**EBCOG** 



The European Board and College of Obstetrics and Gynaecology



# Standards of Care for Women's Health in Europe

## **Report of a Working Party**

EUROPEAN BOARD AND COLLEGE OF OBSTETRICS & GYNAECOLOGY (EBCOG)

(www.ebcog.eu)

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Obstetric and Neonatal Services (Volume 1)

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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 to the post natal period including care of the newborn
- To develop agreed Standards of gynaecological care for benign and malignant conditions affecting the health of women

## Membership:

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## 1.0 Background

The Maastricht Treaty (1992)<sup>1</sup> forms the basis of a dedicated common public health strategy of the European Union (EU) and its Article 219 specifies that "The member states of the EU decided to coordinate their health policies and programmes with the co-operation of the European Commission to ensure a high level of health protection and to prevent widespread severe illness". Subsequently, Article 152 of the Treaty of Amsterdam (1997)<sup>2</sup> 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. 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 as well<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). Overall each year there are maternal deaths ranging from 335 to 1000 in Europe during and because of pregnancy and delivery 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>4</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>5</sup> or guidelines for the care of women during pregnancy,<sup>6, 7, 8</sup> during labour, <sup>9, 10, 11</sup> care of the newborn<sup>12, 13</sup> and the treatment of gynaecological cancers<sup>14, 15</sup> Furthermore, there are no uniform Standards for data collection systems across the member states for meaningful comparisons.<sup>4</sup> In order to improve outcomes we need to develop core Standards to assess perinatal health related problems and their causes.

## 2.0 Process of Developing Standards of Care

The Council of the European Board and Council of Obstetrics and Gynaecology (EBCOG) agreed in November 2010 that a Working Party 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 in order to establish a baseline which could support the development of Standards of Care.

## 2.1: Feedback from the Council members of the EBCOG.

All members of the Council were sent a questionnaire to ascertain from the individual National Societies whether they had up to date clinical guidelines and Standards of Care developed by their own National Societies. About 50% of member states do have local guidelines available but none, apart from the UK, has Standards of Care. <sup>16,17</sup>.

## 2.2: The review of the published literature

2.2.1: The European Perinatal Health Report- EURO-PERISTAT Project (2008)<sup>4</sup> report 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)* 

2.2.2: A survey and comparison of the 25 member states of the EU as regards national guidelines on Antenatal care  $(2006)^6$  reported huge variations in the number of tests being done during pregnancy. Of interest is to note that countries with a Gross National Product below average were found to recommend more tests than the others.

2.2.3: 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 however 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, even life threatening episodes of pregnancy complications categorised as maternal morbidity. These data are a good indicator of quality of care during pregnancy and labour and it has now been acknowledged that data about *maternal morbidity* is not recorded well.<sup>4, 5</sup>

2.2.4: The Royal College of Obstetricians and Gynaecologists (RCOG) has published two documents detailing Standards of Care which are heavily 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 agreed that the European-wide Standards would be produced by adapting the RCOG's two documents to take into account the variation of clinical practice across Europe.

## 3.0: Purpose and layout of this Document

The purpose of this document is to promote common *Standards of Care in Obstetrics and Gynaecology* in order to improve and harmonise the care of women in Europe. This document would provide guidance for the development of equitable and high quality services, so that a similar Standard of healthcare can be expected throughout all member states of the EU. The Standards should act as an incentive 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 act to inform patients and consumer rights organisations about the care they might expect to receive.

The Standards for Obstetrics cover the pathway of maternity care during pre-pregnancy, pregnancy and post-delivery. The Standards for Gynaecology address Standards for various areas of service provision ranging from benign conditions to the treatment of cancers. Each *clinical service Standard* comprises a mixture of clinical and organisational Standards. Each set of Standards has been supported by a list of auditable indicators which should act as a benchmark for improvement.

## 4.0: Streamlining Standards for Postgraduate Training

One of the fundamental concerns of EBCOG relates to issues around the quality of training for our future generation of "doctors in training" in order to sustain high quality services in Europe. This is especially important as European integration allows free movement of persons, services, capital and goods. Therefore a separate set of Standards to facilitate a uniform quality of training is also desired.

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 lead to the effective delivery of clinical services and also provide excellent training.

# 5.0: Benefits of Implementation of Standards and Audit Indicators

It is envisaged that the Standards will help to provide equitable, safe and patient-focused services to ensure the best outcomes for women's health. The implementation of Standards is an incremental process. When Standards are implemented they become an integral part of the audit process and of quality

development. In order to achieve these Standards, data from 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 across Europe, inconsistencies of care across the EU will be addressed and the most effective clinical care will be delivered.

## **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 coordinated care and to provide women with informed choices that best meet their needs. There should be a clinical governance framework in place to monitor the quality of care provided to women and their families.

Safety should remain the top priority in clinical practice.

Maternity service working environment must facilitate the implementation of these Standards.

### **Patient Focus**

- 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-pregnancy counselling should be available.
- 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.
- Staff working in maternity services should be competent in recognising, advising and referring women who would benefit from more specialist services.
- Maternity services should ensure that there are comprehensive, culturally sensitive, multidisciplinary policies, 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.

## Accessibility

- 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.
- Communication and 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.
- The provision of maternity services should also be based on an up to date assessment of the needs of the local population.
- Parents of stillborn babies or babies with identifiable medical or physical problems should receive timely and appropriate care and support in an appropriate environment.

## **Process of Service Provision**

- 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 suggestive of domestic abuse and serious psychiatric illness.
- Interpreting services should be provided for women where the local language is not their first language. Relatives should not act as interpreters.
- There should be a personal handover of care on the labour ward when midwives' or nurses' and doctors' shifts change.
- Maternity services should utilise local protocols in line with evidence-based guidelines for the provision of high quality clinical care.
- Maternity healthcare 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.

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

### **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.

- Clinical governance structures should be implemented in all places of birth.
- 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.
- Where an incident has occurred, every unit should follow a clear mechanism for managing the situation, including investigation, learning and communication and, where necessary, implementing changes to existing systems, training levels or staffing.
- 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.
- 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.
- A compliments, comments and complaints procedure should be in place to enable women to express their views about their pregnancy and childbirth experience.
- 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.

## **Clinical Audit**

- There should be an audit system in place to monitor important aspects of maternity care, and ensure an audit cycle to effect change.
- All maternity healthcare providers should ensure that all staff participate in the relevant audit into maternal, perinatal or infant deaths or other trigger events.
- 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.
- There should be a lead clinician for audit.

## **Staffing and Competence**

- 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.
- Training should be provided to all healthcare professionals on how to communicate information in an effective, sensitive manner.
- 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.
- Skilled staff should be available to support parents during maternal or neonatal death, stillbirth or miscarriage.
- The qualifications of each staff member must be documented. The competences of each staff member should be assessed, logged and regularly updated.

- Percentage of women given information in advance of screening tests.
- Percentage of women receiving appropriate pain relief of their choice.
- Percentage of women reporting that they were fully informed about the choices in maternity care.
- Percentage of non-local language speaking women who were satisfied with translation and advocacy services.
- Follow up of complaints and action taken.
- Percentage of maternity professionals (doctors, midwives and nurses) who have had training in obstetric complications and emergencies (such as cardiac arrest and haemorrhage).
- Percentage of maternity professionals who are trained in recognising the significance of past serious psychiatric history and domestic abuse.
- Percentage of maternity professionals who are trained in current antenatal screening guidelines.
- Documentary evidence of staff knowledge of and availability of comprehensive clinical guidelines. Evidence of compliance with guidelines (notes review obstetric review meeting records).
- Documentary evidence of policies and working practices that clearly demonstrate that personal handover of care takes place with adequate time for discussion.
- Documentary evidence of multi-professional attendance at obstetric case review and audit meetings, when appropriate.
- Evidence that each unit has a clearly defined protocol to ensure that doctors in training and newly appointed specialists have been observed performing examinations and procedures and their competency signed off before they may perform these procedures without direct supervision.
- Staff involvement in risk management: for example, percentage who have completed incident forms and had feedback (staff questionnaire).

## Planning for Care: Pre-Pregnancy Services

## Rationale

Pre-pregnancy care should enable women to protect and 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 well being prior to conception, and also provides an opportunity to advice as regards general health issues.

## **Standards**

- 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.
- 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; specifically: epilepsy, diabetes, congenital or known acquired cardiac disease, autoimmune disorders, obesity or a history of mental illness.<sup>4</sup>
- Specific pre-pregnancy services should be available to women with a poor obstetric or medical history, a previous poor foetal or obstetric outcome, or where there is a family history of significant illness.
- 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 and hard to reach groups and asylum seekers and refugees.

• 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.

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

## 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 threatened 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 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 the life threatening condition of ectopic pregnancy.<sup>22</sup>

### **Service Standards**

- Formal arrangements should be in place for referral to the early pregnancy assessment service, which allows women with previous early pregnancy problems to self-refer for initial assessment and they should be managed according to agreed local care pathways, including screening for infection (including chlamydia) and providing anti-D prophylaxis.
- Healthcare providers should ensure that early pregnancy assessment units have access to high quality ultrasound scanning with appropriate expertise and a service of clinical bio-chemistry so that an accurate diagnosis of the viability of pregnancy can be made and an ectopic pregnancy could be ruled out.
- Women who may miscarry should have access to a choice of management options such as surgical/medical/conservative.
- There should be clearly defined care pathways for the management of women who may have an ectopic pregnancy.
- A suitable environment should be provided for worried or distressed mothers and their partners with access to counselling and appropriate information.

- Evidence that guidelines and an algorithm for the pathway of care for women presenting with problems in early pregnancy are regularly updated.
- Rates of medical, surgical and conservative management of miscarriage and ectopic pregnancy.
- Rate of failed diagnosis of ectopic pregnancy
- Number of ruptured ectopic pregnancies per year following diagnosis in early pregnancy unit
- Appropriate use of anti D prophylaxis
- The rate of positive infection testing including chlamydia

## **Routine 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 health behaviour during pregnancy.<sup>4</sup>

Poverty, low social status and poorer care for migrants are associated with poor pregnancy outcomes. These inequalities in perinatal health carry long term consequences. This can be further compromised by more limited access to care during pregnancy and differential 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.

## **Standards**

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

- A risk and needs assessment including previous obstetric, medical and social history, must be carried out at the booking visit and this assessment should be repeated at each subsequent antenatal visit to identify new risk factors in order to modify plan of care.
- Once pregnancy is confirmed, women with complex needs should be referred to be seen by a clinically appropriate professional as soon as possible.
- The unit should have clearly defined protocols and care pathways for the antenatal care of normal women and women with high risk pregnancies.
- Focused antenatal care should be culturally sensitive and women's wishes should be respected.

- 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.
- Evidence that >90% of women should have confirmation of intra-uterine pregnancy by ultrasound scanning by 13 weeks.
- Evidence that appropriate appointments have been scheduled for antenatal foetal abnormality and metabolic disorders screening according to national guidelines.
- Percentage of mothers with diabetes and/or epilepsy provided with a higher dose of folic acid supplementation and recorded in booking assessment (Target >90%).
- Percentage of women with special needs appropriately referred to specialist clinics (Target>95%)
- Percentage of normal women who have received standardised antenatal care according to the nationally agreed recommendations (Target >90%).

## **Antenatal screening**

## Rationale

An integral component of antenatal care is the timely diagnosis and appropriate management of maternal problems and the detection of foetal conditions to inform choice and the continuing plan of care.<sup>8</sup>

## **Standards**

- All women should be offered a comprehensive, high-quality antenatal screening and diagnostic Service (serum and ultrasound), designed to detect foetal 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 mid-trimester for detailed assessment of the foetus/foetuses.
- All healthcare providers should ensure that antenatal tests and screening are offered to women as options (with the purpose and consequence of each test explained), rather than as a routine part of the process of being pregnant.
- All maternity healthcare providers should ensure that where women request or decline services or treatment, their decision is respected and documented.
- All women who are identified in the screening programme as at risk of rhesus immunisation or other diseases should be managed and treated according to an agreed protocol.

## **Auditable indicators**

#### **Documentary evidence of:**

- Percentage of eligible women (booking< 13 weeks) offered the two ultrasound scans stated above (target >90%)
- Percentage of eligible women accepting serum screening tests for structural and chromosomal abnormalities

- Percentage of pregnancies with foetal anomalies not correctly diagnosed using current screening policies
- Percentage of women reporting being offered information and choice about antenatal tests and screening (survey of women)
- Total number of terminations of pregnancies performed after prenatal diagnosis of severe congenital anomalies and expressed as 1000 total births
- Percentage of amniocentesis or chorionic villus sample tests performed per 1000 births
- Percentage of amniocentesis or chorionic villus sample tests that were negative
- Pregnancy loss rate following amniocentesis
- Pregnancy loss rate following chorionic villus sampling

## Care of Women with Special Needs, including Immigrants

## 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 and improve 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.<sup>4</sup>

## **Standards**

- 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.
- Women with complex medical conditions must be offered assessment by a specialist. These conditions include epilepsy, neurological disorders, diabetes, 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.
- 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.
- Joint working arrangements should be in place between maternity services and local services with responsibility for dealing with domestic abuse and information about these services should be made available to all pregnant women.

- All women who have a drug and/or alcohol problem should receive their care from a specialist multiprofessional team.
- 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.
- A system of clear referral pathways should be established so that pregnant women who require additional care are treated by the appropriate specialist teams.

- Percentage of women with a pre-existing medical condition who are assessed and managed by an appropriate multidisciplinary team
- Percentage of women with a pre-existing medical condition who have a documented plan of care
- Evidence that written information is available for the care of women from disadvantaged groups
- Evidence of local strategies to engage hard to reach women and those at risk of, or suffering, domestic abuse
- Evidence of the availability of translation, interpreting and advocacy services

## **Mental Health Conditions in Pregnancy**

## 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>

## **Standards**

- All maternity care providers and mental health care providers should have in place joint arrangements for maternity and mental health services.
- Women with a 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.
- All women who are at identified risk of serious post-partum mental illness should be assessed and managed by a psychiatric specialist or team and a system of close supervision following birth should be established.
- 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.

- Evidence of local joint working arrangements within a perinatal mental health network
- Percentage of maternity case notes recording that women are asked about family and personal history of mental health problems
- Percentage of women with mental illness who received pre-pregnancy counselling
- Percentage of all women being followed up by a psychiatric specialist or team
- Percentage of women developing post-partum depression
- Number of women committing suicide within one year of delivery (per 10,000 deliveries)

## Medical Conditions developing 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>

## **Standards**

- Multidisciplinary, high-quality teamwork is essential. Professionals should communicate with other professionals and colleagues.
- A system of clear referral paths should be established so that pregnant women who require additional care are managed and treated by the appropriate specialist teams when problems are identified.
- 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.
- 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.
- The obstetrician in charge/on-call should be aware of all obstetric patients in hospital, whether they have a medical, surgical or an obstetric problem.
- 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.

- Evidence of local protocols for management of obstetric complications
- Evidence of audit of appropriate management for women who develop complications
- Evidence of the existence of protocols for the management of pregnant women in the accident and

emergency services

- Evidence of local arrangements for transfer to intensive care
- Evidence of local development of early warning chart for critical illness

## **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 the units of similar size and the national data.<sup>4, 9, 12, 16</sup>

### **Standards**

#### General

- All maternity units and labour wards should have a named, lead midwife/nurse, obstetrician, paediatrician and anaesthetist.
- Healthcare providers should ensure that staffing levels and competencies on labour wards comply with the complexity of the clinical work load.
- 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.
- Maternity care providers must ensure that all healthcare professionals directly involved in childbirth in any set-up are competent in basic adult, obstetric, neonatal resuscitation and immediate care.

#### **Midwives/Nurses**

• 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.

#### **Obstetricians**

- Healthcare providers should ensure that a specialist is involved in the decision to undertake any caesarean section.
- A specialist should be available immediately to deal with obstetric emergencies and also to support doctors in training as and when requested.
- Any extreme planned pre-term delivery requires review, as early as possible, by staff with appropriate expertise in the interpretation of foetal wellbeing tests.

#### Anaesthetists

- There should be a lead obstetric anaesthetist with anaesthetics service within specialist maternity units.
- Arrangements should be in place in specialist maternity units to ensure that a specialist anaesthetic service is available at all times during childbirth.
- 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 close supervision and help are needed.

#### **Paediatricians**

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

### **Organisation and documentation**

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

• There is a written risk management policy, including trigger incidents for risk and adverse incident

reporting.

- There should be a multi-professional input in protocol and Standard setting.
- Meetings involving all relevant professionals should be held to review adverse events.

#### Multidisciplinary working and communication

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

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

Communication is a keystone of good clinical practice.

- There should be effective systems of communication in place between all team members and each discipline, as well as with women and their families.
- Employers should ensure that staff have both the appropriate competence in their local language and good communication skills.

#### **Staffing levels**

- 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.
- Specialised maternity units dealing with a complex obstetrics 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 for doctors in training.
- Maternity units dealing with a low risk obstetric population should conduct a risk assessment exercise to determine their individual requirements as regards their requirements for onsite presence of obstetrician.

#### **Emergencies and transfers**

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

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

#### **Environment and facilities**

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

- Facilities should be reviewed at least bi-annually and plans made to rectify deficiencies within agreed timescales
- The audit process should involve user groups and a user satisfaction survey
- Dedicated and appropriate facilities for bereaved parents should be available

### Auditable Standards

- Percentage of induction of labour by methods such as artificial rupture of membranes, use of prostaglandins, oxytocin infusion or any other methods used
- Mode of delivery by age groups and parity (spontaneous, operative vaginal, elective and emergency C-Section)
- Percentage of women by parity receiving augmentation of labour with oxytocin infusion
- Percentage of women by parity having episiotomy
- Percentage of women by parity having grade three or grade four perineal tears
- Number of intrapartum stillbirths per 1000 births
- Percentage of newborns with Apgar scores less than 7 at 5 minutes
- Percentage of babies born with weight less than 1,500 grams and admitted to neonatal intensive care unit
- The percentage of neonatal deaths attributable to congenital anomalies
- Percentage of women with postpartum haemorrhage of 1,000 ml or more and/or requiring transfusion.

- Percentage of women allowed trial of vaginal birth following previous caesarean section
- Number of women having emergency caesarean hysterectomy for severe postpartum haemorrhage (presented as number divided by 10,000 deliveries)
- Number of women requiring intensive care unit admission following delivery (presented as number divided by 1,000 deliveries).
- Number of babies with neonatal birth injury, neonatal encephalopathy and post delivery transfer of babies to the tertiary units (presented as number divided by 1,000 deliveries).

## **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>

## **Standards**

- All healthcare providers should have appropriate arrangements in place for protecting patients from the risks of acquiring healthcare-associated infections.
- Specifically in maternity services these should include:
  - o aseptic technique policy
  - o safe handling of sharps policy
  - prevention of occupational exposure to blood-borne viruses policy
  - disinfection policy
  - antimicrobial prescribing policy
  - uniform policy
- Maternity service providers must ensure that the prevention and control of infection is included in introduction programmes for new staff and in training and on-going education programmes for all staff.
- Maternity service providers should ensure that there is adequate provision of suitable hand washing facilities and antibacterial hand rubs.
- Maternity service providers should ensure that information relating to hand washing and visiting restrictions is provided for women and visitors.
- 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.

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

- Documentation of the introduction programme for all new staff that includes prevention and control of infection.
- Evidence of a monthly report on the occurrence of wound infections
- Evidence of a written antibiotics policy in the unit
- Rates of acquired infections: maternal and newborn
- Re-admission rates due to infection

# Maternal Mortality and Morbidity associated with Childbearing

## Rationale

Mothers in Europe still die in childbirth - approximately 5 to 15 / 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, even life threatening episodes of pregnancy complications (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.<sup>4, 18, 26</sup>

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 14 quality indicators of severe maternal morbidity as reported in the annual report of Scottish maternal morbidity.<sup>27,28</sup>

## **Standards**

• Systems should be in place to record and investigate maternal deaths both directly and indirectly associated with childbearing using the internationally approved definitions and the indicators of maternal mortality and obstetric causes of death.<sup>4</sup>, **Error! Bookmark not** 

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- Appropriate interpretation of the causes of maternal deaths requires particular attention to the proportion of "unknown causes".<sup>4</sup>
- Risk management systems should be in place to capture data on severe maternal morbidity. **Error! Bookmark not defined.**
- 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 a recurrence of similar events.

## Auditable Indicators

- Percentage of women with severe maternal morbidity (per 1,000 births)\*Error! Bookmark not defined.
- Maternal mortality per 100,000 births
- Evidence that risk management meetings are held regularly to review all cases of severe maternal morbidity.
- Evidence that actions agreed at each MDT meeting have been fully implemented.
- Evidence that the training needs of trainee doctors identified in these case reviews have been addressed.

The Scottish Confidential Audit of severe maternal morbidity report<sup>28</sup> provides the numbers and rates of the 14 categories of severe maternal morbidity for each obstetric unit.<sup>16</sup> The EBCOG working party recommends that all provider units should work towards setting up systems for collecting data on these quality indicators of severe maternal morbidity.<sup>\*</sup>

<sup>&</sup>lt;sup>\*</sup> The 14 categories of severe maternal morbidity are: major obstetric haemorrhage; eclampsia; renal or liver dysfunction; cardiac arrest; pulmonary oedema; acute respiratory dysfunction; coma; cerebro-vascular dysfunction; status epilepticus; anaphylactic shock; septicaemic shock; anaesthetic problems; massive pulmonary embolism; intensive care; or coronary care admission.

## 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 must 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.<sup>4</sup>

## **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:

- Relevant factors from the antenatal, intrapartum and immediate post-natal period
- Details of the healthcare professionals involved in her care and that of her baby, including roles and contact details especially supporting breast feeding (see generic care Standard for terminology)

## **Auditable Indicators**

- Percentage of newborn babies who are exclusively breast fed during the first 48 hours after birth.
- Percentage of babies being breast fed at the time of discharge from hospital.
- Evidence of arrangements for 24-hour access to advice for support in infant feeding following discharge

## **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. The effective use of networks will ensure the best possible outcome.

All maternity care providers have a duty of care 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.

## **Standards**

- All consultant-led obstetric units should have a named consultant paediatrician who has responsibility and a special interest in neonatology.
- All examinations of the baby should be performed by a suitably qualified healthcare professional who has up-to-date training in neonatal examination techniques.
- 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.
- 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.

- Guidelines should be in place to minimise the number of infants who require rewarming or avoidable admission to special care baby unit (SCBU).
- The newborn blood spot screening (heel prick) tests for phenylketonuria, congenital hypothyroidism, cystic fibrosis, MCADD (medium chain acyl CoA dehydrogenase deficiency) should be offered and discussed with all women and their partners following the birth of the baby.**Error! Bookmark not defined.**
- 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.
- Parents of babies with identifiable medical or physical problems should receive timely and appropriate care and support in an appropriate environment
- 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.

## Auditable indicators

## Documentary evidence of:

- Named consultant paediatrician with responsibility for neonatal care
- Guideline for management of babies at high risk of hypoglycaemia audit of avoidable admissions to SCBU
- Percentage of maternity staff who have had training in neonatal examination techniques
- Percentage of baby examinations carried out by midwives
- Percentage of babies who have received the newborn infant and physical examination within 72 hours of birth
- Percentage of bloodspot tests taken at 5–8 days
- Percentage of blood spot tests taken that was of high enough quality for testing.
- Re-admission rate of neonates with a diagnosis of dehydration or hypoglycaemia
- Percentage of mothers intending to breast feed at birth, initiating breast feeding and still breast feeding at 6–8 weeks postpartum
- Re-admission rates for poor feeding and dehydration
- Re-admission rates for hypernatraemic dehydration

- Foetal and neonatal mortality rates of all births of at least 24 completed weeks per 1000 births at 4 weeks
- Percentage of newborns admitted with congenital anomalies which were not diagnosed during pregnancy
- Neonatal mortality of preterm babies born < 34 weeks
- Percentage of clinical and non-clinical staff with contact with parents and babies that have received level 2 child protection training every 3 years

## **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. Accesses to on-site intensive care for very preterm infants determines their survival and future quality of life<sup>4</sup> 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>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 that have the capacity to meet demand.

### **Standards**

- Managed 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.
- 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.
- 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*.
- All maternity services must have systems in place for identifying high-risk women, informing plans of care for women admitted with threatened preterm delivery, and for transporting preterm babies in a warmed transport incubator to the nearest tertiary unit.

- Prompt referral to an obstetrician with appropriate expertise should be made in all cases of threatened preterm labour to assess the need for a tocolytic and to avoid delay in the administration of corticosteroids.
- Recommendations for the care of babies born at the threshold of viability, agreed nationally by the expert groups should be followed by local guidelines.
- 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 access for women from disadvantaged or minority groups.

## **Audit indicators**

### **Documentary evidence of:**

- number of inappropriate *in utero* or neonatal transfers, such as level III transfers
- number of transfers out of an agreed network
- percentage of preterm babies (born at less than 34 weeks of gestation) whose mothers received antenatal steroids
- percentage of babies born at less than 30 weeks of gestation whose temperature on admission was less than 36°C
- percentage of babies born at less than 30 weeks of gestation who required artificial ventilation who were not offered surfactant
- percentage of very preterm babies delivering in units without a neonatal intensive care unit (level 3)
- the existence of a maternity and neonatal clinical network
- multidisciplinary input and appropriate referral in complex cases, such as a retrospective case note review
- a record of all transfers and transfer requests
- agreed pathways of care and standardised protocols and guidelines

## Supporting families who experience Bereavement, Pregnancy Loss, Stillbirth or Early Pregnancy Loss

## Rationale

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

## **Standards**

- Maternity care providers should ensure there are comprehensive, culturally sensitive, multidisciplinary 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.
- Skilled staff should be available to support parents following maternal or neonatal death, stillbirth or miscarriage.
- 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.
- Local guidelines must include clear communication pathways between secondary care and the primary care team with both the woman's general practioners and community midwife informed of any death within one working day.
- Parents of stillborn babies or babies with identifiable medical or physical problems should receive timely and appropriate care and support in an appropriate environment.
- Maternity services should provide appropriate facilities reflecting cultural beliefs and sensitivities.
- Following the death of a baby, 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 clinician (obstetrician and/or paediatrician) to discuss the results of a post-mortem examination and other investigations.

• Following the death of a baby, a post-mortem examination should be performed by a specialist perinatal pathologist. The results of 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.

## **Audit indicators**

### **Documentary evidence of:**

- Each maternity unit has written clear guidelines in place
- Percentage of couples agreeing to the post mortem examination
- Percentage of parents declining post mortem examination
- Percentage of babies where post-mortem examination has been be able to identify the cause of death by using internationally agreed criteria

## **Training Standards**

## Standard 1-

## **Generic Standards of Training**

- 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.
- All units should have written advice for doctors in training covering the labour ward, when to seek help and what procedures they may perform without direct supervision.
- All new professional staff should have an appropriate induction and should be offered a mentor. Trainee doctors should also have a named educational supervisor.
- 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. Error! Bookmark not defined.

## **Standard 2- Pre-pregnancy Services**

- All doctors in training should be trained and able to take a full social history, such as routine enquires about domestic abuse, drug addiction and alcohol abuse, as well as topics perceived as intrusive, such as HIV testing.
- The trainee should attend dedicated specialist pre-pregnancy clinics for women with poor foetal or obstetric outcomes to learn counselling skills.

## **Standard 3- Early Pregnancy Emergency Services**

• The trainees should demonstrate their competence in early pregnancy ultrasound scanning (trans-abdominal and trans-vaginal) as regards viability, twinning and the diagnosis of an ectopic pregnancy. A log book should be kept.

• The trainee should maintain a log book to collect data to audit their performance as regards failure to diagnose an incomplete miscarriage and a failed diagnosis of a non-ruptured ectopic pregnancy.**Error! Bookmark not defined.** 

## **Standard 4-Routine Antenatal Care**

- All trainees should demonstrate their skills for the identification and initial management for serious medical and mental health conditions and referral to the multi disciplinary teams for advice.<sup>21, 25</sup>
- 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.

## **Standard 5- Antenatal Screening**

- The trainee should be able to demonstrate that all the cases initially assessed and managed by them meet the local protocols.
- The senior trainees specialising in foetal medicine should undertake audit of the cases where they have undertaken independent diagnostic scanning or an invasive procedure to determine their accuracy and adherence to the national screening policies. Error! Bookmark not defined.

## **Standards 6, 7 and 8- Antenatal Care for Women with Complex Issues**

- The trainees should provide evidence of attending joint antenatal/internal medicine clinics dealing with pregnant women suffering from complex medical disorders.
- Senior trainees should attend specialist meetings to acquire knowledge of the way that common medical conditions interact with pregnancy.
- 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.

- 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.
- 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.

## **Standard 9 - Intrapartum Care**

- 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 (100%).
  - Consultant supervision while managing women with major obstetric haemorrhage, eclampsia and placenta praevia.
- 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.**Error! Bookmark not defined.**
- The trainee should demonstrate regular attendance at the departmental training sessions in intrapartum foetal monitoring, drills on crash emergency Caesarean section and obstetric emergencies such as massive post partum haemorrhage.
- Trainees should demonstrate attendance at the combined perinatal meetings.

## **Standard 10 - Infection Control**

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

## **Standard 11 - Maternal Mortality and Morbidity**

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.

## **Standard 12 - Post-natal Care**

- 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.
- 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.

## Standards 13 and 14 - Care Of the Newborn

- The trainee should understand the basic principles of neonatal resuscitation. This can be demonstrated by attending a hands-on-training course on newborn resuscitation
- The trainees should demonstrate their understanding of problems of prematurity. This can be achieved by counselling parents who may be anticipating a premature birth of their baby.
- 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. This can be demonstrated by counselling parents about the events in labour and the prognosis of the baby.

## **Standard 15 - Supporting Families with Poor Obstetric Outcome**

- The trainees should demonstrate their understanding of issues around potential personal, cultural or religious preferences for the expression of grief.
- Understanding issues around the management of the dead baby and the sensitivities around the post-mortem (PM) examination, especially counselling and obtaining consent for PM.

## **APPENDIX 1**

# A summary of European Perinatal Health Report (2008) by the EURO-PERISTAT Project $^{\rm 4}$

The team worked in collaboration with SCPE, EUROCAT and EURONEOSTAT. This report is based on 2004 data provided by the first two organisations. The report also had access to EURONEOSTAT data set of 2006. The limitation of this report is highlighted by the following facts:

- <u>SCPE Surveillance of Cerebral Palsy in Europe</u> This report **covers 16 countries** and has been in existence since 1998.
- <u>EUROCAT European Surveillance of Congenital Anomalies</u> was established in 1979 and covers 30% of births in 19 countries.
- <u>EURONEOSTAT</u> European information system to monitor short and long term morbidity to improve quality of care and patient safety for very low birth weight infants. This is a new initiative of linking a network of neonatal intensive care units within Europe and to provide hospital based data on very low birth weight babies weighing <1500 gm. This is a relatively new project and its data relates mainly to 2006.

The above report has clearly 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.

The number of **data sources used for each country varied** between one (Slovak Republic) to 17 (for the four countries of the UK). All data from Belgium was regional. Although Belgium has a national data collecting system for all the births but the system cannot provide real time information. Spain also provides data on many of the EURO-PERISTAT indicators from the region of Valencia only. All EU member states have a similar registration system which covers all births and deaths. In most countries the data source includes only a limited number of variables related to perinatal health.

#### Foetal and neonatal and maternal mortality rates as reported by EURO-PERISTAT:

- At least 28 completed weeks of gestation (rates vary between 2-4.9/1000)
- Stillbirths at 22 or more completed weeks (2.6-9.1/1000)
- Neonatal mortality from 0-27 days after live birth. This ranged from 2-5.7/1000 live births.
- Neonatal deaths related to congenital anomalies.
- The percentage of babies weighing <2500 gm (4.2% 8.5% of live births)

- Preterm birth rates (5.5% 11.4%). One has to be cautious about these figures because various countries describe different gestational weeks for definition of preterm. While many European countries have specified the type of specialised units where these babies should be delivered, these specifications and their classifications differ therefore the percentage of very preterm babies born in units designated as most specialist range vary widely from 26% to 96%.
- Termination of pregnancy for foetal abnormalities (ranges between 0 10.7/1000 births). *This again reflects differences in prenatal screening policy and uptake, differences in termination laws, practices and cultural attitudes.*
- Cerebral palsy rates. Multiple births contribution has risen from 17% to 24%. Cerebral palsy tends to be higher among low birth weight and preterm babies.
- Maternal mortality ratio (up to 42 days postpartum). This ranges between 2-10/100,000 live births. *The variation in maternal mortality relates to systems of ascertaining and counting maternal deaths more thoroughly, as in some countries, pregnancy is not always noted on the death certificate and quite often diagnostic coding is unreliable.*
- Multiple birth rates range between 11-12/1000 women to 25/1000 women. Some of the variation in multiple birth rates may be due to differences in the use of assisted reproductive techniques, which accounted for up to 5% of all births only 6 countries could provide complete data on this indicator.

## **Obstetric Outcome indicators**

- Rate of caesarean sections ranged from 14% in the Netherlands to 33% in Portugal and 38% in Italy.
- Instrumental delivery rates range from <3% of all deliveries in the Czech Republic to more than 12% in Ireland, Portugal and in the Valencia region of Spain.
- Labour was induced in <9% of all deliveries in the Baltic countries and more than 30% in Northern Ireland and Malta.
- Episiotomy rates ranged from 9.7% of all vaginal deliveries in Denmark, 16.2% in England to 82% in Valencia and 52% in Italy.

## **Social Determinants of Pregnancy Outcome:**

### Smoking

11 countries could provide data. The rate for smoking during pregnancy varied from 5-7% in Lithuania to 21% in France.

#### Breast Feeding

• Data was reported by 13 countries which essentially came from population based surveys. Some countries like Denmark do not collect data because 95% of all newborn in Denmark are breast fed. In the remaining countries of Europe the range for breast feeding is 42.3% to 90.7%.

### Service Delivery Issues and Standards of Care

#### Do size of the Maternity Unit matter?

- In some countries small maternity units deliver fewer than 500 women / year. Small units deliver <3% of all births in Denmark, Sweden, Ireland, Portugal and Scotland whereas these units deliver 19% or more of all births in Cyprus, Latvia, Lithuania, Estonia and Germany.
- In both the South and North of Europe births are mainly concentrated in very large maternity units.
- Home births are rare except in the Netherlands where 30% of births take place at home. In the UK this ranges from under 1% in Northern Ireland to 3.1% in Wales.

The observation is that the low volume of deliveries in very small maternity units may lead to suboptimal care for women with obstetric complications while large units may be unwieldy and impersonal. The concentration of births into large units may also lead to longer travel time for pregnant women and thus possibly an increase in unintended out of hospital deliveries. The challenge is to look at comparative data on outcomes versus size of maternity unit.

#### What is desirable in Future?

Here is the list of the used/recommended indicators in the EURO-PERISTAT Project Report 2008.

#### Foetal, Neonatal and Child Health

#### Core Indicators

- Foetal mortality rate by gestational age, birth weight, plurality
- Neonatal mortality rate by gestational age, birth weight, plurality
- o Infant mortality rate by gestational age, birth weight, multiple births
- o Birth weight distribution by vital status, gestational age, plurality
- Gestational age distribution by vital status

#### Recommended Indicators

- Prevalence of selected congenital anomalies
- Distribution of Apgar scores at 5 minutes
- o Causes of perinatal deaths due to congenital anomalies
- Prevalence of cerebral palsy

#### Further Developments

- Prevention of hypoxic ischaemic encephalopathy
- Prevalence of late induced abortion
- o Severe neonatal morbidity among babies at high risk

#### **Maternal Health**

#### Core Indicators

o Maternal mortality ratio by age, mode of delivery

#### **Recommended Indicators**

- o Maternal mortality ratio by cause of death
- Prevalence of severe maternal morbidity

#### **Further Developments**

- Prevalence of trauma to the perineum
- Prevalence of faecal incontinence
- Postpartum depression

#### **Population Characteristics/Risk Factors**

#### Core Indicators

- Multiple birth rate by number of foetuses
- Distribution of maternal age
- Distribution of parity

#### Recommended Indicators

- o Percentage of women who smoked during pregnancy
- o Distribution of mother' education

#### Further Developments

• Distribution of mothers' country of origin

#### **Healthcare Services**

#### Core Indicators

• Mode of delivery by parity, plurality, presentation, previous caesarean section

#### **Recommended Indicators**

- Percentage of all pregnancies following fertility treatment
- Distribution of timing of first antenatal visit
- Distribution of births by mode of onset of labour
- Distribution of place of birth (according to number of annual deliveries in the maternity unit)
- Percentage of infants breast fed at birth
- o Percentage of very preterm babies delivered in units without a neonatal intensive care unit

#### Further Developments

- Positive outcomes of pregnancy (births without medical intervention)
- o Neonatal screening policies
- Content of antenatal care

## Justification for Using EUROCRAT Indicators:

- Multiple pregnancy rates have been rising in European countries. Maternal and infant mortality rates are higher in multiple than singleton pregnancies. Multiple pregnancy rates are higher among older women, as are infertility problems. Adverse outcome is higher among first births and among births to women of high parity.
- Migration from former colonies, where there is political unrest and from economically less favoured to more affluent parts of Europe, this is an important factor. Outcomes tend to be poorer in some migrant groups.
- Distribution of maternal age to assess the risks of teenage pregnancy or women aged 35 and older.
- Distribution of parity (outcome is higher among first births than among births for women of high parity).
- When born very preterm, some multiple births impose considerable cost to health services.

- Percentage of women who smoked during pregnancy
- Distribution of mother's educational level

These 2 indicators represent lifestyle and social characteristics associated with socio-economic status in general and very much influence pregnancy outcome.

#### Maternal Age

Early and late childbearing are associated with higher than average preterm birth, growth restriction and perinatal mortality. Increased risks for younger mothers have been associated with social and healthcare factors, including lack of antenatal care, unwanted pregnancies, poor nutrition and lower social status. Older mothers have a higher prevalence of pregnancy complications including congenital anomalies, hypertension and diabetes. Older maternal age is a risk factor for maternal mortality and morbidity.

#### Issues

Mothers are increasingly having children later in life throughout Europe and this can affect transient perinatal health outcomes.

#### Recommendations

- Antenatal surveillance policies should be in place to meet the needs of older pregnant women and the provision of information about the risks associated with delayed childbearing. The prevention of teenage pregnancy is a policy concern in many countries.
- Collect data on the distribution of maternal age in years at delivery

#### Assisted Reproductive Treatment

- Births that follow assisted reproductive techniques are low but their percentage will continue to increase due to demographic changes such as maternal age and new developments in assisted reproductive techniques.
- Compared with spontaneously conceived children, those conceived with ART have a higher risk of
  adverse outcomes, specifically perinatal death, preterm delivery, low birth weight and congenital
  anomalies. ART by definition includes all women where the following have been offered; ovulation
  induction, intra-uterine insemination with or without ovulation induction, in vitro fertilisation (ICSI),
  frozen embryo transfer, in vitro maturation. 13 countries provided some data but only 6 countries
  provided data by type of ART. There are methodological issues:
  - o Whether relevant information is collected systematically
  - Who collects and reports the information
  - What proportion of data is missing (ranging from 0.2% to 6.6%)
  - Are less invasive procedures under reported or not.

In all, there is a wide range of births from ART in Europe (1.7% to 4.9%).

#### Early Antenatal Care

This should begin in the first trimester. Early antenatal care makes it possible to identify specific conditions that may need careful surveillance throughout pregnancy to recognise social problems for which women may need help from social or mental healthcare services; making appointments for antenatal care, antenatal screening and its schedule and identifying major risk factors in health behaviour during pregnancy.

- Timing of the first antenatal visit provides an indicator of access to antenatal care.
- Data were reported by 17 countries on the proportion of women who were booked for care during first trimester. The range was 65.3% to 95.9%.

#### Mode of Onset of Labour

- The definition of induction of labour varies between countries or even between maternity units within the same country. In some places induction of labour includes only those cases where drugs have been used and in some countries ARM is also included.
- Countries also differ in the way they classify caesarean section rates. Elective section rate varied from 8% to 14%.
- Rates of induction of labour vary between 9% to 37.9%. Therefore the definition of induction of labour must be harmonised within and across countries, and induction and augmentation should be clearly distinguished in order to improve the rigour of comparison between countries.

#### Data on Spontaneous Vaginal Delivery

- Only 9 countries could provide data on spontaneous vaginal delivery rates, along with augmentation rates and whether patients had an episiotomy or not.
- Episiotomy rates varied widely. It was noted to be 80% for all vaginal deliveries in Valencia compared to 9.7% in Denmark.
- Third degree and fourth degree tears incidence ranged between 2% (Italy) to 3.5% in Denmark.

#### Maternal Mortality

Maternal deaths are subdivided into direct and indirect obstetric causes of death. A chapter of the 10<sup>th</sup> Revision of International Classification of Diseases (ICD10) is devoted to the set of obstetric causes of death. However the situation is very different for maternal morbidity, an indicator that has no widely agreed upon definition. This lack of consensus means that there is no agreement on its definition or available data sources. Beyond providing statistics, studying the circumstances that surround maternal mortality, the chain of events that lead to each death – helps to prevent these avoidable deaths in the

future. Therefore data on maternal morbidity is very important in order to prevent an avoidable maternal death.

Confidential Enquiries into Maternal Deaths are conducted in many European countries with especially strong traditions in France, The Netherlands and the United Kingdom. Regrettably not all member states conduct Confidential Enquiries.

#### Issues

The first major difficulty in assessing maternal mortality at maternal deaths tends to be under- reported. Not all deaths that are directly or indirectly associated with child bearing are so recorded. European countries (Austria, France, Finland, The Netherlands and the UK) that have implemented a specific system to analyse maternal deaths have also conducted studies showing that underestimation of maternal deaths varies from 30% to 50% depending on the initial level recorded in the routine national cause of death records.

The second difficulty comes from the small numbers recorded and the resulting statistical variability. There are 3 levels of maternal mortality ratios. The highest (MMR >9.9) are principally located in Eastern Europe, while the lowest are in the South (Spain, Italy, Greece) and the middle values are for countries (Sweden, Germany) of Europe. It is worthy of note that the countries that have enhanced their system of recording maternal deaths also have high to medium levels of maternal mortality.

Only 11 European states provided maternal deaths by mode of delivery data. Eight of those 11 also provided data on maternal deaths for which the mode of delivery was not stated.

#### Severe Maternal Morbidity

One would have expected that data on the prevalence of embolism, eclampsia, blood transfusion and surgery for postpartum haemorrhage would be easy to collect through the data files which exist at hospital level. However 16 member states provided at least one of the components of maternal morbidity indicator. Only 3 countries provided all the categories including admission to ICU (France, the Netherlands and Germany).

Maternal Morbidity Rates for hysterectomy for postpartum haemorrhage and eclampsia; are the two complications most frequently reported. These figures show large disparities in these measures between countries. The following indicators are a bare minimum which need to be recorded:

- Eclampsia
- ICU admission
- Blood transfusion of more than 3 units
- Massive postpartum haemorrhage requiring hysterectomy

#### • Pulmonary embolism

The EBCOG working party has recommended that all the provider units should collect data on 14 indicators as described below. The Scottish Confidential Audit of severe maternal morbidity report<sup>28</sup> provides the numbers and rates of the following 14 categories of severe maternal morbidity for each obstetric unit:

- Major obstetric haemorrhage,
- Eclampsia,
- Renal or Liver dysfunction
- Cardiac Arrest
- Pulmonary oedema
- Acute Respiratory dysfunction
- Coma
- Cerebro-Vascular dysfunction
- Status Epilepticus
- Anaphylactic Shock
- Septicaemic Shock
- Anaesthetic Problems
- Massive Pulmonary Embolism
- Intensive care or coronary care admission

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