



Assessment of the safety and quality of hospital care for mothers and newborn babies in Montenegro

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WHO Collaborating Center
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CONTENT LIST

Acknowledgments	Page	4
Abbreviations	Page	4
Executive Summary	Page	5
1. Introduction	Page	8
2. Objectives	Page	13
3. Methodology	Page	14
4. Results	Page	15
4.1. Physical structures	Page	15
4.2. Case Management	Page	16
4.3. Guidelines & audits	Page	19
4.4 Access to care	Page	19
4.7. Human rights	Page	20
5. Conclusions	Page	21
6. Recommendations	Page	22
7. References	Page	26
Annexes	Page	29

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ABBREVIATIONS

CDC	Centers for Diseases Control, Atlanta, United States
EBM	Evidence Based Medicine
ENMR	Early neonatal mortality rate
EU	European Union
HMIS	Hospital Management & Information System
IMPAC	Integrated Management of Pregnancy and Childbirth
IMR	Infant mortality rate
MMR	Maternal mortality rate
MoH	Ministry of Health
NICE	National Institute for Health and Care Excellence, Department of Health, UK
NICU	Neonatal Intensive Care Unit
PCPNC	Pregnancy, Childbirth, Postpartum and Newborn Care manual, WHO
PMR	Perinatal mortality rate
QoC	Quality of Care
UNICEF	United Nation Children Fund
VE	Vaginal examination
WHO	World Health Organization
WHO CC	WHO Collaborating Centre

EXECUTIVE SUMMARY

Ensuring adequate quality of care (QoC) is a primary objective of Health 2020, the European strategic framework drawing the policy directions for the 53 member states in the WHO European Region (5). Adequate QoC is recognized as essential for the health and well-being of the population, but also as a basic aspect of human rights (6,7). Evidence suggests that coverage of essential intervention does not ensure adequate health outcomes, without broader consideration given to the QoC aspects (10-14). At facility level, poor QoC is a major contributor to avoidable maternal and neonatal mortality and morbidity.

A first mission for evaluating QoC in selected maternities in Montenegro was organized in 2011. In 2016, the Ministry of Health (MOH), in partnership with the UNICEF Country Office Montenegro, with the technical support of the WHO Collaborating Centre (WHO CC) in Maternal and Child Health, Institute for Maternal and Child Health IRCCS Burlo Garofolo Trieste, Italy, organized a second mission with the following objectives:

- a. assess progress made since the previous WHO assessment in 2011 and identify remaining critical issues concerning the quality of maternal and newborn care in selected hospitals in Montenegro;
- b. suggest further actions needed to improve quality of maternal and newborn care at facility level, taking into account each underlying factor influencing the quality of care;
- c. provide the opportunity for a national team of assessors to become familiar with the assessment tools and methods.

The assessment was also meant as a way of introducing managers and health professionals to the concept of peer review and quality improvement in hospitals.

The mission was held in between 18 and 27 January 2016. Only 3 maternities were selected for this assessment (National Clinical Centre in Podgorica, General Hospital of Berane, General Hospital of Nikšić) therefore the results of this assessment cannot be generalized to the overall quality of care in all maternities in Montenegro.

The methods of the mission followed the standard WHO methodology. The main tool used was the WHO Hospital care for mothers and newborn babies: quality assessment and improvement tool" World Health Organization. This tool allows for a systematic assessment of all different domains relevant to the final QoC provided at hospital level. More specifically, the WHO tool includes the following domains: physical structure; staffing and basic services; statistics, health management information system and medical records; pharmacy management and medicine availability; equipment and supplies; laboratory support; ward infrastructures, case management (normal labour and vaginal birth, caesarean section, maternal complications and emergencies, routine neonatal care, sick newborn care, advanced newborn care), monitoring and follow-up; policies and organization of services; infection prevention; guidelines and audit; access to hospital care and continuity of care; mother and newborn rights.

The evaluation pointed out good progress in respect to the previous assessment held in year 2011:

- A National Group for Perinatal Care started to exist, and members of the group participated to this assessment.
- Currently in the assessed maternities there are good physical structures (water, electricity and heating) and good hygiene.
- In some labour wards equipment has been replaced and renovated: delivery beds, overhead heaters, newborn resuscitation equipment. In most units equipment is fairly new and in good working order.
- Episiotomy doesn't appear to be routinely practiced any more.
- Many outdated **procedures** have been dismissed, for example the routine aspiration of amniotic fluid for normal births and immediate cord clamping. Cord is now clamped and cut after the first minute of life
- Skin to skin contact is practiced and breastfeeding is facilitated, although it could be improved through "rooming-in".
- There are good team dynamics, and dedicated staff.

Nevertheless, some of the suggestions from the previous 2011 assessment have not been followed, and several areas for improvement in the quality of care for women, babies and their families remain. A list of primary areas that need improvement is reported below.

- Some of the maternity **ward rooms** are narrow and overcrowded, which makes personal hygiene challenging and it is indeed a barrier to practicing rooming-in and breast feeding “on demand”. Still there are not single-patient **room dedicated to labour and delivery in most hospitals**. The option of having an active birth, with choice of position and freedom from restrictions in childbirth is still not in place.
- There is the need to monitor the **appropriateness of the indication to cesarean section**.
- Many **outdated harmful practices persist** (enema, pubic shaving, non vertical positions for delivery and Kristeller manoeuvre).
- **Companionship in labour** is either not allowed, or discouraged.
- The **nutrients for parenteral nutrition** for preterms are not always available (aminoacids and lipids) while literature underlines their importance for preterms babies below 1500g of weight.
- **Pain prevention, assessment and relief** in the sick newborn care are not performed, also in surgical cases. There is an urgent need of national guidelines about pain prevention and treatment for babies.
- National **guidelines** and protocols are missing in almost every field.
- With the exception of neonatal resuscitation there has been **little training** for health professionals working in the hospitals.
- Audits of clinical cases is not a practice.

As additional results from this mission, capacities in the national team were developed. The recently set-up **Montenegro National Team for Perinatal Health**, which includes a team of professionals involved in perinatal care, showed the capacity to work in a multidisciplinary and motivated way. It is now important to consolidate and support this group.

Several recommendations are made in this report on how to improve the QoC for mothers and newborn in Montenegro. The main recommendations for future actions include the following:

1. The Montenegro **National Team for Perinatal Health** should aim, in the nearest future, at assessing all the other hospital birthing facilities in Montenegro, to properly **define the priorities** that need addressing at national level.
2. A series of **training** for health staff at hospital level should be organized, to update knowledge of the international evidence-based guideline on the key aspect of case management. We suggest to include the following training session: skills and drills in obstetric emergencies, care in normal labour, indications for caesarean section, breastfeeding, ‘Low birth weight infants’ care. The recently updated WHO Effective Perinatal Care (EPC) training package could be used for this purpose. The team of the WHO Collaborating Centre in Trieste could technically support these activities.
3. **National guidelines** should be developed and disseminated. Following this, there should be an activity to monitor their use in clinical practice.
4. It is crucial that the **role of the midwives** must be re-addressed and regulated at a national level. Midwives competencies, responsibilities and skills must be protected and enhanced in order to promote their autonomy as primary care givers for normal labour and birth.
5. More attention need to be given to respect of human rights at childbirth. It’s in the **woman rights** to be involved in the process of care. It is her right to care for her own child and it is the child’s right to be cared for by its own mother and it is the father’s right to be involved in the care. Activities to enhance respect of human rights at childbirth may include: dissemination of the charter of rights of women at

childbirth, seminars and congresses. Follow up activities need to be put in place to ensure that progress are made in this field.

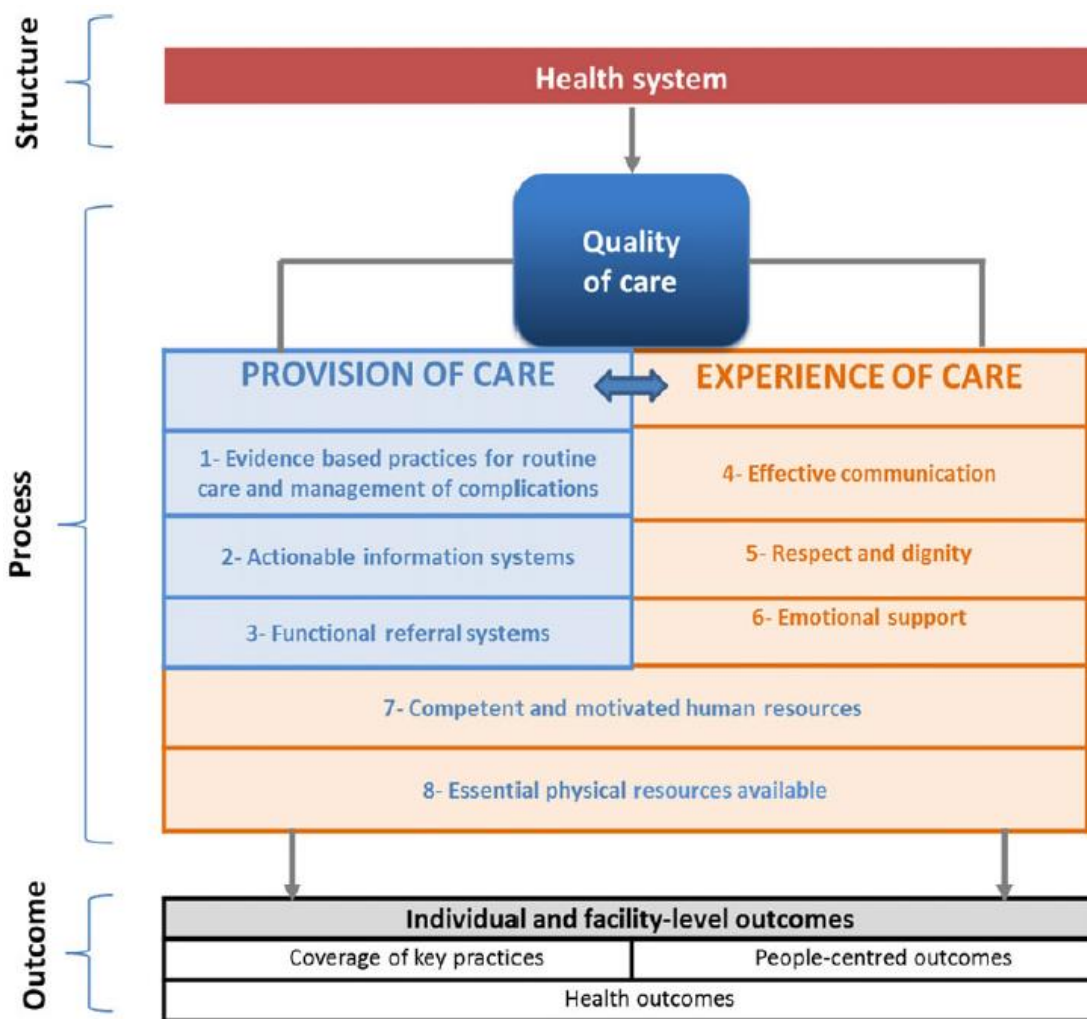
6. As a practical goal for the Montenegro perinatal health services, we suggest to aim at achieving the **“Family Friendly” Perinatal Health Service status**. This status is granted to services that provide safe and effective health care and that answers the medical, social and psychological needs and expectations of the service users.

1. INTRODUCTION

Ensuring adequate QoC is a primary objective of Health 2020, the European strategic framework drawing the policy directions for the 53 member states in the WHO European Region (5). Adequate QoC is recognized as essential for the health and well-being of the population, but also as a basic aspect of human rights (6,7).

WHO vision defines quality of care as ‘the extent to which health care services provided to individuals and patient populations improve desired health outcomes’ (1). QoC is defined as a multi-dimensional concept; in order to achieve high quality care, health care needs to be safe, effective, timely, efficient, equitable, and people-centred (Box 1) (1,8,9).

Figure 1. WHO Quality of Care Framework for Maternal and Newborn Health ¹



WHO has conceptualized a Quality of Care Framework for Maternal and Newborn Health (Figure 1) (1). Based on this framework (Figure 1), QoC for pregnant women and newborns in facilities requires competent and motivated human resources and the availability of essential physical resources (1). The process of care is composed by two complementary domains: the “provision of care” and the “experience

of care". For the "provision of care" evidence-based practices for routine and emergency care, actionable information systems where record keeping enables review of the care provided, and functional referral systems between different levels of care should be in place (1). For the "experience of care", effective communication, respect and dignity, and emotional support should be ensured (1). Continuity of care across all services, units, and levels of the system is also fundamental (1,10).

Box 1. Dimension of Quality of Care ^{1,8,9}

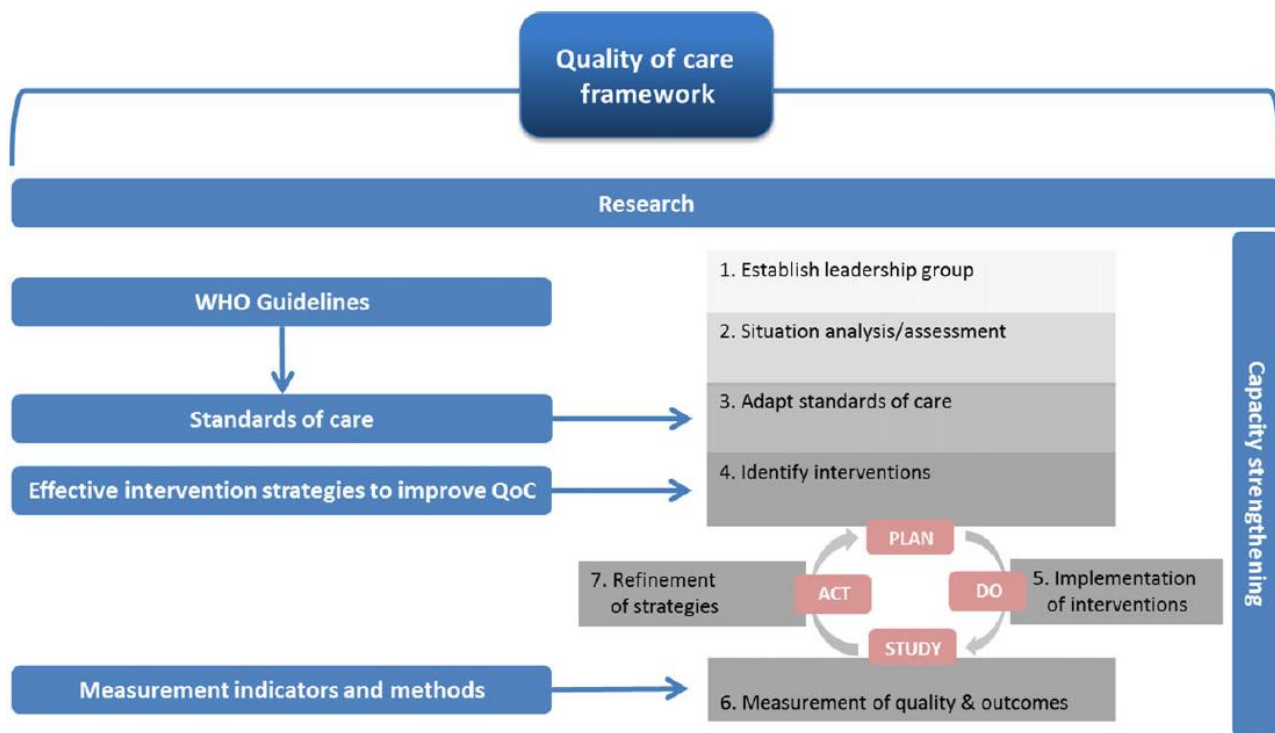
- ❖ **Safe:** delivering health care which minimises risks and harm to service users, including avoiding preventable injuries and reducing medical errors
- ❖ **Effective:** providing services based on scientific knowledge and evidence-based guidelines
- ❖ **Timely:** reducing delays in providing/receiving health care
- ❖ **Efficient:** delivering health care in a manner which maximises resource use and avoids wastage
- ❖ **Equitable:** delivering health care which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location or socioeconomic status
- ❖ **People-centred:** providing care, which takes into account the preferences and aspirations of individual service users and the cultures of their communities.

Evidence suggests that coverage of essential intervention does not ensure adequate health outcomes, without broader consideration given to the QoC aspects (10-14). At facility level, poor QoC is a major contributor to avoidable maternal and neonatal mortality and morbidity, particularly in countries where care is delivered mainly at hospital level (11-13). Substandard QoC can be harmful to mothers and newborn babies, besides representing a cost for patients, the health system and the whole community (1,11,13). Low quality of care impedes the fulfillment of the right to health of women and babies and can act as a disincentive for accessing health services (1,11,13, 14). On the opposite, benefits of improved QoC include: improved health outcomes, cost-saving, greater patients' and staff satisfaction, and decreased risk of litigation.

A number of strategies to improve maternal and newborn QoC have been proposed in the last years by WHO, in collaborations with other UN partners. In line with its organizational mandate, WHO has developed a framework for a QoC Improvement Strategy (Figure 2), where six strategic areas have been identified to contribute to ending preventable mortality and morbidity among mothers and newborns (1). These includes: (a) research, (b) development of guidelines, (c) identification of standards of care, (d) identification of effective intervention strategies for quality improvement, (e) development of monitoring indicators at global, national and facility levels, and (f) capacity strengthening for quality improvement research, measurement and programming (Figure 2). In the WHO vision, quality improvement should achieve the given standards both for "provision of care" and for "experience of care" (1).

This mission focuses specifically on one of the WHO approaches to improve QoC, by using a WHO Tool for quality Assessment and Quality improvement (15).

Figure 2. WHO approach to improve Quality of Care¹



Health system reforms in Montenegro and current health indicators

Reforming activities of Montenegro’s health system started in 2003 by development of the overarching legislative and strategic documents in the health sector, while the process of health system reorganization started in 2004. The health system reform continued and accelerated after Montenegro become an independent state in 2006. Following the beginning of negotiations on the EU accession in June 2012, planning of the health sector development is done within the EU social, legal and economic framework, as stipulated in the key priorities of the 2020 Health policy. Being a WHO member state, Montenegro also aligns its policy with the policies of the UN member states.

Further activities will be aimed at strengthening safety and quality of the health care and rational spending in the health sector. In the meantime, many strategic documents which regulate different areas in the health system have been developed in line with the strategic priorities and strategic directions of the future development.

In recent years the improvement in quality of perinatal and paediatric care has been evident, with Montenegro achieving standards in quality performance which are not far off from other European countries.

In the last 20 years, the maternal mortality rate (MM), infant mortality rate (IMR), perinatal mortality rate (PMR) and early neonatal mortality rate (ENMR) (i.e. within the first week of life) has seen a steady decline. See Figure 3-6 (Source: The European Health for All database (16)).

Figure 3. Maternal mortality rate in Montenegro over the last 20 years (16)

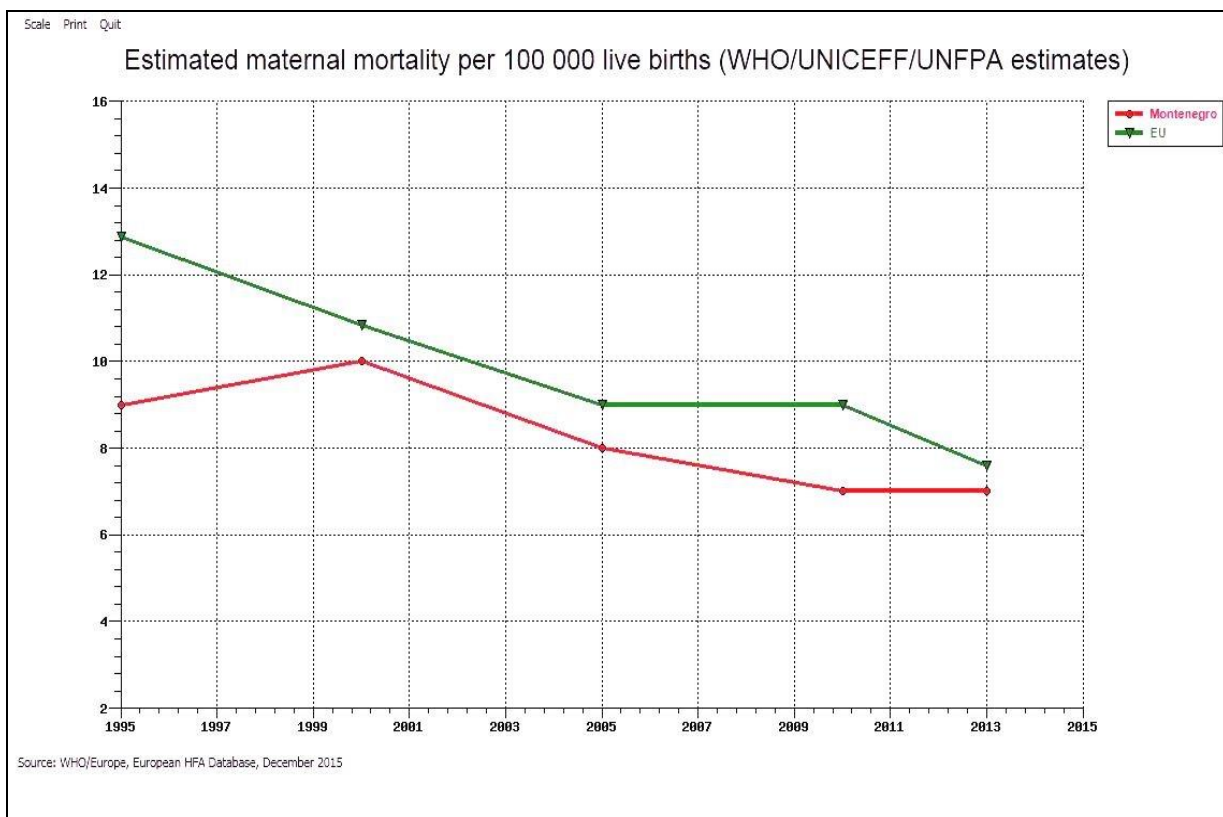


Figure 4. Infant mortality rate in Montenegro over the last 20 years (16)

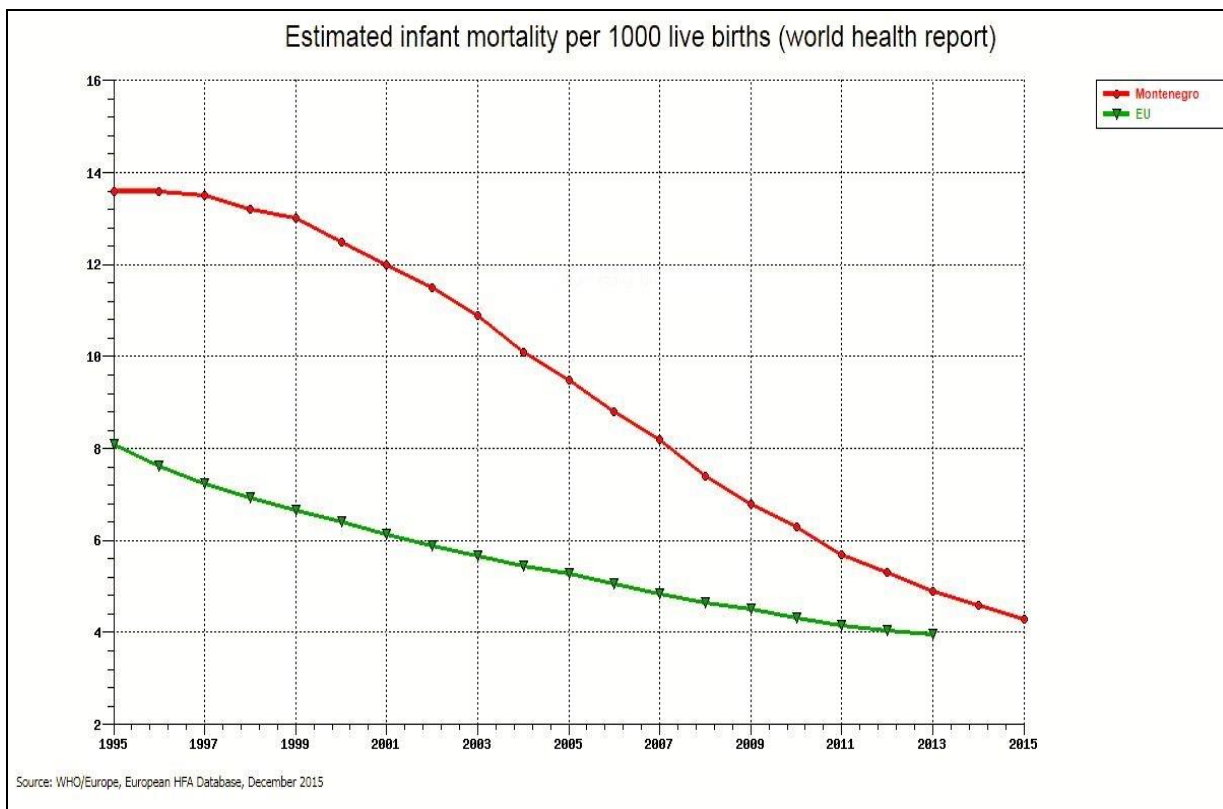


Figure 5. PMR – Perinatal mortality rate in Montenegro over the last 20 years (16)

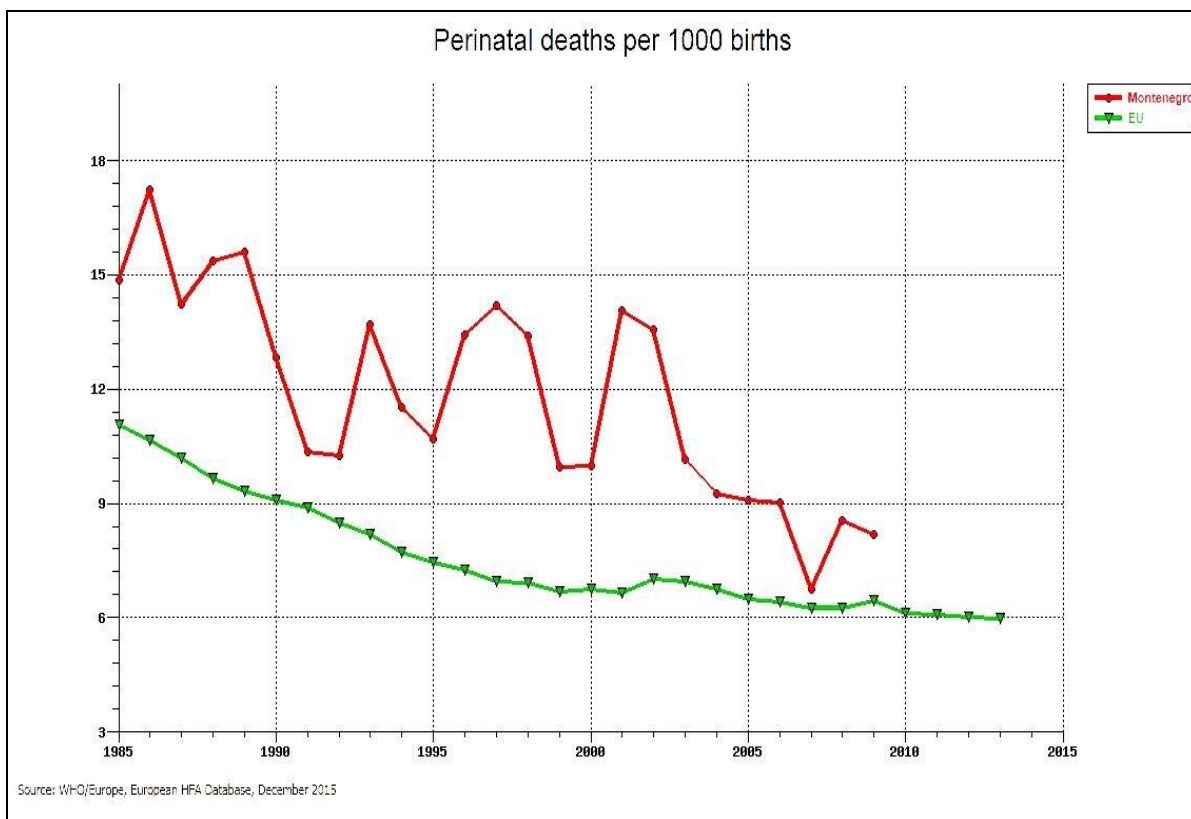
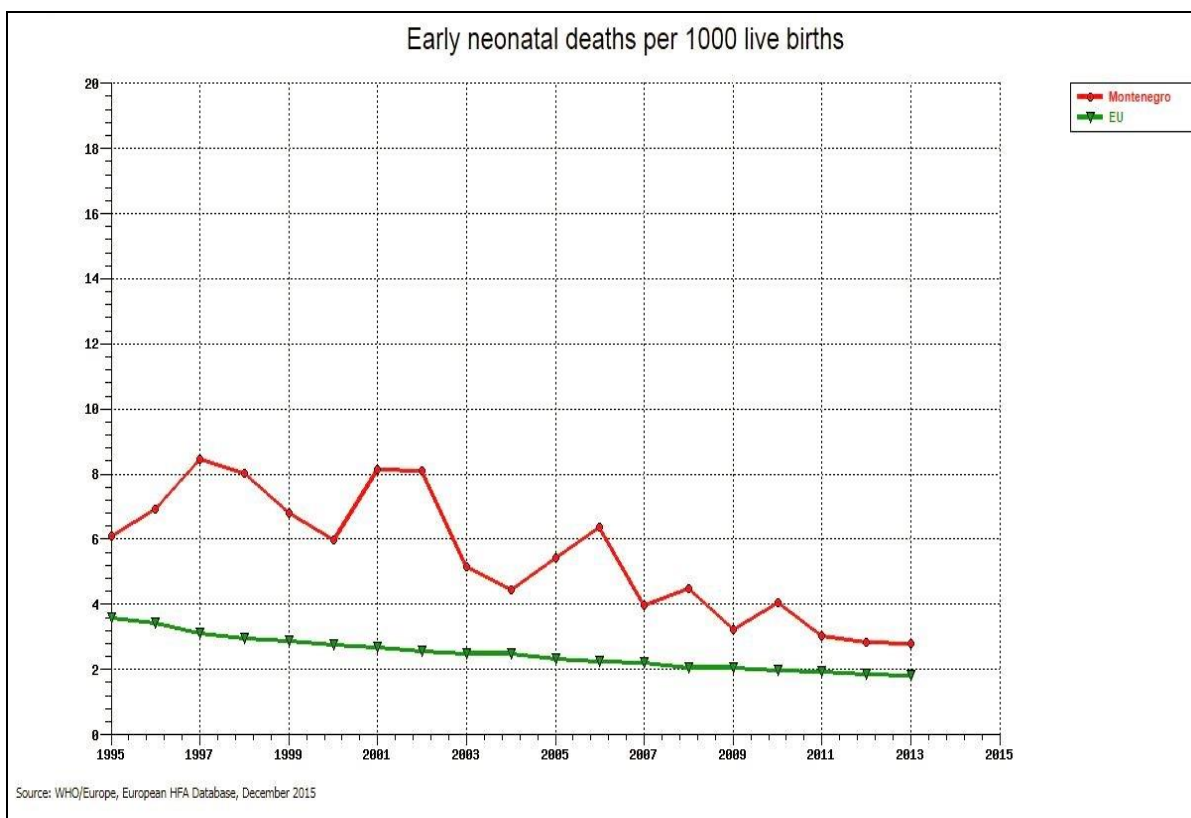


Figure 6. ENMR – early neonatal mortality rate in Montenegro over the last 20 years (16)
(newborns dead within 7 days of life)

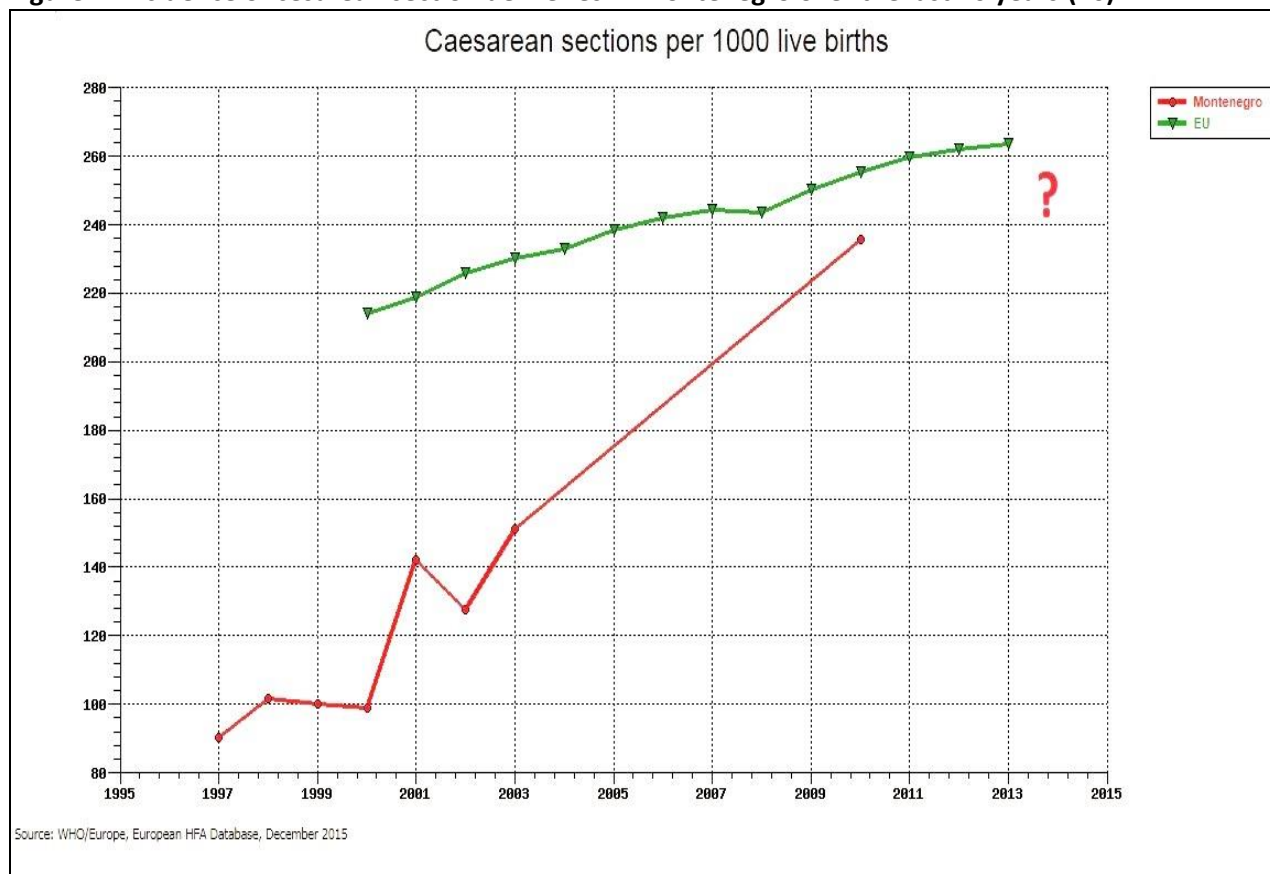


Despite these progresses, it must be acknowledge that other indicators of health care process, suggest possible gaps in the quality of care delivered. For example, Montenegro’s caesarean section rate has been considerably increasing over the last 20 years (Figure 7), and this is a trend which is common to the majority of European Countries.

To our knowledge, the caesarian section rate in Montenegro is not subject to routine monitoring, in order to evaluate appropriateness: the Robson’s classification of cesarean section indications is not used.

This rate is relatively high when compared to WHO expected standards, which suggest a rate of 15% as ideal (*“There’s no evidence that health care quality continues to improve once a country’s rate exceeds 15 percent”*) (17).

Figure 7: Incidence of cesarean section deliveries in Montenegro over the last 20 years.(16)



2. OBJECTIVES OF THE QUALITY ASSESSMENT

In agreement with the Ministry of Health (MOH) and with UNICEF Country Office (CO) Montenegro, the following where the objectives of this assessments:

- d. **assess progress made since the previous WHO assessment in 2011 and identify remaining critical issues concerning the quality of maternal and newborn care in selected hospitals in Montenegro;**
- e. **suggest further actions needed to improve quality of maternal and newborn care at facility level, taking into account each underlying factor influencing the quality of care;**
- f. **provide the opportunity for a national team of assessors to become familiar with the assessment tools and methods.**

The assessment was also meant as a way of introducing managers and health professionals to the concept of peer review and quality improvement in hospitals.

3. METHODOLOGY

The main tool used for this assessment was the 2nd edition of **“Hospital care for mothers and newborn babies: quality assessment and improvement tool (WHO QA&QI Tool) (15)**. The tool has been technically in 2014 based on the latest guidelines and recommendations from WHO and other scientific societies by the WHO Collaborating Centre for Maternal and Child Health, Institute for Maternal and Child Health IRCCS Burlo Garofolo Trieste, Italy.

The WHO tool support hospital staff and health authorities in a process of improving the quality health care provided to mothers and newborn babies, by an in-depth analysis of the care provided at local level, and by facilitating the development of a plan of action to improve the quality of care. The WHO tool adopts a participatory approach that facilitates wider involvement and sustained improvement of practice.

The following are the main characteristics of the WHO QA Tool:

- Based on international standards (e.g. WHO guidelines and recommendations, guidelines from other scientific societies and eminent organizations, such as the RCOG and NICE, Cochrane reviews etc.).
- Systematic. All main areas relevant to quality of care for mothers and newborns are assessed.
- Action oriented. It identifies areas most in need of improvement and it helps develop an action plan.
- Participatory. It involves health professionals and service users in the assessment.
- Based on the principles of “peer review” which are defined as a “standards-based survey conducted by medical professionals in order to assess the quality of professional performance of peers, aimed to improve the quality of patient care”.
- Includes interviews to mothers and to staff using a predetermined grid of questions.

The WHO QA&QI Tool allows for a systematic assessment of all different domains relevant to the final QoC provided at hospital level. More specifically, the WHO tool includes the following domains: physical structure; staffing and basic services; statistics, health management information system, and medical records; pharmacy management and medicine availability; equipment and supplies; laboratory support; ward infrastructures, case management (normal labour and vaginal birth, caesarean section, maternal complications and emergencies, routine neonatal care, sick newborn care, advanced newborn care), monitoring and follow-up; policies and organization of services; infection prevention; guidelines and audit; access to hospital care and continuity of care; mother and newborn rights.

Every area observed is scored on performance, using WHO standards and Evidenced- Based Medicine (EBM) literature as references. The aim of the score is to guide discussion at local facility level in order to identify priority needs in terms of changes in practice and also to then expand these considerations into initiatives at national level.

Substantial changes were made in many chapters of the second edition (2014) compared to the first edition of the tool (2009), in order to update the tool in line with newer WHO guidelines and recommendations as well as with other international standards. It is therefore important to stress that the assessment conducted in year 2011 and the one conducted in 2016 are not directly comparable.

According to the WHO methodology, the assessment team was multidisciplinary; it included, both in the international and in the national team, professionals with expertise in obstetrics, midwifery, and neonatology. The assessment is also meant to develop capacities among a national team of specialist, as identified by the Ministry of Health. Additionally, junior doctors (two for each hospital) joined the assessors’ team, to act as interviewers. Approximately 50 women and 50 staff members were interviewed using the standard interview form of the WHO QA Tool.

In agreement with MoH, and with UNICEF CO, three hospitals were selected for this first mission: National Clinical Centre in Podgorica, General Hospital of Berane, general Hospital of Nikšić.

The agenda of the mission is reported as ANNEX 1.

4. RESULTS

4.1 Physical Structure, Laboratory and Pharmacy Standards

The main strength and weakness observed in this are reported in Table 1. Overall several strengths but also several weakness were identified.

Table 1. Physical Structure, Laboratory and Pharmacy-strength and weakness

	MAIN STRENGTHS	MAIN WEAKNESS
Physical Structure	<p>There are no more reported problems with water supply and electricity cuts.</p> <p>The physical structure of the two peripheral hospitals is overall good. Service users in the National Clinical Centre in Podgorica benefit from a newly renovated labour ward with individual labour and delivery rooms but unfortunately find themselves in overcrowded maternity wards.</p>	<p>Although rooms designed for labour appear to be comfortable they are not used for the active phase of labour, but only for the delivery.</p> <p>The labour rooms are usually large with 3 or 4 beds, no screen for privacy and in some cases big windows opened onto large corridors. In one facility the delivery bed is situated right in front of the nurses station. Lights are not dimmed and doors are kept open with staff entering without much attention to the physiological needs of labouring women.</p> <p>Observations were made in the interviews with patients in regard to too few toilets & showers“, and “the occasional lack of hot water“</p>
Staffing	There is generally good team work.	Interviews with staff have suggested as possible area of improvement increase” low salaries and understaffing“.
Statistics, HMIS	Medical records are usually filled with clarity, although poor in nursing and clinical notes and clear diagnostic and therapeutic plans.	Data are poorly used at local level , not used for a quality improvement process
Pharmacy	<p>Spaces and storage of medicines and supplies are well organized, in a clean and clear way.</p> <p>A National List of essential medicines is in place.</p>	<p>The “Cold chain” is not always maintained: often there are no thermometers in the fridge and the temperature is not recorded.</p> <p>Misoprostol is not available at national level and neither other intra-venous antihypertensive drugs.</p> <p>It is urgent to procure nutrients for parenteral nutrition in newborns, which are not always available.</p>
Laboratory	Good standards for spaces, hygiene, staffing, organization, and number of available tests in all the laboratories visited.	Not all laboratories perform micro sampling methods on newborn blood samples.
Infection Prevention	There is now adequate spaces to practice effective hand washing with WHO posters as job aids in place. Rooms, other spaces, furniture and equipments are clean and well maintained. The systems for sterilization are efficient.	Some outdated practices on infection control persist like for example swabbing surfaces for bacterial contamination screening.

4.2 Case management

Finding son case management is summarized in the following three tables on midwifery care, obstetric care, and newborn care. Overall several strengths but also several weakness were identified.

a) Midwifery care

Table 2. Midwifery care strength and weakness

MAIN STRENGTHS	MAIN WEAKNESS
<p>Labour and delivery rooms are mostly well equipped with delivery beds, good source of lighting, clear work surfaces, thermometers, clocks and heating, etc.</p> <p>Episiotomy doesn't appear to be routinely practiced any more.</p> <p>Midwives have been observed to be caring and emphatic.</p>	<p>Some inappropriate practices persists in some hospitals, like enemas and pubic shaving, however the rate of routine episiotomies seem to have reduced.</p> <p>An admission CTG, with no real indication, is still in use.</p> <p>Many vaginal examination are conducted without clear indications and at short intervals.</p> <p>An excess of medicalization (sedatives, spasmolytic) arises from direct observations and analysis of the clinical records.</p> <p>There is no a clear check list for monitoring women after delivery, in normal or problematic situations.</p> <p>Midwives are not autonomous practitioners for normal labour and births. They lack professional recognition and status. A good example of this is the fact that midwives are able to assess labour progress and perform VEs (vaginal examinations), however they are not allowed to document it in the notes and never on the paragraph which is left to the obstetric team to fill out and interpret. In one of the hospitals midwives have no access to computerized medical records as they lack the password (exclusive to medical staff). This means they have no way of checking important antenatal notes of labouring women presenting to the unit.</p> <p>It has been noted that in some units, not in all of them, labouring women are still made to birth on their backs.</p> <p style="text-align: center;"><u>Specific on the use of partograph</u></p> <p>The Standard WHO partograph with 4 hours action line is not used. Instead there is another paragraph which is filled out and interpreted solely by members of the obstetric team.</p> <p>There is no protocol/standard/algorithm for the appropriate use of partograph. Recording of labour data (moulding, descent of head, oxytocin and additional notes) on partograph is poor.</p> <p>The partograph does not seem to be used as a support in labour management interventions and decision making.</p> <p>Debrief Meetings to discuss clinical cases and management take place regularly, however not all health professionals are included. Midwives, for example, are not included in discussion.</p>

b) Obstetric care

Table 3. Obstetric care strength and weakness

<p>In the referral centre indication for caesarean sections follow international guidelines and current caesarian section rate seems to be adequate in respect to the case mix.</p> <p>Medical records are usually filled in with clarity, although sometimes are lacking regular clinical monitoring and clear therapeutic diagnostic programs.</p> <p>There are protocols in place (in English or Serbian language) for different obstetric complications and maternal conditions.</p> <p>A national hospital infection prevention protocol for use in surgery (including obstetrics and gynaecology) is known and implemented.</p> <p>Antibiotic prophylaxis at cesarean section is appropriate according to international consensus in 2 out of 3 hospitals. .</p>	<p>In peripheral facilities there is no availability of performing instrumental deliveries and the rate of induction of labour is low. This, combined with an “on-call” system for obstetric staff during night time and weekends results in cesarean section being a popular choice for managing deliveries.</p> <p>There are no algorithms or flowchart for intervention related to case management, not even for cases of obstetric emergencies, neither is there a specific area dedicated for managing emergencies.</p> <p>There are no specific protocols or guidelines when transferring “at risk” pregnancies from the peripheral areas to the capital (for example: no loading dose of MgSO4 for hypertension, or single dose of corticosteroids in case of threatened pre term labour).</p> <p>Use of regional anesthesia for cesarean sections is very limited (both elective and emergency).The use of spinal anesthesia is increasing, although slowly and with an ample margin for improvement.</p> <p>Monitoring of high risk obstetric patients could be improved, starting the introduction of standardized patient vital charts for different diagnosis and different alerts. Achieving this at national level would be the gold standard.</p> <p>Antibiotic prescription need to be improved, according to the international evidence-based guidelines. On reviewing medical records of pregnant women transferred to the main hospital, it showed that an incorrect antibiotics therapy was given. In one of the hospitals women are still receiving antibiotic therapy for 3 or 4 days after a caesarean section without a specific indication.</p>
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c) Newborn care

Table 4. Newborn care strength and weakness

MAIN STRENGTHS	MAIN WEAKNESS
<p>There is adequate equipment ready for immediate newborn care in the labour wards of the three hospitals visited such as overhead heaters, resuscitation bags and masks, aspirators and oxygen</p>	<p>Some of the oxygen bags appeared to be quite old and would benefit in being replaced by newer ones.</p> <p>Common to other areas observed, newborn care also</p>

<p>canisters.</p> <p>Good consideration is given now to the importance of preventing newborn hypothermia and “warm chain” is well maintained (this is a good improvement compared to the 2011 assessment).</p> <p>Immediate cord clamping and routine suctioning of newborns are not practiced any more.</p> <p>Babies are placed in immediate “skin to skin” contact with their mothers and this lasts for the first two hours of the baby’s life. This is a very important achievement and it is a big improvement since previous report.</p> <p>Breastfeeding is initiated while in “skin to skin” contact and procedures such as bathing the baby are postponed after this. This is a very important achievement and it is a big improvement since previous report.</p> <p>Prophylaxis of Newborn Haemorrhagic disease is done at national level by administering vitamin K to every newborn.</p>	<p>lacks in local or national guidelines and in standardized protocols and algorithms of care management.</p> <p>Newborn ophtalmic prophylaxis for the prevention of bacterial conjunctivitis is not a recommendation at a national level.</p> <p>It is of extreme importance that the practice of newborn babies “rooming in” with their mothers during hospital stay is implemented in every hospital. Currently babies are separated from the mothers after birth, therefore not allowing for breast feeding to be ‘on demand’ but instead to be regulated by a rigid schedule.</p> <p>Mothers should also be involved as much as possible in the care of their infants who require special care.</p> <p>In caring for well and for sick babies, we recommend more attention in trying to reduce as much as possible situation that cause stress to the newborn and avoid, whenever possible, painful procedures. Excessive handling, bright lights and noise levels should be kept to a minimum especially during night hours.</p> <p>No-pharmacological and complementary therapies to avoid or reduce pain in sick newborns or surgical infants are still not the current practice (and common knowledge): this is definitely an area that needs improvement.</p> <p>It has come to our attention that yet there is an over diagnosis of “neonatal asphyxia”. This could indicate different problems: one of them could be that the definition of perinatal or neonatal asphyxia used by some doctors is too wide, alternatively it could indicate that not all units are able to promptly recognise foetal distress in labour and act accordingly. It could also mean that neonatal resuscitation competencies need improving.</p> <p>In some district hospitals, doctors, during festivities, only work with an “on- call” system. This hampers the management of neonatal emergencies that require immediate action.</p> <p>Caution should be used in utilizing oxygen in neonatal resuscitation, especially in premature babies; use of pulsy oxymetry should be mandatory. This is an area where urgent updates in clinical practice are needed in order to be in line with current international recommendations.</p> <p>Medical records are usually filled out with clarity,</p>
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	although in peripheral hospitals sometimes these are lacking in regular clinical monitoring and clear therapeutic diagnostic plans.
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4.3 Guidelines and Audits

Findings on guidelines and audits are summarized in the following table. Overall several strengths but also several weakness were identified.

Table 5. Guidelines and Audits strength and weakness

MAIN STRENGTHS	MAIN WEAKNESS
<p>Some guidelines are available.</p> <p>There is good team work (observation also emerged from the interviews).</p> <p>In selected facilities, some case reviews are conducted</p>	<p>National guidelines are lacking or they are not updated and not systematically used.</p> <p>Algorithms, flowchart and other job aids to support case management are lacking, both for obstetric cases and newborn cases, and emergencies.</p> <p>Clear protocols on criteria for case referral are needed.</p> <p>Protocols on antibiotic used are needed.</p> <p>There is lack of continuous professional education. Interviews with staff have suggested as possible area of improvement to increase the number of professional education events.</p> <p>In most facilities and units, there is no routine practice to conducting clinical reviews or audits.</p>

Access to care and continuity of care

Findings on Access to care and continuity of care are summarized in the following table. Overall several strengths but also several weakness were identified.

Table 6. Access to care and continuity of care

MAIN STRENGTHS	MAIN WEAKNESS
<p>There is an easy access to hospital services.</p> <p>There is continuity between the services of antenatal care, care in the hospital and a mother controls and newborn after delivery.</p> <p>Some out of pocket payment may occur, although this was difficult to document.</p>	<p>Clear protocols on criteria for case referral are needed.</p> <p>No regular discussion on case referral is performed.</p>

Human Rights

Findings on human rights are summarized in the following table. Overall several strengths but also several weakness were identified.

Table 7. Human rights strength and weakness

MAIN STRENGTHS	MAIN WEAKNESS
<p>Communication with women has been noted to be caring and empathic.</p> <p>Women in labour are encouraged to move around and eat and drink as they wish.</p> <p>Inflated Birth Balls for encouraging active labour are available and midwives are excellent in supporting women in labour, especially in one of the units visited.</p> <p>In the interviews it has clearly emerged that mothers are really pleased with the “commitment of health professionals</p>	<p>Some inappropriate practices persists in some hospitals, like enemas and pubic shaving, however the rate of routine episiotomies seem to have reduced.</p> <p>It was sometimes possible to observe a lack of respect for the privacy and the needs of mothers. The labour rooms are usually large with 3 or 4 beds, no screen for privacy and in some cases big windows opened onto large corridors. In one facility the delivery bed is situated right in front of the nurses station. Lights are not dimmed and doors are kept open with staff entering without much attention to the physiological needs of labouring women.</p> <p>Observations were made in the interviews with patients in regard to too few toilets & showers“, and “the occasional lack of hot water“</p> <p>A poor involvement in medical decisions from service users was noticed.</p> <p>Companionship in labour is not allowed, or discouraged. Women’s partners face many difficulties in order to be with their spouses during labour and birth, even economic barrier</p> <p>There is a lack of pain relief options in labour.</p> <p>There is lack of pain prevention and management in newborns.</p> <p>Interviews with mothers have suggested as possible areas for improvement having “rooming in” with their infants, the active participation of fathers and family members to the care of the baby as well as the care of the mother.</p>

5. CONCLUSIONS

In interpreting this report, it should be stressed that the assessment mission focused only on 3 maternities in Montenegro, therefore results of the assessment should not be generalized to the quality of care in all maternities of Montenegro.

The improvements observed in the last 5 years in the 3 assessed maternities showed that in these facilities definitely measurable progresses were made. The following are the main aspect of good quality of care observed:

- ▶ A **National Group for Perinatal Care** was formed, and members of the group participated to this assessment.
- ▶ Currently in the assessed maternities there are **good physical structures** (water, electricity and heating) and good hygiene.
- ▶ In some labour wards **equipment** has been replaced and renovated: delivery beds, overhead heaters, newborn resuscitation equipment. In most units equipment is fairly new and in good working order.
- ▶ **Episiotomy** doesn't appear to be routinely practiced any more.
- ▶ Many outdated procedures have been dismissed, for example the routine aspiration for newborns of amniotic fluid in the absence of any indication and immediate cord clamping. The umbilical cord is now clamped and cut after the first minute of life, skin to skin contact is practiced and breastfeeding is facilitated, although it could be improved through the implementation of "rooming-in" in every hospital. Clean warm towels and blankets are in place to maintain "warm chain" at delivery and basic resuscitation equipment is ready and in working order.
- ▶ There are good team dynamics, and dedicated staff.
- ▶ The NICU in Podgorica is the only ward in the country dedicated to care of preterm babies and advance newborns care: we have observed very good staff, with great attitude and knowledge on their patients' clinical problems. There are proper devices and instruments for dealing with different issues that are common with preterm birth and others newborns pathologies. The neonatologists and nurses work well as a team. However there is a heavy understaffing: 5 Neonatologists for 800 newborns/year. One out of nine of all the 7000 babies born in Montenegro a year is admitted to Podgorica's NICU. This kind of workload is far too heavy for the staff working there.

Nevertheless some of the suggestions from the 2011 report on quality of care for mothers and newborns have not been followed, and still several areas for improvement in quality of care to women, babies and their families remain. The most important improvements needed are reported below.

- ▶ Still there are not single-patient **room dedicated to labour and delivery in most hospitals**. The option of having an active birth, with choice of position and freedom from restrictions in childbirth is still not in place.

- ▶ Some of the maternity **ward rooms** are narrow and overcrowded, which makes personal hygiene challenging and it is indeed a barrier to practicing rooming-in and breast feeding “on demand”.
- ▶ There is the need to monitor the **appropriateness of the indication to cesarean section**.
- ▶ Many **outdated harmful practices persist** (enema, pubic shaving, non vertical positions for delivery and Kristeller manoeuvre).
- ▶ **Companionship in labour** is either not allowed, or discouraged.
- ▶ The **nutrients for parenteral nutrition** for preterms babies are not always available (aminoacids and lipids) while literature underlines their importance for preterms babies below 1500g of weight.
- ▶ **Pain prevention, assessment and relief** in the sick newborn care are not performed, also in surgical cases. There is an urgent need of national guidelines about pain prevention and treatment for babies.
- ▶ Some outdated procedures like, for example, superficial swabs (cutaneous, auricular...) are still being performed because of Hospital regulation.
- ▶ National **guidelines** and protocols are missing in almost every field.
- ▶ With the exception of neonatal resuscitation there has been **any training session** for health professionals working in the hospitals.
- ▶ Clinical **record keeping is substandard** and data is not systematically analysed and used to develop solutions/recommendation to improve quality of care.
- ▶ The national **data collection system** could be modified to allow a more analytical analysis of the incidence of morbidity and complications in sub-groups of mothers and infants.
- ▶ **Audits** of clinical cases is not a practice.

7. RECOMMENDATIONS FOR IMPROVING THE QUALITY OF CARE

At each facility, specific recommendations were made, and an action plan to improve the quality of care for mothers and children, at local level, was drafted.

The main recommendations for future actions at national level from this mission are reported below.

- 1) This mission focused only on 3 maternities in Montenegro, so results of the assessment should not be generalized to the quality of care in all maternities in Montenegro. **It is now important to consolidate and support as much as possible the newly born “Montenegro’s National Perinatal Group”**. This team, which includes different professionals involved in perinatal care, should aim in the nearest future at assessing all the other maternity hospitals in Montenegro. This will then allow, at a national level, to properly **define the**

priorities that need addressing in perinatal care. Following this, the group will then have to decide on what actions to take, appoint someone responsible for the implementations, seek what resources are available, decide on a timescale and set out an appropriate monitoring program. The WHO CC could further technically support this process.

- 2) Montenegro's National Perinatal Group could also plan a series of updating activities and practical **trainings courses** that must reach out to all of the birthing facilities. Example of these updates could be: skills and drills in obstetric emergencies, care in normal labour, indications for caesarean section, breastfeeding, 'Low birth weight infants' care, and so on. The recently updated WHO "Effective Perinatal Care (EPC)" training package could be used for this purpose (19). The team of the WHO Collaborating Centre in Trieste could technically support these activities.
- 3) We also suggest consolidating a smaller working group with the aim of studying and then undertaking a formal **Auditing** activity on selected critical cases in both obstetrics and neonatology. The WHO manual '*Beyond the Numbers - Reviewing maternal deaths and complications to make pregnancy safer*' could help in this process (20).
- 4) **National guidelines need to developed.** We endeavor the identification and the progressive incorporation in daily clinical practice of evidenced-based international guidelines that can be adapted to Montenegro's health care system priorities and needs. Following this, there should be an activity to monitor their use in clinical practice.
- 5) We stress the importance of an agreed **national procedures for referral** when transferring high risk pregnancies and sick newborn to the main hospital in Podgorica. These procedures should have clear and standard shared forms which incorporates the cascade of interventions needed in each specific circumstance (i.e. stabilisation of patient prior to transfer, early recognition and initiation of necessary medications and treatment).
- 6) **Medical records** and any type of clinical documentation should be made available also to nurse and midwives. It would be helpful to develop a standard national format for recording medical information, including detailed information on diagnosis, treatment and monitoring.
- 7) We urgently suggest agreeing on a national guideline which specifies **appropriate indication for caesarean section** and then monitor its application. The Robson's classification of caesarean section indications might be used, with a regular data collection and analysis, both at national and facility level.
- 8) **Number of staff** in the single unit for intensive newborn care- unit were currently 800 newborns/year are managed, i.e. one out of nine of the 7000 newborns of Montenegro- needs to be increased. This is critical for the appropriate treatment of the most severe cases of sick neonates. In order to guarantee a shorter and more appropriate reaction time to emergencies, facilities should avoid the "on call" system for obstetric staff during night time and festivities; the presence of **specialized staff during night and week-ends** should be ensured in all hospitals.
- 9) With all this in mind it is crucial that the **role of the midwives** must be re-addressed and regulated at a national level. Midwives competencies, responsibilities and skills must be protected and enhanced in order to promote their autonomy as primary care givers for normal labour and birth.

- 10) It will be necessary, in the medium term, to rethink on how to **adapt spaces** available in the different facilities. We recommend setting up individual labour and birthing rooms, which allow for privacy and freedom of movement as well as companionship in labour. This would also allow mothers and father to care more independently for their baby, especially if the baby is sick or unwell.
- 11) **Pain prevention, assessment and relief**, especially for of sick infants and surgical cases, including both pharmacological therapy (including opioids) and non-pharmacological approach must be improved. We suggest to develop a guideline specific to this, to properly diffuse it, and to monitor its implementation.
- 12) We have indeed noticed that there are many places for hand washing which are well equipped and functioning (clean, soap available, “visual aids” present). This, however, is not enough to guarantee staff actually washing their hands correctly. We suggest implementing a mandatory “hand washing” workshop exercise, with regular updates. We also recommend a way of **monitoring compliance** with correct hand washing in order to effectively observe wherever good hand washing takes place or not. In order to achieve this the hospital’s management should identify staff responsible for collecting and monitoring data on nosocomial infection and to also monitor staff’s hand washing behaviors.
- 13) The national **data collection system** could be modified to allow every single hospital to independently collect its own statistics and analyze its own work. For example individual hospitals could look at the local caesarean section rate, together with the incidence of complications. Or, for example, in Newborn care it would be worthwhile combining gestational age or weight at birth, Apgar score and outcome while differentiating between babies born in the hospital where they are inpatients (“in-born”), with babies transferred from another facility (“out-born”), frequency of babies born with a diagnosed malformation, etc. There is a good example of this type of data collecting in the BABIES Matrix del CDC, Atlanta, USA (18).
- 14) Each hospital facility should start practicing an “**Audit**” activity in order to monitor its level of care and self identify areas of improvement.
- 15) More attention needs to be given in respecting human rights at childbirth. It’s in the **woman rights** to be involved in the process of care. It is her right to care for her own child and it is the child’s right to be cared for by its own mother and it is the father’s right to be involved in the care. In this regard, many of the new international recommendation in terms of de-medicalization of care to mothers and babies are well known by our Montenegrin colleagues. However, it will take time for these recommendations to become the norm and to be implemented by the majority of staff working in the Country’s hospital facilities. To give an example there seems to be a certain ‘cultural resistance’ to the presence of the women’s companion in the labour room. This indicates there is a need to not only educate the service users on the benefits of companionship in labour, but it needs to be understood and taken on board by the health professionals as well. Let’s not forget that WHO itself recommends “**companionship**” in labour as an “appropriate technology” to increase rate of spontaneous deliveries, enhance women experience and satisfaction and (perhaps mostly importantly) reduce operative delivers, including caesarean sections (and relative costs associated). Activities to enhance respect of human rights at childbirth may include: dissemination of **the charters on rights of women and newborn** (see references 21-24), organizing seminars and congresses on the subject. Follow up activities need to be put in place to ensure that progress is made in this field. Also please see the following WHO

paper on the subject: **'WHO Recommendations on health promotion interventions for Maternal and Newborn care' (25)**, which includes community participation to quality improvement processes.

- 16) The next challenge for Montenegro could be to achieve a **"Family Friendly" Perinatal Heath Service status**. This status is granted to services that provides safe and effective health care provision and that also answers the medical, social and psychological needs and expectations of the service users.

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ANNEX 1. AGENDA OF THE MISSION

Day #	Date	Activities	Place	Timeframe
1	17 Jan. 2016 (Sunday)	Arrival to Podgorica, MNE		
2	18 Jan	Workshop with the national team (Podgorica)	Ministry of health	09:00 – 17:00
3	19 Jan	Assessment of facility #1 (Podgorica)	KBC Crne Gore	09:00 – 17:00
4	20 Jan	Assessment of facility #1(Podgorica)	KBC Crne Gore	09:00 – 17:00
	21 Jan	Travel to Berane		07:00 – 09:30
5	21 Jan	Assessment of facility #2 (Berane)	General hospital Berane	10:00-17:00
6	22 Jan	Assessment of facility #2 (Berane)	General hospital Berane	09:00 – 17:00
	23 Jan	Travel to Niksic		07:30 – 08:30
7	23 Jan	Assessment of facility #3 (Niksic)	General hospital Niksic	09:00 – 17:00
8	24 Jan (Sun)	Day off		
	25 Jan	Travel to Niksic		07:30 – 08:30
9	25 Jan	Assessment of facility #3 (Niksic)	General hospital Niksic	09:00 – 17:00
10	26 Jan	Workshop within the team of international and national assessor (Podgorica)	Ministry of health	09:00 – 17:00
11	27 Jan. 2016 (Wednesday)	Final restitution meeting (Podgorica)	Ministry of health	10:00-12:00