Република Северна Македонија

Министерство за здравство

NATIONAL PERINATAL CARE MASTER PLAN

STRATIFIED MODEL OF OBSTETRIC AND NEWBORN CARE PROVISION

World Health Organization

Contents

Abbreviations

AC	**Abdominal circumference**
AIDS	Acquired Immunodeficiency Disease Syndrome
AKAZUM	Agency for Quality and Accreditation of Health Care Institutions
BMI	Body Mass Index
BW	Birth Weight
CCU	Critical Care Unit
CH	Clinical Hospital
CME	Continuous Medical Education
DCRZ	Drzaven Centar za Reproduktivno Zdravje
DRG	Diagnosis Related Groups
DVT	Deep Vein Thrombosis
ECG	Electrocardiography
EFW	Estimated Fetal Weight
EmONC	Emergency Obstetric and Neonatal Care
EU	European Union
GDP	Gross Domestic Product
GH	General Hospital
HCT	Hematocrit
HFA Database	Health for All Database
HIF	Health Insurance Fund
HIS	Health Information System
HIV	Human Immunodeficiency Virus
IPH	Institute for Public Health
LBW	Low Birth Weight
MALMED	Makedonska Agencija za Lekovi i Medicinski sredstva
MTHFR	Methylenetetrahydrofolate reductase
NCPAP	Nasal Continuous Positive Airway Pressure
NICU	Neonatal Intensive Care Unit

NUTS	Nomenclature of Territorial Units for Statistics
OECD	Organisation for Economic Co-operation and Development
P4P	Pay-for-Performance
PT	Prothrombin Time
PTT	Partial Thromboplastin Time
RDS	Respiratory Distress Syndrome
RH	Rhesus factor
RPR/VDRL	Rapid Plasma Reagin/Venereal Disease Research Laboratory
SCRH	State Center for Reproductive Health
SDG	Sustainable Development Goals
SEEHN	South Eastern European Health Network
SH	Specialized Hospital
SHGO	Specialized Hospital for Gynecology and Obstetrics
SMC	Safe Motherhood Commetee
SSO	State Statistical Office
TF	Task Force
UCGO	University Clinic for Gynecology and Obstetrics
UCCD	University Clinic for Children's Disease
UN	United Nations
UNFPA	United Nations Population Fund (Activities)
UNICEF	United Nations Children's Emergency Fund
VBAC	Vaginal birth after caesarean section
WHO	World Health Organization
WHO Euro	World Health Organization for Europe
WoRH	Women of Reproductive Age

Executive Summary

The focus of the global health agenda and worldwide efforts remains achieving the best possible outcomes for mothers and babies by all countries. These efforts have been catalyzed by the third goal of the 2030 sustainable development which affirms countries commitment to ensuring healthy lives and the promotion of well-being and survival for mothers and babies.

The Republic of North Macedonia declared strategic priority of country government for the next years to strengthen the health system and to fast-track progress towards improving maternal and newborn health outcomes and to accelerate path toward achieving ambitious targets of Sustainable Development Goal (SDG).

The Perinatal Care Master Plan is the conclusion of a combined effort by the Macedonian Ministry of Health and the World Health Organization in line with strategic priority. It provides consolidated set of analysis of current organization of perinatal care system across full spectrum of service delivery and prospective recommendations on improving maternal and neonatal health outcomes through establishment of risk-appropriate care, rationalization and optimization of maternal and newborn service provision with strong quality assurance system and respective health information support.

The Master Plan concentrates at key strategic areas which must be tackled in order to achieve the set goals:

- services delivery (includes service organization by levels of care, infrastructure, equipment, human resources, transport and referral system)
- quality of care and health information systems.

The Master Plan also encompasses the detailed Implementation Plan, which outlines the practical plan for transforming the recommended model into reality by converting them into gradual and realistic steps, whilst taking into account budgetary constrains, required resources, professional capacity and other factors potentially affecting (accelerating or hampering) implementation process.

I. Introduction. Country Context

1.1 Geography and population

The Republic of North Macedonia is a landlocked country situated in southeast Europe on the Balkan Peninsula. It covers an area of 25 713 square meters, with estimated east-west distance around 220 km and north-south - 160 km.
Topographically, it is mostly mountain terrain, specifically around the western border and in close proximity of the eastern border.

The road infrastructure is in phase of active reconstruction and improvement. The capital, Skopje, is located on the northern part, very central to the border with Serbia and Kosovo. The most distant towns on southwestern part of the country is Bitola (~ 171 km) and on southeastern part - Strumica (~ 149 km). The distance between the two is 175 km [1].

In general, due to the small size of the country, the distances between different geographic points are not very long considering transport of high risk pregnant women and sick newborns. Yet, due to the predominantly mountainous terrain, specifically on the western part of the country, with unfavorable road infrastructure and strict climate conditions in winter time, the fast and easy access to the health care institutions of the higher level of care can be challenged.

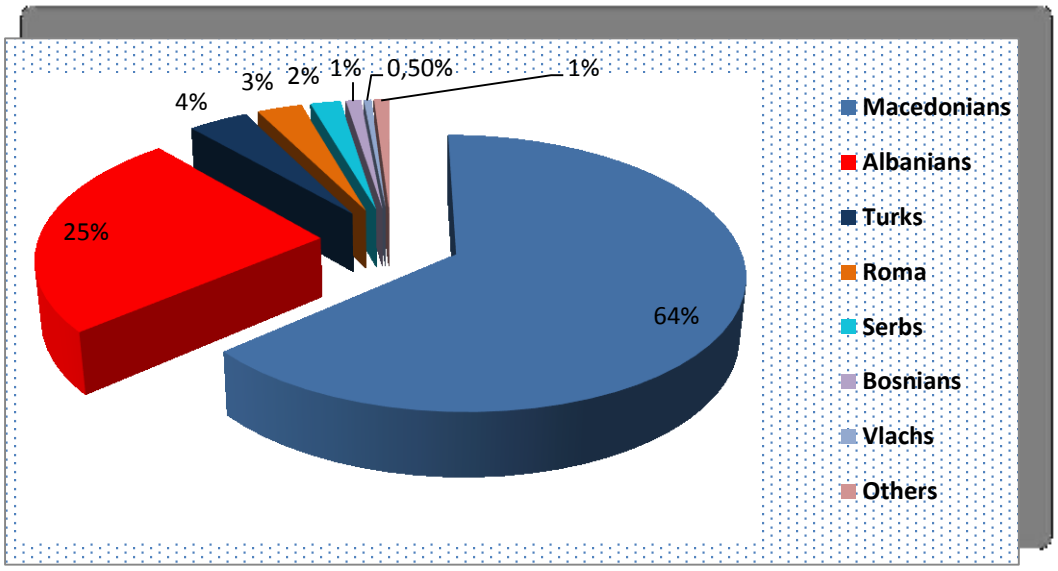
The Republic of North Macedonia adopted the Nomenclature of Territorial Units for Statistics (NTUS) in 2007, according to which the country is divided into 8 non-administrative regions (East, Northwest, Pelagonija, Polog, Skopje, Southeast, Southwest and Vardar). Administratively the Republic of North Macedonia unites 80 municipalities and the City of Skopje and 1733 villages [2].

According to the surface area, the largest region of North Macedonia is Pelagonia, yet with low density of population (50 inhabitants/km^2). The smallest region of the country is represented by Skopje which has a highest population density (~ 319 inhabitants/ km^2) and constitutes one fourth of country total population. The rural municipalities are present in all regions, though the majority of the population still resides in urban areas. The Polog and the Southwestern are regions with highest share of rural population.

Figure 1. Administrative map of the Republic of North Macedonia

The total population according to the State Statistical Office for 2018 is 2 077 132 inhabitants. The ethnic composition of the population is mixed with marked predominance of Macedonians and Albanians, 64% and 25% respectively (Figure 2) [3].

Figure 2: Ethnic composition of the Republic of North Macedonia



Source: State Statistical Office, 2003

No significant fluctuation in population size was observed during the last five years in the Republic of North Macedonia (Table 1) [3].

Table 1: Population of the Republic of North Macedonia in the last 5 years

Year	2014	2015	2016	2017	2018
Population	2,070,739	2,079,308	2,081,206	2,083,160	2,077,132

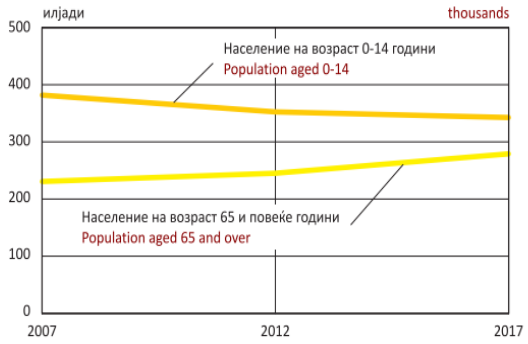
Source: State Statistical Office

Yet, population is experiencing a pronounced aging over the last decade (Figure 3a,b) [3]. Additionally, the increasing trend is observed in maternal age during the first birth (Figure 4a), which impacts both the fertility and natural growth of population along with pregnancy outcomes. Despite of increasing trend, the parameter is below the neighboring countries and EU average (Figure 4b) [4].

As expected, the Republic of North Macedonia is witnessing strong decline of natural increase and the total fertility rate (Figures 4,5). The documented fertility rate in 2017 of 1.43 births per woman is below the EU average (1.59 in 2017) and far below the replacement level (2.1) [4-6].

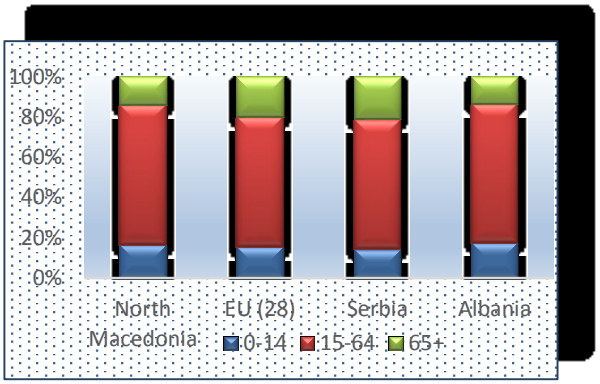
The described population dynamics have significant impact on the health system and are critical for projecting selected reproductive health indicators and for health planning purposes.

Figure 3a: Age structure of the population in the period 2007-2017, Republic of North Macedonia



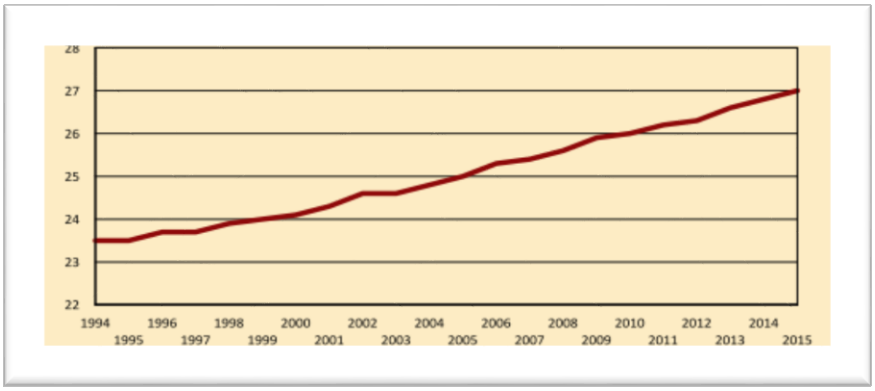
Source: State Statistical Office

Figure 3b. Age structure of the population in 2018, comparison with EU and neighboring countries



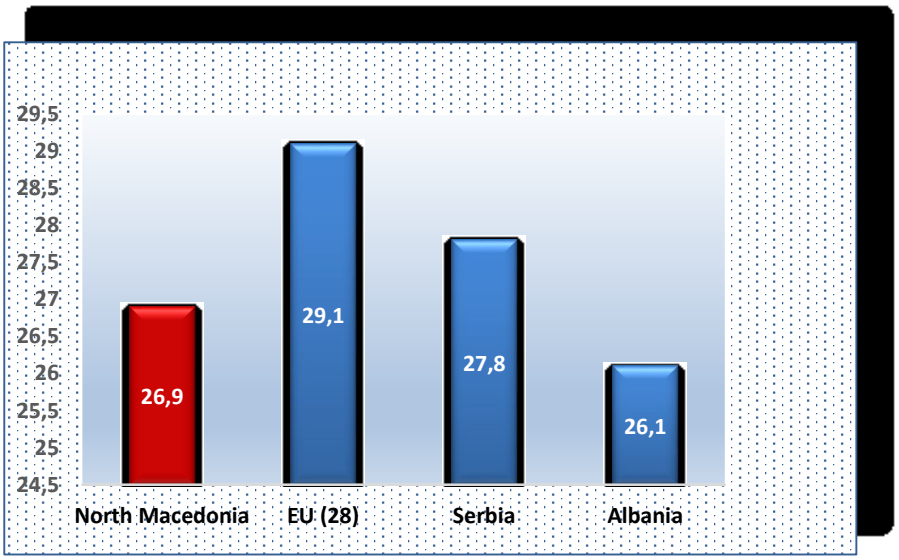
Source: WHO EURO. European Health Information Gateway (HFA database)

Figure 4a: Maternal mean age at the first birth, Republic of North Macedonia



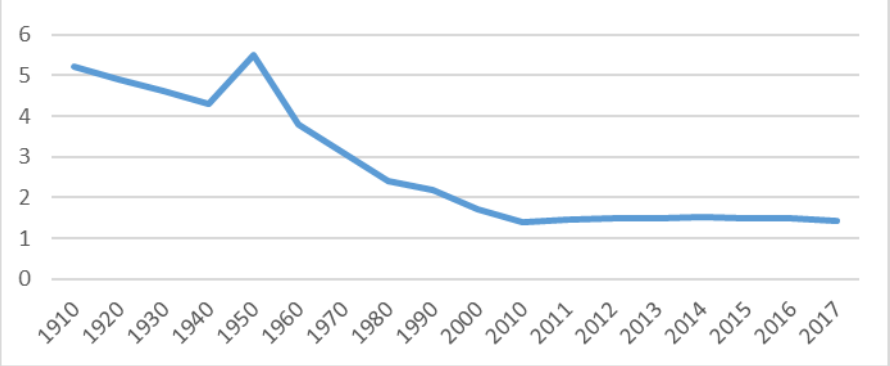
Source: State Statistical Office

Figure 4b: Maternal mean age at the first birth, comparison with EU and neighboring countries, 2017



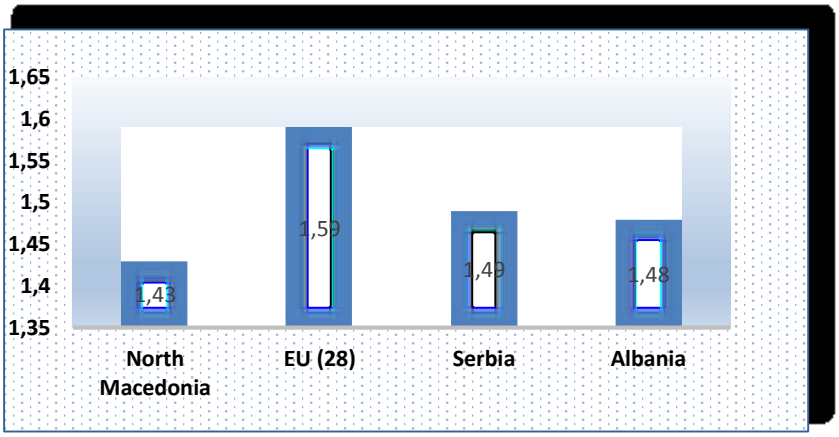
Source: WHO EURO. European Health Information Gateway (HFA database)

Figure 5a: Total fertility rate trend, Republic of North Macedonia (1910-2017)



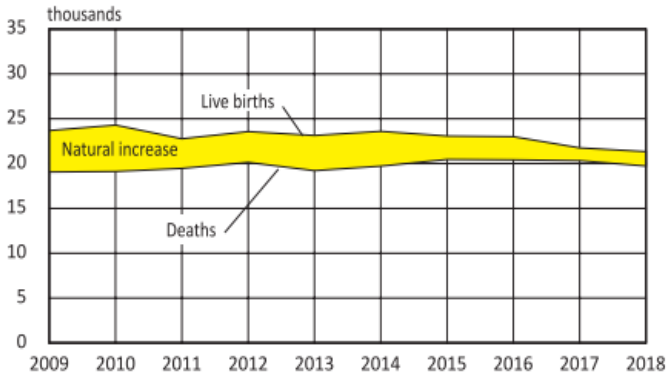
Source: State Statistical Office

Figure 5b: Total fertility rate, comparison with EU and neighboring countries, 2017



Source: WHO EURO. European Health Information Gateway (HFA database)

Figure 6: Natural growth trend (2008-2018)



Source: State Statistical Office

1.2. Health System in the Republic of North Macedonia

1.2.1 Organization and governance

The Republic of North Macedonia inherited a strong and well-established health care system with nationwide distribution of health service resources along with high financial accessibility ensured through the long experience of health insurance coverage.

Despite of the strong heritage, once a healthcare leader in the region, the country is now struggling to maintain its health care system at an average level and a good reputation. Similar to most post-socialistic countries, the Republic of North Macedonia is characterized by highly centralized health system with almost all key decisions made by the government and the Ministry of Health, without any input from the municipalities.

The health system of the country is regulated by two main laws: the Law on Health Care (1991 and the new Law on Health Care 2012, consolidated text 2016) [7] and the Law on Health Insurance (2000, consolidated text 2016) [8] through legislative, administrative and market mechanisms. The legislative power is vested in the parliament, while the administrative regulation is implemented through various permissions and licensing procedures of the Ministry of Health, the Agency for Medicines and Medical Aids (Agencija za lekovi i medicinski sredstva, MALMED) [9] and the Health Insurance Fund (HIF) [10].

The key institutions in the health care system are the Ministry of Health and the HIF. The Ministry of Health is primarily responsible for health policymaking, implementation and monitoring of these policies and enforcing health legislation. The HIF acts as an independent agency and purchaser of health services both from public and private health providers. It was established under the Health Insurance Law, adopted in 2000.

The new Law on Health Care in 2012 [7] raised further the leadership role of the Ministry of Health through establishing the Health Network - geographically equally distributed network of public and private providers of primary, secondary and tertiary health care services. The network aimed to improve health strategic planning and ensure equal distribution of health care resources throughout the country. The Ministry of Health issues certificate to both public and private health care providers for participating in Health Network. Importantly, only memebers of the Health Network are eligible for getting contract and being reimbursed by HIF.

All 21 health care institutions providing inpatient perinatal care services are certified by the Ministry of Health and are part of the Health Network.

The health care in the Republic of North Macedonia is relatively easily accessible (geographically, economically and time-wise) for the population, given that it is delivered within an equally widespread network of health care institutions. Around 90% of the population gets a health service in less than 30 minutes [11].

The general health service provision is organized around three levels of care: primary, secondary and tertiary [7]. Similar to many other countries, the system is oriented towards strengthening the primary health care as the basis of the system and "a gate keeper". Patients requiring higher level of care are referred by the primary health care provider to ambulatory-policlinic treatment or hospital treatment. The network of health care institutions at secondary level is widespread, with certain differences in terms of infrastructural capacity and availability of staff and equipment. Antenatal care is provided at the primary health care level, while intranatal care (both obstetric and neonatal) - at secondary and tertiary levels.

Despite the widespread network of different health care institutions, the system does not function as an integrated and coordinated one, services are often fragmented. The linkages are poor between antenatal and obstetric/neonatal care service providers. In fact, antenatal care is provided by obstetrician/gynecologist, working at primary care level, while obstetric and neonatal care - by obstetrician/gynecologist and pediatricians/neonatologists from secondary and tertiary level clinics and information flow is week among parties. Importantly, the current system of health care organization does not ensure risk-appropriate care which leads to inefficient utilization of resources and unfavorable health care outcomes.

1.2.2 Health financing

The Republic of North Macedonia experienced significant fall of health financing over the last decades. The total health expenditure as share of GDP dropped from 9% in 1990 to 6.5% in 2014, which is slightly below the EU 13 average (6.8%). Yet, the public sector health spending as a share of total health expenditure raised substantially up to 69.2% by 2013. The increasing trend reversed again and dropped to 63.3% in 2014, which is below the average of public spending in the EU13 (72.9% in 2014). The out-of-pocket expenditure mainly comprises of payments for private hospital services [12].

The State Health Insurance provides a broad spectrum basic benefit package, payed through HIF and covers almost all treatments and rehabilitation services, including full range of antenatal, obstetric and neonatal care from public health care institutions, members of the Health Network.

The DRGs system of reimbursement was introduced in the Republic of North Macedonia in 2009 and since that hospitals have been paid by a combination of DRGs and conditional budgets. Still, the DRGs system requires further refinement and strengthening [12].

The perinatal care services are financed through DRGs system and all the clinics providing obstetric and neonatal services are reimbursed with similar schemes according to the DRG code, except University Clinic for Obstetrics and Gynecology which in addition to the regular reimbursement by DRG code receives supplemental payment for complex and high-resource care for each obstetric/neonatal case managed in this hospital [13]. This payment mechanism has a significant implication for the overuse of the budgetary resources, given that the high-cost university clinic is overloaded with normal labor and deliveries from all over the country.

Ambulatory services, including antenatal care are reimbursed using capped fee-for-service payment principle. The antenatal care services are provided by primary health care ob/gyns, who receive capitation-based payment, yet for managing pregnancy cases PHC ob/gyns is reimbursed with increased capitation fee (63 MKD according to the latest modification) [14].

The pay-for-performance (P4P) system was introduced in the Republic of North Macedonia in 2012. Yet, it was mainly used as a remuneration scheme and did not serve primary purpose of improving the quality of health care services [12]. In the field of perinatal care the system targets ambulatory care services, providing outpatient antenatal care yet the performance goals set are mostly administrative, not reflective of actual quality of antenatal care.

1.2.3 Maternal and newborn health

The health and wellbeing of the mothers, infants and children has long been prioritized and is in the heart of several strategic initiatives undertaken by the government of the Republic of North Macedonia.

Committed to uphold the decreasing trends in maternal and infant mortality in the country, the Ministry of Health, urged by a series of incidental maternal deaths in 2009, endorsed a Safe Motherhood Strategy for the period 2010–2015 [15], in cooperation with the United Nations Children's Emergency Fund (UNICEF, 2013). The Strategy addressed four key periods of motherhood - preconception, antenatal, intranatal and postnatal care, and incorporated targeted actions for adolescents, women of reproductive age, newborns and

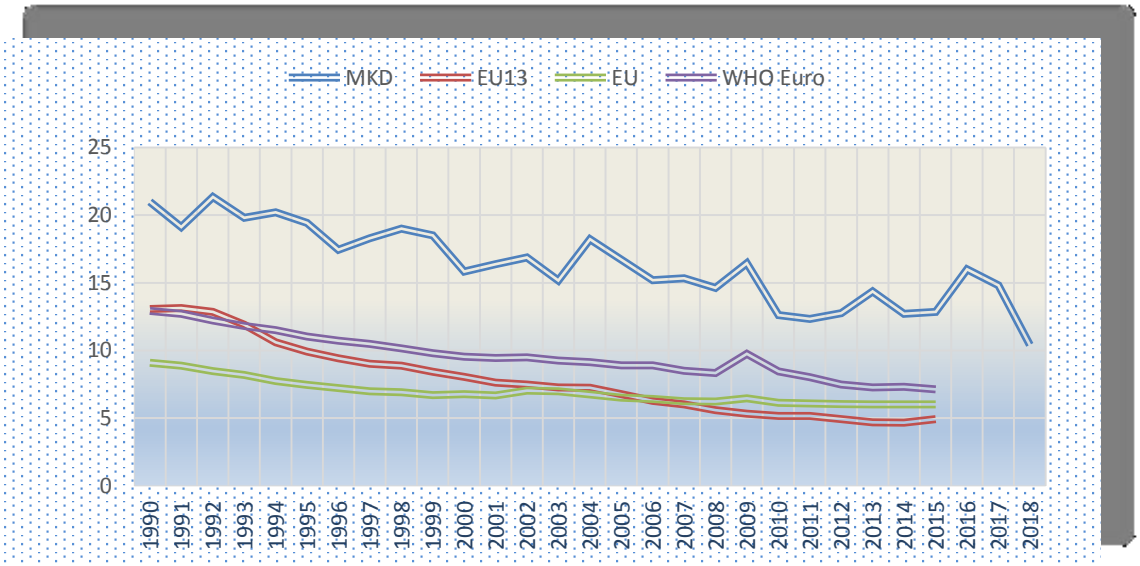
infants. The Strategy comprehensively envisioned development of respective clinical guidelines/protocols, upgrade of educational programs at medical institutions and nursing colleges, and establishment of continuous medical education system for medical personnel of community nursing units and maternity wards nationwide. Importantly, to respond proactively to the strategy aims and objectives, the Ministry of Health raised the funding for preventive programs in maternal and child health by as much as 50% in 2011 [16].

Simultaneously, the Ministry of Health initiated development of the National Strategy on Sexual and Reproductive Health that was enacted in 2009 for the period 2010–2020 [17]. With financial support from the United Nations Children's Emergency Fund and United Nations Population Fund, the Strategy was developed by an interdisciplinary team of representatives of the Ministry of Health and civil society organizations, and with contribution from other line ministries and agencies, including Ministry of Labour and Social Policy, Ministry of Education and Science, Ministry of Local Self-Government, Agency for Youth and Sports, and the Health Insurance Fund.

As a result of the concerted efforts of country government and donor organizations, bilateral and multilateral agencies, the Republic of North Macedonia witnessed sound progress toward improving perinatal care indicators. The positive trend was specifically pronounced until 2015.

The perinatal mortality decreased from 21/1000 live birth in 1990 to 12.8/ 1000 live birth in 2015, then increased to 16/1000 livebirth in 2016 and fall again to 10.4/1000 livebirth in 2018(Figure 7) [18]. The country is still behind the EU average of 6/1000 livebirth and EU13 average of 5/1000 livebirth along with WHO EURO average of 7/ per 1000 live births (2010) [4].

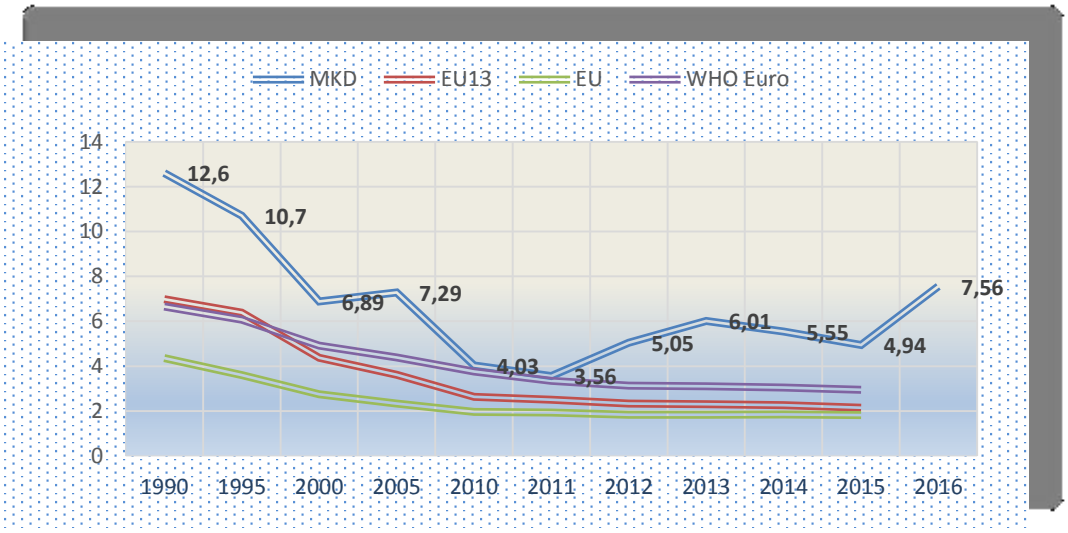
Figure 7: Perinatal mortality trend (per 1000 live birth)



Source: WHO EURO. European Health Information Gateway (HFA database)

The positive trend was also observed in early neonatal mortality indicator. The rate declined sharply from being 12.6 /1000 livebirth in 1990 to 3.5/1000 livebirths in 2010, almost reaching the WHO EURO average of 3.35/1000 livebirth. It remained somewhat stable until 2015 and increased again to 7.6/1000 livebirths in 2016 (Figure 8)[19]. Yet, the accuracy of the perinatal and neonatal mortality statistics is questionable and may not be reflective of actual number of mortality cases.

Figure 8: Neonatal mortality trend (per 1000 livebirth)



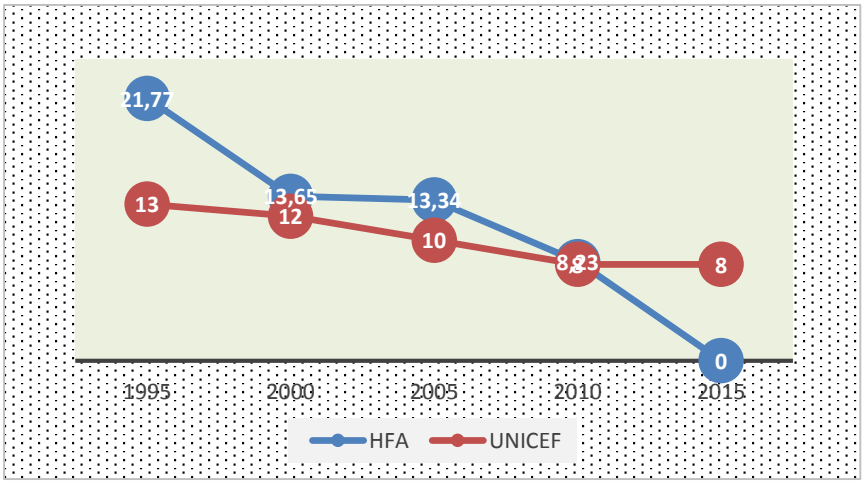
Source: The world Bank IBRD IDA

Maternal mortality statistics in the country is even more debatable, characterized by a significant level of inaccuracy, under-reporting and under-recording due to the misclassification. According to the official statistics and WHO Health For All Database, there were no cases of maternal mortality documented in the Republic of North Macedonia during the recent years (since 2010) [20]. Yet, immaturity of maternal mortality registration and cause-of-death ascertainment system suggests limited ability of the country both to count and correctly classify the causes of maternal death. Additionally, there is significant discrepancy in maternal mortality statistics by different sources.

The routine maternal mortality audit system is in the process of establishment with the initiative from the Ministry of Health and technical support from the WHO EURO and UNFPA. The

comprehensive system intends to contribute significantly to improvement of maternal mortality statistics in the country along with overall improvement of the quality of perinatal care.

Figure 9: Maternal Mortality rate (per 1000 000 livebirth) by different sources



/

Sources: WHO, European Health for all database,
UNICEF Data: Monitoring the situation of children and women

In general, the tangible progress has been observed in perinatal care indicators during the last decades which derive from consolidated efforts and investments from government and international donor assistance programs toward improving maternal and infant health in the country. Yet, some downward trend remained constant or reversed since 2015, which alarmed both health professionals and the government of the Republic of North Macedonia and underscored the needs for implementing rapid and effective reforms for strengthening further the perinatal care service provision in the country to facilitate the achievement of best possible outcomes.

The proposed Master Plan provides in-depth analysis of current organization of perinatal care system across diverse channels of service delivery and suggests tangible and feasible recommendations on reorganization of existing system based on the well-established successful model of other countries, adjusted to the local specific. The reform intends to ensure that each pregnant woman and newborn have access to health care facilities with capacity to provide high quality, safe and effective care in line with their specific health care needs, which will eventually accelerate path toward sustainable improvement of maternal and newborn health outcomes in the Republic of North Macedonia.

II. Master Plan Goal

Improve maternal and neonatal health outcomes through development of comprehensive model of perinatal care service delivery with strong quality control and health information system.

III. Perinatal Care Service Delivery – Current Organization

3.1 Antenatal care. Primary Health Care gynecologists

Antenatal care services in the Republic of North Macedonia are provided through the extensive network of Primary Health Care gynecologists (PHC gynecologists). With the reform of primary health care between 2005 and 2007, PHC gynecologists along with general practitioners of medicine, dentistry and pediatricians have been privatized and since then operate as private entities [12].

PHC gynecologists organize their work in either single or group practices. Yet, each PHC gynecologist is mandated by law to be associated with a medical nurse to form a medical team. The PHC gynecologists provide their services in area they choose, not necessarily linked with hospitals [7-8].

All PHC gynecologists, which deliver antenatal care services under government health insurance are obliged to contract with the HIF. This contract is based on a blended capitation model. According to the model, each PHC ob/gyn has a number of registered patients for which the capitation payment is applied [12].

The Republic of North Macedonia practices a free choice of PHC gynecologists by patients, except for patients under the age of 14 for whom parents take on this right and obligation. In addition to the free choice, patients can change their physician without providing relevant justification. Yet, the number of changes of primary care physician is limited to two per year.

There are 153 PHC gynecologists contracted by the HIF [[21]. The geographic distribution of PHC gynecologists is disproportional.

According to the data provided by HIF, the distribution of PHC gynecologists among municipalities of the Republic of North Macedonia is reflected in Table 2 [21]:

The average number of women per PHC gynecologists is not similar among regions and ranges from 2614 to 5022. Lowest average is documented in Skopje region (2614/PHC gynecologist) reflective of highest number of PHC gynecologists accumulated in Skopje. In contrast, the highest average is observed in Polog region (5022/PHC gynecologist) with only two municipalities having the PHC gynecologist.

Highly disproportional is average distribution of women/PHC gynecologist among municipalities. The lowest average was documented in Vinitsa with 186 women per PHC gynecologist and Veles, where 6 PHC gynecologists take care for only 1639 women (average 273/PHC gynecologist). Contrary, the highest average was documented in municipality Tetovo, where 8 gynecologists serve as much as 42056 women (average 5257/PHC gynecologist).

Interestingly, the data also shows that the choice of PHC gynecologists is not solely based on the geographically close location. Number of patients enrolled in PHC gynecologist's capitation is not proportional to the number of women of reproductive age in that municipality. In some municipalities PHC gynecologist has much lower number of patients compared to the number of women of reproductive age in the area they serve. For instance, in municipality Vinitsa, there is one PHC ob/gyn, serving 186 patients, which constitutes only 4% of women of reproductive age in that municipality (4663). Yet, in nearby municipalities (Delchevo, Berovo), PHC ob/gyns serve twice the number of women of reproductive age of their municipalities (220% and 200% respectively). The observed trend may be indicative of the raised choice of some PHC gynecologists due to their higher competence and quality of care provided and may lead to disproportional and inefficient utilization of existing resources (Table 2).

Table 2: Distribution of PHC gynecologists by municipalities/regions.

Region	Municipality	Women of reproduct. age (WoRA)	PHC gyn. #	Patients #	Patient / WoRA %	Patients / PHC gyn

Vardar Region	Veles	12304	6	1639	13.3%	273
	Gradsko	777				
	Demir Kapija	822				
	Kavadartsi	8871	4	17511	197.4%	4378
	Lozovo	494				
	Negotino	4473	2	4556	101.9%	2278
	Rosoman	895				
	Sveti Nikole	3827	1	4564	119.3%	4564
	Chashka	1784				
Total in Vardar R		**34247**	**13**	**26631**	**77.8%**	**2873 (Av)**
Eastern Region (ER)	Berovo	2743	2	5488	200.1%	2744
	Vinitsa	4663	1	186	4.0%	186
	Delchevo	3542	2	7806	220.4%	3903
	Zrnovtsi	670				
	Karbintsi	926				
	Kochani	8820	5	15725	178.3%	3145
	Makedonska Kamenitsa	1738				
	Pehchevo	1059				
	Probishtip	3194	1	3019	94.5%	3019
	Cheshinovo - Obleshevo	1422				
	Shtip	11372	5	15745	138.5%	3149
Total in ER		**40149**	**16**	**47969**	119.5%	**2680 (Av)**
Southwestern Region (SWR)	Vevchani	553				
	Debar	5587	3	6866	122.9%	2289
	Debartsa	819				
	Kichevo	15186	4	14981	98.7%	3745
	Makedonski Brod	1210				
	Ohrid	12261	4	15049	122.7%	3762
	Plasnitsa	1326				
	Struga	18267	6	17033	93.2%	2839
	Centar Zhupa	2201				
Total in SWR		**57410**	**17**	**53929**	93.9%	**3158 (Av)**
Southeastern Region (SER)	Bogdantsi	1758				
	Bosilovo	3241				
	Valandovo	2609	1	536	20.5%	536
	Vasilevo	3121				
	Gevgelija	5080	2	7006	137.9%	3503
	Dojran	750				
	Konche	810				
	Novo Selo	2498				
	Radovish	6909	3	5953	86.2%	1984
	Strumitsa	13504	5	22511	166.7%	4502
Total in SER		**40280**	**11**	**36006**	89.4%	**2631 (Av)**

Pelagonia Region	Bitola	21128	8	22187	105.0%	2773
	Demir Hisar	1610				
	Dolneni	3348				
	Krivogashtani	1218				
	Krushevo	2035				
	Mogila	1253				
	Novatsi	614				
	Prilep	16849	4	18882	112.1%	4721
	Resen	3525	2	3898	110.6%	1949
Total in PR		**51580**	**14**	**44967**	87.2%	**3148 (Av)**
Polog Region	Bogovinje	8485				
	Brvenitsa	4517				
	Vrapchishte	7767				
	Gostivar	23205	5	23934	103.1%	4787
	Zhelino	8056				
	Jegunovce	2662				
	Mavrovo i Rostusha	2472				
	Teartse	5977				
	Tetovo	23999	8	42056	175.2%	5257
Total in PR		**87140**	**13**	**65990**	75.7%	**5022 (Av)**
Northeastern Region (NER)	Kratovo	1873	1	2913	155.5%	2913
	Kriva Palanka	4233	2	8259	195.1%	4130
	Kumanovo	27139	8	31167	114.8%	3896
	Lipkovo	8131				
	Ramkovtse	748				
	Staro Nagorichane	752				
Total in NER		**42876**	**11**	**42339**	98.7%	**3646 (Av)**
Skopje Region	Aerodrom	168346	58	151635	90.1%	2614
	Arachinovo					
	Butel					
	Gazi Baba					
	Gjorche Petrov					
	Zelenikovo					
	Ilinden					
	Karposh					
	Kisela Voda					
	Petrovets					
	Saraj					
	Sopishte					
	Studenichani					
	Centar					
	Chair					
	Chucher – Sandevo					
	Shuto Orizari					

Total in SR		**168346**	**58**	**151635**	90.1%	**2614**
Total in MKD		**522028**	**153**	**492 354**	**94.3%**	**3 218**

The blended capitation model of gynecologists includes fixed and variable components of the capitation. The structure of the capitation is made of 70% fixed amount of payment and 30% variable amount for the achievement of performance targets set as part of the P4P scheme. The realization of the preventive services is evaluated on an annual basis. The performance targets for the PHC gynecologists include [8]:

- Rational use and prescription of the medications recommended by the HIF
- Number of sick-leaves prescription issued by the PHC gynecologist
- Number/proportion of preventive screenings (PAP-tests) performed
- Number/proportion of microbiological examinations for pregnant women performed at 12-30 weeks of gestation
- Number/proportion of colposcopic examination as a prevention of malignant genital diseases.

None of these performance targets measures actual quality of antenatal care service delivery. It is highly recommended to include some critical ANC quality indicators in PHC gynecologist's performance targets, which will allow tracking individual performance of PHC gynecologists in provision of ANC services, identification of gaps and planning of corrective measures accordingly.

Since September 2018, the new regulation was endorsed, according to which the value of capitation for antenatal care services was determined to be higher compared to the regular capitation of PHC gynecological services of non-pregnant women (the value of the capitation point amounts 63 MKD starting from October, 2019) [10]. Despite of endorsed new regulation, the PHC gynecologists still are not getting an increased capitation payment for pregnancy management.

Adjustment of the coefficient aimed to compensate for potential higher volume of services to be provided by PHC gynecologists for pregnant women. The higher volume of antenatal care services is further raised by established practice of unlimited utilization of ANC services by pregnant women. The capitation payment covers unlimited number of ANC visits pregnant woman may wish to perform and as such, is not related with additional burden to the HIF [22]. Yet, the lab and other diagnostic services are payed additionally by

the HIF and therefore, if performed without justified medical needs may lead to irrational utilization of existing resources not necessarily linked to better pregnancy outcomes.
It is recommended to rationalize the number and content of ANC visits in line with WHO most recent recommendations on antenatal care for a positive pregnancy experience.

The information on antenatal care visits is entered by PHC gynecologists in so called "maternity books", which in most of the cases is a paper-based document [23]. Despite of the fact that there is a maternity module incorporated into the electronic system "Moj Termin", still the data on antenatal care is not entered into the system. Hence, there is a very week information flow among primary and secondary care antenatal and obstetric care providers, which hampers the process of continuity of care. It is imperative to improve the recording system for antenatal care and transit from paper-based recording to the unified electronic system, which ensures smooth information flow and access to the medical information for different level health care professionals.

Points of strength

- Widespread network of PHC gynecologists providing ANC - high geographic access;
- Full financial coverage of ANC by HIF;
- National clinical protocol on ANC available, updated according to the latest WHO recommendation;
- Health Information System Moj Termin encompasses electronic module on antenatal care;
- Performance based payment system (P4P) on place.

Points of weakness

⇒ Disproportional and inefficient utilization of PHC human resources: wide range of capitation attached to the PHC gynecologists (from 186 to 4663), not proportional to the number of women in municipality;

⇒ Pay for Performance – not operational. None of the performance targets measures actual quality of antenatal care service delivery;

⇒ ANC practices not in line with national protocol and WHO recommendations;

⇒ Poor ANC documentation, limited to paper-based recording, no information entered into the e-health system - impedes information flow/exchange, data analyses and continuity of care.

Key recommendations

⇒ Raise the competence of PHC gynaecologists up to the standards. Update the skills and knowledge of PHC gynaecologists on ANC and principles of risk-appropriate care;

⇒ Rationalize the number and content of ANC visits in line with WHO recommendations and create mechanisms for making it operational (link with HIF financing scheme);

⇒ Include key ANC quality indicators in PHC gynaecologists' performance targets, to track individual performance of PHC gynaecologists in provision of ANC services;;

⇒ Improve the electronic recording system for antenatal care, strengthen the legislative framework, mandate transition from paper-based recording to the unified electronic system to ensure smooth information flow and access to the medical information for different level health care professionals. Link quality data entry with P4P. Use network quality collaboratives to improve recording system.

3.2 Clinics with perinatal care services

3.2.1 Types of clinics, geographic distribution

According to the Health Protection Law, and its last modification in 2016 [7], there are four categories of hospitals in the country, providing in-patient care for all health care fields, including the care for mothers and their babies:

- General Hospitals
- Clinical Hospitals
- Specialized Hospitals
- University Hospital

The hospital categories diverge by their capacity (determined by infrastructure, number and proficiency of human resources, availability of equipment and supplies capacity) and by the complexity of care provided. Both the capacity and complexity of care raises exponentially from general hospital, having the most limited capacity and providing basic care, to clinical or specialized hospital, dealing with complicated cases, yet not requiring multidisciplinary involvement and university hospitals with most advanced capacity and complex care provided.

The health network determines types of health care services provided in certain geographic areas, physical and human resources and hospital bed stock as well as type and amount of medical equipment and diagnostic services for each category of hospitals.

The Ministry of Health has an authority to certify and assign a specific category to the hospitals, based on their capacity, geographic location, population served etc. Certified by the Ministry of Health hospitals are contracted by the Health Insurance Fund [12].

Additionally, the Agency for Quality and Accreditation of Health Care Institutions is mandated to provide accreditation to the hospitals based on predefined standards of quality. Yet, the accreditation process is still infantile, without core principals and mechanisms for external quality assurance being operational (Chapter 5.1).

Clinics with perinatal care services

By 2019, in-patient perinatal care services for mothers and babies were provided by 21 hospitals in the Republic of North Macedonia. The largest share of facilities with perinatal services is represented by general hospitals (13 clinics), followed by clinical hospitals (4 clinics), specialized hospitals (3 clinics) and one university hospital (one clinic), which

provides tertiary level care for both mothers and newborns (Figure 10a). Somewhat different is distribution of deliveries by type of hospital with much lower share of deliveries managed in general hospitals (33% vs 62%) [24].

Importantly only one tertiary level hospital manages as much as 22% of country deliveries (Figure 10b), pinpointing significant overload of tertiary level hospital with normal deliveries.

Figure 10a: Distribution of hospitals with perinatal services by type of hospital

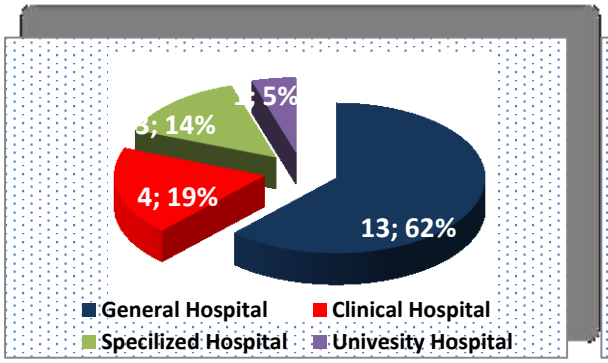
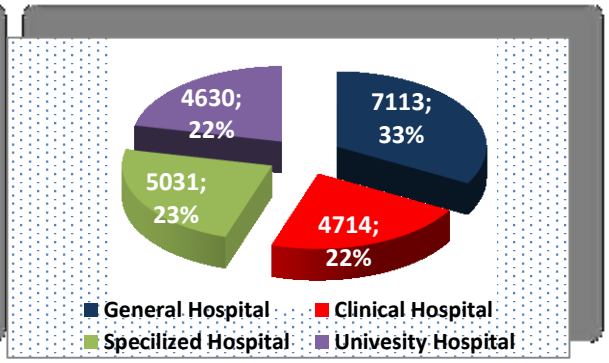


Figure 10b: Distribution of deliveries by type of hospital

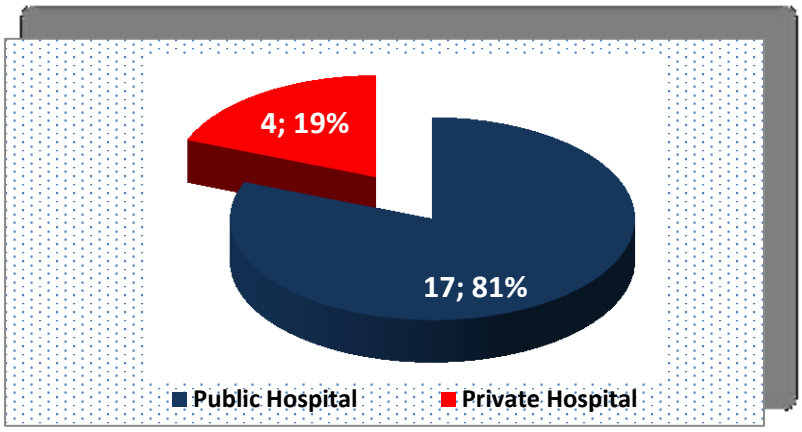


University clinic has large operational neonatal intensive care unit (NICU) with 11 intensive, 11 intermediate and 15 continuous care beds. Additionally, there is one more University Clinic for Children's Disease (UCCD) in Skopje, providing care to the newborns with most complicated health care needs. The UCCD's NICU department encompasses 12 intensive, 0 intermediate and 4 continuous care beds. The UCCD is the only health care facility which accepts external newborn referrals from all over the country.

The NICU department is also operational at the private clinic in Skopje – Sistina, which provides complex care for newborns, yet, the expensive services are not covered by the HIF and are fully reimbursable by families.

Most hospitals providing inpatient care for mothers and babies are publicly owned. Only four hospitals are in private ownership, one general, one clinical hospital and two specialized hospitals (Figure 11).

Figure 11: Distribution of hospitals with perinatal services by type of ownership



The facilities with perinatal services (perinatal care clinics) are relatively proportionally redistributed throughout the country to ensure geographic access to at least basic perinatal care services within 40-60 min of drive from any location of the country. Yet, Skopje has the highest concentration of perinatal care facilities, providing most complex obstetric and neonatal care. The distribution of hospitals by geographic regions and type of ownership is presented in Table 3.

Table 3: Distribution of hospitals by geographic regions, type of hospital and ownership

Region	PC facilities	Type of hospital	Type of ownership
Vardar	Veles	General Hospital	Public
	Kavadarci	General Hospital	Public
Eastern Region	Shtip	Clinical Hospital	Public
	Kochani	General Hospital	Public
Southwestern Region	Debar	General Hospital	Public
	Kichevo	General Hospital	Public
	Ohrid	General Hospital	Public
	Struga	General Hospital	Public
Southwestern Region	Gevgelija	General Hospital	Public
	Strumica	General Hospital	Public
Pelagonia Region	Bitola	Clinical Hospital	Public
	Prilep	General Hospital	Public

	Plodnost	Specialized Hospital	Private
Polog Region	Tetovo	Clinical Hospital	Public
	Gostivar	General Hospital	Public
Northeastern Region	Kumanovo	General Hospital	Public
Skopje Region	UCGO	University Clinic	Public
	SHGO	Specialized Hospital	Public
	Remedica	General Hospital	Private
	Sistina	Clinic Hospital	Private
	Sante Plus	Specialized Hospital	Private

UCGO - University Clinic for Gynecology and Obstetrics
SHGO - *Specialized Hospital of Gynecology and Obstetrics*

There were totally 21 488 deliveries in the Republic of North Macedonia in 2018. The average number of perinatal care clinics per 10 000 deliveries amounts 9.8, which is adequate compared with other countries of the region (Table 4) [25]. Relatively low is the number of tertiary level perinatal care facilities per 10 000 deliveries.

Table 4: Total number of perinatal care facilities per 10 000 deliveries

Country	BE	DK	FR	GE	IT	PL	PO	GEO	RNM
PC facilities	12.3	4.0	5.5	14.3	11.6	12.4	5.2	16.8	**9.8**
Level III facilities	1.3	0.6	0.8	1.9	2.2	0.2	2.3	1	**0.5**

The distribution of the clinics by deliveries in municipality area is not proportional. Highest density of clinics is documented in Southwestern and Vardar regions and the lowest ones in Northwestern and Polog regions (Table 5).

Table 5: Perinatal care facilities per 10 000 deliveries per geographic region

Region	# of perinatal care facilities	# of deliveries in region	Perinatal care facilities per 10000 deliveries

Vardar	2	905	22.1
Eastern Region	2	1047	19.1
Southwestern Region	4	1487	26.9
Southeastern Region	2	1153	17.3
Pelagonia Region	3	2002	15.0
Polog Region	2	2407	8.3
Northeastern Region	1	1251	8.0
Skopje Region	5	11236	4.4

3.2.2 Load of deliveries

The load of deliveries in perinatal care facilities represents key indicator that describes the workload of the hospital and medical personal, and ensures maintenance and enhancement of professional competence.

The total 21 488 deliveries which occurred in the Republic of North Macedonia in 2018 were not proportionally distributed among different regions and perinatal care clinics (Table 6) [24]. The load of deliveries among perinatal care facilities ranged drastically from 21 (Debar) to 4630 (University Clinic for Gynecology and Obstetrics (UCGO). Out of twenty one hospitals providing childbirth services only six (29%) have annual deliveries over 1000 women, which is purportedly the low threshold of deliveries required for maintenance of professional competence. As much as seven hospitals (33%) have annual number of deliveries even lower than 500 women, which questions accomplishment of adequate clinical expertise, quality of care and optimal organization of work in these facilities.

Table 6: Per-facility load of deliveries, 2018

Region	PC facilities	Type of hospital	Load of deliveries in 2018
Vardar	Veles	General Hospital	505
	Kavadarci	General Hospital	400
Eastern Region	Shtip	Clinical Hospital	878

	Kochani	General Hospital	169
Southwestern Region	Debar	General Hospital	21
	Kichevo	General Hospital	218
	Ohrid	General Hospital	481
	Struga	General Hospital	767
Southeastern Region	Gevgelija	General Hospital	140
	Strumica	General Hospital	1013
Pelagonia Region	Bitola	Clinical Hospital	765
	Prilep	General Hospital	720
	Plodnost	Specialized Hospital	517
Polog Region	Tetovo	Clinical Hospital	1734
	Gostivar	General Hospital	673
Northeastern Region	Kumanovo	General Hospital	1251
Skopje Region	UCGO	University Clinic	4630
	SHGO	Specialized Hospital	4132
	Remedica	General Hospital	755
	Sistina	Clinical Hospital	1337
	Sante plus	Specialized Hospital	382
Total			**21 488**

As was already mentioned, there is only one tertiary level hospital in the country, which manages as much as 22% of country deliveries (Figure 10b). The fact is indicative of significant overload of tertiary level hospital with normal deliveries and underutilization of other, regional clinics.

There may be two potential reasons responsible for the observed trend. First of all, there is a free choice of the clinics for women, as such women give preference to the stronger facility with higher capacity. The observation is proved by highly disproportional distribution of municipality deliveries vs facility deliveries (Chapter 3.2.3).

On the other hand, there is no clear criteria and obligation for the lower level regional facilities to manage certain complicated obstetric/neonatal cases. Hence, even mild complications, which can be managed locally, become subject for referral.

There is a burning need to strengthen the capacity of regional clinics to attract more women and reduce burden on university hospital and also to establish the clear criteria of obstetric and neonatal cases which needs to be managed at each level of hospital with strong monitoring system on place to control adherence to the established criteria and performed referrals.

Distribution of deliveries by gestational age

Deliveries at the low gestational age are associated with significantly increased risk of morbidity and/or mortality for the babies unless the strong resources (both human and technical) are on place for provision of high quality comprehensive and advanced care. Distribution of deliveries by gestational age in Macedonia shows that the high-risk deliveries

for low gestational age (<34 weeks of gestation) happens in clinical hospitals along with specialized clinics and even sometimes in general hospitals with a very limited resources and thus not appropriate for providing needed advanced care (Table 7) [24].

Table 7: Deliveries in public hospitals by gestational age and type of hospital, 2018*

Type of hospital	Hospital name	Gestational week group				
		22-28	29-33	34-36	37+	Total
General Hospitals	**Total**	**7**	**24**	**172**	**6155**	**6358**
General Hospital	Gostivar		4	7	662	673
General Hospital	Kichevo			2	216	218
General Hospital	Kumanovo		4	29	1218	1251
General Hospital	Ohrid	1	1	31	448	481
General Hospital	Prilep	2	5	27	686	720
General Hospital	Struga	2	4	15	746	767
General Hospital	Strumica		1	34	978	1013
General Hospital	Veles		1	14	490	505
General Hospital	Kocani			5	164	169
General Hospital	Debar		1		20	21
General Hospital	Gevgelija		2	2	136	140
General Hospital	Kavadarci	2	1	6	391	400
Specialized Hospitals	**Total**	**4**	**11**	**134**	**3983**	**4132**
Specialized Hospital	Gynecology and Obstetrics Chair	4	11	134	3983	4132
Clinical Hospitals	**Total**	**7**	**16**	**98**	**3256**	**3377**
Clinical Hospital	Bitola	1	5	23	736	765
Clinical Hospital	Shtip	2	6	16	854	878
Clinical Hospital	Tetovo	4	5	59	1666	1734
University Clinic	**Total**	**153**	**354**	**458**	**3665**	**4630**
University Clinic	Gyn.-gy & Obst.	153	354	458	3665	4630

**The data disaggregated by gestational age are available only from public clinics*
< 34 weeks of gestation babies, which were not delivered at tertiary level university clinic

Totally 12% of babies delivered before 34 weeks of gestation were not born at the tertiary level hospitals with full-blown NICU, which is not significantly higher compared with expected normal statistics globally. Yet, these babies are at increased risk in the Republic of North Macedonia under the circumstances when the newborn transport system is very weak and inadequate in the country (Chapter 3.5).

3.2.3 Facility deliveries vs municipality deliveries

Importantly, deliveries in perinatal care facilities are not always proportional to the deliveries in municipality area, meaning that women are not exclusively guided by advantage of geographically close location in choosing the delivery clinic. Sometimes they prioritize distant perinatal care facilities, which have stronger capacity and provide better quality care. This tendency results in inefficient utilization of existing resources and unwelcomed overload of some of the facilities and underload of others (Table 8) [24].

Table 8: Deliveries in perinatal care facility vs. municipality area

Region	PC facilities	Type of hospital	Delivery in municipality area	Delivery in hospital
Vardar	Veles	GH	600	505
	Kavadarci	GH	309	400
Eastern Region	Shtip	CH	390	878
	Kochani	GH	309	169
Southwestern Region	Debar	GH	179	21
	Kichevo	GH	375	218
	Ohrid	GH	457	481
	Struga	GH	590	767
Southwestern Region	Gevgelija	GH	205	140
	Strumica	GH	553	1013
	Bitola	GH		765

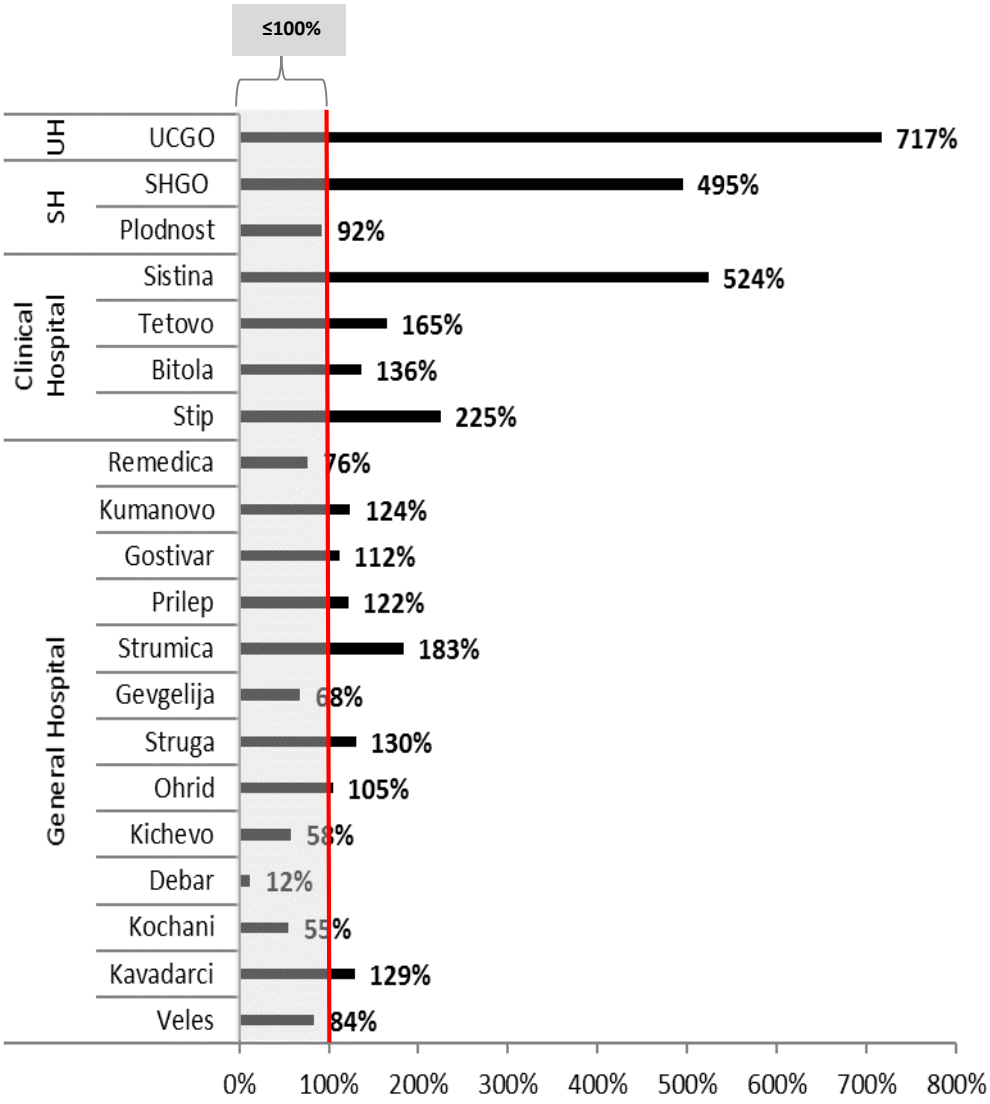
Pelagonia Region	Plodnost	SH	563	517
	Prilep	GH	592	720
Polog Region	Tetovo	GH	1052	1734
	Gostivar	GH	603	673
Northeastern Region	Kumanovo	GH	1012	1251
Skopje Region	UCGO	UC	646	4630
	SHGO	SH	834	4132
	Remedica	GH	992	755
	Sistina	CH	255	1337
	Sante plus	SH	433	382

The Figure 12 shows relative proportion of deliveries in hospitals vs deliveries in their respective municipalities by types of hospitals. The relative proportion equal to 100% is indicative of equal number of deliveries in hospitals and municipality areas, likely explained by common preference of women to stay for the delivery in close geographic proximity.

The relative proportion less than 100% shows an established trend for women to deliver in stronger capacity clinics, not necessarily near their geographic location. Finally, relative proportion over 100% demonstrates prioritization of this clinic not only by women from local municipality but from other geographic locations as well.

It should be noted that the information on the municipality may suffer from some extend of inaccuracy given the migration of the population from one municipality to the other, not necessarily reflected in official personal data of the individual.

Figure 12: Relative proportion of hospital deliveries vs municipality deliveries*



**Specialized hospital Sante-plus was closed temporarily in 2018 and thus is not presented in the figure*

The Figure 12 clearly indicates that stronger capacity of the clinics – higher the relative proportion of deliveries in hospital vs municipality area. The university clinic has a highest relative proportion of deliveries - 717%, meaning that women are extensively coming for the delivery in this perinatal care facility from all over the country because of its high capacity. The established trend causes inefficient utilization of resources due to significant overload of the tertiary level clinic with normal deliveries. The tertiary level clinics ideally should be reserved for the most complicated maternal/fetal cases requiring complex, multidisciplinary care.

Specialized and clinical hospitals also have relative proportion of deliveries significantly higher than 100%. Expectedly, general hospitals with comparably limited capacity have lowest relative proportion of deliveries. Only 12% of delivering women from Debar municipality area choose local general hospital for childbirth, the rest migrate to other areas with stronger perinatal care clinics.

The documented established trend of delivery migration is critically important and is extensively utilized along with other important characteristics for appropriate planning of optimal organization of perinatal care service delivery and for making evidence-based decisions on strengthening/upgrading the capacity of some of the hospitals, while merging others without any potential for growth with stronger nearby hospitals (Annex I).

With comprehensive transport system on place, there should be no justification in endangering women by allowing them to give birth in clinics with low volume of deliveries and correspondingly low capacity and experience to manage emergency complications both for mothers and babies.

The efforts need to be placed where possible on strengthening the perinatal services of health care facilities or merging those with unacceptably low capacity and volume of deliveries with larger and stronger clinics with perinatal services. The exceptions could be the remote areas with complicated geographic access, specifically in winter times. In these facilities emergency obstetric and neonatal services should be maintained despite of the low load of deliveries. Yet, women should be advised to avoid deliveries in such clinic unless the critical need arise.

Points of strength

- Adequate geographic distribution of perinatal services – good geographic access ensured;
- High level of hospital deliveries – 99.9%;

Points of weakness

⇒ Highly disproportional distribution of deliveries, not comparative to municipal deliveries:

- low load of deliveries in many regional hospitals, incompatible with maintenance of adequate clinical expertise, quality of care and optimal organization of work;
- dramatic overload of hospitals in Skopje;
- suboptimal capacity of regional clinics;

⇒ Lack of risk-appropriate care: capacity and resources of clinics not always relevant with health care needs of delivering women and/or baby;

⇒ Irrational use of the budgetary resources due to the overload of high-cost tertiary level university clinic with normal deliveries.

Key recommendations

⇒ Establish risk-appropriate care to ensure that each mother and newborn is delivered and cared for in a facility appropriate for his or her healthcare needs.

- define clearly requirements for each level of care, including infrastructure, equipment, human resources, diagnostic capability and define scope of services (Chapter 4.1)
- stratify hospitals according to their individual capacity, geographic location;

⇒ Train PHC gynaecologists on principles of risk-appropriate care, encourage them to direct pregnant women to the level I or level II health care facility, unless level III subspecialized care required;

⇒ Create Perinatal Care Networks, where the health care facilities of different levels, PHC gynecologists and patronage nurses will be united based on their geographic location, level of care provided and individual capacity. Establish permanent information flow between facilities within network to ensure continuity of care and

higher level clinics serving as "support facility" to lower level perinatal care facilities and PHC gynecologists (Chapter 4.1);

⇒ Strengthen capacity of perinatal care clinics with focus on regional facilities through human resource strengthening (Chapter 3.4) and infrastructure & equipment improvement (chapter 3.3) to attract more women and reduce burden on tertiary level university hospital;

⇒ Merge perinatal departments of facilities with unacceptably low capacity and volume of deliveries with larger and stronger perinatal care clinics;

⇒ Establish clear criteria of obstetric and neonatal cases which needs to be managed at each level of hospital with strong monitoring system on place to control adherence to the established criteria and performed referrals.

3.3 Infrastructure and equipment

The Republic of North Macedonia inherited a health care system with relatively acceptable geographic distribution of facilities, yet with inefficient infrastructure, characterized by large and sometimes understaffed hospitals and inefficient service provision. This general trend applies to the perinatal care service provision as well.

The physical infrastructure of facilities providing childbirth services are giant, with unutilized and unnecessary over-space, most frequently planned in an old, obsolete style, not compliant with WHO recommended "family friendly" principles. In majority of hospitals there are common delivery rooms with 2-3 delivery beds, not equipped to support free birth positions at delivery and mobility during labor pains, rooms without privacy and confidentiality respected, not supportive of the presence of companion, separate outdated "pre-delivery" room for women in labor.

In general, medical equipment and capital investments in the publicly owned health facilities are funded through the Ministry of Health. As part of the continuous investment in public health infrastructure since 2006, some new advanced diagnostic equipment (i.e magnetic resonance imaging units, computer tomography scanners) and some basic equipment were procured for the public general and clinical hospitals. The additional investments were placed to upgrade the equipment in three leading hospitals providing obstetric and neonatal services (UHOG, SHGO, CH Tetovo) and managing almost half of the deliveries in the country [26,27].

Despite of these investments, medical facilities in the country are still relatively poorly equipped with advanced technologies, compared with neighboring countries. This probably relates to a very slow uptake of investment in health infrastructure after 1991.

According to the findings from "Evaluation of the Emergency Obstetric and Neonatal Care (EmONC) Availability, Use and Quality in Macedonia" carried out in the country in 2018, the basic equipment for managing the childbirth (delivery beds, infant warmers etc.) are available in all EmONC facilities. Yet, there are significant differences across hospitals in availability of more advanced equipment, their quality and functionality [27].

The evaluation documented shortage or inadequateness of equipment for neonatal resuscitation, which is of critical importance primarily for the survival of newborns, and then for their long-term health outcomes.

Part of the resuscitation equipment, such as positive pressure bag and masks, oxygen source, suction equipment, feeding tubes, sterile gloves and supplies, baby towels, blankets for covering the mother and baby are commonly accessible. Yet, there is a pronounced lack of more sophisticated resuscitation equipment such as laryngoscopes with different sized blades, endotracheal tubes etc. Even in cases when equipment are present, they are not easily accessible to the places where it is administered.

The air-oxygen blender, which dispenses a continuous and precise blend of medical air and oxygen is important for provision of mixed air and oxygen in a safe, easy and controlled manner. Yet, it is not present in the delivery room of any of the hospitals. Newborn ventilators, less invasive, simple and effective equipment for respiratory support - nasal continuous positive airway pressure (NCPAP) machines are available only at NICUs. There is a distinct shortage of infusion pumps both for mothers and babies.

Deficit was also documented in availability of diagnostic equipment: the mobile X-ray equipment is not available to any neonatal unit, except NICU, the shortage was also observed in availability of neonatal echocardiography equipment and portable obstetric ultrasound equipment in the delivery area at clinical hospitals.

The EmONC evaluation assessed also availability and functionality of the operating room equipment such as the anesthetic equipment, essential surgical instrument sets, oxygen source, electric suction machines, laryngoscopes, cardiac monitors, blood derivatives etc. Majority of essential equipment was available and functional, yet, in some facilities there were obsolete machines for anesthesia and suction. The evaluation evidenced shortage of infusion pumps, pulse oximeters, defibrillators and equipment for monitoring vital functions. Importantly, in some of the hospitals, there was no separate operating room for obstetric and

gynecological patients and both obstetric interventions and gynecological operations were carried out in the same operating room, which contradicts current recommendations of safety and infection prevention.

Finally, many hospitals lack centralized supply of oxygen, which is mainly provided through outdated oxygen balloons.

To sum up, both the infrastructure and equipment of majority of hospitals, providing childbirth services in the Republic of North Macedonia are insufficient and require investment and upgrade according to the proposed requirements (Chapter 4) depending on the level and complexity of care provided by specific hospital.

Points of strength

⇒ Government prioritized and put investment in upgrade of equipment and infrastructure of several large facilities with perinatal services (i.e SCOG, Tetovo, Chidren's hospital etc.).

Points of weakness

⇒ Physical infrastructure of facilities often old, outdated, giant, with unutilized and unnecessary over-space;

⇒ No "family friendly" environment, common delivery rooms with 2-3 delivery beds, not supportive of the presence of companion, separate outdated "pre-delivery" room for women in labor;

⇒ Number of individual delivery rooms not in line with country requirements (Chapter 4.3.1)

⇒ Shortage or inadequateness of equipment, specifically for advanced care (i.e equipment for neonatal resuscitation, equipment for respiratory support – NCPAP, ventilator, air-oxygen blender etc.);

⇒ Shortage of advanced diagnostic capabilities (i.e portable X-ray).

Key recommendations

⇒ Rehabilitate infrastructure of perinatal care departments/clinics and reorganize them in line with set requirements according to the respective level of care (Chapter 4.1), specifically in regions. Create a family friendly infrastructure to delivering women;

⇒ Transform common "delivery theaters" into the individual "family friendly" delivery rooms. Ensure the recommended proportion: one individual delivery room/300-400 deliveries;

⇒ Transform "pre-delivery" rooms into the individual delivery rooms;

⇒ Improve equipping of facilities in line with set requirements according to the respective level of care, with focus on advance respiratory support equipment for neonates (Chapter 4.1);

⇒ Improve diagnostic capacity of clinics in line with set requirements according to the respective level of care (Chapter 4.1). Ensure all level II facilities have portable obstetric ultrasound equipment and mobile X-ray equipment on place.

3.4 Human resources

The number, distribution and the competences of health workforce represents the foundation of the health system and largely determines the quality and comprehensiveness of health service provision to the population.

The Ministry of Health and the professional associations and chambers are main institutions mandated for registration and certification of health care professionals in the Republic of North Macedonia. Upon graduation, health professionals are required to pass a state examination and to become members of their respective professional associations, thus automatically becoming part of the licensing system.

The formal continuous medical education system is on place in the country, which is tied to a credit-system and obliges medical doctors to attend accredited continuous medical education trainings as a requirement for re-licensing every 7 years. The continuous medical education courses are accredited jointly by the Macedonian Chamber of Medicine and the Macedonian Medical Association [28-29].

Significant gaps are present in education system of mid-level health professionals. Despite of long-established training program and wide institutional network of nurses and midwives, there is still no system of their accreditation, licensing or re-licensing, no requirements for nursing or midwifery continuing medical education on place [30]. Yet, some

progress has been made recently in establishment of the Chamber of Nurses and Midwives, which will take over the responsibility for professional development of mid-level health professionals.

Although responsible for the overall health system planning and management, the Ministry of Health still lacks a clear comprehensive strategy and vision for defining the health personnel needs and human resources in health planning. The established Health Network has a mandate and potential to provide some guidance and serve as the basis for future human resources planning in the health. Yet, this mandate had not been implemented yet.

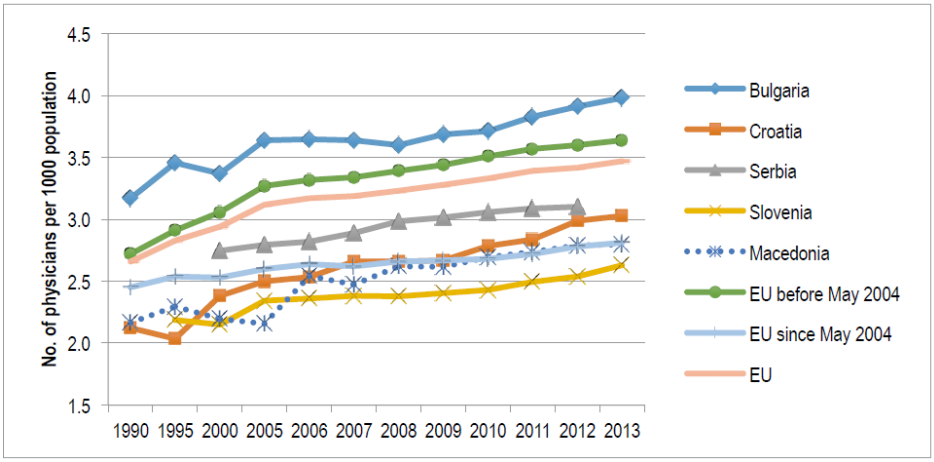
In the light of adoption of the Global Strategy on human resources for health (2016), the Republic of North Macedonia initiated development of a national action plan for human resources for health. It started by undertaking a situation analysis, developing a national profile on human resources in health that assesses the availability of human resources, level of education and specializations, as well as projections on future needs [28, 31].

Organized by the Ministry of Health and supported by the WHO Country Office in Skopje, the process involved stakeholders from the Agency for Quality and Accreditation of Health Institutions, the Directorate for Electronic Health, the Health Insurance Fund, the Institute of Public Health, the Ministry of Health and the State Statistical Office, as well as professional associations and chambers.

The analysis of available data and the consultative process showed a significant lack of human resources in the health sector in general, and in specific areas in particular.

Despite of the documented slow increase in health workforce between 1990 and 2013, the proportion of physicians in Macedonia (2.8 per 1,000 population in 2013) is still below the majority of neighboring and EU countries, specifically those that became EU members before May, 2014 (Figure 13) [28].

Figure 13: Number of physicians per 1000 population in the Republic of North Macedonia and selected countries, 1990 to 2013

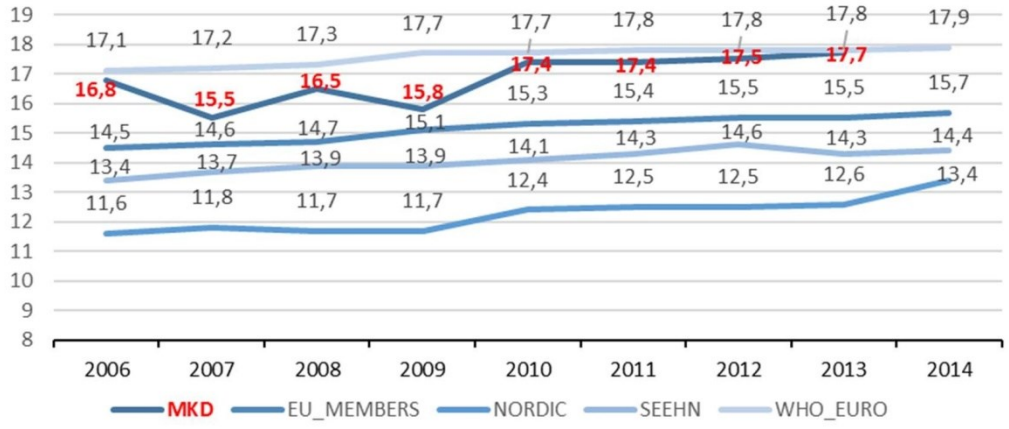


Source: WHO Regional Office for Europe, 2016a.

In health profile for human resources, gynecologists were regarded as one of the most deficient type of health professionals along with neonatologist. According to the profile, there are totally 332 obstetrician-gynecologists (ob/gyn) certified in the country, 138 of which are occupied at the primary health care level and only the remaining 198 ob/gyn provide the childbirth services [28].

Based on the data from Institute of Public Health, in the Republic of North Macedonia in 2013 there were reported 17,7 specialists of gynecology and obstetrics per 100.000 population (Figure 14). In the time frame 2006-2013, the parameter varied between 15.5 and 17.7, mainly in upward trend with some fluctuations and was higher compared with EU Member states, Nordic and SEEHN countries, outranked only by average for the WHO EURO [4, 31].

Figure 14. Number of ob/gyns per 100 000 population in the Republic of North Macedonia compared to European region (2006-2014)



/

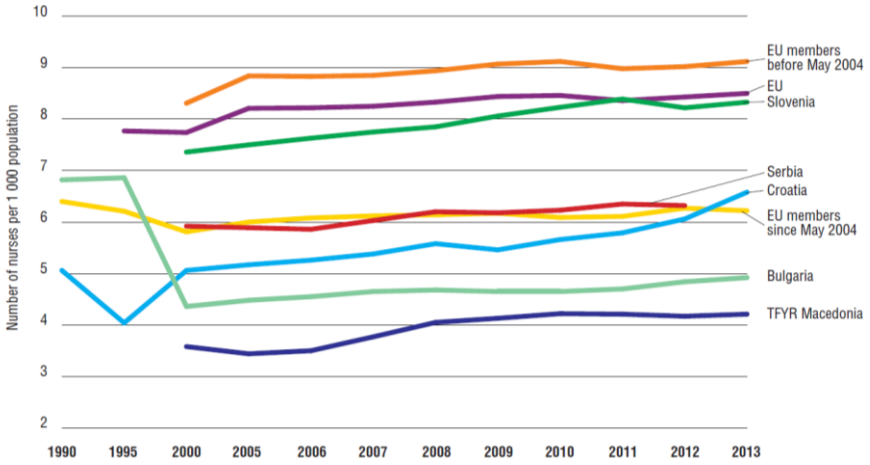
Yet, the parameter is cumulative and is calculated based on both PHC and secondary care ob/gyns.

The distribution of ob/gyns, specifically at secondary level is highly disproportional. While there is a documented oversupply of ob/gyns in Skopje hospitals, specifically at the tertiary level UCOG (55 ob/gyns), the regional clinics suffer from pronounced deficiency of obstetric staff. These clinics are frequently supplied by ob/gyns from the Skopje hospital on rotational bases and are double reimbursed for supplementary rotational shifts [32]. The need is evident for appropriate health resource planning with incentivization system established in deficit regions, and employment restrictive regulations applied for Skopje hospitals in line with actual needs of health professionals in these hospitals.

Scare are human resources in neonatology, with only few health professionals (3) state licensed in neonatology. Commonly, pediatricians trained in neonatology take the responsibility for provision of neonatal services. Majority of them have combined duties for pediatric department and neonatology department, which questions availability of needed specialist on place in emergency cases [32]. It is strongly recommended to revise existing specialization program in neonatology so that the country has valid specialization system which produces specialized, licensed, appropriately trained pool of neonatologists for the country.

The nurse-to-population ratio had been increasing slowly at the national scale since 2005, reaching 4.2 per 1000 population in 2013, but remains well below the European averages and those of other countries in the region (Figure 15) [4,28].

Figure 15: Number of nurses per 1000 population in the Republic of North Macedonia and selected countries, 1990 to 2013

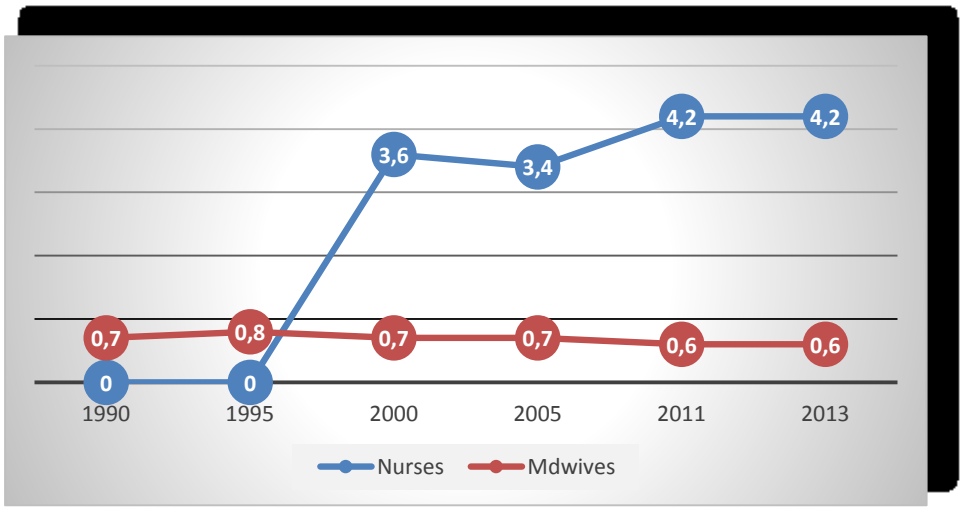


Source: WHO Regional Office for Europe, 2016.

There are no documented reasons for the low nursing supply in the Republic of North Macedonia. Possible explanation includes migration of nurses to other countries due to the lack of professional prestige and remuneration along with still missing licensing and accreditation systems for the mid-level health professionals.

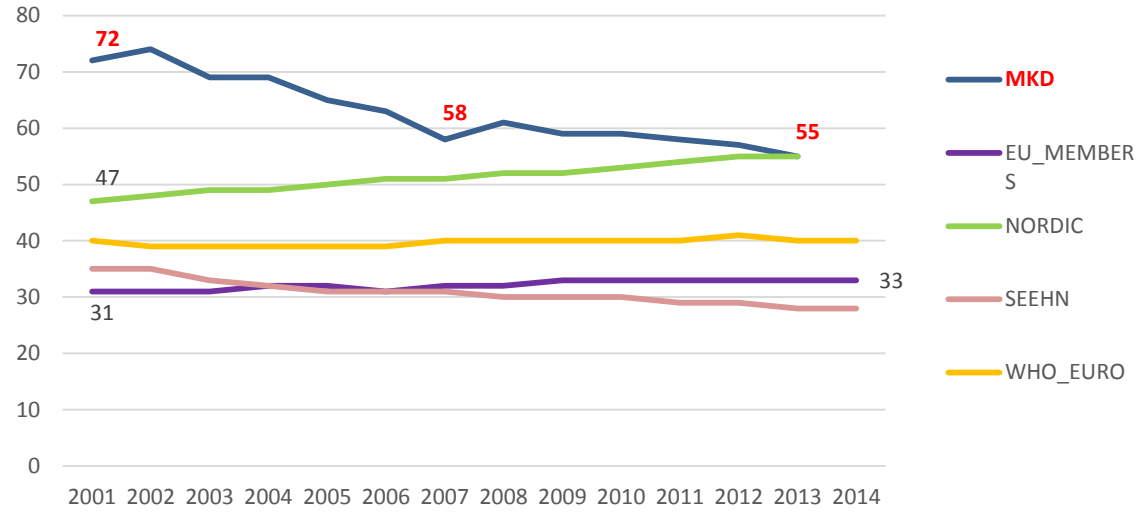
In contrast to the slow but steady increase of nursing supply, the number of midwives per 1000 population decreased slightly from 0.7 in 1990 to 0.6 in 2013 (Figure 16) [28].

Figure 16: Nurses and midwives workforce in the country per 1000 population, 1990–2013



Yet, the average number of midwives per 100 000 population in the Republic of North Macedonia is higher compared with average WHO EURO, EU, Nordic and SEEHN countries (Figure 17) [4].

Figure 17: Number of midwives per 100.000 population (2001 – 2013)



HFA database, WHO Regional Office for Europe 2017

Important milestone in achieving the main principles of community health with its participatory process to improve population health in general and maternal and newborn health in particular are patronage nurses, comprised of nurses and/or midwives with completed secondary or higher level of education. Each of them cover specifically defined micro-geographic-region of approximately 5000-6000 population. By profile, they are polyvalent with established standards: one patronage nurse per 1.000-1.500 families (i.e 3.000-5.000 population). In 2017, the number of patronage nurses in the Republic of North Macedonia was 311, or one patronage nurse per 1650 women of reproductive age. 31% of patronage nurses are represented by midwives, while the rest are nurses [33]. Patronage nurses play important role in preconception care (identification of women planning to become pregnant shortly, promotion of pre-pregnancy folium intake, healthy nutrition and lifestyle etc.), early identification of pregnant women and appropriate referral for antenatal care and finally, postnatal patronage both for mothers and babies. It is significant for the country to have a strategy for continuous refilling of the supply of patronage nurses to prevent their shortage due to the aging problem [34, 35].

The exact number and distribution of practicing and available health workforce in perinatology is not known due to the absence of comprehensive nationwide human resource registry. The data presented below is based on self-reports from health care facilities and hence may suffer from the certain degree of inaccuracy (Table 9) [36].

Table 9: Human resource distribution across perinatal care facilities (2019)

PC facilities	Ob total	Ob from other clinic*	Ob Resid	Neon/ Ped- ped depart**	Neon/ ped- neonat. depart***	Neonat from other clinic*	Neon/ Ped Resid	Anesth	Anesth from other clinic*	Anesth Resid.	Midwives (obst. dep)	Midwives (neon. dep)
Kocani	3	No	3	4	0	No	1	2	No	0	9	3
Prilep	5	Yes (4)	4	5	2	No	2	6	Yes (4)	3	11	3
Stip	5	No	5	6	3	No	3	5	No	4	9	3
Kumanovo	7	Yes (6)	4	5	1	Yes	2	6	Yes (1)	1	7	4
Veles	4	Yes (2)	2	4	0	No	2	2	Yes (1)	2	5	5
Ohrid	5	Yes (1)	2	10	5	No	1	2	Yes (7)	3	5	4
Bitola	7	No	3	5	2	Yes	3	6	Yes (4)	5	9	9
Gevgelija	3	Yes (on call)	0	2	0	No	1	0	Yes (on call)	2	7	2
Strumica	8	No	2	3	0	No	2	6	No	1	6	8
UCGO	55	No	3	0	12	No	7	12	Yes (2)	5	21	24
Struga	8	No	2	6	0	No	3	3	No	1	12	6
SHGO Cair	17	No	7	0	8	No	2	5	No	4	13	12
Debar	1	No	1	2	0	No	1	1	No	1	11	11
Plodnost	8	No	1	0	3	No	0	4	No	0	7	7
Tetovo	12	No	5	8	5	No	4	8	No	4	8	5
Sistina	22	No	0	22	8	No	0	8	No	0	9	6
Remedika	10	No	0	0	4	No	0	4	No	0	6	6
Kicevo	3	No	2	3	0	No	1	1	No	0	5	No
Gostivar	8	No	0	8	0	No	3	1	Yes (5)	0	11	2
Kavadarci	2	Yes (2)	2	2	0	Yes	2	1	Yes (1)	1	11	1

**Specialists supplemented from other clinics, when there is a local deficit*

***Pediatricians/neonatologists working in pediatric department, but in case of need taking neonatal duties*

**** Pediatricians/neonatologists working in neonatal department*

The table shows disproportional distribution of health professionals providing perinatal care services with some of the clinics overstaffed and others experiencing significant deficiency in 24/7 access to specialist health professionals, nurses and midwives. In deficient clinics there is a permanent need to supplement specialists from other hospitals.

Potential threat to the human resource represents aging of health professionals. In many clinics ob/gyns, pediatricians, midwives are close to the retirement age and government needs to plan and implement adequate replacement measures to address proactively the aging problem of health workforce. The measurers include detailed analyses of health workforce supply, their distribution and age structure and planning the residency programs according to the actual needs of health workforce with retirement plans taken into consideration. During the last decades the documented problem of general deficiency in number and composition of health professionals in the country deepened further due to the massive professional migration of health workforce from the Republic of North Macedonia to neighboring countries in search of the better reimbursed jobs and dissatisfaction with status and career opportunities for medical doctors within the country [32].

Additionally, the financial incentive is responsible for raised motivation of specialist gynecologists to get occupied in primary care, rather than work in secondary care, thus excavating more pronounced shortage of health professionals in perinatal care clinics.

There is also an evident increasing trend of health workforce migration from the public to private sector, which drains the human resource capacities from the public domain.

As was already described, the tendency is also evident for specialists to move from regions to Skopje UCGO, which leads to unnecessary overstaffing of the UCGO and shortage of specialists in regions [39].

The named challenges underscores the need by country government in establishing of more sophisticated reimbursement, incentivization system for health professionals, specifically those in deficient areas, undertaking proactive measures for increasing job satisfaction of doctors and nurses, for attracting more young professionals, in order to stop and reverse the dangerous trend of health professionals' flow-out and deterioration.

Given the dynamics of labor market in health system it is highly recommended to perform a regular human resource health planning in line with country's on-going needs, challenges and health system specifics.

Importantly, with stratification of the perinatal care services there is an urgent need to strengthen the clinical capacity of health care professionals to provide high-quality level-appropriate care. The intensive and continuous level-appropriate trainings, applying various forms and methods of health professionals teaching (theoretical course, practical skills-gaining exercises, on-the-job and rotational trainings) are strongly recommended for all level perinatal health professionals (ob/gyns, neonatologists, nurses, midwives etc). These rigorous chain of trainings should be developed by respective professional associations, adjusted to the needs of specific perinatal care levels and incorporated into the CME system. The periodic courses must be mandatory to all health professionals providing perinatal care services in the Republic of North Macedonia and should serve as a precondition for relicensing.

Points of strength

⇒ Continuous Medical Education system on place;

⇒ Professional associations present in obstetrics/neonatology/midwifery;

⇒ Operational residency programs on place, financially supported by government.

Points of weakness

⇒ Lack of evidence-based human resource planning; overstaffed Skopje hospitals, deficiency in regional clinics – irrational use of human resources;

⇒ Absence of accurate and complete data on human resources and their distribution;

⇒ Suboptimal system for health professional's continuous education;

⇒ Need for competency strengthening of perinatal care health professionals;

⇒ Need for subspecialization system refinement in neonatology;

⇒ Migration of specialist gynecologists from secondary care to primary care, excavating shortage of health professionals in secondary care;

⇒ Migration of specialists from regions to Skopje, deepening shortage of specialists in regions;

⇒ Health workforce migration from public to private sector, draining the human resource capacities from the public domain;

⇒ Health workforce migration from MKD to other countries.

Key recommendations

⇒ Establish a system for evidence-based human resource planning – make annual analysis of the health workforce supply and distribution, calculate the needs and plan and implement strategies accordingly. Rationalize distribution of specialists according to the needs through setting employment incentivization system for regions and limitation in Skopje hospital employments;

⇒ Create a comprehensive human resource registry for both high and middle-level health professionals;

⇒ Address the aging problem through detailed analyses of health workforce supply, their distribution and age structure and planning the residency programs according to the actual needs of health workforce with retirement plans taken into consideration;

⇒ Refine specialization program in neonatology to ensure country has specialized, licensed, appropriately trained pool of neonatologists;

- Revise existing 2-year subspecialization program to concentrate more on gaining hands-on, practical skills in neonatal care procedures
- Introduce end-of subspecialization OSCE exam to ensure health professionals possess required clinical skills and knowledge
- Revise "neonatologist" licensing rules:

a) issue neonatologist license to all doctors practicing in NICU for over 2 years;

b) issue neonatologist license after successful completion of a 6-month specialization program and passing OSCE exam for those practicing neonatology for over 2 years, but not operating in NICU. Short course (6 month) of specialization program needs to be developed for this category of health professionals;

c) issue neonatologist license to paediatricians not falling into category "a" and "b", after successful completion of a 2-year full specialization program and passing OSCE exam.

⇒ Raise the competence of health workforce through:

- active engagement of respective professional associations in development of level-appropriate curriculum for high and mid-level perinatal care professionals;
- incorporation of developed curriculum into continuous medical education program;
- training extensively and mandatorily all high- and mid-level perinatal care health professionals with theoretical and practical courses, on-the-job and rotational trainings;

⇒ Support incentivization of obstetricians, neonatologists, midwives and nurses to reduce massive professional migration and workforce drain. Raise social recognition of midwives and nurses. Strengthening the role of midwives in management of normal labor/delivery.

3.5 Transport system

The safe transport of pregnant/postpartum women and newborn infants between hospitals is recognized as an essential component of effective functioning and organization of perinatal care. The global experience suggests that perinatal outcomes are significantly improved when high-risk infants are ideally transported before delivery (in-utero transport), or transported after delivery with safe, well equipped transport. Yet, the current organization of transport system in the Republic of North Macedonia is not systemized and not well operational.

Maternal transport is carried out through general ambulance system. All clinics have their ambulance cars, responsible for transport of any type of patient, including maternal. Although ambulances are available free of charge in all facilities, there is a distinct problem with their maintenance and relevant equipping, including supplies and equipment for maintaining vital functions. Additionally, the equipping of ambulance vehicles is not adjusted to maternal needs. Significant challenges are also present in organization of maternal transfer, information flow between key parties, timeliness, adequacy of care provided during the

transportation. Referrals are frequently performed by the referring hospitals without relevant agreement and notification to receiving health care facility.

Even more deplorable is the organization of neonatal transport. There is a pronounced shortage of all key components of neonatal transport: vehicle supplies, adequate equipment and skilled personal for ensuring safe neonatal transport.

Currently, neonatal referral in the Republic of North Macedonia is under the formal responsibility of the UCCD in Skopje. At the moment, there are two vehicles allocated for newborn transport. One of them is very old, not adequately equipped and solely utilized for emergency cases and for inter-clinic transports within Skopje. The other vehicle is well equipped with a transport incubator, ventilator as well as other essential medical equipment (ECG monitor, pulse oximeter, aspirator, oxygen supply, blood pressure monitor etc.). Yet, this vehicle is shared with pediatric and other departments of the clinic and mostly used for their transfers. For neonates this very well-equipped vehicle is mainly used for out-of-country transport or transfer to the airport. The significant challenge is that the sick newborns from regions are transported by routine ambulance vehicles which are in ownership of the regional clinics and not at all equipped to meet the health needs of critically ill newborns. The documented pattern creates a very serious risk for newborns with significant health problems requiring quality transport and needs immediate attention and addressing.

The neonatal transport is supposed to be staffed with doctor specialists - mainly pediatricians and nurses, occupied at NICU. In general, there is a distinct shortage of personal for transport, since the assigned to transport pediatric team has a duty at the NICU and are not always available. At the moment, there are 6 doctors and 7 nurses who incorporate newborn transport responsibilities. Yet, these well-skilled doctors and nurses are not participating in transporting the sick newborns from regional clinics. These babies are transported by local ambulance cars and accompanied by regional clinic pediatricians, not always skillful in managing critically ill neonates, which deepens more the health risk of sick newborns.

The country does not have clear, evidence-based requirements set for maternal and newborn transport vehicles and for transport team [41,8].

It is imperative to set relevant requirements and reorganize the neonatal transport system in line with these requirements to ensure that the newborns and mothers are transported

between clinics with well-equipped vehicles and managed during transport by appropriately skilled personal.

Beside challenges in transport vehicle and human resources, there is significant problem in organization of maternal/newborn referral. There is no standardized procedure for maternal and newborn transport operation, the process is chaotic and not well coordinated [41,8].

Additionally, the documentation on maternal and newborn referral is very poor, paper based and not standardized and complete, which hampers the information flow between referral initiating, transporting and referral receiving institutions and hence threatens continuity of care. There is also very limited possibility to extract accurate data on maternal and newborn transport from paper-based incomplete and non-systematized documents, which hinders the process of assessment of transport system operation, identification of gaps and their proper addressing.

Finally, there is no precise and well-defined list of maternal-newborn conditions that require referrals to the higher level facility, which results in unnecessary referrals, placing additional risk both to mothers and babies and in irrational utilization of existing limited resources [41,8].

There is an urgent need for reforming the existing and establishing the strong transport system both for mothers and babies with all essential constituents on place: enough supply of relevant vehicles, appropriate equipment/medication and supplies, skilled and competent personal. Additionally, it is critical to establish a standardized and coordinated process of maternal-newborn referral based on the clear referral guidelines and maternal-newborn referral criteria, with well-defined roles and responsibilities of all parties involved in the transport, appropriate documentation reflective of objective picture of system operation and adequate information flow between parties (Chapter 4.4).

Points of strength

- ⇒ Small size of the country with only one referral clinic for mothers and one for newborns – no need for centralized transport coordination center;
- ⇒ One very well-equipped neonatal transport on place;
- ⇒ Ambulance cars, used for maternal transport present at each hospital;

⇒ Maternal-newborn referral module present in electronic health system.

Points of weakness

⇒ Suboptimal organization of maternal-newborn transport, not standardized system for operation;

⇒ Absence of standardized requirements for maternal and newborn transport modality, transport personal;

⇒ Newborns transported by local ambulance cars not equipped at all for safe transport of high-risk neonates. Well-equipped neonatal transport mainly used for pediatric patient transport or for transport of neonates out of country;

⇒ Equipping of local ambulance cars not adjusted to the needs of pregnant/delivering women;

⇒ Newborns during transport accompanied by local pediatric staff, not always skillful in management of high-risk newborns;

⇒ Poor paper-based documentation of maternal-newborn referral, impossible to extract accurate and complete data on maternal and newborn transport; no data on maternal-newborn transport is present in e-health system.

⇒ Poor information flow between parties;

⇒ Absence of precise and well-defined list of maternal-newborn conditions that require referrals to the higher level facility - results in unnecessary referrals, irrational utilization of existing limited resources.

Key recommendations

⇒ Standardize the process of maternal-newborn referral with clearly defined roles and responsibilities of referral implementing parties (referring, transporting and receiving centers) and ensure their fulfillment (Chapters 4.4.1 and 4.4.2);

⇒ Define and implement requirements for maternal and newborn transport modality:

- transport personal (number and competencies)

- transport vehicle (number of vehicles needed, their equipment and supply) (Chapters 4.4.3 and 4.4.5) ;

⇒ Ensure that newborns are transported by specialized cars well equipped for safe management of high-risk neonatal conditions; add one fully equipped neonatal transport;

⇒ Ensure that clinic ambulances are adjusted for maternal transport according to the set requirements;

⇒ Define requirements for maternal and newborn transport documentation to ensure smooth information flow and effective coordination between respective parties (Chapter 4.4.4);

⇒ Establish a comprehensive system for electronic registration of all maternal-newborn referrals in Moj Termin through:

- ensuring that the existing e-system captures all key information on maternal-newborn referrals
- mandating quality and complete data entry into the system by responsible parties, set quality and complete data entry as a performance measure linked with reimbursement.

⇒ Establish an on-going monitoring system, that regularly assesses and analyses the transport system operation.

IV. Perinatal Care Service Delivery – Suggested model

4.1 Stratified model of perinatal care service delivery. Perinatal networks

Health care facilities that provide perinatal care for mothers and newborns in the Republic of North Macedonia are suggested to be classified on the basis of their functional capabilities and organized within a regionalized system of perinatal care. The goal of perinatal care stratification is to ensure that pregnant women and newborns have access to appropriate levels of high quality, safe and effective care, in time, before, during and after delivery. In regionalized stratified perinatal care system each mother and newborn is delivered and cared for in a facility appropriate for his or her healthcare needs, which facilitate the achievement of optimal outcomes.

Below is provided suggested uniform, nationally applicable criteria that stratifies maternal and neonatal care into 3 levels of complexity and recommended referral of high-risk patients to higher-level centers with appropriate resources, personnel and functional capabilities to address the required increased complexity of care.

Levels of maternity and newborn care implies the extend of care provided to the mothers and newborns and is in accordance with international recommendations on stratification of perinatal care services with adjustment to the Macedonian context [42,43]. The level of care is determined by the capability of individual facility, including infrastructure, equipment, availability and competencies of medical personnel.

Women should be encouraged to have regular antenatal visits and plan their timetable to be able to arrive to a facility with appropriate level of perinatal care according to their level of risk.
Maternity and newborn care services are recommended to be organized around three levels: Level I (basic), Level II (specialty), Level III (subspecialty) care.

Perinatal care networks

The health care facilities of different levels are recommended to be united in perinatal care networks, where facilities will be combined based on their geographic location, level of care provided and their individual capacity. Six perinatal networks will be created in total (Skopje, Kumanovo, Bitola, Tetovo, Stip and Strumica). Each network will encompass minimum one level II perinatal care facility, one/several level I perinatal care facilities, PHC gynecologists

and patronage nurses operating within the geographic frame. The members of the network will form a teams, jointly responsible for quality ante-, intra- and postnatal care and for continuity of care within the network. There will be regular communication established between parties in the form of quarterly meetings.

Minimum three core functions will be taken over and implemented by perinatal care networks:

- creating sustainable and permanent information flow between different parties on antenatal, intranatal and postpartum care to ensure continuity of care for each pregnant woman;
- establishing “support system", where higher level clinics (level II) serve as a “support facility” to level I perinatal care facilities, PHC gynaecologists and/or patronage nurses. Support system envisions 24/7 access to both distant and on-site consultation by any party in need within the frame of the network. Beside consultation, support system also encompasses needs-based rotational supply of deficient human resources – specialist ob/gyns, paediatricians, midwives to the health care facility in need within network;
- creating network quality collaboratives for joining efforts toward improving quality of ante-, intra- and postnatal care. Situational analysis will be performed on regular bases, where key challenges and best practices within network will be discussed and analyzed. Specific performance measures will be developed and tracked to monitor performance of perinatal networks.

The perinatal networks will be accountable to Safe Motherhood Committee, where the network leads will regularly report on operation of the network, key challenges and accomplishments. Inter-network collaboration, share of experience and lessons learned will be encouraged and supported by Safe Motherhood Committee.

The tentative scheme of perinatal care networks is proposed in Annex II. The final composition of perinatal care networks should be endorsed by respective regulatory act.

4.1.1 Level I (Basic Care)

Level I perinatal care facilities provide basic delivery services mainly for normal labor and deliveries or for those with mild complications. Yet, these facilities should have a capacity and can manage more complicated maternal and newborn conditions in special cases, when transportation of women or newborn to the higher-level facility is hampered either due to the patient's unfavorable medical status (when risk of transportation outweighs the benefit of case management in resource-limited facility) or due to the severe geographic/climatic conditions. In this case the management of the patient is done in close coordination with higher level facility from perinatal network (Chapter 4.1). In case of need, the on-site visit or distant consultation of the health care professional from higher level "support facility" should be organized.

The level I perinatal care facilities have relatively limited resources and this kind of facilities can mainly be allocated at general hospitals. Yet, some general hospitals with strong capacity may provide more advanced, level II maternal and neonatal care.

4.1.1.1 SERVICES

LEVEL I MATERNITY CARE:

- Manage uncomplicated pregnancy & labor and mild complications according to the national guideline/protocol;
- Timely identify potential severe complications and arrange appropriate referral (facility should have a referral policy clearly defining the list of complications for which transfer must be made);
- Stabilize severe maternal complications before transfer to level II or level III facility;
- Manage complicated cases only when transportation of woman to the higher level facility is not possible;
- Provide assisted delivery (vacuum extraction/forceps) in emergency situations;
- Perform Caesarean section within 30 minutes after making decision under general or regional anesthesia;
- Provide postpartum care.

LEVEL I NEWBORN CARE:

- In case of need, provide neonatal resuscitation according to the national protocol.

- Evaluate and provide care of healthy and stable full-term newborns (37 0/7 – 41 0/7), that don't need and are not expected to need special intervention in accordance with approved national guidelines and protocols;
- Stabilize and provide care for sick infants and those born <37 0/7 week of gestation before their referral to the higher level facility;

4.1.1.2 STAFFING

A level I health care facility providing basic maternal/newborn care is required to have:

- A certified obstetrician/gynecologist with experience in performance of operative delivery present in-house 24 hours a day;
- A certified pediatrician /neonatologist skilled in neonatal resuscitation present in-house 24 hours a day (can be shared with pediatric department);
- A certified anesthesiologist present in-house 24 hours a day (can be shared with surgery department).
- Midwives and nurses, possessing the knowledge and skills required for managing normal labor and delivery and taking care of healthy newborn;

An adequate nurse/patient ratio:

- 1:2 for patients in labor
- 1:1 for patients in second stage of labor
- 1:5 for patients in postoperative recovery
- 1:10 for postpartum patients without complications
- 1:12 for newborns requiring only routine care.

All deliveries should be attended and managed by an obstetrician and certified midwife. Newborn assessment and observation should be performed by neonatologist/pediatrician.
All delivery room personal (ob/gyn, neonatologist/pediatrician, midwife, nurse) must possess skills to perform newborn resuscitation.
The level I facility must have a detailed referral plan, which also implies access to 24-hour distant or on-site consultation of health professional from a higher-level "support facility" of perinatal network (Chapter 4.1).

4.1.1.3 INFRASTRUCTURE AND EQUIPMENT

INFRASTRUCTURE

All level I maternities should have an isolated obstetric area with:

- individual "family friendly" delivery rooms in compliance with established requirements. The required number of delivery rooms should be calculated as follows: minimum 1 delivery room per 300-400 annual turnover of deliveries
- postnatal wards with infant cribs (taking into consideration the requirement for rooming-in (placing mother and newborn together) in line with established requirements
- designated room for newborn care in line with established requirements
- operating room, in line with established requirements.

EQUIPMENT

Individual delivery room has essential equipment for care of <u>delivering woman</u> on place and in working condition:

- wall clock with second hand
- wall thermometer
- heat source
- stethoscope
- electric suction equipment
- comfortable maternity bed ready for instrumental delivery- transformer
- centralized oxygen outlet for mothers or oxygen from cylinder with flowmeter.

Individual delivery room has essential equipments for care of <u>neonate</u> on place and in working condition:

- radiant heated bed
- stethoscope
- centralized oxygen and air outlet for newborn with flow meter
- positive pressure bag and masks capable of delivering up to 100% oxygen to the infant
- electric suction equipment for infant
- feeding tubes (6-8 Fr)

- neonatal pulse oximeter for non-inavsive blood oxygen monitoring.

Obstetric department has essential equipment for care of <u>delivering woman</u> on place and in working condition

- cardiopulmonary resuscitation cart/set for mothers (a positive pressure bag, laryngoscope with blades, orotracheal tubes)
- cardiac monitor
- intravenous infusion pump
- cardioversion/defibrillation capability for mothers
- cardio-tocography machine
- instruments and equipment for assisted deliveries (forceps, vacuum extractor).

Neonatal care room has essential equipment for care of <u>neonate</u> on place and in working condition

- radiant warmer for adequate thermal support
- incubator
- positive pressure bag and masks capable of delivering up to 100% oxygen to the infant, with maximum 500 ml flow through with adjustable pop off valve for generating pressure of up to maximum of 50 cm H_2O
- humidifier
- platform scale with metric indicators
- oxygen therapy equipment (oxygen hood, nasal canula for short-term administration of oxygen)
- endotracheal tubes in all the appropriate sizes for neonates
- laryngoscope with premature and infant size straight blades (00,0, 1)
- suction catheters 12FG or 10FG (short) and 6FG (long)
- intravenous infusion pump
- equipment for phototherapy
- pulse oximeter
- equipment for determination of blood glucose at the bedside – glucometer
- temperature probes (if possible, skin thermometer probes)
- four wall mounted electrical outlets for each space in the neonatal care room

- one oxygen, medical air and suction outlet for each bed space in the neonatal care room.

Obstetric operating room in addition to the general operating room requirements has essential equipment for care of neonate on place and in working condition;

- radiant heated bed
- stethoscope
- wall thermometer
- centralized oxygen or cylinder-oxygen and air outlet for newborn with flow meter
- positive pressure bag and masks capable of delivering up to 100% oxygen to the infant
- electric suction equipment for infant
- feeding tubes (6-8 Fr)
- neonatal pulse oximeter for non-invasive blood oxygen monitoring

4.1.1.4 SUPPORT SERVICES

- Blood and fresh frozen plasma available 24 hours daily from local stocks or another facility based on prearranged agreement;
- Anesthesia services available for obstetric emergencies including caesarean section 24 hours daily on place;
- Radiologic services (obstetric ultrasound) available 24 hours daily on place or on call;
- Essential clinical laboratory services available.

LABORATORY SERVICES:

The facility must have the capability of performing the following essential laboratory services on site or through appropriate referral 24 hours a day (may be on call at night shifts and weekends):

- Complete blood count; hematocrit (HCT) (in emergency results ready within 60 min after request)
- Major blood groups and Rh typing; blood crossmatch (in emergency results ready within 60 min after request)
- Serum glucose, sodium, chloride, potassium, bicarbonate, creatinine, calcium (in emergency results ready within 45 min after request)

- Serum protein and albumin (in emergency results ready within 45 min after request)
- Screening for anti-rhesus antibodies (Coombs' test indirect) (in emergency results ready within 120 min after request)
- Liver function tests (in emergency results ready within 120 min after request)
- Prothrombin time (PT), partial thromboplastin time (PTT) (in emergency results ready within 120 min after request)
- Bacterial cultures with sensitiveness (in emergency results ready within 72 hours after request)
- Urinalysis (in emergency results ready within 45 min after request)
- Direct and indirect serum bilirubin (in emergency results ready within 120 min after request)
- Group B streptococcus, hepatitis B surface antigen, RPR/VDRL, HIV, gonorrhoea.

4.1.1.*5 REFERRAL/TRANSPORT*

- The level I perinatal care facility must be in permanent communication with the referral receiving center and have a comprehensive transport plan for ensuring timely referral and/or on-site/distant consultation for the complicated maternal and newborn cases;
- The health care facility must have a clear criterion with well-defined list of maternal and new-born conditions, which require referral to the higher-level health care facility.
- The health care facility is in charge of filling all required documentation as outlined in Chapter 4.4.4 and entering the complete and accurate data on each maternal and newborn referral into the electronic system.

4.1.2 Level II (Specialty Care)

Level II units offer high level obstetric care for both normal uncomplicated deliveries as well as high risk pregnancies and all emergency pregnancy and delivery complications, which do not require subspecialized care. Level II neonatal care manages healthy and preterm infants (≥34 0/7 weeks of gestation) with physiologic immaturity or who are moderately ill with respiratory problems that are expected to resolve rapidly. These facilities/departments have the required infrastructure, manpower, technologies to provide the appropriate care.

4.1.2.1 SERVICES

LEVEL II MATERNITY CARE:

- Manage uncomplicated pregnancy and labor according to the national guideline/protocol;
- Manage all maternal complications, which do not require subspecialized care according to the national/international guidelines and protocols;
- Identify women with serious medical complications, requiring subspecialized care, stabilize them before transfer and perform timely referral to level III facility (facility should have a referral policy clearly defining the list of complications/conditions for which transfer must be made);
- Provide postpartum care after uncomplicated and complicated labor and delivery.

4.1.2.2 STAFFING

A level II health care facility providing specialty maternal/newborn care is required to have:

- Team of licensed obstetricians/gynecologists to ensure continuous 24 hours in-house availability of minimum two specialists;
- Minimum two certified obstetrician/gynecologist with at least 5 years' experience in obstetrics including experience in performance of hysterectomy and other obstetrical operative procedures (available within 30 min after the call);
- Team of licensed pediatricians/neonatologists trained in Neonatal Resuscitation Program to ensure continuous 24 hours in-house availability and provision of expanded neonatological services. Subspecialists-neonatologists would be an asset;
- Pediatric cardiologist and pediatric surgeon (permanent staff member or consultants on contractual base);
- General surgeon (permanent staff member or consultants on contractual base);
- At least 2 anesthesiologists available in house 24 hours a day and experienced in the performance of spinal epidural and general anesthesia (can be shared with other departments of hospital);
- Nurses/midwives - number and level of their competence must ensure adequate care for all pregnant, parturient and postpartum women and newborns.

An adequate nurse/patient ratio:

- 1:2 for patients in labor
- 1:1 for patients in second stage of labor
- 1:5 for patients in postoperative recovery
- 1:10 for postpartum patients without complications
- 1:12 for newborns requiring only routine care
- 1:4 for newborns requiring specialty care.

4.1.2.3 INFRASTRUCTURE AND EQUIPMENT

All Level II health care facilities should have an isolated obstetric area with:

- individual "family friendly" delivery rooms in compliance with established requirements. The required number of delivery rooms should be calculated as follows: minimum 3 delivery room per 900-1200 annual turnover of deliveries
- postpartum wards with infant cribs (taking into consideration the requirement for rooming-in (placing mother and newborn together) in line with established requirements
- neonatal special care room in line with established requirements
- operating room designated only for obstetric patients
- intensive care room for postpartum/postoperative women
- wards for pathologic pregnancies.

EQUIPMENT

Individual delivery room has essential equipment for care of <u>delivering woman</u> on place and in working condition:

- wall clock with second hand
- wall thermometer
- heat source
- stethoscope
- electric suction equipment
- comfortable maternity bed ready for instrumental delivery- transformer
- centralized oxygen outlet for mothers
- cardio-tocography machine (1:2 delivery rooms).

Individual delivery room has essential equipment for care of neonate on place and in working condition:

- radiant heated bed
- stethoscope
- centralized oxygen and air outlet for newborn with flow meter
- positive pressure bag and masks capable of delivering up to 100% oxygen to the infant
- electric suction equipment for infant
- feeding tubes (6-8 Fr)
- neonatal pulse oximeter for non-invasive blood oxygen monitoring
- air/oxygen blender
- laryngoscope with premature and infant size blades (00,0, 1) (1:4 delivery rooms).

Obstetric department has essential equipment for care of delivering woman on place and in working condition

- cardiopulmonary resuscitation cart/set for mothers (a positive pressure bag, laryngoscope with blades, orotracheal tubes)
- cardiac monitor
- intravenous infusion pump
- cardioversion/defibrillation capability for mothers
- instruments and equipment for assisted deliveries (forceps, vacuum extractor).

Neonatal specialty care room has essential equipment for care of neonate on place and in working condition

- radiant warmer for adequate thermal support
- newborn incubator
- platform scale with metric indicators
- oxygen therapy equipment (oxygen hood, nasal canula for short-term administration of oxygen)
- endotracheal tubes in all the appropriate sizes for neonates
- umbilical vessel catheters and insertion tray
- intravenous infusion pump
- equipment for phototherapy

- pulse oximeter
- equipment for determination of blood glucose – glucometer (bed side)
- cardio monitor (with neonatal arm cuff for external measurement of blood pressure)
- newborn ventilator and/or nasal continuous positive airway pressure (*NCPAP*)
- ophthalmoscope
- device for neonatal hearing screening.

Obstetric operating room in addition to the general operating room requirements has essential equipment for care of neonate on place and in working condition;

- radiant heated bed
- stethoscope
- wall thermometer
- centralized oxygen and air outlet for newborn with flow meter
- positive pressure bag and masks capable of delivering up to 100% oxygen to the infant
- electric suction equipment for infant
- feeding tubes (6-8 Fr)
- neonatal pulse oximeter for non-invasive blood oxygen monitoring
- air/oxygen blender.

All Level II health care facilities are required to have essential diagnostic imaging readily available at place:

- portable obstetric ultrasound equipment present in the delivery area
- mobile X-ray equipment available to the neonatal units
- portable head ultrasound for newborns available to the neonatal units or through written agreement (on call)
- neonatal echocardiography equipment available in house or through written agreement (on call).

4.1.2.4 SUPPORT SERVICES

- Blood bank services available at all times. An appropriately trained technician in-house 24 hours daily. Main blood components readily available, from local stocks or another facility based on prearranged agreement;

- Anaesthesia services available for obstetric emergencies including caesarean section 24 hours daily;
- Radiological and ultrasound services in-house; obstetric diagnostic imaging available 24 hours a day (on-call), with interpretation by physicians with experience in maternal disease and its complications;
- Essential clinical laboratory services available 24 hours daily.

LABORATORY SERVICES:

The facility must have the capability of performing the following essential laboratory services on site or through appropriate referral 24 hours a day:

- Complete blood count; haematocrit (HCT) (in emergency results ready within 60 min after request)
- Major blood groups and Rh typing; blood crossmatch (in emergency results ready within 60 min after request)
- Serum glucose, serum sodium, chloride, potassium, bicarbonate, creatinine, calcium (in emergency results ready within 45 min after request)
- Serum protein and albumin (in emergency results ready within 45 min after request)
- Serum magnesium (in emergency results ready within 45 min after request)
- Screening for anti-rhesus antibodies (Coombs' test indirect); (in emergency results ready within 120 min after request)
- Liver function tests (in emergency results ready within 120 min after request)
- Prothrombin time (PT), partial thromboplastin time (PTT) (in emergency results ready within 120 min after request)
- Bacterial cultures with sensitiveness (in emergency results ready within 72 hours after request)
- Direct and indirect serum bilirubin (in emergency results ready within 120 min after request)
- Blood gases/pH (in emergency results ready within 45 min after request)
- Urinalysis (in emergency results ready within 45 min after request)
- Group B streptococcus, hepatitis B surface antigen, RPR/VDRL, HIV, gonorrhoea.

4.1.2.5 REFERRAL/TRANSPORT

- The level II perinatal care facility must be in permanent communication with the referral receiving center and have a comprehensive transport plan for ensuring timely referral and/or on-site/distant consultation for the complicated maternal and newborn cases;
- The health care facility must have a clear criterion with well-defined list of maternal and new-born conditions, which require referral to the higher-level health care facility.
- The health care facility is in charge of filling all required documentation as outlined in Chapter 4.4.4 and entering the complete and accurate data on each maternal and new-born referral into the electronic system.

4.1.3 Level III (Subspecialty Care)

Level III facilities providing tertiary level maternity care should be reserved for the most complicated pregnancies and deliveries, which require interdisciplinary management and / or continuous life support. Such level maternities must be located within/nearby tertiary multiprofile medical centers with capabilities for all medical and surgical specialties, intensive care etc.

Level III neonatal care envisions having operating Neonatal Intensive Care Units (NICU) which provide care and treatment for all very low gestation (<34 0/7 weeks) infants, in addition to all other newborns requiring intensive care.

4.1.3.1. SERVICES

LEVEL III MATERNITY CARE

- All level I and level II services plus management of all kinds of maternal complications, provision of highly specialized complex and comprehensive services for pregnant and delivering women according to the national/international guidelines and protocols through utilization of high technologies and participation of multidisciplinary team;
- Provide postpartum care after uncomplicated and complicated labor and delivery.

LEVEL III NEWBORN CARE

All level I and level II care plus:

- Sustained life support
- Comprehensive care for infants born at <34 0/7 weeks gestation and infants born at all gestational ages with critical illness
- Prompt and readily available access to a full range of pediatric medical subspecialists;
- Full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide
- Advanced imaging, with interpretation on an urgent basis.

4.1.3.2. STAFFING

- Team of licensed obstetricians/gynecologists to ensure continuous 24 hours in-house availability of minimum 3 specialists;
- Minimum five certified obstetrician/gynecologist with at least 5 years experience in obstetrics including experience in performance of hysterectomy and other obstetrical operative procedures; obstetrician/gynecologist with described experience and competencies should be available 24 hours in-house;
- Team of licensed pediatricians/neonatologists trained in Neonatal Resuscitation Program to ensure continuous 24 hours in-house availability and provision of expanded neonatological services;
- Wide range of pediatric subspecialists (available within 30 min after the call): cardiologist, surgeon, neurologist, genetics specialist, hematologist, endocrinologist, ophthalmologist, pulmonary specialist, gastrointestinal specialist, nephrologist;
- Wide range of subspecialists to provide care for pregnant/delivering women (available within 30 min after the call): cardiologist, surgeon, neurologist, hematologist, endocrinologist, ophthalmologist, pulmonary specialist, gastrointestinal specialist, nephrologist, urologist, infectious disease specialist;
- Anesthesiologist available in house 24 hours a day and experienced in the performance of spinal, epidural and general anesthesia;
- Nurses/midwives - number and level of their competence must ensure adequate care for all pregnant, parturient and postpartum women and newborns.

An adequate nurse/patient ratio:

- 1:2 for patients in labor
- 1:1 for patients in second stage of labor

- 1:5 for patients in postoperative recovery
- 1:10 for postpartum patients without complications
- 1:12 for newborns requiring only routine care

NICU nurse-patient ratio:

- 1:2 for newborns requiring ventilatory support and intensive care
- 1:3 for newborns not requiring ventilatory support but still needing intensive care
- 1:4 for newborns requiring intermediate care
- 1:6 for newborns requiring continuous care.

4.1.3.3 INFRASTRUCTURE AND EQUIPMENT

All Level III health care facilities should have an isolated obstetric department with:

- individual "family friendly" delivery rooms in compliance with established requirements; the required number of delivery rooms should be calculated as follows: minimum 3 delivery room per 900-1000 annual turnover of deliveries;
- postpartum wards with infant cribs (taking into consideration the requirement for rooming-in (placing mother and newborn together) in line with established requirements;
- neonatal care room in line with established requirements;
- operating room designated only for obstetric patients;
- intensive care room for postpartum/postoperative women;
- wards for pathologic pregnancies
- Neonatal Intensive Care Unit (NICU) with intensive, intermediate and continuous care wards in line with established requirements
- Critical Care Unit fully equipped and functional in line with established requirements, which provide complex care for postpartum women with polyorganic and multisystem failure, including respiratory support and invasive cardiovascular monitoring (can be shared with other departments of multiprofile hospital).

EQUIPMENT

Individual delivery room has essential equipment for care of <u>delivering woman</u> on place and in working condition:

- wall clock with second hand

- wall thermometer
- heat source
- stethoscope
- electric suction equipment
- comfortable maternity bed ready for instrumental delivery - transformer
- centralized oxygen outlet for mothers
- cardio-tocography machine (1:2 delivery rooms)
- cardiopulmonary resuscitation cart/set for mothers: a positive pressure bag (1:1 delivery room), laryngoscope with blades (1:2 delivery room), orotracheal tubes (1:2 delivery room)
- cardiac monitor (1:2 delivery room)
- intravenous infusion pump.

Individual delivery room has essential equipment for care of <u>neonate</u> on place and in working condition:

- radiant heated bed
- stethoscope
- centralized oxygen and air outlet for newborn with flow meter
- positive pressure bag and masks capable of delivering up to 100% oxygen to the infant
- electric suction equipment for infant
- feeding tubes (6-8 Fr)
- neonatal pulse oximeter for non-invasive blood oxygen monitoring
- air/oxygen blender
- laryngoscope with premature and infant size blades (00,0, 1) (1:2 delivery room)
- endotracheal tubes in all the appropriate sizes for neonates (1:2 delivery room).

Obstetric department has essential equipment for care of <u>delivering woman</u> on place and in working condition

- cardioversion/defibrillation capability for mothers
- instruments and equipment for assisted deliveries (forceps, vacuum extractor).

Neonatal care room has essential equipment for care of <u>neonate</u> on place and in working condition

- radiant warmer for adequate thermal support

- platform scale with metric indicators
- oxygen therapy equipment (oxygen hood, nasal canula for short-term administration of oxygen)
- single use sets for long lines
- intravenous infusion pumps
- cardiorespiratory monitors with neonatal cuffs for measuring blood pressure
- equipment for phototherapy
- equipment for determination of blood glucose – glucometer
- ophthalmoscope.

Obstetric operating room in addition to the general operating room requirements has essential equipment for care of neonate on place and in working condition;

- radiant heated bed
- stethoscope
- wall thermometer
- centralized oxygen and air outlet for newborn with flow meter
- positive pressure bag and masks capable of delivering up to 100% oxygen to the infant
- electric suction equipment for infant
- feeding tubes (6-8 Fr)
- neonatal pulse oximeter for non-invasive blood oxygen monitoring
- air/oxygen blender
- laryngoscope with premature and infant size blades (00,0, 1) (1 per 2 operating rooms).

All Level III health care facilities are required to have essential diagnostic imaging readily available at place:

- portable obstetric ultrasound equipment present in the delivery area
- mobile X-ray equipment available to the neonatal units
- head ultrasound for newborns available in house
- neonatal echocardiography equipment available in house
- computer tomography (CT) capability available in house (to be accomplished by 2023, meanwhile the service can be available in nearby building).

4.1.3.4 SUPPORT SERVICES

- Blood bank services available at all times. All blood components obtainable on emergency bases either on the premises or by pre-arrangement with anther facility.
- Fully equipped and functional NICU and CCU.
- Full-scale clinical laboratory services available 24 hours daily.

LABORATORY SERVICES:

The facility must have the capability of performing the wide range of laboratory services on site or through appropriate referral 24 hours a day:

- Complete blood count; haematocrit (HCT) (in emergency results ready within 60 min after request)
- Major blood groups and Rh typing; blood crossmatch (in emergency results ready within 60 min after request)
- Serum glucose, serum sodium, chloride, potassium, bicarbonate, creatinine, calcium (in emergency results ready within 45 min after request)
- Serum protein and albumin (in emergency results ready within 45 min after request)
- Serum magnesium (in emergency results ready within 45 min after request)
- Screening for anti-rhesus antibodies (Coombs' test indirect); (in emergency results ready within 120 min after request)
- Liver function tests (in emergency results ready within 120 min after request)
- Prothrombin time (PT), partial thromboplastin time (PTT) (in emergency results ready within 120 min after request)
- Bacterial cultures with sensitiveness (in emergency results ready within 72 hours after request)
- Direct and indirect serum bilirubin (in emergency results ready within 120 min after request)
- Blood gases/pH (in emergency results ready within 45 min after request)
- Urinalysis (in emergency results ready within 45 min after request)
- Group B streptococcus, hepatitis B surface antigen, RPR/VDRL, HIV, gonorrhoea.

Reorganization of perinatal care service delivery

Reorganization of perinatal care service delivery envisions strengthening of the capacity of all facilities providing perinatal care services through improved infrastructure and equipment in line with the set requirements for respective level of facility and human resource capacity building. It is recommended to strengthened and upgrade to level II complex obstetric and neonatal care five public facilities (Bitola, Tetovo, Stip, Kumanovo, Strumica) in different strategic geographic locations (outside of Skopje). The deficiencies of these clinics to meet fully the level II infrastructure and human resource requirements please see in Annex III. The remained regional public clinics (6) with perinatal care services needs to be strengthened to provide the full-scale level I care. The decision on upgrade of services was grounded on complex analyses of individual capacity of the clinics, load of delivery, geographic location, potential for strengthening, established delivery trend in municipalities etc. With remodeled service delivery, each perinatal network will have strong facility with level II perinatal services able to manage locally complex obstetric and neonatal cases, not requiring subspecialty care. Additionally, facilities with level I perinatal services will be strengthened to provide high quality care for normal deliveries and those with mild complications. As such, women in regions will have access to high capacity clinics with strong perinatal care services in close geographic proximity, which eventually will reduce dramatic burden of deliveries for Skopje and tertiary level clinic.

Regional per-facility analyses and proposed recommendations for reorganization of perinatal care service delivery by geographic regions and facilities according to the above described levels of obstetric and neonatal care please see in Annex I.

Maps on current and prospective distribution of clinics with perinatal services by proposed levels of care please see in Annex II.

4.1.4 NICU

The Neonatal Intensive Care Unit (NICU) is organized with personnel and equipment to provide continuous life support and comprehensive care for extremely high-risk newborn infants and those with critical illness.

The NICU is subdivided into the three levels of care depending on conditions managed and availability of appropriate space, equipment and technology: intensive, intermediate and continuous care. All these steps of neonatal care should be integrated in one facility, designated as NICU.

4.1.4.1 Clinical criteria for levels of NICU

The following clinical conditions are managed at intensive, intermediate and continuous levels of NICU:

Intensive care

- Newborn <32 0/7 weeks of gestation;
- Newborn requiring any type of respiratory support (HFNC, CPAP, MV)
- Post-extubation period <24 hours
- Newborns requiring surgical intervention during neonatal period
- Newborns on inotropic and prostaglandin infusion
- Repeat apnea/ cyanosis accompanied with bradycardia
- Endocrine and metabolic disorders, requiring intensive continuous monitoring and complex care
- Exchanged blood transfusion (full or partial)
- Pleural, peritoneal drainage, first 24 hours after removal
- Peritoneal dialysis
- Seizures
- Full parenteral feeding
- Shock
- Arrhythmia.

Intermediate care

- Partial parenteral feeding
- Postoperative period <48 hours
- Congenital anomalies, requiring intensive monitoring within 72 hours after birth
- 24 hours following MRI
- Newborn with sepsis (during the treatment period)
- Meningitis, osteomyelitis, urinary tract infection
- Hypoglycemia, which requires intensive investigation and complex treatment
- Newborn which require respiratory support (mask, hood)

- Newborn 32 0/7 – 33 6/7 week of gestational and/or 1250-1800 g, without demonstrated criteria for “intensive care”
- Newborn with abstinence syndrome
- Hyperbilirubinemia with risk of exchange transfusion, identified within 24 hours after birth
- Newborn with congenital or acquired surgical disorder, which requires close monitoring and further investigation.

Continuous care

- Hyperbilirubinemia, which requires phototherapy
- Feeding problems
- Reconvalescenting babies from intensive and intermediate care
- Newborn without patrone
- Nonstable weight gain.

4.1.4.2 NICU organization and space requirements

The NICU should ideally be located near the delivery area and cesarean delivery room and should be easily accessable from the hospital’s ambulance entrance. It should be located away from the routine hospital traffic.

Intensive care may be provided in individual patient rooms but ideally in separate areas according to the NICU subdivision: intensive, intermediate and continuous care.

The number of nursing and medical personnel required in NICU is greater than in less acute neonatal care areas.

The nurse-patient ratio:

- 1:2 newborn on ventilatory support in intensive care
- 1:3 newborn not on ventialtory support in intensive care
- 1:4 newborn in intermediate care
- 1:6 newborn in continuous care

In addition, the amount and complexity of equipment required at NICU is also considerably greater. In multipatient room, there should be minimum 6 m^2 of floor space allocated for each newborn bed. Beds should be separated by at least 1.2 m apart measured from the edge of one bed to the edge of neighboring bed.

NICU shell have minimum 6 intensive care beds, 6 intermediate and 6 continuous care beds, in total 18 beds. The number of intensive care beds should not exceed the number of intermediate or continuous care beds.

The equipment requirements for NICUs operating in the Republic of North Macedonia (currently UCGO, UCCD and Sistina) per 6 intensive, intermediate and continuous care beds is described below (Chapter 4.1.4.3).

4.1.4.3 Essential equipment for NICU

Three levels of NICU care: intensive, intermediate, continuous

(Requirements are calculated for 6 beds per level)

Equpment	Intensive care	Intermediate care	Continious care
Patient outlets: 2 vacuum outlets, 2 oxygen outlets with flow meters, 2 compressed air outlets, 8 electical outlets, holder for monitor and pump	6 (one set per NICU bed)	6 (one set per NICU bed)	0
Patietn outlet: 1 vacuum outlet, 1 oxygen outlet with flow meter, 2 compressed air outlets, 4 electical outlets, holder for monitor and pump	0	0	6 (1 set per NICU bed)
The isolate infant incubator, modular controller-based incubator with doubled wall, which enables simultaneous control of temperature and humidity parameters, is height and slope adjustable	3 (additional 1 in the NICU)	0	0
The standard incubator, with 6 output (port)	3 (additional 1 in the NICU)	6	1
Open resuscitation bed with temperature servocontrol (the additional bed should be necessary for transfer from delivery room or operating theatre)	2	2	1
Neonatal monitor /T; P; RR; T/A invasive and non-invasive, SP02/	6 (at least 2 for invasive blood pressure monitoring)	6 (without invasive blood pressure monitoring)	2 (without invasive blood pressure monitoring)
Neonatal Ventilator	6 /at least 1 with HFO and 4 with CPAP options/	0	0
Air-oxygen warmer and humidifier	6	3	1
Oxygen blender with flow meter and tubing	6	2	1
Neonatal laryngoscope with different sizes blades (00, 0 and 1)	In each emergency table, at least 1 table	In each emergency table, at least 1 table	In each emergency table, at least 1 table

Neonatal ambu bag with 0 and 1 size masks	6	2	1
Electrical weight scale	In each room	In each room	In each room
Portable examination lights	1 in the NICU		
Pulse oximeter and oximeter probe	6	6	4
X-ray view box or a computer and monitor to review digital images	1 in the NICU		
Emergency table with emergency drugs and supplies	1 per level	1 per level	1 per level
Refrigarator for medication/baby formula	1 in the NICU		
Sterilization for bottle	1 in the NICU		
Phototherapy lump	6	6	3
Umbilical vessel catheterization set	At least 1 in the NICU		
Blood gases analizator	In the NICU		
Glucometer	1 per level	1 per level	1 per level
Portable X-ray	1 in the NICU		
Portable ultrasonongraph /with NUS and neonatal ECHO probe/	In the hospital		
Dispenser for hand hygyene with non-alchohol dezinfactant and wash-basin. The longest distance between each bed should be less than 6 meters	In each room	In each room	In each room
Single usage towel dispenser	In each room	In each room	In each room
Stethoscope with neonatal head	At each bad	At each bad	At each bad
Infusion pump	6	6	6
Syrunge Pump	12	6	3

4.2 Maternal and newborn referral criteria

4.2.1 Maternal referral criteria

a) Maternal conditions to be managed at Level I perinatal care facility:

- Low risk women with singleton term pregnancies (37 0/7 – 41 0/7) with vertex presentation who are expected to have uncomplicated birth
- Term twin gestations
- Uncomplicated obstetric history (without stillbirth, neonatal death, izoimmunization, gestational diabetes, preeclampsia, hemorrhage)
- Uncomplicated cesarean deliveries
- Mild preeclamsia
- Postpartum infection (metroendometritis, fever)
- History of Cesarean section or other uterus surgery
- Absence of extragenital pathologies
- Pregnant woman height ≥150 sm
- BMI ≤ 35 or ≥17

b) Maternal conditions, that are subject to referral from level I perinatal care facility and should be managed at level II perinatal care facility:

- Maternal anamnesis:
  - Genital tract anomaly
  - Pregnant woman height <150 sm
  - BMI >35 or < 17

- Extragenital diseases:
  - Arterial hypertension (level I)
  - Pulmonary hypertension (level I)
  - Gestational diabetes, non insulindependant
  - Chronic cholecystitis
  - Chronic hepatitis
  - Severe iron deficiency anemia (<8 g/dl)
  - Thalassemia
  - Epilepsy
  - Pyelonephritis
  - Bronchial asthma
  - Acute respiratory condition without respiratory failure
  - Antiphospholipid syndrome

- Infectious diseases (acute cytomegalovirus, toxoplasmosis, herpes, chlamydia)

- Obstetric conditions:
  - Childbirth 34 0/7 - 33 6/7 weeks of gestation
  - Premature rapture of membranes (≥34 0/7 weeks of gestation)
  - Pre-eclampsia (except severe pre-eclampsia)
  - Multiple pregnancy (3 fetuses)
  - Vaginal birth after caesarean section (VBAC)
  - Low-lying placenta
  - Placenta previa
  - Large for gestational age fetus
  - Fetus abnormal presentation/breech presentation
  - Delayed childbirth > 41 0/7 weeks of gestation
  - Stillbirth
  - Fetus congenital anomalies, without need for specialist permanent monitoring and / or surgical intervention;
  - Obstetrical hemorrhage
  - Intrauterus fetal growth restriction (estimated fetal weight (EFW) <10th percentile or abdominal circumference (AC) 5th percentile on ultrasound examination, or abdominal circumference discordant with other growth parameters, decreased amniotic fluid or zero or reverses diastolic flow on umbilical artery doppler)
  - Any other conditions of pregnant woman and newborn not listed in the level III referral criteria.

c) Maternal conditions, that are subject to referral from level I and level II perinatal care facility and should be managed at level III perinatal care facility:

- Exstragenital pathologies:

  Cardiovasculatory system diseases:

  - Heart failure
  - Mitral valve stenosis;
  - Prosthetic heart valves

- Arrhythmias (heart rhythm disorders) with haemodinamic disorders
- Large vessel aneurysm
- Ischemic heart disease
- Pulmonary hypertension II-III degree
- Cardiomyopathy
- Arterial hypertension II degree

Autoimmune and systemic diseases:

- Connective tissue diseases (lupus erythematosus, scleroderma, dermatomyositis, rheumatoid arthritis, systemic vasculitis, Reino disease, thrombocytopenic purpura)
- Congenital thrombophilia
- Prothrombin gene, factor V deficiency;
- Methylenetetrahydrofolate reductase (MTHFR) deficiency, homocystinuria

Endocrine system diseases:

- Diabetes I-II type, decompensated
- Gestational diabetes, insulin dependent
- Adrenal insufficiency
- Hyperaldosteronism
- Pheochromocytoma
- Hypophysis adenoma

Gastrointestinal tract diseases:

- Liver acute yellow atrophy
- Portal hypertension
- Splenomegaly with hypersplenism symptoms
- Pregnancy cholestasis
- Esophageal varices
- Acute cholecystitis
- Acute pancreatitis

Hematological diseases:

- Hemolytic anemia
- Sickle cell disease
- Intracellular anemia
- Severe and life-threatening anemia, not responding to treatment

Infectious diseases:

- Acute hepatitis
- Active tuberculosis
- HIV infection / AIDS
- Leptospirosis
- Leishmaniosis

Neurological diseases:

- Uncontrolled epilepsy (resistant to antiepileptic treatment), requires polytherapeutic treatment
- Myotonic or muscular dystrophy
- Acute myelitis

Kidney and urinary tract disease:

- Glomerulonephritis
- Post-transplant condition
- Vasorenal hypertension
- Renal insufficiency
- One kidney

Respiratory system diseases:

- Mukoviszidose
- Pulmonary failure II-III degree

Malignant tumors.

- Obstetric conditions:
    - Delivery 22 0/7 – 33 6/7 weeks of gestation
    - Eclampsia and posteclampsia conditions
    - Preterm onset of labor without delivery at 22 0/7 to 33 6/7 weeks of gestation
    - Multiple pregnancy (> 3 fetuses)
    - Obstetric embolism
    - Postpartum sepsis (peritonitis, septicemia, septicopiaemia)
    - Fetal complications due to serologic incompatibility (edema, hepatosplenomegaly, ascites)
    - History of two and more C-sections.

- All other obstetric and neonatal conditions that require multidisciplinary subspecialized care and/or critical care with full-scale cardio-pulmonary and multisystem support.

4.2.2. Newborn referral criteria

a) Newborn conditions to be managed at Level I perinatal care facility:
    - Healthy term newborns not requiring special care
    - Newborns following short neonatal resuscitation in the period of recovery, and without systemic involvement
    - Neonatal physiologic jaundice and mild pathologic jaundice requiring short term phototherapy with good response on it
    - Mild birth injuries with spontaneous resolution.

b) Newborn conditions that are subject to referral from level I perinatal care facility and should be managed at level II perinatal care facility:

- Gestational age 34 0/7 – 36 6/7 weeks of gestation
- Newborns with mild RDS requiring oxygen support more than 24 hours
- Transient tachypnea of the newborn lasting more than 48 hours
- Moderate birth asphyxia (Apgar score at 1st minute >3 and <6, and at 5th minute >5 and <7)
- Moderate pathologic jaundice with slow response to phototherapy

- Newborns with RH sensibilization
- Infants of Diabetic mothers (pre-existing and gestational)
- Conatal infections with slow response to antibiotic treatment and systemic involvement
- Large for gestational age newborn (Macrosomia)
- Moderate seizures with good response to therapy.

c) Newborn conditions that are subject to referral from level I and level II perinatal care facility and should be managed at level III perinatal care facility NICU department:
   - Gestational age 22 0/7 – 33 6/7 weeks
   - Severe intrauterine growth restriction
   - Severe RDS
   - Meconium aspiration syndrome
   - Severe birth asphyxia (Apgar score in the 1st minute <4, and in the 5th minute <6)
   - Birth injuries requiring additional interventions and investigations
   - Suspected or confirmed intracranial hemorrhage
   - Suspected or confirmed necrotic entrocolitis
   - Neonatal jaundice not responding to phototherapy and raising serum bilirubin levels with a tendency to reach the threshold for exchange transfusion
   - Congenital heart diseases
   - Severe endocrine and/or metabolic system disorders, with need of continuous monitoring of relevant specialist and/or specialized tests
   - Congenital anomalies requiring specialized investigations
   - Conditions with marked thermoregulation inability
   - Infants of drug addicted mothers
   - Recidivate vomiting
   - Congenital pneumonia
   - Pneumothorax
   - Refractory hypoglycemia
   - Intensive hemolysis of any cause
   - Anemia of the newborn requiring blood transfusion
   - Conditions requiring surgical interventions
   - Complicated sepsis and / or meningitis

4.3 Recommendation for the optimal number of inpatient beds

4.3.1 Maternity care beds

a) Delivery rooms/beds

Assumption: individual delivery rooms in all maternity clinics – one delivery bed/delivery room

- Recommended proportion: 1 delivery room/beds per 300-400 deliveries
- Number of deliveries in the Republic of North Macedonia: 21 488 (2018)
- Minimum recommended number of total delivery rooms/beds: 54
- Current capacity: 48
- Deficiency: 6

b) Postpartum maternity beds

- Recommended proportion: 12 postpartum beds per 1000 deliveries
- Number of deliveries in the Republic of North Macedonia: 21 488 (2018)
- Recommended number of total postpartum beds: 258
- Current capacity: 354
- Deficiency: 0

Even through there is no deficiency in overall number of postpartum beds in the Republic of North Macedonia, per--facility analysis showed deficiency in two large clinics – UCOG and Specilized Hospital Mother Teresa, which needs to be corrected shortly (Table 10).

Table 10. Postpartum beds' needs

Hospital	# of deliveries	Postpartum beds		
		Currently	Standard 12/1000	deficit-suficit+
GH Debar	21	12	2	+10
GH Gevgelija	140	8	3	+5
GH Gostivar	673	16	9	+8
GH Kavadarci	400	10	5	+5
GH Kicevo	218	10	3	+7
GH Kocani	169	16	3	+13
GH Kumanovo	1251	20	15	+5
GH Ohrid	481	12	6	+6
GH Prilep	720	20	9	+11
GH Struga	767	13	10	+3
GH Strumica	1013	18	13	+5
GH Veles	505	18	6	+12
GH Remedika	755	12	9	+3
SH Mother Teresa	4132	35	50	-15
SH Sante Plus	382		5	
SH Plodnost	517	7	6	+1
CH Bitola	765	24	10	+15
CH Tetovo	1734	24	21	+2
CH Stip	878	18	11	+7
CH Sistina	1337	22	16	+7
UCGO Skopje	4630	44	56	-12
Total		**354**	**258**	**+96**

c) Level III maternity beds (pregnancy and obstetric)

Proportion of women developing pregnancy and obstetric complications requiring Level III care ranges from 0.5% to 1.5%. Calculations on required number of level III pregnancy and obstetric beds are made both for assumed complications rate 0.5% and 1.5 %

c.1) 5 pregnant women/1000 develop pregnancy complications requiring Level III care (0.5%)

*Assumption: average length of stay in hospital – **14 days***

- Number of deliveries in the Republic of North Macedonia: 21 488 (2018)
- Number of women in need of level III bed: 107
- Patient days: 1504
- Average daily census: 4,1
- **Recommended number of level III pregnancy pathology beds**: 0.91 x 4.1+ 2.6 x √4.1 = **9 beds**
- Current capacity: 20 pregnancy pathology beds
- Deficiency: 0

c.2) 15 pregnant women/1000 develop pregnancy complications requiring Level III care (1.5%)

*Assumption: average length of stay in hospital – **14 days***

- Number of deliveries in the Republic of North Macedonia: 21 488 (2018)
- Number of women in need of level III bed: 322
- Patient days: 4512
- Average daily census: 12.4
- **Recommended number of level III pregnancy pathology beds**: 0.91 x 12.4+ 2.6 x √12.4 = 19 **beds**
- Current capacity: 20 pregnancy pathology beds
- Deficiency: 0

c.3) 5 delivering women /1000 develop obstetric complications requiring Level III care (0.5%)

*Assumption: average length of stay in hospital – **11 days***

- Number of deliveries in the Republic of North Macedonia: 21 488 (2018)
- Number of women in need of level III bed: 106

- Patient days: 1181
- Average daily census: 3.2
- **Recommended number of level III obstetric care beds**: 0.91 x 3.2+ 2.6 x √3.2 = **7 beds**
- Current capacity: 44 postpartum beds at tertiary level + 11 obstetric intensive care beds
- Deficiency: 0

c.4) 15 delivering women/1000 develop obstetric complications requiring Level III care (1.5%)

*Assumption: average length of stay in hospital – **11 days***

- Number of deliveries in the Republic of North Macedonia: 21 488 (2018)
- Number of women in need of level III bed: 322
- Patient days: 3542
- Average daily census: 9.7
- **Recommended number of level III obstetric beds**: 0.91 x 9.7+ 2.6 x √12.4 = 16 **beds**
- Current capacity: 44 postpartum beds at tertiary level + 11 obstetric intensive care beds
- Deficiency: 0

4.3.2 Neonatal Intensive Care Beds

a) **Intensive care beds:**

- Recommended proportion: 1 per 1000 deliveries
- Number of deliveries in the Republic of North Macedonia: 21 488 (2018)
- **Recommended number of total intensive neonatal care beds: 21**
- Current capacity: 23 (11 at UCOG and 12 at UCCD)
- Deficiency: 0

b) **Intermediate care beds:**

- Recommended proportion: 2 per 1000 deliveries

- Number of deliveries in the Republic of North Macedonia: 21 488 (2018)
- **Recommended number of total intermediate neonatal care beds: 43**
- Current capacity: 11 (at UCOG)
- Deficiency:32

c) **Continuing care beds:**

- Recommended proportion: 3 per 1000 deliveries
- Number of deliveries in the Republic of North Macedonia: 21 488 (2018)
- **Recommended number of total normal neonatal care beds: 64**
- Current capacity: 19 (15 at UCOG and 4 at UCCD)
- Deficiency:45

4.4 Maternal and neonatal transport

Well organized and operational transport system and coordinated care represents the foundation of effective functioning and organization of perinatal care and key for improving maternal and infant health outcomes. In over 50% of cases it is not possible to predict maternal and infant complications and there is an urgent need for safe transport to the higher level facility with appropriate capacity to manage complicated maternal and/or newborn conditions.

Safe transport of the perinatal patient requires skilled personnel, appropriate equipment, and effective communication between parties, involved in transport.

This section presents the general recommendations for organization of effective maternal and newborn transport system in the Republic of North Macedonia.

The main objective of well-organized maternal and infant transport is to improve safety and quality of maternal and infant transportation through:

- improving coordination between different parties involved in referral process
- enhancing capacity of transport system
- defining and implementing standardized referral criteria for mothers and newborns.

For establishment of comprehensive and effective transport system, it is recommended to:

- endorse and implement standardized criteria for maternal and newborn referral (Chapter 4.2)
- develop standard procedure with clearly defined roles and responsibilities of referral implementing parties (referring, transporting and receiving centers) and ensure their execution (Chapter 4.4.2)
- develop standardized list of required documentation to ensure effective information flow and exchange between parties (Chapter 4.4.4)
- establish clear communication and effective coordination between respective parties
- define requirements and ensure their fulfilment for maternal and newborn transport modality (Chapters 4.4.3 & 4.4.5) :
    - transport personal (number and competencies)
    - transport vehicle (number of vehicles needed, their equipment and medication)
- monitor and track operation of transport system.

4.4.1 Referral/transport process

The maternal and infant interhospital referral envisions transport of high-risk mothers and / or neonates to the higher level health care facility, which has an appropriate capacity and resources to manage complicated conditions. The process requires effective communication between facilities and a clear understanding of the responsibilities of the parties involved in referral;

- Referring health care center
- Receiving health care center
- Transport.

Given that in MKD there is one main referral receiving hospital for mothers – UCOG and one referral receiving hospital for neonates - UCCD, there is no need for creation of referral operating center, managing and coordinating referrals to various clinics. Instead, referral receiving center shell take over the responsibility for proper organization of maternal and newborn referral (Chapter 4.4.2.3).

Maternal and newborn transportation shell be implemented by appropriately equipped and staffed vehicles (Chapter 4.4.5). Maternal transport shell be performed by routine ambulance cars with additional equipment and supplies for managing obstetric cases (Chapter 4.4.5.1). These ambulance cars should be maintained and located at each level I and level II perinatal care facility.

Newborn transport shell be implemented by specific neonatal transport cars. To meet minimum requirement for timely and safe transport, it is recommended to have two fully equipped neonatal transport vehicles available in the Republic of North Macedonia. There were 92 newborn transfers performed to the UCCD in 2018 (the only health care facility currently available in the Republic of North Macedonia, which receives external referrals), meaning that there is an average of 1 transfer per 4 days throughout the year. Yet, the referral cases may not be evenly redistributed throughout the days of the year. There may be a case when 2-3 referrals are requested per day, which requires availability of two neonatal cars. Hence, it is recommended to have one fully operational and equipped neonatal transport car and one additional reserve for emergency cases in order to meet the requirements of timely and safe transport of newborns.

Sometimes maternal and newborn condition can be stabilized and managed locally by visit of relevant clinician from higher level “support facility” or through distant consultation without need of patient transport. In such cases, higher level facility within perinatal network takes

responsibility for organization of on-time distant consultation/visit of clinician from "support facility".

4.4.2. Roles and responsibilities of parties involved in referral process

4.4.2.1 Referring center responsibilities

Referring center is the health care facility, which requests maternal/newborn referral to the higher-level health care facility (referral receiving center). The referring center is responsible for:

1. Timely and prompt initiation of patient referral according to the developed and approved referral criteria.
2. Appropriate informing of the relevant parties on upcoming referral by referral initiating health care provider (administration/management of the referring center, receiving health care center, patient parents/relatives).

   Telephone consultation with the receiving care provider is recommended to initiate the referral process and to prepare the receiving provider. This consultation may aid the referring care provider in developing plan for stabilizing the patient before and during transport. A discussion between the referring health care provider and receiving care provider regarding the mother/neonate will result in one of three possible dispositions:
   - Required care can be provided at the referring center. The receiving care provider under these circumstances has only a consultative role;
   - The mother/neonate requires further observation, investigation, or other preparation before possible transport. Continued contact between the providers is necessary;
   - Transport of the mother/neonate is necessary. The optimal time, transport personnel, and additional information regarding the mother/neonate should be discussed. The process of stabilization of the patient at the referring center should be reviewed and documented;
3. Effective pre-transport stabilization of mother/neonate in case of confirmed referral;
4. Appropriate informing of patient/parents/relatives on the clinical condition of the patient, justification for the referral and all potential risks associated with patient transportation;
5. Obtaining standardized consent form to authorize patient transfer;

6. Preparing all the required standardized medical documentation for referral before patient transportation and sending them with patient to the referral receiving center;
7. In case of neonatal transport (with specialized neonatal transport vehicle), documenting the time of referral transport request, arrival of transport and time of patient leaving the referring center.

   In case of maternal transport (with local ambulance car), documenting the time patient leaving the referring center.
8. Entering the required information on maternal/newborn transport into the e-system.

4.4.2.2 Transport team responsibilities:

- Ensuring the transport equipment and resources are operational and in line with patient clinical needs;
- In case of delay in arriving to the referral requesting center (meteorological conditions, break down of the vehicle, car accident etc.) immediately informing respective parties (both referral requesting center and receiving center) on expected delay and potential need for mobilization of alternative transport resource;
- Clinical assessment of patient;
- In case of need, pre-transport stabilization of patient jointly with referral requesting center providers;
- Ensuring all required patient documentation from referring center is on place and properly filled;
- During the transportation permanent monitoring of clinical condition and vital signs (T, HR, RR, T/A, SpO2) of the patient;
- In case of need, provision of essential medical care and emergency support;
- In case of deteriorated patients clinical conditions, timely informing referral receiving center in order to reassess the patient's clinical needs and ensure readiness of referral receiving center in responding quickly and promptly to the patient's emerging clinical needs.

4.4.2.3 Referral receiving center responsibilities

Referral receiving center is the health care facility, which accepts maternal/newborn referral from lower level health care facility (referring center). For maternal referrhals it is UCOG, for newborn referral, it is UCCD.

The referral receiving center is responsible for:

1. Receiving the request for referral 24/7/365
2. Gathering the comprehensive information regarding the patient: name, personal identification number (if present), age (gestational and postnatal age in case of neonates), clinical status, medical care provided at referring center, indication for referral;
3. Making the decision jointly with referral requesting center on patient referral or appropriate consultation (distant or on-place);
4. In case of clinical consultancy request:
    - Identifying and contacting the consultant with appropriate for the patient's clinical needs expertise, providing comprehensive information regarding the patient's clinical status and consultancy needs;
    - Ensuring prompt and timely communication between identified consultant and the consultation requesting center.
5. In case of newborn referral request:
    - Mobilize newborn transport vehicle and identify a transport team appropriate for the patient's clinical needs;
    - Sending the transport team to the referral requesting center as up;
    - Documenting the time of referral transport request and sending the transport to referring center.
6. Ensuring readiness and availability of technical (i.e. incubator, ventilator, radiant warmer etc.), human (specialists, nurses etc.) and laboratory resources according to the patient's individual needs;
7. Admitting all referrals directly to the receiving unit to avoid unnecessary delays in the emergency department;
8. Documenting the time of admission/ clinical status of patient according to the required standards;
9. Appropriate informing of patient/parents/relatives on the clinical condition of the patient, treatment strategy, expected potential risks;
10. Periodic communication and clinical status update on the referred patient with appropriate health care providers from the referring facility should be maintained.

4.4.3 Transport personnel

For effective maternal and newborn referral, it is critical to ensure high competency and relevance of transport team to individual needs of patients.

The composition of the transport team should be decided according to the consultations with the referring and receiving health care providers and based on the medical needs of the patient. Transport team members should be selected from appropriately trained physicians, nurse practitioners. The minimum number of transport team members should be three, of which one is the operator of the transport vehicle. The other team members should be comprised of a high-level health professional (doctor) with expertise in the field required for the needs of patient and/or a middle-level health professional (nurse)/fellow/ trained resident etc.

4.4.3.1 Neonatal transport team

Neonatal transport team members should have the collective expertise sufficient to provide the following, if necessary:

- Observation and stabilization of the newborn throughout the transport;
- Monitoring of body temperature, respiratory status, and cardiovascular status;
- Delivery and monitoring of oxygen therapy;
- Initiation and maintenance of IV access and therapy;
- Supportive care for a wide variety of emergency conditions, including advanced neonatal resuscitation and respiratory support.

4.4.3.2 Maternal Transport Team

Maternal transport team members should have the collective expertise sufficient to provide the following, if necessary:

- Monitoring of vital signs, uterine contractions, deep tendon reflexes, and fetal heart rate;
- Monitoring the administration of intravenous infusions and usage of tocolytic, antihypertensive, anticonvulsant, and other appropriate medications;
- Care for a wide variety of emergency conditions including delivery and neonatal resuscitation.

4.4.4 Maternal and neonatal referral documentation

Appropriate documentation is essential for continuing care of mothers and newborns and evaluation of the referral process. Both the referring, receiving centers should have responsibilities to provide adequate documentation of clinical data.

Very importantly, the key information on maternal-newborn referral should be entered into the electronic system by respective parties (Chapter 4.4.4.1 and 4.4.1.2). Currently only paper-based information is filled on all ambulance transfers, which makes it impossible to distinguish and analyze data on maternal referral. Similarly, paper-based information is present for newborn referral with questionable completeness and quality of data. Hence, it is imperative by all parties involved in maternal-newborn transport system to complete all the information required and enter into the electronic system (in relevant module of "Moj Termin"), which will allow quick data extraction and analysis to assess performance of the transport system, identify gaps and plan corrective measures accordingly.

4.4.4.1 Maternal referral documentation

Referring center documentation:

The following documents should be available to the receiving center for the transported patient:

- Copy of complete antenatal record
- Current medical record summary with preliminary or final ICD diagnoses indicated
- Copy of personal ID

The following information should be entered into the electronic module (Moj Termin) by referring center:

- Patient name, personal ID (if applicable), date of birth
- Referral requesting center/provider
- Time of referral request
- Clinical indication for referral, preliminary clinical diagnoses with ICD code indication
- Transport team members, their names
- Time of transport team arrival at the referring clinic/time of consultation provided (if applicable)

Transport team documentation:

The transportation card should be filled by transport team, containing the following information on patient:

- Patient name, personal ID, date of birth
- Referral requesting center
- Time of referral request
- Time of transport team arrival at the referring clinic (if applicable)
- Time of leaving the referring clinic (if applicable)
- Time of arrival at the receiving center
- Transport team members, their names
- Monitoring and care provided during transportation
- Consent to authorize the patient transfer
- Preliminary clinical diagnoses with ICD 10 code indication.

Referral receiving center documentation:

- Maintain an electronic record on the request for maternal admission detailing the following information:
  - date/time of patient admission
  - patient information (if not filled by referring center)
  - diagnoses (ICD code) (if not filled by referring center)
  - name of referring center (if not filled by referring center)
- Send a summary of care of both mother and/or infant to the referring center.

4.4.4.2 Newborn referral documentation

Referring Center documentation:

The following documents should be available to the receiving center for the transported patient:

- Current neonatal medical record summary with the following information provided:
  - Maternal pregnancy/history
  - Date and time of birth
  - Gestational age, anthropometric info (birth weight, height, head circumference)
  - Neonatal resuscitation steps provided in delivery room (if any)
  - Medical intervention/monitoring provided at the referring center

  - Results of clinical/laboratory/diagnostic tests
  - Vaccination/routine screening
  - Preliminary or final clinical diagnoses (ICD code)
  - Time of discharge from the clinic
- Copy of parent/guardian personal ID
- Copy of birth certificate (if available).

The following information should be entered into the electronic module (Moj Termin) by referring center:

- Newborn name, sex, date of birth, gestational age
- Referral requesting center/provider
- Time of referral request
- Clinical indication for referral, preliminary clinical diagnoses with ICD code indication
- Transport team members, their names
- Time of transport team arrival at the referring clinic/time of consultation provided

Transport team documentation:

Filling the transportation card, which contains following information on patient:

- Newborn last name, sex, date of birth, gestational age
- Referral requesting center/provider
- Time of referral request
- Time of transport team arrival at the referring clinic
- Time of leaving the referring clinic
- Time of arrival at the receiving center
- Transport team members, their names
- Monitoring and care provided during transportation
- Consent of parent/guardian to authorize the patient transfer
- Preliminary clinical diagnoses with ICD 10 code indication

Referrhal Receiving Center documentation:

- Maintain an electronic record on the request for newborn admission detailing the following information:

- date/time of referral request
- date/time of patient admission
- patient information (name, sex, date of birth, gestational age) (if not filled by referring center)
- diagnoses (ICD code) (if not filled by referring center)
- name of referring center (if not filled by referring center)

- Send a summary of care provided to newborn/care outcome to the referring center.

4.4.5 Maternal and neonatal transport equipment

Adequate equipment and supply of transport system is essential for ensuring effective maternal and newborn referral.

Organization and maintenance of transport equipment and supplies is the responsibility of vehicle owner institution with contribution from transport team on functionality of equipment and adequacy of quantity and quality of supplies/medication.

4.4.5.1 Maternal transport equipment/supplies

Maternal transport should have all the equipment and medication for provision of general advanced life support required for all ambulance cars [44]. Beside general equipment and supplies, maternal transport should have additional specific equipment and medication for obstetric complications:

Additional equipment/supplies:

- Drape towel or under pad
- Sterile gloves
- Bulb syringe or aspirator
- Cord clamps and/or umbilical ties
- Infant receiving blanket or swaddling materials with a head covering
- Fetal doppler
- Infusion pump
- Oxygen mask
- Newborn resuscitation supplies and equipment.

Additional medications:

a) Antenatal corticosteroids to accelerate fetal lung maturity

- Betamethasone for injection (12 mg IM is usual dose)
- Dexamethasone for injection (6–10 mg IM is usual dose)

b) Eclampsia management medications
   - Magnesium sulfate 6 gram bolus IV, then 2 grams/hr IV. Additional dose of 2 grams over 5-10 minutes for persistent seizures (repeat x 1)
   - Calcium gluconate 1 gram IV to reverse magnesium overdose
   - Sodium amobarbital 250 mg IV over 3 minutes (can substitute another short-acting benzodiazepine)

c) Oxytocics
   - Oxytocin (Pitocin) 10 units per ampule / vial
   - Misoprostol (Cytotec) 100 mcg tablets
   - Methylergonovine (Methergine) 200 mcg ampules
   - Carboprost (Hemabate) 250 microgram ampule / vial

d) Tocolytics
   - Magnesium Sulfate (dosage same as for eclampsia)
   - Nifedipine (Procardia) 10 mg p.o. every 20 minutes. Maximum dosage is 100 mg.
   - Terbutaline Sulfate (Brethine) for injection (0.25 mg subcutaneously at 20 to 60 minute intervals is usual dose).

e) Antibiotics for Group B strep prophylaxis

   - Penicillin G 5,000,000 units IV
   - Ampicillin 2 grams IV
   - Cefazolin 2 grams IV
   - Vancomycin 1 gram IV

f) Antihypertensives

   - Labetalol (Trandate) IV. Dosage is repeated and/or adjusted at 20 min. intervals according to patient response. May sequentially give 20 mg, then 40 mg, then 80 mg, then an additional 80 mg, if insufficient response to the lower doses. Maximum dosage is 220 mg–300 mg.

- Hydralazine (Apresoline) 5-10 mg IV every 20 minutes. Maximum dosage is 30 mg.
- Nifedipine (Procardia) 10 mg p.o. every 20 minutes. Maximum dosage is 100 mg.

4.4.5.2 Neonatal transport equipment/supplies

Neonatal equipment

a) Equipment to maintain a neutral thermal environment for the neonate should include:

- transport incubator, which meets the following requirements:
  - a heat source that requires minimal time for preheating and should maintain ambient temperature within the desired range of 29º to 36º C. The control for temperature setting should be readily accessible and easy to operate, and there should be provision for easy determination of ambient temperature. It is essential to have a fail-safe alarm system that will recognize overheating or underheating.
  - provide an environment in which the oxygen supply is constant and controllable.
  - provide unrestricted visibility of the neonate with a functional independent light source for general illumination provided in or on the incubator.
  - easy accessibility to the neonate resulting in minimal interference with thermal protection and oxygen supply.
- thermometer
- blanket.

b) Equipment for oxygen delivery and monitoring should include:

- oxygen tanks
- air tanks
- pressure gauges
- flowmeters
- oxygen blender
- oxygen tubing and adapters

- oxygen hood or nasal cannulas (preterm and term)
- neonatal oxygen masks (preterm and term)
- neonatal resuscitation manual bag and mask
- continuous positive airway pressure apparatus
- mechanical ventilator.

The following guidelines are related to the use of oxygen during transport:

- a portable supply of oxygen and compressed air in cylinders adequate to last the entire journey with surplus to cover unexpected needs and delays should be carried. Proper restraint of these cylinders is mandatory throughout the transport.
- oxygen cylinders in use should be provided with pressure gauges and flow meters.

c) Devices to maintain the patency of the airway and gastric decompression must be readily available and should include:

- bulb syringe
- regulated suction with gauge
- suction catheters (#6, 8, 10 Fr)
- feeding tube (#6, 8 Fr) with a 20 mL syringe

d) Equipment for vital sign monitoring should include:

- a continuous heart rate monitor
- neonatal stethoscope
- body temperature monitor
- noninvasive blood pressure monitoring devices
- pulse oximeter for noninvasive monitoring of oxygen saturation

e) Equipment for monitoring blood glucose must be available.

f) If intravenous therapy is required, an infusion pump that is portable, battery-powered, fail-safe, and calibrated to ensure accurate delivery of calculated fluid microvolumes must be used. Critical neonates may require multiple intravenous lines requiring additional infusion pumps.

g) The equipment and supplies required for resuscitation of a neonate must be available, portable and should include:

1. Endotracheal intubation

- laryngoscope handle with blades (#00, 0, 1)
- laryngoscope spare bulbs (if necessary)
- laryngoscope spare batteries
- endotracheal tubes (#2.5, 3.0, 3.5, 4.0 mmID)
- oral airways (sizes 00 and 0)
- neonatal resuscitation manual bag and masks
- pressure manometer (to monitor PIP and PEEP if manual ventilation is necessary)
- disposable stylet (#6 Fr)
- adhesive tape or commercial endotracheal tube holders
- scissors

2. Intravenous infusion
   - intravenous needles and catheters (#22, 23, 24, 25, 26 gauge)
   - syringes (1, 3, 6, 12, 20, 35 mL)
   - intravenous armboard
   - intravenous tubing and T connector
   - infusion device
   - tape or site dressing.

i) Equipment for handwashing and personal protection

- antiseptic solution or towelettes
- gloves
- infectious waste disposal bags
- soiled linen disposal bags
- sharps box.

Neonatal medication

Medications should include the following drugs or an approved therapeutic equivalent based on local program protocols.

- naloxone hydrochloride
- normal saline
- phenobarbital
- prostaglandin E1 (requires refrigeration)
- sodium bicarbonate (4.2%)

- adenosine
- ampicillin
- atropine
- calcium gluconate
- dextrose solution (D5W)
- dextrose solution D10W)
- epinephrine (1:10,000)
- fentanyl
- gentamicin
- midazolam
- morphine sulfate
- sterile water
- surfactant (needs refrigeration).

V. Quality of Care and Health Information System

5.1 Quality of Care

The core national health indicators have shown a pronounced improving trend since independence of the country, which reflects continuous policy efforts and dedication of the country government to improve the quality of health care service delivery. Additionally, the post-2000 reforming period, and in particular the 2006 health care reform, envisioned to improve population health and to set up a health care system that is responsive to the needs of the population through several important initiatives and among them establishing the strong health care quality assurance system.

Yet, no operational and efficient system is still on place for monitoring and control that could feed the process of quality improvement in any field of the health care service provision including perinatal health.

The quality culture is not established in the health care system and the quality improvement initiatives are mainly sporadic, not organized in a systemic and coordinated manner.

The section below describes some aspects of health care quality monitoring and assurance already on place in the Republic of North Macedonia and also provides brief overview of still existing gaps and recommendations for improvement.

5.1.1 Quality improvement initiatives

Standardization of care

Standardization of clinical practice has been a cornerstone of improved performance and the quality of health care service provision through minimization of wide variation that exists in many areas of practice, specifically in the field of perinatology. Variations in health care service delivery has proved to increase the risk of errors and malpractice. As such, standardization of any process of care through use of unified evidence-based guidelines, protocols and checklists reduces harmful events and improves performance.

There is no comprehensive and operational system on place in the Republic of North Macedonia for development, approval, dissemination and implementation of the clinical practice guidelines and protocols in any field of health care, including perinatal health.

The process of elaboration of the clinical guidelines and protocols was initiated in 2005 and was limited solely to the translation of international protocols, without any adaptation and any discussion among health care professionals and experts in the field, leading to lack of acceptance and implementation by clinicians. The first set of guidelines was issued in a series of 5 books (hardcopies, not available to all clinicians) and included gynecologic, obstetric and pediatric guidelines. The guidelines for primary health care were issued in 2010/11 [8].

Later on, in 2014 according to the ministerial policy on practicing evidence-based medicine and with technical support from the UNFPA, there was a first attempt to establish a standardized process of development, adoption/adaptation of the clinical practice guidelines in the country. Several workshops were held on the subject in the field of obstetrics and neonatology with support and involvement of international technical expertise.

At the end of 2017, the National Committee for Development of Clinical Guidelines was established within the Ministry of Health with intent to institutionalize the guidelines and protocols development process in the country. Through this committee only few guidelines and protocols were elaborated in the field of obstetrics and gynecology (Postpartum hemorrhage, Pregnancy risk detection, Cervical carcinoma detection), that are evidence-based, translated from internationally recognized sources and, most importantly, adopted and adapted to the local specifics. The rest of the guidelines and protocols existing in the field are simply translated from international sources, never tailored to the country context [45,46].

In fact, the development of clinical guidelines is only the ground stage in standardization of care and improvement of quality of provided services. The elaboration process should be followed by nationwide distribution and dissemination of guidelines & protocols among all relevant clinicians, their training in use of these protocols and, most importantly, practical implementation of developed guidelines with strong monitoring system on place to track the process of implementation, identify and fill the gaps accordingly.

These critical stages in standardization of care (dissemination, implementation of protocols and monitoring process) are not established and operational in the Republic of North Macedonia. The dissemination process is limited to placement of guidelines at the MOH website, which may not be easily accessible and acceptable for all health care professionals [47].

There is an urgent need to institutionalize mechanism for the entire process of clinical practice guidelines and protocols development, dissemination, promotion and systematic monitoring of compliance of perinatal care practices to the standardized clinical protocols. The development and dissemination/promotion should ideally fall under the responsibility of respective

professional associations, while the monitoring part should be mandated to respective quality assurance unit/institution under the MOH, potentially Safe Motherhood Committee - the most relevant and responsible consultative body in the field of perinatology.

Performance-based payment

The attempts to link the payment system with performance of health care providers has long been in the agenda of government health strategy in the Republic of North Macedonia. A performance-based payment mechanisms were first introduced in 2012, encompassing P4P, conditional budgets and preventive health targets with the aim of improving overall quality and efficiency of care, but this mechanism have never achieved its original aim [12].

Grounded on the accumulated evidence and experience, the HIF developed specific mechanisms to purchase health services with set objective to provide incentives for improving the efficiency and quality of health services covered by the HIF, to remunerate physicians and to move away from fixed salaries. The HIF signs annual performance-based contracts with diverse spectrum of health care providers for both curative and preventive services. These contracts encompass stipulations regulating the feed-forward and feedback reporting by health care providers, as well as sanctioning procedures for failure of accomplishing the set targets [12, 48, 49]. However, in regard with perinatal care the system is limited to PHC ob/gyns, providing antenatal care, yet the performance targets do not include any aspects and does not measure the quality of antenatal care service provision. It has a very few (5) targets, mainly administrative, among clinical aspects the targets include gynecological screening tests coverage for women of reproductive age (i.e PAP test). As such, the introduced model still resembles more of a modified fee-for-service scheme, solely based on type and quantity of services provided and not having any mandate or responsibility to monitor and evaluate the qualitative aspects of care provision at least for perinatal care and does not exercise any quality-related sanctions thereof.

Maternal and perinatal death review system

Counting and reviewing every maternal, newborn death and stillbirth is an important strategy for reducing preventable maternal and perinatal mortality. Capturing information on the cases of death facilitates understanding the underlying contributing causes and avoidable factors for systematic, critical analysis of quality of care provided.

A mortality audit in a no-blame environment, by interdisciplinary team, which investigates the circumstances surrounding each death including any collapses in care is an established mechanism, that highlights breakdowns in care provided at each level and ultimately improves quality of services throughout the health system and prevents future deaths.

There was no any system established in the Republic of North Macedonia for revision of maternal and perinatal death cases until recently when with technical support from the WHO EURO and UNICEF, the introduction of the perinatal audit system and training for pre-selected group of professionals was conducted. Following the training, the group of experts was nominated by the MoH to initiate the perinatal deaths audit process according to the proposed WHO methodology and based on three delays model. 34 cases of perinatal deaths (newborn deaths and stillbirths) over 27 weeks of gestation are already reviewed, resulting in production of respective recommendations.

As such, the perinatal audit process started, but requires further extensive efforts to become the solid and sustained measure for improving the quality of perinatal services.

Additionally, there is no maternal mortality and near-miss cases review system on place. Near-miss cases review process yields important information regarding severe morbidity and is a valuable tool to critically look at health system performance, identify gaps and initiate corrective steps through convergent actions. The near miss cases review is specifically applicable for countries like the Republic of North Macedonia with very few maternal death cases and thus limited capacity to investigate health system gaps contributing to the fatal maternal outcome.

Perinatal care quality indicators

The quality indicators represent a critical tool for providing an objective picture, assessing, improving and incentivizing the performance of individual health care institutions and the healthcare system as a whole.

Umbrella organizations such as the World Health Organization, Organization for Economic Co-operation and Development (OECD) etc, have taken an international lead in encouraging health system performance measurement by proposing the set of quality indicators in various health care field, including perinatal health that reflect a robust picture of health care quality to be tracked and monitored.

The Republic of North Macedonia has not established yet a comprehensive system for development and implementation of quality indicators, for data collection, analysis, public reporting and using for performance improvement and decision making.

Yet, there is some set of indicators, which are reportable by health care institutions and regulated by and outlined in the Rulebook. These indicators are general, not specific for obstetric and neonatal care and not reflective of actual quality of perinatal care provided by clinics [50].

There is a distinct need for expanding the mandate of quality indicators, for routine performance measurement and creation of the robust framework for systematic development, implementation and gradual proliferation of obstetric and neonatal care indicators in combination with the collection of comprehensive data through already established e-health system. The process will facilitate to accurate evaluation of effectiveness and efficiency and to raising the quality and productivity of the perinatal care in the country.

Recommended list of obstetric and neonatal quality indicators to be introduced and monitored

- Elective delivery prior to 39 completed weeks of gestation
- 30-days obstetric readmission
- Incidence of episiotomy
- Cesarean rate for low-risk first birth women
- Prophylactic antibiotic in C-section
- Appropriate DVT prophylaxis in women undergoing cesarean delivery
- Appropriate use of antenatal steroids
- Postpartum hemorrhage requiring blood transfusion
- Postpartum hemorrhage requiring hysterectomy
- Intranatal stillbirth rate
- Antenatal stillbirth rate
- Birth trauma rate
- Term newborns transferred to NICU
- Pregnant/delivering women transferred to CCU
- Infants under 34 weeks of gestation delivered at level III facility
- Nosocomial blood stream infections in neonates
- Exclusive breastfeeding at hospital discharge
- Early neonatal death among term newborns
- Neonatal iatrogenic pneumothorax rate

Hospital accreditation

In the attempt to improve the quality of health care, in 2014, the government of the Republic of North Macedonia established the hospital accreditation process performed through the Agency for Quality and Accreditation of Health Care Institutions (see below). The accreditation is mandatory for all hospitals licensed and operating in the country and is performed on regular bases. Accreditation status is provided either for one, three or five years depending on the accomplished standard. After expiring, hospitals are mandated to regain accreditation status through the assessment of compliance with set requirements and standards. As stipulated in the law, facilities not compliant with accreditation standards and requirements and thus not getting the "accredited" status are not eligible for providing hospital-based health care services. Yet, there is no actual penalties applied for hospitals not going through the "mandatory" accreditation process, as such the law is never fulfilled and accreditation mechanisms are not operational [51].

Additionally, despite of original intention to establish a regular system for hospital accreditation as an incentive for improving capacity of national hospitals to provide quality care, the standards and measures utilized by the agency so far for hospital accreditation are minimal, defining the bottom level of care, mainly linked to the structural indicators and not reflective of actual quality of care provided by the health institutions. Finally, the hospital accreditation process is currently focused on general aspects of care, not targeting any specific clinical field. Yet, the Agency for Quality and Accreditation of Health Care Institutions already started working on development of perinatal care accreditation program, which is yet at the initial stage – the process started for development of perinatal care measures and standards [7,51].

5.1.2. Organizational structure for quality assurance

There is no formal and fully functional institution, responsible for the entire scope of quality assurance and control in perinatal health. The quality functions are mostly fragmented and divided between several institutions, operating at different levels:

- Agency for Quality and Accreditation of Health Care Institutions – operates at national level;

- State Center for Reproductive Health (Drzaven centar za reproduktivno zdravje) - operates at national level;
- Committee for Quality Management - operates at health care facility level.

Agency for Quality and Accreditation of Health Care Institutions

The Agency for Quality and Accreditation of Health Care Institutions (Agencija za kvalitet i akreditacija na zdravstvenite ustanovi vo Makedonija) was established by the government of the Republic of North Macedonia in July, 2014 with intention to institutionalize the efforts for creating the robust system of health care quality control and assurance at the national scale.

Despite of the prospective wide scope of operation and comprehensive mandate, the agency is newly established, still at the basic stage of development. It is limited to the general hospital accreditation process, for preparation of standards of care, assessments of health services and accreditations of health care institutions.

Committee for Quality Management

According to the Law for Health Protection, last version of 2012 and amendments of 2016, the quality monitoring and improvement structure - Committee for Quality Management was formally established at each operating hospital in the Republic of North Macedonia. The Committee is mandated to track the quality of provided services, to monitor the progress in accomplishment of health care quality indicators, to review near miss and mortality cases and plan and implement other facility-based quality improvement measures [7]. Yet, the established structure commonly has a formal function, not actually involved in developing and monitoring the quality improvement initiatives in the hospital.

It is imperative to strengthen the capacity and the role of the local committees in designing and implementing facility-based perinatal care quality tracking and improvement strategies, including but not limited to institutionalization of quality indicators, establishment of mortality and near miss cases review system, development and sustaining perinatal quality collaboratives etc.

State Center for Reproductive health

The State Center for Reproductive Health was established in 2014 with support from the Ministry of Health and financed by the Annual Preventive Programs of the Ministry of Health. The SCRH is currently under the auspices of the University Clinic for Gynecology and Obstetrics [52]. The State Center for Reproductive Health collects key perinatal care data from different sources, performs analyses and produces annual reports. Given the experience in data analytics and reports producing, the State Center for Reproductive Health may serve as a center, responsible for institutionalization of perinatal care quality indicators, which includes indicators development, data collection, analysis, public reporting and recommendations producing.

Finally, there is a Safe Motherhood Committee operating under the Ministry of Health, which has no official mandate for quality assurance, but has a capacity to serve as an umbrella institution for accumulating and overseeing all quality initiatives performed at different levels of health system in the field of perinatal health care.

Points of strength

- ⇒ Institutional structure for quality assurance is on place (Agency for Quality and Accreditation of Health Care Institutions, facility-based committees for Quality Management, State Center for Reproductive health)
- ⇒ Development of standardized mechanisms for guidelines/protocols update/development initiated
- ⇒ Perinatal audit process initiated
- ⇒ Pay for Performance (P4P) system introduced
- ⇒ Accreditation process initiated.

Points of weakness

- ⇒ Institutional structure on place, yet the capacity and authority needs strengthening
- ⇒ Standardization of care started with development of system for guidelines/protocols development/update, but system does not yet target dissemination and, most importantly, implementation of protocols.
- ⇒ Accreditation system on place but accreditation mechanisms not applied. Accreditation in specific clinical fields, including perinatal care is at the initial stage of

implementation. Accreditation measures mostly structural, less reflective of actual quality processes;

⇒ Performance-based payment on place but without mandate or responsibility to monitor and evaluate the qualitative aspects of care provision.

Key recommendations

⇒ Raise clinical standards by instituting mechanisms for evidence-based guidelines regular development/revision/update, dissemination, implementation, monitoring of compliance;

⇒ Create a valid hospital accreditation mechanism, extend the existing mandate of accreditation program to perinatal care, reflecting actual quality of care, not simply structural measures;

⇒ Establish a framework of perinatal care quality indicators: develop definitions, data collection and analytical systems;

⇒ Improve the system of performance-based financing through introducing selected quality indicators as a condition for Health Insurance Fund contracting/reimbursement;

⇒ Establish/strengthen routine maternal and perinatal audit system.

5.2 Health Information System

The strong health information system (HIS) is essential for adequate assessment, identification of the health care needs of population within its borders and planning & implementing the effective health care strategies. It intends to collect, manage, analyze, and disseminate accurate health data in a timely manner, so that the health care managers and policy makers can track the health system progress, identify gaps and use the data for making evidence-based decisions. To accomplish these objectives, HIS should be well-defined, comprehensive, functional, adaptable, scalable, and resilient.

Upon recommendation to set up a strong health information system by the World Bank supported Health Sector Transition Project (1996–2002), the Republic of North Macedonia has undertaken efforts to create a comprehensive system involving the Ministry of Health and the HIF [7,53].

An Integrated Health Information Strategy was developed by the Ministry of Health in 2006 with aim to recommend the necessary actions for rectifying deficiencies in health information systems and putting in place frameworks for optimal development and utilization of health information. The strategy has revealed existing diversity in technical and information technology capacities among various health care providers, a lack of unified and standardized system for data entry, which hampered both the data utilization, usability and comparability across the country. The integrated strategy proposed several key initiatives for development of comprehensive and well-functional health care information system (i.e. creation of unified coding systems, electronic health records and cards etc.).

A unified coding system and the DRG in hospital care were introduced and started to be implemented in 2009, followed by the electronic health records and the electronic health card in 2013 [12].

Importantly, a National Integrated Healthcare Information System called "Moj Termin" was launched in 2013 as a substantial step forward in creation of sophisticated and truly integrated health information system, with fully fledged data gathering and management structure to be in the next several years [12]. "Moj Termin", initially being a simple internal tool for reducing waiting times at three tertiary care facilities with appointment and an electronic health records module, gradually expanded across more than 5000 health care providers and service points, with more then 18.000 users (10.000 doctors). "Moj Termin" aggregates data on three health areas: Healthcare, Health Prevention and Public Health [54].

In the field of Healthcare, the system includes: Electornic Health Records (EHR), electornic health appointment system, waiting lists, E-referrals, E- prescriptions, daily medical reports, module for monitoring the pregnancy and delivery etc [54].

In 2015, the government institutionalized the integrated health information system through establishing the Directorate for e-health, as a semi-independent authority for health data collection and management. This Directorate is responsible for health data collection and management, and provision of health statistics on wide range of health indicators, including perinatal health. Importantly, the Directorate for e-health has data exclusively from clinics which are part of the Health Insurance Network - mainly public hospitals [54]. There is a distinct need to expand the data collection process to private hospitals as well through appropriate regulations, mandating private hospitals to enter the data into the system.

The other conventional sources of data in the field of perinatology are:

- The civil registration and vital statistics system - registers vital events (births and deaths) and supports issuing corresponding official documents on these events. The system operates with multispectral collaboration and involvement: Ministry of Health, Ministry of Justice and the State Statistical Office [55].
- The State Statistical Office (SSO) – collects nationwide data on vital statistics, which are publicly available. The institution is governed by the state authorities, and is linked to the Civil Registration System. The state statistical office has limited portfolio, not mandated for in-depth data analytics on wide range of other health indicators [56].
- State Center for Reproductive Health (SCRH) - collects the perinatal data from all over the country and produces annual publication titled "Perinatal Results" that accumulates aggregated annual data.

The existing extensive data capacity ensured through E-health Directorate is not fully utilized, and the data are mostly collected and analyzed on some simple perinatal care indicators. Yet, the system has a capacity to present the wide range of data both cumulative and disaggregated by facility: number and structure of admitted patients, all relevant information regarding deliveries (length of the gestation, mode of delivery, delivery complications, multiple pregnancies etc.), newborns (disaggregated by birth weight and gestational age), perinatal outcomes (live births, stillbirths) etc.

Additionally, the hospital-based obstetric and neonatal data are not fully linked with antenatal care records. Importantly, there is an integrated e-system on place, which targets and reflects both antenatal and obstetric/neonatal care. However, the data are not commonly entered into the system by primary health care ob/gyns for antenatal care which impedes the continuity of care and smooth information flow between outpatient and inpatient perinatal care providers.

There is a clear necessity to train health professionals for quality and complete data entry into the system. Not all health professionals, specifically those providing ANC are literate in computer use and if are, still majority do not feel obliged to enter complete and accurate data into the system.

As such, it is strongly recommended to strengthen the legislative ground for mandating the quality data entry and stipulate provisions for incompliance with data quality and completeness requirements both for ambulatory ANC and inpatient obstetric and neonatal services.

There is also no universal and holistic system for perinatal data collection/analysis/ exchange and data coordination between different sources/institutions, the data often are fragmented. It is recommended to standardize the perinatal health information system, with respective strong regulation, clearly defining the roles and responsibilities of different institutions (i.e civil registration, SSO, Institute of Public Health, State Center for RH, Agency for Quality and Accreditation) in data collection, data transfer/exchange, analysis, reports producing and sharing.

It also should be emphasized that the completeness and quality of maternal mortality statistics in the Republic of North Macedonia is poor due to the limited capacity of the country both to count and to correctly classify the causes of maternal death. The civil registration system is not strong and not able to accurately attribute the cause of death necessary for calculating reliable estimates of MMR. The Reproductive Age Mortality Study, which is often applied by countries with immature civil registration system for measuring the magnitude of overall and cause-specific maternal mortality, have never been conducted in the country. Triangulation of different sources and establishment of maternal mortality active surveillance is critical to ensure reliable maternal mortality statistics in the country.

Additionally, an important area that requires further efforts is the population-based data. First and foremost, the population census of 2002 as the central reference tool for all types of health care analysis, including perinatal health, urgently requires an update. There is a lack of population-level and individual-level data (e.g. health outcomes by regions, age, economic status and ethnicity) as well as of household, consumption and health surveys.

Furthermore, there is an important lack of data that assesses health system efficiency, such as data on health workforce by regions, institutions and professions and data on resource utilization.

Finally, the question of data transparency and public reporting requires appropriate attention and needs to be resolved properly. It is commonly believed that the universal availability of accumulated health data at the level of the facility and above improves clinical performance, increases accountability of health institutions and helps patients and payers to make better decisions concerning the choice of providers.

Yet, public reporting and data transparency should be done prudently, without harming and scaring neither patients nor health care professionals/institutions since the latter might feel

threatened by negative image, potential punitive measures and, consequently, may be prone for data distortion and refusal for cooperation.

To sum up, the Republic of North Macedonia established a truly integrated health information system which is a tremendous resource for various cross-sectional data analyses and aggregation, it also incorporates features that are useful for health policy & resource planning and health care quality tracking, linking quality with payment etc. Yet, the resource is not fully utilized and, most importantly, the data entering system is not fully-operational and entered data is not used for in-depth analysis and evidence-based decision making.
Further improvement of data systems should be acknowledged as crucial in all future reforms to support health policy development in the Republic of North Macedonia.

Points of strength

⇒ Sophisticated and truly integrated health information system on place

Points of weakness

⇒ Discrepancy in statistics between different sources, fragmented data;
⇒ Suboptimal quality of maternal and neonatal mortality/stillbirth statistics;
⇒ Sophisticated and truly integrated health information system (Moj Termin) on place, but not utilized for health care performance monitoring and improvement;
⇒ Antenatal care records not present in e-system, poor informational linkage between antenatal and obstetric/neonatal care;
⇒ No electronic data on maternal and newborn transport;
⇒ Poor data entry practices; Health professionals not mandated to enter complete and accurate data into the system;
⇒ Not all health professionals, specifically those providing ANC literate in computer use and operation in e-system.

Key recommendations

⇒ Avoid fragmented data collection, ensure data exchange, coordination and verification between different sources, link integrated HIS with other conventional sources: State Statistics Office, Civil Registry etc;

⇒ Improve mortality statistics through triangulation of different data sources, establishing a system of maternal death active surveillance;

⇒ Standardize and institutionalize system for routine perinatal data collection, analyses, report producing and data utilization for policy informing and health decision making;

⇒ Revise and refine module on maternal and newborn transport in e-health system to reflect all key data on transport system operation;

⇒ Raise health professional's competences in utilization of e-health system where needed;

⇒ Establish strong legislative ground mandating quality and complete data entry by respective parties/health professionals;

⇒ Link complete and quality data entry into the system with performance targets (P4P) to motivate health professionals and ensure quality data entry.

VI. References

[1]. Automotosojuz na Makedonija. Available from: http://www.amsmspi.mk/mk/oddalecenost.asp. Accessed on 28.03.2019;

[2]. State Statistical Office. Key indicators. Accessed on 30.03.2019;

[3]. Statistical Yearbook of the Republic of North Macedonia (2019). State Statistical Office of the Republic of North Macedonia;

[4]. World Health Organization. Regional Office for Europe. European Health for All database (HFA-DB). Available from: https://gateway.euro.who.int/en/datasets/;

[5]. Eurostat. Fertility statistics. Available from: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Fertility_statistics. Accessed on 24.03.2019;

[6]. M.Roser. Fertility Rate. OurWorld In Data.org. 2019. Available from: 'https://ourworldindata.org/fertility-rate;

[7]. Government of the Republic of North Macedonia. Law on Health Protection in Republic of North Macedonia (2019) ("Official Gazette of the Republic of Macedonia" nos. 43/2012, 145/2012, 87/2013, 164/2013, 39/2014, 43/2014, 132/2014, 188/2014, 10/2015, 61/2015, 154/2015, 192/2015, 17/2016, 37/2016 and 20/2019 and "Official Gazette of the Republic of North Macedonia" no. 101/2019);

[8]. Government of Macedonia. Law on health insurance. Official Gazette of the Republic of Macedonia No 25/2000, changes up to "Official Gazette of the Republic of North Macedonia" no. 142/2016);

[9]. Агенцијата за лекови и медицински средства на Република Македонија. Available from: https://malmed.gov.mk/;

[10]. Health Insurance Fund of the Republic of North Macedonia. Available from: http://www.fzo.org.mk/default-en.asp;

[11]. Health Strategy of the Republic of Macedonia, 2020. Safe, efficient and just health care system. Ministry of Health. Skopje, February, 2007;

[12]. Milevska Kostova N, Chichevalieva S, Ponce NA, van Ginneken E, Winkelmann J. The former Yugoslav Republic of Macedonia: Health system review. Health Systems in Transition, 2017; 19(3):1–160;

[13]. Key Informant - Health Insurance Fund representative;

[14]. Health Insurance Fund. Media press. Available from: http://www.fzo.org.mk/WBStorage/Files/SoopstenieGinekolozi2018.pdf;

[15]. Ministry of Health of the Republic of North Macedonia. Strategies. Available from: http://zdravstvo.gov.mk/wp-content/uploads/2012/12/strategija-bezbedno-majcinstvo.pdf;

[16]. Official Gazette of the Republic of North Macedonia 9/19. Available from: http://zdravstvo.gov.mk/wp-content/uploads/2019/02/9.2019-programi-2019-javno-zdravje.pdf;

[17]. Ministry of Health of the Republic of North Macedonia. Available from: http://zdravstvo.gov.mk/wp-content/uploads/2012/12/strategija-seksualno-i-reproduktivno-zdravje.pdf;

[18]. Report of the Institute for Health Protection of Mothers and Children. Health Center, Skopje (2019);
[19]. The World Bank Report, IBRD IDA. Available from: https://databank.worldbank.org/reports.aspx?source=2&series=SH.DYN.NMRT&country=MKD;
[20]. Trends in maternal mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. ISBN 978 92 4 156514 1;
[21]. Health Insurance Fund.Internal Database;
[22]. Health Insurance Fund. Sample contract between the HIF and Primary Gynecologist. Available from: http://www.fzo.org.mk/WBStorage/Files/Dogovor%202014%20Ginekologija.pdf;
[23]. Key informant - PHC gynecologist. September, 2019;
[24]. E-health Directorate database, 2019;
[25]. Sheba Medical Center. Perinatal Care Master Plan, 2011;
[26]. Key Informants - Ministry of Health and hospital representatives;
[27]. Ministry of Health: Report on Assessment of the Emergency Obstetric and Neonatal Care. UNFPA, 2018;
[28]. Profile of Human Resources for Health in the Republic of North Macedonia. Ministry of Health, 2017;
[29]. Doctor's Chamber of the Republic of North Macedonia. Available from: http://lkm.org.mk/mk/zapis.asp?id=278;
[30]. Key informant - member of the Association of the Nurses and Midwives of the Republic of North Macedonia;
[31]. Institute for Public health. Available from: www.iph.mk;
[32]. Key informant – core group members;
[33]. Polivalent Patronage Services. Health Center Skopje, 2017;
[34]. Ministry of Health of the Republic of Macedonia. Rule book for changes and additions to the Rule book on the criteria for determining the organizational units of the public healthcare institutions. Official Gazette of the Republic of Macedonia no. 04/2007;
[35]. Ministry of Health of the Republic of Macedonia. Information about the ongoing activities to expand the scope and type of services provided by the polyvalent patronage service in the Republic of Macedonia, 2011;
[36]. Individual statistics from clinics;
[37]. HFA Database, WHO Regional Office for Europe, 2017. Note: republic of NM has reported data until 2013;
[38]. Polivalent Patronage Services. Health Center Skopje, 2017;
[39]. Budget of the HIF. Available from: http://www.fzo.org.mk/WBStorage/Files/1.%20JZU.pdf Accessed October, 22nd, 2019;
[40]. Sofijanova A, Sajkovski A, Fidanovski D, Hristovski A, Koich L. Audit of Premature Infants and Critically Ill Neonates Requiring Ex-Utero Transport by the First Macedonian Neonatal Emergency Transport Service: A Retrospective Descriptive

Study. *Macedonian Journal of Medical Sciences. 2009 Jun 15; 2(2):145-148.* doi:10.3889/MJMS.1857-5773.2009.0041
[41]. Key Informant – representative from Legal Department of MOH;
[42]. Guidelines for Perinatal Care, 8th Edition. AAP Committee on Fetus and Newborn and ACOG Committee on Obstetric Practice;
[43]. American Academy of Pediatrics (2012). Levels of Neonatal Care. *Pediatrics 130 (3):* 587- 97.
[44]. Tennessee Perinatal Care System. Guidelines for Transportation. (Sixth Edition);

[45]. The World Bank. The Health Sector Management Project. Available from: https://projects.worldbank.org/en/projects-operations/project-detail/P086670;
[46]. Ministry of Health of the Republic of North Macedonia. Guideline for prevention and treatment of the primary postpartum haemorrhage. 2018. Available from: http://zdravstvo.gov.mk/upatstvo-za-prevencija-i-tretman-na-primarna-postpartalna-hemoragija/ Accessed October 12th 2019;
[47]. Ministry of Health. Upatstva. Available from: http://zdravstvo.gov.mk/upatstva-3/;
[48]. РЕПУБЛИКА МАКЕДОНИЈА ФОНД ЗА ЗДРАВСТВЕНО ОСИГУРУВАЊЕ НА МАКЕДОНИЈА.2014 Available from: http://www.fzo.org.mk/WBStorage/Files/Dogovor%202014%20Opsta%20Medicina.pdf;
[49]. Health Insurance Fund. Преглед на склучени договори на здравствени установи со ФЗОМ. Available from: http://www.fzo.org.mk/default.asp?ItemID=DE1582942BD97545BC84131875D00AC5;
[50]. Ministry of Health. ПРАВИЛНИК ЗА ВИДОВИТЕ НА ИНДИКАТОРИТЕ ЗА КВАЛИТЕТ НА ЗДРАВСТВЕНАТА ЗАШТИТА. Available from: http://zdravstvo.gov.mk/wp-content/uploads/2012/12/pravilnik-indikatori-za-kvalitet.pdf;
[51]. Agencija za kvalitet I akreditacija na zdravstveni ustanovi. Available from: https://www.akazum.gov.mk/wp-content/uploads/2019/10/Standardi-za-akreditacija-na-ZU-bolnici.pdf;
[52]. Government of the Republic of North Macedonia. Program for active health care protection of the mothers and children in Republic of Macedonia. 2018;
[53]. World Bank. 1996. Macedonia - Health Sector Transition Project (English). World Development Sources, WDS 1996. Washington, DC: World Bank. Available from: http://documents.worldbank.org/curated/en/689651468773712751/Macedonia-Health-Sector-Transition-Project;
[54]. Key informant – representative from E-health Directorate, Ministry of Health;
[55]. Office for Management of Registers of Birth, Marriages and Death. Ministry of Justice. Available from: https://www.uvmk.gov.mk/en/dokumenti-na-upravata;
[56]. State Statistical Office. Republic of North Macedonia. http://www.stat.gov.mk/OblastOpsto_en.aspx?id=31.