, that in many cases expert opinion is the only evidence available and that this is acceptable as long as the strength of this evidence is made explicit in the guideline. SIGN produced a grading for recommendations depending on the strength of the evidence on which they are based (Table 2). The aim of SIGN is to develop validated evidence based guidelines and promote their implementation at a local level.[58] Draft SIGN guidelines are presented for debate at National Workshops for health professionals before being submitted to the Editorial board for final appraisal.[58]

Level	Type of Evidence
Ia	Evidence obtained from meta-analysis of randomised controlled trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies
IV	Evidence obtained from expert committee reports or opinions and / or clinical experience of respected authorities

Table 1 SIGN Grading of evidence. From Clinical Guidelines. Criteria for Appraisal for National Use. SIGN 1995. [57]

Grade	Recommendation
A (Evidence levels Ia, Ib)	Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation
B (Evidence levels IIa, IIb, III)	Requires availability of well-conducted clinical studies but no randomised clinical trials on the topic of the recommendation
C (Evidence level IV)	Requires evidence from expert committee reports or opinions and / or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality

Table 2 SIGN Grading of recommendations based on the strength of evidence. From Clinical Guidelines. Criteria for Appraisal for National Use. SIGN 1995.[57]

Between 1990 and 1995, £26 million was allocated to Clinical Audit in Scotland. The majority (2/3) was distributed to health boards for local audit. Since 1995, the funding for audit has changed in Scotland and it is now included within the general budget for health boards. In 1996/1997 £2.7 million, was allocated to CRAG and this has been used mainly to fund national projects but also to support SIGN and SCARC.

CRAG has been the driving force behind the establishment of clinical audit in Scotland over the past decade. It has established a framework for audit but has also recognised the path ahead and has extended and developed its role accordingly, particularly with respect to clinical guidelines.

The National Centre for Clinical Audit

The National Centre for Clinical Audit was set up in 1995, is funded by the Department of Health and is based in BMA House in London. It aims to provide a centralised source of information about audit projects so that national or local groups can access details of similar or related projects. This should go some way to prevent inappropriate duplication of effort and to learn from the experience of others. The centre is based on a "partnership" of a wide range of professional organisations from the British Medical Association to the British Orthoptic Society. It is hoped that this partnership will facilitate a multi-professional approach to audit and ultimately improve clinical practice. The Royal College of Obstetricians and Gynaecologists has chosen not to be a partner in this body.

The Eli Lilly National Audit Centre

The Eli Lilly Clinical Audit Centre was established in 1992 and is based in the Department of General Practice and Primary Health Care of the University of Leicester. The centre itself is funded by Lilly Industries and Lecestershires Family Health Services Association (FHSA). Individual projects are, however, being funded by a variety of external sources.

The main remit of the centre is research and development of effective methods of audit predominantly in relation to primary care. In addition it provides evaluated audit protocols to Audit Groups, runs educational courses and produces a quarterly journal called Audit Trends. At present the main areas of research being undertaken by the centre relate to: implementing change in clinical practice; a regional evaluation of the Audit Programme; measures of patient satisfaction and opinion of services and multi-disciplinary audit.

The Kings Fund

The King Edward's Hospital Fund for London (the King's Fund) was established a hundred years ago and is now a permanent charitable endowment. It was set up to benefit the hospital service in London and traditionally bestowed grants upon individual hospitals. Its remit has, however, diversified as health care itself has evolved. It now seeks to promote "good practice and innovation in all aspects of health care" and is no longer restricted to London. It is achieving these aims through a number of initiatives including a Development Centre, a Management Centre, a Policy Institute and Organisational Audit.

In 1995, the Kings Fund Organisational Audit developed a stringent accreditation scheme for acute hospital trusts and general practices. Ninety-nine hospitals have been involved in the scheme to date and twenty-seven have been fully accredited. The scheme aims to promote continual improvement within each trust through audit.

The Kings Fund has placed particular emphasis on the rights of patients and more recently has focused on evidence based practice. The Fund continues to bestow grants for external research projects, including those aiming to implement research findings in a clinical setting. Sixteen centres are currently involved in PACE (Promoting Action on Clinical Effectiveness) where the aim is to bring clinical practice into line with research evidence.

The Medical Audit Programme was set up in 1989 with the aim of identifying audit activity, disseminating practical information about audit and promoting effective audit.

Background to Gynaecology Audit Project in Scotland (GAPS)

GAPS was based on an idea initiated by the Scottish Executive of the Royal College of Obstetricians and Gynaecologists and is funded by the Clinical Resource and Audit Group of the Scottish Office (CRAG). The first wave of funding was allocated in 1992 and three topics were audited: therapeutic termination of pregnancy, the management of endometriosis and the management of cancer of the vulva. The project received widespread support from gynaecologists in Scotland, particularly for the therapeutic termination audit which was associated with significant improvements in care.[59]

A second wave of funding was granted in 1994 and this has enabled three further topics to be addressed: laparoscopic sterilisation, endometrial sampling and the investigation and initial management of infertility.

GAPS has now been superseded by a general clinical effectiveness initiative for reproductive health, funded by the Scottish Office, which takes a broader approach to similar quality issues and oversees ongoing projects such as the Scottish Contribution to the Confidential Enquiry into Maternal Deaths and the Scottish Perinatal Mortality Audit.

1.4 AUDIT METHODOLOGY

Introduction

Basic Principles

- Choose a topic*
- Agree standards of good quality care*
- Define criteria for selecting and identifying cases*
- Calculate sample size*
- Decide what data to collect and how to collect it*
- Analyse the results*
- Disseminate results and recommendations*
- Re-audit*

Formats for Audit

- Random Case Note Review Meetings*
- Routinely Collected Data*
- Adverse Events*
- Occurrence Screening*
- Criterion Based Audit*
- Clinical Outcome Indicators*

Introduction

Audit can be defined in many ways and can take many different forms, from informal meetings among clinicians within a hospital unit to formal regional or even national audits such as the GAPS project. This section will focus mainly on the advantages and disadvantages of different methods for undertaking audit which have been described and developed in recent years.

Clinical audit aims to critically appraise care with a view to making improvements. It is now well accepted that audit in the health service should be multi-disciplinary and can address three main dimensions of care: the structure (resources and facilities e.g. equipment, staffing, beds), the process of health care (the ways these resources are applied e.g. making diagnoses, medical interventions, communication with patients and other clinicians) and the outcome for patients (e.g. mortality, morbidity and quality of life).[60]

Audits of structure and process are based on the premise that resources and good practices result in good outcomes, but this is not necessarily true. Outcome audit, in many cases, remains difficult to do because of confounding variables and the difficulty in defining outcome endpoints.[61]

Basic Principles

Audit is not simply about observing care and fundamental principles for undertaking an audit include the following:

1 *Choose a topic*

Some topics are more suitable for audit than others e.g. very common problems, very expensive interventions, controversial areas of care, aspects of care which are perceived as being "badly done" or areas associated with wide variation in care. Topics where there is good scientific evidence for certain management approaches and where there is scope to introduce changes in policy and medical practice are ideal. Shaw described the ideal subject as being "a common, well defined, clinically significant diagnosis or treatment where management has a clear effect on outcome".[60] More challenging and complex topics may be addressed but the conclusions which can be drawn may be more limited.

2 *Agree standards of good quality care.*

The standards involved should be *evidence based* wherever possible. The evidence should ideally be derived from systematic literature review and meta-analysis. Where the evidence is insufficient or inconclusive the standard adopted should be based on the consensus of "experts" in the relevant area. Highlighting deficiencies in scientific evidence may in itself stimulate further clinical research. Cost effectiveness and local availability of resources may determine the details of the standard.

3 *Define criteria for selecting and identifying cases*

The cases may be selected at random or by systematic sampling. They may be identified through an adverse outcome, through routinely collected data or include all cases in the allotted audit period. Suitable cases can be prospectively identified or case notes can be reviewed retrospectively.

4 Calculate sample size

This is particularly important if comparisons are to be made between different centres or if targets for improvements in care between two rounds of audit have been set.

5 Decide what data to collect and how to collect it

Money may be available through local audit committees to help fund this - including money for audit assistants, computers and software. Direct input of information into a computer database by those collecting data is the most labour saving method but in many cases data collection sheets have to be completed in the first instance.

Data should be kept to the key elements necessary to assess whether the criteria for good quality care are being met. Simple coding for computerisation of data can be used.

6 Analyse Results and Draw Conclusions

The data collected should answer the questions the audit set out to answer. Data retrieval should be simple and the data should be analysed as any scientific data would be. Conclusions about the impact of the audit should be made cautiously and the possible influence of confounding factors taken into consideration.

7 Disseminate results and recommendations

This may take the form of local, regional or national meetings where the work is presented, publications and the development of guidelines, protocols or algorithms.

8 Re-audit

To assess the impact of the audit and to demonstrate any improvements in care. These principles can be represented as a cycle or loop (see Figure 2).

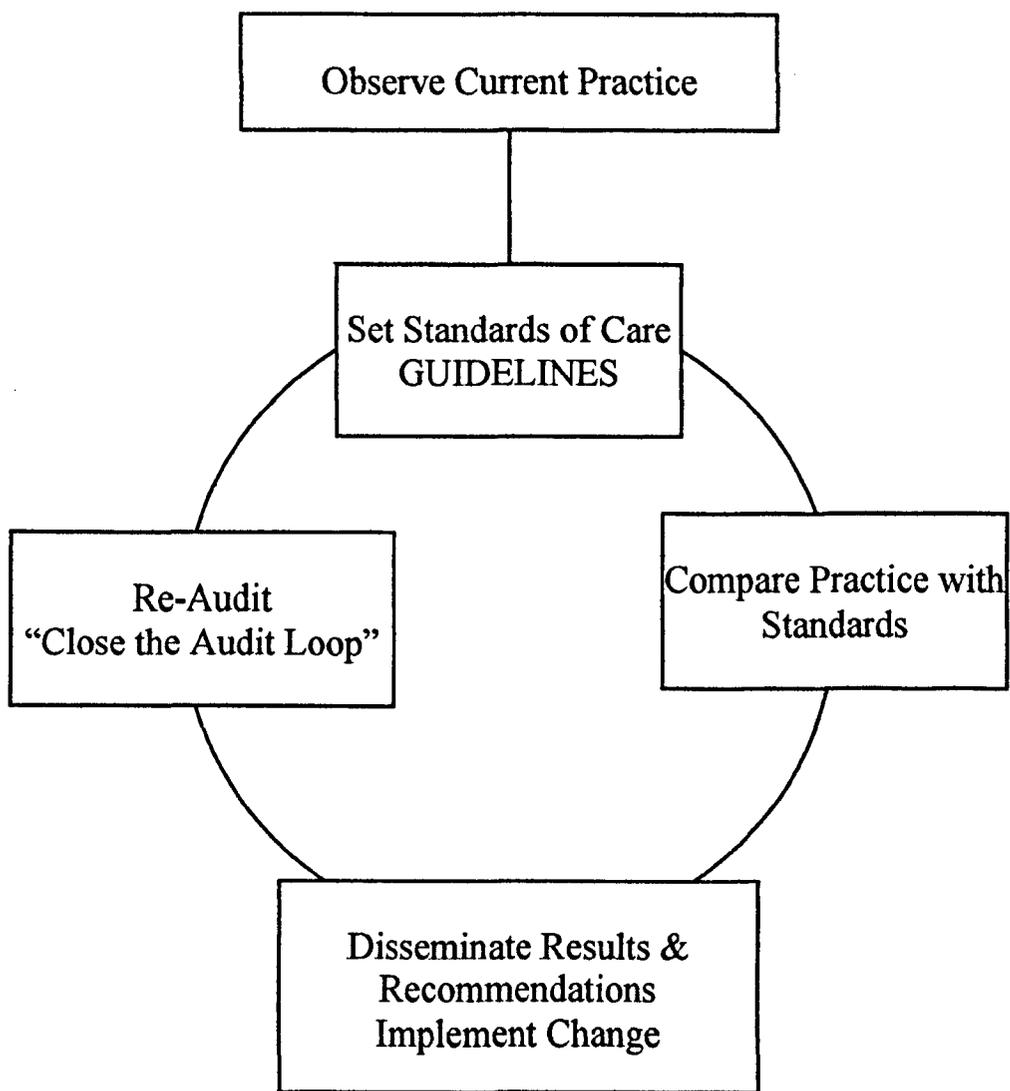


Figure 2 The Audit Cycle

Formats for Audit

A number of different methodological approaches to audit have been described. The most widely utilised of these are discussed below.

1 Case Note Review Meetings

This can be undertaken either at random [62] or in a systematic manner. It is simple and requires little in the way of resources or time. It does rely on staff of all levels attending the meeting and appraising the findings in a non-confrontational and constructive manner. It is, however, limited by the fact that only a minority of case notes are reviewed and major deficiencies in care may be missed. Immediate changes in policy can be agreed upon at the time of the discussion and improvements in the quality of recording of information in cases have been observed.[62]

2 Routinely Collected Data

This involves using data which are routinely collected but not necessarily specifically for the purposes of audit. It should, in theory, be cheap, consistent and give a minimum data set on every patient.[63] In practice, however, the data may not be appropriate for the purposes of audit, may be inaccessible or of poor quality. High levels of missing or inaccurate data are common.[64,65] Coding of interventions, diagnoses and outcomes may be misleading and even inaccurate. Attempts have been made to improve this e.g. by ranking diagnoses in-patients with co-morbidity. Inaccuracies arise if the coding becomes too complicated and a degree of subjectivity is required.[63] In addition the data collected may not be comprehensive enough to answer complex clinical questions.[66] Routine data can be used simply to identify suitable cases followed by review of the case notes. Routinely collected data can be used for Comparative Audit where computer held statistics (e.g. on mortality, hospital stay, complications) can be compared between different clinicians, different centres or the same centre over a period of time.[67] This may prove an efficient way of monitoring patterns of care and improving care but there is potential for it to be misused if there is no assessment of quality or the complex issues that surround performance.[68]

3 Adverse Events

In this type of audit serious, clearly defined events are used to identify cases. The causes and contributory factors that culminated in the bad outcome are investigated and assessed. This may be done at a local level (e.g. morbidity and mortality meetings) or on a larger scale through the confidential enquiries.[17]

These reviews are retrospective and, at a departmental level, do not always respect the confidentiality of the staff involved and are often perceived as a source of scape-goating. In this sort of environment, it may be difficult for a truly objective assessment of management to be made, in the knowledge that the outcome was bad. Where deficiencies are highlighted, changes in protocol can be agreed at the time of the meeting.

The national Enquiries into maternal deaths and perioperative deaths are confidential and are assessed thoroughly by a multidisciplinary team before conclusions are drawn. This process itself takes time and when the reports

are published, the cases may be several years old and no longer relevant. The reports are also limited by a failure to identify "near miss" cases. They do, however, appear to influence practice through the recommendations that are made but these are voluntary and not compulsory changes.

4 Occurrence Screening

Identification of specific incidents, particularly if they are associated with adverse outcomes, is a common method of auditing clinical practice (e.g. mortality and morbidity meetings and confidential inquiries). A set of criteria which can be relevant to a particular area of care, or which are applicable to all conditions, is used to screen all or a series of patients. The medical records of those cases where the criteria have not been met can then be peer reviewed. It can be used to monitor patterns of care, is systematic and would appear to be a valid source of screening.[69] Occurrence screening is however based on two main principles: the first is that specific criteria are used to determine what is deficient care; and the second, the premise that it is more efficient to make changes in areas of care where performance has been demonstrated to be bad.[70]

5 Criterion Based Audit

Criterion based audit allows large numbers of records to be screened for key elements of care which are compared to explicit standards.[71] This is in essence the method which was used in the GAPS Infertility Audit. The exact methodology is explained in Section 2.

Shaw reviewed this method of audit and recommended that between 12 and 15 key elements of care should be addressed.[71] He suggested that only a small amount of time would be needed for clinicians to draw up the standards for care and that "only those records that fail substantially to meet them (*the criteria*) are selected for further review".[71]

One of the advantages of criterion based audit is that data can be collected from case notes by trained non-medical audit assistants, thereby saving time for medical staff.[72] It also allows identification of substandard care in cases where the outcome has not been adverse - but it does rely on good quality medical record keeping. The structured format allows the audit to be readily repeated after a period of time.

6 Clinical Outcome Indicators

These have been discussed earlier in the introduction. Suffice to say that the end point is not always easy to define and that the characteristics of the patient population need to be included in the equation when comparing different centres. It may be that better communication with general practitioners and computerisation of shared records between hospital and general practice may facilitate more accurate information about long term outcome.[73]

2 METHODS

2.1 DEVELOPING STANDARDS FOR THE AUDIT

Guideline Documents

Literature Review

Panel Discussion

Consensus Survey

2.2 MEASURING PRACTICE

Questionnaire Survey of Reported Practice

Case Note Review of Actual Practice (Hospital Out Patient Clinics)

Case Note Review of Actual Practice (Primary Care)

Patient Satisfaction Survey

Survey of Psychological Health

2.3 DISSEMINATION OF THE RESULTS

Feedback Reports

Publications in the Medical literature

Local and National Presentations

2.4 RE-AUDITING

2.1 DEVELOPING STANDARDS FOR THE AUDIT

The project was essentially a criterion based audit [71] based on the format established and used successfully in previous GAPS audits.[59] The first step in the audit cycle (see page 31) was to set standards or establish criteria for good quality care. This was achieved through a combination of four approaches that are outlined below.

1 Guideline Documents

The standard setting exercise was initially based upon the recommendations of six guideline documents published in recent years including those produced by the Royal College of Obstetricians and Gynaecologists, the World Health Organisation and the Scottish Office. [74-79] These guideline documents identified topics for consideration in developing standards for good quality care. There were, however, numerous conflicts between the documents as to what was recommended even with regards to simple tests and investigations. They, therefore, provided only a foundation on which to build and were combined with other approaches to develop robust criteria for good quality care.

2 Literature Review

A review of the relevant literature over the past 20 years was undertaken using the electronic databases Medline and BIDS-EMBASE. The data from these were used to supplement, and in some cases supplant, the recommendations of the guideline documents. Particular attention was paid to relevant systematic reviews and meta-analyses.

3 Panel Discussion

The next contribution was made by the GAPS Infertility Panel (Appendix 1). This was an invited panel composed of four infertility specialists, one general gynaecologist, two general practitioners and a health economist. A clinical andrologist was introduced into the panel after the initial meeting.

A list of suggested criteria was drawn up by the author (Vivienne Souter) following review of the literature and infertility guidelines (as above). The proposed criteria were discussed by the panel and finally twenty-two suggested criteria for good quality care were drawn up for hospital practice and eleven for general practice were established. The criteria are shown in Tables 3 and 4.

There should be agreed local guidelines for the investigation, management and referral of infertile patients.
Diagnostic laparoscopy and dye transit, rather than HSG, should be the primary investigation of the female genital tract.
The female partner's rubella status should be checked.
A mid luteal plasma progesterone level should be checked in a regularly menstruating female as the basic test of ovulation.
The female partner should be advised to take folic acid supplements while attempting to become pregnant (0.4-0.5mg daily).
A pelvic examination of the female partner should be performed.
Temperature charts are of limited use and couples should be discouraged from keeping them.
Tubal surgery should not be undertaken for severe damage to the fallopian tubes as the success rates from IVF are higher.
The initial investigation of the male partner should include two semen analyses at least one month apart.
The post coital test should not be used in the routine investigation of the infertile couple.
Drug treatments are ineffective in the treatment of idiopathic male infertility and should not be used.
Drug treatments for endometriosis in women with this condition and infertility do not improve conception rates and should not be prescribed for this purpose.
The investigation of infertility should involve both partners from the outset
A plan of investigation with a specific end-point should be set down in the notes and made clear to the couple concerned.
Gonadotrophins should not be prescribed in units which do not have access to monitoring with ultrasound and oestradiol assays, 7 days a week.
Women with oligomenorrhoea or amenorrhoea should be referred to a gynaecologist regardless of the duration of their infertility.
Counselling by trained counsellors should be available to all couples.
Investigation of the female genital tract should not be performed in patients with oligomenorrhoea until they have had 6 months of ovulatory cycles in response to clomiphene, except in cases where the history or examination is suggestive of tubal damage.
A general examination of both partners should be performed.
A genital examination of the male partner should be performed.
Couples with unexplained infertility, mild endometriosis and male factor infertility should only be offered IVF when their infertility is of 4 years or more in duration.
Investigation of the female genital tract should be delayed in couples with hitherto unexplained infertility until the infertility is of at least 2 years duration.

Table 3 Suggested criteria for good quality care in *hospital practice*.

The investigation of infertility should include both partners from the outset.
There should be agreed local guidelines for the investigation, management and referral of infertile patients.
The presence of amenorrhoea, oligomenorrhoeae, oligospermia, a history suggestive of pelvic pathology or abnormal findings on examination of either partner should result in early referral to a specialist clinic.
A day 21 plasma progesterone level should be the basic investigation of ovulation in a regularly menstruating female.
A full medical, social and sexual history of both partners should be obtained.
The female partner should be advised to take folic acid supplements while attempting to achieve pregnancy.
The female partner's rubella status should be checked.
Treatment of anovulation with clomiphene should always be initiated by a specialist hospital clinic rather than in general practice.
The initial investigation of the male partner should include two semen samples at least one month apart.
Temperature charts are of limited use and couples should be discouraged from completing them.
A pelvic examination of the female partner, a genital examination of the male partner and a general examination of both partners should be performed by the referring general practitioner.
There are no other biochemical or hormonal investigations of the female partner that are relevant in general practice.

Table 4 Suggested criteria for good quality care in *general practice*.

4 Consensus Survey

In order to achieve a consensus on these suggested criteria from Scottish clinicians, a postal questionnaire survey was undertaken. The questionnaire asked responders both about their level of agreement with the suggested criteria for good quality care and their own practices in relation to the criteria. The criteria fell into three broad categories: *clinical arrangements*, *initial investigation*, and *management*. Responders were asked to indicate their level of agreement with each criterion as *strongly agree*, *agree*, *disagree* or *strongly disagree*. The questionnaires for gynaecologists and for GPs are shown in Appendices 2 and 3 respectively. In the previous GAPS audits the over all balance of agreement with the suggested criteria was quantified by an "agreement score".[80] The agreement score was calculated by allocating each response of *strongly agree* a score of +2; of *agree* +1; of *neutral* 0; of *do not feel qualified to answer* 0; of *disagree* -1 and of *strongly disagree* -2. The scores for each criterion were summed and expressed as a percentage of the maximum possible score had all responders 'strongly agreed'. This was intended to produce an indication of the over all strength of the agreement of responders so that the criteria could be ranked. In this audit the order of the criteria did not change whether the rank was based on the "agreement score" or on the percentage of responders who agreed or strongly agreed with the criterion. As a result, in this audit a cut-off point of agreement of 66% (approximately 2/3) was adopted, above which the consensus in favour of a criterion was described as "stronger". This was an arbitrary cut-off, endorsed by members of the project's multi-professional steering committee. The use of the word stronger was used to indicate that the percentage of responders agreeing with the criterion was a clear majority. Criteria that were supported by between 50 and 65% of clinicians were categorised as "weaker consensus" and those with support from less than 50% of clinicians were rejected.

All 168 consultants and senior registrars in obstetrics and gynaecology and a stratified sample of 500 of the 3471 principals in general practice in Scotland were included in the survey. The mailing list for gynaecologists was based on names and addresses obtained from the Royal College of Obstetricians and Gynaecologists and updated by a telephone enquiry of the 26 gynaecology units in Scotland.

The sample of general practitioners was provided by the Information and Statistics Division of the Common Services Agency and was stratified for the doctor's age and sex, and the location of the practice (either urban or rural). This aimed to produce a sample which was representative of the demographic distribution of Scottish general practitioners as a whole and to avoid bias as a result of factors such as ready access to the secondary care in urban as opposed to rural practices. Two representative General Practice groups, the Scottish Council of the Royal College of General Practitioners and the Scottish General Medical Services Committee of the British Medical Association, were contacted about the Infertility Audit. Both gave their support to the project. The covering letter that was sent out with the questionnaire for general practitioners carried the signatures of the chairmen of these bodies as well as those of the GAPS Investigators.

A second copy of the questionnaire with a reminder letter was sent to those gynaecologists who had not responded within three weeks. General practitioners were sent two reminders: first three weeks and then six weeks after the initial mailing.

2.2 MEASURING PRACTICE

There were three main components to this: a questionnaire survey of reported practice, a case note review and a survey of patient satisfaction.

Questionnaire Survey of Reported Practice

Gynaecologists and general practitioners were surveyed as to their current practices in relation to the suggested criteria for good quality care for infertility (i.e. *clinical arrangements, initial investigation and management*). The survey was carried out in conjunction with the postal questionnaire inquiring about clinicians' support for the suggested criteria. The questionnaires are shown in Appendices 2 and 3.

Case Note Review of Actual Practice (Hospital Out Patient Clinics)

Twelve hospitals participated in the case note review (Appendix 4). The hospitals were located throughout Scotland and included both teaching and district general hospitals as well as the four tertiary referral centres for infertility. A consultant in each hospital (Appendix 4) agreed to act as co-ordinator and, with their co-operation, audit assistants with a medical secretarial background were recruited and paid on an item-for-service basis from the project grant.

The aim was to collect data from 1600 case notes based on the resources available within the funding of the project so as to provide as representative a sample as possible.

The audit assistants each identified between 60 and 200 consecutive infertility patients attending out patient clinics in each hospital. Patients attending both for the first time and for return visits were included.

A case note review document was designed to record information (Appendix 5), relating to the agreed criteria, from the case notes and the referral letter from the general practitioner. Each audit assistant received a training session from one of the two research fellows (Vivienne Souter / Gillian Penney) on retrieving data from the case notes and recording it in the case note review document. Thus data were collected in a standardised manner in all 12 participating hospitals.

A total of 1510 case notes were reviewed and forms returned to the GAPS Office in Aberdeen where the information was entered into a computer database (Borland Paradox).

Case Note Review of Actual Practice (Primary Care)

As this was the first GAPS Project to involve GP's, this component of the audit took the form of a pilot exercise. The aim was to collect information concerning patients who had consulted their GP about difficulty conceiving but who had not been referred to a hospital specialist.

Regional GP subcommittees were contacted in Edinburgh, Aberdeen and Dundee to try to recruit volunteer practices. Glasgow was excluded because of an impending study assessing the impact of infertility guidelines and there was concern that this might bias the project.

The subcommittees in the other three cities provided the names of local practices that were then contacted by phone. Interested practices, were sent a description of the project, written instructions and a consent form.

Twenty-five practices agreed to participate. Each was visited by one of the research fellows (VS/GP) and the instructions for identifying suitable cases explained in person. These practices were not a random or representative sample and tended to be motivated practices with previous audit experience.

Seventy-five suitable patients were prospectively identified during the six month audit period. Information was collected from the case notes on standard data collection forms by the research fellows (VS/GP). The standardised data collection form is shown in Appendix 6.

The data from both rounds of audit were entered into a Borland Paradox database. Analysis was performed using SPSS for Windows (Mann Whitney U test) and Epi-Info (Chi squared test). Significance was accepted at the five percent level.

Patient Satisfaction Survey

Part of the impetus for the GAPS infertility audit was the reported dissatisfaction amongst patients about infertility care.[4,5] As a result, a postal survey of patient satisfaction was included as part of the audit to assess satisfaction and try to identify any aspects of care which patients were unhappy with (Appendix 7).

In addition, the audit was cross sectional in design rather than longitudinal, it was therefore not possible to assess pregnancy or live birth rates as an indicator of outcome. Patient satisfaction was assessed by means of a postal questionnaire survey with the aim of using it as an indicator of one aspect of outcome.

The survey of satisfaction amongst the female patients attending the clinic was carried out during both the first and second rounds of audit. The male partner satisfaction study was performed only in the second round.

A covering letter and a stamped addressed envelope were enclosed with the questionnaire. The covering letter explained the aims of the project, that responses were anonymous and that participation was entirely voluntary. Non-responders were not re-mailed.

The content of the questionnaire was drawn from a number of sources. Areas that had been identified as important to patients in satisfaction surveys in general were included, as well as aspects of care that had been highlighted as deficient in previous surveys specifically of infertility patients.

Additional material was obtained from structured interviews with ten couples currently undergoing infertility investigation and treatment and two members of the patient representative group "Issue". Final alterations were made following a pilot study involving twenty patients.

The questionnaire consisted of twenty questions and covered the following areas: waiting times at the clinic, the doctor's attitude, information and explanation, emotional help and counselling (Appendix 7). Questions were both episode-specific (relating to the most recent hospital visit) and about experience of the clinic in general, including overall satisfaction with the service.

Responders were also asked to rank five aspects of their care from one to five, in order of relative importance to them (one being the most important and five being the least important).

There were three areas where patients were given space to make comments or expand on their answers. Patients were also invited to make written comments about unsatisfactory or upsetting experiences at the clinic, anything that had been especially encouraging or helpful and any changes which they thought would improve the service.

The remit of GAPS was primarily to address the management of infertility by gynaecologists and so the questionnaire was addressed to the female partner specifically. The GAPS infertility Committee subsequently agreed, however, that the second round of the survey should include questions for the male partner as well as the female. The questionnaire for the male partner is shown in Appendix 8. The questionnaire was composed of nine questions, six of which were identical to questions asked to the female partner. Three further questions asked if the male partner had attended the infertility clinic and whether he felt this was appropriate or not.

The results of the questionnaire were entered into a Borland Paradox Database and analysed using Microsoft Excel (ANOVA) and Epi Info (Mantel-Haenszel Test).

Survey of Psychological Health

The aim of the health status questionnaire was to assess psychological health in the population being audited. This was initially anticipated as being used as an outcome measure. As the audit progressed however, it became clear that the issues surrounding this area were complex and that it was not likely to be useful as an outcome measure. The audit did, however, provide a valuable opportunity to study psychological wellbeing in a large population of infertile women using a standardised and objective psychological instrument.

The questionnaire was designed to measure across a broad spectrum from positive mental health through to the experience of considerable psychological distress of potential clinical significance.

The questionnaire included three scales from the Short Form 36 Health Survey (SF-36) which is a standardised, well-validated instrument for which published population norms are available.[81-84] These scales included the five-item mental health dimension of the SF-36 which is also known as the Mental Health Inventory or MHI-5 and can be used alone as a mental health screening instrument.

The scales were chosen to measure emotional well being in its widest sense and to take account of the wider impact of mental health or emotional distress on social health and daily life. They included social functioning (two items, nine levels), emotional role (three items, four levels) and mental health (five items, 26 levels).

One item on general health from the SF-36 was also included. This asked responders to rate their general health on a five point scale (very good, good, average, poor, very poor). Many population and health service surveys have used this item which has been shown to be associated with indicators of physical health. It was included to validate the assumption that the sample population in this study was of relatively young, physically healthy women.

The SF-36 scales were included to give sensitivity to good mental health and low levels of distress, however, the interpretation of scores in terms of clinical significance is not clear. Transformed scores out of a maximum of 100 were used

for the SF-36 as described by Medical Outcomes Trust.[81] Lower scores on all scales indicate poorer mental health.

In the second round of audit, the twelve item version of the General Health Questionnaire (GHQ-12 NFER-Nelson, Windsor) was included as a measure of emotional distress. The GHQ was developed as a screening instrument to detect individuals at risk of developing mental illness, particularly anxiety and depression. Higher scores are associated with a degree of psychological disturbance that is potentially clinically relevant.[85] The GHQ-12 was scored using the standard 0/0/1/1 method and a score of > 6/12 (0.5) or 8/12 (0.7) was taken as a positive score.[82]

The information was entered into a Borland Paradox Database and analysed using SPSS for Windows and Epi-Info (Kruskal-Wallis, Mantel Haenszel, Mann-Whitney, correlation and t-tests). The Spearman rank correlation coefficients were calculated for the GHQ-12 and each of the SF-36 dimensions (role emotional, role social and mental health). Internal consistency and reliability coefficients were calculated for the GHQ-12 and the mental dimension of the SF-36 (MHI-5). Significance was accepted at the five-percent level.

The analysis of this part of the study was restricted to the second round of audit where both instruments (the GHQ-12 and selected SF-36 items) were used. This allowed corroboration and validation of the results using two instruments.

Ethical Approval

Approval for the project, including the patient satisfaction survey, was sought from the Medical Ethics Committees serving all twelve hospitals. There were no objections to the survey but the Committee serving two of the hospitals stipulated that questionnaires be sent only to women who had given prior written consent. Thus, in ten hospitals, postal questionnaires were sent to all women attending out patient clinics with infertility during the audit period. In the remaining two hospitals, questionnaires were sent only to those women from whom the clinic staff had obtained prior written consent.

This was re-evaluated after the first round of audit and ethical approval was obtained so that questionnaires could be sent to all patients in each of the twelve centers.

2.3 DISSEMINATION OF THE RESULTS

Feedback Reports

The main form of disseminating the results of the project was through feedback reports after the first round of audit. One report related only to care in general practice and was initially sent to all 500 GP's who had been mailed in the questionnaire survey. Subsequently CRAG provided funding to send a copy of the report to all principals in general practice in Scotland.

The second, more comprehensive, report was sent to all consultants and senior registrars in gynaecology in Scotland. It covered the results of the audit at all levels of care and discussed the evidence base behind each of the suggested criteria for good quality care. The results of the patient satisfaction survey were also included.

After completion and analysis of the second round of audit a summary of the results was included in a Clinical Effectiveness Newsletter which was sent to all general practitioners and consultants in obstetrics and gynaecology in Scotland.

Publications in the medical literature

The results of the audit were reported in publications in the medical literature.[86-88]

Local and National Presentations

Each of the full feedback reports carried a covering letter offering to present the results at unit meetings of participating hospitals. The results were presented at four of the participating hospitals.

As well as presenting the results locally the work was also presented at a national level (Scottish Consultants Meeting, Dunkeld, December 1995; CRAG Clinical Audit Symposium, December 1995; North of Scotland Obstetric and Gynaecological Society, Dundee, June 1996; RCOG Clinical Audit Meeting, November 1996; and the RCOG Senior Staff Conference, Glasgow June 1997) and at one international meeting (BMA Annual Meeting, Istanbul, September 1996).

2.4 RE-AUDITING

The final step was to repeat the assessment of care following dissemination of the results to clinicians to measure the impact of the audit. One year after the first round of audit, the case note review and patient survey were repeated in the same 12 hospitals as before to assess any changes in care. In the second round of audit each centre identified between 30 and 200 consecutive women eligible for the audit. A total of 1080 case records were reviewed in the second round of audit.

The case note review in the twenty five volunteer general practices was not repeated because of the limitations of the results obtained from the first round of audit and the difficulties recruiting practices.

3 RESULTS

3.1 REVIEW OF THE LITERATURE RELATING TO THE DIAGNOSIS AND INITIAL MANAGEMENT OF INFERTILITY

Introduction

Clinical Arrangements

Initial Investigations

Management

Primary Care criteria not included in the criteria for hospital practice

3.2 THE CONSENSUS SURVEY AND REPORTED PRACTICE

Criteria with Scientific Evidence and Stronger Consensus Amongst Clinicians.

Criteria with Scientific Evidence but with Weaker Consensus Amongst Clinicians.

Criteria Lacking Scientific Evidence but with Stronger Consensus Amongst Clinicians.

Criteria Lacking Scientific Evidence and with Weaker Consensus Amongst Clinicians.

3.3 THE HOSPITAL CASE NOTE REVIEW

The Investigation and Initial Management of Infertility: Two Rounds of Audit

The first round of audit

Changes between the first and second rounds of audit

Variations in Care

Rubella immunity

Seeing patients as couples

Drug treatments for endometriosis

The postcoital test

3.4 RESULTS RELATING TO PRIMARY CARE ALONE

Introduction

Postal Questionnaire Survey

Case Note Review in Primary Care: A Pilot Study

Audit of General Practice Referral Letters in the Hospital Records

3.5 THE PATIENT SATISFACTION SURVEYS

The Female Partner

Patient Satisfaction in the First Round of Audit
Changes in Patient Satisfaction between the Two Rounds of Audit

The Male Partner

3.6 A SURVEY OF PSYCHOLOGICAL HEALTH IN WOMEN WITH INFERTILITY

3.1 REVIEW OF THE LITERATURE RELATING TO THE DIAGNOSIS AND INITIAL MANAGEMENT OF INFERTILITY

Introduction

The impetus for the choice of infertility as an audit topic by the GAPS Steering Committee came from the number of relevant guideline documents published in recent years. [74-79] In the main, it was from these that the suggested criteria for good quality care were drawn (Tables 3 and 4). The twenty-two suggested criteria for gynaecologists fell into three broad groups: clinical arrangements, initial investigation and management. In this chapter, each of these twenty-two criteria will be discussed along with the relevant recommendations from the guideline documents and evidence from the published literature.

There was overlap of some of these twenty-two criteria with the eleven for primary care. Those primary care criteria that are not included among the criteria for hospital practice will be discussed thereafter.

Clinical Arrangements

1. *"There should be agreed local guidelines for the investigation, management and referral of infertile patients."*

Literature Review

Effectively disseminated and implemented clinical practice guidelines have been shown to improve both the process and outcome of care.[89] In 1993 Emslie et al. published a randomised controlled trial of disease-specific clinical practice guidelines for the management of infertility in general practice.[90] They showed a significant improvement in the process of care in relation to all aspects of the guidelines after their introduction.

Guideline Documents

"Each district, or preferably region, should have its agreed protocol of basic investigation"

"the regionally agreed protocol for investigations and management should be followed at all stages" (RCOG Fertility Committee 1992) [75]

"The use of protocols should be mandatory and applicable to all levels of care. An element of flexibility should be present, however, to permit practical application" (SOHHD 1993) [77]

2. *"A plan of investigation with a specific end-point should be set down in the notes and made clear to the couple concerned."*

Literature Review

There is no evidence that this will affect outcome in terms of pregnancy rates but a clearly defined plan has been highlighted as something that patients would find helpful.[5]

Guideline Documents

".....a plan of possible investigations and treatments should be set down. The Working Group consider that it is essential that there is a defined plan of investigation with a specific end point." (SOHHD 1993)[77]

3. *"Counselling by trained counsellors should be available to all couples"*

Literature Review

There is a wealth of published, if at times conflicting, literature documenting the psychological problems experienced by infertile couples. These problems include anxiety, depression, stress, low self esteem, marital conflict and sexual problems and it appears that the female partner is most vulnerable to these.[91-100]

Although it has been reported that a higher than average percentage of infertile women have depressive symptoms, this has not been a universal finding and most couples appear to cope well.[97,99,101] Subjective reporting of the distress associated with infertility is probably higher than objective measures of psychological symptomatology. Doctors may, however, underestimate the level of the distress suffered by patients.[102]

Counselling is generally perceived as being 'a good thing' and the Human Fertilisation and Embryology Authority (HFEA) has stipulated that all people seeking licensed treatment must be given the opportunity to receive counselling.[103] Many patients too, express a need for counselling and yet the uptake of counselling where it is available is low.[104,105]

Patients have reported subjective benefits from counselling but there are few published studies demonstrating objective improvements in psychological well being following short term counselling.[104,106,107] One trial randomised

couples undergoing IVF either to a control group, given information about the treatment programme, or to an experimental group, given the same information and non directive counselling.[108] There was no demonstrable reduction in anxiety or depression levels in the counselling group.

The lack of provision of emotional support and counselling within infertility services is, however, something that has been repeatedly highlighted by patient satisfaction surveys. [5,108,109]

Guideline Documents

"Trained counsellors should be made available in sufficient numbers to allow adequate counselling of couples at all levels of care." (SOHHD 1993)[77]

Initial Investigation

4. *"The investigation of infertility should include both partners from the outset"*

Literature Review

A male factor is probably the commonest single factor implicated in infertile couples [110,111] and yet patient surveys have suggested that couples are not always seen together and in some cases the male partner is discouraged from attending clinic visits.[5,109]

Guideline Documents

"The investigation of infertility should involve both partners from the outset."
(SOHHD 1993)[77]

"all patients should be seen as couples" (RCOG Fertility Committee 1992)[75]

"Evaluation of the male should take place in each couple coming to consultation for infertility, and must be performed right at the beginning of couple investigation"
WHO 1993 [78]

5. *"A general examination of both partners should be performed"*

Literature Review

Endocrine disorders and abnormalities of gonadal development, may be accompanied by physical signs e.g. galactorrhoea, abnormal sexual and non-sexual hair growth and secondary sexual characteristics.[226]

In over 900 couples with unexplained or male factor infertility, Eimers et al. reported *no* variables on physical examination that were related to the chance to conceive.[112] There is otherwise very little information about the effectiveness or cost effectiveness of routine general examination in the infertility clinic.

Guideline Documents

Physical examination of both partners (including a genital examination of the male and a pelvic examination of the female) is recommended by the World Health Organisation.[78]

6. *"A genital examination of the male partner should be performed"*

Literature Review

Honig et al. retrospectively reviewed 1,236 men referred to a male infertility clinic.[113] A significant underlying medical problem was identified in 13 patients (1.1%). Ten of the patients had tumours, six of which were testicular in origin. A relevant abnormality was diagnosed in eight of the 13 patients (61.5%) on physical examination. Eleven of the 12 who provided a semen sample had an abnormal analysis. Two of the men were azoospermic, nine were oligospermic and one had a normal sperm count. The authors concluded that physical examination of the male partner should be part of the routine assessment of the infertile couple. An alternative conclusion, however, would be that 11 of the 13 men with a medical problem underlying their infertility had an abnormal semen analysis and that those men should certainly be examined. Dunphy et al. reviewed 544 couples and concluded that examination of the male partner is of no value in predicting *outcome*. [114]

It may be that while examination of the male may be of limited prognostic value, it is in some cases diagnostic. Testicular cancer is the commonest cancer diagnosis in males aged 15-44 years (16% of all malignant cancers in males) and the trend in this cancer is upwards.[11] There has also been renewed interest in the treatment of varicocele with the publication of a randomised controlled trial reporting an increased pregnancy rate following high spermatic vein ligation in

men with abnormal semen analyses [115], however the efficacy of this procedure remains controversial.[116]

Guideline Documents

"In the case of the male partner full genital examination should be carried out, particularly if a problem is suspected " (RCOG Fertility Committee 1992)[75]

7. *"A pelvic examination of the female partner should be performed"*

Literature Review

There is little in the published literature about abnormal findings on pelvic examination of the female partner or general examination of either partner. Eimers et al. reported that no variables on physical examination were related to the chance to conceive in over 900 couples with male factor or unexplained infertility.[112]

Guideline Documents

A general examination of both partners and a pelvic examination of the female partner is recommended by the RCOG Fertility Committee.[75]

8. *"Women with oligomenorrhoea or amenorrhoea should be referred to a gynaecologist regardless of the duration of their infertility"*

Literature Review

The management of ovulatory disorders is probably the most successful of infertility interventions but women with oligomenorrhoea or amenorrhoea require investigation before deciding on the most appropriate drug treatment. Treatment with bromocriptine in women with hyperprolactinaemia, and ovulation induction in women with hypogonadotrophic amenorrhoea, are associated with excellent cumulative conception rates which approach those of normal fertility. The results for women with oligomenorrhoea are lower but still good. [110,117] There are no randomised controlled trials comparing the management of these conditions by general practitioners, as opposed to hospital specialists.

Guideline Documents

"If anovulation is confirmed, or if there is oligomenorrhoea, then further investigation is best left to the infertility clinic." (RCOG Fertility Committee)[75]

9. *"A mid luteal plasma progesterone level should be checked in a regularly menstruating female as the basic test of ovulation"*

Literature Review

It is argued by some that if a woman has normal menstrual cycles she can be "assumed to be usually ovulating".[118] Measurement of the mid luteal plasma progesterone level is well established as presumptive evidence of ovulation.[119,120,121] A single mid luteal urinary pregnanediol level may be a more cost effective and convenient method of checking ovulation.[122,123]

Guideline Document

"Progesterone should be measured in every patient."

"In patients with longer cycles, progesterone should be measured twice a week from day 14 until the onset of a period to detect a latent rise." (WHO 1992)[78]

"Confirm ovulation by taking blood in the mid luteal phase for assay of progesterone." (RCOG Fertility Committee 1992)[75]

"If the cycle is irregular, varying from 28 to 42 days, then weekly plasma progesterone levels should be carried out starting from day 21 to confirm ovulation." (RCOG Fertility Committee 1992)[75]

10. *"The initial investigation of the male partner should include two semen analyses at least one month apart"*

Literature Review

There is little doubt that semen analysis should be part of the initial investigation of the infertile couple and the recommendation from the GAPS panel was for at least two specimens to be obtained. There is, however, a lack of information about the proportion of men attending infertility clinics who have a normal semen analysis on the first occasion followed by an abnormal result on re-testing and whether performing two analyses is really cost effective. Wide variations in semen parameters within the same individual over time are well recognised and factors such as the length of abstinence and febrile illness can affect the results.[124-129] In addition, an abnormal sperm count may alter the prognosis given to the couple, the decision to refer them for assisted reproduction or review by a specialist urologist or andrologist. These facts support the recommendation for at least two samples and this is certainly the case if the first sample is abnormal.

Guideline Documents

"Two samples should be collected for initial evaluation. If the results of these two assessments are markedly different, additional samples should be obtained because a man's sperm count can vary considerably." (WHO 1992)[76]

"At least one semen analysis is always mandatory" (WHO 1993)[78]

"If the first sample is normal, there is no need for a repeat analysis." (WHO 1993) [78]

"As the quality of semen may vary substantially between samples, two specimens should be requested before a firm opinion is drawn, particularly if one is abnormal." (RCOG Fertility Committee 1992)[75]

11. *"The postcoital test should not be used in the routine investigation of the infertile couple"*

Literature Review

The postcoital test is used widely in Europe but there is a lack of consensus on the methodology of the test and what constitutes a normal result.[2]

This confusion is mirrored in a plethora of conflicting evidence in the literature[130]: some authors regarding the postcoital test as an essential component of the infertility work up [131,132] while others show it to be of very limited value.[133-136] The picture is further muddled by the lack of consistency in published studies as regards how the test is performed and the criteria used for normality. Even using a standardised protocol, the reproducibility of this test has been shown to be poor with wide inter observer variation.[137]

The postcoital test may have a role in couples where sexual dysfunction is suspected[135] but in general it lacks validity as a routine infertility investigation and is perceived as stressful and embarrassing by patients.[102]

12 *"The female partner's rubella status should be checked"*

Literature Review

The adverse effects of maternal rubella infection on the fetus are well recognised. Although there is a national immunisation programme with high uptake rates [138], in 1996 there was an epidemic of rubella in Scotland [139] and in the first half of that year there were four reported cases of rubella in pregnancy (Personal Communication, Dr Cowden Scottish Centre for Infection and Environmental Health, Ruchill Hospital, Glasgow).

It is very rare for maternal re-infection to cause problems, however cases of congenital rubella after anticipated maternal immunity have been reported.[140] The antibodies produced by vaccination are generally lower than those of natural immunity and decline with time.[141] Long term follow up of a Swedish cohort showed that of those who successfully seroconverted at vaccination, 22% had antibody HAI (haemagglutination-inhibition) titres of less than 1 in 16 and 6% had no detectable antibodies, 16 years later.[141]

Guideline Documents

"Rubella antibodies should be checked so that vaccination can be given if necessary before pregnancy occurs" (WHO 1992)[78]

13. *"Temperature charts are of limited use and couples should be discouraged from keeping them"*

Literature Review

Temperature charting is not an accurate method of timing ovulation [142,144] and causes unnecessary stress for patients.[102] Approximately a third of ovulatory cycles will not be associated with the classic biphasic temperature pattern [142,143] and the use of temperature charts to time intercourse has not been shown to improve conception rates. As conception is most likely to occur following intercourse on the day of ovulation or the two days preceding this day [145] (before the rise in basal body temperature), temperature charting may in fact have a deleterious effect.

Guideline Documents

"Temperature charts are of limited use and couples should be discouraged from keeping them unless there is a specific purpose." (RCOG Fertility Committee 1992)[75]

14. *"Diagnostic laparoscopy and dye transit, rather than hysterosalpingography, should be the primary investigation of the female genital tract"*

Literature Review

The findings of laparoscopy and hysterosalpingogram (HSG) have been reported as being in agreement in between 55 and 85% of cases.[146-151] HSG has a significant false positive rate and this is particularly so for bilateral tubal obstruction.[148,151,233] The false negative rate for HSG is probably in the region of 15% [147,152,153] and it is clear that laparoscopy is superior at detecting other abnormalities such as pelvic adhesions and endometriosis.[149,151,153]

HSG using an oil based contrast medium may have a therapeutic effect but its high viscosity and potential complications has resulted in water based contrast being used most commonly.[149]

Guideline Documents

Diagnostic laparoscopy "rather than hysterosalpingography, should be used as the primary investigation of the female genital tract, so that lesions such as endometriosis and peritubal adhesions can be diagnosed." (RCOG Fertility Committee 1992)[75]

"laparoscopy is the 'gold standard' for the accurate assessment of tubal patency." (WHO 1993)[78]

15. *"Investigation of the female genital tract should be delayed in couples with hitherto unexplained infertility until the infertility is of at least 2 years duration"*

Literature Review

There is a great deal of literature surrounding investigation of the female genital tract but much less addressing the timing of this. Indirect evidence which supports this criterion includes the high conception rates in the first two years of infertility [154] and the value of history taking in identifying patients at increased risk of having tubal damage.[155,156] Forman et al. found that a history of the use of an intra-uterine contraceptive device (IUCD), previous laparotomy, severe dysmenorrhoea and vaginal discharge were all associated with an increased risk of pelvic adhesions.[157] The use of oral contraceptives, medroxyprogesterone acetate and barrier methods of contraception are associated with a lower risk of tubal damage.[156] Opsahl and Klein reported the incidence of bilateral distal tubal obstruction was more than ten times higher in patients with a positive history i.e. pelvic inflammatory disease; venereal disease; use of an intra-uterine contraceptive device (IUCD); a previous ruptured appendix; a septic abortion; chronic pelvic pain or previous pelvic surgery.[155] There were abnormal pelvic findings at laparoscopy in more than 70% of the patients with a *negative* history. Of those with a negative history however, only 12/198 (6%) had tubal obstruction while the rest had adhesions (23%) or endometriosis (48%).[155] These findings, unlike tubal obstruction, are more likely to be associated with a reduced chance of conception rather than an absolute barrier to it occurring and therefore would not usually merit early intervention. History is therefore helpful in the selection of women for an earlier, rather than later, test of tubal patency.

Recently there has been increasing interest in the role of chlamydia serology in deciding on the most appropriate timing and type of test of tubal patency.

Exposure to genital chlamydia trachomatis infection is associated with pelvic inflammatory disease (PID), infertility and ectopic pregnancy.[9] In most cases of tubal damage however there is no history of PID [158] IgG antibodies to chlamydia are more common in infertile patients with tubal damage (present in approximately 80% of those with tubal damage as opposed to 20% of those with normal tubes) and the level of the antibody correlates to some extent with the severity of the damage.[158,159] Dabekhausen et al. found patients with tubal factor infertility at laparoscopy were nine times more likely to have chlamydia antibodies but only 2.6 times more likely to have an abnormal hysterosalpingogram (HSG) than those without antibodies.[159] They concluded that chlamydia serology is a better screening test than HSG. Chlamydia serology may also be a useful adjunct in deciding when to perform the first test of tubal patency.

Guideline Documents

"Laparoscopy can be arranged at an early stage if a problem is suspected from the history or examination, but if preliminary investigations are normal and there are

no abnormal features on history or examination, then this can be delayed until the duration of infertility is at least two years.” (RCOG Fertility Committee 1992)[75]

16. *“Investigation of the female genital tract should not be performed in patients with oligomenorrhoea until they have had 6 months of ovulatory cycles in response to clomiphene, except in cases where the history or examination is suggestive of tubal damage.”*

Literature Review

The cumulative conception rate for anovulatory patients treated with clomiphene is high [110] and there is a small but not insignificant risk associated with laparoscopy [160,161] and to a lesser extent with hysterosalpingography.[152,162] Many patients with abnormal findings at laparoscopy will be identified from a thorough medical history [155,156] and chlamydia serology which may also have a role to play in the timing of the first test of tubal patency [158,163] (see criterion 15).

Management

17. *"The female partner should be advised to take folic acid supplements while attempting to become pregnant"*

Literature Review

The role of diet, and particularly folic acid, in the prevention of neural tube defects has featured in the medical literature for many years. The Medical Research Council (MRC) randomised controlled trial conclusively demonstrated that periconceptual folic acid supplements (4mg/day) significantly reduce the incidence of neural tube defects (relative risk 0.28, 95% confidence interval 0.12-0.71) in women who have had a previous pregnancy affected by a neural tube defect.[164] A number of studies support the use of folic acid supplementation in the prevention of first occurrences of neural tube defects.[165-167] The average daily dietary folate in young women in the UK is estimated at 0.2mg and it would be difficult for most to achieve adequate intakes with dietary measures alone. Naturally occurring folates in food are also less predictable, are affected by storage and preparation of the food and are absorbed less readily than the folic acid in supplements. Despite the Department of Health recommendations [168], a number of studies have suggested that advice about folic acid supplements is not reaching women at risk of pregnancy [168-170] nor in some cases, health care workers.[171,172]

Folic acid supplements in pregnancy have been implicated in increasing seizure frequency in epileptic women [173], but these patients are at increased risk of fetal neural tube defects and should be advised to take periconceptual supplements. Those being treated with carbamazepine or sodium valproate are at particular risk.[174,175]

Guideline Documents

"all women who are planning a pregnancy should be advised to take 0.4mg of folic acid as a medicinal or food supplement from when they begin trying to conceive until the twelfth week of pregnancy"

[To prevent recurrence of neural tube defects in men or women with a history of spina bifida themselves or a previously affected child, the daily dose should be 4mg] (Department of Health Expert Advisory Group on Folic acid and Neural Tube Defects 1992)

18. *"Drug treatments are ineffective in the treatment of idiopathic male infertility and should not be used"*

Literature Review

There have been many studies looking at currently available drug treatments (including vitamin C, clomiphene, tamoxifen and androgens) for idiopathic male infertility. As yet, improvements in pregnancy rates have not been conclusively demonstrated with any of these treatments [74,176-180] and there is as yet no clear role for the use of antibiotics in these patients even in the presence of leucospermia.[181,182]

The Cochrane Collaboration has produced systematic reviews of the evidence relating to some of these drug treatments in the management of oligospermia including:

1 *Androgens (mesterolone or testosterone) versus placebo or no treatment [183]*

The meta analysis of eight randomised controlled trials failed to demonstrate any benefit in pregnancy rates (odds ratio 1.1; 95% confidence interval 0.75-1.61).

2 *Anti-oestrogens (clomiphene or tamoxifen) versus placebo or no treatment.[184]*

Meta analysis of five truly randomised trials showed no beneficial effects of anti-oestrogens in terms of pregnancy rates (odds ratio 1.26; 95% confidence interval 0.28-3.24). The overall meta analysis, which included 10 trials, just failed to reach significance at the 5% level (odds ratio 1.54; 95% confidence interval 0.99-2.4) and the authors conceded the meta analysis was not robust.

3 Bromocriptine versus placebo or no treatment.

Overall there was no improvement in either the sperm parameters or the pregnancy rates (odds ratio 0.7; 95% confidence interval 0.15-3.24).

4 Kinin enhancing drugs (Kallikrein or an angiotensin converting enzyme inhibitor versus placebo or no treatment).[185]

There was no significant benefit in terms of sperm density but a possible improvement in motility and morphology. The overall meta analysis suggested a significant improvement in pregnancy rates with these drugs but some of the trials were of poor quality and the authors conceded that the meta analysis was not robust. Conversely the two truly randomised trials showed no benefit. There is not sufficient evidence to warrant the use of these drugs in the management of infertility associated with abnormal semen analysis.

Guideline Documents

“Many (other) drugs have been used empirically to treat idiopathic male subfertility, but controlled trials have shown these to be ineffective” (Effective Health Care 1992)[74]

19. “Drug treatments for endometriosis in women with this condition and infertility do not improve conception rates and should not be prescribed for this purpose”

Literature Review

Drug treatments for infertility-related endometriosis have not been shown to significantly improve conception rates and more research is needed to assess the value of surgical management in this condition.[186,187] Hughes et al. produced a systematic review of ovulation suppression for the Cochrane Database [188] comparing ovulation suppression with danazol, medroxy progesterone acetate, gestrinone, combined oral contraceptive pills and gonadotrophin releasing hormone (GnRH) analogues with placebo or no treatment. They also compared any of the above agents with danazol in patients with endometriosis associated infertility. Success was measured in terms of pregnancy rates. The odds ratio for pregnancy after ovulation suppression compared to placebo or no treatment was 0.83 (the 95% confidence interval was 0.5-1.39). The data were statistically homogeneous and the authors were confident in their conclusion that there was no benefit in terms of pregnancy rates with these drugs. There was a similar conclusion when comparing the pregnancy rate for other ovulation suppression agents versus danazol. The odds ratio was 1.2 (the 95% confidence interval was 0.85-1.68).

Therefore, although these drugs are useful in the management of pain associated with endometriosis, they do not improve pregnancy rates. Indeed, in most cases they render the patient sterile during the period of treatment and are associated with significant side effects such as androgenic effects (danazol), hot flushes and osteoporosis (GnRH analogues).[189]

Guideline Documents

“Medical treatments have been shown to be ineffective” (Effective Health Care 1993)[74]

20. *“Gonadotrophins should not be prescribed in units which do not have access to monitoring with ultrasound and oestradiol levels, 7 days a week”*

Literature Review

High cumulative conception rates with relatively low rates of multiple pregnancy and hyperstimulation have been reported using oestradiol and transvaginal ultrasound to monitor a variety of different ovulation induction regimes.[117,190,191] As well as the medical implications of these complications, multiple pregnancy has substantial cost implications.

Guideline Documents

“Stimulation of ovarian function with gonadotrophins should be restricted to specialist infertility centres with access to intensive monitoring with plasma oestradiol and ultrasound.” (RCOG Guidelines for the Use of Gonadotrophic Hormone Preparations for Ovulation Induction 1994) [192]

21. *“Tubal surgery should not be undertaken for severe damage to the fallopian tubes as the success rates from IVF are higher”*

Literature Review

Reconstructive tubal surgery in patients with severe tubal damage (particularly if it involves the distal fallopian tube) is associated with low intra-uterine pregnancy rates and high ectopic pregnancy rates.[193-199] In 1994 the live birth rate for women with tubal disease treated with IVF was 13.2% per cycle, comparing well with the overall live birth rate for all causes of infertility (14.2% per cycle).[200] Overall 3% of clinical pregnancies following IVF were ectopic.[200]

The reported results following tubal surgery are varied and are influenced by factors such as patient selection and follow up. Live birth rates as high as 50% and ectopic rates as low as 2% have been reported following salpingostomy.[193-199] However, the pregnancy rates in non-specialist centres may be very much lower than this.[201]

The extent of tubal damage and pelvic adhesions influences the intra-uterine and ectopic pregnancy rates [193,197] and makes comparison of success rates between different series very difficult. Other factors that may influence success are the use of microsurgical technique, magnification [194,202] and surgical training.[203] Salpingolysis is associated with higher pregnancy rates than salpingostomy and this success does seem to be treatment-dependent.[204,205] Salpingoscopy may be of value in the selection of patients for whom tubal surgery is most likely to be successful.[199, 206]

Guideline Documents

“In general tubal surgery is followed by poor results in the presence of dense and extensive adhesions, thick immobile tubes or hydrosalpinges greater than 20mm ampullary diameter”. (RCOG Fertility Committee 1992)[75]

“Magnification is not essential for procedures such as adhesiolysis but in salpingostomy and especially tubo-cornual anastomosis magnification is essential.” (RCOG Fertility Committee 1992)[75]

Microsurgery “should be concentrated in the hands of a limited number of surgeons and so a limited number of centres should offer it.” (RCOG Fertility Committee 1992)[75]

“Resources currently devoted to tubal surgery could be more efficiently used if reallocated to a more appropriate mix of tubal surgery for less severe disease and IVF-ET for the rest”. (Effective Health Care 1993)[74]

"Given that patients with blocked fallopian tubes may be treated with IVF or tubal surgery, it is recommended that assessment to decide which procedure is indicated should be performed in a centre that conducts both IVF and tubal surgery". (SOHHD 1993)[77]

"Surgery should be performed by experienced gynaecologists with ready access to microsurgical equipment". (SOHHD 1993)[77]

22. *"Couples with unexplained infertility, mild endometriosis and mild male factor infertility should only be offered IVF when their infertility is of four years or more in duration"*

Literature Review

The optimal time at which IVF is undertaken is to some extent arbitrary, but should represent predominantly a balance between the chances of IVF-independent conception and the anticipated success rates from IVF itself. This will depend on both the success rate of the clinic providing the treatment (which varies from 9 to 26% per cycle in the UK) [200] and the characteristics of the couple themselves.[207]

The success rates per treatment cycle of IVF start to fall after the age of 30 years and this fall becomes steeper after the age of 35. [207] Success rates also fall with increasing duration of infertility and the absence of a previous successful pregnancy.[207] The success of IVF is not significantly affected by the cause underlying female infertility but unexplained infertility may be associated with lower fertilisation rates.[207]

The cumulative conception rate for couples with untreated unexplained infertility has been reported as between approximately 33 and 60% in the first three to four years of trying to conceive. [208-211] In one small series this figure was even higher.[212] Thereafter the chance of conception levels off to 1-2% percent per cycle and falls by approximately 2% for every one year increase in the female partner's age over 30 years.[210, 112] The cumulative conception rates for mild male factor and endometriosis are lower.[213]

The HFEA 1995 Annual Report documented an overall live birth rate of 14.2% per cycle of IVF.[200] In comparison Collins et al. studied over 2000 untreated couples who had tried unsuccessfully to conceive for a year or more at the time of registration at an infertility clinic.[213] The cumulative live birth rates three years after registration were 33.3% (95% CI = 27.6 -39.0) for unexplained infertility, 29.2% (95% CI = 20.2-38.2) for oligospermia, 20% (95% CI = 7.0-33.0) for mild endometriosis and 25% (95% CI = 21.8-28.7) for all patients. Interestingly, a previous pregnancy with the same partner also appears to be associated with a 70-80% improvement in the prognosis.[112, 213]

There is a parallel downward trend in the live birth rate after IVF in women over the age of 30 years and this fall is steepest between 35 and 40 years.[207,214] Overall the live birth rate per treatment cycle falls from 20% at 25 years to 8% at 40 years.[207] There appears to be very little difference in success rates between women with endometriosis and those with unexplained infertility but having a previous successful pregnancy as a result of IVF is associated with an improved prognosis.[207,215]

Generalisations about the timing of IVF are, therefore, difficult to make and individual factors such as the female partner's age, the local resources available and the couple's wishes are inevitably influential. Other factors which may be taken into consideration are the relative chances of success of alternative

treatments and the complexity and costs of these alternatives in comparison to IVF.[118] Overall however, the chances of spontaneous conception with expectant management for the first 3 to 4 years of unexplained infertility, mild endometriosis and mild male factor infertility are similar or higher than the cumulative conception rates after 3 cycles of IVF *in most couples*.

Guideline Documents

"Unless there are extenuating circumstances, unexplained infertility should be of at least 4 years duration by the time (IVF) treatment begins." (SOHHD 1993)[77]

Primary Care Criteria not included in the Criteria for Hospital Practice

1. *"A full medical, social and sexual history of both partners should be obtained"*

Taking a medical history is important in determining the need for investigation, the type of investigations and the timing of referral to a gynaecologist. In a study from Norway, thirty percent of infertile women gave a history of pelvic inflammatory disease (as compared to 11% in the fertile population) and 13% had experienced amenorrhoea (3.3% in the fertile population).[216] The presence of these factors in the patient's history would therefore suggest early investigation and specialist referral. Risk factors for tubal damage in particular, may be identified through the patient's history and are associated with an increased prevalence of abnormalities on laparoscopy.[155,156].

The stability of the relationship between the couple should be assessed before embarking on treatment and the general practitioner may well be in an ideal position to do this if both partners are registered with the practice. In approximately 6% of cases coital dysfunction underlies infertility and questions should be asked specifically about sexual intercourse.[110]

Other factors that may influence fertility and treatment including cigarette smoking, alcohol consumption, the female partner's body mass index and even occupational exposure to teratogens.[217-220]

2. *"There are no biochemical or hormonal investigations of the female partner (other than a day 21 plasma progesterone level) that are relevant in general practice"*

The GAPS Steering Committee agreed that women with infertility associated with oligomenorrhoea or amenorrhoea should be referred to a gynaecologist. Further hormonal tests in women with regular menstrual cycles are rarely helpful. In these women, treatment of mild abnormalities in prolactin levels with bromocriptine does not significantly improve fertility and abnormal thyroid function is not a common finding.[221-224] Measurements of FSH, LH and oestradiol are unlikely to yield relevant information in this setting.

3. *"Treatment of anovulation with clomiphene should always be initiated by a specialist hospital clinic rather than in general practice"*

Clomiphene is generally perceived as a fairly innocuous drug however it is associated with an increased risk of multiple pregnancy and some infertility specialists recommend ultrasound monitoring of follicular development during treatment.[219] It may also be associated with an increased risk of ovarian cancers, particularly with prolonged use.[225]

3.2 THE CONSENSUS SURVEY AND REPORTED PRACTICE

The methodology for the questionnaire is discussed in Sections 2.1 and 2.2. The questionnaire is shown Appendix 2.

The response rate to the questionnaire was ninety-four percent (157/168). The results are, however, based on the responses of the 143 consultants and senior registrars in obstetrics and gynaecology who said that they see infertility patients in the course of their job. Approximately one third (33%) of those 143 said they consider themselves to have a special interest in infertility.

The first purpose of the questionnaire was to assess gynaecologists' consensus view on the 22 audit criteria presented above. On the basis of the review of research evidence and of the survey findings, the suggested criteria for good quality care have been categorised into five groups:

- Criteria with scientific evidence and stronger consensus amongst clinicians.
- Criteria with scientific evidence but with weaker consensus amongst clinicians.
- Criteria lacking scientific evidence but with stronger consensus amongst clinicians.
- Criteria lacking scientific evidence and with weaker consensus amongst clinicians.
- Criteria that were rejected on the basis of failing to reach a consensus (i.e. less than 50% agreement) amongst clinicians.

As discussed in Sections 2.1, an arbitrary cut-off point of 66% (approximately 2/3) agreement was adopted, above which the consensus in favour of a criterion is described as "stronger". Criteria which were supported by between 50 and 65% of clinicians were categorised as "weaker consensus" and those with support from less than 50% of clinicians were rejected. Thirteen of the 22 criteria in the questionnaire were supported by 66% or more of responders and were classified as having stronger support, three had weaker support (50-65% agreement with the criterion) and four were rejected (fewer than 50% of responders agreeing with the criterion).

The results of the survey will be presented in five sections based on the above groups. Each section will be preceded by a table summarising the level of agreement with each criterion and the ranking of the level of agreement in relation to the criteria overall.

The criteria that received most support were that "there should be agreed local guidelines for the investigation management and referral of infertile patients" and "the investigation of infertility should involve both partners from the outset". The agreement with each criterion, their rank based on the level of agreement and the SIGN grading (see Table 2) are summarised in Table 5.

Those that were least well supported were that "couples with unexplained infertility, mild endometriosis and male factor infertility should only be offered in vitro fertilisation (IVF) when their infertility is of 4 years or more in duration" and that "the investigation of the female genital tract should be delayed in couples with hitherto unexplained infertility until the infertility is of at least 2 years duration".

The principles of performing a general examination of both partners (39% agreement) and a genital examination of the male partner (40% agreement) were also rejected. Performing a pelvic examination of the female partner was strongly supported (79% agreement).

Rank	Suggested Criteria For Good Quality Care Hospital Care	Grade	Agree %
1=	The investigation of infertility should involve both partners from the outset	C	93
1=	There should be agreed local guidelines for the investigation, management and referral of infertile patients.	A	93
1=	Diagnostic laparoscopy and dye transit, rather than HSG, should be the primary investigation of the female genital tract.	B	93
2	A mid luteal plasma progesterone level should be checked in a regularly menstruating female as the basic test of ovulation.	B	92
3	A plan of investigation with a specific end-point should be set down in the notes and made clear to the couple concerned.	C	90
4	Women with oligomenorrhoea or amenorrhoea should be referred to a gynaecologist regardless of the duration of their infertility.	C	89
5	Gonadotrophins should not be prescribed in units which do not have access to monitoring with ultrasound and oestradiol assays, 7 days a week	C	87
6	The female partner's rubella status should be checked.	B	84
7	The female partner should be advised to take folic acid supplements while attempting to become pregnant (0.4-0.5mg daily).	A	82
8	A pelvic examination of the female partner should be performed.	C	79
9	Tubal surgery should not be undertaken for severe damage to the fallopian tubes as the success rates from IVF are higher.	B	78
10	Temperature charts are of limited use and couples should be discouraged from keeping them.	B	77
11	The initial investigation of the male partner should include two semen analyses at least one month apart.	B	67
12	The post coital test should not be used in the routine investigation of the infertile couple.	B	65
13	Investigation of the female genital tract should not be performed in patients with oligomenorrhoea until they have had 6 months of ovulatory cycles in response to clomiphene, except in cases where the history or examination is suggestive of tubal damage.	C	62
14	Counselling by trained counsellors should be available to all couples.	C	61
15	Drug treatments are ineffective in the treatment of idiopathic male infertility and should not be used.	A	56
16	Drug treatments for endometriosis in women with this condition and infertility do not improve conception rates and should not be prescribed for this purpose.	A	55
17	A genital examination of the male partner should be performed.	C	40
18	A general examination of both partners should be performed.	C	39
19	Couples with unexplained infertility, mild endometriosis and male factor infertility should only be offered IVF when their infertility is of 4 years or more in duration.	C	32
20	Investigation of the female genital tract should be delayed in couples with hitherto unexplained infertility until the infertility is of at least 2 years duration	C	25

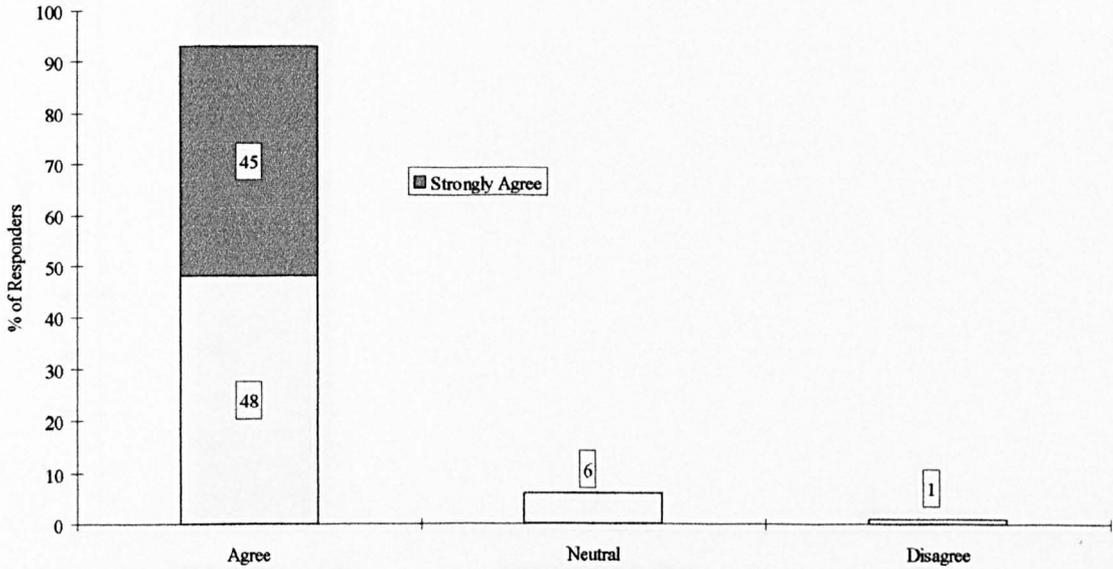
Table 5 Summary of agreement with each criterion in the questionnaire survey. Those criteria with Grade A evidence are shaded.

Rank	Criteria For Good Quality Care Hospital Care	Agree %
1=	There should be agreed local guidelines for the investigation, Management and referral of infertile patients. <i>GRADE A</i>	93
1=	Diagnostic laparoscopy and dye transit, rather than HSG, should be the primary investigation of the female genital tract. <i>GRADE B</i>	93
2	A mid luteal plasma progesterone level should be checked in a regularly menstruating female as the basic test of ovulation. <i>GRADE B</i>	92
6	The female partner's rubella status should be checked. <i>GRADE B</i>	84
7	The female partner should be advised to take folic acid Supplements while attempting to become pregnant (0.4-0.5mg daily). <i>GRADE A</i>	82
9	Tubal surgery should not be undertaken for severe damage to the fallopian tubes as the success rates from IVF are higher. <i>GRADE B</i>	78
10	Temperature charts are of limited use and couples should be Discouraged from keeping them. <i>GRADE B</i>	77
11	The initial investigation of the male partner should include two semen analyses at least one month apart. <i>GRADE B</i>	67

Table 6 Criteria with **scientific evidence and stronger consensus** among clinicians. Those criteria with Grade A evidence are shaded.

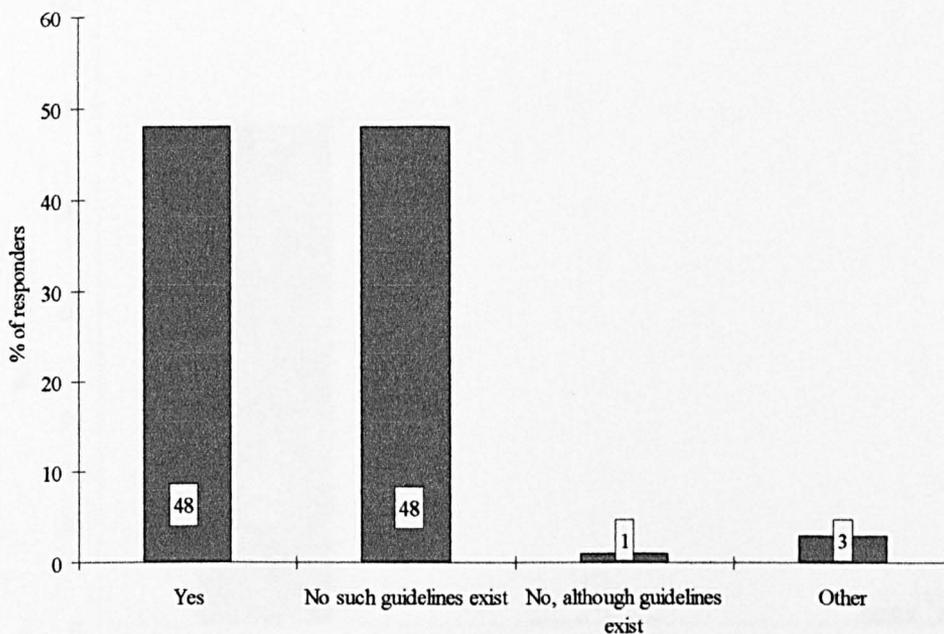
The following graphs summarise the responses of gynaecologists in relation to their level of agreement with each suggested audit criterion. Reported practices in relation to the criteria are also shown.

Criterion: *There should be agreed local guidelines for the investigation, management and referral of infertile patients. [Grade A]*

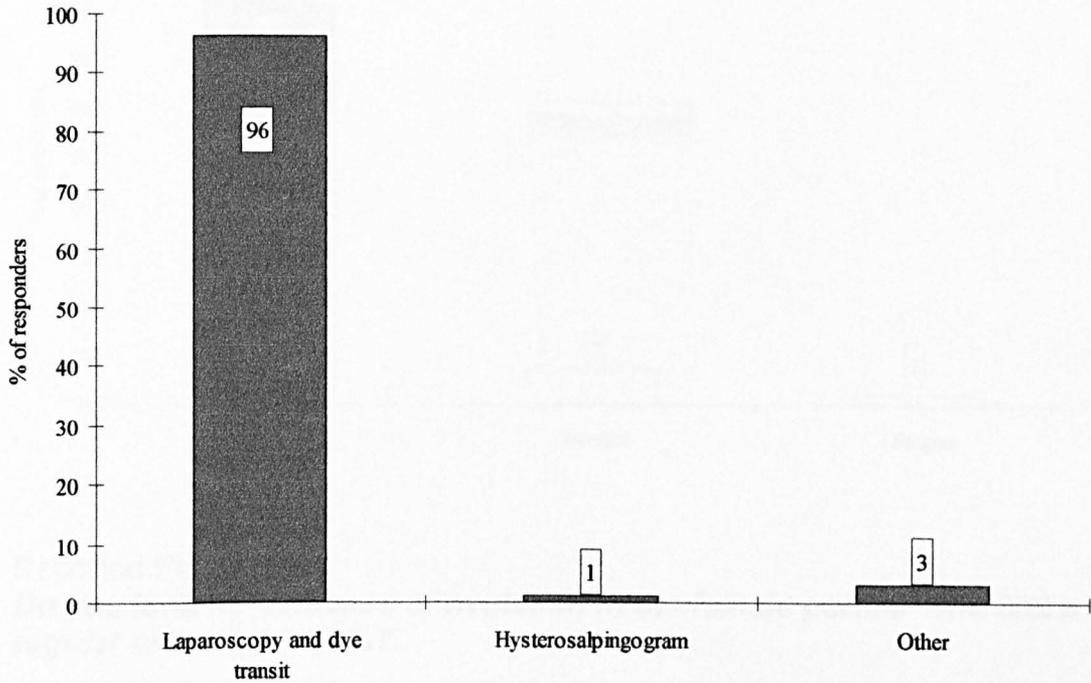


Reported Practice:

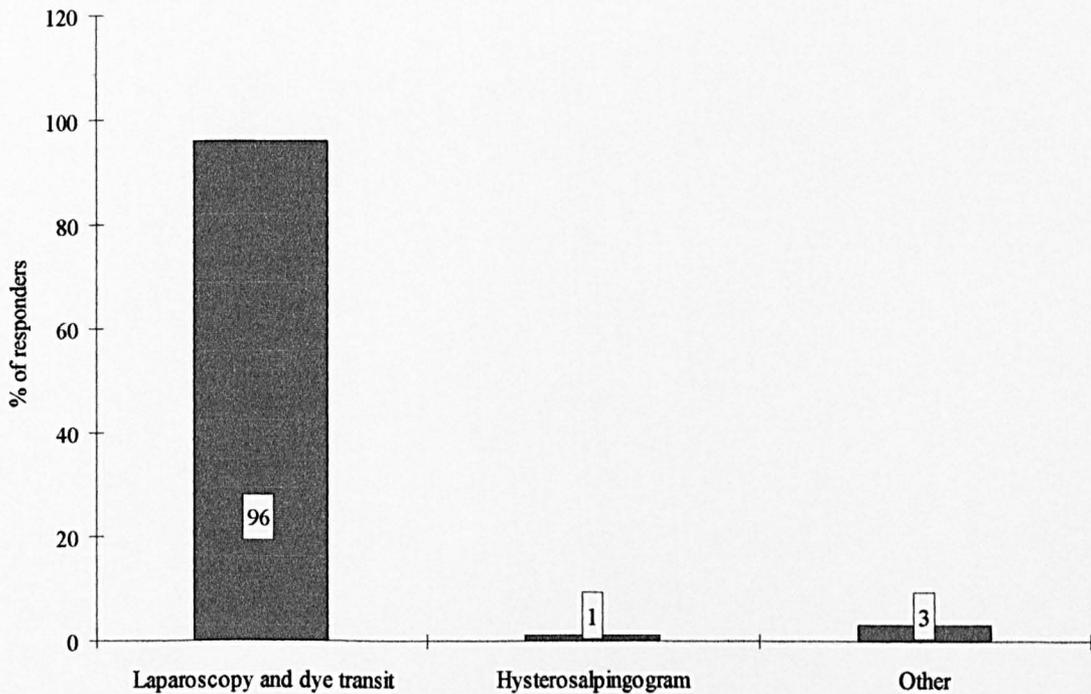
Do you follow local guidelines in the initial investigation, management and referral of infertile patients?



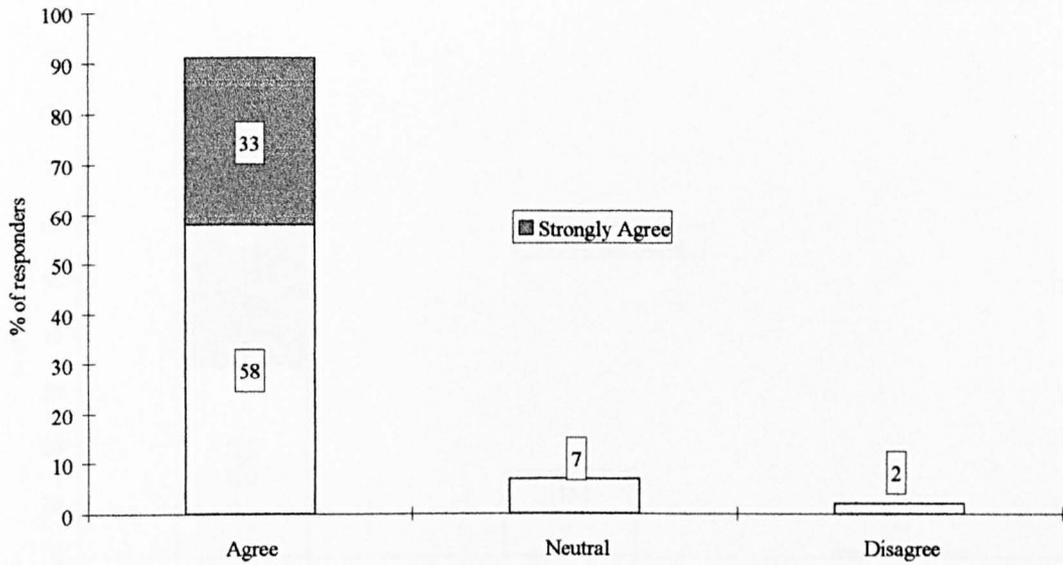
Criterion: *Diagnostic laparoscopy and dye transit, rather than hysterosalpingography should be the primary investigation of the female genital tract. [Grade B]*



Reported Practice: *What is your primary investigation of the female genital tract?*



Criterion: ***A mid luteal plasma progesterone level should be checked in the regularly menstruating female as the basic test of ovulation.*** [Grade B]



Reported Practice:

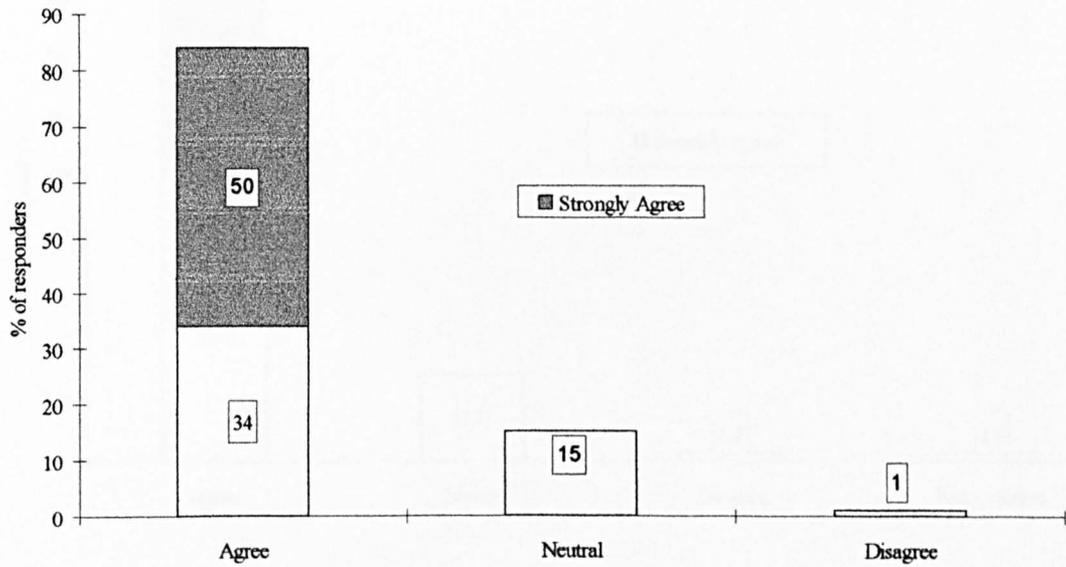
Do you look for evidence of ovulation in the female partner who has a regular menstrual cycle?

93% said 'yes', by measuring mid-luteal plasma progesterone in one or more cycles'

4% said 'yes' but used methods other than mid-luteal plasma progesterone'

3% said that 'further evidence is unnecessary in these women'

Criterion: **The female partner's rubella status should be checked. [Grade B]**

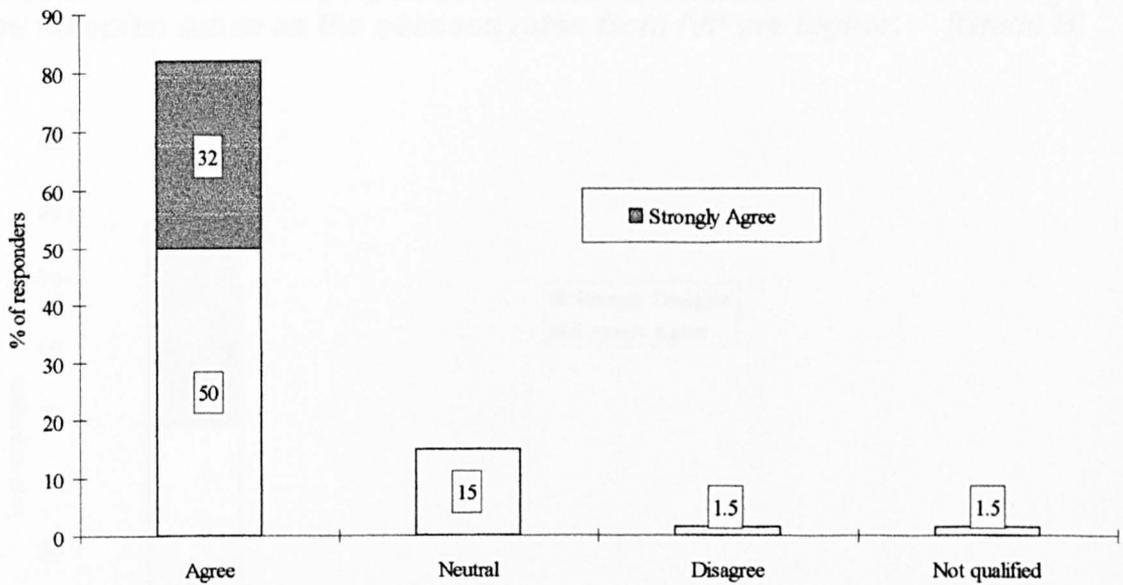


Reported Practice:

Do you routinely check the female partner's rubella status?

68% said 'yes'.

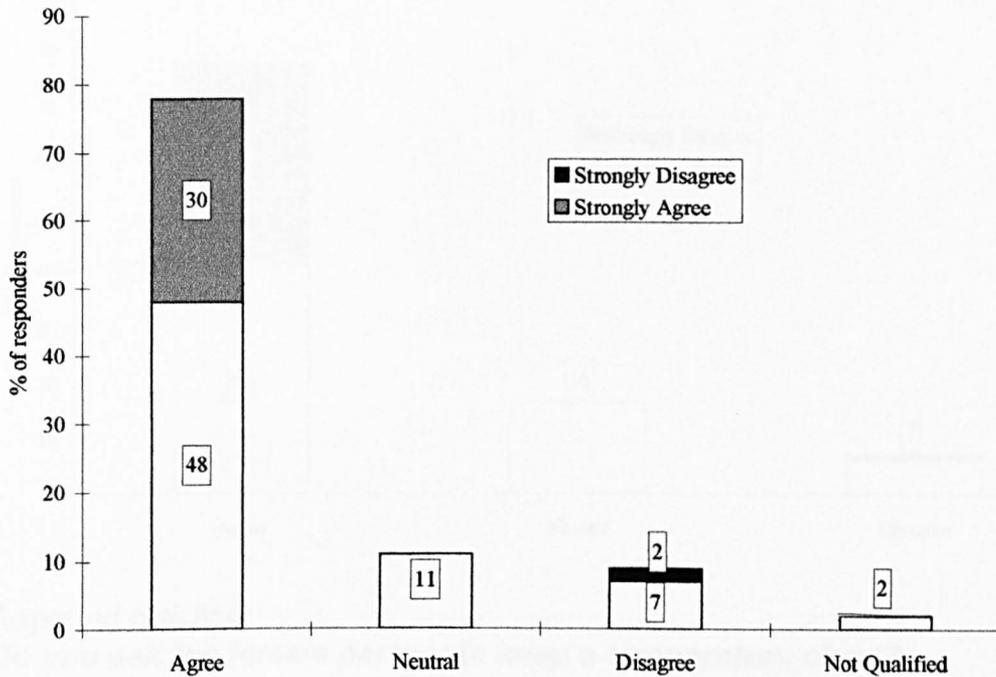
Criterion: *The female partner should be advised to take folic acid supplements while attempting to become pregnant. [Grade A]*



Reported Practice: *Do you advise women who are attempting to become pregnant to take daily folic acid supplements?*

55% of responders said 'yes'.

Criterion: Tubal surgery should not be undertaken for severe damage to the fallopian tubes as the success rates from IVF are higher. [Grade B]



Reported Practice:

Do you perform reconstructive tubal surgery on infertility patients (other than reversal of sterilisation) in the course of your job?

Fifty-six consultants (39%) from 26 of the 29 Scottish hospitals, said they perform reconstructive tubal surgery other than reversal of sterilisation. Of those:

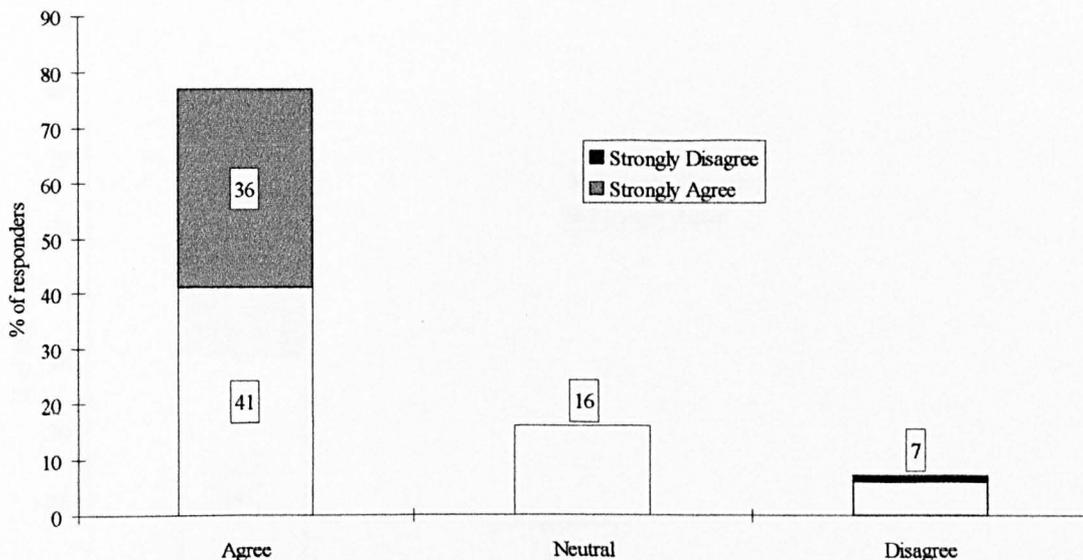
Please estimate the average number of cases per year:

The estimated average number of cases was seven per year.

If yes, do you use microsurgical technique and / or an operating microscope?

- 19% use microsurgical technique and an operating microscope
- 42% use microsurgical technique without an operating microscope
- 19% use neither microsurgical technique nor operating microscope

Criterion: **Temperature carts are of limited use and couples should be discouraged from keeping them. [Grade B]**

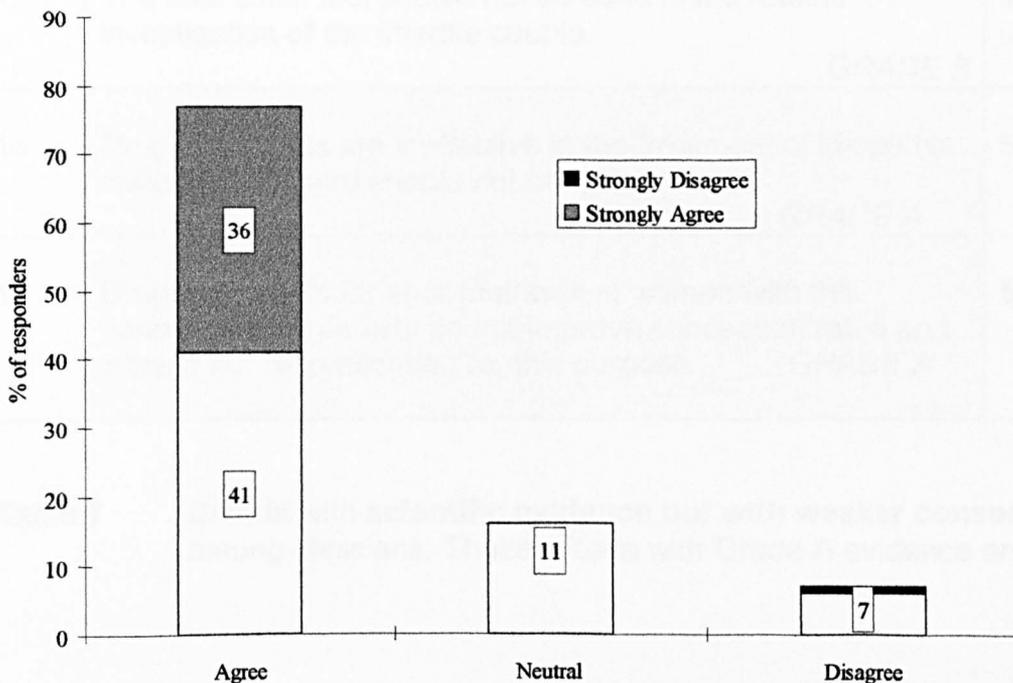


Reported practice:

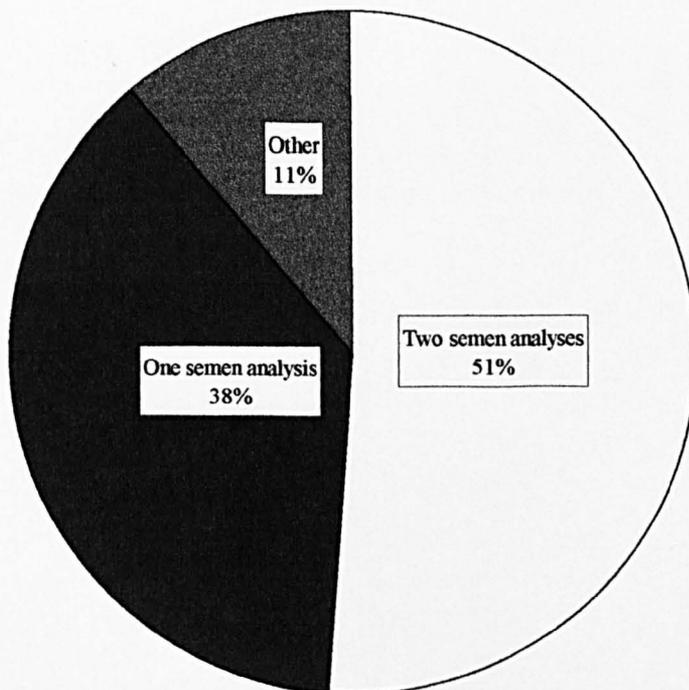
Do you ask the female partner to keep a temperature chart?

8% of responders said they ask the female partner to keep a temperature chart.

Criterion: The initial investigation of the male partner should include two semen analyses at least one month apart. [Grade B]



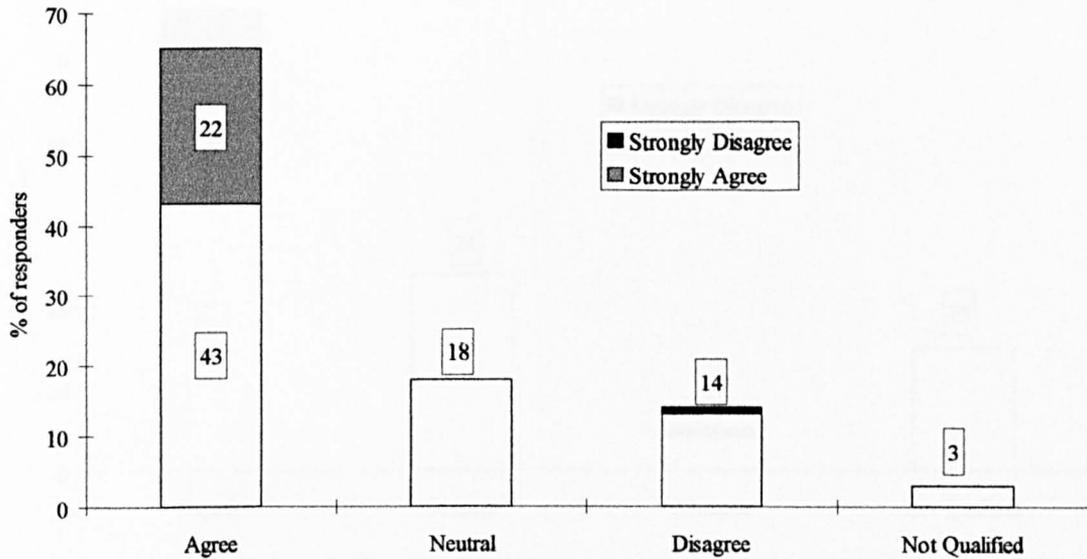
Reported Practice: Do your initial investigations of the male partner include semen analysis?



Rank	Criteria For Good Quality Care Hospital Care	Agree %
12	The post coital test should not be used in the routine investigation of the infertile couple. <i>GRADE B</i>	65
15	Drug treatments are ineffective in the treatment of idiopathic male infertility and should not be used. <i>GRADE A</i>	56
16	Drug treatments for endometriosis in women with this condition and infertility do not improve conception rates and Should not be prescribed for this purpose. <i>GRADE A</i>	55

Table 7 Criteria with **scientific evidence but with weaker consensus** among clinicians. Those criteria with Grade A evidence are shaded.

Criterion: *The post coital test should not be used in the routine investigation of the infertile couple. [GRADE B]*

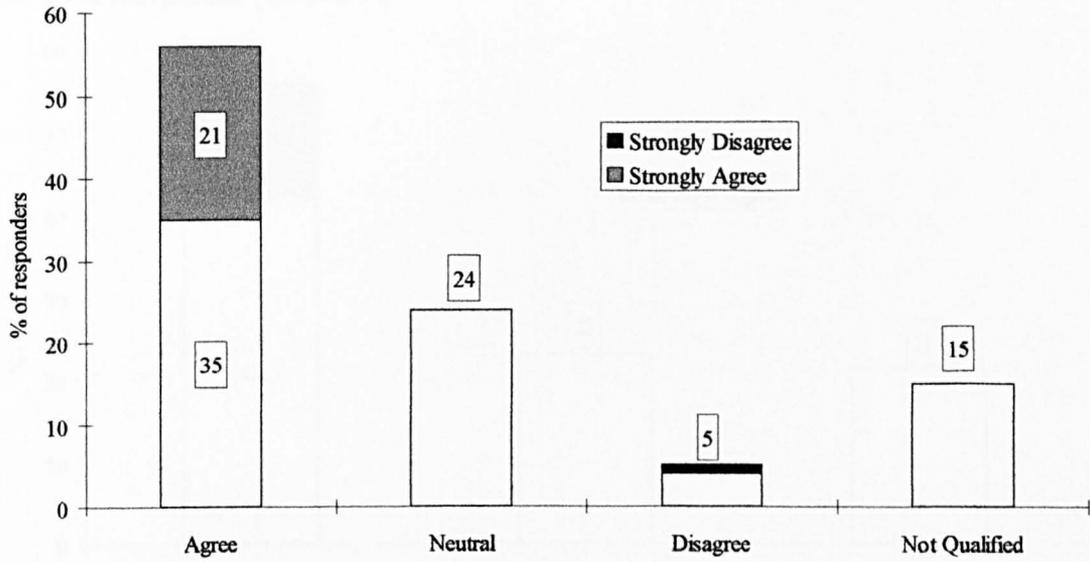


Reported Practice:

Do you arrange for a post coital test to be performed?

Routinely in all couples	2% (3/142)
If a coital problem is suspected	17% (24/142)
I do not think it is a useful test in the routine investigation of the infertile couple	58% (82/142)
If infertility is otherwise unexplained after basic investigation	26% (37/142)
If there is an abnormal semen analysis	4% (5/142)

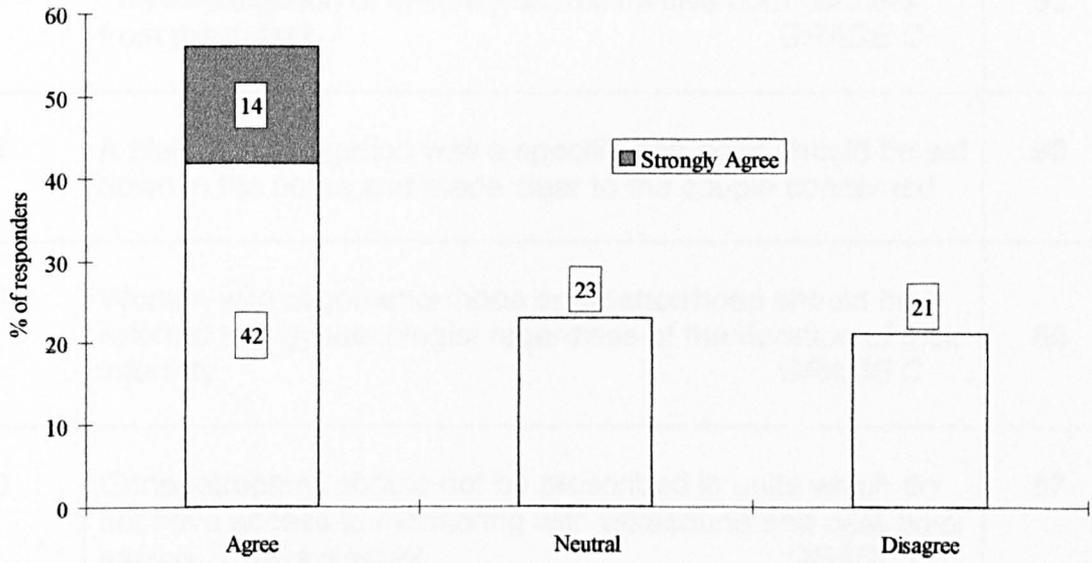
Criterion: **Drug treatments are ineffective in the treatment of idiopathic male infertility and should not be used. [GRADE A]**



Reported practice: **Do you use drug treatments in the management of idiopathic male infertility?**

7% said 'yes'.

Criterion: **Drug treatments for endometriosis in women with this condition and infertility do not improve conception rates and should not be prescribed for this purpose. [Grade A]**



Reported Practice:

Do you use drug treatments in the initial management of infertile patients with endometriosis who are otherwise asymptomatic?

Twenty seven per cent (38/141) said 'yes'.

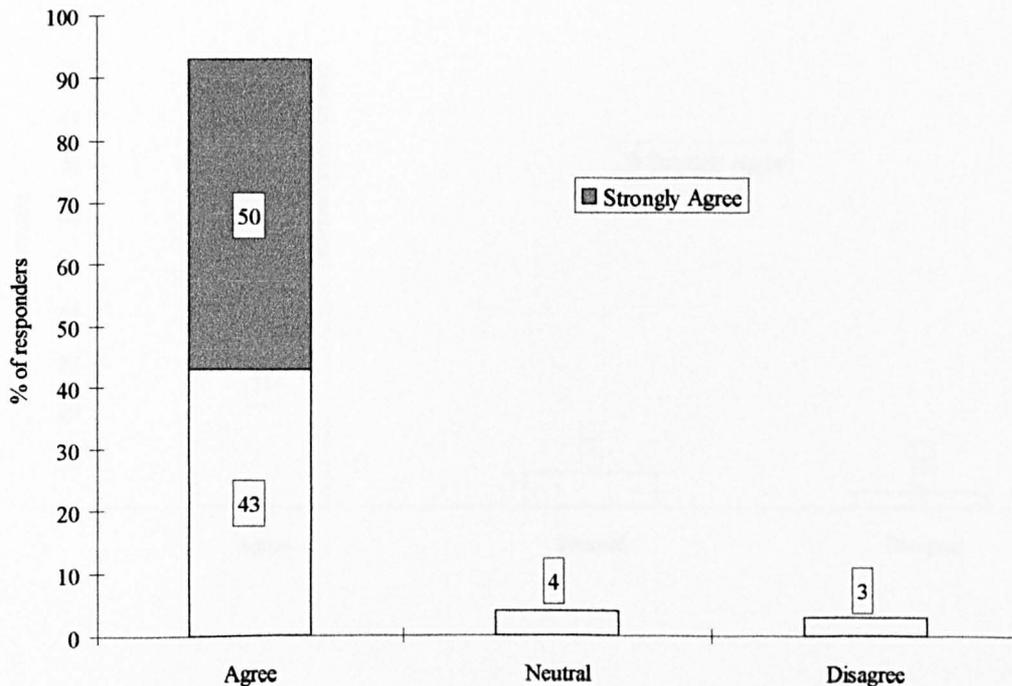
Rank	Suggested Criteria For Good Quality Care Hospital Care	Agree %
1=	The investigation of infertility should involve both partners from the outset. <i>GRADE C</i>	93
3	A plan of investigation with a specific end-point should be set down in the notes and made clear to the couple concerned.	90
4	Women with oligomenorrhoea or amenorrhoea should be referred to a gynaecologist regardless of the duration of their infertility. <i>GRADE C</i>	89
5	Gonadotrophins should not be prescribed in units which do not have access to monitoring with ultrasound and oestradiol assays, 7 days a week. <i>GRADE C</i>	87
8	A pelvic examination of the female partner should be performed. <i>GRADE C</i>	79

Table 8 Criteria lacking scientific evidence but with stronger consensus amongst clinicians. Those criteria with Grade A evidence are shaded.

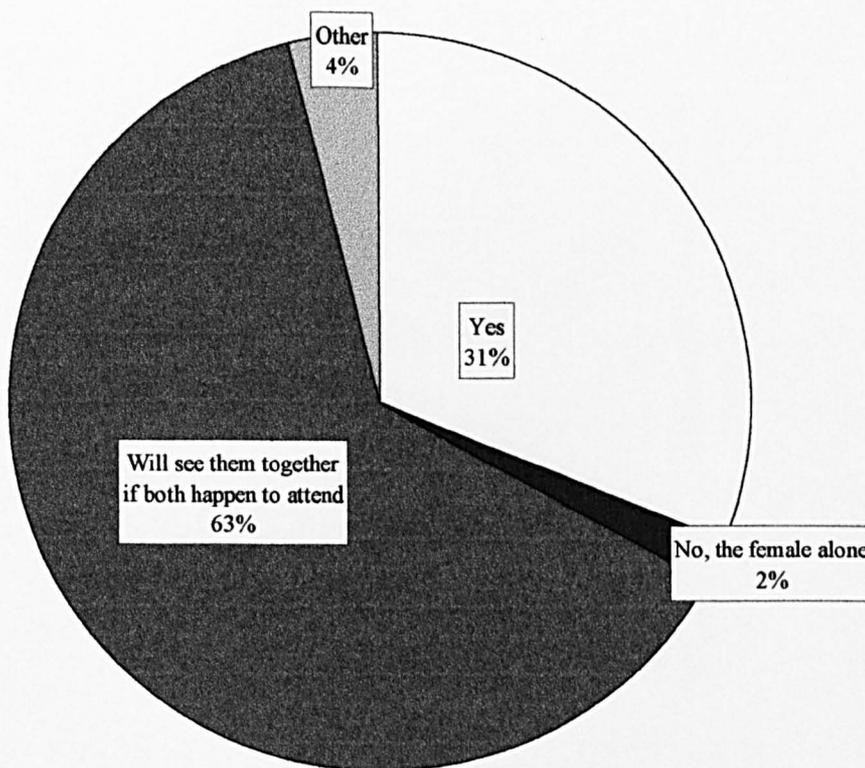
The suggested criteria in this section, despite addressing important aspects of care, are lacking in *directly* applicable studies. In a climate of evidence based practice it is tempting to avoid these areas in clinical audit and guideline development. Not all subjects are, however, amenable to randomised controlled trials nor are randomised controlled trials always appropriate. In these circumstances consensus of opinion is of value in establishing standards for practice.

The above criteria have therefore been allocated a grading of "C" ("Requires evidence from expert committee reports or opinions and / or clinical experience of respected authorities.") as recommended by the Scottish Intercollegiate Guidelines Network (Table 2).

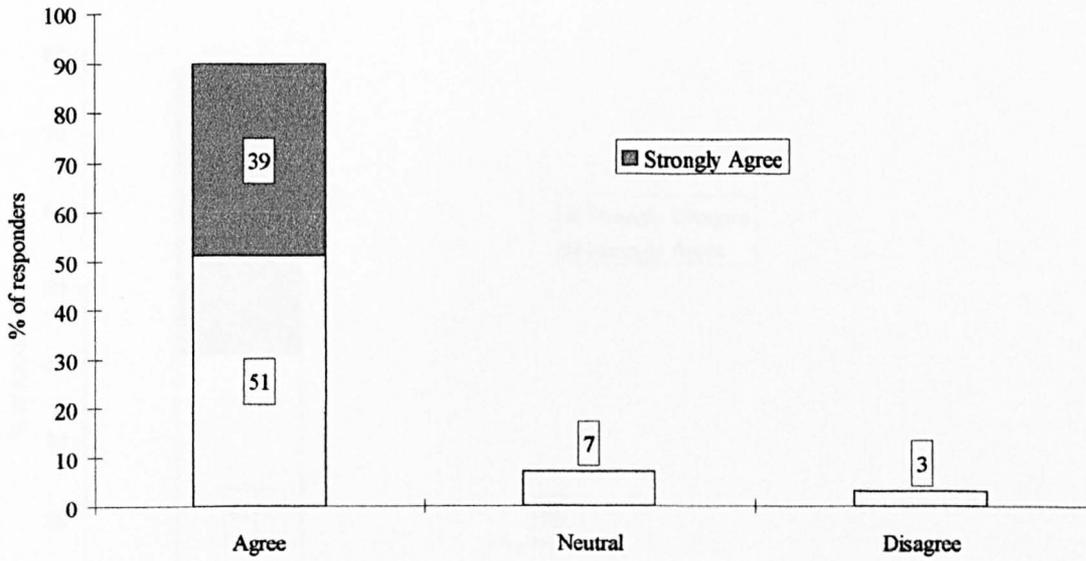
Criterion: **The investigation of infertility should include both partners from the outset. [Grade C]**



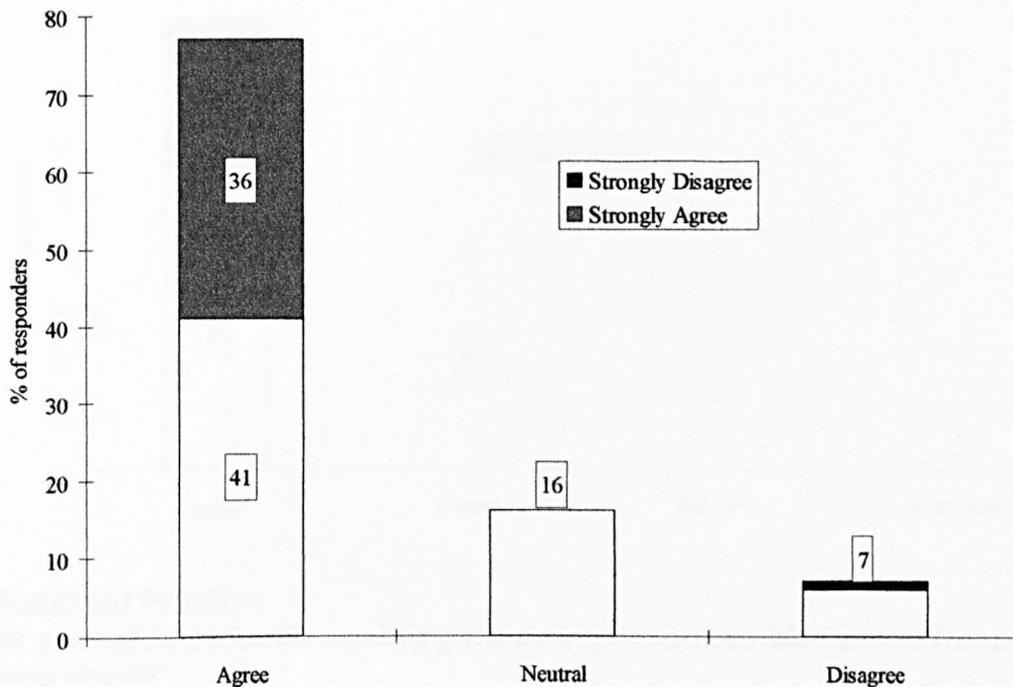
Reported Practice: **Do you ask to see the couple together at the clinic?**



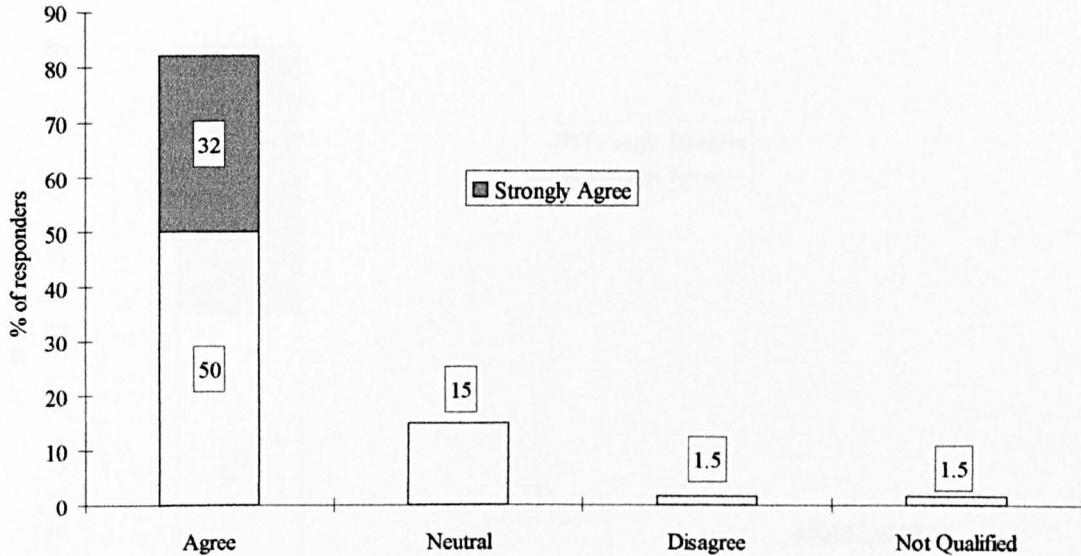
Criterion: A plan of investigation with a specific end-point should be set down in the notes and made clear to the couple concerned. [Grade C]



Criterion: Women with oligomenorrhoea or amenorrhoea should be referred to a gynaecologist regardless of the duration of their infertility.
 [Grade C]



Criterion: *Gonadotrophins should not be prescribed in units which do not have access to monitoring with ultrasound and oestradiol levels, seven days per week. [Grade C]*



Reported Practice:

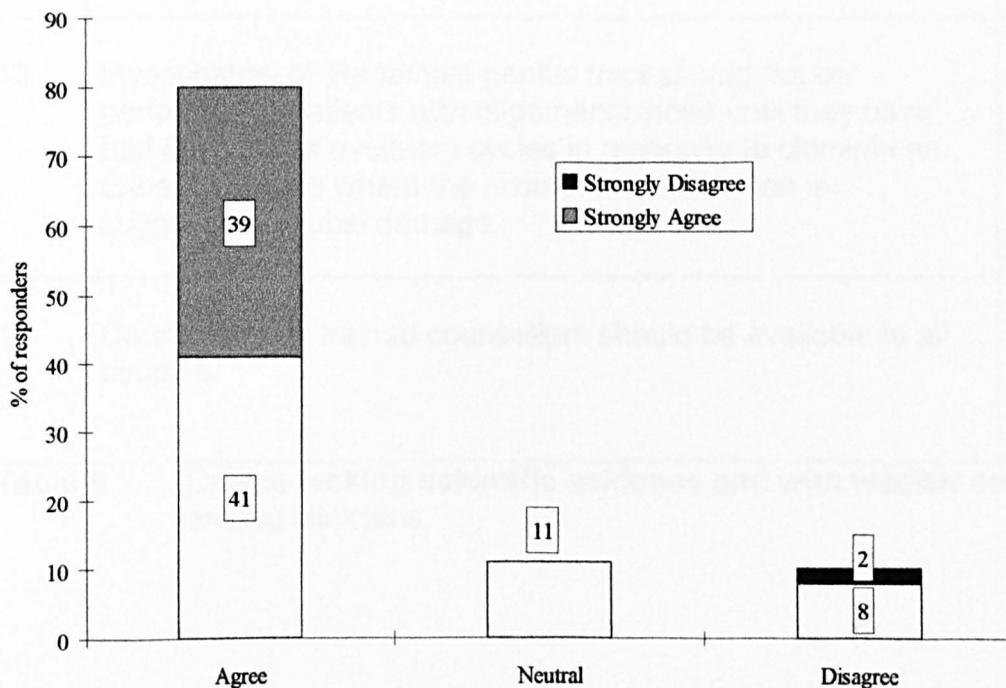
Is ovulation induction using gonadotrophins provided at the hospital where you work?

Clinicians indicated that ovulation induction using gonadotrophins was available at 69% (20/29) of hospitals.

If Yes, Is monitoring of these techniques using ultrasound scanning and oestradiol assays available in the hospital seven days per week?

Forty per cent (8/20) have access to monitoring using ultrasound scanning and oestradiol assays seven days per week and ten per cent (2/20) do not. In the remaining 10 hospitals there was discordance among different members of staff from the same unit as to whether this was or was not available.

Criterion: ***A pelvic examination of the female partner should be performed.***
 [Grade C]



Reported Practice:

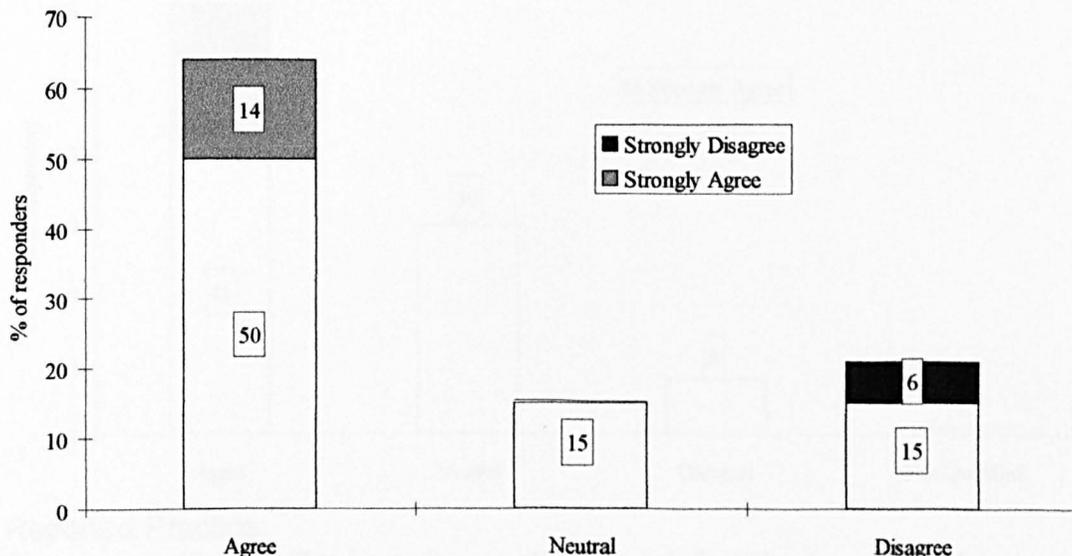
Is it your usual practice to perform a pelvic examination of the female partner?

'Yes, in all cases'	77%	(110/143)
'Yes, if the history indicates a problem'	6%	(8/143)
'No'	15%	(22/143)
'Other'	2%	(3/143)

Rank	Suggested Criteria For Good Quality Care Hospital Care	Agree %
13	Investigation of the female genital tract should not be performed in patients with oligomenorrhoea until they have had 6months of ovulatory cycles in response to clomiphene, Except in cases where the history or examination is suggestive of tubal damage.	62
14	Counselling by trained counsellors should be available to all couples.	61

Table 9 Criteria lacking scientific evidence and with weaker consensus among clinicians.

Criterion: *Investigation of the female genital tract should not be performed in patients with oligomenorrhoea until they have had six months of ovulatory cycles in response to clomiphene, except in cases where the history or examination is suggestive of tubal damage. [Grade B]*



Reported Practice:

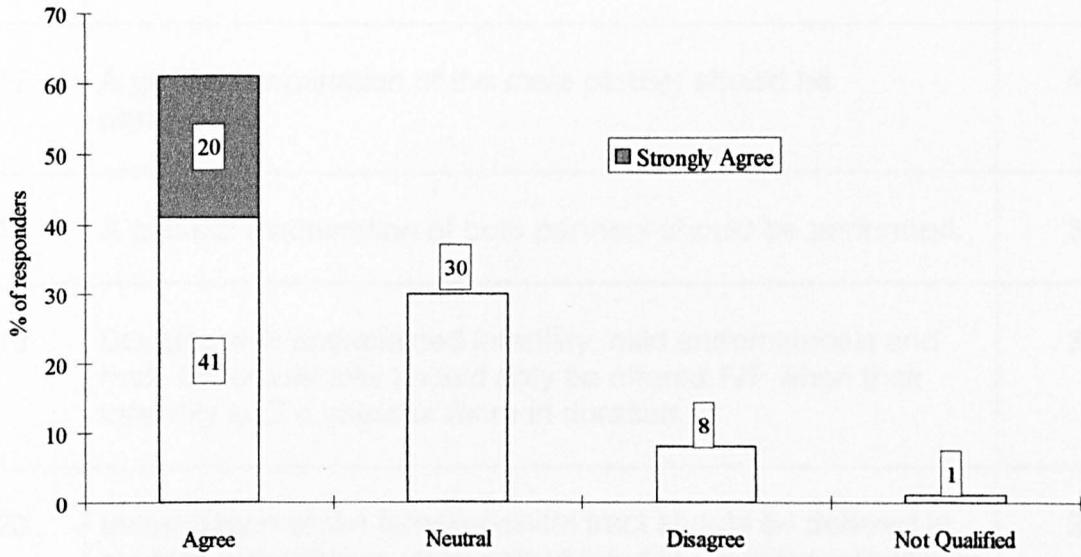
Would you treat an ovulatory disorder before proceeding to diagnostic laparoscopy and dye transit in a patient who has no history suggestive of tubal damage?

Seventy three per cent (105/143) answered 'yes'.

If yes, for how many cycles would you treat the patient before proceeding to laparoscopy?

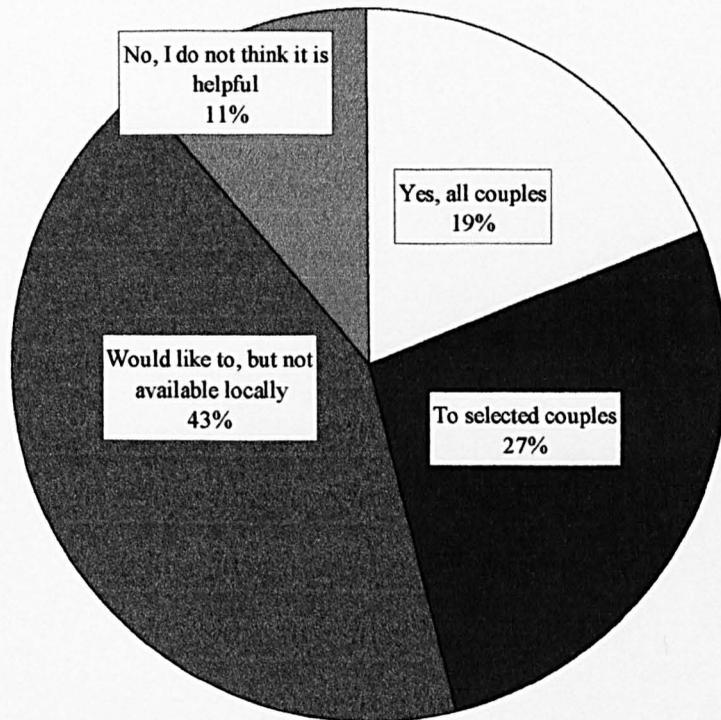
The mean number of cycles of clomiphene or tamoxifen for which they would treat was six. Eleven responders said they would treat with gonadotrophins prior to laparoscopy. The mean number of cycles for which they would treat was again six.

Criterion: **Counselling by trained counsellors should be available to all couples. [Grade C]**



Reported Practice:

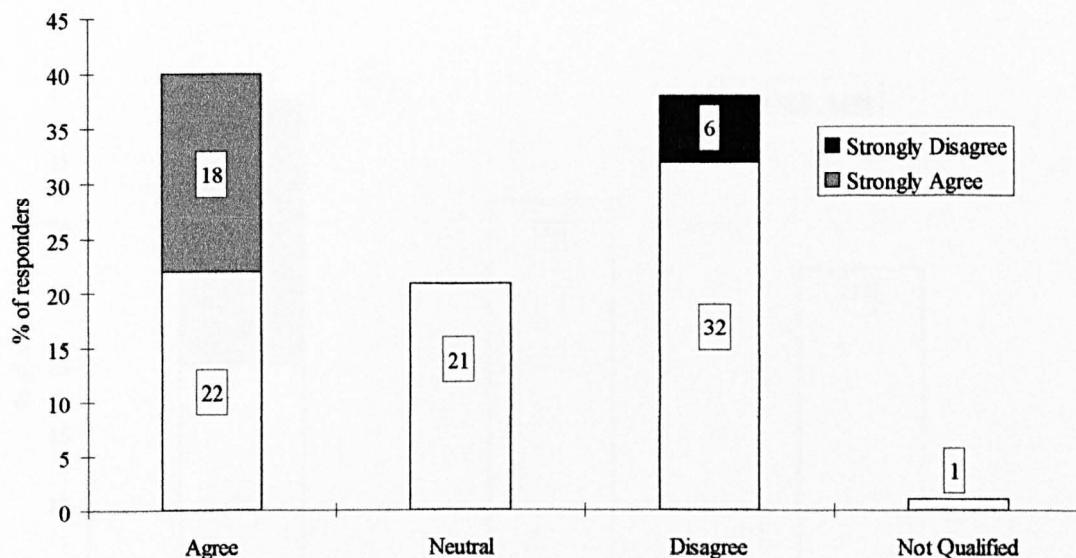
Do you routinely offer couples undergoing infertility investigation or treatment the opportunity to see a trained counsellor?



Rank	Suggested Criteria For Good Quality Care Hospital Care	Agree %
17	A genital examination of the male partner should be performed.	40
18	A general examination of both partners should be performed.	39
19	Couples with unexplained infertility, mild endometriosis and male factor infertility should only be offered IVF when their Infertility is of 4 years or more in duration.	32
20	Investigation of the female genital tract should be delayed in couples with hitherto unexplained infertility until the infertility is of at least 2 years duration.	25

Table 10 Criteria that were rejected by clinicians (less than 50% agreement with the criterion).

Criterion: ***A genital examination of the male partner should be performed.***
 [Grade C]

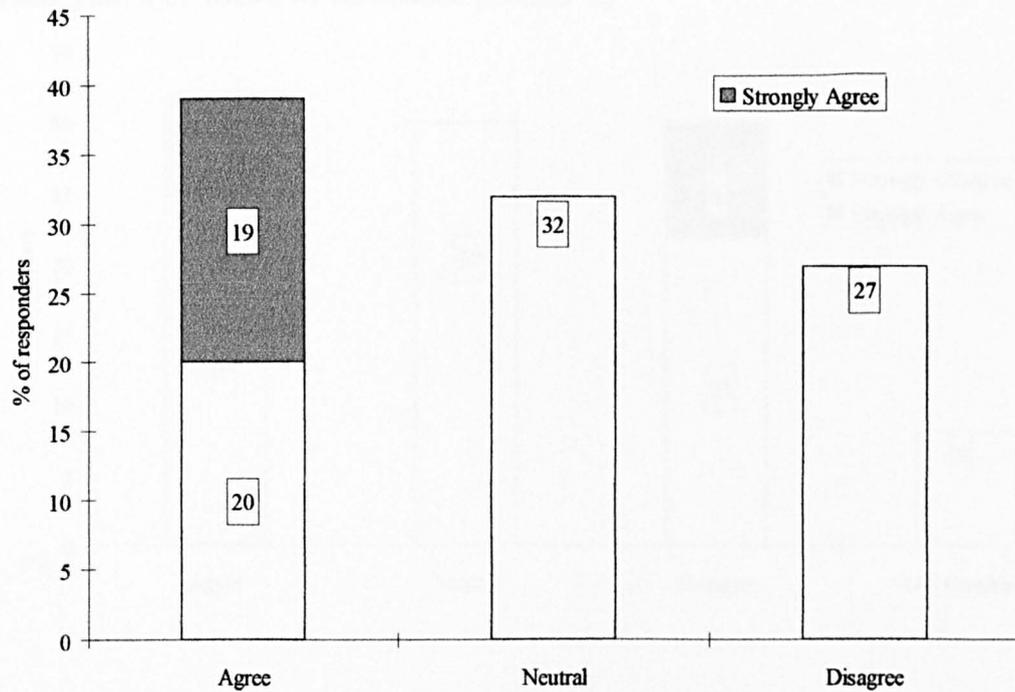


Reported Practice:

Is it your usual practice to perform a genital examination of the male partner?

'Yes'	21%	(30/141)
'No'	19%	(26/141)
'Only if the semen analysis indicates a problem'	29%	(41/141)
'Other'	31%	(44/141)

Criterion: ***A general examination of both partners should be performed.***
 [Grade C]

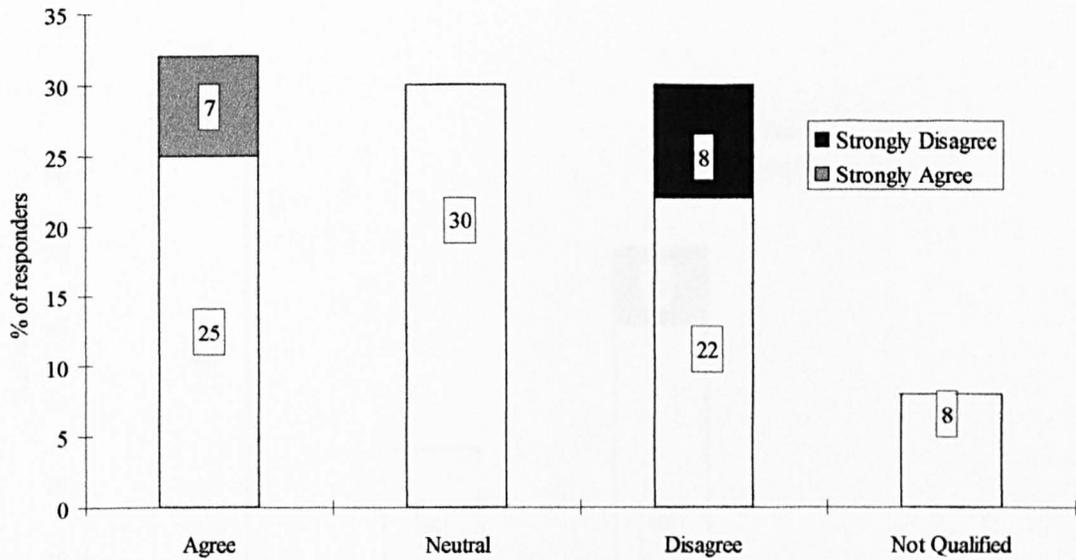


Reported Practice:

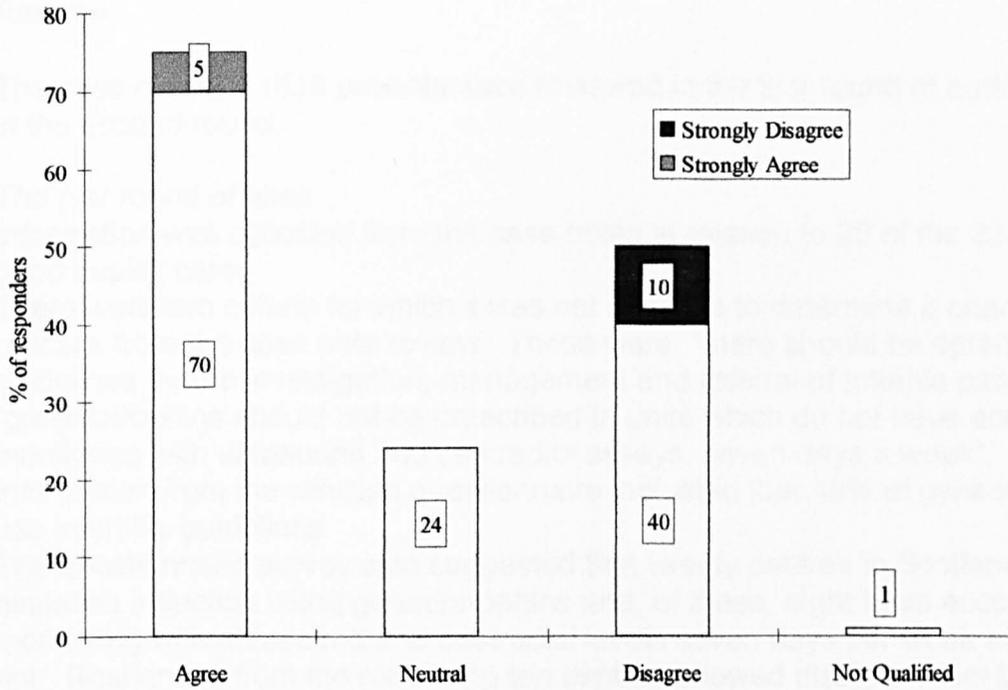
Is it your usual practice to perform a general examination of both partners?

'Yes'	28/143	20%
'No'	23/143	16%
'The female partner only'	86/143	60%
'The female partner only'	0/143	0%
'Other'	6/143	4%

Criterion: ***Couples with unexplained infertility, mild endometriosis and mild male factor infertility should be offered IVF when their infertility is of four years or more in duration. [Grade C]***



Criterion: ***Investigation of the female genital tract should be delayed in couples with hitherto unexplained infertility until the infertility is of at least two years duration. [Grade C]***



3.3 THE HOSPITAL CASE NOTE REVIEW

The Investigation and Initial Management of Infertility: Two Rounds of Audit Results

The case notes of 1510 patients were reviewed in the first round of audit and 1080 in the second round.

The first round of audit

Information was collected from the case notes in relation to 20 of the 22 criteria for good quality care.

There were two criteria for which it was not possible to determine a change in practice from the case note review. These were: "there should be agreed local guidelines for the investigation, management and referral of infertile patients" and "gonadotrophins should not be prescribed in units which do not have access to monitoring with ultrasound and oestradiol assays, seven days a week".

Information from the clinician questionnaire indicated that 48% of gynaecologists use infertility guidelines.

The questionnaire survey also suggested that twenty centres in Scotland perform ovulation induction using gonadotrophins and, of these, eight have access to monitoring with ultrasound and oestradiol levels seven days per week and two do not. Responses from the remaining ten centres showed disagreement between different members of staff in the same units about whether this was or was not available.

In both the first round and second round of audit, for 13 of the 20 suggested criteria at least half of all patients were managed in line with the suggested standard (Tables 11 and 12). There were however changes in the overall adherence to the criteria and significant differences within individual centers between the two rounds of audit.

The criteria which were met least related to: performing a genital examination of the male partner (which was rejected in the consensus survey); documenting advice about folic acid supplements; checking rubella immunity and using drugs to treat endometriosis as part of the management of infertility.

Variations in Care

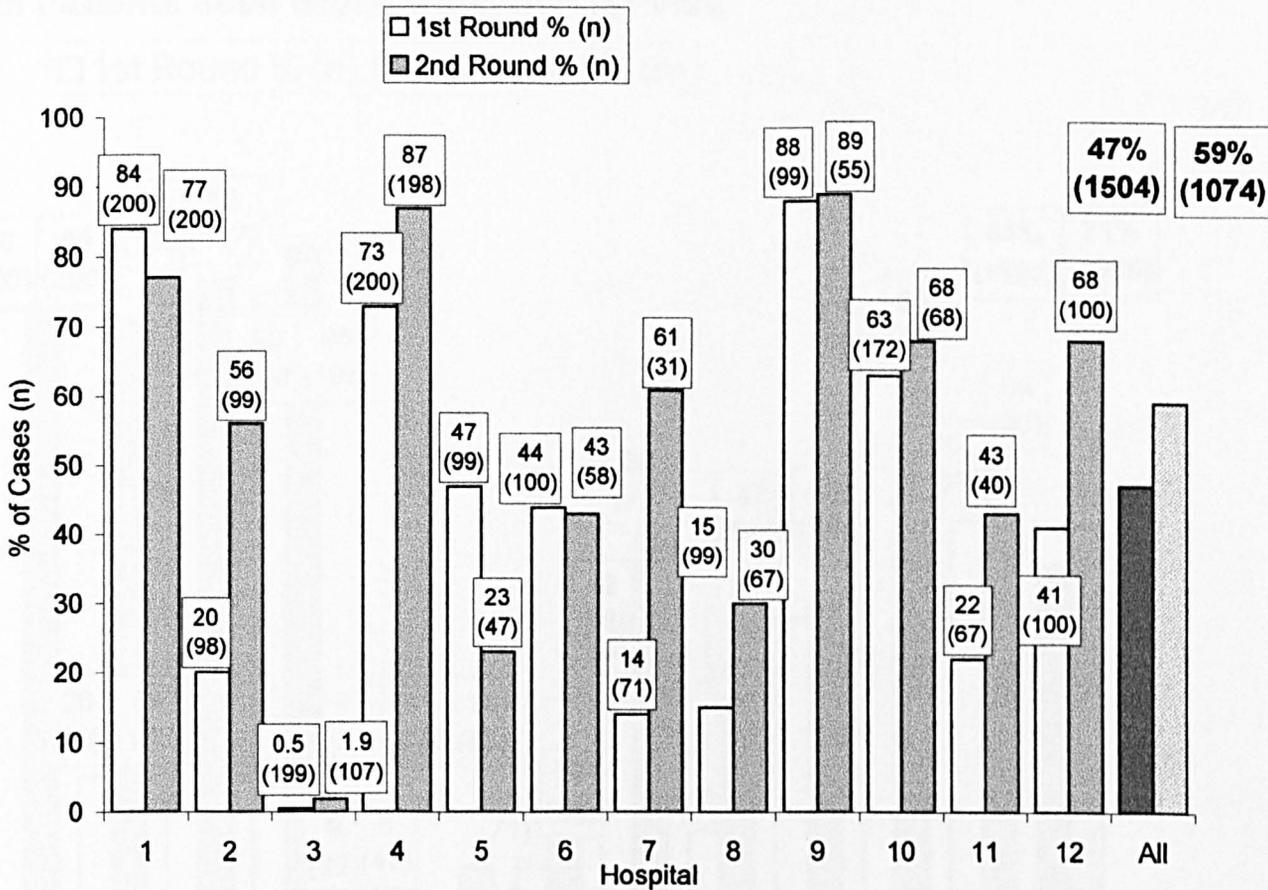
Wide variations in care were noted among different centres. To illustrate these variations, four examples are presented below showing the differences among the 12 centres and the changes between the first and second rounds of audit. The four criteria relate to:

- Rubella immunity
- Seeing patients as couples
- Drug treatments for endometriosis
- The postcoital test

Rubella Immunity

Between the two audit periods, there was an increase overall in the proportion of patients whose rubella status had been checked and statistically significant ($p < 0.05$) increases in six individual centres (Hospitals 2, 4, 7, 8, 11 and 12). However, in the second audit period, there were still five centers where less than half of case notes documented that this had been checked. There was also a statistically significant ($p < 0.05$) decrease in Hospital 5.

Rubella Immunity Checked by Hospital or General Practitioner



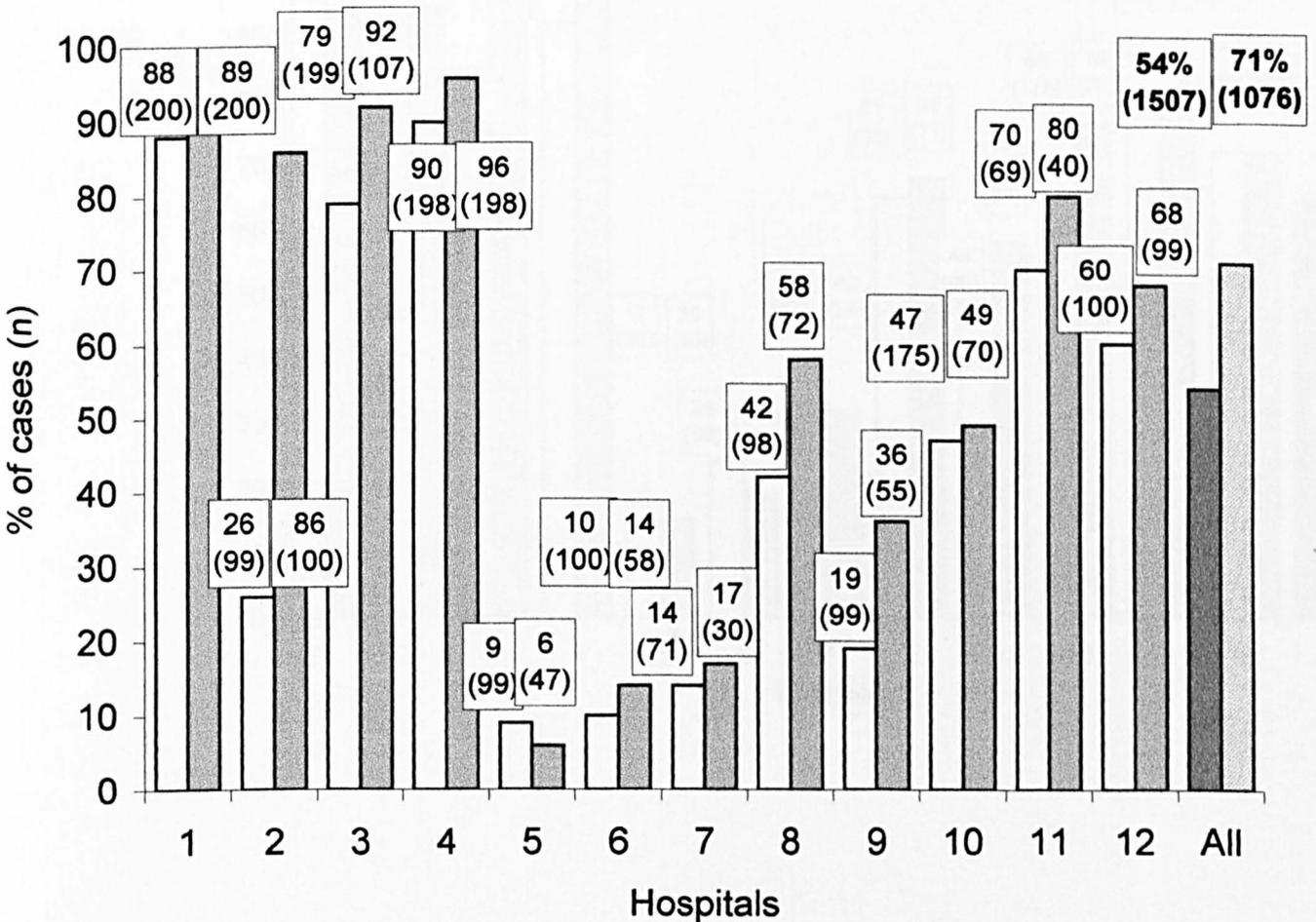
Seeing Patients as Couples

There was a statistically significant increase ($p < 0.01$) in the percentage of patients overall who were seen with their partner at the first hospital visit.

Statistically significant increases ($p < 0.05$) were also observed in five individual centres: Hospitals 2,3,4,8 and 9. However, in three hospitals (5, 6 and 7) fewer than 1 in 5 patients were seen with their partner at the hospital first visit both in the first and second rounds.

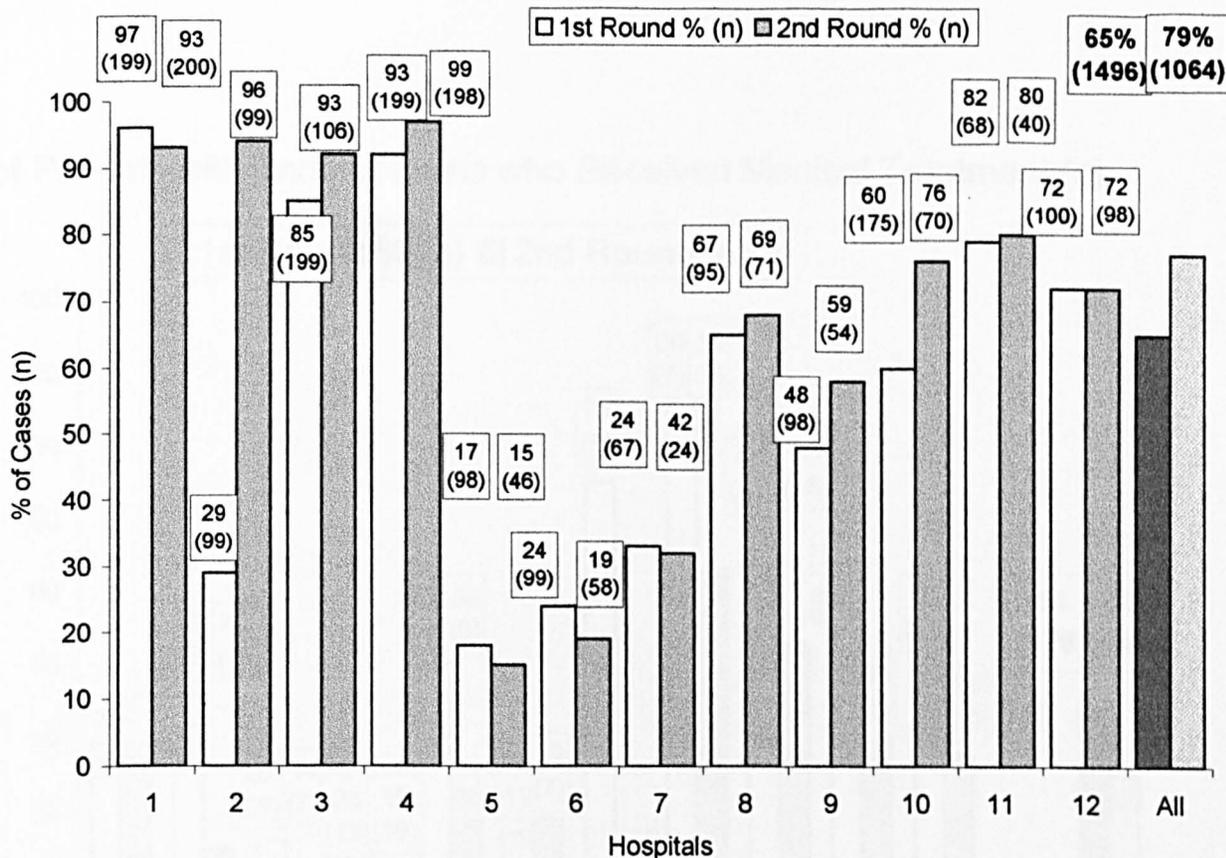
% of Patients Seen with Partner at First Visit

□ 1st Round % (n) ■ 2nd Round % (n)



Overall, more than three-quarters of couples had been seen together on at least one occasion in the second round of audit. This represented a statistically significant ($p < 0.01$) improvement over the first round (79% versus 65%). Statistically significant ($p < 0.05$) improvements were made in four individual centres (Hospitals 2,3,4 and 10) however, in three centres (Hospitals 5,6 and 7) less than half of patients had attended with their partner even in the second round of audit.

% of Couples Seen Together at Some Point

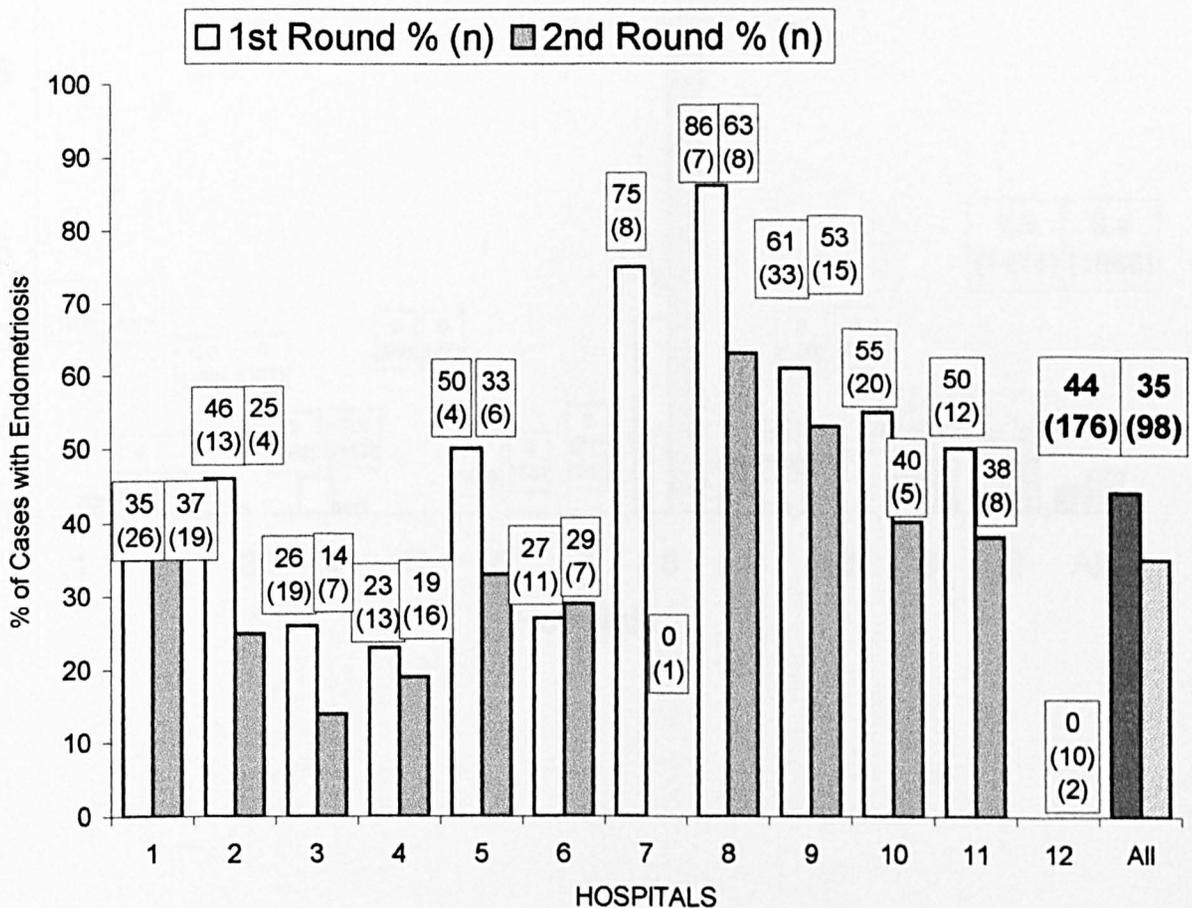


Drug Treatments for Endometriosis

The number of patients at each centre who had endometriosis was small. Of those patients for whom data were available, the notes suggested that 45% (39/87) of patients in the first round of audit who were given medical treatments for endometriosis were symptomatic (e.g. pelvic pain, dysmenorrhoea, dyspareunia) as compared to 43% (15/35) in the second round of audit. It was not possible to determine accurately how significant these symptoms were. Considerable interpretation of the notes would have been needed to do so and this was not possible using non-medical audit assistants to collect data.

Overall, there was a decrease in the percentage of patients who received medical treatment between the two rounds of audit but this was not statistically significant.

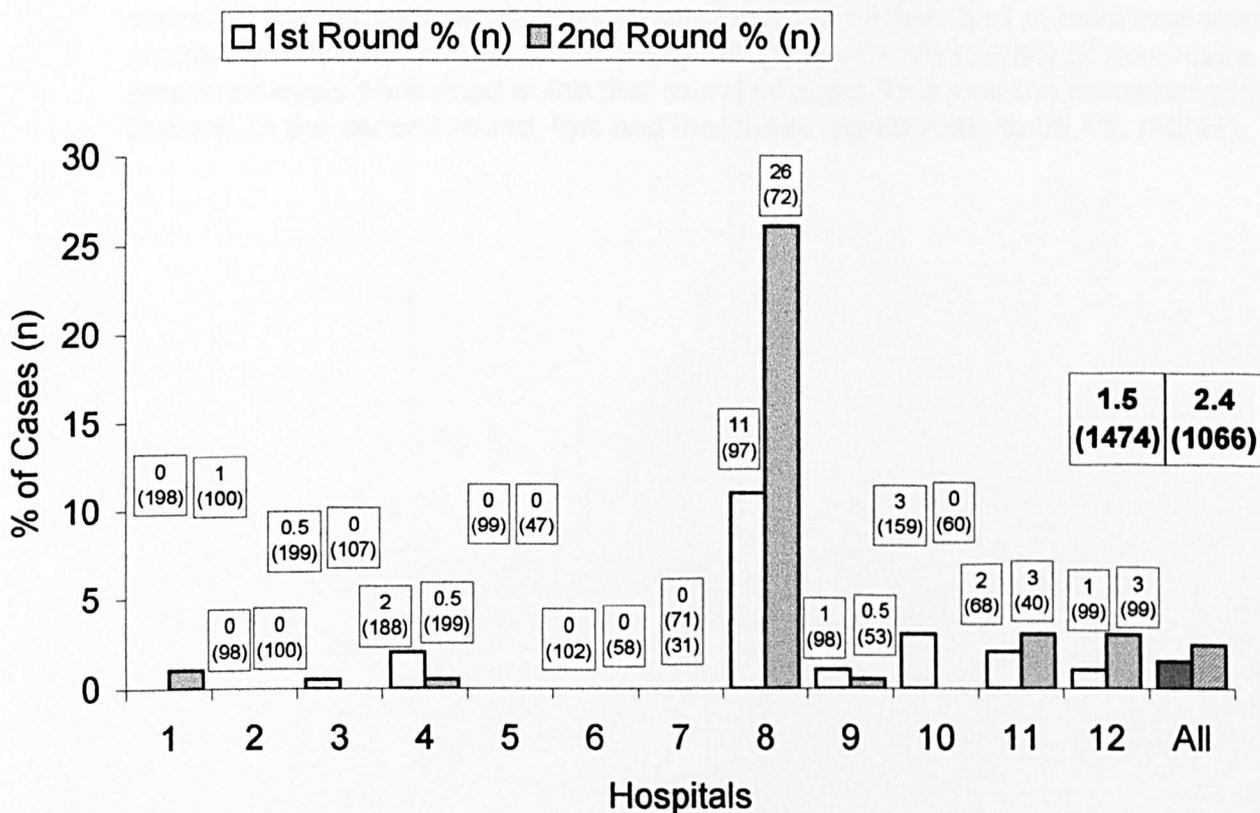
% of Patients with Endometriosis who Received Medical Treatment (n)



The Postcoital Test

The postcoital test was performed in only 1-2% of cases overall however 11% of couples attending Hospital 8 in the first round and 26% in the second, underwent the postcoital test. This was statistically different from the other 11 centers ($p < 0.01$) and increased significantly between the two rounds of audit.

Postcoital Test Performed



Changes between the first and second rounds of audit

The results of the case note reviews for both the first and second rounds of audit are shown in Tables 11 and 12. The second round of audit demonstrated significant changes in care in line with nine of the suggested criteria for good quality care. (Table 11)

In nine areas of care there was no significant change in practice between the two audits and in two areas there was significant change in practice away from that suggested by the criteria for good quality care (Table 12). As discussed above, changes in practice relating to two of the criteria (use of infertility guidelines and monitoring of treatment with gonadotrophins) could not be determined from the case note review.

Although there was no significant increase in the percentage of male partners having at least two semen analyses, there was a statistically significant increase overall in the percentage of cases where the male partner had at least one semen analysis performed. In one center (Hospital 5) only 67.4% (58/86) of men had a semen analysis performed in the first round of audit. This was the lowest of all the centers. In the second round, this had increased significantly to 85.1% (40/47).

Aspects of Care where there was a significant change in line with Criteria for Good Quality Care (p<0.05)	1st Round (n)	2nd Round (n)
Couple seen together for first hospital visit	54.2% (817/1507)	71.0% (764/1076)
Couple seen together by GP or at hospital clinic at any time	65.3% (977/1496)	78.9% (840/1064)
Rubella immunity checked by GP or hospital clinic	46.5% (699/1502)	59.3% (636/1073)
Advice about folic acid documented in case notes	13% (195/1465)	46.5% (463/995)
Management plan clearly documented in case notes	94.1% (1395/1482)	96.3% (1013/1052)
Pelvic examination performed at hospital clinic	52.8% (795/1507)	66.3% (702/1059)
Pelvic examination not performed by GP or hospital clinic	41.2% (609/1479)	27.6% (287/1040)
Drug treatments given for male infertility	3.8% (56/1460)	1.4% (15/1068)
Genital examination of male partner performed at hospital clinic	22.4% (321/1431)	30.5% (320/1051)
Genital examination of male partner performed at hospital clinic or by GP	23.6% (336/1425)	35.3% (359/1016)
General examination of the female partner performed at hospital clinic	56.4% (849/1505)	68.0% (723/1063)
General examination of the male partner performed at hospital clinic	25.8% (369/1429)	38.7% (406/1048)
General examination of the both partners performed at hospital clinic	23.3% (332/1426)	37.4% (390/1042)
Tubal surgery performed	4.8% (71/1489)	2.6% (28/1071)

Table 11 Practices where there were significant changes in care in line with the suggested criteria for good quality care between the two rounds of audit.

No Significant Change in Practice (p>0.05)	1st Round (n)	2nd Round (n)
Mean duration of infertility at time of hospital referral in patients with oligomenorrhoea /amenorrhoea	21 months	26 months
Patient asked to keep a temperature chart by hospital clinic	0.6% (10/1578)	0.6% (6/1054)
Male partner had 2 or more semen analyses	57.5% (869/1510)	60.4% (652/1080)
*Male partner had at least one semen analysis (p=0.004)	84.8% (1280/1510)	88.7% (958/1080)
Postcoital test undertaken	1.5% (22/1474)	2.4% (26/1066)
Trial of medical clomid/bromocriptine in women with oligomenorrhoea or amenorrhoea before test of tubal patency	48.6% (53/109)	36.8% (32/87)
Mean duration of infertility at time of referral for IVF	54 months	46 months
% of cases of cases of unexplained infertility where the infertility was of at least 24 months duration at time of test of tubal patency	60.6% (86/142)	54.1% (53/98)
**Offered counselling (<i>patient questionnaire</i>)	13.8% (109/787)	16.3% (83/508)
Drug treatments for endometriosis	43.7% (77/176)	34.7% (34/98)
Significant Change Away from Criteria for Good Quality Care (p<0.05)	1st Round (n)	2nd Round (n)
Mid luteal plasma progesterone checked	62.4% (616/987)	49.1% (346/704)
Diagnostic laparoscopy as first test of tubal patency	85.7% (707/825)	79.2% (437/552)

Table 12 Practices where there were no significant changes in care and those where there were significant changes away from the suggested criteria for good quality care, between the two rounds of audit.

* There was no significant improvement in this criterion between the two rounds of audit but there was a significant increase in the number of male partners having at least one semen analysis performed (p<0.05).

**The information about whether counselling was offered was obtained from both the patient questionnaire.

3.4 RESULTS RELATING TO PRIMARY CARE ALONE

Introduction

Postal Questionnaire Survey

Case Note Review in Primary Care: A Pilot Study

Audit of General Practice Referral Letters in the Hospital Records

Introduction

As in the hospital audit, information about actual, as well as reported practice, was sought in primary care. This was achieved in three ways:

- A postal questionnaire survey of general practitioners inquiring about their opinion in relation to 12 suggested criteria for good quality care and about their management of infertile couples.
- A pilot study where general practice case records were directly reviewed.
- An audit of general practice referral letters in hospital case records.

Postal Questionnaire Survey

The postal questionnaire of general practitioners was sent out in May 1995 to a stratified random sample of 500 principals in general practice in Scotland. The questionnaire is shown in Appendix 3 and the methods for this survey are described in Section 2.2. Eighty-three percent (414/500) of general practitioners surveyed responded to the questionnaire. [86]

Pilot Study of General Practice Case Records

Standardised information was collected from the general practice case notes of patients who were attending their general practitioner alone for initial investigation and management of infertility. Patients who were concurrently under the care of a hospital gynaecologist were excluded. Twenty-five volunteer practices participated and seventy five case records were reviewed.

Audit of General Practice Referral Letters in Hospital Case Records

Actual practice was measured by collecting information from the general practice referral letters in 1241 hospital case records of women attending out patient clinics for the investigation and initial management of infertility in the first round of audit in 1996 and 892 in the second round of audit in 1997.

In order to compare any changes between the two rounds of audit, only the referral letters of those patients attending the hospital clinic *for the first time* in each round of audit were used. In this way, like could be compared with like and the referral letters of patients who had been attending the clinic for a prolonged period of time were not compared with more recent referrals. A small pilot study was also carried out where information was collected from the general practice records of patients.

Postal Questionnaire Survey

A response rate of 83% (414/500) was obtained to the questionnaire survey. Each of the 12 criteria for good quality care is shown in Table 13 along with the percentage of general practitioners who agreed with the criterion.

Arranging to See Couples Together

The most strongly supported criterion was that 'the investigation of infertility should include both partners from the outset'. Ninety per cent of responders agreed with this and 66% arrange to see both partners together at the surgery if they are both registered with the practice.

History and Examination

Eighty-two per cent agreed that 'a full medical, social and sexual history of both partners should be obtained' and 84% reported this as their usual practice. Thirty-eight per cent agreed that 'a pelvic examination of the female partner, a genital examination of the male partner and a general examination of both partners should be performed by the referring general practitioner'. Forty-one percent usually perform a full examination of both partners, 14% only perform a pelvic examination of the female and 27% do not think examination of either partner is necessary in general practice.

Investigation of the Male Partner

Sixty per cent agreed that 'the initial investigation of the male partner should include two semen analyses at least one month apart'. Seventy-seven per cent include this in their initial investigations but 11% said they could not readily organise semen analysis and eight per cent did not think it was an appropriate investigation in general practice.

Investigation of the Female Partner

Eighty-four per cent agreed that 'a day 21 plasma progesterone level should be the basic investigation of ovulation in a regularly menstruating female' and 78% arrange this test.

Only 42% agreed that 'temperature charts are of limited use and couples should be discouraged from keeping them' and 29% usually ask the female partner to keep a chart.

Seventy-five per cent agreed that 'the female partner's rubella status should be checked' and 49% reported doing so.

Management

Seventy-four per cent agreed that 'the female partner should be advised to take folic acid supplements while attempting to become pregnant' but only 53% cent actually give this advice.

Eighty-eight per cent agreed that 'the presence of amenorrhoea, oligomenorrhoea, oligospermia, a history suggestive of pelvic pathology or abnormal findings on examination of either partner should result in early referral to a specialist clinic'.

Eighteen per cent prescribed clomiphene independently suggesting that they did not agree with the preceding criterion. Most responders (65%), however, agreed that clomiphene should be initiated by a hospital specialist.

Guidelines

Eighty-nine per cent agreed that there should be local guidelines for the investigation, management and referral of infertile patients. Twenty-seven per cent currently follow such guidelines, 66% were unaware of any local infertility guidelines and five per cent had local guidelines but did not follow them. Ninety-three per cent would welcome guidelines.

Rank	Suggested Criteria For Good Quality Care in General Practice	Agree %
1	The investigation of infertility should include both partners from the outset.	90
2	There should be agreed local guidelines for the investigation, management and referral of infertile patients.	89
3	The presence of amenorrhoea, oligomenorrhoea, oligospermia, a history suggestive of pelvic pathology or Abnormal findings on examination of either partner should result in early referral to a specialist clinic.	88
4	A day 21 plasma progesterone level should be the basic investigation of ovulation in a regularly menstruating female.	84
5	A full medical, social and sexual history of both partners should be obtained.	82
6	The female partner's rubella status should be checked.	75
7	The female partner should be advised to take folic acid supplements while attempting to achieve pregnancy.	74
8	Treatment of anovulation with clomiphene should always be initiated by a specialist hospital clinic rather than in general practice.	65
9	The initial investigation of the male partner should include two semen samples at least one month apart.	60
10	Temperature charts are of limited use and couples should be discouraged from completing them.	41
11	A pelvic examination of the female partner, a genital examination of the male partner and a general examination of both partners should be performed by the referring general practitioner.	38
12	There are no other biochemical or hormonal investigations of the female partner that are relevant in general practice.	19

Table 13 Results of the general practice questionnaire survey. The 12 suggested criteria for good quality care for the management of infertility in general practice. The criteria are ranked according to the percentage of responders who agreed or strongly agreed with the statement as a criterion for good quality care.

Case Note Review in Primary Care: A Pilot Study

General practice subcommittees were contacted in three regions (Tayside, Aberdeenshire and Lothian) to recruit general practices that were agreeable to participate in a prospective case note audit. Twenty-five practices volunteered. General practitioners identified patients who consulted them with infertility over a six month period. Patients were eligible for the audit whether they were attending with infertility for the first time or if this was an ongoing problem. Women who were attending a hospital specialist for infertility management were excluded. The case notes were then reviewed by one of two audit researchers (VS/GP) and standardised data recorded. The case notes of seventy-five women were reviewed in this way.

Information was collected in relation to 13 aspects of care that were relevant to the criteria for good quality care in the postal questionnaire survey. These are shown in Table 14 along with the percentage of records where the criterion had been met.

Criterion for Good Quality Care	% of cases where criterion was met (n=75)
Couple seen together at the surgery any time.	5
Duration of infertility documented.	84
Pelvic examination of female partner.	33
Day 21 plasma progesterone checked.	63
Other hormonal tests in regularly menstruating woman.	44
Rubella status checked.	56
Asked to keep a temperature chart.	4
Advice about folic acid documented.	19
Treated with clomiphene.	9
Medical history of male partner obtained.	13
Genital examination of male partner.	5
Semen analysis performed or arranged.	33
Inquired about coital frequency.	7

Table 14 The percentage of cases where information from the *general practice case notes* suggested that the criterion for good quality care had been met.

Audit of General Practice Referral Letters in the Hospital Records

The First Round of Audit

Information, relating to the aspects of management which had been undertaken in primary care, was collected from the general practice referral letters in 1241 hospital case notes of patients attending gynaecologists with infertility during the first round of audit in 1996. The percentage of case notes where the general practice referral letter suggested the criterion had been met is shown in Table 15.

History and Examination	%	(n)
Couple seen together by general practitioner	17	(215/1237)
Medical history of male partner obtained	36	(426/1179)
Medical history of female obtained	85	(1037/1226)
Genital examination of male partner performed	1	(12/1166)
Pelvic examination of female partner performed	17	(211/1224)

Basic Investigation of the Female Partner	%	(n)
Day 21 progesterone	48	(598/1241)
Temperature charting	1	(12/1241)
Rubella Status checked	10	(12/1241)

Hormonal Investigations Performed for Women with a Regular Menstrual Cycle (n=813)	%	(n)
Thyroid function tests	19	(152/813)
Plasma FSH/LH	22	(175/813)
Plasma Oestradiol	8	(68/813)
Plasma prolactin	17	(135/813)

Hormonal Investigations Performed for Women with an Irregular Cycle /Oligomenorrhoea / Amenorrhoea (n=393)	%	(n)
Thyroid function tests	20	(78/393)
Plasma FSH/LH	29	(114/393)
Plasma Oestradiol	12	(45/393)
Plasma prolactin	17	(89/393)

Periconceptual Folic Acid Supplements	%	(n)
Advice to female partner documented in letter	2	(19/1214)

Semen Analysis	%	(n)
At least one performed	34	(420/1241)
Two or more performed	6	(73/1241)

Table 15 The percentage of cases where information from the *general practice referral letter* in the hospital case notes suggested that the criterion for good quality care had been met.

Comparison Between the Two Rounds of Audits

Since it was not possible to for general practitioners to improve pre-existing referral letters, only new referrals from primary care were used to compare the first and second rounds of audit. There were 459 patients attending for their initial hospital consultation for infertility in the first round of audit, and 343 in the second round. The results of the review of the general practice referral letters for new patients review are shown in Table 16.

The results are very consistent between the two rounds of audit. There was however a significant increase in the percentage of male partners who had a semen analysis performed in primary care: 36.4% in the first round and 42.8% in the second round ($P < 0.05$). There were other small increases in relation to examination of the couple and history taking.

Aspect of Care	1 st Round of Audit (1996)	2 nd Round of Audit (1997)
Duration of Infertility (months)	Mean=28 Median=18 Range=1-192 (n=426)	Mean=27 Median=18 Range=1-216 (n=309)
Medical history of male partner recorded	38.7% (167/431)	33.0% (111/336)
Medical history of female partner recorded	86.8% (394/454)	83.3% (280/336)
*General examination of male partner recorded	4.0% (17/428)	9.0% (30/332)
*General examination of female partner recorded	26.8% (121/452)	35.7% (120/336)
*Genital examination of male partner recorded	0.7% (3/422)	5.8% (19/330)
Pelvic examination of female partner recorded	19.4% (87/449)	22.9% (77/336)
Couple seen together by general practitioner	20.1% (92/457)	20.7% (71/343)
Day 21 progesterone	51.0% (234/459)	49.6% (170/343)
Temperature charting	1.3% (6/459)	0% (0/343)
*Rubella immunity checked	9.2% (42/459)	14.3% (49/343)
Hormonal Investigations Performed in Women with a <i>Regular</i> Menstrual Cycle	1 st Round of Audit (n=438)	2 nd Round of Audit (n=236)
Thyroid function tests	16.5% (54/328)	16.1% (38/236)
Plasma FSH/LH	20.4% (67/328)	20.3% (48/236)
Plasma oestradiol	6.7% (22/328)	8.5% (20/236)
Plasma prolactin	14.0% (46/328)	15.3% (36/236)
Hormonal Investigations Performed in Women with an <i>Irregular</i> Menstrual Cycle / Oligomenorrhoea / Amenorrhoea	1 st Round of Audit (n=111)	2 nd Round of Audit (n=95)
Thyroid function tests	20.7% (23/111)	21.0% (20/95)
Plasma FSH/LH	33% (37/111)	28.4% (27/95)
Plasma oestradiol	8.1% (9/111)	5.3% (5/95)
Plasma prolactin	17.1% (19/111)	13.7% (13/95)
Semen Analysis		
* At least one semen analysis performed /arranged (p<0.05)	36.4% (167/459)	42.8% (147/343)
Two or more semen analyses performed /arranged	6.1% (28/459)	9.0% (31/343)
Advice about Folic Acid documented	2.2% (10/452)	3.0% (10/329)

Table 16 Comparison of the general practice letters for new referrals between the first and second rounds of audit.
Statistically significant increase (p<0.05).

3.5 THE PATIENT SATISFACTION SURVEYS

The Female Partner

Patient Satisfaction in the First Round of Audit

Changes in Patient Satisfaction between the Two Rounds of Audit

The Male Partner

The Female Partner

Patient Satisfaction in the First Round of Audit

Of the women surveyed 59% (806/1366) responded to the questionnaire. The response rates for individual hospitals ranged from 45% (31/69) to 81% (79/97). Information from the case note review was linked up with the results of the questionnaire to give more background information about the responders. There were no significant differences between responders and non-responders in terms of age (ANOVA $p=0.72$) or whether they had a previous successful pregnancy (Mantel-Haenszel test $p=0.25$). The mean age of responders (and of non-responders) was 30 years and only 27% of them had a history of one or more successful pregnancies.

The average number of clinic attendances was 2.7 and the average duration of infertility was three years. Thirty-one per cent had attended the clinic only once. The diagnosis was unavailable or not yet established in 51% (415/806) of cases. Of those with an established diagnosis, 25% had unexplained infertility, 22% (84/391) were due to a male factor, 16% were due to an ovulatory problem, 9% were due to tubal damage, 7% were due to endometriosis and 21% were due to other or multiple factors.

Overall Satisfaction

Overall satisfaction with medical care was high with 87% (692/800) of women saying they were satisfied or very satisfied with the care they had received. Eleven per cent (92/800) were dissatisfied and only 2% (15/800), very dissatisfied. There was no significant difference in overall satisfaction with the clinic between those attending for the first time (250/278; 90% satisfied) and those who had attended more than once (422/495; 89%) (Chi-squared test $p=0.74$) nor between those who had been seen by a consultant on a least one occasion (469/534; 89% satisfied) and those who had never been seen by a consultant (223/266; 84% satisfied) (Chi-squared test $p=0.076$). There were, however, significantly more satisfied patients among those who attended a dedicated infertility clinic (533/601; 89%) as compared to those who attended a general gynaecology clinic (145/178; 81%) (Chi-squared test $p=0.004$). There was also a significant difference in satisfaction between those patients who attended the clinic with their partner on at least occasion (435/486; 89% satisfied) and those who had never attended with their partner (243/293; 83% satisfied) (Chi-squared test $p=0.006$). Of 495 patients who had attended the clinic on more than one occasion, satisfaction was more common among those who had been seen by only one doctor (175/190; 92%) compared to those who were seen by more than doctor (248/305; 81%) (Chi-squared test $p=0.0007$).

Organisational Aspects of the Clinic

Women were divided over the type of clinic they would prefer to attend given a choice. While 40% (319/800) said they would prefer to attend a dedicated infertility clinic, 10% (82/800) favoured a mixed gynaecology clinic and 50% (399/800) said the type of clinic was not important to them.

Thirty-nine per cent (312/796) had not been asked to bring their partner to the clinic at any time and 18% (147/794) had experienced problems with a lack of continuity of medical staff.

Waiting Time at the Clinic

Responders were asked about the time they had waited at their most recent clinic visit. Forty-nine per cent (393/804) did not see a doctor until after their allotted appointment time but, of those taken late, 69% (273/393) felt that the delay was acceptable. The average reported delay was 25 minutes and overall, 6% of patients waited an hour or more beyond their appointment time.

The doctor's attitude

More than 90% of women felt that the doctor at their most recent clinic visit listened to what they had to say, behaved politely and appeared good at his or her job. However, approximately 1 in 5 patients thought the doctor did not show an interest in them as a person, did not seem sympathetic, was not easy to ask questions of or did not let them take part in decision making (Table 17). Twelve per cent (93/771) said the doctor did not explain things to them and 45% (360/805) had questions they would have liked to ask at the clinic, but did not have the opportunity to do so.

Information and explanation

Twenty-one per cent (160/759) felt there had been little or no information given to them about the possible causes of their infertility. Overall, only 33% (257/784) had received written information from their clinic and 78% (603/771) would like more literature. Forty-seven per cent (419/792) felt they had not been given a clear plan for the future and, of 387 women who had received drug treatments, 23% (90/387) reported receiving little or no information about their treatment or possible side-effects.

Investigations

Ninety-four per cent (614/650) of patients who had undergone investigations said these had been explained to them but 20% thought that there had been excessive repetition of tests. More than a quarter (27%; 161/592) said it had taken too long for the investigations to be carried out and 32% (195/603) felt that the time taken to receive results was too long.

Emotional support and counselling

Only 14% (109/787) felt they had been given enough help from the clinic with the emotional aspects of infertility. Fourteen per cent of responders said they had been offered counselling and 57% (431/761) said they would take up infertility counselling if it was offered to them at this point in time.

Ranking of Aspects of Care

Responders were asked to rank five aspects of care (Table 18) in order of importance to them, one being the most important and five the least important. A total of 618 (77%) of the responders answered this question completely. Women who omitted the question or answered incompletely were excluded. "The doctor's attitude" was most commonly ranked number one, closely followed by "the information and explanation given". "The waiting time at the clinic" was least commonly ranked as number one. The ranks were summed for each of the aspects of care to give an overall rank (Table 18). Again, "the information and explanation given" and "the doctor's attitude" were ranked most highly of the five aspects of care.

Written Comments

All 806 questionnaires that were returned were reviewed and the written comments categorised into common themes. A total of 598 women (74% of responders) made written comments. Of those, 25% praised the attitude of the clinic staff (Table 19). Eleven per cent (66/598) of comments related to problems with a lack of continuity of medical staff and 9% (53/598) to dissatisfaction with the doctor's attitude towards them.

When asked to suggest any changes which they felt may improve the service, 10% (59/598) 'cited more written information'. Greater availability of 'counselling' and 'more help with the emotional aspects of infertility', 'more information and explanation', 'greater continuity of medical staff' and 'more frequent clinic appointments' were also among the other most common suggestions (Table 20).

A number of quotes that illustrate some recurring themes in the written comments are shown in Table 21.

Did the doctor at your most recent hospital visit:	Response of "Yes"	
	Number	(%)
behave politely towards you?	782/794	(98)
appear good at his/her job?	741/778	(95)
listen to what you had to say?	739/786	(94)
explain things to you?	687/781	(88)
make it easy for you to ask questions?	632/781	(81)
show an interest in you as a person?	616/775	(79)
appear sympathetic?	600/755	(79)
let you take part in any decisions?	590/751	(79)

Table 17 Responses from female responders to specific questions about the attitude of the doctor at the most recent clinic visit.

Aspect of care	Overall Rank (Sum of scores)	Responders who ranked it as number one.	
		Number (n=620)	(%)
The information & explanation given	1 (1265)	211	(34)
The doctor's attitude	2 (1360)	241	(39)
The way the investigations are done	3 (1618)	107	(17)
Help with the emotional side of infertility	4 (2237)	33	(5)
The waiting time at the clinic	5 (2828)	26	(4)

Table 18 The overall rank given to each of five suggested aspects of care and the percentage of female responders who chose each one as the most important to them.

Subject of the Written Comments	Responders	
	Number (n=598)	(%)
Praising the attitude of the staff in general	150	(25)
Problems with a lack of continuity of medical staff	66	(11)
Dissatisfaction with the doctors attitude towards them	53	(9)
Inadequate information and explanation	42	(7)
Good explanation and information	41	(7)

Table 19 The five commonest subjects of written comments made by female responders in the patient satisfaction questionnaire.

Suggestions as to how the service could be improved	Responders	
	Number (n=598)	(%)
More written information	59	(10)
More counselling / help with the emotional aspects of infertility	54	(9)
More explanation and information	33	(5)
Greater continuity of medical staff	30	(5)
More frequent clinic appointments	25	(4)

Table 20 Written suggestions made by female partners as to how they would suggest the service could be improved.

"I have found several nurses and doctors very understanding and I now realise I am not the only one with this problem"

"You can talk freely with the doctor and he explains everything which makes my husband and I feel so much easier with our situation"

"Some of the questions I've asked which were really worrying me were treated as though they were trivial"

"Doctors could use more interpersonal skills to ask about me as a person. I have never been asked how I felt about any aspect of my treatment"

"Doctors in this field need to be able to put their patients at ease. It's a very stressful and emotionally draining time for a couple. Doctors need to be aware of this and show it to patients"

"Written leaflets explaining treatments and procedures could be given out"

"I found the reading material very helpful. It helped in the discussion between me and my husband"

"Explanation of investigations and time scales would be helpful"

"Seeing different doctors at every visit whose opinions vary considerably, we have a distinct sense of inconsistency of care"

Table 21 Selected quotes from responders illustrating some of the commonest themes among the written comments in the female partner satisfaction questionnaire.

Changes in Patient Satisfaction between the Two Rounds of Audit

The response rate in the second round of audit was 47% (512/1080). The results of the second round of audit are summarised below. The responses were very similar between the two rounds of audit. Significant differences were seen in two areas. These were increases in the percentage of patients who were asked to bring their partner to the clinic and in the percentage given written information.

	1 st Round of Audit		2 nd Round of Audit		
	Number	%	Number	%	
Response rate	(806/1366)	59	512/1086	47	
Taken on time at clinic	411/804	51	239/509	47	
Delay acceptable	273/393	69	184/269	68	
Any unanswered questions	360/805	45	215/508	42	
Satisfaction with this visit	692/800	86	446/510	87	
Asked to bring partner	484/796	61	379/506	75	P<0.001
Should partner be invited?	Not asked		467/506	92	
Advised about folic acid	Not asked		178/502	35	
Investigations explained	614/650	94	423/458	92	
Repetition of investigations	120/598	20	78/417	19	
Investigations too slow	161/592	27	119/425	28	
Results take too long	195/603	32	123/401	31	
Little/ no information about causes	160/759	21	89/487	18	
Most information about causes	599/759	79	398/487	82	
Drug treatments not explained	90/387	23	56/215	26	
Enough emotional help	109/787	14	72/499	14	
Been offered counselling	113/792	14	83/508	17	
Would take up counselling	431/761	57	253/489	52	
Given written information	257/784	33	202/508	40	P=0.001
Request more written information	603/771	78	381/501	76	
Given a clear plan	419/792	53	281/503	56	
Overall satisfaction with care	692/800	87	453/509	89	
<i>Did the doctor at your most recent hospital visit:</i>	Response="Yes"		Response="Yes"		
	Number	%	Number	%	
behave politely towards you?	782/794	98	504/510	99	
appear good at his/her job?	741/778	95	478/500	96	
listen to what you had to say?	739/786	94	477/507	94	
explain things to you?	687/781	88	448/505	89	
easy for you to ask questions?	632/781	81	427/506	84	
show an interest in you?	616/775	79	418/501	83	
appear sympathetic?	600/755	79	397/497	80	
let you take part in any decisions?	590/751	79	385/485	79	

Table 22 Comparison of the responses to female partner's satisfaction survey between the first and second rounds of audit.

The Male Partner

Introduction

At the time of the second round of audit in 1997, a short satisfaction questionnaire for the male partner (Appendix 8) was sent out along with the questionnaire for the female partner. The response rate was 46% (502/1080).

Results

Eighty-seven percent (438/502) of responders had attended the clinic with their partner on at least one occasion. Fifty-six percent (282/502) said they had been asked by their partner to attend and only 49% had been invited to attend by the hospital clinic. Fifteen percent said they had not been asked to attend at any time. Ninety-eight percent (477/489) thought that men should attend the clinic with their partner. Of those who had attended the clinic, 88% were satisfied or very satisfied with the most recent visit and the majority rated aspects of the doctor's attitude highly. The results are summarised in Table 23.

The doctor at the hospital clinic:	Male Partner	Female Partner	
Listened to what I had to say	95% (412/434)	94% (477/507)	Chi ² =3.8 p=0.05
Showed an interest in me as a person	78% (334/428)	83% (418/501)	
Behaved politely towards me	99% (424/427)	99% (504/510)	
Appeared good at his/her job	96% (411/427)	96% (478/500)	
Made it easy for me to ask questions	87% (373/429)	84% (427/506)	
Appeared sympathetic	81% (344/425)	80% (397/497)	
Explained things to me	90% (387/428)	89% (448/505)	
Let me take part in any decisions	81% (338/419)	79% (385/485)	

Table 23 Comparison of male to female responses about the doctor's attitude in the patient satisfaction questionnaire.

There were no significant differences in satisfaction with the doctor's attitude between male and female partners. Men appeared less likely to feel that the doctor showed interest in them as a person but this just failed to reach significance ($p=0.05$). Thirty-one percent said they still had questions they would have liked to ask at the end of the clinic visit as compared to 42% of the female partners ($\text{Chi}^2=11.5$; $p<0.05$). Forty-six per cent said they had received written information and 65% requested more literature. Only 13% felt they had been given enough help with the emotional aspects of infertility.

3.6 PSYCHOLOGICAL HEALTH IN WOMEN WITH INFERTILITY

Response Rates

Analysis of the psychological survey of the patient questionnaire was performed for the second round of audit (see Methods and Discussion Section 2.2 and Discussion Section 4.3). Forty-seven percent (512/1080) of patients answered part or all of the psychological section of the questionnaire.

No significant differences were identified between responders and non-responders in terms of age, primary or secondary infertility, duration of infertility, number of clinic attendances or diagnostic category (Table 24).

Characteristics of the Sample Population

The mean age of responders was 31 years (range 19 to 47 years) and the mean duration of infertility was 36 months. Forty-per cent had attended the clinic on only one occasion (range one to 18 attendances). Sixty-one per cent had primary infertility (para 0+0) and 23% (117/512) had a history of one or more pregnancies progressing past 24 weeks gestation.

GHQ-12 Scores

Forty-seven percent (507/1080) of women surveyed answered the GHQ-12. Scores of $\geq 6/12$ (0.5) or $\geq 8/12$ (0.66) have been recommended as 'positive' scores and associated with potentially clinically significant levels of psychological distress.[85] The test author has recommended that a score of $\geq 6/12$ is used as the threshold for "caseness". [85]

In this study, the mean score was 5.9/12. Forty-seven percent (239/507) of responders had a positive score of $\geq 6/12$, and 32.5% had a score of $\geq 8/12$. The response rate to the questionnaire was low and the responders to the questionnaire cannot be assumed to be representative of infertility patients as a whole. If, given the unlikely but possible situation, that the above responders were the only ones in the entire study population that had positive GHQ-12 scores, still 22.1% (239/1080) of the all women involved in the infertility audit would have had a positive score and 15.3% (165/1080) had a score of $\geq 8/12$.

Scores for the Items from the SF-36

Five hundred and twelve women answered part or all of the selected questions from the SF-36. The mean scores were compared with the published normative data for women in the same age bracket (16 to 24 years, 25 to 34 years and 35 to 47 years).[84] The infertility patients had lower scores in all three dimensions suggesting poorer mental health. These differences were statistically significant for social functioning in all three age groups ($p < 0.01$), for emotional role in responders aged 25 to 34 years ($p < 0.01$) and for the mental health dimension in responders aged 16 to 34 years. (Table 25).

Correlation between GHQ-12 and SF-36 Scores

The GHQ-12 scores were significantly correlated ($p = 0.01$) with the SF-36 scores for the 'role emotional' items (Spearman Rank Correlation = -0.620), the 'role social' items (Spearman Rank Correlation = -0.677) and the mental health (MHI-5) items (Spearman Rank Correlation = -0.757).

Internal Consistency for the GHQ-12 and MHI-5

Cronbach's alpha was 0.85 for the GHQ-12 and 0.88 for the mental health dimension of the SF-36 (MHI-5). The reliability coefficients were 0.83 for the GHQ-12 and 0.88 for the MHI-5.

Scores and Demographic Details

There was a significant correlation between age and both the GHQ-12 score (Spearman rank correlation coefficient = -0.137; $p < 0.01$) and the MHI-5 (Spearman rank correlation coefficient = 0.202; $p < 0.01$) suggesting a trend towards better psychological wellbeing in older women.

There was no significant difference in the GHQ-12 scores between the 448 women who owned or had access to a car (5.8/12) and the 57 who did not (6.6/12). There was no significant difference in the GHQ-12 scores between the 478 women who owned their own home (5.8/12) and the 124 who rented a home (6.1/12).

Physical Health

Ninety three percent (474/510) reported their health overall to be excellent, very good or good. Six per cent (33/510) said it was fair and one per cent (3/510) said it was poor. There was a statistically significant correlation between the GHQ-12 score and general health, poorer general health being associated with poorer psychological wellbeing (Spearman rank correlation coefficient = -0.180; $p < 0.01$).

Duration of Infertility

The GHQ-12 score appeared to be independent of the duration of infertility (correlation coefficient = 0.03) and there was no significant difference between responders whose infertility was greater or less than two years duration or greater or less than three years.

There was, however, a positive correlation between the number of times the patient had attended the clinic and the GHQ-12 score (Spearman rank correlation coefficient = 0.211; $p < 0.01$). The GHQ-12 was significantly higher in women who had attended the clinic on more than occasion (mean score = 6.3) than in those who had only a single visit (mean score = 5.2) ($p < 0.01$).

Past Reproductive History

Women who had at least one existing child (or a pregnancy that had proceeded to at least 24 weeks gestation) had similar GHQ-12 scores (mean score = 6/12) to those who had no children (mean score = 6/12).

Diagnostic Category

The mean score for the GHQ-12 (6.4/12) for the 111 women with an identified female cause for infertility (tubal, ovulatory or endometriosis) was higher than the score (5.7/12) for the 393 women in any of the other diagnostic categories (unexplained infertility, male factor, coital problem, cause not yet established, other or mixed) but this difference failed to meet statistical significance ($P = 0.07$). Although the mean score was higher, there was no significant difference between the mean GHQ-12 score in 35 women with a tubal problem (6.7/12) as compared to those in any of the other diagnostic categories (5.8/12). There was no significant difference in the GHQ-12 scores between those responders for whom a probable cause for their infertility had been established and those whose infertility was unexplained or the diagnosis not yet established.

Perceived Need for Emotional Help

Eighty-six percent (425/495) of responders to the GHQ-12 felt there was not enough help with the emotional aspects of infertility. The mean GHQ-12 (6.0/12) in this group was not statistically different from the mean GHQ-12 (5.5/12) in the fourteen percent of responders who felt there was enough help with the emotional aspects of infertility.

Women who said they would take up counselling had significantly higher scores for both the GHQ-12 ($p < 0.01$) and for the three items of the SF-36 ($p < 0.01$), than those who said they would decline counselling (Table 26). Forty-three percent (108/252) of responders who indicated that they would attend counselling had a GHQ-12 score of $\geq 6/12$ compared to 20.5% (48/234) of those who would not. Sixty-six percent (150/229) of those responders with a positive GHQ-12 score ($\geq 6/12$) said they would attend counselling if it was offered to them.

	Responders (n=504) % (Number)	Non-Responders (n=566) % (Number)	Mean GHQ-12 in Responders
Male factor	14 (73)	14 (79)	5.3
Ovulatory problem	13 (64)	14 (77)	6.5
Tubal	7 (35)	6 (35)	6.6
Coital	0.2 (1)	0.3 (2)	7.0
Endometriosis	2 (12)	2 (13)	5.4
Unexplained	14 (69)	15 (85)	6
Not yet established	41 (206)	39 (220)	5.7
Other	3 (17)	3 (18)	5.6
Mixed	5 (27)	6 (37)	6.0

Table 24 The percentage of responders and non-responders in each diagnostic category in the survey of psychological health and the mean GHQ-12 for each diagnostic category.

	Mean Scores by Age Group Jenkinson et al 1993				Mean Scores by Age Group GAPS 1997		
	18-24	25-34	35-44		16-24	25-34	35-47
Age (years)							
Social Functioning	85.7	87.1	86.7		66.9*	72.2*	77.2*
Emotional Role	78.8	80.6	80.3		69.3	68.3*	75.5
Mental Health	70.2	71.6	71.6		56*	61.6*	66.5

Table 25 Mean scores for items of the SF-36 from Jenkinson et al. [84] and the results for the present study for different age groups.
*Statistically significant difference (P<0.05).

	Mean Score	
	"Yes" to counselling	"No" to counselling
GHQ-12	6.8	4.9*
SF-36 Mental Health Scale	55.4	69.1*
SF-36 Social Functioning Scale	21.3	81.7*
SF-36 Role emotional Scale	60.3	81.5*

Table 26 Mean scores for the GHQ-12 and the three selected items of the SF-36 in those patients who answered "yes" or "no" to the question "At this point in time would you take up an offer to speak to an infertility counsellor?"
Higher scores on the SF-36 are associated with greater psychological wellbeing.
Higher scores on the GHQ-12 are associated with an increased risk of clinically significant psychological disturbance, specifically anxiety and depression.
* Statistically significant difference (P<0.05).

4. DISCUSSION

- 4.1 **DISCUSSION OF THE METHODOLOGY**
 - The Choice of Topic**
 - Agreeing a Consensus**
 - Searching for Evidence**
 - Criterion based Audit**
 - The Advantages*
 - The Disadvantages*
 - Ethical Approval**
 - Dissemination of Results**

- 4.2 **DISCUSSION OF THE RESULTS**
 - The Consensus Surveys**
 - Questionnaire Survey of Hospital Gynaecologists*
 - Questionnaire Survey of General Practitioners*
 - The Hospital Case Note Review**
 - General Practice Referral Letters*
 - The Hospital Notes*
 - The Patient Satisfaction Survey**
 - The First Round of Audit*
 - Changes Between the Two Rounds of Audit*
 - The Questionnaire for the Male Partner*
 - Psychological Health in Infertile Women**

- 4.3 **DISCUSSION OF THE PROJECT OVERALL**

- 4.4 **THE FUTURE: WIDER CLINICAL EFFECTIVENESS INITIATIVES AND THE ROLE OF AUDIT WITHIN THIS**
 - Evidence Based Medicine**
 - Overview*
 - Searching for Evidence*
 - Critical Appraisal*
 - Systematic Reviews*
 - The Cochrane Collaboration*
 - NHS Centre for Reviews and Dissemination*
 - "Evidence Based Medicine"*
 - Clinical Practice Guidelines**
 - SIGN Approach to Guideline Development*
 - Criteria for Guidelines*
 - Concerns about Guidelines*
 - Legal Implications*
 - Dissemination and Implementation*
 - Guidance from the Government*
 - Managed Care**
 - Changing Physician Behaviour**

4.1 DISCUSSION OF THE METHODOLOGY

The Choice of Topic

Infertility was in many respects a good topic for audit. It is a common problem and contributes substantially to the gynaecological outpatient workload in Scotland.[77] It would appear to be a growing problem in terms of the number of patients presenting for treatment, although whether there has been a real increase in prevalence remains controversial.[7]

The management of infertility is evolving in terms of effective treatment options, many of which are costly both financially for the health service and emotionally for patients.[102, 227-230] A number of infertility guideline documents have been published but practices are known to vary widely between centres.[2,3,231] In addition, patients have expressed dissatisfaction with infertility services.[4,5,109] Whilst assisted reproductive techniques are regulated by the HFEA, the investigation and initial management of infertility, including the use of ovulation induction, is not.[200]

There were a number of reasons, however, why infertility proved to be a less suitable topic. The wide variations in care reflected to some extent a paucity of clear research evidence about many practices, particularly relating to fundamental aspects of care.[186,232] Many 'infertile' patients conceive spontaneously and large studies are required to distinguish between intervention dependent and intervention independent pregnancies. In addition, the decision trees are often complex in infertility care and multiple factors (such as patient age, parity and availability of resources) influence decisions about management. These factors may not be obvious in data collected for the purposes of audit. Infertility is also a highly emotive problem and patient preferences may influence the decisions doctors make.

Agreeing a Consensus

There is widespread agreement that criteria for quality initiatives such as guidelines and audit should be evidence based wherever evidence is available.[233] Where evidence does not exist or is unclear, then consensus represents the next best compromise. The dictionary definition of 'consensus' is "an opinion held by all or most".[234] Therefore, if 50% or more of the responders agreed with a suggested criterion for good quality care then a consensus had been reached in favour of that criterion.

The strength of consensus in this survey was marked by a cut-off of 66% above which support for a statement was described as being 'stronger'. This was an arbitrary cut-off, endorsed by members of the project steering committee. It was designed to highlight those criteria where there was a clear majority in favour in comparison to those where there was only a fine margin of agreement.

In previous GAPS surveys the results were expressed as an 'agreement score'[80] The agreement scores were calculated by allocating each response of *strongly agree* a score of +2; of *agree* +1; of *neutral* 0; of *do not feel qualified to answer* 0; of *disagree* -1 and of *strongly disagree* -2. The scores for each criterion were summed and expressed as a percentage of the maximum possible score had all patients strongly agreed. It was decided, however, in this project to use the percentage of responders who agreed with the criterion as an indication of the

support for it, for two reasons. Firstly, if a clinician disagreed with a criterion he was unlikely to implement it whatever his level of disagreement.[241] Secondly the percentage agreement was simpler and did not change the ranking of the criteria in the infertility audit from that of the agreement score, in most cases.

Formal methods for achieving a consensus have been described but these are most applicable to groups with a small number of participants.[235,236]

The consensus exercise in this audit could have been restricted to a smaller group of 'infertility experts' but carrying out a survey of all consultants and senior registrars in gynaecology had other potential benefits. It was hoped that it would engender a sense of ownership of the project, encourage clinicians to review their own practices and allow them to compare their practices with those of other clinicians. More recently, however, a review from the Cochrane Database of Systematic Reviews concluded that there was no evidence of a significant improvement in the delivery of care by adding consensus processes such as this, to audit.[237]

The project was initiated by gynaecologists to audit gynaecology practice. However, although gynaecologists and general practitioners are the main providers of infertility care, other professionals, particularly urologists, also manage infertility patients but were not a primary focus for the project. The inclusion of urologists in the project would have provided a more complete picture.

Searching for Evidence

The suggested criteria for good quality care were based on a combination of review of published literature, including recent guideline documents, and discussion by the GAPS panel (Appendix 1). The literature review was based primarily on searches of the electronic databases Medline and BIDS-EMBASE over the past 20 years, paying particular attention to relevant systematic reviews and meta-analyses.

The development of computer databases and new software has made accessing relevant evidence easier but searching using Medline and other similar databases is not without problems.

The first problem is, that far from all medical research is published, and there is a publication bias towards those studies that show a significant difference between the study groups.[238] The second is that, although there are more than 60 commercially available biomedical databases, these are by no means comprehensive: only 3700 (25% of) biomedical journals are carried by Medline and 4700 by Excerpta Medica (Embase).[239,240]

There are additional problems with indexing of the papers included in the databases e.g. 'randomised controlled trial' has only been indexed in Medline since 1991. Indexing terms are, in some cases, wrongly allocated by professional indexers and authors may not specify their study methods clearly enough in the paper to allow appropriate indexing. Skill and training are required by the searcher to access the relevant studies using the index words. At least 50% of relevant trials are missed by experienced searchers and in the field of infertility this figure is probably a lot higher.[239,240]

There is a wealth of published literature on infertility but for many aspects of the initial management of infertility (e.g. initial investigations and examination of the couple) there is very little research information available. Fundamental steps in the investigation of patients are often not as readily amenable to randomised

controlled trials as treatment interventions, and may not have much influence on outcome in terms of pregnancy rates. They do, however, take time, cost money and sometimes have adverse psychological and physical effects on patients.[229] Rationalisation of the initial investigation and management of infertile couples may release more of the limited financial resources for more expensive treatment interventions such as in vitro fertilisation (IVF) and ovulation induction.

When studies are available, many are *not* based on randomised controlled trials.[232,239]

There are a number of published meta-analyses and the Cochrane Database of Systematic Reviews now includes a Subfertility Review Group which will be discussed later in the Discussion.[180,186,187,241] Relevant information from the Cochrane Database was used in the literature review. As the reviews from the Subfertility Review Group grow these should enable researchers and clinicians to assess the literature more effectively in future.

Criterion Based Audit

The Advantages

Previous GAPS projects have taken the format of criterion based audit and this worked well within a hospital setting. One of the advantages of this type of audit is that data can be collected by non-medical audit assistants. In this study, most audit assistants were existing hospital secretaries, some of whom had worked on previous GAPS audits. They had ready access to case notes, were able to identify the relevant patients, understood gynaecological terminology and knew where to find the required information in the case notes. Collecting the information from the case notes was in most cases simple. Occasional problems arose with reading or understanding the doctor's writing but this was readily rectified by discussion with the relevant clinician.

In criterion based audit, standard information is collected and this allows changes over time and differences among centres to be compared. Data collection does not interfere with the patient's clinical management and involves very little, if any, input from clinicians.

The Disadvantages

Deciding upon criteria for this type of audit is not always easy. For areas with most diversity in practices, research evidence is often limited or controversial, as discussed above. The absence of scientific evidence to support a practice does not mean that it is ineffective. Some practices are not amenable to randomised controlled trials. Rosser gives the example of a randomised controlled trial of cervical smears in the prevention of cervical cancer.[242] Surprisingly, however, some areas that we take as implicit in our daily practices have never been subjected to rigorous scientific evaluation.

Once the criteria had been agreed, the information needed from the case notes to measure practice relevant to each criterion had to be determined. For some of the criteria (e.g. delaying laparoscopy in couples with unexplained infertility or ovulation induction with clomiphene prior to laparoscopy) a number of different items of information were needed (e.g. the duration of infertility, the results of tests of ovulation, the patient's menstrual cycle and the duration of treatment with clomiphene). For two of the criteria (the use of infertility guidelines and monitoring

of ovulation induction) it was not possible to determine related practices from the case note review.

As infertility care crosses boundaries between primary and secondary care, information from both the general practice referral letter and the hospital case notes was required even for relatively simple criteria such as testing for ovulation. Criterion based audit is most amenable to simple statements about care and assessing the more subtle aspects of management can make the process complex and cumbersome. Analysis of the data collected was, therefore, not simple.

This type of audit also relies on accurate documentation in the case notes; but what is recorded does not always reflect what has happened to the patient. The use of structured case notes may, in future, help in ensuring all information is collected and that it can be audited in a simple way.

Criterion based audit assesses the process of care, with the somewhat optimistic assumption that this equates with good outcome for the patient. Live births would obviously be the best outcome indicator for infertility care and other indicators such as multiple pregnancy and complications of investigations or treatments could be secondary indicators. In reality, substantial improvements in the process of care are probably accompanied by much smaller improvements in outcome.[243] This could not be tested in a cross sectional study such as this. Finally, with any audit there is the potential for the 'Hawthorne Effect' when practice improves while clinicians are being observed.

Ethical Approval

There has been some controversy as to where audit stands in relation to medical ethics committees.[244] However, in 1994, a report of a working group to the Royal College of Physicians Committee on Ethical Issues in Medicine concluded that "Activities such as medical audit..... constitute medical practice and as such do not require independent ethical review".[245] The report also stated that "Research involving access to medical records....without direct patient involvement, requires neither explicit individual patient consent nor independent ethical review..". This would suggest that in the present study, the case note review would not require ethical approval or patient consent but the patient questionnaire would.

All of the relevant ethics committees were informed about the project. Most committees required a formal application and, in one case, mandatory attendance at a committee meeting. Three of the twelve committees, however, recognised the existence of the project but deemed that formal approval was not required for the project.

As a result of the decision by one ethical committee, questionnaires could only be sent to patients who had given written consent to participate in the satisfaction survey. All of the questionnaires were anonymised by coding and this was made clear to the patients in the covering letter. Completion of the questionnaire was entirely voluntary and the letter reassured patients that their decision to participate would not adversely affect their care in anyway.

The explanation given for the ethical committee decision was concern about confidentiality being broken if the letter was opened by someone other than the patient. Although this is a genuine possibility, most hospital correspondence, including appointments for infertility clinics, is sent through the post and risks a

similar breach of confidentiality. The decision was reviewed by the ethics committee in 1997 and subsequently reversed for the second round of audit.

Dissemination of Results

Dissemination of the results constitutes one of the most crucial aspects of audit. The main method of disseminating the results of this audit was through two feedback reports sent out at the end of the first round of audit. One report was mailed to all consultants and senior registrars in obstetrics and gynaecology in Scotland and a second shorter report to all principals in general practice. For hospital clinicians, each report was individualised so as to highlight the main recommendations from the audit for the centre where the clinician worked. The findings of the audit were presented at a number of local and national meetings including post-graduate meetings and outreach visits to participating centres. Some of the results of the audit were also published in peer reviewed journals.[86-88]

The most effective ways of promoting changes in clinical practices remain unclear. The use of written information would appear to have a relatively small influence on clinical behaviour and sending educational reminders to clinicians may be just as effective as medical audit and feedback in promoting improvements in care.[237] The recipients of the feedback reports were mainly consultants who should be the leaders in terms of making changes in clinical practices within departments. Many patients are, however, seen by more junior members of staff. Considerable resources would have been needed to provide a report for all of these doctors and this was not possible in the present project. Unless the audit findings were made available to these doctors through post-graduate education initiatives or local guidelines, their practices would not have been influenced. In addition, many junior doctors change posts as often as every six months and regular updates or departmental guidelines would be needed to keep these members of staff up to date.

Senior staff can, however, be a powerful force in implementing changes in practice and the support of professionals who lead clinical departments is really needed to do so.[246,247] Focusing on consultants and senior trainees was probably the most likely way of being effective.

Interventions which may be more effective than written reports include those that facilitate clinical changes (eg. office facilitators) or reinforcing methods (eg. reminders or structured case notes) used in combination with information dissemination.[243] These were not used in the current study but may have increased the impact of the audit.

Clinical practice guidelines for infertility have been shown to improve the process of care in a number of settings and in the management of infertility in particular.[90] The development of guidelines was out with the remit of the project however, the Royal College of Obstetricians and Gynaecologists (RCOG) has now developed evidence based guidelines for the Investigation and Management of Infertility. The role of clinical practice guidelines will be examined later in the Discussion section.

4.2 DISCUSSION OF THE RESULTS

The Consensus Surveys

Questionnaire Survey of Hospital Gynaecologists

The consensus surveys achieved high response rates for both hospital gynaecologists and general practitioners, suggesting both a willingness to participate in audit and an interest in the management of infertility.

The results of the questionnaires demonstrated that, for a number of aspects of care, what clinicians believe should happen and what they actually do in practice, are very different. This dichotomy was most apparent in relation to relatively simple practices (e.g. 93% of clinicians agreed that clinical guidelines should be used but only 48% said they were actually using such guidelines; 94% agreed that both partners should be seen together from the outset but only 31% routinely made arrangements to do this). The reasons for this disparity remain unclear but may reflect reluctance to question or change pre-existing practices.

Clinicians' opinions were concordant on most aspects of infertility care but some varied widely (e.g. with regard to the importance of infertility counselling, the use of the post coital test and the efficacy of drug treatments for endometriosis associated infertility). In the case of infertility counselling, the variation in opinion may reflect uncertainty in the medical literature as to the effectiveness of this intervention. However, there is substantial published literature and compelling research evidence about the post coital test and drug treatments for endometriosis and this has been reinforced by the publication of reviews and meta-analyses on these subjects. While the GAPS project documented these observations, it did not address the reasons why opinion varied so much.

For the criteria relating to genital examination, clinicians favoured examining the female partner but not the male partner. There is, however, very little published research in this area that could be used to support examination of either partner. Infertility would appear to be perceived as primarily a female, rather than couple-based, problem to most gynaecologists and they are obviously more experienced in female examination. Several gynaecologists expressed the opinion in written comments on the questionnaires that they did not feel trained or proficient at examining the male partner. Joint clinics with urologists may be the answer and these are currently undertaken in some Scottish hospitals.

For some of the criteria, including the use of drugs for the management of idiopathic male infertility, a minority (15% in this case), did not feel qualified to comment on this statement. It would appear that clinicians are not always well informed about existing scientific evidence or that if they are, they value personal experience as highly, or more highly, than scientific evidence.

Gynaecologists strongly supported the need for clinical practice guidelines for infertility.

Questionnaire Survey of General Practitioners

It was not possible to survey all Scottish general practitioners because of the resources that this would involve. A representative picture of the opinions and current practices of general practitioners in Scotland was, however, sought by stratifying the sample using factors that may influence the management of infertility.

The high response rate suggests that infertility is an area of interest to general practitioners and the survey highlighted simple changes which could improve care in general practice.

General practitioners sometimes encounter logistical problems that may impede implementing change. These include difficulties organising semen analysis and employing a couple based approach when both partners are not registered with the same practice. There is also a minority of general practitioners who believe that this is a specialist problem and do not feel it is appropriate to investigate or examine couples in primary care.

Opinion amongst general practitioners, as well as reported practice, was at odds with published scientific evidence in relation to the use of temperature charting. It is perhaps easier for general practitioners do something rather than nothing for patients and this would seem like an innocuous approach. Temperature charting is, however, often stressful for patients and probably does little to improve conception rates. It is hoped that the audit will raise awareness of this.

General practitioners expressed an interest in infertility but were not always well equipped to investigate infertility patients. They agreed with most of the suggested criteria but disagreed that they should not be performing more detailed hormonal investigations in primary care. The case note review however subsequently revealed that these tests were often being used inappropriately in general practice.

Infertility guidelines have been shown to improve the process of care [90] and support for these appears to be strong amongst general practitioners. Evidence-based, locally developed guidelines are available to a minority of Scottish general practitioners.

Although general practitioners are enthusiastic to be involved in infertility care, the questionnaire survey and the case note audits (below) suggest they need guidance to ensure appropriate investigation, timely referral and to avoid duplication of tests across the primary-secondary care interface. Liason with hospital gynaecologists at a local or national level is probably the most effective way to develop guidelines.

The Hospital Case Note Review

General Practice Referral Letters

The review of referral letters suggested that the majority of patients were not undergoing investigation of infertility in general practice. Of those who were investigated, a day 21 progesterone level in the female partner and a semen analysis in the male partner were the tests most commonly carried out. These are probably the most relevant infertility investigations in primary care.

As in the pilot case note review and the postal questionnaire, the emphasis in primary care was on the female partner and in most cases no investigation of the male. In some cases, the male partner may have been undergoing investigation at a different general practice. Ideally there would be communication of the other partner's results between general practitioners in these cases.

Less than a fifth of general practice referral letters contained information about the female partner's rubella status. The rubella status may have been checked but if it

is not recorded in the referral letter then the test may be unnecessarily duplicated in secondary care.

Many patients with regular menstrual cycles were undergoing unnecessary hormonal tests. Paradoxically, only a minority of patients whose clinical history (e.g. oligomenorrhoea or amenorrhoea) would merit these investigations, actually had the tests.

For those patients who did undergo investigation by their general practitioners, there was often duplication of tests and physical examinations across the primary secondary care interface.

If patients are to be investigated in primary care, then general practitioners require guidance as to what they should do. Tests and examinations should be coordinated and communicated between primary and secondary care providers.

This has the potential to reduce costs and delay in investigation. General practitioners appear willing to embrace guidelines in this area.

There was very little change observed in the management of infertility in primary care between the two rounds of audit. Small increases were observed in the percentage of male partners who had semen analysis and who underwent physical examination. This lack of change may reflect the ineffectiveness of written reports to disseminate results and recommendations, inertia to change established practices or other, less apparent, obstacles to change.

Other explanations include the possibility that a year between the two rounds of audit was insufficient time to implement change or that this type of audit is simply not an effective means of changing practices in primary care. There is a need for further research into the most effective ways of making changes in primary care. Some hospitals in England require that general practitioners complete a standard infertility referral form which includes information and test results before the patient is seen by a hospital gynaecologist. Emslie et al provided general practitioners with a similar form in Aberdeen.[90] These approaches may be a more effective way of defining the roles of primary and secondary care in the management of infertility.

The Hospital Notes

The hospital case note review demonstrated wide variations in care among different centres, even for simple practices such as testing for rubella immunity, seeing both partners together and the use of drug treatments for endometriosis-associated infertility. Some variations in care were remarkably localised such as the use of the post coital test in one particular centre. This could be the result of the practices of even a single individual. It could also reflect protocols that have become entrenched in the practices of the hospital and are infrequently critically reviewed.

Taking into consideration the findings of the consensus survey and the case review, the following recommendations were made:

- Both partners should be investigated together from the outset.
- A full medical history of both partners should be obtained.
- A mid luteal (usually Day 21) plasma progesterone level should be checked in the regularly menstruating female partner.
- Unnecessary investigations (e.g. FSH / LH levels in women with regular menstrual cycles) should be avoided.
- Temperature charting by the female partner should be discouraged.

- The female partner's rubella status should be checked.
- The female partner should be given advice about periconceptual folic acid supplements.
- The male partner should have two semen analyses at least one month apart.
- The presence of amenorrhoea, oligomenorrhoea, oligospermia, a history suggestive of pelvic pathology or abnormal findings on examination of either partner should result in early referral to a specialist clinic.

Modest statistically significant improvements in the process of care were made between the two rounds of audit in the hospital setting overall. There were significant changes in care in line with nine of the suggested criteria for good quality care, no significant changes in practice in another nine areas and significant changes in practice away from two of the suggested criteria for good quality care.

The number of cases reviewed in some of the individual centers was small but statistically significant improvements were observed within some centres between the two rounds of audit. It was not practical in the current thesis to present all of the results of the two rounds of audit for the individual participating centres. The results relating to four selected areas of practice are shown in 3.3. While some changes within individual centres were statistically significant, others were not. For some areas of practices the initial audit showed a high percentage of cases were managed in accordance with the suggested standard (e.g. they did not recommend temperature, did not prescribe drug treatments for idiopathic male infertility, did not use the postcoital test and performed tubal surgery on few if any patients). It was, therefore, not possible to demonstrate or realistic to expect substantial improvement.

Changes in practice were not observed in many cases. Changes in care do take time to implement. It may have been too early to detect a difference for some of the criteria within the time frame of the study. Some changes (e.g. offering counseling to patients) also require resources and it may simply not be feasible to implement these within current departmental budgets.

Although the case note review suggested that many of the criteria were met, this audit has demonstrated that infertility practice in Scotland has failed to meet with published infertility guidelines in a number of areas of practice.[74-79] This may be a fault of the guidelines themselves. In most cases, they have not been accompanied by clear supporting evidence, have not been presented in a user friendly format and have not been widely disseminated to clinicians. This audit would suggest that the failure to meet with guideline recommendations has not been a failing in clinicians, who have actively participated in the audit and produced demonstrable changes in practice.

The audit included all out patients during the study period and did not sample only selected cases based, for example, on adverse outcomes, type of infertility or membership of patient representative group. The audit covered both district generals, teaching hospitals and tertiary referral centres for infertility and should, therefore, be representative of patient care in the country as a whole. Inevitably some of the patients whose notes were reviewed in the first round of audit would be included in the second round, but the number of total cases was felt to be large enough that this would not significantly influence the results. In addition, clinicians had the opportunity to amend any deficiencies in care for many of the criteria in the audit, in the year between the two rounds of audit.

Some of the results were difficult to interpret in relation to the criteria. These included the duration of infertility when the patient with oligomenorrhoea or amenorrhoea was referred to a specialist. The information which would have been most relevant was when the delay between when the patient first presented for infertility care and when they were referred to a hospital specialist. It was not possible to determine this from the GP referral letter or hospital case notes and the overall duration of infertility was used as a reflection of this.

Significant improvements were demonstrated relating to nine of the suggested criteria for good quality care. The influence of the audit in stimulating these changes is also difficult to assess but there were no other obvious infertility initiatives that might explain the changes observed in this time period. A direct effect of the audit would be supported by the fact that the significant improvements were made in relation to three of the criteria strongly supported by clinicians (e.g. seeing the patient with her partner, giving advice about folic acid and checking immunity to rubella).

It would appear that the audit also had an educational role, as a small but significant improvement was seen in the number of male partners who had a genital examination when this criterion was supported by only 40% of responders to the consensus questionnaire.

Male factor is the single commonest cause of infertility and, although gynaecologists have the greatest input into the management of infertile couples, their care is inevitably more focused on the female partner.[110] While the majority agree that a pelvic examination of the female should be performed, there is little objective research evidence to support this. The deficiency in evidence does not necessarily imply that this examination is not valuable, but recent research relating to the surgical treatment of varicocele, would suggest that genital examination of the male partner may be equally important.[115]

It is more difficult to explain the deterioration in the number of patients having a mid luteal progesterone level checked and in those undergoing diagnostic laparoscopy as their primary test of tubal patency. Both of these practices were strongly supported by clinicians in the consensus questionnaire. It is fair to say that the majority of women with regular menstrual cycles are regularly ovulating and it may be that this was not a valid criterion.[120] Commercial kits for the detection of the luteinising hormone surge, which are now readily available to the general public, may have had a role in this.

The small reduction in diagnostic laparoscopy as the primary test of tubal patency would appear to be explained at least in part by an increase in the use of tests other than hysterosalpingography. The use of alternative tests increased from 0.4% to 2.5% ($p < 0.001$) between the two rounds of audit. While techniques such as HyCoSy may have a role in the assessment of tubal patency, they do not have the advantages of direct visualisation of the pelvis and laparoscopy remains the preferred method.[248, 151, 153]

There were nine areas of care where there was no significant change in care. Drug treatments for endometriosis do not improve conception rates and render patients infertile during treatment.[186] This criterion was given a grading of "A". It was, however, only weakly supported by clinicians and although there was a slight improvement in practice between the two rounds of audit, this did not reach statistical significance. This criterion was covered in a previous GAPS audit with very similar findings.[249] There was also an increase in the number of male

partners who had a sperm count however, there was no significant difference in those having two or more counts which was the basis for the criterion. The failure of opinion and practice to follow research evidence remains difficult to explain. There has been considerable controversy about the impact of audit on clinical practice and whether it is an effective means of changing clinicians practices. This, and previous GAPS audits would suggest that it can be effective.[59]

The format of this audit allowed clinicians to have input into the development of criteria for good quality care and gave them an opportunity to compare their opinions and practices with those of their colleagues in an anonymous arena. It also highlighted discrepancies between opinion and practice. While the criteria related to delaying laparoscopy and referral of patients for IVF were rejected by clinicians, in practice the majority of patients were in fact managed in this way. It is not possible to assess how much the format of the audit had on its success. The audit met with widespread support from obstetricians and gynaecologists in Scotland and was associated with improvements in the process of infertility care. It remains uncertain as to what effect this has had on outcome, in terms of successful treatment of infertility. The audit involved considerable input in terms of time and resources and more research is needed to assess the most effective ways of changing clinical practices. An analysis of the cost effectiveness of infertility in primary and secondary care would also have been very interesting but was outwith the scope of the project.

Case Note Review in Primary Care: A Pilot Study

The pilot case note review included 75 patient records at 25 volunteer general practices. Positive findings from this were that more than half of case notes documented the duration of infertility, the female partner's rubella status and the day 21 progesterone level. Temperature charting was only recommended in a small percentage of cases (4%).

There was, however, very little evidence of couple based investigation of infertility in general practice and documentation that a semen analysis had been performed was present in only a third of cases. Even fewer case notes documented any information about the male partner's medical history, coital frequency or the findings on genital examination of the male. In addition, almost half of regularly menstruating women had hormone levels checked which were probably unnecessary.

The findings suggest that general practitioners are willing to become involved in managing infertility but need guidance as to the most appropriate investigations. Overall the observed practices in this group fell short of the reported practices in the general practice questionnaire survey. It may be that other centres are doing better and that the general practices audited are not representative of Scottish primary care as a whole.

While the pilot study practices may not be representative it would seem more likely that these general practitioners would, if anything, perform better than the average Scottish practice. They participated in the audit voluntarily, appeared interested and motivated and were willing to allow audit from out with primary care.

As a result of the potential biases it was decided not to repeat the primary case note review in the second cycle of audit. In addition it was time consuming and much of the information could be obtained from general practice referral letters in the hospital case notes.

Those practices that participated received feedback through a short report and personal communication at site visits. Informal feedback about the audit from the participating general practitioners was positive.

As a result of the potential biases the conclusions that can be drawn are limited. The aim of the pilot study was to assess the feasibility of a combined primary and secondary care audit. There is no doubt that this was achievable in this group. Any future formal studies would have to involve a representative sample of practices and this is difficult to achieve. Although there are incentives to participate in audit (and benefits to a busy general practitioner if the data collection and collation is performed for them), participation in this type of audit is at the discretion of the practice.

The Patient Satisfaction Survey

The First Round of Audit

This is the largest questionnaire survey of infertile women that has been carried out in the UK. The response rate was not high and it may be that responders were self-selected biasing the results. Unlike some previous surveys,[4,5] however, the questionnaire was mailed to patients currently undergoing investigation and treatment, not specifically to members of patient representative groups. The response rate of 59% is lower than the 77% reported by Owens and Read when they surveyed members of the National Association for the Childless [4] but almost twice as high as the 31% achieved by Bromham et al [109] who included patients who were not members of self-help groups.

Patient satisfaction is difficult to assess and define. In general, surveys produce high levels of overall satisfaction with medical care making it more difficult for practitioners and managers to prioritise areas of service development. More specific questions are needed to provide useful information about the service being provided.[250] This survey collected detailed information about specific aspects of care as well as asking about the relative importance of some of these from the patient's perspective.

A common criticism of patient satisfaction surveys is that they focus primarily on organisational or 'hotel' aspects of care which are relatively easy to define and measure and are attractive to managers as performance indicators.[251] One such question included in the present survey related to the waiting time at the clinic. The majority of patients were understanding of the delay at their clinic and waiting times were given a low priority in relation to other aspects of care, suggesting that the managerial emphasis which is often placed on this, does not reflect patients' priorities.

Similarly, patients did not appear to have any strong feelings about attending a general gynaecology clinic as opposed to a specialist infertility clinic, suggesting that in general, specialist infertility clinics were not perceived as offering more to patients. Interestingly, however, there was greater satisfaction among those attending dedicated infertility clinics. There was also an association between continuity of care and overall satisfaction.

The two aspects of care which were ranked most highly in terms of importance were "*the information and explanation given*" and the "*doctor's attitude*". The

survey identified a need for more information and explanation, particularly in relation to the possible causes of infertility and drug treatments. A minority of patients had received any written information and a large majority reported they would like more literature. Almost half left the clinic with unresolved questions or without a clear plan about possible future investigations and treatments. More effective and frequent use of written information is clearly indicated as having the potential to address some of the patients' information needs.

The survey highlighted the importance of the doctor's attitude which was ranked highly by patients. Improvements related to this may be made by doctors by allowing couples to take part in decision making and by giving them the opportunity to initiate questions.

The time taken for investigations to be performed and for results to reach patients has been criticised in previous studies.[4,5] More than a quarter of women echoed these sentiments but it is worth noting that "*the way the investigations are done*" ranked lower overall than "*the information and explanation given*", and "*the doctor's attitude*". A small number of those women who made written comments felt that clinic visits were too infrequent and some of the comments suggested a lack understanding of the importance of the duration of infertility in making decisions about appropriate treatment. Specific explanation and written information about the time scale for investigations and treatment at the initial clinic visit may be helpful to patients.

Most women felt that they had not been given enough help with the emotional aspects of infertility. This is something that has been repeatedly highlighted in patient surveys [4,5,252] and infertility guideline documents.[75,77] It would seem that this area is still not being adequately addressed in out patient clinics. One of the reasons for this may be the small number of published studies clearly demonstrating benefits of counselling.[104,106,253] In addition, if more than half of women did indeed take up the offer of counselling, as this survey suggested, the financial costs to an already stretched service would be considerable.

Interestingly however, "*help with the emotional side of infertility*" was not ranked highly in comparison to the other areas of care. It would seem sensible that aspects of care which are less costly and perceived as higher priorities by those using the service should be addressed first.

Finally, more than a third of women had not been asked to bring their partner to the clinic at any time. It is paradoxical that although a male problem is the single commonest identifiable factor in infertility [110], infertility is still perceived as a predominantly female problem. Many written comments related to the fact that the partner had been left in the waiting room or ignored during the consultation. There were few women who said they did not want their partner to attend and most were positive about their partner being involved. There overall satisfaction with care was greater among those women who attended with their partner on a least one occasion. This may be a reflection of satisfaction with other positive features in clinics where partners are encouraged to attend rather than the couple based approach per se. Other possible explanations include overall satisfaction being higher among those women with supportive partners or that women who attend with their partner are treated differently at outpatient clinics.

In conclusion, the women who responded to the questionnaire were, in general, satisfied with their care and it was only on asking more specific questions that any inadequacies in the service were identified. Areas for improvement were identified. These related to giving patients more explanation and written

information (particularly about the causes of infertility, the time scale for investigation and treatment, and drug treatments), streamlining the process of investigation and ensuring that patients have the opportunity to ask questions. In addition, there was a need for a more couple-centred and holistic approach. It was clear that if resources allowed, patients would appreciate more help with the emotional aspects of infertility.

Changes between the Two Rounds of Audit

There were two areas in particular, that were highlighted by the first patient survey. The first was that patients would appreciate more written information and the second that most felt they had not been given enough help with the emotional aspects of infertility.

There was no change in the percentage of patients who felt they had been given enough help with the emotional aspects of infertility between the two rounds of audit but there was a significant increase in the percentage of patients who were given written information. There was also a statistically significant increase in the percentage of patients who were asked to bring their partner to the clinic. These changes were small but occurred in areas highlighted as important by patients, clinicians and infertility guidelines. There was no significant change in satisfaction overall and it is not possible to prove conclusively that the above changes were the result of the audit.

Perhaps what is more interesting than the changes, is the consistency in answers between the two rounds of audit. This suggests that despite the low response rates the answers to the questions were less likely to be spurious.

One of the questions asked only in the second round of audit was whether the patient had been given advice about folic acid. There was documented evidence of this in 47% of the case notes reviewed while 35% of patients actually remembered receiving such advice. It may be that the responders to the patient questionnaire were not representative of the group as a whole or that not all patients remembered this advice being given.

Giving patients written information represents a relatively simple change in practice. Improving care in terms of the emotional aspects of infertility is much more difficult to achieve. Doctors have limited time with patients and limited resources are available for infertility counselling within the NHS. In addition, opinion about the benefits of counselling was divided amongst gynaecologists in the consensus questionnaire.

Changes in this area would probably require changes in organisation and funding at a higher level.

The Questionnaire for the Male Partner

This questionnaire was only used in the second round of audit. The results suggested a high level of satisfaction and very similar responses to those of the female partners.

It is difficult to know how representative the responders to this questionnaire are of male partners in general. They may represent those who are more motivated or who are already involved in the investigations and treatment. This would be supported by the fact that 88% of responders had attended the clinic with their partner on at least one occasion as opposed to 78% found in the case note review.

Approximately half of men were aware of being asked by the hospital to attend the clinic but one in seven had not been asked to attend by either the hospital or their partner. This may be a problem with communication or a lack of recognition of the importance of the male partner in infertility management, by gynaecologists .

Significantly fewer men than women left the clinic with unanswered questions but the majority still indicated that they would appreciate more written information. The percentage of male partners (13%) who felt they had not had enough help with the emotional aspects of infertility was very similar to the percentage of female partners (14%). This is interesting because women attending with infertility have been reported to express more psychological symptoms than men.[91,100] This survey suggests men also feel there is a need for more emotional help. There is very little published literature addressing the non-physical effects of infertility on the male partner. Glover et al reported that men experienced high levels of anxiety at the time of attendances at sub-fertility clinics and, along with other authors, highlighted the need for more research in this area.[99,254]

The lack of information on the male partner reflects a continuing lack of appreciation of the importance of early involvement of the male partner in infertility investigation.

Psychological Health in Infertile Women

Infertility is undoubtedly a stressful and distressing experience for many couples and associations with anxiety, depression, low self esteem, sexual and marital problems have been reported. [91,92,97,98,107,227,255-258]. Qualitative studies have consistently shown that women with infertility report poor emotional and psychological health [91,92,97] but, contrary to popular perceptions, quantitative work has produced conflicting reports as regards the impact on mental health and the prevalence of clinically significant psychological disturbance. [258,259] Using standardised psychological tests, positive cases have been reported in between one per cent and 52% of subfertile women.[98,101,256,260,261] (Table 27). In addition to the wide variation in prevalence there have also been differences in the reported predictive factors for depression in this group of women.

The first objective of the psychological section of the questionnaire was to evaluate the emotional well being of women undergoing infertility investigation and treatment in Scotland and to identify those who were at risk of clinically relevant mental illness (particularly anxiety and depression). It also aimed to identify some of the factors which may predict women at particular risk of developing clinically relevant psychological ill health in relation to infertility. In this way, evidence was sought as to the extent to which inadequacies in care felt by patients, reflected clinically relevant need, measured by objective psychological testing.

This study differed from previous similar studies by virtue of its large size, the use of standardised instruments to assess psychological morbidity and the inclusion of only women undergoing investigation and initial management of infertility as opposed to those undergoing assisted reproductive techniques.[100,108]

In addition, the study aimed to produce as representative a sample as possible by including all women attending participating clinics during the study period. This differs from several previous studies where patients have been recruited patients from a variety sources including potentially self-selecting populations such as members of patient representative groups, who may not be representative of the infertile population as a whole.[92,96,227,255]

Items from the SF-36 were included in the patient questionnaire in the first round of audit but the GHQ-12 was added only in the second round. As discussed in Methods Section 2.2, it was not felt that the psychological survey could be feasibly used as an outcome measure and it was decided therefore to concentrate on the more comprehensive questionnaire in the second round of the audit.

The questionnaire in the second round of audit included two psychological instruments. This allowed the results of the GHQ-12, which was used in its entirety, to be correlated with the results of the selected SF-36 items and particularly the results of the MHI-5. This was not as robust as comparing the results of the GHQ-12 with a standardised psychiatric interview of the responders but it did give some validity to the use of the GHQ-12 in the population being studied (i.e. women undergoing initial investigation and management of infertility).

Author	Instrument	Patient Population	No. of Women	Positive Cases
Domar 1992	Beck Depression Inventory Centre for Epidemiological Studies Depression Scale	All stages of management including IVF/GIFT	338	37% 25%
Van Balen 1993	Symptom Checklist-90	All stages of management	108	10%
Berg 1990	Symptom Checklist-90	All stages of management including volunteer subjects from infertility self help group.	104	52%
Bell 1981	Delusions-Symptoms-States Inventory State of Anxiety and Depression	All stages of management	20	22%
Downey 1989	Brief Symptom Inventory	First clinic appointment	59	8.5%
Laffont 1994	General Health Questionnaire-28	IVF only	117	47%
Daniluk 1988	Symptom Checklist-90	All stages of management	43	0%
Slade 1997	Beck Depression Inventory	IVF only	144	28%
Oddens 1999	Women's Health Questionnaire	Awaiting IVF	281	24.9%

Table 27 Summary of the published studies using standard psychological instruments to measure psychological well being in women undergoing infertility investigation and treatment.

The GHQ-12 is a well known and widely used psychological instrument. It was developed as a screening tool to detect individuals with potentially clinically significant psychological disturbance, particularly anxiety and depression and has been validated against existing 'gold standard' psychological instruments and psychiatric interview. [85,262-269]

It has been used in diverse populations including general practice, accident and emergency departments, postnatal patients, cancer patients, gynaecology outpatients and infertility patients.[108,264,267,270-272] As a screening instrument, it is not diagnostic and cases identified as "positive" require further psychiatric assessment. The reported sensitivities and specificities depend on the threshold for a positive test but are in the range of 70% and 80% respectively.[264,266] The GHQ-12 is derived from longer versions of the GHQ but has been shown to be of similar sensitivity to these.[262]

The GHQ-36 has been used by other researchers in the study of infertile patients and a good correlation with other standardised instruments for measuring psychological health was demonstrated in these patients.[108] There are published GHQ-12 scores for women of reproductive age in population samples but there are no published data reporting the sensitivity and specificity for clinically significant psychiatric disturbance in an infertile population.

In this survey, the GHQ-12 was used primarily as a measure of the overall psychological health of the study population rather than to identify the prevalence of psychiatric illness among infertility patients. Ideally the GHQ-12 would also have been administered concurrently to a matched control group of Scottish women with at least one child. This was not feasible within the confines of the study. The results do, however, give some indication of the percentage of women attending outpatient clinics with infertility who have potentially significant psychiatric disturbance.

The second psychological instrument used was the SF-36. Like the GHQ-12, the SF-36 has been well validated and widely used as a measure of physical and psychological health but it has not been specifically evaluated in an infertile population.[82-84] The SF-36 is generally used as a measure of physical and psychological health. The five-item mental health dimension (the Mental Health Inventory or MHI-5) has been validated as a measure of mental health and has been used as a stand alone mental health screening instrument.[263, 273-277] Jenkinson et al [84] published normative data on the SF-36 in a population based on a sample of adults of working age. This was obtained through a postal survey of a random sample of 13,042 subjects between 18 and 64 years of age, drawn from computerised registers of family health services authorities in four English counties. Of those mailed, 9332 (72%) responded to the questionnaire. This was a large sample and the authors reported that its sociodemographic characteristics were similar to those of the general population based on population estimates and the social class distribution from the national census. The data were broken down by age and sex (both of which were found to influence the SF-36 scores) allowing comparisons to be made with the data in the present study.

Non-parametric tests were used to compare the scores for the GHQ-12 and the selected SF-36 dimensions so as to avoid distributional bias. Significant correlations were seen between scores on the SF-36 and the GHQ-12. The strongest of these were between the scores for the GHQ-12 and the MHI-5, and GHQ-12 and 'role social' dimensions of the SF-36. This suggests that the MHI-5

and the GHQ-12 were being answered consistently by responders and that the GHQ-12 scores reflect psychological wellbeing in this population.

Internal consistency between items was assessed using Cronbach's alpha. This was greater than the recommended value of 0.8 for both the GHQ-12 and the MHI-5.

It was expected that the majority of women attending with infertility would be young and physically well. While it may have been preferable from a methodological perspective to use the complete SF-36, in this context, the researchers were concerned that the scales inquiring about physical health and functioning would diminish the acceptability of the questionnaire to infertility patients who may see it as irrelevant to them and thus fail to respond. It was decided therefore to use only the items directly relevant to this study. Responses to a single item on general health confirmed the view of this population as physically healthy, the vast majority reporting their health to be very good or excellent health.

The three psychological scales of the SF-36 which were considered to be the most relevant to infertile patients were the 'role emotional', 'role social' and mental health dimensions. As discussed above, the five items of the mental health dimension have been used as a stand alone measure of mental health (MHI-5). Unlike the GHQ-12, the MHI-5 does not measure "caseness" and its significance to clinical psychiatric disturbance is uncertain. It can, however, be used to compare mental health between populations and in the same population over time. In this study, it was also used to validate the results of the GHQ-12.

The overall response rate to the survey was 47% although this was achieved by contacting patients on only one occasion. This is not uncommon in similar studies.[258] Although biases between responders and non-responders cannot be excluded, there were no significant demographic or clinical differences between them based on analysis of routine data that were available for the whole of the sample population. This and the comparatively large sample size, mean that the data can be interpreted with reasonable confidence although the conclusions that can be drawn are limited by the response rate. While it seems more plausible that any bias would be towards a higher prevalence of psychological distress among responders than non-responders, this remains unknown. It is possible that very distressed patients may have decided not to respond and the results of the study underestimate psychological distress associated with infertility.

The results of the SF-36 variables in the present study suggest that women undergoing investigation and initial management of infertility have poorer mental health, social and emotional functioning than women of a similar age in the general population. Interestingly, there were significantly poorer scores for emotional functioning in all three age groups of infertility patients as compared to the results from the standardised population. This is supported by studies reporting isolation as one of the most prominent findings among infertile women and higher levels of fertility related stress among those who have less social support. [96,227]

A high prevalence of "caseness" was observed in this study using the GHQ-12. This finding is supported by a number of, but by no means all, studies in this area and the topic remains controversial. There are several factors that might explain differences. These factors include variations in the duration of infertility, the stage of investigation and treatment, primary or secondary infertility, the source from

which patients had been recruited to the study and the psychological instrument used.

It was hoped that the current study would identify risk factors for significant psychological distress among women attending outpatient clinics with infertility. A significant trend towards poorer mental health and social functioning in younger women was observed. Age appears to have some affect on GHQ-12 and SF-36 scores but this affect was observed over a wider age range than in the present study and the trend is for a deterioration in psychological wellbeing with increasing age.

Most of the other observations were in fact negative. As in the study reported by Domar et al [98] no significant association was demonstrated between parity and psychological score.

This is in contrast to the duration of infertility. Domar et al [98] reported that objective measures of depression were greater in women whose infertility was between two and three years in duration as compared to those who had a history of less than one year or more than six years in duration. Berg and Wilson [256] found that scores for depression did not change significantly with time but that emotional strain was high for the first year of infertility, normalised in the second year and then markedly rose thereafter. Some subjective studies suggest that perceived depression increases with the duration of infertility particularly after two years.[91,97,278] This has not however been a consistent finding.[227] In the current study, there was no statistically significant correlation between the GHQ-12 score and the duration of infertility. In particular, no statistically significant differences were observed in women whose infertility was of between two and three years duration or of greater than six years in duration.

Daniluk [279] reported that scores for depression were highest at the time of the first clinic visit. In the present study women who were attending the clinic for the first time had significantly lower GHQ-12 scores and there was a significant trend towards higher scores as the number of clinic attendances increased. The reasons for this remain unclear. It may be that women who have attended for the first time feel positive the possibility of treatment and have not received any bad news about investigations or their prognosis. Women who repeatedly attend the clinic without becoming pregnant may become increasingly pessimistic and disheartened. However, there was no significant difference in the GHQ-12 scores between women with different diagnoses and no difference between those for whom the cause of the infertility was and was not established.

The majority of women indicated that there was not enough help with the emotional aspects of infertility and the answer to this question appeared to be independent of the patients psychological wellbeing as assessed by the GHQ-12. Patients who said they would take up counselling if it was offered to them, were however, significantly more likely to have a positive GHQ-12 score and to have poorer scores for the SF-36 than those who said they would decline counselling. Therefore, patients do to some extent self select themselves for counselling. Forty-three percent of those who said they would take up counselling had a positive GHQ-12 score. The use of a standardised questionnaire such as the GHQ-12, in an out patient setting may be a more efficient way of selecting patients for counselling.

Despite the call from infertility patients for more emotional help, uptake of counselling has been reported as low. Possible barriers to the provision of widespread counselling include a failure of recognition of the emotional impact of

infertility by doctors and uncertainty as to the most effective interventions to offer patients. There is also evidence that doctors underestimate the degree of psychological distress being experienced by individual infertility patients.[102] Infertility counselling is generally perceived as being "a good thing" and 61% of gynaecologists in Scotland who responded to the GAPS infertility questionnaire survey, said they agreed that counselling should be available to all infertile couples.

There is however, little objective evidence of its benefits.[94] Domar et al reported an improved psychological profile in women receiving infertility care after a ten week group behavioural programme.[106] In contrast, a randomised controlled trial of patients undergoing IVF, demonstrated no difference in GHQ scores between those who had counselling and those who received information alone.[108]

Logistical problems for patients, such as to how to access counselling and uncertainty about the costs may be another factor.

This study suggests high levels of psychological disturbance and poor mental health and social functioning among infertile women attending gynaecological out patient clinics in Scotland. Factors such as parity, diagnosis and duration of infertility do not appear to be predictive of psychological health. Young age, increasing numbers of clinic attendances and willingness to attend counselling appear to be associated with poorer mental wellbeing. The use of a short questionnaire in an out patient setting may identify those at particular risk of developing clinically relevant anxiety and depression. Infertility patients perceive help in this area as being inadequate but more research is needed to determine the most effective ways of dealing with the emotional aspects of infertility.

4.3 DISCUSSION OF THE PROJECT OVERALL

The GAPS Infertility Project demonstrated the feasibility of a large, multi-centre criterion based audit across the interface between primary and secondary care. Both general practitioners and hospital gynaecologists embraced the project. Whether this reflected a general interest in audit or a more specific interest in infertility is difficult to say.

Wide variations in care were seen among different centres and the reasons for these remain unclear.

Modest improvements in the process of care were observed over the duration of the project. There were no other obvious explanations for these changes aside from the audit itself but the possibility of unidentified external influences cannot be excluded.

The patient questionnaire survey suggested high levels of satisfaction with care overall but it also highlighted specific areas of care that could be readily improved. Some relevant changes were observed between the two rounds of audit. A lack of help with the emotional aspects of infertility was reported by patients but there has been little done to address this. This may reflect a lack of appreciation of these problems by clinicians, a lack of clear evidence of effective interventions in terms of counselling, lack of resources or other organisational constraints.

The survey of psychological health among female infertility patients suggested significant levels of psychological disturbance and poor mental health. This used objective measures of psychological wellbeing and was consistent with patients' perceived need for more help. Whether it will be possible in future to provide help in this area within the NHS is uncertain.

The project observed changes in care over time but did not assess the obstacles to making changes in this area, other than by assessing the opinions of clinicians. The majority of the suggested criteria for good quality care were, however, supported by the clinicians surveyed. In 18 of 22 cases, at least 50% of responders agreed with the suggested criteria for good quality care and in 13 cases, 66% or more agreed.

The reasons for the limited scale of changes in care may include inadequate time between the two rounds of audit to allow changes to be made, failure to target all the people contributing to patient care, organisational constraints, ineffective feedback and clinician inertia to change. Financial constraints may have played a part but many of the recommendations from the audit were suggested reduction in inappropriate or ineffective tests. It had been hoped to perform a limited cost analysis as part of the audit but the time and resources needed for this proved to be out with the scope of the project.

The conduct of the GAPS audit involved considerable manpower, effort and financial input but achieved only modest changes in practice. At the outset of the project, audit was perceived as potentially a major means of improving health care. More recently, it has become clear that doctors remain key, although not sole, vehicles for change and that the role of audit is as a contributory part of much wider clinical effectiveness initiative. The last section will discuss the future in terms of clinical effectiveness and the role of audit within this.

4.4 THE FUTURE: WIDER CLINICAL EFFECTIVENESS INITIATIVES AND THE ROLE OF AUDIT WITHIN THIS

Evidence Based Medicine

Overview

There is a growing awareness of the need for greater quality assurance in health care. This has arisen from three main areas: the variation in clinical practices, a lack of 'evidence based medicine' and increasing costs. Individual institutions are also recognising that the pursuit of evidence based practices promotes an image of good quality care and commitment to the patient's welfare.[280] Evidence based medicine has been defined as "the process of systematically finding, appraising and using contemporaneous research findings as the basis for clinical decisions".[281] There are four main principles in evidence based medicine: clearly identifying the clinical question which needs answering; systematically searching the literature for the best available relevant evidence; critically evaluating the scientific evidence; and translating the conclusions from that evaluation into decisions about the management of patients or healthcare policy.[281] The fifth caveat is the need for continuous evaluation of performance [282] and this is where audit meets evidence based medicine.

Variations in clinical practice are well recognised both within and among countries [283-285] and the management of infertility is no exception to this.[3] The reasons underlying this variation are not entirely clear. The epidemiology of the population including the age distribution, the prevalence of certain diseases, race and wealth are all factors but variation persists even when these are adjusted for. The availability of manpower has been identified as a factor but it is less strongly associated with an increase in interventions in the NHS than it is in the predominantly privately funded health care system of the USA.[285] In contrast, in England and Wales the allocation of resources to hospital regions would appear to be a factor.[285]

Giraud described the variations in clinical practice as "counter to a discipline which has a scientific basis" and suggestive of "either important gaps between the results of research and medical practice or a profound uncertainty in the practice of medicine".[286] Some see variation as compromising the equity and quality of care as well as increasing costs [287,288] while others resent attempts to control clinical practice.[289] There is undoubtedly a balance to be struck as such variations are increasingly perceived as unacceptable by purchasers and consumers of health care as well as much of the medical profession.[282,290,292] It is well recognised that, in the words of the NHS Management Executive, "Clinical practice is still insufficiently responsive to the changing evidence of best practice"[32] and that research findings are poorly translated into clinical care.[284] The reasons behind this are complex and while basic scientific research flourishes, there has been relatively little research into the implementation and assessment of scientific research in a clinical setting.[292] Increasingly, however, the importance of evidence based practice, both in terms of effectiveness and cost effectiveness, has been recognised by health professionals and embraced by the Government.[32]

Searching for Evidence

Having acknowledged the potential value of evidence based medicine, there are difficulties to be overcome in its development and implementation. These include: inadequate scientific evidence; difficulties identifying relevant scientific evidence; a lack of the epidemiological and statistical skills needed for critical appraisal of the literature and implementing change based on the conclusions.

There are also limitations to evidence based medicine and although there are many advocates, others have expressed caution. There are situations where evidence is not appropriate for clinical applications such as very expensive treatments that have only small clinical benefits.[293] In addition, application to a clinical situation depends on a number of individual factors such as the patient's wishes, cultural differences and co morbidity.[293] The application of evidence based practice varies depending on the context among different geographical areas and countries e.g. within the NHS funding of infertility services at all levels varies considerably.

The concerns about evidence based medicine relate not only to its applicability to individual clinical situations and patients but also to the quality of evidence on which to base it.[294] The following subsections discuss this further.

Critical Appraisal

The amount of up to date knowledge possessed by doctors declines with increasing time since their graduation [295] but this is not an irrevocable situation. Effective continuing medical education and teaching critical appraisal of the literature can improve clinical decision making and health outcomes.[296,297] Sadly however, clinical epidemiology and biostatistics have received relatively little attention in traditional undergraduate medical education and the subjects themselves have been received by medical students with a similar lack of enthusiasm. Many doctors are therefore lacking in the skills needed to critically appraise the literature.[282] Added to that, the pressure of work is such that on average, clinicians are able to allot only half an hour on average every week to reading.[298]. Systematic reviews would seem to be the answer and the Cochrane Collaboration has the potential to completely revolutionise this situation.

Systematic Reviews

Every year, around 2 million health related research papers are published in more than 20000 biomedical journals throughout the world.[291] In this climate, standard textbooks could not possibly be up to date for any length of time and clinicians cannot realistically be expected to read and appraise the literature even in relatively small area of interest.

The basis of the Cochrane Database is the systematic review. Unlike traditional medical reviews, these state the objectives of the review and outline the criteria by which studies are eligible for inclusion; systematically search for studies meeting these criteria (usually by a combination of searching electronic databases, hand searching of journals and seeking out unpublished studies); assess the characteristics and methodological quality of the studies; decide on exclusion and inclusion of the studies and critically analyse the results including meta-analysis where appropriate.[299]

Systematic reviews, therefore, allow clinicians ready access to unbiased information about therapeutic interventions on which they can make decisions

about clinical practice and counsel patients. The work of the Cochrane Collaboration in this area is discussed below.

The Cochrane Collaboration

One of the main protagonists of evidence based medicine was the epidemiologist and clinical trialist Archie Cochrane. In the 1970's, he highlighted the lack of evidence based practice and the need for systematic reviews or summaries of randomised controlled trials. He subsequently cited obstetrics and gynaecology as the specialty that was least scientific in its approach. In response to this, the Oxford Database of Perinatal Trials, led by Iain Chalmers was established in the 1980's and "Effective Care in Pregnancy and Childbirth" published in 1989. The group has now become part of the Cochrane Collaboration.

The Cochrane Centre was set up in Oxford in 1992 and was funded by the NHS Research and Development Programme. From this, an international network called the Cochrane Collaboration has developed. The aims of the Collaboration are to produce, maintain and disseminate systematic reviews of randomised controlled trials in a wide range of medical fields.

There are now 44 Collaborative Review Groups. These are mostly international and multidisciplinary and in many cases include consumer input. Each group covers a special area of interest. The groups prepare reviews (following systematic literature review often including extensive hand searching) and maintain a specialised register of randomised controlled trials. Each review undergoes both internal and external peer review before inclusion in the database. There is a standard layout for the review and this includes the eligibility criteria for inclusion of controlled trials, an assessment of the methodology of the trials (both those included and excluded) and an analysis which is frequently a meta-analysis of the results. The results are discussed and conclusions drawn about the implications for clinical practice.

The Database of Systematic Reviews is published electronically as part of the Cochrane Library and distributed in the form of compact or floppy disk, or through the Internet. It is updated 3-4 times per year. There are at present 159 complete reviews and 199 protocols. The Cochrane Library includes three further databases. These are a Database of Abstracts of Reviews of Effectiveness (which contains more than 1600 references to reviews of effectiveness produced outwith the Collaboration), the Cochrane Controlled Trials Register (which currently includes 11000 randomised controlled trials) and the Cochrane Review Methodology Database (which currently has almost 400 references).

There are three Collaborative Review Groups that relate directly to Obstetrics and Gynaecology. These are the Cochrane Pregnancy and Childbirth Group, the Menstrual Disorders Group and the Cochrane Subfertility Review Group. Since the inception of the Infertility Audit Project which is the basis of this thesis, the Subfertility Group has produced 15 complete reviews. Five of these include areas covered in the GAPS Infertility Audit and support the criteria that the audit measured.

This would appear to be a largely untapped resource. A telephone questionnaire survey published in 1994 found departments of obstetrics and gynaecology in only 16% of district general hospitals and 62% of teaching hospitals surveyed had access to the Oxford Database of Perinatal Trials.[300]

The NHS Centre for Reviews and Dissemination (CRD)

The NHS CRD was established in 1994 and is based in the University of York. The Centre works in close association with the Cochrane Collaboration to produce systematic reviews about the effectiveness and cost effectiveness of health care.[301] It also maintains two databases: the Database of Abstracts of Reviews of Effectiveness (DARE) and the NHS Economic Evaluation Database (NEED) with the aim of giving NHS health professionals easy access to these reviews. Both of these databases are available free of charge via the internet. DARE is also available on disc or CD-ROM as part of the Cochrane Library.

The Centre's second remit is to disseminate results of good research including that of the NHS Research and Development Programme. Effective Health Care Bulletins covering a wide range of topics, including the management of subfertility, have been published by the University of York.[74] The Bulletins review, summarise and interpret the available evidence in a systematic way including discussion of cost effectiveness. Since 1995 the CRD has also produced 'Effectiveness Matters', a less detailed quarterly review.

Rigorous systematic reviews such as those produced by the CRD and the Cochrane Collaboration provide standards on which to base clinical audit.

Effective audit can also be used as part of the process of implementing research findings into clinical practice.[302]

"Evidence Based Medicine"

This journal has been produced by the BMJ Publishing Group since 1995. The journal reviews the contents of 70 clinical journals along the lines of the American College of Physicians (ACP) Journal Club.[303] It publishes summaries of the best studies, as well as editorials and systematic reviews.

Clinical Practice Guidelines

Development of Guidelines in Scotland

In the last four years funding for quality assurance initiatives has moved away from audit per se and into the realms of clinical practice guidelines, both in Scotland and the UK as a whole. In Scotland, CRAG has been at the forefront of developing this idea and has supported the establishment of the Scottish Intercollegiate Guidelines Network (SIGN).

In 1993, the Scottish Office published a report called "Clinical Guidelines" based on the findings of a CRAG Working Group into this area.[304] The report defined guidelines as "systematically developed statements which assist in decision making about appropriate health care for specific clinical conditions". CRAG favoured a multi-disciplinary approach to the development of guidelines at a national level and adaptation of these for use at a local level. It recommended that the term "clinical guideline" should imply a general statement of principle and "protocol" more specific adaptation of these for use at a local level. Clinical audit was seen as integral to the process of developing, monitoring and evaluating guidelines.

Clinical guidelines have been shown to improve the quality of care but they have other potential effects including reducing variation in care, giving treatment information to patients and shaping health policy, keeping clinicians up to date and reassuring them that their treatment policies are appropriate. [280] Guidelines highlight research areas that need further evaluation and may provide medicolegal protection and prompt health providers to employ the intervention.[280]

Criteria for Guidelines

Guidelines should, wherever possible, be based on evidence obtained through systematic review of the literature.[233] It is not always possible to transpose scientific findings directly into clinical practice.[235] Issues of safety, resources, applicability, responsibility and local factors need to be taken into account and a consensus agreed as to how these findings should be best used and implemented.[235] Guidelines need to be dynamic and change with developments in medical science.[304] They should also be responsive to feedback from audit of their effectiveness.[304,233]

Successfully implemented guidelines have been shown to significantly improve care in a wide range of specialties, and specifically in the field of infertility.[90] They are not substitutes for clinical judgement and should not be transposed into mandatory protocols.[305,306] Guidelines also need to be frequently reviewed and updated.

Concerns about Guidelines

While there has been support for guideline development, there has also been concern. Potential problems of guidelines include poor evidence base, inappropriate application to individual situations and conflicts between cost control, doctors' interests, the welfare of the health system overall and the patient's interests.

Particular concerns as regards the evidence base relate to guidelines based on a consensus of expert opinion. Agreeing a consensus may reduce guidelines to a common denominator, rather than the best achievable standards. Such guidelines may reinforce scientifically unsound practice.[307]

Fears about restricted clinical freedom and discouragement of innovation have also been expressed. [58,305, 307, 308] However, guidelines cannot be applied uniformly in every clinical situation and decision making has to be based on individual circumstances.[31,308] Guidelines tend to work well for simple conditions but for more complex clinical situations there is no doubt that experience is essential. They should not be used by junior staff to enable them to practice above their clinical experience, neither should they stunt experienced doctors from developing new interventions. For areas of care that are very specialised or rare guidelines should be empowering rather than restrictive in a climate of rapidly changing science. Clinical conditions where there are recognised variations in clinical practices which affect outcome or where effective care is not delivered uniformly are particularly amenable to guideline development.[58]

There can be problems in terms of different goals for guidelines. These include cost reductions and reducing medical litigation as well as improving care and these may not always be compatible.[306] The aim of the GAPS infertility audit was primarily to improve care, however, many of the suggested criteria for good quality care were aimed at reducing unnecessary or ineffective interventions such as post coital tests, drug treatments for endometriosis and inappropriate tubal surgery. In addition to this, the audit identified areas where spending could be reduced in streamlining blood tests performed in primary care. Effective care is not always the most expensive.

Guidelines should be there to help doctors make decisions in individual clinical situations, not dictate them. They may discourage further research and may restrict care to a minimum standard rather than striving for the best achievable.

Clinical practice is complex and evidence based interventions need to be assessed under clinical conditions.[309]

Legal Implications of Guidelines

There has also been considerable concern about the legal implications [307] however, the introduction of multiple guidelines in the USA has not been followed by a deluge of guideline related negligence lawsuits.[310] There are two main issues surrounding this area. Firstly the guidelines themselves may be challenged as to their validity. Guidelines can be referred to by an expert witness but they cannot be substituted for expert testimony.[31,310]

The second issue relates to doctors who deviate from guidelines and lay themselves open to litigation. Negligence requires evidence that the clinician did not provide care of to a standard which would reasonably be expected for a doctor of that grade in these circumstances as judged by expert testimony.[310]

In practice guidelines may in fact protect clinicians who follow them, from medicolegal claims.[31,310,311] As long as guidelines remain such, and not protocols, there is no barrier to diverging from the guideline if this is accompanied by well documented justification for this decision.[310]

Dissemination and Implementation

Effectively implemented guidelines have been shown to improve both the process and outcome of patient care.[90] Specifically Emslie et al. demonstrated improvements in the management of infertility patients in general practice, in a randomised controlled trial of clinical practice guidelines.[90]

Guidelines which are valid and reliable are logically going to be more widely accepted, but crucial to their success are effective dissemination and implementation strategies. Factors which are associated with increased compliance with guidelines include local involvement in their development or modification engendering a sense of ownership, patient specific reminders at the time of the consultation, promotion by opinion leaders, financial incentives and multi disciplinary input into their development.[246,308,312,313,314] The format of guidelines should provide an easy reference summary and a longer more explicit summary of the evidence and methodology of the document.[314] Audit of the implementation of the guidelines and feedback to clinicians has the potential improve compliance.[315]

Guidance from the Government on Guidelines

In 1996 the NHS Management Executive published "Clinical Guidelines: Using clinical guidelines to improve patient care within the NHS".[31] This Report covered many of the issues discussed above and like SIGN favoured graded, evidence based guidelines produced on a national basis and drawn upon for local use. It identified five key reasons for developing guidelines for an area of care:

- 1 excessive disability, morbidity or mortality associated with the condition.
- 2 treatment available with the potential to reduce disability, morbidity or mortality.
- 3 wide variation in practice.
- 4 resource intensive (i.e. high volume low cost or low volume high cost).

5 crosses boundaries of care either between disciplines or between levels of care.

The Department of Health has made it clear that guidelines should be used in provider purchasing contracts, although in this report it re-iterated the Clinical Outcomes Group recommendation that, "only those based on evidence from randomised controlled trials should be used in contract specification".[31] While there is little doubt that contracting could be used in the implementation of guidelines, 1997 has seen a change of Government and plans to dismantle the internal market for health care. The future for contracting in this way is very uncertain.

Managed Care

The philosophy of managed care has sprung mainly from the USA, fuelled by the rising costs of fee for service reimbursement. The aim of managed care is in essence to deliver care at lower cost while still maintaining quality by establishing clinical rules to guide practice. In the USA this has been in association with variations in the arrangements made for reimbursement of doctors by medical insurance companies away from the traditional fee for service.[316] In the UK a managed care approach could potentially be adopted in purchaser-provider contracting.

Infertility is one of the areas that is particularly amenable to this approach because of wide variations in clinical practices, a firm outcome measure (live birth), the high cost of treatment and geographical inequities in funding of the service both in the UK and the USA.

Hull described three components to managed care in infertility: cost effectiveness, the appropriate use of proven clinical methods and audit of the services provided.[317] Managed care demands the development of guidelines or standards of care which are evidence based in terms of effectiveness and cost effectiveness. These can be used as the basis to audit the service provided. However there remains controversy as to whether managed care, which like all types of monitoring involves high administrative costs, can save money and improve quality.[316] It restricts patient and clinician choice and may be associated with less patient satisfaction with care.[316,318]

Whether the internal market will continue within the NHS is uncertain and the implications of managed care in the UK remain to be seen. It may be, however, that if patients in some areas continue to fund their own infertility investigations and treatment, then managed care may be a way of providing a rational service at a reasonable cost.

We have reached a cross roads in medicine now where it is being recognised that improvements in medical care are not dependent solely upon improvements in technology but in the way we apply existing science and technology to medicine.[312]

Changing Physician Behaviour

Doctors are not the only workers in health care who need to be aware of evidence based practice. Individuals involved in medical education, nursing staff, health care strategists and managers within the National Health Service should all be aware of it. However, the point of confluence of clinical effectiveness initiatives remains primarily the doctor, and fundamental to virtually all improvements in care are changes in physician behaviour. This is probably one of the most challenging aspects of evidence based medicine and, like its other components, implementation also should be evidence based.

Grol has reviewed the principal approaches to changing practice and has summarised them as educational, epidemiological, marketing, behavioural, social interaction, organisational and coercive.[319] The details of this are out with the scope of this discussion except to say that although the present project has focused on the first five of these which are individual-based but there are other external stimuli to change.

There is compelling evidence that continuing medical education initiatives can change physician behaviour and consequently improve health care outcomes. [243] The most effective means of promoting change include patient reminders, opinion leaders, patient mediated interventions (eg. patient education leaflets), outreach visits and a multifaceted activities.[243] Audit with feedback and Continuing Medical Education (CME) conferences without practice reinforcing strategies appear to be much less effective.[243] The results of CME in changing behaviour can be large but are most often small.[243]

A recent randomised controlled trial studied the impact of educational outreach visits and free access to the Cochrane Database to encourage a more evidence based approach to obstetrics.[247] This showed an improvement in only one of four aspects of evidence based practice assessed in the study between intervention and control groups. Large variations in clinical practice were observed between different centres and mismatches between the policies claimed by staff and actual clinical practice, similar to the results of the GAPS infertility audit, were reported .[320]

Doctors' attitudes to evidence based medicine are also important in the process of changing care. McColl et al. in a questionnaire survey of general practitioners found the majority supported evidence based medicine and recognised its ability to improve care.[321] Less than half, however, had heard of the Cochrane Database of Systematic Reviews, 20% had access in their surgery to Medline or other bibliographic databases and only 17% had access to the world wide web.[321] Lack of personal time was cited as the principle reason for not pursuing an evidence-based approach.[321] Personal and organisational inertia were also mentioned as hindering progress in this area.

5 CONCLUSIONS

5 CONCLUSIONS

The main objectives of the thesis were met in the course of the GAPS Audit of the Investigation and Initial Management of Infertility.

A comprehensive review of the development of clinical audit over the past 10 years was performed. This highlighted the considerable ground that has been gained in this area in a relatively short time period and the transition of the Government's approach from simply measuring care to a much more comprehensive clinical effectiveness program. It also demonstrated a growing realisation of the limitations of clinical audit when used in isolation, and the need for greater understanding and implementation of other effective means of improving clinical care.

The project demonstrated that large scale multicentre audit which crosses the primary-secondary care interface is feasible and, at least in the present audit, was supported by both hospital gynaecologists and general practitioners alike. The audit was accompanied by modest changes in both the observed process of care in 12 Scottish centres and patients' experience of care. In addition, it identified variations and deficiencies in care and made recommendations to improve these. Small changes in the management of infertile couples by general practitioners were demonstrated in three areas of care but the impact of the audit on primary care appears to have been considerably less than that in hospital practice.

The patient questionnaires highlighted patients' perceptions of infertility care and, using objective measures, suggested that significant levels of psychological distress may be experienced by many of these patients. The clinical significance of these psychological findings and effective ways to address emotional distress in infertility patients remain controversial. There is no doubt that the conclusions that could be drawn from the present psychological study were limited by the low response rate to the questionnaire and the lack of a matched fertile control group.

The basis of the project was the promotion of good quality care through audit. It is now recognised that while audit is important in monitoring care, audit with dissemination of the results to clinicians is not the most effective means of achieving improvements in practices. The project provided information for clinicians but did not provide any resources to facilitate change and relied on the initiatives of individual clinicians. Although some gynaecologists made significant changes in practice, others were recalcitrant to change or unable to implement it within their practice. Further research is needed to determine the obstacles to change and the most effective ways of overcoming them.

REFERENCES

1. Templeton A, Fraser C, Thompson B. The epidemiology of infertility in Aberdeen. *British Medical Journal* 1990;301:148-52.
2. Oei SG, Keirse MJ, Bloemenkamp KW, Helmerhorst FM. European postcoital tests: opinions and practice. *British Journal of Obstetrics & Gynaecology* 1995;102:621-24.
3. Helmerhorst FM, Oei SG, Bloemenkamp KW, Keirse MJ. Consistency and variation in fertility investigations in Europe. *Human Reproduction* 1995;10:2027-30.
4. Owens DJ, Read MW. Patients' Experience with and Assessment of Subfertility Testing and Treatment. *Journal of Reproductive and Infant Psychology* 1984;2:7-17.
5. Pfeffer, N. and Quick, A. *Infertility Services A Desperate Case* London. London: The Greater London Association of Community Health Councils; 1988.
6. Information and Statistics Division, C.S.A.S.H.S. *Births in Scotland 1976-1995*. Edinburgh: Common Services Agency; 1997.
7. Templeton A, Fraser C, Thompson B. Infertility-epidemiology and referral practice. *Human Reproduction* 1991;6:1391-1394.
8. Westrom L. Incidence, prevalence, and trends of acute pelvic inflammatory disease and its consequences in industrialized countries. *American Journal of Obstetrics and Gynecology* 1980;7:880-92.
9. Kihlstrom E, Lindgren R, Ryden G. Antibodies to *Chlamydia trachomatis* in women with infertility, pelvic inflammatory disease and ectopic pregnancy. *European Journal of Obstetrics & Gynaecology and Reproductive Biology* 1990;35:199-204.
10. Irvine S, Cawood E, Richardson D, MacDonald E, and Aitken J. Evidence of deteriorating semen quality in the United Kingdom: birth cohort study in 577 men in Scotland over 11 years. *British Medical Journal* 1996;312:467-71.
11. Forman D, Moller H. Testicular Cancer. *Cancer Surveys* 1994;19/20:323
12. Chen SH, Wallach EE. Five decades of progress in the management of the infertile couple. *Fertility and Sterility* 1994;62:665-85.
13. Handyside AH, Lesko JG, Tarin JJ, Winston RML, Hughes MR. Birth of a normal girl after in vitro fertilization and pre-implantation diagnostic testing for cystic fibrosis. *New England Journal of Medicine* 1992;327:905-9.
14. Diedrich K, Felberbaum R, Kupker W, al-Hasani S. New approaches to male infertility: IVF and microinjection. *International Journal of Andrology* 1995;18(Suppl 2):78-80.
15. Recent deliberations on the case of human fetal oocytes and on pregnancies in post-menopausal women by the British Human Fertilisation and Embryology Authority [editorial]. *Human Reproduction* 1995;10:239-44.
16. Department of Health. *Working for Patients*. London: HMSO; 1989.
17. Department of Health, Welsh Office, Scottish Office Home and Health Department. *Report on Confidential Enquiries into Maternal Deaths in the United Kingdom*. London: HMSO; 1996.
18. Roberts JS, Coale JG, Redman RR. A history of the Joint Commission on the Accreditation of Hospitals. *Journal of the American Medical Association* 1987;258:940.
19. Smits HL. The PSRO in Perspective. *New England Journal of Medicine* 1981;305:253-9.

20. O'Leary DS. The Joint Commission looks to the future. *Journal of the American Medical Association* 1987;258:951-2.
21. Epstein AM. The outcomes movement- will it get us where we want to go? *New England Journal of Medicine* 1990;323:266-9.
22. Schroeder SA. Outcome assessment 70 years late: are we ready? *New England Journal of Medicine* 1987;316:160-1.
23. Legislated Clinical Medicine [editorial]. *Lancet* 1990;335:1004-6.
24. Lohr KN, Schroeder SA. A strategy for quality assurance in Medicare. *New England Journal of Medicine* 1990;322:707-12.
25. Himmelstein DU, Woolhandler S. Cost without benefit: administrative waste in U.S. health care. *New England Journal of Medicine* 1987;316(3):161-2.
26. Williamson JD. Quality Control, medical audit and the general practitioner. *Journal of the Royal College of General Practitioners* 1973;23:697-706.
27. Towards the More Effective Use of Diagnostic Radiology: A Review of the Work of the Royal College of Radiologists Working Party on the More Effective Use of Diagnostic Radiology, 1976 to 1986 [editorial]. *Clinical Radiology* 1988;39:3-6.
28. Bowden D, Walshe K. When medical audit starts to count. *British Medical Journal* 1991;303:101-3.
29. Implementation of "Working for Patients" (Cm 555). *Medical Audit*. Edinburgh: HMSO; 1989.
30. Department of Health. Working for Patients: Medical Audit (NHS review working paper no.6). London: Her Majesty's Stationary Office; 1989.
31. NHS Management Executive. Clinical Guidelines: Using clinical guidelines to improve patient care within the NHS. Leeds: Department of Health; 1996.
32. NHS Management Executive. Promoting Clinical Effectiveness. Leeds: Department of Health; 1996.
33. NHS Management Executive. EL(93)59. Clinical Audit in the HCHS: Allocation of Funds 1993/1994. London: Department of Health; 1993.
34. NHS Management Executive. EL(93)59. Clinical Audit: meeting and improving standards in healthcare. Leeds: Department of Health; 1993.
35. NHS Management Executive. Clinical Audit in HCHS: Funding for 1994/95 and Beyond. Leeds: Department of Health; 1993.
36. NHS Management Executive. Clinical Audit: 1994/95 and Beyond. Leeds: Department of Health; 1994.
37. NHS Management Executive. The New health Authorities and the clinical Audit Initiative: Outline of Planned Monitoring Arrangements. Leeds; Department of Health; 1995.
38. NHS Management Executive. Arrangements for Clinical Audit in Primary Health Care. Leeds: Department of Health; 1996.
39. CASPE Research. Evaluating Medical Audit: the role of the commissioner in audit: Findings of a national survey of commissioning authorities in England. London: CASPE; 1994.
40. CASPE Research. Evaluating Audit: Nursing and therapy audit: a review of the regions role. London: CASPE; 1994.
41. CASPE Research. Audit Activities of the Medical Royal colleges and their Faculties in England. London: CASPE; 1995.
42. CASPE Research. Evaluating Medical Audit: The development of Audit: findings of a national survey of commissioning authorities in England. London: CASPE Research; 1995.

43. CASPE Research. Evaluating Audit: Provider audit in England: a review of twenty-nine healthcare provider units in England. London: CASPE; 1995.
44. CASPE Research. Evaluating Audit: North Staffordshire's joint clinical audit programme: Case Study. London: CASPE; 1996.
45. CASPE Research. Evaluating Audit: Wythenshaw hospital clinical research programme: a case study. London: CASPE; 1996.
46. NHS Management Executive. Clinical Audit in the NHS. Using Clinical Audit in the NHS: a position statement. Department of Health: Leeds; 1996.
47. Amess, M., Walshe, K., Shaw, C. et al. The audit activities of the medical Royal Colleges and their Faculties in England. London: CASPE Research; 1995.
48. Interim RCOG Guidelines on medical Audit. London: Royal College of Obstetrics and Gynaecology; 1990.
49. Smith R, editor. Audit in Action. London: British Medical Journal; 1992.
50. Hawkins JM. The Oxford Paperback Dictionary. 3rd Edition ed. Oxford: Oxford University Press; 1978.
51. McNicol GP. A rather sad document. British Medical Journal 1979;2:844-8.
52. Hall H. Say "no" to audit. World Medicine 1979;14:21-2.
53. Doll R. Monitoring the National Health Service. Proceedings of the Royal Society of Medicine 1973;66:729-40.
54. Chambers R, Bowyer S, Campbell I. Investigation into the attitudes of general practitioners in Staffordshire to medical audit. Quality in Health Care 1996;5:13-9.
55. Webb SJ, Dowell AC, Heywood P. Survey of general practice audit in Leeds. British Medical Journal 1991;302:390-2.
56. Clinical Outcomes Working Group. Clinical Outcome Indicators. Edinburgh: The Scottish Office; 1996.
57. Scottish Intercollegiate Guidelines Network (SIGN). Clinical Guidelines. Criteria for Appraisal for National Use. Edinburgh: SIGN; 1995.
58. Petrie JC, Grimshaw JM, Bryson A. The Scottish Intercollegiate Guidelines Network Initiative: Getting validated guidelines into local practice. Health Bulletin 1995;53:345-8.
59. Penney GC, Glasier A, Templeton A. Multicentre criterion based audit of the management of induced abortion in Scotland. British Medical Journal 1994;309:15-9.
60. Shaw CD. Smith R, editors. Audit in Action. London: British Medical Journal; 1992; The Background. p. 3-9.
61. Maresh M. Maresh M, editors. Audit in Obstetrics and Gynaecology. Oxford: Blackwell Scientific Publications; 1994; What is Audit? p. 3-17.
62. Heath DA, Hoofenberg R, Bishop JM, Kendall MJ, Wade OL. Medical Audit. Journal of the Royal College of Physicians London 1980;14:200-1.
63. McKee M. Routine data: a resource for clinical audit. Quality in Health Care 1993;2:104-110.
64. Barrie JL, Marsh DR. Quality of data in the Manchester orthopaedic database. British Medical Journal 1992;304:159-162.
65. Pringle M, Hobbs R. Large computer databases in general practices - of little use unless high quality data are collected. British Medical Journal 1991;302:741-2.
66. Yudkin PL, Redman CWG. Obstetric audit using routinely collected computerised data. British Medical Journal 1990;301:1371-3.

67. Emberton M, Rivett R, Ellis RW. Comparative Audit: A new method of delivering audit. *Ann R Coll Surg England* 1991;73:117-20.
68. Copeland GP. Comparative audit: fact versus fantasy. *British Journal of Surgery* 1993;80:1424-5.
69. Brennan TA, Localio RJ, Laird NL. Reliability and validity of judgements concerning adverse events suffered by hospitalised patients. *Medical Care* 1989;27:1148-58.
70. Bennet J, Walshe K. Occurrence screening as a method of audit. *BMJ* 1990;300:1248-51.
71. Shaw CD. Criterion based audit. *British Medical Journal* 1990;300:649-51.
72. Donabedian A. Evaluating the quality of medical care. *Millbank Memorial Fund Quarterly* 1966;44(suppl):166-206.
73. Nixon SJ. Defining essential hospital data. *British Medical Journal* 1990;300:380-1.
74. The Management of Subfertility [editorial]. *Effective Health Care* 1992;31-24.
75. Fertility Committee of the Royal College of Obstetricians and Gynaecologists. Infertility guidelines for practice. London: RCOG Press; 1992.
76. World Health Organisation. WHO Laboratory manual for the examination of human semen and sperm-cervical mucus interaction. Cambridge: Cambridge University Press; 1992.
77. Scottish Office Home and Health; Scottish Health Service Advisory Council. Infertility services in Scotland. Edinburgh: HMSO; 1993.
78. Rowe PJ; Comhaire FH; Hargreave TB, et al. WHO manual for the standardised investigation and diagnosis of the infertile couple. Cambridge: Cambridge University Press; 1993.
79. Van den Eede B. Investigation and treatment of infertile couples: ESHRE guidelines for good clinical and laboratory practice. *Human Reproduction* 1995;10:1246-71.
80. Penney GC, Glasier A, and Templeton A. Agreeing criteria for audit of the management of induced abortion: an approach by national consensus survey. *Quality in Health Care* 1993;2167-9.
81. Medical Outcomes Trust. How to score the SF-36 Health Survey. Boston: Medical Outcomes Trust; 1994.
82. Garrat AM, Ruta DA, Abdalla MI, Buckingham JK, Russell IT. The SF-36 questionnaire: an outcome measure suitable for routine use within the NHS? *British Medical Journal* 1993;306:1440-4.
83. Brazier JE, Harper R, Jones NMB, O'Cathain A, Thomas KJ, Usherwood T, and Westlake L. Validating the SF-36 health survey questionnaire: a new outcome measure for primary care. *British Medical Journal* 1992;305:160-164.
84. Jenkinson C, Coulter C, Wright L. Short form 36 (SF-36) health survey questionnaire: normative data for adults of working age. *British Medical Journal* 1993; 306:1437-1440.
85. Goldberg D, Williams P. A users guide to the general health questionnaire. 1988 Windsor: NFER Nelson.
86. Souter VL, Penney G, Gorman DR. A survey of infertility practices in primary care in Scotland. *British Journal of General Practice*. 1997;47:727-8.
87. Souter VL, Irvine DS, Templeton AA. Laboratory techniques for semen analysis: a Scottish survey. *Health Bulletin* 1997;55:140-9.

88. Souter VL, Penney GC, Hopton JL, Templeton AA. Patient satisfaction with the management of infertility. *Human Reproduction* 1998;13(7):1831-6.
89. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* 1993;342:1317-22.
90. Emslie C, Grimshaw J, Templeton A. Do clinical guidelines improve general practice management and referral of infertile couples? *British Medical Journal* 1993;306:1728-31.
91. Lalos A, Lalos O, Jacobsson L, von Schoultz B. The psychosocial impact of infertility two years after completed surgical treatment. *Acta Obstetrica et Gynecologica Scandinavica* 1985;64:599-604.
92. Andrews FM, Abbey A, Halman LJ. Stress from infertility, marriage factors, and subjective well-being of wives and husbands. *Journal of Health & Social Behavior* 1991;32:238-53.
93. Drake TS, Grunert GM. A Cyclic Pattern of Sexual Dysfunction in the Infertility Investigation. *Fertility and Sterility* 1979;32:542-5.
94. Edelmann RJ and Connolly KJ. Psychological aspects of infertility. *British Journal of Medical Psychology* 1986;59:209-19.
95. Kemeter P. Studies on psychosomatic implications of infertility - effects of emotional stress on fertilization and implantation in in-vitro fertilization. *Human Reproduction* 1988;3:341-52.
96. Berg BJ, Wilson JF. Psychiatric morbidity in the infertile population: a reconceptualization. *Fertility and Sterility* 1990;53:654-61.
97. Moller A, Fallstrom K. Psychological consequences of infertility: A longitudinal study. *Journal of Psychosomatic Obstetrics and Gynaecology* 1991;12:27-45.
98. Domar AD, Broome A, Zuttermeister PC, Seibel M, Friedman R. The prevalence and predictability of depression in infertile women. *Fertility and Sterility* 1992;58:1158-63.
99. Hinton R, Meadoecroft J, Wardle P. Psychological distress and sub fertility [letter]. *Journal of the Royal Society of Medicine* 1995;88:237-8.
100. Slade P, Emery J, Lieberman BA. A prospective longitudinal study of the emotions and relationships in in-vitro fertilization treatment. *Human Reproduction* 1997;12:183-90.
101. Hearn MT, Yuzpe AA, Brown SE, Casper RF. Psychological characteristics of in vitro fertilisation participants. *American Journal of Obstetrics and Gynaecology* 1987;156:269-74.
102. Kopitzke EJ, Berg J, Wilson JF, and Owens D. Physical and emotional stress associated with components of the infertility investigation: Perspectives of professionals and patients. *Fertility and Sterility* 1991;55:1137-43.
103. Human Fertilisation and Embryology Authority. Code of Practice. London: H.F.E.A.; 1995
104. Bresnick E, Taymor ML. The role of counseling in infertility. *Fertility and Sterility* 1979;32:154-6.
105. Herson M, Harris CP, Elstein M, Russell CA, Seif MW. Review of the organized support network for infertility patients in licensed units in the UK. *Human Reproduction* 1995;10:960-4.
106. Domar AD, Zuttermeister PC, Seibel M, Benson H. Psychological improvement in infertile women after behavioral treatment: a replication. *Fertility and Sterility* 1992;58:144-7.

107. Tarlatzis I, Tarlatzis BC, Diakogiannis I, Bontis J, Lagos S, Gavriilidou D, Mantalenakis S. Psychosocial impacts of infertility on Greek couples. *Human Reproduction* 1993;8:396-401.
108. Connolly KJ, Edelmann RJ, Bartlett H, Cooke ID, Lenton E, Pike S. An evaluation of counselling for couples undergoing treatment for in-vitro fertilization. *Human Reproduction* 1993;8:1332-8.
109. Bromham DR, Balmer B, Clay R, Hamer R. Disenchantment with infertility services: A survey of patients in Yorkshire. *British Journal of Family Planning* 1988;14:3-8.
110. Hull MGR, Glazener CMA, Kelly NJ, Conway DI, Foster PA, and Hinton RA. Population study of causes, treatment, and outcome of infertility. *British Medical Journal* 1985; 291:1693-7.
111. Randall JM and Templeton AA. Infertility: The Experience of a Tertiary Referral Centre. *Health Bulletin* 1991;49:148-53.
112. Eimers JM, te Velde ER, Gerritse R, Vogelzang ET, Looman CWN, Habbema JDF. The prediction of the chance to conceive in subfertile couples. *Fertility and Sterility* 1994;61:44-52.
113. Honig SC, Lipshultz LI, Jarow J. Significant medical pathology uncovered by a comprehensive male infertility evaluation. *Fertility and Sterility* 1994;62:1028-1034.
114. Dunphy BC, Kay R, Barratt CL, Cooke ID. Is routine examination of the male partner of any prognostic value in the routine assessment of couples who complain of involuntary infertility? *Fertility and Sterility* 1989;52:454-6.
115. Madgar I, Weissenberg R, Lunenfeld B, Karasik A, Goldwasser B. Controlled trial of high spermatic vein ligation for varicocele in infertile men. *Fertility and Sterility* 1995;63:120-4.
116. Nieschlag E, Hertle L, Fishedick A, Behre HM. Treatment of varicocele: Counselling as effective as occlusion of the vena spermatica. *Human Reproduction* 1995;10:347-53.
117. Balen AH, Braat DD, West C, Patel A, Jacobs HS. Cumulative conception and live birth rates after the treatment of anovulatory infertility: safety and efficacy of ovulation induction in 200 patients. *Human Reproduction* 1994;9:1563-70.
118. Hull MG. Indications for assisted conception. *British Medical Bulletin* 1990;46:580-95.
119. Abdulla L, Diver MJ, Hipkin LJ, Davis JC. Plasma progesterone levels as an index of ovulation. *British Journal of Obstetrics and Gynaecology* 1983;90:543-8.
120. Hull MGR, Savage PE, Bromham DR, Ismail AAA, Morris AF. The value of a single serum progesterone measurement in the midluteal phase as a criterion of a potentially fertile cycle ("ovulation") derived from treated and untreated conception cycles. *Fertility and Sterility* 1982;37:355-60.
121. Wathen NC, Perry L, Lilford RJ, Chard T. Interpretation of single progesterone measurement in diagnosis of anovulation and defective luteal phase: observations on analysis of the normal range. *British Medical Journal* 1984;288:7-9
122. Collins WP, Collins PO, Kilpatrick MJ, Manning PA, Pike JM. The concentrations of urinary oestrone-3-glucuronide, LH and pregnanediol-3-glucuronide as indices of ovarian function. *Acta Endocrinologica* 1979;90:336-48.

123. Sauer MV, Paulson RJ. Utility and predictive value of a rapid measurement of urinary pregnanediol glucuronide by enzyme immunoassay in an infertility practice. *Fertility and Sterility* 1991;56:823-6.
124. Schwartz DW, Laplanche A, Jouannet P, David G. Within-subject variation of human semen in regard to sperm count, volume, total number of spermatozoa and length of abstinence. *Journals of Reproduction and Fertility* 1979;57:391-5.
125. Jouannet P, Czyglik F, David G. Study of a group of 484 fertile men Part 1: Distribution of semen characteristics. *International Journal of Andrology* 1981;4:440-9.
126. Johnson L. A re-evaluation of daily sperm output of men. *Fertility and Sterility* 1982;37:811-6.
127. Schwartz D, Ducot B, Auroux M, Collin C. Within-subject variability of the percentage of morphologically abnormal spermatazoa among fertile men: biological and measurement components. *Human Reproduction* 1986;1:369-71.
128. Purvis K, Tollesfsrud A, Rui H. Stability of sperm characteristics in men with disturbances in sperm quality. *International Journal of Andrology* 1989;12:171-8.
129. Mallidis C, Howard EJ, Baker HWG. Variation in semen quality in normal men. *International Journal of Andrology* 1991;14:99-107.
130. Griffith CS, Grimes DA. The validity of the postcoital test. *American Journal of Obstetrics and Gynecology* 1990;162:615-20.
131. Hull MGR, Savage PE, Bromham DR. Prognostic value of the postcoital test: prospective study based on time-specific conception rates. *British Journal of Obstetrics and Gynaecology* 1982;89:299-305.
132. Eimers JM, te Velde ER, Gerritse R, van Kooy RJ, Kremer J, Habbema JDF. The validity of the postcoital test for estimating the probability of conceiving. *American Journal of Obstetrics and Gynecology* 1994;171:65-70.
133. Giner J, Guillermina M, Luna J, Aznar R. Evaluation of the Sims-Huhner post coital test in infertile couples. *Fertility and Sterility* 1974;25:145-8.
134. Kovacs GT, Newman GB, Henson GL. The postcoital test: What is normal? *British Medical Journal* 1978;1(6116):818.
135. Harrison RF. The diagnostic and therapeutic potential of the postcoital test. *Fertility and Sterility* 1981;36:71-5.
136. Collins J, So Y, Wilson EH, Wrixon W, Casper RF. The postcoital test as a predictor of pregnancy among 355 infertile couples. *Fertility and Sterility* 1984;41:703-8.
137. Glatstein IZ, Best CL, Palumbo A, Sleeper L, Friedman AJ, Hornstein MD. The reproducibility of the postcoital test: a prospective study. *Obstetrics and Gynecology* 1995;85:396-400.
138. Primary vaccination uptake rates. Glasgow. Scottish Centre for Infection and Environmental Health. 1996; 96/26. SCIEH Weekly Report.
139. Rubella. Glasgow; Scottish Centre for Infection and Environmental Health: 1996. Volume 30 No.96/18. p.1
140. Robinson J, Lemay M, Vaudry WL. Congenital rubella after anticipated maternal immunity: Two cases and a review of the literature. *Pediatric Infectious Disease Journal* 1994;13:812-5.
141. Christenson B, Bottiger M. Long-term follow-up study of rubella antibodies in naturally immune and vaccinated young adults. *Vaccine* 1994;12:41-5.

142. Lenton EA, Weston GA, and Cooke ID. Problems in using basal body temperature recordings in an infertility clinic. *British Medical Journal* 1977;1803-5.
143. Bauman JE. Basal body temperature: unreliable method of ovulation detection. *Fertility and Sterility* 1981;36:729-33.
144. Quagliarello J and Arny M. Inaccuracy of basal body temperature charts in predicting urinary luteinizing hormone surges. *Fertility Sterility* 1986;45:334-7.
145. Wilcox AJ, Weinberg CR, Baird DD. Timing of sexual intercourse in relation to ovulation. *New England Journal of Medicine* 1995;333:1517-21.
146. Kierse MJNC, Vandervellen R. A comparison of hysterosalpingography and laparoscopy in the investigation of infertility. *Obstetrics and Gynecology* 1973;41:685-8.
147. Snowden EU, Jarrett JC, Dawood MY. Comparison of the diagnostic accuracy of laparoscopy, hysteroscopy and hysterosalpingography in evaluation of female fertility. *Fertility and Sterility* 1984;41:709-13.
148. World Health Organisation Task Force on the Diagnosis and Treatment of Infertility. Comparative trial of tubal insufflation, hysterosalpingography, and laparoscopy with dye hydrotubation for assessment of tubal patency. *Fertility and Sterility* 1986;46:1101-7.
149. Watson A, Vandekerckhove P, Lilford R, Vail A, Brosens I, Hughes E. A meta-analysis of the therapeutic role of oil soluble contrast media at hysterosalpingography: A surprising result? *Fertility and Sterility* 1994;61:470-7.
150. Adelusi B, AlNuaim L, Mankanjuola D, Khashoggi T, Chowdhury N, Kangave D. Accuracy of hysterosalpingography and laparoscopic hydrotubation in diagnosis of tubal patency. *Fertility and Sterility* 1995;63:1016-20.
151. Opsahl MS, Miller B, Klein TA. The predictive value of hysterosalpingography for tubal and peritoneal infertility factors. *Fertility and Sterility* 1993;60:444-8.
152. Rice JP, London SN, Olive DL. Reevaluation of Hysterosalpingography in Infertility Investigation. *Obstetrics and Gynecology* 1986;67:718-21.
153. Swart P, Mol BWJ, Van der Veen F, Van Beurden M, Redekop WK, Bossuyt PMM. The accuracy of hysterosalpingography in the diagnosis of tubal pathology: A meta-analysis. *Fertility and Sterility* 1995;64:486-91.
154. Vessey MP, Wright NH, McPherson K, Wiggins P. Fertility after stopping different methods of contraception. *British Medical Journal* 1978;1:265-9.
155. Opsahl MS, Klein TA. Tubal and peritoneal factors in the infertile woman: Use of patient history in selection of diagnostic and therapeutic surgical procedures. *Fertility and Sterility* 1990;53:632-7.
156. Bahamondes L, Bueno JGR, Hardy E, Vera S, Pimentel RN, Ramos M. Identification of main risk factors for tubal infertility. *Fertility and Sterility* 1994;61:478-82.
157. Forman RG, Robinson JN, Mehta Z, Barlow DH. Patient history as a simple predictor of pelvic pathology in subfertile women. *Human Reproduction* 1993;8(1):53-5.
158. Minassian SS, Wu CH. Chlamydia antibody enzyme-linked immunosorbent assay and associated severity of tubal factor infertility. *Fertility and Sterility* 1992;58:1245-7.

159. Dabekausen YAJM, Evers JLH, Land JA, Stals FS. Chlamydia trachomatis antibody testing is more accurate than hysterosalpingography in predicting tubal factor infertility. *Fertility and Sterility* 1994;61:833-7.
160. Musich JR, Behrman SJ. Infertility laparoscopy in perspective: Review of five hundred cases. *American Journal of Obstetrics and Gynecology* 1982;143:293-303.
161. Peterson HB, Hulka JF, Philips JM, Sydney MW. Laparoscopic sterilisation: American Association of Gynaecologic Laparoscopists 1991 membership survey. *Journal of Reproductive Medicine* 1993;38:574-6.
162. Acton CM, Devitt JM, Ryan EA. Hysterosalpingography in infertility - An experience of 3,631 examinations. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 1988;28:127-33.
163. Martin DC, Khare VK, Miller BE. Association of Chlamydia trachomatis immunoglobulin gamma titers with dystrophic peritoneal calcification, psammoma bodies, adhesions, and hydrosalpinges. *Fertility and Sterility* 1995;63:39-44.
164. Wald N, Sneddon J, Densem J, Frost C, Stone R. Prevention of neural tube defects: Results of the Medical Research Council vitamin study. *Lancet* 1991;338:131-7.
165. Lawrence KM, James N, Miller M, Tennant GB, Campbell H. Double-blind randomised controlled trial of folate treatment before conception to prevent recurrence of neural-tube defects. *British Medical Journal* 1981;282:1509-11.
166. Czeizel AE, Dudas I. Prevention of the first occurrence of neural-tube defects by periconceptual vitamin supplementation. *New England Journal of Medicine* 1992;327:1832-5.
167. Werler MM, Mitchell AA. Case-Control study of vitamin supplementation and neural tube defects. Consideration of potential confounding by lifestyle factors. *Annals of the New York Academy of Sciences* 1993;678:276-83.
168. Clark NAC, Fisk NM. Minimal compliance with the Department of Health recommendation for routine folate prophylaxis to prevent fetal neural tube defects. *British Journal of Obstetrics and Gynaecology* 1994;101:709-10.
169. Odibo AO, Greenwood C, Selinger M. Minimal compliance with the Department of Health recommendation for routine folate prophylaxis to prevent fetal neural tube defects [Letter]. *British Journal of Obstetrics and Gynaecology* 1995;102:171.
170. Balen A. Minimal compliance with the Department of Health recommendation for routine prophylaxis to prevent fetal neural tube defects [Letter]. *British Journal of Obstetrics and Gynaecology* 1995;102:171-4.
171. Nelson-Piercy C, de Swiet M. Minimal compliance with the Department of Health recommendation for routine prophylaxis to prevent fetal neural tube defects. *British Journal of Obstetrics and Gynaecology* 1995;102:171.
172. Pearce HR, Smith NA, Bingham JS. Periconceptual folic acid: knowledge amongst health care workers in a London teaching hospital. *British Journal of Family Planning* 1996;22:20-1.
173. Strauss RG, Bernstein R. Folic acid and Dilantin antagonism in pregnancy. *Obstetrics and Gynecology* 1974;44:345-7.
174. Epilepsy and pregnancy. *Drugs and Therapeutics Bulletin* 1994;32:49-51.
175. Kaneko S, Kondo T. Antiepileptic agents and birth defects: Incidence, mechanisms and prevention. *Drugs* 1995;3:41-55.

176. Hovatta O, Koskimies AI, Ranta T, Stenman H, Seppala M. Bromocriptine treatment for oligospermia: a double blind study. *Clinical Endocrinology* 1979;3:1-24.
177. Wang C, Chan C, Wong K, Yeung K. Comparison of placebo, clomiphene citrate, mesterolone, pentoxifylline and testosterone rebound therapy for the treatment of idiopathic male infertility. *Fertility and Sterility* 1983;40:358-65.
178. Sokol SZ, Steiner BS, Bustillo M, Peterson G, Swerdloff RS. A randomised comparison of the efficacy of clomiphene citrate in male infertility. *Fertility and Sterility* 1988;49:865-70.
179. WHO task force on the diagnosis and treatment of infertility. Mesterolone and idiopathic male infertility: a double-blind study. *International Journal of Andrology* 1989;12:254-64.
180. O'Donovan PA, Vandekerckhove P, Lilford RJ, Hughes E. Treatment of male infertility: is it effective? Review and meta-analyses of published randomised controlled trials. *Human Reproduction* 1993;8:1209-22.
181. Harrison RF, Blades D, De Louvois J, Hurley R. Doxycycline treatment and human fertility. *Lancet* 1975;1:605-7.
182. Comhaire FH, Rowe RJ, Farley TMM. The effect of doxycycline in infertile couples with male accessory gland infection: a double blind prospective study. *International Journal of Andrology* 1986;9:91-6.
183. Vandekerckhove P, Lilford R, Vail A, et al. Lilford R, Hughes E, Vandekerckhove P, editors. *The Cochrane Database of Systematic Reviews*. Issue 1 ed. Oxford: The Cochrane Collaboration; 1997; The medical treatment of idiopathic oligo/asthenospermia: androgens (mesterolone or testosterone) versus placebo or no treatment.
184. Vandekerckhove P, Lilford R, Vail A, et al. Lilford R, Hughes E, Vandekerckhove P, editors. *Subfertility Module of The Cochrane Database of Systematic Reviews*. Issue 1 ed. Oxford: The Cochrane Collaboration; 1997; The medical treatment of idiopathic oligo- and/or asthenospermia: antioestrogens (clomiphene or tamoxifen) versus placebo or no treatment.
185. Vandekerckhove P, Lilford R, Vail A, et al. Lilford R, Hughes E, Vandekerckhove P, editors. *Subfertility Module of the Cochrane Database of Systematic Reviews*. Issue 1 ed. Oxford: The Cochrane Collaboration; 1997; Kinin enhancing drugs for idiopathic male infertility.
186. Hughes EG, Fedorkow DM, Collins JA. A quantitative overview of controlled trials for endometriosis-associated infertility. *Fertility and Sterility* 1993;59:963-70.
187. Adamson GD, Pasta DJ. Surgical treatment of endometriosis-associated infertility: Meta-analysis compared with survival analysis. *American Journal of Obstetrics and Gynecology* 1994;171:1488-506.
188. Hughes E, Fedorkow D, Collins J, et al. Lilford R, Hughes E, Vandekerckhove P, editors. *Subfertility Module of The Cochrane Database of Systematic Reviews*. Issue 1 ed. Oxford: The Cochrane Collaboration; 1997; Ovulation Suppression vs Placebo in the Treatment of Endometriosis.
189. Duncan, C., editor. *Monthly Index of Medical Specialities (MIMS)*. January 1997. London: Haymarket Publishing Services Ltd; 1997.
190. Kupferminic MJ, Lessing JB, Peyser MR. Ovulation induction with gonadotrophins in women with polycystic ovary disease. 1991;31:61-64.

191. Check JH, Chase JS, Adelson HG, Lauer C, Schubert B. A conservative treatment protocol with human menopausal gonadotrophins aimed at reducing multiple births. *Journal of Perinatal Medicine* 1993;21:315-319.
192. RCOG Guidelines. Use of Gonadotrophic Hormone Preparations for Ovulation Induction. London: RCOG: 1994.
193. Hulka JF. Adnexal adhesions: A prognostic staging and classification system based on a five-year survey of fertility surgery results at Chapel Hill, North Carolina. *American Journal of Obstetrics & Gynecology* 1982;144:141-7.
194. Fayez JA, Suliman SO. Infertility surgery of the oviduct: comparison between macrosurgery and microsurgery. *Fertility and Sterility* 1982;37:73-8.
195. Verhoeven HC, Berry H, Frantzen C, Sclosser H. Surgical treatment for distal tubal occlusion. *The Journal of Reproductive Medicine* 1983;26:293-303.
196. Donnez J, Casanas-Roux F. Prognostic factors of fimbrial microsurgery. *Fertility and Sterility* 1986;46:200-4.
197. Mage G, Pouly J, Bouquet de Jouliniere J, Chabrad S, Riouallan A, Bruhat M. A preoperative classification to predict the intrauterine and ectopic pregnancy rates after distal tubal microsurgery. *Fertility and Sterility* 1986;46:807-10.
198. Schlaff WD, Hassiakos DK, Damewood MD, Rock JA. Neosalpingostomy for distal tubal surgery and impact of surgical technique. *Fertility and Sterility* 1990;54:984-90.
199. Singhal V, Li TC, Cooke ID. An analysis of factors influencing the outcome of 232 consecutive tubal microsurgery cases. *British Journal of Obstetrics and Gynaecology* 1991;98:628-36.
200. HFEA Third Annual Report. London: Human Fertilisation and embryology Authority; 1994.
201. Watson AJS, Gupta JK, Dalton ME, Liliford RJ. The results of tubal surgery in the treatment of infertility in two non-specialist hospitals. *British Journal of Obstetrics and Gynaecology* 1990;97:561-8.
202. Winston RML. Is Microsurgery Necessary for Salpingostomy? The Evaluation of Results. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 1981;21:143-52.
203. Oelsner G, Boeckx W, Verhoeven HC, Koninckx P, Brosens I. The effect of training on microsurgical technique. *American Journal of Obstetrics and Gynecology* 1985;152:1054-8.
204. Gomel V. Salpingo-ovariolysis by laparoscopy in in infertility. *Fertility and Sterility* 1983;40:607-10.
205. Tulandi T, Collins JA, Burrows E, Jarrell JF, McInnes RA, Wrixon W. Treatment-dependent and treatment-independent pregnancy among women with periadnexal adhesions. *American Journal of Obstetrics and Gynecology* 1990;162:354-7.
206. Marana R, Rizzi M, Muzii L, Catalano GF, Caruana P, Mancuso S. Correlation between the American Fertility society classification of adnexal adhesions and distal tubal occlusion, salpingoscopy, and reproductive outcome in tubal surgery. *Fertility and Sterility* 1995;64:924-9.
207. Templeton A, Morris JK, Parslow W. Factors that affect outcome of in-vitro fertilisation treatment. *Lancet* 1996;348:1402-6.
208. Templeton AA, Penney GC. The incidence, characteristics, and prognosis of patients whose infertility is unexplained. *Fertility and Sterility* 1982;37:175-82.

209. Verkauf BS. The incidence and outcome of single-factor, multifactorial, and unexplained infertility. *American Journal of Obstetrics and Gynecology* 1983;147:175-81.
210. Collins JA, Rowe TC. Age of the female partner is a prognostic factor in prolonged unexplained infertility: a multicenter study. *Fertility and Sterility* 1989;52:15-20.
211. Kliger BE. Evaluation, therapy, and outcome in 493 infertile couples. *Fertility and Sterility* 1984;41:40-6.
212. Barnea ER, Holford TR, McInnes DRA. Long-term Prognosis of Infertile Couples With Normal Basic Investigations: A Life-Table Analysis. *Obstetrics and Gynecology* 1985;1:24-6.
213. Collins JA, Burrows E, Wilan AR. The prognosis for live birth among untreated infertile couples. *Fertility and Sterility* 1995;64:22-8.
214. Bopp BL, Alper MM, Thompson IE, Mortola J. Success rates with gamete intrafallopian transfer and in vitro fertilisation in women of advanced maternal age. *Fertility and Sterility* 1995;63:1278-83.
215. Tan SL, Doyle P, Maconochie N, Edwards RG, Balen A, Bekir J. Pregnancy and birth rates of live infants after in vitro fertilisation in women with and without previous in vitro fertilization pregnancies: A study of eight thousand cycles at one center. *American Journal of Obstetrics and Gynaecology* 1994;170:34-40.
216. Sundby J, Schei B. Infertility and subfertility in Norwegian women aged 40-42. Prevalence and risk factors. *Acta Obstetrica et Gynecologica Scandinavica* 1996;75:832-7.
217. Grodstein, F. and Goldman, M. B. Cramer D. W. Infertility in women and moderate alcohol use. *American Journal of Public Health* 1994;84:1429-1432.
218. Smith E M, Hammonds-Ehlers M, Clark MK, Kirchner HL, and Fuortes L. Occupational exposures and risk of female infertility. *J Occup Environ Med* 39, 138-147. 1997.
219. Kousta E, White DM, and Franks S. Modern use of clomiphene citrate in induction of ovulation. *Human Reproduction Update* 1997;3:359-365. 1997.
220. Joesbury KA, Edirisinghe WR, Philips MR, and Yovich JL. Evidence that male smoking affects the likelihood of a pregnancy following IVF treatment: application of the modified cumulative embryo score. *Human Reproduction* 1998;13:1506-1513.
221. Lenton EA, Sobowale OS, and Cooke ID. Prolactin concentrations in ovulatory but fertile women: treatment with bromocriptine. *British Medical Journal* 1997;2:1179-1181.
222. Glazener CMA, Kelly NJ, Hull MGR. Prolactin measurement in the investigation of infertility in women with a normal menstrual cycle. *British Journal of Obstetrics & Gynaecology* 1987;94:535-8.
223. Shalev E, Shlomo E, Ziv M, Ben-Ami M. Routine thyroid function tests in infertile women: Are they necessary? *American Journal of Obstetrics & Gynecology* 1994;171:1191-2
224. Glazener CMA, Kelly NJ, Hull MGR. Luteal deficiency not a persistent cause of infertility. *Human Reproduction* 1988;3:213-7.
225. Rossing MA, Daling, JR, Weiss, NS, Moore, DE, and Self, SG. Ovarian tumors in a cohort of infertile women. *New England Journal of Medicine* 1994;331:771-776.

226. Speroff L, Glass RH, Kase NG, Brown C, editors. *Clinical Gynaecological Endocrinology and Infertility*. Fourth ed. Baltimore: Williams & Wilkins; 1989.
227. Abbey A, Halman LJ, Andrews FM. Psychosocial, treatment, and demographic predictors of the stress associated with infertility. *Fertility and Sterility* 1992; 57:122-128.
228. Collins A, Freeman EW, Boxer AS, Tureck R. Perceptions of infertility and treatment stress in females as compared with males entering in vitro fertilization treatment. *Fertility and Sterility* 1992; 57: 350-356.
229. Eimers JM, Omtzigt AM, Vogelzang ET, van Ommen R, Habbema JD, and te Velde FR. Physical complaints and emotional stress related to routine diagnostic procedures related to routine diagnostic procedures of the fertility investigation. *Journal of Psychosomatic Obstetrics and Gynecology* 1997;18:31-35.
230. Collins JA, Feeny D, and Gunby J. The cost of infertility diagnosis and treatment in Canada in 1995. *Human Reproduction* 1997;12:951-958.
231. Glatstein IZ, Harlow BL, and Hornstein MD. Practice patterns among reproductive endocrinologists: further aspects of the infertility investigation. *Fertility and Sterility* 1998;70:263-269.
232. Olive DL. Analysis of clinical fertility trials: a methodologic review. *Fertility and Sterility* 1986;45:157-71.
233. Baker R, Fraser RC. Development of review criteria: linking guidelines and assessment of quality. *British Medical Journal* 1995;311:370-3.
234. Neufeldt V, Sparks AN. *Websters New World Dictionary*. Pocket Books: 1995.
235. Fink A, Kosecoff J, Chassin M, Brook M. Consensus Methods: Characteristics and Guidelines for Use. *American Journal of Public Health* 1984;74:979-83.
236. Jones J and Hunter D. Consensus methods for medical and health services research. *British Medical Journal* 1995;311:376-380.
237. Thomson MA, Oxman AD, Davis DA, Haynes RB, Freemantle N. and Harvey EL. Audit and Feedback to improve health professional practice and health care outcomes. *The Cochrane Database of Systematic Reviews* 2. 1999.
238. Easterbrook PJ, Berlin JA, Gopalan R, Mathews DR. Publication bias in clinical research. *Lancet* 1991;337:867-72.
239. Vandekerckove P, O'Donovan PA, Lilford RJ, Harada TW. Infertility treatment: from cookery to science. The epidemiology of randomised controlled trials. *British Journal of Obstetrics and Gynaecology* 1993;100:1005-36.
240. Dickersin K, Sherer R, and Lefedvre C. Identifying relevant studies for systematic reviews. *British Medical Journal* 1994;309:1286-1291.
241. Watson A, Vandekerckhove P, Lilford R, Vail A, Brosens I, Hughes E. A meta-analysis of the therapeutic role of oil soluble contrast media at hysterosalpingography: A surprising result? *Fertility and Sterility* 1994;61:470-7.
242. Rosser, W. Application of evidence from randomised controlled trials to general practice. *Lancet* 1999;353:661-664.
243. Davis DA, Thomson MA, Oxman AD, and Haynes RB. Changing physician performance: A systematic review of the effect of continuing medical education strategies. *Journal of the American Medical Association* 1995;274:700-705.

244. Scott PV and Pinnock CA. Local ethics committees. BMA's advice about approval of clinical audit studies is confusing. *British Medical Journal* 1997;315:60.
245. Independent ethical review of studies involving personal medical reports. Report of a working group to the Royal College of Physicians committee on ethical issues in medicine. *Journal of the Royal College of Physicians London* 1995;29:446.
246. Lomas J, Enkin M, Anderson GM, Hannah WJ, Vayda E, Singer J. Opinion Leaders VS Audit and Feedback to Implement Practice Guidelines. Delivery After Previous Cesarean Section. *Journal of the American Medical Association* 1991;265:2202-6.
247. Wyatt JC, Paterson-Brown S, Altman DG, Bradburn MJ, and Fisk N. M. Randomised trial of educational visits to enhance use of systematic reviews in 25 obstetric units. *British Medical Journal* 1998;317:1041-1046.
248. Ayida G, Harris P, Kennedy S, Seif M, Barlow D. Hysterosalpingo-contrast sonography (HyCoSy) using Echovist-200 in the out patient investigation of infertility patients. *British Journal of Radiology* 1996; 69: 910-913.
249. Penney GC, Templeton A. Impact of a national audit project on gynaecologists in Scotland. *Quality in Health Care* 1995; 4: 37-39.
250. Bruster S, Jarman R, Bosanquet N, Weston D, Erens R, Delbanco TL. National survey of hospital patients. *British Medical Journal* 1994;309:1542-1549.
251. Fitzpatrick R. Surveys of patient satisfaction I. Important general considerations. *British Medical Journal* 1991; 302: 887-889.
252. Hall JA, Dornan MC. Meta-Analysis of Satisfaction with Medical care: Description of Research Domain and Overall Satisfaction Levels. *Social Science Medicine* 1988;27:637-644.
253. Rosenfield DL, Mitchell E. Treating the emotional aspects of infertility: counseling services in an infertility clinic. *American Journal of Obstetrics and Gynecology* 1979;15:177-180.
254. Glover L, Gannon K, Sherr L, Abel PD. Psychological distress before and immediately after attendance at a male sub-fertility clinic. *Journal of the Royal Society of Medicine* 1994;87:448-9.
255. Andrews FM, Abbey A, Halman LJ. Is fertility problem stress different? The dynamics of stress in fertile and infertile couples. *Fertility and Sterility* 1992;57:1247-1253
256. Berg BJ, Wilson JF. Psychological functioning across stages of treatment for infertility. *Journal of Behavioral Medicine* 1991;14:11-26.
257. Golombok S. Psychological functioning in infertility patients. *Human Reproduction* 1992;7:208-212.
258. Oddens BJ, den Tonkelaar I, Nieuwenhuyse H. Psychosocial experiences in women facing fertility problems – a comparative study. *Human Reproduction* 1999;14:255-261.
259. Griel AL. Infertility and psychological distress: a critical review of the literature. *Social Science in Medicine* 1997;45:1679-1704.
260. Bell JS. Psychological problems among patients attending an infertility clinic. *Journal of Psychosomatic Research* 1981;25:1-3.
261. Laffont I, Edelmann RJ. Psychological aspects of in vitro fertilization: a gender comparison. *Journal of Psychosomatic Obstetrics and Gynecology* 1994;15:85-92.

262. Goldberg DP, Gater R, Sartorius N, Ustun TB, Piccinelli M, Gureje O, Rutter C. The validity of two versions of the GHQ in the WHO study of mental illness in general health care. *Psychological Medicine* 1997;27:191-197.
263. McCabe CJ, Thomas KJ, Brazier JE, Coleman P. Measuring the mental health status of a population: A comparison of the GHQ-12 and the SF-36 (MHI). *British Journal of Psychiatry* 1996;169:517-521.
264. Van Hemert AM, Heijer M. Den, Vorstenbosch M, Bolk JH. Detecting psychiatric disorders in medical practice using the General Health Questionnaire. Why do cut-off scores vary? *Psychological Medicine* 1995;25:165-170.
265. Jacob KS, Bhugra D, Mann AH. Validation of the 12-item General Health Questionnaire among ethnic Indian women living in the United Kingdom. *Psychological Medicine* 1997;27:1215-1217.
266. Goldberg DP, Oldehinkel T, Ormel J. Why GHQ threshold varies from one place to another. *Psychological Medicine* 1998;28:915-921.
267. N Schmitz, J Kruse, and W Tress. Diagnosing mental disorders in primary care: The General Health Questionnaire (GHQ-12) and the Symptom Check List (SCL-90-R) as screening instruments. *Social Psychiatry and Psychiatric Epidemiology* 1999;34:360-366.
268. N. Schmitz, J. Kruse, and W. Tress. Psychometric properties of the General Health Questionnaire (GHQ-12) in a German primary care sample. *Acta Psychiatrica Scandinavica* 1999;1006:462-468.
269. Hotopf M, Sharp D, Lewis G. What's in a name?: A comparison of four psychiatric assessments. *Social Psychiatry and Psychiatric Epidemiology* 1998;33:27-31.
270. Le Fevre P, Devereux J, Smith S, Lawrie SM, Cornbleet M. Screening for psychiatric illness in the palliative care inpatient setting: A comparison between the Hospital Anxiety and Depression Scale and the General Health Questionnaire-12. *Palliative Medicine* 1999;13:399-407.
271. Lee DTS, Yip ASK, Chiu HFK, and Chung TKH. Screening for postnatal depression using the double-test strategy. *Psychosomatic Medicine* 2000;62:258-263.
272. Chaturvedi SK, Chandra PS, Prema SV, Issax MK, Sudarshan CY, Beena MB, Kulkarni S, Rangan U. Detection of psychiatric morbidity in gynecology patients by two brief screening methods. *Journal of Psychosomatic Obstetrics and Gynecology* 1994;15:53-58.
273. Berwick DM, Murphy JM, Goldman PA. Performance of a five-item mental health screening test. *Medical Care* 1992;29:169-172.
274. Ware JE, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36). *Medical Care* 1992;30:473-481.
275. McHorney CA, Ware JE Jr, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Medical Care* 1993;31:247-63.
276. Whooley MA, Avins AL, Miranda J, Browner WS. Case-finding instruments for depression. Two questions are as good as many. *J Gen Intern Med* 1997;12:439-45.
277. Holmes WC. A short, psychiatric, case-finding measure for HIV seropositive outpatients: performance characteristics of the 5-item mental health subscale of the SF-20 in a male, seropositive sample *Medical Care* 1998;36:237-43.

278. Lalos A, Lalos O, Jacobsson L, von Schoultz B. Psychological Reactions to the Medical Investigation and Surgical Treatment of Infertility. *Gynecol. Obstet. Invest* 1985;20:209-217.
279. Daniluk JC. Infertility: intrapersonal and interpersonal impact. *Fertility and Sterility* 1988;49:982-990.
280. Woolf, SH, Grol R, Hutchinson A, Eccles M and Grimshaw J. Clinical guidelines: Potential benefits, limitations and harms of clinical guidelines. *British Medical Journal* 1999;318:527-530.
281. Rosenberg W, Donald A. Evidence based medicine: an approach to clinical problem solving. *British Medical Journal* 1995;310:1122-6.
282. Davidoff F, Haines B, Sackett D, Smith R. Evidence based medicine. *British Medical Journal* 1995;310:1085-6.
283. McPherson K, Strong PM, Epstein A, Jones L. Regional Variations in the Use of Common Surgical Procedures: Within and Between England and Wales, Canada and the United States of America. *Social Science Medicine* 1981;15A:273-88.
284. Hayward J. Purchasing clinically effective care. National directives cannot be fulfilled without local collaboration. *British Medical Journal* 1994;309:823-4.
285. Chassin MR, Koseoff K, Park PE, Winslow CM, Kahn KL, Merrick NJ. Does Inappropriate Use Explain Geographic Variations in the Use of Health Care Services? A Study of Three Procedures. *Journal of the American Medical Association* 1987;258:2533-7.
286. Giraud A. Uncertainty in Medicine: can it be reduced? *Quality in Health Care* 1992;1:150-1.
287. Fowkes FGR, McPake BI. Regional variations in outpatient activity in England and Wales. *Community Medicine* 1986;8:286-91.
288. Berwick DM. Controlling Variation in Health Care: A Consultation from Walter Shewhart. *Medical Care* 1991;29:1212-25.
289. Bunke JP. Can professionalism survive in the marketplace? *British Medical Journal* 1994;308:1179-80.
290. Smith R. Scientific basis of health services. *British Medical Journal* 1995;311:961-2.
291. Grahame-Smith D. Evidence based medicine: Socratic dissent. *British Medical Journal* 1995;310:1126-7.
292. Davidoff F. The scientific basis of health services. *British Medical Journal* 1995;311:961-2.
293. Sheldon TA, Guyatt GH, and Haines A. Getting research findings into clinical practice: when to act on the evidence. *British Medical Journal* 1998;317:139-142.
294. Feinstein AR and Horwitz RI. Problems in the "Evidence" of "Evidence based medicine". *American Journal of Medicine* 1997;103:529-535.
295. Ramsey PG, Carline JD, Inui TS, Larson EB, LoGerfo JP, Norcini JJ, and Wenrich MD. Changes over time in the knowledge base of practicing internists. *Journal of the American Medical Association* 1991;266:1103-1107.
296. Bennett KJ, Sackett DL, Haynes RB, Neufield VR, Tugwell P, Roberts R. A Controlled Trial of Teaching Critical Appraisal of the Clinical Literature to Medical Students. *Journal of the American Medical Association* 1987;257:2451-4.

297. Davis DA, Thomson MA, Oxman AD, Haynes RB. Evidence for the Effectiveness of CME. A review of 50 Randomised controlled Trials. *Journal of the American Medical Association* 1992;268:1111-7.
298. Cooke IE and Sackett DL. Cooke IE and Sackett DL, editors. Evidence-based obstetrics and gynaecology. London: Balliere Tindall. 1996; p535 10. *Clinical Obstetrics and Gynaecology*.
299. Farquhar, C. and Vandekerckhove, P. Cooke IE and Sackett DL, editors. The Cochrane Library. London: Balliere Tindall. 1996; p.569 10. *Clinical Obstetrics and Gynaecology*.
300. Paterson-Brown S, Fisk NM, Wyatt JC. Uptake of meta-analytical overviews of effective care in English obstetric units. *British Journal of Obstetrics and Gynaecology* 1995;102:297-301.
301. Watt J, Droogan J, Wilson P. The NHS Centre for Reviews and Dissemination: A Resource for Clinical Audit. *Audit Trends* 1996;4:155-7.
302. Mugford M, Banfield P, O'Hanlon M. Effects of feedback of information on clinical practice: a review. *British Medical Journal* 1991;303:398-402.
303. Haynes RB. The origins and aspirations of the ACP Journal Club. *ACP Journal Club* 1991; A18.
304. CRAG. Clinical Guidelines. Edinburgh: The Scottish Office; 1993.
305. Feder G. Clinical Guidelines in 1994. *British Medical Journal* 1994;309: 1457-8.
306. Zinberg, S. Evidence-based practice guidelines: A current perspective. *Obstetrical and Gynecological Survey* 1997;52:265-266.
307. Delamothe T. Wanted: guidelines that doctors will follow. *British Medical Journal* 1993;307:218.
308. Buchan H. Clinical guidelines: acceptance and promotion. *Quality in Health Care* 1993;2:213-4.
309. Van Weel, C. and Knottnerus, J. A. Evidence-based interventions and comprehensive treatment. *Lancet* 1999;353:916-918.
310. Hurwitz B. Clinical guidelines and the law. *British Medical Journal* 1995;311:1517-8.
311. Miller FH, Harrison A. Malpractice liability and physician autonomy. *Lancet* 1993;342:973-5.
312. Scoenbaum SC, Gottlieb LK. Algorithm based improvement in clinical quality. *British Medical Journal* 1990;301:1374-7.
313. North of England Study of Standards and Performance in General Practice. Medical Audit in general practice. I: Effects on doctor's clinical behaviour for common childhood conditions. *British Medical Journal* 1992;304:1480-4.
314. Grimshaw J, Russel IT. Achieving health gain through clinical guideines: II Ensuring guidelines change medical practice. *Quality in Health Care* 1994;3:45-52.
315. Fowkes FGR, Davies ER, Evans KT, Green G, Nolan DJ, Hugh AE. Multicentre Trial of Four Strategies to Reduce Use of a Radiological Test. *Lancet* 1986;1:367-70.
316. Eisenberg JM. Economics. *Journal of the American Medical Association* 1995;273:1670-1.
317. Hull MGR. Managed care of infertility. *Current Opinion in Obstetrics and Gynecology* 1996;8:305-13.

318. Miller RH, Luft HS. Managed Care Plan Performance Since 1980. A Literature Analysis. *Journal of the American Medical Association* 1994;271:1512-9.
319. Grol, R. Beliefs and evidence in changing practice. *British Medical Journal* 1997;315: 418-421.
320. Clinical Standards Advisory Group. *Women in normal labour*. London: HMSO; 1995.
321. McColl A, Smith H, White P, and Field J. General practitioners' perceptions of the route to evidence based medicine: a questionnaire survey. *British Medical Journal* 1998;316:361-365.

APPENDICES

APPENDICES

- APPENDIX 1 The GAPS Infertility Panel
- APPENDIX 2 Questionnaire for Hospital Gynaecologists
- APPENDIX 3 Questionnaire for General Practitioners
- APPENDIX 4 Co-ordinating consultants and centres that participated in the case note review
- APPENDIX 5 Case note review document for hospital practice
- APPENDIX 6 Case note review document for primary care
- APPENDIX 7 Patient satisfaction questionnaire
- APPENDIX 8 Patient satisfaction questionnaire for the male partner
- APPENDIX 9 Psychological Health Status Questionnaire
- APPENDIX 10 A survey of infertility practices in primary care in Scotland
- APPENDIX 11 Patient satisfaction with the management of Infertility

APPENDIX 1

The GAPS Infertility Panel

Grantholders

Gillian Penney
Allan Templeton

Clinical Research Fellow

Vivienne Souter

Specialist Topic Advisers

Stewart Irvine
Sheila Lawson
John Mills
Christine West
Robin Yates

General Practice Advisers

Ann Rennie
Ron Seiler

Additional members of the GAPS II Steering Committee

Anna Glasier
Marion Hall
Tahir Mahmood

APPENDIX 2
Questionnaire for Hospital Gynaecologists

1 Do you see infertility patients in the course of you job?

- (a) Yes
- (b) No

If No, please return the questionnaire at this stage

Please answer the following questions about your own clinical practice

2 Do you consider yourself to have a special interest in infertility?

- (a) Yes
- (b) No

3 Where do you see infertility patients?

- (a) At a dedicated infertility clinic?
- (b) At a general gynaecology outpatient clinic?
- (c) Other
Please Specify

4 Do you follow local guidelines in the initial investigation, management and referral of infertile patients?

- (a) Yes
- (b) No, although such guidelines exist
- (c) No such guidelines exist as far as I am aware
- (d) Other
Please Specify

5 Do you ask to see the couple together at the clinic?

- (a) Yes, I ask both partners to attend the clinic.
- (b) No, but I will see them together if they both happen to attend the clinic.
- (c) No, I see the female partner alone.
- (d) Other
Please Specify

6 Is it your usual practice to perform a general examination of both partners?

- (a) Yes
- (b) No, I don't feel this is necessary
- (c) The female partner only
- (d) The male partner only
- (e) Other
Please specify

7 Is it your usual practice to perform a genital examination of the male partner?

- (a) Yes
- (b) No, I don't feel this is necessary
- (c) Only if the history or semen analysis indicates a problem.
- (d) Other
Please specify

8 Do your initial investigations of the male partner include semen analysis?

- (a) Yes, two semen analyses at least one month apart.
- (b) Yes, one semen analysis
- (c) Other
Please specify

9 Do you arrange for a post coital test to be performed?

- (a) Yes, routinely in all couples under investigation
- (b) Yes, if there is an abnormal semen analysis
- (c) Yes, if infertility is otherwise unexplained after basic investigation
- (d) Yes, if a coital problem is suspected
- (e) No, I do not think this is a useful test in the routine investigation of the infertile couple.
- (f) Other
Please specify

10 Is it your usual practice to perform a pelvic examination of the female partner?

- (a) Yes, I always perform a pelvic examination
- (b) No, I don't think this is necessary
- (c) Yes, if the history indicates a problem
- (d) Other
Please specify

11 Do you look for evidence of ovulation in the female partner who has a regular menstrual cycle?

- (a) No, further evidence is unnecessary in such women
- (b) Yes, by measuring mid-luteal plasma progesterone in one or more cycles
- (c) Yes, using another method
Please specify

12 Do you look for evidence of ovulation in the female partner who has an irregular menstrual cycle?

(a) Yes, with weekly serum progesterone levels starting day 21 of the cycle.

(b) Other

Please specify

13 Do you routinely check the female partner's rubella status?

(a) Yes

(b) No

14 Do you ask the female partner to keep a temperature chart?

(a) Yes

(b) No

15 What is your primary investigation of the female reproductive tract?

(a) Laparoscopy and dye transit

(b) Hysterosalpingogram

(c) Other

Please Specify

16 Do you use a double puncture technique at diagnostic laparoscopy?

(a) Yes, in all cases

(b) Yes, if there is poor visualisation of the pelvic organs

(c) Seldom or never

(d) Other

Please Specify

17 Would you treat an ovulatory disorder before proceeding to diagnostic laparoscopy and dye transit in a patient who has no history suggestive of tubal damage?

(a) Yes

(b) No, I would perform a diagnostic laparoscopy first

(c) Other

Please Specify

If Yes, for how many cycles would you treat the patient before proceeding to laparoscopy?

(a) With clomiphene

(b) With gonadotrophins

18 Do you advise women who are attempting to become pregnant to take daily folic acid supplements (0.4-0.5mg)?

- (a) Yes
- (b) No

19 Do you prescribe a limited trial of clomiphene for women with unexplained infertility?

- (a) Yes, in most or all cases
- (b) Yes, in selected cases
- (c) No, I do not believe it has any place in the treatment of these patients.
- (d) Other

Please Specify

20 Do you use drug treatments in the initial management of infertile patients with endometriosis who are otherwise asymptomatic?

- (a) Yes
 - (b) No
 - (c) Other
- Please Specify

21 Do you use drug treatments in the management of male infertility?

- (a) No
 - (b) Yes
- Please Specify

22 Do you perform reconstructive tubal surgery on infertility patients (other than reversal of sterilisation) in the course of your job?

- (a) No
 - (b) Yes
- Please estimate the average number of cases/year

If YES, do you use

- (a) Microsurgical technique?
- (b) An operating microscope?
- (c) Neither (a) or (b)

23 Do you perform tubal surgery on infertile patients with severe tubal damage?

- (a) Yes, as my first line of treatment
 - (b) Yes, but only if IVF is not available to the patient
 - (c) No
 - (d) Other
- Please Specify

Questionnaire for Hospital Gynaecologists

24 Is ovulation induction using gonadotrophins provided at the hospital where you work?

- (a) Yes
- (b) No
- (c) Don't know

IF YES,

Is monitoring of these techniques with ultrasound scanning and oestradiol assays available in the hospital seven days per week?

- (a) Yes
- (b) No
- (c) Don't know

25 Do you routinely offer couples undergoing infertility investigation or treatment the opportunity to see a trained counsellor?

- (a) Yes, I offer this to all couples
- (b) Yes, but only to selected couples
- (c) I would like to but there are no local facilities to do this as far as I am aware.
- (d) No, I do not think independent counselling is helpful.

National Consensus on "Good Quality Care" Applicable to the Management of Infertility by Hospital Gynaecologists in Scotland

The following list of statements which relate to infertility has been drawn up following a literature review and discussion with a panel of gynaecologists and GP's. Please indicate your level of agreement with each statement as representing an important criterion for good quality care.

(There are no "right" answers, these statements are presented simply as a starting point for your consensus view).

Your level of agreement with each statement should be as follows

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree
6. Do not feel qualified to answer

Clinical Arrangements

1. There should be agreed local guidelines for the investigation, management and referral of infertile patients.
2. A plan of investigation and treatment with a specific end-point should be set down in the notes and made clear to the couple concerned.
3. Counselling by trained counsellors should be available to all couples.

Indicate level of agreement (1-6) in appropriate box.

1

2

3

Initial Investigation

4. The investigation of infertility should include both partners from the outset.
5. A general examination of both partners should be performed.
6. A genital examination of the male partner should be performed.
7. A pelvic examination of the female partner should be performed.
8. Women with oligomenorrhoea or amenorrhoea should be referred to a gynaecologist regardless of the duration of their infertility.
9. A mid-luteal plasma progesterone level should be checked in a regularly menstruating female as the basic test of ovulation.

4

5

6

7

8

9

Questionnaire for Hospital Gynaecologists

10. The initial investigation of the male partner should include two semen analyses at least one month apart.

10

11. The post coital test should not be used in the routine investigation of the infertile couple.

11

12. The female partner's rubella status should be checked.

12

13. Temperature charts are of limited use and couples should be discouraged from keeping them.

13

14. Diagnostic laparoscopy and dye transit, rather than hysterosalpingography should be the primary investigation of the female genital tract.

14

15. Investigation of the female genital tract should be delayed in couples with hitherto unexplained infertility until the infertility is of at least two years duration.

15

16. Investigation of the female genital tract should not be performed in patients with oligomenorrhoea until they have had 6 months of ovulatory cycles in response to clomiphene, except in cases where the history or examination is suggestive of tubal damage.

16

Management

17. The female partner should be advised to take folic acid supplements while attempting to become pregnant (0.4-0.5mg / day).

17

18. Drug treatments are ineffective in the treatment of idiopathic male infertility and should not be used.

18

19. Drug treatments for endometriosis in women with this condition and infertility, do not improve conception rates and should not be prescribed for this purpose.

19

20. Gonadotrophins should not be prescribed in units which do not have access to monitoring with ultrasound and oestradiol assays, 7 days per week.

20

21. Tubal surgery should not be undertaken for severe damage to the fallopian tubes as the success rates from IVF are higher.

21

22. Couples with unexplained infertility, mild endometriosis and mild male factor infertility should only be offered IVF when their infertility is of 4 years or more in duration.

22

APPENDIX 3
Questionnaire for General Practitioners

Please answer the following questions about your own clinical practice

1 Do you follow local guidelines in the initial investigation, management and referral of infertile patients?

- (a) Yes
 - (b) No, although such guidelines exist
 - (c) No such guidelines exist as far as I am aware
 - (d) Other
- Please Specify

2 If both partners are patients in your practice, do you usually arrange to see them together at the surgery?

- (a) Yes
 - (b) No
 - (c) Other
- Please Specify

3 Is it your usual practice to obtain a full medical history of both partners?

- (a) Yes
 - (b) No
 - (c) Other
- Please Specify

4 Is it your usual practice to perform a physical examination?

- (a) No, I do not think this is necessary in general practice
 - (b) A general examination of both partners (excluding a genital examination)
 - (c) A genital examination of the male only
 - (d) A genital examination of the female only
 - (e) I perform a genital and general examination of both partners whenever possible.
 - (f) Other
- Please specify

Questionnaire for General Practitioners

5 Do your initial investigations of the male partner include semen analysis?

- (a) Yes
- (b) No, I do not think this is appropriate in general practice
- (c) No, because I cannot readily organise semen analysis
- (d) Other
Please Specify

6 Do you ask the female partner to keep a temperature chart?

- (a) Yes
- (b) No

7 Do your initial investigations include confirmation of ovulation in the female partner?

- (a) Yes
- (b) No
- (c) Other
Please Specify

8 Do you routinely check the female partner's rubella status?

- (a) Yes
- (b) No
- (c) Other
Please Specify

9 Do you advise women who are attempting to become pregnant to take daily folic acid supplements (0.4-0.5mg)?

- (a) Yes
- (b) No

10 Do you ever initiate treatment of the female partner with clomiphene?

- (a) Yes
- (b) No

11 Would you welcome infertility guidelines in general practice.

- (a) Yes
- (b) No

Questionnaire for General Practitioners

National Consensus on "Good Quality Care" Applicable to the Management of Infertility by General Practitioners in Scotland

The following list of statements which relate to infertility has been drawn up following a literature review and discussion with a panel of gynaecologists and GP's. Please indicate your level of agreement with each statement as representing an important criterion for good quality care.

(There are no "right" answers, these statements are presented simply as a starting point for your consensus view).

Your level of agreement with each statement should be as follows

1. Strongly agree
2. Agree
3. Neither agree or disagree
4. Disagree
5. Strongly disagree
6. Do not feel qualified to answer

1. There should be agreed local guidelines for the investigation, management and referral of infertile patients.

2. The investigation of infertility should include both partners from the outset.

3. A full medical, social and sexual history of both partners should be obtained.

4. A pelvic examination of the female partner, a genital examination of the male partner and a general examination of both partners should be performed by the referring general practitioner.

5. The female partner's rubella status should be checked.

6. A day 21 plasma progesterone level should be checked in a regularly menstruating female as the basic test of ovulation.

7. There are no other biochemical or hormonal investigations of the female partner that are relevant in general practice.

8. The initial investigation of the male partner should include two semen analyses at least one month apart.

9. Temperature charts are of limited use and couples should be discouraged from using them.

10. The presence of oligomenorrhoea, oligospermia, a history suggestive of pelvic pathology or abnormal findings on examination of either partner should result in early referral to a specialist clinic.

Indicate level of agreement (1-6) in appropriate box.

1

2

3

4

5

6

7

8

9

10

Questionnaire for General Practitioners

11. The female partner should be advised to take folic acid supplements while attempting to become pregnant (0.4-0.5mg / day).

11

12. Treatment of anovulation with clomiphene should always be initiated by a specialist hospital clinic rather than in general practice.

12

APPENDIX 4

Co-ordinating consultants and centres that participated in the case note review

**Professor Iain Cameron
The Western Infirmary, Glasgow**

**Dr Bob Galloway
Monklands Hospital, Airdrie**

**Dr David Gilmour
The Royal Alexandria Hospital, Paisley**

**Professor Ian Greer
Glasgow Royal Infirmary**

**Dr Russell Lees
Raigmore Hospital, Inverness**

**Dr Tahir Mahmood
Forth Park Hospital, Kirkcaldy**

**Prof Naren Patel
Ninewells Hospital, Dundee**

**Dr Sam Prigg
Crosshouse Hospital, Kilmarnock**

**Dr Alan Shepherd
St John's Hospital, Livingston**

**Dr George Smart
The Royal Infirmary of Edinburgh**

**Dr Ken Stewart
Stirling Royal Infirmary**

**Professor Allan Templeton
Aberdeen Royal Infirmary**

APPENDIX 5

Case note review document for hospital practice

Unique patient No
 Secretary No.
 Consultant No.

Information from Referral Letter

Investigations Prior to Referral to this Clinic

1 Date of referral letter
 2 Patient referred by: GP
 Another hospital
 Dr within this hospital
 3 Duration of infertility at time of referral Months

4 Medical history taken? Male Female
 Yes
 No

5 General examination performed? Normal
 Abnormal
 Not done

6 Genital examination performed? Normal
 Abnormal
 Not done

7 Both partners seen together at surgery?
 Yes
 No
 Not determined from notes

8 Which of the following have been performed / arranged?

Day 21 progesterone Tick All That Apply
 Serum progesterone tracking
 Temperature charting
 Rubella immunity
 Prolactin
 Thyroid function
 Oestradiol
 Laparoscopy/hydrotubation (LHT)
 Hysterosalpingogram (HSG)
 Endocervical swab for chlamydia

9 Was semen analysis performed / arranged? 1 2 3
 Date of test / / / / / /

10 Patient advised to take folic acid? Yes
 No

Investigations / Examinations

29 What test was performed / arranged by the clinic to check ovulation while the patient was receiving no treatment?

- Day 21 progesterone
- Serial blood progesterone levels
- Urinary pregnanediol levels
- Other (specify)
- No test arranged

30 Was the patient ovulating? Yes

- No (Ask doctors if uncertain)
- Not documented

31 Was the female partner asked to keep a temperature chart?

- Yes
- No

32 Rubella antibodies checked?

- Performed / arranged: no results
- Performed / arranged: immune
- Performed / arranged: borderline
- Performed / arranged: not immune
- No record of rubella status

33 General examination?

- Normal
- Abnormal
- Not performed

34 Pelvic examination?

- Normal
- Abnormal
- Not performed

35 Chlamydia tested for?

- Swab
- Blood
- No

36 What was 1st test of tubal patency?

- No test performed / arranged
- LHT
- HSG
- HSG & LHT in theatre at same time
- Other method
- Specify

37 Date of test

38 If LHT, operative technique?

- Single puncture
- Double puncture

- 39 What was a 2nd test of tubal patency?
 No 2nd test performed / arranged
 LHT
 HSG
 HSG & LHT in theatre at same time
 Other method
 Specify

40 Date of test

- 41 If LHT, operative technique?
 Single puncture
 Double puncture

Treatment

- 42 Did the female partner receive drug treatment to stimulate ovulation before having a LHT or HSG?
 No
 Clomiphene
 Tamoxifen
 Bromocriptine
 Gonadotrophins

- 43 For how many cycles was the patient treated prior to having an LHT / HSG?
 With Clomiphene
 With Tamoxifen
 With Bromocriptine
 With Gonadotrophins

- | 44 Was the patient ovulating while being treated: | Yes | No | Not checked |
|---|--------------------------|--------------------------|--------------------------|
| With Clomiphene | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| With Tamoxifen | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| With Bromocriptine | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| With Gonadotrophins | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

45 Was the female partner given drug treatments for endometriosis?

- Patient did not have endometriosis
 Endometriosis but not treated
 Danazol
 Provera
 Gestrinone
 Other
 Specify

- 46 Is the female partner currently receiving treatment with:
 Clomiphene
 Gonadotrophins

47 For how many cycles has the patient been treated with clomiphene?

48 Was the patient advised to take folic acid? Yes
No

49 Was tubal surgery performed? Yes
No

If yes,

Photocopy the operation notes and discharge letters from the tubal surgery and laparoscopy

Male Partner History and Examination

50 Age

51 Past history of testicular problem / surgery?
Yes
No
Not documented

52 Past history of sexually transmitted disease?
Yes
No
Not documented

53 Past / present medical problems?
Yes
No

54 General examination? Normal
Abnormal
Not performed

55 Genital examination? Normal
Abnormal
Not performed

56 How many semen analyses were:
arranged?
performed?

57 Date of test(s) 1 2 3
/ / / / / /

58 Has a postcoital test been arranged / performed?
Yes
No

APPENDIX 6
Case note review document for primary care

Unique patient No
GP No.

1 Date of most recent appointment

2 Postcode

3 Date of 1st clinic appointment for infertility

4 Duration of infertility at 1st visit

5 No. of attendances at surgery with infertility

6 No. of different GP's seen

7 Couple seen together at 1st visit? Yes
No

8 Couple seen together at any visit? Yes
No

Female partner's history

9 Age
10 Parity +

11 Menstrual pattern

Regular cycle
Irregular cycle
Oligomenorrhoea
Primary amenorrhoea
Secondary amenorrhoea
Secondary amenorrhoea
Not documented

12 History of pelvic inflammatory disease? Yes
No

13 History of Sexually transmitted disease? Yes
No

14 Endometriosis? Symptomatic
Asymptomatic
No endometriosis

(Ask doctors if uncertain)

15 Past ./ present medical disorders? Yes
No

16 General examination? Normal
 Abnormal
 Not performed

17 Pelvic examination? Normal
 Abnormal
 Not performed

18	Repeat tests			
	1	2	3	4
Day 21 progesterone (no ovulation treatment)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Day 21 progesterone (on ovulation treatment)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Weekly plasma progesterone tracking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Performed /arranged: no results =1
 Performed: ovulating =2
 Performed: not ovulating =3
 Not performed =4

19 Temperature charting performed / arranged Yes
 No

20 Rubella antibodies checked?
 Performed / arranged: no results
 Performed / arranged: immune
 Performed / arranged: borderline
 Performed / arranged: not immune
 No record of rubella status

21 Serum FSH	<input type="checkbox"/>	Tick All That Apply
22 Serum LH	<input type="checkbox"/>	
23 Prolactin	<input type="checkbox"/>	
24 Oestradiol	<input type="checkbox"/>	
25 Testosterone	<input type="checkbox"/>	
26 Progesterone challenge test	<input type="checkbox"/>	
27 FBC	<input type="checkbox"/>	
28 Thyroid function	<input type="checkbox"/>	
29 Pelvic ultrasound	<input type="checkbox"/>	
	<input type="checkbox"/>	

Performed /arranged: no results =1
 Performed: normal =2
 Performed: abnormal =3
 Not performed =4

Male partner's history

30 Age

31 History of testicular problem /surgery? Yes
 No

32 History of Sexually transmitted disease? Yes
No

33 Past / present medical disorders? Yes
No

34 Any sexual problems?
Yes
No
Not documented

35 Coital frequency noted? Yes
No

36 General examination? Normal
Abnormal
Not performed

37 Genital examination? Normal
Abnormal
Not performed

38 Semen Analysis
Date of test(s) 1 2 3
 / / / / / /

39 How many semen analyses were:
arranged?
performed?

Treatment

40 Has the female partner had Clomiphene from her GP?

Yes
No
if yes, for how many cycles

41 Was the patient advised to take folic acid?
Yes
No

42 Did the male partner have drug treatment for infertility?

- No
- Clomiphene
- Tamoxifen
- Bromocriptine
- High dose vitamin C
- Mesterolone
- Prednisolone
- Other
- Specify

43 Diagnostic category:

- Male factor
- Ovulatory problem
- Tubal
- Coital dysfunction
- Endometriosis
- Unexplained
- Not yet established
- Other
- Mixed
- Please specify if mixed / other

44 Follow up

- Return for further tests
- Return with partner
- Refer to hospital
- Pregnant
- No further investigations / treatment
- Refer for adoption
- Other
- Specify

APPENDIX 7
Patient satisfaction questionnaire
Code No.

THE FOLLOWING QUESTIONS ARE ABOUT YOUR MOST RECENT VISIT TO THE HOSPITAL CLINIC

Tick One Box For Each Question

- | | | | |
|----|---|--|---|
| 1. | At your most recent visit to the hospital clinic, were you taken at your appointment time?
How long after your time were you taken? | Yes, I was taken on time or early | <input type="checkbox"/> |
| | | No, I was taken after my time | <input type="checkbox"/> |
| | | <div style="border: 1px solid black; display: inline-block; padding: 2px 10px;"> minutes late </div> | |
| 2. | Do you feel the time you had to wait at the hospital clinic before you were taken was: | Too long | <input type="checkbox"/> |
| | | Acceptable | <input type="checkbox"/> |
| 3. | <p>Did the doctor at your most recent visit to the hospital clinic.....</p> <p>Listen to what you had to say?</p> <p>Show an interest in you as a person?</p> <p>Behave politely towards you?</p> <p>Appear good at his/her job?</p> <p>Make it easy for you to ask questions?</p> <p>Appear sympathetic?</p> <p>Explain things to you?</p> <p>Let you take part in any decisions?</p> | <p>Yes</p> <input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/> | <p>No</p> <input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/> |
| 4. | Were there are any questions that You would have liked to ask but couldn't at your most recent clinic visit? | Yes, a lot of questions | <input type="checkbox"/> |
| | | A few questions | <input type="checkbox"/> |
| | | None | <input type="checkbox"/> |
| 5. | Overall were you satisfied with your most recent visit to the hospital clinic? | Very Satisfied | <input type="checkbox"/> |
| | | Satisfied | <input type="checkbox"/> |
| | | Dissatisfied | <input type="checkbox"/> |
| | | Very Dissatisfied | <input type="checkbox"/> |
| 6. | Have you been asked to bring your partner to the hospital clinic at any time? | Yes | <input type="checkbox"/> |
| | | No | <input type="checkbox"/> |
| 7. | Do you think your partner should be asked to attend the hospital clinic with you? | Yes | <input type="checkbox"/> |
| | | No | <input type="checkbox"/> |

Patient Satisfaction Questionnaire

8. Have you been given advice about folic by the hospital clinic? Yes No

9. Have the investigations that have been organised by the hospital clinic? **Tick one box for each part of the question**

	Yes	No
Been explained to you	<input type="checkbox"/>	<input type="checkbox"/>
Involved too much repetition of tests	<input type="checkbox"/>	<input type="checkbox"/>
Taken too long to be done	<input type="checkbox"/>	<input type="checkbox"/>
Taken too long for you to get results	<input type="checkbox"/>	<input type="checkbox"/>
I haven't had any investigations yet	<input type="checkbox"/>	<input type="checkbox"/>

—Please make any further comments about your investigations

10. Have you been told enough by the hospital clinic about what is thought to be the **cause** of your infertility? Everything was explained Most things were explained Most things were *not* explained Nothing was explained

11. Have you been given enough information at the hospital clinic about **drug treatments** and possible **side effects**? Everything was explained Most things were explained Most things were *not* explained Nothing was explained **I haven't had any drug treatments**

12. Have you been given **written Information** (eg. leaflets, books, diagrams) about any of these subjects by the hospital clinic? Yes No

13. Would you have liked to receive **more written information**? Yes No

14. Have you had any problems with being seen by different doctors at the hospital clinic? Yes No I've only been seen by one doctor

Please explain your answer to Question 14

15. Have you been given a clear **plan** of possible investigations and treatments which *may* be offered to you in future? Yes No

Patient Satisfaction Questionnaire

16. What sort of hospital clinic would you prefer to be seen at? One for infertility patients alone
A mixed gynaecology clinic
It is not important to me

17. Has the clinic given you help with the emotional side of having difficulty becoming pregnant? Yes
No

18. Has the clinic offered to arrange an appointment for you with an **infertility counsellor** (someone, other than the doctors at the clinic, who knows a lot about infertility, the options that are open to you and the of emotions you may be feeling) ? Yes
No

19. Have you received any infertility counselling arranged by the hospital clinic ? Yes, I found it helpful
Yes, but I did not find it helpful
No, I have not had any counselling

20. At this point in time would you take up an offer to speak to an infertility counsellor? Yes
No

21. Please rank the following aspects of your care 1 - 5, 1 being the most important to you and 5 being the least important.

- The waiting time at the clinic
- The doctor's attitude
- The information & explanation given
- The way the investigations are done
- Help with the emotional side of infertility

Please enter a number in each box using each number only once

22. Overall are you satisfied with the hospital clinic ? Very Satisfied
Satisfied
Dissatisfied
Very Dissatisfied

Please comment on any aspects of your experiences at the clinic that you have found unsatisfactory or upsetting.

Please comment on anything that you have found especially encouraging or helpful.

Would you like to suggest any changes which you think would improve the service?

APPENDIX 8

Questionnaire for the male Partner

1. Have you ever attended the hospital clinic with your partner? Yes
 No

Tick all that apply

2. Were you asked to attend the clinic? Yes, by my partner
 Yes, by the clinic staff
 No

3. Do you think men should attend the clinic with their partner? Yes
 No
Please explain your answer

4. Did the doctor at your most recent visit to the hospital clinic.....

	Yes	No
Listen to what you had to say?	<input type="checkbox"/>	<input type="checkbox"/>
Show an interest in you as a person?	<input type="checkbox"/>	<input type="checkbox"/>
Behave politely towards you?	<input type="checkbox"/>	<input type="checkbox"/>
Appear good at his/her job?	<input type="checkbox"/>	<input type="checkbox"/>
Make it easy for you to ask questions?	<input type="checkbox"/>	<input type="checkbox"/>
Appear sympathetic?	<input type="checkbox"/>	<input type="checkbox"/>
Explain things to you?	<input type="checkbox"/>	<input type="checkbox"/>
Let you take part in any decisions?	<input type="checkbox"/>	<input type="checkbox"/>

5. Were there are any questions that you would have liked to ask **but couldn't** at your most recent clinic visit? **Tick one box only**
 Yes, a lot of questions
 A few questions
 None

6. Have you been given **written information** (eg. leaflets, books, diagrams) about any of these subjects by the hospital clinic? Yes
 No

7. Would you have liked to receive **more written information**? Yes
 No

8. Has the clinic given you help with the **emotional side** of infertility? Yes
 No

Tick one box only

9. Overall were you **satisfied** with your **most recent visit** to the hospital clinic? Very Satisfied
 Satisfied
 Dissatisfied
 Very Dissatisfied
 I haven't attended the clinic

Please suggest any ways in which the clinic could be improved from your point of view.

APPENDIX 9
Psychological Health Status Questionnaire

Please answer each question by marking as indicated. If you are unsure about the answer please give the best answer you can.

In general would you say your health is:

Tick one box

Excellent

Very good

Good

Fair

Poor

During the past 4 weeks have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Tick one box on each line

YES

NO

a. Cut down the amount of time you spent on work or other activities

b. Accomplished less than you would like

c. Didn't do work or other activities as carefully as usual

During the past four weeks to what extent has your physical health or emotional problems interfered with you normal social activities with family, friends, neighbours or groups?

Tick one box

Not at all

Slightly

Moderately

Quite a bit

Extremely

These questions ask about how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

Psychological Health Status Questionnaire

How much of the time during the past 4 weeks **(Circle one number on each line)**

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Have you been a very nervous person?	1	2	3	4	5	6
b. Have you felt so down in the dumps that nothing could cheer you up? <input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
c. Have you felt calm and peaceful? <input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
d. Have you felt downhearted and low? <input type="checkbox"/>	1	2	3	4	5	6
e. Have you been a happy person? <input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

Tick one box

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

<input type="checkbox"/>

We would be grateful if you could fill in your occupation and your partner's occupation:

Your occupation

--

Your partner's occupation

--

Delete as
appropriate
Part time /full time

Part time /full time

Psychological Health Status Questionnaire

If one or both of you are not working at present please fill in your last job.

Your last job

Delete as appropriate
Part time /full time

Your partner's last job

Part time /full time

Is your home

Privately owned?
Rented?

Does your household own or have the use of a car or a van?

Yes
No

Psychological Health Status Questionnaire

Put a circle around the answer which you think best says how you have been.

How much of the time over the **past 4 weeks** have you:

Been able to concentrate on whatever you're doing?	Not at all	No more than usual	Rather more than usual	Much more than usual
Lost much sleep over worry?	Not at all	No more than usual	Rather more than usual	Much more than usual
Felt that you are playing a useful part in things?	Not at all	No more than usual	Rather more than usual	Much more than usual
Felt capable of making decisions about things?	Not at all	No more than usual	Rather more than usual	Much more than usual
Felt constantly under strain?	Not at all	No more than usual	Rather more than usual	Much more than usual
Felt you couldn't overcome your difficulties?	Not at all	No more than usual	Rather more than usual	Much more than usual
Been able to enjoy your normal day-to-day activities?	More so than usual	Same as usual	Less so than usual	Much less than usual
Been able to face up to your problems?	More so than usual	Same as usual	Less so than usual	Much less able
Been feeling unhappy and depressed?	Not at all	No more than usual	Rather more than usual	Much more than usual
Been losing confidence in yourself?	Not at all	No more than usual	Rather more than usual	Much more than usual
Been thinking of yourself as a worthless person?	Not at all	No more than usual	Rather more than usual	Much more than usual
Been feeling reasonably happy all things considered?	More so than usual	About the same as usual	Less so than usual	Much less than usual

GHQ-12 David Goldberg, 1978. Reproduced by permission of the Publishers, NFER-Nelson, Darville House, 2 Oxford Road East, Windsor SL4 1DF, England. All rights reserved

APPENDIX 10

A Survey of Infertility Practices in Primary Care in Scotland
V.L. Souter, G. Penney, D.R. Gorman, A.A. Templeton
British Journal of General Practice. 1997;47:727-8

Summary

An 83% response rate was obtained to a postal questionnaire survey of general practitioners, carried out as part of a national infertility audit in Scotland. This provided information about how general practitioners are managing infertility and their opinions with respect to twelve suggested criteria for good practice in a primary care setting.

Introduction

Infertility is a common problem affecting at least 1 in 7 couples at some time in their reproductive lives.¹ Infertility comprises a small part of the workload in primary care : an average general practitioner in Scotland is estimated to see only 1 or 2 new couples per year.² In recent years however, rapid advances have been made in the treatment of infertility and there is increasing public awareness of infertility issues and demand for infertility services.

Since 1992, a number of guideline documents covering the investigation and initial management of infertility have been published.²⁻⁴ These guidelines provided a basis against which to measure current practice and opinions in primary care.

Method

In May 1995, a questionnaire was sent to a sample of 500 of the 3491 principals in general practice in Scotland. The sample was stratified using the age and sex of the general practitioner and the geographical location of the practice.

Through the questionnaire practitioners were asked to indicate their current practice with regard to seeing couples together, history-taking, physical examination, temperature charting, confirming ovulation, semen analysis, confirming rubella immunity, advice about folic acid supplements, initiating treatment with clomiphene and the use of local guidelines.

Responders were also asked to indicate their level of agreement with 12 suggested "criteria for good quality care" which were drawn from published guideline documents,³⁻⁵ the medical literature and discussion by a panel of gynaecologists and general practitioners.

Results

The response rate was 83% (414/500). Agreement with the suggested criteria is summarised in Table 1. Responders' reported practices are described below.

Arranging to See Couples Together

The most strongly supported criterion was that "the investigation of infertility should include both partners from the outset". Ninety per cent of responders agreed with this and 66% arrange to see both partners together at the surgery if they are both registered with the practice.

History and Examination

Eighty two percent agreed that "a full medical, social and sexual history of both partners should be obtained" and 84% reported this as their usual practice.

Thirty eight per cent agreed that "a pelvic examination of the female partner, a genital examination of the male partner and a general examination of both partners should be performed by the referring general practitioner". Forty one percent usually perform a full examination of both partners, 14% only perform a pelvic examination of the female and 27% do not think examination of either partner is necessary in general practice.

Investigation of the Male Partner

Sixty per cent agreed that "the initial investigation of the male partner should include two seminal analyses at least one month apart". Seventy seven per cent include this in their initial investigations but 11% said they could not readily organise semen analysis and 8% did not think it is an appropriate investigation in general practice.

Investigation of the Female Partner

Eighty four per cent agreed that "a day 21 plasma progesterone level should be the basic investigation of ovulation in a regularly menstruating female" and 78% arrange this test.

Only 42% agreed that "temperature charts are of limited use and couples should be discouraged from keeping them" and 29% usually ask the female partner to keep a chart.

Seventy five per cent agreed that "the female partner's rubella status should be checked" and 49% reported doing so.

Management

Seventy four per cent agreed that "the female partner should be advised to take folic acid supplements while attempting to become pregnant" but only 53% cent actually give this advice.

Eighty eight per cent agreed that "the presence of amenorrhoea, oligomenorrhoea, oligospermia, a history suggestive of pelvic pathology or abnormal findings on examination of either partner should result in early referral to a specialist clinic". Eighteen per cent prescribe clomiphene independently.

Guidelines

Eighty nine per cent agreed that there should be local guidelines for the investigation, management and referral of infertile patients. Twenty seven per cent currently follow such guidelines, 66% were unaware of any local infertility guidelines and 5% had local guidelines but did not follow them. Ninety three per cent would welcome guidelines.

Discussion

We have sought to obtain a representative picture of the opinions and current practices of general practitioners in Scotland by stratifying the sample using factors which may influence the management of infertility.

The high response rate suggests that infertility is an area of interest to general practitioners and the survey has highlighted simple changes which could improve care in general practice and bring practice into line with the evidence and the expressed opinion of general practitioners. In some areas, however, opinion as well as reported practice was at odds with published scientific evidence.

Infertility guidelines have been shown to improve the process of care⁶ and support for these appears to be strong. The availability of evidence-based, locally available guidelines may stimulate appropriate changes in practice.

Acknowledgements

Gynaecology Audit project in Scotland is funded by the Clinical Resource and Audit Group (CRAG) of the Scottish Office Department of Health. The views expressed in this paper are those of the authors and do not represent the views of CRAG or the Department. We thank Sue Burney from the Information and Statistics Department of the Common Services Agency, Elaine Stirton the project secretary, the general practitioners who contributed to the survey and the members of the GAPS Infertility Panel (Dr John Mills, Dr Christine West, Dr Stewart Irvine, Dr Robin Yates, Dr Sheila Lawson, Dr Ron Seiler and Dr Ann Rennie).

References

- 1 Templeton A, Fraser C, Thompson B. The epidemiology of infertility in Aberdeen. *BMJ* 1990;301:148-152.
- 2 Scottish Office Home and Health, Scottish Health Service Advisory Council. *Infertility services in Scotland*. Edinburgh: HMSO, 1993.
- 3 Fertility Committee of the Royal College of Obstetricians and Gynaecologists. *Infertility guidelines for practice*. London: RCOG Press, 1992.
- 4 World Health Organisation. *WHO Laboratory manual for the examination of human semen and sperm-cervical mucus interaction*. Cambridge: Cambridge University Press, 1992.
- 5 Emslie C, Grimshaw J, Templeton A. Do clinical guidelines improve general practice management and referral of infertile couples? *BMJ* 1993;306:1728-1731.

Table 1

Rank	Criteria For Good Quality Care in General Practice	Agree %
1	The investigation of infertility should include both partners from the outset.	90
2	There should be agreed local guidelines for the investigation, management and referral of infertile patients.	89
3	The presence of amenorrhoea, oligomenorrhoea, oligospermia, a history suggestive of pelvic pathology or abnormal findings on examination of either partner should result in early referral to a specialist clinic.	88
4	A day 21 plasma progesterone level should be the basic investigation of ovulation in a regularly menstruating female.	84
5	A full medical, social and sexual history of both partners should be obtained.	82
6	The female partner's rubella status should be checked.	75
7	The female partner should be advised to take folic acid supplements while attempting to achieve pregnancy.	74
8	Treatment of anovulation with clomiphene should always be initiated by a specialist hospital clinic rather than in general practice.	65
9	The initial investigation of the male partner should include two semen samples at least one month apart.	60
10	Temperature charts are of limited use and couples should be discouraged from completing them.	41
11	A pelvic examination of the female partner, a genital examination of the male partner and a general examination of both partners should be performed by the referring general practitioner.	38
12	There are no other biochemical or hormonal investigations of the female partner that are relevant in general practice.	19

Table 1 The 12 suggested criteria for good quality care for the management of infertility in general practice. The criteria are ranked according to the percentage of responders who agreed or strongly agreed with the statement as a criterion for good quality care.

APPENDIX 11

Patient Satisfaction with the Management of Infertility
V.L. Souter, G. Penney, J.L. Hopton, A.A. Templeton
Human Reproduction 1998;13(7):1831-6

Abstract

- Objective** To assess patient satisfaction with the investigation and initial management of infertility.
- Design** A postal questionnaire survey.
- Setting** Scotland
- Subjects** 1366 women attending out patient clinics for the investigation and initial management of infertility at 12 hospitals throughout Scotland.
- Results** The response rate to the questionnaire was 59%. Overall, 87% of responders were satisfied or very satisfied with their care but a number of deficiencies were identified. Thirty nine percent had never been asked to bring their partner to the clinic and 86% felt they had not been given enough help with the emotional aspects of infertility. Forty seven percent felt they were not given a clear plan for the future and 23% of those who had been given drug treatments reported receiving little or no information about the treatment or possible side effects. Overall, only a third had been given any written information and 78% expressed a wish for more written information. Women ranked *"the information and explanation given"* and the *"attitude of the doctor at the clinic"* highly in comparison to other aspects of their care, including *"help with the emotional aspects of infertility"*.
- Conclusions** In general women were satisfied with their care but improvements may be made by giving more explanation and written information and by adopting a more couple-centred approach. Where resources allow, clinics should take steps to address the emotional aspects of infertility.

Introduction

Infertility is a common problem which affects an estimated 14% of couples at some point during their reproductive lives¹. Patient representative groups have expressed disquiet about infertility services and this has been reflected in the results of patient satisfaction surveys in the U.K²⁻⁴. This postal questionnaire survey was performed as part of the Gynaecology Audit Project in Scotland (GAPS) Audit of the Investigation and Initial Management of Infertility and aimed to obtain the views of infertile women attending gynaecology out patient departments at 12 Scottish Hospitals.

Methods

A postal questionnaire survey of 1366 patients was carried out as a part of a prospective audit of the management of infertility in Scotland. Twelve hospitals participated in the study. These centres covered a wide geographical area and comprised both district general and teaching hospitals,

including the four tertiary referral centres for infertility in Scotland. Each centre identified between 71 and 200 consecutive women attending gynaecology out patient clinics with infertility between July 1995 and April 1996.

The main issues addressed by the questionnaire (waiting times at the clinic, the doctor's attitude, information and explanation, emotional help and counselling) were drawn from a number of sources. Areas which had been identified as important in patient satisfaction surveys in general were included, as well as those aspects of care highlighted as deficient in previous surveys of infertile patients. Additional material was obtained from unstructured interviews with ten infertile couples currently undergoing investigation and treatment and two members of a patient representative group for infertility. Final alterations were made following a pilot study involving twenty patients.

The questionnaire was in the form of twenty main questions, which were both episode-specific questions (relating to the most recent hospital visit) and about the clinic in general, including overall satisfaction with the service. In 14 of the 20 questions, the responder had the option of answering only "yes" or "no" while in a further five, there were four answer options (e.g. very satisfied, satisfied, dissatisfied and very dissatisfied) so that the strength of the responder's feelings on the subject could be assessed. One of the questions was sub-divided to cover eight aspects relating to the doctor's attitude at the most recent hospital visit (see Table I). The remaining question asked responders to rank five aspects of their care (see Table II) one to five in order of relative importance to them: one being the most important to them and five being the least important.

The questions were interspersed by three areas where patients were invited to make comments or expand on their answers. The final page of the questionnaire was divided into three areas where responders were asked to make written comments specifically about unsatisfactory or upsetting experiences at the clinic, anything that had been especially encouraging or helpful and any changes which they thought would improve the service.

A covering letter and a stamped addressed envelope were enclosed with the questionnaire. The covering letter explained the aims of the project, that responses were anonymous and that participation was entirely voluntary. Non-responders were not re-mailed.

Approval for the survey was sought from the Medical Ethics Committees serving all twelve hospitals. There were no objections to the survey but the Committee serving two of the hospitals stipulated that questionnaires only be sent to women who had given prior written consent. Thus, in ten hospitals, postal questionnaires were sent to all women attending out patient clinics with infertility during the audit period. In the remaining two hospitals, questionnaires were sent only to those women from whom the clinic staff had obtained prior written consent. The questionnaires were sent as soon as possible after the index visit.

The results of the questionnaire were entered into a Borland Paradox Database and analysed using Microsoft Excel (ANOVA) and Epi Info (Mantel-Haenszel Test).

Results

Of the women surveyed 59% (806/1366) responded to the questionnaire. The response rates for individual hospitals ranged from 45% (31/69) to 81% (79/97). There were no significant differences between responders and non-responders in terms of age (ANOVA $p=0.72$) or whether they had a previous successful pregnancy (Mantel-Haenszel Test $p=0.25$). The mean age of responders (and of non-responders) was 30 years and only 27% of them had a history of one or more successful pregnancies.

Overall Satisfaction

Satisfaction with medical care was high, with 87% (692/800) of women saying they were satisfied or very satisfied with the medical care they had received. Eleven percent (92/800) were dissatisfied and only 2% (15/800), very dissatisfied.

Organisation of the clinic

Women were divided over the type of clinic they would prefer to attend. While 40% (319/800) preferred the option of a dedicated infertility clinic, 10% (82/800) favoured a mixed gynaecology clinic and 50% (399/800) said the type of clinic was not important to them. Thirty nine percent (312/796) had not been asked to bring their partner to the clinic at any time and 18% (147/794) had experienced problems with a lack of continuity of medical staff. Responders were asked about the time they had waited at their most recent clinic visit. Forty nine percent (393/804) did not see a doctor until after their allotted appointment time. Among these, the average reported delay was 25 minutes. Of those taken late, 69% (273/393) felt that the delay was acceptable. However the mean delay of 19 minutes for those who found the wait acceptable was significantly shorter than the mean of 41 minutes for those who found the delay unacceptable (ANOVA $p<0.001$). Overall, 6% waited an hour or more beyond their appointment time.

The doctor's attitude

More than 90% of women felt that the doctor at their most recent clinic visit listened to what they had to say, behaved politely and appeared good at his or her job. However, approximately 1 in 5 patients thought the doctor did not show an interest in them as a person, did not seem sympathetic, was not easy to ask questions of, or did not let them take part in decision making (Table 2). Twelve percent (93/771) said the doctor did not explain things to them and 45% (360/805) had questions they would have liked to ask at the clinic, but did not have the opportunity to do so.

Information and explanation

Twenty one percent (160/759) felt there had been little or no information given to them about the possible causes of their infertility. Overall, only 33% (257/784) had received *any* written information from their clinic and 78% (603/771) would like more literature. Forty seven percent (419/792) felt they had not been given a clear plan for the future and, of 387 women who had

received drug treatments, 23% (90/387) reported receiving little or no information about their treatment or possible side effects.

Investigations

Ninety four percent (614/650) of patients who had undergone investigations said these had been explained to them but 20% thought that there had been excessive repetition of tests. More than a quarter (27%; 161/592) said it had taken too long for the investigations to be carried out and 32% (161/592) felt that the time taken to receive results was too long.

Emotional support and counselling

Only 14% (109/787) felt they had been given enough help from the clinic with the emotional aspects of infertility. Of the 113 (14%) who had been offered counselling, only 19 patients said they had actually received this. Of those 19, 15 said they found it helpful. Fifty seven percent (431/761) of responders said they would take up infertility counselling if it was offered to them at this point in time.

Ranking of Aspects of Care

Six hundred and eighteen (77%) of the responders answered this question completely. Women who omitted the question or answered incompletely were excluded. "*The doctor's attitude*" was most commonly ranked number 1, closely followed by "*the information and explanation given*". "*The waiting time at the clinic*" was least commonly ranked as number 1. The ranks were summed for each of the aspects of care to give an overall rank (Table 2). Again, "*the information and explanation given*" and "*the doctor's attitude*" were ranked most highly of the 5 aspects of care.

Written Comments

All 806 questionnaires which were returned were reviewed and the written comments categorised into common themes. Five hundred and ninety eight women (74% of responders) made written comments. Of those, 25% praised the attitude of the clinic staff (Table 3). Eleven percent (66/598) of comments related to problems with a lack of continuity of medical staff and 9% (53/598) to dissatisfaction with the doctor's attitude towards them. When asked to suggest any changes which they felt may improve the service, 10% (59/598) cited more written information. Greater availability of counselling and more help with the emotional aspects of infertility, more information and explanation, greater continuity of medical staff and more frequent clinic appointments were also amongst the most common suggestions (Table 4). A number of quotes which illustrate some recurring themes in the written comments are shown in Table 5.

Discussion

This is the largest questionnaire survey of infertile women that has been carried out in the UK. Unlike some previous surveys,^{3,4} the questionnaire was mailed to patients currently undergoing investigation and treatment, not specifically to members of patient representative groups. The response rate of 59% is lower than the 77% reported by Owens and Read when they surveyed members of the National Association for the Childless³ but almost

twice as high as the 31% achieved by Bromham et al.² who included patients who were not members of self-help groups.

Patient satisfaction is difficult to assess and define. In general, surveys produce high levels of overall satisfaction with medical care making it more difficult for practitioners and managers to prioritise areas of service development. More specific questions are needed to provide useful information about the service being provided.⁶ This survey collected detailed information about specific aspects of care as well as asking about the relative importance of some of these.

A common criticism of patient satisfaction surveys is that they focus primarily on organisational or "hotel" aspects of care which are relatively easy to define and measure and are attractive to managers as performance indicators.⁷

Only one such question was included in the present survey and this related to the waiting time at the clinic. Women who found their delay unacceptable had waited significantly longer than those who found it acceptable. The watershed would appear to lie somewhere between 20 and 40 minutes. Waiting times were, however, given a low priority in relation to other aspects of care, suggesting that the managerial emphasis which is often placed on this, does not reflect patients' priorities.

The two aspects of care which were ranked most highly in terms of importance were "*the information and explanation given*" and the "*doctor's attitude*". The survey identified a need for more information and explanation, particularly in relation to the possible causes of infertility and drug treatments. A minority of patients had received any written information and a large majority reported they would like more literature. Almost half left the clinic with unresolved questions or without a clear plan about possible future investigations and treatments. More effective and frequent use of written information is clearly indicated as having the potential to address some of the patients' information needs.

The survey also highlighted the importance of the doctor's attitude which was ranked highly by patients. Improvements may be made by allowing couples to take part in decision making and giving them the opportunity to initiate questions.

The time taken for investigations to be performed and for results to reach patients has been criticised in previous studies^{3,4}. More than a quarter of women echoed these sentiments but it is worth noting that "*the way the investigations are done*" ranked lower overall than "*the information and explanation given*", and "*the doctor's attitude*". Five per cent of those women who made written comments felt that clinic visits were too infrequent and some appeared to lack understanding of the importance of the duration of infertility in making decisions about appropriate treatment. Specific explanation and written information about the time scale for investigations and treatment at the initial clinic visit may be helpful to patients.

Most women felt that they had not been given enough help with the emotional aspects of infertility. This is something that has been repeatedly highlighted in patient surveys^{2,4} and infertility guideline documents.^{8,9} It would seem that this area is still not being adequately addressed in out patient clinics. One of the reasons for this may be the relatively few published studies clearly demonstrating benefits of counselling.^{9,10,11} If more than half of women did indeed take up the offer of counselling, as this survey suggested, the financial

costs to an already stretched service would be considerable. Interestingly however, *"help with the emotional side of infertility"* was not ranked highly in comparison to the other areas of care. It may be that aspects of care which are less costly and perceived as higher priorities by those using the service should be addressed first. The project aimed to address the management of infertility by gynaecologists and so the questionnaire was addressed to the female partner specifically.

Finally, more than a third of women had not been asked to bring their partner to the clinic at any time. It is paradoxical that although a male problem is the single commonest identifiable factor¹², infertility is still perceived as a predominantly female problem. Many written comments related to the fact that their partner had been left in the waiting room or ignored during the consultation. There were few women who said they did not want their partner to attend and most were positive about their partner being involved. It is planned to include a questionnaire for the male partner in a second round of this audit.

Conclusions

The women who responded to the questionnaire were in general satisfied with their care and it was only on asking more specific questions that inadequacies in the service were identified. Improvements may be made by giving patients more explanation and written information (particularly in relation to the causes of infertility, the time scale for investigation and treatment, and drug treatments), by streamlining the process of investigation and by ensuring that patients have the opportunity to ask questions. Clinics should strive for a more couple-centred and holistic approach and, where resources allow, take steps to address the emotional aspects of infertility.

Acknowledgements

Gynaecology Audit project in Scotland is funded by the clinical Resource and Audit Group (CRAG) of the Scottish Office Department of Health. The views expressed in this paper are those of the authors and do not represent the views of CRAG or the department.

The authors would like to thank Dr Barbara Thomson and Dr Margaret Reid for their advice about the questionnaire. We would also like to thank all the responders to the questionnaire and the staff of the gynaecology units in the following 12 hospitals who contributed:

Aberdeen Royal Infirmary
Crosshouse Hospital, Kilmarnock
Forth Park Hospital, Kirkcaldy
Glasgow Royal Infirmary
Monklands Hospital, Airdrie
Ninewells Hospital, Dundee
Raigmore Hospital, Inverness
Stirling Royal Infirmary
St Johns Hospital, Livingston
The Royal Alexandria Hospital, Paisley
The Royal Infirmary of Edinburgh
The Western Infirmary, Glasgow

Table I Answers to specific questions about the attitude of the doctor at the most recent clinic visit.

Did the doctor at your most recent hospital visit:	Response of "Yes"	
	Number	(%)
behave politely towards you?	782/794	(98)
appear good at his/her job?	741/778	(95)
listen to what you had to say?	739/786	(94)
explain things to you?	687/781	(88)
make it easy for you to ask questions?	632/781	(81)
show an interest in you as a person?	616/775	(79)
appear sympathetic?	600/755	(79)
let you take part in any decisions?	590/751	(79)

Table II The overall rank given to each of five suggested aspects of care and the % of responders who chose each one as the most important to them.

Aspect of care	Overall Rank	Responders who ranked it as number one.	
	(Sum of scores)	Number (n=620)	(%)
The information & explanation given	1 (1265)	211	(34)
The doctor's attitude	2 (1360)	241	(39)
The way the investigations are done	3 (1618)	107	(17)
Help with the emotional side of infertility	4 (2237)	33	(5)
The waiting time at the clinic	5 (2828)	26	(4)

Table III The five commonest subjects of written comments made by responders.

Subject of the Written Comments	Responders	
	Number (n=598)	(%)
Praising the attitude of the staff in general	150	(25)
Problems with a lack of continuity of medical staff	66	(11)
Dissatisfaction with the doctors attitude towards them	53	(9)
Inadequate information and explanation	42	(7)
Good explanation and information	41	(7)

Table IV Written suggestions made by responders as to how they would suggest the service could be improved.

Suggestions as to how the service could be improved	Responders	
	Number (n=598)	(%)
More written information	59	(10)
More counselling / help with the emotional aspects of infertility	54	(9)
More explanation and information	33	(5)
Greater continuity of medical staff	30	(5)
More frequent clinic appointments	25	(4)

Table V Selected quotes from responders illustrating some of the commonest themes among the written comments.

"I have found several nurses and doctors very understanding and I now realise I am not the only one with this problem"

"You can talk freely with the doctor and he explains everything which makes my husband and I feel so much easier with our situation"

"Some of the questions I've asked which were really worrying me were treated as though they were trivial"

"Doctors could use more interpersonal skills to ask about me as a person. I have never been asked how I felt about any aspect of my treatment"

"Doctors in this field need to be able to put their patients at ease. It's a very stressful and emotionally draining time for a couple. Doctors need to be aware of this and show it to patients"

"Written leaflets explaining treatments and procedures could be given out"

"I found the reading material very helpful. It helped in the discussion between me and my husband"

"Explanation of investigations and time scales would be helpful"

"Seeing different doctors at every visit whose opinions vary considerably, we have a distinct sense of inconsistency of care"

References

- 1 Templeton A, Fraser C, Thompson B. (1990) The epidemiology of infertility in Aberdeen. *British Medical Journal*, 301, 148-152.
- 2 Bromham DR, Balmer B, Clay R, Hamer R. (1988) Disenchantment with infertility services: A survey of patients in Yorkshire. *British Journal of Family Planning*, 14, 3-8.
- 3 Owens DJ, Read MW. (1984) Patients' Experience with and Assessment of Subfertility Testing and Treatment. *Journal of Reproductive and Infant Psychology*, 2, 7-17.
- 4 Pfeffer N, Quick A. (1988) Infertility Services A Desperate Case. The Greater London Association of Community Health Councils, London.
- 5 Hall JA, Dornan MC. (1988) Meta-Analysis of Satisfaction with Medical care: Description of Research Domain and Overall Satisfaction Levels. *Social Science Medicine*, 27, 637-644.
- 6 Bruster S, Jarman B, Bosanquet N, Weston D, Erens R, Delbanco TL. (1994) National Survey of Hospital Patients. *British Medical Journal*, 309, 1542-9.
- 7 Fitzpatrick R. Surveys of patient satisfaction. I. Important general considerations. (1991) *British Medical Journal*, 302, 887-9.

7 Fertility Committee of the Royal College of Obstetricians and Gynaecologists. (1992) *Infertility guidelines for practice*. London, RCOG Press.

8 Scottish Office Home and Health, Scottish Health Service Advisory Council. (1993) *Infertility services in Scotland*. Edinburgh, HMSO.

9 Bresnick E, Taymor ML. (1979) The role of counseling in infertility. *Fertility & Sterility*, 32, 154-156.

10 Rosenfield DL, Mitchell E. (1979) Treating the emotional aspects of infertility: counseling services in an infertility clinic. *American Journal of Obstetrics and Gynecology*, 15, 177-180.

11 Domar AD, Zuttermeister PC, Seibel M, Benson H. (1992) Psychological improvement in infertile women after behavioral treatment: a replication. *Fertility & Sterility*, 58, 144-147.

12 Hull MGR, Glazener CMA, Kelly NJ, Conway DI, Foster PA, Hinton RA. (1985) Population study of causes, treatment, and outcome of infertility. *British Medical Journal*, 291, 1693-1697.

