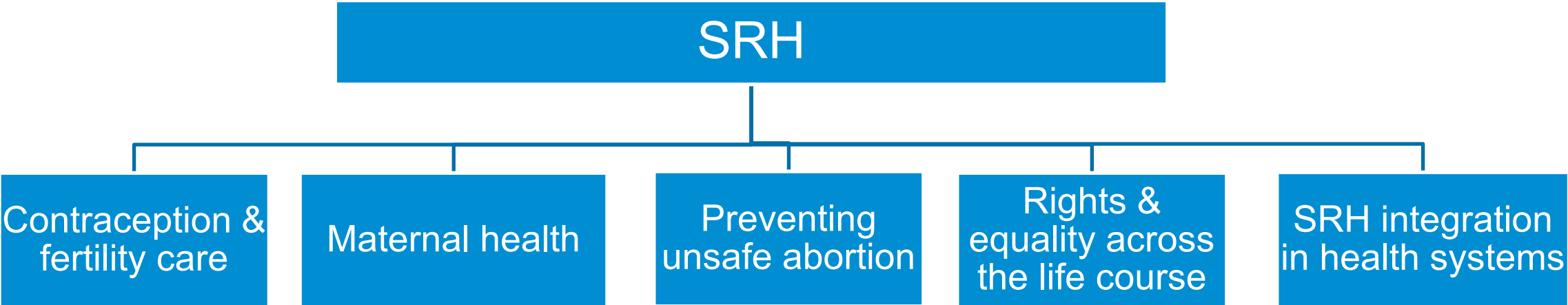


TREATMENT AND DIAGNOSTIC GUIDELINES, ESSENTIAL MEDICINES LISTS, ESSENTIAL IN VITRO DIAGNOSTICS LIST SESSION

Sexual and Reproductive Health and Research Department Update

Mariana Widmer, Scientist, WHO/SRH/MPH

Department of Sexual and Reproductive Health and Research (SRH)



17 July 2024
Updated recommendations for the treatment of *Neisseria gonorrhoeae*,... *Chlamydia trachomatis*, and...

16 July 2024
Recommendations for the treatment of *Trichomonas vaginalis*, *Mycoplasma genitalium*, *Candida*

29 October 2024
WHO guideline on the prevention and diagnosis of rheumatic fever and rheumatic heart disease

21 December 2023
WHO recommendations on the assessment of postpartum blood loss and... use of a treatment bundle

19 July 2024
Consolidated guidelines on differentiated HIV testing services

Laboratory and point-of-care diagnostic testing for sexually transmitted infections, including HIV

18 September 2024
WHO recommendation on screening of pregnant women for intrapartum antibiotic prophylaxis for the... prevention...

**guidelines led by HHS or NCD*

**guideline led by MCA*

Contraception & fertility care

- **No new medicines/diagnostics recommended**
- 8 new IVDs for HIV and HPV have been prequalified by WHO in the last year



Year PQ	Type of assay	Prod. Name	Manufacturer
2024	HIV NAT	Accupower HIV-1 Quantitative RT-PCR	Bioneer corp
2024	HPV vir tech	cobas 4800 HPV	Roche Molecular Inc
2024	HPV NAT	xpert HIV-1 viral load XC	Cepheid AB
2024	HPV NAT	Alinity m HIV-1	Abbot Molecular Inc
2024	HPV NAT	xpert HIV-1 viral Qual XC	Cepheid AB
2023	HPV NAT	cobas HIV-1/HIV-2 qual nucl acid test cobas 6800/880 and cobas HIV-1/HIV-2 qual	Roche Molecular Inc
2023	HPV NAT	SAMBA II HIV-1 Qual whole blood test	Diag for the Real World
2023	HPV vir tech	cobas HPV	Roche Molecular Inc

- No new medicines/diagnostics recommended



Blood loss measurement recommended—no defined way.



Care bundle for PPH recommended (massage, oxytocic, TXA, IV fluids).



Universal vs risk-based screening; ATB per 2015 guideline (AMP or PCN G).



Use of echocardiography for screening recommended.

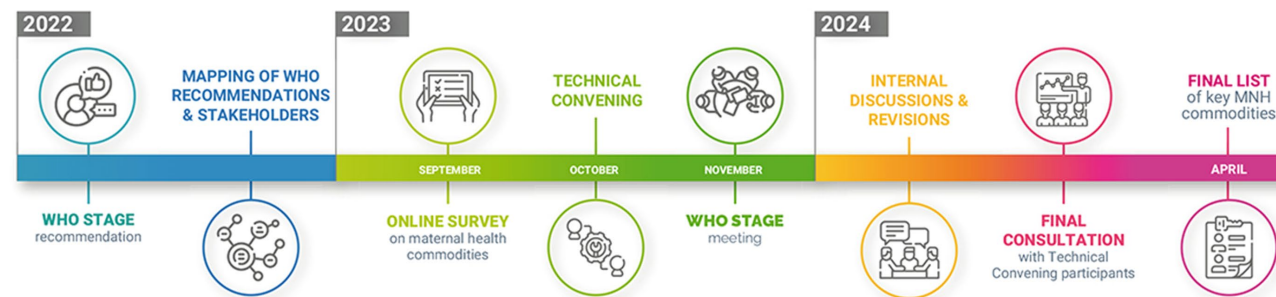
Maternal Health – Target Product Profiles



- **Target population:** pregnant women and adolescents
- **Indication:** with risk factors/with the disease
- **Safety:** no embryo-fetal toxicity nor teratogenicity
- **Administration:** non-invasive preferred
- **Stability:** stable at 30°C
- **Volumes:**
 - PTL/PTB: 15 million PTB/year
 - PE: 7 million PE/year

Maternal Health: List of key WHO-recommended MNH commodities *

- Published in 2024.
- It aims to accelerate progress towards the SDGs. It fosters coordinated action and streamlines care delivery across the entire continuum.
- It includes commodities that are:
 - Critical for reducing maternal, fetal, and newborn deaths
 - Essential for providing high-quality care



*work led by MCA

List of priority MNH commodities (Maternal)

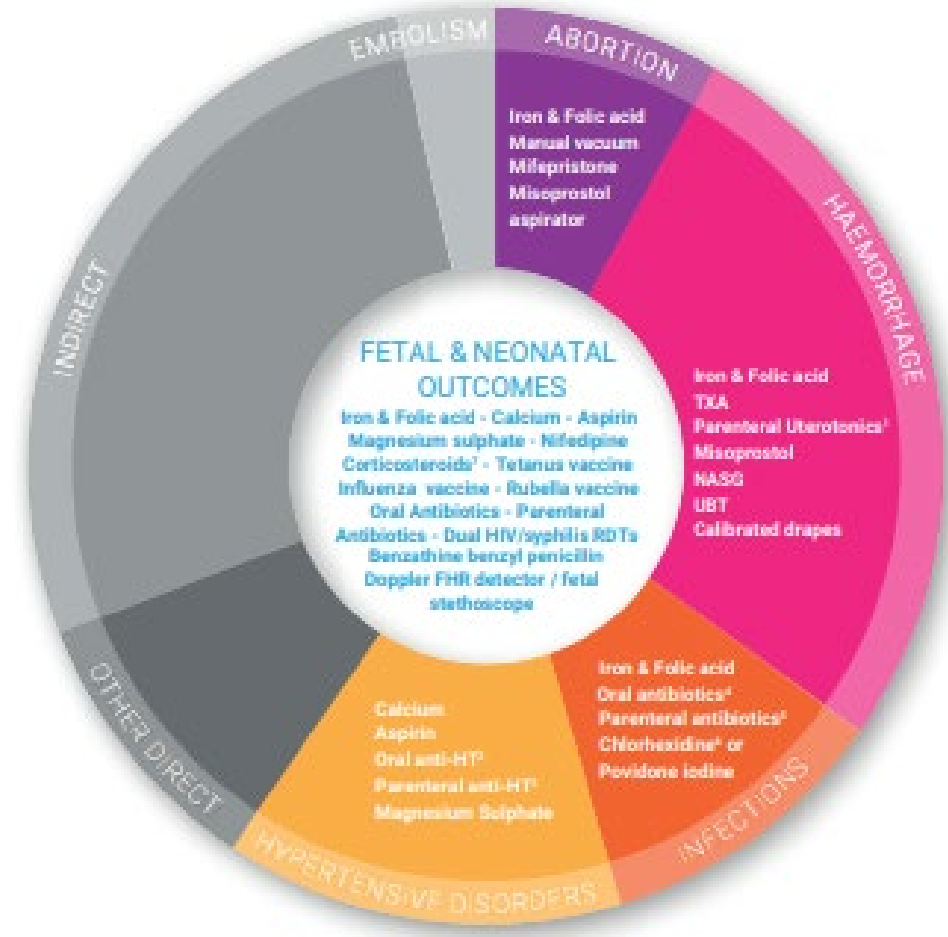
Maternal health commodities

KEY

- Alcohol-based chlorhexidine
- Aqueous chlorhexidine or povidone iodine
- Aspirin
- Benzathine benzyl penicillin
- Calcium
- Calibrated drapes
- Dexamethasone or betamethasone
- Doppler fetal heart rate (FHR) detector or fetal stethoscope
- Dual HIV/Syphilis RDTs
- Elemental Iron & Folic Acid
- Ergometrin
- HS-Carbetocin
- Hydralazine
- Inactivated influenza vaccine
- Labetalol
- Magnesium Sulphate (19)
- Manual vacuum aspirator (MVA)
- Methyldopa
- Mifepristone
- Misoprostol
- Nifedipine
- Non pneumatic anti-shock garment (NASG)
- Oral Antibiotics
- Oxytocin
- Parenteral Antibiotics
- Rubella vaccine
- Tetanus vaccine
- Tranexamic acid
- Uterine Balloon Tamponade (UBT)

ENABLING

- Automated and semi-automated blood pressure measuring devices (BPMs)
- Commodities for assisted vaginal delivery (Forceps or Vacuum extractor)
- Commodities for blood grouping and matching
- Commodities for GRAM Staining
- Commodities to evacuate retained products after birth
- Hemoglobinometer
- Isotonic crystalloids
- Non-mercury thermometer
- Safe blood & blood products
- Ultrasound
- Ultrasound for Uterine Artery Doppler



List of priority MNH commodities (Neonatal)

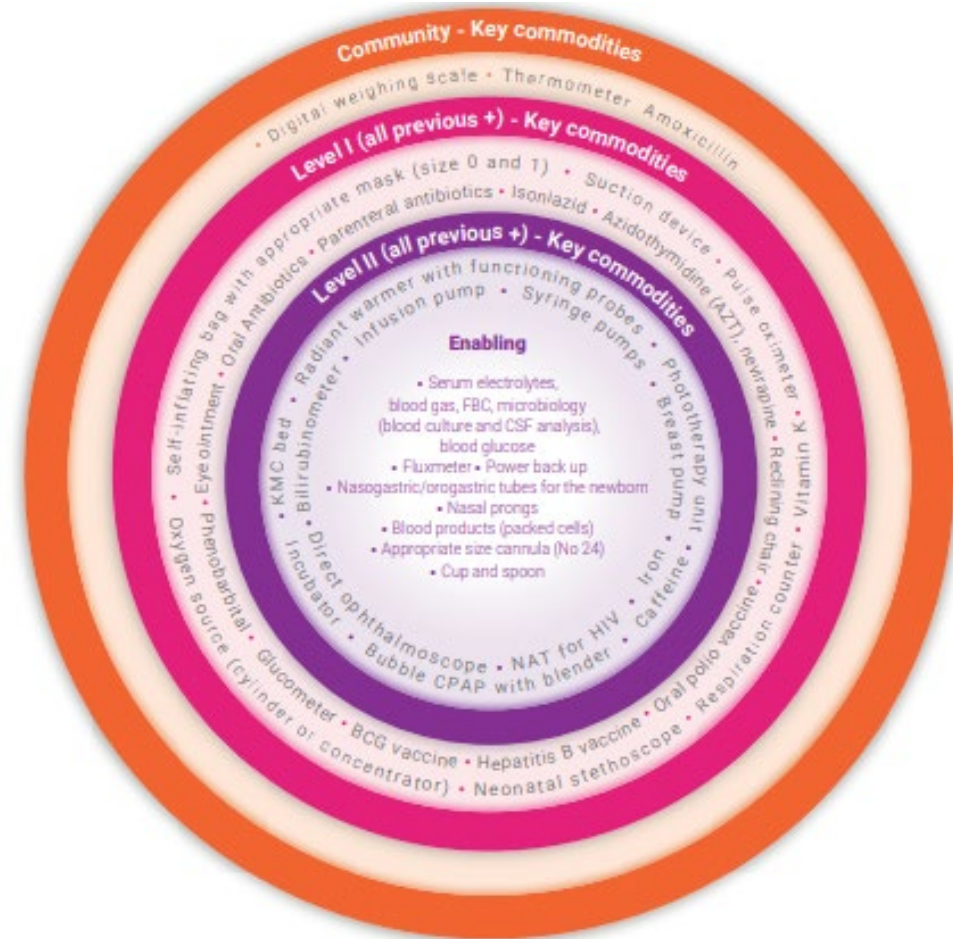
Newborn health commodities

KEY

- AZT (zidovudine), Nevirapine
- BCG vaccine
- Bilirubinometer
- Breast pump
- Bubble CPAP with blender
- Caffeine
- Digital weighing scale
- Direct ophthalmoscope
- Glucometer
- Hepatitis B vaccine
- Incubator
- Infusion pump
- Iron
- Isoniazid
- KMC bed
- Neonatal stethoscope
- Nucleic Acid Test (NAT) for HIV
- Oral Antibiotic: Amoxicillin
- Oral Azithromycin and Erythromycin
- Oral polio vaccine
- Oxygen source (cylinder or concentrator)
- Parenteral Antibiotics: Ampicillin and Gentamicin, procaine benzylpenicillin
- Phenobarbital
- Phototherapy unit
- Pulse oximeter
- Radiant warmer with functioning probes
- Reclining chair
- Respiration Counter
- Self-inflating bag with appropriate mask, (size 0 & 1)
- Suction device
- Syringe pumps
- Thermometer
- Topical tetracycline and erythromycin
- Vitamin K (Phytomenadione)

ENABLING

- Blood products (packed cells)
- Commodities to measure serum electrolytes, blood gas, FBC, microbiology (B/C and CSF analysis), blood glucose
- Cup and spoon
- Fluxmeter
- Nasal prongs
- Nasogastric/orogastric tubes for the newborn
- Power back up



Access to quality assured medicines in SRH

- Access to quality assured SRH medicines in LMIC is a significant concern.
- Evidence shows that 30-50% of medicines used in pregnancy in LMIC are of substandard quality.
- To ensure access to quality assured SRH medicines in LMICs, it is crucial for stakeholders at multiple levels to implement effective interventions.

Pregnant and Lactating Women and Girls Task Force (PLWG)



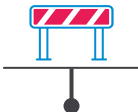
Public health needs

PLWG continue to have limited access to health interventions due to historical exclusion from clinical trials.



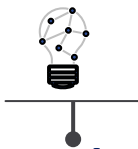
Momentum

- .WHA resolution
- .WHO Clinical Trials workstream.
- .Increasing engagement among stakeholders for a proactive approach to PLWG health needs.



Barriers

Initiatives to promote inclusion of PLWG exist but are often fragmented and disconnected.



Opportunity

WHO's convening power to heighten awareness and foster coordination and collaboration to improve health interventions for PLWG.

ACCESS to quality assured medicines for MNCH in LMICs				
Funding	R&D; extension label indications; repurposing drugs	Reg., QA, supply chain, budgets	Healthcare providers' training	Advocacy
Donors	Pharma Industry NGOs	Health systems and Finance	Health systems NGOs	Communities NGOs
WHO and special programmes Public health needs, research coordination, norms & standards, country implementation				
Countries' needs				

Task Force

Led by SRH and RFH



Thank you

Back-up slides

8 new IVDs for HIV and HPV have been prequalified by WHO in the last year

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)
2024	HIV NAT	Accupower HIV-1 Quantitative RT-PCR	HIV-1111	RoW	Bioneer Corporation	Bioneer Corporation, Bioneer Global Center, 71, Techno 2-ro, Yuseong-gu, Daejeon, Daejeon-gwangyeoksi 34013 Republic of Korea
2024	HPV Virological Technologies	cobas 4800 HPV	05235804190, 05235782190, 05235910190, 05235901190, 05235855190, 05235839190, 05235812190, 05235871190, and 05235863190.	CE-marked	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA
2024	HIV NAT	Xpert HIV-1 Viral Load XC	GXHIV-VL-XC-CE-10	CE-marked	Cepheid AB	Cepheid AB located at Röntgenvägen 5 Solna, 17127, Sweden
2024	HIV NAT	AInity m HIV-1	08N45-090	CE-marked	Abbott Molecular Inc.	1300 East Touhy Avenue, Des Plaines, IL 60018 USA
2024	HIV NAT	Xpert HIV-1 Qual XC	GXHIV-QA-XC-CE-10	CE-marked	Cepheid AB	Cepheid AB located at Röntgenvägen 5 Solna, 17127, Sweden
2023	HIV NAT	cobas HIV-1/HIV-2 Qualitative nucleic acid test for use on the cobas 6800/8800 and cobas HIV-1/HIV-2 Qualitative Nucleic acid test for use on the cobas 5800/6800/8800 Systems	07862113190, and 09040528190	CE-marked	Roche Molecular Systems, Inc.	Roche Molecular Systems, Inc., located at 1080 US Hwy 202 South Branchburg Township, 8879, United States of America
2023	HIV NAT	SAMBA II HIV-1 Qual Whole Blood Test	4500-12	CE-marked	Diagnostics for the Real World Ltd	Diagnostics for the Real World in San Jose, CA, USA
2023	HPV Virological Technologies	cobas HPV	07460155190, 07460171190, 07002238190, 06997546190, 06997511190, 06997538190, 06997503190	CE-marked	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA

Preterm birth

TPP	Drugs to prevent PTB	Drugs to manage PTL
Indication	Pregnant women and adolescents with risk factors for PTB	Pregnant women and adolescents at GA<37w with spontaneous PTL
Target population	Pregnant across a range of GA, including 1 st trimester	Pregnant across a range of GA
Efficacy	Reduction in incidence of PTB or in adverse fetal/neo outcomes	Extension of pregnancy to permit corticosteroids administration, or reduction in adverse fetal/neo outcomes
Safety	No embryo-fetal toxicity/teratogenicity Comparable to current therapies	Idem
Administration	Non-invasive preferred	Idem
Stability	Stable at 30°C	idem
Volumes	Estimations based on incidence of PTB (10.6% = 15 M PTB/year)	idem



Preeclampsia

TPP	Drugs to prevent Preeclampsia	Drugs to treat Preeclampsia
Indication	Prophylactic treatment of pregnant women with risk factors for PE	Treatment of women with PE regardless severity of disease
Target population	Pregnant women with risk factors for PE	Pregnant and postpartum women with PE
Efficacy	Reduction in incidence of PE or in adverse fetal/neo outcomes	Reduction in incidence of adverse outcomes or signif. difference in extending pregnancy duration
Safety	No embryo-fetal toxicity/teratogenicity No clinical adverse effects	Idem
Administration	Non-invasive preferred	Idem
Stability	Stable at 30°C	Idem
Volumes	Estimations based on incidence of PE (5% = 7 M PE/year)	Idem