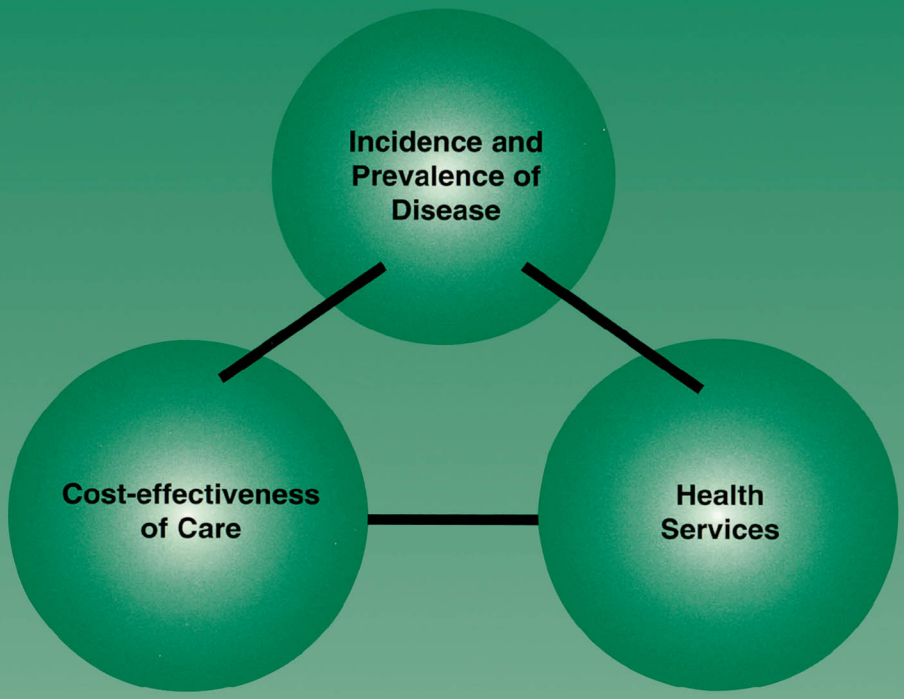
GYNAECOLOGY

CDA Wolfe



HEALTH CARE NEEDS ASSESSMENT

The epidemiologically based needs assessment reviews

SECOND SERIES

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Edited by A Stevens and J Raftery

Gynaecology

Health Care Needs Assessment

the epidemiologically based needs assessment reviews

Second series

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Gynaecology

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Foreword

Everyone involved in the purchasing, planning and prioritization of health care needs accurate, comprehensive and well-packaged information to answer at least four crucial questions. With what population or patients are we concerned? What services are provided? What is the evidence of the effectiveness of services? What is the optimum set of services? In other words: What is the need and how can it be best met?

These questions are answered in part by epidemiological literature and in part by the products of the evidence-based health care movement. The *Health Care Needs Assessment* series neatly combines these two elements and offers a perspective across an entire disease or service area. A purchaser or practitioner reading one of these chapters is rapidly brought up-to-speed with the whole spectrum of care.

Many positive comments, including evidence supplied to the House of Commons' Health Committee, have demonstrated the value and importance of the first series. The additional topics in the second series extend the range of information available covering both areas where the assessment of need and effectiveness of services has long been discussed, such as aspects of gynaecology and low back pain, and ones in which there has been less interest, such as dermatology. The new series will be welcomed by purchasers of health care in the United Kingdom but it should also be of value to all those concerned with assessing and meeting health care needs, from central government to individual practitioners.

Graham Winyard
Medical Director, NHS Executive
September 1996

Preface

This book forms part of the second series of health care needs assessment reviews. The first series, published in 1994, comprises reviews of 20 diseases, interventions or services selected for their importance to purchasers of health care. Importance is defined in terms of burden of disease (mortality, morbidity and cost), the likely scope for changing patterns of purchasing and the wish to see a wide range of topics to test the method used for needs assessment. The first series also includes an introductory chapter, explaining the background to needs assessment and a conclusive chapter, bringing together the main findings of the disease reviews.

The eight reports have been chosen, using the same importance criteria to increase the coverage of all health service activity. There has been a small change in emphasis, away from disease groups (strictly *Breast Cancer* only), to services and in some cases entire specialties (*Dermatology* and *Gynaecology*). The change has been partly to maintain coverage of substantial areas in each report (where otherwise a relatively small disease group would now require an individual chapter) and also to reflect the wishes of the users for the topic areas to be consistent with the scope of purchasing plans if at all possible.

As before the authors have been selected on the basis of academic expertise and each chapter is the work of individual authors. The reviews do not necessarily reflect the views of the National Health Service Executive that sponsored the project, nor indeed the current professional consensus. Each review should be in no way regarded as setting norms; rather it should be used as a valuable source of evidence and arguments on which purchasing authorities may base their decisions.

There have been other changes since the first series which have influenced the range of reviews and the content of individual reviews. First districts have merged and a population base of 250 000 is no longer the norm. Denominators are now expressed as per 100 000, or per million population. Second the term purchasers no longer strictly means just district health authorities. Some small steps have therefore been taken in the direction of making the material relevant to primary care purchasing. This is particularly so in the *Low Back Pain* review, in which the focus is on the presenting symptom as in general practice rather than on a confirmed diagnosis following secondary care. Third the science of systematic reviews and meta-analyses has developed remarkably since the production of the first series. While this important development has been of great use to purchasers, the role of the needs assessment in covering entire disease and service areas remains unique. Both objectives of providing baseline information for purchasers to assist with the knowledge-base of all the processes around purchasing and designing a method for needs assessment have largely been vindicated by comments received on the first series and the demand for a second series.

The editors wish to acknowledge the contribution of those who helped with the origination of the project: Graham Winyard, Mike Dunning, Deirdre Cunningham and Azim Lakhani; and also members of the current Steering Group: Mark Charny, Anne Kauder and Graham Bickler; as well as those at Wessex who have enabled the project to run smoothly: Ros Liddiard, Pat Barrett and Melanie Corris.

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Introduction

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Needs assessment means different things according to who uses the term, when and where. Some of these uses are reviewed in this introduction. Our understanding of needs assessment stems from the wish to provide useful information for those involved in the priority setting and purchasing of health care.

We are concerned with population health care need and define it as 'the population's ability to benefit from health care'[1,2,3] as did Culyer 20 years ago.[4] Mention of health care is important because for the purposes of commissioning health services it is crucial that there be some benefit from the interventions that follow from the assessment of need. The benefit can be immediate or in the future, physical or psychological, personal or communal. The intervention can concern health promotion, diagnosis, or palliation as well as treatment. We argue that needs are worth assessing when something useful can be done about them. The two essential determinants of a population's ability to benefit are the:

- incidence and/or prevalence of a health problem
- effectiveness of the interventions available to deal with it.

These two components form the core of the protocol used in the chapters that follow.

Current service provision although not a determinant of need is also highly relevant if needs assessment is to have any value in action. We need to know how things stand before we can change them. The reliance of our approach on these three elements is shown in Figure 1. The effectiveness corner of the triangle includes *cost*-effectiveness because this allows us to consider the *relative* priority of different needs.

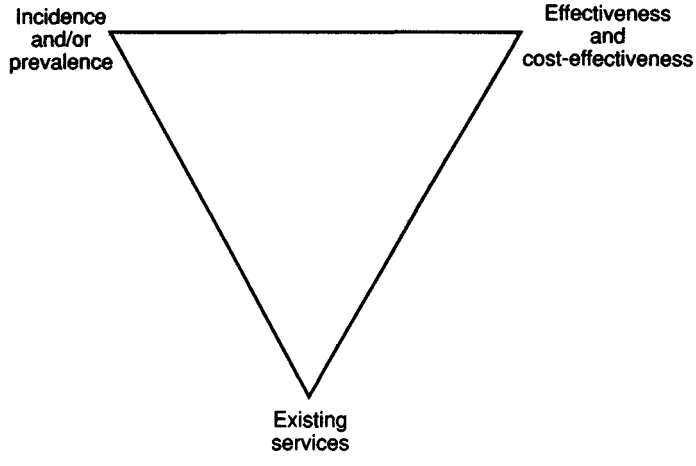

Figure 1: The elements of health care needs assessment.

We also distinguish need from demand (what people would be willing to pay for or might wish to use in a system of free health care) and from supply (what is actually provided).[1,2,3] This helps to classify health service interventions according to whether they reflect need, demand or supply (or some combination). It also highlights the need for caution in the use of information sources which often say more about supply (e.g. utilization rates) or demand (e.g. patient preference surveys) than they do about need. It also reminds health care commissioners of the importance of drawing together needs, supply and demand as shown in Figure 2. The central area of overlap is the optimum field for service provision, i.e. where need, supply and demand are congruent.

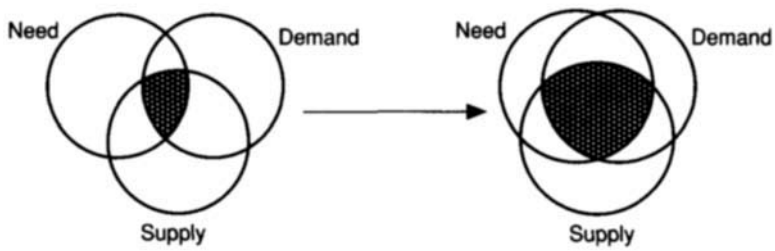

Figure 2: Drawing need, demand and supply together: the role of the purchasers of health care.

We also suggest three practical tools for health care needs assessment (see page xvi):

1 epidemiological
2 comparative
3 corporate.

Alternative approaches

There is a considerable range of alternative approaches to needs assessment depending on their purpose and context.

Social services assessment

In UK public policy the community care reforms which have stressed individual needs assessment for social care. Local authority social services departments must assess the needs of individuals for personal social services that mainly cover the elderly, the mentally ill and people with learning disabilities.[5]

Individual health care needs assessment

In health care too, the mentally ill have become subject to increased individual assessment through the care programme approach which is designed to cover all severely mentally ill individuals who are about to be discharged from hospital.[6] However individual health care needs assessment has existed as long as medicine and is the key feature of much of health care. The clinical focus regards need as the best that can be done for a patient in a particular setting. In primary care the establishment of routine health checks in the UK,

especially for the over 75s, is an example of formalized individual needs assessment, which raised controversy in its imposition of mass individual needs assessment that includes people who are not necessarily in any need.[7,8]

Participatory priority setting

In the US needs assessment is often used as a term for participatory priority setting by organizations, which are usually public sector or voluntary rather than for profit. These involve three elements: defining the needs of organizations or groups, setting priorities and democratic involvement.[9] At state level the now famous Oregon approach to priority setting has much in common with needs assessment for health care commissioning in the UK but the explicit use of the participatory democratic element in the US was striking.[10] Even in the UK health policy since 1991 has attributed growing importance to the role of the public. This has been both in the form of central exhortation[11,12] and in local practice as many district health authorities have tried to involve the public in priority setting.[13] Public involvement has also occurred unintentionally through the media: a series of controversial cases, notably Child B who was denied a second NHS funded bone marrow transplant for leukaemia on the basis of the likely ineffectiveness of the treatment, have raised national debates.[14]

Primary care approaches

Other approaches, some imposed from above and some experimental from below are emerging from attempts to establish needs assessment in primary care. The routine assessment of the over 75s is an example of a top-down initiative and is unusual in requiring individual needs assessment by general practitioners of an entire age group.[7,8] Bottom-up experimental approaches tend to be based around data gathering through different means including for example rapid participatory appraisal, the analysis of routinely available small area statistics and the collation of practice-held information.[15,16] The analysis of small area statistics has a long tradition, including the use of Jarman indicators[17] and belongs to the comparative method of health care needs assessment – principally identifying a need for further analysis. Examining practice-held information including the audit of general practice case notes has had a growing role and is potentially much more relevant to population needs assessment than audit in secondary care. Because primary care case notes have a wide population coverage (90% of a practice population in three years) and each primary health care team has a relatively small population, it is possible for a primary health care team to expose practice population needs (given a knowledge of the effectiveness of interventions) through case note analysis. The development of computerized case notes in general practice could dramatically increase the scope for this approach.

Local surveys

In health authorities the use of local surveys has increased. These can cover multiple client groups and involve the collection of objective morbidity data. Local bespoke surveys of morbidity[18] can be supplemented by the interpretation of semi-routine data from national surveys such as the General Household Survey[19] and the OPCS Disability Survey.[20,21] Directors of Public Health annual health reports often include both local surveys and elements of such data. These can collect valuable information, although there is a risk that when local surveys are both limited to a selective range of client groups, and are centred around subjective information, they will give disproportionate importance to a selective range of interests.

Specialty-specific documents

Documents setting out the service requirements of client groups of an individual specialty are sometimes also treated as needs assessments. These often recommend the augmentation of services (within that specialty). Their validity as needs assessment documents depends on the explicitness and thoroughness of their research base.

Clinical effectiveness research

Finally, perhaps the most important contribution to needs assessment has been the major expansion of clinical effectiveness research in the UK and elsewhere. In the UK the Department of Health's research programme and especially its emphasis on 'health technology assessment' is a major attempt to evaluate the effectiveness of many health care interventions and therefore inform the health care needs which underlie them.[22,23]

In determining the differences between these various approaches to needs assessment it is helpful to ask the following questions:

1 **Is the principal concern with health or social services?** The effectiveness component of need for social services is often not recognized. The reason for this may be that there is seldom a clear-cut distinction between what works and what does not. More housing or more education is seldom seen as undesirable. In health care, by contrast, some interventions work spectacularly well but a point arises at which increased intervention *is* undesirable. Excessive medication or surgery may not only be of no benefit but can be harmful. It could be argued that in social care the potential open-endedness of benefit and therefore of spending makes it more important to assess the effectiveness of interventions and make a judgement of what the need is. The spectre of rationing in a politically charged context often deters such explicitness.

2 **Is the needs assessment about population or individuals?** Many approaches to needs assessment are necessarily concerned with individuals. Local authority social services programmes and primary care health checks focus on individuals. Traditional clinical decision making and also some purchasing decisions such as extra-contractual referrals concern individuals. The media focus is almost always on the individual. Although individual needs assessment can be seen as the opposite end of the spectrum from population based needs assessment the underlying logic is the same.

   The purchaser (population needs assessor) is concerned with meeting the aggregate needs of the population. For some client groups where individuals are either few or prominent in their health care costs, such as in the case of mentally disordered offenders they may well need to be individually counted or even individually assessed to provide the population picture.[24,25] Wing *et al.* consider the purchaser's population view and the individual clinical view of mental health need to be 'largely identical'.[26] In part they say this because individual needs can be aggregated but in part they recognize the importance of service effectiveness as integral to the need equation.

3 **Is there a clear context of allocating scarce resources?** Needs assessments that fail to acknowledge resource limitations are common but are of restricted value to health care commissioners. This can be a problem with individual clinical needs assessment, which can put great pressure on health budgets and squeeze the care available to patients with weak advocates. However clinicians work within an (often) implicit resource framework. Population health care needs assessment makes that framework explicit. Some population approaches also fail to acknowledge resource issues. This can be a problem with population surveys if they are neither set in the context of effectiveness, nor make it clear that they are

exploratory. It is also a difficulty with specialty-specific documents recommending levels of service within the specialty.[27] Examples abound as many specialties are anxious to protect or enhance the resources available to them.[28] This may be justified but they risk being little more than a group extension of an unbounded clinical decision making procedure.

4 **Is the needs assessment about priority setting within the context of a variety of competing needs or is it about advocacy for a single group or individual?** This is closely related to the resource context question. Specialty-specific documents, client group surveys and even policy directives which focus on single groups often represent advocacy rather than balanced contributions to priority setting. Surveys about, for example, the needs of a particular ethnic minority are of limited help in guiding purchasers unless seen in the context of equivalent surveys of other groups. Whether a policy directive is advocacy based or priority based depends on how it comes about. A set of recommendations based on lobbying will be much more prone to distorting resource use than one based on research. Arguably the Child B case moved from a priority setting to an advocacy framework when the debate moved from the health authority to the law courts.

5 **Is the needs assessment exploratory or definitive?** Some approaches to needs assessment are exploratory in that they highlight undefined or under-enumerated problems. This is particularly true of lifestyle surveys that estimate the size of risk groups such as alcohol abusers or teenage smokers. Surveys of the needs within specific client groups can also fall within this category but they differ from population surveys in that they often involve advocacy. If effectiveness of interventions has been determined prior to a population survey then this approach is compatible with epidemiological health care needs assessment.

6 **Is the determination of the most important needs expert or participatory?** The epidemiological approach to needs assessment is essentially an expert approach (with a population perspective). It seeks to be as objective as possible although no judgement of relative needs can be truly objective. Interpretation of data is partly subjective and the rules for decision making are inevitably value-laden. However the setting of priorities using an epidemiological and cost-effectiveness framework is markedly different from a process based on democratic consensus. Attempts to merge the two as in Oregon and in the local experience of many health authorities can have merit but the outcome will nearly always depend on the relative emphasis given to the provision of objective information and the extent to which participants can interpret them. As a general rule the expert approach to priority setting is more viable the further it is from the clinical decision making. At one extreme the World Health Organization's assessment of relative need operates by very clear cost-effectiveness rules.[29] At the other extreme the individual clinical decisions are rightly very open to patient views. District health authorities have to reconcile the two.

Underlying all of these questions is the further question: 'Who carries out the needs assessment and for what purpose?' Provided the assessment's aims and context are clearly stated and clearly understood there is a place for all of these approaches to needs assessment. Many can be subsumed within the approach used in this book in that they provide information about:

- numbers in a particular group, i.e. incidence and prevalence
- the effectiveness and cost-effectiveness of interventions
- the distribution of current services and their costs.

There is more information available on these elements of epidemiology-based needs assessment. Epidemiological studies contribute to the first point in the list above; effectiveness and outcomes research, i.e. evidence-based health care, to the second and assessments of current services to the third. The bringing together of the three themes in this book has been supported elsewhere at the extremes of individual and global needs assessments. For example Brewin's approach to measuring individual needs for mental health

care identifies need as present when *both* function is impaired *and* when it is due to remedial cause.[30] Bobadilla *et al.*, in prescribing a minimum package for public health and clinical interventions for poor and middle income counties across all disease groups, identify both 'the size of the burden caused by a particular disease, injury and risk factor and the cost effectiveness of interventions to deal with it'.[29] Table 1 summarizes different approaches to health care needs assessment using the criteria discussed above.

Tools

In the first series of health care needs assessment we suggested three tools for needs assessment:

1 the epidemiological
2 comparative
3 corporate approaches.[2,3]

The definition of health care needs as the 'ability to benefit' implies an epidemiological approach. That is an assessment of how effective, for how many and, for the purposes of relative needs assessment, at what cost. However comparisons between localities (the comparative approach) and informed views of local service problems (the corporate approach) are important too.

The value of the 'comparative approach' is well demonstrated in the assessment of need for renal replacement therapy.[31] Increases in dialysis and transplantation in the UK closer to levels seen in better-provided European countries has been demonstrated over time to meet real needs. The need to change replacement levels from 20 per million in the 1960s, to 80 per million was suggested by both the comparative and epidemiological approach, i.e. of identifying incident end-stage renal failure and the effectiveness of renal replacement therapy. The comparative method does not however easily lead to cost-effectiveness considerations and is less successful in assessing which modality of renal replacement therapy is to be preferred; as the different balance between haemodialysis, peritoneal dialysis and transplantation rests on a variety of factors. The cost-effectiveness of different modalities is critical to priority setting. The comparative approach can however prompt key questions and therefore sets the priorities for more detailed analysis.

Almost every chapter of the first series of health care needs assessment expressed doubts about the extent and reliability of much of the routine data available for comparative analysis. The data on activity and prescribing, for example, would need to be linked to disease codes to represent faithfully true disease episodes. Disease registers such as those provided by the cancer registries can be invaluable and developments in information technology and unique patient numbers offer great scope for improved comparative analyses.

The 'corporate approach' involves the structured collection of the knowledge and views of informants on health care services and needs. Valuable information is often available from a wide range of parties, particularly including purchasing staff, provider clinical staff and general practitioners. Gillam points out that 'the intimate detailed knowledge of health professionals amassed over the years is often overlooked' and he particularly commends the insight of general practitioners, a suggestion well taken by many health authorities.[32] The corporate approach is essential if policies are to be sensitive to local circumstances. This approach might explore: first, a particularly prominent local need – such as the identification of severely mentally ill patients discharged from long-stay mental hospitals and lost to follow-up; second, consequences of local service considerations such as the balance between secondary and primary and local authority community care – as has been noted in the case of district nursing services;[33] third, where local needs differ from expectations based on national averages or typical expectations (due to local socioeconomic or environmental factors); and fourth, local popular concerns which may attach priorities to particular services

Table 1: Different approaches to health care needs assessment

Criterium	Health/social focus	Individual population based	Resource/scarcity clear	Competing needs/advocacy	Definitive/exploratory	Expert/participatory
Population health care needs	Health	Population	Yes	Competing	Definitive	Expert
Individual health care needs	Health	Individual	Sometimes	Either	Definitive	Expert
Social services assessments	Social	Individual	Sometimes	Competing	Both	Both
Participatory planning	Social	Population	Sometimes	Competing	Definitive	Participatory
Oregon-style planning	Health	Population	Yes	Competing	Definitive	Both
Primary health care checks	Health	Individual	No	Competing	Exploratory	Expert
Primary health care case note audit	Health	Individual	No	Competing	Both	Expert
Population surveys	Health	Population	No	Competing	Exploratory	Expert
Client group surveys	Health	Population	No	Advocacy	Exploratory	Both
Specialty recommendations	Health	Population	No	Advocacy	Definitive	Expert
Effectiveness reviews	Health	Population	Yes	Competing	Definitive	Expert

or institutions (effectiveness considerations being equal). The need for cottage hospitals as opposed to large primary care units or other modes of community service provision might be an example. Clearly the potential pitfalls of informal corporate assessment of need are bias and vested interest that could cloud an objective view of the evidence. Nevertheless corporate memory should not be ignored.

The 'epidemiological approach' has been described fully.[3] It is worth reiterating that the epidemiological approach goes wider than epidemiology. It includes reviews of incidence and prevalence and also evidence about the effectiveness and relative cost-effectiveness of interventions, which, for service planners is increasingly seen as a focal concern. The epidemiological approach to needs assessment has helped pioneer what is now a sea-change towards evidence-based health care purchasing.

Evidence-based health care requires some rating of the quality of evidence. The first series required contributors to assess the strength of recommendation as shown in Table 2 adapted from the US Task Force on preventive health care.[34] This is now a mainstay of evidence-based medicine and it is retained in the present series.

Table 2: Analysis of service efficacy

Strength of recommendation	
A	There is good evidence to support the use of the procedure
B	There is fair evidence to support the use of the procedure
C	There is poor evidence to support the use of the procedure
D	There is fair evidence to reject the use of the procedure
E	There is good evidence to support the rejection of the use of the procedure
Quality of evidence	
(I)	Evidence obtained from at least one properly randomized controlled trial
(II-2)	Evidence obtained from well-designed cohort or case controlled analytic studies, preferably from more than one centre or research group
(II-3)	Evidence obtained from multiple timed series with or without the intervention, or from dramatic results in uncontrolled experiments
(III)	Opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees
(IV)[a]	Evidence inadequate owing to problems of methodology, e.g. sample size, length or comprehensiveness of follow-up, or conflict in evidence

Table adapted from US Task Force on Preventive Health Care.
[a]The final quality of evidence (IV) was introduced by Williams *et al.* for the surgical interventions considered in the first series.[35]

The changing background

Health care needs assessment was thrown into the spotlight in 1989 by the National Health Service Review.[36] The review, by separating purchasers and providers, identified population health care purchasing and therefore health care needs assessment as a distinct task. Since the beginning of the 1990s however a variety of circumstances has changed including the activities and research encompassed by health care needs assessment.

District health authority changes

The nature of the purchaser of health care at district health authority has changed in several ways. First, district mergers have resulted in larger purchasing units. Second the amalgamation of district health authorities with family health services authorities has extended the scope of purchasing and encouraged a more integrated approach to primary and secondary care services. Third the abolition of regional health authorities has necessitated careful purchasing of specialist services (these were formerly purchased regionally). Fourth the relationship between purchasers and providers of health care is showing some signs of maturing, as it has become obvious that large monopsonists (dominant purchasers) and monopolists have to work fairly closely together. Fifth there has been increased involvement of general practitioners (see below). These changes make districts potentially more sophisticated assessors of health care needs – although in practice such sophistication has been slowed by the administrative upheaval caused by the changes.

Cost containment

The second critical background circumstance affecting health care needs assessment is the increasing recognition of the need for cost containment. Although costs have always been constrained by the NHS allocation, new pressures have resulted from a variety of sources.

- Increased patient expectations – some of which have been encouraged centrally – particularly those concerning waiting times.
- New technologies with either a high unit cost, e.g. new drugs such as Beta Interferon for multiple sclerosis and DNase for cystic fibrosis, or which widen the indications for treatment, e.g. new joint replacement prostheses which have a longer life-span and can be given to younger patients.[37,38]
- New pressures at the boundaries between day health and social care in the problems of community care, and more recently with the criminal justice system – in the case of mentally disordered offenders.[39]

In theory the logic of needs assessment allows the identification of over-met need – in the sense of relatively ineffective and expensive services – as easily as undermet needs. In practice the former is more difficult to identify and much more difficult to correct. This further focuses attention on a limited number of areas and especially on a limited number of the most important cost pressures such as Beta Interferon.

General practitioner fundholding and GPs in purchasing

The third major background change has been the growing relative importance of general practice fundholding as a purchasing entity. In 1991 GP fundholding covered only around 10% of the population. One of the more striking aspects of the NHS reforms has been the expansion of fundholding which now (1996) covers more than half the population of England and Wales.[40] The scope of standard fundholding has been extended to cover the bulk of elective surgery outpatient care (except maternity and emergencies), community nursing and various direct access services. Some 70 total purchasing pilots have been established where GPs take on the entire NHS allocation for their patients. Side by side with these experiments in budget delegation is a variety of schemes whereby GPs are consulted, or otherwise involved in the commissioning of services.

Health care needs assessment in this book was designed primarily with district health authorities in mind. This reflected the dominant status of health authorities as purchasers at the time and also the size of the

populations they covered. A population perspective makes more sense the larger the population, not least because the expected numbers of cases and their treatments are more predictable in larger populations. This is an issue for locality purchasing in general[41] and has even been a problem for district health authority purchasing when it comes to tertiary services and the rarer secondary services. The average GP sees only one case of thyroid cancer every 25 years and only eight heart attacks every year.[42] General practitioner fundholders cover populations ranging from 7000 to around 30 000. The total purchasing pilots which cover populations up to 80 000 only slightly ameliorate this. For GPs needs assessment as defined in this series is most likely to be applicable at the level of consortia with a large population. But taken together with GP involvement in profiling the population through case note audit and other means, needs assessment in primary care offers fruitful possibilities.

Evidence-based health care

The fourth main background change is in the drive from the research community itself. The evidence-based medicine and knowledge-based purchasing movement has been partly driven by imperatives to cost containment against a background of increasing health care costs as technology advances and by the acknowledgement that not all health care is effective[22,43] and by the differences in cost-effectiveness. The result is that needs assessment and cost-effectiveness assessment have become very closely related.

Use of the health care needs assessment series

Evidence for the usefulness of the epidemiological approach has come from the results of a survey of directors of public health in the UK[45], a Department of Health focus group on the first series, the House of Commons Health Committee's[46] review of the process by which authorities set priorities, and a national survey of contracting.[47] Two contrasting themes arising from these sources emerge.

1 There is an increasing appetite in health authorities for reliable material which assists priority setting. Health care purchasers are increasingly establishing a knowledge base across the whole range of health care, even if change is most effectively carried through by being reasonably selective.
2 Contracts themselves are not (yet) disease-based – usually built up from specialties they lack a starting point from which needs assessment can play a part. Thus although needs assessment has a role in setting the perspective for contracting, the guarantee that detailed implementation will take place is lacking. In part this reflects staffing shortages and the competing claims of other foci for purchasing (mergers, extra contractual referrals, waiting list initiatives, efficiency drives etc.). In part early attempts to develop disease-specific foci were hampered by poor quality data on patient treatment and particularly costs. This will become less of a problem not just with the growth of health technology assessment to provide the evidence base but also with initiatives such as the National Steering Group on Costing which has led to the costing of health care resource groups (HRGs) in six specialties.[48,49]

These surveys and experience with the first and second series have confirmed the usefulness of the protocol for health care needs assessment. Its six main elements remain:

1 a statement of the problem (normally a disease or intervention)
2 identifying the relevant sub-categories

3 the incidence and prevalence of the condition
4 the nature and level of service provided
5 the effectiveness (including the cost-effectiveness) of the service or treatments
6 models of care.

In addition authors have considered appropriate outcome measures, targets, the routine information available and current research priorities.

To extend the coverage and to link health care needs assessment more closely to the specialty basis of service planning this second series has moved away from single interventions and diseases to include groups of interventions (terminal and palliative care), groups of diseases/problems (sexually transmitted diseases, child and adolescent mental health) and whole specialties (gynaecology, dermatology and accident and emergency services) (Table 3). Only one review, on breast cancer, is defined as a disease group. Several of the reviews however use diseases as sub-categories. Back pain is defined more by the diagnostic cluster it represents than a disease group or aetiology.

Table 3: Health care needs assessment topics

	Series 1	Series 2
Cause	Alcohol misuse Drug abuse	
Diagnosis		Low back pain
Intervention	Total hip replacement Total knee replacement Cataract surgery Hernia repair Prostatectomy for benign prostatic hyperplasia Varicose vein treatments	
Group of interventions	Family planning, abortion and fertility services	Terminal and palliative care
Disease	Renal disease Diabetes mellitus Coronary heart disease Stroke (acute cerebrovascular disease) Colorectal cancer Dementia Cancer of the lung	Breast cancer
Heretogenous group of diseases/problems	Lower respiratory disease Mental illness	Genitourinary medicine services Child and adolescent mental health
Service/specialty	Community child health services	Gynaecology Dermatology Accident and emergency departments
Client group	People with learning disabilities	

We believe that each of the authors of the eight reviews has admirably matched the task of reviewing the components of health care needs assessment of their disease topic. Furthermore the original protocol has stood up well in its first few years. This has been so against a turbulent background in health care purchasing and a background of only slow progress in the development and availability of health care information. At the same time epidemiologically-based needs assessment has been reinforced by its overlap with other initiatives towards effective health care as well as by its uniquely wide coverage of entire diseases, groups of interventions and specialties.

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Gynaecology

CDA Wolfe

1 Summary

Introduction and statement of the problem

Gynaecology is the specialty concerned with diseases of women, which excludes breast disease, in the UK. The gynaecology service encompasses a range of preventive, medical and surgical interventions in primary and secondary care settings. Gynaecological symptoms and conditions may be managed exclusively in primary care or with additional secondary care provided by a number of specialty departments. For genital tract infections, excluding human immunodeficiency virus (HIV), women may be referred to genitourinary medicine and family planning departments as well as gynaecology and acute abdominal pain referred to general surgery. This chapter provides a framework for assessing the needs for the major components of the service and the scope for shifts in service provision from the secondary to primary care sector, inpatient to day case surgery and conventional to minimal access surgery (MAS) which are all major purchaser and provider issues.

This assessment relies on the 1991/92 morbidity survey from general practice and 1993/94 hospital episode statistics for the UK. Data are presented by international classification of disease (ICD) category with the equivalent Office of Population and Censuses and Surveys (version 4R) surgical operation codes (OPCS4R). The health care resource grouping (HRG) data for the same time period have been analysed but there are reservations over data quality. The categories of the gynaecological service have been grouped into 13 groups mirroring broad pathological and health service groupings which closely reflect important ICD codes as follows:

- subfertility
- pelvic inflammatory disease (PID)
- lower genital tract infections
- endometriosis
- menopause
- urinary incontinence/utero-vaginal prolapse
- menstrual disorders
- pelvic pain
- premenstrual syndrome
- ectopic pregnancy
- early pregnancy loss
- genital tract cancer – secondary prevention
- genital tract cancer.

Termination of pregnancy and subfertility have been considered in another needs assessment.[1]

Incidence and prevalence

- The overall burden of gynaecological disease is not estimable as studies of incidence and prevalence, especially in the UK have not been undertaken.
- The most prevalent conditions include menstrual disorders, pelvic pain, early pregnancy loss, urinary incontinence, menopause and lower genital tract infections (Table 4, page 24).
- There are problems of case definition and diagnosis with several conditions: silent PID, endometriosis, pelvic pain, premenstrual syndrome.

Services available

- In primary care gynaecology accounts for some 1500 consultations per 10 000 female population and 2250 consultations per 10 000 women–years at risk. A further 500 women consult per 10 000 women–years at risk with 700 consultations per 10 000 women – years at risk for candida and trichomoniasis infections of the genital tract. Over the past ten years there has been a doubling of the reports of genitourinary diseases and a 150% increase in consultations for menopausal symptoms.
- The main reasons for consultation in primary care in order of magnitude are:
  a) candidiasis
  b) disorders of menstruation
  c) menopause
  d) pelvic pain
  e) PID.
- A typical gynaecological secondary care service consists of general and specialist outpatient clinics including colposcopy, cancer and subfertility, and inpatient gynaecological beds, the majority of inpatients receiving an operation. Because of directives from the Department of Health there is an expanding day case surgery service. It is estimated that between 25–40% of hospital episodes are non-elective. Up to 17% of all gynaecological surgery is performed outside scheduled operating theatre sessions.
- In secondary care there are no routine data on outpatient activity. There are 7000 ordinary admissions per 100 000 female population for the main gynaecological ICD codes, of which 2000 are for gynaecology and 5000 for pregnancy related disorders relevant to the gynaecological service.
- The main non-pregnancy related reasons for admission are:
  a) disorders of menstruation
  b) non-inflammatory disorders of the cervix (mainly preinvasive lesions of the cervix)
  c) genital prolapse
  d) the menopause.
- This assessment estimates there to be 1.7 ordinary cases to every day case. The number of bed days for gynaecology equates to 1.5% of all beds and 4% of the acute sector beds.
- The operative intervention rate is estimated at 3000 per 100 000 females over the age of 15. The major operative categories are:
  a) dilatation and curettage (D&C)
  b) evacuation of the retained products of conception (ERPC)
  c) hysterectomy
  d) laparoscopy
  e) prolapse operations
  f) operations of the vagina and cervix.
  It is estimated that 37% of all procedures are undertaken as day cases.

- A Scottish needs assessment estimated that gynaecological services cost in the region of £15 million for a female population of nearly half a million, of which 73% was for inpatient care.
- The balance between services provided in primary and secondary care varies between districts and is dependent on local expertise and resources. Secondary care gynaecological services impinge on services in primary care, community gynaecological services provided in reproductive health departments and services provided in genitourinary medicine (GUM) departments.
- The main areas of overlap in service provision are in the diagnosis and treatment of PID, lower genital tract infection, the menopause, pelvic pain and the medical management of menstrual disorders.

Effectiveness of services

- There is no strong evidence on which to base decisions on how gynaecological services should be delivered in totality, or the optimum balance of care between primary and secondary care sectors, or between specialties in secondary care for certain conditions.
- There is very little evidence on the longer term outcome of MAS for gynaecological conditions.
- Although the resource implications of the increased use of day surgery are established, the benefits to women in terms of quality of care remain unevaluated.

The evidence of effectiveness for the sub-categories is outlined here but a full review is presented in section 6.

- As with much of medicine, gynaecological practice is in the main not based on evidence based medicine and this is particularly so for surgical procedures. More recently evaluations, often unrandomized, of new technologies for MAS have been undertaken but there is evidence that implementation of these techniques by departments, before evidence is available, has occurred.

Subfertility

- The average maternity rate of *in vitro* fertilization (IVF) is 12% per treatment cycle.[2] Effectiveness is reduced in clinics treating women over the age of 35.
- There is no evidence of increased effectiveness overall of IVF over gamete intra-fallopian transfer (GIFT).
- There is currently no effective treatment for male infertility and the main success in treating male infertility is by artificial inception by donor (AID).

Pelvic inflammatory disease and lower genital tract infections

- Strategies for detection and screening have been incomplete in the UK[3] although there is evidence from Sweden that widespread screening for chlamydia has virtually eradicated the disease.[4] In primary care the routine testing of women for chlamydia in younger women in the UK has been shown to be cost-effective.[5]
- A meta-analysis of trials of antibiotics for the treatment of PID indicated there was a lack of uniformity among studies regarding diagnosis, care and follow-up. Pooled cure rates ranged from 75–94%, with Doxycycline and Metronidazole being the least effective regimen. They concluded that clinical treatment of acute PID is likely to be inappropriate in many women and inadequate for chlamydia in much of the remainder.
- Bacterial vaginosis has a 75% cure rate at one month using a combination of Metronidazole and Clindamycin.[6]

Endometriosis

- Most regimens to treat endometriosis have not been shown to be effective. The most commonly prescribed drugs, Danazol and leutinizing hormone releasing hormone (LHRH) are costly but equally effective in relieving symptoms.
- With regard to fertility all treatments, medical and surgical, appear to be ineffective but assisted conception techniques appear to be successful.[7]

Menopause

- The effectiveness of hormone replacement therapy (HRT) in reducing the incidence of the long-term risks associated with the menopause such as osteoporosis and cardiovascular disease remain unclear. The effect of the newer preparations and different methods of administration on longer term outcome have not been assessed.
- Trial evidence has demonstrated that HRT relieves symptoms effectively.[8]
- Reductions of up to 20% in cardiovascular disease have been observed in cohort studies using older preparations.[9]
- Trials have shown that after ten years of HRT use bone loss is substantially prevented[10,11] but protection is reduced once HRT is stopped.
- Decision analysis studies have demonstrated the potential benefits of HRT but many assumptions are made. Roche and Vessey[12] consider the benefits in terms of reduced mortality and treatment costs are greater for women who have had a hysterectomy receiving unopposed oestrogen therapy than for women with a uterus receiving combined therapy, with a net gain to the NHS of £137 per woman being suggested if women who have had a hysterectomy are treated with oestrogen therapy.

Urinary incontinence/utero-vaginal prolapse – stress incontinence

- The success of pelvic floor re-education varies from 60–90% but when compared with surgery physiotherapy compares poorly.[13]
- No single operation could be offered to all women in all situations as a first choice.[14]
- Colposuspension and sling operations appeared to be the most effective procedures.
- There is no trial evidence to support or refute the use of repair of prolapse operations.

Menstrual disorders

- The effectiveness of D&C in the management of menstrual disorders in younger women has been questioned and the use of alternative outpatient endometrial sampling techniques has been shown to be effective.
- There is trial evidence that certain medical treatments of menstrual disorders can be effective. Minimal access surgery alternatives to invasive abdominal operations have been assessed by trial but the longer term benefits are not established and whilst both procedures continue to be carried out in units the financial benefits of MAS will be lost. The long-term advantages of transcervical resection of the edometrium (TCRE) are not established although TCRE appears to be cost-effective in the short term.[15] The use of laparoscopically assisted vaginal hysterectomy (LAVH) has been shown to be cost-effective in the short term.[16]

Pelvic pain

- There is insufficient evidence of the effectiveness of therapies to enable guidelines to be established.[17]

Premenstrual syndrome (PMS)

- The use of stress management, relaxation techniques, exercise and dietary change including oil of evening primrose oil supplementation, although often helping women with mild symptoms has not been shown to be effective in trials.[18]

Ectopic pregnancy

- There is fair evidence to recommend that operative laparoscopy be used in some ectopic pregnancies.[19]

Early pregnancy loss

- The evidence that progestational agents are effective at reducing recurrent miscarriage is inconclusive.
- Mifepristone is an effective antiprogestational agent for evacuating the contents of the uterus but its use for miscarriage remains to be assessed.[20,21]

Genital tract cancer – secondary prevention

- There is no trial evidence to support screening for cervical cancer but evidence that in countries where screening has been co-ordinated centrally mortality from the disease has fallen.
- The use of certain local ablative therapies for cervical intraepithelial neoplasia has been shown to be effective, especially large loop excision of the transformation zone (LLETZ).
- There is no evidence that screening for ovarian or endometrial cancers is effective.

Genital tract cancer

- There is generally no trial evidence to support the current surgical procedures undertaken for the various gynaecological cancers.
- For ovarian cancer the use of platinum based therapy in combination with other agents probably improves survival.
- The use of platinum as adjuvant therapy in women with persistent or recurrent cervical cancer has a response rate of 30%.[22]

Models of care

- The overall models of care that are developed locally will be dependent on those factors analysed at a national level in this chapter and include the need for the service, the current patterns of service and scope to move towards those practices identified as being both effective, cost-effective and acceptable to women.
- A needs assessment group comprising gynaecologists, general practitioners (GPs), nurses, public health physicians and local users of the service, along with information and health economics support should identify the necessary information on which to base decisions on the models of service to be provided.
- The areas purchasers should be concerned with will be determined locally but could include patient information, monitoring patient satisfaction, shifts in service provision: secondary to primary care, inpatient to day case surgery, conventional to MAS, development of guidelines and development of tertiary level services.

- Information provision should be co-ordinated across the levels of care and between specialties.
- The written provision of information on any diagnostic or therapeutic intervention is particularly relevant when it involves the genital tract as the implications for a woman's sexuality and femininity of the interventions need to be discussed, e.g. abnormal smear results, hysterectomy, removal of ovaries.
- Assessment of patient satisfaction should be an integral component of any service or intervention evaluation.
- Evaluation of shifts of service to primary care is required as their cost effectiveness has not been established. One of the aims of such a shift is to reduce duplication across the sectors and guideline development is integral to this process. The conditions where a shift in service provision to primary care could be considered include:
  a) the initial management of subfertility and follow-up after management in secondary care
  b) the prevention and management of PID and lower genital tract infections
  c) the management of the menopause
  d) the medical management of incontinence
  e) the initial management of menstrual disturbance
  f) the management of chronic pelvic pain and PMS
  g) the follow-up of an abnormal smear.
- National targets for day case surgery have been set and adapted locally. To achieve these targets dedicated day case facilities are required with skilled staff to enable efficient use of theatre time and the appropriate support for women. Current targets are set for D&C, laparoscopy and termination of pregnancy.
- The replacement of D&C with hysteroscopic sampling or vabra or pipelle endometrial sampling techniques provides the service with increased flexibility in that not only can the proportion of women having day care be increased but the procedures can be performed in outpatient clinics.
- The development of see and treat clinics for diagnostic and therapeutic procedures has the advantage of reducing waiting list times along with reducing patient anxiety. The service does require specialist training and the back up of appropriate resuscitation facilities. The procedures that could be undertaken include colposcopy and ablative therapy for preinvasive lesions of the cervix, the diagnosis of menstrual disorders with hysteroscopy or other endometrial sampling techniques, minor procedures of the cervix and vagina such as cervical polypectomy and the use of vaginal ultrasound for the diagnosis of pelvic pathology.
- Although early pregnancy assessment units have not been assessed for their cost-effectiveness, the development of a specialist service where women can be directly referred from primary care for both diagnosis and management without the need to involve accident and emergency (A and E) or ultrasound services would reduce duplication and probably provide a more sympathetic service.
- The Royal College of Obstetricians and Gynaecologists has produced guidelines for training in MAS that require integration into local accreditation programmes.[23] Few gynaecological MAS procedures have been subject to rigorous clinical and economic evaluation and purchasers should consider specifying in contracts that new MAS techniques may only be used within an evaluative framework. Whilst MAS is not the major intervention for a particular condition the benefits to the service in terms of reduced lengths of stay will not be realized. The main areas where MAS has a significant role and where a shift could be implemented are in emergency surgery[24] and alternatives to hysterectomy.
- The aim of guidelines for management and referral is to provide a seamless service across sectors and between specialties and require ownership from all the relevant health care professionals. An outline of the models of care that could be developed using guidelines is described on page 8.

Subfertility

- A comprehensive subfertility service for a population of 100 000 will result in around 100 referrals and cost around £300 000 per year, including the additional costs for neonatal care. The total cost to the NHS which also includes administrative and accommodation overheads and the extra neonatal intensive care costs has been estimated to be just under £900 000 (1992 prices).[2]
- Guidelines should be developed to increase primary care involvement in the preliminary diagnosis of subfertility. Subfertility clinics in secondary care should be provided in a dedicated clinic with support of relevant investigative services including radiology and reproductive endocrinology. It is estimated that there be at least one secondary care service per 500 000 population and one tertiary centre per 2 million population. Tertiary centres should offer donor insemination, ovulation induction, tubal surgery, IVF and have links with endocrine laboratories.

Pelvic inflammatory disease/lower genital tract infections

- Investment in preventive strategies for lower genital tract infections may be the most cost-effective way to reduce eventual upper genital tract infection, including PID and subsequent tubal surgery. Multi-agency collaboration is a strategy advocated in the Health of the Nation *Key Area Handbook* to tackle this issue.[25]

Menopause

- Whether women are seen in general practice, gynaecological outpatients or a specialist clinic the principles of management remain the same. It is considered that hospital clinics could not cope with the information and therapy needs of the population. Important elements of the service include information provision and monitoring of symptoms. Guidelines for referral to secondary care should be developed and such centres should be involved in clinical trials of the effectiveness of HRT.

Urinary incontinence/utero-vaginal prolapse

- Guidelines for investigation in primary care and referral to secondary care should be developed. Colposuspension and sling operations have the best cure rates for stress incontinence. There is a place for tertiary referral centres for complex cases and repeat operations where expertise and a high volume of surgery for such women exists.
- Support from continence advisors has been advocated. The Scottish Needs Assessment Programme estimated that five physiotherapists be employed to develop management of urinary incontinence for a female population of 500 000.[26] There is no conclusive evidence however that physiotherapy is effective and there are problems with the monitoring of improvement of symptoms whilst receiving therapy.

Menstrual disorders

- The development of guidelines for the investigation and medical management of menstrual disorders in primary care is required as this disorder is the most prevalent condition seen in both primary and secondary care.
- Criteria for the use of D&C should be developed and a shift of service to hysteroscopy or other endometrial sampling techniques agreed. A local shift from total abdominal hysterectomy (TAH) to TCRE should be agreed and patients undergoing such procedures as LAVH enrolled into clinical trials as the evidence for their use is not strong.

Ectopic pregnancy/early pregnancy loss

- The ability of GPs to perform pregnancy tests to exclude the possibility of an ectopic pregnancy or miscarriage should be considered. A service which includes the routine use of ultrasound scanning in the management of a possible ectopic pregnancy is required. Referral to an early pregnancy assessment unit with diagnostic tests and skilled personnel appears to be efficient but their effectiveness has not been proven. Training of gynaecologists using the RCOG guidelines will reduce the requirement for removal of the ectopic pregnancy by laparotomy and units should have targets set to manage a high proportion of ectopic pregnancies by laparoscopy.

Genital tract cancer – secondary prevention

- The NHS cervical screening programme has published guidelines for the management of the screening programme generally.[27] The Health of the Nation *Key Area Handbook* on cancer provides useful checklists on the various elements of a successful programme (Appendix VI). These include a defined target programme, screening the female population at 3–5 year intervals, personal invitations to women and a health education programme, quality of the cervical smear test and follow-up of abnormal smears and implementation of treatment (fail-safe protocols).
- The latter is within the remit of the gynaecological service in conjunction with the cervical screening programme locally. There are guidelines on fail-safe action for GPs, clinics, laboratories, the FHSA and the programme manager.[28] Salfield and Sharp estimated the need for diagnostic colposcopies at 1300 per 100 000 women but this estimate requires local adaptation depending on the policy for colposcopy for cervical intraepithelial neoplasia (CIN) 1.[29] They estimated there would be 600 treatment and 2000 follow-up sessions per 100 000 women.
- The colposcopy service requires dedicated clinic space with the facilities for 'see and treat' sessions under local anaesthetic. The guidelines for follow-up need to be developed with the screening programme group and involve local GPs and cytology nurses.

Genital tract cancer

- Although there is little trial evidence for the management of gynaecological cancers, the expert advisory group on cancer has recommended that there be a concentration of oncology services.[30] Gynaecological cancers require multi-disciplinary management and guidelines for the staging, management and follow-up need to involve health care professionals in the cancer units/centres and specialist nurses in primary care.

Outcome measures

There are outcome measures that are suggested for each of the sub-categories of the service but the development of health-related outcome measures in gynaecology is poor.

Targets

The models of care outline the shifts in service that are required but due to variations in the current levels of service provision it would not be sensible to set targets apart from at a local level. Targets could be set for development of guidelines for the shift of services to primary care, the use of day case surgery and MAS and

the development of tertiary level services such as cancer centres. Specific targets can be set in line with national strategies for various sub-categories.

Information

This assessment has relied on the routine morbidity returns from selected general practices in 1992/93 along with hospital episode statistics (HES) data and its regrouping as HRGs from the UK for the financial year 1993/94. As there is no linkage between primary and secondary level care the referral patterns to secondary care can not be assessed and this is information required when developing guidelines across the sectors. There appears to be no easy way of estimating the elective/emergency split or proportion of day cases for gynaecology. Local provider unit databases usually produce these data for contract monitoring and purchasers require these categories for monitoring the shifts in service provision.

The quality of these data has been a cause for concern and the use of HES data to produce HRGs appears to have confused the situation further. The training of relevant clerical and health care professional staff to code diagnoses and operations accurately and completely is central to the type of data required to produce HRGs.

Provider units will need to record not only day case/elective splits but also 'see and treat' episodes. The development of gynaecology outpatient audit systems should facilitate the collection of such data and provide important information on the case-mix in the outpatient setting which is currently not recorded.

2 Introduction and statement of the problem

This section outlines the aims of the assessment, describes the setting and content of gynaecology services in primary and secondary care settings and outlines the 13 headings under which the gynaecology service will be considered. The relevance of day case and MAS will be discussed.

Introduction

Gynaecology is the specialty concerned with diseases of women, which now excludes breast disease, in the UK. It has developed in a short period of time from a specialty dealing in a compartmentalized way with disorders of menstruation, urinary problems and genital tract prolapse and the treatment of cancer to one managing the problems of women in a more holistic way and encompassing all aspects of their sexual and reproductive lives. Gynaecological complaints are amongst the most common presenting to GPs and gynaecological disease accounts for nearly 5% of hospital activity within the NHS and a considerable proportion of activity in the private sector. Because of the wide range of preventive, medical and surgical services encompassed under the term gynaecology this assessment:

- provides a framework for assessing the needs for the major components of the gynaecological service
- assesses the scope for shifts in service provision from:
  a) the secondary to primary care sector.
  b) inpatient to day case surgery.
  c) conventional surgery to MAS.

Gynaecological disease prevention, diagnosis and management can be considered to occur at a variety of levels (Box 1).

Box 1: Levels of gynaecological service

- prevention
- secondary prevention
- primary care consultation
- primary care procedure
- outpatient consultation
- outpatient procedure
- day care procedure
- inpatient assessment
- inpatient procedure
- palliative care

Diagnosis and treatment are provided at both the primary and secondary care level, gynaecology accounting for some 1500 consultations per 100 000 female population in primary care[31] (Appendix II) and 7000 ordinary admissions per 100 000 female population into hospital in the UK[32] (Appendix III). However HRG data suggest a rate of nearly 3000 per 100 000 female population. The consultation rate in primary care excludes women who go to family planning clinics with a gynaecological condition and hence primary care data are an underestimate. It is also unclear whether this type of consultation is made more frequently by certain groups e.g. ethnic minorities.

In the secondary care setting gynaecological advice is usually provided by a consultant team with the relevant gynaecological nurse support. A typical gynaecological secondary care service consists of the following components (Box 2).

Box 2: Gynaecological services

- outpatient clinic activities
- colposcopy service for cervical smear abnormalities
- inpatient admissions to gynaecology beds with the majority of patients receiving an operation
- day case admissions for surgical procedures
- emergency service for women attending the accident and emergency (A and E) department
- subfertility service

Regional centres provide specialist services for oncology and radiotherapy and advanced treatments for subfertility, such as IVF. Whether a hospital has a urodynamic service for women suffering from incontinence or clinics for problems relating to the menopause depends on the interests of the consultants. Psychosexual counselling may also be offered in some departments but is not considered further as no routine data are available.

It is unusual for individual consultants to provide only an obstetric service or a gynaecology service; the normal pattern is for each doctor to cover both services. The junior medical staff in larger departments may have separate duties during weekdays and when on call out of hours. In terms of the physical arrangements, the obstetric facilities (clinic accommodation, antenatal and postnatal wards, delivery suites, obstetric theatre and maternity nursery) in many hospitals are separate from the gynaecology facilities. The obstetric unit may be in a separate building adjacent to the main hospital building or even in a hospital in a different location. Over a third of hospital departments of obstetrics and gynaecology in England and Wales are on split sites.[33]

Gynaecological services are provided by specialists who also manage pregnancy and its complications. There is an arbitrary division of pregnancy into that managed by the gynaecological service and that by the obstetric service. This relates to early pregnancy loss during the first half of pregnancy, before viability of the fetus, which is managed in the gynaecological service. Termination of pregnancy has been considered in another needs assessment.[1]

Data sources

In total there were 2000 ordinary admissions to hospital per 100 000 women for non-pregnant conditions. Taking both the general practice survey consultation rate of 150 per 100 000 female population[31] and HES data together, this represents a ratio of eight women consulting in primary care for every ordinary admission. There were additionally 5000 admissions per 100 000 women for pregnancy-related gynaecological problems.

For the purposes of this assessment gynaecological activity has been divided to mirror both physiological and pathological processes and current service provision, relevant to both purchasers and providers and will be dealt with in these groupings (Box 3).

Box 3: Sub-categories of gynaecological needs assessment

1 subfertility
2 pelvic inflammatory disease
3 lower genital tract infections
4 endometriosis
5 menopause
6 urinary incontinence/utero-vaginal prolapse
7 menstrual disorders
8 pelvic pain
9 premenstrual syndrome
10 ectopic pregnancy
11 early pregnancy loss
12 genital tract cancer – secondary prevention
13 genital tract cancer

Family planning services and GU medicine are covered elsewhere in the series.

Day case and minimal access gynaecological surgery

In the 1990s there have been directives from the Department of Health and consequently purchasers to reduce the use of inpatient beds and expand the use of day surgery. There has also been a drive by providers to avail themselves of the emerging technologies for MAS. Both these initiatives affect the gynaecology service.

Day case

A day case is defined as an individual admitted to hospital for an elective admission, who is discharged home on the same day and who underwent an operation. Procedures recommended as suitable for day surgery are planned, clean surgical procedures which require a total operating time not exceeding 30 minutes. The advantages of day case surgery are that costs are lower, waiting lists reduced, risks of cross-infection and thrombotic complications are reduced and there is greater convenience for patients.

Targets for day case surgery

Targets have been set by regions and by the National Audit Office[34] and require local adaptation to take into account socio-economic circumstances and case-mix.

Procedure	upper quartile	optimistic
dilatation and curettage	73%	86%
laparoscopy and sterilization	16%	65%
termination of pregnancy	40%	70%

Gabbay and Francis used the Delphi study methodologies to assess what specialists considered the proportion of cases of a particular operation that could be undertaken as a day case.[35] This ranged from a median of 55% for cone biopsy to 70% for cervical polypectomy, D&C and incision of a Bartholins gland.

Minimal access surgery

- It has been forecast that MAS will account for up to 70% of surgical procedures within ten years.
- Few procedures have been subject to rigorous clinical and economic evaluations[36] and there is a need to develop evaluation methodologies. Sculpher discusses some of the controversies surrounding the introduction of new technologies.[37] There are two issues that require consideration:
  a) how does the cost of new technologies compare with that of existing technologies?
  b) what additional benefits, in terms of patient outcome are being generated by these technologies?

MAS includes procedures such as laparoscopy to replace conventional abdominal laparotomies and new therapies such as TCRE to replace hysterectomy. 50% of gynaecologists were using TCRE in 1991 although there was no evidence at that time that TCRE was as effective as hysterectomy at reducing menstrual symptoms.[38] The longer term follow-up of women undergoing MAS operations replacing hysterectomy requires the full benefits to be assessed. There may be short-term benefits such as reduced post-operative pain but disadvantages longer term, for example retreatment to relieve repeat symptoms. A lack of follow-up means that the overall outcome advantages are not established.

Adopting the patient as consumer perspective it is possible to see how MAS may influence surgical thresholds operating on people considered previously not to warrant it. This therefore influences the private individual's trade-off. The availability of MAS alternatives to hysterectomy, for example, has been widely publicized in the lay press and gynaecologists have claimed that a patient-led demand has been an important factor behind the rapid diffusion of these procedures.

The short-term impact of MAS is a shorter stay in hospital but there will be constraints on reducing the demand for hospital beds whilst MAS is not the key process and alternatives are still used. There has over recent years been a general reduction in post-operative length of stay.[39] In one region in the UK the average length of stay per episode in gynaecology fell from 5.1 days in 1975 to three in 1985.[40]

It may be argued that more widespread use of MAS is being superimposed on to a system already displaying a reduced need for hospital beds and that the additional savings resulting from MAS may not be as significant as is frequently claimed.

Although there may be decreased length of stay initially, readmission for further surgery[41] with an 11% repeat TCRE/hysterectomy rate needs to be taken into account. There is evidence that TCRE does reduce theatre time and requires fewer staff and less anaesthetic demand and overall operative costs are reduced.[15] There is a resource imposed in the transition to MAS. Clinicians at the foot of the learning curve are not as effective as more experienced clinicians in undertaking a new form of MAS.

The implications of MAS on community-based health services are not quantified. There is a need to move to multi-centre trials and have similar skills and experience in both arms of the trial. Incorporation of patient preference into the evaluations is important.[15]

3 Sub-categories

Gynaecological services divide into sub-categories which closely mirror important ICD codes. They are relevant to both purchasers and providers as they also reflect specific clinical services. This section considers 13 categories.

Subfertility (ICD 628)

An *Effective Health Care Bulletin*[42] and the family planning, abortion and fertility services needs assessment[1] have succinctly reviewed the evidence of the effectiveness of subfertility services and this needs assessment summarizes the findings and updates the literature. Two conditions; PID and endometriosis, although resulting in subfertility, are addressed under separate headings as they have other implications for the gynaecological service, infertility being the longer term outcome.

Subfertility can be defined as two or more years of involuntary failure to conceive. Of the subfertile couples 70% have not conceived before (primary subfertility) and 30% have conceived previously (secondary subfertility).[42]

Currently subfertility is diagnosed in both primary and secondary care settings with treatment usually being initiated in the secondary care setting and with the possibility of continued treatment in primary care.

Subfertility is associated with considerable social and mental distress.[43]

Pelvic inflammatory disease (ICD 614)

The term PID has come to represent clinically suspected endometritis and/or salpingitis that has not been objectively confirmed pathologically or visually.[44] Less than half of the cases of PID cause symptoms and produce visual salpingitis. Pelvic inflammatory disease can present to the GP or the A and E department staff as acute pelvic pain which requires urgent diagnosis and treatment or as chronic pelvic pain. Management can be undertaken by gynaecologists or GUM physicians in conjunction with primary care. Pelvic inflammatory disease is associated with a risk of infertility as a result of fallopian tube damage.

Chronic, subacute and/or latent endometrial infection may present in a large number of women, but a consensus definition of the clinically subtle infections is lacking and the magnitude of the problem is unknown.

Lower genital tract infections (ICD 616)

Vaginal discharge is a common presenting complaint in both primary and secondary care settings and like PID is managed by primary care, GUM and gynaecology. Vaginal discharge can result from a variety of bacterial, parasitic, viral, atrophic and traumatic causes which are often difficult to differentiate clinically from physiological causes of excessive vaginal discharge. The organisms which are most commonly associated with vaginal discharge include *Candida albicans*, *Trichomonas vaginalis*, *Gardnarella vaginalis*, gram negative rods, *Chlamydia trachomatis*, Herpes and wart virus infections. Bacterial vaginitis is a common lower genital tract infection and women with it have 100–1000 times more virulent bacteria per ml of vaginal flora than women without this infection and it is associated with postpartum and post-hysterectomy infection.

Bartholins cysts and abscesses are a relatively common gynaecological emergency and arise as an obstruction to the duct of the Bartholins gland and present as either labial swellings or acutely as abscesses.

Endometriosis (ICD 617)

Endometriosis is a condition in which there is functional endometrium outside the uterine cavity. The disease process is usually limited to the pelvis and clinical manifestations include pain, dyspareunia, menstrual disorders, subfertility and the presence of pelvic masses. The disease remains a mystery in terms of aetiology and pathogenesis. Whether it is a cause or consequence of childlessness also remains the subject of debate.[45]

Menopause (ICD 627)

Menopause literally means cessation of menstruation and the WHO suggests it be defined as the permanent cessation of menstruation resulting from loss of ovarian follicular activity whereas the climacteric includes the period immediately prior to the menopause and at least the first year after the menopause.

The main reason for contact with a GP and referral to the gynaecological services is for advice and management of symptoms associated with the menopause which may be menopause specific or confounded by age and other conditions. The most characteristic symptoms are hot flushes, night sweats, palpitations, headaches, vaginal dryness and dyspareunia.[46] The main chronic diseases associated with the menopause are osteoporotic bone disease and atherosclerotic cardiovascular disease.

Hormone replacement therapy increases levels of circulating oestrogens that fall at the menopause as a result of the loss of ovarian follicular activity and it is possible that some of the risks and benefits of HRT are secondary to these changes.[47] The geographical and secular variations in many of the conditions traditionally associated with the menopause cannot be attributed to differences in the use of HRT or endogenous oestrogen levels and suggest that while the menopause may be a risk factor, there are other determinants which are likely to have a profound influence.[47]

Urinary incontinence/utero-vaginal prolapse (ICD 618)

Urinary incontinence is defined as a condition in which involuntary loss of urine is a social or hygienic problem and can be objectively demonstrated.

A National Institute of Health Consensus Conference in 1988 highlighted the magnitude of the problem of incontinence. It is not part of the normal ageing process, leads to stigmatization and social isolation and in the US more than half of those with incontinence have had no evaluation or treatment, most health care professionals are not taught about incontinence and ignore the problem and inadequate staffing of nursing homes prohibits proper treatment and contributes to neglect of residents.

The causes of incontinence are numerous and this assessment focuses on genuine stress incontinence and detrusor instability which are the mainstay of gynaecological involvement with female incontinence. The management of incontinence is obviously not solely within the remit of the gynaecologist – primary care, urology, general medicine and surgery being involved in managing the condition.

Utero-vaginal prolapse is predominantly a problem of middle and old age in women who have had children. The initial damage generally occurs during childbirth, with further potential for weakness of the pelvic floor occurring after the menopause.[48]

Menstrual disorders (ICD 626)

Menstrual disorders involve a range of physiological and pathological (benign and malignant) changes in the hypothalamic pituitary ovarian and genital tract axis. This assessment will focus on the generic management

of the most prevalent conditions which influence the gynaecological service, i.e. menorrhagia. Menorrhagia is the excessive loss of menstrual blood.[49]

The main issues that remain unresolved are:

- the balance of management that can be undertaken in primary care without referral to the gynaecological outpatient department
- the balance between medical and surgical treatments
- the use of day case and MAS.

Some conditions that present as menstrual disorders are discussed elsewhere (e.g. endometriosis, PID, malignant neoplasms).

The other problem is that in routine practice there is rarely any objective measurement of menstrual loss.

Pelvic pain (ICD 625)

Pelvic pain refers to lower abdominal pain that can occur during the reproductive years and includes both gynaecological and non-gynaecological causes. The gynaecological causes include PID, pelvic pathology such as benign and malignant ovarian cysts and fibroids, endometriosis and PMS.

The subjective nature of the label of pelvic pain means the epidemiology is unclear. Painful menstruation can either be primary, which is more common in younger women, or secondary to other pelvic pathologies such as PID, endometriosis and fibroids and represent another symptom of diseases whose management is discussed elsewhere. The term 'severe pain requiring time off work' has been used to classify the pelvic pain syndrome and is estimated to occur in 3–10% of young women and is the primary cause for these women to visit their GPs. The label pelvic pain now tends to be reserved for the 60–70% of patients with lower abdominal pain who apparently have negative gynaecological laparoscopy.[50] There is some evidence that this is associated with pelvic congestion.[51]

Premenstrual syndrome

The epidemiology of PMS is unclear as symptoms can be diverse and duration and timing in relation to the menstrual cycle variable. Budeiri *et al.* reviewing the literature estimated that 199 symptoms and signs, along with 65 different assessment questionnaires have been employed in the study of PMS.[52] There is little conclusive information on the aetiology or treatment of PMS, although it attracts significant media attention. Premenstrual syndrome is of importance in the needs assessment of gynaecology as the label is recognized and services provided although the extent to which need, demand and supply of services is addressed by the NHS must remain an assumption.

Ectopic pregnancy (ICD 633)

Ectopic pregnancy is the siting of a pregnancy outside the uterine cavity, the most common site being the fallopian tube. By virtue of its site, as pregnancy advances the surrounding anatomical structure can not support the growing pregnancy and the ectopic pregnancy causes acute pain and often severe haemorrhage which may result in maternal death or severe morbidity.

Early pregnancy loss (ICD 630, 631, 632, 634)

Recurrent miscarriage

Recurrent miscarriage is defined as the loss of three or more consecutive pregnancies before 20 weeks gestation.[53] The aetiology is not fully understood and causes include infection, medical disorders, chromosomal abnormalities in the fetus, parental translocations and structural abnormalities of the genital tract.[54] Recently interest has focused on the immunologically mediated miscarriage and the role of 'blocking' antibodies.[54] An association with polycystic ovary syndrome is found with 80% of women with recurrent miscarriage.[55]

Miscarriage

Miscarriage is defined as loss of pregnancy before viability and the WHO definition has a weight cut-off of less than 500 g.

Genital tract cancer – secondary prevention

Cervix (ICD 233.1)

Squamous cell carcinoma, which accounts for 95% of cervical tumours, occurs most commonly at the squamo-columnar junction of the cervix and is characterized by a disordered morphology of the squamous epithelium which, by virtue of its site, is accessible for exfoliate cytology. Premalignant changes in cervical cytology are usually present and detectable for several years before an invasive lesion becomes clinically evident (the lead time). The dilemma is that the natural history of an abnormal smear is still not fully established with many minor abnormalities regressing over time and not requiring treatment.[56] Dyskariotic cells are derived from the surface epithelium of the cervix with cervical intraepithelial neoplasia (CIN) or invasive disease. Cervical intraepithelial neoplasia ranges from I (mild), II (moderate) to III (severe/carcinoma *in situ*).

Cervical cancer presents with local symptoms such as vaginal bleeding or discharge. The disease progresses locally and involves the ureters, bladder and rectum in later stages. Death is often associated with ureteric obstruction.

Screening aims to detect CIN-I–III lesions and early asymptomatic invasive lesions (stage 1), which if appropriately treated have a good prognosis. The management of abnormal smears involves primary care, family planning services, GUM departments and the gynaecological colposcopy services.

Other sites

There are no defined pre-invasive stages for cancers of the ovary and endometrium. Ovarian cancer has less than a 35% five-year survival rate as it is usually asymptomatic until widely disseminated. Methods to detect ovarian cancer at an early stage have been investigated as five-year survival is then as high as 85%.[57] There are currently national screening programmes for cervical and breast cancers and suggestion that screening for ovarian and endometrial cancers using ultrasound and CA 125 measurements are a possibility.[58–60] There are criteria for any potential screening programme that should be considered before implementation.[61] The disease needs to be of public health importance which ovarian cancer could be considered to be.The natural history should be known which is not clear for ovarian or endometrial cancer and diagnosis should be feasible which it is in both cases.

Genital tract cancer (ICD 182, 183, 186)

Three gynaecological cancers: cervix, uterus and ovary are among the ten most common malignancies in women and are managed by the gynaecological service along with radiotherapists and oncologists as appropriate.There is debate as to where the management of cancers should be sited and the role of cancer centres for gynaecological cancers. Other gynaecological cancers are rarer and not considered in this assessment (vulva, vagina, fallopian tube) but the principles discussed for the main sites are relevant for these cancers.

4 Incidence and prevalence

This section estimates the incidence and prevalence rates and hence potential for services needs for gynaecological conditions. The denominators are given wherever possible for the relevant female population e.g. reproductive age group (15–44 years).

Introduction

There are no data on the overall incidence or prevalence of gynaecological conditions. This section provides some estimates based mainly on specific research studies and therefore these data have to be interpreted with caution. It is not possible to give incidence/prevalence rates by age group for most conditions. Table 1 details broad estimates of incidence/prevalence.

Sub-categories

Subfertility

At any point in time the proportion of women of childbearing age experiencing subfertility is between 9–14%.[42,62] A health authority with a population of 100 000 with 18 400 women aged 20–44 with an established subfertility service may expect around 92 (0.5%) new consultant referrals each year and this demand is likely to increase due to trends towards later first pregnancies and an increasing number of remarriages and will be sensitive to changes of some sexually transmitted diseases. Demand is increasing due to raised public awareness of treatment possibilities.[63]

Pelvic inflammatory disease

The commonest organisms implicated in tubal occlusion are *Chlamydia trachomatis*, *Neisseria gonorrhoea* and anaerobic bacteria frequently associated with bacterial vaginosis. Infections with *N. gonorrhoea* and *C. trachomatis* are estimated to produce PID in 10–50% of cases. An epidemiological review[65] indicated the limited impact prompt treatment would have on subfertility rates because of:

1 the role of silent PID, which accounts for more than half of the tubal occlusion found in most clinical series of infertile couples
2 the failure to show that any current PID treatment regimens have a positive impact on future fertility.

Table 1: Incidence and prevalence of sub-categories (see text for full details of how estimates were calculated)

Sub-category	Incidence	Prevalence (females)
1 Subfertility	92/100 000 (0.5%) (total population M+F)	9–14% (age 15–44)
2 PID-Chlamydia	19/1000 (persons aged 15–59 attending GUM clinics)	5–12% (age 15–44)
3 Lower genital tract infection		4–28% (age 15+)
4 Endometriosis		1.3% (age 25–29)–8.1% (age 40–45)
5 Menopause		18% total population
6 Urinary incontinence		women (45+) attending menopause clinics 6–13% objective evidence 3–8%
7 Menstrual disorders – menorrhagia		20% (age 15–44)
8 Pelvic pain	10% females (aged 15+)	25% (age 15+)
9 Premenstrual syndrome		20–95% (age 15–44) 5% severe
10 Ectopic pregnancy	12/100 maternities 9/1000 pregnancies	
11 Early pregnancy loss – spontaneous miscarriage	12% clinically recognizable pregnancies	
– recurrent miscarriage	0.8–1% clinically recognizable pregnancies	
12 Cancer-2^0 prevention		
– cervix CIN III	53/100 000 females	
13 Cancer – cervix	17/100 000 females	
– uterus	15/100 000 females	
– ovary	20/100 000 females	

Taylor-Robinson estimates, conservatively, that genital and associated infections and their sequelae cost the UK at least £50 million a year for diagnosis and treatment.[3]

Chlamydia infections occur twice as frequently as gonorrhoea in most populations studied.[65] Serotypes D and K of *C. trachomatis* are causes of sexually transmitted disease and are an important cause of morbidity. Such infection cause up to half of all mucopurulent or follicular cervicitis and in developed countries up to 60% of PID.[66] There are only a few prevalence studies in general practice, gynaecology or antenatal clinic settings. In these 5–12% of women of child bearing age have been found to be infected.[67–70]

The organisms that lead to chronic PID and subfertility are those isolated from women often referred to GUM or gynaecology departments and include gonorrhoea and chlamydia which are reported in KC60

returns in England and Wales.[36] The trends of reporting are downwards but represent incomplete data. In 1992 just under 9000 cases of gonorrhoea and 66 000 cases of non-specific genital infection including chlamydia were reported.

Ashton *et al.* estimated the incidence of sexually transmitted diseases (met need based on GUM returns KC60) for both men and women in a reference population of 100 000 to be 1140.[1] The annual rate was 19 per 1000 population aged 15–59. A further 10% are treated outside GUM clinics. Some sexually transmitted diseases may go on to affect about 10–50% of cases although it is difficult to make estimates.

The use of intrauterine contraceptive devices (IUCD) by women in non-mutually monogamous relationships has been linked to higher than expected levels of genital tract infection and this also leads to tubal problems later.[71]

Lower genital tract infections

The prevalence of vaginitis ranges from 4% in asymptomatic college students to 10–28% in gynaecology and termination of pregnancy clinics.[72–74] Risk factors include being caucasian, prior pregnancy, IUCD, post-hysterectomy and abortion. Approximately 5–10% of women who complain of vaginal discharge have no pathological cause identified.

Endometriosis

Endometriosis is a common cause of gynaecological morbidity with an estimated prevalence of between 2.5–3.3%.[75] In a family planning cohort in the UK Vessey *et al.* estimated the prevalence rates to increase from 0.13 per 1000 woman–years in 25–29 year olds to 0.81 in 40–45 year olds.[76] A definitive diagnosis can only be made by laparoscopy or laparotomy and the prevalence of endometriosis at laparoscopy has been estimated at 1–2% of women of reproductive age.[77]

Menopause

The median age of the menopause in western women is 50 years, ranging from 35–59 years. Nutritional status and smoking are the main factors determining the age of the menopause. With increased life expectancy it is estimated that 18% of the population is postmenopausal. Most women will be postmenopausal for one-third of their life.

Symptoms

The main reason for contact with the health services is for treatment of symptoms associated with the menopause which may be menopause specific or confounded by age or other conditions. The most characteristic symptoms are hot flushes, night sweats, palpitations and headaches and it has been suggested that at least 80% of women are affected. Psychological symptoms are reported increasingly in the perimenopausal period and in a western survey affected 25% of women. Vaginal dryness, atrophic vaginitis and dyspareunia are said to be universal menopausal problems.[46]

Chronic diseases associated with menopause

The incidence of most chronic diseases increases with age and osteoporotic bone disease and atherosclerotic cardiovascular disease are two major causes of morbidity in women which have been suggested to be exacerbated by the menopause. However the two- to three-fold secular increase in the last 30 years in osteoporotic hip fractures in the UK can not be attributed to any changes in the age at menopause, or to changes in HRT[78] and geographical variations in many of the conditions traditionally associated with the

menopause suggest that while the menopause may be a factor there are other determinants which are likely to have a more profound influence. It is therefore not clear how much these conditions can be remedied by HRT. The hormonal epidemiology of the menopause has mainly been determined in studies of western women and extrapolation to ethnic minorities is problematic. Exogenous factors, in particular diet, have been suggested to play a role in determining sex hormone levels and should be considered when devising preventive programmes.[47] The influence of diet, physical exercise and smoking on hormonal status is incompletely understood.

Cardiovascular disease

There were nearly 68 500 female deaths from myocardial infarction in England and Wales in 1992.[79]

Osteoporosis

Bone resorption is increased and cortical bone in the peripheral skeleton is lost at a rate of approximately 1% per annum. Rates of loss of vertebral trabecular bone are much higher; approximately 5–6% per annum during the early postmenopausal years and about half of all the bone loss that occurs in women may be attributed to the menopause. The incidence of fractures of the distal radius in women increases approximately 10–12-fold between the ages of 50 and 75. Approximately 25% of caucasian women have radiological evidence of vertebral compression by the age of 65. The incidence of femoral neck fracture doubles every five to seven years after the age of 70 and approximately 16–20% of women die as a consequence. HIPE data showed that over the age of 65, 82% of admissions for fractured neck of femur were in women of whom 83% were over 75.[80] Postmenopausal bone loss is insidious and causes no symptoms until fracture occurs, by which time it is too late to restore bone mass. There were over 900 deaths from fractured neck of femur in England and Wales in 1992.[79] Recent studies implicate physical activity, calcium nutrition and sex hormone status are the three most important determinants of peak bone mass.[81]

Urinary incontinence/ utero-vaginal prolapse

A MORI poll in 1991 estimated 3.5 million and possibly 10 million people in the UK suffered from incontinence.[82] Thomas *et al.* estimated that one-third of women over the age of 35 were incontinent, twice each month or more. 85–90% of urinary incontinence is due to genuine stress incontinence or detrusor instability and it is not unusual for them to coexist. Versi and Cardozo estimated the incidence of a complaint of a poor stream or incomplete emptying in 5.6–13% of perimenopausal and postmenopausal women attending a menopause clinic.[84] Objective demonstration of an imbalance in micturition function, as measured by urodymnamics is in the region of 3–8%.[84]

Genuine stress incontinence is associated with pregnancy, vaginal delivery and the menopause.[85] It is the involuntary urethral loss of urine without detrusor instability. Detrusor instability affects up to 10% of the population.

Estimates of the prevalence of prolapse are not available. Women who have a vaginal hysterectomy for prolapse may be coded simply as hysterectomy and the estimates of prolapse operations are an underestimate of the problem. Long lengths of labour and instrumental delivery are thought to be contributors to prolapse and with the advent of augmentation of labour and increasing caesarean section rates it is likely that the prevalence of prolapse will decline over the next few decades, although with increased life expectancy the number of menopausal women will increase and the effect this will have on prevalence rates is not known.[86]

Menstrual disorders

Menorrhagia is the excessive loss of menstrual blood and affects up to 20% of women in their reproductive years.[49] Excessive menstrual bleeding is the most common cause of iron deficiency in the UK affecting 20–25% of the fertile population.[87] It would appear that the upper limit of normal menstrual loss is between 60–80 ml.[88] Menorrhagia is however difficult to assess objectively in the absence of anaemia which is said to be present in 66% of women with menorrhagia.

In one population study 26% of those women with menstrual losses well within the normal range considered their periods heavy, whilst 40% of those with heavy losses considered their periods light.[49]

In those women over the age of 40 dysfunctional uterine bleeding (DUB) is the most common reason for a woman to consult her GP. Dysfunctional uterine bleeding is related to oestrogen withdrawl or hyperstimulation of the endometrium and represents 60% of cases. Specific gynaecological pathology (endometriosis, adenomyosis, fibroids (leiomyomata)) represents 35% and endocrine or haematological causes represent less than 5%.

Fibroids are present in 20% of the caucasian population with a three- to nine-fold increase in the African/Afro-Caribbean population over the age of 35. The proportion who develop menorrhagia varies from 17–61% with about 30% overall.[89]

Although the Oxford Family Planning Association Study is not representative of the UK female population data from this cohort have demonstrated that social class has a modest influence but parity and age (30–39 years) have strong influences on rates of menstrual disturbances (excluding fibroids).[90] Kuh and Stirling have reported socioeconomic variations in the risk of D&C and of hysterectomy are large.[91] They suggest lessening the socioeconomic gradient in risk of admission and surgery for diseases of the female genital tract, particularly for menstrual disorders, could have important resource implications.[91]

Pelvic pain

A survey by the RCOG revealed that 52% of laparoscopies were performed for pelvic pain.[92] Davies *et al.* estimated the incidence of pelvic pain syndrome to be 0.56–3.6 per 1000 women, with an average of 0.98 per 1000 women and the prevalence to be between 13.8–90 per 1000 women, with an average of 24.4. Using UK 1991 population estimates they calculated that this represents about 14 000 incident cases (7900–51 000) and 345 000 (195 200–272 800) prevalent cases.[93]

Premenstrual syndrome

Mild psychological symptoms occur in as many as 95% of women in the reproductive age range but only 5% will have severe symptoms that disrupt their lives. A diagnosis is not in the strictest sense possible, hence the prevalence estimates of between 20–95% of women of reproductive age are quoted.[18]

Ectopic pregnancy

The incidence of ectopic pregnancy appears to be rising in several industrialized countries especially with the advent of more sensitive pregnancy tests and ultrasound techniques. Factors which are associated with an increased incidence include tubal surgery, use of the progesterone-only pill, PID and the IUCD.[94] Ectopic pregnancy accounts for 10.3% ($n = 19$) of maternal deaths,[30] the main reason for death being haemorrhage. In a hospital-based series Norman estimated the incidence to be 11.9 per 1000 maternities and 9.1 per 1000 pregnancies (miscarriages and induced abortions plus total births).[95] Chow *et al.* estimate that in industrialized countries ectopic pregnancies account for 1.2–1.4% of all reported pregnancies.[96]

Ectopic pregnancy is more common in women of older age, lower parity and who have had a previous ectopic pregnancy with a three-fold increased risk of death from ectopic pregnancy amongst black compared with caucasian women.[94] 50% of ectopic pregnancies can be attributed to PID.[97]

Early pregnancy loss

Recurrent miscarriage

Observed frequencies of 0.8–1% of clinically recognizable pregnancies have been reported.[98]

Miscarriage

Spontaneous abortion is the commonest complication of pregnancy, affecting roughly one in four of all women who become pregnant.[99] The overall incidence of clinically recognizable spontaneous abortion before 20 weeks of gestation is approximately 12% .[100] The incidence of subclinical pregnancy loss may be as high as 60%.[101] Most early fetal losses are abnormal karyotypes but caffeine, alcohol and smoking have all been implicated in the past.

Genital tract cancer – secondary prevention

In the UK 4.5 million smears are performed annually of which 2.4% show mild dyskariosis and 3.4% are reported as showing borderline changes, although in younger women the borderline rate is about 4.9%.[102] There are no routine data collected on CIN I and II. Cancer registries collect data on CIN III/carcinoma *in situ* with registration rates of 53 per 100 000 females in the UK in 1986 with 13 609 registrations.[103] The standardized registration ratio varies significantly between region (36 in South West Thames to 134 in Yorkshire) but whether this is due to true incidence variations or registration differences is unclear.

Some postulate that as the CIN registration rate has been increasing in the UK mortality rates would have been even higher had cervical screening not been in place. This is probably true but the magnitude of the increasing incidence is not possible to calculate because the natural history of the disease is not fully understood and because the incidence trends of *in situ* lesions are also not clearly understood.[27]

Genital tract cancer (ICD 182, 183, 186)

The incidence of ovarian cancer (ICD 183) is approximately 20 per 100 000 with endometrial cancer (ICD 182) 15 and cervical cancer (ICD 186) 17.3.[104] The directly age standardized rates (World standard per 100 000 women) are 12.26 ovary, 8.7 endometrium and 13 cervix. Mortality data show significant variation in age standardized mortality ratios between district.[104] The overall mortality rates in the UK are 19.7 per 100 000 for ovary (including other adnexal tumours), 14.3 for endometrium and 16 for cervix.[104]

There were nearly 5200 cases of ovarian cancer in England and Wales in 1988. Ovarian cancer is predominantly a disease of older women, the incidence rising over the age of 30 to more than 50 per 100 000 in the over 65s. The regional standardized registration ratios indicate lower rates generally in the north but also in Oxford and South Western.[104]

Nearly 3800 new cases of cancer of the endometrium were registered in 1988 in England and Wales. Endometrial carcinoma is rare in women under 40 and the incidence rises to around 50 per 100 000 in 70–74 year olds.[104] Although there are significant differences in registration in the UK there is no obvious pattern in the standardized registration ratios.

There were nearly 4500 cases of cervical cancer in England and Wales in 1988. Carcinoma of the cervix is rare before the age of 20, peaks in incidence at 35–44 and then again at 60–64; over 90% of tumours being

squamous cell carcinomas. In general the standardized registration ratio is higher in the north of England and lowest in the Thames regions. Although only 15.5% of cases occur in women under 35 it is the most common cancer in this age group, accounting for 25% of all new cancers.[104]

For all three cancers there is no significant overall trend in age-specific incidence rates over the past decade. However a study in the UK, adjusting for the hysterectomy rate, demonstrated an increased incidence of endometrial cancer of between 15–20%.[105] As the population ages the risk of endometrial cancer will increase but will be influenced by the use of oral contraceptive, HRT and hysterectomy rate. As large numbers of women with these exposures or attributes age into higher risk groups, age-specific rates are likely to fall.

International FIGO data[106] indicate considerable variation of survival by stage at each site (Table 2) which has a particular bearing on the current state of effectiveness of interventions.

Table 2: Disease stage at diagnosis[106]

	Stage I (%)	Stage II (%)	Stage III (%)	Stage IV (%)
Ovary	10	8	60	17
Endometrium	75	14	6	5
Cervix	35	35	25	5

The reasons for these variations in survival are reflected in the proportions of cases presenting at each stage (Table 3). England and Wales data indicate five-year survival rates overall of 30% ovary, 70% endometrium and 60% cervix.[104]

Table 3: Five-year survival rates[106]

FIGO stage	Ovary (%)	Endometrium (%)	Cervix (%)
I	85	75	78
II	50	57	57
III	25	30	31
IV	5	10.6	7.8
Overall	32.7	67.7	55

5 Services available

There are no national guidelines on what constitutes a typical gynaecological service, patterns of delivery having been built up over the years based on a combination of need, demand and supply. A typical district general hospital would employ at least three to four whole-time equivalent consultant obstetricians and gynaecologists. With the 'New Deal' the number of trainee medical staff has increased and such a unit may be supported by two to four middle grade staff (staff grade, senior registrar/registrar) and eight SHOs. Each consultant team would undertake one to two gynaecology outpatient sessions per week with two to three operating sessions. A gynaecology ward of 30 beds with day case facilities would be required for this workload.

Approximately 75% of the gynaecology budget is spent on hospital cases with only 25% on prevention and management in primary care.

Current service utilization using routine data sources is outlined below.

Primary care

Women with gynaecological symptoms may not consult a GP, preferring to self-medicate for such conditions as candida with over-the-counter (OTC) preparations from pharmacies.

Between the ages of 15 and 64 the consulting rate for women exceeds that for men, particularly for genitourinary disease. There has been a 103% increase in the prevalence of urogenital candida consultations between 1981 and 1982 and 1991 and 1992. Similarly a 154% increase in menopause/postmenopause consultations to 328 per 10 000 female–years at risk.[31]

- Overall 1500 women consult their GPs a year per 10 000 women–years at risk for gynaecological diseases including early pregnancy loss with 2250 consultations per 10 000 women–years at risk.
- A further 500 women consult per 10 000 women–years at risk with 700 consultations per 10 000 women–years at risk for candidiasis and trichomoniasis infections.
- Specific consultation rates are detailed in Appendix II. The main reasons for consultation in order of magnitude are outlined in Table 4.

Table 4: Main consultation categories in primary care[31]

Condition	ICD code	Patients consulting per 10 000 women–years at risk	Consultations per 10 000 women–years at risk
Candidiasis	112	521	690
Disorders of menstruation	626	449	676
Menopause/ postmenopause	627	328	583
Pain associated with female organs	625	278	394
Pelvic inflammatory disease	614–16	212	198

Outpatient facilities in secondary care

Gynaecology outpatients are usually separate from medical and surgical outpatient space. Gynaecological referrals are now not all seen in a general clinic, specialty clinics are common for the following categories of the service:

- termination of pregnancy
- colposcopy
- subfertility
- urogynaecology
- menopause
- oncology – combined clinics with oncologist and radiotherapist which may be in another department of the hospital.

There are no routinely collected data on use of gynaecological outpatients or the procedures undertaken in outpatients e.g. hysteroscopy, pipelle and vabra sampling of the endometrium.

Emergency facilities in secondary care

Unfortunately the published HES data do not provide an elective/emergency split.[32] The HRG data do split work into elective and emergency although the data across the specialty are not easily estimated. Of the 692 000 cases in the female reproductive system groups 167 500 (24%) were emergency admissions.

A survey in south London by the author indicates that around 40% of consultant episodes are emergency, of which 50% are for early pregnancy problems.

The model of referral, triage and management of emergencies is usually similar to medical and surgical specialties. There are changes to service provision that are emerging and which are discussed in the subsections. These include the development of early pregnancy assessment units for the management of problems of pregnancies under 20 weeks gestation. The increasing use of MAS requires operating theatres to be appropriately equipped and staff appropriately trained to provide the service.

Dowie indicated in his survey of gynaecology that most emergency operations were done outside normal theatre hours in six of the seven departments surveyed.[33] According to Korner statistics in 1987/88 17% of the total number of gynaecology cases in a London associate teaching hospital were operated on outside scheduled theatre session.

Appendix III, page 86 details the proportion of emergency cases by HRG category.

The main conditions and procedures are as follow.

- **Early pregnancy loss and threatened miscarriage** Evacuation of retained products of conception.
- **Ectopic pregnancy** Excisison of ectopic pregnancy laparoscopy/ laparotomy.
- **Ovarian cyst** Diagnostic and therapeutic laparoscopy/ laparotomy.
- **PID** Diagnostic and therapeutic laparoscopy.
- **Bartholin's abscess** Bartholin's cyst marsupialization.

It is not clear in the HRG data (Appendix III, page 86) what emergency diagnoses are considered in the category m 20, non-inflammatory diseases of vulva and vagina. Admissions for carcinoma of the ovary appear to be frequent as emergencies, probably with acute abdominal symptoms.

Ordinary and day case admissions into secondary care

The hospital episode statistics collect data on ordinary and day case admissions, operations and length of stay by ICD and surgical OPCS4R groupings[32] (see section 10). This assessment bases service availability on the UK data for the financial year 1993/94. Unfortunately no summary data are provided for gynaecology alone and either include breast disease or obstetric and pregnancy loss and general practice in one meaningless category.

Appendix III details the types of data available and the admissions and operations performed for the ICD and OPCS4R sub-categories of gynaecology. It is not possible to cross-tabulate operation by ICD code to assess the interventions undertaken for a particular pathology. Appendix III details the inpatients cases (ordinary and day case) by ICD.

There were a total of nearly 2000 cases per 100 000 female population aged over 15, with a further 5000 for pregnancy related disorders, totalling nearly 7000 per 100 000.

The most common categories are listed in Table 5 which are in contrast to the main categories seen in primary care (Table 4). Non-inflammatory disorders of the cervix mainly relate to precancerous lesions of the cervix.

Table 5: Main inpatient ICD 9 categories[32]

Condition	Number per 100 females
Disorders of menstruation	455
Non-inflammatory disorders of cervix	177
Genital prolapse	137
Menopause and postmenopause	117
Uterine leiomyoma	111

Appendix III details the admissions, splitting ordinary and day case admissions for the ICD sub-categories and bed days and lengths of stay. The proportion of ordinary to day cases for the main gynaecological categories is approximately 1.7 ordinary cases to one day case admission. The number of bed days equates to 1 300 000 days which is 1.5% of the total bed days in the UK and 4% of the acute sector according to HES data.

Appendix III lists the operations by OPCS4R codes with a total of 680 000 operations, equivalent to nearly 3000 per 100 000 females over the age of 15. The major operations are displayed in Table 6. Exploration of the vagina is a non-specific operation which relates to assessment of the vagina probably for postmenopausal bleeding.

Table 6: Main inpatient operations[32]

Condition	Number
Curettage of uterus	166 146
Other evacuation of contents of uterus	154 222
Abdominal excision of uterus	59 376
Endoscopic bilateral occlusion of fallopian tubes	50 969
Biopsy cervix uteri	23 031
Diagnostic endoscopic examination of uterus	21 853
Prolapse operations (P22 and 23)	21 248
Exploration of vagina	20 538
Destruction of lesions of cervix uteri	19 622

Appendix III details the operation by OPCS4R shortlist and splits ordinary and day cases and bed days. The proportion of ordinary to day cases varies by type of operation as does the use of bed days. Details of the waiting times in 1993/94 in the UK by main ICD categories and certain operation types are also given. There is significant regional variation. Appendix III also details the HRG data for 1993/94 in the UK. Overall 37% of the surgical admissions were treated as day cases. The accuracy of the data on ectopic pregnancy and termination of pregnancy are questionable as there appear to be a large number of admissions without operation.

Overall gynaecological service assessment

There are no routine data which provide overall cost/resource information for a gynaecology service. An example of how such data can be generated is provided by the Scottish Forum for Public Health Medicine.

The Scottish Forum for Public Health Medicine estimated that £15 000 000 per annum was spent for a female population of nearly 500 000 – 73% on hospital expenditure.[26] The costings (average cost in 1992) for each procedure involved (Table 7) and a programme budget based on activity were produced. Approximate proportions of the budget for each aspect of the service identified are outlined in Table 8.

Table 7: Average costs of gynaecology procedures[26]

Procedure	Elective (el)/ emergency (em)/day case	Cost (£)
Outpatient clinics		127
Inpatient day case		129
Inpatient case		104
Colposcopy		115
Smear		11
Hysterectomy	el	1241
Hysterectomy	em	1628
Vaginal repair	el	1568
Vaginal repair	em	2279
Hysteroscopy	all	231
D&C	el	404
D&C	em	597
D&C	day case	231
Open sterilization	el	838
Laparoscopy/lap. sterilization	el	447
Laparoscopy/lap. sterilization	em	640
Laparoscopy/lap. sterilization	day case	231
Termination of pregnancy	el/em	431
Termination of pregnancy	day case	231
Other operations	el	666
Other operations	em	808
Other operations	day case	231

Services available – sub-categories

All consultation rates in primary and secondary care are detailed in Appendices II and III respectively.

Subfertility

Initial investigations in primary or secondary care settings will result in a broad diagnosis in about 70% of patients. There is little uniformity in the diagnostic criteria and service availability used for diagnosing patients. In the secondary care setting subfertility is managed in both general gynaecology and specialist clinics.

The HES operative data are difficult to interpret as a range of diagnostic (diagnostic endoscopic examination of uterus (Q 18), curettage of uterus (Q10) and therapeutic operations (open myomectomy

Table 8: Programme budget for gynaecology services; proportion for each element of the service

Group	Unable to group (%)	Bleeding (%)	Cancers (%)	Inflam-matory diseases (%)	Benign tumours (%)	Meno-pausal symptoms (%)	Incon-tinence (%)	Prolapse (%)	TOP (%)	Steril-ization (%)	Infertility (%)	Others (%)	Total (%)
Prevention			13.00										13.00
Primary care	1.4					9.00	1.1				1.2	1.00	13.7
OP clinics	15.3		3.00										18.3
OP procedures			1.3										1.3
Day case surgery		0.8	0.1	0.1	0.02	0.3	0.2	–	2.5	0.6	0.3	1.7	6.62
IP surgery		5.2	2.9	2.7	2.00	1.7	1.4	12.00	5.5	3.00	2.00	7.5	45.9
IP no surgery		0.4	0.7	2.7	0.01	0.05	0.04	0.2	0.2		0.02	4.7	9.02
IP terminal care			0.2									0.03	0.23

OP = outpatient, IP = inpatient

(Q09), therapeutic endoscopic operations on uterus (Q17), open reversal of female sterilization (Q29)) interventions may be employed for subfertility.

- The IVF/GIFT rates are not available from HES.
- The waiting times for subfertility admission are on average 101 days, median 64 (Appendix III).

Pelvic inflammatory disease

Pelvic inflammatory disease is managed acutely in A and E departments and electively in gynaecology and GUM outpatient clinics.

Appendix III details the HES data for PID: salpingitis and oophoritis (ICD 614.0–614.2), inflammatory diseases of pelvic cellular tissue and peritoneum (ICD 614.3–614.9), inflammatory diseases of uterus, vagina and vulva (ICD 615, 616). The combined inpatient rates equate to 160 per 100 000 women aged over 15. It is not possible to interpret the operation codes as the interventions that are possible for PID are not specific. They include diagnostic procedures such as laparoscopy and therapeutic procedures which include laparoscopy and laparotomy with a variety of specific surgical procedures to relieve the sequelae of PID such as salpingolysis.

Buchanan and Vesssey showed that in the UK between 1975–85 the incidence of hospitalization for PID rose by 28%.[107] This increase occurred for both acute and chronic PID and was greatest in women in their 20s. The mean length of stay fell to four days in 1985 and the use of laporoscopy increased steadily over the time period to 54%. In a 6.5–8.5 years follow-up study this group showed that women discharged after a diagnosis of PID were nearly ten times more likely to be admitted for gynaecological pain, five and a half times more likely to be admitted for endometriosis, eight times more likely to be admitted for hysterectomy and nearly ten times more likely to be admitted with an ectopic pregnancy.[108]

HES data indicate the mean lengths of stay to be between three to six and six days, with a median of between two to six days for the sub-categories of PID.

Lower genital tract infection

Lower genital tract infections are managed in both gynaecology and GUM outpatient clinics. They may also be managed by self-medication in primary care with OTC preparations such as canestan. The HES data are only relevant for operations of the Bartholin's gland with an operation rate of 23 per 100 000 female population aged over 15, of which 20% were day cases.

There are no clinic attendance data for chlamydial infection prior to 1988. Large increases were seen between 1978 and 1986 in the number of attendances for non-specific genital infection of which 50% were thought to be due to *Chlamydia trachomatis*. Clinic returns in 1988 indicated 120 cases of chlamydial infection per 100 000 population aged 15–64. The 1992 returns indicate the number of new cases of trichomoniasis has declined to a rate of nearly 50 per 100 000 female population aged 15–44.[36]

The number of new cases of candidiasis recorded in GUM clinics has remained at about 60 000 per year since 1983.[36]

Endometriosis

The disease has no separate code in the general practice survey or HES data. In the US it is estimated that there were 18 hospital admissions for endometriosis per 100 000 women aged 15–44 in 1980 but the proportion of diagnostic and therapeutic procedures was not clear and readmissions were not considered.[109]

Menopause

Despite several active, predominantly teaching hospital, menopause clinics most of the care for menopause problems and prescription of HRT is clearly based in primary care.

A study in Oxfordshire indicated that there is a low overall use of HRT in the general postmenopausal population despite the recent media coverage of its benefits in the prevention of osteoporosis and subsequent fractures.[110] There is considerable uncertainty among GPs as to the balance of beneficial and harmful effects of HRT in the long term, particularly relating to its use for prevention of osteoporosis and cardiovascular disease. Most doctors would be prepared to participate in randomized controlled trials to determine the long-term effects of this increasingly widely used treatment.[111] The authors found that about 9% of women aged 40–64 were prescribed HRT. A study of perimenopausal women showed considerable interest (more than 75%) among perimenopausal women in taking HRT to prevent osteoporosis.[112] In a survey of women attending a general practice 59% of respondents wished to have more information about HRT and 80% more information about the menopause before its onset.[113]

Urinary incontinence/utero-vaginal prolapse

The general practice survey collects information on consultations for utero-vaginal prolapse, which is associated with incontinence, and genitourinary problems (Appendix II). Although genitourinary problems are not specific for incontinence (also includes eneuresis, bedwetting) it is the only category which reflects the burden of the condition and is not useful when considering the need for gynaecological services.

The specific operations undertaken for incontinence (m codes, Appendix IV) total nearly 7500 equating to 32 operations per 100 000 female population aged over 15.

The majority of women complaining of urge or stress incontinence are seen in general gynaecology outpatient clinics. There are specific urogynaecology clinics, more often in teaching hospitals.

The overall admission rate equates to a rate of nearly 140 per 100 000 females aged over 15 years.

- Prolapse procedures utilize 242 000 bed days with a mean length of stay of eight days, median six.[32]
- Repair of prolapse operations occur at a rate of 100 per 100 000 women aged over 15.
- The mean waiting time for admission was 147 days, median 105.

Menstrual disorders

Coulter *et al.* estimated 21% of gynaecology referrals in the mid 1980s in Oxfordshire were for menstrual disorders with significant variations in practice referral rates.[114]

The Effective Health Care report on the management of menorrhagia indicated that there is considerable variation in practice and uncertainty about the most appropriate management strategies.[115] A total of 822 000 prescriptions were issued in the UK in 1993 to 345 000 women for menorrhagia at an annual cost of £7.12 million and the most commonly prescribed drugs are norethisterone (38%), mefenamic acid (27%), combined oral contraceptive (11%); with tranexamic acid, the most effective drug, only prescribed in 5% of women.[115]

The possible operations undertaken for menstrual disorders include diagnostic – dilation of cervix uteri (D&C) and endoscopic examinations of the uterus and therapeutic – abdominal excision of uterus (hysterectomy (TAH)), vaginal excision of the uterus and open myomectomy endoscopic operations on the uterus (Appendix III).

HES data are difficult to interpret for menstrual disorders. The hospital admission rate for uterine leiomyomata of the uterus is 111 per 100 000 female population aged over 15. Disorders of menstruation accounted for a further 455 admissions per 100 000 female population aged over 15.

Coulter *et al.* demonstrated that although D&C rates declined in the US between 1977–90 they remained static in the UK, with a rate of 70 per 10 000 women in the UK compared with 11 in the US in 1988–90.[116] It was the most common procedure in the Oxford region; 40% of the women being under the age of 40 with a significant variation between districts and with day case rates varying from 22–82% (compared with National Audit Office targets of 86%). The problem with interpreting D&C rates is that the use of other outpatient endometrial sampling procedures, such as vabra and pipelle, are not recorded in HES data. In 1993/94 22 000 hysteroscopies were carried out in the UK, an increase of 22% on 1992/93.[32]

Hysterectomies are performed both abdominally and vaginally for a range of gynaecological conditions of which menstrual disorders contribute about half. Hysterectomy rates vary up to six-fold between countries, with the UK having a relatively low rate in the 1970s.[117] They showed that the variation was correlated in the UK with the number of GPs per 1000 population. 54% of the variation was accounted for by the number of GPs and whole-time equivalent gynaecologists. Coulter explored possible reasons for the variation in the hysterectomy rates: primary care interest in gynaecological conditions such as menorrhagia varies and hence referral rates to gynaecologists; patient's decision to consult their GP and gynaecologist's decision to operate also vary.[118]

In the Oxford survey more than 22% of women had undergone a hysterectomy. The problem with looking at hysterectomy rates is that they take no account of the proportion of women who have had the operation and are no longer at risk. Coulter *et al.* estimated that 60% of GP referrals for menorrhagia are treated within five years with a hysterectomy.[114]

Coulter *et al.* suggested that the referral rates from general practice were an important determinant of resource use and she demonstrated that as many as 43% of patients referred to gynaecology outpatient departments had presented to their GPs less than a month previously. Gath *et al.* commented that the prevalence of perceived menstrual problems is much higher than the number of women who actually consult their GPs about them.[119] Coulter *et al.* estimated hysterectomy rates to be on the increase with levels of 30 per 10 000 women in 1989/90.[116]

Pelvic pain

It has been estimated that one-third of gynaecological clinic presentations are for pelvic pain.[120] Pelvic pain consumes significant health care resources.[93] The lifetime costs are estimated to be £770 per woman. Total annual costs are estimated at £158.4 million, i.e. 0.6% of the NHS budget at 1990/91 prices.

The general practice survey data are difficult to interpret as women will present with pelvic pain associated with specific gynaecological conditions, non-gynaecological conditions as well as the pelvic pain syndrome.

Premenstrual syndrome

There are no routine data, although surveys suggest nearly all women suffer from symptoms but only 5% have severe symptoms, probably requiring at least an outpatient opinion and further investigations such as laparoscopy.

Ectopic pregnancy

Ectopic pregnancies can miscarry spontaneously or resorb, thereby either not presenting to the service at all or presenting to A and E departments as a miscarriage. Those women that present to A and E or the GP with pain, bleeding and shock are the most likely to be labelled as having an ectopic pregnancy.

The operative interventions are not specific to ectopic pregnancy and include therapeutic endoscopic operations on the uterus (Q17) and unilateral excision of adnexa of uterus (Q23).

Early pregnancy loss

Surgical evacuation of the uterus accounts for around three-quarters of emergency gynaecological operations. Data from the HES indicate that there were 1 170 192 inpatient cases equating to 5000 per 100 000 female population aged over 15.

Gilling-Smith *et al.* surveyed A and E departments in England and Wales to assess how women with bleeding in pregnancy were managed.[121] Although 88 (94%) of the 94 departments dealt with bleeding in early pregnancy, only 64 (73%) of these had gynaecologists on site. Of the 86 departments with ultrasound facilities on site, 40 (47%) could not obtain an ultrasound scan outside normal working hours. Nine (56%) of the 16 departments that did not stock either ergometrine or oxytocin had no gynaecology staff on site.

Recurrent miscarriage problems may be dealt with in general gynaecology outpatient clinics or specialist/research centres but there are no data to quantify how many such clinics exist.

Genital tract cancer – secondary prevention

Cervix

Recent Korner KC53 and KC61 (pathology laboratory activity) data (1991/92) indicate that the number of smears performed has increased to 4.5 million a year in the UK.[25]

The follow-up of 'abnormal' smears and implementation of treatment (fail-safe protocols) is the area of the screening service which affects the gynaecological service (Appendix VI). This will involve the gynaecology outpatient services and colposcopy in particular, along with treatment both as inpatients and day cases.

Data from the HES indicate an admission rate of 84 per 100 000 female population aged over 15 for carcinoma *in situ*.

Genital tract cancer

A woman will usually present to her GP in the first instance and the data show consultation rates of ten per 10 000 patients.[31] There were 38 712 inpatient admissions, equating to a rate of nearly 500 per 100 000 females aged over 15. It is not possible to break this down further into surgical procedures, other therapies, recurrences, progression or palliative care. From the operation codes it is not possible to assess which procedures were performed for gynaecological cancer.

Day case and minimal access gynaecological surgery

There are striking differences between units in terms of the use of day surgery and targets based on the proportions of specific procedures undertaken as day cases would need to take into account the same procedures undertaken in outpatient departments (e.g. colposcopy, cervical laser treatment, endometrial sampling). The case severity and presence of comorbidities may influence these proportions and should be adjusted for in any comparison.

Henderson *et al.* showed that the proportion of D&Cs performed as day cases varied from 1–43%. The same group also showed that the proportion of women being treated as day cases increased from 16% in 1976 to 26% in 1985.[122] Explaining within country variations Morgan and Beech suggest that the following factors be taken into consideration:

- characteristics of the patient e.g. age, severity
- characteristics of the health care systems e.g. supply of beds and staffing levels
- clinical practice style e.g. surgical technique and anaesthesia
- organization of hospital care e.g. availability of theatres.[123]

A recent small audit of day case surgery indicated that with the recent changes to anaesthetic practice, despite considerable morbidity after their return home, only 8% of patients said they would have preferred an overnight stay.[124]

Data from the HES shown in Table 9 indicate the proportions of common gynaecological procedures performed as day cases (Appendix III). The HRG data suggest 34% of gynaecological procedures are undertaken as day cases (Appendix III).

Table 9: Proportion of cases performed as day case procedures

Operation	%
Bartholin's abscess/cyst	13
D&C	44
ERPC	35
Diagnostic endoscopy	55
Therapeutic endoscopy	15

The National Audit Office estimated that 70% of the existing day case and inpatient waiting lists could be treated by day case surgery. The problems in its implementation are:

- lack of information to assess performance
- lack of specialist facilities
- inappropriate and insufficient use of existing facilities
- poor management
- clinicians' preference for traditional approaches
- disincentives for managers to prescribe change.[34]

Of the top ten day case procedures two were gynaecological: termination of pregnancy (3%) and D&C (5%).

6 Effectiveness of services

The evidence of effectiveness of aspects of the gynaecological service is reviewed here. The section is not intended as a complete, extensive review of all areas but provides purchasers with the balance of evidence for the various components of the service.

There have been Effectiveness Health Care Bulletins for two aspects of the service; subfertility[42] and menorrhagia[115] and the evidence for the other areas has been sourced from literature searches and review articles.

As with many other specialties in medicine the overall evidence of effectiveness of current interventions is not good. There are no evaluations of a complete gynaecological service and therefore models have to be built up using the components suggested in section 7. The National Perinatal Epidemiology Unit was set up to undertake rigorous trials and evaluations in the field of obstetrics and has done much to promote evidence-based medicine in the specialty. Gynaecologists should therefore be aware of the need for trials to assess their practice.

The evidence to support surgical procedures is generally weak, although trials of the newer developments in MAS have been undertaken. However procedures still slip into routine practice before evidence of effectiveness is available.

For the medical management of gynaecological conditions trials have often been small and outcome assessed poorly and the ethos of multicentre trials needs to be generated. Despite evidence of effective, cheap drugs for the management of menorrhagia, practitioners still prescribe ineffective and more expensive drugs.

Subfertility

Active and sensitive provision of information and support are important components of a high quality subfertility service. Stress is reduced in those couples who feel involved in and in control of their treatment (A-III).[125] The role of counselling has not been shown to be effective.

Assisted conception techniques include artificial insemination, IVF-ET (*in vitro* fertilization and embryo transfer) and GIFT (gamete intra-fallopian transfer). In 1990 the average pregnancy rate with IVF-ET was 17% per treatment cycle.[2] This translates into an average maternity rate of 12% (per treatment cycle) and 14% per couple treated because some couples have more than one cycle. The average number of treatment cycles per patient in 1990 in the UK was 1.16[2] and three cycles is considered by experts to be a reasonable limit. There is no evidence of increased effectiveness overall of IVF-ET over GIFT.

The effectiveness of IVF is reduced if the sperm used is of poor quality; effectiveness is also influenced by maternal age (AIII).[2] *In vitro* fertilization clinics providing a service for women aged over 35 have lower than average success rates.[2] Fetal abnormality occurs but not at statistically different levels to unassisted conceptions.[126] Maternal mortality and morbidity data are not available but recommendations that multiple pregnancies should be avoided have been made (AIII).[2]

The problem that is managed least successfully in terms of conceptions has been that of poor sperm quality or function; there is currently no completely effective treatment for male infertility. The administration of systemic corticosteroids to the 10% of men thought to have an immunological basis to their sterility is of doubtful efficacy and treatment may produce unpleasant and often unacceptable side-effects.[42,127] The main success in managing male infertility is by artificial insemination by donor (AID) and the provision of donor insemination should be an integral part of a district infertility service. There will also be a small demand for this service for the partners of males who are HIV positive and wish to conceive. There may be an increased need for AID, as the extent of male infertility becomes clinically recognized.

Medical treatments for ovulatory dysfunction caused by hyperprolactinaemia or hypothalamic amenorrhoea appear to be very effective at re-establishing fertility to normal levels (AII-2).[128]

There is a significant level of spontaneous pregnancy among untreated women with endometriosis and medical and surgical treatments have been shown to be ineffective. For couples who have failed to conceive, where mild or moderate endometriosis is implicated, assisted conception techniques appear to be successful (AII-2).

Assisted conception techniques appear the most effective treatment for unexplained subfertility (AII-1). Medical treatments may have some effect upon maternity rates and these require further investigation.

Pelvic inflammatory disease

Health education as it is currently provided in the school system is thought to have little influence upon sexual and contraceptive behaviour of young people and hence on PID.[129]

The use of barrier methods of contraception by those not in mutually monogamous relationships is an important part of any strategy to reduce PID and secondary infertility caused by sexually transmitted diseases (AIII).

Apart from primary prevention early diagnosis and treatment of sexually transmitted diseases plays an important part in reducing their incidence by shortening the time during which people can pass on infection to others (AIII). Strategies for detection and screening have been haphazard, so that the identification of infected individuals, with or without symptoms has been incomplete.[3] In Sweden a programme of widespread screening for chlamydial infection has virtually eradicated the disease.[4] There is evidence however that a small increase in 15–19 year olds may herald a resurgence and the differences between the Swedish population and that in the UK may mean such a reduction would not be seen in this country. High

risk screening of women undergoing termination of pregnancy has been suggested as a more cost-effective way forward (BII-2).[130] In primary care it has been modelled that a routine test for chlamydial infection in asymptomatic 18–24 year old women during gynaecological examination was found to be cost-effective but this was not the case for older women (BIV).[5]

Chlamydia trachomatis can be diagnosed from swabs detecting endocervical chlamydial antigens and serum chlamydial antibodies but the woman may not present as she is often asymptomatic. The tests are expensive. A ligase chain reaction assay of urine to diagnose *Chlamydia trachomatis* has been shown to be highly effective for its detection in urine from women with or without symptoms of chlamydial genitourinary tract infection.[131] Standard regimens of tetracyclines, doxycycline or erythromycin appear to be effective against chlamydia in most circumstances (AI).[132] A meta-analysis of trials of antibiotics to treat PID indicated there was a lack of uniformity among studies regarding diagnosis, care and follow-up. Pooled cure rates ranged from 75–94%. Doxycycline and metronidazole was the least effective regimen (75% cure rate). Ciprofloxacin was the cheapest.[133] They concluded that clinical treatment of acute PID is still likely to be wholly inappropriate in many women and suboptimal in a high proportion of the remainder.

Lower genital tract infections

Health promotion initiates should be in line with local strategies for the Health of the Nation targets.[134]

Contact tracing should become a matter of routine for all diagnosed cases of sexually transmitted disease.

Appropriate antimicrobial therapy is effective for chlamydial infection with cure rates of 80–90% (AI). Bacterial vaginosis can be treated with oral metronidazole and clindamycin intravaginal creams, with 75% being disease free one month after treatment (AI)[6] but whether a single dose or seven-day course is more cost-effective is unclear.

Bartholin's abscesses can either be surgically marsupialized or incised. Andersen *et al.* (AI) compared marsupialization with incision and curettage and primary suture of the abscess under antibiotic cover in a prospective trial of 32 patients.[135] The time for healing was significantly less in the suturing group than the marsupialization group, with the same length of stay.

Endometriosis

The aetiology and natural history of endometriosis is not known and thus most regimens have not been shown to be effective in the long term, hence the whole spectrum of strategies employed. Currently clear recommendations for treatment of endometriosis in symptomatic women can be made.[45] Medical treatment works only temporarily with the disease recurring once stimulation by ovarian steroids returns.[136] Endometriosis is more common in subfertile women and women with pelvic pain and logically these should be the main indications for treatment.[45] None of the trials show that medical treatment improves fertility.[45]

Hormonal treatment of symptomatic endometriosis is less of an issue if pain interferes with quality of life. As treatment is expensive and with side-effects the therapy should be contingent on the goals of treatment for each patient. Several modalities can be employed in managing the patient with endometriosis but the ultimate selection is determined by evaluating a number of criteria including age, extent of disease, severity of symptom and pain.

Treatment with progestogens alone has apparently been successful but they are prescribed less frequently than the androgenic steroid danazol.[137] Danazol reduces breakthrough bleeding but there is no evidence that pregnancy rates are any higher with this drug than progestogens.[138] A newer approach is ovarian suppression with luteinizing hormone releasing hormone (LHRH) analogues. However both danazol and LHRH are costly and have limitations for long-term use. Large multicentre trials of GnRH and danazol show equal

effectiveness in relieving symptoms and resolving visible endometriotic lesions (AI).[139,140] Both preparations have side-effects that need to be considered when managing patients.

All medical approaches seem to offer relief of symptoms but the optimum duration of treatment is not clear and the relative merits in terms of pregnancy rates, disease eradication, side-effects and long-term benefits or disadvantages have yet to be compared with each other, with surgical methods and, in mild cases, with placebo.

For women wanting to become pregnant surgical intervention is indicated in those with moderate or severe disease associated with ovarian fixation, peritubal adhesions, or ovarian endometriomas (BIII). If surgery is indicated electrodiathermy is the conventional method with laser a more expensive alternative but one which allows treatment at the same procedure as diagnosis (BIII).[141] Comparison of conservative surgery with medical treatment or expectant management has shown no difference in the outcome in women with mild or even moderate endometriosis.[137,142,143] Likewise a combined surgical and medical approach seems to offer no advantage in mild disease, although it is the method most favoured in advanced cases.[137,142,143]

The *Effective Health Care Bulletin* on the management of subfertility states that there is a significant level of spontaneous pregnancy among untreated women with endometriosis. Medical treatments have been shown to be ineffective. Surgical treatments also appear ineffective. For couples who have failed to conceive naturally assisted conception techniques appear successful (AII-2).[42]

The debate about management continues and results of large trials on which to base rational management are awaited. Although there is a move to minimally invasive techniques for the treatment of endometriosis their effectiveness remains to be confirmed in controlled clinical trials.

A study in Leeds suggested that if a patient has a recurrence of endometriosis it may be possible for the GP to initiate retreatment with the same or alternative medication prior to a revaluation by the gynaecological team (CIII).[144] Surveillance and continuing prescription in primary care is required after hospital management.

Menopause and hormone replacement therapy

This assessment is predominantly concerned with the effectiveness of the gynaecological services. The debate over the effectiveness of HRT on chronic diseases such as osteoporosis, breast cancer and cardiovascular disease continues and only an outline is provided here but it is important to ensure that where menopause services are provided, information and management strategies incorporate consideration of the longer term benefits of HRT.

Symptoms

Placebo-controlled trials have shown consistently that HRT relieves flushes, sweats and the symptoms of lower genital tract atrophy and most have reported beneficial psychological effects (AI).[8]

Cardiovascular disease

Meade and Berra reviewing 12 retrospective case-control studies suggested that HRT reduced coronary risk by about 25% but little or no effect was seen for stroke (AII-2).[9] Reviewing the ten prospective cohort studies reductions of 20% for cardiovascular disease and 15% for stroke were observed (AII-2). There are no comparable data of treatment with patches or implants. It is not known whether opposed oestrogen therapy diminishes these beneficial effects as progesterone reduces the HDL cholesterol-raising effect of oestrogen. In the prospective studies notably the nurses study in the US it is not clear how much of the observed

reduced risk is due to a selection bias of healthier women to the study. Posthuma *et al.* suggest that unintended selection of relatively healthy women for oestrogen therapy may have influenced the reported beneficial effect of oestrogen therapy on cardiovascular disease and it is unclear how much of the cardioprotection is due to this selection.[145]

Osteoporosis

Screening

Law *et al.* reviewed the studies using bone density measurements in women with hip fracture and age-matched controls and confirmed that it is a poor screening test.[80]

No simple cost-effective screening test is available. An *Effective Health Care Bulletin*[7] stated that there have been no scientific trials assessing the effectiveness of population bone screening programmes in preventing fractures in elderly women. The bulletin suggests that bone density measurements are poor at identifying which women will go on to have a fracture in later life. Less than a quarter of women are likely to attend for screening and take HRT over a long period of time. It is likely that a bone screening programme will lead to the prevention of no more than 5% of fractures in elderly women. Given current evidence it would be inadvisable to establish a routine population-based bone screening programme for menopausal women with the aim of preventing fractures.

A report of the Department of Health's Advisory Group on Osteoporosis recommends the use of bone density measurement in individual clinical decision-making in certain high risk groups.[146]

The only randomized controlled trial of exercise in premenopausal women showed that exercise significantly increases the mineral density of the young female skeleton (AI).[147]

Randomized controlled trials of up to ten years in duration have shown that oestrogen replacement substantially or totally prevents postmenopausal bone loss as have observational studies and bone loss is prevented for as long as treatment is maintained (AI).[10,11] The effect of oestrogen/progesterone preparations on the incidence of fractures has not yet been assessed but a preventive effect is likely because the combination prevents rapid postmenopausal bone loss in the same way as oestrogen alone.

The conclusions in the review by Law *et al.* are that increasing physical activity is the most important strategy for reducing the hip fracture rate and this would half the rate (AIII).[80] Similarly a reduction in smoking premenopausally can reduce the risk by a quarter. Although HRT more than halves the risk of fracture, once stopped the protection is reduced thereby reducing its utility. If it were to be beneficial it would need to be continued indefinitely from the onset of the menopause. In postmenopausal women with low bone density, bone loss can be slowed or prevented by exercise along with calcium supplementation or oestrogen/progesterone replacement (AI).[148] How long therapy needs to be continued to have an impact on fractures is unclear.

Overall benefits

A non-quantitative epidemiological overview of oestrogen replacement therapy with or without progestogens concluded that the benefits outweigh the risk.[149] A quantitative analysis came to similar conclusions for women after hysterectomy and women at high risk of cardiovascular disease.[150] Gorsky *et al.* evaluated the relative risks and benefits of exogenous oestrogen use among women entering the climacteric and considered oestrogen use for relief of symptoms or prevention of disease.[151]

Decision analysis was used to assess the value of HRT in a hypothetical cohort of 10 000 women assumed to be aged 50 years and health outcomes were extrapolated to age 75. The health benefits of postmenopausal oestrogen replacement were found to exceed the health risks incurred. The study assumes universal

compliance with HRT and much of the data was derived from the nurses study in the US and may not be representative of the UK situation. Khaw illustrated the estimated changes in annual rates of certain menopause related events of ten years HRT (Table 10).[47]

Table 10: Illustrative estimated changes in annual rates[a] by ten-year age group in England and Wales associated with hormone replacement therapy (HRT) unopposed oestrogen or combined with progestogen for ten days a month, for ten years (Source:[47])

	Heart disease	Stroke	Breast cancer	Uterine cancer	Hip fracture	Net balance of events
Estimated annual rates per 100 000 by age group						
45–54 years	30	17	62	2	18	
55–64 years	171	60	101	8	66	
65–74 years	600	243	135	16	231	
75+ years	2419	1938	259	34	1480	
Unopposed oestrogen						
Relative risk	0.6	0.8	1.2	4.0	0.5	
Change in annual rates per 100 000 by age group						
45–54 years	−12	−3	+12	+8	−9	−4
55–64 years	−68	−12	+20	+32	−33	−61
65–74 years	−240	−49	+27	+64	−126	−324
75+ years	−968	−388	+52	+136	−740	−1908
Oestrogen with progestogen						
Relative risk	0.8	0.9	1.3	1.0	0.5	
Change in annual rates per 100 000 by age group						
45–54 years	−6	−2	+18	0	−9	−1
55–64 years	−34	−6	+30	0	−33	−43
65–74 years	−120	−24	+41	0	−126	−229
75+ years	−484	194	+78	0	−740	−134

[a] Ischaemic heart disease, cerebrovascular disease, breast cancer, endometrial cancer mortality rates from OPCS; hip fracture estimated incidence rates from HIPE data

Mode of delivery

The oestradiol patch is an alternative to oral oestrogens for women with menopause symptoms. It should be combined with an oral progestogen for women who have not had a hysterectomy. The theoretical advantage of the transdermal route is of unproven clinical benefit and the contraindications are the same as for oral HRT. Patches are not yet indicated for preventing osteoporosis and are more expensive than other oestrogen preparations. It is still not yet known whether transdermal oestradiol will protect against ischaemic heart disease in the way that ovarian or oral oestrogen does. Subcutaneous oestrogen is more effective than oral oestrogen in preventing osteoporosis, probably owing to the more physiological (premenopausal) serum oestradiol concentrations achieved. Subcutaneous oestrogen also avoids problems of compliance that occur with oral treatment.[152] Progestogen-releasing intrauterine systems can also be used to deliver progestogen direct to the endometrium in women who still have a uterus.

Cost-effectiveness

In the US Weinstein and Tosteson, using some assumptions, showed that oestrogen replacement therapy was found to be cost-effective with rates ranging between $9130 and $12 620 per additional life saved.[153] For women who have not had a hysterectomy ten- and 15-year courses of oestrogen combined with progesterone have been evaluated. The baseline assumptions were that breast cancer incidence and ischaemic heart disease deaths were unaffected and the study did not take into account the occurrence of fractures of the wrist or vertebrae. Under these assumptions combined therapy was more costly, with ratios ranging from $86 100 to $88 500.

Unless combined therapy is found to confer protection against IHD the most cost-effective strategies for women with no prior hysterectomy may involve screening perimenopausal women to detect women at highest risk of hip fracture followed by selective treatment. In a UK analysis Roche and Vessey concluded that the benefits in terms of reduced mortality and treatment costs are greater for women without a uterus receiving unopposed oestrogen therapy than for women with a uterus receiving combined therapy.[12] Indeed a net cost to the NHS of £137 per woman is suggested if hysterectomized women are treated with oestrogen therapy (Table 11).

Table 11: Average cost per woman treated for 15 years and followed up until age 79

Costs	ORT (£)	O+P (£)
Direct costs:		
Drug	110	453
Monitoring	117	117
Indirect costs:		
Breast cancer	13	13
Ischaemic heart disease	(18)	(9)
Cerebrovascular disease	(65)	(33)
Fractured neck of femur	(20)	(20)
Total cost	137	521

Figures in paranthesis are savings. All costs are discounted at 5% per annum.[12]
ORT = oestrogen replacement therapy.
O+P = oestrogen plus progesterone.

Coulter has estimated that 20% of the female population in the UK will have had a hysterectomy by the age of 50 and thus a strategy aimed at this group alone would have major public health implications.[118] As Weinstein and Tosteson indicate all conclusions from such analyses must be regarded as highly speculative because of the vast uncertainty that surrounds the possible effects of oestrogen and progesterone on heart disease.[153] In terms of cost-effectiveness they conclude that HRT compares favourably with other accepted health care interventions. Daly *et al.* similarly concluded that long-term prophylactic treatment of hysterectomized women and treatment of symptomatic women with a uterus compare favourably with other accepted health care interventions.[154] They estimated the cost per QALY to range from £700 for ten years of treatment with oestrogen alone HRT for women with mild menopausal symptoms to £6200 for combined therapy for women with mild symptoms.

Grady *et al.* estimated life expectancies and risks of certain sentinel events in groups: women without risk, women with cardiovascular disease and women at risk of breast cancer, fractured neck of femur, or cardiovascular disease.[150] Assumptions had to be made for the long-term effect of combined therapy. In the

first optimistic setting addition of a progesterone to the oestrogen regimen was assumed not to change the relative risk of disease from oestrogen, except to prevent the increased risk of endometrial cancer. In the second more pessimistic scenario addition of progesterone was assumed to provide only two-thirds of the cardiovascular risk reduction while the relative risk of breast cancer was increased. Women who had undergone a hysterectomy had about the same change in life probability of disease and life expectancy as that of women with no special risk using combined therapy under optimistic assumptions. However because these women do not need to take progesterone the estimates are less certain.

Side-effects

The risk of endometrial cancer brought about by oestrogen can be virtually eliminated by cyclical treatment with progesterones.[155] Pooled data on the risk of breast cancer show a modestly increased relative risk of about 1.3 for 15 years of oestrogen use[156] but there is sufficient concern over the potential risk that largescale trials are proposed to estimate the risk of cancer with HRT.

Urinary incontinence/utero-vaginal prolapse

Stress incontinence

First-line investigations that can be performed in primary care include microscopy and culture of urine to exclude an infective cause of incontinence and the maintenance of a fluid balance chart which enables the clinician to obtain a better understanding of the problem.[157] The overlap of symptomatology between stress incontinence and detrusor instability is such as to make a diagnosis impossible without resource to urodynamic studies. Videocysto-urethrography may help with difficult cases. There is a poor correlation between clinical diagnosis and urodynamic diagnosis.[158] Urodynamic investigations are of three types:

1 simple and non-invasive (e.g. pad tests and frequency/volume charts), suitable for primary care
2 basic urodynamics suitable for district general hospitals
3 complex urodynamics suitable for a tertiary referral centre.

Conservative treatment is of use for those women with mild symptoms or with comorbidities but the majority will require surgery. Simple measures such as providing explanations, use of intravaginal tampons and sponges have been advocated (BIII).[157] Physiotherapists are treating considerable numbers of patients with stress incontinence but the efficacy data are still required to enable rationalization of resources to cater for the whole population.[159] There is no satisfactory method of measuring pelvic floor function and of monitoring progress during treatment. The success of pelvic floor re-education varies from 60–90% but when compared to surgery (Burch colposuspension) physiotherapy compares poorly.[13] In the study by Mantle and Versi all physiotherapy departments surveyed offered pelvic floor exercises and 93% inferential therapy.[159]

Hilton suggested the use of an algorithm to influence decision making with regard to incontinence which includes looking at predisposing factors, precipitating factors, conservative measures, urodynamic testing and, if stress incontinence is demonstrated, types of treatment.[160]

Jarvis reviewed the six common surgical procedures in over 200 studies and concluded that no single operation could be offered to all women in all situations as a first choice.[14] Only seven RCTs were identified and there is a need to have clearly defined inclusion and exclusion criteria and objective follow-up measures. The procedures with a continence rate of over 85% were the Marshall-Marchetti-Krantz operation, colposuspension, endoscopic bladder neck suspensions and bladder sling operations with only the

colposuspension (87–92%) and sling operations (89–99%) having higher confidence intervals. For recurrent stress incontinence only colposuspension, endoscopic bladder neck suspension and sling operations had continence rates in excess of 80%.

There has been long debate over whether coincidental hysterectomy influences the incidence of continence when performed at the same time as the continence operation. Jarvis has pointed to the limited evidence on this that greater objective cure rates have been observed for genuine stress with hysterectomy than bladder buttress without.[14]

Detrusor instability

It is necessary to make the diagnosis urodynamically. Many drugs, including HRT, have been used to treat detrusor instability but none are universally successful and none shown to be effective. Surgical interventions range from urethral dilation followed by otis sphincterotomy to intermittent self-catheterization.[161] Habit retraining in the form of bladder drill, biofeedback, hypnotherapy and acupuncture have been successfully used and improve symptoms in up to 80% of women but not in the trial setting (CIII). Severe symptoms usually require surgery and the 'clam' ileocystoplasty is amongst the more effective procedures[162] but side-effects are quite significant. Combined stress and detrusor incontinence is probably best treated with initial medical methods and followed by surgery.[163]

Utero-vaginal prolapse

The nature of the intervention depends on the presenting symptoms which include 'something coming down', urinary incontinence, discharge and bleeding. If urinary symptoms are present appropriate investigations should be undertaken.

Non-surgical therapies include HRT for mild degrees of prolapse, ring pessaries and pelvic floor exercises. There is no trial evidence of effectiveness.

The type of surgical operation depends on the degree of prolapse and associated symptoms but is commonly a variation on a vaginal hysterectomy and repair of the pelvic floor. Recurrence rates of up to 25% are quoted (BIII).[48]

Menstrual disorders

Diagnosis

The diagnosis of menstrual abnormalities and postmenopausal bleeding requires a structured history and examination, along with a scheme for investigations in order that the following broad categories of disorders can be distinguished:

- young women with oligomenorrhoea
- post-contraceptive pill amenorrhoea
- polycystic ovarian syndrome
- diseases of the hypothalamic pituitary ovarian axis
- endometrial cancer or changes associated with mucosal atrophy in postmenopausal women.

Most women under the age of 40 with menstrual problems present with heavy frequent periods and most suffer from dysfunctional uterine bleeding, with no gross pelvic disease found on examination or investigation. Endometrial hyperplasia and adenocarcinoma of the endometrium are rare in this age group.

Diagnostic techniques

Dilatation and curettage is a diagnostic test for endometrial pathology but its sensitivity under the age of 40 has been repeatedly questioned[164] and should be replaced by other methods of endometrial sampling in the main[116] but their effectiveness has not been compared with D&C. The newer diagnostic methods have generally been considered to be of higher patient acceptance. Dilatation and curettage is an important operating theatre resource utilizer.

Ample evidence now exists that D&C will not reliably detect submucous fibroids and hysteroscopy is currently the diagnostic method of choice (AII-2).[165] The RCOG has indicated that in women under the age of 40 it is unlikely that D&C will detect gross pelvic disease and advocates the use of hysteroscopy.[23] The vabra aspirator is more sensitive than the pipelle.[166] The pipelle and Novak curette are alternatives but may be less effective in detecting abnormality because less surface area is sampled. The hysteroscope visualizes the endometrium and is not only useful in diagnosis but also for treatment such as removal of polyps, resection of endometrium and submucous fibroid resection (BIII). De Jong *et al.* reported that outpatient hysteroscopy considerably reduces the need for hospital admission and can provide early investigation of a spectrum of gynaecological disorders.[167] However no randomized controlled trials have been carried out to compare endometrial sampling with D&C.

The diagnosis of fibroids is either made clinically on examination, with or without ultrasound imaging to differentiate uterine enlargement from other pelvic pathology. Scanning is estimated to have a sensitivity of 80%.[168] Further diagnostic procedures are rarely indicated but include laparoscopy or laparotomy.

Treatment

The effectiveness of reassurance and counselling in appropriate women is unknown.[115] The management of menstrual disorders is complicated by a variety of decisions based on age, reproductive status and severity of symptoms. Medical management aims to reduce the psychological sequelae of a hysterectomy but may not effectively control the symptoms. About 50% of women referred with perceived menorrhagia are depressed or anxious and might benefit from psychiatric treatment or counselling rather than gynaecological management.[169]

The Effective Health Care report details the trial evidence for the management of menorrhagia.[115] There were 31 RCTs of drug therapies which included objective measurement of menstrual loss and three randomized controlled trials of surgery, comparing hysterectomy with MAS techniques.

The general problems with the drug trials are:

- inconsistency of entry criteria
- inconsistency of reporting side-effects
- comparison of different doses in different trials
- poor baseline pre-treatment observations
- short length of follow-up
- inappropriate analysis of blood loss.

In general the evidence is only suggestive because insufficient RCTs directly compare the top ranking drugs. The costs of medical treatments vary from several pounds for the oral contraceptive to £25 for danazol for a five-cycle treatment with five days of bleeding.[170] Other drugs include non-steroidal anti-inflammatory drugs, anti-fibrinolytics and ethamyslate.

There are several effective treatments for menorrhagia, though there is no evidence for the effectiveness of the most commonly prescribed agents – progestogens, such as norethisterone.[171] A number of trials have shown only a 20% reduction in blood loss for menorrhagia of progestogens and their use as first-line agents

should be questioned (AI).[172] There is objective evidence of efficacy of the combined oral contraceptive[173] and prostaglandin inhibitors[174] even in the presence of an IUCD[175] but not fibroids and anti-fibrinolytic agents[176] which may also be effective in cases of menorrhagia induced by IUCDs.[177] All these agents reduce menstrual loss by an average of 50%. The evidence suggests that tranexamic acid is the most effective and acceptable of the currently available drug treatments and mefenamic acid also appears effective (AI).[115]

Danazol and luteinizing hormone releasing hormone (LHRH) agonists may be even more effective and produce amenorrhoea but side-effects preclude their prolonged use (AI).[172,178] The newer agent gestrinone may prove to be better tolerated but be equally effective (AI)[179] even to the extent of reducing the size of fibroids.[180]

There is evidence that the hormone releasing intrauterine systems are effective but these are not yet licensed for use in the UK (AI).[115] This may well have the effect of moving more care to the community although currently they are not readily available for contraception.

The management of menorrhagia associated with fibroids with progesterone or prostaglandin synthetase inhibitors or oral contraceptives is not established. Recently analogues of LHRH have been used to suppress ovarian function and have objectively reduced the size of fibroids and relieved menstrual symptomatology in the short term[181] and probably represent an alternative to surgery for women with medical complications to surgery and for symptomatic women perimenopausally, although further trials are required.

Surgery

Surgery includes myomectomy, abdominally or hysteroscopic resection[182] especially in younger women wishing to retain fertility or hysterectomy or endometrial ablation if the family is complete. About two-thirds of hysterectomies are performed for menorrhagia (BIII).

Preoperative gonadotrophin hormone releasing hormone (GnRh) has been shown in the trial setting to reduce peroperative blood loss and operative time.[183,184]

Hysterectomy

Hysterectomy has a morbidity rate as high as 43% of procedures[185] and a mortality rate of six per 10 000.[186] Hysterectomy has been associated with adverse psychological and sexual sequelae but the case for a specific post-hysterectomy syndrome is not proven.[187] Whilst most psychiatric and sexual problems after hysterectomy occur in women with pre-existing problems some new cases develop and there is a need to assess women's emotional as well as physical response to surgery and provide effective information.

Clarke *et al.* looked at the satisfaction with length of stay (LOS) after hysterectomy and indicated that shorter LOS did not reduce substantially the benefits of hysterectomy compared with longer LOS (more than six days), although there were cost savings of £155 a day in the short LOS group.[188] However a high proportion of women in this group identified that their LOS was too short. The longer LOS group also had better access to community services.

McKee and Wilson reporting the conclusions of a Royal Society of Medicine meeting on hysterectomy, indicated the following issues required consideration in purchaser/provider discussions:[189]

- lack of assessment of longer term outcomes after hysterectomy
- limited understanding of the means of assisting patient choice.

Coulter reported that two-thirds of women had no preference for the type of treatment. She suggested GPs should assess the symptom severity, quality of life and preference for treatment.

Alternatives to total abdominal hysterectomy

An abdominal hysterectomy takes 45–60 minutes to perform and women may need to remain in hospital for up to seven days with 9–11 weeks convalescence.[41,190]

Endometrial ablation can be performed by transcervical resection of the endometrium (TCRE), coagulation with a rollerball electrode, laser ablation or radiofrequency-induced thermal ablation. With laser ablation most patients are discharged after an overnight stay in hospital and return to full activities within ten days.[191] Rollerball coagulation takes about 25 minutes and most patients return to full activity within one week, with 30–40% of women becoming amenorrhoeic and 55–60% having reduced menstrual flows which is similar to the results of laser ablation and radiofrequency-induced thermal ablation.[191–193]

Dwyer *et al.* demonstrated reduced morbidity with TCRE compared with TAH (AI) with a follow-up period of four months at which point there was a 10% failure rate with TCRE. This trial had a 46% morbidity rate with TAH and 25% psychiatric morbidity rate which is similar to previous studies. There was less satisfaction with TCRE than TAH, although satisfaction levels were high (85% TCRE, 94% TAH). Sculpher *et al.* analysing the same trial data concluded that up to four months post-operation TCRE had a cost advantage over abdominal hysterectomy in terms of health service resource costs.[15] However given the fact that a group of women required retreatment due to resection failure and that follow-up was short the long-term cost and benefits of endometrial resection need to be evaluated before widespread diffusion is justified. The cost of TCRE was estimated at £560 (range £420–£1691) versus TAH at £1060 (range £826–£2278). These costings took no account of time off work which was four to five times longer after hysterectomy than TCRE. In another trial Gannon *et al.* concluded that for women with menorrhagia who have no pelvic pathology TCRE is a useful alternative to abdominal hysterectomy, with many short-term benefits (AI).[189] These studies did not compare TCRE with vaginal hysterectomy.

Pinion *et al.* compared TAH, TCRE and endometrial laser ablation in a trial of 204 women with DUB.[194] Hysteroscopic endometrial ablation was superior in terms of operative complications and post-operative recovery. Satisfaction after hysterectomy was significantly higher but between 70% and 90% of the women were satisfied with the outcome of hysteroscopic surgery. The hysteroscopic procedures were significantly shorter and lengths of stay shorter (7.5 days TAH, 2.5 days hysteroscopic) (AI). In a non-randomized study Magos *et al.* followed-up TCRE patients for up to 2.5 years.[195] Results were best in women aged over 35 years and 4% underwent hysterectomy at a later date and menstrual symptoms were improved in over 90% of patients (AII-2).

Transcervical resection of the endometrium requires extensive training.[196]

Laparoscopically assisted vaginal hysterectomy

An argument for performing oophorectomy at the time of hysterectomy has been put forward to prevent the occurrence of subsequent ovarian pathology, although this is debated vigorously and the issue of consent is crucial.[46] To reduce the morbidity and use of resources associated with TAH a laparoscopically assisted vaginal hysterectomy may allow a vaginal hysterectomy to be performed with removal of the ovaries laparoscopically. Hunter *et al.* reviewing the procedure undertaken on a case series concluded that LAVH can be successful in most women selected for the procedure and there appears to be rapid return to normal activities and work (CII-2).[197] Boike *et al.* reviewing the literature concluded that despite the reduced length of stay LAVH was more expensive but was a useful technique for converting some TAHs into vaginal procedures if adnexal procedures were indicated.[198] Raju and Auld in a trial of 80 women with uterine size of less than 14 weeks demonstrated reduced lengths of stay and subsequent costs with similar morbidity rates in LAVH patients.[16] The debate as to whether to perform a vaginal hysterectomy or LAVH is ongoing and depends on the evidence of effectiveness of prophylactic oophorectomy (BI). Summitt *et al.* in the US compared LAVH with vaginal hysterectomy in an outpatient setting and concluded that other than LAVH

being more expensive than simple vaginal hysterectomy the outcomes were comparable but the number of women in the trial was only 56 (BI).[199]

Stovall *et al.* have shown outpatient vaginal hysterectomy to be a safe and acceptable method of treatment for selected patients in an uncontrolled study of 35 patients (BII-2).[200] Clinch[201] described the reduction in length of stay in Belfast after vaginal hysterectomy from 6.6 days in 1986 to 3.4 in 1992, confirming the report of others[200] that early discharge is possible. However Clinch eluded to the problems in inner cities of return to hospital for post-operative complications.[201]

There are no trials comparing surgery with medical management for menorrhagia.

Pelvic pain

A Lancet editorial[17] indicated insufficient evidence of the effectiveness of therapies to enable guidelines for the management of pelvic pain to be established. In a single blind placebo controlled trial Reginald *et al.* showed that acute attacks of pelvic pain can be relieved by the intravenous administration of dihydroergotamine, which has been shown venographically to relieve congestion (BI).[50] Psychotherapy is said to be an important part of therapy. Farquar *et al.* showed in a double blind RCT that medroxyprogesterone with psychotherapy and pain counselling was superior to placebo (AI).[202] Pelvic pain associated with benign ovarian pathology such as torsion or haemorrhage into a cyst is effectively managed by surgery which incudes laparoscopy or laparotomy.

Premenstrual syndrome

The most effective therapy is abolition of the ovarian cycle by drugs or surgery but is only appropriate in severe cases and can be affected by the oral contraceptive, continuous progesterone, oestradiol patches and implants and gonadotrophin releasing hormone analogues. Treatment of women with moderate symptoms has not been properly evaluated in trials until recently . The use of stress management, relaxation techniques, exercise and dietary change including oil of evening primrose oil supplementation although often helping women with mild symptoms has not been shown to be effective in trials.[18] Neither has the use of progestogens or progesterone.

Ectopic pregnancy

Vaginal or abdominal ultrasound can exclude the possibility of an ectopic pregnancy by confirming an intrauterine pregnancy on the grounds that a combination of both intra- and extra-uterine pregnancies is extremely rare (1 per 30 000 pregnancies). Human chorionic gonadotrophin (HCG) estimation remains the primary biochemical diagnostic test used in the differential diagnosis of abdominal pain in women of reproductive age. The use of laparoscopy provides a positive diagnosis in more than 90% of cases and a falsely negative diagnosis in 3–4% of cases which tend to be early in pregnancy.[203] The confidential enquiry into maternal deaths[204] highlights the potential for a poor outcome if management is suboptimal, with 14 out of 19 cases during the period 1988–90 having had suboptimal care (AIII).

Magos *et al.*[24] suggested that most gynaecological emergencies including ectopic pregnancy that have traditionally been managed by laparotomy can be treated effectively by laparoscopy (BII-2).[205] Apart from the obvious advantage of avoiding large scars the patient faces less discomfort, reduced morbidity, a shorter stay in hospital and an earlier return to normal activities (BII-2).[24,206] Brumsted *et al.* compared laparoscopy and laparotomy for ectopic pregnancy and showed that post-operative analgesia requirements were reduced with laparoscopy.[207] Poorly controlled or uncontrolled series to assess the effectiveness of laparoscopic

removal of the ectopic remain the order of the day and Grimes in a review of endoscopic management of ectopic pregnancy concluded that the quality of evidence was less than ideal but there was fair evidence to recommend that operative laparoscopy be used in some ectopic pregnancies (BII-2).[19]

Early pregnancy loss

Recurrent miscarriage

When assessing the efficacy of treatments for recurrent miscarriage it must be remembered that about 60% of these women will be successful in their next pregnancy without intervention.

Meta-analyses have been conducted which used multiple endpoints but Goldstein *et al.* showed no effect of progestational agents on 'normal' outcome (rather than a decrease of miscarriage alone) of high-risk pregnancies.[208] Daya *et al.* in another meta-analysis, found progesterone in early pregnancy useful but indicated that there is a need for a trial of women with biochemical evidence of luteal phase progesterone deficiency (BI).[209]

Cervical cerclage has not been shown to be effective for recurrent miscarriage.[210]

Miscarriage

Evacuation of the retained products of conception (ERPC) is an acceptable management to reduce blood loss and infection which currently accounts for about three-quarters of emergency gynaecological operations in the UK (AII-2).[211]

Pilot studies of medical abortion using the antiprogesterone Mifepristone and the new synthetic prostaglandins indicate these to be safe and effective methods of evacuating the uterus (AI).[20,212,213] These data would indicate the potential for decreasing surgical workload along with the associated surgical morbidity and releasing surgical beds. Medical abortion has been shown to be a satisfactory alternative to surgical vacuum extraction in the trial setting of women undergoing legal induced abortion (AI).[212] Both procedures were highly acceptable to women with preferences but over 50 days gestation the choice for surgical aspiration was greater. There will be women who require surgical evacuation for heavy bleeding and in some women prostaglandins are contraindicated.[214] There is no evidence that ERPC is effective when ultrasound indicates the uterine cavity is empty of retained products.

Current common practice is for admission through A and E to a gynaecology ward and/or straight to the operating theatre with a return to the ward prior to discharge. The concept of an early pregnancy assessment unit with direct access from primary care to diagnostic testing facilities such as pregnancy testing service, ultrasound and counselling services has been employed. These units reduce the need for out of hours operating but have not been formally evaluated (BIII).[215] (D Hamilton-Fairley, personal communication, 1994.)

Gilling-Smith *et al.* have shown that the use of management guidelines and the provision of advisory leaflets to patients on discharge significantly enhances the service provided to women with such bleeding both by improved diagnostic accuracy and by reducing the numbers of unnecessary admissions or referrals.[216]

Genital tract cancer – secondary prevention

Cervix

Premalignant changes in the cervical epithelium may be detected by cytology and the cervical smear meets many of the criteria of an effective screening modality but a randomized controlled trial of cervical screening has not been undertaken (AII-2). The fact that the natural history of preinvasive lesions is not known is the major drawback. The test is cheap and simple. The British Columbia cohort study estimated the sensitivity to be 78%, specificity 96% with a positive predictive value of 25%.[217] The disease is readily diagnosed histologically and there is successful treatment for early stage disease. The most persuasive evidence that screening for squamous cell cancer of the cervix is effective comes from comparison of the trends in incidence and mortality in populations which introduced mass screening with different intensities at different times. Since the mid 1960s mortality has declined in most developed countries but especially in those that have a highly developed screening programme for carcinoma of the cervix.[218] Mortality has declined to a lesser extent in countries where only a proportion of the population is screened formally, most women having a smear taken when they visit their doctor for another reason. As a randomized controlled trial of the effect of screening for cervical cancer on mortality was never undertaken it is impossible to decide whether the decline in mortality is due solely to the introduction of screening or due to improvements in socioeconomic status, changes in sexual habit or an increase in the hysterectomy rate. Macgregor *et al.* suggested that screening has been effective in reducing the incidence of and mortality from cervical cancer in North East Scotland as the incidence had fallen mainly in the well-screened age group of 40–69 years (AII-2 in Scotland).[219]

Follow-up of abnormal smears and implementation of treatment (fail-safe protocols)

Mild and moderate dyskaryosis will be identified in 1–2% of women screened and of these around 30% will have CIN III which was underestimated by the smear. The proportion of smears classified as borderline or mildly dyskaryotic may represent 4–5% of all smears. Because of the paucity of information available to determine unequivocally what the optimal management policy for mild and moderate dyskaryosis is the Aberdeen Birthright Project was set up to evaluate the safety and effectiveness of a cytology-based approach to the management of these degrees of abnormality.

The natural history of CIN I (mild dysplasia) remains unclear and the Europe Against Cancer Programme suggested each case needs to be decided on an individual basis.[220] Usually a repeat smear is recommended within six months. Alternatively two to three consecutive negative smears should be obtained within 12–18 months before the woman may be returned to routine screening. If a district policy is to simply observe CIN I then the local circumstances must be taken into consideration, including the undercall rate and the patient default rate. Until recently there has been no justification for managing mild dyskaryosis by immediate colposcopy, although a survey by the British Society of Colposcopy and Cervical Pathology found that half the respondents considered that a single mildly dyskaryotic smear should be referred for colposcopy.[221] Johnson *et al.* using decision analysis modelling estimated that repeating a smear after a mildly dyskaryotic report is almost as effective as an immediate refferal to a colposcopy unit.[222] However a conservative policy is not financially cheaper; an average of six additional smears are required to save each colposcopy referral.

Anxiety levels are high in women attending colposcopy clinics and information provision can allay womens' fears, although specific counselling techniques have not been shown to reduce anxiety any more than information provision alone.[223] (CDA Wolfe, personal communication, 1996.)

Over 90% of colposcopies take place in gynaecology departments. The role of colposcopy in GUM clinics needs to be researched[224] although reports have demonstrated that such clinics are feasible.[225] Advice from the NHS Executive to the Royal College of Obstetricians and Gynaecologists[226] on GP involvement in

colposcopy indicates that training to a clinical assistant level is required and proper equipment and nursing back up is essential. Evidence must be available to demonstrate a particular GP will perform sufficient procedures to maintain professional expertise.

The International Agency for Research into Cancer study of screening histories comparing women who developed invasive cervical cancer with those that did not demonstrated that the relative protection against cervical cancer in women with two or more previously negative smears participating in centrally organized screening programmes is 15-fold in first year, 12-fold in second and eight-fold in the third year, indicating that screening is effective if coverage is high (AII-2).[227] Centrally organized programmes were more effective than uncoordinated screening. Case-control studies have illustrated similar relative protection for those who have had a smear less than three years previously.[228,229]

Cervical intraepithelial neoplasia is arbitrarily classified as CIN I, II or III but many pathologists consider it a continuum from mild at one end to undifferentiated at the other. There is general agreement that high grade (CIN III) lesions should be treated (AII-2) but the natural history and consequently management of lesser degrees of abnormality remains somewhat unclear. The NHS cervical screening programme does not recommend immediate colposcopy for CIN I. The results of the Aberdeen Birthright study conclude that cytological surveillance, although safe, is not an efficient strategy for managing women with mildly abnormal smears, although a detailed cost-effectiveness analysis has not been presented.[230] They suggest women with any degree of dyskaryosis in a smear should be referred for colposcopy as only one in four women with mild dyskariosis reverted to normal over the two-year study period. The other important finding of the Aberdeen study was that one-third of women with CIN III had an index smear showing mild dyskariosis and that one in eight women defaulted from follow-up. Routine colposcopy would lead to 30% more referrals but would reduce cytological surveillance. The remaining potential disadvantage of immediate referral is the risk of overtreatment.[231] Although large-loop excision of the transformation zone is safe and effective (AI)[232] unnecessary treatment should be avoided. Without data from other prospective studies we must rely on cross-sectional and retrospective studies. All large studies have suggested that cytological surveillance is safe both individually and at a poulation level.[233,234] The smears of up to half the women will return to normal without treatment. The semi-quantitative polymerase chain reaction may allow a distinction between high and low grade disease in women with mild cytological abnormalities but needs large population-based studies.[235]

There is currently no routine clinical role for cervicography in either primary cervical screening or in the further assessment of patients with abnormal cytology. Although there may be a role for cervicography in the surveillance of patients with mild dyskaryosis or borderline changes to reduce the frequency of referral for formal colposcopy this requires further evaluation.[28,236]

There is similarly no international agreement on the management of CIN II or III (moderate and severe dysplasia and carcinoma *in situ*) which constitute 1.5–2% of all smears. Colposcopy is indicated with biopsy of abnormal areas and treatment if CIN II or more is diagnosed.

CIN II or III can be treated either by local destructive therapy or conization of the cervix. Local treatment may be cryotherapy, heat coagulation, laser coagulation or loop excision. Conization may be by cold knife conization, electric cautery or laser. It is generally agreed that the method of treatment is not considered to be of particular importance with regard to outcome, provided the pathologist receives some material for examination.[28] The mode of treatment may have relevance when deciding service provision options. Large-loop excision of the transformation zone (LLETZ) has enabled the colposcopist to make a diagnosis and treatment at just one outpatient visit without the need for pre-treatment cervical biopsy (AI).[232,237] There has been some concern over the pathological interpretation of the margins of such a procedure.[238] A controlled trial of LLETZ versus carbon dioxide laser vapourization showed reduced operative time, post-operative haemorrhage and discomfort in the LLETZ group. There was no significant difference in CIN recurrence rates. There are reduced capital outlays for LLETZ treatment.[239] A randomized controlled

trial concluded that outpatient loop diathermy excision is an equally effective, quicker, safer and more reliable excisional technique than laser excisional conistion (AI).[240]

Woodman *et al.* undertook a trial of women with human papilloma virus infection occurring alone or in association with CIN I or II.[241] Patients were randomized to carbon dioxide laser or nothing. They reported the short-term efficacy of laser but cautioned that the substantial rate of spontaneous regression (26% (CI 19–33)) within one year suggests that intervention is frequently unnecessary, although there was no long-term follow-up in this study, as in Aberdeen.

Close follow-up by repeat smear is essential after treatment for up to three years. Colposcopy is not essential but may enhance detection of persistent disease. Residual disease is detected in between 5–15% of treated women, depending on the technique used and the grade of CIN treated. The risk of new disease developing is between 2–5% and the risk of invasive cancer in the order of 0.2% .[242]

Other sites

Recent studies on self-selected women using transabdominal and transvaginal ultrasound, CA 125 and doppler ultrasound[58,60,243] do not provide evidence that screening the general population for ovarian cancer with the present state of knowledge and available technology is useful or cost-effective. Before implementing a population-based screening programme the acceptability and feasibility of such a service, along with evidence of the effectiveness of such a test on reducing the incidence and mortality from these conditions are required. Bourne *et al.* screening self-selected women with a family history (one or more first-degree relatives) of ovarian cancer had a false-positive rate of 5.2% and a predictive value of a positive screen result of 7.7%.[244] The odds against finding primary ovarian cancer were 12 to one. A register for families with ovarian cancer in two or more relatives has been established by the UKCCC. No evidence exists that those families with predisposition to BRCAI locus on chromosome 17q would benefit from screening although screening of affected relatives in multiple case families aged 25–70 should be performed which would only involve very few scans. Bourne *et al.* suggested that there is a potential for transvaginal pulsed doppler ultrasonography, particularly with colour flow imaging, in the detection of endometrial cancers.[59]

There is no trial evidence to support population screening for these diseases. A feasibility study of a randomized controlled trial of ovarian cancer screening among women attending a breast screening centre in Reading,UK showed an uptake of 82% of eligible women.[245] The results indicated that the expected odds of being affected given a positive result in the general population would be about 1 : 12. A full RCT of ovarian cancer screening with mortality as the end point is needed to assess this and a multicentre European trial is currently underway and in a second feasibility study in Copenhagen, Denmark, not linked to the breast screening programme, the uptake was 64% with abnormalities detected in 12% and a false-positive laparotomy rate of 2%. Scanning of high-risk women is more feasible but the effect on survival has not yet been established.

Genital tract cancer

In general gynaecological oncology clinical research has been conducted in uncontrolled, non-randomized studies, with short follow-up periods, although more recently efforts have been made to produce overviews of treatment regimens with the planning of large multicentre trials. As there are few data based on randomized controlled trials evidence from special advisory groups and review articles form the basis of these recommendations (BIII).

Staging of the disease is central to appropriate management. The majority of staging procedures are low cost such as full blood count, urea and electrolytes, chest X-ray and others of intermediate cost such as cystoscopy, barium enema, intravenous pyelogram, CT scan and possibly MRI scans.

Ovarian cancer

The management of ovarian cancer was the subject of review by a SMAC panel (III).[246]

Early symptoms are vague and diagnosis can only be confirmed by a staging laparotomy by a consultant gynaecologist with full staging procedures included in the operation. Finn *et al.* indicated that only 30% of tumours were adequately staged.[247] Mayer *et al.*[248] and Eisenkop *et al.*[249] suggest that patients staged and treated by a trained gynaecological oncologist in the US have increased survival compared with those managed by a non-specialist but control for other factors associated with oncological care was not considered.

The standard surgical procedure for the disease is total abdominal hysterectomy, bilateral salpingo-oophorectomy and omentectomy along with debulking of the tumour (BIII). Early stage disease (IA and IB) in which the tumour is well differentiated and removed completely requires no adjuvant therapy but if the tumour is greater than stage I or poorly differentiated, chemotherapy may be beneficial. Residual disease after surgery also responds to chemotherapy, particularly using platinum and its analogues, especially carboplatin but quality of life can be a major problem (AI). There are no gynaecology-specific quality of life measures to assess this aspect of therapy. Palliation is a major aspect of care.

Germ cell tumours in the younger age group respond to specialist chemotherapy with tumour marker control and should be treated in centres specializing in this field. Borderline tumours are another special group for which referral to a specialist unit is recommended. As 90% of ovarian tumours present with disease that might benefit from chemotherapy it is important to have patients entered into randomized controlled trials. Those patients who are curable by surgery and who do not require further adjuvant therapy have not been clearly defined. The United Kingdom Coordinating Committee on Cancer Research is currently co-ordinating trials of adjuvant therapy. The MRC gynaecological cancer working party[250] in its overview of available data on adjuvant therapy suggest trials of at least 700 patients will be required. The Advanced Ovarian Trialists Group[251] undertook an extensive meta-analysis which was inconclusive but suggested that survival was enhanced by immediate platinum-based therapy and that platinum in combination was better than single-agent platinum when used at the same dose (AI). Cisplatinum and carboplatin appeared equally effective. There is evidence that doxorubicin confers highly significant survival benefit compared with cyclophosphamide and cisplatin alone. There is now a large study comparing the combination of all three drugs with carboplatin alone (ICON-2) in patients with advanced disease. Incorporating paclitaxel into first line and chemotherapy improves the duration of progressive-free survival and of overall survival in women with incompletely reseded stage II and stage IV ovarian cancer.[252]

Gillis *et al.*[253] reported that data from three ovarian cancer data sets indicated better survival in teaching versus non-teaching units but what 'teaching constituted in terms of multi-disciplinary treatment' was not stated.

Grant *et al.* in a retrospective analysis of clinical histories stated that patients with ovarian cancer who are managed by a specialized gynaecology unit are more likely to have adequate initial surgery and a longer median survival time.[254]

An audit of the surgical management of ovarian cancer[255] indicated considerable variation in the management in one region with optimal cytoreduction infrequently being achieved with substantially worse five-year survival rates than in other series.

Endometrial cancer

The most common symptoms associated with endometrial cancer are irregular and postmenopausal bleeding. The use of vaginal ultrasound scanning, along with colour flow doppler studies are an increasingly used method for the exclusion of benign intrauterine pathology as less than 10% of postmenopausal bleeding is caused by endometrial cancer. If the scan is suggestive of an intrauterine pathology

hysteroscopically guided endometrial biopsy, if possible under local anaesthetic, is a more sensitive diagnostic test than D&C.

The standard surgical treatment is total abdominal hysterectomy and there are claims that high energy radiation to the pelvic lymph glands reduces the recurrence rate (AII–2). The use of medroxyprogesterone acetate post-operatively is not indicated for women with disease confined to the endometrium with moderately to well differentiated tumour (AI).[256] Alternative agents such as tamoxifen have been shown to have modest activity. Women with poorly differentiated tumours or with extensive myometrial invasion should be considered for post-operative radiotherapy.

Cervical cancer

There is no uniformity in the UK in the diagnosis and management of microinvasive carcinoma of the cervix.[257] The frequency of recurrence, lymph node metastases and death is low and non-radical surgery appears to give satisfactory results (AII-2).[257] The procedures employed include cone biopsy and simple hysterectomy for women who have completed their family.

Those women with borderline 1a and 1b tumours, if fit for surgery, appear to benefit from a Wertheims hysterectomy which is essentially a hysterectomy with pelvic lymph node dissection and removal of a vaginal cuff. There is however no clear superior benefits of surgery over radiotherapy. Unfit patients and those with more advanced disease benefit from radiotherapy with or without adjuvant chemotherapy. In general until there is clinical trial evidence confirming the place of radiotherapy following surgery in node positive patients, clinicians may well continue to use it. Recurrence can be treated with chemotherapy or palliative radiotherapy. If recurrence occurs post-radiotherapy a Wertheims hysterectomy or pelvic exenteration for central recurrence could be considered. Cervical cancer is relatively resistant to chemotherapy but platinum based regimens have the greatest success with responses of 30% in patients with persistent or recurrent disease.[22]

Pelvic exenteration is used for cervix, vagina and vulval cancers and in specialist centres five-year survival rates are 50%. Although only about 6% of women treated for cervical cancer will experience a recurrence that is localized solely to the pelvis and are thus potentially curable by ultraradical surgery; few centres manage more than a handful of cases a year and cases should be referred to regional or supraregional oncology centres.[258]

7 Models of care

The needs of women for gynaecological services spans all sectors of the health service and currently there are no published evaluations of a model integrated service, or a model service specification.

This section identifies the main components that require incorporation into any strategy or service specification from patient information to the development of tertiary level services in order that an effective, efficient service is planned. The main considerations are patient information, monitoring patient satisfaction, shifts to primary care, day case surgery and MAS and guideline development for management of all level of services.

In each part consideration is given to both the content of the service and the training needs of health care professionals.

Although these models of service are based on the evidence of this assessment they are still only suggestions that require local adaptation and evaluation.

Overall gynaecological service assessment

Gynaecological services are provided in primary care and in hospital settings at secondary and tertiary levels. The involvement of gynaecology services spans primary prevention through to palliative care with a differing input from each sector in the range of activities. This assessment has examined the needs for services and the scope for shifts in service provision from the secondary to primary care sector, inpatient to day case surgery and conventional to MAS. There are no previous overall models of service from which to draw recommendations.

The overall models of care that are developed locally will be dependent on those factors analysed at a national level in this chapter and include the need for services, the current patterns of service and scope to move towards those practices identified as being both effective, cost-effective and acceptable to women. The development of these models will therefore be dependent on the ability to identify the needs (see section 10), assess current service provision (local corporate needs assessment and information) and to provide the training and resources required to deliver effective services.

A needs assessment group comprising gynaecologists, community gynaecologists, genitourinary medicine specialists, GPs, nurses, public health physicians and local users of the service, along with information and health economics support should identify the necessary information on which to base decisions on the service to be provided in both the primary and secondary care sector. This has been an approach taken in Scotland[26] which identified areas in which the service should change which included a shift to day case surgery, replacement of D&C with outpatient endometrial sampling techniques, developing urinary incontinence and gynaecological oncology services.

Components of service

Outlined in this section are the main components of service that should be considered. As with much of medicine gynaecological practice has not been developed using evidence-based medicine principles and recommendations have been made taking into account not only the often weak evidence of effectiveness but the views of practitioners and users of the service. The main components for consideration when developing models of service are listed in Box 4.

Box 4: Components to consider when developing services

- Patient information
- Monitoring patient satisfaction
- Shift to primary care
- Shift to day case and 'see and treat' surgery
- Shift to minimal access surgery
- Guidelines for management and referral by sub-category of the service including the development of tertiary level services

Information

Informing women about specific gynaecological conditions and their management, especially operative procedures and what to anticipate post-operatively, in a letter or leaflet, is necessary. These information leaflets should be co-ordinated across the levels of care, providing the same messages.

The RCOG has produced standards for communication for common surgical procedures and a series of patient leaflets on common gynaecological disorders. The Audit Committee consider communications vitally important and worthy of audit.[259]

Sensitive provision of information is considered an important component of the subfertility service and stress is reduced in those couples who feel involved in and in control of their treatment.[125]

Information regarding the prevention of lower genital tract infections and PID should be produced in conjunction with health education departments and GUM clinics and be in line with local Health of the Nation strategies.

Roberts[113] illustrated the need for more information provision for women about the menopause before its onset and about HRT.

Versi *et al.* [157] advocate the use of explanatory materials for women with urinary incontinence which could be developed in conjunction with the community incontinence advisors.

Many units have leaflets which discuss menstrual disturbances and their management. They provide information on the options for treatment and the effects of treatment. There are widely available books on hysterectomy for the lay public which address questions commonly asked by patients.

Gilling-Smith *et al.* showed that the use of advisory leaflets to patients on discharge from hospital significantly enhanced the service provided to women with miscarriage.[121]

Leaflets explaining what an abnormal smear means and how it is managed should be provided in colposcopy clinics and be written in conjunction with the local cervical cancer screening group. Information regarding cancer and palliative care should also be available and developed by the cancer centres in conjunction with services supporting women when they leave secondary care e.g. hospices and Macmillan nurses.

Monitoring patient satisfaction

In general within the NHS there are moves to monitor patient satisfaction with the service. The surveys need to have a representative sampling frame and a good response rate to be of benefit to those delivering care. The areas for questioning could include outpatient facilities, day case surgery, inpatient stay and follow-up. Satisfaction surveys should be an integral part of any service or intervention evaluation.

Shift to primary care

Although there are initiatives to shift services to primary care the evidence for their cost-effectiveness is usually not available and evaluation of these shifts needs to be an integral part of contract specification. Shifts can either be to management in a community setting by community gynaecologists, often linked with reproductive health services, management by health care professionals in general practice or management by secondary care gynaecologists in primary care. The latter has become an increasing trend in districts with fundholding general practices but the evidence for their effectiveness is lacking and some consider them to be an inappropriate use of resource, few practices having enough patients to sustain outpatient clinics.

Any shift from secondary care should have the aim of providing a more co-ordinated service with reduced duplication of the process of care which currently occurs when care is split between sectors. The shift should be facilitated by the development of guidelines to increase the appropriateness of care. This assessment has estimated that for every eight women consulting in primary care only one ordinary admission is generated.

The main conditions seen in primary care are detailed in Table 4 and consist of those relating to the management of genital infection, menopause, menstrual disturbances and pelvic pain. Unfortunately routine data in secondary care outpatient clinics are not recorded and it is not clear, other than through local audits, which conditions are more likely to be referred to secondary care. The case-mix will vary from unit to unit depending on the skills in primary and secondary care settings but is broadly similar to that seen in primary care. The HES data confirm that menstrual disorders and the menopause are prevalent conditions along with

non-inflammatory disorders of the cervix and utero-vaginal prolapse. The management of these conditions in primary care may reduce the need for referral to secondary care if it is effective or merely delay the need for secondary level intervention.

The conditions where a shift in service provision has scope include:

- initial management of subfertility, including endometriosis and follow-up after management in secondary care
- prevention and management of PID and lower genital tract infections
- management of the menopause
- medical management of incontinence
- initial management of menstrual disturbance
- management of chronic pelvic pain and PMS
- follow-up of abnormal smear results.

The shift of care to primary care has implications for GPs and practice nurses and until the opportunity costs of inpatient and community staff have been evaluated decisions should be deferred.[260] There are also considerable training issues to be identified for health care professionals in primary care.

Shift to day case and 'see and treat' surgery

The Audit Commission and local commissioning authorities targets for day surgery include a basket of gynaecological interventions: D&C, laparoscopy and sterilization and termination of pregnancy.

To achieve these targets dedicated day case facilities are required with skilled staff to enable the efficient use of theatre time and the appropriate support for women. Day case units need to improve management by developing an operational policy, adequate managerial control and good management information.[34]

As Morgan and Beech state the 'transferred costs' must not be overlooked when weighing up the benefits of short stay or day surgery.[123] Morgan and Beech state that the rationale for advocating a reduction in length of stay and increased use of day surgery is to increase efficiency by reducing the cost per case while maintaining quality of care.[123] Mechanisms to promote change in clinical practice styles include independent professional audit, peer review and clinical directorate involvement by clinicians. When assessing the level of resources released in hospitals from an expansion of day care, marginal costs rather than average costs are required. Day case surgery costs are typically 40–50% less, depending on the procedure, than inpatient treatment.[123] However the conclusions were based on studies in the 1970s and 25–30% may be a more realistic figure now, the majority of the difference being for the 'hotel' element.

The replacement of D&C with hysteroscopic sampling or vabra and pipelle endometrial sampling techniques provides the service with increased flexibility in that not only can the proportion of women having day care be increased but the procedures can be performed in outpatient clinics.

See and treat clinics for minor procedures have developed haphazardly but have the potential for reducing waiting times for procedures along with the concomitant reduction in anxiety for the woman. The service requires trained staff to operate the equipment along with training in resuscitation. The service could include diagnostic techniques such as colposcopy, hysteroscopy, endometrial sampling techniques and transvaginal ultrasound. Treatments could include those for cervical CIN and minor vaginal and cervical abnormalities such as cervical polypectomy.

The development of early pregnancy units have probably enabled women to be more efficiently diagnosed and treated.

Shift to minimal access surgery

It has been suggested by Royston *et al.*[261] that some form of accreditation after a recognized training scheme would go a long way towards allaying the fears of the public over MAS. Training will be costly but litigation should be reduced and the royal colleges should be responsible for maintaining standards of teaching on recognized courses, setting criteria for accreditation and supervising a national audit of all laparoscopic procedures. The RCOG report on training in gynaecological endoscopic surgery[23] indicates how the college proposes to establish a MAS training and certification committee which will formulate criteria certification for different levels of complexity of MAS which should be a prerequisite to practising in the area (Appendix V).

Subsequent to the MISTLETOE (minimally invasive surgical techniques, laser endothermal and electroresection) survey in 1993/94 by the RCOG guidelines for good practice have been reported[262] on behalf of the British Society of Gynaecological Endoscopy. These include procedures, follow-up and training issues.

Few procedures in gynaecological practice have been subject to rigorous clinical and economic evaluation and purchasers should specify that new techniques be used within an evaluative framework whether this be locally developed or as part of a multicentre trial.

Whilst MAS is not the major intervention for a particular condition the benefits to the service in terms of reduced lengths of stay will not be realized and as discussed in section 2 the benefits of MAS on reducing length of stay may not be as dramatic as claimed. The main areas where MAS has a significant role is in emergency surgery[24] and alternatives to hysterectomy.

Guidelines for management and referral for sub-categories of service

Specific models of care for the sub-categories of the service are detailed below. There should be a move towards combined, co-ordinated guidelines for the management of gynaecological conditions which should include the relevant health care professionals in secondary care along with primary care doctors, nurses and therapists. These guidelines can be audited and monitoring specified in the gynaecology contract. As outlined in the section on effectiveness the strength of evidence is often weak which does make guideline development problematic.

Subfertility

Although not specifically within the remit of the gynaecologist or the gynaecology service there is a need to reduce the prevalence of those risk factors associated with subfertility and for contracts to be placed with primary care, family planning units, gynaecology and GUM units for screening of and treatment of sexually transmitted diseases such as chlamydia which may account for up to 14% of subfertility.[263] The Health of the Nation targets should go some way to addressing this problem.[25]

The comprehensive subfertility service for a population of 100 000 will result in around 100 referrals and cost around £300 000 per year, including the additional costs for neonatal care. The total costs to the NHS, which also include administrative and accommodation overheads and the extra neonatal intensive care costs have been estimated to be just under £900 000 (1992 prices).[2]

District subfertility services should develop guidelines for referral and treatment with specialist tertiary centres in order to enhance the continuity and quality of care and to keep tight contractual control on activity and costs. Emslie *et al.* indicated through a randomized controlled trial that the receiving of guidelines led to improvements in the process of care of infertile couples within general practice.[264] This effect was enhanced when the guidelines were embedded in a structured infertility management sheet for each couple. The Royal

College of Obstetricians and Gynaecologists has also recently published guidelines for the specialist management of subfertility.[265] The document provides an overview of current practice in infertility with a statement of good practice.

Agreed protocols should be developed which include increased primary care involvement in semen analysis and mid-luteal progesterone estimations. In secondary care subfertility should have a dedicated clinic with allied facilities such as HSG, laparoscopy, semen analysis with the support of a reproductive endocrinology service. Those clinics offering donor insemination and ovulation induction require appropriate laboratory and scanning facilities.

Resources currently allocated to tubal surgery could be more efficiently used if reallocated to a more appropriate mix of tubal surgery for women with less severe disease and assisted conception for those with more severe pathologies.

Tertiary centres have a responsibility for referrals from primary and secondary care along with a role in the organizing and audit of regional services. They should offer donor insemination, ovulation induction, tubal surgery, IVF and have links with endocrine laboratories.

It is estimated there should be at least one secondary care clinic per 500 000 population and one tertiary centre per 2 million population.

Fertility services for people belonging to ethnic minorities should be based at centres which are near concentrations of ethnic populations. They should aim to meet fertility needs within the bounds of a person's culture. This service development will give specific practitioners with an interest in fertility the chance to develop a lead role in ethnic health care.[1]

Redmayne and Klein[266] discuss how IVF has become one of the few examples of explicit rationing with three of six purchasing authorities studied deciding against buying the service. The decisions reflected local factors such as the presence of local providers and the views of the public and health professionals. Purchasers should be cognizant that if services are not provided locally that access to out of district centres is feasible for couples. Bull and Lyons[267] describe how purchasing IVF services in East Sussex was developed. A district group drew up clinical policy to govern access to the service which included such factors as the couple being in a stable heterosexual relationship and having no living children and with a limitation of two cycles per couple.

Pelvic inflammatory disease and lower genital tract infection

Investments in prevention of lower genital tract sexually transmitted diseases may be the most cost-effective way to reduce eventual upper genital tract infection, including PID and subsequent tubal infertility. The Health of the Nation key area of sexually transmitted disease has targets relating to organisms relevant to PID and the *Key Area Handbook*[268] expands upon the strategies to be developed. It indicates the need for collaboration between all possible agencies involved with the at-risk population and includes GUM clinics, family planning services, primary health care teams, drug agencies, schools and other agencies, which presumably includes the gynaecology services.

Ashton *et al.* make specific recommendations for public education.[1]

Protocols for the management of acute and chronic PID should cover diagnostic serology and microbiology, diagnostic laparoscopy and appropriate antimicrobial therapy. A meta-analysis of trials of antibiotics to treat PID indicated there was a lack of uniformity among studies regarding diagnosis, care and follow-up. Pooled cure rates ranged from 75–94%. Doxycycline and metronidazole was the least effective regimen (75% cure rate). Ciprotoxalin was the cheapest.[133] Clinical treatment of acute PID is still likely to be inappropriate in many and inadequate for chlamydia in much of the remainder.

Endometriosis

It is difficult to assess the current state of service provision and hence the changes that could be suggested as endometriosis is not coded separately. Protocols should be developed between primary and secondary care sectors to enable the following to be possible:

- diagnosis is by laparoscopy, hence early referral from primary care to the secondary care sector is necessary
- treatment should be initiated by gynaecologists with re-prescription through primary care
- there is a place for follow-up of women in primary care as well as in the gynaecology department and shared protocols should be developed. These may be part of the protocol developed for the management of subfertility.

Menopause

Whether women are seen in general practice, gynaecological outpatients or a specialist menopause clinic the principles of management remain the same. Further investigation is rarely required prior to prescribing HRT. Women should be assessed about three months after commencing therapy. It is considered that the hospital clinics could not cope with the information and therapy needs of the population. These need to be given consideration of the development of menopause clinics in the community, particularly in family planning and well woman clinics.

The important elements of the service are adequacy of information and education, inclusion of the partner in decision making where appropriate and monitoring of menopausal symptoms.[267,269] Information from the Osteoporosis Society indicates that within the NHS there are nine clinics in London, all at teaching units and 23 in the rest of England, of which the majority are in teaching units. Criteria for referral to secondary care clinics should be developed and include women with an early menopause, increased risk of osteoporosis, cardiovascular disease and severe or uncontrollable symptoms. Such clinics should link with research activities such as multicentre clinical trials of therapy and basic research into the menopause.

Urinary incontinence/utero-vaginal prolapse

- **Primary care** An investigation protocol should be in place which includes history, examination, mid-stream urine analysis and the use of the pad test and frequency/volume charts.
- **Secondary care** Diagnosis should include urodynamic investigations to distinguish between stress incontinence and detrusor instability. The evidence for non-surgical interventions for stress incontinence is not strong but depending on the woman's wishes and fitness for surgery should be an available option. Colposuspension and sling operations have the best cure rates.

There should be consideration of referring complex cases and repeat operations to centres with facilities for more sophisticated investigations and with expertise and a high volume of surgery for such women.

Support from continence advisors should be available. The Scottish Needs Assessment Programme[26] estimated that five physiotherapists should be employed to develop the management of urinary incontinence for a female population of nearly 500 000. There is no conclusive evidence however that physiotherapy is effective and there are problems with the monitoring of improvement of symptoms whilst receiving therapy (see section 5).

Menstrual disorders

Guidelines for assessing menstrual disorders in primary and secondary care should be developed locally and include a structured history and estimation of haemoglobin or serum ferritin concentrations. Further endocrine investigations should be undertaken according to guidelines and completed as efficiently as is feasible. The development of guidelines for the medical management of menstrual disturbance in primary care would appear to be a priority. General practitioners should offer at least one course of effective drug therapy prior to referral for surgical treatment.[115] The cost implication in shifting prescribing habits from the use of norethisterone to tranexamic acid is estimated at 20% of the drug costs but as norethisterone is ineffective in the short term, money spent on it is wasted; in addition many women treated in this way would be referred for surgery. It is also estimated that if tranexamic acid were to replace all other drugs used there would be a net saving of at least 10% on the total drug bill for menorrhagia.[115] Drug use in primary care should be monitored to identify prescribing of relatively ineffective drugs.

Criteria for using D&C should be developed and a shift of service to hysteroscopy or other endometrial sampling techniques agreed. The increased use of day case services and see and treat clinics should be developed to enable the Audit Commission targets to be met.[34]

A shift from TAH to TCRE should be agreed. Patients undergoing such procedures as LAVH should be enrolled into trials as the evidence for their use is not established.

The Effective Health Care report[115] recommends that all options should be discussed with the woman, allowing her to make an informed choice.

Pelvic pain

Guidelines should be in place to exclude specific gynaecological conditions and non-gynaecological causes of pelvic pain.[270] Assessment should include laparoscopy. The trial evidence does not allow conclusions to be drawn on specific therapies but the need for adequate explanation and possibly counselling should be considered, particularly if hysterectomy is to be considered.

Premenstrual syndrome

Currently it is assumed that the majority of women with PMS are seen and treated in primary care. Given the current state of knowledge regarding the definition and treatment it seems to be appropriate for the majority of women. Referral to gynaecology clinics should enable the use of standardized diagnostic scales in the secondary care settings. Women should be treated following guidelines and entered into trials where appropriate.

Ectopic pregnancy and early pregnancy loss

Both in the US and UK failure of the pregnant woman with an ectopic pregnancy to seek medical attention contributes to the death rate. Protocols should be developed both in primary care, A and E and gynaecological departments for the diagnosis of ectopic pregnancy.

The ability of GPs to perform pregnancy tests to exclude the possibility of an ectopic pregnancy should be considered. All junior medical staff should be made aware of the possibility of an ectopic pregnancy in a woman of reproductive age who presents with pelvic pain or bleeding. Direct access to a diagnostic ultrasound scan is a priority which gynaecological departments should consider along with protocols for referral of women with miscarriage or possible ectopic pregnancy.

Referral to an early pregnancy assessment unit with diagnostic tests and skilled personnel appears to be efficient, although the cost-effectiveness of such a service has not been established.[214] (D Hamilton-Fairley, personal communication, 1996.)

Training of gynaecologists to perform laparoscopic surgery should be in line with RCOG recommendations for MAS training, with the aim of reducing the proportion of laparotomies performed for ectopic pregnancies (Appendix V).

Appropriate senior level anaesthetic support should be available for the resuscitation of these women.[203]

Appropriate support services should be available to advise the woman on future contraception and to cope with bereavement.

Cancer of the cervix – secondary prevention

The Royal Colleges of Pathologists, Obstetricians and Gynaecologists and General Practitioners issued guidelines for good practice when setting up cervical cancer screening programmes.[271] These have been updated by an NHS cervical screening programme working party.[27,272] The NHS Cervical Screening Programme national co-ordinating network was set up to co-ordinate and promote research, the development and co-ordination of educational and professional development for women and health care professionals, running the service and to promote measures which would improve the quality of the service and to develop information systems. A programme matrix has been developed which provides a framework to ensure a comprehensive programme is developed. Recommendations from these bodies along with salutary lessons that can be learnt from a case review of 100 cases of invasive cervical cancer[273] outline main areas the service should be concerned with of which gynaecology services are a part, particularly for the follow-up of abnormal smears, management of CIN and invasive disease. Also the Europe Against Cancer Programme has published guidelines for quality assurance in cervical cancer screening.[219]

The Health of the Nation *Key Area Handbook on Cancer*[268] provides useful checklists of the various elements of a successful screening programme and these are expanded on in this assessment (Appendix VI).

- **Defined target population** Based on accurate family health service authority (FHSA) registers which will allow a call/recall system to operate. In 1985 the Department of Health gave districts the responsibility of organizing computer management schemes in conjunction with the FHSA. In 1988 the age limits for inclusion in the system were changed to 20–64. Whilst the FHSA GP lists may be reasonably accurate in many parts of the country there are particular problems with inner-cities where women with an increased risk of cervical carcinoma often reside. A study in an inner-city district has estimated that only 31% of those called for a smear by the FHSA fulfilled the criteria for being called.[274] The main reasons for not fulfilling the criteria were that the woman no longer lived at the address or that the address was incorrect, that she had had a smear in the last three years or was older than 65. Integral to the whole process of call/recall is the computerized age–sex register maintained by the FHSA which may not be of sufficiently high quality for this purpose in deprived inner-city areas with high mobility of the population. The mobile population is less likely to register with a GP and the GPs may fail to inform the FHSA of changes known to them. Recent Korner KC53[275] and KC61[102] (pathology laboratory activity) data (1991/92) indicate that the number of smears performed has increased to 4.5 million, with a response rate to screening of 48%.[275] This increase has an impact on gynaecology outpatients, colposcopy services and operating theatre utilization.
- **Screening the female population at three- to five-yearly intervals**[227] Screening takes place in the age group 20–64. The Department of Health[276] advised districts to screen women aged 20–64.

Elkind *et al.* reported that 50% of districts operated five-yearly programmes, 29% three-yearly and 21% a combination of three- and five-yearly programmes.[272] The current coverage of screening is 80% in the target age group, with a considerable variation between regions from 64% in NE Thames to 88% in Trent and Wessex.[275] As 40% of deaths occur in women over the age of 65 it is necessary to put additional effort into ensuring that there is a good screening uptake by older women. There should also be no upper age limit for women who have never had a smear.

- **Personal invitation to women and health education** An invitation letter is considered fundamental to good coverage which gives the women a choice of location for the smear test. 86% of districts give this choice but only half state where these are.[272] Only 55% of districts include health leaflets routinely and very few ethnic minorities whose cultural and religious beliefs may not make the offer of screening acceptable are targeted. A randomized controlled trial has failed to show any benefit from counselling women with an abnormal smear result (CDA Wolfe, personal communication, 1996).

The importance of reducing risk factors associated with cervical cancer needs to be stressed to women. With advances in the knowledge of the disease and its aetiology, different information may be given by health care professionals in the future but at present discussion of barrier methods of contraception and the possible association of cervical cancer with heavy smoking is advisable. Education of doctors and patients is inadequate and there is a need for a sustained programme of public and professional learning aimed at ensuring that the potential benefits and requirements of an effective screening programme are appropriately understood. Education of the women at risk towards an understanding of the objectives of the programme is essential. This is clear from the high incidence of invasive cervical disease occurring in women who have never been screened.[272] Efforts must be directed to ensure that all women, including those of lower socioeconomic status, are offered screening programmes. Majeed *et al.* illustrated how routine data from FHSAs practice indicators of deprivation could explain over half the variation in cervical smear uptake rates in terms of census and FHSA data.[277] These variables may have a role in explaining variations in performance of practices and in producing adjusted measures of practice performance. Practices with a female partner had independent and significant effects on uptake rates.

- **Quality of the cervical smear test** There are two components to the false-negative rate of cervical smears. 10–15% of smears are reported as negative because either cells were not exfoliated or were not picked up by the person taking the smear.[56] This may be partly dependent on the type of spatula used to take the smear, certain designs being more appropriate in women with varying shapes of cervix. In a study comparing cytological results with colposcopic biopsy findings, Giles reported a 58% false- negative rate on cytology for small lesions (less than two quadrants of the cervix).[278] This observation is of importance as 6% of the general population have these lesions on smear.

The National Audit Office found that although laboratories were committed to the principles of external quality assessment, two of the three regions visited did not have it in place. They recommend that purchasers should specify laboratory fail-safe mechanisms in their service contracts and require regular reports on their performance.[279] Organization of training programmes, proficiency-testing and systems of quality control are needed. A uniform nomenclature for both cytology and histopathology is recommended.

- **Follow-up of abnormal smears and implementation of treatment (fail-safe protocols)** In the UK a disturbingly high proportion of women found to have abnormal smears have not been adequately investigated or treated.[280] Ellman and Chamberlain found that 13% of patients with invasive cancer were also not followed up. Elkind *et al.*[273] showed that 43% of district pathology laboratories highlight abnormal smear results for GPs and 93% of districts have fail-safe systems to ensure appropriate follow-up of abnormal smears. Every screening programme should designate an individual as responsible for its management. Protocols for the management of women with abnormal results should be drawn up. There are guidelines on fail-safe action[28] for GPs, clinics, laboratories, the FHSA and the programme manager.

Salfield and Sharp[29] have calculated the demand for colposcopy services based on:

- number of women screened
- clinical policy for the referral of women with non-negative smears

- the rate and category of non-negative smears
- clinical referrals to the service.

They estimated a demand of 1320 for diagnostic colposcopy per 100 000 women.

They then estimated demand for treatment dependent on:

- number of women having diagnostic colposcopies
- % discharged after one colposcopy assessment
- % discharged after follow-up colposcopy
- average number of attendances/woman for treatment: 156 cone biopsies, 39 inpatient laser treatments, 584 outpatient laser treatments.

If the average number of lasers/woman = 1.04 the total number of treatment sessions = 607. Demand for follow-up would be 2117.

Colposcopy services have in the main been added to existing gynaecological services and as such are not in purpose built environs. A colposcopy service should consider the following recommendations:

- adequate information provision about colposcopy and treatment prior to appointment in the clinic along with speedy communication of results and management plans
- dedicated space within the clinic for equipment and resuscitation
- a lead clinician and nurse. The clinic numbers should be high enough to maintain the skills of the staff and be in the region of 400 per year. Practitioners should have been on a colposcopy course
- a high proportion of treatments should occur as outpatients under local analgesia
- guidelines for follow-up and communication with primary care.

Genital tract cancer

Although there is no evidence from trials of gynaecological cancers the specialist reports and the expert advisory group on cancer[95] all advocate the concentration of oncology services. This would appear necessary on several counts. A critical number of cases of each type of gynaecological cancer would be referred to enable appropriate training of surgeons, radiotherapists, oncologists and nurse specialists. This quantity of work would also enable audit to occur and for patients to be routinely randomized to trials. Even within these centres there may not be the expertise to deal with the very rare tumours and the identification of supra-regional centres for referral should be in place e.g. chorionic carcinoma. Details of the expert advisory group on cancer's consultation document are outlined in Appendix VII as they will determine the model of service in the future, although local adaptations may be necessary.

The RCOG's subspecialty training committee advises on a number of subspecialties of which gynaecological oncology is one. They recommended services be concentrated at regional or sub-regional referral centres with gynaecologists, oncologists and radiotherapists working together as multi-disciplinary teams. Colorectal and urological surgical expertise should be available.

There is a need for patients to be randomized into trials and for clinicians to be aware of the trial options. Similarly the audit of a unit's gynaecological oncology performance should be undertaken. It will be necessary to specify in contracts that guidelines for gynaecological malignancy management be drawn up and audited. This has successfully been undertaken in South East Thames.[281]

8 Outcome measures

This section outlines possible areas for development of outcome indicators. There also needs to be development of proxy outcome measures in areas where the evidence of effectiveness is strong e.g. the proportion of D&Cs performed in women younger than 40 could be a marker for the management of menstrual disorders. The current outcome assessments include the following.

Subfertility, PID and lower genital tract infections

- The incidence and prevalence of sexually transmitted diseases would to some extent provide an indication of the effectiveness of preventive services. However as outlined in the section on PID, these data do not exist and routine statistics underestimate the met need and do not quantify the extent of sub-clinical PID. The use of DoH returns from GUM clinics indicates to a certain degree the need for services and the outcome of preventive strategies.[36]
- There are several outcome measures used by researchers and subfertility units but the most useful reproductive outcome for health care planners is the maternity rate, although it is rarely reported in the literature.[42] Purchasers should also take into account the characteristics of the women treated, the length of follow-up and number of treatment cycles.
- Measurement of mortality and morbidity associated with investigation and treatment for subfertility, conception and delivery should be in place, including perinatal and neonatal events (through the national Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI)).

Menopause

- The prescriptions for HRT per 1000 women aged over 50 would provide a guide to the uptake of services and the consequent benefit.
- Quality of life measures have been employed in assessing the effectiveness of HRT but require further development.[154]
- Routinely available mortality data for fractured neck of femur and cardiovascular disease are proxies for risk associated with the menopause.

Urinary incontinence/utero-vaginal prolapse

- There are problems with the subjective and objective measures used to monitor success of interventions. Subjective patient questionnaires, urethral closure pressure and the position of the bladder neck and proximal urethra within the abdominal cavity would be suitable measures at an individual patient level.

Menstrual disorders

- Menstrual disorders can result in physical, psychological and social impairment of women but surprisingly little is known about the benefits of the various treatments in terms of improved health.
- The SF-36 has been shown to be a valid and reliable measure of general health status in women with menorrhagia.[282] Ruta *et al.*[283] have developed a patient-administered questionnaire which is a valid,

reliable measure of health status. This tool can be used to guide selection for treatment and in the assessment of patient outcome following treatment.

- A pictorial blood loss assessment chart has been developed which holds promise of increasing the precision of assessment of the severity of menorrhagia.[284]

Ectopic pregnancy

- Ectopic pregnancy is strongly associated with PID, which in turn is related to sexually transmitted disease. The Health of the Nation targets, if achieved, will reduce the number of women at risk of ectopic pregnancy.
- The number of maternal deaths attributed to ectopic pregnancy reported to the Confidential Enquiry at a national level may provide indicators of substandard care.[204]

Genital tract cancer – secondary prevention

- Cervix: the registration of CIN at the cancer registries.

Genital tract cancer

- Registration and survival rates by district are reported by stage and site through cancer registries.[104]

9 Targets

Section 7 outlines the shifts in service that are required but due to variations in the current levels of service provision it would not be sensible to set targets apart from those based on current local provision of gynaecological services. Targets could be set for the setting up of a district working party, development of guidelines for the shift of services to primary care, the use of day case surgery and MAS and the development of tertiary level services such as cancer centres. There are however specific targets that can be currently considered in various of the sub-categories of the service.

Subfertility

- Each district should have access to a designated clinical team responsible for the initial investigation of infertility and to specialist IVF or GIFT treatment at a regional or inter-regional level.
- Each district to purchase facilities, or referral of couples for artificial insemination by donor.

Pelvic inflammatory disease and lower genital tract infections

The Health of the Nation targets include several in the area of HIV/AIDS and sexual health that are relevant to PID and lower genital tract infection.[285] The targets are:

To reduce the incidence of gonorrhoea by at least 20% by 1995 (baseline 1990), as an indicator of HIV/AIDS trends. This represents a reduction from 61 new cases per 100 000 population 1990 to no more than 49.

The Faculty of Public Health Medicine have set targets for sexually transmitted diseases.[286]

- A target of 75 cases of chlamydia infection per 100 000 population aged 15–64 by 2000. It would appear from the 1992 returns that this has been achieved already.
- By the year 2000 all middle and secondary schools should, as part of a wider programme of health promotion, provide education on safer sex behaviours and on sexually transmitted diseases and the services available for their treatment.
- Health education must be appropriate to the age and culture of those being targeted and must be conducted in such a way that it does not encourage sexual activity among young adolescents who are not yet sexually active.
- By the year 2000 all health care providers diagnosing sexually transmitted disease should undertake contact tracing as a matter of routine.
- By the year 2000 all physicians and other relevant staff should receive appropriate training in counselling for the prevention of HIV and other sexually transmitted diseases.

Genital tract cancer

The Health of the Nation targets for cervical cancer are:

To reduce the incidence of invasive cervical cancer by at least 20% by the year 2000 (baseline 1986) from 15 per 100 000 population in 1986 to no more than 12 per 100 000. Each district to develop a screening service which has the components outlined in the models of service.

Local targets are essential as populations differ with regard to mobility and ethnic groups and have to be agreed across the sectors contributing to the service locally.

The national target will be achieved by taking the local minimum contribution based on the 20% reduction of their 1986 ICD 180 registrations.

Interim suggested targets for Health of the Nation targets are:

- 90% women aged 20–64 invited for screening
- 80% women aged 20–64 adequately screened at least five-yearly
- all districts to consider the use of the Exeter FHSA system for call/recall programmes.

10 Information

The conditions encompassed in this needs assessment are detailed in Appendix I. These include the ICD 9 codes (Appendix I) which are currently used for reporting primary and secondary care activity and remain similar in ICD 10. There have only been minor changes to the coding for ICD 10 which will only help to clarify certain diseases e.g. carcinoma *in situ* of the cervix and CIN I-III. Diagnostic related groups and health care resource groupings (Appendix I) are appended as they will in the future provide more relevant groupings for commissioning agencies; dividing disease groupings into those with and without interventions and into those requiring minor, intermediate and major levels of intervention.[287,288] The HRGs are groups of finished consultant episodes (FCEs)/cases which are expected to consume similar amounts of resource. These groups are defined on the basis of procedure and diagnoses and each group contains cases with a range

of procedures and diagnoses. These are currently coded using ICD 9 and surgical OPCS4R codes. Information on the principal and secondary procedures and the primary and secondary diagnoses, together with information about age, specialty and the method of discharge, is used to assign each record to a particular HRG. The limitation of HRGs is errors in coding and a lack of detailed costing information. The HRGs for gynaecology are divided into procedure HRGs (m1–m13) and medical HRGs for episodes without procedures (m14–m31).[289] The HRG version two *National Statistics for England* contains 10.2 million records covering all NHS inpatient episodes. There are concerns about the quality of the data which are derived from HES. This assessment uses version two which is compiled using the 1993/94 financial year data.[290]

The corresponding surgical OPCS4R codes (three-digit-P-lower female genital tract, Q-upper female genital tract) are similarly enumerated (Appendix I).[291]

The only recent source of data available on the demand for gynaecological consultation is the fourth national survey of morbidity in general practice[31] which is a survey of selected practices in England and Wales. Data are collected by ICD 9 category. Appendix II details the consultation rates per 10 000 person–years at risk by ICD 9 code and the current service availability is considered in more detail in section 5.

There are no data on rates of referral to secondary care for diagnosis and treatment. The only data recorded are the hospital episode statistics (HES) which are published annually. This assessment utilizes the UK HES data for financial year 1993/94.[31] The details of HES for the gynaecology services are considered in section 5.

Unfortunately the only routinely available information in both primary and secondary care is currently by ICD which restricts the analysis in terms of resource groups. Using the routine HES data it is not possible to assess the appropriateness of the interventions as cross-tabulation of ICD and OPCS4R codes is not routinely performed. This is particularly relevant when there are no baseline data on the need for services and hence intervention rates alone are meaningless.

The HRG data are derived from HES. There are inconsistencies between the data sets such that total admissions per 100 000 females remain in doubt. The HRG data are firstly allocated to a procedure code and if admitted and no procedure undertaken allocated a medical code. Appendix III data require further analysis to determine why 16% of women were admitted to hospital without a procedure.

- The number of women admitted with cancer and pregnancy related problems without procedures is the major concern.
- In the HRG 1993/94 data supplied by the case-mix office the statistics for HRG by specialty also includes some codes which are suspect: n04: other maternity events, n01: normal delivery, n09: neonatal: low dependency along with f codes which are not gynaecology specific.[290]
- There would appear to be a need to train the relevant clerical and clinical staff to code diagnoses and operations accurately and completely.
- Routine data collection of outpatient attendances by diagnosis should be considered as it is not currently possible to assess the referral patterns of gynaecological problems to secondary care and the proportion of gynaecological outpatients that are subjected to intervention.
- Routine collection of data on 'see and treat' patients should be considered and either incorporated into day case data or produced separately.

Specific concerns regarding the categories of the gynaecology service are outlined as follow.

Pelvic inflammatory disease and lower genital tract infections

- More rapid assimilation by the reporting system of national GUM clinic returns is required. The use of electronic data capture and transfer systems would speed up reporting, and make the collection and analysis of the data easier.
- Surveillance systems should be instituted for monitoring patients with STDs seen by health service providers other than GUM physicians in order that all local cases are captured.
- The current RCGP and HES categories do not allow sensible clinical groupings to be made.

Early pregnancy loss

- Data on medically managed miscarriage should be collected.

Genital tract cancer

- Cancer registration data and SMRs can be obtained from cancer registries and are published by OPCS annually. The accuracy of death certification may be a constraint in using this indicator as coding errors, particularly between the cervix and other parts of the uterus are known to occur.
- A future indicator of the screening service could use cancer registry data as registrations of carcinoma of the cervix become more accurate and timely. Standardized registration ratios could be used as proxies for incidence. If cancer registration data are used constraints such as the completeness and accuracy of ascertainment[292] and the length of time to publication of the data by OPCS need to be considered.

Because of the small number of events in each district or region the 95% confidence intervals of the SMR or standardized registration rates will be wide. Consequently interpretation of these data has to be cautious. The SMR for carcinoma of the cervix varies significantly between regions which may reflect differences in the risk of cervical cancer incidence and/or case fatality. Interpretation of the SMR should be in conjunction with data on risk, such as registration rates. The SMR may also be affected by effectiveness of management of abnormal smears and invasive disease in a district or region.

- The Health of the Nation *Key Area Handbook* on cancer recommends three-yearly registration rates be estimated. For carcinoma *in situ* (ICD 233.1) there is known to be variability between regions and whether this is artefactual is not known.
- Returns and annual analyses of the number of smears, number of abnormal smears are reported in the DH(KC53 and 61) data.

The Health of the Nation *Key Area Handbook* on cancer recommends the following information be prepared annually on the women aged 20–64.

- The proportions of women adequately tested in past systems, ceased from recall, with no computer record, presumed non-responders and waiting times for cytology.
- Currently the cancer registries use a generic stage for all sites. The FIGO gynaecology staging scheme should be adopted for these sites or algorithms developed to convert them accurately.

11 Research

This section outlines broad and specific areas where research is required to enable the need for gynaecology services to be estimated more accurately and the effectivess of interventions assessed in controlled trial settings. The general research themes include the following.

- The incidence and prevalence of the main sub-categories of gynaecology in the UK are unknown and no overall rates of gynaecological disease have been estimated. Such studies would enable needs assessments to be based on more certain grounds.
- With a shift of service provision to primary care being recommended centrally for certain parts of this service, evaluations of this shift and its implications on training, resources and outcome should be undertaken.
- The impact of MAS on service models and resources requires evaluation.

Obstetricians and gynaecologists have been exposed to evidence-based medicine techniques for many years, the forerunner to the Cochrane Collaboration being the National Perinatal Epidemiology Unit at Oxford, which involved clinicians in trials of a wide range of maternity issues.

- This chapter illustrates how little evidence-based medicine data are available for gynaecology and how new techniques are still introduced without formal evaluation.

Areas for research for the various sub-categories of the service are outlined.

Subfertility, PID and lower genital tract infections

- Further detailed epidemiological studies are required to assess the feasibility of preventive strategies to reduce the prevalence of sexually transmitted diseases. This could include defining more precisely the prevalence of PID using relatively cheap, insensitive but specific tests.[293] The evaluation of screening programmes to detect PID should be considered in the UK.
- The development of a vaccine for chlamydia is required.[294]
- The assessment of the prognostic value and cost-effectiveness of different diagnostic techniques is required along with the development of protocols for their use.
- The extent of infertility and fertility problems in the general population requires estimation. Gunnell and Ewing[295] demonstrate how a postal questionnaire can be used to inform purchasing needs for subfertility. However they surveyed women only between the ages of 36–50. There is a need for well designed randomized controlled trials to evaluate the effectiveness of the many medical treatments for different causes of subfertility, particularly for endometriosis.

Endometriosis

- Research into the aetiology and natural history of endometriosis is required. Dose response studies, not only for the new GnRH agonists but also for danazol are necessary.

Menopause

- The influence of ethnicity, diet, physical exercise and smoking on the hormonal status of the menopause require study.
- Substantial RCTs of postmenopausal HRT should be set up, as most of the recommendations to date have been made from observational studies and it is possible that the reported benefits are attributable to lack of similarity between users and non-users. Particular aspects that could be researched include cardiovascular disease and cancer. Assessment of the most effective methods of delivery (e.g. intrauterine, transdermal) of HRT are required.

Urinary incontinence/utero-vaginal prolapse

- Evidence for the effectiveness of interventions for incontinence using multicentre trials is required.
- The aetiology and mechanisms of prolapse require elucidation.
- The effectiveness of HRT in reducing prolapse rates requires assessment.

Menstrual disorders

- Evaluation of different strategies to help women to cope with their perceived heavy periods in order to avoid unnecesary drug or surgical treatment should be undertaken.
- Further assessment of the management of menorrhagia by medical regimens is required using RCTs.
- Long-term follow-up trials of MAS for menstrual disorders should include detailed cost-effectiveness analysis.
- The outcome of repeat endometrial ablation requires investigation.
- Trials of medical treatment versus MAS procedures are required, assessing effectiveness, cost-effectiveness in terms of blood loss, quality of life and patient acceptability.
- Investigation into whether women prefer surgical or medical treatment, or resultant complete amenorrhoea or light bleeding for menstrual disorders should be undertaken.
- Evaluation of 'see and treat' clinics for menstrual disorders should be undertaken.
- An accurate, acceptable and objective method for the routine measurement of menstrual blood loss should be developed.
- Exploration of the different mechanisms and approaches to providing information to woman on treatment options is required.

Premenstrual syndrome

Budeiri *et al.* reviewing the entry criteria and scales for measuring treatment outcomes for PMS, suggest that regulatory authorities could perhaps provide guidance to which scales would be acceptable when drugs for clinical trials for PMS are sumbitted for assessment.[52] Consensus is required given the poor performance of most current treatments of PMS.

Early pregnancy loss

- Trials of medical management versus surgical evacuation are required, including patient acceptability.
- Trials of medical management of miscarriage in primary care should be considered.
- Formal evaluation of early pregnancy assessment units is required.

Genital tract cancer – secondary prevention

Cervix

The current national priorities for health service research in the Health of the Nation *Key Area Handbook*[267] are as follow.

- Evaluation of the effectiveness of the current programme, including issues of cost-effectiveness and efficiency.
- Development of programmes/strategies to establish and monitor standards for screening.
- Evaluation of the effectiveness of different screening intervals including the extra costs of more frequent screening and building on existing estimates, to feed into policy development.
- Identify which groups of women do not come forward for screening. This information would help formulate strategies to improve uptake.
- There is a need for studies to assess the most cost-effective ways of managing abnormal smears.
- A trial to address the issues of the management of women without CIN and possibly CIN I is required.
- Evaluation of the reasons for the regional variations in carcinoma *in situ* registrations.

Other sites

- Multicentre trials of the effectiveness of screening for ovarian and endometrial cancers on survival are required before the development of screening services.

Genital tract cancer

- There will be a need to evaluate the quality of gynaecological oncology services in light of the Expert Advisory Group's suggestions. Measures to assess the co-ordinated service and the type of hospital need to be developed. Health service researchers have failed to determine what aspects of health service delivery influence the variations in survival from cancer, if indeed they do. Research aimed at assessing the quality of care and outcome should be a priority.
- The evaluation of guideline adherence in this subspecialty area of gynaecology and its effect on outcome requires investigation.
- For ovarian cancer multicentre trials of adjuvant therapy with combination therapy are required to answer the questions: which agent, at what dose (particularly with respect to platinum) and in what combination.
- Quality of life measures for gynaecological cancers should be developed which can be used for the routine, as well as research, assessment of outcome.

Appendix I Diagnostic codes

Diagnostic codes, three-digit (ICD 9) from HES data 1993/94

Malignant neoplasm of genitourinary organs:

179	Malignant neoplasm of uterus, part specified
180	Malignant neoplasm of cervix uteri
181	Malignant neoplasm of placenta
182	Malignant neoplasm of body of uterus
183	Malignant neoplasm of ovary and other uterine adnexa
184	Malignant neoplasm of other and unspecified female genital organs

Benign neoplasm:

218	Uterine leiomyoma
219	Other benign neoplasm of uterus
220	Benign neoplasm of ovary
221	Benign neoplasm of other female genital organs

Diseases of other endocrine glands:

256	Ovarian dysfunction

Inflammatory disease of female pelvic organs:

614	Inflammatory disease of ovary, fallopian tube, pelvic cellular tissue and peritoneum
615	Inflammatory diseases of uterus, except cervix
616	Inflammatory disease of cervix, vagina and vulva

Other disorders of female genital tract:

617	Endometriosis
618	Genital prolapse
619	Fistulae involving female genital tract
620	Non-inflammatory disorders of ovary, fallopian tube and broad ligament
621	Disorders of uterus, not elsewhere classified
622	Non-inflammatory disorders of cervix
623	Non-inflammatory disorders of vagina
624	Non-inflammatory disorders of vulva and perineum
625	Pain and other symptoms associated with female genital organs
626	Disorders of menstruation and other abnormal bleeding from female genital tract
627	Menopausal and postmenopausal disorders
628	Infertility, female
629	Other disorders of female genital organs

Pregnancy with abortive outcome:

630	Hydatidiform mole
631	Other abnormal product of conception
632	Missed abortion
633	Ectopic pregnancy
634	Spontaneous abortion
635	Legally induced abortion
636	Illegally induced abortion
637	Unspecified abortion
638	Failed attempted abortion
639	Complications following abortion and ectopic and molar pregnancies

Diagnostic related groups

Diseases and disorders of the female reproductive system (DRG 353–369)
Pregnancy, childbirth and the puerperium (DRGs 370–384)

Major diagnostic category 13 – Medical partitioning

Malignancy age >69 and/or cc		Yes	366
		No	367
Infection			368
Menstrual and other female reproductive system diagnoses			369

Major diagnostic category 13 – Surgical partitioning

Pelvic evisceration, radical hysterectomy and radical vulvectomy			353
Uterine and adnexal			
Ovarian and adnexal malignancy			357
Other malignancy		Yes	354
Age >69 and/or cc		No	355
Non-malignancy		Yes	358
Age >69 and/or cc		No	359
Female reproductive system, reconstructive procedures			356
Vagina, cervix and vulva procedures			360
Laparoscopy and incisional tubal interruption			361
D&C, conization and radio-implant	Principle diagnosis malignancy	Yes	363
		No	364
Endoscopic tubal interruption			362
Other female reproductive system OR procedures			365

Major diagnostic category 14

Pregnancy, childbirth and puerperium (relevant codes)			
Postpartum and post-abortion – procedure			377
	no procedure		376
Ectopic pregnancy			378
Threatened abortion			379

cc = complication/comorbidity

HRG text labels

HRG	HRG text lable
m01	Minor Procedures Vulva/Labia
m02	Minor Procedures Vagina/Perineum
m03	Minor Procedures Cervix/Uterus
m04	Minor Procedures Uterus/Adnexae
m05	Intermediate Procedures Vulva/Labia
m06	Intermediate Procedures Vagina/Perineum

m07	Intermediate Procedures Vagina/Uterus
m08	Intermediate Procedures Uterus/Adnexae
m09	Major Procedures Vulva/Labia
m10	Major Procedures Uterus/Perineum
m11	Major Procedures Uterus/Adnexae
m12	Complex Major Procedures Vulva/Labia
m13	Complex Major Procedures Uterus
m14	Threatened Abortion
m15	Spontaneous Abortion
m16	Ectopic Pregnancy
m17	Termination of Pregnancy
m18	Contraceptive Care/Sterilization
m19	Infertility
m20	Non-inflammatory Disease of Vulva/Vagina
m21	Inflammatory Disease of Vulva/Vagina/Cervix
m22	Non-inflammatory Disease of Cervix
m23	Ovary/Tube/Pelvic Inflammation
m24	Non-inflammatory Disease of Tube/Ovary
m25	Fibroids/Menstrual Disordes/Endometriosis
m26	Genital Prolapse
m27	Carcinoma of Uterus
m28	Carcinoma of Ovary >69 or w cc
m29	Carcinoma of Ovary <70 w/o cc
m30	Other Gynaecological Malignancy >64 or w cc
m31	Other Gynaecological Malignancy <65 w/o cc
m32	Other Gynaecological Conditions

cc = complication/comorbidity
w = with

Operation codes three-digit OPCS 4R codes

P. LOWER FEMALE GENITAL TRACT

Vulva and female perineum (P01–P13)

p01	Operations on clitoris
p03	Operations on Bartholin gland
p05	Excision of vulva
p06	Extirpation of lesion of vulva
p07	Repair of vulva
p09	Other operations on vulva
p11	Extirpation of lesion of female perineum
p13	Other operations on female perineum

Vagina (P14–P31)

p14	Incision of introitus of vagina
p15	Other operations on introitus of vagina
p17	Excision of vagina
p18	Other obliteration of vagina
p20	Extirpation of lesion of vagina
p21	Plastic operations on vagina
p22	Repair of prolapse of vagina and amputation of cervix uteri

p23	Other repair of prolapse of vagina
p24	Repair of vault of vagina
p25	Other repair of vagina
p26	Introduction of supporting pessary into vagina
p27	Exploration of vagina
p29	Other operations on vagina
p31	Operations on pouch of Douglas

Q. UPPER FEMALE GENITAL TRACT

Uterus (Q01–Q20)

Q01	Excision of cervix uteri
Q02	Destruction of lesion of cervix uteri
Q03	Biopsy of cervix uteri
Q05	Other operations on cervix uteri
Q07	Abdominal excision of uterus
Q08	Vaginal excision of uterus
Q09	Other open operations on uterus
Q10	Curettage of uterus
Q11	Other evacuation of contents of uterus
Q12	Intrauterine contraceptive device
Q13	Introduction of gamete into uterine cavity
Q14	Introduction of abortifacient into uterine cavity
Q15	Introduction of other substance into uterine cavity
Q16	Other vaginal operations on uterus
Q17	Therapeutic endoscopic operations on uterus
Q18	Diagnostic endoscopic examination of uterus
Q20	Other operations on uterus

Fallopian tube (Q22–Q41)

Q22	Bilateral excision of adnexa of uterus
Q23	Unilateral excision of adnexa of uterus
Q24	Other excision of adnexa of uterus
Q25	Partial excision of fallopian tube
Q26	Placement of prosthesis in fallopian tube
Q27	Open bilateral occlusion of fallopian tubes
Q28	Other open occlusion of fallopian tube
Q29	Open reversal of female sterilization
Q30	Other repair of fallopian tube
Q31	Incision of fallopian tube
Q32	Operations on fimbria
Q34	Other open operations on fallopian tube
Q35	Endoscopic bilateral occlusion of fallopian tubes
Q36	Other endoscopic occlusion of fallopian tube
Q37	Endoscopic reversal of female sterilization
Q38	Other therapeutic endoscopic operations on fallopian tube
Q39	Diagnostic endoscopic examination of fallopian tube
Q41	Other operations on fallopian tube

Ovary and broad ligament (Q43–Q56)

Q43	Partial excision of ovary
Q44	Open destruction of lesion of ovary
Q45	Repair of ovary
Q47	Other open operations on ovary
Q48	Oocyte recovery
Q49	Therapeutic endoscopic operations on ovary
Q50	Diagnostic endoscopic examination of ovary
Q52	Operations on broad ligament of uterus
Q54	Operations on other ligament of uterus
Q55	Other examination of female genital tract
Q56	Other operations on female genital tract

Appendix II Morbidity survey in general practice 1991/92 (MSGP4)[31]

Patients consulting and consultation rates per 10 000 female person–years at risk.

Patients consulting rates: rates of patients who consulted at least once during the year at a defined level of diagnostic detail.

Person–years at risk: the sum of the number of days each patient in a particular category was registered with a study practice during the year, divided by the number of days (365) in the year.

Consultation: each diagnosis or reason for contact recorded during a contact; for each contact one or more consultations were recorded.

Condition	ICD	Patients consulting per 10 000 person–years at risk	Consultations per 10 000 person–years at risk
Candidiasis	112	521	690
Trichomoniasis	131	6	7
Malignant neoplasm			
– Uterus, unspecified	179	1	1
– Cervix	120	3	12
– Body uterus	182	2	5
– Ovary + adnexae	183	4	14
Uterine leiomyomata	218	13	16
Other benign neoplasm uterus	219	–	1
Benign neoplasm			
– Ovary	220	1	2
– Other	221	1	1
Pelvic inflammatory disease (PID)	614–616	212	198
Endometriosis	617	11	24
Genital prolapse	618	45	71
Non-inflammatory disorders of ovary, fallopian tube and broad ligament	620	9	14
Disorders of uterus not classified elsewhere	621	5	6
Non-inflammatory disorders cervix	622	22	26
Non-inflammatory disorders vagina	623	64	78

Continued

Continued.

Condition	ICD	Patients consulting per 10 000 person–years at risk	Consultations per 10 000 person–years at risk
Non-inflammatory disorders vulva	624	5	6
Pain associated with female organs	625	278	394
Disorders of menstruation	626	449	676
Menopause/post-menopause	627	328	583
Infertility	628	31	57
Early pregnancy loss	630–639	53	69

Appendix III Hospital episode statistics: financial year 1993/94

The hospital episode statistics cover all specialties and include private patients treated in NHS hospitals. They are based on consultant episodes (a period of care under one consultant within one provider) and the clinical specialty is based on the clinical qualifications of the consultant. The definitions of bed days, episodes and admissions are described in the hospital episode statistics introduction.

Definitions of fields from hospital episode statistics data

Ordinary admissions:
A patient not admitted electively and any patient admitted electively with the expectation that they will remain in hospital for at least one night, including a patient admitted with this intention who leaves hospital for any reason without staying overnight. A patient admitted electively with the intent of not staying overnight but who does not return home as scheduled should be counted as an ordinary admission.

Day case admission:
A patient admitted electively during the course of a day with the intention of receiving care but does not require the use of a hospital bed overnight and who returns home as scheduled. If this original intention is not fulfilled and the patient stays overnight, such a patient should be counted as an ordinary admission.

Bed day episodes:
The period of time in days between start date of the episode and the end date of episode for finished episodes, or the period of time in days between the start date of episode and the end date of the current period for unfinished episodes (i.e. duration of episode). The number of bed days is based on ordinary admissions only.

Elective admission:
A patient whose admission date is known in advance, thus allows arrangements to be made beforehand.

Emergency admission:
A patient admitted to hospital at short notice because of clinical need.

Mean waiting time:
This is based on valid cases only and it is calculated for any category as the total waiting times for that category divided by the corresponding number of admission episodes.

Median waiting time:
The waiting time for the middle case when all valid cases in a category are ranked by waiting time.

Number of women per 100 000 female population with gynaecological diagnoses

Diagnostic codes three-digit (ICD 9) from HES data 1993/94.

		Inpatient cases ordinary admission and day cases	Number/ 100 000 females[a]
Malignant neoplasm of genitourinary organs			
179	Malignant neoplasm of uterus, part unspecified	846	4
180	Malignant neoplasm of cervix uteri	8769	344
181	Malignant neoplasm of placenta	376	4
182	Malignant neoplasm of body of uterus	6304	27
183	Malignant neoplasm of ovary and other uterine adnexa	20 010	86
184	Malignant neoplasm of other and unspecified female genital organs	2407	10
Benign neoplasm			
218	Uterine leiomyoma	25 825	111
219	Other benign neoplasm of uterus	591	3
220	Benign neoplasm of ovary	3742	16
221	Benign neoplasm of other female genital organs	625	3
Diseases of other endocrine glands			
256	Ovarian dysfunction	4016	17
Inflammatory disease of female pelvic organs			
614	Inflammatory disease of ovary, fallopian tube, pelvic cellular tissue and peritoneum	20 238	87
615	Inflammatory diseases of uterus, except cervix	1337	6
616	Inflammatory disease of cervix, vagina and vulva	15 063	65
Other disorders of female genital tract			
617	Endometriosis	14 432	62
618	Genital prolapse	31 961	137
619	Fistulae involving female genital tract	1381	6
620	Non-inflammatory disorders of ovary, fallopian tube and broad ligament	17 779	76
621	Disorders of uterus, not elsewhere classified	11 275	48
622	Non-inflammatory disorders of cervix	41 119	176
623	Non-inflammatory disorders of vagina	17 223	74
624	Non-inflammatory disorders of vulva and perineum	6302	27
625	Pain and other symptoms associated with female genital organs	39 448	170
626	Disorders of menstruation and other abnormal bleeding from female genital tract	105 812	455

Continued

Continued.		Inpatient cases ordinary admission and day cases	Number/ 100 000 females[a]
627 Menopausal and postmenopausal disorders		30 757	132
628 Infertility, female		27 099	117
629 Other disorders of female genital organs		2262	10
			1967
Pregnancy with abortive outcome			
630 Hydatidiform mole	630–679	1 170 192	5031
631 Other abnormal product of conception			
632 Missed abortion			
633 Ectopic pregnancy			
634 Spontaneous abortion			
635 Legally induced abortion			
636 Illegally induced abortion			
637 Unspecified abortion			
638 Failed attempted abortion			
639 Complications following abortion and ectopic and molar pregnancies			
Total		6998	

[a] OPCS England Population projections: females aged over 15 years

HES 1993/94 data: admissions, bed days and length of stay by diagnostic shortlist

OA = ordinary admission, DC = day case, OA+DC = inpatients, BD = bed days of ordinary admission, LOS = length of stay

Malignant neoplasm of cervix uteri (diagnostic shortlist 120)

OA		7970	
DC		790	
OA+DC	=	8769	
BD		65 367	
mean LOS	=	8.2	
median LOS	=	4	

Malignant neoplasm of uterus, other and unspecified (diagnostic shortlist 122)

OA		6613	
DC		537	
OA+DC	=	7150	
BD		60 226	
mean LOS	=	9.1	
median LOS	=	6	

Benign neoplasm of uterus (diagnostic shortlist 152)

OA		22 397	
DC		4019	
OA+DC	=	26 416	(98% fibroids)

BD		155 150
mean LOS	=	6.9
median LOS	=	6

Benign neoplasm of ovary (diagnostic shortlist 153)

OA		3712
DC		30
OA+DC	=	3742
BD		30 277
mean LOS	=	8.2
median LOS	=	7

Diseases of female genital organs excluding breast (diagnostic shortlist 37–370)

OA		231 653
DC		151 835
OA+DC	=	383 488
BD		981 353

Subdivisions of diseases of female genital tract

Salpingitis and oophoritis (diagnostic shortlist 371)

OA		2249
DC		356
OA+DC	=	2605
BD		13432
mean LOS	=	6
median LOS	=	6

Inflammatory diseases of pelvic cellular tissues and peritoneum (diagnostic shortlist 371)

OA		14 420
DC		3075
OA+DC	=	17 495
BD		51 723
mean LOS	=	3.6
median LOS	=	2

Inflammatory diseases of uterus, vagina and vulva (diagnostic shortlist 373)

OA		10 945
DC		5455
OA+DC	=	16 400
BD		26 744
mean LOS	=	2.4
median LOS	=	1

Uterovaginal prolapse (diagnostic shortlist 373)

OA		30 842
DC		1119
OA+DC	=	31 961
BD		241 826
mean LOS	=	7.8
median LOS	=	6

Menstrual disorders (diagnostic shortlist 375)

OA		45 924
DC		32 220
OA+DC	=	78 144
BD		203 407
mean LOS	=	4.4
median LOS	=	3

Infertility, female (diagnostic shortlist 628)

OA		9738
DC		17 361
OA+DC	=	27 099
BD		17 028
mean LOS	=	1.8
median LOS	=	1

Complications of pregnancy, childbirth and puerperium (diagnostic shortlist 38–41)

OA		1 079 701
DC		90 491
BD		3 284 836
mean LOS	=	1.8
median LOS	=	1

Carcinoma *in situ* of cervix (ICD 233.1)
Total 19 577

Operations by principal operation (three-digit OPCS 4R) OA and DC combined, NHS hospitals, HES, UK 1993/94

P. LOWER FEMALE GENITAL TRACT

Vulva and female perineum (P01–P13)

p01	Operations on clitoris	117
p03	Operations on Bartholin gland	5367
p05	Excision of vulva	5093
p06	Extirpation of lesion of vulva	1485
p07	Repair of vulva	180
p09	Other operations on vulva	6392
p11	Extirpation of lesion of female perineum	660
p13	Other operations on female perineum	2569

Vagina (P14–P31)

p14	Incision of introitus of vagina	304
p15	Other operations on introitus of vagina	810
p17	Excision of vagina	144
p18	Other obliteration of vagina	75
p19	Excision of band of vagina	201
p20	Extirpation of lesion of vagina	2873

p21	Plastic operations on vagina	204
p22	Repair of prolapse of vagina and amputation of cervix uteri	1308
p23	Other repair of prolapse of vagina	19 940
p24	Repair of vault of vagina	505
p25	Other repair of vagina	739
p26	Introduction of supporting pessary into vagina	848
p27	Exploration of vagina	20 538
p29	Other operations on vagina	1758
p31	Operations on pouch of Douglas	296

Q. UPPER FEMALE GENITAL TRACT

Uterus (Q01–Q20)

Q01	Excision of cervix uteri	9416
Q02	Destruction of lesion of cervix uteri	19 622
Q03	Biopsy of cervix uteri	23 031
Q05	Other operations on cervix uteri	1447
Q07	Abdominal excision of uterus	59 376
Q08	Vaginal excision of uterus	14 141
Q09	Other open operations on uterus	1507
Q10	Curettage of uterus	166 146
Q11	Other evacuation of contents of uterus	154 222
Q12	Intrauterine contraceptive device	3404
Q13	Introduction of gamete into uterine cavity	1128
Q14	Introduction of abortifacient into uterine cavity	7223
Q15	Introduction of other substance into uterine cavity	1298
Q16	Other vaginal operations on uterus	430
Q17	Therapeutic endoscopic operations on uterus	9945
Q18	Diagnostic endoscopic examination of uterus	21 853
Q20	Other operations on uterus	1166

Fallopian tube (Q22–Q41)

Q22	Bilateral excision of adnexa of uterus	2650
Q23	Unilateral excision of adnexa of uterus	8281
Q24	Other excision of adnexa of uterus	1867
Q25	Partial excision of fallopian tube	1448
Q26	Placement of prosthesis in fallopian tube	22
Q27	Open bilateral occlusion of fallopian tubes	1856
Q28	Other open occlusion of fallopian tube	136
Q29	Open reversal of female sterilization	1138
Q30	Other repair of fallopian tube	1409
Q31	Incision of fallopian tube	1085
Q32	Operations on fimbria	172
Q34	Other open operations on fallopian tube	485
Q35	Endoscopic bilateral occlusion of fallopian tubes	50 969
Q36	Other endoscopic occlusion of fallopian tube	326
Q37	Endoscopic reversal of female sterilization	433
Q38	Other therapeutic endoscopic operations on fallopian tube	1087
Q39	Diagnostic endoscopic examination of fallopian tube	7169
Q41	Other operations on fallopian tube	12 827

Ovary and broad ligament (Q43–Q56)

Q43	Partial excision of ovary	3372
Q44	Open destruction of lesion of ovary	143
Q45	Repair of ovary	158
Q47	Other open operations on ovary	752
Q48	Oocyte recovery	2039
Q49	Therapeutic endoscopic operations on ovary	3629
Q50	Diagnostic endoscopic examination of ovary	1198
Q52	Operations on broad ligament of uterus	144
Q54	Operations on other ligament of uterus	617
Q55	Other examination of female genital tract	5967
Q56	Other operations on female genital tract	53

Operations by principle operation (OPCS 4R shortlist) ordinary admissions (OA) day cases (DC) and bed days of ordinary admissions (BD), NHS Hospitals, UK, 1993/94

Principal operation shortlist

P	**Lower genital tract**
OA	42 558
DC	29 848
BD	223 571
PA	**Vulva and female perineum**
OA	13 651
DC	8212
BD	43 835
PA1	**Operations on Bartholin gland**
OA	4359
DC	1008
BD	5250
PB	**Vagina**
OA	28 907
DC	21 636
BD	179 736
PB1	**Repair of prolapse of vagina**
OA	21 232
DC	16
BD	152 978
Q	**Upper genital tract**
OA	307 069
DC	239 718
BD	973 100
QA	**Uterus**
OA	247 541
DC	187 814
BD	775 486

QA1	**Operations on cervix uteri**
OA	15 659
DC	37 857
BD	26 467
QA2	**Excision of uterus**
OA	73 465
DC	52
BD	527 945
QA3	**Evacuation of contents of uterus**
OA	133 920
DC	126 448
BD	171 790
QB	**Fallopian tube**
OA	48 329
DC	45 031
BD	149 341
QB1	**Excision of adnexa of uterus**
OA	12 782
DC	16
BD	80 617
QB2	**Open occlusion of fallopian tube**
OA	1789
DC	203
BD	5501
QB3	**Endoscopic occlusion of fallopian tube**
OA	19 563
DC	31 732
BD	22 284
QB4	**Other endoscopic operations on fallopian tube**
OA	4466
DC	4223
BD	8463
QC	**Ovary and broad ligament**
OA	11 199
DC	6873
BD	48 273
R	**Female genital tract associated with pregnancy, childbirth and puerperium**
OA	613 740
DC	852
BD	2 126 725

Waiting times: mean and median (days) by main diagnosis (diagnostic shortlist), NHS hospitals, 1993/94

	Waiting time	
	mean	median
Malignant neoplasm of cervix uteri	19.1	13
Malignant neoplasm of uterus and other and unspecified	20.9	14
Benign neoplasm of uterus	95.4	60
Benign neoplasm of ovary	40.4	21
Salpingitis and oophoritis	99.4	60
Inflammatory disease of pelvic cellular tissue and peritoneum	106.4	62
Inflammatory diseases of uterus, vagina and vulva	67.1	40
Utero-vaginal prolapse	146.6	105
Menstrual disorders	90.5	56
Infertility female	101.3	64
Total cases all causes including gynaecology	**90.6**	**41**

Waiting times by principal operation (OPCS4 shortlist) UK,1993/94

P. LOWER FEMALE GENITAL TRACT

	Selected codes	
	mean	median
Repair of prolapse of vagina	157.1	117
Excision of uterus	107.1	69
Evacuation of contents of uterus	33.1	11
Total	**96.4**	**54**

HRG	Label	N cases	% Chap.	% day	% Emerg.	Mean	Std day	Q1	Med	Q3	Trim Pt.	% Trim
m01	Min Pxs Vulva/Labia	1411	0.20	62.7	2.3	1.1	0.8	1	1	2	3	9.5
m02	Min Pxs Vag/Perineum	12955	1.87	45.8	14.1	1.3	0.8	1	1	2	3	10.0
m03	Min Pxs Cerv/Uterus	42217	6.10	86.6	1.1	1.0	1.0	0	1	2	5	2.4
m04	Min Pxs Uterus/Adnexae	257675	37.23	49.3	28.5	1.1	0.8	1	1	1	3	3.6
m05	Inter Pxs Vulva/Labia	14838	2.14	34.1	33.2	1.3	0.7	1	1	2	3	7.5
m06	Inter Pxs Vag/Perineum	4807	0.69	37.5	8.8	2.3	1.9	1	2	3	8	7.1
m07	Inter Pxs Cerv/Uterus	29503	4.26	64.9	1.8	1.3	0.9	1	1	2	3	5.9
m08	Inter Pxs Uterus/Adnexae	105256	15.21	57.3	2.4	1.1	0.8	1	1	2	3	5.8
m09	Maj Pxs Vulva/Labia	1115	0.16	23.6	7.4	12.0	10.5	2	10	18	47	4.5
m10	Maj Pxs Vag/Perineum	22488	3.25	0.5	1.0	6.6	2.0	5	6	8	12	5.5
m11	Maj Pxs Uterus/Adnexae	86034	12.43	1.0	12.7	6.1	1.8	5	6	7	10	6.1
m12	Comp Maj Pxs Vulva/Labia	69	0.01	0.0	2.9	22.7	9.8	15	21	32	56	2.9
m13	Comp Maj Pxs Uterus/Adnexae	532	0.08	0.2	4.1	10.2	3.4	8	10	12	20	9.0
m14	Threatened abortion	25079	3.62	3.8	82.5	1.0	1.1	0	1	2	5	2.5
m15	Spontaneous Abortion	10899	1.57	2.6	85.6	0.7	0.7	0	1	1	2	7.9
m16	Ectopic Pregnancy	560	0.08	0.2	93.9	1.6	1.9	0	1	2	7	3.9
m17	Termination of Pregnancy	2146	0.31	49.8	11.7	1.0	1.1	0	1	2	5	1.3
m18	Contracept Care/Steril'n	126	0.02	31.7	20.6	2.0	2.2	0	1	4	10	1.2
m19	Infertility	1250	0.18	47.8	15.3	0.5	0.6	0	0	1	2	8.3
m20	Non Infl Dis of Vulva/Vag	8033	1.16	4.5	77.6	1.0	1.1	0	1	1	5	4.3
m21	Infl Dis of Vulva/Vag/Cerv	1490	0.22	7.3	79.8	1.0	1.2	0	1	1	5	9.6
m22	Non Infl Dis of Cerv	1418	0.20	48.3	13.0	0.9	1.1	0	1	1	5	9.8
m23	Ovary/Tube/Pelvic Infl	7018	1.01	0.5	96.1	1.9	1.5	1	2	3	6	4.4
m24	Non Infl Dis of Tube/Ovary	4313	0.62	7.1	81.4	1.7	1.5	1	1	2	6	6.9
m25	Fibs/Menst Disds/End'sis	13925	2.01	9.8	63.9	1.1	1.2	0	1	2	5	4.2
m26	Genital Prolapse	2778	0.40	15.9	11.1	2.2	2.6	0	1	3	10	7.7
m27	Carcinoma of Uterus	1230	0.18	8.9	40.5	6.7	7.0	2	4	10	29	7.3
m28	Carcinoma of Ovary >69 or w cc	4019	0.58	26.3	35.8	5.1	5.7	1	3	8	23	7.0
m29	Carcinoma of Ovary <70 w/o cc	10288	1.49	31.7	18.0	1.6	1.4	1	1	2	6	12.2
m30	Oth Gyn Malig >64 or w cc	2201	0.32	5.6	45.2	8.9	8.7	2	6	13	34	6.6
m31	Oth Gyn Malig <65 w/o cc	3389	0.49	18.5	29.3	2.9	2.5	1	2	4	11	12.0
m32	Other Gynae Condns	13061	1.89	16.6	64.3	1.2	1.2	0	1	2	5	4.8

Appendix IV Outlet of bladder operations in females (M51–M58) (HES, 1990/91), UK

		n	%
M51	Combined abdominal and vaginal operations to support outlet of female bladder	1516	20
M52	Abdominal operations to support outlet of female bladder	4561	61
M53	Vaginal operations to support outlet of female bladder	346	6
M55	Other operations on outlet of female bladder	96	1
M56	Therapeutic operations on outlet of female bladder	265	4
M58	Other operations on outlet of female bladder	700	9
Total		7484	

Appendix V Stratification of laparoscopic procedures by levels of training

(Royal College of Obstetricians and Gynaecologists, 1994)

LEVEL 1 DIAGNOSTIC LAPAROSCOPY

LEVEL 2 MINOR LAPAROSCOPIC PROCEDURES

Laparoscopic sterilization
Needle aspiration of simple cysts
Ovarian biopsy
Minor adhesiolysis (not involving bowel)
Ventro-suspension
Diathermy to endometriosis – Revised AFS Stage I

LEVEL 3 MORE EXTENSIVE PROCEDURES REQUIRING ADDITIONAL TRAINING

Laser/diathermy to polycystic ovaries
Laser/diathermy to endometriosis – Revised AFS Stage II and III
Linear salpingostomy and/or salpingectomy for ectopic pregnancy
Laparoscopic uterosacral nerve ablation
Salpingostomy for infertility
Salpingectomy/salpingo-oophorectomy
Adhesiolysis for moderate and severe adhesions
Adhesiolysis involving bowel laparoscopic ovarian cystectomy
Laparoscopic/laser management of endometrioma
Laparoscopically-assisted vaginal/sub-total hysterectomy (without significant associated pathology)

LEVEL 4 EXTENSIVE ENDOSCOPIC PROCEDURES REQUIRING SUBSPECIALIST OR ADVANCED/TERTIARY LEVEL ENDOSCOPIC SKILLS

Myomectomy
Laparoscopic surgery for revised AFS Stage III and IV endometriosis
Pelvic lymphadenectomy. Pelvic side-wall/ureteric dissection
Presacral neurectomy
Dissection of an obliterated Pouch of Douglas
Laparoscopic incontinence surgical procedures

LEVEL 1 DIAGNOSTIC PROCEDURES

Diagnostic hysteroscopy – plus target biopsy
Removal of simple polyps
Removal of intrauterine contraceptive device (IUD)

LEVEL 2 MINOR OPERATIVE PROCEDURES

Proximal fallopian tube cannulation
Minor Asherman's Syndrome
Removal of pedunculated fibroid or large polyp

LEVEL 3 MORE COMPLEX OPERATIVE PROCEDURES REQUIRING ADDITIONAL TRAINING

Division/resection of uterine septum
Endoscopic surgery for major Asherman's Syndrome
Endometrial resection or ablation
Resection of submucous leiomyoma
Repeat endometrial resection or ablation

Appendix VI Cervical screening Health of the Nation targets

Purchasers

Interventions for NHS purchasers and providers (*Key Area Handbook*).

- Region retains responsibility for monitoring the running of the programme by districts.
- DHAs
  a) health promotion activities
  b) build alliances with other agencies such as the network and HEA
  c) purchasing cervical screening services of high quality
  d) availability of services to eligible population
  e) maximize attendance for screening
  f) set targets for purchasing high quality diagnostic, therapeutic and support services for women with abnormal smears.

Providers

- Health promotion.
- High quality screening, treatment and support services.
- Ensure women with an abnormal smear are followed-up promptly.
- Maintain good liaison with the network.

FHSAs

- Handling the recall system.
- Personal invitation and response to queries.
- Efficient, straightforward methods for checking medical records against the FHSA list.
- Support for practices failing to reach targets, including training for practice nurses.
- Training of practice nurses.

Primary health care team

- Understand and promote the programme.
- Follow-up non-responders.
- Liaise with district co-ordinator.
- Be involved in follow-up and treatment arrangements and model as necessary to provide an efficient and effective service.
- Minimize anxiety in women recalled for further assessment.

(Department of Health, 1993)

Appendix VII Expert Advisory Committee on Cancer. (A policy framework for commissioning cancer services 1994)

The Expert Advisory Committee on Cancer report is a consultative policy framework for commissioning cancer services which will determine the philosophy of purchasing cancer care and where and how much will be purchased. As outlined in this assessment the report focuses on a patient centred approach. Cancer services need to be flexible to respond to emerging technologies and new research findings. The general principles should include the following.

1 Access to uniformly high quality of care in the community or hospital to ensure maximum possible cure rates and best quality of life.
2 Promotion of early recognition of symptoms and availability of screening.
3 Clear information and assistance regarding treatment options and outcomes available.
4 Services to be patient centred.
5 Primary care team is central and continuing element in cancer care and communication between sectors must be of a high quality if the best possible care is to be achieved.
6 Psychosocial aspects of cancer care should be considered at all stages.
7 Cancer registration and careful monitoring of treatment and outcomes is essential.

Recommendation that there must be three levels of care.

1 Primary care as focus of care.
2 Designated cancer units in DGHs to manage commoner cancers (which probably do not include the gynaecological cancers).
3 Designated cancer centres to manage all cancers, including common cancers and less common cancers by referral from cancer units. They will provide specialist diagnostic and therapeutic techniques including radiotherapy.

Element of report for gynaecological services.

1 Need to develop arrangements for the close integration of primary and secondary care, including referral protocols and management protocols.
2 Appropriate training of surgeons (the RCOG subspecialty training scheme for gynaecological oncology).
3 Multi-disciplinary consultation and management requires a minimum of five sessions of the non-surgical oncology type even in the smaller cancer units. The access to specialist nurses with site-specific skills and specialist skills (e.g. lymphoedema management and cytotoxic chemotherapy administration).
4 Chemotherapy if it is to be given in a cancer unit should only be if appropriate facilities and sufficiently experienced multi-disciplinary teams are available. Treatment protocols should be the same as those of the cancer centre. Radiotherapy is usually transferred to the centres.

Contracting

Appropriate contractual arrangements will be reached by purchasing authorities with a cancer centre which will deliver a full range of cancer treatments to encompass treatment programmes for less common and rare cancers and those treatments which are too specialized, technically demanding or capital intensive to be provided in the cancer unit. Chorioncarcinoma is a rare tumour that will be managed in a small number of cancer centres to ensure adequate specialization.

A cancer centre should serve a population of at least 1 000 000 and no less than 750 000.

Specialist centre facilities – paediatric and adolescent cancer services

Assessment and management of rare cancers in multi-disciplinary teams and the accumulation of expertise in these treatments. Specialist surgical services including reconstructive surgery, intensive chemotherapy, full range of radiotherapy, with appropriate number of clinical oncologists to ensure specialist application, medical oncology, sophisticated diagnostic facilities, special expertise in palliative care and rehabilitation.

Contracts should be developed for each site with agreed protocols for referral and diagnosis and co-ordinated delivery of care at all levels.

Appendix VIII Glossary of terms

AID	artificial insemination by donor
CIN	cervical intraepithelial neoplasia
D&C	dilatation and curettage
DRG	diagnostic related groups
DUB	dysfunctional uterine bleeding
ERPC	evacuation of the retained products of conception
GIFT	gamete intra-fallopian transfer
GUM	genitourinary medicine
HES	hospital episode statistics
HIV	human immunodeficiency virus
HRT	hormone replacement therapy
HRG	health care resource grouping
HSG	hysterosalpingogram
ICD	international classification of disease
IUCD	intra-uterine contraceptive device
IVF	*in vitro* fertilization
IVF-ET	*in vitro* fertilization and embryo transfer
LAVH	laparoscopically assisted vaginal hysterectomy
LLETZ	large loop excision of the transformation zone
MAS	minimal access surgery
PID	pelvic inflammatory disease
PMS	premenstrual syndrome
RCOG	Royal College of Obstetricians and Gynaecolgists
TAH	total abdominal hysterectomy
TCRE	transcervical resection of the endometrium

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