

# Standards of Care for Women's Health in Europe



## EBCOG

European Board and College of Obstetrics and Gynaecology

## Obstetric and Neonatal Services 2014





# The Working Party

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## 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 for maternity care, from pre-pregnancy through intrapartum care to the post natal period including care of the newborn

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## Foreword

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Every year, more than five million women across the European Union give birth and about two million women have failed pregnancies. Over the past 50 years there has been a steady improvement in the provision of care during pregnancy and labour. Maternal and infant morbidity and mortality rates have declined significantly across the EU28 Member States.

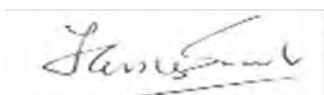
However, inequalities in access to women's health care still exist among the EU Member States. Maternal mortality is a major indicator of health system performance. Between 335 and 1,000 women die each year of pregnancy related causes. In developed countries with access to high level health care, more than 50% of these deaths are avoidable. Moreover, despite all the developments in care, the stillbirth rate has not declined to the same extent as that of neonatal deaths, and there is still a significant level of infant mortality and disability. Annually, in Europe, more than 25,000 babies are stillborn, another 25,000 die before their first birthday, 40,000 of the survivors (approximately 8/1000 liveborns) have sensory or motor impairment and a further 90,000 have major congenital abnormalities.

There are few EU wide agreed health indicators or guidelines for the care of women during pregnancy and labour and for the care of the newborn. Furthermore, there are no uniform standards for data collection systems across the member states for meaningful comparisons.

The Maastricht and Amsterdam Treaties commit the European Union to complement national health policies to improve public health, prevent human illness and diseases and to obviate sources of danger to human health. Therefore, to improve outcomes and address issues of health service delivery, EBCOG has developed core Standards of Care for Obstetrics and Gynaecology which have been approved by the societies of obstetrics and gynaecology in all EU/EEA member countries and beyond, and by the UEMS.

These standards have been produced after extensive consultation with stakeholders across Europe, including organisations representing women's interests. We believe that these standards, which are based on the best available evidence and supported by a set of quality outcome indicators, are an invaluable tool for commissioners of health services and health service providers to plan and deliver equitable, high level, quality-assured care to women, their babies and their wider families. These standards take account of the full care pathway from pre-pregnancy, through pregnancy and possible complications, to postnatal and neonatal care. They also address requirements for the training and support of doctors and healthcare professionals.

These standards have been defined following exhaustive consultation, taking into account the different situations and circumstances in the EU28 Member States and other European countries that are members of EBCOG. We believe that these standards should be adopted by the Ministries of Health across Europe. This would be an enormous step forward in improving access to, and the quality of women's health care within the EU and beyond and in ensuring that all women and their babies get the best possible care.



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# Glossary of Terms Used in the Document

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<b>Clinical guideline</b>	A systematically developed, evidence-based guidance that assists in healthcare decision making for a specific clinical condition
<b>Clinical protocol</b>	A list of things that must be done in specific situations to achieve a specific outcome and no deviations are allowed
<b>Standard operating procedure (SOP)</b>	A set of written instructions applied to an activity undertaken at an organisational level
<b>Care pathway</b>	A list of steps 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
<b>Clinical standard</b>	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
<b>Clinical audit</b>	A process of quality improvement which involves a systematic review of care against clearly defined criteria. The ultimate objective is to improve patient care
<b>Stakeholder</b>	A person, group or organisation who may be affected by the guidance given for service development
<b>Primary care</b>	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
<b>Secondary care</b>	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
<b>Consumer</b>	A woman, her family, or other representatives, who are currently or have previously utilised the healthcare services being described





<b>Clinical governance</b>	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
<b>Educational supervisor</b>	A senior clinician responsible for one or more trainees overseeing their training programme and progression, sometimes referred to as a tutor or trainer.
<b>Risk management</b>	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
<b>Root cause analysis</b>	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
<b>Multi-disciplinary</b>	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
<b>Open access clinic</b>	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
<b>Out-patient clinic</b>	Offers general diagnosis or treatments without an overnight stay
<b>Specialist clinic</b>	Provides advanced diagnostic or treatment for specific conditions such as sexual health clinics, fertility clinics, pre-natal diagnosis clinics, etc.
<b>Ambulatory care clinic</b>	Offers out-patient based, usually same day surgery services, for minor surgical procedures not requiring hospitalisation.
<b>Healthcare provider</b>	An individual or organisation (hospital or clinic) that provides preventive, therapeutic or rehabilitative healthcare services in a systematic way to individuals, families or communities
<b>Specialist nurses</b>	Nurses who have specialist clinical experience and training and are involved in the care of patients in defined clinical areas



## BACKGROUND

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The Maastricht Treaty (1992) forms the basis for 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”<sup>1</sup>. Subsequently, Article 152 of the Treaty of Amsterdam (1997) enlarged the healthcare duties of the EU, clearly stating that EU action shall compliment 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<sup>2</sup>. There is a strong connection between perinatal health and chronic disease of adulthood. There is a considerable gap in life expectancy at birth in the EU member states<sup>3</sup>.

There are more than five million births each year in the EU and about two million women have failed pregnancies (spontaneous and induced abortion, as well as ectopic pregnancies). Each year there are 335-1000 maternal deaths in Europe and more than 50% of deaths are avoidable<sup>4</sup>. Furthermore about 25,000 babies are stillborn every year in the EU and another 25,000 die before their first birthday. More than 40,000 of the survivors (approximately 8/1000) have severe respiratory or motor impairment and a further 90,000 have major congenital anomalies.<sup>5</sup>

Currently, considerable inequalities in access to women’s health exist among the member states of the EU. There are few EU-wide agreed health indicators<sup>6</sup> or guidelines for the care of women during pregnancy<sup>7-9</sup>, during labour,<sup>10-12</sup> care of the newborn<sup>13</sup>, and the treatment of gynaecological cancers<sup>14-15</sup>. There are no uniform standards for data collection systems across the member states to allow meaningful comparisons.<sup>4</sup> In order to improve outcomes we need to develop core standards..

Variations in care can then be assessed by monitoring individual provider’s performance, using high quality data related to process and outcome indicators as described in this document. This document will hopefully make an important contribution to achieving that goal.



## **EBCOG Process of Developing Standards of Care for Obstetric and Neonatal Services**

The Council of the European Board and College of Obstetrics and Gynaecology (EBCOG) agreed that a Working Party (WP) be established to oversee the development of core Standards of Care. In order to facilitate this exercise, it was decided to gather information from the representatives of the member countries to ascertain what currently exists. It was also agreed to review published reports from different European sources to establish a baseline which could support the development of Standards of Care.

### **The Working Party**

The EBCOG Working Party on Standards of Care was set up with the aim of developing Europe-wide standards of care for women's health services. Its remit was firstly to review current evidence based published standards of care in the member states of the European Union and secondly, to develop these unified standards.

The Working Party, Chaired by Dr Tahir Mahmood, included the EBCOG Officers Group, and representatives of the EBCOG Council.

### **Situation Analysis of the EBCOG Member Countries**

All members of the Council were sent a questionnaire to ascertain from their individual National Societies whether they had up to date clinical guidelines and Standards of Care statements. About 50% of member states had local clinical guidelines available but none, apart from the UK, had standards of care<sup>16,17</sup>. There was also a misunderstanding among the respondents about the definitions of a guideline, clinical protocol and standards.

## The Review of the Published Literature

The European Perinatal Health Report-EURO-PERISTAT Project report<sup>4</sup> provided incomplete comparative data from three different sources. *This report has pointed out that some of the differences in the indicators arise from differences in definitions, data quality, and coverage by data collection systems and completeness of recording (See Appendix 1).*

A survey and comparison of the member states of the EU as regards national guidelines on antenatal care (2006) reported huge variations in the number of tests done during pregnancy. It is interesting to note that countries with a Gross National Product below average were found to recommend more tests.

The World Health Organisation and others<sup>18,19,20</sup> have published comparative data on maternal mortality and on a selective number of maternal morbidity indicators in the EU countries. It is apparent that the patterns of causes and timing of death and age specific mortality ratios varied between countries with different levels of *maternal mortality rates*. For every maternal death, there are many serious, life threatening episodes of maternal morbidity. These data are good indicator of quality of care during pregnancy and labour but maternal morbidity data are recorded well.

The Royal College of Obstetricians and Gynaecologists (RCOG) have published two documents detailing standards of Care which are based on the guidelines published by the RCOG and National Institute of Clinical Excellence (NICE). The document detailing *Standards for Maternity Care*<sup>16</sup> has a set of 30 Standards whereas the second document, *Standards in Gynaecology*<sup>17</sup> has a set of 20 Standards. These two documents have in the past been shared with the members of the Council of EBCOG.

The Working Party considered all the published documents within the EU during the production of this document.

## Authorship and Consultation

Each standard was circulated to all the members of the Working Party and in depth discussion took place at the working party meetings. An interim WP report was also presented at the council meeting to seek views from the Council and the feedbacks were invited not only from the Council but also from the National societies. All comments were carefully considered at the meetings of the WP. The final report was approved by the UEMS, the EBCOG Executive and Council in November 2011. This report has been updated in 2014 to take account of new evidence.



## Purpose and Layout of this Document

The purpose of this document is to promote common *Standards of Care in Obstetrics and Neonatal Services* in order to improve and harmonise the care of women in Europe. This document provides 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 a driver to all stakeholders, such as clinicians and other healthcare providers, healthcare managers, insurance companies and politicians to implement quality assured women's services. The standards will also inform patients and consumer rights organisations about the care they might expect to receive.

The standards for Obstetrics and Neonatal Services care cover the care pathway during pregnancy encompassing three phases: pre-pregnancy, pregnancy, childbirth and post-delivery including care of the newborn. Each *Clinical Standard* comprises a mixture of clinical and organisational standards. Each set of standards has been supported by a list of *Auditable Indicator* which should act as a benchmark for improvement.

## EBCOG Standards: Towards Enhancing Postgraduate Training

One of the fundamental concerns of EBCOG relates to issues around the quality of training in our speciality for the delivery of high quality services. This is especially important as European integration allows free movement of persons, services, capital and goods. Therefore a separate set of *Training Standards* has been added to facilitate a uniform quality of healthcare professional training.

Currently, EBCOG operates a voluntary system of hospital visitation to accredit the training units against an agreed template, overseeing the structure and process of delivering post-graduate training. It is envisaged that the implementation of the European-wide Standards of Care would ultimately not only lead to the effective delivery of clinical services but would also provide excellent training.



## **EBCOG Standards: Towards Improving Quality of Care**

It is envisaged that the standards will help to provide equitable, safe and patient-focused services. The implementation of standards is an incremental process. When standards are implemented they should become an integral part of the audit process and of quality development. In order to achieve these standards, data from clinical audit may provide evidence to make a case for additional resources.

All stakeholders involved in women's healthcare should be working towards achieving the standards described within this document to ensure a contemporary, safe service, meeting the needs of women and their families.

We are confident that by the implementation of these standards of care, inconsistencies in care across the EU will be addressed and the most effective clinical care will be delivered.

We urge the EU Public Health Committee to consider developing unified "data systems" to accurately capture clinical activities across the EU member states in order to promote EU wide national audits of maternal well-being. Such data collection should also include items related to maternal morbidity, mortality and patient related outcomes.



# STANDARD 1

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## Generic Standards of Care for Maternity Services

### Rationale

Maternity services must ensure that women are able to choose the most appropriate care through each phase of their maternity experience. Good professional communication is essential for effective and co-ordinated care and to provide women with informed choices that best meet their needs.

There should be a clinical governance programme in place to monitor the quality of care provided to women and their families. This programme should incorporate risk management, clinical audit, complaints handling and implementing continuing professional development.

Safety should remain the top priority in clinical practice.

Maternity services should involve all stakeholders, consumers and providers of primary and secondary care in the development of their local service delivery models.

The maternity service working environment must facilitate the implementation of these standards.

### 1. Patient Focus

1.1 All pregnant women should be offered information on the full range of options available to them throughout pregnancy, birth and early parenthood, including locally available services, screening tests, types of antenatal and post-natal care and place of birth. Pre-conception counselling should be available.

1.2 Healthcare professionals should work in partnership with women and their families, respecting their views and striving to ensure safe and positive outcomes for women and babies at all times.

1.3 Staff working in maternity services should be competent in recognising, advising and referring women who would benefit from more specialist services.

1.4 Maternity services should ensure that there are comprehensive, culturally sensitive, multidisciplinary policies, standard operating procedures, services and facilities for the management and support of families who have experienced a maternal loss, early or mid-pregnancy loss, stillbirth or neonatal death.

## 2. Accessibility

2.1 Women should be offered evidence-based information and support to enable them to make informed decisions regarding their care. Information should include details of where they will be seen and who will undertake their care. Addressing women's choices should be recognised as being integral to the decision making process.

2.2 The information should be provided in a form that is accessible to pregnant women who have additional needs, such as those with physical, cognitive or sensory disabilities. These women may have communication difficulties which should be recognised and catered for.

2.3 The provision of maternity services should also be based on an up to date assessment of the needs of the local population.

2.4 Consideration should be given to develop open access/ambulatory care clinics where women concerned about the well-being of their baby can be seen around the clock.

2.5 Parents of stillborn babies or babies with identifiable medical or physical problems should receive timely care and support in an appropriate environment.

2.6 All outpatient antenatal clinics should meet national standards in relation to health and safety.

## 3. Process of Service Provision

3.1 There should be effective systems of communication between all team members in each discipline, as well as with women and their families. The team members should be trained to recognise signs of domestic abuse and serious psychiatric illness.

3.2 Interpreting services should be provided for women where the local language is not their first language. Relatives should not act as interpreters.



3.3 There should be a personal handover of care on the labour ward when midwives or nurses and doctors' shifts change.

3.4 Maternity services should utilise local protocols in line with evidence-based clinical guidelines for the provision of high quality clinical care.

3.5 Maternity healthcare providers should ensure that maternity services develop the capacity for every woman to have a designated midwife/nurse to provide care when in established labour for 100% of the time.

3.6 The plan of care should take into account relevant factors from the antenatal, intrapartum and immediate post-natal period and include details of the multi-disciplinary healthcare professionals involved in the mother's care and that of her baby.

3.7 Post-natal care should include the provision of information to both mothers and partners on breastfeeding, infant care, parenting skills and accessing local community support groups. Such services should be supported by the specialist midwives/nurses with these key skills.

3.8 Each service should have standard operating procedures and policies in place which should be regularly updated.

3.9 All specialist clinics should have clearly defined referral pathways, for all services being provided.

## 4. Clinical Governance Structure

A comprehensive clinical governance framework monitors the quality of care provided to women and their families, encourages clinical excellence, enables the continuous improvement of standards and provides clear accountability. Safety is the top priority in clinical care.

4.1 Clinical governance structures should be implemented in all places of birth.

4.2 All health professionals must have a clear understanding of the concept of risk assessment and management to improve the quality of care and safety for mothers and babies, while reducing preventable adverse clinical incidents.

4.3 When an incident has occurred, every unit should carry out a root cause analysis. Lessons can be learnt and, where necessary, changes to existing system can be made.

4.4 Maternity services should comply with evidence-based guidelines for the provision of high-quality clinical care, including the provision of antenatal, intrapartum and postpartum care, induction of labour and caesarean section.

4.5 There should be evidence that appropriately trained and experienced professionals obtain informed consent for interventions and investigations, and this should be documented. Intrapartum consent is not optimal but may be necessary and valid.

4.6 A compliments, comments and complaints procedure should be in place to enable women to express their views about their pregnancy and childbirth experience.

4.7 The person in overall charge of incident reporting, the clinical risk manager, must ensure that forms are completed whenever an identified trigger event has occurred or whenever an incident has occurred which is outside the normal or expected.

## 5. Clinical Audit

5.1 There should be an audit system in place to monitor important aspects of maternity care, and ensure an audit cycle to effect change.

5.2 All maternity healthcare providers should ensure that all staff participate in the relevant audit into maternal, perinatal or infant deaths or other trigger events.

5.3 The department should have a portfolio of clinical audits with clearly defined topics, action plans, re-audit and documentation to demonstrate improvements in outcome or care.

5.4 There should be a lead clinician for audit. Doctors in training should be encouraged to take part in the local clinical audits and they should be mentored by their educational supervisors within the department.

## 6. Staffing and Competence

6.1 Midwives, nurses and obstetricians should be competent to obtain the relevant information and identify serious conditions occurring during pregnancy or a history of a potentially serious past obstetric event.



6.2 Training should be provided to all healthcare professionals on how to communicate information in an effective, sensitive manner.

6.3 All professionals providing maternity care should undertake regular, specific, continuing on-site training in obstetric emergencies, the early identification and referral of women with obstetric or other complications, including cardiac arrest.

6.4 Skilled staff should be available to support parents during maternal or neonatal death, stillbirth or miscarriage.

6.5 The qualifications of each staff member must be documented. The competences of each staff member should be assessed, logged and regularly updated.

## 7. Training Standards

7.1 In order to ensure competency, postgraduate trainees should be observed performing examinations and procedures as part of their formative assessment of skills. Only those signed off as “competent”, may be allowed to operate independently.

7.2 All units should have written advice for doctors in training covering the labour ward, to include when to seek help and what procedures they may perform without direct supervision.

7.3 All new professional staff should have an appropriate induction and should be offered a mentor. Trainee doctors should also have a named educational supervisor.

7.4 Every unit should have a clinical audit lead and they should develop their own portfolios of clinical audits. Each trainee should be supported to undertake at least one clinical audit each year to complement their knowledge of clinical governance.

## 8. Auditable Indicators

8.1 Percentage of women who undergo prenatal screening tests at the correct time.

8.2 Percentage of women receiving appropriate pain relief of their choice during labour.

8.3 Presence of translation and advocacy services for non-local language speaking women.

8.4 Ratio of midwives or obstetric nurses /women in labour (Percentage of time one-to-one care provided).

8.5 Follow-up of complaints and action taken (target 100% responded to within 28 days).

8.6 Percentage of maternity professionals (doctors, midwives and nurses) who have had training in obstetric complications and emergencies (such as cardiac arrest and haemorrhage).

8.7 Percentage of maternity professionals who are trained in recognising the significance of past serious psychiatric history and domestic abuse.

8.8 Percentage of maternity professionals who are trained in current antenatal screening guidelines.

8.9 Documentary evidence of staff knowledge of and availability of comprehensive clinical guidelines.

8.10 Documentary evidence of multi-professional attendance at obstetric case review and audit meetings, where appropriate.

8.11 Evidence that each unit has a clearly defined protocol to ensure that doctors in training and newly appointed specialists have their competency signed off before they perform a procedure without direct supervision.

8.12 Staff involvement in risk management: for example, percentage who have completed incident forms and had feedback (staff questionnaire).

# STANDARD 2

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## Pre-pregnancy Services

### Rationale

Pre-pregnancy care should enable women to control their fertility and to ensure that any pregnancies are intended and optimally timed for good medical and social outcomes. Pre-pregnancy care should also include providing information on the use of folic acid supplementation.

Pre-pregnancy services may also provide information as regards local antenatal screening policies and multi-disciplinary services available during pregnancy.

Pre-pregnancy care for women with special needs is also important to promote social as well as physical stability and wellbeing prior to conception, and also provides an opportunity to advise on general health issues.

### 1. Clinical Standards

1.1 All providers of maternity services should work in collaboration with local health authorities to provide pre-pregnancy advice, including nutrition and exercise, benefits of breast feeding, sexual health and avoidance of alcohol, drugs and smoking and advice regarding healthy lifestyle.

1.2 Pre-pregnancy counselling and support should be provided for women of childbearing age with existing serious medical or mental health conditions which may be aggravated by pregnancy; e.g.: epilepsy, diabetes, hypertension, nephropathies, congenital or known acquired cardiac disease, autoimmune disorders, obesity or a history of mental illness.

1.3 Specific pre-pregnancy services should be available to women with a poor obstetric or medical history, a previous poor fetal or obstetric outcome, or where there is a family history of significant illness.

1.4 Services should be flexible enough to meet the needs of all women, including pregnant teenagers, those with learning and physical disabilities, women from ethnic minorities, vulnerable women, hard to reach groups, asylum seekers and refugees.



1.5 All healthcare providers of maternity services should ensure that contact details are easily accessible to all women so that the first contact following a positive pregnancy test occurs as soon as possible.

## **2. Training Standards**

2.1 All doctors in training should be trained and able to take a full family and patient history, including social issues such as domestic abuse, drug addiction and alcohol abuse, as well as topics perceived as intrusive, such as HIV testing.

2.2 The trainee should attend dedicated specialist pre-conception clinics for women with poor fetal or obstetric outcomes to learn counselling skills.

## **3. Auditable Indicators**

3.1 The percentage of women seen by a healthcare provider in the pre-conception period and having taken folic acid for more than one month up to conception.

3.2 Evidence that maternity services are reaching women from disadvantaged and minority groups and communities, early in their pregnancy and maintaining contact before and after birth.

# STANDARD 3

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## Early Pregnancy Emergency Services

### Rationale

A significant number of women will develop pain and bleeding in early pregnancy and require timely assessment in a specialist setting to diagnose and manage cases of miscarriage and ectopic pregnancy. Poor clinical outcomes are linked to inappropriate management.

Women having a spontaneous pregnancy loss can be managed by three management options (surgical/medical/conservative). Conservative methods of managing women with spontaneous incomplete miscarriage <13 weeks, when appropriate, are as effective as the other two methods of management.<sup>21, 22</sup>

A well organised early pregnancy assessment unit should also provide co-ordinated care for the management of women with ectopic pregnancy.<sup>22</sup>

### 1. Clinical Standards

1.1 Formal arrangements should be in place for referral to the early pregnancy assessment service. Women with previous early pregnancy problems should be able to self-refer for initial assessment. Management should be by agreed local care pathways, including screening for infection (including Chlamydia) and providing anti-D prophylaxis.

1.2 Healthcare providers should ensure that early pregnancy assessment units have access to high quality ultrasound scanning service and clinical bio-chemistry to aid accurate diagnosis.

1.3 Women who miscarry should have access to a choice of management options such as surgical/medical/conservative.

1.4 There should be clearly defined care pathways for the management of women who may have an ectopic pregnancy.

1.5 A suitable environment should be provided for worried or distressed mothers and their partners with access to counselling and appropriate information.



## 2. Training Standards

2.1 The trainees should demonstrate their competence in early pregnancy ultrasound scanning (trans-abdominal and trans-vaginal).

2.2 The trainee should keep a log book of cases and audit their practice.

## 3. Auditable Indicators

3.1 Evidence that guidelines and an algorithm for the pathway of care for women presenting with problems in early pregnancy are regularly updated.

3.2 Rates of medical, surgical and conservative management of miscarriage and ectopic pregnancy.

3.3 Rate of failed diagnosis of ectopic pregnancy.

3.4 Number of ruptured ectopic pregnancies per year following diagnosis in early pregnancy unit.

3.5 Appropriate use of anti D prophylaxis.

3.6 The rate of positive infection testing including Chlamydia

# STANDARD 4

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## Antenatal Care

### Rationale

The booking visit is an important opportunity to establish a continuing trusting relationship between the woman and her healthcare provider by the 12th completed week of pregnancy. Early pregnancy care makes it possible to identify specific clinical risk factors that may require focused antenatal care and surveillance throughout pregnancy; to recognise social problems for which women may need help from social or mental health services and to inform women about healthy behaviour during pregnancy.

Poverty, low social status and immigrant status are associated with poor pregnancy outcomes. These inequalities in perinatal health carry long term consequences<sup>13</sup>. This can be further compromised by more limited access to care during pregnancy and substandard care due to language limitations and cultural differences.

Children conceived through Assisted Reproductive Techniques (ART), compared with those conceived spontaneously, have a higher risk of adverse outcome. ARTs are more likely to result in multiple pregnancies.<sup>23</sup>

An individualised plan of care should be developed through detailed history taking and sharing of information. Women benefit from the support and advocacy of a known healthcare provider throughout their pregnancy.

### 1. Clinical Standards

1.1 At the first contact, pregnant women should be offered information about: how the baby develops during pregnancy, nutrition and diet, including supplements, exercise, the benefits of the screening tests and the pregnancy care pathway.

1.2 At the first contact, pregnant women should be offered information about locally available services for pregnancy care, birth and post-natal care.

1.3 A risk and needs assessment including previous obstetric, medical and social history, must be carried out at the booking visit. This assessment should be repeated at each subsequent antenatal visit to identify new risk factors and the plan of care modified as appropriate.

1.4 Once pregnancy is confirmed, women with complex needs should be referred to a clinically appropriate professional as soon as possible.

1.5 The unit should have clearly defined protocols and care pathways for the antenatal care of normal women and women with high risk pregnancies.

1.6 Focused antenatal care should be culturally sensitive and women's wishes should be respected.

## 2. Training Standards

2.1 All trainees should demonstrate their skills for the identification and initial management for serious medical and mental health conditions and referral to the multidisciplinary teams for advice.

2.2 All trainees must undertake supervised training for the early recognition and management of severely ill pregnant women and should attend advanced life support skills courses.

## 3. Auditable Indicators

3.1 Evidence that >90% of women have complete information regarding their ethnicity, country of birth and age at the time of booking recorded and total needs assessment regarding their medical needs during pregnancy recorded and a plan agreed by the 12th completed week of pregnancy.

3.2 Evidence that >90% of women should have confirmation of intra-uterine pregnancy by ultrasound scanning by 13 weeks.

3.3 Evidence that appropriate appointments have been scheduled for antenatal fetal abnormality and metabolic disorders screening according to national guidelines.

3.4 Percentage of mothers with diabetes and/or epilepsy provided with a higher dose of folic acid supplementation and recorded in booking assessment (target >90%).

3.5 Percentage of women with special needs appropriately referred to specialist clinics (target >95%).

3.6 Percentage of normal women who have received standardised antenatal care according to the nationally agreed recommendations (target >90%).



# STANDARD 5

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## Antenatal Screening

### Rationale

An integral component of antenatal care is the timely diagnosis and appropriate management of maternal problems and the detection of fetal conditions to inform patients and plan care.

### 1. Clinical Standards

1.1 All women should be offered a comprehensive, high-quality antenatal screening and diagnostic service (serum and ultrasound), designed to detect fetal problems at an early stage. Early ultrasound also determines gestational age and detects multiple pregnancies. This should be followed by a second ultrasound scan in the mid-trimester for detailed anatomical assessment of the foetus/foetuses.

1.2 All healthcare providers should ensure that antenatal tests and screening are offered to women as options (with the purpose and consequences of each test explained), rather than as a routine part of the process of being pregnant.

1.3 All maternity healthcare providers should ensure that when women request or decline services or treatment, their decision is respected and documented.

1.4 All women who are identified as being at risk of rhesus immunisation or other diseases should be managed and treated according to an agreed protocol.

### 2. Training Standards

2.1 The trainee should be able to demonstrate that all the cases initially assessed and managed by them meet the local protocols.

2.2 The senior trainees specialising in fetal medicine should undertake audit of the cases where they have undertaken independent diagnostic scanning or invasive procedures to determine their accuracy and adherence to national screening policies<sup>16</sup>.

### 3. Auditable Indicators

3.1 Percentage of eligible women (booking < 13 weeks) offered the two ultrasound scans stated above (target >90%).

3.2 Rate of eligible women accepting serum screening tests for structural and chromosomal abnormalities.

3.3 Rate of pregnancies with fetal anomalies missed using current screening policies.

3.4 Rate of women reporting being offered information and choice about antenatal tests and screening (survey of women).

3.5 Total number of terminations of pregnancies performed after prenatal diagnosis of severe congenital anomalies and expressed as 1000 total births.

3.6 Rate of amniocentesis or chorionic villus sample tests performed per 1000 births.

3.7 Rate of amniocentesis or chorionic villus sample tests that were negative.

3.8 Pregnancy loss rate following amniocentesis.

3.9 Pregnancy loss rate following chorionic villus sampling.

# STANDARD 6

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## Care of Pregnant Women with Pre-existing Medical Conditions and/or Special Needs

### Rationale

Mothers with pre-existing medical conditions are at a higher risk of serious complications and morbidity. When a need is identified, a plan of care must be provided by an appropriate multidisciplinary team to optimise outcomes.

Social factors have been shown to contribute to poor outcomes for both mother and baby. Some women and their families require specially developed services to ensure access, early engagement and continuing support and care.

Local protocols should be in place to carefully assess and support the needs of the immigrant population, especially those from economically impoverished countries and those who do not speak the host country's language.

### 1. Clinical Standards

1.1 Women with complex medical conditions must be offered assessment by a specialist. These conditions include epilepsy, neurological disorders, diabetes, hypertension, asthma, renal disease, congenital or known acquired cardiac disease, autoimmune disorders, haematological disorders, obesity, severe mental health disorder and any condition for which they are under continuing specialist medical review.

1.2 Maternity services must have arrangements in place (through clinical and local social services networks) including protocols for information sharing and a contact person, to ensure that women from disadvantaged groups have adequate support.

1.3 Migrant women may be at risk from previously undiagnosed existing medical conditions. Clinicians should ensure that a comprehensive medical history has been taken at booking and, where appropriate, a full clinical assessment of their overall health is undertaken as soon as possible.

1.4 Interpreting services should be provided for women where the local language is not their first language. Relatives should not act as interpreters. Arrangements should be in place for interpreting services in the community, especially in emergency or acute situations.

1.5 Joint working arrangements should be in place between maternity services and local services with responsibility for dealing with domestic abuse. Information about these services should be made available to all pregnant women.

1.6 All women who have a drug and/or alcohol problem should receive their care from a specialist multi-professional team.

1.7 A system of clear referral pathways should be established so that pregnant women who require additional care are treated by the appropriate specialist teams.

## 2. Training Standards

2.1 The trainees should provide evidence of attending joint antenatal/internal medicine clinics dealing with pregnant women suffering from complex medical disorders.

2.2 Senior trainees should attend specialist meetings or courses to acquire knowledge of the way that common medical conditions interact with pregnancy.

2.3 The trainees where possible should attend “simulated scenarios training days” to optimize the understanding of care pathways, particularly for acute illness or complications.

2.4 The trainees should demonstrate their understanding of local procedures and the systems of the organization for patient safety. This can be demonstrated by reporting “adverse events” and by attending risk management meetings.

2.5 The senior trainees should consider undertaking an audit of outcomes of pregnancies among the socially deprived and those with serious medical problems to assess adherence to local guidelines.



### **3. Auditable Indicators**

3.1 Rate of women with a pre-existing medical condition who are assessed and managed by an appropriate multidisciplinary team.

3.2 Rate of women with a pre-existing medical condition who have a documented plan of care.

3.3 Evidence of local strategies to engage hard to reach women and those at risk of, or suffering from, domestic abuse.

3.4 Evidence of the availability of translation, interpreting and advocacy services.

3.5 Evidence that written information is available for the care of women from disadvantaged groups.

# STANDARD 7

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## Care of Pregnant Women with Mental Health Disorders

### Rationale

Psychological morbidity in the perinatal period has a significant impact on the woman and her family. Unidentified or inadequately treated mental illness during pregnancy and following birth can have serious consequences.<sup>24</sup>

### 1. Clinical Standards

1.1 All maternity care providers and mental health care providers should have joint arrangements in place for pregnant women who have or develop mental health problems.

1.2 Women with a pre-existing mental disorder who are pregnant or planning a pregnancy and women who develop a mental disorder during pregnancy or the post-natal period, should be offered culturally sensitive information, assessment and treatment by a psychiatric specialist or team.

1.3 All women who are at identified risk of serious post-partum mental illness should be assessed and managed by a psychiatric specialist or team. A system of close supervision following birth should be established.

1.4 All professionals involved in the care of women immediately following childbirth should be able to distinguish normal emotional and psychological changes from significant mental health problems. Women who require to be admitted to a psychiatric hospital following delivery should be admitted to a specialist psychiatric mother and baby unit.

### 2. Training Standards

2.1 The trainees should provide evidence of attending joint antenatal/mental health clinics dealing with pregnant women suffering from complex mental health disorders.

2.2 Senior trainees should attend specialist meetings or courses to acquire knowledge of the way that common mental health disorders interact with pregnancy.

2.3 The trainees where possible should attend “simulated scenarios training days” to optimise the understanding of care pathways, particularly for acute mental illness.

2.4 The trainees should demonstrate their understanding of local procedures and the systems of the organisation for patient safety. This can be demonstrated by reporting “adverse events” and by attending risk management meetings.

2.5 The senior trainees should consider undertaking an audit of outcomes of pregnancies among the mentally ill to assess adherence to local guidelines.

### **3. Auditable Indicators**

3.1 Evidence of local joint working arrangements within a perinatal mental health network.

3.2 Percentage of maternity case notes recording that women are asked about family and personal history of mental health problems.

3.3 Percentage of women with mental illness who received pre-conceptional counselling.

3.4 Percentage of women with mental illness being followed up by a psychiatric specialist or team.

3.5 Percentage of women developing post-partum depression.

3.6 Percentage of women committing suicide within one year of delivery (per 10,000 deliveries).

# STANDARD 8

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## Care of Women developing Medical Conditions during Pregnancy

### Rationale

A purpose of antenatal care is the early detection of problems that require additional support. Maternity services need to be responsive and, when complications arise, provide all necessary facilities and expertise to ensure the best possible outcome for mother and baby.<sup>25</sup>

### 1. Clinical Standards

1.1 Multidisciplinary, high-quality teamwork is essential. Professionals should communicate with other professionals and colleagues.

1.2 A system of clear referral pathways should be established so that pregnant women who require additional care are managed and treated by the appropriate specialist teams when problems are identified.

1.3 Women with complicated pregnancies and those receiving care from a number of specialists should receive the support and advocacy of a known healthcare provider throughout pregnancy.

1.4 The development and routine use of an obstetric 'early warning chart' may help in the more timely recognition, treatment and referral of women, who have, or are developing, a critical illness.

1.5 The obstetrician in charge/on-call should be aware of all obstetric patients who have a medical, surgical or an obstetric problem.

1.6 All healthcare providers should ensure that maternity services have adequate facilities, expertise, capacity and back-up for timely and comprehensive obstetric emergency care, including transfer to intensive care.

## 2. Training Standards

2.1 The trainees should provide evidence of attending joint antenatal/internal medicine clinics dealing with pregnant women suffering from complex medical disorders.

2.2 Senior trainees should attend specialist meetings or courses to acquire knowledge of the way medical conditions may develop during pregnancy and how they can interact with gestation.

2.3 The trainees where possible should attend “simulated scenarios training days” to optimise the understanding of care pathways, particularly for acute illness or complications such as eclampsia.

2.4 The trainees should demonstrate their understanding of local procedures and the systems of the organisation for patient safety. This can be demonstrated by reporting “adverse events” and by attending risk management meetings.

2.5 The senior trainees should consider undertaking an audit of outcomes of pregnancies among those who developed serious medical problems to assess adherence to local guidelines.

## 3. Auditable Indicators

3.1 Evidence of local protocols for management of obstetric complications.

3.2 Evidence of audit of appropriate management for women who develop complications.

3.3 Evidence of the existence of protocols for the management of pregnant women in the accident and emergency services.

3.4 Evidence of local arrangements for transfer to intensive care.

3.5 Evidence of local development of early warning chart for critical illness.

# STANDARD 9

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## Care of Obese Pregnant Women

### Rationale

Obesity not only affects mental, physical and emotional health but also increases the prevalence of hypertension, diabetes, sexual dysfunction, infertility and cardiovascular disease leading to impaired health and a lower quality of life.

Obese women are at significantly increased risk of recurrent early pregnancy loss, fetal developmental abnormalities, gestational diabetes mellitus, pre-eclampsia and deep venous thrombosis. There is also an increased risk of dysfunctional labour, operative delivery, unexplained stillbirths. Obesity is also a risk factor for maternal death during pregnancy<sup>25-26</sup>.

Maternal obesity is recognised as being associated with adiposity in the offspring. This effect is independent of shared genetic and environmental factors.

The World Health Organisation (WHO) in 1997 formally recognised obesity as a global epidemic and a major health problem<sup>27</sup>.

### 1. Clinical Standards

1.1 Maternity services should work with other local community services to put arrangements in place to ensure that all women of childbearing age have access to services offering advice on weight management and lifestyle changes to optimise their weight before pregnancy.

1.2 Support services should offer advice regarding smoking cessation and to take higher doses of folic acid supplementation daily before conception. Obese women also need additional vitamin D supplementation daily during pregnancy and while breast feeding.

1.3 There should be multidisciplinary input for development of clear policies and protocols in each maternity unit for the care of women with BMI >30. These protocols should include consideration of:

- a. Referral criteria
- b. Facilities and equipment within the unit

- c. Care during pregnancy (especially fetal abnormality screening)
- d. Surveillance for pre-eclampsia and deep vein thrombosis
- e. Care during labour (anaesthetic risk assessment, intrapartum fetal and maternal surveillance and manual handling requirement during childbirth).
- f. Post-delivery (deep vein thrombosis prophylaxis and breast feeding support)
- g. Management of obstetric emergencies

1.4 Obese women at their first antenatal visit should be risk assessed and provided with accessible information about the risks associated with their pregnancy and how they may be minimised. Women with a high BMI ( $>40$ ) should also be seen by the anaesthetic team.

1.5 Each unit should have an agreed screening policy for gestational diabetes mellitus (GDM), preferably using the criteria defined by the WHO (Appendix 2).

1.6 Women with a BMI  $>30$  should be risk assessed (against agreed list of risks) at each antenatal visit, at term and when admitted in labour to develop focused care strategies.

1.7 The obstetrician on call/in charge and consultant anaesthetist on call/in charge should be informed when a women with a high BMI ( $>40$ ) has been admitted in labour. The obstetric unit should have appropriate neonatal services.

1.8 Each maternity unit should have protocols in place for monitoring during labour, pain relief, labour augmentation, operative delivery, wound management, and sepsis prophylaxis.

1.9 All professionals involved in the care of women with high BMI should be up to date about hospital policies and protocols, risk assessment tools and proposed plans of action.

1.10 All health professionals involved in the care of women with high BMI should receive training in manual handling techniques.

## 2. Training Standards

2.1 The trainees should demonstrate their understanding of problems associated with pregnancy in obese women. This can be achieved by undertaking an audit of pregnancy outcomes for women with BMI $>40$ .

2.2 The senior trainee should demonstrate his/her surgical skills by carrying out Caesarean Sections on obese women.



### 3. Auditable Indicators

3.1 Percentage of women with booking BMI >30 who were commenced on higher dose folic acid supplementation daily prior to conception.

3.2 Percentage of women who required more than one mid trimester ultrasound scan for fetal anomaly and the baby was born with an abnormality.

3.3 Percentage of women with a booking BMI >30 with other risk factors for venous thromboembolism, who had pharmacological thromboprophylaxis prescribed ante-natally and continued postnatally.

3.4 Percentage of women with a booking BMI >30 who had a glucose tolerance test during pregnancy.

3.5 Percentage of women with booking BMI >30 who did not have a glucose tolerance test during pregnancy but had babies born weighing >4000 gm at term.

3.6 Percentage of women with a booking BMI >40 who had antenatal anaesthetic review.

3.7 Percentage of women with a booking BMI >40 who had pharmaceutical thromboprophylaxis prescribed postnatally.

3.8 Percentage of operative vaginal deliveries or caesarean sections in women with booking BMI > 40 who were attended by a senior obstetrician and anaesthetist at the time of birth.

3.9 Percentage of healthcare professionals who have attended training in manual handling techniques.

3.10 An audit of unexplained still births in the unit where mother's BMI at booking was >30 and had a GDM screening done.

# STANDARD 10

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## Prevention of Preterm Birth

### Rationale

Preterm birth (PTB) is a widespread, serious medical and social problem with a worldwide incidence which ranges between 6% and 15%. This percentage is growing in relation to the fact that today some of those cases that in the past were classified second trimester “late” miscarriages are included in the statistics. The incidence of PTB rising in the industrialized countries is linked to the rise of maternal age, life style changes, obesity and multiple pregnancies following assisted reproductive treatments.

The aim of perinatal medicine is to identify specific risk factors and manage high risk patients with appropriate prophylactic tools.

### 1. Clinical Standards

1.1 All maternity care providers should be capable of identifying risk factors (table 1) for PTB and should be able to commence preventive strategies such as prophylactic lifestyle advices, therapeutic interventions in relation to risk factors and cervical length (CL) assessment during second trimester

1.2 Women at high risk for preterm birth should be referred to or managed in collaboration with a centre with NICU facilities

1.3 An in utero referral system should be in place ensuring that women delivering <32 weeks, will eventually deliver in a centre with NICU facilities

1.4 In all cases of women presenting with symptoms of preterm birth, true and false preterm labour should be distinguished on the basis of CL and/or of validated biomarkers for impending preterm labour.

1.5 Tocolytic drugs should be restricted to those with limited maternal side effects (oxytocin antagonist; Ca-channel blocker, PG antagonist for pregnancies < 34 weeks).

1.6 In high risk cases, a single course of corticosteroids given to the mother should be considered.

1.7 Magnesium Sulphate infusion (MgSO<sub>4</sub>) should be given in cases of preterm labour at < 32 weeks

1.8 A specialist outpatient clinic for counseling of women who had a preterm birth in their previous pregnancy should be available

**Table 1**

MATERNAL RISK FACTORS OF PRETERM BIRTH
<p><b><u>Maternal characteristics</u></b>            Age (&lt;18, &gt;36 yrs)            BMI (&lt;19, &gt;30)            Life style (cigarette smoking, diet restriction, drug abuse, alcohol abuse, poor hygienic control)            Physical stress and employment (heavy lifting &gt;5 Kg, standing &gt; 6 hrs/day, working &gt;42 hrs/week)</p> <p><b><u>Pre-existing conditions</u></b>            Diabetes Mellitus            Chronic Arterial Hypertension            Asthma            Lupus anticoagulant            Endocrinological diseases (Hypothyroidism and hyperthyroidism)            Congenital/acquired uterine malformations</p> <p><b><u>Obstetrical/ Gynecological history</u></b>            Previous PTBs            Previous miscarriages or abortions            Previous caesarean section            Interpregnancy interval &lt;1 year            Previous cervical surgery</p> <p><b><u>Current pregnancy</u></b>            Amniocentesis/Villocentesis            Multiple pregnancies            IVF/ICSI            Male gender of the fetus</p>

## 2. Training Standards

2.1 The trainees should be able to assess risk factors for PTB and know how to apply preventive strategies.

2.2 The trainees should be able to measure cervical length using vaginal ultrasound and to use validated biomarkers for impending preterm labour.

2.3 The trainees should be able to decide when to give antenatal corticosteroids to the mother.

2.4 The trainees should know the side-effects of tocolytic drugs and contra-indications for their use.

### 3. Auditable Indicators

3.1 Evidence of the written local protocols for preventive strategies (first trimester risk assessment; additional diagnostic tools such as ultrasound assessment of cervical length) evidence-based interventions.

3.2 Evidence of accessibility to vaginal ultrasound for CL measurement, 24/7/365.

3.3 Rate of women who had a cervical length measurement between 19-24 weeks.

3.4 Percentage of women delivering <34 weeks and were prescribed corticosteroids.

3.5 Percentage of women who received antenatal corticosteroids but delivered at term.

3.6 Percentage of women who delivered preterm (<37 weeks) and very preterm (<32 weeks) and were prescribed with specific drugs: progesterone, oxytocin receptor antagonist, Ca-channel blocker, PG antagonist and who had a cervical cerclage or pessary.

3.7 Each unit should collect data for perinatal outcomes and maternal side effects for all pregnancies managed with tocolytic drugs (specifying which drug and how often), cervical cerclage, pessary.

# STANDARD 11

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## Intrapartum Care

### Rationale

The organisation of the labour ward should have a vigorous and transparent clinical governance framework in place applicable to each birth setting. Evidence-based, local protocols, regularly updated, should ensure effective multidisciplinary working for the efficient delivery of services. The services should be supported by appropriately skilled and trained professionals who are fit for purpose. The organisation must ensure that all the professional staff have the opportunity and support for continuing professional development. The activity of the unit should be subject to regular audit and benchmark its rates of obstetric interventions against units of similar size and the national data<sup>16, 25</sup>

### 1. Clinical Standards

#### 1.1 General

1.1.1 All maternity units and labour wards should have a named, lead midwife/nurse, obstetrician, paediatrician and anaesthetist.

1.1.2 Healthcare providers should ensure that staffing levels and competencies on labour wards comply with the complexity of the clinical work load.

1.1.3 Specialised maternity units require a 24-hour anaesthesia and analgesia service with specialist supervision, access to intermediate and intensive care, clinical bio-chemistry, blood bank, other support services and an integrated neonatal care service.

1.1.4 Maternity care providers must ensure that all healthcare professionals directly involved in childbirth are competent in basic adult, obstetric, neonatal resuscitation and immediate care.



## **1.2 Midwives/Nurses**

1.2.1 Maternity care providers should ensure that maternity services develop the capacity for every woman to have a designated midwife/nurse to provide care for them when in established labour for 100% of the time.

## **1.3 Obstetricians**

1.3.1 Healthcare providers should ensure that a specialist is involved in the decision to undertake any caesarean section.

1.3.2 A specialist should be available immediately to deal with obstetric emergencies and also to support doctors in training as and when requested.

1.3.4 Any extreme planned preterm delivery requires review, as early as possible, by staff with appropriate expertise in the interpretation of fetal wellbeing tests.

## **1.4 Anaesthetists**

1.4.1 There should be a lead obstetric anaesthetist with anaesthetics service within specialist maternity units.

1.4.2 Arrangements should be in place in specialist maternity units to ensure that a specialist anaesthetic service is available at all times during childbirth.

1.4.3 Trainee anaesthetists must be able to obtain prompt advice and help from a designated anaesthetist at all times. They and their specialists must know the limits of their competence and when supervision and help are needed.

## **1.5 Paediatricians**

1.5.1 All specialist maternity units should have a named, lead neonatologist/paediatrician.

1.5.2 There must be 24-hour availability in obstetric units of a neonatologist/paediatrician or equivalent resident, trained and assessed as competent in neonatal advanced life support.



## **1.6 Organisation and Documentation**

1.6.1 The organisation should have a robust and transparent clinical governance framework which is applicable to each birth setting.

1.6.2 There should be a written risk management policy, including trigger incidents for risk and adverse incident reporting.

1.6.3 There should be a multi-professional input in protocol and standard setting.

1.6.4 Regular meetings involving all relevant professionals should be held to review adverse events.

## **1.7 Multidisciplinary Working and Communication**

Effective multidisciplinary working is essential for the efficient delivery of the service.

1.7.1 A labour ward forum or equivalent, comprising midwives/nurses, obstetricians, anaesthetists, paediatricians, support staff and managers should meet at least every 3 months.

1.7.2 Communication is the keystone to good clinical practice.

1.7.3 There should be effective systems of communication in place between all team members and each discipline, as well as with women and their families.

1.7.4 Employers should ensure that staff have both the appropriate competence in their local language and good communication skills.

## **1.8 Staffing Levels**

1.8.1 Midwifery/nursing staffing levels should be calculated and implemented according to birth setting and case mix categories to provide one-to-one care in established labour.

1.8.2 Specialised maternity units dealing with a complex obstetric work load should consider the on-site availability of specialist staff around the clock. This would not only improve the quality of care for women but would also improve training opportunities.

1.8.3 Maternity units dealing with a low risk obstetric population should conduct a risk





assessment exercise to determine their individual requirements as regards the onsite presence of obstetrician.

## **1.9 Emergencies and Transfers**

1.9.1 Each birth setting should have protocols based on clinical, organisational and system needs.

1.9.2 There should be local arrangements with the ambulance service for attendance at emergencies or when transfer is required.

## **1.10 Environment and Facilities**

Facilities in birth settings should be of an appropriate standard and take account of the views of service users by being less clinical, non-threatening and more home like whenever possible.

1.10.1 Facilities should be reviewed at least bi-annually and plans made to rectify deficiencies within agreed timescales.

1.10.2 The audit process should involve service user groups and a user satisfaction survey.

1.10.3 Dedicated and appropriate facilities for bereaved parents should be available.

## **2. Training Standards**

2.1 The trainee's log book should clearly demonstrate the following:

- Consultant presence in theatre at "assisted vaginal delivery" (Target=100%)
- Consultant in theatre when trainee is carrying out C/S for women with BMI > 40 (Target =100%).
- Consultant supervision while managing women with major obstetric complications such as haemorrhage, eclampsia and placenta praevia (Target=100%).

2.2 The trainee should demonstrate his/her understanding of root cause analysis of a serious neonatal or maternal adverse outcome related to an intra-partum event.

2.3 The trainee should demonstrate regular attendance at departmental training sessions in intrapartum fetal monitoring and obstetric emergency drills (crash emergency Caesarean section, massive post partum haemorrhage and eclamptic fit, etc).

2.4 Trainees should demonstrate attendance at the combined perinatal meetings.

### **Auditable Indicators**

3.1 Percentage of induction of labour by methods such as artificial rupture of membranes, use of prostaglandins, oxytocin infusion or any other methods.

3.2 Mode of delivery by age groups and parity (spontaneous, operative vaginal, elective and emergency C-Section).

3.3 Percentage of women by parity receiving augmentation of labour with oxytocin infusion.

3.4 Percentage of women by parity having episiotomy.

3.5 Percentage of women by parity having grade three or grade four perineal tears.

3.6 Rate of intrapartum stillbirths per 1000 births.

3.7 Percentage of newborns with Apgar scores less than 7 at 5 minutes.

3.8 Percentage of babies born with weight less than 1,500 grams (VLBW).

3.9 Percentage of neonatal deaths attributable to congenital anomalies.

3.10 Percentage of women with postpartum haemorrhage of 1,000 ml or more and/or requiring transfusion.

3.11 Percentage of women allowed trial of vaginal birth following previous caesarean section.

3.12 Rate of women having emergency caesarean hysterectomy for severe postpartum haemorrhage (presented as number divided by 10,000 deliveries).

3.13 Rate of women requiring intensive care unit admission following delivery (presented as number divided by 1,000 deliveries).

3.14 Rate of babies with neonatal birth injury, neonatal encephalopathy and post-delivery transfer to NICU (presented as number divided by 1,000 deliveries).

# STANDARD 12

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## Infection Prevention and Control

### Rationale

Good infection control will reduce hospital acquired infections. Infection in healthcare settings is a major cause of morbidity and occasional mortality.<sup>1</sup>

### 1. Clinical Standards

1.1 All healthcare providers should have appropriate arrangements in place for protecting patients and staff from the risks of acquiring healthcare-associated infections.

1.2 Specifically, in maternity services these should include:

- aseptic technique policy
- safe handling of sharps policy
- prevention of occupational exposure to blood-borne viruses policy
- disinfection policy
- antimicrobial prescribing policy
- uniform policy

1.3 Maternity service providers must ensure that the prevention and control of infection is included in training, in introduction programmes for new staff and in on-going education programmes for all staff.

1.4 Maternity service providers should ensure that there is adequate provision of suitable hand washing facilities and antibacterial hand rubs.

1.5 Maternity service providers should ensure that information relating to hand washing and visiting restrictions is provided for women and visitors.

1.6 All birthing pools and equipment should be thoroughly cleaned and dried after every use, in accordance with local infection control policies. Local information and guidelines regarding prevention of legionella build up in water supply from seldom used pools should be obtained and adhered to. Healthcare providers should use universal precautions and follow local infection control guidelines.



1.7 Guidance and policies should be in place to prevent mother-baby transmission of pre-existing conditions such as HIV, hepatitis B and streptococcus B.

## **2. Training Standards**

2.1 The trainees should demonstrate their understanding of local unit policies of infection control and the use of antibiotics prophylaxis in obstetric practice.

### **3. Auditable Indicators**

3.1 Documentation of the introduction programme for all new staff that includes prevention and control of infection.

3.2 Evidence of a monthly report on the occurrence of wound infections.

3.3 Evidence of a written antibiotics policy in the unit.

3.4 Rates of acquired infections: maternal and neonatal.

3.5 Re-admission rates due to infection.

# STANDARD 13

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## Maternal Mortality and Morbidity associated with Childbearing

### Rationale

Mothers in Europe still die in childbirth - approximately 1 to 33 per 100,000 births. Maternal deaths are sentinel events pointing to the dysfunction of the health system; worryingly about half of these cases are associated with sub-standard care and are potentially avoidable. Thankfully, the incidence of maternal deaths is slowly declining. However for every maternal death, there are many serious, life threatening episodes (9.5 to 16 cases per 1000). Adverse outcomes are more common among older women and among teenage mothers. Post-partum haemorrhage accounts for a great proportion of cases of maternal mortality and morbidity.

The Euro-Peristat project has recommended that *data on five indicators* of severe maternal morbidity should be collected routinely: *eclampsia, surgery for post-partum haemorrhage, blood transfusion, a stay longer than 24 hours in the intensive care unit and thrombo-embolism*.

The EBCOG working party recommends that all provider units should work towards setting up systems for collecting data on several quality indicators of severe maternal morbidity<sup>28,29</sup>.

### 1. Clinical Standards

1.1 Systems should be in place to record and investigate maternal deaths both directly and indirectly associated with childbearing using the internationally approved definitions.

1.2 Appropriate interpretation of the causes of maternal deaths requires particular attention to the proportion of “unknown” causes.

1.3 Risk management systems should be in place to capture data on severe maternal morbidity.

1.4 Multi disciplinary team (MDT) meetings must be held monthly to discuss all cases of severe maternal morbidity to identify weaknesses in the provision of care and action plans should be agreed to prevent recurrence.

1.5 Route cause analysis of all the adverse outcomes should be carried out to address areas of clinical risk and a remedial action plan put in place.

## 2. Training Standards

2.1 The trainee should provide evidence of participation in a Multi disciplinary team meeting where root cause analysis has been carried out of a case of severe maternal morbidity. This can be demonstrated by a case study for the training portfolio.

### 3. Auditable Indicators

3.1 Rate of women with severe maternal morbidity (per 1,000 births).\*

*The EBCOG working party recommends that all provider units should work towards setting up systems for collecting data on the following quality indicators of severe maternal morbidity:*

- ✓ Major Obstetric Haemorrhage(>1000 ml);
- ✓ Eclampsia;
- ✓ HELLP Syndrome;
- ✓ Disseminated Intravascular Coagulation;
- ✓ Placenta Accreta;
- ✓ Post-partum Hysterectomy;
- ✓ Grade 3 and Grade 4 Perineal Tears;
- ✓ Renal Failure;
- ✓ Acute Liver Dysfunction;
- ✓ Cardiac Arrest;
- ✓ Massive Pulmonary Embolism;
- ✓ Pulmonary Oedema;
- ✓ Acute Respiratory Dysfunction;
- ✓ Cerebro-vascular dysfunction;
- ✓ Coma;
- ✓ Shock (Anaphylactic, Septicaemic, Haemorrhagic);
- ✓ Anaesthetic problems;
- ✓ Intensive Care Admission;
- ✓ Coronary Care Admission.

3.2 Maternal mortality rate per 100,000 births.

3.3 Evidence that risk management meetings are held regularly to review all cases of severe maternal morbidity.

3.4 Evidence that actions agreed at each MDT meeting have been fully implemented.

3.5 Evidence that the training needs of trainee doctors identified in these case reviews have been addressed.



# STANDARD 14

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## Post-natal Care of the Mother

### Rationale

Every mother must receive continuing assessment and support throughout the post-natal period to give her the best possible start with her new baby and for the change in her life and responsibilities.

Breast feeding should be initiated during the first 48 hours after birth and should be maintained. It is beneficial for the baby's health and its success depends on the support, information, and assistance of healthcare professionals during pregnancy and in the immediate post-partum period.

### 1. Clinical Standards

A documented, individualised post-natal plan of care should be developed with the woman, ideally in the antenatal period or as soon as possible after birth. This should take into account:

- 1.1 Relevant factors from the antenatal, intrapartum and immediate post-natal period.
- 1.2 Details of the healthcare professionals involved in her care and that of her baby, including roles and contact details especially supporting breast feeding.
- 1.3 Contraceptive counseling to women in the high risk category.

### 2. Training Standards

- 2.1 The trainees should demonstrate their ability to recognise the risks, signs and systems of domestic violence and child abuse. This can be achieved by attending a theoretical course.
- 2.2 The trainees should demonstrate their understanding of effective methods of contraception which can be prescribed to women in the high risk category prior to being discharged.





### **3. Auditable Indicators**

3.1 Percentage of newborn babies who are exclusively breast fed during the first 48 hours after birth.

3.2 Percentage of babies being breast fed at the time of discharge from hospital.

3.3 Evidence of arrangements for 24-hour access to advice for support in infant feeding following discharge.

# STANDARD 15

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## Neonatal Care

### Rationale

Most babies are, and remain, healthy. The newborn infant physical examination is a key element of the child health surveillance programme. Early recognition and treatment of some problems can have a significant impact on the health of the child.

Mothers need to be effectively supported in the feeding method of their choice and to be fully informed that breast feeding has many positive long-term healthcare benefits and provides the optimal nutrition for the baby.

Some babies may have, or can develop, problems for which timely and appropriate treatment is essential<sup>13</sup>. The effective use of networks will ensure the best possible outcome.

All maternity care providers have a duty to provide up-to-date information for the prevention of major morbidities, including sudden infant death syndrome (SIDS) and to protect children from harm. Staff must be aware of child protection and safeguarding issues and be able to identify where abuse might be occurring and take appropriate action.

### 1. Clinical Standards

1.1 All consultant-led obstetric units should have a named consultant paediatrician who has responsibility and a special interest in neonatology.

1.2 All examinations of the baby should be performed by a suitably qualified healthcare professional who has up-to-date training in neonatal examination techniques.

1.3 All newborn infants should have a complete clinical examination within 72 hours of birth. Prompt referral for further medical investigation or treatment should be provided through agreed clinical care pathways.

1.4 Babies at high risk of hypoglycaemia (e.g. small for dates or born to women with diabetes) should be closely monitored in the post-natal period. Clear guidelines should be in place.

1.5 Guidelines should be in place to minimise the number of infants who require rewarming or avoidable admission to special care baby unit (SCBU).

1.6 The newborn blood spot screening (heel prick) tests for phenylketonuria, congenital hypothyroidism, cystic fibrosis, MCADD (medium chain acyl CoA dehydrogenase deficiency) should be discussed and offered to all women and their partners following the birth of the baby.

1.7 Maternity services should have agreed arrangements for the transfer of a recently delivered mother and her newborn baby to a linked secondary or tertiary unit should problems arise.

1.8 Parents of babies with identifiable medical or physical problems should receive timely and appropriate care and support in an appropriate environment.

1.9 A lead midwife/ nurse with responsibility for child protection should be appointed who monitors multi-agency arrangements and ensures staff are up-to-date and follow local child protection policies.

## 2. Training Standards

2.1 The trainee should understand the basic principles of neonatal resuscitation. This can be demonstrated by attending a hands-on-training course on newborn resuscitation.

2.2 The trainees should understand issues around the management of a baby born with low Apgar scores and being admitted to the special care baby unit.

2.3 The trainees should demonstrate their understanding of problems of prematurity. This can be achieved by counselling parents who may be anticipating the premature birth of their baby.

2.4 The trainees should demonstrate their understanding of issues around preterm births, including the long term outcomes.

2.5 The trainees should demonstrate their understanding of issues regarding breastfeeding support and evaluation.

### 3. Auditable Indicators

- 3.1 Named consultant paediatrician with responsibility for neonatal care.
- 3.2 Evidence of local protocols in place for management of babies at high risk of hypoglycaemia, supported by an audit of avoidable admission to SCBU.
- 3.3 Percentage of maternity staff who have had training in neonatal examination techniques.
- 3.4 Percentage of babies who have received a complete physical examination within 72 hours of birth.
- 3.5 Percentage of newborns admitted with congenital anomalies which were not diagnosed during pregnancy.
- 3.6 Percentage of blood spot tests taken at 5–8 days.
- 3.7 Percentage of blood spot tests taken that was of high enough quality for testing (per 1,000 births).
- 3.8 Re-admission rate of neonates(per 1,000 births) with a diagnosis of dehydration or hypoglycaemia.
- 3.9 Percentage of mothers intending to breast feed at birth, initiating breast feeding and still breast feeding at 6–8 weeks postpartum.
- 3.10 Re-admission rates for poor feeding and dehydration and for hypernatraemic dehydration.
- 3.11 Fetal and neonatal mortality rates of all births of at least 24 completed weeks per 1,000 births at 4 weeks.
- 3.12 Neonatal mortality of preterm babies born < 34 weeks.
- 3.13 Percentage of clinical and non-clinical staff with contact with parents and babies that have received level 2 child protection training every 3 years.

# STANDARD 16

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## Rationalising Care of Babies Born Prematurely

### Rationale

Preterm birth is a distressing event for parents and families and can have lifelong consequences. Timely access to an appropriate level of neonatal care and expertise results in the best outcome. Newer medical innovations in neonatal care continue to improve the chance of survival for extremely premature babies but the provision of such highly skilled care imposes considerable costs. An access to on-site intensive care for very preterm infants determines their survival and future quality of life<sup>13</sup>. This is especially true in many European countries where currently maternity services are delivered by small obstetric units, some of them delivering less than 500 women a year. There is a huge variation across the member states as regards access to neonatal intensive care unit<sup>4,13</sup>. In that context, managed clinical networks are highly desirable.

Good maternity care relies upon collaboration, with a full range of services for the needs of the mother or baby. This requires links between health and social care and provision within maternity and neonatal care networks to meet demand.

### 1. Clinical Standards

1.1 Maternity and neonatal care networks should include effective arrangements for managing the prompt transfer and treatment of women and their babies experiencing problems or complications.

1.2 Because extremely premature births may take place rapidly when no senior members of the team are available, advance liaison should take place whenever possible between the consultant obstetrician, consultant paediatrician and senior midwife to ensure that there is prospective understanding on the management and on who will be present at the delivery.

1.3 Special care baby unit facilities should be available on-site in *all consultant-led units* and there should be a defined, rapid, access route to neonatal intensive care in *all consultant-led units*.



1.4 All maternity services must have systems in place for identifying and transporting women at high risk of preterm delivery to the nearest tertiary care unit, and for the transport of preterm babies.

1.5 Prompt referral to an obstetrician with appropriate expertise should be made in all cases of threatened preterm labour to assess the need for tocolytic agents and to avoid delay in the administration of corticosteroids.

1.6 Recommendations for the care of babies born at the threshold of viability (agreed nationally by the expert groups) should be followed.

1.7 The assessment and planning of services should take into account the availability of information technology equipment and networks, local transport services, access to facilities for wheelchairs or baby buggies and for women with physical, sensory or learning disabilities, and from disadvantaged or minority groups.

## 2. Training Standards

2.1 The trainee should understand the basic principles of neonatal resuscitation. This can be demonstrated by attending a hands-on-training course on newborn resuscitation.

2.2 The trainees should demonstrate their understanding of problems of prematurity. This can be achieved by counselling parents who may be anticipating the premature birth of their baby.

2.3 The trainees should demonstrate their understanding of issues around preterm births, including the long term outcomes.

### 3. Auditable Indicators

3.1 Rate of inappropriate *in utero* or neonatal transfers, such as transfers to units with NICU.

3.2 Number of transfers out of an agreed network.

3.3 Percentage of preterm babies (born at less than 34 weeks of gestation) whose mothers received antenatal steroids.

3.4 Percentage of babies born at less than 30 weeks of gestation whose temperature on admission was less than 36°C.

3.5 Percentage of babies born at less than 30 weeks of gestation who required artificial ventilation and were not offered surfactant.

3.6 Percentage of preterm babies less than 32 weeks delivered in units without NICU.

3.7 The existence of a maternity and neonatal clinical network.

3.8 A record of all transfers and transfer requests.

3.9 Evidence of agreed pathways of care and standardized protocols in place.

3.10 Percentage of Very Low Birth Weight babies fed with breast milk at discharge from NICU.



# STANDARD 17

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## Supporting Families who Experience Bereavement, Early Pregnancy Loss or Stillbirth

### Rationale

Bereavement is extremely traumatic. Providers of maternity care need to ensure support and information for women and their families both during the acute event and afterwards<sup>25</sup>.

### 1. Clinical Standards

1.1 Maternity care providers should ensure there are comprehensive, culturally sensitive, multi-disciplinary policies, services and facilities for the management and support of families (and staff) who have experienced a maternal loss, early or mid-pregnancy loss, stillbirth or neonatal death.

1.2 Skilled staff should be available to support parents following maternal or neonatal death, stillbirth or miscarriage.

1.3 Information that includes details about investigations (including post-mortem), birth and death registration and options for disposal of the body should be available in different languages with particular cultural beliefs or sensitivities appropriately reflected.

1.4 Parents of stillborn babies or babies with identifiable medical or physical problems should receive timely care and support in an appropriate environment.

1.5 Maternity services should provide appropriate facilities reflecting cultural beliefs and sensitivities.

1.6 Local guidelines must include clear communication pathways between secondary care and the primary care team regarding any death within one working day.

1.7 Following the death of a baby, a post-mortem examination should be performed by a specialist perinatal pathologist and the placental and post-mortem histology should be available within 6 weeks of the examination. The woman and her partner should be given the opportunity to meet with the lead clinicians to discuss the results of the post-mortem examination and other investigations.

## **2. Training Standards**

2.1 The trainees should demonstrate their understanding of issues around the management of the dead baby and the sensitivities around the post-mortem (PM) examination, especially counselling and obtaining consent for PM examination.

2.2 The trainees should demonstrate their understanding of issues around potential personal, cultural or religious preferences for the expression of grief.

## **3. Auditable Indicators**

3.1 Evidence of written, clear protocol in place in each maternity unit.

3.2 Percentage of couples agreeing to the post mortem examination.

3.3 Percentage of parents declining post mortem examination.

3.4 Percentage of babies where post-mortem examination has been able to identify the cause of death by using internationally agreed criteria.



# STANDARD 18

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## Routine Data Collection for Pregnancy and Childbirth

### Rationale

All countries in Europe have legal requirements regarding civil registration of births and deaths. All European countries also have governmental statistics agencies which manage these data.. Since 2000, EU DG SANCO has supported the EURO-PERISTAT projects which have allowed these data to be pooled.

Agreement on definitions and what data needs to be collected allows valid comparisons to be made.

### 1. Clinical Standards

1.1 Systems should be in place to record and analyse routine perinatal data using the internationally approved definitions.

1.2 Possibilities for linkage with other data sources should be built in.

1.3 The publication of annual reports at national/regional level should be supported by national/regional government.

1.4 These reports should contain conclusions which will serve policy-makers.

1.5 The indicators and data bases should be constructed in such a way that transfer of aggregate data (e.g. for a EURO-PERISTAT report) is safe and efficient.



## **2. Auditable Indicators**

2.1 Annual national/regional report by using outcome indicators as described in the recent EURO-Peristat Project<sup>4</sup>.

2.2 National Publications related to the EURO-Peristat report.

2.3 Annual publication of a regional/national report describing indicators related to maternal morbidity and mortality as described in this document.

2.4 National collection of data for the sustainability of future European Peristat reports.

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# APPENDIX 1

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## A summary of European Perinatal Health Report (2010) by the EURO-PERISTAT Project

### A HEALTHY START: THE HEALTH AND CARE OF PREGNANT WOMEN AND BABIES IN EUROPE IN 2010

#### I. MONITORING PERINATAL HEALTH IN EUROPE

Healthy mothers and children are building blocks for a strong future in Europe. While infant mortality continue to decline, the burden of mortality and morbidity in the perinatal period — pregnancy, childbirth, and the postpartum — remains a major concern. This is because of the high number of births per year (over 5 million in Europe), the youth of the population harmed by adverse perinatal events (babies and women of childbearing age), and the long-term consequences of disabling complications of pregnancy such as very preterm birth or severe hypoxia.

The principal factors behind perinatal mortality and morbidity include very preterm birth, fetal growth restriction, and congenital anomalies. Babies born preterm and with low birth weight are more likely to die and to have long-term neurological and developmental disorders than those born at term. The incidence of these complications has increased in many countries, reflecting limited achievements in preventing high risk situations, compared with the medical advances that have reduced mortality for these infants. Stillbirths have declined less rapidly than neonatal deaths and, in many cases, their causes remain unknown. Women continue to die during childbirth, and substandard care is associated with a significant proportion of these deaths. As they grow up, babies born with major congenital anomalies or very preterm and with low birth weight may have important medical, social, and educational needs. These burdens fall disproportionately on socially disadvantaged women and babies and contribute to lifelong health inequalities.

Research on the early origins of adult diseases underscores the vital importance of the perinatal period for future health. Pregnancy complications which cause short-term morbidity — such as preterm birth and fetal growth restriction — are also associated with the development of chronic illnesses such as hypertension and metabolic disease across the life course. Further, risk factors for poor perinatal outcome — smoking, obesity, and alcohol use during pregnancy — continue to exert an effect through the child's increased susceptibility to asthma, obesity, and developmental delays.

Despite the risks faced by women and children during pregnancy and childbirth, pregnancy is not an illness. Achieving optimal perinatal health thus involves a balance between intervening to manage and prevent complications, while minimising interventions that have negative side effects on health and induce anxiety among pregnant women and their families. Unnecessary medical interventions also contribute to the costs of providing health care without achieving gains in health.

The Euro-Peristat project aims to provide health professionals, health planners, and users of the healthcare systems with comparable data about the health and care of pregnant women and their babies in Europe. It uses routinely collected data, thus adding value to the resources used to generate them and providing opportunities for sharing and use of information. While many countries collect routine data nationally about women and children, these data are not available in currently existing international databases. The first Euro-Peristat report, published with 2004 data in 2008, found wide differences in indicators of perinatal health and care between the countries in Europe. Documenting this variation is important because it shows that gains are possible in most countries, provides information about alternative options for care provision, and raises important questions about the effectiveness of national healthcare policies and the use of evidence-based care.

The data in this report can be used as a point of comparison for individual countries. For those indicators for which reliable data exist, countries can benchmark performance in providing effective health services and promoting the health of mothers and their newborn babies. Another aim is to reveal the strengths and weaknesses of perinatal health information systems and to encourage countries to invest in the resources needed to improve the completeness and quality of the data necessary for evidence-based public policy.

## **II. THE Euro-Peristat PROJECT**

The project's goal has been to develop valid and reliable indicators that can be used for monitoring and evaluating perinatal health in the EU. The project began in 1999 as part of the EU's Health Monitoring Programme and has enlisted the assistance of perinatal health professionals (clinicians, epidemiologists, and statisticians) from EU member states and Iceland, Norway, and Switzerland as well as other networks, notably SCPE (a network of European cerebral palsy registries), ROAM (Reproductive Outcomes and Migration Collaboration), and EUROCAT (a network of European congenital anomaly registries), to develop its recommended indicator list. Our indicator list was developed by a series of successive Delphi consensus processes with members of our network as well as external advisors.

Twenty-nine countries currently participate in Euro-Peristat, including all current EU member states (except Bulgaria) and Iceland, Norway, and Switzerland. Romania, Switzerland, and Iceland have joined the project since our previous report. One person from each country is a representative on the Scientific Committee, but many countries have constituted teams comprising experts in the field of perinatal health surveillance (please see [www.europeristat.com/our-network/country-teams.html](http://www.europeristat.com/our-network/country-teams.html), for a full list of participants).

The current Euro-Peristat indicator list includes 10 core and 20 recommended indicators, grouped into 4 themes: (i) fetal, neonatal, and child health, (ii) maternal health, (iii) population characteristics and risk factors, and (iv) health services. Core indicators are those that are essential to monitoring perinatal health, while recommended indicators are considered desirable for a more complete picture of perinatal health across European countries.

Euro-Peristat aims to compile population-based data at a national level from routine sources (ie, administrative or health registers, hospital discharge reporting systems, or routine surveys). If national level data are not available, population-based data for regions or constituent countries are collected. In defining our indicators, Euro-Peristat has sought to reduce the differences in indicators that are attributable to differences in data collection systems and definitions. We have accomplished this by selecting definitions most likely to be feasible and by carefully designing the data collection instrument. Country participants are actively engaged in checking and interpreting the data.

## Collaborations

Two European networks contributed to the report — SCPE (Surveillance of Cerebral Palsy in Europe) and EUROCAT (European Surveillance of Congenital Anomalies). The objectives, scope, and methods of both of these networks are described in Chapter 8. SCPE provided information about the indicator on cerebral palsy.

This essential indicator of the longer term consequences of perinatal events relies on networks that register all cases of cerebral palsy within a geographic area. EUROCAT, a collaborative network of population-based registries for the epidemiologic surveillance of congenital anomalies in Europe, provided data on their prevalence. The EUROCAT network has carried out the work of harmonising definitions across Europe and compiling data from registries in European countries. Annual reports on these data are made available on their website.

## Scope and Format of this Report

In order to provide timely data, Euro-Peristat made a decision to publish its results from 2010 in 2 stages. This report constitutes the first stage and provides key data on our indicators in 2010 and trends since 2004. The second stage, the release of the full set of Euro-Peristat tables, will take place after the summer of 2013 to give us more time to verify the complete set of data for each indicator and to analyse our indicators by subgroups. Some additional indicators will be issued in this second step (prevalence of selected congenital anomalies, parents' occupational classification, and birth without obstetric intervention). Ongoing work about social inequalities in perinatal health outcomes will also be released then.

We use the same format as in our first report; each indicator is presented separately and includes the justification for selecting the indicator, the methods for collecting and interpreting it, availability of data, results, and a summary of key points. Countries are not ranked for the presentation of data about indicators in 2010. The Euro-Peristat project avoids a league-table approach to international comparisons intended solely to identify the best and worst performers. There are many reasons that indicators vary between countries, and we aim to stress this point in the way the data are presented. Countries without data are included in all figures and tables presenting 2010 data. One of the goals of this report is not only to describe and analyse existing data, but also to point out the gaps in perinatal health information systems. This is another reason that we have not ranked countries.

## III. HIGHLIGHTS OF HEALTH AND HEALTH CARE IN EUROPE IN 2010

### HEALTH OUTCOMES

#### **Fetal, neonatal, and infant mortality rates vary widely between the countries of Europe.**

Fetal mortality rates at or after 28 weeks of gestation ranged from lows under 2.0 per 1000 live births and stillbirths in the Czech Republic and Iceland to 4.0 or more per 1000 in France, Latvia, the region of Brussels in Belgium, and Romania. The countries from the United Kingdom also had higher fetal mortality rates.

Neonatal mortality rates ranged from 1.2 per 1000 live births in Iceland to 4.5 in Malta and 5.5 in Romania. After excluding births and deaths before 24 weeks of gestation, these rates fell, ranging from 0.8 per 1000 live births in Iceland to 4.3 in Romania. Infant mortality rates ranged from 2.3 per 1000 live births in Iceland and Finland to 5.5 in Malta, 5.7 in Latvia, and 9.8 in Romania. Countries where terminations of pregnancy are not legal or access is very restricted may have higher fetal, neonatal, and infant mortality rates due to deaths attributed to lethal congenital anomalies.

**Europe experienced across-the-board declines in fetal, neonatal, and infant mortality, although rates of change differed.**

Most countries contributing data to Euro-Peristat in 2004 and 2010 experienced declines in their fetal, neonatal, and infant mortality rates. For fetal mortality, the decreases (on average 19%; range: 0-38%) tended to be more pronounced for western European countries with higher mortality rates in 2004 (Denmark, Italy, and the Netherlands). Some countries with low mortality rates in 2004, such as the Czech Republic, achieved significant continued improvements in outcomes. Decreases in neonatal mortality averaged 24% (range: 9% to 50%), and infant mortality fell 19% (range: 6%-40%). The largest declines were in 3 Baltic countries: Estonia, Latvia, and Lithuania. Decreases were again most pronounced for countries with higher mortality rates in 2004, although some countries with lower mortality in 2004 also showed significant continued improvements (Slovenia, Finland, and Austria, for example). Neonatal and infant mortality were low (under 2 and 3 per 1000 live births for neonatal and infant mortality, respectively) in some European countries.

**Preterm babies born before 28 weeks of gestational age constitute over one-third of all deaths, but data are not comparable between countries.**

About one-third of all fetal deaths and 40% of all neonatal deaths were of babies born before 28 weeks of gestational age. Unfortunately, between-country differences in legislation governing registration of births and deaths and misclassification of stillbirths and neonatal deaths make it difficult to compare mortality at these early gestations. Euro-Peristat presents fetal mortality rates at 28 weeks of gestation and over and neonatal mortality at 24 weeks of gestation and over because our analyses have shown that these cut-offs provide more comparable data and thus allow more useful comparisons. However, given the large proportion of deaths before 28 weeks, it is essential to improve information systems in Europe by developing common guidelines for recording these births and deaths.

Another related issue is the variation in notification procedures for terminations of pregnancy at 22 weeks or later. These are included in fetal mortality rates in some but not all countries, and only some countries which include them can distinguish terminations from spontaneous deaths. Six percent of all fetal deaths were terminations in Scotland versus 40-50% in France. Terminations were 13% of fetal deaths in Hungary, 15% in Switzerland, and 19% in Italy.



### **The percentage of low birthweight babies is geographically patterned, partially reflecting differences in population birth weight, and was stable over time in most countries**

The percentage of live births with a birth weight under 2500 g varied from under 4 to over 9% in Europe. Countries from northern Europe had the lowest percentages of low birth weight (Denmark, Estonia, Ireland, Latvia, Lithuania, Finland, Sweden, Iceland, and Norway). The proportion of VLBW babies ranged from 0.6 (Iceland) to 1.9 (the region of Brussels in Belgium). Proportions of low birth weight remained similar in the 2 study periods. However, the rate of babies with low birth weight declined in some countries (France, Scotland, England and Wales, Malta, and Poland) whereas it increased in others (Luxembourg, Spain, Brussels, the Czech Republic, Slovakia, and Portugal).

### **Preterm birth rates were similar in 2004 and 2010 in many countries; differences in rates and trends raise questions about possible preventive strategies**

The preterm birth rate for live births varied in 2010 from about 5 to 10% in Europe. We observed relatively lower preterm birth rates (below 6.5%) in Iceland, Lithuania, Finland, Estonia, Ireland, Latvia, Sweden,

Norway and Denmark, and higher rates (above 8.5%) in Cyprus (10.4%) and Hungary (8.9%). Rates were around 8% in Austria, Germany, Romania, the Czech Republic, Luxembourg, Portugal, the Netherlands, and all regions of Belgium. In comparison to 2004, proportions of preterm live births were similar for many countries. However, they increased over this period in Luxembourg, the Brussels region, the Czech Republic, Slovakia, Portugal, Northern Ireland, and Italy, while they declined in Norway, Scotland, Germany, England and Wales, Denmark, and Sweden. The fact that rates are stable or declining in many countries goes against widely held beliefs that preterm birth rates are rising and raises questions about policies and practices associated with divergent trends between countries.

### **Maternal deaths are rare in Europe, but under-reporting is widespread.**

Generally speaking the maternal mortality ratio in Europe is low, due to both the very low level of fertility (fewer than 2 children per woman, as shown in Chapter 2) and the high levels of care. The range in Europe is from lows under 3 per 100 000 (in Estonia, Italy, Austria, and Poland) to highs over 10 per 100 000 live births (Latvia, Hungary, Slovenia, Slovakia, and Romania). There is good evidence that maternal deaths derived from routine statistical systems are under-reported, and this must be suspected particularly where ratios are very low. Confidential enquiries and record linkage are recommended to obtain complete data on pregnancy-related deaths and also to make it possible to understand how these deaths

happened and to make recommendations to prevent the recurrence of those that could have been prevented. When confidential enquiries are undertaken, as in France, the Netherlands, and the UK, almost half the maternal deaths are associated with substandard care. This should not occur in high-income countries.

Because mortality is rare, Euro-Peristat also collects data on severe maternal morbidity, which occurs in approximately 1% of all deliveries. However, the comparability of these indicators, when derived from hospital discharge systems and other routine sources, is still limited. Ongoing work is focused on assessing the quality and completeness of the data about diagnoses and procedures in routine hospital discharge systems so that we can propose better definitions.

### **An estimated 140000 fetuses and babies had a major congenital anomaly in the EU-27 countries in 2010**

Data from EUROCAT were used to derive the overall prevalence of major congenital anomalies diagnosed during pregnancy, at birth, or in early infancy — 26 per 1000 births in 2010. This prevalence has shown a recent very shallow decrease, and there is a need to improve primary prevention policies to reduce environmental risk factors in the pre- and peri-conceptual period. Four fifths of cases were live births, the vast majority of whom survived the neonatal period and may have special medical, educational, or social needs.

The largest group of congenital anomalies is congenital heart disease. An overall 0.81 perinatal deaths per 1000 births in 2010 were associated with congenital anomalies according to data from 13 EUROCAT registries. The rate of terminations of pregnancy for fetal anomaly (TOPFA) varies widely between countries from none (Ireland and Malta) to 10.5 per 1000 births (Paris, France), reflecting differences in prenatal screening policies and uptake and in abortion laws, practices, and cultural attitudes. The rate of live births with certain anomalies, such as spina bifida and Down syndrome, in a given country is inversely related to its rate of terminations of pregnancy for fetal anomaly.

### **Cerebral palsy registers in collaboration with their clinical networks make it possible to assess a group of rare conditions that develop in the perinatal period and lead to lifelong activity limitations and participation restrictions**

The increased survival of newborn babies in all birth weight and gestational-age groups correlates with a decrease in the prevalence of certain subtypes of cerebral palsies. For example, the proportion of babies born between 1980 and 1998 with a birth weight over 2500 g who developed bilateral spastic cerebral palsy decreased from 58 to 33 per 100 000 live births. In the same 2 decades, the proportion of cerebral palsy in the babies born at a gestational age between

32-36 weeks decreased by 3% annually. These downward trends coincided with a decrease of one third in the proportion of bilateral spastic cerebral palsy in babies with a birth weight between 1000 and 1499 g.

## **POPULATION RISK FACTORS**

### **Age at childbirth has increased in Europe**

The age at which women bear children in Europe varies widely, and this has an impact on the health of mothers and babies. Both early and late childbearing are associated with higher than average rates of preterm birth, growth restriction, perinatal mortality, and congenital anomalies. Overall, teenage pregnancies are uncommon in Europe with a median of 2.7% of births to mothers aged younger than 20 years. However, some countries of eastern Europe have higher proportions. The UK also stands out from its neighbours with a high proportion of very young mothers (over 5%). The situation in Europe contrasts with the United States where 9.2% of births are to mothers under 20

(CDC: Births: final data for 2010: [www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61\\_01.pdf](http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_01.pdf)).

At the other end of the age spectrum, the percentage of older mothers, defined as women giving birth at 35 years or older, ranged from 10.9% in Romania to 34.7% in Italy. The proportion of women bearing children later in life varies substantially, but in 40% of countries or regions, at least 20% of births were to women aged 35 years or more, and the proportion of births in this age group increased substantially in almost every country. Only Finland experienced a decrease between 2004 and 2010 in this proportion. The increase was relatively small in the United Kingdom (under 1 percentage point), and substantially larger (over 5 percentage points) in Italy, Estonia, Hungary, the Czech Republic, and Spain.

Encouraging earlier childbearing may require policies to support young parents and working mothers, as well as informing the public about possible consequences of having children at later ages.

### **More than 1 woman in 10 smoked during pregnancy in many countries despite declines between 2004 and 2010**

Maternal smoking during pregnancy may be considered the most important preventable factor associated with adverse pregnancy outcomes. It is a well-established risk factor for adverse perinatal outcomes. It can impair normal fetal growth and development and thus increase the risk of low birth weight, preterm birth, intrauterine growth restriction, and some congenital anomalies. Smoking cessation is one of the most effective interventions for improving mothers' and



children's health and thus serves as an indicator of the quality of antenatal preventive healthcare services.

Smoking during pregnancy or in the last trimester varied from under 5% in Lithuania and Sweden to 14% in Catalonia in Spain, 15% in Northern Ireland, 16% in Wales, 17% in France, and 19% in Scotland. Countries that had data points for 2004 and 2010 reported slightly lower proportions of smokers in the last trimester in 2010 — by about 1-3%. In France, the Netherlands, and the UK, the decrease was more pronounced. Some countries were not able to provide data on smoking Belgium, Ireland, Greece, Italy, Hungary, Austria, Portugal, Romania, Slovakia, Iceland, and Switzerland. In many countries, the quality of data needs to be improved, and this indicator is likely underestimated. Given the adverse effects of smoking on fetal and infant health and since pregnancy care is considered an ideal setting for intervention, having high quality and comparable information on smoking before and during pregnancy should be a priority.

### **Monitoring social status and pregnancy outcomes is a challenge in Europe**

Social disadvantage remains a major determinant of poor perinatal outcome and requires effective action. Many perinatal health indicators, including maternal mortality, preterm birth, congenital anomalies, and duration of breast feeding, are inversely related to variables that are proxy measures of social disadvantage, such as the mother's level of education and the parents' parents' occupational classification. The distribution of mothers' levels of education varies widely between the European countries that provided data for this indicator; for instance, between 22 and 61% are reported to have some postsecondary education. Many countries cannot provide data on mothers' educational levels, which was one of the reasons that Euro-Peristat added a second indicator of social status, parents' occupational classification, to its list of indicators. Further research will be required into the possibility of effectively comparing measures of education level and occupational class as it seems unlikely that the countries that do not record mothers' educational levels will do so in the near future. However, even if educational and occupational levels are not comparable, collecting these data — either or both, according to availability — will make it possible to compare fetal and neonatal mortality outcomes between these groups within countries and call attention to the differences related to social factors.

### **Foreign-born women constitute a large proportion of pregnant women in many countries**

International migration to Europe may be accompanied by health disparities in perinatal outcomes between migrants and women born in receiving countries and also between groups of migrants. The percentage of foreign-born mothers ranged from lows of 3% (the Czech Republic) to over 60% (in Luxembourg and the Brussels region of Belgium), and the proportion of women with a foreign nationality from less than 1% in Iceland and Poland to 30% in Latvia. The

proportions of foreign-born or foreign-nationality mothers in most countries in Western Europe exceeded 20%. Data are available in many countries to permit an analysis of health outcomes by mothers' countries or regions of birth. This will be one of the themes pursued in the future by the Euro-Peristat network.

### **More than 1 in 10 pregnant women are obese in countries with data, but many countries do not monitor this indicator**

Maternal weight before and during pregnancy can affect the course of pregnancy, its outcome, and the offspring's lifelong health, yet 18 countries have no available national data on the body mass index of pregnant women. Both underweight and overweight women experience higher rates of adverse outcomes. In countries that could provide data, from 2.5 to 8.7% of delivering mothers were underweight; the highest proportions were in Poland (8.7%), France (8.3%), and Wallonia (7.1%), and the lowest in Sweden (2.5%), Scotland (2.6%), Finland (3.6%), and Germany (3.6%). Obese women accounted for 7.1 (Poland) to 20.7% (Scotland) of all pregnant women. In most countries, more than 10% of childbearing women are obese. This indicator should be monitored in more European countries in view of the possible changes in proportions of underweight, overweight, and obese women in the upcoming generations of women of childbearing age and the impact of these changes on perinatal health outcomes and long-term health.

## **HEALTH SERVICES AND CARE**

### **Artificial reproductive techniques (ART) are used in up to 5 to 6% of all deliveries; differences in multiple birth rates reflect, in part, the impact of these practices**

Up to 5 to 6% of births in some countries may occur after use of some form of ART, although the use of the less invasive procedures is under-reported in most data systems or not reported at all. Births after in vitro fertilisation (IVF) account for 2 to 4% of all births.

One of the consequences of ART is an increase in multiple pregnancies, unless only one embryo is transferred. Babies from multiple pregnancies have a 10-fold risk of preterm birth and are 4 times more likely to die in the neonatal period. Multiples have higher risks of congenital anomalies and growth restriction, and their mothers' higher risks of morbidity and mortality. There are wide differences in multiple birth rates in Europe — from lows of 9 to 13 per 1000 women with live births or stillbirths in Romania, Latvia, Lithuania, and Poland to more than 20 per 1000 in Brussels, the Czech Republic, Denmark, Cyprus, Spain, and Malta. These differences reflect the age distribution of the European population: the incidence of multiple pregnancy is higher for older mothers, separately from their higher prevalence of subfertility and higher utilisation rate of ART. Twin birth rates decreased in Denmark, the Netherlands, and Norway, which had the highest twinning rates in 2004. The twinning rate increased slightly in Finland, Sweden, and

Northern Ireland, and increased further in the other countries. Many countries are implementing policies to prevent multiple pregnancies in assisted conception, and the decrease in twin rates observed in some countries may be the result of these policies.

### **Most women begin antenatal care in the first trimester, but differences in the organisation of health systems make it difficult to compare data about late care between countries**

The vast majority of women begin antenatal care during the first trimester; care begins in the second or third trimester for 2% (Poland) to 33% (Malta) of all women. Half the countries reported between 4 and 7% of women with care starting after the first trimester (10 of 19). The percentage of women with no antenatal care at all ranges from 0 to 2.8%. Some of the variation in late care is related to differences in how timing of antenatal care is recorded. In systems where the majority of antenatal care takes place outside hospital, it may be the first visit to hospital rather than the first contact with a health care provider during pregnancy which is recorded. Nonetheless, given the importance of starting care early in pregnancy, this variation raises questions about whether the most vulnerable women in each country have access to appropriate health care. Using this indicator in conjunction with mothers' educational level and country of birth could provide a useful basis for comparing the ability of healthcare systems to provide access to care for all pregnant women.

### **Congenital anomaly screening differs across Europe**

In Europe some congenital anomalies are very commonly diagnosed through antenatal screening programmes. For some anomalies, antenatal diagnosis leads to better preparation of families and health services for an affected baby and can improve the care provided. For other anomalies, antenatal diagnosis is commonly followed by the option of termination of pregnancy for fetal anomaly. Data from EUROCAT illustrate wide-ranging differences in antenatal screening policies and how their implementation can affect differences between European countries in their antenatal diagnosis rates.

### **Variations in caesarean section rates testify to differences in approaches to obstetric care**

The variation in caesarean section rates in Europe reflects the differences in approaches to childbirth in Europe. The risk factors for caesarean section — such as maternal age or parity — are not sufficiently marked to explain the wide disparities. Countries with high proportions of older mothers have both high (Italy and Portugal) and lower (the Netherlands and Finland) rates. Cyprus had the highest overall caesarean rate, at 52.2%, followed by Italy with 38.0%, Romania with 36.9%, and Portugal with 36.3%. Germany, Luxembourg, Malta, Poland, and Switzerland also had rates of 30% or higher. Everywhere else, rates were below 30%. The Netherlands, Slovenia, Finland, Sweden, Iceland, and Norway had rates below 20%.

### **Caesarean rates have risen almost everywhere, especially in Eastern Europe**

Apart from slight reductions in Finland and Sweden, caesarean rates rose everywhere between 2004 and 2010. Increases occurred among countries with both high and low levels of caesarean deliveries in 2004. Increases ranged from under 0.2% in Italy to over 7% in Lithuania, Slovakia, and Poland. In general, increases were most marked in the countries of central and Eastern Europe and in Germany and Austria.

### **Variations in obstetric practices raise questions about how scientific evidence is integrated into clinical decisions**

In addition to the wide variations reported above for caesarean deliveries, other obstetric practices differ in Europe. Rates of instrumental vaginal delivery exceeded 10% in Ireland, the Flanders region of Belgium, the Czech Republic, Spain, France, Luxembourg, the Netherlands, Portugal, the 4 countries of the United Kingdom, and Switzerland and accounted for fewer than 2% of deliveries in the Czech Republic, Latvia, Lithuania, Poland, and Romania, and at least 2% but fewer than 5% in Estonia, Italy, Cyprus, and Slovenia. Episiotomy rates ranged from 5% to 70% of vaginal deliveries. They were around 70% in Cyprus, Poland, Portugal, and Romania, 43-58% in Wallonia and Flanders in Belgium and in Spain, 16-36% in Wales, Scotland, Finland, Norway, Estonia, France, Switzerland, Germany, Malta, Slovenia, Luxembourg, the Brussels region in Belgium, Latvia, and England, and 5-7% in Denmark, Sweden, and Iceland. Episiotomy rates have fallen or stayed the same in many countries with data from 2004, with the exception of England, Scotland, and the Netherlands, where they rose.

### **Multiple models of obstetric and neonatal care provision exist in Europe; understanding their strengths and weaknesses could help to improve healthcare systems in all countries**

The organisation of delivery and postpartum services is an important domain for public policy. Most pregnant women have normal pregnancies requiring little or no obstetric intervention. However, when risks arise, access to highly specialised care can be essential for both mother and baby. Organising access to risk-appropriate health care for mothers and babies is thus a central pillar of a successful perinatal health system and one in which government policy and regulation play an important role. Data from this report find wide differences in the ways that European countries have addressed this challenge.

Some countries concentrate care in large units, while others provide care in small ones. Overall, few births occurred in maternity units with fewer than 500 births in 2010, but this varied considerably by country, as did the care provided in small units. For example, in the UK and some Nordic countries, care in small units is provided by midwives for women with

uncomplicated pregnancies. In contrast, in Cyprus, which has a very high caesarean section rate, 61.9% of births took place in units of this size, while in 8 countries, from 10 to 20% of births did. At the other end of the size spectrum, more than a quarter of births in Denmark, Sweden, and England took place in units with more than 5000 births, while Slovenia, Latvia, Scotland, and Ireland had even larger proportions of births in units with more than 5000 births; in 14 countries or regions, more than a third of births took place in units with 3000 or more births.

In most European countries, less than 1% of births took place at home. In England, this figure was 2.5%, in Wales 3.7%, in Iceland 1.8%, and in Scotland 1.4%. In the Netherlands, where home births have been a usual option for women with uncomplicated pregnancies, 16.3% of all births occurred at home. This is, however, a substantial change from 2004, when this proportion exceeded 30%. Women in the Netherlands now also have the option of giving birth in a birth centre (a homelike setting) under care of a primary midwife; there are 26 birth centres in the country, and 11.4% of births occurred in them. Almost all birth centres are adjacent to or in hospitals. Similar facilities exist in some hospitals in the UK, but births in them cannot usually be identified separately.

The regionalisation of care for high-risk births is associated with better survival for very preterm infants. Many, but not all, countries in Europe have clearly designated levels of care that make it possible to assess whether high-risk babies are born in specialised maternity units with on-site neonatal intensive care. Most of these countries also have data on their place of birth. The proportion of very preterm babies born in the most specialised units varies widely. It would be useful to develop a common European classification for maternity and neonatal units to facilitate monitoring the care of these high-risk babies. Whether these classifications exist or not, it is important for countries to be able to monitor where these infants are born.

### **The percentage of babies breast fed at birth ranges from 54% to 99%**

Breast feeding provides benefits for babies including important nutritional advantages and improved resistance to infections. Success of breast feeding during the first 48 hours after birth depends on public health policies and healthcare practices during pregnancy and in the immediate postpartum. Data on breast feeding at birth are available from 19 countries or regions. More than 95% of babies received some breast milk at birth in the Czech Republic, Latvia, Portugal, and Slovenia. Rates were lowest in Ireland, Scotland, Cyprus, France, and Malta (54-69%). Data collection in every country and greater precision and consistency in defining the modes of breast feeding are necessary to assess the efficacy of national policies and to know to what extent the recommendations to promote it are achieved.



#### IV. NEXT STEPS IN PERINATAL HEALTH REPORTING IN EUROPE

This report demonstrates the feasibility and value of using statistical indicators to monitor perinatal health at a European level. Our results also illustrate, however, that continuing international collaboration is needed to improve the consistency of definitions and to prioritise the development of methods for collecting data for many perinatal health indicators.

Many of the questions about mothers' and babies' health raised by this report will remain unanswered unless health information systems are improved and extended to record key data items.

**Investments in national surveillance systems are needed; no country was able to provide all the data required to compile the full set of Euro-Peristat indicators, and availability of some key indicators was poor**

Even though the availability of indicators improved between 2004 and 2010, no country could provide the full set of Euro-Peristat indicators. Indicators with limited availability include those needed to monitor prevention policies: smoking during pregnancy, maternal underweight and overweight, timing of antenatal care initiation, breast feeding, and measures of social status. Data on maternal health are also lacking. The quality of data for these indicators and use of different definitions in some countries also impedes comparisons between countries. A European-wide perinatal survey would be one way to get a good baseline for essential indicators on maternal risk factors and care and to develop better common definitions that could be integrated into routine systems.

**Routine systems for ascertainment of very preterm births and maternal deaths require improvement**

Standardising the definition of stillbirths and enabling them to be distinguished from terminations of pregnancy is a priority for international comparisons, since the current guidelines are inadequate. Routine systems tend to under-report maternal mortality. Further work to enhance data about maternal deaths is essential, for example, by using data linkage and by creating specific systems to ascertain and analyse the causes of a wider range of pregnancy-related deaths.

### **Wider use of data linkage, building on methods already in use in Europe, would yield immediate gains for perinatal health monitoring in many countries**

Linking of data from two or more routine systems can extend the scope, coverage, and quality of perinatal data, as can be seen from the experience of the many countries which already link data either routinely or for specific projects. Both national and international efforts are necessary to remove the obstacles to combining data from statistical and healthcare organisations, such as difficulties of coordination between different administrations. Challenges can arise from European Data Protection legislation and differences between member states in how they choose to implement it. Data linkage and the associated need for data protection is an area where countries have a lot to learn from each other and can benefit from sharing experiences.

### **A sustainable European surveillance system requires an active network of clinicians, researchers, and statisticians from all countries**

The skills and motivation that underpin high quality health information are strong in Europe. That we are able, in this report, to provide comprehensive data from 29 countries in Europe on a large spectrum of indicators describing perinatal health testifies to the commitment of our network members to having comparable European data on mothers and children during pregnancy, childbirth, and the postpartum period. The efforts of our Scientific Committee members and data providers have been impressive; many of our indicators require additional data analysis beyond what is routinely produced nationally; our members have participated in multiple rounds of data checking and provided their opinions and insights into these data in several meetings. Furthermore, our Scientific Committee members have guided us through complex situations as national health information systems reorganise and institutions change. Maintaining and reinforcing the EURO-PERISTAT network is thus central to our strategy for achieving sustainable health reporting in Europe.

## **V. CONCLUSION**

The Euro-Peristat network developed an action plan for sustainable perinatal health reporting in 2010 which endorsed the idea of producing a comprehensive European perinatal health report every 4 or 5 years. If this path is followed, the next report would cover data from 2014 or 2015 and be issued in 2017 or 2018.

Whether this aim is achievable depends mainly on the availability of political and financial support at both European and national levels. Currently, the future of health surveillance in Europe is uncertain. The new EU health programme Health for Growth 2014-2020 does not prioritise programmes to reinforce information systems and many health information projects, including the European Community Health Indicators Monitoring project (ECHIM), have been discontinued because of absence of funding. More generally, there is concern that the current health agenda — as set out in the new research programme Horizon 2020 — gives no encouragement or support to research on public health, health systems, or health policy.



Nonetheless, these issues are a priority in many countries and on the European level, as shown by our experience with the first *European Perinatal Health Report*. Data from this report were widely used by health providers, planners, policy makers, researchers, and users across Europe and beyond. The report was downloaded more than 8000 times from our website. More than 100 media articles reported its publication. Individual European countries increasingly rely on this reference list of indicators to evaluate their policy initiatives and benchmark their performance (see Chapter 2 for some examples).

Our indicators have been analysed by our team and others to gain insight into the factors that affect the health of women and children in Europe. The Euro-Peristat network has published 20 articles in peer-reviewed journals based on these data (see our website [www.euro-peristat.com](http://www.euro-peristat.com) for a full list of articles). Others have also used the Euro-Peristat data — which are made available freely on our website — for research on perinatal health in their own countries. We expect that research on these new data from 2010 — which will allow exploration of the reasons for time trends in maternal and health system risk factors as well as health outcomes — will further highlight the value of having comparable data from the countries in Europe.



## APPENDIX 2

### The Use of Uniform Diagnostic Criteria for Gestational Diabetes Mellitus (GDM) in Europe - An Opinion Paper

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#### Introduction

‘The International Association of Diabetes and Pregnancy Study Groups’ (IADPSG) advises to screen for existing but unknown diabetes at the first prenatal clinic visit, especially in high risk populations (1). If overt diabetes or GDM has not been diagnosed in early pregnancy or enrollment is at 24 weeks gestation or later, IADPSG advises that every woman should undergo a 75g 2-h oral glucose tolerance test (OGTT) using more stringent diagnostic criteria for GDM and one abnormal is enough to diagnose GDM (FPG  $\geq$  92mg/dl(5.1mmol/l); 1-h plasma glucose  $\geq$  180mg/dl(10mmol/l); 2-h plasma glucose  $\geq$  153mg/dl(8.5mmol/l) (71). These criteria are the first diagnostic criteria for GDM based on perinatal outcome and therefore unique. Internationally, the

IADPSG recommendation for screening for and diagnosing GDM nevertheless remains controversial since this will lead to a significant increase in the number of women labelled and treated as GDM. Other raised comments are the paucity of data on the cost-effectiveness of such screening strategy, the arbitrary OGTT threshold values given the linear relationship between maternal glucose values and impaired outcome, the uncertainty on the clinical relevance of treatment of mild GDM based on the IADPSG criteria and the uncertainty on the risk of women who have had mild GDM to develop type 2 diabetes (T2DM) postpartum (2,3).

While the American Diabetes Association (ADA) has since December 2010 adopted the IADPSG recommendations, the American College of Obstetricians and Gynecologists (ACOG) and an independent expert panel assigned by the National Institute of Health (NIH) continue to promote to use of an universal two-step screening strategy with the non-fasting 50g glucose challenge test (GCT) and if abnormal followed by the 3-hour 100g OGTT (4-6). Recently both the World Health Organization (WHO) and the Endocrine Society revised their guidelines and now several national societies all over the world also advise the use of the IADPSG criteria for the diagnosis of GDM (7,8). The latest 2014 ADA recommendations, specify that further research is needed to establish a uniform approach to diagnosing GDM and leave open the option between the one-step IADPSG recommendation or the two-step screening strategy as recommended by the NIH Consensus Conference (9).

Screening practice and policy is very inconsistent across Europe, hampered by lack of consensus and poor clinician awareness of GDM and its diagnosis (10). Comparison between countries is very difficult due to the different diagnostic strategies and subpopulations. The development of a uniform screening strategy for GDM in Europe is therefore recommended. This will lead to an opportunity for more women to be diagnosed early and receive appropriate treatment for GDM. Adapting a uniform screening strategy will also facilitate and stimulate research in the domain of GDM in Europe.

## **An initiative of EBCOG to develop a Consensus on the use of Uniform Diagnostic Criteria for Gestational Diabetes in Europe**

Developing a consensus on screening for GDM in Europe is challenging, since ethnic populations are diverse across Europe and health care delivery systems are also very different. Many national societies have recently revised or will soon revise their guidelines after the new WHO recommendations. Most national societies in Europe do not recommend a universal one-step screening strategy with an OGTT, in part due to the associated workload and costs. A steering committee has been appointed by EBCOG to prepare a proposal for the use of uniform diagnostic criteria for GDM in Europe. The steering committee includes members of EBCOG and members of the Diabetic Pregnancy Study Group (DPSG) associated with the European Association for the Study of Diabetes. The proposal is currently under review by the national societies.

## Screening for Overt Diabetes in Early Pregnancy

Since the frequency of obesity and T2DM in young adults is also increasing in Europe and since the use of a simple screening test will lead to more women being diagnosed early with overt diabetes, the steering group proposes to recommend screening for overt diabetes especially in high risk groups (Table 1) using the cut-off values for diabetes outside pregnancy at preconception or at the latest at first antenatal contact (figure 1).

**Table 1: Women at high risk of diabetes and gestational diabetes**

- Previous gestational diabetes
- Family history of diabetes (1st degree relative with diabetes)
- Previous macrosomia (infant birth weight >4000g or >90th percentile)
- Polycystic ovarian syndrome
- Ethnicity: Mediterranean, South-Asian, African Black, Northern-African, Caribbean, Middle-Eastern, Hispanic

It is generally considered that there is not enough evidence to recommend universal screening and treatment of GDM before 24 weeks of gestation. The IADPSG Consensus Panel and WHO recommend that a FPG  $\geq$  92mg/dl (5.1mmol/l) in early pregnancy be classified as GDM (1, 7). This is however debated as this recommendation was merely based on data extrapolated from the cut-off value used on the 75g OGTT later in pregnancy.

Due to the lack of clear evidence about which women would benefit most from screening and treatment of GDM in early pregnancy and due to lack of evidence on which screening strategy for GDM should be used, the steering group has not made any recommendations on which diagnostic criteria for GDM should be used in early pregnancy.

Maternal obesity is also an important independent risk factor for congenital anomalies, gestational hypertension, macrosomia and birth trauma (11,12). In line with the recommendation of ACOG, the current EBCOG proposal is therefore that preconception assessment and counselling are strongly encouraged for overweight and obese women and should include the provision of specific information concerning the maternal and fetal risks of obesity in pregnancy, as well as encouragement to undertake a weight-reduction programme (13). To avoid excessive weight gain during pregnancy (according to the IOM guidelines), the recommendation is now also to offer lifestyle advice to every woman early in pregnancy (14).

## Figure1: A Proposal for the use of Uniform Diagnostic Criteria for Gestational Diabetes in Europe

**First prenatal visit:** screening for unknown overt diabetes especially in high risk women:

FPG  $\geq 126$ mg/dl (7.0mmol/l) or HbA1c  $\geq 6.5\%$  (47mmol/mol) or random glycaemia  $\geq 200$ mg/dl (11.1mmol/l)

**A specific screening strategy (universal 1 step; two-step or risk factor-based) cannot yet be recommended but, when screening for GDM at 24-28 weeks of pregnancy is performed, a 2-h 75g OGTT with the new WHO criteria should be**

FPG  $\geq 92$ mg/dl (5.1mmol/l)

1-h  $\geq 180$  mg/dl (10 mmol/l)

2-h  $\geq 153$  mg/dl (8.5 mmol/l)

→  
Yes

**Treat as overt diabetes**

↓  **$\geq 1$  abnormal value**

**Treat as GDM**

**6-12 weeks postpartum:** 2-h 75g OGTT (non-pregnancy diagnostic criteria)

**Lifelong screening at least every 3 years**  
HbA1c, FPG or 2-h 75g OGTT

GDM: gestational diabetes; FPG: fasting plasma glucose; OGTT: oral glucose tolerance test; HbA1c: glycated hemoglobin

## **Proposal for the use of the new WHO Diagnostic Criteria for Gestational Diabetes in Europe at 24-28 Weeks of Pregnancy**

In line with the recent WHO recommendation, the current EBCOG proposal is now to use the 75g OGTT with the new WHO diagnostic criteria for GDM at 24-28 weeks of pregnancy (Figure 1). The use of a uniform 2-hour 75-g OGTT with the same diagnostic criteria in pregnancy, will lead to an important simplification and facilitate research in the domain of GDM in Europe. However, it should be investigated if higher OGTT threshold values might be used to reduce the number of women diagnosed as having GDM, especially if other risk factors like maternal age, obstetric history and BMI are included in the final diagnosis (G.H.A. Visser & H.W.de Valk, AJOG 2013). Moreover, more research is necessary to evaluate what the best screening strategy would be across different populations in Europe. Therefore, no clear recommendation has now been made on whether a universal one-step, a two-step or a risk factor based screening approach should be used. More data are needed especially on the cost-effectiveness of a universal one-step screening strategy with the 75g OGTT using the new WHO diagnostic criteria compared to other screening approaches for GDM in European populations. Other screening strategies using the new WHO diagnostic criteria, such as a two-step screening strategy with the 50g GCT followed by the 75g OGTT if the GCT is abnormal or selective screening according to risk factors, should also be evaluated prospectively in European populations.

More data are also necessary on the most predictive risk factors for GDM across different European populations. Since maternal age at first pregnancy continues to increase progressively, age is in this current proposal not withheld as a risk factor, since women are now very often older than 30 years at first pregnancy. It is also not clear which BMI cut-off is the most sensitive and most specific to detect GDM across different European populations. A specific BMI cut-off is therefore currently also not proposed as a risk factor.

## **Postpartum Screening Strategy for Glucose Intolerance in Women with a History of GDM**

The best postpartum screening strategy for glucose intolerance among women with a history of GDM is still debated. Shortly after delivery glucose homeostasis is generally restored to normal, but women with GDM are at high risk of developing T2DM (15). The current proposal is to screen women with a history of GDM at 6-12 weeks postpartum using the 2-h 75g OGTT with non-pregnancy diagnostic criteria. Women with a history of GDM should have lifelong screening for the development of diabetes or pre diabetes, at least every 3 years. Currently there is insufficient evidence to recommend one test over the other and therefore HbA1C, FPG, or 75-g 2-h OGTT are appropriate to test for diabetes and pre diabetes. Women with a history of GDM, found to have pre diabetes should receive specific lifestyle interventions or metformin to prevent diabetes.



## Conclusion

Because screening/diagnosis of GDM is very inconsistent in Europe, the development of a uniform screening/diagnostic strategy for GDM is necessary. This will lead to an opportunity for more women to be diagnosed early and receive appropriate treatment for GDM. Adapting a uniform screening strategy will also facilitate and stimulate research in the domain of GDM in Europe.

The current proposal by EBCOG is therefore to screen for overt diabetes especially in high risk groups with the cut-off for diabetes outside pregnancy at preconception or at the latest at first prenatal contact. When screening for GDM is performed at 24 weeks gestation or later, the proposal is now to use the 2-h 75g OGTT with the new WHO diagnostic criteria for GDM. However, more research is necessary to evaluate what the best screening strategy would be across different populations in Europe and which OGTT threshold values should be used. A clear recommendation has therefore not yet been made on whether a universal one-step, a two-step or a risk factor based screening approach should be used.

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<b>UEMS</b>	Union Européenne des Médecins Spécialistes
<b>FIGO</b>	International Federation of Gynecology and Obstetrics
<b>ACOG</b>	American Congress of Obstetricians & Gynecologists
<b>EAPM</b>	European Association for Perinatal Medicine
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<b>EUGA</b>	European Urogynaecological Association
<b>ENTOG</b>	European Network of Trainees in Obstetrics and Gynaecology
<b>EFC</b>	European Federation of Colposcopy
<b>EMAS</b>	European Menopause and Andropause Society
<b>ESC</b>	European Society of Contraception and Reproduction Health
<b>ESG</b>	European Society of Gynecology
<b>ESGE</b>	European Society for Gynaecological Endoscopy
<b>ESIDOG</b>	European Society for Infectious Diseases in Obstetrics and Gynaecology
<b>EURAPAG</b>	European Association of Paediatric and Adolescent Gynaecology
<b>ISPOG</b>	International Society of Psychosomatic Obstetrics and Gynaecology
<b>ISUOG</b>	International Society of Ultrasound in Obstetrics and Gynecology
<b>DPSG</b>	Diabetic Pregnancy Study Group
<b>MJCSM</b>	Multidisciplinary Joint Committee of Sexual Medicine
<b>DOTW</b>	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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