Long-acting reversible contraception
the effective and appropriate use of long-acting reversible contraception

National Collaborating Centre for Women’s and Children’s Health

Commissioned by the National Institute for Health and Clinical Excellence

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Update information 2019
In March 2019 we revised our decision on how to implement the recommendations of our October 2017 review. Although no new evidence was identified, we noted significant changes in how we commission and provide contraceptive services in England. We have removed the recommendations in the short version of the guideline that no longer fit with current practice, and have deleted or redacted the content related to those removed recommendations in this guideline. There are also many new LARC products now available. See our Long-acting reversible contraception: implementation resource summary for links to the latest information, which is available in the short version of the guideline (along with links to the October 2017 review) at: http://www.nice.org.uk/cg30
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Stakeholder organisations

Addenbrookes NHS Trust
Amber Valley Primary Care Trust
Anglesey Local Health Board
Ashfield and Mansfield District Primary Care Trust
Association of British Healthcare Industries
Association of Surgeons of Great Britain and Ireland
Association of the British Pharmaceuticals Industry (ABPI)
Barnet Primary Care Trust
Bedfordshire & Hertfordshire NHS Strategic Health Authority
Bournemouth Teaching Primary Care Trust – Poole
British Association for Counselling and Psychotherapy
British Association for Sexual Health and HIV (BASHH)
British National Formulary (BNF)
British Psychological Society
CIS'ters
Cochrane Fertility Regulation Group
Colchester Primary Care Trust
Co-operative Pharmacy Association
Croydon Primary Care Trust
Dacorum Primary Care Trust
Department of Health
Down’s Syndrome Association
Ealing Primary Care Trust
East Kent Coastal Primary Care Trust
Faculty of Family Planning and Reproductive Health Care
Faculty of Public Health
Family Planning Association
Fibroid Network Charity
Gateshead Primary Care Trust
Healthcare Commission
Herefordshire Primary Care Trust
Hertfordshire Partnership NHS Trust
Ipswich Primary Care Trust
Janssen-Cilag Ltd
Johnson & Johnson Medical Ltd
L’Arche UK
Leeds Teaching Hospitals NHS Trust
Medicines and Healthcare products Regulatory Agency (MHRA)
Microsulis Medical Ltd
Mid Staffordshire General Hospitals NHS Trust
National Association of Nurses for Contraception and Sexual Health (NANCSH)
National Association of Theatre Nurses
National Collaborating Centre for Acute Care
National Collaborating Centre for Cancer
National Collaborating Centre for Chronic Conditions
National Collaborating Centre for Mental Health
National Collaborating Centre for Nursing and Supportive Care
National Collaborating Centre for Primary Care
National Council for Disabled People, Black, Minority and Ethnic Community (Equalities)
National Institute for Health and Clinical Excellence (NICE)
National Osteoporosis Society
National Patient Safety Agency
National Public Health Service – Wales
NHS Direct
NHS Information Authority (PHSMI Programme)
NHS Modernisation Agency

Long-acting reversible contraception
NHS Quality Improvement Scotland
North Tees and Hartlepool NHS Trust
Nottinghamshire Healthcare NHS Trust
Organon Laboratories Ltd
Patient Involvement Unit for NICE
Pfizer Ltd
Princess Alexandra Hospital NHS Trust
Queen Mary’s Hospital NHS Trust (Sidcup)
Rotherham General Hospitals NHS Trust
Rotherham Primary Care Trust
Royal College of General Practitioners
Royal College of General Practitioners Wales
Royal College of Midwives
Royal College of Nursing (RCN)
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Psychiatrists
Royal Pharmaceutical Society of Great Britain
Schering Health Care Ltd
Scottish Intercollegiate Guidelines Network (SIGN)
Sheffield Teaching Hospitals NHS Trust
South & Central Huddersfield Primary Care Trust
South Birmingham Primary Care Trust
SSL International plc
Tameside and Glossop Acute Services NHS Trust
The Royal Society of Medicine
The Royal West Sussex Trust
The Survivors Trust
Trafford Primary Care Trusts
University College London Hospitals NHS Trust
Vale of Aylesbury Primary Care Trust
Welsh Assembly Government (formerly National Assembly for Wales)
Abbreviations

ALOs  Actinomyces-like organisms
BMD  bone mineral density
BMI  body mass index
BNF  British National Formulary
BTB  breakthrough bleeding
CHC  combined hormonal contraceptive
CI  confidence interval
COC  combined oral contraceptive
CVD  cardiovascular disease
DFFP  Diploma of the Faculty of Family Planning and Reproductive Health Care
DH  Department of Health
DMPA  depot medroxyprogesterone acetate
eMC  Electronic Medicines Compendium
ENG  etonogestrel
FPC  family planning clinic
FFPRHC  Faculty of Family Planning and Reproductive Health Care
GDG  Guideline Development Group
GP  general practitioner
GPP  good practice point
GU  genitourinary
HDL  high-density lipoprotein
HIV  human immunodeficiency virus
HRT  hormone replacement therapy
HTA  Health Technology Assessment
IUS  intrauterine system
ICER  incremental cost effectiveness ratio
IUD  intrauterine device
LARC  long-acting reversible contraception
LDL  low-density lipoprotein
LNG  levonorgestrel
LoC  letter of competence
LSHTM  London School of Hygiene and Tropical Medicine
MBL  menstrual blood loss
MHRA  Medicines and Healthcare products Regulatory Agency
MI  myocardial infarction
MPA  medroxyprogesterone acetate
NCC-MH  National Collaborating Centre for Mental Health
NCC-WCH  National Collaborating Centre for Women’s and Children’s Health
NET-EN  norethisterone enantate
NHS  National Health Service
NICE  National Institute for Health and Clinical Excellence
NICU  neonatal intensive care unit
NMC  Nursing and Midwifery Council
NSAID  non-steroidal anti-inflammatory drug
OC  oral contraceptive pill
OR  odds ratio
PCT  primary care trust
PID  pelvic inflammatory disease
POC  progestogen-only oral contraceptive
POICs  progestogen-only injectable contraceptives
POSDIs  progestogen-only subdermal implants
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td>QALY</td>
<td>quality adjusted life year</td>
</tr>
<tr>
<td>RCOG</td>
<td>Royal College of Obstetricians and Gynaecologists</td>
</tr>
<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
</tr>
<tr>
<td>RR</td>
<td>risk ratio</td>
</tr>
<tr>
<td>SD</td>
<td>standard deviation</td>
</tr>
<tr>
<td>SPC</td>
<td>Summary of Product Characteristics</td>
</tr>
<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
</tr>
<tr>
<td>STIF</td>
<td>sexually transmitted infections foundation course</td>
</tr>
<tr>
<td>TTP</td>
<td>time to pregnancy</td>
</tr>
<tr>
<td>UKSPR</td>
<td>UK Selected Practice Recommendations for Contraceptive Use</td>
</tr>
<tr>
<td>VTE</td>
<td>venous thromboembolism</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WHO-MEC</td>
<td>World Health Organization Medical Eligibility Criteria for Contraceptive Use</td>
</tr>
<tr>
<td>WHOSPR</td>
<td>World Health Organization Selected Practice Recommendations for Contraceptive Use</td>
</tr>
<tr>
<td>WMD</td>
<td>weighted mean difference</td>
</tr>
</tbody>
</table>
Bias
Influences on a study that can lead to invalid conclusions about a treatment or intervention. Bias in research can make a treatment look better or worse than it really is. Bias can even make it look as if the treatment works when it does not. Bias can occur by chance or as a result of systematic errors in the design and execution of a study. Bias can occur at various stages in the research process, for example, in the randomisation, collection, analysis, interpretation, publication or review of research data.

Blinding or masking
The practice of keeping the investigators or subjects of a study ignorant of the group to which a subject has been assigned. For example, a clinical trial in which the participating patients or their doctors are unaware of whether they (the patients) are taking the experimental drug or a placebo (dummy treatment). The purpose of ‘blinding’ or ‘masking’ is to protect against bias. See also double blind study.

Case–control study
A study that starts with the identification of a group of individuals sharing the same characteristics (for example, people with a particular disease) and a suitable comparison (control) group (for example, people without the disease). All subjects are then assessed with respect to things that happened to them in the past, for example, things that might be related to getting the disease under investigation. Such studies are also called retrospective as they look back in time from the outcome to the possible causes.

Case report (or case study)
Detailed report on one patient (or case), usually covering the course of that person’s disease and their response to treatment.

Case series
Description of several cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison (control) group of patients.

Clinical trial
A research study conducted with patients which tests out a drug or other intervention to assess its effectiveness and safety. Each trial is designed to answer scientific questions and to find better ways to treat individuals with a specific disease. This general term encompasses controlled clinical trials and randomised controlled trials.

Cohort
A group of people sharing some common characteristic (for example, patients with the same disease), followed up in a research study for a specified period of time.

Cohort study
An observational study that takes a group (cohort) of patients and follows their progress over time in order to measure outcomes such as disease or mortality rates and make comparisons according to the treatments or interventions that patients received. Thus, within the study group, subgroups of patients are identified (from information collected about patients) and these groups are compared with respect to outcome, for example, comparing mortality between one group that received a specific treatment and one group that did not (or between two groups that received different levels of treatment). Cohorts can be assembled in the present and followed into the future (a ‘concurrent’ or ‘prospective’ cohort study) or identified from past
records and followed forward from that time up to the present (a ‘historical’ or ‘retrospective’ cohort study). Because patients are not randomly allocated to subgroups, these subgroups may be quite different in their characteristics and some adjustment must be made when analysing the results to ensure that the comparison between groups is as fair as possible.

**Confidence interval**
A way of expressing certainty about the findings from a study or group of studies, using statistical techniques. A confidence interval describes a range of possible effects (of a treatment or intervention) that is consistent with the results of a study or group of studies. A wide confidence interval indicates a lack of certainty or precision about the true size of the clinical effect and is seen in studies with too few patients. Where confidence intervals are narrow they indicate more precise estimates of effects and a larger sample of patients studied. It is usual to interpret a ‘95%’ confidence interval as the range of effects within which there is 95% confidence that the true effect lies.

**Control group**
A group of patients recruited into a study that receives no treatment, a treatment of known effect, or a placebo (dummy treatment), in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.

**Controlled clinical trial**
A study testing a specific drug or other treatment involving two (or more) groups of patients with the same disease. One (the experimental group) receives the treatment that is being tested, and the other (the comparison or control group) receives an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. A controlled clinical trial where patients are randomly allocated to treatment and comparison groups is called a **randomised controlled trial.**

**Cost effectiveness analysis**
A type of economic evaluation where outcomes are expressed in natural units, for example, number of cases cured, number of lives saved, etc.

**Crossover study design**
A study comparing two or more interventions in which the participants, upon completion of the course of one treatment, are switched to another. For example, for a comparison of treatments A and B, half the participants are randomly allocated to receive them in the order A, B and half to receive them in the order B, A. A problem with this study design is that the effects of the first treatment may carry over into the period when the second is given. Therefore a crossover study should include an adequate ‘wash-out’ period, which means allowing sufficient time between stopping one treatment and starting another so that the first treatment has time to wash out of the patient’s system.

**Cross-sectional study**
The observation of a defined set of people at a single point in time or time period – a snapshot. (This type of study contrasts with a **longitudinal study,** which follows a set of people over a period of time.)

**Decision-analytic model**
A mathematical simulation of the real world, where cost and outcome data derived from various sources are incorporated, resulting in the estimation of the relative cost effectiveness between two or more interventions; it enables economic evaluation of alternative courses of action, therefore contributing to decision making.

**Dominance**
A possible result of comparison between two alternatives in economic evaluation; one intervention is said to dominate its comparator when it is both more effective and less costly.
Double blind study  A study in which neither the subject (patient) nor the observer (investigator or clinician) is aware of which treatment or intervention the subject is receiving. The purpose of blinding is to protect against bias.

Dysmenorrhoea  Painful menstrual bleeding.

Economic evaluation  The comparative analysis between two or more interventions, in terms of both their costs and outcomes.

Evidence-based clinical practice  Evidence-based clinical practice involves making decisions about the care of individual patients based on the best research evidence available rather than basing decisions on personal opinions or common practice (which may not always be evidence based). Evidence-based clinical practice therefore involves integrating individual clinical expertise and patient preferences with the best available evidence from research.

Evidence table  A table summarising the results of a collection of studies which, taken together, represent the body of evidence supporting a particular recommendation or series of recommendations in a guideline.

Exclusion criteria  See selection criteria.

Experimental study  A research study designed to test whether a treatment or intervention has an effect on the course or outcome of a condition or disease, where the conditions of testing are to some extent under the control of the investigator. Controlled clinical trial and randomised controlled trial are examples of experimental studies.

Extrapolation  The projection or extension of directly established knowledge to an area not currently open to observation on the basis of known data.

Fraser guidelines  A set of criteria which must be applied when medical practitioners are offering contraceptive services to under-16s without parental knowledge or permission. These guidelines stem from the legal challenge by Victoria Gillick in the early 1980s to medical practitioners’ right to provide children under 16 years of age treatment or contraceptive services without parental permission. On occasion practitioners may refer to assessing whether a young person is Gillick competent.

Gillick competence  See Fraser guidelines.

Gold standard  A method, procedure or measurement that is widely accepted as being the best available.

Hazard ratio  In survival analysis, a summary of the difference between two survival curves, representing the reduction in the risk of death on treatment compared with control, over the period of follow-up.

Health economics  A field of conventional economics which examines the benefits of healthcare interventions (for example, medicines) compared with their financial costs.

Heterogeneity  Or lack of homogeneity. The term is used in meta-analysis and systematic review when the results or estimates of effects of treatment from separate studies seem to be very different, in terms of the size of treatment effects, or even to the extent that some indicate beneficial and others suggest adverse treatment effects. Such results may occur as a result of differences between studies in terms of patient populations, outcome measures, definition of variables or duration of follow-up.

Homogeneity  This means that the results of studies included in a systematic review or meta-analysis are similar and there is no evidence of heterogeneity. Results are usually regarded as homogeneous when
differences between studies could reasonably be expected to occur by chance.

**Incidence**
The rate of occurrence of new cases of a particular disease in a population being studied.

**Inclusion criteria**
See selection criteria.

**Incremental cost effectiveness ratio**
A method of presentation of results of an economic evaluation; it expresses the additional (incremental) cost incurred for an additional unit of benefit gained, by adopting an intervention over its comparator.

**Intervention**
Healthcare action intended to benefit the patient, for example, with drug treatment, surgical procedure or psychological therapy.

**Kaplan–Meier method**
A nonparametric technique for estimating time-related events (the survivorship function). Ordinarily it is used to analyse death as an outcome. It may be used effectively to analyse time to an endpoint, such as remission.

**Level one service**
Minimum level of provision within primary care sexual health services.

**Longitudinal study**
A study of the same group of people at more than one point in time. (This type of study contrasts with a cross-sectional study, which observes a defined set of people at a single point in time.)

**Masking**
See blinding.

**Menarche**
The beginning of the menstrual function, particularly the first menstrual period of a female.

**Menopause**
The period of natural cessation of menstruation, usually occurring between the ages of 45 and 50 years, signalling the end of a woman’s reproductive capacity.

**Menorrhagia**
Excessive or prolonged menstrual bleeding.

**Metromenorrhagia**
Uterine bleeding between menstrual periods and increased flow of bleeding during menstrual periods.

**Meta-analysis**
Results from a collection of independent studies (investigating the same treatment) are pooled, using statistical techniques to synthesise their findings into a single estimate of a treatment effect. Where studies are not compatible, for example, because of differences in the study populations or in the outcomes measured, it may be inappropriate or even misleading to statistically pool results in this way. See also systematic review and heterogeneity.

**Non-experimental study**
A study based on subjects selected on the basis of their availability, with no attempt having been made to avoid problems of bias.

**Nulliparity**
Having never given birth to a viable infant.

**Observational study**
In research about diseases or treatments, this refers to a study in which nature is allowed to take its course. Changes or differences in one characteristic (for example, whether or not people received a specific treatment or intervention) are studied in relation to changes or differences in other(s) (for example, whether or not they died), without the intervention of the investigator. There is a greater risk of selection bias than in experimental studies.

**Odds ratio**
Odds are a way of representing probability, especially familiar for betting. In recent years odds ratios have become widely used in reports of clinical studies. They provide an estimate (usually with a confidence interval) for the effect of a treatment. Odds are used to convey the idea of ‘risk’ and an odds ratio of one between two
treatment groups would imply that the risks of an adverse outcome were the same in each group. For rare events the odds ratio and the relative risk (which uses actual risks and not odds) will be very similar. See also relative risk and risk ratio.

**Oligomenorrhoea**
Reduction in the frequency of menstrual bleeding.

**Osteopenia**
Decreased calcification or density of bone.

**Osteoporosis**
A reduction in the amount of bone mass that can lead to fractures after minimal trauma.

**Peer review**
Review of a study, service or recommendations by those with similar interests and expertise to the people who produced the study findings or recommendations. Peer reviewers can include professional, patient and carer representatives.

**Perimenopausal**
The time leading up to menopause when oestrogen levels begin to drop.

**Placebo**
Placebos are fake or inactive treatments received by participants allocated to the control group in a clinical trial, which are indistinguishable from the active treatments being given in the experimental group. They are used so that participants and investigators are ignorant of their treatment allocation in order to be able to quantify the effect of the experimental treatment over and above any placebo effect due to receiving care or attention.

**Placebo effect**
A beneficial (or adverse) effect produced by a placebo and not due to any property of the placebo itself.

**Postpartum**
Occurring in or being the period following childbirth.

**Power**
See statistical power.

**Premenstrual syndrome**
Symptoms manifested by some women prior to menstruation including irritability, insomnia, fatigue, headache and abdominal pain.

**Prevalence**
The number of cases of disease or other eventualities which occur in a population at or during a given time.

**Prospective study**
A study in which people are entered into the research and then followed up over a period of time with future events recorded as they happen. This contrasts with studies that are retrospective.

**p value**
If a study is done to compare two treatments then the p value is the probability of obtaining the results of that study, or something more extreme, if there really was no difference between treatments. (The assumption that there really is no difference between treatments is called the ‘null hypothesis’.) Suppose the p value was 0.03. What this means is that, if there really was no difference between treatments, there would only be a 3% chance of getting the kind of results obtained. Since this chance seems quite low we should question the validity of the assumption that there really is no difference between treatments. We would conclude that there probably is a difference between treatments. By convention, where the value of p is below 0.05 (that is, less than 5%) the result is seen as statistically significant. Where the value of p is 0.001 or less, the result is seen as highly significant. P values just tell us whether an effect can be regarded as statistically significant or not. In no way do they relate to how big the effect might be, for which we need the confidence interval.

**Qualitative research**
Qualitative research is used to explore and understand people’s beliefs, experiences, attitudes, behaviour and interactions. It generates non-numerical data, for example, a patient’s description of
their pain rather than a measure of pain. In health care, qualitative techniques have been commonly used in research documenting the experience of chronic illness and in studies about the functioning of organisations. Qualitative research techniques such as focus groups and in-depth interviews have been used in one-off projects commissioned by guideline development groups to find out more about the views and experiences of patients and carers.

Quantitative research

Research that generates numerical data or data that can be converted into numbers, for example, clinical trials or the National Census, which counts people and households.

Random allocation or randomisation

A method that uses the play of chance to assign participants to comparison groups in a research study, for example, by using a random numbers table or a computer-generated random sequence. Random allocation implies that each individual (or each unit in the case of cluster randomisation) being entered into a study has the same chance of receiving each of the possible interventions.

Randomised controlled trial

A study to test a specific drug or other treatment in which people are randomly assigned to two (or more) groups: one (the experimental group) receiving the treatment that is being tested, and the other (the comparison or control group) receiving an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. (Through randomisation, the groups should be similar in all aspects apart from the treatment they receive during the study.)

Relative risk

A summary measure which represents the ratio of the risk of a given event or outcome (for example, an adverse reaction to the drug being tested) in one group of subjects compared with another group. When the ‘risk’ of the event is the same in the two groups the relative risk is one. In a study comparing two treatments, a relative risk of two would indicate that patients receiving one of the treatments had twice the risk of an undesirable outcome than those receiving the other treatment.

Reliability

Reliability refers to a method of measurement that consistently gives the same results. For example, someone who has a high score on one occasion tends to have a high score if measured on another occasion very soon afterwards. With physical assessments it is possible for different clinicians to make independent assessments in quick succession and if their assessments tend to agree then the method of assessment is said to be reliable.

Retrospective study

A retrospective study deals with the present and past and does not involve studying future events. This contrasts with studies that are prospective.

Risk ratio

Ratio of the risk of an undesirable event or outcome occurring in a group of patients receiving experimental treatment compared with a comparison (control group).

Sample

A part of the study’s target population from which the subjects of the study will be recruited. If subjects are drawn in an unbiased way from a particular population, the results can be generalised from the sample to the population as a whole.

Screening

The presumptive identification of an unrecognised disease or defect by means of tests, examinations or other procedures that can be applied rapidly. Screening tests differentiate apparently well people who may have a disease from those who probably do not. A screening
test is not intended to be diagnostic but should be sufficiently sensitive and specific to reduce the proportion of false results, positive or negative, to acceptable levels. People with positive or suspicious findings must be referred to the appropriate healthcare provider for diagnosis and necessary treatment.

**Selection criteria**
Explicit standards used by guideline development groups to decide which studies should be included and excluded from consideration as potential sources of evidence.

**Sensitivity analysis**
A technique used in economic evaluation in order to test the robustness of the results under the uncertainty/imprecision in the estimates of costs and outcomes, or under methodological controversy.

**Statistical power**
The ability of a study to demonstrate an association or causal relationship between two variables, given that an association exists. For example, 80% power in a clinical trial means that the study has an 80% chance of ending up with a p value of less than 5% in a statistical test (that is, a statistically significant treatment effect) if there really was an important difference (for example, 10% versus 5% mortality) between treatments. If the statistical power of a study is low, the study results will be questionable (the study might have been too small to detect any differences). By convention, 80% is an acceptable level of power. See also p value.

**Sterilisation – female**
Surgical contraceptive methods, whereby the fallopian tubes undergo bilateral ligation or interruption.

**Sterilisation – male**
Surgical contraceptive method, whereby the vas deferens undergoes bilateral ligation or interruption.

**Systematic review**
A review in which evidence from scientific studies is identified, appraised and synthesised in a methodical way according to predetermined criteria. May or may not include a meta-analysis.

**Validity**
Assessment of how well a tool or instrument measures what it is intended to measure.

**Variable**
A measurement that can vary within a study, for example, the age of participants. Variability is present when differences can be seen between different people or within the same person over time, with respect to any characteristic or feature that can be assessed or measured.
Contraception can be divided into two broad categories: hormonal and nonhormonal. There are two categories of hormonal contraception: combined oestrogen and progestogen and progestogen-only. Long-acting reversible contraception (LARC) is defined in this guideline as methods that require administering less than once per cycle or month.

Included in the category of LARC are the copper intrauterine devices (nonhormonal) and three progestogen-only methods of contraception (intrauterine system, injectables and the implants). The combined vaginal ring is not licensed in the UK and is therefore excluded from this guideline.

In 2003/04, about 8% of women aged 16–49 years in Great Britain used LARC as a method of contraception.1 [EL = 3]

1.1 Aim of the guideline

Clinical guidelines have been defined as ‘systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions’.2 The guideline has been developed with the aim of providing guidance on LARC. The effectiveness of barrier and oral contraceptive pills is dependent on their correct and consistent use. In contrast, long-acting reversible methods have effectiveness that does not depend on daily adherence. Currently there is a very low uptake of LARC (around 8% of contraceptive usage in 2003/04).1 A number of factors contribute to this. Issues for providers include the initial cost, which may be thought of as too high, particularly if the methods may not be used or required for the intended duration, the need for specific clinical skills (including awareness of current best practice, insertion practice and ability to give information or advice on the methods available) and facilities. Expert clinical opinion is that LARC methods may have a wider role and an increase in their use could help to reduce unintended pregnancy. The current very low uptake suggests that healthcare professionals need better guidance and training so that they can help women to make an informed choice from a full range of contraceptive methods. Enabling women to make an informed choice about LARC and addressing consumer preferences is an important objective of this guideline.

There are no current formal professional or NHS guidelines covering this topic that are widely used or tailored to cover UK practice. This guideline offers best practice advice for all women of reproductive age who may wish to regulate their fertility through the use of long-acting reversible contraceptive methods and considers specific issues for the use of these methods in women during the menarche and before the menopause. The guideline also identifies specific issues that may be relevant to particular groups, including women with HIV, learning disabilities and physical disabilities, and under-16s.

1.2 Areas outside the remit of the guideline

The guideline does not include any contraception for men because there are currently no long-acting reversible methods. The guideline does not cover methods of contraception that are intended to result in permanent sterilisation. Contraceptive methods that are related to coitus or that require frequent (more than once per cycle (month) for women) repeat administration – for example, the combined oral contraceptive (COC) pill or progestogen-only pills – are also not included. Post-coital or emergency contraceptive methods including intrauterine device (IUD) insertion for that use are also not covered. The use of these technologies for non-contraceptive reasons (such as heavy menstrual bleeding or hormone replacement therapy) is outside the scope of this guideline.
1.3 For whom is the guideline intended?

This guideline is of relevance to those who work in or use the National Health Service in England and Wales. In particular:

- professional groups who are involved in the care of women seeking advice on contraception (including general practitioners, gynaecologists, nurses, and practitioners in community contraceptive clinics, sexual health clinics and hospital services)
- those responsible for commissioning and planning healthcare services, including primary care trust commissioners, Health Commission Wales commissioners, and public health and trust managers
- women seeking advice on contraception, their families and other carers.

A version of this guideline for women seeking contraceptive advice, their families and the public is available, entitled Long-acting reversible contraception – understanding NICE guidance. It can be downloaded from the NICE website (www.nice.org.uk/CG030) or ordered via the NHS Response Line (0870 1555 455) and quote reference number NO916.

1.4 Who has developed the guideline?

The guideline was developed by a multi-professional and lay working group (the Guideline Development Group or GDG) convened by the National Collaborating Centre for Women’s and Children’s Health (NCC-WCH). Membership included: two consumers, two general practitioners, two family planning nurses, three specialist family planning doctors and one genitourinary medicine physician.

Staff from the NCC-WCH provided methodological support for the guideline development process, undertook systematic searches, retrieval and appraisal of the evidence, and wrote successive drafts of the guideline.

All GDG members’ interests were recorded on a standard declaration form that covered consultancies, fee-paid work, shareholdings, fellowships, and support from the healthcare industry in accordance with guidance from the National Institute for Health and Clinical Excellence (NICE).

1.5 Other relevant documents

This guideline is intended to complement other existing and proposed works of relevance, including A Strategic Framework for Promoting Sexual Health in Wales (January 2000),3 The National Strategy for Sexual Health and HIV (in England; July 2001),4 and the subsequent implementation plan (June 2002).5 Improving access to contraception, and to the range of methods available as an integral part of broader sexual health services, is an essential element in achieving this aim.

1.6 Guideline development methodology

This guideline was commissioned by NICE and developed in accordance with the guideline development process outlined in The Guideline Development Process – Information for National Collaborating Centres and Guideline Development Groups (available at www.nice.org.uk/page.aspx?o=201982).6

Literature search strategy

The aim of the literature review was to identify and synthesise relevant published evidence. However, evidence submitted by stakeholder organisations was considered and, if relevant to the clinical questions and of equivalent or better quality than evidence identified in the literature searches, was also included. Relevant guidelines produced by other development groups were identified using internet resources, including the National Guideline Clearinghouse, Scottish Intercollegiate Guideline Network (SIGN) and Turning Research into Practice (TRIP). The reference lists in these guidelines were checked against subsequent searches to identify missing evidence.
Evidence to answer the clinical questions formulated and agreed by the GDG was identified using biomedical databases via the OVID platform. Searches were performed using relevant medical subject headings and free-text terms. No language restrictions were applied to the searches. Both generic and specially developed search filters were employed when necessary. Databases searched were MEDLINE (1966 onwards), EMBASE (1980 onwards), Cochrane Central Register of Controlled Trials (4th Quarter 2004), Cochrane Database of Systematic Reviews (4th Quarter 2004), Database of Abstracts of Review of Effects (4th Quarter 2004), and Cumulative Index to Nursing & Allied Health Literature (1982 onwards). POPLINE®, a specialist reproduction database maintained by Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs, was also utilised.

Searches to identify economic studies were undertaken using the above databases, as well as the Health Economic Evaluations Database and the National Health Service Economic Evaluations Database.

There was no systematic attempt to search grey literature (conferences, abstracts, theses and unpublished trials). Hand searching of journals not indexed on the biomedical databases was not carried out.

A preliminary scrutiny of titles and abstracts was undertaken and full copies of publications that addressed the clinical questions were obtained. Following a critical appraisal of each publication, studies that did not report relevant outcomes or were not relevant to a particular clinical question were excluded.

Searches were rerun at the end of the guideline development process, thereby including evidence published and included in the literature databases up to 1 February 2005. Any evidence published after this date was not considered for inclusion. This date should be considered for the starting point for searching for new evidence for future updates to this guideline.

Further details of literature searches can be obtained from the NCC-WCH.

**Synthesis of clinical effectiveness evidence**

Evidence relating to clinical effectiveness was reviewed using established guides7–13 and classified using the established hierarchical system shown in Table 1.1.13 This system reflects the susceptibility to bias that is inherent in particular study designs.

The type of clinical question dictates the highest level of evidence that may be sought. In assessing the quality of the evidence, each paper receives a quality rating coded as ‘++’, ‘+’ or ‘−’. For issues of therapy or treatment, the highest possible level of evidence (EL) is a well-conducted systematic review or meta-analysis of RCTs (EL = 1++) or an individual RCT (EL = 1+). Studies of poor quality are rated as ‘−’. Usually, studies rated as ‘−’ should not be used as a basis for making a recommendation, but they can be used to inform recommendations. For issues of prognosis, the highest possible level of evidence is a cohort study (EL = 2−).

**Table 1.1** Levels of evidence for intervention studies11

<table>
<thead>
<tr>
<th>Level</th>
<th>Source of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1−</td>
<td>Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High-quality systematic reviews of case–control or cohort studies</td>
</tr>
<tr>
<td>2+</td>
<td>High-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal</td>
</tr>
<tr>
<td>2−</td>
<td>Case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>3</td>
<td>Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>4</td>
<td>Non-analytical studies (for example, case reports, case series)</td>
</tr>
<tr>
<td>5</td>
<td>Expert opinion, formal consensus</td>
</tr>
</tbody>
</table>
For each clinical question, the highest available level of evidence was selected. Where appropriate, for example, if a systematic review, meta-analysis or RCT existed in relation to a question, studies of a weaker design were not included. Where systematic reviews, meta-analyses and RCTs did not exist, other appropriate experimental or observational studies were sought. For diagnostic tests, test evaluation studies examining the performance of the test were used if the efficacy of the test was required, but where an evaluation of the effectiveness of the test in the clinical management of patients and the outcome of disease was required, evidence from RCTs or cohort studies was used.

In contraception research, investigators have not attempted to directly measure the true efficacy of a contraceptive method, compared with a control group using no method, because ethical concerns do not permit the withholding of contraception.\textsuperscript{14,15} For this guideline, the selection criteria for including studies as a source of evidence were based on the comparability of the study population and contraceptive devices to that of the UK, as determined to be appropriate by the Guideline Development Group.

Evidence was synthesised qualitatively by summarising the content of identified papers in evidence tables and agreeing brief statements that accurately reflected the evidence. Quantitative synthesis (meta-analysis) was performed where appropriate.

Summary results and data are presented in the guideline text. More detailed results and data are presented in the accompanying evidence tables. Where possible, dichotomous outcomes are presented as relative risks (RRs) with 95% confidence intervals (CIs), and continuous outcomes are presented as mean differences with 95% CIs or standard deviations (SDs). Meta-analyses based on dichotomous outcomes are presented as pooled odds ratios (ORs) with 95% CIs, and meta-analyses based on continuous outcomes are presented as weighted mean differences (WMDs) with 95% CIs.

**Health economics**

The aim of the economic input to the guideline was to inform the GDG of potential economic issues related to long-acting reversible contraception. The objective was to assess the relative cost effectiveness between LARC methods and other contraceptive methods that were considered as relevant comparators by the GDG. For this purpose, a systematic review of the economic literature was undertaken, together with a cost effectiveness analysis based on a decision-analytic economic model that was developed for this guideline.

The search strategies adopted for the systematic review were designed to identify any economic study related to LARC. Abstracts of all papers identified were reviewed by the health economists and were excluded if they did not relate to the economic questions being considered in the guideline. The relevant papers were retrieved and critically appraised. Potentially relevant references in the bibliographies of the reviewed papers were also identified and reviewed. All papers reviewed were assessed by the health economists against standard quality criteria for economic evaluation.

The decision-analytic model was developed by the health economists with the support of the GDG, who provided guidance on the data needed to populate the model and on the assumptions required to make appropriate comparisons. Full details on the methodology, the structure of the model and the underlying assumptions, the data used (clinical effectiveness and UK-based cost data), the range of values used in the sensitivity analysis, as well as the full results of the economic analysis are also presented in Chapter 8.

**Forming and grading recommendations**

For each clinical question, recommendations were derived using, and explicitly linked to, the evidence that supported them. Initially guideline recommendations were based on an informal consensus. Consensus was achieved at formal GDG meetings to finalise the agreement of recommendations and audit criteria.

Each recommendation was graded according to the level of evidence upon which it was based using the established system shown in Table 1.2.\textsuperscript{15} For issues of therapy or treatment, the best possible level of evidence (a systematic review or meta-analysis or an individual RCT) would
equate to a grade A recommendation. For issues of prognosis, the best possible level of evidence (a cohort study) would equate to a grade B recommendation. However, this should not be interpreted as an inferior grade of recommendation because it represents the highest level of relevant evidence. Indirect evidence on contraceptive devices not licensed in the UK was extrapolated to form recommendations reflecting a lower grading.

External review

The guideline has been developed in accordance with the NICE guideline development process. This has included giving registered stakeholders the opportunity to comment on the scope of the guideline at the initial stage of development and on the evidence and recommendations at the concluding stage. The developers have carefully considered all of the comments during the two stages of consultation by registered stakeholders and validation by the Institute. After the second consultation, changes were made to the final document. A summary of these changes is presented in Appendix A.

Outcome measures used in the guideline

For this guideline, the effectiveness of contraceptive methods has been assessed against a number of outcomes which were agreed by the GDG on the basis of their relevance to patients and professionals. These outcomes are contraceptive effectiveness (measured by failure rates, i.e. pregnancy per 100 women-years); impact on menstrual bleeding; discontinuation and acceptability of method; and impact on longer-term reproductive health. Side effects from methods include hormonal effects – menstrual disturbances, skin effects, bone mineral density, mood (premenstrual symptoms and depression) – and risks of thromboembolic disease. Specific consideration was given to the effectiveness and use of these methods in specific groups of women, such as women who are breastfeeding, teenagers, women at risk of sexually transmitted infection and HIV, women aged over 35 years and women with other conditions such as diabetes, epilepsy and HIV which may impact on their contraceptive choices.

Table 1.2 Classification of recommendations

<table>
<thead>
<tr>
<th>Class</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>• At least one meta-analysis, systematic review, or randomised controlled trial (RCT) that is rated as 1++, and is directly applicable to the target population, or&lt;br&gt;• A systematic review of RCTs or a body of evidence that consists principally of studies rated as 1+, is directly applicable to the target population and demonstrates overall consistency of results, or&lt;br&gt;• Evidence drawn from a NICE technology appraisal&lt;br&gt;</td>
</tr>
<tr>
<td>B</td>
<td>• A body of evidence that includes studies rated as 2++, is directly applicable to the target population and demonstrates overall consistency of results, or&lt;br&gt;• Extrapolated evidence from studies rated as 1++ or 1+&lt;br&gt;</td>
</tr>
<tr>
<td>C</td>
<td>• A body of evidence that includes studies rated as 2+, is directly applicable to the target population and demonstrates overall consistency of results, or&lt;br&gt;• Extrapolated evidence from studies rated as 2++&lt;br&gt;</td>
</tr>
<tr>
<td>D</td>
<td>• Evidence level 3 or 4, or&lt;br&gt;• Extrapolated evidence from studies rated as 2+, or&lt;br&gt;• Formal consensus&lt;br&gt;</td>
</tr>
<tr>
<td>D(GPP)</td>
<td>• A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group&lt;br&gt;</td>
</tr>
</tbody>
</table>
2. Summary of recommendations and practice algorithm

2.1 Summary of recommendations

Chapter 3 Contraceptive use and principles of care

Contraceptive provision
Women requiring contraception should be given information about and offered a choice of all methods, including long-acting reversible contraception (LARC) methods. (Chapter 3.2)

Women should be provided with the method of contraception that is most acceptable to them provided it is not contraindicated. (Chapter 3.8)

Contraceptive service providers should be aware that

- all currently available LARC methods (intrauterine devices [IUDs], the intrauterine system [IUS], injectable contraceptives and implants) are more cost effective than the combined oral contraceptive pill even at 1 year of use
- IUDs, the IUS and implants are more cost effective than the injectable contraceptives
- increasing the uptake of LARC methods will reduce the number of unintended pregnancies. (Chapter 8.6)

Provision of information and informed choice
Women considering LARC methods should receive detailed information – both verbal and written – that will enable them to choose a method and use it effectively. This information should take into consideration their individual needs and should include: (Chapter 3.5)

- contraceptive efficacy
- duration of use
- risks and possible side effects
- non-contraceptive benefits
- the procedure for initiation and removal/discontinuation
- when to seek help while using the method.

Counselling about contraception should be sensitive to cultural differences and religious beliefs. (Chapter 3.5)

Healthcare professionals should have access to trained interpreters for women who are not English speaking, and to advocates for women with sensory impairments or learning disabilities. (Chapter 3.5)
Contraceptive prescribing
A medical history – including relevant family, menstrual, contraceptive and sexual history – should be taken as part of the routine assessment of medical eligibility for individual contraceptive methods. (Chapter 3.6)

Healthcare professionals helping women to make contraceptive choices should be familiar with nationally agreed guidance on medical eligibility and recommendations for contraceptive use. (Chapter 3.6)

When considering choice of LARC methods for specific groups of women and women with medical conditions, healthcare professionals should be aware of and discuss with each woman any issues that might affect her choice. (Chapter 3.5/3.6)

Healthcare professionals should exclude pregnancy by taking the menstrual and sexual history before initiating any contraceptive methods. (Chapter 3.6)

Healthcare professionals should supply an interim method of contraception at the first appointment if required. (Chapter 3.6)

Healthcare professionals should ensure that informed consent is obtained from the woman whenever any method of LARC is being used outside the terms of the UK Marketing Authorisation. This should be discussed and documented in the notes. (Chapter 3.6)

Women who have a current venous thromboembolism (VTE) and need hormonal contraception while having treatment for the VTE should be referred to a specialist in contraceptive care. (Chapter 5.7)

Contraception and sexually transmitted infection
Healthcare professionals providing contraceptive advice should promote safer sex. (Chapter 3.11)

Healthcare professionals providing contraceptive advice should be able to assess risk for sexually transmitted infections (STIs) and advise testing when appropriate. (Chapter 3.11)

Healthcare professionals should be able to provide information about local services for STI screening, investigation and treatment. (Chapter 3.11)

Contraception for special groups
Healthcare professionals should be aware of the law relating to the provision of advice and contraception for young people and for people with learning disabilities. Child protection issues and the Fraser guidelines should be considered when providing contraception for women younger than 16 years.* (Chapter 3.13)

Women with learning and/or physical disabilities should be supported in making their own decisions about contraception. (Chapter 3.13)

Contraception should be seen in terms of the needs of the individual rather than in terms of relieving the anxieties of carers or relatives. (Chapter 3.13)

When a woman with a learning disability is unable to understand and take responsibility for decisions about contraception, carers and other involved parties should meet to address issues around the woman’s contraceptive need and to establish a care plan. (Chapter 3.13)

Training of healthcare professionals in contraceptive care
Healthcare professionals advising women about contraceptive choices should be competent to: (Chapter 3.14)

* See the Department of Health’s Best Practice Guidance for Doctors and Other Health Professionals on the Provision of Advice and Treatment to Young People under 16 on Contraception, Sexual and Reproductive Health (July 2004), available from www.dh.gov.uk.
• help women to consider and compare the risks and benefits of all methods relevant to their individual needs
• manage common side effects and problems.

Contraceptive service providers who do not provide LARC in their practice or service should have an agreed mechanism in place for referring women for LARC. (Chapter 3.14)

Healthcare professionals providing intrauterine or subdermal contraceptives should receive training to develop and maintain the relevant skills to provide these methods. (Chapter 3.14)

IUDs and the IUS should only be fitted by trained personnel with continuing experience of inserting at least one IUD or one IUS a month. (Chapter 4.10/5.10)

Contraceptive implants should be inserted and removed only by healthcare professionals trained in the procedure. (Chapter 7.9)

Chapter 4 Copper intrauterine devices (IUDs)

Decision making
Women should be given the following information.

Contraceptive efficacy
• IUDs act by preventing fertilisation and inhibiting implantation. (Chapter 4.1)
• The licensed duration of use for IUDs containing 380 mm² copper ranges from 5 to 10 years, depending on the type of device. (Chapter 4.1)
• The pregnancy rate associated with the use of IUDs containing 380 mm² copper is very low (fewer than 20 in 1000 over 5 years). (Chapter 4.2)
• There is no evidence of a delay in the return of fertility following removal or expulsion of IUDs. (Chapter 4.8)

Effect on periods
• Heavier bleeding and/or dysmenorrhoea are likely with IUD use. (Chapter 4.5)

Risks and possible side effects
• Up to 50% of women stop using IUDs within 5 years; the most common reasons for discontinuation are unacceptable vaginal bleeding and pain. (Chapter 4.4)
• There is no evidence that IUD use affects weight. (Chapter 4.6)
• Any changes in mood and libido are similar whether using IUDs or the IUS, and the changes are small. (Chapter 4.6)
• The risk of uterine perforation at the time of IUD insertion is very low (less than 1 in 1000). (Chapter 4.7)
• The risk of developing pelvic inflammatory disease following IUD insertion is very low (less than 1 in 100) in women who are at low risk of STIs. (Chapter 4.7)
• IUDs may be expelled but this occurs in fewer than 1 in 20 women in 5 years. (Chapter 4.3)
• The risk of ectopic pregnancy when using IUDs is lower than when using no contraception. (Chapter 4.7)
• The overall risk of ectopic pregnancy when using the IUD is very low, at about 1 in 1000 in 5 years.
• If a woman becomes pregnant with the IUD in situ, the risk of ectopic pregnancy is about 1 in 20, and she should seek advice to exclude ectopic pregnancy. (Chapter 4.7)
• Contraceptive implants are medically safe for women to use if oestrogen is contra-
  indicated (Chapter 7.6)
• There is no evidence of an effect of Implanon use on bone mineral density.
  (Chapter 7.6)
• Implanon is not recommended as a contraceptive method for women taking liver
  enzyme-inducing drugs. (Chapter 7.12)

Practical details of fitting implants
Provided that it is reasonably certain that the woman is not pregnant, Implanon may
be inserted: (Chapter 7.8)
• At any time (but if the woman is amenorrhoeic or it has been more than 5 days
  since menstrual bleeding started, additional barrier contraception should be used
  for first 7 days after insertion)
• Immediately after abortion in any trimester
• At any time postpartum.

Advice for women at time of fitting
Women should be informed that Implanon insertion and removal both cause some
discomfort and bruising but that technical problems are unusual (less than 1 in 100).
(Chapter 7.8)

Follow-up and managing problems
No routine follow-up is needed after implant insertion. However, a woman should
be strongly encouraged to return at any time to discuss problems, if she wants to
change her method of contraception, or if it is time to have the implant removed.
(Chapter 7.13)

Irregular bleeding associated with implant use can be treated with mefenamic acid
or ethinylestradiol.* (Chapter 7.4)

There is no evidence of a teratogenic effect of Implanon use but, if a woman becomes
pregnant and continues with the pregnancy, the implant should be removed.
(Chapter 7.6)

If an Implanon implant cannot be palpated (due to deep insertion, failed insertion or
migration) it should be localised by ultrasound investigation before being removed.
Deeply inserted implants often need to be removed by an expert. (Chapter 7.8)

2.2 Future research recommendations

The scarcity of robust evidence to answer important clinical questions on the use of LARC
methods by women in the UK has posed great challenges to the developers of this guideline. In
the majority of cases, the guideline recommendations are based on extrapolated evidence that
is indirect or of poor methodological quality. The GDG has made the following recommend-
ations for research on the basis of its review of the evidence. The GDG regards these questions
as being the most important research areas in terms of improving NICE guidance on the use of
LARC, and the care of women choosing LARC, when this guideline is updated in 4 years’ time.

In making these recommendations for research, the guideline developers consider it important
and relevant that the research should be specific to the UK population because there are cultural
differences in the response to side effects and non-contraceptive effects of hormonal contra-
ceptives. In addition, freedom to choose any contraceptive method and the provision of a free

* The recommendation on treating irregular bleeding after insertion of a contraceptive implant has been changed (this
is recommendation 1.5.4.2 in the NICE guideline). Although the evidence does show that mifepristone is effective
at controlling irregular bleeding associated with implants, it is not licensed for this indication. The revised
recommendation reads: ‘Irregular bleeding associated with implant use can be treated with mefenamic acid or
ethinylestradiol.’
contraceptive health service in the UK can influence important outcomes such as continuation rates and patterns of method switching.

**Typical use of contraception**

Few women use contraception perfectly (that is, exactly in accordance with the product instructions) and consistently. Pregnancy rates during typical use reflect effectiveness of a method among women who use the methods incorrectly or inconsistently. Few data are available on typical use of any contraceptive method among women in the UK. Much of the data on contraceptive effectiveness used in the guideline comes from clinical trials or surveys undertaken in other countries such as the USA. Large prospective cohort studies are required to compare the contraceptive effectiveness of LARC methods with non-LARC methods during typical use in the UK.

**Patterns of LARC use**

Most women will need to use contraception for more than 30 years. Patterns of contraceptive use vary with age, ethnicity, marital status, fertility intention, education and lifestyle. Large prospective cohort studies are required to identify:

- patterns of use (initiation, continuation and switching between methods) of LARC methods compared with non-LARC methods
- factors which influence the patterns of use of LARC.

**Uptake and acceptance of LARC**

In addition to individual circumstances and needs, a woman’s choice and acceptance of LARC may be influenced by potential health disbenefits (side effects and risks) as well as non-contraceptive benefits (such as alleviation of menorrhagia) of LARC. Large population studies of appropriate design are required to determine these effects on the uptake of LARC methods and the implications for NHS resources.

**Bone mineral density in women using DMPA**

The effect of injectable contraceptives on bone mineral density in women who have used depot medroxyprogesterone acetate (DMPA) for longer than two years is uncertain. Adequately powered surveys or cross-sectional studies are required to examine the recovery of bone mineral density following discontinuation of DMPA after long-term and very long-term use. Studies are also required to examine the risk of bone fractures in older women.

### 2.3 LARC selection algorithm
3. Contraceptive use and principles of care

3.1 Normal fertility

During sexual intercourse, spermatozoa are deposited into the vagina. They migrate through the cervix and uterine cavity to the fallopian tubes where, if they meet the egg, fertilisation can take place. The embryo then travels down the fallopian tube and enters the uterine cavity where implantation takes place. The length of a menstrual cycle varies from 21 days to 35 days. Ovulation usually takes place 12–16 days before the start of the next period. For a woman with a 28-day menstrual cycle (the first day of menstruation being day 1), ovulation takes place around day 14. After ovulation, the egg usually lives for up to 24 hours. After ejaculation, sperm can survive for up to 7 days in the genital tract. Most pregnancies can be attributed to sexual intercourse during a 6-day period ending on the day of ovulation, with the highest estimated conception rates associated with intercourse 2 days before ovulation. This information is used as the basis for methods of contraception relying on fertility awareness (periodic abstinence) and informs the advice relating to the use of emergency contraception and what action to take when oral contraceptive pills are missed. Misunderstandings about inherent fertility and about the time in the cycle when pregnancy is most likely to occur lead to incorrect and inconsistent use of barrier methods and oral contraceptives.

In the general population it is estimated that 84% of women would conceive within 1 year of regular unprotected sexual intercourse. This rises cumulatively to 92% after 2 years and 93% after 3 years.

The conception rate per menstrual cycle is known as fecundability. Natural female fertility declines with age. The decline with age in rates of conception is seen after 30 years of age and is more marked after age 35 years.

3.2 Contraceptive provision

In 1994 at the International Conference on Population and Development (ICPD) in Cairo, Egypt, government delegations from 179 countries, including the UK, agreed a Programme of Action to stabilise the world’s population. The Programme of Action defined reproductive rights and stated that people should have the freedom to decide if, when, and how often to have children. ICPD further called for universal access to a full range of high-quality, affordable, accessible and convenient sexual and reproductive health services.

Since 1974 contraception has been provided free of prescription charges in the UK. It is provided by general practitioners (GPs), community (NHS) family planning clinics (FPCs) and, increasingly, in some not-for-profit charitable clinics such as Brook (usually limited to young people under 25 years). Contraception is also provided in sexual health clinics, NHS walk-in centres and some genitourinary medicine clinics. Some pharmacies provide emergency contraception free through specific NHS protocols. In Great Britain in 2003/04 almost 57% of women aged 16–49 years had used at least one service in the previous 5 years. Most (81%) had visited their GP surgery but 32% had used a community FPC. Not all settings provide all methods of contraception, and not all doctors are competent to fit intrauterine devices (IUDs) or systems (IUS) or contraceptive implants (refer to Medical Foundation for AIDS and Sexual Health (MedFASH) Sexual Health Standards at www.medfash.org.uk/). Women attending FPCs are more
likely to use a long-acting method of contraception, particularly implants and IUD/IUS, than those consulting their GP.

In the UK, because contraceptives are provided free of charge, cost plays no part in determining an individual’s choice of method and does not influence continuation rates or method switching. In countries where contraceptives are not free and where the consultation and procedure may also be charged to the user, cost plays a much bigger part in uptake and continuation and data from these countries must be extrapolated to the UK with caution. In one state in the USA in the early 1990s women were offered a payment of $500 if they had Norplant® inserted and further annual payments of $50 for each year they kept it. Cost, however, is relevant to the service provider and may determine the choice of methods available in some settings. Some local formulary committees withhold approval of the newer, more expensive contraceptive methods (such as the contraceptive patch and newer brands of oral contraceptive pill) arguing that there is no evidence of superiority over existing cheaper methods. Providers’ attitudes towards, knowledge of, and preferences for particular methods of contraception influence the choices made by the users. If women/couples are not informed about all available methods of contraception, their choices are restricted.

**RECOMMENDATION**

Women requiring contraception should be given information about and offered a choice of all methods, including long-acting reversible contraception (LARC) methods.

### 3.3 Contraceptive prevalence

Almost everyone in the UK uses contraception at some time in their lives. Contraceptive prevalence has increased dramatically in the last 30 years. In Great Britain in 2003/04, 52% of all women aged 16–49 years were using a reversible method of contraception and just under a quarter had either been sterilised (11%) or had a partner who was sterilised (12%). Of women ‘at risk’ of pregnancy (i.e. in a heterosexual relationship, presumed fertile and not actively trying to become pregnant) only 2% were not using any method of contraception. The pattern of contraceptive use varies with age, ethnicity and race, marital status, fertility intentions and education. In Great Britain in 2003/04, the oral contraceptive pill was the most popular method of contraception among women aged 16–49 years (25% of women use it) while the next most popular method was the male condom (23% of women). Long-acting methods of contraception (injectables, implants, IUDs and IUS) were used by 8% of women. In general, the IUD/IUS tends to be adopted by older, parous women while injectable contraceptives such as Depo-Provera® and contraceptive implants such as Implanon® are more commonly used by younger women and women without children. Most hormonal methods of contraception have an effect on vaginal bleeding patterns. For women with certain religious beliefs, methods which cause irregular bleeding can be a major inconvenience. Not all methods are available in all countries and not all available methods are marketed in the UK. Women coming to the UK from elsewhere may be using a method which is unavailable or (e.g. norethisterone enantate, NET-EN) only licensed for short-term use in the UK.

The average age of first intercourse in the UK has stabilised for both men and women at 16 years and the average age of first childbirth has risen to almost 30 years. Since the mean age of menopause is 51 years and the total fertility rate in the UK in 2004 was 1.7, most women/couples will need to use contraception for more than 30 years.

**Unintended pregnancy**

Despite the widespread use of contraception, unintended pregnancy is common. In England and Wales the abortion rate for the quarter January–March 2004 was 18.6 per 1000 women of reproductive age. The abortion rates were 33.6 per 1000 for women in the 20–24 year age group, 28.1 per 1000 women in the 16–19 years age group and 3.9 per 1000 women in women under 16 years of age. Not all unintended pregnancies end in abortion. It has been suggested that as many as 30% of pregnancies which end in childbirth are unplanned when they are conceived. A UK questionnaire survey of pregnant women (n = 12,106) designed to investigate the association of duration of OC usage with time to conception reported that
### Table 3.1 Current use of contraception by age in Great Britain (women aged 16–49 years); data from the Office for National Statistics

<table>
<thead>
<tr>
<th>Current use of contraception</th>
<th>Use by each age range (%)</th>
<th>Use by all ages the during the indicated period (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonsurgical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pills¹</td>
<td>26</td>
<td>58</td>
</tr>
<tr>
<td>Minipill</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>Combined pill</td>
<td>20</td>
<td>29</td>
</tr>
<tr>
<td>Male condom</td>
<td>33</td>
<td>36</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>IUD</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Injection/implant</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Safe period/rhythm method/Persona</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Cap/diaphragm</td>
<td>–</td>
<td>1</td>
</tr>
<tr>
<td>Foam/gels</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Hormonal IUS</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Female condom</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Emergency contraception²</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Total using at least one non-surgical method</td>
<td>50</td>
<td>70</td>
</tr>
<tr>
<td>Surgical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterilised</td>
<td>–</td>
<td>1</td>
</tr>
<tr>
<td>Partner sterilised</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Total using at least one method</td>
<td>50</td>
<td>71</td>
</tr>
<tr>
<td>Total not using any method</td>
<td>50</td>
<td>29</td>
</tr>
</tbody>
</table>

¹ Includes women who did not know the type of pill used.
² Category included for the first time in the 2000/01 questionnaire.
29.4% of the pregnancies were unintentional. Most data suggest that true method failure accounts for fewer than 10% of unintended pregnancies, the rest arising either because no method was used at the time conception occurred (30–50%) or because the method was used inconsistently or incorrectly. Failure due to inconsistent use of oral contraception and condoms was reported to be the main cause of pregnancy among women undergoing termination. It is important for repeat unwanted pregnancies to be prevented rather than aborted. Repeat abortions are common, estimated to be between 27% to 48% of all induced abortions.

Teenage pregnancy

In 2001, 7.4% of all births in England and Wales were to women aged under 20. In 2003, the under-18 years conception rate was 42.3 per 1000 women (aged 15–17 years) and 46% of these conceptions resulted in legal abortions. In 2002, the under-16 conception rate was 7.9 per 1000 women (aged 13–15 years) and 55.7% of these conceptions led to abortions. In 2003, the age-standardised abortion rate was 17.5 per 1000 resident women aged 15–44 years (17.0 in 2002). The abortion rate was the highest at 31.4 per 1000, for women in the 20–24 year age group (30.7 in 2002). The under-16 years abortion rate was 3.9 in 2003 compared with 3.7 per 1000 in 2002. Infant mortality rates for children born to teenage mothers are 1.3-fold higher than that for total births, due mainly to low birth weight and congenital anomalies. Based on a report by the Social Exclusion Unit (SEU) on teenage pregnancy in 1999, the Department of Health has developed a national strategy to:

- reduce the rate of teenage conceptions, with the specific aim of halving the rate of conceptions among under-18s by 2010, with an interim reduction of 15% by 2004
- set a firmly established downward trend in the under-16 years conception rate by 2010
- increase the participation of teenage parents in education and work, to reduce their risk of long-term social exclusion.

3.4 Efficacy and effectiveness of contraception

The effectiveness of a method of contraception is judged by the failure rates associated with its use. Table 3.2 shows failure rates for typical use of methods currently available in the USA. The rates are estimated from US studies, including the National Survey of Family Growth, and show the percentage of couples who experience an accidental pregnancy during the first year of use of each method. Similarly collected data are not available for effectiveness of contraceptives in UK use. Effectiveness rates for LARC from a variety of sources are shown in the individual method chapters in this guideline. The effectiveness of a contraceptive depends on its mode of action and how easy it is to use. Pregnancy rates during perfect use of a method reflect its efficacy. If a method prevents ovulation in every cycle in every woman, it should have an efficacy of 100%, since if there is no egg there can be no conception. Only if a mistake is made, or if the method is used inconsistently, will a pregnancy occur. Imperfect use with long-acting methods of contraception is usually due to provider error – undetected uterine perforation during IUD insertion, for example.

The contraceptive implant Implanon® inhibits ovulation for 3 years and is extremely effective as the user has to take no action once the implant is inserted. The combined pill is probably as effective at preventing ovulation and pregnancy; failure rates for perfect use are only 0.1 in 100 within the first year of use. True pill failures are due to incomplete inhibition of ovulation mainly among women who metabolise the pill rapidly. Inhibition of ovulation, however, depends on the pill being taken perfectly. With imperfect use ovulation can occur and typical-use failure rates are 8 in 100 within the first year of use (Table 3.2).

LARC methods are more effective than barrier methods or oral contraceptives because they demand much less – or are independent of the need for – adherence. Failure rates associated with typical use are virtually the same as those associated with perfect use. Active steps must be taken if a woman wishes to stop using an IUD, IUS or implant while discontinuation of other
<table>
<thead>
<tr>
<th>Method</th>
<th>Women experiencing an unintended pregnancy within the first year of use (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Typical use(^a)</td>
</tr>
<tr>
<td>No method</td>
<td>85</td>
</tr>
<tr>
<td>Spermicides</td>
<td>29</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>27</td>
</tr>
<tr>
<td>Periodic abstinence</td>
<td></td>
</tr>
<tr>
<td>Calendar</td>
<td>25</td>
</tr>
<tr>
<td>Ovulation method</td>
<td></td>
</tr>
<tr>
<td>Sympto-thermal(^f)</td>
<td></td>
</tr>
<tr>
<td>Post-ovulation</td>
<td></td>
</tr>
<tr>
<td>Cap(^g)</td>
<td></td>
</tr>
<tr>
<td>Parous women</td>
<td>32</td>
</tr>
<tr>
<td>Nulliparous women</td>
<td>16</td>
</tr>
<tr>
<td>Sponge</td>
<td></td>
</tr>
<tr>
<td>Parous women</td>
<td>32</td>
</tr>
<tr>
<td>Nulliparous women</td>
<td>16</td>
</tr>
<tr>
<td>Diaphragm(^f)</td>
<td>16</td>
</tr>
<tr>
<td>Condom(^g)</td>
<td></td>
</tr>
<tr>
<td>Female (Reality)</td>
<td>21</td>
</tr>
<tr>
<td>Male</td>
<td>15</td>
</tr>
<tr>
<td>Combined pill and minipill</td>
<td>8</td>
</tr>
<tr>
<td>Evra patch(^h)</td>
<td>8</td>
</tr>
<tr>
<td>NuvaRing</td>
<td>8</td>
</tr>
<tr>
<td>Depo-Provera</td>
<td>3</td>
</tr>
<tr>
<td>Lunelle</td>
<td>3</td>
</tr>
<tr>
<td>IUD</td>
<td></td>
</tr>
<tr>
<td>Progestasert (progesterone T)</td>
<td>2</td>
</tr>
<tr>
<td>ParaGard (copper T)</td>
<td>0.8</td>
</tr>
<tr>
<td>Mirena (LNG-IUS)</td>
<td>0.1</td>
</tr>
<tr>
<td>Norplant and Norplant-2</td>
<td>0.05</td>
</tr>
<tr>
<td>Female sterilisation</td>
<td>0.5</td>
</tr>
<tr>
<td>Male sterilisation</td>
<td>0.15</td>
</tr>
</tbody>
</table>

\(^a\) Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides, withdrawal, periodic abstinence, the diaphragm, the male condom, the pill and Depo-Provera are taken from the 1995 National Survey of Family Growth corrected for underreporting of abortion.

\(^b\) Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

\(^c\) The percentages becoming pregnant are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

\(^d\) Foams, creams, gels, vaginal suppositories and vaginal film.

\(^e\) Cervical mucus (ovulation) method supplemented by calendar in the pre-ovulatory and basal body temperature in the post-ovulatory phases.

\(^f\) With spermicidal cream or jelly.

\(^g\) Without spermicides.

\(^h\) Some of the methods listed in this table are not available in the UK and some of the methods available in the UK are not available in the USA and therefore are not listed here. This table does not include any data on Implanon. ParaGard\(^d\) is the TCu 380A IUD.
methods (including injectables) is passive. In a cohort study of US teenagers using Norplant (n = 200), pills (n = 100) or condoms (n = 99), there were no pregnancies among Norplant users while one-third of teenagers using pills or condoms had conceived.54

Pregnancy rates are still often described by the Pearl Index (PI) – the number of unintended pregnancies divided by the number of women-years of exposure to the risk of pregnancy while using the method. The PI is expressed as the pregnancy rate per 100 woman-years (a woman-year is defined as 13 menstrual cycles).55 If, out of 100 women using a contraceptive method for 13 cycles, one becomes pregnant the PI is 1.0.

Failure rates of most methods decrease with time since women most prone to failure will become pregnant soon after starting a method.51 Over time, a cohort of couples still using a method increasingly comprises couples in which the woman is unlikely to become pregnant (because they are good at using the method, highly motivated to avoid pregnancy, or are infertile). So, the longer a contraceptive trial lasts, the lower the pregnancy rate is likely to be. Furthermore, failure rates in most clinical trials are often underestimated because all of the months of use of the method are taken into account when calculating failure rates, regardless of whether or not intercourse has occurred during that cycle. For long-acting methods of contraception such as IUDs and implants, the pregnancy rate with time (cumulative pregnancy rate) is more informative and is presented as the standard measure of contraceptive effectiveness in this guideline.

The effectiveness of all methods of contraception is likely to be higher in clinical trials than in real life56 since trial participants are not representative of the general population of contraceptive users and the routine daily recording of contraceptive use (mandatory in trials) enhances adherence. Randomised placebo-controlled trials are widely regarded as the gold standard for determining effectiveness of drugs and other therapeutic interventions. However, use of a placebo is unethical in trials of a contraceptive method since all contraceptive users wish to avoid pregnancy. While RCTs between like methods (one type of copper IUD versus another, or one brand of combined pill versus another) are possible, it is extremely difficult to recruit people willing to participate in RCTs comparing different types of contraceptive. In developed countries most women are well informed about contraceptive choice and have strong views about methods they do – and particularly do not – want to use.57,58

The effectiveness of some hormonal methods of contraception is affected by the body weight of the user. Women of a high body weight have higher failure rates with pills,59 Norplant60,61 and patches.62 Body weight may also influence bleeding patterns; women with a low body weight are more likely to experience amenorrhoea while using Norplant.63 Trials of effectiveness in populations of women with a much lower body weight than that of the average UK female population (such as women from Thailand or Indonesia) may underestimate failure rates and the side effects profile.

### 3.5 Provision of information and informed choice

Accurate, up-to-date information is essential to enable users to make an informed and voluntary choice of a contraceptive method. User satisfaction and successful use of contraception depend on adequate knowledge and accurate perceptions of the method. Counselling is a face-to-face communication in which one person helps another make decisions and act on them.64 The ultimate goal of contraceptive counselling is to allow women to choose a method they feel most comfortable with and will continue using, taking into account their lifestyle preferences and concerns. Contraceptive counselling helps women to learn more about contraception and combats misinformation about contraceptive methods. In addition, counselling can provide the basis for informed consent and set the stage for increased user satisfaction with the method chosen. Informed choice is facilitated by promoting understanding of the relative effectiveness of the method, how it works, insertion and removal procedures, correct use, common side effects, health risks and benefits, when to seek medical advice, information on return to fertility after discontinuation, and advice on STI protection and sexual health.

A UK questionnaire survey of family planning physicians at six centres on counselling Norplant users (n = 521) reported that patient counselling contributed to increasing patient acceptance of
Norplant. Eighty-two percent of women accepted the implants despite an overall rate of menstrual bleeding irregularities of 13%. Pre-insertion counselling occurred 100% of the time at these centres and physicians and nurses were responsible for counselling 78% and 39% of the time, respectively.65 [EL = 3]

Knowledge and concerns about contraceptive methods

Using a series of semi-structured focus groups, a UK study assessed women’s knowledge of the effectiveness of various contraceptive methods and of the risks of thrombosis associated with hormonal contraceptives. Women (n = 45) tended to underestimate the effectiveness of hormonal contraceptives, particularly implants, and to overestimate the risk of thrombosis associated with hormonal contraceptives.66 [EL = 3] Many were more concerned about the adverse effects (especially bleeding irregularities and weight gain) than about effectiveness.

A US questionnaire survey (n = 249, aged 12–20 years) reported that knowledge of Norplant among the general adolescent population was poor. However, young women who were using Norplant were 11 times more likely than those using other types of contraceptive methods to be more knowledgeable about Norplant, having received additional counselling from healthcare providers.67 [EL = 3]

Source of information

An audit in the UK undertaken to develop informational materials about new contraceptive products reported that women received information about a broad range of contraception available, but that 33% of women came with their ‘own agenda’ and were sure before the visit about which method they wanted.57 [EL = 3]

One survey (n = 4500) in the Netherlands reported that women were well informed about all aspects of contraception as a result of formal and informal education at school, from their families, and by the media. Most of these women (86%) viewed their contraceptive choices as their own. The GP was regarded as the most important and reliable source of information (73%).58 [EL = 3]

Effect of information on satisfaction and continuation

A Finnish survey of LNG-IUS users (n = 17 360) evaluated the impact of advance information on user satisfaction with the method. User satisfaction was associated with information (on menstrual disturbances, pelvic inflammatory disease (PID), greasiness of hair or skin, and the possibility of pregnancy) given at the time the LNG-IUS was inserted. Women who received information about the possibility of amenorrhoea were more satisfied when compared with the women who were less well informed (OR 5.0, 95% CI 4.1 to 5.9).68 [EL = 3]

A survey of new DMPA users in Bolivia (n = 352) reported that women who received information on the efficacy, side effects and amenorrhoea of DMPA had higher continuation rates than those who did not receive such information. Women advised to return to the clinic if experiencing problems were 2.7 times more likely to continue DMPA at 1 year, and those advised of amenorrhoea were 2.5 times more likely to return for a second injection of DMPA compared with women who did not receive such information from the provider.69 [EL = 3] Similar findings were reported from a study of 350 new DMPA users in Mexico where detailed, structured, pre-treatment counselling resulted in fewer method discontinuations at 12 months compared with routine contraceptive counselling (15% versus 39% overall and 9 % versus 32% for menstrual disturbance including amenorrhoea).70 [EL = 1+]

One RCT (n = 636) in the UK assessed the effectiveness of providing educational leaflets versus verbal information in improving knowledge of contraception in women taking the combined pill. Baseline knowledge of contraception in the control group was poor. Written information had a significant effect on knowledge of factors associated with pill failure. Improvement in knowledge occurred with the provision of summary leaflets (adjusted OR 4.04, 95% CI 1.68 to 9.75), the Family Planning Association’s leaflet (OR 3.43, 95%CI 1.45 to 8.09) and asking questions (OR 3.03, 95% CI 1.30 to 7.00). This study suggested that provision of educational leaflets on contraception and/or asking women relevant questions, though time-consuming, may help improve women’s knowledge of contraception.71 [EL = 1+]
Method of information giving

The provision of written information may enhance understanding. One RCT (n = 461) in the USA evaluated three different approaches to increase women’s understanding of risk of pregnancy associated with various contraceptive methods. A table with categories of contraceptives communicated relative contraceptive effectiveness better than the tables with numbers. However, without the presentation of the numbers, women grossly overestimated the absolute risk of pregnancy while using contraception. A table, developed by the World Health Organization (WHO), presenting a combination of categories of contraceptives and a general range of risk for each category may provide the most accurate understanding of both relative and absolute pregnancy risk.72 [EL = 1–]

A survey (n = 211) in the USA reported that women relied heavily on their own experiences in assessing the risks and benefits of oral contraceptives. Written information was cited more frequently than medical personnel as a major source of information on cardiovascular and cancer risks and the benefits of OCs. The internet played a minimal, if any, role in educating women about OCs.73 [EL = 3]

RECOMMENDATIONS

Women considering LARC methods should receive detailed information – both verbal and written – that will enable them to choose a method and use it effectively. This information should take into consideration their individual needs and should include:

- contraceptive efficacy
- duration of use
- risks and possible side effects
- non-contraceptive benefits
- the procedure for initiation and removal/discontinuation
- when to seek help while using the method.

Specific groups

One survey (n = 406) in the USA which examined the relationship between reading ability and knowledge of family planning reported that women with low reading skills were 2.2 times more likely to want to know more about birth control methods (95% CI 1.1 to 4.4). They were 4.4 times more likely to have incorrect knowledge about when they were most likely to become pregnant (95% CI 2.1 to 9.0) than women with good reading skills. This raised additional questions of whether women with low reading skills understand the concept of informed consent prior to accepting contraceptive use.74 [EL = 3]

An interview survey (n = 32) of Somalian women attending a UK well-woman clinic reported that effective contraceptive care and service provision needed to take into account the cultural interpretation of reproduction and family planning within a wider social and religious context in order to meet the needs of these women.75 [EL = 3]

RECOMMENDATIONS

Counselling about contraception should be sensitive to cultural differences and religious beliefs.

Healthcare professionals should be able to provide information that is in a format appropriate for all women with special needs.

For women whose first language is not English, written information about contraceptive methods should be available in their preferred language.

Healthcare professionals should have access to trained interpreters for women who are not English speaking, and to advocates for women with sensory impairments or learning disabilities.
3.6 Contraceptive prescribing

Most contraceptive users are medically fit and can use all available methods safely. However, a few medical conditions are associated with theoretical increased health risks with certain contraceptives, either because the method adversely affects the condition (for example, combined hormonal contraceptives may increase the risk of a woman with diabetes developing cardiovascular complications), or because the condition or its treatment affects the contraceptive (some anti-epileptic drugs interfere with the efficacy of hormonal methods). Since most trials of new contraceptive methods deliberately exclude subjects with serious medical conditions, there is little direct evidence on which to base sound prescribing advice. In an attempt to produce a set of international norms for providing contraception to women and men with a range of medical conditions which may contraindicate one or more contraceptive methods, the WHO has developed a system to address medical eligibility criteria for contraceptive use (WHO-MEC).76 Using evidence-based systematic reviews,77 the document classifies conditions into one of four categories. Category 1 includes conditions for which there is no restriction for the use of the method while category 4 includes conditions which represent an unacceptable health risk if the contraceptive method is used (absolutely contraindicated). Classification of a condition into category 2 indicates that the method may generally be used but that more careful follow-up is required. Category 3 conditions are those for which the risks of the method generally outweigh the benefits (relatively contraindicated). Provision of a method to a woman with a category 3 condition requires careful clinical judgement since use of that method is not recommended unless there is no acceptable alternative. The WHO-MEC document is available on the internet63 and a system is in place to incorporate new data into the guidelines as they become available. A UK version of the WHO-MEC document is currently under development by the FFPRHC and will be published by the end of 2005.

In an attempt to provide evidence-based guidance on safe and effective contraception, the WHO produced the Selected Practice Recommendations for Contraceptive Use (WHOSPR).77,78 The UK Selected Practice Recommendations for Contraceptive Use (UKSPR), a document adapted by the FFPRHC for use in the UK, provides guidance on assessment before providing contraceptives, including when to start a method, history taking, follow-up, and the management of common side effects.79

The vast majority of women who use hormonal contraception do not have any medical problems and they are young. Providers need to recognise the very few who may be at risk of the rare but serious complications of hormonal contraception. Taking a careful history (including family history) and observing obvious physical characteristics (such as obesity) provides a lot of useful information. The WHO distinguishes between examinations and investigations which are essential for safe prescribing of contraception and those which 'do not contribute substantially to safe and effective use of the contraceptive method' but which are commonly done.77 Routine breast and pelvic examination, cervical smears and blood tests such as the measurement of serum cholesterol fall into the latter category. The only tests considered mandatory in the UK are the measurement of blood pressure before starting combined hormonal contraception, and pelvic examination before IUD/IUS insertion.

When prescribing contraceptives beyond the duration of product licence, healthcare professionals need to inform the woman and discuss with her the evidence supporting use outside licence, document all this information in case records and obtain her consent.80 [EL = 1–4]

The UKSPR, in agreement with the WHOSPR, recommends the ideal time in the cycle when a particular method of contraception should be initiated and how best to switch methods. Recognising that this may not always be the most convenient time, the UKSPR further recommends that all methods can be started at any time in the cycle provided it is reasonably certain that the woman is not pregnant. It is not necessary to undertake pregnancy testing before a method is started, even later in the cycle. Pregnancy can be excluded by taking a menstrual and contraceptive history and asking about sexual activity. A test is indicated only if the history suggests that there is a risk that the woman might be pregnant.
RECOMMENDATIONS

A medical history – including relevant family, menstrual, contraceptive and sexual history – should be taken as part of the routine assessment of medical eligibility for individual contraceptive methods.

Healthcare professionals helping women to make contraceptive choices should be familiar with nationally agreed guidance on medical eligibility and recommendations for contraceptive use.

Healthcare professionals should exclude pregnancy by taking the menstrual and sexual history before initiating any contraceptive method.

Healthcare professionals should supply an interim method of contraception at the first appointment if required.

Healthcare professionals should ensure that informed consent is obtained from the woman whenever any method of LARC is being used outside the terms of the UK Marketing Authorisation.* This should be discussed and documented in the notes.

3.7 Health benefits of contraception

The non-contraceptive health benefits of LARC influence the uptake and continuation of the methods. They are summarised below. It is not possible to quantify the potential savings to the NHS that these additional health benefits might make (for example, the LNG-IUS is also licensed for the management of menorrhagia; women who use the method for contraception may be much less likely to report menorrhagia than women who are sterilised). The non-contraceptive benefits have, therefore, not been included in the cost effectiveness models.

Most couples use contraception for over 30 years. Additional health benefits beyond pregnancy prevention offer significant advantages and influence acceptability. In a nationwide sample of 943 US women, satisfaction with oral contraception was most likely among women aware of the non-contraceptive benefits of the pill and who experienced few side effects.69

Existing combined hormonal methods improve menstrual bleeding patterns, alleviate dysmenorrhea, acne and sometimes pre-menstrual syndrome and reduce the risk of ovarian and endometrial cancer. Increasing numbers of women choose the LNG-IUS and DMPA because of the amenorrhea they confer. One non-comparative study \( (n = 165) \) in Austria assessed long-term acceptability of LNG-IUS and reported that cessation of menstruation occurred in 47% of women at 3 years, over 80% of whom considered this to be a positive change.81 \( [EL = 3] \) Perimenopausal women appreciate the facility to continue using the LNG-IUS into the menopause when it can be used to deliver the progestogen component of HRT.

The non-contraceptive benefits can influence continuation rates of contraception. One study in the USA demonstrated that women who experienced troublesome dysmenorrhea prior to using the COC were 8 times more likely to continue using the pill than women who did not report dysmenorrhea.82

3.8 Acceptability

Continuation rates are often regarded as a surrogate for acceptability of a method. This is simplistic. Many factors determine acceptability and continuation of a method may only reflect that it is the best of a bad lot. In recent years clinical trials have routinely included questions on acceptability at regular follow-up intervals but this is at best a crude measure of what is a complex issue. There is evidence to demonstrate that the acceptability of a contraceptive method (and continuation rate) is increased when users are well informed about the side effects and risks.89

* Check the Summary of Product Characteristics of individual devices for current licensed indications.
The current uptake of LARC in Great Britain is low (8% of contraceptive usage in 2003/04). In a national survey of 1688 US women (where fewer than 2% used contraceptive implants and under 3% used injectables), women gave three major reasons for not using LARC: lack of knowledge, fear of side effects/risks, and satisfaction with the method they were currently using. Women aged 30 years or older and those with a college education were half as likely as younger women and those without college education to mention fear of side effects as their main reason for not using implants. Important reasons for choosing a contraceptive included: how well it works, ease of use and protection against STI and HIV.

Contraceptive choice is strongly influenced by the provider’s views and by the advice and information that he/she gives to the potential user. Providers may hold very different views from users. In a study of the acceptability of methods of contraception which confer amenorrhea, providers thought that having a regular period was important to their clients while women themselves did not feel that it was important. The methods which a provider is able to offer also influence contraceptive choice. If a provider is unable to insert contraceptive implants, he/she is less likely to offer the method or, indeed, to be sufficiently well informed to give good information. Women may settle for a method which is easily available from their GP rather than have to travel to another service to obtain something different.

Acceptability of the chosen method is likely to be fundamental to correct and consistent use and to continuation. If a woman is unhappy with her method, for whatever reason, she is likely to discontinue it. If choice determines effective use and continuation, it can be argued that it should supersede considerations of cost.

**RECOMMENDATION**

Women should be provided with the method of contraception that is most acceptable to them provided it is not contraindicated.

### 3.9 Adherence

Many couples use contraception inconsistently and/or incorrectly. Inconsistent or incorrect use accounts for the difference between perfect use and typical use failure rates. Some methods are easier to use than others. The IUD/IUS and implants are inserted and removed by a healthcare professional and are completely independent of adherence for efficacy. Their failure rates are accordingly very low (Table 3.2) and typical and perfect use rates are almost the same. Progestogen-only injectables last 8 to 12 weeks, but still demand the motivation and organisational skills required to attend for repeat doses. Adherence to oral contraception is not easy. In one US study, 47% of women reported missing one or more pills per cycle and 22% reported missing two or more pills per cycle. In a study using electronic diaries to record adherence, 63% of women missed one or more pills in the first cycle of use, and 74% in the second cycle. Typical use failure rates are even higher with methods of contraception (condoms, diaphragms, withdrawal and natural family planning) which rely on correct use with every act of intercourse.

A descriptive review assessed the impact of health concerns on adherence to hormonal contraceptives. It reported that contraceptive-related knowledge among sexually active adolescents was poor and the general public had many concerns about the safety of hormonal contraception. The development of side effects, especially those related to menstruation, caused adolescents and young women to feel that their general and reproductive health was being threatened. Counselling tailored to address specific reasons for non-adherence in this population may be beneficial.

### 3.10 Discontinuation

In an international review of discontinuation rates after 1 year of use of hormonal contraception, rates varied from 19% (for Norplant) to 62% (the combined pill). Many of these data come from clinical trials in which continuation rates are almost always higher than in ‘real life’. Data
specific to the UK are lacking. Discontinuation rates are higher for methods which do not require removal by a healthcare professional, as is clear from Table 3.3 (note that this table does not include any data on Implanon), which shows the percentage of couples in the USA still using each method at the end of 1 year. Reasons for discontinuation are often associated with perceived risks and with real or perceived side effects. In a US study of 1657 women initiating or changing to use a new contraceptive pill, 32% of new starts and 16% of switchers had discontinued the method within six months. Of those who discontinued, 46% did so because of side effects (most of which they did not discuss with a healthcare professional and most of which would have resolved themselves within weeks). In Sweden a common reason for discontinuation of the oral contraceptive pill is weight gain (perceived to be caused by the pill) and fear of health risks such as breast cancer.

Discontinuation rates from countries where access to contraception is limited and/or expensive may differ from those in the UK, for example, in developing countries. Similarly, data from countries where women are characteristically of significant lower body weight (such as Indonesia or Thailand) than women in the UK may overestimate the effectiveness of hormonal methods of contraception and the side effect profile.

Continuation rates influence the effectiveness of contraception, since women often change to a less effective method or spend some weeks or months using no method while they decide what to use next. More than four-fifths of women in the US study who stopped the pill, despite being at risk of pregnancy, either failed to adopt another method or changed to a less effective one.

Data from the US National Survey of Family Growth demonstrate high rates of method switching (61% of unmarried women will change their method over a period of 2 years). Switching to a less effective method is common. However, data specific to the UK are lacking.

Continuation rates of LARC are also fundamental to cost effectiveness. A method which costs £100 works out at £1.66/month if used for 5 years; discontinued after only 1 year of use the cost is £8.33/month.

3.11 Contraception and sexually transmitted infection

Sexual activity not only risks pregnancy but also sexually transmitted infection (STI) including HIV. Whilst methods of contraception are not designed to protect against STI, men and women who wish to protect themselves from STI should use a condom with every act of intercourse. Only the male condom has been shown to prevent some STIs including HIV. The sexual behaviour of potential users of contraception has relevance to method choice. For example, the IUD is relatively contraindicated for a woman with multiple partners.

LARC is not protective against STIs and HIV. There is some concern that use of hormonal methods of contraception may increase the risk of STIs including HIV. (For more information see relevant chapters.)

WHO-MEC advises that for women at risk of STI including HIV, correct and consistent use of condoms is recommended, either alone or with another contraceptive method.

RECOMMENDATIONS

Healthcare professionals providing contraceptive advice should promote safer sex.

Healthcare professionals providing contraceptive advice should be able to assess risk for sexually transmitted infections (STIs) and advise testing when appropriate.

Healthcare professionals should be able to provide information about local services for STI screening, investigation and treatment.
Table 3.3 Percentage of women continuing use at the end of the first year (United States); adapted with permission from Trussell^435

<table>
<thead>
<tr>
<th>Method</th>
<th>Women continuing use at one year(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No method</td>
<td>42</td>
</tr>
<tr>
<td>Spermicides</td>
<td>42</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>43</td>
</tr>
<tr>
<td>Periodic abstinence</td>
<td>51</td>
</tr>
<tr>
<td>Calendar</td>
<td></td>
</tr>
<tr>
<td>Ovulation method</td>
<td></td>
</tr>
<tr>
<td>Sympto-thermal^d</td>
<td></td>
</tr>
<tr>
<td>Post-ovulation</td>
<td></td>
</tr>
<tr>
<td>Cap^e</td>
<td></td>
</tr>
<tr>
<td>Parous women</td>
<td>46</td>
</tr>
<tr>
<td>Nulliparous women</td>
<td>57</td>
</tr>
<tr>
<td>Sponge</td>
<td></td>
</tr>
<tr>
<td>Parous women</td>
<td>46</td>
</tr>
<tr>
<td>Nulliparous women</td>
<td>57</td>
</tr>
<tr>
<td>Diaphragm^e</td>
<td>57</td>
</tr>
<tr>
<td>Condom^f</td>
<td>57</td>
</tr>
<tr>
<td>Female (Reality)</td>
<td>49</td>
</tr>
<tr>
<td>Male</td>
<td>53</td>
</tr>
<tr>
<td>Combined pill and minipill</td>
<td>68</td>
</tr>
<tr>
<td>Evra patch</td>
<td>68</td>
</tr>
<tr>
<td>NuvaRing</td>
<td>68</td>
</tr>
<tr>
<td>Depo-Provera</td>
<td>56</td>
</tr>
<tr>
<td>Lunelle</td>
<td>56</td>
</tr>
<tr>
<td>IUD</td>
<td></td>
</tr>
<tr>
<td>Progestasert (progesterone T)</td>
<td>81</td>
</tr>
<tr>
<td>ParaGard (copper T)</td>
<td>78</td>
</tr>
<tr>
<td>Mirena (LNG-IUS)</td>
<td>81</td>
</tr>
<tr>
<td>Norplant and Norplant-2</td>
<td>84</td>
</tr>
<tr>
<td>Female sterilisation</td>
<td>100</td>
</tr>
<tr>
<td>Male sterilisation</td>
<td>100</td>
</tr>
</tbody>
</table>

**Emergency contraceptive pills**: treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%^g.

**Lactational amenorrhea method**: LAM is a highly effective, temporary method of contraception.^h

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^a Among couples attempting to avoid pregnancy, the percentage who continue to use a method for 1 year.

^b The percentages becoming pregnant are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

^c Foams, creams, gels, vaginal suppositories and vaginal film.

^d Cervical mucus (ovulation) method supplemented by calendar in the pre-ovulatory and basal body temperature in the post-ovulatory phases.

^e With spermicidal cream or jelly.

^f Without spermicides.

^g The treatment schedule is one dose within 120 hours after unprotected intercourse, and a second dose 12 hours after the first dose.

^h However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches 6 months of age.

^NB. Some of the methods listed in this table are not available in the UK and some of the methods available in the UK are not available in the USA and therefore are not listed here. This table does not include any data on Implanon. ParaGard^i is the TCu 380A IUD.
3.12 User autonomy and consent

The law and policy governing access to contraception is well developed in the UK, in that all women have had access to free contraception since 1974 via a number of providers.92 Not all methods are available to all women equally as a result of regional variation. Globally, reproductive rights are not always recognised, leading to statements such as: ‘Reproductive rights rest on the recognition of basic rights of couples and individuals to decide freely and responsibly the number and spacing and timing of their children and to have the information to do so, and the right to attain the highest standard of sexual and reproductive health.’ (para 95, Beijing Platform for Action, 1995)93 Reproductive and sexual health care including family planning services and information is recognised as a key intervention for improving the health of women and children, but also as a human right. Right to access, choice and benefit of scientific progress (evidence-based information) are considered important in making an informed choice of contraceptive methods.63 For the process of seeking consent to be meaningful, refusal of treatment needs to be one of the patient’s options. Competent adults are entitled to refuse treatment even when the treatment would clearly benefit their health. Ethical guidance for obtaining consent, points of law and model documentation are available.94–97

3.13 Contraception for special groups

Adolescents

Young people aged 16 and 17 are generally presumed to have the ability to consent to their own medical treatment, including contraceptive treatment. Healthcare professionals can provide contraceptive advice and treatment to a young person under the age of 16 years without parental involvement if the young person is judged to understand the advice provided and its implications, and her/his physical or mental health would otherwise be likely to suffer, and so provision of advice or treatment is in their best interests.98 It is considered to be good practice to follow the criteria outlined by Lord Justice Fraser in the case of Gillick versus West Norfolk and Wisbech Area Health Authority (AHA) and the Department of Health and Social Services (DHSS) when deciding whether a patient under 16 years is competent to consent to treatment. These criteria (known as the Fraser guidelines or ‘Gillick competence’) are that:

• the young person will understand the professional’s advice
• the young person cannot be persuaded to inform their parents
• the young person is likely to begin, or to continue having, sexual intercourse with or without contraceptive treatment
• unless the young person receives contraceptive treatment, their physical or mental health, or both, are likely to suffer
• the young person’s best interests require them to receive contraceptive advice or treatment with or without parental consent.

The consent of a competent young person cannot be overruled by a parent. If a person under the age of 18 years refuses to consent to treatment, it is possible in some cases for their parents to overrule their decision, though this is generally very rare. This right can only be exercised on the basis that the welfare of the young person is paramount. In this context welfare does not simply mean their physical health. The psychological effect of having the decision overruled would have to be taken into account and this option would normally only be pursued when the young person was thought likely to suffer ‘grave and irreversible mental or physical harm’ as a result of their refusal to consent to treatment.99
Young people under the age of 16 years have as great a right to confidentiality as any other patient. If someone under 16 is not judged mature enough to consent to treatment, the consultation itself can still remain confidential unless there are exceptional circumstances which suggest that the young person’s health, safety or welfare is at risk. In this case local child protection procedures should be followed.100 (www.dh.gov.uk/assetRoot/04/06/72/04/04067204.pdf)

The FFPRHC provides guidance on contraceptive choices for young people,101 and DH provides guidance for healthcare professionals on the provision of contraceptive services for under-16s.102

**People with learning disabilities**

People over the age of 16 years are usually regarded as competent to decide their own treatment unless demonstrated otherwise. This applies to people with learning disabilities as much as any other person. It should not be assumed that adults or children are unable to make decisions about their own treatment simply because they have a learning disability. A key factor in assessing a person's ability to give consent is whether she/he can understand and weigh up the information needed to make the decision about contraceptive treatment. If information is presented in an appropriate way (for instance using simple language or pictorial aids) many people with learning disabilities will be able to consent to their own treatment. The involvement of specialists from learning disability teams or speech or language therapists can be helpful in assessing the individual’s capacity to give consent to treatment though the patient’s right to confidentiality should be borne in mind before involving anyone else.98,103

Currently no one else can give consent on behalf of an adult who is not judged to have the capacity to make a decision on their own behalf. However, healthcare professionals may treat the person if it would be in their best interests to do so. The High Court has ruled that ‘best interests’ go further than the medical interests of the person to include factors such as their general wellbeing and quality of life, their relationships with people close to them, and their religious or spiritual beliefs. Although the healthcare professional is legally responsible for deciding what is in the patient’s ‘best interests’, any decision should ideally reflect the views of the individual’s family, carers or friends. Any decision must be guided by what is genuinely in the best interests of the individual and not what would make life easier for their family or carers. Where there is serious disagreement between healthcare professionals and a patient's family that cannot be resolved, an application may be made to the High Court.104 (www.dh.gov.uk/assetRoot/04/01/91/59/04019159.pdf)

The Mental Capacity Act 2005, which is expected to be implemented in 2007, will define what is meant by capacity and clarify the law on who can make decisions on behalf of people judged to lack capacity.

**People with physical disabilities**

There is a tendency to assume incorrectly that men and women with physical disabilities are not sexually active and have no need of contraception.

People with learning and physical disabilities have the same right to information and help with contraception as non-disabled people. Physical disabilities may influence the acceptability, safety and appropriateness of certain methods of contraception. A woman with a disability which makes dealing with monthly menstruation and sanitary protection difficult may appreciate a method which is associated with amenorrhoea. Combined hormonal contraception (CHC) may be less safe for a woman confined to a wheelchair, since immobilisation is associated with an increased risk of venous thromboembolism and so is CHC. Insertion of an IUD, and the need to check the threads regularly, may prove difficult for some women with a disability. These factors need to be taken into consideration when discussing contraception with women with disabilities.
RECOMMENDATIONS

Healthcare professionals should be aware of the law relating to the provision of advice and contraception for young people and for people with learning disabilities. Child protection issues and the Fraser Guidelines should be considered when providing contraception for women younger than 16 years.*

Women with learning and/or physical disabilities should be supported in making their own decisions about contraception.

Contraception should be seen in terms of the needs of the individual rather than in terms of relieving the anxieties of carers or relatives.

Where a woman with a learning disability is unable to understand and take responsibility for decisions about contraception, carers and other involved parties should meet to address issues around the woman’s contraceptive need and to establish a care plan.

3.14 Training of healthcare professionals in contraceptive care

Medical and nurse training are, for the most part, delivered separately. The gold standard basic competency-based training for doctors in the provision of basic sexual and reproductive healthcare, which includes contraception, is the Diploma of the Faculty of Family Planning and Reproductive Health Care (DFFP). The DFFP includes the provision of some of the long-acting methods of contraception and is currently held by approximately 10,000 doctors in the UK, many working in general practice. Additional competency-based training is required to obtain the qualifications for the provision of intrauterine methods (IUD and IUS) and for subdermal methods of contraception. These qualifications are also awarded by the Faculty of Family Planning and Reproductive Health Care and are known as letters of competence (LoC) in intrauterine techniques and in subdermal techniques, respectively. All Faculty qualifications are recertifiable on a five-yearly cycle. The Membership of the Faculty of Family Planning and Reproductive Health Care (MFFP) is specific to the field of sexual and reproductive health and is obtained through examination similar to other College memberships.

The structure of nurse education has changed and many of the old, validated courses are about to or have now expired. In the past, the national boards had responsibility for standards and curricula for training and though these were variable there was some standardisation and recognition within family planning and contraception. In the ensuing reorganisation, Scotland, Wales and Northern Ireland replaced their national boards but England did not. Standards are now the remit of the Nursing and Midwifery Council (NMC), but curricula and course structure is delegated to individual higher education institutes. This has meant that training in family planning and contraception has been addressed in different ways according to the set-up within individual universities. For example, it may be part of degrees in general practice, sexual health or women’s health or as stand-alone modules in contraception, reproductive or women’s health.

In 2004 the Royal College of Nursing (RCN) published a Sexual Health Competency framework which was developed in partnership with a number of organisations. This framework is designed to act as a template which reflects the levels of competency expected from registered practitioner through to consultant practitioner levels, and should help to underpin training in the future.105 The RCN recommends that all nurses working in general practice, family planning, contraception and genitourinary (GU) clinics should undertake a two-day Sexually Transmitted Infections Foundation course (STIF details are available at www.bashh.org), and that family planning and GU-trained nurses should regularly update their knowledge and skills to maintain their competence to practise. Training guidance is available from the RCN for nurses working in this field in the following areas: contraception and sexual health in primary care,106 inserting intrauterine devices,107 and inserting and/or removing subdermal implants.108 Details of these are

* See the Department of Health’s Best Practice Guidance for Doctors and Other Health Professionals on the Provision of Advice and Treatment to Young People under 16 on Contraception, Sexual and Reproductive Health (July 2004), available from www.dh.gov.uk.
available from www.rcn.org.uk. An RCN-accredited Sexual Health Skills distance-learning programme has recently been developed. It is aimed at nurses who want a holistic foundation in sexual health but who may not specialise in this field. The course is validated by the University of Greenwich.

A survey undertaken by the Contraceptive Education Service run by the Family Planning Association and the Health Education Authority identified that 88% of GPs had some training in family planning but two-thirds had family planning qualifications issued in the 1970s. Just 12% had recent training, with practice nurses more likely to have attended update training courses. There are no training data available for healthcare professionals working in community contraceptive services. However, job descriptions for staff grade, associate specialist and consultants specify that candidates should hold either the diploma or membership of the Faculty of Family Planning and Reproductive Health Care or an equivalent qualification with evidence of recertification if appropriate.

For nurses working within community contraceptive services, a recognised family planning qualification or equivalent is required. Training for both nurses and doctors involves a theoretical component and practical placement. Doctors training in GU medicine now need to obtain the DFFP as part of their specialist registrar training but there is no requirement by the RCOG for specialist registrars to attend a DFFP theory course and the level of contraceptive knowledge amongst trainees could benefit from improvement.

Most of the practical, hands-on training takes place in community contraceptive services. The issues of adequate funding to support training need to be discussed locally, regionally and nationally so that the future workforce is adequately equipped to provide level one services in primary care and accurate contraceptive advice in secondary care.

RECOMMENDATIONS

Healthcare professionals advising women about contraceptive choices should be competent to:

• help women to consider and compare the risks and benefits of all methods relevant to their individual needs
• manage common side effects and problems.

Contraceptive service providers who do not provide LARC within their own practice or service should have an agreed mechanism in place for referring women for LARC.

Healthcare professionals providing intrauterine or subdermal contraceptives should receive training to develop and maintain the relevant skills to provide these methods.

3.15 Cost effectiveness of LARC methods versus other reversible contraceptive methods

The economic analysis undertaken for this guideline demonstrated that all LARC methods avert a higher number of pregnancies compared with COC and male condom, for all time frames considered in the economic model, i.e. up to 15 years of contraceptive use. For 1 year of use, two of the LARC methods, the IUD and the injectable, dominate both COC and male condom. For periods of contraceptive use equal to 2 years and above, all LARC methods dominate COC and male condom (i.e. they are not only more effective but also less costly than COC and male condom). Results of the economic analysis are reported in Chapter 8.

3.16 Brief overview of features common to progestogen-only methods

This guideline discusses four methods of LARC, the copper IUD and the three progestogen-only contraceptive methods. Common features of POC regardless of dose and route of administration are described here.
Contraception can be divided into two broad categories, hormonal and nonhormonal. There are two categories of hormonal contraception, combined (oestrogen plus progestogen) and progestogen-only. Included in the category of LARC are the copper intrauterine device and three progestogen-only methods of contraception (injectables, implants and the intrauterine system).

Long-acting delivery systems have the theoretical advantage of providing very constant release rates of steroid hormone (compared with daily administration) and also avoid the first-pass effect through the liver, enabling lower doses of steroids to be used. However, the injectable preparations deliver a higher dose of hormone, while the oral preparation, implants and intrauterine systems deliver much lower doses.

**Mode of action**

The mode of action depends on the dose of hormone. Higher doses (injectables) inhibit follicle development and ovulation completely, alter the characteristics of cervical mucus interfering with sperm transport, and cause endometrial changes including atrophy. Intermediate doses (the subdermal implant Implanon) inhibit ovulation but allow follicular development, while very low doses (intrauterine delivery systems and the Norplant implant) inhibit ovulation only inconsistently and rely mainly on their effect on cervical mucus. In addition to the effect on the ovary and cervical mucus, all methods have an effect on the endometrium. The intrauterine system has a very marked effect, causing endometrial atrophy and inhibiting implantation.

**Side effects**

**Bleeding disturbances**
Progestogen-only methods disrupt regular menstrual cycles and the resulting ‘bleeding disturbance’ is the most common cause for discontinuation of the method. The mechanism of action of the method determines the predominant bleeding pattern. Bleeding patterns depend on the degree of suppression of ovarian activity. If normal ovulation occurs consistently a woman will experience menstrual bleeds at a frequency characteristic of her normal cycle. If both ovulation and follicle development are completely suppressed, amenorrhoea will result and many women do experience amenorrhoea while using Depo-Provera. If ovulation or follicular development sufficient to stimulate endometrial growth occur irregularly, bleeding will be erratic and unpredictable (implants) unless there is endometrial atrophy (LNG-IUS) when, regardless of the effect on ovarian activity, amenorrhoea is common. A local effect on the endometrium of the continuous administration of progestogens also probably contributes to the bleeding patterns.

**Ovarian cysts**
The incomplete suppression of ovarian activity is a recipe not only for erratic bleeding, but also for the development of ovarian follicular cysts. These occur in 20% of women using the LNG-IUS. They are almost always asymptomatic.

**Metabolic side effects of progestogens**
These are said to be associated with a range of common minor symptoms including acne, hirsutism, headache, mood change and weight gain or bloating. All are common complaints among women not using contraception. Depo-Provera may be associated with more significant weight increase than other POC.

**Ectopic pregnancy**
Ectopic pregnancy is regarded as a side effect of the POC due to the theoretical effect of progestogens on tubal motility. The best data are for Norplant, and show no increased risk compared with women not using contraception. Ectopic pregnancy is discussed in more detail in subsequent chapters.

**Cancer**
In the large meta-analysis reporting a relative risk of 1.24 for use of the COC, an increased relative risk of breast cancer for both oral and injectable progestogen-only methods of contraception (RR 1.17 for both) was demonstrated, although for injectables this was not statistically significant. In a review of other pooled analyses no significant associations were found. There
are much fewer data for POC than for COC and women with risk factors for breast cancer may be preferentially prescribed POC. Recent anxieties about the contribution of progestogens to the increased risk of breast cancer associated with HRT have not yet spread to POC. There is no evidence for any increased risk of other cancers and indeed some evidence to suggest a reduction in the risk of endometrial cancer.

Cardiovascular disease including venous thromboembolism
There is no evidence for an increase in the risk of stroke, myocardial infarction or VTE in association with POC. An association between VTE and progestogen used for the treatment of gynaecological conditions such as anovulatory dysfunctional uterine bleeding is likely to be due to prescriber bias since the COC – often the method of choice – is contraindicated in women with known risk factors for VTE. A very weak association between use of Norplant and hypertension may be due to observer bias.

A systematic review of three cohort studies and one cross-sectional study reported no significant association of high blood pressure with the use of progestogen-only pills for up to 2–3 years of follow-up. [EL = 3]

Gall bladder disease
A weak association between use of Norplant and gall bladder disease has been described but there is no evidence of any association with other POC.

Bone mineral density
No study has demonstrated any adverse effect of progestogen-only implants on bone mineral density. It is unlikely therefore that use of oral or intrauterine POC would be harmful. Injectable methods, however, deliver higher doses of progestogen suppressing ovarian activity and causing hypoestrogenism and loss of bone mineral density and there are concerns that their use may increase the risk of osteoporosis. (Refer to the forthcoming NICE clinical guideline Osteoporosis: assessment of fracture risk and the prevention of osteoporotic fractures in individuals at high risk – www.nice.org.uk/page.aspx?o=33923.)

Return to fertility
Mean time to pregnancy (TTP) after stopping contraception varied with the preceding contraceptive method and with its duration of use. Return to fertility occurs within days of cessation of all POC methods except injectables. The delay following discontinuation of DMPA is well recognised but pregnancy rates eventually reach those associated with cessation of other methods.

The methods described in the following chapters do not represent an order of recommended priority.
References

8. Guyatt GH, Sackett DL, Cook DJ. Users’ guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid? Evidence-Based Medicine Working Group. JAMA 1993;270:2598–601.
9. Guyatt GH, Sackett DL, Cook DJ. Users’ guides to the medical literature. II. How to use an article about therapy or prevention. B. What were the results and will they help me in caring for my patients? Evidence-Based Medicine Working Group. JAMA 1994;271:703–7.
Long-acting reversible contraception

79. Faculty of Family Planning and Reproductive Health Care, Royal College of Obstetricians and Gynaecologists. UK Selected Practice Recommendations for Contraceptive Use. London: FPFRHC and RCOG; 2003.
Long-acting reversible contraception


408. Beethuizen R, van Beek A, Massai R, Makarainen L, Hout J, Bennink HC. Bone mineral density during long-term use of the


