Standards of Care for Women's Health in Europe

EBCOG

European Board and College of Obstetrics and Gynaecology

Gynaecology Services 2014

The Working Party

Terms of reference:

Aim

To develop Europe-wide Standards of care for women's health services

Remit

- To review current evidence-based published standards of care in the member states of the European Union

- To develop agreed standards of gynaecological care for benign and malignant conditions.

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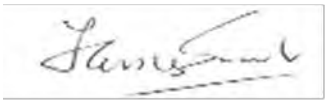
Foreword

Over the past decade there has been an unprecedented emphasis on enhancing the quality of clinical care. This has been supported by the publication of a large number of clinical guidelines, protocols and policy documents by countries and institutions in Europe.
However, there is disparity in accessibility to sexual and reproductive health services, in the quality of care and in clinical outcomes between countries and even within different regions of the same country. Significant variations in survival following cancer surgery exist.Inequity in the treatment of common gynaecological conditions, such as heavy menstrual bleeding has a huge impact on women's lives and on their families. Such inequitable access to the delivery of healthcare systems has an economic and societal impact.There is a compelling need to improve delivery of care.

The European Board and College of Obstetrics and Gynaecology (EBCOG), being a representative body of the obstetricians and gynaecologists in its thirty six member countries, has set up a working party to look at various models of health service delivery, both within EU28 and beyond in order to address these issues. Following extensive discussion and consultation with stakeholders, including input from European organisations representing women's interests, the Working Party has produced this document outlining the standards of care for various clinical conditions which affect women throughout their lives.

These standards define a roadmap of quality service underpinned by clinical governance, safety and patient experience. The standards cover 25 key clinical areas including sexual and reproductive health, fertility regulation, the prevention and treatment of female cancers, benign gynaecology and access to emergency gynaecology treatment. Each standard is based on the best available evidence and supported by a set of quality outcome indicators to benchmark services. The standards address the necessary requirements for training and support for doctors and healthcare professionals.

We are confident that these standards of care will be adopted by the Ministries of Health and also be used by healthcare professionals to deliver the best possible health care. This will fulfil our aspiration of providing equitable and safe services with the best possible outcomes for women seeking gynaecological care anywhere in EU28 and beyond.



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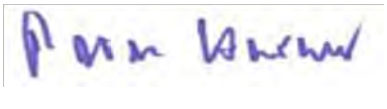

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Glossary of Terms Used in the Document

Clinical guideline	A systematically developed, evidence based guidance that assists in decision making about the appropriate healthcare for a specific clinical condition
Clinical protocol	A list of things that must be done in specific situations to achieve a specific outcome and no deviations are allowed
Standard operating procedure (SOP)	A set of written instructions applied to an activity undertaken at an organisational level
Care pathway	A list of steps which are taken for the care of a patient over time for a specific clinical problem with expected progress and outcomes. It may include referral arrangements between different health care providers/clinicians and organisations, instructions for investigations required at different levels of care and treatments recommended
Clinical standard	A specific and measurable target which reflects the care that a health service and prudent healthcare professional should provide in order to be effective and safe for the patient
Clinical audit	A process of quality improvement which involves a systematic review of care against clearly defined criteria. The ultimate objective is to improve patient care
Stakeholder	A person, group or organisation who may be affected by the guidance given for service development
Primary care	This describes the first level of care in the healthcare system. It is usually a General Practitioner or a family doctor but may be another healthcare provider, such as a specialist nurse or midwife who may be the patient's first point of contact. This is sometimes referred to as community care
Secondary care	Care which is provided by medical specialists with access to a range of investigations and treatment in a specialist setting. Some of these may take place as in-patient care, often hospital based but not always
Consumer	A woman, her family, or other representatives, who currently or previously utilised the healthcare services being described

Clinical governance	A framework through which health organisations create an environment to ensure continuous improvement in the quality of their services and safeguard high standards of care
Educational Supervisor	A senior clinician responsible for one or more trainees overseeing their training programme and progression, sometimes referred to as a tutor or trainer
Risk management	An approach for improving the quality of care and involving various methods for the early identification of adverse events, by using either staff reports, patient complaints, local or national alerts or a systematic review of patient records
Route cause analysis	A formal group review of the chronology of the events of cases with adverse outcomes to look at case management, why it happened and possibly offer suggestions for the alternative management of similar clinical scenarios in future
Multi-disciplinary	Involves a combination of two or more clinical departments/clinicians developing a clinical care package for a patient. It is about crossing boundaries and thinking across different disciplines
Open access clinic	An out-patient or ambulatory care clinic/facility primarily devoted to care in an out-patient setting. This clinic is staffed by appropriately trained staff, equipped with diagnostics offering specialised tests and treatments. Quite often the patient can call in or make an appointment to be seen
General out-patient clinic	Offers general diagnosis or treatments without an overnight stay
Specialist clinic	Provides advanced diagnostic or treatment for specific disease or parts of the body such as sexual health clinics, fertility clinics, etc
Ambulatory surgery clinic	Offers out-patient based, usually same day surgery services, for minor surgical procedures not requiring hospitalisation
Healthcare provider	An individual or organisation (hospital or clinic) that provides preventive, therapeutic or rehabilitative healthcare services in a systematic way to individuals, families or communities
Specialist nurses	Nurses who have specialist clinical experience and training and are involved in the care of patients in defined clinical areas

BACKGROUND

The Maastricht Treaty (1992)[1] forms the basis of a dedicated common public health strategy of the European Union (EU). Article 219 specifies that "The member states of the EU decided to co-ordinate their health policies and programmes with the co-operation of the European Commission to ensure a high level of health protection and to prevent widespread severe illness". Subsequently, Article 152 of the Treaty of Amsterdam (1997)[2] enlarged the healthcare duties of the EU, clearly stating that EU action should complement national health policies to improve public health, prevent human illness and diseases and to obviate sources of danger to human health, thus encouraging a common approach to clearly defined public health problems. Currently, considerable inequalities in access to women's health care and in life expectancy exist among the member states of the EU and beyond.

For example, although cancer survival rates are improving overall across Europe, the most up to date EU comparisons show that countries from central and Eastern Europe have worse survival rates than many other countries in western and northern Europe. The gap appears to be narrowing in breast cancer survival rates but not for ovarian and cervical cancers. There remain huge variations in breast and cervical cancer screening and human papiloma virus immunisation programmes as well.[7-10]

Furthermore there remains inequitable access and variable outcomes in other clinical conditions such as infertility, urinary incontinence and menstrual disorders across Europe. Such disparities in health care provision require urgent attention.

The promotion of sexual health is closely tied to the promotion of fundamental human rights, such as non-discrimination, privacy, protection from violence, access to information and the right to expression that support meaningful participation in society and politics.[16-17]

Across Europe there are huge differences in teenage pregnancy rates, the age of first intercourse, contraceptive availability and use,and access to abortion. HIV knowledge and STI rates also vary widely. This situation is complicated by a failure to collect standardised reproductive indicators and age specific data. The migrant/refugee population in Europe is particularly at risk of poor outcomes[18-20.]

Variations in outcome can only be addressed by setting unified standards of care and by monitoring individual providers' performance using high quality data.

This document will make an important contribution to achieving that goal. [11-15]

EBCOG Process of Developing Standards of Care for Gynaecology

The Council of EBCOG agreed that a Working Party be established to oversee the development of core standards of care in Gynaecology. It was decided to gather information from representatives of the member countries and to review published reports from different sources in order to establish a baseline to support the development of these standards.

The Working Party

The EBCOG Standards Working Party was set up with the aim of developing Europe-wide standards of care for women's health services.

The Working Party, Chaired by Dr Tahir Mahmood, included the EBCOG Officers Group, representatives of European Subspecialist Societies and Special Interest Groups and an invited external expert. The Working Party met several times and communicated electronically on a regular basis.

Situation Analysis of the EBCOG Member Countries

All the members of Council were sent a questionnaire to ascertain from the individual member states whether they had up to date clinical guidelines and standards of care for gynaecology developed by their own National Societies. About 50% of member countries responded that guidelines were available but that it was not possible to quality assure them or to ascertain whether all the health care providers were using them. There was a clear misunderstanding among clinicians about the definition of a guideline, protocol or standard and they were using these terms interchangeably. The United Kingdom was the only country where a document describing standards of care had been published.

The Review of the Published Literature

Websites of the European Union (Brussels and Luxembourg), the WHO website and PubMed were searched for key policy documents and publications providing comparative EU-wide outcome data. The documents published by the Royal College of Obstetricians and Gynaecologists (RCOG) of the United Kingdom (UK) detailing standards of care for Gynaecology [21] and the relevant Guidelines published by The National Institute of Clinical Excellence and Healthcare (NICE) were considered.

Authorship and Consultation

Each specialist society represented was allocated and produced the relevant standard(s).Manuscripts were discussed, reviewed and revised by the Working Party in the presence of the representative. The final draft document was circulated to the respective specialist society, and European public health organisations before being submitted to the EBCOG Executive and Council. Comments from all the stakeholders were considered at the final editorial process.

Purpose and Layout of this Document

The purpose of developing this document is to set common standards of care in gynaecology in Europe and beyond. This document sets out issues related to the equitable access to services.
This document will provide guidance for the development of equitable and high quality services, so that a similar standard of healthcare can be expected in all member states of the EU. The standards should act as incentives to implement clinical guidelines and to quality assure women's services.

The standards described here address various areas of service provision, ranging from benign conditions to the treatment of cancers. Each clinical service standard is comprised of a mixture of clinical and organisational standards, dealing with: patient focus, accessibility and the process of service provision and the competency of the staff providing this service. Each set of Standards is supported by a list of auditable indicators which should act as a benchmark for improvement.

EBCOG Standards: Towards Enhancing Postgraduate Training

One of the fundamental aims of EBCOG is to ensure the high quality training of our future generations of Obstetricians and Gynaecologists. This is required if high quality services are to be achieved and sustained across Europe. This is especially important as "European integration allows free movement of persons, services, capital and goods". A set of standards to facilitate uniform quality of training is necessary.
The purpose of accrediting a training unit is to drive up quality and satisfy the needs of all the stakeholders.

Currently, EBCOG operates a voluntary system of hospital visiting to accredit the training programmes against an agreed template. It is envisaged that the implementation of European-wide standards of care will ultimately lead to the effective delivery of not only clinical services but also of post graduate training. By setting these professional standards, EBCOG is facilitating the work of the national regulatory bodies to ensure that appropriate data is collected.

EBCOG Standards: Towards Improving Quality of Care

It is envisaged that the standards will provide equitable, safe, effective clinical care with good patient experience and best outcomes for women and their families. They should serve the following purposes:

- Providers may use the standards for the quality assurance of local services, to identify gaps and develop a local risk management strategy
- The Ministry of Health may consider using the standards to inform service contracts and the performance management of women's services.
- Trainers should consider using these standards to streamline postgraduate training and the supervision of doctors in training. They are encouraged to develop local clinical audits using these quality indicators to inform their own practice.
- The EBCOG Standing Committee on Training Recognition can use these standards to quality assure systems for post graduate training.
- The EU Public Health Committee should consider developing a unified "data system" to accurately capture clinical activities across the EU member states in order to promote EU-wide national audits of maternal wellbeing, maternal morbidity, mortality and patient related outcomes.

There is no overall timescale for their implementation but it is anticipated that the standards will be an integral part of the audit and commissioning process. Where high standards are not achieved, data from audits may provide evidence to support a business case for additional resources.

Women's health services should be working towards achieving the standards contained in this document to ensure a contemporary, safe service meeting the needs of women and families.

We are confident that the adoption and implementation of these standards across Europe, will not only address inconsistencies in care across the EU, but also enable the most cost-effective clinical care to be delivered.

STANDARD 1

Generic Standards for the Provision of Gynaecology Services

Rationale

Women's health services must be accessible so that women are able to receive the most appropriate care for their needs.

A good clinician must be polite, empathetic and honest, treating patients with dignity, as an individual, and respecting their rights to privacy and confidentiality. It is important to take time to listen and understand patients's specific needs, issues and to use these standards as a guide for best practise.

Gynaecology services must comply with the best available scientific evidence in order to provide high quality care. Patient related outcomes should be regularly benchmarked with other units providing similar services.

A multidisciplinary approach should be adopted where appropriate to ensure effective delivery of service in specialised areas.

Each gynaecology unit should have a clinical governance programme incorporating: risk management, clinical audit, continuing professional development and training, complaints handling, and a policy for continual service improvement [22].

1. Patient focus

1.1 Communication

1.1.1 A clearly defined referral pathway should be in place from primary care to specialist services.

1.1.2 The pre-appointment communication (letter, text/SMS, telephone call, fax, e-mail) for clinic attendance should provide clear information about the patient's first visit to the clinic and give information on what to expect and how to prepare for the appointment.

1.1.3 A summary of the woman's care should be available, when appropriate, to her primary care physician within an agreed timeframe. Information should only be shared among professionals with the consent of the woman. If there are public health issues, then they should be dealt with according to national legislation.

1.1.4 Each unit should have a patient-centred mechanism in place to communicate urgent results to the woman and her doctor and also to deal with treatment related queries.

1.2 Patient Information

1.2.1 There should be clear,up to date verbal and written information on relevant aspects of treatment available. Information should be available in other languages as appropriate for the ethnic mix in the region. There should be easy, open access to written information/web based leaflets, guidelines and relevant websites, including contact details of patient support groups. Information should be written in plain language with review dates noted.

1.2.2 Local strategies on information sharing should be reviewed regularly to reflect the needs of the local population and advances in communication technology.

1.2.3 Local protocols should be developed to support equal access to healthcare needs for all vulnerable groups including the migrant population and those who do not speak the host country's language. They should respect cultural differences relating to women's health and modesty.

1.2.4 Interpreting services should be used whenever appropriate. Members of the family should not be used as translators. Units need to be aware that in some cultures women are reluctant to share information relating to women's health with males. Where possible units should be sensistive to this issue and identify a way to communicate that builds trust.

1.3 Patient Protection Issues and Confidentiality

1.3.1 There should be a clear pathway for referral to local child protection teams, including the management of young people who are sexually active. Guidelines should be in place in all relevant clinical areas.

1.3.2 A policy should be in place to support and refer potential victims of domestic and sexual abuse.

1.3.3 Health professionals should be appropriately trained to recognise vulnerable individuals.

1.3.4 Migrants in an irregular situation seeking medical assistance should not be apprehended at or next to medical facilities.

1.4 Well-being of Women Services

1.4.1 All units should consider providing facilities for patient-led support groups.

1.4.2 Local arrangements should be in place for prompt access to a dietician, drugs and alcohol misuse, and smoking cessation services. The referral pathways should be well publicised to clinicians and patients.

1.5 Environment

1.5.1 The environment should meet all national standards in relation to health and safety.

1.5.2 There should be an interview room to allow discreet consultation.

1.5.3 Seats of various heights and widths should be provided in the clinics, as low chairs may be unsuitable for women with mobility problems. Clinics should be accessible and provide facilities for all patients with disabilities.

1.5.4 Each unit should have Standard Operating Procedures (SOPs) and policies in place which should be regularly updated.

1.5.5 All laboratory facilities linked to gynaecological services should be in full compliance with the European Union Tissue and Cell Directives.

1.5.6 There should be a designated examination room to provide privacy. Facilities must be provided to give the woman privacy to undress and dress. A garment should be available to ensure dignity whilst awaiting clinical examination. Drapes must be available to maintain dignity.

1.5.7 Equipment should be regularly maintained and tools and reagents should be checked for expiry and replaced on time.

1.6 Gynaecological Examination

1.6.1 An explanation must be provided as to what the examination will involve so the woman has a clear idea of what to expect, including any potential pain or discomfort. She must be given an opportunity to ask questions.

1.6.2 Verbal consent should be obtained before all pelvic examinations. A chaperone should be available, irrespective of the gender of the gynaecologist.

1.7 Record Keeping

1.7.1 Accuracy of record keeping is an integral part of clinical care. Poor record keeping is a common contributing factor in many medical negligence claims.

1.7.2 Patient records must be written legibly and indelibly, ideally in black ink and have the patient's name and hospital number or date of birth on each page. Every entry (whether conventional or electronic) deletion or alteration in the case notes should be dated, timed and signed by the clinician. Any abbreviations used in the case notes should conform to agreed terminology.

1.7.3 The reports of investigations and laboratory results and letters must be signed and dated before being filed in the notes. Any appropriate action and follow-up required should be taken and clearly recorded before being filed. The development of an electronic records system is encouraged.

1.7.4 Processes should be in place to ensure that patients' health and other sensitive information is safeguarded against loss, damage or unauthorised access and kept confidential in accordance with legislation and guidance.

1.7.5 Procedures should be in place to facilitate the transfer of records for those whose residence status may cause them to move frequently.

2. Staffing

2.1 Each Gynaecology unit should have a head with an overall responsibility for clinical service and training.

2.2 Staff must be competent, up-to-date with their continuing professional development and able to establish and maintain good professional relationships with patients and colleagues.

2.3 All new professional staff should have appropriate introduction to the working of the unit and should be offered a mentor where appropriate.

2.4 Arrangements must be in place to ensure that temporary staff employed on short term contracts (locum trainees, bank or agency staff) receive an appropriate introduction to the working of the unit and are provided with appropriate supervision. If possible, patients' requests for a specific health professional should be supported.

2.5 Staff should receive regular training in health and safety, communication skills and consumer service.

2.6 Appropriate administrative support should be given to the service.

3. Clinical Governance Structure

3.1 There should be nominated responsible personnel for risk management in each clinical area e.g., clinic, ward, operating theatre, endoscopy suite, general practice, to deal with risk issues timely.

3.2 Risk management strategy should be in place. This should include:

- Identification, monitoring and control of risks;
- Embedding continual risk assessment in all clinical areas;
- Promoting awareness and understanding of patient safety issues within the unit and providing feedback;
- Risk management manual containing policies, protocols and clinical practice guidelines.

3.3 Each unit should have easily accessible referenced, protocols derived from the best scientific evidence and adapted to local use. These should be reviewed and updated at regular intervals.

3.4 All units should have a patient safety risk register to identify all incidents and corrective actions taken. A local 'trigger list' should be developed to encourage reporting.

3.5 All units should have a process for root cause analysis in place to investigate an unexpected severe incident or death. Each report should include learning points and an action plan.

3.6 All units should have policies and processes in place that protect patient safety when new technologies are introduced.

3.7 Each unit should have a multidisciplinary programme of clinical audit that monitors local practice against disease-specific/service standards of care.

3.8 Each unit should ensure that protocols operate to best practise, are patient-centred and individualised.

4. Training Standards

4.1 All doctors in training should have a named educational supervisor.

4.2 All training units should ensure that postgraduate trainees are observed by their supervisors performing clinical/pelvic examinations and procedures as part of their formative assessment of skills.

4.3 All training units should have written advice for doctors in training on seeking advice and on procedures they may perform without direct supervision.

4.4 All training units should have a Postgraduate Educational Programme.

4.5 All training units should have established audit programme where doctors in training are encouraged to present their audit projects.

5. Auditable Indicators

5.1 All the standards described in this chapter may be subject to regular audit. The ideal target for the achievement of all auditable indicators is 100%. There should be evidence of progressive improvement.

5.2 An audit of a small number of randomly selected medical records should be undertaken to ensure that the content of the notes are in line with the standards described in this chapter.

5.3 Patient satisfaction questionnaires, focus groups and feedback sessions are needed to ascertain what proportion of patients received appropriate information prior to their visit to the clinic.

5.4 There should be an audit programme that both responds to clinical incidents and demonstrates excellence in following the agreed care pathways.

5.5 Evidence of a risk management strategy.

STANDARD 2

Emergency Gynaecology, Acute Abdominal Pain in Women

Rationale

Acute abdominal pain is a major reason for emergency referral of women. Prompt diagnosis and management is essential to reduce morbidity and mortality. It could be life-saving in cases of ectopic pregnancy.[2]

Women presenting with acute abdominal pain may require a multi-disciplinary approach and prompt access to a dedicated emergency gynaecological service.

1. Patient Focus

1.1 Women who are at increased risk of ectopic pregnancy (e.g. previous ectopic, tubal surgery) and those at other risks (e.g., cyst torsion, Pelvic Inflammatory Disease (PID)) should consult a health professional early if symptoms develop.

1.2 Timely and clear information should be provided on the diagnostic procedures, clinical findings, the results of investigations and the treatment options.

1.3 Women should be counselled regarding possible implications on their future fertility and their understanding should be ascertained.

1.4 Consideration should be given to patients' family, their employment needs and other commitments.

1.5 Women should have the opportunity to make informed decisions about their care and treatment.

2. Accessibility

2.1 Women should have direct access to emergency services.

2.2 All emergency services should have access to gynaecological input at all times.

2.3 All emergency services accepting women should have access to laboratory, imaging facilities, blood transfusion services, emergency surgery and intensive care.

3. Environment

3.1 Services should provide a setting allowing for the appropriate privacy.

3.2 Services should have the facilities for triage.

4. Process

4.1 Complicated pregnancy in all women of reproductive age should be considered and ectopic pregnancy excluded.

4.2 All emergency services should have facilities for urgent β-hCG measurement.

4.3 The service should have protocols for the investigation and management of the patient presenting with pelvic pain. The protocol should have a clear algorithm for the management of acute abdominal pain in women; one for pregnant and another for non-pregnant women.

4.4 The service should be multi-disciplinary encompassing anaesthesiologists, general surgeons, urologists etc.

4.5 Pregnant Women with Acute Abdominal Pain

4.5.1 Ectopic pregnancy should be diagnosed by clinical assessment, trans-vaginal ultrasound scanning and quantitative β-hCG estimation.

4.5.2 Haemodynamically unstable patients should be urgently assessed and managed by a senior gynaecologist together with a senior anaesthesiologist to expedite surgery and ensure patient safety.

4.5.3 Haemodynamically stable women should be reviewed by a senior gynaecologist to decide on management and treatment options(surgical,medical or conservative).

4.5.4 The laparoscopic approach is the standard surgical intervention for haemodynamically stable patients with tubal ectopic pregnancy.

4.5.5 The laparoscopic approach may be considered for haemodynamically unstable tubal ectopic pregnancy provided that surgical expertise is available.

4.5.6 Quantitative β-hCG estimation, close follow-up arrangements and patient compliance should be ensuredin case of medical conservative management.

4.6 Non-Pregnant Women with Acute Abdominal Pain

4.6.1 Once pregnancy has been excluded, other gynaecological emergency conditions, such as complicated ovarian pathologies and PID must be considered and a management plan made by a senior gynaecologist.

4.6.2 Women with acute abdominal pain often need a multi-disciplinary diagnostic approach once gynaecological conditions are excluded.

4.6.3 If a decision is taken to proceed with surgery, a laparoscopic approach is the preferred option.

4.6.4 Patients (guardians/parents/carers as appropriate) who are discharged following the management of their acute abdominal pain should be given detailed discharge instructions, follow-up arrangements as appropriateand contact details given in case of an emergency.

5. Staffing and Competence

5.1 There should be a lead obstetrician/gynaecologist with responsibility for emergency gynaecology services.

5.2 There should be dedicated midwives/ nurses and named (rostered) medical staff in the emergency service on a twenty four hour basis.

5.3 All staff should be competent and receive regular updates and training on basic life support and managing emergency gynaecology.

5.4 Ultrasound sonography should be performed by experienced and well-trained staff.

6. Training Standards

6.1 All trainees should have regular training to ensure competency in dealing with acute emergencies, including basic life support.

6.2 Training in transvaginal ultrasound scanning is essential for all staff required to provide a scanning service in the provision of emergency gynaecology.

6.3 Training should be provided to ensure that all gynaecologists involved in emergency services are proficient in the laparoscopic management of patients with ectopic pregnancy.

6.4 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity, safeguarding children and vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Waiting times between arrival at the emergency unit, triage, diagnosis, initiation of treatment and/or discharge should be benchmarked against best practise.

7.2 Rate of unsuspected and suspected ectopic pregnancies re-admitted as ruptured ectopics- each case to be audited, discussed and analysed.

7.3 Rate of negative laparoscopies in women presenting with acute abdominal pain - each case to be audited.

7.4 Rate of successful outcome of ectopic pregnancy following medical or conservative management - Unsuccessful cases should be audited.

7.5 Rate of re-admissions within 24 and 48 hours after discharge from emergency gynaecology service.

7.6 Annual patient satisfaction survey about service experience.

STANDARD 3

Early Pregnancy Loss

Rationale

Women suffering from miscarriage are usually distressed and vulnerable. They want a reason why the pregnancy has not been successful and have anxieties about future pregnancies. Management of this clinical condition requires a holistic approach based on the best available evidence. The clinic should provide timely diagnosis, information, counselling and management. [24]

1. Patient Focus

1.1 Information on the physiology of pregnancy and pregnancy loss should be available to women and their families.

1.2 Women should also be offered a range of management options for early pregnancy loss and opportunities to discuss management of future pregnancies.

1.3 Emotional support should be offered to all women with early pregnancy loss. Specialist counselling should be available for selected women.

1.4 Written information should be provided with regard to tests and the sensitive disposal of pregnancy material.

2. Accessibility

2.1 An open access service with appropriate expertise and support should be available as a seven day service with mimimum waiting time.

3. Environment

3.1 The clinics should have a designated reception area and should also provide a supportive environment with appropriate privacy.

3.2 There should be an appropriately furnished room for breaking bad news and to discuss future management options.

3.3 A professional counsellor should be available.

3.4 Information material of various kinds should be available.

4. Process

4.1 There should be clearly defined and evidence based protocols in place, offering a full range of options for managing women with early pregnancy loss including conservative, medical and surgical management.

4.2 Patients should be provided with verbal and written information about the investigation and treatment options.

4.3. All services should have written protocols for the management of women with pregnancy of unknown location, suspected ectopic pregnancy and pregnancy of unknown viability.

4.4 Cases of recurrent miscarriages should be referred to the appropriate clinic for investigation and further management.

4.5 Multi-disciplinary working arrangements should be in place with radiology, genetics, immunology, microbiology, endocrinology,haematology and psychology and psychiatry departments.

5. Staffing and Competence

5.1 Each unit should have a lead consultant with special expertise in managing early pregnancy problems.

5.2 All staff providing pelvic ultrasound scanning should be appropriately trained and certified.

5.3 All units must have full clinical and laboratory support.

6. Training Standards

6.1 All trainees in Obstetrics and Gynaecology should acquire competence in the management of women with early pregnancy loss and fulfil the requirements of the EBCOG Log Book.

6.2 Doctors in training should maintain a log book to demonstrate their competence in early pregnancy ultrasound scanning.

6.3 Training should be provided on the basic consultation, effective and sensitive communication, the initiation of appropriate investigations and management according to the departmental protocols.

6.4 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity, safeguarding children and vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Rate of patient choice and uptake of different methods of management together with success rates and failure rates.

7.2 Annual patient satisfaction survey about service experience.

STANDARD 4

Recurrent Miscarriage

Rationale

Women suffering from recurrent first trimester miscarriage are frequently distressed and anxious to find a cause and possible solution in order to allow them to achieve a successful pregnancy in the future. Management of this condition requires specialised services which provide management based on the best available evidence[25].

1. Patient Focus

1.1 Information and support on pregnancy physiology and losses should be accessible to women and their families.

1.2 Women should also be offered follow-up visits at a specialised clinic to undergo appropriate investigations and to discuss possible management in a subsequent pregnancy. A high risk pregnancy care plan should be provided to such patients during their future pregnancy.

2. Accessibility

2.1 Specialised clinics with appropriate expertise should be available.

2.2 Multi-disciplinary working arrangements should be in place, with genetics, immunology, microbiology, endocrinology, haematology, psychology and radiology departments.

3. Environment

3.1 The clinics should provide a supportive environment with the appropriate level of privacy.

3.2 A professional counsellor should be available.

3.3 Information material of various kinds should be available.

4. Process

4.1 Couples with recurrent miscarriages should be referred to the appropriate clinic. Personal, social and environmental risk factors should be taken into account at the initial assessment and during investigations and counselling.

4.2 Management should be based on the best available evidence with clear guidelines and protocols.

4.3 Patients should be provided with written information about the investigation and treatment options.

4.4 Laboratories with the appropriate facilities must provide all the investigations, including karyotyping and screening tests to exclude thrombophillia and other related conditions according to the protocols.

4.5 Other tests including hysteroscopy and ultrasound imaging (two and three-dimensional)to exclude uterine abnormalities should be available.

4.6 Patients who may require uterine surgery should be referred to a specialised gynaecologist for evaluation and further management.

4.7 Medical management of recurrent miscarriage should be based on protocols derived from best available evidence and regularly updated.

4.8 Women with antiphospholipid syndromes or other types of thrombophilias should be given acetyl acetic acid and low molecular weight Heparin from the diagnosis of an intra uterine pregnancy, according to the best available evidence. An individualised venous thromboembolic disease risk assessment should be made in early pregnancy. Heparin administration should continue for six weeks postnatally.

4.9 Patients (and their partners) should be regularly updated on the process, given an indication of the time-frame and counselled regarding the potential impact on work and family life.

5. Staffing and Competence

5.1 Each unit should have a lead consultant with special expertise in managing recurrent miscarriages.

5.2 All units must be adequately staffed to provide multidisciplinary support.

5.3 Emotional support should be offered to women with recurrent miscarriage. Specialist counselling should be available for selected women. All staff should attend induction and refresher courses on breaking bad news and providing emotional support.

5.4 A policy on how to communicate effectively with women and their partners should be in place

6. Training Standards

6.1 According to the EBCOG training programme, trainees in Obstetrics and Gynaecology should attend the recurrent miscarriage unit to fulfil the requirements of the Log Book.

6.2 Training should be provided on basic consultation, initiation of the appropriate investigations, and referral pathways to specialised units.

6.3 Regular training in communication skills, breaking bad news, cultural/gender awareness and equality and diversity should be provided.

7. Auditable Indicators

7.1 Rate of successful pregnancy outcome in patients attending the service.

7.2 Rate of successful pregnancy outcome for each treatment modality.

7.3 Patient satisfaction survey with the service.

STANDARD 5

Pelvic Inflammatory Disease (PID)

Rationale

Pelvic inflammatory Disease is an infection of the upper genital tract. It can be life threatening and frequently has serious long-term sequelae including infertility, chronic pelvic pain and ectopic pregnancy.

The diagnosis is not always simple and straightforward. Many women suffer subclinical infection and its associated symptoms. Prevention, early diagnosis and appropriate management are essential to reduce the risk of adverse sequelae.

1. Patient Focus

1.1 Information should be widely available on primary and secondary prevention strategies.

1.2 Women with lower abdominal pain and/or unexplained fever should receive appropriate investigation and management by trained and competent health care providers.

1.3 Women should receive up to date information about the natural course of the disease, its cause, mode of transmission, treatment options, side effects and limits of treatment regimens.

1.4 Psychological, sexual and partner-related aspects should be addressed.

1.5 Counselling should take into account and respect the lifestyle of the women.

1.6 Partner notification and/or treatment should be discussed. Contact tracing and partner testing should be arranged.

2. Accessibility

2.1 There should be open and free access in the community setting to preventive measures.

2.2 Emergency services should be available for patients with acute symptoms.

3. Environment

3.1 Primary and secondary care settings should all provide discrete, confidential, patient-centred and non-judgemental care.

3.2 There should be access to appropriate haematology and microbiology facilities.

3.3 All gynaecologists offering specific care should operate within a multi-professional environment with access to surgery, anaesthesiology, radiology, urology and internal medicine.

3.4 All units should have facilities for gynaecology examination, vaginal pH testing, KOH solution in water, microscopy, and different collection tools for cultures and cervical cytology.

3.5 All units should be equipped with an abdominal as well as a trans-vaginal ultrasound scanning facility.

4. Process

4.1 There should be well defined care pathways in place to ensure appropriate initial treatment and later specialised management.

4.2 All units should have diagnostic and treatment guidelines derived from the best available scientific evidence.

4.3 There should be proper facilities, trained personnel and equipment to perform a diagnostic and operative laparoscopy.

4.4 For patients with uncertain diagnosis, or not responding to treatment within 24 hours, multidisciplinary consultation(s) should be considered.

4.5 Patients with PID should be risk-assessed and HIV testing offered when appropriate.

5. Staffing and Competence

5.1 All health care professionals in primary care should be well informed about preventive care measures.

5.2 All gynaecologists should be trained and competent in diagnosing Pelvic Inflammatory Disease.

5.3 Further diagnostic workout and treatment should be led by a gynaecologist with a special interest in benign gynaecology and/or infectious disease.

5.4 The treating gynaecologist should be acquainted in dealing with sexual and reproductive health in general.

6. Training Standards

6.1 All health care professionals dealing with primary prevention should have appropriate up-to-date training.

6.2 Doctors in training should attend theoretical courses to learn prevention, diagnosis, differential diagnosis and management of PID.

6.3. All gynaecologists treating this condition should be capable of undertaking laparoscopy at ESGE level 1 & 2.

6.4 All gynaecologists taking care of women with PID should be up to date with their CPD.

6.5 Regular training in communication skills, cultural/gender awareness, equality and diversity and in safeguarding children and vulnerable adults should be provided.

7. Auditable Indicators

7.1 Percentage adherence to national or (if not available) recognised international recommendations and guidelines.

7.2 Number of admissions, treatments and days of admission.

7.3 Documentation of notifiable diseases like gonorrhoea, Chlamydia and other STI according to the national policies.

7.4 Annual patient satisfaction survey.

STANDARD 6

Vulvovaginitis

Rationale

Vulvovaginitis is associated with distressing symptoms, impaired sexual function and has psychological implications. It is one of the most frequent reasons why women consult a gynaecologist.

In addition, during pregnancy vulvovaginitis may be linked to obstetric complications such as chorioamnionitis, preterm delivery and preterm rupture of the membranes.

The extensive use of prescribed treatments and self-medication, complementary therapies and repeated consultations lead to a high financial burden.

1. Patient Focus

1.1 Women with vulvovaginal complaints should receive appropriate investigations and treatment advice given by trained and competent health care provider.

1.2 Psychological, sexual and partner-related aspects should be addressed.

1.3 Counselling should take into account and respect the lifestyle of the women.

1.4 Women should receive up to date information about the natural course of the disease, its cause, mode of transmission, treatment options, side effects and limits of treatment approaches.

1.5 In specific cases partner notification and/or treatment should be discussed.

1.6 In the case of vulvovaginal complaints in children, sexual abuse must be considered. These children should be referred to a specialist in this area.

2. Accessibility

2.1. All women should have easy access to gynaecologists or other health care providers who are appropriately trained in providing basic diagnostic workup and treatment according to the best available evidence.

3. Environment

3.1 Community, primary and secondary care settings should all provide discrete, confidential, patient-centred, non-judgemental care.

3.2 Children should be seen in an appropriate environment.

3.3 Units should have access to a local service to deal with diagnostic investigations of vulvovaginal samples.

3.4 All units should have facilities for examination, including phase-contrast microscopy, pH testing, KOH solution, different collection tools for cultures, cervical and vulval cytology and access to colposcopy and biopsy tools.

4. Process

4.1 There should be well defined care pathways in place to ensure appropriate initial treatment and later specialised management[26].

4.2 All units should have diagnostic and treatment guidelines available and regularly updated.

4.3 A list of referral contact details must be at hand for expert advice if needed including a genito-urinary infection specialist, dermatologist, paediatric gynaecologist, microbiologist, psychologist and sexologist.

5. Staffing and Competence

5.1. All gynaecologists should be trained in best available evidence in managing vulvovaginitis

5.2. Women with chronic recurrent diseases require a specialised workup and treatment regimen and should be referred to a gynaecologist with a special interest in lower genital tract disease.

5.3 All professionals involved in managing children with vulvovaginal symptoms should be competent in child protection policies and procedures. The safeguarding of children is paramount.

6. Training Standards

6.1 Doctors in training should attend courses that include diagnosis and management of vulvovaginitis.

6.2 All gynaecologists taking care of women with vulvovaginitis should be up to date with their CPD.

6.3 Regular training in communication skills, cultural/gender awareness, equality and diversity and in safeguarding children and vulnerable adults should be provided.

7. Auditable Indicators

7.1 Prevalence data of various STIs in the screened population.

7.2 Percentage of women correctly diagnosed and treated for vulvovaginitis using best available guidelines.

7.3 Number of children seen and audit of their appropriate referral and management according to the local protocol.

7.5 Annual patient satisfaction survey.

STANDARD 7

Contraception and Sexual Health

Rationale

Global maternal mortality and morbidity could be decreased by reducing unintended pregnancies and providing good contraception services for both women and men.

Prevention of unintended pregnancies is therefore one of the most important objectives of women's preventive health care and a key element of women's empowerment[17-20].

Male sexual behaviour and contraception have an important impact on women's health, such as sexually transmitted infections (STI), unintended pregnancy, spread of HIV, sexual assault and violence. This has not been fully addressed in many European countries. There is a need for services to address these issues.

1. Patient Focus

1.1. The contraceptive needs of each individual should be assessed taking into account her/his priorities, values and attitudes, her/his biological and medical condition and psychosocial profiles.

1.2. All women and men have the right to evidence-based information on all available contraceptive method. Myths and misconceptions should be dispelled to ensure informed choice.

1.3. Both women and men should have the opportunity to address sexual health problems (screening for sexually transmitted infections, violence, sexual dysfunction etc.), in view of the close link between contraception and sexual health.

1.4 Multi-agency partnership approach would support the development of integrated sexual and reproductive healthcare services including psychological evaluation and counselling.

2. Accessibility

2.1. All services should be easily accessible, (five day service) and be complemented by the provision of emergency contraception out of hours and at weekends.

2.2. All services should provide information in different languages, according to the population they serve.

2.3 All services should have a wide range of contraceptive methods available.

2.4 All services should have antibiotics, emergency contraception and post-exposure HIV prophylaxis available.

2.5 All services should have on-site urine tests for pregnancy and access to trans-vaginal ultrasound scanning.

2.6 All services should have access to referral for safe termination of pregnancy within national legislation.

3. Environment

3.1. All services should have a designated reception area, constantly staffed during working hours.

3.2 The service should provide a setting allowing for appropriate privacy and confidentiality.

3.3 All services should have a link with providers of termination of pregnancy, outpatient and emergency gynaecology, sexually transmitted infections, urology and social services.

4. Process

4.1 History taking and clinical examination are essential. Gynaecological examination and genital examination of men may be indicated.

4.2 All services should provide counselling on evidence-based efficacy, advantages and disadvantages of the available methods of hormonal, non-hormonal, including long acting and permanent contraception as well as on sexual health.

4.3 Medical eligibility criteria as described for contraception by WHO should be applied.

4.4 Both men and women should be informed of sexually transmitted infections (STI) and the additional protection that male condoms afford. Information on the different condoms type and instruction on their use should be given. This should include advice on what to do if a condom bursts or slips off. The need for emergency contraception and STI protection should be emphasised.

4.5 Services should provide counselling regarding vasectomy and female sterilisation and an appropriate referral process should be established.

4.6 All services should provide balanced and detailed educational materials regarding the different methods.

4.7 The insertion and removal of Intra Uterine Contraceptive Devices (IUDs) and implants should be performed by well-trained health care professionals.

4.8 Protocols for the use of emergency contraception should be followed.

4.9 There should be an integrated outreach programme in the community.

4.10 All services should offer, or offer referral for, screening, diagnostic tests and treatment of STIs (including for HIV positive women or men).

5. Staffing and Competence

5.1 All services should have a lead clinician with an interest and expertise in contraception and sexual health.

5.2 Staff members should be trained to perform female and male genital examinations, pap smears, STI screening and ultrasound scanning when indicated.

5.3. Staff members should be able to insert and remove IUDs and implants.

5.4 All staff members should be formally trained in contraceptive and sexual health counselling.

5.5 All staff members should be able to educate, inform and counsel women and men of all sexual orientations and those from migrant or ethnic groups in a non-judgemental and empathic way.

6. Training Standards

6.1 Doctors in training in Obstetrics and Gynaecology should have access to contraceptive services to fulfil the requirements of the EBCOG curriculum.

6.2 Doctors in training should maintain a log book to demonstrate their competence in various aspects of contraception counselling and care and communicating their benefits.

6.3 Doctors providing the service should be trained and achieve competence in counselling, insertion and removal of IUDs and implants.

6.4 Regular training in communication skills, cultural/gender awareness, equality and diversity and in safeguarding children and vulnerable adults should be provided.

7. Auditable Indicators

7.1. All services should audit their practice against Medical Eligibility Criteria.

7.2. Each service should have systems for ensuring identification and notification of serious untoward incidents.

7.3 Uptake for various methods of contraception.

7.4 Annual patient satisfaction survey.

STANDARD 8

Male Contraception

Rationale

Male sexual behaviour and contraception have an important impact on women's health, such as STI, unintended pregnancy, spread of HIV, sexual assault and violence. This is not fully addressed in many European countries. There is a need for services to address these issues.

1. Patient Focus

1.1 Men´s concerns and needs should be assessed taking into account their psychosocial and cultural background.

1.2. Non judgemental and non directive communication and counselling should be provided.

1.3. Confidentiality should be assured.

1.4. Due to the close link between contraception and sexual health, the patients should have the opportunity to access help with sexual health problems if required.

1.5 A multi-agency partnership approach would support the development of integrated sexual and reproductive healthcare services.

1.6 The contraceptive needs of each individual man should be assessed taking into account his priorities, values and his biomedical and psychosocial profiles.

1.7 Every man has the right to evidence-based information on all available contraceptive methods. Myths and misconceptions should be dispelled to ensure informed choice.

1.8 Men should have the opportunity to address sexual health problems.

2. Accessibility

2.1 All services should be easily accessible, (five day service) and be complemented by the provision of emergency contraception out of hours and at weekends.

2.2 All services should provide information in different languages according to the population they serve.

2.3 All services should have condoms, antibiotics and post-exposure HIV prophylaxis available.

3. Environment

3.1 All services should have links with urology, dermatology and STI services.

3.2 All services should have a designated reception area constantly staffed during working hours.

3.3 The service should provide a setting allowing for appropriate privacy and confidentiality.

4. Process

4.1 All services should provide counselling on the best evidence-based methods of male contraception, including their efficacy, advantages and disadvantages.

4.2 Men should be informed about different types of condoms and receive instructions on their use. This should include advice on what to do if a condom bursts or slips off. The need for emergency contraception and STI prevention should be emphasised.

4.3 Services should provide counselling regarding vasectomy and an appropriate referral process should be established.

4.4 All services should offer, or offer referral for, screening and diagnostic methods and treatment for STIs including care for HIV positive men.

4.5 All services should provide balanced and detailed educational materials regarding the different methods of contraception.

5. Staffing and Competence

5.1. All services should have a lead clinician with an interest and expertise in sexual and reproductive health.

5.2. All staff members should be formally trained in contraceptive and sexual health counselling and have undergone communication training.

5.3 Staff members should be able to perform a physical examination and STI screening.

5.4 All staff members should be able to inform and counsel men of all sexual orientation in a non-judgemental and empathic way.

5.5 All staff members should receive regular updates on contraception and STIs.

6. Training Standards

6.1 Doctors in training should have access to contraceptive services to fulfil the requirements of their curriculum.

6.2 Doctors in training should maintain a log book to demonstrate their competence in various aspects of contraception prescribing.

6.3 All services should have regular clinical governance meetings (training and education, risk management, communication issues, areas for improvement, review of protocols and research).

6.4 Regular training in communication skills, cultural/gender awareness, equality and diversity and in safeguarding children and vulnerable adults should be provided.

7. Auditable Indicators

7.1 Each service should have in place systems for ensuring identification and notification of serious untoward incidents.

7.2 Percentage of males presenting and counselled by the service as regards various methods of contraception and STIs.

7.3 Annual patient satisfaction survey.

STANDARD 9

Safe Termination of Pregnancy

This Standard only applies to countries where termination of pregnancy is legal

Rationale

With due regard to national legislation, access to the safe termination of pregnancy is part of women's sexual and reproductive rights and empowerment[19-20].

Women seeking termination of pregnancy are frequently in emotional distress. They need support and non-directive counselling with unbiased information to help them come to a decision.

1. Patient Focus

1.1. Women seeking a termination of pregnancy should be treated with respect and in a non-judgemental way.

1.2. Women should have ample opportunity to express any ambivalence and ask any questions they may have regarding their decision. In case of persistent ambivalence or unresolved issues around the decision making, specialised counselling should be readily available.

1.3 Women from different backgrounds should have culture sensitive counselling and interpreters should be available.

1.4 Women should get non-directive counselling and balanced information about the different methods of termination of pregnancy available in the country (medical and surgical) and possible complications.

1.5 Adolescents, women with coexisting physical and psychiatric disorders and women at risk of partner violence or abuse or severe family disruption should be offered specific counselling.

2. Accessibility

2.1 Services for termination of pregnancy should be easily accessible five days a week during office hours.

2.2. Fast track appointments should be available when appropriate.

2.3 Services should be provided by teams based on national guidance that are clear on the legal restrictions. They should be responsive to the needs of women and offer choices and preferences for method of management of termination of pregnancy.

3. Environment

3.1 A welcoming, safe environment is essential if women are to express their concerns easily.

3.2 All services should have a special reception area ensuring confidentiality and privacy.

3.3 All services should have easily accessible information and educational material about medical and surgical termination of pregnancy.

3.4 All services should have relevant translation services.

3.5 All services should have facilities for gynaecological examination, STI Screening, basic laboratory testing including blood grouping and βhCG measurements. Ultrasound services to determine location, viability and gestational age are required as standard.

3.6 The service delivery facilities (operating room, anaesthesia, equipment) should meet the national requirements.

3.7 Intra-operative ultrasound scanning should be available.

3.8 All services should have a formal arrangement with local emergency gynaecology services.

5. Process

4.1 All women seeking termination of pregnancy should be seen as soon as possible, at least within 5 days.

4.2 Between the decision and the actual termination of pregnancy, reflection for a limited period of time is advised according to the needs of the individual patient and to national legislation.

4.3 All methods of contraception should be discussed before the intervention. The option of long acting methods should be mentioned including immediate placement of an IUD or an implant.

4.4 All services should provide non-directive counselling.

4.5 All services should have local protocols according to national guidelines, regarding early and late medical and surgical terminations of pregnancy.

4.6 All services should have local protocols for the prevention of infections and rhesus immunisation.

4.7 There should be written guidelines on the management of women using the service who are under the legal age of consent.

5. Staffing and Competence

5.1 All services should have a lead clinician with an interest and expertise in termination of pregnancy, contraception and sexual health.

5.2 Staff members should be competent to counsel women in a non-directive way, make time to listen and respond to the emotional needs of women (and their partners).

5.3 Staff members should be able to perform the procedures offered by the service.

6. Training Standards

6.1 Doctors in training should attend theoretical courses to learn about termination of pregnancy and the law in their countries.

6.2 Doctors in training, with the exception of those who are conscientious objectors, should have access to the local termination of pregnancy services to fulfil the requirements of their curriculum.

6.3 Doctors providing the service should be trained and achieve competence in counselling about the methods of termination of pregnancy.

6.4 Doctors in training should maintain a log book to demonstrate their competence in managing women who request pregnancy termination including their post procedure contraceptive needs.

6.5 Regular training in communication skills, cultural/gender awareness, equality and diversity and in safeguarding adolescents and vulnerable adults should be provided.

7. Auditable Indicators

7.1. Uptake and documentation of surgical and medical termination of pregnancy and the incidence of complications.

7.2 Frequency of women with repeat terminations of pregnancy in the same service.

7.3 Documentation of post termination contraceptive planning.

7.4 Another standard could be the percentage of women who are screened or treated for Chlamydia prior to the procedure.

STANDARD 10

Paediatric and Adolescent Gynaecology (PAG)

Rationale

The physical and psychological wellbeing of children and adolescents is crucial for their future general and reproductive health. Gynaecological conditions are common and can be disruptive. Rare conditions require specialist multidisciplinary management. Inappropriate provision of care can result in poor outcomes and adverse long term consequences. [27]

1. Patient Focus

1.1 Children and adolescents should receive the best evidence-based specialist treatment in order to preserve their future reproductive potential.

1.2 Surgical procedures for PAG conditions should primarily be based on minimally invasive techniques.

1.3 Female genital mutilation (FGM) is unacceptable under any circumstances. Legislation should be encouraged in those countries where such practices are not already classified as illegal.

1.4 Appropriate information for children, their parents or guardians should be available.

2. Accessibility

2.1 An easy access, non-judgemental service should be available where the welfare of the child is the primary focus.

2.2 Age-appropriate sex and contraceptive education should be available.

2.3 Vaccination against human papilloma virus should be promoted and offered to all adolescents. National prevention programmes should be encouraged.

3. Environment

3.1 Children and adolescents with gynaecological problems should be seen in appropriate and designated clinical environments.

3.2 All services should have a non-threatening reception area.

3.3 All services should have age appropriate displays and posters to provide patient information.

4. Process

4.1 Clinical networks should be established to allow for the multidisciplinary management of rare and complex conditions and the development of clinical, educational and referral pathways according to the best available evidence.

4.2 Disorders of sex development should be classified and managed according to the 2006 Consensus Document

4.3 Processes should be put in place to ensure a comprehensive and seamless transition of care of adolescents with gynaecological conditions to adult care.

6. Staffing and Competence

5.1 There should be a named clinical lead for PAG.

5.2 All professionals involved in managing children with gynaecological problems should be competent in child protection procedures. The safeguarding of children is paramount.

5.3 The team of clinicians providing this service should be competent in the medical and surgical interventions required.

6. Training Standards

6.1 Training to be provided in PAG recognised centres.

6.2 Trainers to be members of or work in close collaboration with national PAG Societies.

6.3 Training should be based on well established curriculum and training programme.

6.4 Regular training in age appropriate communication skills,cultural/gender awareness and the safeguarding of children and adolescents should be provided.

7. Auditable Indicators

7.1 Evidence of defined PAG health networks including multidisciplinary working.

7.2 Staff trained in child protection procedures.

7.3 Audit of surgical PAG procedures and outcomes in children.

7.4 Prevalence and supportive management of cases of FGM.

7.5 Proportion of adolescents able to access vaccination for human papilloma virus.

STANDARD 11

Heavy Menstrual Bleeding

Rationale

Menstrual disorders are the commonest presentation to gynaecological clinics. They interfere with a woman's physical, social, emotional wellbeing and negatively impact on quality of life. Women's health services should clearly set out management strategies for heavy menstrual bleeding.[28]

Women with heavy menstrual bleeding should have access to services both in the community and hospital care which provide efficient management, appropriate counselling and support to make informed choices about their management.

1. Patient Focus

1.1 The term heavy menstrual bleeding needs to be clearly defined and articulated so that patients know when to seek support.

1.2 Women should have access to clear and unbiased information to include diagnostic tests and treatment options, their outcomes and complications.

1.3 Women with heavy menstrual loss should have the opportunity to make an informed decision about their management with a primary aim of improving quality of life.

1.4 Services should be customised to meet the needs for special groups such as adolescents and peri-menopausal women and those from different ethnic background.

1.5 Treatment should be based on a woman's own subjective evaluation and the impact on her quality of life. Professionals should listen to the needs of the patient and recommend timely interventions based on the facts the patient presents (i.e. impact on quality of life).

2. Accessibility

2.1 Referral pathways from primary to hospital care should be agreed locally to ensure appropriate initial assessment and management of heavy menstrual bleeding in primary care.

2.2 Local protocols, derived from the best available evidence, should be agreed and incorporated into the referral care pathways. A time-frame should be set to manage the problem effectively.

2.3 Women should have access to all modalities of managing heavy menstrual bleeding. Appropriate referral to a specialist centre may be required.

2.4 Care and referral pathways should be designed to ensure appropriate and speedy management of women who have results suspicious of cancer.

3. Environment

3.1 Development of “one stop” services, with facilities for ultrasound scanning and outpatient hysteroscopy should be encouraged.

3.2 Facilities for insertion of Levonorgestrel-releasing Intrauterine System (LNG-IUS), should be available in both primary and hospital care settings.

4. Process

4.1 Ultrasound scanning is the first line investigation to exclude abnormality.

4.2 If there is a history of irregular vaginal bleeding, inter-menstrual bleeding and post-coital bleeding, cervical pathology should be considered. If cervical pathology is suspected, guidelines should be in place for further investigation and diagnosis.

4.3 A multidisciplinary approach including haematological advice should be sought for the management of adolescents without obvious pathology suffering from heavy menstrual bleeding particularly if presenting since menarche.

4.4. Following exclusion of associated pathology and management of associated anaemia, medical treatment should be given according to the best available evidence. Acceptable haemoglobin levels should be agreed upon in the protocols. Differences in initiating treatment for anaemia exist in different countries.

4.5. Failures to respond to first line medical treatment, persistent inter-menstrual bleeding are indications for outpatient endometrial sampling (possibly obtained at hysteroscopy).

4.6. Services should be able to provide a range of therapeutic modalities including least invasive ones such as LNG-IUS, second generation endometrial ablation techniques and hysteroscopic surgery. Uterine Artery Embolisation (UAE) may be an option in some regions for large uterine myomas.

4.7. Continuity of care for women with menstrual problems is essential for teams to deliver ongoing care for menstrual problems

4.8 Hysterectomy should be considered only if the woman has not responded to other treatments or declines other options after appropriate counselling for the least invasive available approach.

4.9 Healthy ovaries should not be routinely removed and appropriate counselling and consent is an essential requirement, whereas, removal of the fallopian tubes should be considered.

4.10 Management of associated iron deficiency anaemia should be an integral part of the care pathway and should be corrected prior to carrying out major surgery for heavy menstrual bleeding.

4.11 Protocols should be in place for thrombo-prophylaxis and infection prophylaxis for women undergoing major surgery.

5. Staffing and Competence

5.1 Gynaecology units should ensure competency/accreditation of staff involved in the management and those providing treatment modalities for heavy menstrual bleeding including insertion of LNG-IUS, laparoscopic surgery and imaging procedures.

5.2 Referral to another unit should be considered if the woman's choice falls beyond the area of expertise which exists in the local service.

5.3 Maintenance of surgical and imaging skills requires regular assessment and evaluation including audit of the number of procedures performed by operators.

5.4 Clinicians adopting new surgical techniques should be appropriately trained and accredited.

6. Training Standards

6.1 Professionals need to be able to communicate, empathise and understand the issues facing patients and the impact on their quality of life.

6.2 The trainee should attend hands on training courses in diagnostic and operative hysteroscopy, insertion of LNG-IUS, ultrasound scanning and second generation endometrial ablation techniques.

6.3 The trainees should demonstrate their competence in diagnostic and operative procedures by maintaining a log book of all the procedures performed and peri-operative outcomes.

6.4 Trainees wishing to learn advanced laparoscopic surgical techniques should be rotated to units with adequate work load.

6.5 Regular training in communication skills, cultural/gender awareness, equality and diversity, safeguarding vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Percentage of women in different age groups with heavy menstrual bleeding having endometrial sample before trial of treatment with the first line drugs.

7.2 Proportion of women without obvious uterine anatomical abnormality receiving each of the treatment modalities in the gynaecology unit.

7.3 An audit of the gynaecology unit's surgical activity and complications.

7.4 An audit of randomly selected case notes to ascertain that women were counselled about the risks of intra-operative and post-operative complications.

7.5 Audit of patient satisfaction for each modality and for the service provided.

7.6 Audit on the timing and delivery of interventions.

STANDARD 12

Chronic Pelvic Pain

Rationale

Chronic pelvic pain in women is well recognised as a major health problem affecting up to 24% of women worldwide (WHO). It has a significant impact on the quality of life of the woman and her family. It is a common cause of referral to the health service. It also affects economic productivity and has implications for healthcare systems and society.

All women with symptoms of chronic pelvic pain need access to a full range of appropriate services for assessment, counselling and management[29].

1. Patient Focus

1.1 There should be clear information available about the services provided, their location and working hours.

1.2 There should be clear information on the investigations and choice of treatments available.

1.3 The patients should be provided with an explanation about the possible diagnoses, various management options, patient support groups, the expected treatment outcome and possible complications of the treatment.

2. Accessibility

2.1 An integrated care pathway between primary, secondary and tertiary care should be in place.

2.2 A multi-disciplinary approach should have quality-assured communication lines, interdisciplinary networks and regular meetings should be held.

3. Environment

3.1 Gynaecological units should have a referral pathway to specialised pain management clinics when required.

3.2 Gynaecology services should have a multi-disciplinary approach to the management of these patients. There should be clearly defined referral arrangements with other services such as neurology, psychiatry, physiotherapy, and counsellors (complementary and alternative medicine, neuropathies specialists etc).

3.3 Gynaecological units should have an environment where the patient feels listened to and cared for.

4. Process

4.1 Protocol-led services should be available in general practice, gynaecology departments and dedicated pain-clinics.

4.2 Women with chronic pelvic pain of more than six months duration should be referred to secondary care.

4.3 Professionals need to demonstrate empathy and understanding.

4.4 Gynaecologists should exclude gynaecological causes of pelvic pain such as endometriosis, adenomyosis, pelvic adhesions etc. If present, these conditions should be managed by evidence based practice.

4.4 Persistent pain after appropriate gynaecological treatment should be managed through dedicated pain care management services.

4.5 All services should have best evidence guidelines in place for clinical management and follow-up. These should be regularly reviewed.

4.6 Women with deep infiltrating endometriosis (DIE) must be referred to specialised/accredited endometriosis centres.

4.7 Complex cases may require input from other specialties such as neurology, psychiatry, pain-clinics, specific physiotherapy and cognitive therapy. These cases should be referred to tertiary level treatment centres when specific treatment is required.

4.8 The communication between the care providers must be quality assured, preferably based on electronic media.

4.9 Networks should hold regular interdisciplinary network-meetings for case discussion, guideline review and other relevant communication.

5. Staffing and Competence

5.1 Staff, at the different levels and facilities, should have core as well as specialist knowledge of various aetiologies, diagnostic procedures and treatment modalities for chronic pelvic pain.

5.2 Staff dealing with women with chronic pelvic pain should be trained in counselling and specifically in quality of life issues.

5.3 Specialist training programmes, clinical audits and site-visitation programmes, as well as CPD programmes should be implemented according to national standards and specifications.

6. Training Standards

6.1 During their basic medical training, trainees should acquire the basic knowledge of the physiological and neurological background of pain as well as the various aetiologies and diseases that can produce pelvic pain syndromes.

6.2 Training should be provided to assess women with chronic pelvic pain and assess their symptoms using the visual analogue scale.

6.3 Trainees should have time allocated to attend special clinics dealing with various chronic pain conditions in gynaecology.

6.4 Trainees must have dedicated time in the operating theatre at various stages of their specialist training to achieve competence in endoscopic surgery. Specialists dealing with women with severe endometriosis should gain experience at the accredited laparoscopic surgery centres and be up-to-date with their CPD.

6.5 Regular training in communication skills, cultural/gender awareness, equality and diversity, safeguarding vulnerable individuals and quality of life assessment using standardised and validated questionnaires should be provided.

7. Auditable Indicators

7.1 Referral to pain clinic according to the agreed referral care pathway.

7.2 Percentage of women referred to endometriosis centre.

7.3 Referral to other services and their outcomes.

7.4 Qualitative outcomes in terms of improvement in quality of life (QoL) using standardized and validated questionnaires

7.5 Annual patient satisfaction surveys.

STANDARD 13

Benign Vulval Diseases

Rationale

Symptoms and signs on the vulva may signify a wide spectrum of systemic diseases (infectious, dermatological, metabolic, oncologic, neurological, psychological, etc.) rendering clinical diagnosis and treatment very difficult.

Doctors involved in the care of women suffering from vulval disease can be general practitioners, dermatologists, proctologists, gynaecologists and genito-urinary specialists. Dedicated clinics offer a multidisciplinary approach to vulval diseases[30].

The diversity of specialists involved requires setting standards of services to provide an appropriate diagnosis, support and management plan.

1. Patient Focus

1.1 All women should have access to competent staff, preferably in a dedicated vulval clinic, who can provide the correct diagnosis, counselling and treatment.

1.2 Women should be encouraged to seek advice through raising awareness of vulval diseases and of the availability of specialised clinics.

1.3 Patient information should be available to make women aware of the significance of vulval symptoms and to motivate and educate them about adequate treatment and follow-up.

1.4 The woman should be informed that the correct management of her vulval problem may involve various specialists and may require psychological support.

2. Accessibility

2.1 All women should have easy access to a dedicated gynaecologist with specific skills in diagnostic workup and treatment of vulval disease according to the best available evidence.

2.2 An integrated referral pathway from primary care to a vulval clinic should be established.

3. Environment

3.1 A vulval clinic should have discrete and comfortable waiting and examination rooms.

3.2 Facilities for diagnostic procedures should be available, including imaging, biopsy and cytological sampling, colposcopy, direct microscopic examination of discharge and culturing.

3.3 An examination couch of adjustable height and with proper leg support must be available along with good lighting to visualise the vulva and the vagina.

3.4 Appropriate equipment must be available in the examination room.

4. Process

4.1 Protocols for diagnosis and management should be evidence- based and updated on a regular basis.

4.2 Following assessment and examination, the appropriate management plan should be discussed with the patient and initiated.

4.3 Joint management with a dermatologist is standard with appropriate referral to other services such as psychology, neurology, pain management, cognitive physiotherapy and other relevant specialties as required.

4.4 Local multidisciplinary teams should meet regularly to discuss clinical policies and guidelines according to the best available evidence.

5. Staffing and Competence

5.1 Services for vulval disorders should have a lead clinician with the relevant competency and experience.

5.2. The management of vulval diseases is frequently multi-disciplinary and requires input from senior clinicians from other disciplines with an interest in vulval diseases.

5.3 There should be sufficient and dedicated midwives/nurses and healthcare professionals to care for women suffering from vulval discomfort.

5.4 All staff involved in the provision of this service should have and maintain the relevant Continuing Professional Development (CPD).

5.5 All staff providing the service should have special competency and be up to date with their relevant CPD.

6. Training Standards

6.1 All trainees should attend vulval clinics to fulfill their training requirements according to the EBCOG Log Book.

6.2 Advanced training is required for those involved in specialised vulval clinics.

6.3 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity and the safeguarding of children and vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Number of annual referrals to the vulval clinic and their pattern.

7.2 Rate of adequate biopsies taken to support diagnosis and subsequent choice of treatment.

7.3 Rate of appropriate coding for a diagnosis and the correct histological and/or clinical description of the abnormality according to international classification.

7.4 Rate of documented successful response to first-line treatment, including symptom control and quality of life.

7.5 Annual patient satisfaction surveys.

STANDARD 14

Menopause and Hormonal Therapy

Rationale

One third of a women's life span will be spent after the menopause. Menopause has a huge impact on the quality of life of women, their families, healthcare systems and society at large. A holistic approach to the problem should be adopted.

1. Patient Focus

1.1 Clear and objective information should be available to women on all aspects of menopause healthcare issues, in particular prevention of osteoporosis, cardiovascular diseases and cancers, with a special focus on high-risk groups.

1.2 Clear and unbiased information on hormonal and non-hormonal therapies for menopausal symptoms should be readily available.

1.3 Specific counselling on the possible impact on sexual life, including contraception, should be provided.

1.4 A global strategy to ensure a healthy lifestyle should be encouraged and that includes advice as regards: proper physical activity, balanced diet, smoking cessation and moderate alcohol intake,

1.5 Young women who had a premature menopause have special needs. They should have access to specialised clinics to address their sexual and reproductive health.

1.6 An effective management plan is particularly important in cases of premature ovarian failure.

2. Accessibility

2.1 Women should have access to counselling, clinical assessment, basic investigations and unbiased information regarding menopausal issues.

2.2 All services dedicated to menopausal issues should be easily accessible.

3. Environment

3.1 Dedicated menopause clinic services should be available and should serve as referral centres, allowing for the integrated evaluation of complex problems.

3.2 Menopause clinics should have access to specialists such as cardiologists, internal physicians, rheumatologists, orthopaedics, neurologists, oncologists, geneticists, psychologists, psychiatrists etc.

4. Process

4.1 Locally agreed guidelines based on best available evidence should be in place.

4.2 Initial assessment and management of the menopause in primary care settings should be provided. Integrated referral pathways to specialised clinics, particularly for those women with co-morbidity or at high risk, should be in place.

4.3 The risk/benefit ratio should be discussed with women before prescribing hormonal therapy. This discussion should be recorded, including the indication for treatment.

4.4 Multidisciplinary meetings should be held to review complex cases with input from appropriately trained clinicians.

4.5 An appropriate follow-up plan should be formulated for patients attending these services.

4.6 Evidence-based guidelines for managing post-menopausal bleeding in women should be in place. This should take into account whether the woman is on hormonal therapy or not.

4.7 Women with premature menopause should have appropriate guidance and management. Hormonal therapy (HT) should be discussed and a careplan agreed. Younger age groups should be appropriately referred for counselling regarding their reproductive potential, and a long term management strategy should be in place.

4.8 Women with troublesome menopausal symptoms should be offered hormonal therapy unless contraindicated. Follow-up visits should be offered at appropriately regular intervals.

4.9 Women with symptoms who have contraindications to hormonal therapy should be offered holistic treatment strategies, including non-hormonal medications, complementary medicine and lifestyle advice.

4.10 Menopause clinics should include services for oncological patients and a joint protocol should be in place with oncologists. These should specifically offer support and treatment for menopausal issues arising after oncological treatments.

5. Staffing and Competence

5.1 The lead clinician with appropriate experience and skills should be responsible for the provision of these services.

5.2 All staff providing the service should have special competency and be up to date with their relevant CPD.

5.3 Staff should be competent in evaluating risk-benefit ratio for individual post-menopausal women particularly those with co-morbidities.

5.4 Staff dealing with menopausal women should be trained in counselling and specifically in quality of life issues.

6. Training Standards

6.1 All trainees should attend menopause clinics to fulfil their requirements according to the EBCOG Log Book.

6.2 Advanced training will be required for those involved in specialised menopause services.

6.3 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity and the safeguarding of vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Number of new referrals to each clinic, together with the reasons for referral.

7.2 Rates of uptake of different treatments (hormonal, medical and alternative treatments) and complications reported.

7.3 Number of women with premature ovarian failure on HT and their long-term outcome data (including osteoporosis and cardiovascular disease).

7.4 Annual patient satisfaction survey.

STANDARD 15

Benign Breast Pathology

Rationale

Benign breast conditions have a wide range of pathological and physiological causes. Lesions may be visible, palpable or only reported on routine radiography or sonography. Women with benign breast disease often present to gynaecologists. Distinguishing benign breast disease from malignancy is essential for correct management. [31]

1. Patient Focus

1.1 It is important to raise women's awareness of the need for regular breast self-examination.

1.2 It is important to educate all women of the importance of reporting any changes in their breasts to their healthcare provider as required.

1.3 Women should be informed of the signs and symptoms of breast cancer.

1.4 Women should be informed of the risk factors for breast cancer.

1.5 Women at high risk should be made aware of the need for risk assessment and subsequent screening.

2. Accessibility

2.1 Women who present with breast symptoms should be promptly seen by an experienced clinician and have access to clinical assessment and first line investigations.

2.2 Prompt referral to specialised breast clinics should be organised if indicated.

2.3 There should be access to ultrasound scan and sampling when indicated.

3. Environment

3.1 Women should be seen in a friendly, warm environment to relieve their anxiety.

3.2 Ensure privacy and a chaperone be offered if requested at clinical examination.

4. Process

4.1 Protocols and algorithms for diagnosis and further management should be based on the best available evidence.

4.2 A thorough history should be taken, including medication and family history.

4.3 A systematic breast examination should be performed.

4.4 Imaging techniques, including mammography and ultrasound scanning should be carried out.

4.5 Exclusion of malignancy is a priority and prompt referral to a specialist is essential.

4.6 After exclusion of malignant disease, women should be counselled and reassured about the benign nature of their condition.

4.7 Women should be offered a follow-up appointment if indicated.

5. Staffing and Competence

5.1 In countries where gynaecologists are responsible for breast diseases, a lead clinician with appropriate experience and skills should be responsible for the provision of these services.

5.2 All staff providing the service should have special competency and be up to date with their relevant CPD.

5.3 Breast pathology should be managed in a multidisciplinary, integrated breast care service including gynaecological surgeons specialising in breast, radiologists, pathologists and breast care nurses/ midwives.

5.4 The breast care nurse should have appropriate nursing qualifications and have experience in handling and supporting women with benign breast disease

6. Training Standards

6.1 All trainees should attend breast clinics to fulfil their training requirements according to the EBCOG Log Book.

6.2 In countries where gynaecologists are responsible for breast diseases, gynaecologists should have the appropriate training in breast diseases, preferably certified

6.3 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity and the safeguarding of vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Number and pattern of referrals of women to a breast unit.

7.2 Percentage of BI-RADS category 4 mammograms followed by biopsy within 7-10 days, either within the benign breast clinic or after referral to a breast cancer unit.

7.3 Number of days between the availability of the pathology report and documentation that the patient has been informed of the results.

7.4 Rate of misdiagnosis of breast cancer.

7.5 Annual patient satisfaction survey.

STANDARD 16

Breast Cancer Screening

Rationale

Breast cancer is a major health issue and the establishment of national screening programmes is recommended.

Population breast screening programmes should be based within, or be closely associated with, a recognised breast unit[37].

It is essential to define standards for breast cancer screening in order to improve the quality of healthcare available to all women in Europe.

1. Patient Focus

1.1 Information provided should be easily understandable and adapted for high risk and vulnerable groups.

1.2 Women should be informed about the benefits and the adverse effects of screening. The concept of false positive and false negative tests should be discussed.

2. Accessibility

2.1 All women should have access to established and validated methods of screening.

2.2 Screening should be offered to all women in a defined population, based on age.

2.3 Screening should take place in well established screening units.

3. Environment

3.1 Women should be seen in a friendly, warm environment to relieve their anxiety and ensure privacy.

3.2 Ensure privacy and offer a chaperone if requested.

3.3 Waiting times should be kept to a minimum to reduce women's anxieties.

3.4 Imaging equipment, preferably not older than 10 years, for complete and adequate breast diagnosis should be available:

- Mammography Unit (preferable digital)
- Stereotactic biopsy attachment and/or dedicated prone biopsy table
- Ultrasound equipped with a small part probe >=10MHz

3.5 Screening equipment should be up to date, regularly maintained and operated according to the manufacturer's recommendations.

3.6 A standard operating procedure should be in place.

3.7 Screening units should comply with health and safety regulations.

4. Process

4.1 The Unit must have written protocols for screening, diagnosis and management of breast cancer.

4.2 Screening units should have access to an appropriate and dedicated breast pathology service as well as breast cancer specialists.

4.3 All patients should be discussed by a multidisciplinary team.

4.4 Screening results should be communicated efficiently to the woman and her family doctor. It is not recommended that the results are communicated by telephone or e-mail etc.

4.5 The unit should have a data management system for recording all unit activities and an efficient recall system should be in place.

5. Staffing and Competence

5.1 Every health professional involved in the screening programme must be a core member of the associated breast unit and breast screening centres should be a part of breast units.

5.2 The multidisciplinary team, represented at the tumour board and available for consultation, co-treatment and referral should include at least:

- Two dedicated breast radiologists
- Two dedicated breast pathologists

- Two dedicated breast surgeons (gynaecologist or surgeon) and a reconstructive surgeon (plastic surgeon) with demonstrable experience in the treatment of breast cancer.
- One medical oncologist with experience in the treatment of breast cancer who is familiar with palliative and supportive care issues.
- One dedicated radiation oncologist.
- Two Breast Care Nurses with experience in counselling and follow-up of patients.
- One dedicated psychologist or social worker.

5.3 All clinicians involved in the provision of breast cancer screening and management should meet the standards as set out by "The European Society of Breast Cancer Specialists-EUSOMA - *The requirements of a specialist Breast Unit. 2010". (www.eusoma.org)*[38]

6. Training Standards[38]

6.1 Doctors in training should attend theoretical and practical courses to learn about screening to fulfil the training requirement of the EBCOG Logbook.

6.2 Healthcare providers involved in the screening programme should be trained and achieve competence in providing the service including performance of the tests, communication skills, counselling, management and follow-up.

6.3 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity and the safeguarding of vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Percentage of false positive and false negative screening outcomes.

7.2 Percentage of women who had surgery or other treatment initiated within 6 weeks of their first diagnostic examination

7.3 Proportion of cases discussed by the multidisciplinary tumour board.

7.4 Annual patient satisfaction survey

STANDARD 17

Cervical Cancer Screening

Rationale

Screening for cervical cancer can reduce the morbidity and mortality associated with the disease.

Screening is defined as the examination of asymptomatic individuals with a view to identifying those who have occult disease or who are likely subsequently to develop the disease, and would therefore benefit from further investigations or treatment.

In many countries in Europe, population screening has not been well structured or implemented. Opportunistic screening is inevitably less effective than well organised nationwide population screening programmes. [35-36]

1. Patient Focus

1.1 Women should be made aware of options available for screening.

1.2 Population screening should be led by professional bodies, specifically resourced to cover large and diverse populations.

1.3 Population screening should use modern methodology of communication to reach the target population.

1.4 Women should be informed about the benefit sand the adverse effects of screening. The concept of false positive and false negative tests should be discussed.

1.5 Information provided should be easily understandable and adapted for high risk and vulnerable groups.

1.6 The information should be given in such a fashion that confidentiality and efficiency are ensured.

2. Accessibility

2.1 All women should have access to established and validated methods of screening.

2.2 Screening should be offered to all women in a defined population, usually based on age.

2.3 Screening should preferably take place in primary care.

3. Environment

3.1 Women should be seen in a friendly, warm environment to relieve their anxiety.

3.2 Ensure privacy and offer a chaperone if requested for clinical examination.

3.3 Waiting times should be kept to a minimum to reduce women's anxieties.

4. Process

4.1 All women from a target population should be invited for screening.

4.2 A robust system for call and re-call should be in place.

4.3 Screening should be performed by health care providers who have experience with the screening method and are acquainted with the consequences of its possible outcomes.

4.4 Each screening test should be performed in a standardised fashion. The appropriate clinical data set to allow identification and interpretation of the results should accompany the tests.

4.5 Results of screening should be documented and communicated clearly to the patient without delay. The communication should be documented.

4.6 If an abnormal result warrants further diagnostic tests or treatment, this should normally be available within 3 weeks (usually at referral to an oncologist).

4.7 Screening methods should regularly be evaluated for validity and benefit (e.g. through NCI's Cancer Screening Overview PDQ®[2]).

4.8 After the screening test, the clinician should comunicate the findings and details the future plan of action.

5. Staffing and Competence

5.1 All healthcare providers involved in screening should be competent and appropriately trained according to national guidelines.

5.2 The screening service should be appropriately staffed according to the population served.

5.3 All healthcare providers involved in screening should maintain and update their competence.

5.4 Continuing Professional Development (CPD) should be appropriately documented.

6. Training Standards

6.1 Doctors in training should attend theoretical and practical courses to learn about screening to fulfil the training requirement of the EBCOG Logbook.

6.2 Healthcare providers involved in the screening programme should be trained and achieve competence in providing the service including performance of the tests, communication skills, counselling, management and follow-up.

6.3 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity and the safeguarding of vulnerable individuals should be provided.

7. Auditable Indicators

7.1 An agreed set of auditable indicators should be in place and derived from the published national and international guidelines.

STANDARD 18

Gynae-Oncology Services, Including Breast Cancer

Rationale

It is well recognised that the outcome of oncological intervention depends on both the volume and the expertise of the service providers*. Specialised cancer services offer high quality evidence-based care. It is reported that they have reduced morbidity and better survival rates.

In certain countries in Europe, breast cancer care is provided by gynaecological oncologists. Standards of care should also be defined for these services, in line with those of the European Society of Breast Cancer Specialists (EUSOMA) [39-40].

1. Patient Focus

1.1 Patients should be informed about the level of specialisation of the service and the level of expertise. This information should be available publically.

1.2 The patient should be informed of a named and dedicated health care professional (case manager) who will assist her through diagnosis, therapy and follow up.

1.3 The patient should be informed of all treatment options, even if they are not available in the service.

1.4 The patient should be informed of any support services available in the hospital and in the community.

1.5 The patient's spiritual/religious and cultural needs should be met, especially in terminal care. Each woman has a way of coping with the diagnosis and treatment of her cancer, and needs specific psychological support and follow-up.

*** There is no clear definition of a cancer centre. According to the US (NCI) model (adopted also in Europe), cancer centres have a scientific agenda that primarily focuses on basic, clinical or population based research, or any two of the three. In the UK the NHS defines centres on the basis of population Specialised cancer services are those services, treatments and interventions which either require service planning for populations of between one and five million as specified in the relevant NICE guidance. Dedicated services for gynaecological oncology should be distinguishable from general hospitals providing basic care for gynaecological oncological patients. ESGO has clearly defined gynaecological oncological training centres, and similar criteria should be applied to clinical gynaecological oncological services.**

2. Accessibility

2.1 Women with suspected or proven cancer should have access to a gynae-oncology service within 2 weeks.

2.2 All gynaecological oncology services should have access to laboratory, imaging facilities, blood transfusion services, specialised anaesthetic services and intensive care.

3. Environment

3.1 Oncology services should provide a setting allowing for the appropriate privacy and facilities to communicate and care for the patient and her family members.

3.2 The gynae-oncology unit should have facilities for confidential counselling.

3.3 The gynae-oncology unit should be equipped with advanced facilities for minimally invasive surgery.

3.4 Waiting times in outpatients should be kept to a minimum to reduce women's anxieties.

3.5 Gynae-oncology services should have high dependency units (HDU) and blood transfusion services on-site.

3.6 Gynae-oncology services should comply with health and safety regulations.

4. Process

4.1 A gynae-oncology service should provide comprehensive multidisciplinary cancer care.

4.2 The service should have close collaboration with related disciplines, such as medical oncology, radiation oncology, psycho-oncology, pathology, radiology, urology, oncological surgery, reconstructive surgery and palliative care.

4.3 Clear and published care pathways, including detailed protocols, should be defined for patients with various oncological diseases.

4.4 All new cases should be discussed at a multidisciplinary tumour board/team. The diagnosis and management plan should be documented.

4.5 Medical oncological treatment should be performed by specially trained gynaecological oncologists, and if treatment is provided by a medical oncologist this should be done in close collaboration with gynaecological oncologists.

4.6 Complex surgery should, when appropriate, be jointly performed with the relevant oncological surgical specialists and/or reconstructive surgeons.

4.7 The minimally invasive approach is the preferred mode of surgery when indicated and subject to the availability of appropriate expertise.

4.8 Patients requiring radiotherapy should be referred to the radiation oncologist.

4.9 Supportive care should be given in close collaboration with psycho-oncologists and palliative care specialists.

4.10 Treatment should be initiated within 6 weeks of referral to the specialist.

4.11 Patients should be offered support by specialised services during and after the period of treatment.

4.10 An oncological database should be established to monitor activity and evaluate outcomes.

5. Staffing and Competence

5.1 The gynae-oncology service should be headed by a certified lead gynaecological oncologist or a gynaecologist with equivalent qualification and experience.

5.2 The service should be adequately staffed to serve the population of the catchment area.

5.3 The service should be adequately staffed (at least 3 full- or part-time gynaecological oncologists and specialised nursing staff) and it should have an adequate case load (at least 100 new invasive cases of gynaecological cancer and – if applicable – at least 150 cases of breast cancer per year).

5.4 Gynaecological oncologists should be certified subspecialists, trained in an accredited training centre or gynaecologists with equivalent qualification and experience.

5.5 Post-graduate continuing professional development (CPD) should be followed by all staff members according to national/professional society guidelines.

5.6 The gynae-oncology team should include psychologists and nurses specialised in this area and competent in counselling as well as delivering the appropriate clinical care to patients.

6. Training Standards

6.1 Doctors in training should have access to the gynaecological oncological service and be trained in peri-operative care to fulfil the requirements of their curriculum.

6.2 Subspecialist training for gynaecological oncology as defined in the EBCOG/ESGO Subspecialist Training Programme in Gynaecological Oncology and Log Book.

6.3 Doctors providing the service and those in general training should achieve competency in counselling oncological patients.

6.4 Regular updates of all staff on protocols should be organised.

6.5 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity, safeguarding children and vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Percentage of patients seen within two weeks of referral and percentage of patients treated within six weeks.

7.2 Total number of patients, number of new cases and number of radical surgical procedures carried out**.

7.3 Annual surgical morbidity and mortality data.

7.4 Global and disease free 5 year survival rate.

7.5 Annual patient satisfaction survey.

**** Radical surgery:**

Radical abdominal hysterectomy
Radical vaginal hysterectomy
Pelvectomy (ant, post, total)
Urinary diversion after pelvic exenteration
Cytoreductive surgery in ovarian cancer
Lumbo- aortic lymphadenectomy
Intensive surgical staging for ovarian cancer
Second look laparotomy in ovarian cancer
Bowel resection
Pelvic lymphadenectomy
Vulvectomy
Inguinal lymphadenectomy
Total colpectomy
Breast tumorectomy
Axillary lymphadenectomy
Mastectomy
Breast reconstructive surgery

STANDARD 19

Infertility and Assisted Conception

Rationale

Infertility should be recognised as a public health issue. The provision of infertility treatment and assisted conception services is associated with challenging clinical and ethical issues.

Efficacy and cost-effectiveness are paramount and demand that services should meet the standards. The treatment provided is based on the best available evidence.

Infertility is often stressful and the couple should be treated with empathy and receive full support. The infertile couple should have access to a specialised service that will provide a full diagnostic work up and therapy. Treatment should be individualised and be based on the best available evidence[41].

1. Patient Focus

1.1 All men and women who are sub-fertile should have the appropriate information on the availability of diagnostic and therapeutic options, irrespective of their cultural, sexual or religious background.

1.2 Arrangements should be in place for referral of individuals/couples to specific service providing an integrated approach.

1.3 All aspects of infertility must be taken into account including ethical and cultural background.

1.4 Providers of fertility treatment should inform couples about fertility treatment, the treatment and their success rates.

1.5 Prompt referral to specialised services should be considered in older women (> 38 years old).

2. Accessibility

2.1 All individuals with infertility should have access to counselling, clinical assessment and basic investigations.

2.2 All individuals should have access to assisted reproduction units if necessary and without delay.

3. Environment

3.1 Primary and specialist care settings should all provide discrete, confidential, patient-centred non-judgemental care.

3.2 Infertility centres should have dedicated facilities for reception, clinical and counselling activities.

3.3 Infertility centres should have on-site facilities for the storage of confidential records, access to laboratories and the storage of gametes and embryos.

3.4 The centre should have appropriate procedures to ensure compliance with the requirements for safety and environmental quality. Regular evaluation for hazards to laboratory staff and infection control should be carried out.

3.5 Counselling facilities and laboratory facilities, should comply with professional guidelines and legislation.

3.6 The centre should have appropriate on-site amenities for semen collection.

3.7 Laboratories in assisted conception units should fully comply with the European Union Tissues and Cells Directives (2004).

4. Process

4.1 Protocols for pre-conception counselling and pre-conception management of co-morbidity should be in place.

4.2 Integrated protocols for investigations should be in place between primary care and infertility units.

4.3 Further investigations based on advanced reproductive technology should be performed in secondary care centres by properly trained staff with the appropriate facilities.

4.4 Specific treatments, such as ovulation induction, reproductive surgery and assisted conception should only be carried out in specialised centres.

4.5 Protocols based on the best available evidence should be in place for each modality of treatment.

4.6 Treatment should be evidence- based and all centres should provide documentation and meet regulatory standards.

4.7 The management plan, results of investigations, treatment and outcomes should be clearly documented and communicated to patients. Data collection and analysis should be carried out regularly and made available to Commissioners and Regulators when required.

4.8 Infertility units should make all efforts to avoid multiple births by adopting a well-controlled monitoring policy when providing induction of ovulation.

4.9 All IVF centres must have a strategy to minimise multiple births. Elective single embryo transfer should be the standard practice in IVF/ICSI. All fertility centres must contribute to the reduction in multiple births by adopting the transfer of one embryo[4,5, 41].

4.10 Centres should comply with regulatory requirements whether in public or independent sectors.

4.11 Treatment involving gamete/embryo donations hould only be provided following appropriate professional counselling, including the legal, social and cultural implications and with the appropriate informed consent of the recipients.

5. Staffing and Competence

5.1 There should be a named lead clinician for infertility services and for units providing assisted conception services.

5.2 There should be a named quality manager in each specialised centre.

5.3 All staff should be certified by the appropriate professional national body.

5.4 Specialised centres should have regular meetings to discuss and manage cases in a multi-disciplinary environment.

5.5 All staff should take part in post-graduate continuing professional development (CPD) according to national/professional society guidance.

6. Training Standards

6.1 The trainees in Obstetrics and Gynaecology should attend the infertility clinic and the assisted reproduction unit to meet the requirements of the EBCOG Log Book.

6.2 Obstetricians and Gynaecologists should be able to provide appropriate consultation and referral to specialised infertility centres.

6.3 Subspecialty training should be provided according to the EBCOG/ESHRE curriculum.

6.4 All infertility centre staff should be up to date with their knowledge and skills.

6.5 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity and the safeguarding of vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Rate of live births for each treatment modality and for IVF rate of live births per embryo transfer.

7.2 Rate of pregnancy outcomes (e.g., miscarriage, ectopic) for individual treatment modalities.

7.3 Rate of elective single embryo transfer.

7.4 Rate of multiple pregnancies and ovarian hyperstimulation syndrome (OHSS).

7.5 A process of identification and notification of serious untoward incidents should be in place. Documentation that appropriate action has been taken must be demonstrated.

7.6 Annual patient satisfaction survey.

STANDARD 20

Urogynaecology

Rationale

Urinary incontinence affects a large number of women globally and has a huge impact on women's quality of life. Affected women are often reluctant to seek help because of the personal nature of the problem. They need information and support in making informed choices about their care and management. The variation in level of service provision in this area should be addressed and standards formulated[42].

1. Patient Focus

1.1 Women should have information on preventive measures and measures to reduce the impact of this problem on daily activities and quality of life.

1.2 Information should be available to women prior to their attending urogynaecology clinics.

1.3 Individual information should be provided to enable them to make informed choices about their care and management options (conservative, surgical and medical).

1.4 Pre-operative counselling should include operation-specific complications and outcomes. Surgeons should use both their own and national surgical data where available.

2. Accessibility

2.1 Women should have access to care initiated in primary care and referral to a specialised unit when appropriate.

2.2 Where available, community-based continence assessment clinics should be run by trained professionals including physiotherapists for a thorough assessment of symptoms and offer a range of conservative treatments.

3. Environment

3.1 A discrete and comfortable environment should be available.

3.2 Specialised urogynaecology clinics should be equipped with video-urodynamics, ambulatory urodynamics and ultrasound scanning facilities.

3.3 Waiting times in outpatients should be kept to a minimum to reduce women's anxieties.

3.4 Urogynaecology services should comply with health and safety regulations.

4. Process

4.1 An integrated referral pathway from primary care to specialised urogynaecology services should be established[42].

4.2 At the initial assessment, urinary incontinence should be categorised symptomatically as stress urinary incontinence (SUI), mixed (MUI) or urgency (UUI) and a management plan should be formulated based on the category.

4.3 Incontinent women should be offered advice and conservative management prior to more invasive interventions.

4.4 Management of recurrent urinary incontinence should conform to the best available evidence.

4.5 Local multidisciplinary teams should meet regularly to discuss clinic policy and guidelines.

4.6 Local referral pathways for urinary incontinence and pelvic organ prolapse should be agreed and local protocols developed for the management of pelvic floor dysfunction.

4.7 Women with complex pelvic floor dysfunction should be managed by multidisciplinary teams.

4.8 Combined clinics with Urogynaecologists and Coloproctologists should be held to facilitate investigation and counselling of women with faecal incontinence following obstetric anal sphincter injury and for those with bowel dysfunction, in association with pelvic organ prolapse.

4.9 Combined clinics with urogynaecologists and urologists should be available to facilitate the care of women requiring complex reconstructive urological surgeryor urological treatment.

4.10 There should be guidelines and protocols for the provision of aftercare to patients in primary care and the community.

5. Staffing and Competence

5.1 Urogynaecology services should be led by clinicians who regularly undertake a dedicated urogynaecology clinic.

5.2 Lead urogynaecologists should perform regular audits of treatment outcomes of their unit and individuals.

5.3 Clinicians should have an adequate annual workload in the surgical procedures they perform for SUI and urogenital prolapse.

5.4 Clinicians should be up-to-date with professional clinical development, especially in new surgical techniques and subscribe to the relevant CPD programme.

5.5 Staff should be competent in evaluating the risk-benefit ratio of the offered intervention, particularly for those patients with co-morbidities.

5.6 Staff dealing with patients should be trained in counselling and specifically in quality of life issues.

6. Training Standards

6.1 Trainees should attend hands on training courses on urodynamic investigations and new surgical techniques.

6.2 Trainees should maintain a log book of the cases performed, with appropriate outcome measures recorded where possible.

6.3 Clinical supervisors should ensure that trainees' clinical skills meet the competency levels described in the EBCOG curriculum.

6.4 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity and the safeguarding of vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Percentage of incontinent women offered conservative management prior to surgical interventions.

7.2 Percentage of women continent after surgery for urodynamically confirmed stress incontinence.

7.3 Percentage of women having pre-operative urodynamic investigations prior to repeat incontinence surgery

7.4 Percentage of women suffering from complications following surgical procedures for pelvic floor dysfunction.

7.5 Annual audit of new interventions introduced in the unit, outcomes and complications rates.

7.6 Annual patient satisfaction survey.

STANDARD 21

Ultrasound Scanning in Gynaecological Practice

Rationale

Ultrasound scanning is an important investigation for a wide range of gynaecological conditions such as early pregnancy monitoring, management of infertility and management of other gynaecological diseases. The standardisation and accuracy of scanning and its reporting are fundamental when making an appropriate clinical management plan.

1. Patient Focus

1.1 Women should be provided with detailed verbal and/or written information about the procedure of ultrasound scanning, and in particular transvaginal scanning. Their understanding should be verified.

1.2 Counselling should be available prior to the procedure and explanation given with respect to the level of invasiveness and the expected degree of discomfort/pain.

1.3 The results of ultrasound scans should be communicated to the patient by the lead clinician to provide the required reassurance and explanation regarding the findings and the possible diagnosis.

1.4 A full explanation of the advantages and disadvantages of both the abdominal and transvaginal scanning should be discussed with the women. Her wishes regarding the scan approach should be respected

1.5 Women undergoing ultrasound scans, particularly transvaginal ones, should be treated in privacy and with dignity.

1.6 A husband, partner or designated friend should be allowed to join the woman during the investigation is she so wishes.

1.7 A chaperone should be offered if requested.

2. Accessibility

2.1 Scanning facilities should be readily available for women presenting with early pregnancy complications in order to check for viability and to exclude ectopic pregnancy.

2.2 Access to ultrasound scanning should be available at all levels of care including primary, secondary and tertiary.

2.3 Access to more sophisticated imaging services should be made available upon ultrasound suspicion of high grade pathology by ultrasound scanning.

3. Environment

3.1 Ultrasound scan units should ensure the appropriate privacy and be well-equipped with changing and toilet facilities.

3.2 The unit should have the appropriate examination couches for patients as well as appropriate stools for the examiners.

3.3 Units should follow the standard health and safety policy.

3.4 Ultrasound scan machines should be regularly updated, calibrated and maintained.

3.5 A standard operating procedure (SOP) should be in place.

4. Process

4.1 The choice of vaginal or abdominal approach should be available, depending on suspected pathology and taking into account the patient's wishes.

4.2 Vaginal ultrasound scan approach is the preferred option for early pregnancy complications.

4.3 Protocols should be in place for different gynaecological conditions e.g., early pregnancy, adnexal masses, fibroids etc.

4.4 Failure to demonstrate fetal viability should be confirmed by two observers.

4.5 Pregnancy of unknown location should be considered carefully and a protocol should be in place for diagnosis and management.

4.6 Diagnosis of ovarian masses should follow the standard agreed classification of ovarian masses within the department.

4.7 Accurate reporting of the findings is essential for the best clinical interpretation and management.

4.8 A copy of the report should be sent to the referring clinician and the result communicated to the family doctor, when appropriate or required.

4.9 Appropriate image archiving facilities should be in place to allow quality assurance auditing and formulating management plans.

4.10 The result of the scan and its clinical interpretation should remain the responsibility of the referring doctor to avoid any misinterpretation or confusion to the patient.

5. Staffing and Competence

5.1 The unit providing early pregnancy scanning should have a named, lead clinician to oversee clinical and administrative management and ensure standards are applied.

5.2 Units providing ultrasound scanning for gynaecology should have a lead clinician and lead sonographer with the above mentioned responsibilities.

5.3 Personnel providing gynaecological scanning should be appropriately trained and certified by their national professional bodies, regularly updated in knowledge and practice and have the relevant CPD.

6. Training Standards

6.1 All trainees should attend theoretical and practical basic skill courses in ultrasound scan.

6.2 The unit should provide the appropriate supervised, hands-on training to fulfil the requirements of the EBCOG postgraduate curriculum.

6.3 Trainees should maintain a log book of their experience and demonstrate skills in case mix management.

6.4 The training unit should provide regular training updates to ensure the maintenance of skills.

6.5 Clinicians providing gynaecological ultrasound scanning in special categories, e.g., fertility scans, early pregnancy scans, oncology scans etc., should have an adequate case load to ensure maintenance of skills.

6.6 Regular training in communication skills, cultural/gender awareness, equality and diversity and in safeguarding children and vulnerable adults should be provided.

7. Auditable Indicators

7.1 Annual audit for failed diagnosis of ectopic pregnancy.

7.2 Percentage of pregnancy of unknown location.

7.3 Audit and case review for special categories such as fetal demise, ovarian masses and endometrial thickness in post menopausal women.

7.4 Annual patient satisfaction survey.

STANDARD 22

Colposcopy

Rationale

Organised screening has reduced the incidence of cervical cancer and the death rate from the disease by 80% in some European states. National screening policies should be encouraged throughout Europe. The introduction of HPV vaccination and HPV testing may reduce the rate further.

Women with a suspected cervical abnormality should be seen promptly in a setting conducive to professional care.

Colposcopy is not a screening tool but an investigation following the reporting of cytological abnormality on a cervical smear. Treatment should be directed only at those at risk of developing cancer[32].

1. Patient Focus

1.1 An abnormal smear result can cause anxiety which requires referral for colposcopy or treatment. Women should receive an appropriately worded invitation for colposcopy with a contact name, telephone number and clinic times.

1.2 Each woman should receive verbal and written information before colposcopy including a statement on whether or not immediate treatment will be offered.

1.3 Counselling should be available as an integral part of colposcopy.

1.4 The patient should be told that the results of any investigations and further plans for action will be communicated to her.

2. Accessibility

2.1 Low grade cytology (ASC-US, LSIL or equivalent)* should be seen in the colposcopy clinic within 8 weeks of the cytology result being issued.

2.2 High grade cytology (HSIL+ or equivalent including ASC-H)* should be seen in the colposcopy clinic within 4 weeks of the cytology result being issued.

2.3 If cancer is suspected the patient must be seen within 2 weeks.

* Bethesda cytology grading	
ASC-US	**Atypical squamous cells of undetermined significance**
LSIL	**Low grade squamous intraepithelial neoplasia**
ASC-H	**Abnormal squamous cells of uncertain significance (high grade cannot be excluded)**
HSIL+	**High grade squamous intraepithelial lesion or worse.**

3. Environment

3.1 Colposcopy units must be appropriately equipped for diagnostic and therapeutic procedures. Facilities should be regularly inspected.

3.2 Clinical consultation and examination should ensure privacy and a chaperone offered when requested.

3.3 Colposcopy clinics should comply with health and safety regulations and should have first aid facilities on site.

3.4 There should be a standard operating procedure.

4. Process

4.1 Colposcopy clinics should have a clear evidence-based protocol for the management of cervical abnormalities.

4.2 All cases must have a colposcopic examination prior to treatment for abnormal cervical cytology.

4.3 There must be a standardised record of each colposcopic examination and any procedures performed during that examination. This must include:

- Whether the squamocolumnar junction (scj) has been seen ;
- The transformation zone type as defined by the International Federation of Cervical Pathology and Colposcopy.(IFCPC);
- The site of any biopsies;
- Colposcopic opinion.

4.4 Wherever HPV testing is performed, only validated HPV tests must be used and there must be HPV reference laboratories in each country providing HPV testing.

4.5 A system of reviewing and actioning the results should be in place.

4.6 A system of communicating the results and the further plan of action to the patients should be in place.

4.7 The number of major procedures for the treatment of CIN must be minimised.

- Preferable techniques are loop excision/ laser excision in an outpatient setting;
- Treatment for CIN should be performed with local anaesthetic.

4.8 Clinical pathways must be designed to ensure adequate follow up of patients after treatment

4.9 Multidisciplinary meetings involving the cytologist, the pathologist and the clinician should be encouraged .

5. Staffing and Competence

5.1 There should be a named head to monitor quality standards for their service at least on an annual basis.

5.2 All colposcopists should have had formal training and be recognised or certificated as suitable to practice colposcopy. All European training programmes should comply with European Federation for Colposcopy (EFC) training standards.

5.3 All colposcopists should be up to date with their continuing professional development (CPD).

5.4 Nurses who are involved in colposcopy clinics should have appropriate nursing qualifications and have experience in handling and supporting women with suspected pre-invasive disease of the cervix and its treatment.

5.5 The unit should also have adequately trained support staff.

6.Training Standards

6.1 All trainees should attend colposcopy clinics to fulfil their training requirements according to the EBCOG Log Book.

6.2 All gynaecologists who are responsible for colposcopy services should have the appropriate training and preferably be certified. (communication competencies)

6.3 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity, and the safeguarding of vulnerable individuals should be provided.

7. Auditable Indicators

The EFC document provides a full list of auditable standards. For the purpose of EBCOG standards, auditable outcomes should at least include the following:

7.1 Percentage of procedures for CIN performed with local anaesthetic.

7.2 Percentage of all treatments performed with loop or laser excision.

7.3 Percentage of excisional treatments/conizations containing CIN2+.

7.4 Percentage of CIN2+ involving the endocervical or lateral margins.

7.5 Percentage of abnormal cytology and CIN2+ within 12 months of treatment.

7.6 Annual patient satisfaction survey

STANDARD 23

Diagnostic and Operative Hysteroscopy

Rationale

Hysteroscopy is the gold standard for the evaluation of the uterine cavity and the treatment of abnormalities.

Diagnostic hysteroscopy should be performed on an ambulatory basis whenever possible.

Operative hysteroscopic procedures can be performed either in a conventional Operating Room (OR) setting or in an appropriate outpatient setting with efficient OR management, instrumentation and trained personnel[33].

1. Patient Focus

1.1 Women should have access to balanced and unbiased information before attending for either a diagnostic or an operative hysteroscopy.

1.2 For operative hysteroscopy, risk assessment and information on alternative treatment options should be discussed.

1.3 The “one stop approach”(“see and treat”) requires patient counselling, including the possibility of further procedures according to the findings.

2. Accessibility

2.1 Dedicated outpatient diagnostic and operative services should be readily available.

2.2 Inpatient diagnostic and operative services should be available for patients only when outpatient management is not appropriate.

2.3 Access to inpatient admission should be readily available should any complication arise.

3. Environment

3.1 Hysteroscopy units should have in place appropriate and up-to-date equipment, used in accordance with the manufacturers' instructions and local guidelines. The unit should also provide simultaneous ultrasound scanning.

3.2 Clinical consultation and examination should ensure privacy and a chaperone offered when requested.

3.3 Outpatient hysteroscopy clinics should comply with health and safety regulations and should have first aid facilities on site.

3.4 There should be a standard operating procedure..

4. Process

4.1 Pregnancy should be excluded in all women undergoing hysteroscopy.

4.2 The service should be run on up-to-date local protocols, based on the best available scientific evidence.

4.3 In case of complications, there should be access to an emergency gynaecology service.

4.4 The hysteroscopy examination and treatment should be recorded in a standardised format

4.5 Instrumentation and distention medium used should be documented and any immediate or late complications should be registered.

4.6 In case of pathology suspicious of malignancy, histological evaluation must be obtained preferably by directed biopsies.

4.7 There should be clear aftercare instruction for patients.

5. Staffing and Competence

5.1 All personnel in the hysteroscopy unit should adequately been trained (* certificated as per colposcopy)[33].

5.2 Every hysteroscopic clinic should have a record of demonstrable ability on the part of those staff carrying out hysteroscopic procedures with validation of practical and theoretical skills in OR organisation and instrument handling and care.

5.3 Every training unit should have an in vitro dry lab to train and test practical skills in a validated environment.

5.4 Hysteroscopic specialists must have an adequate workload, review their outcome data yearly and should maintain their CPD.

6. Training Standards

6.1 All trainees should attend hysteroscopy clinics to fulfil their training requirements according to the EBCOG Log Book.

6.2 Doctors in training should maintain a log book to demonstrate their competence in various aspects of hysteroscopic procedures and the outcomes.

6.3 All hysteroscopists should have had formal training or be recognised by their experience as suitable to practice by their national and local bodies.

6.4 A formal evaluation of the theoretical knowledge and practical hysteroscopic skills and instrument handling should be provided by performing in house recognised evaluation procedure or the use of a recognised validated evaluation system.

6.5 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity and the safeguarding of vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Number of procedures and pathologies identified and the complications within the unit.

7.2 Number of and peri-operative complications and outcome within the unit.

7.3 Number of diagnostic procedures leading to conversion to procedures requiring general anaesthesia.

7.4 Number of diagnostic and operative hysteroscopies per operator and the complications rate.

7.5 Annual patient satisfaction survey

7.6 Audit of documentation.

STANDARD 24

Laparoscopic Surgery

Rationale

Laparoscopic surgery is reported to improve surgical outcomes and is associated with high patient satisfaction. It is essential to set standards for this highly specialised service which demands the acquisition of the necessary skill and appropriate competency. It is evident that any expansion of laparoscopic surgery without validation of the necessary skills can increase adverse outcomes[34].

1. Patient Focus

1.1 Women should have access to balanced and unbiased information before either a diagnostic or an operative laparoscopy.

1.2 Women undergoing laparoscopic procedures should have appropriate and clear after care instructions.

1.3 Information should be available on the level of expertise, the facilities, the range of procedures and the local quality programme.

1.4 Informed consent should be obtained and include an explanation of the risks involved and alternative interventions.

2. Accessibility

2.1 Women should have access to laparoscopic surgery when indicated and should be referred to units with appropriate expertise.

2.2 Every gynaecological unit should be encouraged to provide basic laparoscopic care (ESGE levels 1 & 2)*.

2.3 There should be a referral pathway to allow the provision of higher level-laparoscopic surgery (ESGE levels 3 & 4).

*(European Society of Gynaecology Endoscopy-ESGE)

3. Environment

3.1 Units should have in place appropriate up-to-date equipment which should be used in accordance with the manufacturers' guidelines.

3.2 An up to date Standard Operating Procedure (SOP) should be in place and regularly updated.

3.3 A training environment should be encouraged and facilities made available.

4. Process

4.1 Appropriate patient selection is important and a standardised protocol on inclusion and exclusion criteria for all treatment modalities should be adhered to.

4.2 Findings and the procedure should be accurately recorded preferably in a standardised format.

4.3 A see-and-treat policy should be discussed with the patient undergoing laparoscopy and preoperative consent should be obtained. See and treat policy should be based on the individual surgeon's competency level.

4.4 A multidisciplinary approach to managing complex cases should be encouraged.

4.5 Clinicians should comunicate the laparoscopic findings and the future plan of action with the patient.

5. Staffing and Competence

5.1 All surgeons should be trained according to the standards set by the ESGE.

5.2 All staff should be familiar with the equipment and should attend regular training.

5.3 There should be evidence of compliance with Continuous Professional Development (CPD).

5.4 There should be dedicated nursing staff for units providing operative laparoscopy who have undergone the necessary training.

6. Training Standards

6.1 All trainees should attend laparoscopic surgery operating lists to fulfil their training requirements according to the EBCOG Log Book.

6.2 Every teaching unit should have an in vitro dry lab for validated system and procedural training.

6.3 All laparoscopists should have had formal training or be recognised by their experience as suitable to practice by their national and/or local bodies.

6.4 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity and the safeguarding of vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Documentation of the incidence of different pathologies, the operative procedures performed and complication rates.

7.2 Documentation of activity for individual surgeon, according to his/her level of certification/expertise.

7.3 Clinical outcomes for each treatment modality.

7.4 Audit of documentation to demonstrate adherence to the local/national standards.

7.5 Clinicians' workload and annual activity in diagnostic and operative procedures and their complication rates.

7.6 Annual patient satisfaction survey.

STANDARD 25

Robotic Surgery

Rationale

Robot assistance in laparoscopy allows complex surgery to be performed. It reduces morbidity for patients as compared to open surgery and also aids the surgeon. As the role of robotic surgery in gynaecology is evolving, there is a compelling need to set standards to ensure safety and efficacy[43, 44].

1. Patient Focus

1.1 Patients should receive verbal and written information about their care and management by the surgeon who will perform the procedure.

1.2 The patient should be informed about the experience of the surgeon/institute with robotic surgery.

1.3 The patient should be informed about risks and complication rates.

1.4 The patient should be informed about alternative approaches, their advantages and disadvantages compared to robot assisted laparoscopy.

1.5 Valid consent should be obtained and clearly documented before the operation takes place.

2. Accessibility

2.1 Accessibility to robotic surgery should be governed by the appropriate case selection and the level of expertise of the care provider.

3. Environment

3.1 There should be a dedicated theatre for this type of surgery.

3.2 There should be a Standard Operational Procedure (SOP).

3.3 All personal in the operating theatre should be adequately trained.

4. Process

4.1 There should be a named lead for the service.

4.2 Robot assisted laparoscopy procedures should be recorded and the findings well documented.

4.3 Local multidisciplinary agreed protocols should be in place to deal with unexpected intraoperative and post-operative complications, and regular training in emergency procedures should be organised.

4.4 Protocols for after care should be in place.

5. Staffing and Competence

5.1 Robot assisted laparoscopic surgery should only be performed by staff appropriately trained for such procedures.

5.2 Following the introduction of robot assistance for laparoscopic surgery the entire team, including nurses, medical and technical staff, should meet at regular intervals to discuss protocols and safety issues.

5.3 Clinicians should be up-to-date with professional clinical development, especially in this new surgical technique.

5.5 Staff should be competent in evaluating risk-benefit ratio, particularly for patients with co-morbidities.

5.6 Staff dealing with patients should be trained in counselling.

6. Training Standards

6.1 Training should be by a validated system as well as procedural (didactic and skills) training.

6.2 A preceptor should provide direct supervision during the entire procedure for at least the first 3 cases. Indirect supervision by an experienced robotic surgeon should be available for at least the first 10 simple (*ESGE Level 1-3*) and at least the first 20 complex (*ESGE Level 4*) robot assisted laparoscopic cases per surgeon.

6.3 Regular training in communication skills, breaking bad news, cultural/gender awareness, equality and diversity and the safeguarding of vulnerable individuals should be provided.

7. Auditable Indicators

7.1 Workload per operator.

7.2 Rate of conversion to open surgery.

7.3 Rate of complications should be documented and analysed within the unit.

7.4 Annual patient satisfaction survey.

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UEMS	Union Européenne des MédecinsSpécialistes
FIGO	International Federation of Gynecology and Obstetrics
ACOG	American Congress of Obstetricians & Gynecologists
EAPM	European Association for Perinatal Medicine
ESGO	European Society of Gynaecological Oncology
ESHRE	European Society of Human Reproduction and Embryology
EUGA	European Urogynaecological Association
ENTOG	European Network of Trainees in Obstetrics and Gynaecology
EFC	European Federation of Colposcopy
EMAS	European Menopause and Andropause Society
ESC	European Society of Contraception and Reproduction Health
ESG	European Society of Gynecology
ESGE	European Society for Gynaecological Endoscopy
ESIDOG	European Society for Infectious Diseases in Obstetrics and Gynaecology
EURAPAG	European Association of Paediatric and Adolescent Gynaecology
ISPOG	International Society of Psychosomatic Obstetrics and Gynaecology
ISUOG	International Society of Ultrasound in Obstetrics and Gynecology
DPSG	Diabetic Pregnancy Study Group
MJCSM	Multidisciplinary Joint Committee of Sexual Medicine
DOTW	Doctors of the World

EFCNI	European Foundation for the Care of Newborn Infants
EMA	European Midwives Association
EIWH	European Institute for Women's Health
EPHA	European Public Health Alliance
PICUM	Platform for International Cooperation for Undocumented Migrants

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