Unitaid
SAVE LIVES FASTER

Landscape report

Small and sick newborn care

Medicines, diagnostics, devices and service delivery models for the prevention, diagnosis and management of conditions in small and sick newborns



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Foreword

Despite remarkable progress in child survival over recent decades, far too many newborns continue to die from causes that we know how to prevent and treat. For Malawi and many countries across Africa, reducing newborn mortality remains one of the most important and urgent health priorities.

The smallest and sickest newborns–including babies born too soon, too small, or with complications at birth–face the greatest risk. Yet these newborns are often the least visible. Their survival depends on timely access to quality care, skilled health workers, essential medicines, functioning equipment, and strong referral systems.

In Malawi, we have made important advances in maternal and newborn health. However, we know that progress will require more than individual interventions. It requires health systems that can consistently deliver integrated care for mothers and newborns, from pregnancy through childbirth and the critical weeks that follow.

This landscape assessment provides an important contribution to that effort. It highlights the tools, technologies, and service delivery approaches that can help improve outcomes for small and sick newborns. Just as importantly, it identifies the barriers that continue to limit access and scale, from financing and procurement challenges to workforce, infrastructure, and service delivery constraints.

The findings reinforce an important reality: the greatest opportunity before us is not simply to develop new solutions, but to ensure that proven solutions reach every newborn who needs them. By strengthening care for small and sick newborns, investing in resilient health systems, and supporting families and communities, we can save lives and improve lifelong outcomes for countless children.

I welcome this assessment as a valuable resource for governments, donors, implementers, manufacturers, and advocates. Together, we must translate its insights into action to strengthen newborn care and expand access to lifesaving interventions.

The future of every nation begins with its children. By investing in the care of the smallest and most vulnerable newborns today, we invest in healthier families, stronger communities, and a more prosperous future for Malawi and beyond.





Hon. Madalitso Chidumu Baloyi
Minister of Health and Sanitation
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Abbreviations

3PL	Third-party logistics
ACS	Antenatal corticosteroids
ACTION-I	Antenatal corticosteroids for improving outcomes in preterm newborns trial
AGA	Appropriate for gestational age
AI	Artificial intelligence
AI/ML	Artificial intelligence / machine learning
AIR	Augmented infant resuscitator
AMC	Advance market commitment
AMR	Antimicrobial resistance
ANA	African neonatal association
ANC	Antenatal care
AOP	Annual operational plan
API	Active pharmaceutical ingredient
AST	Antimicrobial susceptibility testing
bCPAP	Bubble continuous positive airway pressure
BHAP	Belém Health Action Plan
BIO	Binocular indirect ophthalmoscopy
BLES	Bovine lipid extract surfactant
BVM	Bag-valve-mask
CDC	Centers for Disease Control and Prevention
CDST	Clinical decision support tool
CDSTs	Digital clinical decision support tools
CE Mark	Conformité Européenne – certification mark
CHAI	Clinton Health Access Initiative
CHF5633	CHF5633 synthetic surfactant candidate
CHW	Community health worker
CLMC	Comprehensive lactation management center
CLMCs	Comprehensive lactation management centers
CMV	Cytomegalovirus
COVID-19	Coronavirus disease 2019
CPAP	Continuous positive airway pressure
CRP	C-reactive protein test
CSF	Cerebrospinal fluid
CSO	Civil society organization
cTn1	Cardiac troponin 1
DHFF	Direct health facility financing
DHIS2	District health information software 2
DNA	Deoxyribonucleic acid
DRC	Democratic Republic of the Congo
DRF	Drug revolving fund
ECG	Electrocardiogram
ECOWAS	Economic Community of West African States
EFCNI	European Foundation for the Care of Newborn Infants
eLMIS	Electronic logistics management information system
EMA	European Medicines Agency
EML	Essential medicines list
ENAP	Every Newborn Action Plan
EPMM	Ending preventable maternal mortality

EPSS	Ethiopian pharmaceuticals supply service
EWENE	Every Woman Every Newborn Everywhere
FA-BCID	Film array blood culture identification panel
FBC	Full blood count
FCDO	Foreign, Commonwealth & Development Office
FDA	Food and Drug Administration
FIND	Foundation for Innovative New Diagnostics
FiO2	Fraction of inspired oxygen
Fr	French gauge
FSPT	Filtered sunlight phototherapy
g/dL	Grams per decilitre
GA	Gestational age
Gavi	Gavi, the Vaccine Alliance
GBS	Group B streptococcus
GFF	Global Financing Facility
GMP	Good manufacturing practice
GS1	Global standards one
HBB	Helping babies breathe
HIC	High-income country
HIE	Hypoxic ischemic encephalopathy
HIV	Human immunodeficiency virus
HMF	Human milk fortifier
HMIS	Health management information system
HMIS/DHIS2	Health management information system / district health information software 2
ICROP	International classification of retinopathy of prematurity
ICU	Intensive care unit
IDA	International dispensary association foundation
IFU	Instructions for use
iKMC	Immediate kangaroo mother care
ILCOR	International liaison committee on resuscitation
IMNCI	Integrated management of neonatal and childhood illness
IMPAC	Integrated management of pregnancy and childbirth
INSPIRE	Improving National Supply Chains for Maternal and Newborn Health Products Access and Resource Effectiveness
IoT	Internet of things
IPC	Infection prevention and control
IPU	Inter-parliamentary union
IV	Intravenous
JICA	Japan International Cooperation Agency
KEMSA	Kenya Medical Supplies Authority
KIDROP	Karnataka Internet Assisted Diagnosis of Retinopathy of Prematurity
KII	Key informant interview
KMC	Kangaroo mother care
LBW	Low birthweight
LED	Light-emitting diode
LISA	Less invasive surfactant administration

LISA/MIST	Less invasive surfactant administration / minimally invasive surfactant therapy
LMA	Laryngeal mask airway
LMAs	Laryngeal mask airways
LMC	Lactation management center
LMIC	Low- and middle-income country
LMIS	Logistics management information system
LMU	Lactation management unit
LTA	Long-term agreement
MDR	Multidrug-resistant
MgSO4	Magnesium sulfate
MIST	Minimally invasive surfactant therapy
MNCAH	Maternal, newborn, child and adolescent health
MNCH	Maternal, newborn and child health
MNH	Maternal and newborn health
MoH	Ministry of health
MoHFW	Ministry of health and family welfare
MPDSR	Maternal and perinatal death surveillance and response
MRSA	Methicillin-resistant staphylococcus aureus
MSSA	Methicillin-susceptible staphylococcus aureus
MTB/RIF	Mycobacterium tuberculosis / rifampicin resistance
MTTS	Medical technology transfer and services
MUST	Mbarara University of Science and Technology
NBS	New Ballard Score
NEC	Necrotizing enterocolitis
NEML	National essential medicines list
NEST360	Newborn essential solutions and technologies
NFC	Near-field communication
NG	Nasogastric
NGO	Non-governmental organization
NHM	National health mission
NICU	Neonatal intensive care unit
NMR	Neonatal mortality rate
NMRA	National medicines regulatory authority
NSU	Newborn stabilization unit
O2	Oxygen
OaaS	Oxygen-as-a-service
ODA	Official development assistance
OECD	Organization for Economic Co-operation and Development
OEM	Original equipment manufacturer
OOP	Out-of-pocket
PATH	Program for Appropriate Technology in Health
PCM	Phase-change material

pCO2	Partial pressure of carbon dioxide
PCR	Polymerase chain reaction
PCT	Procalcitonin
PHC	Primary health care
PMNCH	Partnership for maternal, newborn & child health
PMTCT	Prevention of mother-to-child transmission
pO2	Partial pressure of oxygen
PoC	Point of care
PPP	Public-private partnership
PQ	Prequalification
pRBC	Packed red blood cells
QI	Quality improvement
QoCS	Quality of care standards
R&D	Research and development
R4D	Results for Development
RDS	Respiratory distress syndrome
RDT	Rapid diagnostic test
RHSC	Reproductive health supplies coalition
RMNCH	Reproductive, maternal, newborn and child health
ROI	Return on investment
ROP	Retinopathy of prematurity
SAA	Serum amyloid A
SADC	Southern African Development Community
SALSA	Surfactant administration through laryngeal or supraglottic airways
SaMD	Software as a medical device
SBBC	Safer births bundle of care
SDG	Sustainable Development Goal
SGA	Small for gestational age
SNCU	Special newborn care unit
SpO2	Peripheral oxygen saturation
SRA	Stringent regulatory authority
SSA	Sub-Saharan Africa
SSN	Small and sick newborn
SSNC	Small and sick newborn care
TB	Tuberculosis
TBA	Traditional birth attendant
Tele-SNCU	Tele-special newborn care unit
TPP	Target product profile
TSB	Total serum bilirubin
U5MR	Under-five mortality rate
UHC	Universal health coverage
UK	United Kingdom
UN	United Nations
UNFPA	United Nations Population Fund
UPS	Uninterruptible power supply
USA	United States of America
USAID	United States Agency for International Development
USD	United States dollar
USG	United States government
UV	Ultraviolet
VEGF	Vascular endothelial growth factor
VKDB	Vitamin K deficiency bleeding
VLBW	Very low birthweight
WHA	World Health Assembly
WHA77	77th World Health Assembly
WHO	World Health Organization
µPAD	Microfluidic paper-based analytical devices

Key definitions

This glossary is organized around three questions that reflect the structure of the report and help orient readers who may be less familiar with newborn health.

1. Who are the newborns?

Understanding the newborns most at risk, the conditions they face and why they account for a disproportionate share of mortality and disability.

Term	Definition
Appropriate for gestational age (AGA)	A newborn whose birthweight falls within the expected range for their gestational age and sex.
Low birthweight (LBW)	Birthweight below 2,500 grams, regardless of gestational age.
Neonatal mortality rate (NMR)	The number of deaths during the first 28 days of life per 1,000 live births.
Neonatal period	The first 28 days of life. This is the period when the risk of death is highest and when most newborn-specific interventions are delivered.
Prematurity	The condition of being born before 37 completed weeks of gestation. Prematurity is a leading cause of newborn illness and death globally.
Preterm birth	Birth occurring before 37 completed weeks of pregnancy.
Small and sick newborns (SSN)	A newborn who is at elevated risk of death, illness or long-term disability because they are born too early (preterm), too small (low birthweight or small for gestational age), or are clinically ill during the newborn period.
Small for gestational age (SGA)	A newborn whose birthweight is below the 10th percentile for babies of the same gestational age and sex.
Very low birthweight (VLBW)	Birthweight below 1,500 grams.

2. What care do they need?

Understanding the interventions, services and models of care that improve survival, health and long-term developmental outcomes for SSNs.

Term	Definition
Continuum of care	The integrated delivery of health services across pregnancy, childbirth, the newborn period and post-discharge follow-up.
Family-centered care	An approach to newborn care that actively involves parents and caregivers as partners in care and decision-making.
Kangaroo mother care (KMC)	A model of care for preterm and low birthweight newborns based on prolonged skin-to-skin contact, breastfeeding support and caregiver involvement.
Levels of newborn care	WHO's framework for organizing newborn services according to complexity and capability.
Oxygen ecosystem	The complete set of systems required to safely provide oxygen therapy, including oxygen sources, delivery devices, pulse oximeters, maintenance systems, trained staff, power supply and financing.
Quality of care (QoC)	The degree to which health services improve desired health outcomes and are safe, effective, timely, efficient, equitable and people-centered..
Small and sick newborn care (SSNC)	The package of preventive, diagnostic, treatment and supportive services required to improve survival and health outcomes for SSNs.

3. What determines whether that care reaches them?

Understanding the health systems, markets, financing, policies, and partnerships that enable or prevent access to quality newborn care.

Term	Definition
Climate-resilient health systems	Health systems that can anticipate, respond to, and recover from climate-related shocks and stresses while maintaining delivery of essential health services.
EWENE (Every Woman Every Newborn Everywhere)	A global initiative led by WHO, UNICEF, UNFPA and partners that supports countries to end preventable maternal and newborn deaths and improve quality of care.
Health system readiness	The extent to which a health system has the workforce, infrastructure, financing, products, information systems and governance needed to deliver quality care.
Market shaping	A set of strategies used to improve access to health products by addressing barriers related to affordability, quality, supply, demand and market sustainability.
Product access	The ability of health systems and patients to obtain and appropriately use quality-assured medicines, diagnostics, devices and other health technologies when needed.
Sustainable Development Goal (SDG) 3.2	The global target to end preventable deaths of newborns and children under five years of age by 2030.

Executive summary

Introduction

Despite substantial progress in child survival over the past two decades, the neonatal period remains the most critical and least improved frontier in reducing under-five mortality. In 2024, an estimated 2.3 million newborns died within the first 28 days of life, accounting for nearly half of all under-five deaths globally. While the global neonatal mortality rate declined significantly between 2000 and 2015, the pace of improvement has slowed markedly in recent years and approximately 66 countries remain off track to achieve SDG target 3.2 to end preventable newborn deaths.

Small and sick newborns (SSNs), including those born preterm, with low birthweight, small for gestational age or clinically ill during the newborn period, represent the population at greatest risk. More than one in four babies born globally meet criteria for at least one SSN phenotype, and these newborns account for more than half of neonatal deaths. The burden is concentrated in low- and middle-income countries (LMICs), particularly in sub-Saharan Africa and South Asia, which together account for more than 80% of global neonatal mortality.

This landscape examines medicines, diagnostics, devices and service delivery innovations relevant to the prevention, diagnosis and management of the three leading causes of neonatal mortality and morbidity: complications of prematurity, intrapartum-related complications and neonatal infections. The analysis focuses on interventions delivered primarily through facility-based newborn care, with particular emphasis on WHO Levels 1 and 2 care, where the greatest opportunities exist to improve outcomes at scale.

The central finding of this landscape is that the greatest barriers to reducing neonatal mortality are no longer a lack of evidence or effective interventions. Rather, they lie in translating proven interventions into routine practice through functional newborn care systems capable of delivering integrated, high-quality care reliably and at scale.

Key messages

- SSNs account for a disproportionate share of neonatal mortality and morbidity, and progress in reducing neonatal deaths remains slow.
- Most high-impact interventions already exist and are recommended in global guidance; the primary challenge is expanding equitable access and effective use.
- District-level Level 2 newborn care has emerged as the critical implementation bottleneck for improving survival outcomes.
- Product access barriers vary substantially across intervention types and require differentiated strategies.
- Quality small and sick newborn care (SSNC) depends on interconnected health-system components functioning together, rather than products or individual service-delivery interventions in isolation.
- Fragmentation across the innovation-to-access pathway continues to slow translation of evidence into implementation.
- Climate-related pressures, conflict, displacement and other shocks can compound existing newborn risks and health-system vulnerabilities, particularly in already underserved settings.

High-level background

The burden of SSN is large, concentrated and inequitable. Prematurity, intrapartum-related complications and infections frequently overlap, creating complex clinical needs that require integrated care rather than disease-specific approaches. Preventable maternal conditions, including syphilis, also contribute substantially to stillbirth, neonatal mortality, prematurity and low birthweight, highlighting the importance of integrated maternal-newborn approaches to improve outcomes. Stillbirth and preterm birth share many of the same causes and risk factors, so efforts to prevent them are most effective when linked across the maternal–newborn continuum, from antenatal care through facility-based newborn care and follow-up. There is emerging evidence around the high number of newborn deaths post discharge. Beyond mortality, survivors face elevated risks of neurodevelopmental impairment, visual impairment, chronic respiratory disease, growth faltering and lifelong disability, making SSNC a human capital and economic imperative as well as a child survival priority.

The policy environment for newborn health is stronger than at any previous point. Global frameworks including WHO Levels and Standards of Care, the WHO–UNICEF Model of Care for SSNs, the Every Woman Every Newborn Everywhere (EWENE) Product Pathway, and WHO Quality of Care Standards provide a clear framework for improving neonatal survival, particularly through

strengthening care around birth and services for SSNs. However, implementation remains uneven across and within countries. The challenge is less the absence of technical guidance than the limited capacity of health systems to translate standards into consistently high-quality care. Persistent gaps in workforce competency, essential equipment and commodities, referral systems, data use and quality improvement mechanisms continue to impede reductions in neonatal mortality at facility level.

Facility- and hospital-based newborn care, particularly Level 2 care, has emerged as a critical bottleneck. Effective care depends on interconnected health-system components functioning together, including political commitment and leadership, sustainable financing, a competent and motivated workforce, appropriate infrastructure, reliable equipment and commodities, robust data systems, functional referral systems, maternal-newborn linkages, family and community involvement, and post-discharge follow-up. Across many high-burden settings, these requirements remain absent, fragmented or only partially functional. These challenges can be amplified in rural, remote, fragile and humanitarian settings, where distance, conflict, displacement, climate-related disruption and interruptions to infrastructure, utilities, supply chains and referral systems can further constrain access to and continuity of quality newborn care.

Product landscape

This landscape identified and analyzed 98 medicines, diagnostics and devices relevant to the prevention, diagnosis, monitoring and treatment of conditions affecting SSNs. Interventions were identified through a structured review of global guidance documents, published and grey literature, expert consultation and stakeholder engagement. Products were assessed against predefined inclusion criteria, including relevance to the leading causes of neonatal mortality and morbidity, potential impact on newborn outcomes, alignment with WHO Levels of Care, feasibility of implementation in LMIC settings, and relevance to current policy and programmatic priorities.

To support prioritization and strategic analysis, interventions were categorized as **Global Standards**, **Global Standards with Significant Access Gaps** or **Emerging Innovations**. This categorization distinguishes between interventions that are already globally recommended and supported by strong evidence, those that remain underutilized despite established effectiveness, and newer and emerging technologies that may address persistent unmet needs in the future.

A central finding of the landscape is that the majority of interventions with the greatest potential to reduce neonatal mortality already exist and are supported by global guidance. The analysis therefore points not to a major innovation gap, but to a substantial access and implementation gap. While continued innovation remains important in selected areas, the greatest opportunities for improving outcomes in the near term lie in expanding access to proven interventions and ensuring they can be delivered reliably within functional newborn care systems.

Product landscape summary

WHO level of care	Medicines – prevention	Diagnostics	Medicines – treatment	Devices	Total
Level 1 – Immediate and essential newborn care	2	8	2	5	**17**
Level 2 – Special newborn care	5	21	17	21	**63***
Level 3 – Intensive newborn care	0	2	4	1	**7**
Cross-cutting	-	4	-	7	**11**
Total	**7**	**35**	**22**	**34**	**98**

**Caffeine citrate is listed twice (as a prevention and treatment medicine) but only counted as one intervention.*

More than half of the prioritized interventions identified in this landscape are intended for delivery at Level 2 facilities, reinforcing the importance of district-level inpatient newborn care as the primary platform for improving outcomes among SSNs. These facilities serve as the critical bridge between basic newborn care and intensive neonatal care, and are increasingly expected to manage prematurity, respiratory distress, neonatal infections, jaundice, feeding difficulties and other common causes of newborn morbidity and mortality. Feeding and nutrition are core components of this care: lactation support, safe feeding of expressed breastmilk and, where available, donor human milk are central for preterm and low-birthweight newborns. In sepsis, infection prevention and control and antimicrobial stewardship are important upstream priorities alongside diagnosis and treatment.

Several themes emerge from the product landscape:

- First, diagnostics and devices represent some of the largest remaining opportunities to improve newborn outcomes.
- Second, product effectiveness is closely linked to service delivery readiness, especially nursing and physical space infrastructure.
- Third, important innovation gaps remain, but they are concentrated in specific areas rather than across the landscape as a whole.
- Finally, product design and procurement need to account for the conditions in which technologies will operate, including unreliable electricity, heat, humidity, dust and limited maintenance capacity.

Understanding these barriers, and how they differ across product categories, is critical to identifying the most effective strategies for improving access and accelerating impact.

Product market access barriers

While the broader landscape assessed 98 products, a subset of nine interventions was selected for deeper market access analysis. These interventions were chosen based on a combination of criteria, including impact on the three primary drivers of newborn mortality, relevance to high-burden LMIC settings and stakeholder interest. Collectively, they represent a diverse cross-section of products that illustrate the range of challenges affecting access to SSNC interventions.

The analysis found that product access barriers vary substantially across interventions. Although many products face common challenges, such as financing constraints or procurement inefficiencies, the underlying drivers of poor access often differ. To better understand these patterns and identify actionable solutions, the nine interventions were organized into four product archetypes. The archetypes group products that face similar combinations of market, health-system, operational and adoption barriers, helping to identify where common strategies may be effective across multiple products. This approach moves beyond product-specific analysis and provides a practical framework for prioritizing investments and interventions across the broader SSNC ecosystem. Note that while the products are grouped by similarity of primary constraints, secondary product-specific constraints and recommendations to overcome these are noted in Sections 3 and 6 respectively. For instance, while bubble continuous positive airway pressure (CPAP) is classified into the first archetype, “Strengthen operational models for improved uptime,” we also note the need for building provider confidence later in the document. Similarly, surfactants are also constrained by price; however, the primary challenge today is that the use of current products is very challenging in Level 2 settings in LMICs.



Product archetypes and barriers

Product archetype	Products	Primary constraints	Strategic implication
Strengthen operational models for improved uptime	• LED phototherapy • Bubble CPAP • Pulse oximeters	Device malfunction, weak maintenance systems, lack of consumables/spare parts, fragmented procurement, limited biomedical engineering capacity, poor uptime monitoring.	Strengthen lifecycle support and uptime management.
Find LMIC-appropriate product or administration	• Surfactants • Sepsis diagnostics • Injectable antibiotics	Products poorly suited for LMIC Level 2 settings, difficult administration requirements, lack of context-appropriate diagnostics, limited innovation pipelines, rising antimicrobial resistance.	Accelerate development of LMIC-appropriate products.
Overcome health systems barriers	• Antenatal corticosteroids • Bag-valve-mask ventilation	Weak provider capacity and skill decay, poor gestational age estimation, limited facility readiness, inadequate training and supervision.	Invest in competencies and service delivery systems.
Make product affordable	• Caffeine citrate	Higher prices relative to alternatives, weak market competition, fragmented demand, low provider familiarity, limited pooled procurement and market-shaping mechanisms.	Market shaping and pooled procurement.

Across all archetypes, several cross-cutting barriers recur. These include fragmented and weak procurement systems combined with limited budgets, weak forecasting and quantification, limited regulatory capacity, limited number of registered products, inadequate financing for recurrent costs, and insufficient integration of maintenance and biomedical engineering considerations into procurement decisions. Climate-related disruptions including energy insecurity, supply chain interruptions and infrastructure vulnerabilities may further exacerbate many of these challenges.

The findings suggest that product access strategies should move beyond standalone commodity procurement towards approaches that address the full set of constraints influencing product availability, functionality, adoption and sustained use. Importantly, they demonstrate that no single intervention strategy will be sufficient. Improving access will require differentiated approaches tailored to the specific barriers affecting different product types, while simultaneously strengthening the broader systems that support delivery of quality newborn care.

Service delivery

Improving outcomes for SSNs is not only a product challenge; it is also a service delivery challenge. Effective products save lives only when delivered as part of high-quality, integrated care. The WHO–UNICEF Model of Care for Small and/or Sick Newborns provides the organizing framework for understanding both the content of care (the "what") and the ten interconnected components required to deliver and scale (the "how").

- **Content of care:** High-quality SSNC extends across a continuum from maternal and essential newborn care through specialized inpatient care, respectful and nurturing family-centered care, and post-discharge follow-up. For preterm and low-birthweight newborns, kangaroo mother care (KMC)/immediate KMC (iKMC) and zero separation are increasingly central to organizing care around the mother-newborn dyad while enabling necessary clinical interventions. Feeding and lactation support, including access to donor human milk where the mother's own milk is unavailable, are core elements of this care.
- **Components of care:** Delivering this care reliably requires ten interconnected components: political commitment and leadership; sustainable financing; competent and motivated human resources; infrastructure and design; equipment and commodities; robust data systems; functional referral systems; maternal-newborn linkages; family and community involvement; and post-discharge follow-up systems. These components need to function together: strengthening individual products or services without addressing the surrounding system will limit their impact.
- **Organization and scale:** District-level Level 2 newborn units are a critical platform for delivering SSNC, but they need to function within broader networks of care linking maternal, community, primary, district and referral services. Sustainable scale-up requires government ownership, integrated care packages, and continuity from antenatal risk identification and childbirth through inpatient care, referral, discharge and follow-up. Delivery models also need to adapt to context, particularly where distance, conflict, displacement or other disruptions affect access, referral, workforce, supplies and continuity of care.

Overall, products remain essential, but their impact depends on functional systems capable of delivering integrated, continuous, family-centered care reliably and at scale.

Ecosystem functions

Improving access to quality SSNC depends on a connected ecosystem of functions spanning evidence and guidance, supply chains, financing, regulation and quality assurance, community engagement and service delivery. Using the six components of the EWENE Pathway to Improving Access to Quality MNH Products as a guiding framework, the landscape describes the function each component serves and the bottlenecks that constrain it.

Across the six components, the most significant constraints arise less from the absence of evidence, products or institutions than from weak connections between functions. Recurring bottlenecks include delayed translation of global guidance into national policy and practice; fragmented procurement and weak forecasting; financing that covers initial purchase but not recurrent costs; slow regulatory pathways and limited post-market quality assurance; weak links between communities and services; and gaps in workforce, referral and data systems.

Addressing these gaps will require a series of interconnected shifts: from guidance to implementation, from product delivery to functional access, and from approved budgets to predictable financing. It will also require moving beyond individual products towards integrated care, beyond registration towards continuous quality assurance, beyond fragmented data towards shared learning, and beyond pilots towards sustainable national ownership. Rather than prescribing stakeholder roles, countries and partners can organize collaboration around clearly defined access and delivery problems, with country ownership, shared outcomes and clear accountability for action.

Recommendations

Improving outcomes for SSNs requires coordinated action across products, service delivery, implementation research, and the broader innovation-to-access pathway. Six headline recommendations emerge from this landscape:

- **Build and scale functional Level 2 newborn care platforms:** Level 2 care is the primary delivery platform for most priority products. Expand equitable access to a comprehensive Level 2 package, supported by the infrastructure, workforce, equipment, referral systems and recurrent financing needed to sustain quality care.
- **Deliver integrated respiratory care packages rather than standalone products:** Bubble CPAP, pulse oximetry, safe oxygen delivery and blending, surfactant, caffeine citrate and antenatal corticosteroids have the greatest impact when introduced as a bundle, with oxygen sources, consumables, maintenance and trained providers planned and procured together.
- **Prioritize access to proven interventions over discovery of new interventions:** Many high-impact products already exist but remain underutilized. Focus investment on the affordability, operational models, service readiness and implementation evidence needed to bring them into routine use, while supporting targeted development of LMIC-appropriate products where clear gaps remain.

- **Strengthen market shaping and sustainable access mechanisms:** Use pooled procurement, demand aggregation, quality-assured supplier panels, regulatory reliance and value-based procurement to improve affordability, supply security and long-term functionality, backed by ring-fenced domestic financing for recurrent costs.
- **Organize care around zero separation and family-centered care:** Deliver Level 2 interventions alongside immediate kangaroo mother care wherever clinically feasible, design new devices to be KMC-compatible, and recognize parents and caregivers as essential partners in care.
- **Improve coordination and accountability across the innovation-to-access pathway:** Align guidance, financing, procurement, regulation and service delivery behind costed national plans, and strengthen data systems, routine monitoring and accountability mechanisms to track progress and guide continuous improvement.

Conclusion

Ultimately, the next frontier in newborn survival is not discovering what works. Many of the highest-impact interventions already exist and are supported by global guidance; the challenge is translating them into reliable access to high-quality care. This landscape points to three interconnected priorities that bring the six headline recommendations together into a single agenda for action: closing product access gaps through differentiated strategies, strengthening Level 2 newborn care as the platform for effective product use, and aligning investments and partnerships across the innovation-to-access pathway behind costed, country-led plans. Achieving this will require a shift from investing in individual products toward equitable, sustainable access to integrated packages of effective, quality-assured medicines, diagnostics and devices. The opportunity now is to translate what is already known, available and achievable into reliable access to high-quality care for every small and sick newborn who needs it.

0. Introduction

0.1 Rationale for the landscape

Despite substantial progress in child survival, the neonatal period remains the most critical and least addressed frontier in reducing under-five mortality. Nearly half of all under-five deaths occur during the newborn period. Beyond survival, millions of SSNs face preventable morbidity and long-term disability. Complications from prematurity, intrapartum events, and infections result in deaths and may lead to lifelong impairments, many of which are avoidable with timely, high-quality care. For example, appropriate oxygen management can prevent retinopathy of prematurity, highlighting how quality care shapes both survival and long-term outcomes. These risks are greatest in low-resource settings, where essential commodities and quality services remain largely inaccessible.

While many evidence-based interventions (medicines, devices, diagnostics and service delivery models) exist, gaps in access, uptake and appropriate use persist, particularly in high-burden settings. Understanding the landscape of established interventions and emerging innovations, the barriers to their effective use and the pipeline for potential new products is critical to identifying high-impact opportunities to address newborn mortality, morbidity and long-term developmental outcomes.

Therefore, this landscape assesses SSNC interventions that address the three leading causes of neonatal morbidity and mortality: complications arising from prematurity, intrapartum-related complications and infection. The analysis focuses primarily on care delivered to the newborn after birth, with a few exceptions including antenatal corticosteroids (ACS) and magnesium sulfate which are administered in the context of imminent preterm birth to support fetal lung maturation and fetal neuroprotection, respectively, during pregnancy because of their direct impact on newborn outcomes. Interventions are organized across the continuum of care, reflecting both the level of the health system where care is delivered and the standards of care required. They are further categorized as global standards that are available, global standards that remain underutilized and emerging innovations. The landscape also identifies whether global standard interventions are included in WHO commodity lists, highlighting potential gaps for future consideration and notes where interventions depend on consumable supplies and supporting infrastructure such as tubing, probes and oxygen delivery components.

Overall, this assessment aims to identify high-impact investment opportunities across commodities, service delivery models and the enabling health system conditions required to accelerate reductions in neonatal mortality and morbidity in LMICs.

Intervention Categorization Definitions
Global Standards: Interventions that are evidence-based and endorsed by global guidelines, and that are integrated into health systems as routine practice.
Global Standards / Significant Access Gaps: Interventions that are evidence-based and endorsed by global guidelines but remain inconsistently available or underused in practice. Limited uptake is typically driven by health system barriers such as cost, supply chain constraints, policy or regulatory gaps, and insufficient provider or patient awareness.
Emerging Innovations: New or evolving products, formulations, technologies, or service delivery approaches that demonstrate potential to improve newborn health outcomes but require additional evidence generation, regulatory review and approval, and/or strengthening of health system readiness before they can be considered global standards.

Figure 0.1: WHO newborn health commodity list

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

0.2 Assumptions and methodology

Interventions included in this landscape were selected based on the following criteria:

Criterion	Scope
Population & mortality focus	Newborns aged 0–28 days, with emphasis on SSNs who account for a disproportionate share of mortality and adverse outcomes. Interventions are prioritized based on relevance to the three leading causes of neonatal mortality: preterm birth complications, intrapartum-related events (including birth asphyxia), and infection.
Level & setting of care	Facility-based, inpatient care. Focus on interventions delivered at level 1 and 2 WHO levels of care, where most newborn care occurs, with selective inclusion of higher-level (level 3) interventions.
Type of care	Interventions administered directly to the newborn and within the scope of newborn services. Maternal and intrapartum interventions are excluded, except where they have a direct and substantial impact on newborn outcomes (e.g., antenatal corticosteroids, magnesium sulfate and maternal RSV vaccine).
Geographic scope	Interventions relevant to LMIC contexts, with a focus on sub-Saharan Africa and South Asia, where the burden of neonatal mortality is highest.

This landscape was developed through a structured and iterative process that combined evidence review, stakeholder engagement and expert validation. Key components of the methodology included:

- **Desk review:** A comprehensive review of peer-reviewed literature, global health reports, normative guidance and strategic documents was conducted alongside mapping of relevant medicines, diagnostics, devices and service delivery innovations. The analysis builds on existing global frameworks, technical guidance and prior newborn health landscapes.
- **Stakeholder consultations:** Findings were informed through targeted stakeholder engagement, including a group consultation session held during the International Maternal and Newborn Health Conference (IMNHC) in Nairobi in 2026, followed by key informant interviews (KIIs) with representatives from CHAI, PATH, NEST360 and the Gates Foundation.
- **Global survey:** A global survey was conducted to support the categorization and prioritization of selected products, tools and interventions. The survey received 190 responses, predominantly from newborn health clinicians and technical experts.
- **External review:** An external review was conducted to validate findings, strengthen the analysis, and identify gaps or emerging considerations. Insights from key informant interviews and written expert review of draft 1 are cited in the text as (expert input, 2026) and are not attributed to individuals or organizations; contributors are listed in the Acknowledgements.

0.3 Structure

The landscape is organized around the following sections:

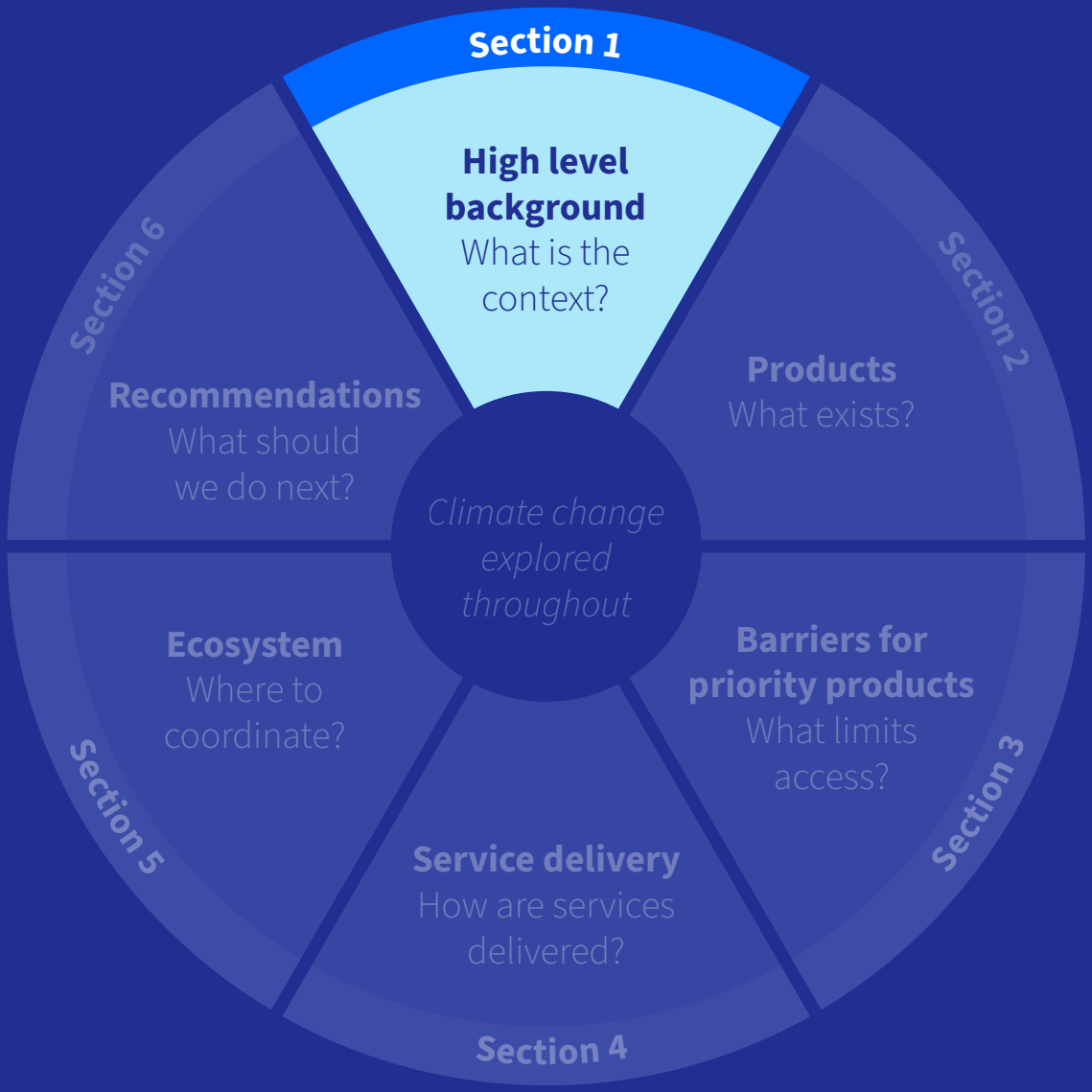
- **Section 1. High-level background** outlines the context for this landscape and introduces the key trends explored in later sections.
- **Section 2. Product landscape** analyzes 98 products (medicines, diagnostics and devices) critical to addressing the top three drivers of newborn mortality.
- **Section 3. Product market access barriers** analyzes the barriers limiting access to 9 priority products, evaluating barriers across affordability, quality, and supply while assessing market dynamics and opportunities for improvement in LMICs.
- **Section 4. Service delivery** examines how services are delivered, including service delivery models and cross-cutting enablers such as workforce capacity, data and financing.
- **Section 5. Ecosystem functions** describes the functions that must work together across the innovation-to-access pathway, where they commonly break down and the implications for action.
- **Section 6. Recommendations** outlines catalytic opportunities for action across the newborn health ecosystem.

Across all sections, the landscape examines the implications of climate change for SSNC because the regions with the highest SSN burden are also among the most climate-vulnerable, with climate-related shocks increasingly shaping newborn risk, health system resilience, product performance and equitable access to care. The analysis also considers how conflict, displacement and humanitarian emergencies can compound these challenges and disrupt access to essential SSNC by disrupting access to care, health services, referral pathways, supply chains and continuity of care.



1. High level background

What is the context?



Section summary

More than one in four babies born globally meets criteria for at least one SSN phenotype, and this population accounts for over half of all neonatal deaths. Progress is slowing – 66 countries are projected to miss Sustainable Development Goal (SDG) 3.2 – and the binding constraint is no longer evidence or policy. It is implementation at district level in the settings where the burden is greatest.

Key takeaways

- **Burden is large, inequitable and driven by three overlapping conditions.** Sub-Saharan Africa and southern Asia account for >80% of neonatal deaths. Prematurity, intrapartum-related events and infections frequently co-occur, requiring integrated rather than vertical care responses spanning the maternal–newborn continuum from the antenatal period, including stillbirth prevention through facility-based newborn care, discharge, post-discharge follow-up and community-based care.
- **The normative roadmap is clear; EWENE Target 4 (≥80% of districts with a functional Level 2 unit, including CPAP) is the operational frontier.** WHO Standards and the Levels of Care framework and the joint WHO-UNICEF Model for Scaling Up Small and Sick Newborn Care define what functional Level 2 district specialized newborn care unit capacity requires. Facility assessments consistently show wide gaps between policy intent and readiness, even in facilities that have received prior support.
- **Four system constraints – workforce, infrastructure, products and financing – reinforce each other.** Insufficient numbers of providers and gaps in knowledge and competencies, overcrowded units without space for mothers (limiting zero separation), inconsistent availability of core essential commodities (CPAP, caffeine citrate, oxygen ecosystem products, thermal care devices, feeding supplies, quality-assured antibiotics and sepsis diagnostics), fragmented procurement and absent recurrent-cost budget lines collectively prevent reliable quality Level 2 care. Because these constraints are interdependent, they must be addressed simultaneously rather than sequentially or in isolation.
- **Inadequate SSNC carries long-term human capital costs.** Survivors face elevated risks of neurodevelopmental impairment, visual impairment, chronic respiratory morbidity and cardiometabolic disease, making SSN outcomes a disability and economic imperative, not only a child survival priority. As survival improves, the quality and timeliness of care will determine whether gains translate into intact survival rather than more chronic disability.

1.1 Burden and definition of SSNs

Overall newborn mortality trends and status

Despite major gains in child survival since 2000, neonatal deaths remain a disproportionately large and persistent share of global under-five mortality. In 2024, approximately 2.3 million newborns died in the first 28 days of life – nearly half of all under-five deaths – out of 4.9 million child deaths overall.[1] Since 2000, 76 million of the 174 million total under-five deaths have been neonatal.[1] Progress has slowed critically. The global neonatal mortality rate fell from 31 to 17 per 1,000 live births between 2000 and 2022, but the rate of annual decline slowed from 3.0% (2000–2015) to 1.8% (2015–2022).

Around 66 countries are projected to miss SDG target 3.2 to end preventable childhood deaths. In 2024 the World Health Assembly adopted resolution WHA77.5 calling for accelerated action to reduce maternal, newborn and child mortality and to achieve SDG targets 3.1 and 3.2.[1,2,3,4,5] The burden is highly inequitable: sub-Saharan Africa (26 per 1,000 live births) and southern Asia (23 per 1,000) together account for more than 80% of global neonatal deaths. Fragile and conflict-affected states face compounding risks through weak governance, underfunded health systems, workforce shortages and recurrent shocks.[1]

Stillbirths – approximately 1.9 million annually – share the same causal pathways (preterm birth, fetal growth restriction) and underscore why interventions must begin in the antenatal period, well before birth.[6,7] Maternal interventions aimed primarily at newborn outcomes – such as antenatal corticosteroids and magnesium sulfate in the context of imminent preterm birth to support fetal lung maturation and neuroprotection respectively; syphilis screening through triple HIV–syphilis–hepatitis B testing and ultrasound-based gestational age dating – are therefore included here, while broader maternal health products are addressed in existing maternal landscapes, including Unitaid's maternal and newborn health (MNH) work.[8] Congenital anomalies also contribute substantially to neonatal mortality, morbidity and lifelong disability but are outside the primary scope of this landscape.

Figure 1.1: Risk architecture

Outcomes

Mortality
2.3 million newborns die each year globally, with the highest risk in the first week of life especially within the first 24 hours.

Morbidity
An estimated 20–30 million newborns require specialized care annually due to complications such as prematurity, birth asphyxia, or infections.

Disability
An estimated ~53 million children under 5 live with developmental disabilities globally, many linked to neonatal complications such as prematurity, birth asphyxia, and infections.

Drivers of mortality

Preterm birth complications
Complications of preterm birth account for ~35–40% of neonatal deaths globally, making it the leading cause of newborn mortality.

Intrapartum related events
Birth asphyxia and related complications contribute to ~20– 25% of neonatal deaths, largely due to inadequate care at delivery.

Infection
Neonatal infections (sepsis, pneumonia, meningitis) cause ~20–25% of deaths, with the highest burden in low-resource settings.

Newborns at risk

SSN (Small & sick newborns)

Preterm
About 13–15 million babies (≈10–11% of births) are born preterm each year and are ~7× more likely to die than term newborns.

Low birth weight (LBW)
Low Birth Weight - means a baby is born weighing less than 2,500 grams (2.5 kg or about 5.5 pounds), regardless of how many weeks of pregnancy have passed.

SGA (Small for gestational age)
Around 23 million babies (~17–20% of births) are SGA annually and face ~2× higher mortality risk than appropriately grown infants.

Determinants

Health systems
An estimated 80% of neonatal deaths are preventable with quality care, yet gaps persist in skilled attendance, newborn services, and access to essential commodities driven by fragmented procurement and weak supply chains at district level.

Socioeconomic
>97% of neonatal deaths occur in low-and middle-income countries, with poverty strongly linked to higher rates of low birthweight and mortality.

Care-seeking and social dynamics
Care-seeking and social dynamics shape outcomes, with factors like adolescent pregnancy increasing the risk of small newborns by ~37%, while care-seeking biases may disadvantage girls in some settings.

Climate
Climate-related stressors such as heat and food insecurity are increasing risks of preterm birth and SGA, compounding vulnerabilities in already high-burden settings.

Defining SSNs

SSN is the operational term used by WHO and EWENE (the global initiative coordinating action to end preventable maternal and newborn deaths) for newborns at substantially elevated risk of mortality and morbidity. This encompasses those born preterm (<37 completed weeks), with low birthweight (LBW, <2,500 g), small for gestational age (SGA, <10th centile for gestational age and sex), or clinically ill at birth regardless of size.[6,7]

Each phenotype carries distinct prevention and care priorities, and they frequently co-occur: a newborn may simultaneously be preterm, LBW and SGA, compounding clinical risk.[8,9] In 2020, an estimated 19.8 million liveborn babies were LBW, 23.4 million were SGA and approximately 13.4 million births were preterm – together representing more than one in four babies born globally.[8]

Burden attributable to SSNs

SSNs account for a disproportionate share of adverse outcomes:

- **Burden:** More than 55% of neonatal deaths globally are attributable to SSN phenotypes; nearly 75% of these occur among preterm newborns.[4]
- **Risk:** Preterm SGA newborns face approximately ten times the mortality risk of term appropriate for gestational age (AGA) peers; term SGA newborns also carry substantially elevated risk.[8,9]
- **Undercounting:** Around three-quarters of stillbirths are preterm, with a significant proportion also growth-restricted – a livebirth-only lens substantially underestimates the perinatal burden.[5]
- **Complexity:** Leading causes of death – complications of prematurity, intrapartum-related events and infections – frequently coexist, requiring integrated rather than vertical care approaches.[1,8]

Beyond survival, SSN survivors face elevated risks of neurodevelopmental impairment, visual impairment, chronic respiratory morbidity, growth faltering and cardiometabolic disease, making SSN outcomes a human capital and disability imperative, not only a child survival priority.[6,8,10]

Equity, social and environmental determinants

SSN births and deaths are shaped by intersecting inequalities:

- **Poverty and health-system access:** Women in the wealthiest quintiles are several times more likely to receive antenatal care and skilled attendance at birth than the poorest, driving stark within-country mortality gaps that reflect cumulative disadvantage in nutrition, housing, education and access to services.[1,11]
- **Gender inequity, adolescent pregnancy and low maternal education:** Reduced autonomy, delayed care-seeking, maternal undernutrition, anaemia and hypertensive disorders all amplify SSN risk. Adolescent mothers face compound biological and social vulnerabilities associated with preterm birth and LBW, while low maternal education is consistently linked to lower health literacy and reduced uptake of antenatal and postnatal services.[1,11]

- **Climate and environmental drivers:** Heat exposure during pregnancy is associated with increased risk of preterm birth and stillbirth; ambient air pollution is consistently associated with preterm birth and LBW. Analyses from 29 LMICs found a measurable share of neonatal deaths attributable to temperature variation, with a significant proportion linked to climate change driven by human activity.[12,13]

SSNs constitute a priority climate-vulnerable population: biological susceptibility and structural disadvantage converge in the same regions facing the highest exposures to heat stress, food insecurity, pollution and health-system fragility.[12,13,14]

Box 1.1: Implications for targeted newborn survival efforts

- SSNs are a large, clearly identifiable high-risk population accounting for a disproportionate share of mortality and morbidity.
- Mortality is driven by a small number of interconnected conditions – complications of prematurity, intrapartum-related events and infections – requiring integrated care.
- The burden is concentrated in settings with limited health system capacity; impact will depend on both intervention effectiveness and delivery feasibility.
- Social, economic and environmental determinants significantly shape both risk and access to care.



1.2 Policy, quality standards and implementation environment

Global strategies and targets

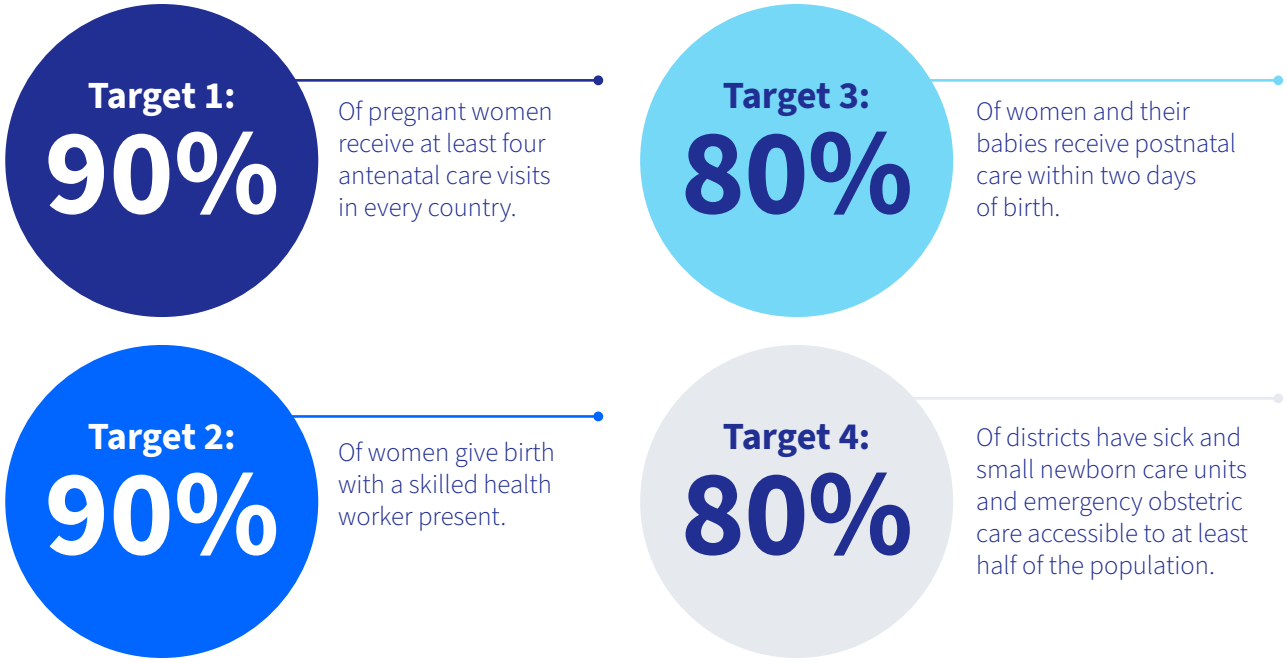
The global agenda is anchored in SDG 3.2, targeting a neonatal mortality rate of at most 12 per 1,000 live births by 2030 and reinforced by World Health Assembly resolution WHA77.5 (2024) on accelerating progress towards reducing maternal, newborn and child mortality.[3,13,14,15] The table below summarizes the principal strategies and their relationship to SSNC.

Table 1.1: Principal global strategies and their relevance to SSNC

Initiative / strategy	Timeframe & lead	Relevance to SSNC	Key targets / actions
Every Newborn Action Plan (ENAP)	2014 onwards; WHO/UNICEF	First global roadmap for ending preventable newborn deaths and stillbirths.	Care around birth - essential and emergency newborn care, care for SSNs.
EWENE – previously ENAP/Ending Preventable Maternal Mortality (EPMM)	2020 onwards; WHO/UNICEF/UNFPA	Integrates maternal and newborn priorities; explicitly emphasizes SSNC as next frontier for mortality reduction.	Coverage targets for antenatal care (ANC) contacts, skilled birth attendance, postnatal care, WHO level-2 SSNC.
SDG 3.2 / WHA 77.5 resolution (2024)	2030 target; UN/WHA 2024	Provides political urgency and accountability framework.	Neonatal mortality rate (NMR) ≤12 per 1,000; under-five mortality rate (U5MR) ≤25 per 1,000.
WHO quality of care standards (QoCS)	2020 onwards; WHO	Normative framework for inpatient SSNC quality (see 1.2.2).	Eight quality domains; provision of care and experience-of-care standards.

EWENE Target 4 – district-level inpatient care for SSNs (at least 80% of districts with a functional Level 2 SSNC unit, including CPAP) – has emerged as a critical bottleneck. Achieving this target requires trained staff, adequate infrastructure and space for mothers to stay with their newborns, functional referral systems, reliable access to quality assured medicines and devices, safe oxygen, infection prevention, data systems, effective KMC, as well as other family-centered neurodevelopmentally supportive models of care. The global policy direction is clear; implementation in the highest-burden settings remains well behind the pace required.[4,11,16]

Figure 1.2: EWENE targets



Quality of care standards and levels of newborn care

WHO's Standards for Improving the Quality of Care for SSNs in Health Facilities (2020) provide the main normative framework for quality inpatient care, defining eight domains that span both provision and experience of care: evidence-based clinical practice, functional referral systems, information systems, effective communication, protection of newborn rights, psychosocial support, competent and motivated staff, and essential physical resources.[10]
These standards are operationalized within WHO's Levels and Standards of Newborn Care framework, which classifies facilities into three levels of inpatient capacity (Levels 1–3) reflecting staff competencies, equipment and service complexity.[10,17] This tiered structure organizes interventions and product needs by level of care:

Level 1 – Immediate and essential newborn care	Essential newborn care at every health facility; encompasses thermal protection, early breastfeeding support, infection prevention, basic neonatal resuscitation and postnatal clinical assessment. All births should receive Level 1 care regardless of facility type.
Level 2 – Special newborn care	District-level inpatient care for moderately preterm (≥32 weeks) and LBW newborns not requiring intensive support. Core interventions include iKMC, CPAP and safe oxygen delivery, pulse oximetry, phototherapy for jaundice, caffeine citrate for apnea of prematurity, intravenous fluids and antibiotic therapy for infection. EWENE Target 4 focuses specifically on achieving functional Level 2 capacity at district scale.
Level 3 – Intensive newborn care	Comprehensive intensive care for the very preterm and extremely preterm (<32 weeks) and critically ill newborns, including mechanical ventilation, advanced hemodynamic and respiratory monitoring and support, surfactant therapy, total parenteral nutrition, screening and treatment for retinopathy of prematurity, cranial ultrasound screening for intraventricular hemorrhage, surgical support and neonatal subspecialty input. Typically sited at provincial or regional referral hospitals.

Key clinical principles cutting across levels include: early risk identification; maternal fetal transfer to higher-level facilities before birth where feasible; zero separation of mother and newborn; thermal protection, including iKMC for eligible preterm and low birthweight newborns with KMC continuing as a core component of care; feeding support; infection prevention and treatment; safe oxygen delivery; respiratory support; timely referral and escalation of care, with appropriate care maintained during transfer; and structured post-discharge follow-up.[10,18] Zero separation underpins this continuum, with iKMC particularly important because it improves survival and repositions families – especially mothers – as active partners in care.[18] WHO and interagency priority product lists complement the standards by identifying the medicines, devices and diagnostics required at each level of care.[10,11,19] Implementation gaps remain substantial, and translating standards into reliable service readiness at facility level continues to be a primary challenge in high-burden settings.[17] Empirical scoring of 64 hospitals across four African countries against WHO standards and level-2 benchmarks found systematic deficits in mother-accommodation, oxygen safety infrastructure and infection prevention capacity, even in facilities that had received training and equipment support – illustrating the distance between normative aspiration and operational reality.[15]

The essential product needs assessed in Sections 2 and 3 are organized according to this levels framework, allowing clinical and market analysis to be directly mapped to the facility capabilities on which they depend.

1.3 Trends shaping technology and innovation

Expanding role of technologies and innovation in newborn care

Innovation for SSNs is advancing across the three leading causes of mortality:

- **Complications of prematurity:** Integrated packages now combine ACS, iKMC, safer oxygen delivery, CPAP, pulse oximetry, caffeine citrate, surfactant where appropriate, assisted feeding, thermal care and post-discharge support. Lower-cost, context-appropriate respiratory devices, neonatal warmers and LED phototherapy are enabling district-level management of prematurity complications.[15,16,17,18,19]
- **Intrapartum-related complications and birth asphyxia:** Innovation increasingly centers on bundles connecting maternal and newborn care at birth: improved fetal monitoring, rapid heart-rate assessment, simulation-based resuscitation training and continuous quality improvement. Emerging evidence supports the effectiveness of this integrated approach in low-resource settings. One such example is the Safer Births Bundle of Care (SBBC), evaluated in a stepped wedge cluster randomized trial across district hospitals in Tanzania, which improved quality of care indicators for neonatal resuscitation and intrapartum monitoring; its design emphasizing low-cost simulation, locally adapted protocols and continuous data feedback was explicitly developed for replication in similar LMIC contexts.[23]
- **Neonatal sepsis:** This includes improved infection prevention and treatment, better diagnostic pathways, reliable access to quality assured antibiotics, safer vascular access and data systems supporting early recognition. Sepsis risk prediction models, reducing avoidable mother-baby separation, improving hygiene and rationalizing invasive procedures are central priorities. Diagnostic innovation remains less mature than respiratory technologies but is likely to be increasingly important for the next decade of mortality reduction.[10,22,24] Limited blood culture capacity means that most neonates are treated for presumed sepsis, often without identification of the causative pathogen or information on antimicrobial susceptibility, which drives empirical antibiotic use. In LMICs, neonatal sepsis pathogens show high resistance to WHO-recommended first- and second-line antibiotics, so diagnostic and antimicrobial stewardship and infection prevention and control remain central.[24,25]

Cross-cutting:

- **Digital tools and AI tele-mentoring:** Clinical decision support, electronic registers, implementation trackers and AI-enabled tools are being applied across leading causes of morbidity and mortality. AI shows promise in fetal monitoring, retinal screening, neonatal deterioration prediction and tele-NICU models. Equity concerns, external validity gaps and concentration of evidence outside highest-burden settings remain important limitations.[20,21]
- **Climate-resilient design:** Solar-powered, battery-supported and energy-efficient solutions are increasingly essential – high-burden regions face the greatest climate vulnerability and energy insecurity.[22] Climate-resilient design is no longer optional for neonatal technologies in LMIC settings.
- **Workforce and competency:** Effective use of innovations depends on skilled, trained, supervised staff at district level; technology without workforce capacity does not reduce mortality. Task-sharing, simulation-based training and tele-mentoring are expanding the competency base in resource-constrained settings.[10,19,20,21]
- **Data systems and quality improvement:** Routine data capture, audit and feedback loops are prerequisites for sustaining gains across all three mortality domains.[7] Facility registers, mortality review and implementation trackers link clinical care to system performance improvement. Tracking service readiness, quality of care and newborn outcomes is also needed to identify gaps and guide quality improvement. Logistics data for quantification, forecasting and tracking commodities, accessories and consumables are equally needed to close supply gaps.
- **Nutrition and feeding:** Feeding receives less attention than other core SSNC interventions, such as respiratory support and infection management, yet feeding difficulties are common among preterm and sick newborns. Otherwise healthy term newborns are also at risk. On postnatal wards, infants assumed to be well are often not routinely assessed and first-time mothers may receive limited lactation support. As a result, inadequate intake and feeding difficulties may go unrecognized until newborns develop preventable complications, including dehydration and hypoglycaemia, and require additional care. Breastmilk feeding, lactation support, expressed breast milk, assisted feeding by cup or nasogastric tube, and donor human milk where available are therefore core components of SSNC.[26,27]

The specific product requirements emerging from these trends are examined in detail in Section 2, which maps the intervention landscape against the WHO levels framework, whereas service delivery models are explored in Section 4.

1.4 Trends shaping service delivery

Newborn products do not operate in isolation. Their impact depends on how they are combined with other interventions and embedded within systems capable of delivering quality care. This is particularly important for SSNs, whose needs often require multiple clinical interventions and system capabilities to come together across the continuum of care. The WHO–UNICEF Model of Care for Small and/or Sick Newborns provides a framework for understanding what is required to translate individual interventions into quality care at district level. The model distinguishes between the content of care–the "what" of care–and ten core components of care that define the "how" of implementation and scale-up. Together, these provide a framework for understanding both what services need to deliver and the systems required to deliver them reliably and at scale.[10,17]

Content of care (the "what"): The content of care encompasses the clinical and supportive interventions required by SSNs, from essential newborn care through specialized inpatient care. Increasingly, these interventions are understood as an integrated continuum rather than as stand-alone services, reflecting the overlapping needs of preterm, low-birthweight and sick newborns.

Components of care (the "how"): Delivering this content requires ten interconnected components spanning political commitment and leadership; sustainable financing; competent and motivated human resources; infrastructure and design; equipment and commodities; robust data systems; functional referral systems; maternal–newborn linkages; family and community involvement; and post-discharge follow-up systems. Together, these components provide the enabling architecture through which quality care can be implemented and scaled at district level. Rather than treating workforce, products, financing or referral as separate inputs, the model emphasizes how these elements need to function together as part of an integrated system of care.

Care delivery principles: Across the content and components of care, several interconnected principles are shaping how SSNC is organized and delivered. These include district-based networks of care; government-led, district-based scale-up; integrated care packages; and continuity of care across maternal, newborn, referral and post-discharge services. Together, these principles reflect a shift away from isolated interventions and facility-level investments towards coordinated systems of care that connect services across levels, place newborns and families at the center, and embed SSNC within government-owned health systems. These principles also need to be adapted to context. In hard-to-reach, climate-vulnerable, fragile and humanitarian settings, distance, mobility, insecurity and disruptions to infrastructure, utilities, supply chains and referral systems can affect both access to care and the ability of health systems to sustain it.[5,12,13,14] Digital technologies, remote support and other adaptations may also help extend specialist expertise and strengthen coordination across networks where access to newborn expertise is limited.

Section 4 explores this framework in greater depth, examining the content of care, the ten components required to deliver it and illustrative approaches through which these components are being operationalized in LMIC settings.

1.5 Key functions across the innovation-to-access pathway

The EWENE Pathway to Improving Access to Quality MNH Products, developed jointly by WHO, UNFPA, UNICEF and Unitaid, provides a framework for understanding how products move from policy and normative guidance through to sustained service delivery (Figure 1.3). Although presented as a pathway, these functions overlap and iterate rather than operate in strict sequence. The Pathway maps ten interdependent domains across six components of the MNH product value chain and makes explicit that weakness in any single domain can interrupt access.[8,21] This landscape uses these six components to describe the core functions required for access (Table 1.2). Many institutions contribute across several functions, and their roles vary by country, product and context; the table therefore leads with functions, lists contributing institution types as illustrative examples only, and summarizes the key bottlenecks affecting each function.

Figure 1.3: The EWENE pathway to improving access to quality MNH products



Key domains influencing access to quality-assured MNH products

Table 1.2: Core functions across the pathway.

Function	What the function involves	Contributing institutions (illustrative, not comprehensive)	Key bottlenecks
Innovation, evidence and normative guidance	Generating and synthesizing evidence; developing target product profiles and fit-for-purpose technologies; setting global clinical guidelines, quality-of-care standards and targets; supporting translation of norms into national policy, protocols and implementation tools.	National governments and ministries of health; normative and technical agencies; research and academic institutions; evidence review panels and technical working groups; product development partnerships and innovation initiatives.	Many neonatal technologies are designed for high-income settings and are not well suited to LMIC operating conditions; implementation research receives limited priority; translation of global guidance into national policies, costed plans and protocols is slow, and implementation often lags behind endorsement.[9]
Supply chain and product access	Manufacturing and supply; quantification and forecasting; procurement and distribution; installation, maintenance, spare parts and after-sales support to keep products functional.	Manufacturers and suppliers; national medical stores and procurement agencies; logistics providers; biomedical engineering services; technical and market-access partners.	Limited biomedical maintenance capacity and spare parts undermine equipment functionality; procurement often prioritizes lowest unit cost over long-term functionality; fragmented logistics data and incomplete facility reporting, including from private and faith-based providers, distort forecasting and contribute to stockouts or over-procurement.

Function	What the function involves	Contributing institutions (illustrative, not comprehensive)	Key bottlenecks
Financing and resource allocation	Domestic budgeting and budget execution; UHC and insurance mechanisms; catalytic and external financing; market-shaping investments; costing and investment cases that cover recurrent as well as capital costs.	Ministries of finance and health; national health insurance schemes; multilateral, bilateral and philanthropic funders; catalytic financing and market-shaping organizations.	High reliance on external financing, with limited integration into national budgets and essential medicines lists; the absence of dedicated budget lines creates unpredictable demand signals; pooled procurement and long-term supply agreements are largely unavailable for SSNC products.[6,23,24]
Regulatory and quality systems	Product registration and regulatory reliance; prequalification and quality assurance; post-market surveillance; professional regulation, clinical practice standards and competency frameworks.	National and regional regulatory authorities; prequalification and standards bodies; professional and clinical standard-setting associations; ministries of health (professional regulation and facility licensing).	Limited regulatory capacity and underuse of collaborative registration and reliance delay authorization of quality-assured products; post-market surveillance is weak; fragmented requirements discourage registration; tendering rules may favour lowest price over quality and lifecycle cost.[6]
Demand generation, community engagement and advocacy	Building political commitment; aligning priorities and messaging; tracking progress against commitments; engaging families and communities in care, service design and accountability.	Global, regional and national advocacy coalitions; professional associations; civil society, parent and community organizations.	Advocacy and priority-setting for newborn health remain fragmented, limiting political visibility and domestic investment; caregivers and communities have limited participation in planning and accountability; weak demand signals from providers and communities, and misinformation, constrain uptake of effective interventions.[6,18]

Function	What the function involves	Contributing institutions (illustrative, not comprehensive)	Key bottlenecks
Service delivery capacity and system readiness	Leading national and subnational implementation; delivering and scaling integrated SSNC; pre-service and in-service training, mentorship and supervision; referral, quality improvement and data systems.	Ministries of health and subnational health authorities; public, private and faith-based facilities; universities, training institutions and teaching hospitals; implementing partners.	Shortfalls in clinical and technical workforce, including biomedical engineering; inadequate neonatal infrastructure; weak referral and post-discharge follow-up networks; and fragmented quality improvement systems limit the capacity to absorb and sustain interventions.[17,18]

Note: Institutions are listed where they commonly contribute; most contribute to several functions, and national governments play a central role across all six.

These bottlenecks are mutually reinforcing and converge into systemic gaps identified in the EWENE Pathway, including fragmented coordination and governance, limited domestic financing, weak monitoring and accountability, slow translation of global guidance into national policy, and insufficient integration of private and faith-based providers into supply planning and service delivery. At market level, SSNC products are typically procured through national systems in small, fragmented markets, often without consistent specifications or transparent pricing, which constrains economies of scale, weakens supplier incentives and contributes to price inconsistency.[6,25] This fragmentation discourages quality-assured suppliers from commercializing products in sub-Saharan African markets, limiting consistent availability of quality-assured products and contributing to stock-outs and high unit prices. Unitaid's published MNH Solutions landscape confirmed these dynamics across multiple LMIC markets, identifying registration barriers, price opacity and distributor capacity gaps as consistently limiting product access even where clinical need and policy intent are aligned.[25]

The functions that must work together across the innovation-to-access pathway, the points at which coordination commonly breaks down and the implications for action are examined in Section 5.

Box 1.2: Climate implications for SSNC

Climate change is not a future risk for newborn health; it is a present and compounding one. The regions bearing the greatest SSN burden are simultaneously those facing the most severe and accelerating climate exposures, creating a dual vulnerability that health systems are not yet designed to manage.

- **Heat and air pollution directly increase SSN risk.** Heat exposure during pregnancy is associated with increased risk of preterm birth and stillbirth; ambient air pollution is consistently linked to preterm birth and low birthweight. Analyses across 29 LMICs found a measurable proportion of neonatal deaths attributable to temperature variation, with a significant share linked to anthropogenic climate change.[11,12,13]
- **SSNs are a priority climate-vulnerable population.** Biological susceptibility (immature thermoregulation, respiratory immaturity, limited physiological reserve) and structural disadvantage converge in the same regions facing the highest exposures to heat stress, food insecurity, pollution and health system fragility.[11,12,13]
- **Energy insecurity directly undermines district-level SSNC.** Unreliable electricity can disrupt some CPAP and oxygen delivery systems as well as phototherapy, incubator function and cold chain storage for temperature-sensitive medicines, including surfactant. Sub-Saharan Africa and southern Asia – which account for over 80% of neonatal deaths – also face the greatest energy insecurity, making climate-resilient health infrastructure a prerequisite, not an enhancement, for reliable Level 2 SNCU function.[14]
- **Climate-resilient product design is now a requirement for LMIC deployment.** Solar-powered, battery-supported and energy-efficient neonatal technologies are increasingly essential for the highest-burden settings. Target product profiles for district-level SSN devices must incorporate climate resilience, including performance under high ambient temperatures, dust exposure and power fluctuation, as core specifications alongside clinical efficacy.[18]
- **Climate adaptation must be integrated into SSNC system design.** Oxygen ecosystems, referral networks, supply chain planning and SNCU infrastructure investments must account for climate-related disruptions: seasonal demand surges, supply chain fragility from extreme weather events and increased heat burden on both patients and health workers. Failure to embed climate resilience into scale-up planning risks eroding hard-won gains in newborn survival.[11,12,13,14]

2. Product landscape

What exists?



Section summary

The landscape includes 98 interventions (medicines, diagnostics and devices) with the potential to prevent, diagnose, monitor or treat the leading causes of neonatal mortality. Although innovation remains important in several areas, the largest gains in newborn survival are likely to come from expanding access to proven interventions and strengthening the service delivery systems needed to support their effective use.

Key takeaways

- **Most priority interventions are already available, but access remains uneven.** Many of the highest-impact interventions for reducing neonatal mortality are established standards of care and are included in global guidance. However, translation into national guidelines, availability, affordability, procurement, maintenance and workforce constraints continue to limit their use in many LMIC settings.
- **Diagnostics and devices account for most opportunities to improve care.** While many essential medicines are well established, significant gaps remain in access to diagnostics, particularly for neonatal sepsis, as well as monitoring technologies, respiratory support and feeding equipment. These products are often critical for identifying complications early and delivering appropriate care to SSNs.
- **Product impact depends on the strength of the delivery platform.** Many interventions rely on complementary consumables, reliable infrastructure, trained health workers, maintenance systems and referral networks. As a result, strengthening Level 2 newborn care platforms and broader health system readiness is essential for translating product availability into improved newborn outcomes.

Level 1 – Immediate and Essential Newborn Care = 17		
Medicines - prevention	1. 7.1% Chlorhexidine 2. Vitamin K (phytomenadione)	
Diagnostics	3. Pulse oximeter 4. Neonatal stethoscope 5. Hemoglobinometer 6. Multi-parameter vitals monitor	7. Heart rate meter 8. Respiratory monitor/counter 15. Dual HIV/syphilis rapid diagnostic test (RDT) 16. Triple HIV/syphilis/hepatitis B RDT
Medicines - Treatment	9. Amoxicillin (oral) 17. Benzathine benzylpenicillin	
Devices	10. Baby scale (Digital) 11. Breast pump 12. Bag-valve-mask (Size 0 and 1)	13. BabySaver tray 14. Augmented infant resuscitator (AIR)

Level 2 – Special newborn care = 63*		
Medicines - prevention	25. Iron supplementation 28. Magnesium sulfate 58. Antenatal corticosteroids (dexamethasone and betamethasone)	59. Maternal respiratory syncytial virus (RSV) vaccination 68. Caffeine citrate
Diagnostics	22. Glucometer 30. Bilirubinometer (serum) 31. Bilirubinometer (transcutaneous) 32. Smartphone image-based jaundice screening 36. Gram stain microscopy 37.Full blood count (FBC) 38. Blood and cerebrospinal fluid culture 39. Phenotypic antimicrobial susceptibility testing (AST) – culture-based 40. PCR pathogen detection 41.Multiplex sepsis panels 42. Procalcitonin (PCT) test	43. C-reactive protein (CRP) test 44. IL-6 45. AI/ML software for sepsis detection 46. Novel biomarkers: NeoSep-SAA and related platforms 47. Microfluidic paper-based analytical devices (µPADs) 48. Integrated sepsis diagnostic platforms 69. Thermometer (including non-mercury) 70. Abdomen-attached temperature monitor 71. Wearable temperature monitoring devices 72. Room thermometer (ambient temperature)
Medicines - treatment	18. Isotonic crystalloids 19. Donor milk 23. 10% IV dextrose 24. Oral glucose (dextrose) gel 26. Packed blood cells (neonatal bags) 29. Phenobarbital 49. Ampicillin (injectable) 50. Gentamicin (injectable) 51. Intravenous aqueous crystalline penicillin G or procaine benzylpenicillin	52. Azithromycin and erythromycin (injectable/oral) 53. Cefotaxime 54. Amikacin (injectable) 55. Cloxacillin (injectable) 56. Cefiderocol 57. Novel antibiotic combinations: flomoxef + fosfomycin/amikacin; fosfomycin + amikacin 60. Oxygen 68. Caffeine citrate (*repeated intentionally*)

Level 2 – Special newborn care = 63*		
Devices	20. Feeding cup 21. Nasogastric (NG) feeding tube 27. Infusion pump 33. LED phototherapy units 34. Fluxmeter / light meter 35. Filtered sunlight phototherapy 61. Bubble CPAP with blenders 62. Nasal prongs (neonatal) 63. Oxygen generation equipment 64. Oxygen concentrators 65. Flow splitters	66. Portable CPAP 67. Oxygen storage and backup (cylinders) 73. Neonatal stationary incubator 74. Neonatal transport incubator 75. Radiant warmer 76. Conductive warmer (heated mattress) 77. Plastic bags / cling wraps / preterm wraps 78. Blankets and wraps 79. KMC bed 80. KMC reclining chair

**Caffeine citrate is listed twice (as a prevention and treatment medicine) but only counted as one intervention.*

Level 3 – Intensive newborn care = 7		
Medicines - prevention	–	
Diagnostics	86. Binocular indirect ophthalmoscope	87. Portable retinal camera
Medicines - treatment	81. Liquid surfactant (animal-derived) – current generation 82. Liquid surfactant (synthetic) – current generation	83. Dry powder surfactant and/or aerosolized versions (under development) 85. Multicomponent fortification of human milk
Devices	84. Laryngeal mask airway (LMA)	

Cross cutting = 11		
Medicines - prevention	–	
Diagnostics	88. Mobile x-ray system 89. Gestational age assessment: New Ballard score and Dubowitz method	90. Point-of-care ultrasound 91. Gestational age assessment: AI-based gestational age estimation using point-of-care ultrasound
Medicines - treatment	–	
Devices	92. Neonatal cannula (24G) 93. Suction pump (manual and electric) 94. Standard syringe pump 95. Syringe driver system	96. Non-electric syringe pump 97. Blood gas analyzer 98. Baby transport trolley

TOTAL = 98			
Medicines - prevention	7	**Medicines - treatment**	22
Diagnostics	35	**Devices**	34

2.1 Scope and approach

This section presents a structured landscape of newborn health products critical to reducing neonatal mortality in LMICs. It focuses on interventions that prevent, diagnose, monitor or treat the three leading causes of neonatal death: prematurity/low birthweight, intrapartum-related complications and neonatal infections. Products are mapped across levels of the health system to identify where targeted action can drive the greatest impact.

Products alone, however, do not improve newborn outcomes. Their effectiveness depends on the context in which they are delivered, including whether facilities have the workforce, infrastructure, referral systems, financing and operational capacity required to use them safely and consistently. For this reason, while this section focuses on the product landscape itself, the broader delivery context including service delivery models, health system readiness and financing constraints is examined in detail in Section 4.

Interventions were selected using the following approach.

Comprehensive long list of interventions: A comprehensive set of more than 180 interventions that prevent, diagnose, monitor or treat the three leading causes of neonatal mortality was compiled: prematurity/low birthweight, intrapartum-related complications and neonatal infections. Established interventions were identified from global sources, including the WHO List of Key Maternal and Newborn Health Commodities, while emerging innovations were identified through published and grey literature.

Shortlist for the landscape: 98 interventions were selected for inclusion in the landscape and mapped to the WHO/UNICEF Levels and Standards of Care framework.

Inclusion and exclusion criteria	
Included	**Excluded**
• Interventions addressing prematurity/low birthweight, intrapartum-related complications and neonatal infections. • Interventions relevant to Level 1 and Level 2 newborn care settings. • Selected emerging innovations and a small number of Level 3 interventions with potential to be decentralized to Level 2. • Selected maternal interventions with direct impact on newborn outcomes (e.g., antenatal corticosteroids, maternal RSV vaccination, magnesium sulfate and congenital syphilis detection due to their contribution to stillbirths and neonatal morbidity and mortality).	• Newborn interventions NOT directly related to the three leading causes of neonatal mortality. • Maternal interventions without a direct impact on newborn outcomes. • Interventions limited to Level 3 care without a clear pathway to decentralization. • HIV and malaria interventions, which are covered extensively in other global health landscapes.

2.2 Intervention analysis

The interventions included in this landscape are organized according to the WHO/UNICEF Levels and Standards of Care framework (see Figure 2.1). Within each standard of care, interventions are grouped by product type (medicines, diagnostics and devices) and assessed based on their current role in newborn care in LMICs.

Each intervention is classified as either a **Global Standard**, a **Global Standard | Significant Access Gaps**, or an **Emerging Innovation**. Global Standard products are evidence-based interventions endorsed by global guidelines and routinely integrated into health systems. Significant Access Gaps interventions are evidence-based interventions that remain inconsistently available or used in practice because of market, financing, service delivery or health system barriers. Emerging Innovations are promising products or delivery approaches that require additional evidence, regulatory approval or implementation experience before broad adoption.

For each intervention, information is provided on its use, current status in LMICs (for Global Standard and Global Standard | Significant Access Gaps products), and key considerations for scale-up (for Emerging Innovations). Where relevant, the analysis also indicates whether an intervention is included in the WHO List of Key Maternal and Newborn Health Commodities, relies on complementary consumables or supporting products for safe and effective use, and has been prioritized for deeper analysis in Section 3.

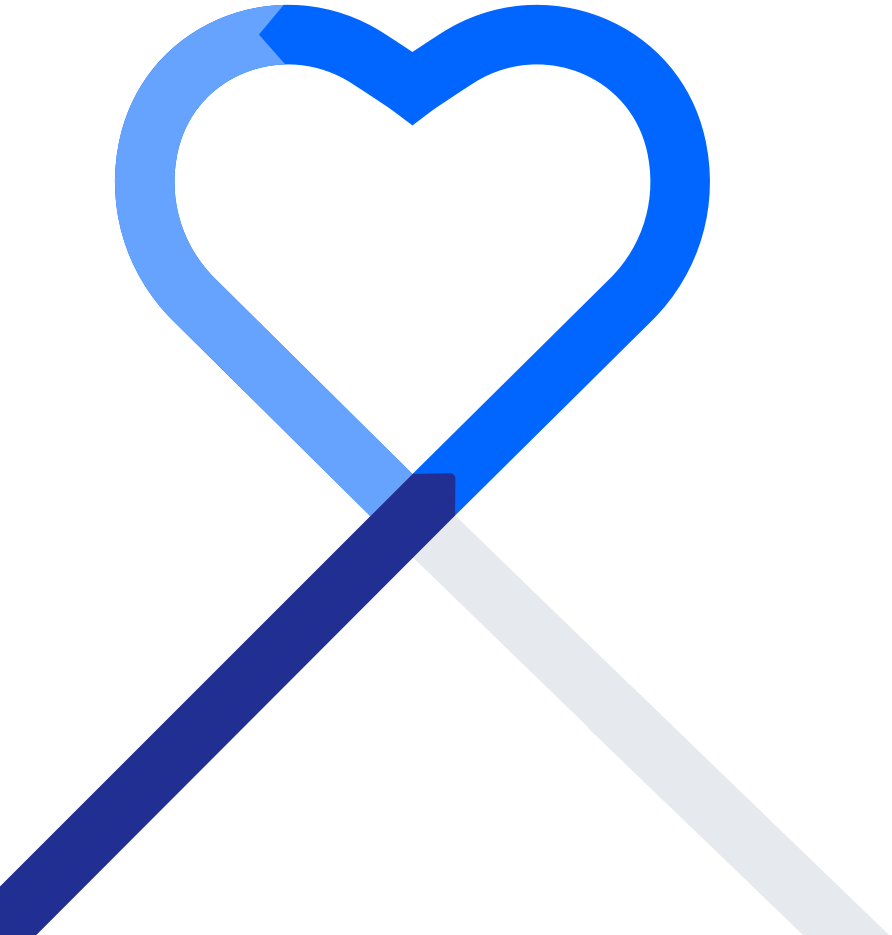


Figure 2.1 WHO/UNICEF levels and standards of care framework

WHO/UNICEF level of care	Standard of care
Level 1: Immediate and essential newborn care	L1.1: Immediate newborn care
	L1.2: Essential newborn care, identification and referral of complications
	L1.3: Neonatal resuscitation for those who need it
	L1.4: Targeted care as needed
Level 2: Special newborn care	L2.1: Assisted feeding and IV fluids
	L2.2: Detection and management of hypoglycaemia
	L2.3: Detection and management of anemia, including blood transfusion
	L2.4: Prevention, detection and management of neonatal encephalopathy and other neurological conditions, including seizure management
	L2.5: Detection and management of neonatal jaundice with phototherapy
	L2.6: Detection and management of neonatal sepsis with injectable antibiotics
	L2.7: Prevention and management of respiratory distress with CPAP / safe administration of oxygen
	L2.8: Prevention of apnea
	L2.9: Thermal care including kangaroo mother care for stable neonates <2,500 gms
Level 3: Intensive newborn care	L3.1: Surfactant treatment
	L3.2: Advanced feeding support
	L3.3: Screening and treatment for retinopathy of prematurity

2.3 Level 1

Level 1 facilities provide immediate and essential newborn care at birth and during the early postnatal period. Their primary role is to ensure that all newborns receive routine preventive and supportive care, identify complications early, initiate basic stabilization when needed and facilitate timely referral to higher levels of care. While Level 1 facilities generally do not provide specialized inpatient care for SSNs, they serve as a critical entry point to the newborn care continuum. The interventions included in this section support four core functions of Level 1 newborn care: immediate newborn care, essential newborn care, neonatal resuscitation for newborns who require it and the identification, stabilization and referral of complications.

Medicines – prevention	Diagnostics	Medicines - treatment	Devices
L1.1 Immediate newborn care			
1. 7.1% Chlorhexidine			
L1.2 Essential newborn care, identification and referral of complications			
2. Vitamin K (phytomenadione) •	***3. Pulse oximeter*** • 4. Neonatal stethoscope • 5. Hemoglobinometer •• 6. Multi-parameter vitals monitor • 7. Heart rate meter 8. Respiratory monitor/counter •	9. Amoxicillin (oral) ••	10. Baby scale (digital) • 11. Breast pump ••
L1.3 Neonatal resuscitation for those who need it			
			12. Bag-valve-mask (Size 0 and 1) •• 13. BabySaver tray 14. Augmented infant resuscitator (AIR) •
L1.4 Targeted care as needed			
	15. Dual RDT • 16. Triple HIV/syphilis/ hepatitis B RDT •	17. Benzathine benzylpenicillin •	
Total = 17			
2	**8**	**2**	**5**

Key

Global Standard Evidence-based interventions endorsed by global guidelines and routinely integrated into health systems.

Global Standard | Significant Access Gaps Evidence-based interventions endorsed by global guidelines but inconsistently available or used in practice due to health system barriers.

Emerging Innovation Promising new products, technologies or delivery approaches that require additional evidence, approval or health system readiness before broad adoption.

Bolded italicized interventions (whether a ***Global Standard***, ***Global Standard | Significant Access Gaps*** or ***Emerging Innovation***) are prioritized and explored further in Section 3.

- Indicates inclusion in WHO Newborn Health Commodity List (2024)
- Indicates significant reliance on consumable supplies, such as tubing, probes, masks, required for safe and effective use.

L1.1: Immediate newborn care

Immediate newborn care encompasses the set of interventions provided at the time of birth and in the first hours of life. These include thorough drying, skin-to-skin contact, delayed cord clamping and hygienic cord care.[26] Appropriate immediate care is essential for all newborns and can be delivered at every level of the health system, including primary care facilities.

Intervention	Use	Analysis
Medicines – prevention		
1. 7.1% chlorhexidine	It is recommended by WHO in settings with high neonatal mortality rates where harmful traditional substances are applied to the cord. Applied to the umbilical cord stump at birth and daily for the first seven days of life to prevent infection.[27,28]	Recent and cross-LMIC data is limited: A cross-sectional survey in four regions of Ethiopia conducted in 2020 – following national scale-up in 2017 – found that 41.2% of neonates born with a skilled birth attendant received chlorhexidine cord care within 24 hours of birth.[29] Coverage of chlorhexidine cleansing was 15.0% in Bangladesh (DHS 2017-18) and 50.7% in Nepal (DHS 2016).

L1.2: Essential newborn care, identification and referral of complications

For SSNs, expressed breastmilk and lactation support are components of supportive care at facility level.[26] Essential newborn care encompasses the routine clinical assessments and interventions provided to all newborns at birth and in the early postnatal period, including identification of complications requiring referral. Clinical examination and basic diagnostic monitoring are fundamental to detecting the leading causes of neonatal morbidity and mortality: prematurity, infection, birth complications and jaundice.[26] Early initiation of breastfeeding within the first hour of birth and exclusive breastfeeding for the first six months are among the most protective interventions for neonatal survival. It should be noted that some thermal care devices such as thermometers, although present in Level 1, are covered in L2.9: Thermal Care Including Kangaroo Mother Care for Stable Neonates <2,500 gms, for better readability.

Intervention	Use	Analysis
Medicines – prevention		
2. Vitamin K (phyto-menadione) •	A single intramuscular dose of vitamin K is administered to all newborns at or shortly after birth to prevent vitamin K deficiency bleeding (VKDB), a potentially fatal hemorrhagic condition. It is recommended by WHO as part of routine essential newborn care.[30]	Coverage surveys indicate that vitamin K prophylaxis remains underutilized in low-income countries, with administration at birth widely practiced in only around half of surveyed settings; coverage is higher among facility births than home births, reflecting persistent gaps in outreach and community-level administration.[31]
Diagnostics		
3. Pulse oximeter •	Non-invasively measures peripheral oxygen saturation (SpO_2) and heart rate via a probe applied to the infant's hand, wrist or foot. It is used for continuous or intermittent monitoring of oxygenation in newborns at risk of hypoxia, including preterm infants, those with respiratory distress and those requiring oxygen therapy.[22]	In primary facilities, pulse oximeters and oxygen are nearly entirely unavailable. Even in higher facilities, pulse oximeters are available in only 54% of general hospitals (level 2).[32] Several studies have also documented lack of pulse oximeter use during both intra and interfacility transport.[33] LMIC-appropriate devices, designed for use in low-resource environments with rechargeable batteries and neonatal probes, are available from manufacturers in Taiwan, South Korea, China and the USA at approximately USD 250 per unit.[22]

Intervention	Use	Analysis
4. Neonatal stethoscope •	A small-diaphragm stethoscope for listening to heart sounds, breathing and bowel sounds during newborn examination. It is a core assessment tool used at all levels of care.[34]	Stethoscopes are among the most widely available diagnostic tools in LMIC facilities.[34] However, there are significant access gaps for neonatal stethoscopes. A 2019 multi-country WHO health facility survey found stethoscopes present in over 80% of facilities providing child health services, though neonatal-specific small-diaphragm models were far less consistently available, particularly at primary care level.[34]
5. Hemoglobinometer ••	A point-of-care (PoC) device for rapid measurement of haemoglobin concentration, used in the newborn assessment to screen for anemia and particularly relevant in preterm infants.[22] The blood sample is typically obtained via a heel-prick.	Coverage at facility level in LMICs is variable; many settings rely on laboratory-based full blood counts where available, or on clinical assessment alone where laboratory capacity is absent.[22] Available data from multi-country assessments suggest PoC hemoglobin devices are still used rarely in LMIC settings.[35]
6. Multi-parameter vitals monitor •	A combined monitoring device that measures multiple vital signs simultaneously, including respiratory rate, oxygen saturation, heart rate and temperature. It is used in newborn care units for continuous monitoring of unstable or at-risk newborns.[22]	Multi-parameter monitors are typically available only at higher-level facilities in LMICs. Cost, maintenance requirements, and the need for reliable power supply limit their availability at district hospital level and below.[22]
7. Heart rate meter	A device for objective measurement of neonatal heart rate, used in assessment at and shortly after birth. Accurate heart rate measurement is a key indicator in both the initial newborn assessment and in guiding resuscitation decisions.[22]	Purpose-built neonatal heart rate meters, such as ECG-based devices, remain uncommon in LMIC settings. Most neonatal units in LMICs rely on pulse oximeters or stethoscopes for heart rate assessment rather than dedicated purpose-built meters.
8. Respiratory monitor/counter •	A device used to count and monitor neonatal respiratory rate, aiding in the detection of tachypnoea (≥60 breaths per minute) and respiratory distress, key clinical signs prompting escalation of care.[22]	Dedicated respiratory monitors are not widely available at primary care level in LMICs. Respiratory rate is typically counted manually by health workers, which is time-consuming and susceptible to error, particularly under high workload conditions.

Intervention	Use	Analysis
Medicines - treatment		
9. Amoxicillin (oral) ••	Used in the outpatient management of possible serious bacterial infections in young infants – particularly in settings where referral to hospital is not feasible. In combination with injectable gentamicin (covered later in level 2), it is part of the WHO-recommended simplified antibiotic regimen for outpatient treatment of possible serious bacterial infection in neonates at primary care level.[30]	Amoxicillin is widely manufactured and procured in LMICs.[36] Oral syrup formulations and dispersible tablets appropriate for neonates are generally available, though consistent supply at community and primary care level varies by country.[30]
Devices		
10. Baby scale (digital) •	Digital baby scales are used to weigh newborns at birth, enabling identification of low birthweight (LBW, <2,500g) and very low birthweight (<1,500g) infants who require additional monitoring and care. Birthweight is one of the most important predictors of neonatal survival.[37]	Available from multiple manufacturers, including LMIC-based producers. However, functional, calibrated scales are not available at all birth facilities, particularly at primary care level in low-resource settings.[38] Non-digital scales are also often used at this level of care, but they may have limited precision for small and preterm newborns, restricting accurate weight-based assessment and management.[49] A NEST360 (2022) readiness assessment found calibrated neonatal scales available in approximately 60% of the 65 facilities surveyed across four sub-Saharan African countries, with only a minority having been calibrated within the preceding 12 months.[34]
11. Breast pump ••	Used to express milk for newborns who are unable to feed directly at the breast – including but not limited to preterm and low birthweight infants in inpatient care. Expressed breastmilk is the preferred feed for all admitted newborns where direct breastfeeding is not possible.	A multi-country assessment of 65 neonatal units across Kenya, Malawi, Nigeria and Tanzania (NEST360 2022) found breast pumps available in fewer than 25% of surveyed facilities.[34]

L1.3: Neonatal resuscitation for those who need it

An estimated 5–10% of newborns require some stimulation to initiate breathing at birth, and approximately 6 million newborns annually require basic resuscitation including bag-and-mask positive pressure ventilation.[26] Every birth facility should be equipped and staffed to provide bag-and-mask resuscitation. Other relevant devices such as heart rate meters were covered previously.

Intervention	Use	Analysis
Devices		
12. Bag-valve-mask (Size 0 and 1) ••	A self-inflating bag-valve-mask (BVM) device provides positive pressure ventilation to a newborn who fails to establish spontaneous breathing after birth. Size 0 masks are used for preterm infants and size 1 for term newborns. It is the primary device for newborn resuscitation at all levels of care and is included on the WHO list of essential neonatal commodities.[30]	A six-country assessment of emergency obstetric and newborn care facilities in Ethiopia, Kenya, Madagascar, Mozambique, Rwanda and Tanzania found that availability was generally high in hospitals (82–100% availability), but substantially lower in lower-level facilities. Across all facility types, the pooled availability was approximately 57%, reflecting major gaps outside hospitals.[39] Single-use devices are often retained for reuse in LMICs, and steam-based high-level disinfection can damage equipment; chemical disinfection protocols show inconsistent staff compliance.[40] Neonatal BVM devices are produced by both global and LMIC manufacturers at USD 5–30 per unit, making cost a relatively minor barrier to procurement.[41,42]
13. BabySaver tray	A portable, low-cost newborn resuscitation kit designed for bedside use at the point of delivery. It includes equipment required for initial resuscitation – bag and mask, suction device and stethoscope – alongside simple visual instructions based on the Helping Babies Breathe (HBB) protocol. Its design reduces the separation and delay associated with moving the newborn to a separate resuscitation station.[22]	The device was developed by a team from Liverpool Women's Hospital and Makerere University, Uganda. A 2025 feasibility and acceptability study in Uganda reported improved bedside resuscitation, reduced morbidity, and strong acceptability among health workers and mothers.[43] Broader multi-site evaluation is required before global recommendations can be made.

Intervention	Use	Analysis
14. Augmented infant resuscitator (AIR) •	The Augmented Infant Resuscitator (AIR) attaches to a standard bag-mask ventilation unit and provides visual and haptic (vibrating) feedback to the resuscitator on the rate and pressure of delivered inflations in real time. This addresses a key limitation of standard bag-mask ventilation – that even trained health workers deliver suboptimal ventilation rates and pressures in stressful resuscitation situations.[44]	The AIR device has been evaluated in simulation and early clinical studies in Uganda and has demonstrated improved ventilation quality in both trained and less experienced resuscitators. Clinical trial data from field settings are limited; its low cost and compatibility with existing resuscitation equipment make it a strong candidate for LMIC deployment if further validation confirms clinical benefit. It is a low-cost device (approximately USD 20–25).[44]

L1.4: Targeted care as needed

This standard of care encompasses targeted interventions for newborns at elevated risk due to maternal conditions. While HIV and malaria are outside the primary scope of the landscape, selected syphilis interventions are included because of their direct impact on stillbirth, congenital syphilis, prematurity and neonatal mortality. Most current efforts in LMICs focus on maternal screening and treatment.

Intervention	Use	Analysis
Diagnostics		
15. Dual HIV/syphilis rapid diagnostics tests (RDTs) ••	Dual HIV/syphilis rapid diagnostic tests are point-of-care tests used primarily in antenatal care to screen pregnant women for HIV and syphilis during a single visit. Their most important role in this landscape is the prevention of adverse pregnancy outcomes, particularly stillbirths associated with untreated maternal syphilis, through early identification and treatment during pregnancy. In addition, these tests help prevent mother-to-child transmission of HIV and syphilis and facilitate timely treatment and follow-up for both mothers and newborns. WHO recommends HIV, syphilis and hepatitis B testing at least once in pregnancy, preferably in the first antenatal care visit.[45]	Dual HIV/syphilis RDTs are increasingly adopted in LMIC antenatal care platforms, but coverage remains uneven as syphilis screening has historically lagged behind HIV testing, many countries still rely on laboratory-based syphilis testing and implementation depends on ANC attendance, test procurement, staff training and confirmatory/treatment algorithms.[46]

Intervention	Use	Analysis
16. Triple HIV/syphilis/ hepatitis B RDTs •	Triple HIV/syphilis/hepatitis B rapid diagnostic tests are point-of-care tests used in antenatal care to screen pregnant women for three major vertically transmitted infections during a single visit. Their primary value in this landscape is the prevention of stillbirth, congenital infection, neonatal mortality, and long-term morbidity through earlier identification and management of maternal infection.	Triple HIV/syphilis/hepatitis B RDTs represent an emerging approach to integrated antenatal screening that may strengthen triple elimination efforts. While promising, adoption remains limited and additional implementation experience is needed to understand their impact on coverage, feasibility and maternal-newborn outcomes.
Medicines - treatment		
17. Benzathine benzylpenicillin (commonly known as benzathine penicillin G or BPG) •	This is the treatment for congenital syphilis in certain neonates at lower risk of syphilis infection. It is administered as a single intramuscular injection and is listed as the first-choice medicine for congenital syphilis in the WHO Model List of Essential Medicines for Children.[36] Note: BPG is also the treatment provided for pregnant women. Here we focus on use for neonates.[45]	Supply shortages have been a recurring problem globally and in LMICs specifically, limiting reliable access.[46] Given BPG's use in other health areas and limited number of active pharmaceutical ingredient (API) vendors, supply shocks are common with only 1 WHO PQ vendor. (expert input, 2026) *Note: Pediatric doses are prepared from adult doses, and availability data for neonates is not available. Insights presented above are in relation to BPG use for pregnant women. It can be inferred that availability for neonates is even lower.*

2.4 Level 2

Level 2 newborn care encompasses the specialized services required for SSNs who need more than routine care but do not require intensive care. Typically delivered in district or secondary-level facilities, Level 2 care includes the assessment, monitoring and treatment of common neonatal complications such as respiratory distress, feeding difficulties, infection, jaundice, hypoglycaemia and thermal instability. These services represent some of the highest-impact interventions for reducing neonatal mortality, with an estimated 20 million newborns requiring this level of care annually.[26] The following section covers interventions that support the delivery of Level 2 newborn care, including assisted feeding and intravenous fluids; detection and management of hypoglycaemia, anemia, neonatal encephalopathy, jaundice and sepsis; prevention of apnea; respiratory support through oxygen therapy and CPAP; and thermal care, including kangaroo mother care for newborns weighing less than 2,500 grams.

Medicines – prevention	Diagnostics	Medicines -treatment	Devices
L2.1 Assisted feeding and IV fluids			
		18. Isotonic crystalloids ••	20. Feeding cup •
		19. Donor milk	21. Nasogastric (NG) feeding tube •• *Suction pump (covered in cross-cutting)*
L2.2 Detection and management of hypoglycaemia			
	22. Glucometer ••	23. 10% IV dextrose •	
		24. Oral glucose (dextrose) gel	
L2.3 Detection and management of anemia, including blood transfusion			
25. Iron supplementation •		26. Packed blood cells (neonatal bags) ••	27. Infusion pump ••
L2.4 Prevention, detection and management of neonatal encephalopathy and other neurological conditions, including seizure management			
28. Magnesium sulfate •		29. Phenobarbital •	

Medicines – prevention	Diagnostics	Medicines -treatment	Devices
L2.5 Detection and management of neonatal jaundice with phototherapy			
	30. Bilirubinometer (serum) •• 31. Bilirubinometer (transcutaneous) •		***33. LED phototherapy units*** • 34. Fluxmeter / light meter •
	32. Smartphone image-based jaundice screening		35. Filtered sunlight phototherapy
L2.6 Detection and management of neonatal sepsis with injectable antibiotics			
	36. Gram stain microscopy •• ***37. Full blood count (FBC)*** ••	***49. Ampicillin (injectable)*** • ***50. Gentamicin (injectable)***	
	38. Blood and cerebrospinal fluid culture •• ***39. Phenotypic antimicrobial susceptibility testing (AST) – culture-based*** •• ***40. PCR pathogen detection*** • ***41. Multiplex sepsis panels*** • ***41. Procalcitonin (PCT) test*** • ***43. C-reactive protein (CRP) test*** • ***44. IL-6*** •	***51. Intravenous aqueous crystalline penicillin G or procaine benzylpenicillin*** • ***52. Azithromycin and erythromycin (injectable/oral)*** • ***53. Cefotaxime*** ***54. Amikacin (injectable)*** ***55. Cloxacillin (injectable)***	
	45. AI/ML software for sepsis detection ***46. Novel biomarkers: NeoSep-SAA and related platforms*** • ***47. Microfluidic paper-based analytical devices (µPADs)*** • ***48. Integrated sepsis diagnostic platforms*** •	***56. Antibiotic (novel): cefiderocol*** ***57. Novel antibiotic combinations: flomoxef + fosfomycin/amikacin; fosfomycin + amikacin***	

Medicines – prevention	Diagnostics	Medicines -treatment	Devices
L2.7 Prevention and management of respiratory distress with CPAP / safe administration of oxygen			
58. Antenatal corticosteroids-for mothers at risk of preterm delivery (dexamethasone and betamethasone) •		60. Oxygen ••	***61. Bubble CPAP with blenders*** ••
59. Maternal respiratory syncytial virus (RSV) vaccination			62. Nasal prongs (neonatal) ••
			63. Oxygen generation equipment ••
			64. Oxygen concentrators ••
			65. Flow splitters •
			66. Portable CPAP •
			67. Oxygen storage and backup (cylinders) ••
			Suction pump (covered in cross-cutting)
L2.8 Prevention of apnea			
68. Caffeine citrate •		***68. Caffeine citrate*** • ***(repeated intentionally)***	
L2.9 Thermal Care Including Kangaroo Mother Care for Stable Neonates <2,500 gms			
	69. Thermometer (including non-mercury) •		73. Neonatal stationary incubator ••
	70. Abdomen-attached temperature monitor •		74. Neonatal transport incubator ••
	71. Wearable temperature monitoring devices •		75. Radiant warmer ••
			76. Conductive warmer (heated mattress)
	72. Room thermometer (ambient temperature)		77. Plastic bags/cling wraps/preterm wraps •
			78. Blankets and wraps
			79. KMC bed •
			80. KMC reclining chair •
Total = 63*			
5	**21**	**17**	**21**

**Caffeine citrate is listed twice (as a prevention and treatment medicine) but only counted as one intervention.*

Key

Global Standard Evidence-based interventions endorsed by global guidelines and routinely integrated into health systems.

Global Standard | Significant Access Gaps Evidence-based interventions endorsed by global guidelines but inconsistently available or used in practice due to health system barriers.

Emerging Innovation Promising new products, technologies or delivery approaches that require additional evidence, approval or health system readiness before broad adoption.

Bolded italicized interventions (whether a ***Global Standard***, ***Global Standard | Significant Access Gaps*** or ***Emerging Innovation***) are prioritized and explored further in Section 3.

- Indicates inclusion in WHO Newborn Health Commodity List (2024)
- Indicates significant reliance on consumable supplies, such as tubing, probes, masks, required for safe and effective use.

L2.1: Assisted feeding and IV fluids

Some SSNs, particularly preterm newborns, may be unable to feed effectively at breast (coordinated sucking, swallowing and breathing does not mature until around 32–35 weeks' gestation) and therefore require alternative feeding by cup, spoon, paladai or gastric tube, which WHO recognises as a standard feeding route for preterm and low-birth-weight infants.[26] SSNs who are unable to feed directly at the breast require assisted enteral or parenteral nutritional support. This standard of care encompasses the provision of expressed breastmilk or donor milk via enteral feeding devices, as well as the use of intravenous fluids for hydration and medication delivery. Enteral feeding via cup or nasogastric tube is preferred over parenteral routes wherever possible, as it preserves gut integrity and reduces infection risk.[26]

Intervention	Use	Analysis
Medicines – treatment		
18. Isotonic crystalloids ••	Isotonic intravenous fluids – primarily 0.9% sodium chloride and Ringer's lactate – are used in newborn care for volume replacement, maintenance hydration and as a vehicle for intravenous medication delivery. They are the recommended first-line fluids for intravenous access in neonates and are listed on the WHO Model List of Essential Medicines for Children.[30]	Isotonic crystalloids are produced generically across LMICs and are generally available at district hospital level and above. The primary constraint is not product availability but reliable intravenous access – including the availability of neonatal-gauge cannulas, trained staff to site intravenous lines in small or preterm infants, and the infusion pumps required to deliver precise small volumes safely.[22] *Note: Infusion pumps are covered later in the document.*

Intervention	Use	Analysis
19. Donor milk	This is used as the preferred feed for preterm and low birthweight infants when maternal milk is unavailable or insufficient, or if neonates are sick and not able to feed. It reduces the risk of necrotizing enterocolitis (NEC), late-onset sepsis and feeding intolerance compared with preterm formula. Donor milk is collected, screened, pasteurized and dispensed from human milk banks.[26,48]	Of an estimated 756 human milk banks operating globally, the majority are located in high-income countries.[49] In Africa, formal milk banking remains nascent: South Africa has approximately 20 established banks, and a small number of facilities in Uganda, Zimbabwe and Malawi have implemented donor milk programs in recent years, often with NGO or research support.[48] In South Asia, India has established a national Lactation Management Center (LMC) program that integrates donor milk services within public hospitals.[50] Nepal has also set up milk banks with PATH support.[51] In 2026, WHO published the first global standards for donor human milk banking, establishing harmonized requirements for the safe and quality-assured operation of human milk banks.[52] *Note: In many LMIC settings, this intervention is likely to be feasible at L3 facilities. Hub-and-spoke models may be considered with the central hub carrying out complex processes and the spokes focusing on distribution and collection.*
Devices		
20. Feeding cup •	These are used to deliver expressed breastmilk (breast pumps covered in L1.2) to preterm and low birthweight infants who cannot yet suckle effectively at the breast. WHO guidelines recommend cup feeding as an alternative to bottle feeding for LBW infants in facility settings.[53]	Feeding cups are broadly available in LMICs.[30] Their use is nevertheless inconsistent in practice: health worker training in cup feeding technique is variable, and in many facilities nasogastric tube feeding is the default for infants who cannot breastfeed.[26]

Intervention	Use	Analysis
21. Nasogastric (NG) feeding tube ●● *Suction pump (covered in cross-cutting)*	These are inserted through the nose or mouth into the stomach to deliver expressed breastmilk or medicines directly to infants unable to feed orally – including very preterm infants (<32 weeks), those with weak suck-swallow-breathe coordination and infants with respiratory distress. They are the standard feeding device for SSNs in neonatal care units.[53]	NG tubes are widely available from multiple manufacturers in standard neonatal sizes (Fr 4–6) and are generally accessible at district hospital level (i.e. level 2) in LMICs. Their use depends on trained nursing staff who can insert and verify tube placement, and on the availability of expressed milk – whether maternal or donated.[35,53]

L2.2: Detection and management of hypoglycaemia

Neonatal hypoglycaemia – defined as a blood glucose level below 2.6 mmol/L (47 mg/dL) – is a common and potentially serious condition in preterm, low birthweight and large-for-gestational-age infants, and in infants of diabetic mothers. Untreated severe or prolonged hypoglycaemia may result in neurological injury and death. Early detection by point-of-care glucose testing and prompt treatment, usually via IV glucose (not covered here), are central to clinical management at secondary care level.[54]

Intervention	Use	Analysis
Diagnostics		
22. Glucometer ●●	A point-of-care glucometer measures blood glucose concentration from a capillary heel-prick sample, enabling rapid bedside diagnosis of hypoglycaemia without laboratory infrastructure. It is the standard tool for glucose monitoring in at-risk neonates – including those who are preterm and small-for-gestational-age – and is used to guide and monitor the response to treatment.[22]	Glucometers are widely available. A NEST360 assessment of neonatal units across Kenya, Malawi, Nigeria and Tanzania identified glucometers as one of the more commonly available point-of-care devices, though consistent access to test strips – and protocols for their use in at-risk neonates – was variable across facilities.[22] In many settings, glucose monitoring is performed selectively in infants with clinical signs rather than as a routine screen for at-risk groups, increasing the likelihood of missed asymptomatic hypoglycaemia.[22] $: Glucometers are widely available at moderate cost from global and LMIC manufacturers, but strips typically represent the dominant ongoing cost.

Intervention	Use	Analysis
Medicines – treatment		
23. 10% IV dextrose •	IV 10% dextrose is the definitive treatment for severe or symptomatic neonatal hypoglycaemia and for infants unable to feed. Neonatal guidelines converge on an initial bolus of 200 mg/kg – 2 mL/kg of 10% dextrose – followed by continuous infusion.[55,56] This bolus dose is identical to that delivered by 0.5 mL/kg of 40% oral dextrose gel, making the gel a direct substitute at treatment initiation rather than a different intervention.[55]	IV dextrose is inexpensive and off-patent; the barriers are delivery rather than product. It requires peripheral venous access in a neonate, sterile technique, controlled infusion and frequent glucose monitoring. Where ready-made 10% solution is unavailable, it must be compounded by diluting 50% glucose, an error-prone step.[57] The therapeutic window is narrow in newborns, who are at risk of both hypo- and hyperglycaemia during infusion, requiring close monitoring throughout.[58] Normative guidance is also inconsistent: WHO's pediatric recommendation is a 5 mL/kg bolus, while neonatal guidelines use 2 mL/kg, and the higher dose has been questioned in the literature.[59]
24. Oral glucose (dextrose) gel	Oral dextrose gel (typically 40% concentration, 0.5 mL/kg per dose) is applied to the buccal mucosa for the treatment – and in some protocols, the prevention – of neonatal hypoglycaemia. The gel is absorbed across the oral mucosa, raising blood glucose more rapidly than feed alone while avoiding the risks associated with IV access.[60] It is routinely used in high-income countries and considered a standard of care for neonatal hypoglycaemia.	A 2022 Cochrane systematic review found that dextrose gel reduces the rate of treatment failure and hypoglycaemia recurrence, and reduces NICU admissions for hypoglycaemia, with no increase in adverse effects.[63] A randomized controlled trial conducted in India found oral dextrose gel to be effective and safe in reducing the need for intravenous glucose admission in a resource-limited setting, providing early LMIC evidence of feasibility.[61]

L2.3: Detection and management of anemia, including blood transfusion

Anemia in the newborn is defined as haemoglobin below 13 g/dL at term, with lower thresholds for preterm infants. Iron supplementation is recommended for preterm and low birthweight infants. Haemoglobinometers are critical diagnostic devices (covered previously). Severe symptomatic anemia requires packed red blood cell transfusion.[26]

Intervention	Use	Analysis
Medicines – prevention		
25. Iron supplementation •	Recommended for preterm and low birthweight infants as a preventive measure against iron deficiency anemia, which can impair neurodevelopmental outcomes. WHO recommends iron supplementation for all LBW infants from 2–3 months of age. This supplementation should be planned at the time of neonatal discharge.[30]	Coverage in LMICs is limited by inconsistent integration into postnatal care protocols and gaps in postnatal follow-up for LBW infants discharged from facility care.[37]
Medicines – treatment		
26. Packed blood cells (neonatal bags) ••	Packed red blood cells (pRBC) are the product of choice for neonatal blood transfusion. For neonates, small-volume packs (typically 50–80 mL) are prepared from standard adult donations.	WHO estimates that ~42% of the global blood supply is collected in high-income countries, which account for only 16% of the population.[62] In sub-Saharan Africa, fewer than 1 in 10 countries in the region meet the WHO minimum threshold of 10 blood donations per 1,000 population.[62] Neonatal-specific small-volume blood packs are rarely available in LMIC blood banking systems, leading to excess exposure and wastage.[63,64]

Intervention	Use	Analysis
Devices		
27. Infusion pump ••	Infusion pumps enable the precise, controlled delivery of intravenous fluids and blood products. For neonatal blood transfusion, accurate volume control is critical, requiring pump accuracy to prevent volume overload, cardiac or metabolic issues in small or preterm infants. Infusion pumps are also used for intravenous medication administration throughout the management of sick newborns.[22]	Infusion pumps are among the most frequently cited equipment gaps in neonatal units across LMICs. A NEST360 multi-country assessment found infusion pumps to be absent or non-functional in a significant proportion of assessed neonatal care units across Kenya, Malawi, Nigeria and Tanzania.[22] In the absence of pumps, gravity-fed intravenous delivery – with the associated risks of imprecise flow rates – is common. Maintenance requirements and limited biomedical engineering capacity are key barriers.[22] $: Cost is also a key barrier.[22]

L2.4: Prevention, detection and management of neonatal encephalopathy and other neurological conditions, including seizure management

Neonatal encephalopathy from hypoxic ischemic encephalopathy (HIE) resulting from intrapartum asphyxia, is a leading cause of neonatal death and long-term neurodevelopmental disability.[65] Seizures are a manifestation of HIE and require prompt anticonvulsant treatment to limit further cerebral injury. Therapeutic hypothermia is the definitive treatment for moderate-to-severe HIE; however, given challenges in LMIC settings, it is excluded from this landscape.[66] At L2, management centers on seizure control with anticonvulsant medicines. Beyond HIE, neonatal neurological injury also arises from preterm birth itself, through intraventricular hemorrhage and white matter injury, with cerebral palsy risk rising steeply as gestational age falls – from 1.2 per 1,000 live births at over 37 weeks to 70.6 per 1,000 below 28 weeks.[67] Interventions in this category therefore span prevention as well as detection and management, and include antenatal magnesium sulfate for fetal neuroprotection.[68]

Intervention	Use	Analysis
Medicines – prevention		
28. Magnesium sulfate •	Magnesium sulfate given intravenously to women at risk of imminent preterm birth, to reduce the risk of cerebral palsy in the surviving infant.[69] WHO has strongly recommended it since 2015 for women at risk of imminent preterm birth before 32 weeks' gestation for prevention of cerebral palsy in the child.[70] The indication is distinct from the eclampsia indication for which magnesium sulfate is more widely stocked, and the two use different regimens and decision points.[71]	A 2024 Cochrane update (six RCTs) found that magnesium sulfate reduced cerebral palsy up to two years' corrected age and death or cerebral palsy, both high-certainty.[68] Uptake is limited, with only 69% of eligible women across 1,075 Vermont Oxford Network hospitals treated in 2022.[67] Documented barriers are the complexity of administration, time pressure and the unpredictability of preterm birth, with education, reminders and simplified administration processes identified as enablers.[72] Wider supply constraints also apply: public-sector availability gaps, a concentrated supply base, short expiry dates and evidence of substandard / falsified products; this evidence comes from the use of magnesium sulfate for eclampsia but may equally apply here.[73]
Medicines – treatment		
29. Phenobarbital •	Phenobarbital (phenobarbitone) is the first-line anticonvulsant for neonatal seizures. It is administered intravenously. Phenobarbital is listed on the WHO Model List of Essential Medicines for Children and is recommended for seizure management.	Phenobarbital is widely available as a generic intravenous and oral formulation in LMICs and is among the most stocked anticonvulsants at facility level.[74] The main product-level challenges are the requirement for intravenous access and the need for careful dose calculation and monitoring to avoid respiratory depression – a known adverse effect of phenobarbital in neonates.[74]

L2.5: Detection and management of neonatal jaundice with phototherapy

Neonatal jaundice (hyperbilirubinaemia) is a common condition in the first weeks of life, affecting the majority of both term and preterm newborns to varying degrees.[22] When bilirubin levels exceed safe thresholds, untreated jaundice can progress to irreversible neurological damage causing permanent disability or death.[26] Effective management requires reliable bilirubin measurement to guide treatment decisions, alongside access to phototherapy.[26]

Intervention	Use	Analysis
Diagnostics		
30. Bilirubinometer (serum) ●●	These instruments (both central laboratory and POC) measure total serum bilirubin (TSB). These are used to diagnose jaundice and to monitor the adequacy of phototherapy. It is the gold-standard diagnostic method; results should ideally be available within six hours to inform timely treatment decisions.[22] Point-of-care serum bilirubin devices (e.g. BiliCheck, BiliCuvette) offer bedside testing as an alternative to central laboratory TSB, with results available within 8-12 minutes from a capillary sample.[75]	Many LMIC facilities lack the laboratory infrastructure to process serum bilirubin samples within clinically meaningful timeframes. A NEST360 service readiness assessment of 65 neonatal units across Kenya, Malawi, Nigeria and Tanzania found that bilirubin measurement capacity was one of the primary drivers of low jaundice management readiness scores at baseline, with improvements recorded in Nigerian facilities between 2019–2021 and 2023. (expert input, 2026) Point-of-care serum bilirubin devices – which measure TSB from a heel-prick blood sample without laboratory infrastructure – are commercially available and represent a more feasible option for LMIC settings, though uptake remains limited.[75] Experts suggest that associated consumables are expensive. (expert input, 2026)

Intervention	Use	Analysis
31. Bilirubinometer (transcutaneous) •	A non-invasive device that estimates bilirubin levels by measuring light reflected through the skin, without requiring a blood sample. It is used for initial screening of at-risk infants and for serial monitoring. A 2021 cost-effectiveness analysis estimated that routine use of transcutaneous bilirubinometry could reduce unnecessary serum testing by 30–50% in moderate-resource settings.[76]	Limited cross-LMIC data on availability, but two studies from Nepal and Tanzania suggest very limited penetration.[77] The need for ongoing calibration remains a significant procurement barrier in most LMIC public health systems. *$: They remain expensive for most LMIC facilities due to high acquisition costs (~USD 3000). Yet, transcutaneous bilirubinometers are considered cost-effective due to reduced need for serum testing.[76]*
32. Smartphone image-based jaundice screening	Software as a Medical Device that estimates bilirubin from a smartphone photograph of the newborn's skin or sclera, offering a non-invasive alternative to visual assessment. The approved implementation requires a proprietary calibration card placed on the infant's sternum to correct for camera and lighting variation, with images captured with and without flash (x1). Positive results require confirmatory serum bilirubin before clinical action (x2).	One product is CE marked and approved in Europe for all skin tones for use by both healthcare professionals and caregivers;[78,79] no FDA clearance was identified for any product.[80] All other tools remain pre-regulatory including a UK sclera-based app,[81] and an Indian dual-image AI prototype.[82] Skin pigmentation is the defining technical constraint: validation in Botswana used spectrophotometry specifically to adjust the existing algorithm for African skin.[83] LMIC validation is active but incomplete, with studies in Mexico, Botswana, Indonesia and the Philippines, several of unknown status.[83,84] Access is gated commercially as well as regulatorily: the calibration card, without which the app does not function, is sold only into approved countries.[79]

Intervention	Use	Analysis
Devices		
33. LED phototherapy units •	Deliver blue light at the therapeutic wavelength, which is absorbed by bilirubin and enables the infant to excrete it from the body. LED devices are preferred over traditional fluorescent and halogen alternatives because they generate minimal heat, reducing the risk of hyperthermia and dehydration in the treated infant.[30] Phototherapy units are included on the WHO list of essential neonatal commodities.[30]	In a NEST360 service readiness assessment of 65 neonatal units in Kenya, Malawi, Nigeria and Tanzania, challenges around real availability were noted for this clinical area.[34] In Malawi, a qualitative study found that one district hospital had access to only a single LED phototherapy lamp, which was at times shared between two infants simultaneously due to high patient volume.[85] $: LMIC-appropriate devices are commercially available from manufacturers in India, Vietnam, Brazil and China at significantly lower cost than models designed for high-income settings.[85] Higher-end models can cost around USD 2,000–3,500.[86]
34. Fluxmeter / light meter •	A handheld, battery-operated irradiance meter used to measure the intensity of blue light delivered during phototherapy, ensuring the infant receives a therapeutic dose. LED phototherapy units degrade over time and it is important to measure their performance through light meters. (expert input, 2026)	Fluxmeters are frequently absent at facilities in LMICs, and phototherapy is commonly administered without irradiance verification, increasing the risk of subtherapeutic treatment. (expert input, 2026) Smaller studies from Nigeria confirm the low use of fluxmeters.[87] Experts suggest that light meters are still expensive for LMIC settings.[87]
35. Filtered sunlight phototherapy	Filtered sunlight phototherapy (FSPT) uses UV/infrared-blocking window film to transmit only the therapeutic blue wavelengths of natural sunlight to treat neonatal jaundice. WHO has cited FSPT as a promising innovation for LMICs.[88] It can also support simultaneous skin-to-skin care.	A randomized controlled non-inferiority trial in Nigeria demonstrated that FSPT showed non-inferiority compared with intensive electric phototherapy for moderate-to-severe jaundice. Current expert consensus positions FSPT as an appropriate option where reliable electric phototherapy is unavailable, rather than a universal replacement; scale-up remains dependent on consistent sunlight availability and local implementation conditions.[86]

L2.6: Detection and management of neonatal sepsis with injectable antibiotics

Neonatal sepsis is a leading cause of newborn death globally and in LMICs.[89] It is classified as early-onset (within the first 72 hours, typically caused by intrapartum transmission of maternal pathogens) or late-onset (after 72 hours, often hospital-acquired).[26]

Box 2.1: Role of infection prevention and control in reducing neonatal sepsis

Neonatal sepsis disproportionately affects low- and middle-income countries, and infection prevention and control (IPC) carries significant weight: babies in LMIC facilities face 3–20 times the risk of healthcare-associated infection seen in high-resource settings, and most invasive bacterial infections in recent LMIC studies involve multidrug-resistant organisms picked up in care.[90] With blood culture often unavailable and antibiotics chosen on clinical signs alone, empirical regimens frequently fail.[91] Two lines of IPC evidence are strong. In community settings, pooled data from three cluster-randomized trials in Nepal, Bangladesh and Pakistan (54,624 newborns) showed that chlorhexidine cord cleansing lowered all-cause neonatal mortality by roughly a quarter (RR 0.77, 95% CI 0.63–0.94), though the benefit has not replicated in hospitals.[92] Within neonatal units, a low-cost bundle in Lusaka – staff training, text reminders, alcohol hand rub, enhanced cleaning and weekly chlorhexidine bathing – was associated with fewer bloodstream infections and lower mortality, in a before-and-after cohort rather than a randomized comparison.[93] What limits progress is infrastructure: WHO and UNICEF estimate that in 2025 just 24% of health-care facilities in least developed countries met the basic standard for environmental cleaning.[94] Core IPC commodities include chlorhexidine digluconate 7.1% for cord, WHO-formulation alcohol handrub with dispensers plus soap and water at point of care, sterile gloves and clean delivery kits with sterile cord clamps and blades, and detergent/disinfectant with colour-coded cleaning cloths.[95,96,97,98] IPC also depends on how care is organized. Overcrowding and understaffing of newborn units increase the risk of transmission, whereas keeping mothers and newborns together (zero separation) and supporting KMC limit unnecessary exposure and handling. Alongside hand hygiene and cleaning, safe care practices such as limiting invasive procedures, aseptic technique for vascular access, and safe preparation and handling of feeds and medicines are core IPC measures. Moreover, experts recommend use of appropriate pediatric formulations which precludes infection risk as a result of deriving pediatric dosage from adult packs. (expert input, 2026).

The clinical diagnosis of neonatal sepsis is non-specific, and laboratory confirmation is frequently unavailable or delayed. While several diagnostics exist for neonatal sepsis, there are major product gaps in LMICs. This has led to the WHO releasing a WHO Target Product Profile for Rapid Diagnostic Tests for Neonatal Sepsis. It provides the technical specifications that a novel sepsis RDT should meet to be clinically useful in LMIC settings, including sensitivity, specificity, turnaround time and operational feasibility criteria.[99] Experts advise careful interpretation of inflammatory markers in settings where perinatal asphyxia is common (expert input, 2026).

Intervention	Use	Analysis
Diagnostics		
36. Gram stain microscopy ••	Classification of bacteria as gram-positive or gram-negative for antibiotic selection.	Availability: One of the most accessible microbiological tools at secondary level in LMICs. Limitations: No pathogen and antimicrobial resistance (AMR) detection; prone to error due to limited blood samples from neonates.[22,99]
37. Full blood count (FBC) ••	Adjunctive markers in the assessment of suspected neonatal sepsis; non-specific but used alongside clinical judgement.[26]	Availability: Available in most district-level hospitals in LMICs with functioning laboratory services.[22] Limitations: No pathogen and AMR detection.
38. Blood and cerebrospinal fluid culture ••	Gold standard for pathogen detection.[100,101]	Availability: Limited availability at tertiary and some secondary levels; low use in LMICs leading to diagnosis based on symptoms which can lead to overdiagnosis and antimicrobial resistance.[102] Limitations: Turnaround time significant in LMICs; automated analyzers very expensive.[102]
39. Phenotypic antimicrobial susceptibility testing (AST) – culture-based ••	Gold standard for resistance testing.[103]	Availability: Low use in LMICs.[22,103] Limitations: Turnaround time significant in LMICs.[22]
40. PCR pathogen detection •	Pathogen-specific DNA detection directly from clinical specimens (blood, cerebrospinal fluid (CSF)) within 3–6 hours.[104]	Availability: Even where machines for TB/HIV are available in LMICs, neonatal-specific PCR assays are not widely adopted. (expert input, 2026) Limitations: Per-test cost (USD 15–40), cold-chain requirements for reagents and equipment maintenance demands limit scale-up. [105,106,107,108,109,110] Moreover, culture may be required given low volumes involved with neonates.

Intervention	Use	Analysis
41. Multiplex sepsis panels •	Similar to PCR pathogen detection but can detect multiple pathogens; results in 4–6 hours.[111]	Availability: Very limited coverage.[112,113] Limitations: High per-test cost (USD 100–200 per run on commercial platforms).[112,113] Additional details: High instrument acquisition cost (USD 100,000–200,000); requires climate-resistant storage.[110,114,115]
42.Procalcitonin (PCT) test •	Biomarker with higher sensitivity and specificity for bacterial sepsis than CRP, particularly in early-onset sepsis; useful for starting/stopping antibiotic treatment.[116]	Availability: Relatively low coverage in LMICs. Limitations: No pathogen and AMR detection; cost per PoC test (typically USD 10–25) remains a significant barrier.[117]
43. C-reactive protein (CRP) test •	Acute-phase inflammatory biomarker for diagnosing/monitoring sepsis (serial measurements required); useful also to avoid excess antibiotic use.[26]	Availability: Limited capability exists in LMICs; however, serial testing requirements make consistent coverage a challenge.[26] Moreover, many labs only provide qualitative CRP tests. (expert input, 2026) Limitations: PoC test expensive at $3–5 per test; staff capacity to interpret findings also limited.[22] Additional details: PoC CRP devices require single-use cartridges with cold-chain storage requirements and face supply chain volatility in many LMICs.[26]
44. IL-6 •	Interleukin-6 (IL-6), a biomarker that rises rapidly within 2–6 hours of the onset of neonatal sepsis, making it a valuable early biomarker before CRP increases.[118]	Availability: Roche recently brought a test to market; no availability in LMICs. Limitations: Requires proprietary analyzers which are very expensive.[119]

Intervention	Use	Analysis
45. AI/ML software for sepsis detection	Algorithms analyze routine clinical and monitoring data (including vital signs, blood count trends, gestational age and clinical observations) to generate early sepsis probability scores or alerts. Several platforms have been evaluated in high-income countries, with some demonstrating earlier detection of culture-positive sepsis compared to standard clinical assessment.[120] Built primarily in digitally enabled, data-rich NICU environments in HICs.	Stage: Application in LMICs is at a nascent stage: most LMIC neonatal units lack the electronic health records, continuous vital sign monitoring and connectivity required to deploy such tools. Evidence needs: Validation in LMICs with different case-mix, pathogen profiles and clinical documentation practices is essential. Regulatory pathways for software-as-medical-device (SaMD) remain underdeveloped in most LMICs.[121]
46. Novel biomarkers: NeoSep-SAA and related platforms •	Serum amyloid A (SAA) is a protein that rises significantly faster than CRP in response to bacterial infection and returns to normal more rapidly after treatment. Potentially useful for early sepsis detection and for guiding safe antibiotic discontinuation. NeoSep-SAA is a PoC platform currently in development.[122]	Stage: A multi-country African study reported promising sensitivity and specificity compared with blood culture, with PoC SAA measurement achieving results within 15 minutes.[122] Current assay formats are not optimized for small blood volumes; no commercial PoC SAA platform has regulatory approval in major LMIC markets.[123,124] Evidence needs: Larger prospective validation studies across diverse LMIC patient populations are needed.[122] Translation from research to scale requires investment in product development, manufacture at accessible cost and integration into LMIC clinical protocols.[123,125]
47. Microfluidic paper-based analytical devices (µPADs) •	Use capillary flow of small liquid volumes through paper substrates to perform multiple biomarker detection (CRP, PCT, cTnI) at or near point of care. Some devices also detect pathogen components. Require minimal blood volumes, low cost, and no laboratory infrastructure or cold chain.[126]	Stage: Demonstrated in research settings, with several groups reporting prototype devices for simultaneous detection of 2–3 biomarkers.[126] Evidence needs: Products need to demonstrate adequate analytical sensitivity and specificity; stability of paper substrate and reagents under high humidity and temperature conditions typical of LMIC settings; and costs below USD 1–2 per test.[126]

Intervention	Use	Analysis
48. Integrated sepsis diagnostic platforms •	These platforms combine pathogen identification, AMR gene detection and host biomarker quantification in a single assay. Unlike multiplexed PCR panels that require prior culture positivity, some integrated platforms are being designed for direct whole-blood testing without prior culture or DNA extraction.[127]	Stage: Several integrated platforms are in development or early clinical evaluation globally, including microfluidic chip-based formats (e.g. T2 Biosystems, SeptiCyte) and combination biomarker-molecular platforms.[128] Evidence needs:[1] validation studies in neonatal populations across LMIC settings with diverse AMR pathogen profiles;[2] neonatal-specific performance studies; and[3] health-economic analyses demonstrating cost-effectiveness in resource-constrained settings.

Sepsis is treated with antibiotics. AMR is an escalating threat: in South Asian and sub-Saharan African settings, gram-negative organisms resistant to first-line antibiotics account for a growing proportion of sepsis cases, limiting empiric treatment options.[129] Antimicrobial stewardship is therefore as important as access to new antibiotics. Where blood culture is unavailable, most neonates are treated for presumed sepsis on clinical signs alone, which can lead to unnecessary antibiotic use and further resistance. Stewardship combines infection prevention to reduce the number of sepsis cases, diagnostics that support earlier and more accurate decisions, and clear guidance on when to start, review and stop treatment. Resistance patterns and diagnostic capacity also differ across levels of care: at Level 2, empirical regimens and clinical review are the main tools, while culture, susceptibility testing and second-line antibiotics are generally more accessible at referral and tertiary facilities.

Intervention	Use	Analysis
Medicines-Treatment		
49. Ampicillin (injectable) •	Injectable ampicillin is the primary first-line antibiotic for empiric treatment of early-onset neonatal sepsis, used in combination with gentamicin. The combination provides broad-spectrum coverage against the principal early-onset pathogens and is recommended by WHO as the first-line empiric regimen for neonatal sepsis.[36,130]	Ampicillin is widely available as a generic intravenous formulation in LMICs. It is included in national essential medicines lists across sub-Saharan Africa and South Asia. Availability at facility level is generally adequate, though cold-chain requirements for reconstituted solutions and reliable IV access for administration remain constraints in some settings.[22,130] *See cefotaxime below for discussion on how the standard ampicillin and gentamicin regimen is often not followed.*
50. Gentamicin (injectable)	Injectable gentamicin is used in combination with ampicillin as first-line empiric therapy for neonatal sepsis. Gentamicin provides coverage for gram-negative organisms.[131] *Note regarding use in Level 1 settings: Where referral is not possible, WHO recommends that infants aged 0–59 days with IMCI signs of clinical severe infection be treated outside hospital (i.e. level 1 settings) with oral amoxicillin plus IM/IV gentamicin for at least 7 days, and those with critical illness with IM/IV ampicillin plus gentamicin for at least 10 days; referral remains the preferred option.[132]*	Gentamicin is among the most widely stocked injectable antibiotics in LMIC hospital formularies and is generally available at district hospital level. Therapeutic drug monitoring to guide dosing in preterm infants, recommended for its narrow therapeutic index, is rarely available in LMIC settings, which increases the risk of toxicity from accumulation, particularly in infants with renal impairment.[22,133] *See cefotaxime below for discussion on how the standard ampicillin and gentamicin regimen is often not followed.*

Intervention	Use	Analysis
51. Intravenous aqueous crystalline penicillin G or procaine benzylpenicillin •	Intravenous aqueous crystalline penicillin G was historically recommended for neonatal sepsis and is still included in the WHO Essential Medicines List (EML) for Children.[36] However, WHO's 2024 clinical guidance for suspected sepsis in 0–59-day-olds recommends the ampicillin + gentamicin regimen. Procaine benzylpenicillin is not recommended as first-line treatment for neonatal sepsis except in settings with high neonatal mortality, when given by trained health workers. in cases where hospital care is not achievable WHO EML for Children.[36]	Supply gaps and stockouts are reported in some national procurement systems. Penicillin G Procaine, Injectable is often not available.[46] In several countries such as Kenya, crystalline penicillin and gentamicin are often used as first line due to high ampicillin resistance. (anecdotal evidence; expert input, 2026)
52. Azithromycin and erythromycin (injectable/oral) •	These antibiotics are used for specific clinical indications in neonatal sepsis management: coverage of atypical organisms (Ureaplasma, Mycoplasma, Chlamydia) associated with early-onset infection following prolonged rupture of membranes; prophylaxis and treatment of pertussis; and selected cases of neonatal conjunctivitis. They are not recommended for empiric broad-spectrum sepsis treatment.[36]	Both azithromycin and erythromycin are widely available in oral and intravenous formulations across LMICs. Oral syrup formulations are accessible at primary care level. Neonatal-specific dosing guidance is less consistently available in facility formularies than for first-line agents.[36]
53. Cefotaxime	WHO's recommendations for management of serious bacterial infections in infants aged 0–59 days recommend the use of cefotaxime (in conjunction with ampicillin and gentamicin IM/IV) for those infants hospitalized with suspected meningitis.[136]	In LMICs, cefotaxime is often used even in cases where meningitis is not suspected: in the multi-country NeoOBS cohort, amikacin plus cefotaxime was the most common empiric regimen for neonatal sepsis, rather than ampicillin and gentamicin.[134] Access is constrained by supply-side fragility, as shortages remain prevalent in public sector hospitals, with cephalosporins among the most affected classes.[135]

Intervention	Use	Analysis
54. Amikacin (injectable)	Amikacin is an antibiotic with activity against gram-negative organisms including many gentamicin-resistant strains. It is recommended on the WHO EML for Children as a second-choice drug for neonatal sepsis – used when first-line ampicillin plus gentamicin is ineffective or when gram-negative AMR is suspected.[36]	Amikacin is available as a generic injectable formulation in most LMICs and is stocked at secondary and tertiary care level. As with gentamicin, therapeutic drug monitoring is recommended but rarely available in low-resource settings. Amikacin, although the most effective aminoglycoside, had a resistance rate of ~87% based on an in-vitro study.[36,136]
55. Cloxacillin (injectable)	Cloxacillin is an anti-staphylococcal penicillin used for the treatment of confirmed methicillin-susceptible Staphylococcus aureus (MSSA) infections, including late-onset neonatal sepsis. It is listed on the WHO EML for Children as a second-choice agent for neonatal sepsis and is recommended for directed therapy once MSSA is identified.[136]	Cloxacillin injectables are generally available at secondary care level in LMICs and are included in most national essential medicines lists.[22,136] Its use requires a confirmed or strongly suspected staphylococcal diagnosis; without microbiology support, it is not suitable for empiric therapy. Methicillin-resistant Staphylococcus aureus (MRSA) prevalence in LMIC neonatal units is variable but reported in increasing proportions in some settings.[22,136]

Novel drugs and regimens are being tested, especially to deal with growing resistance to first-line drugs. If successful, implementing these regimens requires laboratory-confirmed AMR diagnosis and clinical pharmacology input – infrastructure largely absent at secondary level in LMICs.

Intervention	Use	Analysis
Medicines – treatment		
56. Antibiotic (novel): cefiderocol	Cefiderocol is a novel antibiotic with activity against carbapenem-resistant gram-negative organisms, including some pathogens that have become significant causes of late-onset neonatal sepsis in LMIC neonatal units.[137]	Cefiderocol received FDA approval in 2019 and EMA approval in 2020 for adults with limited treatment options. It has not yet been approved or registered in most LMICs, and regulatory pathways for pediatric and neonatal use are still under development. No neonatal efficacy data from LMIC settings are currently available. According to GARDP, clinical development for pediatric use may be initiated in 2028.[138]
57. Novel antibiotic combinations: flomoxef + fosfomycin/ amikacin; fosfomycin + amikacin	Novel antibiotic combinations are being explored as treatment options for drug-resistant neonatal sepsis in settings where first- and second-line regimens are not effective. The combinations of fosfomycin and amikacin (or flomoxef plus fosfomycin/amikacin) have demonstrated efficacy in vitro and in early clinical studies against AMR organisms causing neonatal sepsis.[139]	A 2020 review of fosfomycin plus amikacin combinations for neonatal sepsis identified promising observational and early trial data, including from settings in Greece, India and South Africa, where multidrug-resistant (MDR) gram-negative organisms are prevalent. Systematic clinical evidence from well-designed trials in LMICs remains limited. Fosfomycin is being evaluated within the NeoSep1 trial platform as a component of experimental treatment arms.[140,141]

L2.7: Prevention and management of respiratory distress with CPAP / safe administration of oxygen

Respiratory distress syndrome (RDS), caused by surfactant deficiency in the preterm lung, is a leading cause of morbidity and mortality, affecting the majority of infants born before 30 weeks of gestation (~70%) and declining with increasing gestational age.[27,142] Its prevention and management require a coordinated bundle of interventions across the continuum of care, including antenatal corticosteroids and access to oxygen and respiratory support. The impact of these interventions depends on their combined availability and effective use within a functioning health system. Surfactant therapy, a key component of advanced management, is addressed under Level 3 later in this document. Further, screening and treatment for retinopathy of prematurity (ROP), which is associated with improper oxygen administration to premature neonates, is covered later under Level 3.

Note: Hypothermia is one of the strongest independent predictors of mortality among neonates receiving CPAP and functions as a prerequisite for respiratory interventions to achieve their full impact.[148] (expert input, 2026) See standard of care 2.9 for further details on thermal management.

Intervention	Use	Analysis
Medicines – prevention		
58. Antenatal corticosteroids-for mothers at risk of preterm delivery (dexamethasone and betamethasone) •	ACS – dexamethasone or betamethasone – are administered to women at risk of preterm birth between 24 and 34 weeks of gestation to accelerate fetal lung maturation, reducing the incidence and severity of RDS in preterm newborns. A single course reduces neonatal mortality by approximately 30% and RDS by 35% in high-income settings. They are among the most evidence-based interventions in perinatal medicine and are included on the WHO Model List of Essential Medicines.[144,145]	ACS, especially Dexamethasone, are widely available as generic injectables in LMICs.[18,146] However, they are not commonly used for pregnant women; coverage in LMICs remains low. WHO recommends ACS use under conditions. A major one is accurate gestational age assessment (challenge in LMICs due to limited ultrasound infrastructure and/ or limited provider skills, among others). Further analysis in Section 3.

Intervention	Use	Analysis
59. Maternal respiratory syncytial virus (RSV) vaccination	Maternal respiratory syncytial virus (RSV) vaccination protects infants against severe RSV lower respiratory tract infection. In its May 2025 position paper, based on SAGE recommendations issued in September 2024, WHO recommends that countries introduce either maternal RSVpreF or the monoclonal antibody nirsevimab into national immunisation programs, and advises a single dose of RSVpreF during the third trimester as defined by local guidelines.[147,148] Efficacy in the MATISSE trial was 81.8% against severe RSV lower respiratory tract infection within 90 days of birth and 69.4% within 180 days, alongside reductions in hospitalisation.[149]	Access has changed materially within the past year. WHO prequalified a vaccine with multi-dose vial presentation in September 2026. Gavi's maternal RSV program, which was contingent on prequalification, is now operational, with eligible countries able to apply for funding to integrate the vaccine into routine antenatal care.[150] The WHO position paper itself directs countries to select products on the basis of cost, funding sources, supply security, eligible population and health system capacity.[147]
Medicines – treatment		
60. Oxygen ••	Medical-grade oxygen serves as a critical intervention for preventing and managing low blood oxygen levels (hypoxaemia) in ill newborns, particularly those affected by premature birth complications, respiratory distress syndrome, lower respiratory tract infections, brain injury (encephalopathy), sepsis and other infectious conditions. When administering oxygen to neonates, dose adjustment is essential to ensure adequate treatment without causing harm.[32]	Across LMICs, the availability of oxygen at healthcare facilities remains severely limited: only 12% of primary care centers, 58% of general hospitals and 86% of tertiary hospitals report having oxygen on hand. Supply disruptions and stock shortages are widespread, impacting 93% of primary facilities, 45% of general hospitals and 25% of tertiary hospitals.[32]

Intervention	Use	Analysis
61. Bubble CPAP with blenders ••	Bubble CPAP delivers continuous positive airway pressure to spontaneously breathing newborns via nasal prongs or a nasal mask. Bubble CPAP is the standard of care for preterm RDS at secondary level and is recommended by WHO.[144,151] Delivered oxygen concentration is set by an oxygen blender, which mixes medical air and oxygen to allow titration of FiO_2 between 21% and 100%; without one, a CPAP circuit supplied from a concentrator delivers essentially undiluted oxygen, leaving no means of adjusting dose to the saturation target. Blending is available on some bubble CPAP devices as an integrated feature without requiring medical air and on others only as a separate component.	A NEST360 survey of neonatal units across Kenya, Malawi, Nigeria and Tanzania found bubble CPAP to be available in a significant proportion of assessed units, though equipment functionality, neonatal nasal prong availability, and training for correct setup and patient positioning were variable.[34] Devices have become less expensive, but cost of consumables is significant.
62. Nasal prongs (neonatal) ••	Neonatal nasal prongs deliver low-flow supplemental oxygen to the nasopharynx. They are used for infants requiring supplemental oxygen without the positive pressure of CPAP – including those with moderate hypoxaemia or in recovery from respiratory illness. Correct sizing and positioning are important to ensure effective oxygen delivery and to minimize nasal trauma.[152]	Neonatal nasal prongs are relatively low-cost and are manufactured by multiple suppliers. Availability at facility level in LMICs is generally reasonable, though correct neonatal sizing, e.g. size zero (for very small or preterm infants) is not always available, and single-use prongs are often reused in resource-constrained settings, raising infection control concerns.[152]

Intervention	Use	Analysis
63. Oxygen generation equipment ••	Oxygen production equipment generates medical-grade oxygen, delivered via piped distribution networks, compressed gas cylinders, manifold systems or oxygen concentrators used directly. There are three principal production methods, each operating at different scales: Liquid Oxygen (LOX) Plants for large-volume production and bulk hospital supply; Pressure Swing Adsorption (PSA) Oxygen Plants, widely adopted by hospitals due to their ability to generate oxygen on-site; Vacuum Pressure Swing Adsorption (VPSA) represents a more advanced and energy-efficient variant of PSA and is well-suited for medium- to large-scale oxygen production.[32]	In LMICs, oxygen production infrastructure depends on a combination of supply sources. PSA and VSA plants are being deployed with increasing frequency at secondary and tertiary hospitals, as they offer the capability to provide piped oxygen and refill cylinders. However, their effective operation depends on consistent power supply, ongoing maintenance, skilled personnel, available spare parts and long-term financial sustainability. Notably, many PSA systems acquired during the COVID-19 pandemic were never commissioned, failed shortly after installation or were decommissioned due to the absence of maintenance and funding plans.[32]
64. Oxygen concentrators ••	Oxygen concentrators extract oxygen from ambient air using a molecular sieve, producing a continuous supply of 87–96% oxygen without the need for pressurized cylinders, supply chains or cylinder refilling infrastructure. A concentrator supplying 5–10 litres per minute can support multiple simultaneous low-flow oxygen users in a neonatal unit.[153]	Oxygen concentrators are widely available in LMIC health facilities because of large-scale equipment programs and COVID-19-related procurements. A NEST360 multi-country assessment found concentrators to be one of the more commonly present items in neonatal units across Kenya, Malawi, Nigeria and Tanzania, though functionality rates were variable, with maintenance and filter replacement posing ongoing challenges.[22]
65. Flow splitters •	Flow splitters divide a single oxygen source into two or more channels, enabling one oxygen concentrator or cylinder to simultaneously supply multiple patients. They are used in neonatal units where the number of patients requiring supplemental oxygen exceeds the number of available concentrators, and in settings where central pipeline oxygen is absent.[22]	Flow splitters are a low-cost, practical device widely used in LMIC neonatal units and are commercially available from multiple manufacturers. Their main limitation is that splitting a single concentrator across multiple patients reduces the FiO_2 and flow rate available to each patient; in units with very high occupancy, oxygen delivery may be inadequate without careful management and regular monitoring of each patient's saturation.[22]

Intervention	Use	Analysis
66. Portable CPAP •	Portable CPAP devices are compact, battery-capable continuous positive airway pressure units designed for use in settings with intermittent or absent electricity, or for patient transport. They serve the same respiratory support function as standard bubble CPAP but in conditions where a fixed wall oxygen supply, plumbed water circuit or continuous power is not available.[22]	True portable CPAP devices validated for neonatal use in low-resource settings are still limited in commercial availability. Several devices are in development or early field evaluation, with programs active in East Africa and South Asia.
67. Oxygen storage and backup (cylinders) ••	Compressed oxygen cylinders provide backup oxygen supply when concentrators are non-functional (due to power outages or equipment failure) and serve as the primary oxygen source during patient transport. They are an essential component of a complete oxygen system, particularly in settings with frequent or prolonged power supply interruptions.[22]	Cylinder availability at facility level in LMICs is uneven. Supply chains for cylinder refilling are fragmented in many countries, leading to extended periods without backup oxygen. Smaller portable cylinders for neonatal transport are available but not uniformly present.[22] Safe storage is also a concern, as cylinders may be unsecured or stored within crowded newborn units, creating physical and fire hazards.

Note that pulse oximeters, a critical diagnostic and monitoring device for this standard of care, have been included previously under Level 1 and are not repeated here.

L2.8: Prevention of apnea

Apnea of prematurity (AoP) is the cessation of breathing for 20 seconds or longer, or shorter pauses associated with bradycardia or desaturation. It is a common complication of prematurity, affecting the majority of infants born before 34 weeks of gestation (up to ~80% in very preterm infants). It reflects immature respiratory control and is associated with recurrent hypoxic episodes and risk of neurodevelopmental impairment if untreated. Management requires a coordinated approach, including pharmacologic treatment with methylxanthines (caffeine) alongside appropriate respiratory support. The effectiveness of these interventions depends on their combined availability and appropriate use within a functioning health system.[154]

Intervention	Use	Analysis
Medicines – prevention and treatment		
68. Caffeine citrate •	Caffeine citrate is the first-line pharmacological treatment for apnea of prematurity. It is included in the WHO Model List of Essential Medicines for Children and is recommended for the management of preterm infants with apnea, as well as for those at high risk of apnea. In addition to reducing apnea, caffeine therapy has been shown to improve key clinical outcomes, including reductions in bronchopulmonary dysplasia and improved neurodevelopmental outcomes. Caffeine citrate is a generic formulation.[36]	Access at district hospital level is low and varies considerably: in a multinational survey, caffeine was only available at tertiary neonatal units in LMICs vs. at district hospitals, where awareness of its indications, appropriate dosing and supply chain management was more variable. In general, awareness among providers around caffeine citrate is low in LMICs (expert input, 2026). Less effective alternatives are often used. Data from the UNICEF-led EWENE tracking tool 2025 show only 65 out of 103 countries reported to have it in essential drug list (expert input, 2026). According to Uganda's MOH, Caffeine Citrate is available at 40% of private facilities and 8% of public. Affordability is a major challenge compared to alternatives (other methylxanthines) in many SSA countries (see dosage considerations in Section 3); Limited number of quality-assured vendors and fragmented, low demand translate into high prices for a relatively simple compound.[155] Pricing levels vary from $2.7 per vial in India to >$22 in Kenya, Nigeria and South Africa;[155] Recent market shaping is starting to reduce them. For instance, CHAI has negotiated 70% price reductions in Kenya and this reduced price has since been extended to several other sub-Saharan African markets.

L2.9: Thermal care including kangaroo mother care for stable neonates <2,500 gms

Hypothermia–defined as a temperature below 36.5°C–is a leading preventable cause of neonatal death, particularly among preterm and low birthweight infants, who are highly vulnerable due to immature thermoregulation, limited insulating fat and skin barriers, high surface area-to-body weight ratios, and increased exposure to environmental and procedure-related heat loss after birth. Maintaining normothermia is a core component of neonatal care at all levels.[155]

KMC – sustained skin-to-skin contact between the mother (or other caregiver) and a stable low birthweight or preterm infant – is the primary evidence-based thermal care intervention for infants <2,500g, with benefits extending to nutrition, breastfeeding, infection prevention and neurodevelopment.[156] In contrast with devices that require electricity, KMC is climate smart and climate resilient and is often sufficient for thermoregulation.[157]

Intervention	Use	Analysis
Diagnostics		
69. Thermometer (including non-mercury) •	Accurate temperature measurement is a prerequisite for thermal care management. Non-mercury thermometers include digital axillary thermometers and infrared non-contact devices. WHO recommends the phasing out of mercury thermometers in health facilities.	Digital thermometers are widely available and low cost.[156] Axillary digital thermometers are standard in most LMIC neonatal units. Their use does not require additional training beyond ensuring correct placement and reading. Infrared (non-contact) thermometers have been adopted more widely since COVID-19 but have variable accuracy for neonatal axillary temperature measurement.[156]
70. Abdomen-attached temperature monitor •	An abdominal skin temperature sensor is attached to the anterior abdominal wall of the newborn to provide continuous temperature monitoring, typically used to automatically adjust the incubator temperature.[156]	Abdomen-attached sensors are standard components of incubator systems and are not used independently of the incubator. Their availability in LMICs is therefore linked to functioning incubator infrastructure. Replacement sensors are among the consumable items most commonly out of stock in LMIC neonatal units where incubators are present.[156]

Intervention	Use	Analysis
71. Wearable temperature monitoring devices •	Wearable neonatal temperature sensors (Bluetooth or NFC based) enable continuous or frequent temperature monitoring outside the incubator environment, including during KMC and in open-care settings. They are designed to provide earlier detection of temperature instability compared with periodic manual measurement.[156]	Wearable neonatal temperature monitoring devices are at an early stage of adoption in LMIC settings. Several products have been piloted in South Asia and sub-Saharan Africa with demonstrated feasibility, but cost, connectivity requirements, and the need for compatible data viewing infrastructure limit scale-up. They remain uncommon in routine LMIC neonatal care at present.[156]
72. Room thermometer (ambient temperature)	A wall-mounted or free-standing thermometer measuring ambient air temperature in the delivery room, neonatal unit, KMC ward and transport area. WHO's ten-step "warm chain" identifies a warm delivery room, at least 25–28°C and free from draughts, as the first step in preventing neonatal hypothermia.[158] Adult thermal perception is not a valid proxy: WHO notes that a naked newborn at 23°C loses heat equivalent to a naked adult at 0°C, and that adults should not determine delivery room temperature.[158] WHO suggests that non-mercury devices should be used.[159]	Neonatal hypothermia affects 32–85% of newborns in hospital-based LMIC studies,[160] and measured delivery room temperatures often fall below the WHO threshold, with one study recording a mean of 21.7°C.[161] Room thermometers are inexpensive, ubiquitous and non-regulated, but absent from qualified device lists and so are rarely budgeted or tracked.[18] Evidence is indirect, since ambient temperature control appears only within quality improvement (QI) bundles: in one south Indian hospital, raising delivery room temperature above 25°C alongside kangaroo-method transport and a portable infant warmer reduced admission hypothermia to 17.6%.[160]

Intervention	Use	Analysis
Devices		
73. Neonatal stationary incubator ●●	Closed incubators provide a thermoneutral microenvironment for preterm and low birthweight infants who are clinically unstable or too small to maintain body temperature through KMC alone. They regulate ambient temperature and humidity, reducing insensible water loss and the energy expenditure of thermoregulation. Stationary incubators are standard equipment in secondary and tertiary neonatal care units.[22]	Stationary incubators are present in most secondary and tertiary LMIC hospitals, but functionality is a significant issue. NEST360 assessments found high rates of non-functional incubators across neonatal units in Kenya, Malawi, Nigeria and Tanzania, driven by humidity system failures, servo-control malfunctions and absence of biomedical maintenance capacity.[22] $: Replacement parts for branded high-income country incubators are often unavailable or prohibitively expensive in LMIC procurement systems.[22]
74. Neonatal transport incubator ●●	Transport incubators maintain thermal neutrality and provide monitoring and respiratory support during intra- or inter-facility transfer of unstable newborns (when skin-to-skin/KMC is not possible). They typically include an integrated oxygen supply, pulse oximetry and temperature monitoring, enabling safe transport of critically ill neonates between facilities.[22]	Transport incubators are largely absent from district and secondary hospital levels in LMICs. Where they exist at referral centers, they are often in poor functional condition. In most LMIC settings, neonatal transport is conducted without thermal protection devices or KMC, using improvised methods such as pre-warmed blankets if skin-to-skin contact is not possible. The absence of purpose-built transport incubators contributes to preventable hypothermia-related mortality during inter-facility transfers.[22]
75. Radiant warmer ●●	Open radiant warmers provide radiant heat to newborns positioned beneath an overhead heating element, maintaining normothermia while allowing full clinical access to the infant. They are used for resuscitation at birth, post-operative care and stabilization of newborns who require ongoing procedures or monitoring and for whom a closed incubator would restrict access.[22]	Radiant warmers are among the most commonly procured neonatal thermal care devices in LMIC hospitals and are included in national equipment lists in most countries. Functionality rates, while generally better than for incubators, are still impacted by electrical faults and power supply interruptions. Radiant warmers increase insensible water loss compared with incubators, requiring clinical attention to fluid balance in very preterm infants.[22]

Intervention	Use	Analysis
76. Conductive warmer (heated mattress)	Conductive warmers – including chemically activated warming mattresses and electrically heated mattresses – provide direct thermal conduction from below to maintain temperature in newborns. They are used at birth for immediate resuscitation and thermoregulation, in the delivery room when a radiant warmer is unavailable and during transport. Portable phase-change material (PCM) warmers are activated by heating (typically in hot water or a microwave) and then maintain a temperature of approximately 37°C.[22]	Reusable chemical phase-change heated mattresses are available at secondary and tertiary levels in LMICs. Chemical warmers are available from multiple manufacturers and have been used in community birth settings. PCM warmers have been evaluated in India and several African countries with encouraging results for temperature maintenance in low birthweight infants in community settings. Some warmers are also WHO prequalified.[22] Their affordability and lack of power dependency make them suitable for primary care and community use, though unit cost and supply chain access remain constraints.[22]
77. Plastic bags /cling wraps/preterm wraps •	Where KMC/skin-to-skin is not possible, polyethylene bags (food grade) or wraps may be placed over the body (excluding the face) of very preterm infants immediately at birth, without prior drying, to reduce evaporative heat and water loss. This technique is recommended by the International Liaison Committee on Resuscitation (ILCOR) for infants born at less than 32 weeks' gestation as an immediate thermal care measure.[37]	Polyethylene bags are simple to use. They have been introduced in neonatal resuscitation training programs across LMICs with demonstrated feasibility and effectiveness. The primary challenge is consistent availability at the point of use and ensuring that appropriately sized bags are stocked in every delivery room – and health worker training in the technique for very preterm infants.[37]
78. Blankets and wraps	Blankets and wraps are used to keep babies warm.[39] Although these are not strictly devices, they play a crucial role in thermal management.	Gaps were found in the availability of cloths and blankets in a cross-country study in SSA: only 40% of facilities had cloths and blankets.[39]

Intervention	Use	Analysis
79. KMC bed •	A KMC bed is a purpose-designed mattress or low-profile bed that supports a mother or caregiver in a semi-reclined position while providing skin-to-skin contact with the infant secured against the chest. It enables comfortable, sustained KMC over extended periods and has been associated with higher rates of continued KMC practice than standard hospital beds or chairs alone.[37]	KMC beds are increasingly included in LMIC neonatal unit configurations, particularly in facilities that have adopted structured KMC programs. They are relatively low cost and manufactured by local suppliers in several African and South Asian countries. Availability varies widely between and within countries[162,163] and is often poorly documented. Across countries, KMC is offered at tertiary and district hospitals and in some secondary, primary, teaching and private facilities, but functional coverage remains difficult to estimate.[164]
80. KMC reclining chair •	A KMC reclining chair enables the mother or caregiver to sit comfortably in a semi-reclined position while holding the infant skin-to-skin, typically in a ward or post-discharge home-based KMC context. It is an alternative to the KMC bed for facilities where dedicated beds are not available and for families practicing KMC in non-hospital settings.	KMC chairs are available in some tertiary and secondary facilities in LMICs, often provided by NGO partners or included in unit refurbishment programs. They are not uniformly available at district level.[22]

2.5 Level 3

Level 3 newborn care encompasses the highly specialized services required for newborns with the most severe or complex conditions. Typically delivered in tertiary referral hospitals, Level 3 care includes advanced respiratory support, specialized feeding and nutritional support, surgical and subspecialty services, and intensive monitoring. Approximately 10 million newborns require this level of care each year.[30]

While the primary focus of this landscape is on interventions delivered at Levels 1 and 2, a small number of Level 3 interventions are included because of their potential to be decentralized to Level 2 through product and service delivery innovations. These include surfactant therapy, advanced feeding support, and screening and treatment for ROP. ROP is also closely linked to the quality and monitoring of oxygen therapy delivered across the health system, including in Level 2 facilities, making it an important consideration within the broader neonatal respiratory care ecosystem.

Medicines – prevention	Diagnostics	Medicines – treatment	Devices
L3.1 Surfactant Treatment			
		81. Liquid surfactant-animal-derived (current generation) •	84. Laryngeal mask airway (LMA) •
		82. Liquid surfactant (synthetic (current generation)) •	
		83. Dry powder surfactant and/or aerosolized versions (under development) •	
L3.2 Advanced Feeding Support			
		85. Multicomponent fortification of human milk (global standard)	
L3.3 Screening and Treatment for Retinopathy of Prematurity			
	86. Binocular indirect ophthalmoscope		
	87. Portable retinal camera		
Total = 7			
0	**2**	**4**	**1**

Key

Global Standard Evidence-based interventions endorsed by global guidelines and routinely integrated into health systems.

Global Standard | Significant Access Gaps Evidence-based interventions endorsed by global guidelines but inconsistently available or used in practice due to health system barriers.

Emerging Innovation Promising new products, technologies or delivery approaches that require additional evidence, approval or health system readiness before broad adoption.

Bolded italicized interventions (whether a ***Global Standard***, ***Global Standard | Significant Access Gaps*** or ***Emerging Innovation***) are prioritized and explored further in Section 3.

- Indicates inclusion in WHO Newborn Health Commodity List (2024)
- Indicates significant reliance on consumable supplies, such as tubing, probes, masks, required for safe and effective use.

L3.1: Surfactant treatment

Surfactant replacement therapy is one of the most evidence-based interventions in neonatal medicine. Surfactant is administered to preterm infants with RDS to replace the pulmonary surfactant that is deficient in the immature lung.[26,165] Its introduction into clinical practice in the 1980s and 1990s was associated with dramatic reductions in RDS mortality in high-income countries. Despite this, access to surfactant in LMICs remains limited by cost, cold-chain requirements, and the need for trained staff to administer it safely. Surfactant administration traditionally requires endotracheal intubation, though less invasive delivery methods are increasingly used alongside continued spontaneous breathing on CPAP.[165]

Intervention	Use	Analysis
Medicines – treatment		
81. Liquid surfactant-animal-derived (current generation) •	Animal-derived (natural) surfactants are the current global standard of care for prophylaxis and rescue treatment of RDS in preterm infants. They are administered intratracheally, either via endotracheal tube or, increasingly, via less invasive methods such as the thin catheter technique (less invasive surfactant administration / minimally invasive surfactant therapy, LISA/MIST).[36,166] A newer technique, surfactant administration through laryngeal or supraglottic airways (SALSA), which aims to reduce the need for mechanical ventilation and associated lung injury, is covered later in this table (see Devices: Laryngeal Mask Airway).	Surfactant is available at tertiary neonatal centers in many middle-income countries and at select referral hospitals in lower-income settings. However, it remains out of reach for the majority of preterm infants in LMICs due to its complex administration (requiring intubation or thin catheters). It also requires cold chain storage (2–8°C). A NEST360 landscape assessment found surfactant to be among the interventions with the starkest gap between evidence of effectiveness and LMIC access.[167] High prices are also a major challenge for LMICs.[167]
82. Liquid surfactant (synthetic) – current generation •	Second-generation synthetic surfactants use synthetic analogues to replicate the properties of animal-derived products, without the need for animal-sourced raw materials. These products offer the potential for more consistent batch quality, elimination of animal-derived material and possible lower production costs at scale.[168]	Previous generations of lab-made synthetic surfactants were less effective and discontinued. Lucinactant was the first peptide-based synthetic surfactant approved by the FDA (2012), but it is not being marketed even in HICs as the company is attempting to optimize the product for aerosolized delivery (see below). Another compound, CHF5633, has shown equivalent efficacy to poractant alfa in Phase II trials. The long-term case for synthetic surfactants in LMIC settings will depend on cost reductions at manufacturing scale and entry into LMIC procurement pathways.[22,169]

Intervention	Use	Analysis
83. Dry powder surfactant and/or aerosolized versions (under development) •	An investigational formulation designed for aerosolized delivery to the preterm lung via inhalation, eliminating the need for intubation. If developed successfully, it would enable surfactant delivery to spontaneously breathing infants on CPAP – potentially transforming the feasibility of surfactant treatment in LMIC settings.[170] This may require additional equipment such as a vibrating mesh nebulizer for delivery.	Dry powder surfactant is at early-stage development. Key technical challenges include engineering surfactant particles small enough (1–3 µm diameter) for efficient alveolar deposition; preserving surfactant protein bioactivity through the drying process; and ensuring homogeneous delivery to poorly ventilated regions of the preterm lung. In vitro and animal studies have demonstrated proof of concept for aerosol delivery of synthetic surfactant components, but no product has progressed to Phase II or Phase III clinical trials in human neonates as of 2024–25.[22] Experts believe that such a product is at least 5 years away from the market. (expert input, 2026)
Devices		
84. Laryngeal mask airway (LMA) •	An airway device that can be used to administer surfactant to preterm infants without intubation – a technique known as SALSA. It sits in the pharynx above the larynx rather than passing through the vocal cords, making placement technically easier than intubation. (expert input, 2026) Neonatal LMAs are available from several manufacturers in sizes appropriate for term and near-term infants (size 1, ≥2 kg). Smaller sizes are also reported to be in trials in high-income countries. (expert input, 2026)	Availability at district hospital level in LMICs is limited, and training in correct LMA placement and surfactant instillation technique is not yet widely integrated into LMIC neonatal training curricula.[22] *Note: LMAs are also used as a rescue airway device during neonatal resuscitation when bag-mask ventilation is insufficient and intubation is not possible.*

L3.2: Advanced feeding support

Very low birthweight (VLBW) infants (<1,500g) have high nutritional requirements to support post-natal growth and neurodevelopment, yet expressed breastmilk alone – while the preferred feed – does not provide sufficient protein, calories, calcium, phosphorus and micronutrients to meet these needs. Advanced feeding support at L3 focuses on the nutritional augmentation of human milk through multicomponent fortification.[37]

Intervention	Use	Analysis
Medicines – treatment		
85. Multicomponent fortification of human milk (global standard)	Multicomponent human milk fortifiers (HMFs) are powdered or liquid preparations added to expressed breastmilk to increase its protein, energy, fat, carbohydrate, mineral and micronutrient content for VLBW infants. Standard fortification is typically initiated when an infant is tolerating full enteral feeds, and continued until the infant reaches approximately 36 weeks post-menstrual age or 2,000g. WHO makes a conditional recommendation for multicomponent HMF in VLBW infants, noting low-to-moderate certainty evidence.[37]	Commercial multicomponent HMFs are available in most middle-income countries but remain unaffordable or unavailable in the majority of low-income LMIC settings. Moreover, there are significant regulatory barriers in LMICs, especially in Africa (expert input, 2026). In facilities with donor milk banks (see L2: Assisted Feeding), fortification protocols are more likely to be in place for VLBW infants. In many LMIC neonatal units, fortification is not routinely practiced, and protein and energy deficits in VLBW infants contribute to high rates of extra-uterine growth restriction.[22,37]

L3.3: Screening and treatment for retinopathy of prematurity

ROP is a retinal vascular disorder that affects preterm infants, driven by the disruption of normal retinal function following premature exposure to high oxygen concentrations. Severe ROP can progress to retinal detachment and permanent blindness if not detected and treated early. It is now one of the leading causes of childhood blindness globally, with over 50,000 affected annually – the majority in middle-income countries, where survival of very preterm infants (enabled via oxygen therapy) has improved faster than the capacity for ROP screening and treatment.[171] When detected at threshold or pre-threshold stage, treatment options include laser photocoagulation, intravitreal anti-vascular endothelial growth factor (anti-VEGF) injections (most commonly bevacizumab), and cryotherapy.

Intervention	Use	Analysis
Diagnostics		
86. Binocular indirect ophthalmoscope	Binocular indirect ophthalmoscopy (BIO) is the gold standard method for ROP screening. Using a head-mounted binocular indirect ophthalmoscope and a hand-held condensing lens, an experienced ophthalmologist examines the retina and peripheral vasculature of the dilated eye to stage ROP according to the International Classification of ROP (ICROP). Screening is recommended for all infants born at <32 weeks gestation or <1,500g birthweight, with the first examination at 4–6 weeks of postnatal age.[172]	Binocular indirect ophthalmoscopy requires a trained pediatric ophthalmologist or retinal specialist with neonatal examination skills – a cadre that is severely limited in most LMICs. Many middle-income countries have expanded neonatal survival without commensurate expansion of ROP screening services, resulting in a large and growing population of at-risk infants without access to systematic examination. Sub-Saharan Africa and South Asia have a critical shortage of trained screeners relative to the number of surviving preterm infants.[173] $: Prices typically $500 onwards which can be a constraint, but frugal innovations are coming to the market.
87. Portable retinal camera	Portable digital retinal cameras and lower-cost devices including smartphone-based adapters – capture wide-field digital retinal images that can be interpreted by an ophthalmologist on-site or transmitted remotely for diagnosis. They enable ROP screening by non-ophthalmologist health workers who are trained to capture images, with remote expert interpretation – a model particularly relevant where ophthalmologists are unavailable in neonatal care settings.[173,174]	Portable retinal cameras have been piloted across South Asia and sub-Saharan Africa, with the largest experience in India, where the Karnataka Internet Assisted Diagnosis of ROP (KIDROP) program has demonstrated that trained non-physician technicians can capture diagnostically adequate retinal images for remote grading, enabling systematic ROP screening across rural Karnataka at scale.[175] Clinical validation of smartphone systems for ROP staging is ongoing.[176] $: Smartphone-based retinal imaging systems have reduced equipment costs to under USD 500, making camera-based ROP screening feasible in more settings.

2.6 Cross-cutting diagnostics and devices

This section covers devices that support multiple standards of care across the neonatal care continuum, from primary-level newborn care corners through to tertiary-level special newborn care units. These cross-cutting elements are foundational to the delivery of safe, effective neonatal care and, in many LMIC settings, represent the most significant system-level barriers to achieving quality care at scale.[1,30] Accurate measurement of gestational age and birthweight, and routine recording of stillbirths and newborn outcomes in national health information systems (HMIS), underpin the identification of SSNs and the tracking of progress (see Section 4.2.6).

Intervention	Use	Analysis
Diagnostics		
88. Mobile x-ray system	Portable (mobile) X-ray systems enable bedside imaging of unstable neonates who cannot safely be transported to a fixed radiology suite. Chest X-ray is used to confirm endotracheal tube position, diagnose RDS, pneumothorax, pneumonia and cardiomegaly, and assess response to treatment. It is an essential tool in secondary and tertiary neonatal care units.[177] In facilities without mobile X-ray, radiology interpretations may be delayed or unavailable, limiting diagnostic capacity for respiratory complications.[177]	Mobile X-ray systems are present at tertiary hospitals and some district hospitals in LMICs. Radiation safety infrastructure (lead shielding, dosimetry) may be limited and the availability of skilled radiographers for bedside neonatal examinations is variable.[177] $: Acquisition cost may be an issue at Level 2.

Intervention	Use	Analysis
89. Gestational age assessment: New Ballard Score and Dubowitz Method	Accurate gestational age assessment is fundamental to appropriate risk stratification, management decisions, and prognosis for preterm and low birthweight infants. The New Ballard Score (NBS) is a twelve-criterion tool assessing six neuromuscular and six physical maturity parameters; it can be completed by a trained clinician in 5–10 minutes and is recommended as a practical, well-validated method for postnatal gestational age estimation, including in LMIC settings.[178] The original Dubowitz Score is a more detailed 34-point assessment with higher accuracy but greater complexity, making it less practical in routine clinical use.[179]	These tools require only training and a scoring sheet – and are included in neonatal training curricula across LMICs. The NBS is more widely used in practice. Where antenatal ultrasound dating is available and reliable, it supersedes postnatal clinical scoring in accuracy. In settings without early antenatal care, the NBS remains the primary method of gestational age estimation.[177,178]
90. Point-of-care ultrasound	POCUS products are typically small, handheld wireless probes that connect to a smartphone or tablet for real-time imaging and connectivity.[180] In antenatal care they support gestational age estimation, detection of fetal anomalies and multiple pregnancies, and fetal and uterine Doppler at 10–12 weeks to predict the likelihood of pre-eclampsia, and scanning between 31 and 40 weeks to assess intrauterine growth restriction.[180] WHO recommends one ultrasound scan before 24 weeks of gestation as part of routine antenatal care, reaffirmed in its 2022 update.[181,182] For antenatal corticosteroids specifically, this capability matters: WHO conditions ACS use on accurate gestational age assessment.[70] *Note: For a deeper dive into PoC Ultrasound, please refer to Unitaid landscape on Pre-eclampsia, pages 23-25.*	A desk review updated in October 2024 identified 14 portable devices costing under US$10,000, ranging from roughly US$700 to US$10,000; certification is uneven, with several of the cheapest carrying no FDA clearance.[180,183] At least one handheld device is listed in the WHO compendium of innovative health technologies for low-resource settings 2024,[180,184] and WHO has published a TPP for obstetric ultrasound devices setting minimum and optimal requirements for procurement.[185] Barriers are affordability and integration into health systems (provider training, quality assurance, referral guidelines, capacity to triage and manage complications, maintenance capability and budgeting for ongoing costs).[180,181] Many devices have been used only in research settings.[180]

Intervention	Use	Analysis
91. Gestational age assessment: AI-based gestational age estimation using point-of-care ultrasound	Employs deep-learning algorithms to analyze ultrasound sweep videos or fetal images and automatically estimate fetal gestational age without requiring expert biometric measurements.[180]	As of June 2026, one company (Butterfly Network with integrated AI) has received FDA approval.[186] Studies have shown that AI-enabled low-cost POCUS devices used by minimally trained operators can estimate gestational age with accuracy.[187,188]
Devices		
92. Neonatal cannula (24G) ●●	A 24-gauge intravenous cannula is the standard peripheral IV access device for neonates. It enables the delivery of intravenous fluids, antibiotics, glucose and other medications. Reliable IV access is a prerequisite for the management of neonatal sepsis, hypoglycaemia and virtually all conditions requiring parenteral treatment. Size 24G cannulas are appropriate for term and near-term infants; even smaller gauges (26G) may be required for very preterm infants.[22]	Neonatal-gauge cannulas are included on essential supply lists and are generally available at secondary care level in LMICs, though stockouts occur. The limiting factor in most settings is not availability per se but the nursing skill to site an IV line successfully in a very small or preterm infant. In LMIC settings with high nurse-to-patient ratios, repeated failed cannulation attempts are common, leading to treatment delays.[22]
93. Suction pump (manual and electric) ●●	Suction pumps clear secretions, blood or meconium from the upper airway of newborns who are unable to clear these independently, including during resuscitation, after birth in cases of meconium-stained liquor and in neonates with copious airway secretions. Manual suction devices (bulb syringes, mucus extractors) are the minimum standard; electric suction provides stronger, more controllable negative pressure for thick or copious secretions.[22]	Manual suction devices are widely available. Electric suction pumps are present at secondary and tertiary levels in LMICs but with variable functionality. Catheter sizes appropriate for neonates (Fr 6–8) are not always available.[22] $: Manual is low cost, electric costs more.[22]

Intervention	Use	Analysis
94. Standard syringe pump ••	Electrically powered syringe pumps deliver precise, programmable infusion rates of medications and fluids from a loaded syringe, at volumes as small as 0.1 mL/hour. They are essential for neonatal care – particularly for the safe delivery of antibiotics, vasopressors, analgesics, concentrated dextrose and blood products – where even small volume errors carry significant clinical consequences.[22]	NEST360 multi-country data identified syringe pumps as critically under-available relative to clinical need, with many units having zero functional devices. Maintenance requirements and power supply dependence are the main barriers. The absence of syringe pumps in many settings means that IV medications are delivered by bolus injection or gravity infusion, which significantly increases the risk of medication errors and fluid overload.[22] $: High cost (USD 500–2,500) per pump for standard devices.
95. Syringe driver system •	A syringe driver (or syringe driver system) is a compact, continuous-rate infusion device designed for delivering very-low-volume, continuous medications – such as analgesics and sedatives – at consistent rates over extended periods. It is used for pain management in ventilated or post-operative neonates and for other continuous-infusion indications where standard syringe pumps are not available or appropriate.[22]	Syringe drivers are less common than standard syringe pumps in LMIC neonatal settings and are primarily found at tertiary level. Pain management in LMIC neonates, particularly for procedural pain, remains an underserved area, and the infrastructure to support continuous analgesic infusion is not routinely available outside of major centers.[22]
96. Non-electric syringe pump •	Non-electric syringe pumps are manually driven or spring-loaded devices that deliver controlled, continuous infusion of medications without requiring mains electricity or batteries. They are designed specifically for use in settings with unreliable power supply, enabling safe continuous-rate medication delivery during power outages and in facilities without consistent electrical access.[22]	Several non-electric syringe pump prototypes and early-stage commercial products have been developed for LMIC settings. Field evaluation in LMIC neonatal settings is limited. The primary challenge is achieving the precision and consistency of flow rate over time that is required for neonatal medication delivery – particularly for drugs with narrow therapeutic indices – without electronic feedback control.[22]

Intervention	Use	Analysis
97. Blood gas analyzer ••	Point-of-care blood gas analysis measures pH, pCO_2, pO_2, bicarbonate, base excess, and lactate from a small arterial or capillary blood sample, providing real-time assessment of respiratory and metabolic status in sick newborns. It guides respiratory support, oxygen titration and metabolic treatment in infants with respiratory distress, sepsis and metabolic derangements.[177]	Blood gas analyzers are present at many tertiary and some secondary hospitals in LMICs but are largely absent at district level. There are significant calibration requirements, and there is need for arterial sampling expertise. $: Portable devices for resource-limited settings are available from manufacturers with costs of USD 5,000–20,000 per unit. Reagent cartridge costs are also significant.[177]
98. Baby transport trolley	A neonatal transport trolley is used for safe intra-facility transfer of newborns between the delivery room, neonatal unit and other clinical areas. It provides a stable, warm surface for the infant and may incorporate a warming pad, oxygen supply connection and space for monitoring equipment. Safe intra-facility transport is important in avoiding hypothermia, hypoxia and trauma during transfers.[22]	Neonatal transport trolleys are present at secondary and tertiary care facilities in LMICs. In many district hospitals, newborns are transported in the arms of a nurse or mother without a purpose-built trolley, increasing risk during transfer.[22]



Box 2.2: Climate implications for newborn health products and technologies

Climate change is increasingly shaping not only newborn health risks, but also the reliability, performance and accessibility of the products required to care for SSNs. Many high-burden neonatal settings are simultaneously among the most climate-vulnerable, exposing fragile product ecosystems to heat, flooding, energy insecurity and supply-chain disruption.

- **Several products depend on fragile cold-chain systems.** Medicines and consumables such as surfactants, benzylpenicillin formulations, packed blood products, donor human milk, and some diagnostic cartridges require temperature-controlled storage and transport. Extreme heat, transport delays and power outages increase the risk of product degradation and interrupted availability.
- **Electricity instability directly disrupts life-saving neonatal devices.** CPAP, oxygen concentrators, phototherapy units, incubators, syringe pumps and monitoring equipment depend on reliable electricity and voltage stability. Frequent outages and voltage fluctuations compromise treatment continuity and equipment functionality.
- **KMC is an opportunity:** In contrast with devices that require electricity, KMC is climate smart and climate resilient.
- **Climate conditions affect device durability and performance.** Excessive heat, humidity and dust exposure accelerate equipment wear, battery degradation, sensor failure, overheating and calibration drift – particularly for devices not designed for low-resource environments.
- **Oxygen ecosystems are particularly climate sensitive.** Oxygen generation, storage, transport and delivery systems rely on stable infrastructure and energy supply. Climate-related disruptions can interrupt oxygen availability and weaken one of the most critical components of neonatal respiratory care.
- **Climate-resilient product design and procurement are increasingly essential.** Solar-compatible systems, battery-supported devices, passive thermal protection technologies and products capable of functioning under high ambient temperatures and unstable power conditions are becoming necessary for reliable SSNC delivery in LMIC settings.

3. Product market access barriers

What limits access?



Section summary

The principal barriers to reducing neonatal mortality are often not the absence of effective products, but the challenges of ensuring that proven and emerging interventions are available, affordable, functional and appropriately used within LMIC health systems. Across the priority products analyzed, a small number of recurring market-, health system- and service delivery-related constraints account for many of the persistent access gaps. While this section takes a product-centric view by design, we recognize that quality SSNC depends on functioning care platforms rather than individual products. The systems in which SSNC is delivered are explored in Section 4.

Key takeaways

- **Different products face different barriers, requiring different solutions.** The priority products analyzed span a wide range of market access challenges. Some are constrained primarily by affordability and weak market incentives (e.g., caffeine citrate), others by operational challenges related to maintenance, consumables and equipment uptime (e.g., pulse oximetry, phototherapy and CPAP), while others require innovation to develop products and delivery approaches better suited to LMIC settings (e.g., sepsis diagnostics and surfactants).
- **Service readiness is often as important as product availability.** For many newborn health products, impact depends on the availability of trained providers, reliable infrastructure, consumables, maintenance systems and appropriate clinical protocols. Products such as antenatal corticosteroids, bag-valve-mask resuscitation, oxygen therapy and CPAP demonstrate that access alone is insufficient without the capacity to use products safely and effectively.
- **A small number of cross-cutting constraints affect multiple products simultaneously.** Challenges related to fragmented procurement and limited budgets, limited financing, weak maintenance systems, supply chain gaps, workforce capacity (including supportive supervision), and product suitability for LMIC contexts recur across multiple interventions. Conflict and humanitarian emergencies can further compound these barriers by disrupting supply chains, maintenance and the infrastructure needed to keep products available and functional. Addressing these shared barriers offers an opportunity to improve access across a broad range of newborn health products rather than focusing on individual commodities in isolation.



3.1 Prioritizing products for deeper market access analysis

Section 2 identifies a broad landscape of medicines, diagnostics, devices and emerging innovations with the potential to prevent, diagnose, monitor or treat the leading causes of neonatal mortality. However, not all interventions face the same access challenges, nor do all require the same types of investment, market-shaping efforts or implementation support. This section therefore focuses on a subset of priority interventions where deeper analysis can help identify the barriers most likely to limit impact in LMICs and the actions needed to accelerate equitable access and effective use. Priority interventions were selected using three primary considerations.

- **Relevance to the leading causes of neonatal mortality:** prematurity, intrapartum-related events and neonatal infections.
- **Products and technologies that illustrate different types of market access challenges,** including affordability constraints, fragmented supply chains, quality concerns, maintenance requirements, provider capability barriers and weak market incentives.
- **Representation across the SSNC landscape,** including interventions delivered at different WHO levels of care and spanning the continuum from established global standards to underutilized interventions and emerging innovations.

By focusing on interventions that are both high-impact and representative of broader system challenges, the analysis aims to generate insights that extend beyond individual products and help identify opportunities for strengthening newborn health markets more broadly. The priority products identified through this process are shown below. Together, they represent a diverse set of medicines, diagnostics and devices that address major causes of neonatal mortality and morbidity, while illustrating a range of market access challenges encountered across LMICs. Products listed at Level 1 are also expected to be available at Level 2, so they are considered here in the context of Level 2 care.

Mortality driver	Level and standard of care	Intervention
Cross-cutting	Level 1: Essential newborn care	1. **Pulse oximeter**
Asphyxia	Level 1: Neonatal resuscitation	2. **Bag-valve-mask (Size 0 and 1)**
Neonatal infections	Level 2: Detection and treatment of sepsis	3. **Blood culture, full blood count, CRP, procalcitonin, IL6, novel biomarkers such as NeoSep-SAA/IL6, integrated sepsis diagnostic for bacteremia, PCR pathogen detection, AI/ML software for sepsis detection, multiplex sepsis panels, phenotypic antimicrobial susceptibility testing, microfluidic paper-based analytical devices** 4. Antibiotics: ***ampicillin (injectable), gentamicin (injectable), intravenous aqueous crystalline penicillin G or procaine benzylpenicillin, azithromycin and erythromycin (injectable/oral), cefotaxime, amikacin (injectable), cloxacillin (injectable), cefiderocol, and novel antibiotic combinations***
	Level 2: Jaundice management	5. **LED phototherapy units**
Prematurity	Level 2: Prevention of apnea	6. **Caffeine citrate**
	Level 2: Pre-term respiratory distress prevention	7. **Antenatal corticosteroids**
	Level 2: Safe administration of oxygen	8. **Bubble CPAP kit with O2 blenders**
	Level 3: Surfactant treatment	9. Surfactant: **liquid surfactant-animal-derived (current generation), liquid surfactant -synthetic (current generation),** and **dry powder surfactant and/or aerosolized versions (under development)**

Key

Global Standard Evidence-based interventions endorsed by global guidelines and routinely integrated into health systems.

Global Standard | Significant Access Gaps Evidence-based interventions endorsed by global guidelines but inconsistently available or used in practice due to health system barriers.

Emerging Innovation Promising new products, technologies or delivery approaches that require additional evidence, approval or health system readiness before broad adoption.

3.2 Analytical framework

The analysis was conducted in two stages. First, each priority intervention was assessed through a product access lens to identify the principal barriers limiting availability, adoption and scale in LMICs. Second, the underlying market structure was examined to understand the factors shaping long-term supply, affordability, innovation and sustainability. The product access analysis considers barriers across five dimensions:

- **Innovation and availability,** including product maturity, regulatory status and availability within LMIC markets.
- **Quality,** including quality assurance mechanisms, regulatory oversight, and risks associated with substandard or poor-quality products.
- **Affordability,** including product pricing, procurement costs, reimbursement challenges and financing constraints.
- **Supply and delivery,** including manufacturing capacity, procurement systems, supply chains, consumables, maintenance requirements, infrastructure needs and workforce readiness.
- **Demand and adoption,** including provider awareness, clinical confidence, guideline uptake and factors influencing routine use.

Following the access analysis, each intervention was assessed from a market systems perspective. This included examination of manufacturing landscapes, supplier concentration, market incentives, procurement dynamics, opportunities for local production and potential market-shaping interventions that could improve access, stimulate innovation or strengthen market sustainability. Together, these analyses provide a structured understanding of both the immediate barriers limiting product access and the broader market dynamics that influence long-term scale and impact.

3.3 Access barriers and market structure for priority interventions

The following sections apply the analytical framework described above to each priority intervention. For each product, the analysis examines key barriers across the product access pathway – including innovation and availability, quality, affordability, supply and delivery, and demand and adoption – before considering the broader market structure, including manufacturing landscapes, supplier dynamics and opportunities for market shaping. While the specific barriers vary across products, common themes emerge around financing, procurement, maintenance, consumables, workforce capacity and service readiness. These findings are synthesized later in this section to identify recurring product archetypes and cross-cutting barriers that can inform strategic action.

1. Pulse oximeter

Access insight: Although access has improved post Covid-19, it remains constrained even in secondary settings driven by fragmented procurement and supply chain challenges for consumables, especially probes. It should be noted that these considerations are for Level 2 facilities; a discussion on pulse oximeters at primary facilities is covered in Section 6.3.

Barriers	Analysis
Innovation and availability	• Commonly used in LMICs; Available in 54% of general hospitals and 83% of tertiary hospitals in LMICs;[189] availability improved post Covid-19; availability of neonatal probes can be a challenge. (expert input, 2026) • LMIC-relevant innovations: Multimodal pulse oximetry devices with expanded clinical measurement capability, smartphone-operated and subscription-based offering;[190] low-cost rugged designs from Lifebox and others.[191] With multi-modal devices, temperature, haemoglobin and respiratory rate may be measured among other parameters in addition to SPO2 in one device; several firms are innovating in this area although higher price can be an issue in a cost-driven market. (Further considerations in Section 6.3 on this topic)
Quality	• Fragmented quality and regulatory landscape – manufacturers can align themselves with WHO–UNICEF technical specifications, FDA/CE approvals or national approvals although LMICs have limited regulation of medical devices; 3 devices are NEST360 qualified in the pulse oximeter category.[192] • Devices often not tested with neonates with darker skin tones.[193] • Challenges with neonatal-sized probe durability. Open Oximetry, funded by Unitaid and others, points out to low presence of low-quality devices with insufficient testing and misleading claims.[32] They also note that common conditions in LMICs, such as anemia, cause inaccurate readings in many devices.

Barriers	Analysis
Affordability	• Affordability has improved significantly, ranges from ~$25–$400 in UNICEF's supplies catalog. • Probe, especially neonatal probe, replacement costs are a significant constraint.[194]
Supply and delivery	• Government procurement in LMICs is mostly fragmented (e.g. India, Kenya) with larger quantities procured at the sub-national level coupled with smaller quantities. Government procurement often focuses on price which leads to sub-optimal devices being procured; donor procurement sets price benchmarks in LMICs.[195] • Lack of a supply chain for replacement of devices or spare-parts (probes, batteries or chargers), intensified by the absence of standardization of consumables.[196] • Budgeting practices by the government might not consider operational expenditure and base estimates on initial capital investment.[197] • There appear to be a sufficient number of distributors: about 10–15 distributors in Kenya and Malawi.[198]
Demand and adoption	• Included in the WHO Interagency List of priority medical devices (2016).[199] • Underused in LMICs especially at lower levels; uptake constrained due to lack of reliable oxygen supply and trained staff;[200] there are also many cases of oxygen provision without pulse oximetry; still need for provider training for driving use. (expert input, 2026)

Market analysis insight: The market is functioning well with a significant number of players competing. However, there is limited manufacturing in Africa.

Topic	Analysis
Manufacturing	• Fragmented with distinct players at high and low ends: Medtronic, Masimo, Philips, Nihon serve higher end; cost-focused brands include Mindray, Contec and Lifebox Foundation;[201] includes high income and Asian vendors; no major African vendors.
Market shaping	• Market is healthy, but with varying quality: Large number of players, price competition at the lower end.[201] • Coordinated ordering or harmonized procurement through centralization of quality assured purchases can help further; African manufacturing can be encouraged: Local manufacturing (assembly, then full manufacturing) in Africa may be incentivized.[202]

2. Bag, valve and mask

Access insight: BVM devices are a well-established, low-cost technology with some gaps in proper reuse of reusable equipment. The primary constraint is adequate training and clinical competency in correct technique, with rapid skill decay documented after initial training.

Barriers	Analysis
Innovation and availability	• Well-established, globally standard technology; self-inflating BVM is the most commonly used ventilation device worldwide.[22] Some availability gaps at lower-level facilities, but this is not the critical gap.[142,203,204] • Innovations include the AIR, an electronic add-on providing real-time feedback on ventilation technique and NeoBreathe, a foot-operated resuscitator with integrated suction freeing one hand during use.[22]
Quality	• Reprocessing and sterilization of reusable devices is the primary quality challenge: single-use devices are often retained for reuse in LMICs, and steam-based high-level disinfection can damage equipment; chemical disinfection protocols show inconsistent staff compliance.[40] Design barriers to effective cleaning include mask contours, valve crevices and non-rebreathing valve geometry.[203] • International standards require ISO 13485 quality management systems and minimum USFDA 510(k) or CE marking.[203]
Affordability	• Low unit cost (USD 5–30) makes device procurement a relatively minor barrier.[41,42]
Supply and delivery	• Largely procured by LMIC governments. • UNICEF also acquires and distributes pre-packed kits (Obstetric Surgical Kit, Midwifery Kit, Newborn Kits); UNFPA also holds long-term agreements with manufacturers for quality-assured commodities. Wholesalers (action medeor, IDA Foundation, Imres Medical Solutions, Medical Export Group) also provide procurement channels.[205]
Demand and adoption	• Training is the primary barrier: rapid skill decay is consistently documented – resuscitation skills deteriorate as early as 1 month after HBB training; daily bag-and-mask skill checks and self-evaluation checklists show the highest association with skill retention (PMC-skills).[206] • HBB has been implemented in 80+ countries, equipping hundreds of thousands of providers, and reducing intrapartum stillbirths by 34% and first-day mortality by 30% (PMC-HBB).[206]

Market analysis insight: Healthy product market with multiple global and LMIC manufacturers; previous efforts drove significant price reductions

Topic	Analysis
Manufacturing	• Multiple global and LMIC manufacturers: principal HIC-based players include Laerdal Global Health (Norway –not-for-profit models since 2010), Ambu (Denmark), VBM Medizintechnik (Germany), and Fisher & Paykel Healthcare (New Zealand). Key LMIC manufacturers: GPC Medical Limited (India), Besmed (Taiwan), Phoenix (India).[203] • Some providers such as Laerdal differentiate by providing training.[207] • Training manikin manufacturers include Laerdal, 3B Scientific, Ambu and Gaumard Scientific.[203]
Market shaping	• Moderately healthy product market. • Market shaping efforts around 2016: CHAI pricing agreements for 75 countries achieved 30–61% price reductions in 2016;[142] pricing challenges appear to have been addressed since affordability does not come up as a problem.

3. Next generation sepsis diagnostics

Access insight: The binding constraint is lack of LMIC-appropriate products in this category.

Barriers	Analysis
Innovation and availability	• Portfolio of available products currently not LMIC appropriate: Only culture available partially but high turnaround time for culture; CRP/PCT require repeat measurements and are still expensive; only IL6 test currently available is expensive as it requires a device (See details in Section 2). • This has led to WHO releasing a TPP for rapid tests for neonatal sepsis.[99] • Most promising approaches are looking to identify host-based biomarkers for sepsis confirmation at point of care (e.g. SAA – more details in Section 2. (expert input, 2026))
Quality	• Culture (the only relevant test that is partially available in LMICs): understaffed labs lead to quality concerns. • Several reagents and cartridges, e.g., for CRP and PCT, require refrigeration.[146]
Affordability	• Major challenge: Specific, quick tests are expensive and are largely absent from LMICs.
Supply and delivery	• Among available tests, procurement of microbiology/culture related supplies remains fragmented.
Demand and adoption	• Limited use of diagnostics and higher reliance on clinical decisions due to product and pricing gaps.

Market analysis insight: The market is geared to serving high-income countries and does not work well for LMICs. Opportunities to explore price reductions for PoC CRP/PCT while improved tests emerge.

Topic	Analysis
Manufacturing	• Several global vendors for Molecular/Culture include Abbott, Roche, bioMérieux, Thermo Fisher, Cube Dx; emerging market vendors include SD Biosensor, Mindray, Quidel.[208] • For CRP/PCT, multiple LMIC-based vendors exist. (expert input, 2026)
Market shaping	• Markets not serving LMICs well at the moment; focused on high income markets. • Innovation: Major need to drive innovation of novel diagnostics (new biomarkers or tests with multiple biomarkers, LMIC-appropriate AI/ML tools, etc.) via grant support for validation studies and market shaping tools such as volume guarantees. • Existing diagnostics: Opportunities to explore price reductions for PoC CRP/PCT.

4. Injectable antibiotics for sepsis

Access insight: First-line treatments are generally available (note: this analysis refers to level 2 facilities) and affordable. However, resistance is rising, requiring the use of existing and development of new regimens.

Barriers	Analysis
Innovation and availability	• First-line products widely available, but resistance rising: Injectable ampicillin, gentamicin generally available[209] in level 2 facilities; occasional stock-outs can occur due to supply chain disruptions.[210] • Emerging resistance is increasingly documented in LMIC settings with resistance rates; in a recent study, only 25% of cases responded to first-line treatment.[211] • Second-line products: Products like Amikacin and Cloxacillin are also generally available in secondary facilities. • Given increasing resistance, development of new combinations (e.g. Flomoxef and fosfomycin/amikacin; Fosfomycin and amikacin) and new antibiotics (e.g. Cefiderocol) underway, driven by public health motivated funders.

Barriers	Analysis
Quality	• Drug quality: Several prequalified products exist, but LMICs continue to purchase non-PQ products, some with quality concerns; a review found that 13% of injectable antibiotic samples failed quality tests overall.[212] Ampicillin is temperature sensitive and can degrade if not stored properly;[213] further gentamicin and second-line drugs need to be stored under controlled room temperature. • During administration: IV administration technically challenging in small and preterm neonates and needs trained nursing staff for catheter insertion and maintenance.[191] Therapeutic drug monitoring to guide dosing in preterm infants is rarely available in LMIC settings.[27,187] Lack of AMR testing leads to sub-optimal treatments; some providers tailor treatment based on local knowledge, but need for local resistance studies. (expert input, 2026) • Adult-dose packages are commonly used in hospitals, requiring providers to calculate and provide appropriate dosage which is an error prone process; pediatric doses with limited availability.
Affordability	• First-line and commonly used second-line drugs widely produced and are generally affordable.[214] For instance, injectable gentamicin listed at $6.65 for 50 2 ml ampules at 10 mg / ml strength on UNICEF supplies division portal.
Supply and delivery	• Fragmented procurement by sub-national governments and even hospitals based on lowest price.[215] • Due to low margins, suppliers often exit category leading to supply disruptions in LMICs.[216]
Demand and adoption	• Included in national essential medicines lists across sub-Saharan Africa and South Asia. • General provider awareness exists; however, use of appropriate antibiotics is a challenge.[217]

Market analysis insight: This is a price-sensitive market with limited incentives for quality. There is a need for new innovation to counter resistance.

Topic	Analysis
Manufacturing	• Diverse set of generic manufacturers exist but higher reliance on India and China for APIs. Limited number of players in Africa with sterile injectable capability.
Market shaping	• Focus on lowest price procurements discourages high-quality manufacturers and leads to frequent disruptions due to market exits of players; need to encourage quality production.[220] • Need to support local manufacturing of quality-assured antibiotics in Africa; antibiotics have been identified by African Union as a priority product class for local manufacturing.[221] • Need to support R&D efforts for discovery of novel products and combinations as commercial incentives are poor.

5. LED phototherapy

Access insight: Although LED photometers are generally available, treatment quality is uneven due to ancillary device and consumable needs and operational issues around non-functional equipment in LMICs.

Barriers	Analysis
Innovation and availability	• Available in almost all LMICs (LMIC-adapted products exist on the market), but uptime is a challenge. • Innovation: Locally built phototherapy devices and light meters are currently in development, which when implemented can bring down the cost to a fourth (expert input, 2026). Sunlight-based phototherapy devices are also under development. (expert input, 2026)
Quality	• No WHO PQ, but UNICEF purchases products from a number of producers. • Operational hurdles, particularly equipment maintenance backlogs and irregular monitoring of infants, compromise the quality of treatment.[85,222] • For proper use, it is important to use irradiance/light meters.[223] These can be expensive and may not always be used.[224]
Affordability	• Affordability is a major challenge which leads to rationing use: Typical prices for mid-range LED phototherapy devices vary mostly between $300–$1000.[225] In combination with an irradiance meter, the costs are between $900–$2200 (based on prices in Kenya, Tanzania and Nigeria), reducing feasibility of procurement in LMICs.[224,226] Moreover, several ancillary items e.g. bilirubin diagnostics, light meters need to be procured.[85]

Barriers	Analysis
Supply and delivery	• Holistic procurement by LMICs can be a challenge: Phototherapy requires multi-component supply chain and not just device, as noted above. • LMIC governments are major buyers, but UNICEF also includes it in their supply catalog.[214]
Demand and adoption	• Recommended at level-2 by the WHO interagency list of priority devices (2016)[199] usually covered in LMIC government device procurement budgets.[227] • Underutilization of guidelines on neonatal jaundice and phototherapy owing to training gaps.[85] Challenges in diagnosing neonatal jaundice mask real demand.[85]

Market analysis insight: There is a well-functioning market for equipment. However, there is room for improvement in supply chain efficiency and equipment uptime.

Topic	Analysis
Manufacturing	• Moderately concentrated but functional supplier base: Mix of global OEMs (e.g., GE Healthcare – USA, Philips – Netherlands) and LMIC-focused manufacturers which dominate the market (e.g., Phoenix Brilliance Pro – India, Nice Neotech – India, MTTS Colibri and Firefly – Vietnam, Fanem – Brazil), with MTTS and Phoenix products being NEST360 qualified.[22] Some locally built phototherapy devices also used. • Lower-cost phototherapy devices from Asian companies, some have limited footprint in Africa.[22]
Market shaping	• Barring UNICEF and IDA Foundation, procurement is fragmented – opportunity for pooled procurement. • Potential to improve equipment uptime and strengthening the supply chain.

6. Caffeine citrate

Access insight: Affordability and provider awareness challenges lead to lower uptake, but are being addressed by recent market shaping efforts.

Barriers	Analysis
Innovation and availability	• Appropriate product, not many products registered historically in many LMICs, but this is changing.[155] • Limited guidance on appropriate dosing strengths and vial sizes that causes confusion in some countries and leads to higher prices.[155] Experts point to multiple formulations in Africa: including 10mg/1mL IV/oral, 50mg/5mL oral only product, 60 mg/3mL IV/oral product, 20mg/1mL IV/oral and 50mg/2mL. (expert input, 2026)
Quality	• Few quality assured suppliers[228] (but not the rate limiting step at this point; three products are WHO prequalified as of September 2026. (expert input, 2026))
Affordability	• Affordability is a major challenge compared to alternatives (other methylxanthines) in many SSA countries; Limited number of quality-assured products and fragmented, low demand translate into high prices for a relatively simple compound.[155] • Preventing and treating AoP requires a loading dose followed by daily maintenance dosing that, depending on the infant's gestational age at birth, can continue for several weeks and in the most extremely preterm infants, up to and beyond their original term-corrected age. This means the smallest, most vulnerable babies require the largest cumulative volume of caffeine citrate, compounding the affordability challenge even at the reduced price.[1](expert input, 2026) • Pricing levels vary from $2.7 per vial in India to >$22 in Kenya, Nigeria and South Africa;[155] packaging/sizing choices also influence prices. Ongoing efforts by CHAI via better forecasting, provider support including for registration and catalytic procurement support have started to address this barrier; vial sizes can also influence affordability. (expert input, 2026)
Supply and delivery	• Small and fragmented orders and limited procurement from countries; generally not included in national tenders.[155] • Complex distribution channels.[155]
Demand and adoption	• Included in WHO essential medicines and WHO Recommendations for care of Preterm or LBW infants; also included in many LMIC EMLs (some were included recently).[155] • Provider awareness challenge; they default to other less effective products in the same class. • Detection of apnea a challenge without respiratory monitors in LMIC settings.[155]

Market analysis insight: There is an opportunity to reduce market friction and strengthen quality assured vendors; initial efforts are already underway.

Topic	Analysis
Manufacturing	• Diverse: Key manufacturers in high-income countries (e.g., European: Chiesi Farmaceutici, Ethypharm, Fresenius Kabi, Hikma, Gennisium) but also India-based players (Sun Pharma, Aurobindo, Microlabs). Both large and mid-sized companies are present.
Market shaping	• Market health needs improvement in LMICs: LMIC market largely characterized by small, fragmented orders; national tenders very low. This is currently starting to be addressed by CHAI in some countries (via better forecasting, support to governments, helping improve provider knowledge; Beginnings Fund provided support for catalytic procurement via support to CHAI;[50] (expert input, 2026) over 600k ampules were procured by CHAI supported countries in 2025. • Three WHO PQ products (one from Chiesi and two from Ethypharm), but several firms such as Gennisium and Aurobindo also have Stringent Regulatory Authority (e.g. FDA approval). • Local production may be explored (noting that neonatal products are niche + Caffeine Citrate requires sterile capabilities with good manufacturing practice (GMP) for injectable) (expert input, 2026); one African manufacturer is undergoing NRA review. (expert input, 2026)

7. Antenatal corticosteroids

Access insight: Although antenatal corticosteroids are affordable and widely available, uptake is constrained by low provider knowledge and ability (to measure gestational age and assess risk of imminent birth) to assess which women should receive the drug. Risk of harm due to overuse / inappropriate use also stifles adoption. AI-based tools for estimating gestational age, especially using Point of Care Ultrasound (POCUS), and assessing risk of imminent birth will fill a major gap.

Barriers	Analysis
Innovation and availability	• Appropriate product available;[230] Dexamethasone available as generic injectables in LMICs.[144,231] • Innovation: Although a mature product, WHO studies being conducted to understand possibilities for expanded use (>34 weeks), lower dosing and optimal regimen among others. (expert input, 2026) • Innovation: Efforts around AI-powered POCUS (expert input, 2026), to estimate gestational age and prediction of likelihood of imminent birth underway.

Barriers	Analysis
Quality	• Limited studies, but quality could be a problem: A 2013 multi-country study showed that 32% of Dexamethasone samples had lower than required API. (232) No WHO PQ for this indication. • Dexamethasone to be stored at room temperature (<25°C).[233]
Affordability	• Affordable: ACS are widely available as generic injectables in LMICs at very low cost (a full course costs under USD 1 in generic form).[144,231]
Supply and delivery	• Procurement from regular maternal, newborn and child health (MNCH) budgets in LMICs, limited in volume and numbers.[234]
Demand and adoption	• Included in the WHO essential medicines list.[235] • Provider knowledge and ability is the significant barrier: Under-use and over-use of ACS noted in multiple studies due to low provider knowledge and absence of tools. Safe use of steroids is a broader challenge.[236] • Since inappropriate use can cause harm, WHO recommends ACS use under several conditions which may be difficult to meet in LMIC settings: accurate gestational age assessment (major challenge in LMICs due to limited ultrasound infrastructure and/or limited provider skills[144]), risk of premature birth within 7 days, absence of maternal infection and presence of adequate newborn care. Inadequate number of ANC touch points also a challenge.

Market analysis insight: There is a healthy market; challenges are not driven by market conditions as noted above.

Topic	Analysis
Manufacturing	• Diverse manufacturing dominated by Indian generic multinationals: Dr. Reddy's Laboratories, Sun Pharma, Cipla, Aurobindo from India dominate. China and India dominate APIs.
Market shaping	• Healthy market but considerable dependence on Indian providers: Low margins and pricing disincentivize entry of local players. Markets in individual African LMICs are also relatively small due to muted demand. • Limited room for market shaping, but local manufacturing incentives may be provided as demand challenges get fixed.

8. Bubble CPAP with O2 blenders

Access insight: There are major challenges around quality of treatment due to downtime and inconsistent availability of consumables/patient interfaces like nasal prongs, masks, interface connector, filter disks and circuits.

Barriers	Analysis
Innovation and availability	• Improving availability in LMICs but gaps remain: equipment functionality, consumables availability, and training for correct setup and patient positioning were variable;[237] having the full system including oxygen source and device working at the same time is critical (expert input, 2026); Proliferation of devices, via donations, with proprietary consumables, makes adequate uptime a major challenge. (expert input, 2026) • Innovations include: Devices with no assembly at point-of-care; ultra-low-cost methods; fully non-electric, non-compressed air.[238]
Quality	• Quality of devices: Improvised devices with unregulated pressures and 100% oxygen can cause harm (expert input, 2026); NEST360 qualification an important driver of quality.[22] • Quality of treatment: Understaffing can limit monitoring of neonates undergoing bubble CPAP treatment;[239] Lack of regular training;[237] substantial reuse of equipment and consumables in LMICs, even when material is indicated as single-use; without proper disinfection, this can drive infections. (expert input, 2026)
Affordability	• Low-cost versions start at ~$400 (e.g. Vayu) (240); medium and high cost bundled versions vary between ~$1,000–6,000.[239] • Costs of maintenance, wrap-around support, training, consumables and health worker time affect affordability in LMICs.[239]
Supply and delivery	• Procurement by LMIC governments; selecting the appropriate combination of equipment and sources is highly context dependent, and most procurers may not be savvy enough. (expert input, 2026) • Distribution challenges have been noted.[241] • Supply chain gaps lead to shortage of consumables and spares.[238]
Demand and adoption	• Generally, demand is now well-understood at national levels; however, inadequate budgeting for consumables and spares. (expert input, 2026) • Building provider confidence in CPAP requires substantial effort (expert input, 2026); without this, equipment may lie unused.

Market analysis insight: Distribution and last-mile service models are key challenges.

Topic	Analysis
Manufacturing	• Solid mix of vendors from LMICs and HICs: Key vendors include Vayu Innovations (US with manufacturing in Kenya); Hadleigh/Pumani (USA); Polite (United Kingdom); MTTS Dolphin (Vietnam);[237] Diamedica (UK); InnAccel/Saans (India).
Market shaping	• Moderately healthy market: Limited number of vendors, but many public-health-minded, keeping prices down; smaller market size, low profit margins and high requirements for maintenance support discourage distributors. • Partnership among manufacturers and distributors can help scaling;[239] organizations such as Axmed and Hatch help bring quality assured devices to facilities. (expert input, 2026) • Opportunities to explore models where service uptime is incentivized (e.g. leasing, integrated contracts for equipment, consumables and maintenance – see Section 3.4 for details).

9. Surfactants

Access insight: There are no LMIC-appropriate product/delivery methods available that would allow delivery at Level 2.

Barriers	Analysis
Innovation and availability	• Lack of LMIC-appropriate product or delivery method at L2 level; For L3: product available in some places. • Two possible types of innovations being considered: a) easier-to-use product, e.g., aerosolized delivery (WHO TPP exists, but this is >5 years away); b) LMA-based administration with existing product using the SALSA technique (shorter term). (expert input, 2026)
Quality	• Likely to be less of an issue as market is served by FDA approved suppliers; however, improper storage could lead to challenges.[228] • Requires cold-storage 2–8°C.
Affordability	• Unaffordable in most LMIC settings: Very high prices (>$300 per vial) for LMIC settings vs. LMIC target pricing of $50 *(22)* Vial size also limits affordability. (expert input, 2026) Public procurement prices are somewhat lower, ranging from $140 to $260/vial in Zambia and Uganda respectively. (expert input, 2026)
Supply and delivery	• Limited national procurement. (expert input, 2026)

Barriers	Analysis
Demand and adoption	• WHO inclusion for EML, but not in the Essential Neonatal Commodities List (2024) since it likely focuses till L2. Addition to country EML is necessary but insufficient: Uganda has had surfactant on its national EML since 2023 but is still only meeting an estimated ~4% of need. (expert input, 2026) • Demand comes from a limited number of tertiary facilities. The current requirement for intubation or catheter-based access before administration is a significant constraint at district level.[155] • Skills for laryngoscopy (for simpler SALSA administration) are limited in LMICs. Correct LMA placement and surfactant instillation technique is not yet widely integrated into LMIC neonatal training curricula.[22]

Market analysis insight: Innovation support is needed from public-health focused organizations for bringing next-generation products to the market and for making administration of current product more feasible in LMICs.

Topic	Analysis
Manufacturing	• Limited number of manufacturers, large companies: Most manufacturers in high-income countries as product is complex to make – AbbVie Inc. (USA); BAG Health Care (Germany); Chiesi (Italy); Infasurf Calfactant – ONY Inc. (USA); BLES Biochemicals Inc. (Canada); exception seems to be Tekzima Company (Iran).[242]
Market shaping	• Limited competition: LMIC market relatively small since product available at tertiary level only. Limited number of vendors in market, focusing on HIC, leading to high prices (expert input, 2026); further, even leading LMIC-focused players are not registered in several SSA LMICs which provides an opportunity to increase vendors and thereby competition. • Some market shaping opportunities by supporting innovation: Demand could be stimulated by supporting commercialization of aerosolized delivery of surfactants and bringing them to Level 2. Further, other simpler administrations such as SALSA could be tested in LMICs. Opportunity for reducing prices even for currently available surfactants through demand consolidation. (expert input, 2026)

3.4 Product archetypes

While the priority products address different clinical conditions and operate within different market environments, several recurring patterns emerge. Based on the analysis above, four product archetypes can be identified according to the principal barrier limiting access and scale. Although most products face multiple constraints, the archetypes highlight the primary bottleneck that must be addressed to unlock greater impact. Note that while the products are grouped by similarity of primary constraints, secondary product-specific constraints and recommendations to overcome these are noted in previous sections and Section 6 respectively. For instance, while Bubble CPAP is classified into the first archetype "Strengthen operational models for improved uptime", we also note the need for building provider confidence later in the document. Similarly, surfactants are also constrained by price; however, the primary challenge today is that current product cannot be used in Level 2 settings in LMICs.

Note: While we consider barriers for individual priority products below, we must emphasize that a meaningful portfolio of products along with appropriate service delivery is needed to drive reductions in mortality and morbidity. For preterm respiratory care, for instance, it makes sense to consider a bundle of interventions: antenatal corticosteroids, thermal care, bubble CPAP, continuous oxygen, pulse oximeter, surfactant and caffeine citrate, rather than as standalone interventions. The product lens taken at this stage helps uncover several barriers that are unique to that product.

Product archetype	Products	Key barrier
Strengthen operational models for improved uptime	Pulse oximeters	Constrained by fragmented procurement, maintenance and supply chain challenges for consumables, especially probes.
	LED phototherapy	Treatment quality uneven due to ancillary equipment needs and operational issues around functioning equipment in LMIC conditions.
	Bubble CPAP	Keeping equipment running along with availability of consumables like nasal prongs and other patient interfaces; distribution and last-mile service models are also challenging.
Find LMIC-appropriate product or administration	Sepsis diagnostics	Major product gap for LMICs that deters appropriate treatment and AMR stewardship.
	Injectable antibiotics for sepsis	Increasing resistance rising requiring new regimens. In addition, provider skills to drive proper use of existing second-line drugs a gap.
	Surfactants	Lack of LMIC contextualized product/delivery method.

Product archetype	Products	Key barrier
Overcome health systems barriers	Antenatal corticosteroids	Low provider knowledge to select women for treatment, treatment requires appropriate infrastructure; Low provider ability (to measure gestational age (GA)) in LMIC settings.
	Bag-valve-and-mask	Adequate training and clinical competency in correct technique a challenge, with rapid skill decay documented after initial training.
Make product affordable	Caffeine citrate	Affordability challenges due to market imperfections. Provider awareness challenges lead to lower uptake.

3.4.1 Strengthen operational models for improved uptime

In this category, the availability of the device is not the challenge. Keeping the devices running is usually the challenge due to device malfunction or non-availability of consumables or ancillary equipment. From our analysis above, these include LED phototherapy, pulse oximeter and bubble CPAP. There are multiple approaches that could be explored to overcome these:

- **Equipment standardization, service contracts and maintenance budgets:** Equipment management encompasses the policies and systems that ensure neonatal devices remain functional over their operational lifetime: standardization of device models within a facility or health system (reducing spare parts complexity), allocation of dedicated maintenance budgets (recommended at approximately 7% of capital cost per year), service agreements with manufacturers or biomedical engineering firms, and warranties for new procurements. These systemic measures are essential for converting equipment procurement into sustained clinical functionality.[243]
- **Equipment monitoring systems/predictive maintenance:** Equipment monitoring systems track the operational status, usage and maintenance needs of clinical devices in real time typically via digital logs, barcoding or connected sensors. They enable facility managers to identify non-functional equipment proactively, schedule preventive maintenance and generate procurement requests before critical shortages occur. Digital equipment registries and WhatsApp-based reporting systems have been piloted as low-cost monitoring approaches in LMIC settings.[243]
- **Service contracts:** Rather than purchasing equipment and maintaining infrastructure to provide a service, the onus of providing the product/service can be put on a third-party vendor. The vendor is contracted to provide the product (e.g. oxygen) and is therefore incentivized to keep the equipment running, and consumables in stock.

Box 3.1 describes innovations in the oxygen ecosystem. These could serve as inspiration for provision of services/products with guaranteed uptime.

Box 3.1: Innovations from the oxygen ecosystem

Biomedical engineering support models are increasingly emerging to address the operational limitations of traditional donation-based oxygen programs, which have often focused on equipment procurement without adequate long-term maintenance, infrastructure or service support. Innovation within the oxygen ecosystem is evolving across three interconnected areas:

- Business model innovations: These include Oxygen-as-a-Service approaches that shift financing away from one-time equipment purchases towards bundled oxygen ecosystem support covering maintenance, consumables and infrastructure.
- Technical innovations: These include portable oxygen concentrators, low-cost oxygen analyzers and flow splitters, and PSA oxygen generation systems designed for low-resource settings.
- Implementation and planning innovations: These include CHAI oxygen programs, UNICEF's Oxygen System Planning Tool and implementation partnerships led by organizations including Assist International and NEST360 in Kenya.

Despite this progress, major challenges remain, including fragmented procurement, weak maintenance systems, limited biomedical engineering capacity, unreliable electricity and fragile oxygen supply chains.

3.4.2 Find LMIC-appropriate product or administration

This category covers areas where there is an LMIC product market misfit. Products available on the market may be inherently ill-suited for the realities of LMICs. Novel products (or formulations or administration) may be needed for LMICs in such cases. For instance, as discussed above, current liquid surfactants typically require intubation, which is a challenge in most LMIC Level 2 settings. For this product to reach more neonates, aerosolized delivery will likely be needed. Alternatively, easier forms of administration of existing liquid product using the SALSA technique (surfactant administration through laryngeal or supraglottic airways) may be leveraged but will require extensive training in the novel form of administration. The challenges with sepsis diagnostics were discussed previously; for the right decisions to be made, the right type of diagnostic is needed that works in LMIC settings. Such a diagnostic does not yet exist, and innovation is needed in this area. Finally, given rising antibiotic resistance among neonates, novel antibiotics will be needed to treat sepsis. In other cases, the innovations needed may be smaller but can nonetheless be powerful: pediatric dose packaging of existing medicines can drive uptake of treatment by improving affordability and improving quality of treatment. See Section 6.3 for further details on pediatric dose packs for Caffeine Citrate and injectable antibiotics.

3.4.3 Overcome health systems barriers

These cover products where health system barriers will need to be overcome. For antenatal corticosteroids, WHO recommendation for use is conditional on the presence of appropriate infrastructure for neonate and mother. Given these can be deficient in LMICs, providers may not (rightfully) use this powerful intervention. Moreover, the ability of a provider to estimate gestational age and the likelihood of imminent delivery is limited; this would require provider skill-building as well as development of LMIC-appropriate tools. In case of bag-valve-mask, having skilled providers ready to handle resuscitation properly is a powerful lever. Note that even while overcoming health system barriers, innovation can play a role. AI-generated estimations of gestational age calculated from PoC ultrasound could, for instance, empower the provider to decide confidently whether to provide antenatal corticosteroids or not. Having real-time feedback (e.g. through the AIR device) on whether resuscitation/ventilation is being performed effectively can improve provider skills.

3.4.4 Make product affordable

In some cases, improperly functioning markets can lead to higher prices and therefore low uptake of recommended products. In the case of Caffeine Citrate, alternatives dominate despite poorer efficacy/safety profiles. This is because they are cheaper (and providers are more familiar with them). Affordability challenges can be overcome in several ways depending on context: increasing competition, pooling demand to increase volume and negotiate better prices, and supporting players to reduce cost of goods sold, and appropriate packaging are strategies among others. For Caffeine Citrate, a major provider education initiative is also needed as a secondary measure.

Box 3.2: Climate implications for priority products

Climate-related disruptions are likely to disproportionately affect several of the priority newborn products analyzed in this section because many depend on stable electricity, temperature-controlled storage, functioning oxygen systems and reliable maintenance capacity.

- **Surfactants and some sepsis diagnostic products are highly dependent on cold-chain integrity.** Surfactants, blood products, and certain sepsis diagnostic reagents and cartridges require temperature-controlled storage and transport. Heat exposure, transport disruption and power outages may compromise product quality, reduce diagnostic accuracy and increase wastage.
- **Respiratory care products are highly vulnerable to electricity instability.** Bubble CPAP, oxygen concentrators, pulse oximeters and phototherapy devices rely on continuous power and voltage stability. Frequent outages and surges can interrupt treatment, damage equipment and reduce device lifespan.
- **Oxygen ecosystems face climate-sensitive operational risks.** Extreme weather events, flooding and transport disruption can interrupt cylinder distribution, PSA plant operation, concentrator maintenance and oxygen supply chains, directly affecting neonatal respiratory care capacity.
- **Heat, humidity and dust may reduce functionality of neonatal devices.** CPAP systems, pulse oximeters, phototherapy units, incubators, infusion pumps and syringe pumps are vulnerable to sensor failure, overheating, battery degradation and calibration drift, particularly where equipment is not designed for harsh operating environments.
- **Climate pressures increase the importance of LMIC-appropriate product design and procurement.** Priority products increasingly require solar compatibility, battery backup, low-maintenance operation, resistance to heat and dust exposure, and stronger service and maintenance systems to ensure reliable use in climate-vulnerable settings.

4. Service delivery

How are services delivered?



Section summary

Reducing mortality among SSNs depends not only on access to effective medicines, devices and diagnostics, but on systems capable of delivering high-quality care reliably and at scale. The WHO–UNICEF Model of Care provides a framework for this: defining both the content of care SSNs need (the 'what') and the core components needed to deliver the care (the 'how'). Across LMICs, the challenge is translating these standards into functional district-level systems with the leadership, financing, workforce, infrastructure, products, data, referral systems, maternal–newborn linkages, family engagement and continuity of care needed to sustain quality SSNC.

Key takeaways

- **High-quality SSNC requires an integrated continuum of care.** Care for SSNs builds on quality maternal and essential newborn care and extends through specialized inpatient care, respectful and nurturing family-centered care, and post-discharge follow-up and referral when more advanced care is needed. For preterm and low birthweight newborns, KMC/iKMC and zero separation are increasingly central to how this continuum is organized around the mother–newborn dyad.
- **Scaling SSNC requires strengthening the system that delivers care, not individual interventions alone.** The WHO–UNICEF Model of Care identifies 10 interconnected components needed to translate standards into reliable district-level care. Progress in one component cannot fully compensate for gaps in others, reinforcing the need for coordinated health-system strengthening rather than isolated investments.
- **Persistent health-system constraints undermine both quality and sustainability.** Workforce shortages, overcrowding, unreliable infrastructure, product and supply gaps, weak maintenance systems and inadequate recurrent financing can prevent available interventions and technologies from translating into effective care. Country experience reinforces the importance of sustained government ownership, integration within national systems, and long-term investment in both establishing and maintaining SSN services.

Reducing mortality among SSNs depends not only on the availability of effective medicines, devices and diagnostics, but also on the systems through which these interventions are delivered. Newborn products do not operate in isolation: their impact is shaped by the strength of the surrounding ecosystem, the availability of skilled providers, the strength of referral and transport systems, the reliability of infrastructure and supply chains, and the extent to which care models support continuity of care and family-centered neurodevelopmental care. Across many LMICs, the principal challenge is therefore not simply identifying high-impact interventions but operationalizing them within functional service delivery platforms capable of delivering integrated, continuous and equitable SSNC at scale. This section explores the foundational models underpinning SSNC delivery, the evolving inpatient and networked delivery platforms through which care is organized, and the health system and financing constraints that determine whether newborn products and services reach the point of care and are reliably delivered, functional and appropriately used. This section uses the WHO-UNICEF Model of Care for SSNs as a framework for exploring how service delivery is organized and how its core components shape the effectiveness, scalability and sustainability of SSNC interventions.

Box 4.1: Care delivery principles for SSNC

Across the content and components of care, four interconnected principles shape how SSNC is increasingly organized and delivered:

- **Networks of care:** District-level specialized newborn care units function as hubs for Level 2 inpatient care within tiered networks linking community and primary care with referral hospitals. Effective networks support early identification, stabilization, referral and escalation, specialist oversight and mentorship, and post-discharge follow-up.[10,23,24]
- **Government-led, district-based scale-up:** Sustainable scale-up depends on government-owned newborn services embedded within district health systems rather than isolated facility or project investments. Country experiences demonstrate different pathways towards integrating specialized newborn care with maternal care, referral systems and broader health system structures.[17,24,244]
- **Integrated care packages:** SSNs often require multiple interventions delivered together. Increasingly, services organize these as coordinated packages spanning essential newborn care, resuscitation, thermal and feeding support, respiratory care, oxygen, jaundice and infection management, quality improvement and follow-up, with strong linkages to maternal care.[10,23,245]
- **Continuity of care:** Care extends across the continuum from antenatal risk identification and maternal care through childbirth, inpatient newborn care, referral, discharge and community-based follow-up. For preterm, low-birthweight and other high-risk newborns, structured follow-up is particularly important for feeding and growth, development, caregiver support and timely referral for additional care.[7,246]

Across all four principles, delivery approaches need to be adapted to context. Distance, mobility, climate-related disruption, conflict and displacement can alter how families access care and how referral, workforce, supply and follow-up systems function. This is particularly important in hard-to-reach, pastoralist, fragile and humanitarian settings.

4.1 Content of care

The WHO-UNICEF Model of Care for Small and/or Sick Newborns defines the "what" of care, encompassing both the provision and experience of care as reflected in the WHO quality of care framework. The content of care is organized across four interconnected areas: foundation of quality maternal and essential newborn care for all; special newborn care for SSNs; respectful, nurturing care; and providing appropriate follow-up care. Together, these elements define the clinical, developmental and supportive care that SSNs need across the continuum – from maternal and essential newborn care through specialized inpatient care, family-centered care and developmental care, and post-discharge follow-up.

4.1.1 Build on the foundation of quality maternal and essential newborn care for all

Care for SSNs builds on a strong foundation of quality maternal care and essential newborn care for all. This includes the fundamentals of high-quality periconceptional, antenatal and intrapartum care, as well as coordinated maternal interventions that are primarily directed towards fetal and newborn health, such as antenatal corticosteroids for threatened preterm birth and timely caesarean-section delivery for maternal or fetal indications. Essential newborn care remains equally foundational, including skin-to-skin contact to support thermal protection, bonding, and reduced stress and pain; early initiation of exclusive breastfeeding; delayed umbilical cord clamping; and resuscitation when needed. For SSNs, the way these essential interventions are delivered may need to be adapted according to the newborn's clinical condition and need for specialized care.

4.1.2 Special newborn care for SSNs

Special newborn care combines supportive care with the prevention, recognition and management of conditions associated with prematurity, intrapartum-related complications and infection. At Level 2, thermal, nutritional, and respiratory support and condition-specific management need to function as an integrated package of care rather than as isolated interventions or products. KMC, and increasingly immediate KMC (iKMC), provides a foundation for the care of preterm and low birthweight newborns, integrating thermal protection, breastmilk feeding, infection prevention, caregiver participation and nurturing care with necessary biomedical interventions. iKMC advances a model of zero separation, requiring specialized care to be organized so that mothers and newborns can remain together while necessary treatment is provided.[16,247] This is particularly important for newborns with respiratory distress. KMC/iKMC can be maintained alongside respiratory support, including CPAP and safe oxygen, supporting thermal and physiologic stability while treatment continues. This integrated approach has implications for both service delivery and product design, including ensuring that respiratory support, monitoring, and other technologies can be safely and effectively used in the KMC position. Feeding and nutrition are core components of this package. Care should include lactation support for mothers, safe expression, storage and feeding of the mother's own milk, early enteral feeding as clinically appropriate and, where the mother's own milk is unavailable, access to donor human milk. These services depend on staff trained in lactation support and on the space, equipment and supplies described in Section 4.2.4.

4.1.3 Respectful, nurturing care

High-quality SSNC encompasses both the provision and experience of care. Respectful, nurturing care places newborns and their families at the center of care, recognizing parents and caregivers as active participants rather than visitors. This includes minimizing unnecessary separation, supporting breastfeeding and responsive interaction, minimizing pain and stress, protecting sleep and creating an environment that supports healthy neurodevelopment. KMC anchors this approach for small newborns by keeping mothers and newborns together and supporting breastfeeding, caregiver participation and nurturing developmental care. More broadly, zero separation and family-centered developmental care enable parents and caregivers to remain close to the newborn and participate in care even when specialized treatment is required. Respectful and nurturing care also extends to family wellbeing, including effective communication, psychosocial support and maternal mental health, as well as preparation for care after discharge.

4.1.4 Follow-up care for SSNs

The needs of SSNs extend beyond discharge. Preterm, low birthweight and critically ill newborns remain at increased risk of mortality and growth, feeding, sensory, neurodevelopmental, behavioural and medical complications. Systematic follow-up is therefore an integral component of SSNC to monitor development, identify emerging concerns and support timely management. Follow-up also supports parents and caregivers in caring for their newborn and facilitates referral for additional or specialized care where needed and available. Continuity between facility, primary care and community services is important to support both the newborn and family through the transition from inpatient care to home and link identified needs to appropriate care.

4.2 Components of care

Delivering the content of care described above requires more than the availability of individual interventions or products. The WHO–UNICEF Model of Care for Small and/or Sick Newborns distinguishes between the content of care–the "what" of care–and 10 core components that define the "how" of implementation and scale-up at district level. These components include political commitment and leadership; sustainable financing; competent and motivated human resources; infrastructure and design; equipment and commodities; robust data systems; functional referral systems; maternal–newborn linkages; family and community involvement; and post-discharge follow-up systems. Together, these components provide the enabling architecture through which the content of care can be reliably delivered and scaled at district level. Throughout this section frameworks, approaches, tools and systems are included in tables to illustrate how selected components are being operationalized in real-world settings. The examples listed in tables are illustrative rather than exhaustive.

4.2.1 Vision, political commitment, leadership, national plan

Strong political commitment and leadership are foundational to moving SSNC from isolated projects to sustained, system-wide services. A clear national vision and plan provide the framework for translating commitments into defined priorities, policies, service packages, facility standards, workforce plans, financing arrangements and accountability mechanisms. Government stewardship is critical to coordinating these elements across the health system and sustaining implementation over time. EWENE reinforces this direction by prioritizing expanded access to quality care for SSNs, including functional Level 2 care for SSNs at district level, making care for those that are small and sick a health-system priority rather than solely a specialist or tertiary service.

Country experience illustrates how national leadership and government ownership can enable SSNC scale-up. India, Malawi, Rwanda, Ethiopia, Tanzania and Kenya demonstrate different pathways through which governments have incorporated inpatient newborn care into national or subnational policies, plans and health systems. India's special newborn care unit (SNCU) network remains one of the most extensive examples of government-led district-level expansion, demonstrating how national policy, public-sector investment and sustained government stewardship can support newborn care at scale.[17,24,244,248]

4.2.2 Financing: adequate and sustainable

Adequate and sustainable financing is essential to expanding and maintaining high-quality SSNC. Financing must extend beyond medicines, devices and diagnostics to the recurrent costs of delivering care, including workforce, infrastructure and utilities, consumables, maintenance, referral, data and quality improvement, and follow-up. Yet in many LMICs, financing remains insufficient or fragmented, with critical elements dependent on external or project-based funding. Sustainable scale-up therefore requires the full costs of SSNC to be incorporated into national and subnational planning and budgets, with recurrent costs increasingly financed through domestic health systems. Financing for SSNC draws on external and domestic resources, universal health coverage (UHC) and insurance mechanisms, and evidence to support investment and resource allocation. Key financing considerations include:

- **External financing:** Development assistance has played an important role in supporting maternal and newborn health programs, particularly in low-income countries with high neonatal mortality. However, neonatal care and stillbirth prevention have historically received a disproportionately small share of global health financing relative to disease burden. Recent reductions in bilateral and multilateral funding create substantial risks for continuity of SSNC programs, supply chains, workforce support and procurement systems in several high-burden countries. Dependence on short-term donor financing also contributes to fragmented implementation and challenges sustaining services after initial program support ends.[249,250]
- **Domestic financing:** Limited fiscal space, rising debt burdens and persistent under-prioritization of newborn care continue to restrict domestic investment in SSNC. In many LMICs, capital procurement for newborn units is not matched by sustained financing for consumables, biomedical servicing, equipment replacement, supervision or in-service training. As a result, facilities frequently experience declining functionality over time despite initial investments in devices and infrastructure. These financing gaps are particularly important for respiratory medications, support systems and other equipment-intensive aspects of inpatient newborn care that require continuous operational support rather than one-time procurement alone.[26,27]
- **National UHC frameworks and insurance schemes:** National health insurance systems and UHC benefit packages remain underutilized mechanisms for strengthening SSNC sustainability. Where inpatient newborn care is included within reimbursement systems, facilities may have stronger incentives to maintain staffing, essential commodities and operational readiness for neonatal services. However, coverage of inpatient newborn care remains inconsistent across many LMIC insurance schemes and reimbursement levels are often insufficient to support the true operational costs of high-quality SSNC. Expanding inclusion of newborn inpatient care and associated services, including referral, oxygen and respiratory support, and post-discharge follow-up, within national benefit packages is increasingly recognized as an important policy priority for reducing out-of-pocket costs and improving sustainability of care delivery systems.
- **Investment case and implementation gap:** Evidence from countries including Kenya and Tanzania demonstrates that investment in high-quality SSNC can generate substantial health gains and provide strong value for money. Cost-effectiveness analyzes consistently show that investments in high-quality inpatient newborn care and integrated SSNC delivery can generate substantial survival gains at relatively low cost compared with many other health interventions. However, translation of this evidence into sustained domestic financing has remained inconsistent. In many settings, the challenge is no longer demonstrating the value in investing in SSNC, but securing long-term domestic ownership and recurrent financing needed to sustain services at scale.[248]

Box 4.2: What investment in SSNC delivers: evidence from Kenya and Tanzania

Kenya – Joint NEST360/Ministry of Health investment case:[244]

- Most county-level specialized newborn care units fell below minimum staffing and equipment thresholds for reliable Level 2 care.
- Closing the gap projected to avert thousands of neonatal deaths annually.
- Cost per life saved compares favourably with other high-priority health investments in Kenya.
- Economic returns extend beyond survival: reduced long-term disability costs and improved human capital outcomes for survivors.

Tanzania and the NEST360 network – implementation costing data:[26]

- Recurrent costs, consumable restocking, staff salaries and training, equipment maintenance are systematically absent from facility and district budgets even where capital equipment has been procured.
- The binding constraint to sustained impact is not the initial investment decision but the absence of budget lines for ongoing operational costs.
- Addressing this requires not only increased domestic resource allocation but changes in how ministries of health plan and budget for newborn care infrastructure.

Translating these financing priorities into sustainable SSNC scale-up requires practical approaches to define resource needs, quantify costs and financing gaps, build the case for investment and ensure that recurrent costs are addressed. The tools and financing approaches below illustrate how countries and partners are supporting these functions. These SSNC-specific tools can also complement broader health-sector planning and costing platforms, such as the WHO OneHealth Tool, which enables newborn interventions and associated health-system requirements to be incorporated into national planning, costing and resource-allocation exercises.

Financing approaches and tools	How it works	Implementation experience in LMICs
GFF Small and Sick Newborn Planning & Costing Tool	Supports comprehensive planning and budgeting for district-level SSNC scale-up. Countries define service standards and estimate capital and recurrent requirements across infrastructure, equipment and commodities, workforce and other health-system inputs, enabling comparison of resource needs across facility types and scale-up scenarios.[226]	Applied in Zambia and Ghana to define country-specific requirements, identify resource gaps, estimate costs, and inform planning and budgeting for SSNC scale-up[251,252] and in Ethiopia to support development of the national implementation plan for SSNC.
UNICEF–NEST360 SSNC Equipment Planning and Costing Tool	Translates Level 2 service requirements into equipment and furniture needs and associated costs, including installation and training. Uses standardized specifications and activity-based costing to support procurement and investment planning.[253]	Developed from costing, procurement and implementation experience across Kenya, Malawi, Nigeria and Tanzania, and applied to support equipment planning and budgeting for Level 2 newborn care.
NEST360 investment case approach	Combines assessment of service-readiness gaps and investment requirements with estimates of health impact and economic benefits, helping governments and partners make the case for investment in high-quality SSNC.[254]	Applied in Tanzania and other NEST360 settings to quantify investment needs and demonstrate the health and economic case for sustained SSNC financing.
UNICEF oxygen as a service model	Oxygen-as-a-Service (OaaS) is an emerging financing and service-delivery model that shifts investment from purchasing equipment alone towards paying for reliable oxygen availability or equipment uptime. Facilities pay recurring service fees, while providers may manage installation, preventive maintenance, repairs, spare parts, monitoring and training. By bundling equipment with lifecycle support, OaaS aims to address a common limitation of traditional procurement models: equipment becoming non-functional when maintenance and biomedical engineering systems are weak or underfunded.[255]	Early implementation in African and South Asian settings suggests potential to improve equipment functionality and maintenance accountability compared with traditional procurement models. Scale-up remains limited and depends on sustainable financing, appropriate procurement arrangements and integration into health-system planning.

4.2.3 Human resources: availability and capacity

SSNC depends on an adequate, appropriately trained and supported health workforce. Workforce shortages affect newborn care across all levels of the health system, while Level 2 inpatient care requires providers with competencies to recognize and manage clinical deterioration, deliver and monitor advanced supportive care, stabilize critically ill newborns, and determine when escalation or referral is required. Advanced newborn expertise remains scarce and is often concentrated in urban tertiary facilities, while biomedical engineering capacity to support newborn equipment is also frequently limited.

Adequate staffing is as important as competency. Countries need staffing norms that define the number and mix of health workers required according to level of care, workload and newborn acuity, supported by policies for recruitment, equitable deployment and retention, appropriate remuneration and working conditions, and professional and career pathways. Formal recognition of neonatal nursing and other specialized newborn competencies can further strengthen workforce capacity and retention.

Workforce development must also extend beyond one-time training. Pre-service education and competency-based preparation for SSNC need to be reinforced through structured orientation, mentorship, supportive supervision, continuing professional development and repeated practice. Simulation and low-dose, high-frequency (LDHF) approaches can help maintain clinical skills, while digital decision-support, teleconsultation and remote mentoring can extend access to clinical guidance and specialist expertise. These approaches need to be embedded within national HRH and education systems rather than implemented primarily through stand-alone training programs.

Building and maintaining SSNC competencies: A range of global frameworks, curricula, training programs, simulation approaches and digital tools can help countries define, build and maintain the competencies required for SSNC. Country ownership and institutionalization are central, including integration of SSNC competencies into national curricula, orientation and in-service training, mentorship and supervision, competency assessment, continuing professional development, and where appropriate specialty education and certification.

HR approaches and tools	How it works	Implementation experience in LMICs
COINN neonatal nursing competencies and education	Provides international neonatal nursing competencies spanning clinical care, professional practice, leadership and teamwork, and infant- and family-centered developmental care. COINN-supported approaches include post-diploma education, orientation, preceptor development and clinical nurse educator models.	Particularly relevant where neonatal nursing is not formally recognized as a specialty or standardized preparation is limited. Supports neonatal nursing education, faculty and preceptor capacity, competency assessment, professional recognition and career development.

HR approaches and tools	How it works	Implementation experience in LMICs
Country-led newborn training and competency programs	Countries are institutionalizing newborn competencies through pre-service curricula, standardized in-service training, orientation, mentorship and supervision, simulation, competency assessment and continuing professional development, adapted to national standards, scopes of practice and workforce structures.	Kenya, Ethiopia, Rwanda, Malawi and India illustrate approaches including national newborn training packages, integration into nursing and midwifery education, training-of-trainers, mentorship and coaching, simulation and linkage with QI–demonstrating movement towards country-owned systems for developing and maintaining newborn competencies.
WHO competency-based training modules for SSNC – under development/ field testing	WHO is developing competency-based training modules for SSNC to strengthen the knowledge and practical competencies of health workers providing inpatient care and support alignment with WHO standards and guidance. The modular approach is intended to facilitate adaptation within country education and training systems.	The modules have been field tested in Ghana and Nepal, with additional field testing planned in Kenya in late 2026. Experience from these settings is being used to refine the modules. Once finalized, the modules could provide a standardized WHO resource adaptable for pre-service education, in-service training, continuing competency development and national newborn training programs.
Helping Babies Survive (HBS)	Suite of competency- and simulation-based programs comprising HBB for newborn resuscitation, Essential Care for Every Baby (ECEB) for essential care through discharge, and Essential Care for Small Babies (ECSB) for preterm and low birthweight newborns. Uses simplified algorithms, low-fidelity manikins, hands-on simulation and LDHF practice.[243,256]	HBB has been introduced in more than 80 countries. Scale-up was supported by the Helping Babies Breathe Global Development Alliance (GDA)–founded by USAID, the American Academy of Pediatrics, Laerdal Global Health, Save the Children/Saving Newborn Lives and NICHD–supporting country adaptation, training capacity, equipment access and integration into national programs. Evaluations demonstrate improved knowledge and skills, while LDHF and refresher practice can strengthen skill retention.[257,258,259]
S.T.A.B.L.E. Program	Provides a structured approach to post-resuscitation and pre-transport stabilization: Sugar, Temperature, Airway, Blood pressure, Lab work and Emotional support, with an additional Quality Improvement module.[260]	Implemented internationally, including across LMICs in Africa, Asia and Latin America. Particularly relevant for strengthening stabilization and preparation for referral or transport, supporting continuity across networks of care.[260]

HR approaches and tools	How it works	Implementation experience in LMICs
Simulation manikins and LDHF practice	Enables repeated practice without patient risk. Low-fidelity manikins support basic skills such as bag-mask ventilation, while advanced simulators such as NeoNatalie Live provide physiological and performance feedback during ventilation and resuscitation practice.[261]	Portable, low-cost manikins can remain at facilities for LDHF practice between formal trainings. Advanced simulators provide more objective feedback but may be less scalable because of cost and maintenance requirements.[261]
Digital clinical decision-support and remote competency support	Provides patient-specific, protocol-based guidance at the point of care and may combine clinical decision support, education, data capture and QI. Teleconsultation and remote mentoring can extend specialist support to frontline providers.[262]	PRISMS (Uganda) provides real-time newborn clinical decision support and QI data; NoviGuide provides patient-specific bedside guidance based on neonatal protocols; and NeoTree (Malawi and Zimbabwe) combines newborn assessment, decision support, education, data and QI. These tools provide continuous point-of-care competency reinforcement, although scale and sustainability depend on national integration, provider adoption, infrastructure and technical support.[263]
Tele-special newborn care unit (Tele-SNCU)	Tele-SNCU refers to the use of telemedicine technology to provide remote specialist neonatal clinical support to district-level newborn care units that lack on-site neonatologists or pediatricians. Using video conferencing, remote monitoring platforms and digital data sharing, a neonatologist at a tertiary center can review infants in a district SNCU in real time, guiding management decisions, supporting complex clinical cases and building local clinical capacity through mentorship.[264]	Tele-SNCU programs have been implemented in India (under the NHM SNCU program), Ethiopia and Tanzania, with preliminary evaluations reporting improvements in clinical decision-making quality and reductions in inappropriate transfers to tertiary hospitals. The model is particularly relevant for LMICs that have expanded SNCU infrastructure but have insufficient neonatologists to staff all units in person. Broader scale-up requires reliable internet connectivity at district hospitals, standardized telemedicine platforms and sustainable funding models for specialist time.

4.2.4 Infrastructure and design; appropriate and standardized

The physical environment directly shapes whether high-quality SSNC, including KMC, zero separation and family-centered care can be delivered safely and reliably, and in accordance with the model of care. Functional newborn units require reliable electricity and water, appropriate space, sanitation, infection prevention and thermal control, safe oxygen systems, and sufficient space for mothers and families. Infrastructure must support not only clinical functions but iKMC, zero separation and family participation. Across many LMIC settings, overcrowding, unreliable utilities and inadequate space for families undermine quality of care and constrain implementation of zero separation and iKMC. Basic facility safety measures, including fire extinguishers, fire containment and evacuation protocols, and routine staff drills, may also be inadequate or absent in newborn units. Oxygen safety requires appropriate storage and securing of cylinders to prevent falls and other physical hazards and to reduce fire risks associated with oxygen-enriched environments. Facilities must enable mothers to remain with their newborns, with appropriate space for feeding, KMC and rest, and access to toilets, bathing, food preparation, counselling and privacy.[8,9,17] Facility design should therefore follow the model of care rather than simply accommodate equipment. Appropriate and standardized spaces are needed across the care pathway – from immediate newborn care and stabilization through level 2 inpatient care and tertiary care – with infrastructure increasingly designed to enable mothers and newborns to remain together. Standardized design guidance, including infrastructure specifications and facility layouts, can help countries translate standards of care into functional care environments.

Care environment infrastructure	How it works	Implementation experience in LMICs
Newborn care corner	Designated space at the point of birth for immediate essential newborn care. It provides an appropriately located and organized environment for care at birth and should be integrated within or immediately adjacent to the delivery area.	WHO recommends that every health facility providing intrapartum care has a functional newborn care corner. Health facility assessments across sub-Saharan Africa and South Asia continue to identify gaps in functional space and readiness.[22,26]
Newborn stabilization unit (NSU)	Dedicated space at the first referral level (district hospital) for assessment, stabilization and management of sick newborns beyond essential newborn care. The NSU provides a bridge between the primary care level. Infrastructure should support short-term observation and stabilization and preparation for safe referral when required.[22]	Functional NSUs are present in many district hospitals across LMICs, but staffing, equipment functionality and standard operating procedures vary widely. The operationalization of NSUs as distinct care spaces – separate from the general pediatric ward – is an ongoing priority in national neonatal health strategies across sub-Saharan Africa and South Asia.[22]

Care environment infrastructure	How it works	Implementation experience in LMICs
WHO Level 2 (District) inpatient newborn care	Dedicated inpatient environment for SSNs requiring ongoing specialized care. Design should provide sufficient space for newborns, caregivers, staff, and equipment and support appropriate bed spacing, visibility, patient and equipment flow, IPC, storage, reliable utilities and safe installation, use and maintenance of newborn technologies. Infrastructure should enable KMC/iKMC and mother–newborn co-care within the inpatient care environment, allowing mothers and newborns to remain together while specialized care is provided whenever clinically appropriate.	Scaling functional Level 2 care at district level often requires purpose-built or renovated newborn units rather than adaptation of general pediatric spaces. Standardized infrastructure specifications and layouts can help translate national service standards into facility requirements and support planning, costing, renovation and scale-up.
KMC/iKMC and mother–newborn care spaces	Infrastructure should support KMC and the iKMC model of zero separation, enabling mothers and preterm or low-birthweight newborns to remain together from birth while necessary inpatient care is provided. This requires space for the mother alongside the newborn, with appropriate privacy, rest, breastfeeding and milk expression, hygiene and other basic maternal needs. Design may include dedicated KMC areas as well as mother–newborn care integrated within Level 2 and tertiary newborn units, so that increasing acuity does not automatically require separation.	Implementation of iKMC requires a shift from traditional newborn-unit design towards mother–newborn co-care, and may require redesign or renovation of existing units to accommodate mothers safely alongside newborns throughout hospitalization. Dedicated KMC spaces may continue to support ongoing or step-down care, while inpatient environments increasingly need to be designed around the mother–newborn dyad from admission through discharge.
WHO Level 3-tertiary/ specialized newborn care	Higher-acuity care environments designed to support newborns requiring complex and specialized care including referrals from lower levels of the health system. Infrastructure should provide appropriate space, utilities, medical gases, equipment capacity, IPC, staff visibility and workflow, and multidisciplinary care, while enabling iKMC, mother–newborn co-care and family presence wherever clinically appropriate.	Specialized newborn infrastructure remains concentrated in urban and tertiary referral facilities in many LMICs and requires robust utilities, maintenance, biomedical engineering capacity and infrastructure capable of supporting higher-acuity care. As referral centers within a network of care, tertiary facilities also require infrastructure that supports safe transfer and reception of referred newborns, stabilization on arrival, and appropriate transition or back-referral to lower levels of care.

Care environment infrastructure	How it works	Implementation experience in LMICs
Lactation management units	Dedicated or integrated infrastructure should provide appropriate space for lactation support, milk expression, safe handling and storage of human milk and, where available, donor human milk processing and banking. Requirements range from expression and counselling areas integrated within newborn units to dedicated lactation management centers and human milk banks with appropriate spaces for collection, processing, storage and distribution in line with the WHO's 2026 global standards.[52]	India has developed an extensive public-sector model of comprehensive lactation management centers, while countries including Kenya, Uganda and Nepal have established human milk banking models linked with newborn services. These experiences demonstrate different approaches to integrating lactation support and donor human milk infrastructure within newborn care systems.[48]

Box 4.3: Continuous electricity and water supply

Reliable electricity and water supply are foundational requirements for safe inpatient newborn care, yet persistent infrastructure failures remain a major constraint across many LMIC newborn units. Reliable electricity requires not only continuity of supply, but also electrical systems with sufficient capacity to support the load of newborn care equipment and stable voltage to prevent equipment damage and interruptions in care. Electricity is essential for powering oxygen systems, CPAP devices, phototherapy, radiant warmers, suction equipment, monitoring systems, and refrigeration for medicines and breastmilk storage. Water supply is similarly critical for infection prevention, hand hygiene, equipment cleaning, and safe preparation of feeds and medications.[26] Power supply unreliability is among the most pervasive system barriers to neonatal care quality in LMICs. A NEST360 multi-country assessment found that a substantial proportion of neonatal units in East Africa experienced daily power outages, with median interruption times exceeding two hours. Although backup generators, solar-battery systems and uninterruptible power supply (UPS) units are increasingly used to strengthen resilience, these systems are absent or non-functional in many district hospitals. Even where power is available, inadequate electrical capacity and voltage fluctuations can limit safe equipment use and contribute to equipment failure. Similarly, intermittent water supply, inadequate water storage and distribution, insufficient handwashing facilities, poor sanitation and drainage, and shortages of hygiene consumables can compromise IPC and further compound infection risks in overcrowded neonatal units.

4.2.5 Equipment and commodities: procurement and maintenance

SSNC depends on reliable access to a coordinated set of medicines, devices, diagnostics and consumables matched to the level of care (see Section 2 for the full landscape). Yet availability alone does not guarantee functional access: products may be rendered unusable or inaccessible by missing consumables, incompatible components, lack of spare parts, inadequate maintenance, unreliable electricity, weak supply systems or insufficient biomedical engineering support. CPAP, safe oxygen delivery, pulse oximetry and caffeine citrate illustrate these interdependencies: effective care depends not only on the availability of the core product, but also on the supporting equipment, consumables, infrastructure, supply chains and technical capacity required for its reliable use. Equipment and commodity planning therefore increasingly focuses on functional systems rather than individual products. This includes procuring complete and compatible technology packages, ensuring continuous availability of medicines and consumables, standardizing equipment where appropriate and planning for maintenance, repair, spare parts and replacement throughout the product lifecycle.

Equipment packages and tools	How it works	Implementation experience in LMICs
Technology systems/ respiratory support packages	Equipment is planned and procured as a functional system rather than individual devices. An end-to-end respiratory support package includes all components required for safe and reliable respiratory support: oxygen generation and supply (e.g. concentrators, cylinders, PSA-generated or bulk oxygen supplied through piping); flow and pressure delivery equipment (e.g. flowmeter, nasal interface, CPAP equipment); monitoring (particularly pulse oximetry) with associated consumables and accessories; and reliable power and backup capacity. Planning and procuring these components as a coordinated, compatible system, rather than as separate elements in isolation, is increasingly recognized as critical to ensuring functionality and appropriate use at the point of care.[22]	NEST360 data from multi-country facility assessments demonstrate that the presence of individual devices does not necessarily translate into functional respiratory care. While individual components (concentrators, pulse oximeters) may be present, system-level breakdowns – including non-functional flowmeters, incompatible nasal prongs or missing backup cylinders – undermine effective oxygen delivery at the point of care.[22] This points to a need for novel approaches to planning and managing respiratory support. End-to-end oxygen systems have been promoted through programs such as the Clinton Health Access Initiative (CHAI) and NEST360 Oxygen Systems projects across sub-Saharan Africa and South Asia, emphasizing the need to address oxygen generation and supply, distribution, delivery, monitoring, power and maintenance as an integrated system.[22,265]

Equipment packages and tools	How it works	Implementation experience in LMICs
Equipment standardization, service contracts and maintenance budgets	Equipment lifecycle management includes standardization where appropriate, preventive maintenance and repair, access to spare parts, warranties and service agreements, and dedicated recurrent financing for maintenance and replacement. These measures help translate equipment procurement into sustained clinical functionality.[243]	NEST360 assessments have found substantial gaps between equipment availability and functionality in LMIC newborn units, with 20–40% of neonatal devices reported as non-functional in some assessments. Common constraints include limited maintenance capacity, unavailable spare parts and insufficient biomedical engineering support. These findings reinforce the need to incorporate maintenance and lifecycle costs into procurement and routine health-system budgets.[243]
Equipment standardization and procurement	Technical specifications and target product profiles (TPPs) help define fit-for-purpose requirements for newborn technologies, including performance, safety, usability, durability, power requirements, consumables and maintenance needs. These can inform standardized equipment specifications and procurement, reducing unnecessary variation in device models and improving compatibility of accessories, consumables, spare parts, training and maintenance. Procurement should consider suitability for the intended level of care and operating environment and total cost of ownership, rather than acquisition cost alone.	WHO and UNICEF–NEST360 have developed technical specifications, TPPs and other procurement resources for newborn technologies to support appropriate product selection and procurement in resource-constrained settings. These resources can be adapted into national specifications, essential equipment lists and procurement requirements, helping countries align equipment selection with service-delivery needs and local operating conditions.
Service contracts, maintenance and maintenance budgets	Equipment lifecycle management includes preventive maintenance, corrective repair, access to spare parts, warranties and service agreements, and planned replacement. Maintenance can be delivered through biomedical engineering services, manufacturers or distributors, or contracted service providers. Dedicated recurrent budgets are needed to finance maintenance and repair throughout the expected life of the equipment.	Maintenance frequently remains reactive rather than preventive in LMIC health systems, with equipment repaired only after failure and often remaining out of service because of limited biomedical engineering capacity, unavailable spare parts, long repair times or insufficient maintenance funding. Incorporating maintenance requirements and financing into procurement and budgeting from the outset can reduce equipment downtime and improve sustained functionality.

Box 4.4: System constraints in practice: district-level newborn care across four countries

A comparative analysis across Ethiopia, India, Malawi and Rwanda identified a consistent set of system-level barriers cutting across different health system architectures and funding models.[34] Despite varied national contexts, shared constraints included:

- Ward overcrowding limiting physical implementation of zero-separation and iKMC.
- Shortages of skilled newborn care providers, compounded by chronic nursing shortages, staff rotation and turnover, and limited specialized training and career pathways for neonatal nursing.
- Inconsistent availability of essential medicines, particularly caffeine citrate and effective, quality-assured antibiotics amid rising antimicrobial resistance.
- Frequent equipment failures from weak biomedical maintenance systems.

In each setting, progress required sustained national ownership and multi-year systems investment alongside clinical training and not one-off program inputs.

4.2.6 Robust data systems: effective use of data for quality improvement

Reliable data are essential for understanding who needs care, whether appropriate care is being delivered and whether outcomes are improving. SSNC requires routine systems capable of capturing newborn admissions, birthweight and gestational age, diagnoses, key aspects of care and outcomes and linking these data where possible with maternal records, HMIS and CRVS systems. Data need to be sufficiently complete and standardized to support both national monitoring and accountability and facility-level clinical and management decisions. Data alone, however, do not improve care. Continuous QI approaches combine routine measurement to identify gaps in care, understand their causes, test changes and monitor whether those changes improve performance and outcomes. Standardized clinical practices, audit and feedback, mentorship, team-based problem solving and repeated measurement can support this process. Simulation and other competency-strengthening approaches can also be linked with QI to address identified gaps in clinical practice.

Data and QI tools	How it works	Implementation experience in LMICs
Neonatal data networks and benchmarking – VON / African Neonatal Network (ANN)	Standardized patient-level neonatal data are collected using common definitions to track newborn characteristics, care practices and outcomes. Facility-level reporting and benchmarking allow teams to compare performance over time and across facilities, identify gaps, establish QI priorities and measure improvement.	VON's Global Health Neonatal Quality Improvement Database[266,267] has supported standardized neonatal data collection and QI in resource-limited settings, including through the Ethiopian Neonatal Network. The ANN builds on this approach to support standardized data, benchmarking, collaborative learning and data-driven improvement across participating African newborn units.
Routine newborn data and facility-level QI	Newborn registers, standardized indicators, HMIS, dashboards, mortality and morbidity reviews, and other routine data systems enable facility and district teams to monitor service delivery and outcomes. QI approaches use these data to identify gaps, understand contributing factors, test changes and assess whether those changes improve care and outcomes over time.[268]	Countries are increasingly incorporating newborn indicators into routine health information systems, but gaps in data completeness, consistency and standardized reporting continue to limit their use. Strengthening routine data systems requires not only improved data collection and reporting, but regular review and use of data by facility and district teams to identify gaps and guide quality improvement.[269]
Equipment Monitoring Systems	Equipment monitoring systems track the operational status, utilization and maintenance needs of clinical devices, with connected monitoring technologies enabling real-time or near-real-time visibility into device use, performance and equipment downtime. Digital equipment registries and asset-management systems can complement these data by tracking device location, functionality, maintenance history and repair needs. Together, these systems enable facility managers and biomedical engineering teams to identify non-functional equipment proactively, prioritize preventive maintenance and repair, and inform procurement and replacement decisions.[247]	NEST360 has incorporated equipment functionality and availability into its facility assessment and monitoring approaches, providing greater visibility into the gap between equipment ownership and functional availability for newborn care. Tracking failures and downtime can identify where maintenance systems are breaking down and inform biomedical engineering, spare-parts, procurement and replacement decisions. The value of monitoring ultimately depends on having systems capable of responding to the problems the data identify.[247]

4.2.7 Functional referral systems: network of care, transport

Referral systems encompass the communication, transportation and coordination mechanisms that enable patients to move between levels of care and access appropriate maternal and newborn services when needs exceed the capacity of the current facility. For SSNs, referral is a clinical process rather than simply a transport function. Effective systems require early identification of newborns needing escalation, communication between sending and receiving facilities, pre-referral stabilization, safe thermal and respiratory support during transfer, trained accompanying personnel, fit-for-purpose transport and equipment, and clear referral and counter-referral pathways. Referral systems remain a major weakness in many LMICs, constrained by poor transportation networks, long distances and difficult terrain between facilities, insufficient capacity to stabilize and safely transport newborns and inadequate communication between levels of care. Delays in reaching skilled care contribute to preventable deaths, while inadequate care during transfer can expose newborns to hypothermia, hypoxia and clinical deterioration. The absence of structured protocols, trained personnel and portable equipment can make transfer itself a significant source of risk.[32] Strengthening referral therefore requires an integrated network-of-care approach linking communication, clinical decision-making and stabilization, transport, receiving-facility readiness and continuity between levels of care.[32]



Example	How it works	Implementation experience in LMICs
Emergency referral and transport systems (e.g., M-Mama)	Coordinate communication, emergency transport and referral between levels of care to enable women and newborns with complications to reach appropriate services rapidly. M-Mama is an emergency referral and transportation system (EmRTS) for pregnancy, labour and newborn emergencies that links women with fast, reliable transport to health facilities through a 24/7 toll-free number.	M-Mama was initially developed and implemented in Tanzania and has subsequently been adapted and scaled in Lesotho and Kenya. Implementation demonstrates how a coordinated emergency referral system can expand access in settings where formal ambulance capacity is limited by combining centralized dispatch with available transport options, including community-based vehicles. The model has increasingly been integrated with government emergency referral systems, illustrating a pathway from a project-based transport solution towards nationally owned referral infrastructure.[270]
District-based referral and emergency transport systems – Ghana ACERS	Integrates referral communication and dispatch coordination with locally appropriate emergency transport to connect communities and lower-level facilities with referral care. District Emergency Dispatch Coordination Centers coordinate pre-hospital and inter-facility referrals, while transport options can include conventional ambulances and modified motor-tricycle ambulances appropriate to local geography and availability.	In Ghana, the ACERS project established district-based Referral and Emergency Dispatch Coordination Centers in Gushegu and Nkwanta South, coordinating Ghana Health Service and National Ambulance Service referral activities. Community Emergency Transport System committees and modified motor-tricycle ambulances extended transport capacity at community level; the tricycle ambulances supported 2,774 maternal and newborn emergency referrals during the reported implementation period.

4.2.8 Linkage of maternal and newborn care

Maternal and newborn services need to operate as an interconnected continuum, particularly for women and newborns at increased risk of preterm birth, stillbirth or newborn complications. Antenatal risk identification, accurate assessment of gestational age, management of maternal conditions, appropriate use of antenatal corticosteroids, in-utero referral where feasible, intrapartum monitoring and rapid communication between maternity and newborn teams can help anticipate newborn needs and ensure that appropriate care is available immediately after birth. Strengthening these linkages can generate benefits for both stillbirth prevention and newborn survival. Many interventions that reduce fetal risk during pregnancy and childbirth also reduce the risk of severe complications among liveborn newborns. Linkages must also continue after birth. For preterm and low birthweight newborns, immediate KMC and zero-separation models require maternal and newborn services to be organized so that mothers and newborns can remain together while each receives the care they need. Effective linkage therefore extends across pregnancy, childbirth, and the postnatal period and requires coordination between maternal and newborn teams, shared care pathways and service models that minimize unnecessary separation.

Example	How it works	Implementation experience in LMICs
Remote obstetric consultation	Remote obstetric consultation uses telecommunications – voice calls, video calls or messaging – to connect health workers at primary care facilities with obstetricians or specialists at referral hospitals for real-time clinical guidance during complicated labors or deliveries. It is used to support decision-making on referral, emergency management and operative interventions when specialist support is not physically available.[271,272]	Mobile phone-based obstetric consultation hotlines and telemedicine programs operate in multiple LMICs, including Kenya, Ghana, Nigeria and India. They are particularly relevant in settings where specialist obstetric coverage is limited at first referral level. Evidence on impact on maternal and neonatal outcomes is emerging; program evaluations document high rates of use and reported satisfaction among primary care providers.[264]

Example	How it works	Implementation experience in LMICs
Safer births bundle of care	A facility-based quality-improvement and capacity-building package that integrates intrapartum and immediate newborn care. It combines evidence-based clinical tools and practices–including fetal and neonatal heart-rate monitoring and newborn resuscitation–with simulation-based competency training, low-dose high-frequency practice, clinical mentorship, QI, and routine measurement of care processes and outcomes. By strengthening care across labour, birth and the immediate newborn period as a single continuum, the bundle supports earlier recognition and management of fetal and newborn compromise and closer coordination between maternity and newborn teams.[206]	Implemented at scale in Tanzania, where SBBC has expanded from 30 to more than 150 facilities and has demonstrated significant reductions in birth-related mortality. Implementation has subsequently begun in Nigeria, initially in Borno and Gombe states, and is being introduced in Ethiopia through a planned three-year implementation of SBBC and Essential Newborn Care across more than 150 facilities.[273]
Immediate KMC (iKMC) and zero-separation models of care	Reorganizes maternal and newborn care to enable preterm and low birthweight newborns to remain with their mothers and initiate KMC as soon as possible after birth, including while receiving specialized newborn care. Rather than routinely separating the mother and newborn when either requires ongoing care, zero-separation models coordinate maternity, postnatal and newborn services so that the mother–newborn dyad can be cared for together. This requires aligned clinical workflows, coordination between maternal and newborn teams, and care environments that support the clinical needs of both mother and newborn.	The WHO Immediate KMC Study, conducted in Ghana, India, Malawi, Nigeria and Tanzania, found that initiating KMC immediately after birth for newborns weighing 1.0–1.799 kg reduced 28-day mortality by 25% compared with KMC initiated after stabilization. Implementation required redesigning conventional newborn units to enable mothers and newborns to remain together while specialized care was provided, demonstrating both the survival benefit and service-delivery implications of zero separation.

4.2.9 Family and community involvement and support

Families are essential partners in the care of SSNs. KMC and zero-separation approaches place mothers and caregivers directly within the care team, while respectful communication, feeding support, developmental care and shared decision-making enable families to participate meaningfully during hospitalization. Operationalizing this approach requires more than encouraging caregiver involvement: facilities need appropriate space for families, providers need to recognize caregivers as partners in care and services need to equip families with the knowledge and confidence required to care for their newborn. Family support should also address caregiver wellbeing, including psychosocial support and maternal mental health, recognizing the significant emotional and psychological burden associated with preterm birth, newborn illness and prolonged hospitalization. Community involvement extends this partnership beyond the facility. Community health workers, parent and peer-support groups, and other community platforms can strengthen awareness, early identification of risk, appropriate care-seeking, continued KMC and feeding, and link families to health services when additional care is needed. Community engagement can also help address social, financial and geographic barriers that affect families' ability to access and continue recommended care.[5,19,245]

4.2.10 Post-discharge follow-up systems: at facility and at home

Discharge from inpatient care does not mark the end of risk for SSNs. Preterm, low birthweight and other high-risk newborns remain vulnerable to death, infection, feeding difficulties, growth faltering, readmission and developmental impairment after leaving the hospital, particularly during the early post-discharge period. In one LMIC study of very-low-birthweight preterm infants, 38.7% experienced growth failure within 12 weeks of discharge,[274] illustrating the substantial risk of poor growth during this transition. The transition from facility to home therefore represents a critical period in the continuum of SSNC and requires structured follow-up rather than discharge as a single event. Follow-up care described in Section 4.1 requires an operational system capable of maintaining continuity once the newborn leaves inpatient care. This includes clear discharge criteria and individualized care plans, documentation and communication between facilities and community providers, scheduled follow-up appointments, mechanisms for identifying and tracing high-risk newborns, and referral pathways to appropriate and specialist services where specialized care is needed. Structured post-discharge follow-up typically includes clinical review, growth and feeding monitoring, developmental surveillance or screening for neurodevelopmental delays, visual and hearing impairment, caregiver counselling and referral where indicated.[7,246] Effective follow-up systems connect inpatient newborn units with outpatient, primary and community services so that survival gains achieved during hospitalization translate into longer-term growth, health and development.

Taken together, the WHO–UNICEF Model of Care for Small and/or Sick Newborns demonstrates that improving outcomes requires both the right content of care and the systems needed to deliver it reliably at scale. Neither is sufficient alone: evidence-based clinical, developmental and family-centered care must be supported by an enabling health system capable of delivering that care consistently across the continuum. Strengthening both the "what" and the "how" is therefore essential to translate effective interventions into accessible, high-quality, equitable, and sustainable care for small and sick newborns.

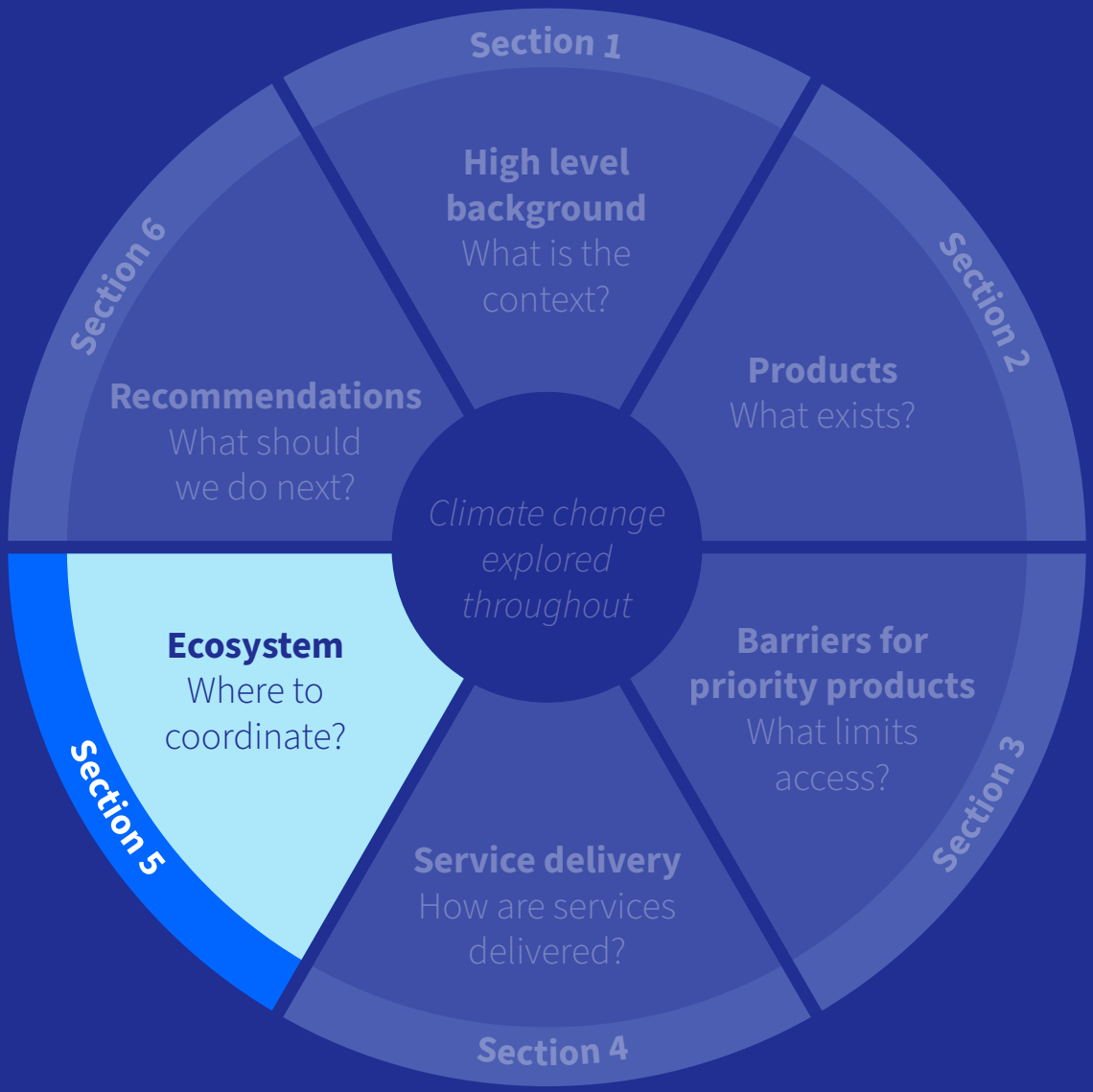
Box 4.5: Climate implications for service delivery

Climate change can affect SSNC both by increasing the need for care and by placing additional pressure on the systems required to deliver it reliably. Climate-related exposures and disruptions therefore reinforce the importance of resilient district-level newborn care systems.

- **Increasing demand for SSNC:** Climate-related exposures, including heat stress, food insecurity, air pollution and environmental shocks, contribute to prematurity, low birthweight, stillbirth and newborn infection risk, increasing demand for KMC, feeding support and inpatient SSNC services in many high-burden settings.[5,12,13,14]
- **Infrastructure and utilities:** Reliable electricity and water are foundational to SSNC, supporting oxygen and respiratory care, phototherapy, monitoring, laboratory systems, thermal care and infection prevention. Climate-related disruptions can compound existing weaknesses in power, water and facility infrastructure, reinforcing the need for resilient systems that can maintain essential newborn services during shocks.[5,13,14]
- **Products and operational resilience:** Many newborn technologies depend on reliable power, appropriate storage, consumables, maintenance and functioning supply systems. Solar power, battery backup, resilient water systems and climate-adapted facility infrastructure can help maintain the functionality of newborn care services in climate-vulnerable settings and align with the Belém Health Action Plan (BHAP) emphasis on climate-resilient health systems.[14]
- **Referral, supply chains and continuity of care:** Climate and environmental shocks can disrupt transport, referral pathways, supply chains, and continuity between facility and community-based care. Building resilience into district newborn care platforms and networks of care can help maintain access to essential services before, during and after disruptions.[5,12,13,14]

5. Ecosystem functions

Where to coordinate?



Section summary

Structural fragmentation across the newborn health ecosystem repeatedly interrupts the innovation-to-access pathway, weakening the translation of clinical evidence into policy, financing, procurement, regulation and routine service delivery. The challenge is not simply the absence of evidence or actors, effective products or relevant institutions, but insufficient coordination across the functions required to ensure equitable and sustained access. This section does not seek to define the mandates of individual organizations or assign them to fixed positions along a linear pathway; many institutions contribute across several functions, and roles vary by country, product and context. Instead, for each of the six EWENE components, Section 5.1 describes the function it serves and the key bottlenecks that constrain it, and Section 5.2 sets out the implications for action across the pathway.

Key takeaways

- **Operational translation gap:** Major delays persist between global guidance, national adoption and facility implementation, leaving many high-impact SSNC interventions underutilized.
- **Equipment functionality is a persistent challenge:** Many neonatal devices become non-functional due to weak maintenance systems, lack of spare parts, restrictions on who can perform repairs and procurement models focused on lowest upfront cost rather than long-term usability.
- **Financing does not reliably reach the point of care:** Budget execution delays, the absence of ring-fenced budget lines and misalignment between short-term donor cycles and national fiscal sustainability cause stockouts even where funds are approved.
- **Community demand and trust are under-addressed:** Low trust in facilities, siloed advocacy and limited capacity to counter misinformation reduce care-seeking, even where products and services are available.
- **Data systems remain weak:** Many countries lack interoperable electronic systems capable of capturing facility-level newborn intervention data, limiting accountability, forecasting and quality-of-care monitoring.
- **Implementation capacity remains a major constraint:** Uptake depends not only on products, but on trained health workers, referral systems, maintenance capacity, supervision and family-centered models of care.
- **Sustainable progress depends on government ownership:** The gaps above ultimately converge on national governments, which shape policy adoption, financing, procurement, workforce deployment and service delivery standards. Lasting improvements require government ownership, institutional capacity, and sustainable financing.
- **Problem-led coordination:** Coordination is most useful when organized around specific access and delivery problems, with country ownership, shared outcomes and clear accountability for action.

5.1 Functions and bottlenecks across the MNH pathway

Persistent bottlenecks across the MNH pathway continue to limit equitable access to essential products, technologies and high-quality service delivery models for SSNs. Using the six components of the EWENE Pathway to Improving Access to Quality MNH Products as a guiding framework, this section describes the function each component serves and the key bottlenecks that constrain it. The subsections below summarize the key bottlenecks in each component, including delayed translation of global guidance into national policy, underinvestment in implementation research, fragmented procurement, inconsistent financing, weak regulatory and maintenance capacity, and limited service readiness. These components are overlapping and iterative rather than sequential, and their configuration differs across countries and interventions. Findings draw on published evidence, policy documents, implementation reports and operational case examples, validated through key informant interviews. Section 5.2 then draws out the implications for action across these components, which frame the priority actions presented in Section 6 (Recommendations).

5.1.1 Innovation and normative policy and guidance

Evidence and normative guidance shape which interventions are recommended for SSNs and how quality care should be delivered, and in turn signal priorities for research, innovation and product development. Their impact depends on translation into national policies, costed implementation plans, essential medicines and equipment lists, procurement specifications, clinical protocols, training curricula, facility standards and supervision systems. Research and innovation also need to respond to the operating realities of Level 1 and Level 2 care, including performance under conditions of unstable electricity, heat, humidity, dust and limited maintenance capacity. Key bottlenecks include:

- **Delayed and inconsistent translation of global guidelines into national policy:** New life-saving standards (e.g., WHO SSNC and WHO Recommendations for the Care of Preterm and LBW Infants guidelines) often face significant time lags before being adopted into National Essential Medicines Lists (NEMLs), national clinical protocols and facility-level job aids.
- **Chronic under-investment in implementation research:** While pre-clinical research is well-funded, implementation research addressing how effective interventions can be introduced, delivered and sustained in low-resource settings remains underfunded relative to other areas of newborn research.
- **Fragmented advocacy and prioritization:** Advocacy for MNH has historically been less consolidated than for some disease-specific programs, which may contribute to inconsistent prioritization in national budgets.[25] Multiple initiatives operate through parallel advocacy structures, which can dilute messaging and reduce collective influence.

- **Limited transition from pilots to national systems:** Demonstration programs often generate useful evidence but do not consistently transition into routine systems, particularly where policy ownership, financing, procurement and workforce pathways are not agreed at the outset.

5.1.2 Supply chain

Supply chains determine whether priority newborn commodities and technologies reach the point of care when needed. This function translates policies, clinical guidance and service delivery needs into operational decisions on what to procure, when to procure and how products move to frontline facilities. It spans quantification and forecasting, purchasing, supplier engagement, storage and distribution, stock visibility and, for devices, installation, maintenance and repair. Public, private and faith-based supply channels often coexist. Key bottlenecks include:

- **Fragmented procurement and demand forecasting:** Limited coordination between clinical needs, quantification, procurement and distribution contributes to unpredictable demand, inefficient purchasing and inconsistent availability of essential newborn products.
- **Weak equipment maintenance and after-sales service:** Essential newborn care equipment, including CPAP and medical oxygen systems, may become non-functional soon after delivery due to a lack of spare parts, environmental compatibility challenges, lack of consumables, inadequate specialized engineers and service contracts. Between 30% and 70% of medical devices in low-resource settings are estimated to be currently non-functional, often because maintenance and spare parts are excluded from initial procurement tenders.[275]
- **Limited visibility into product use and stock levels:** National systems frequently fail to capture facility-level consumption data, leaving forecasting and procurement decisions based on incomplete information. These gaps contribute to both stockouts and overstock of essential products. Only 20–25% of countries report having electronic individual patient records, and LMIS often do not capture MNH product usage at all levels.[6]

5.1.3 Financing and resource allocation

Financing and resource allocation are essential to supporting equitable access to newborn health products and sustaining high-quality services. Sustainable SSNC requires financing that covers the full cost of care, including recurrent costs, not just the initial procurement of products and equipment. National and subnational budgets, insurance and universal health coverage mechanisms, and external financing all play a role in ensuring that workforce, infrastructure, medicines and devices, consumables, utilities, maintenance, referral and transport, data systems, quality improvement and follow-up after discharge are adequately funded. Where these costs are

not covered, families may be required to pay directly, and their ability to pay can determine whether life-saving interventions reach the newborn. Key bottlenecks include:

- **Delays between budget approval and disbursement:** Even when MNH funds are approved in national plans, delays in budget execution can prevent funds from reaching procurement or facilities in time, resulting in artificial stockouts.
- **Misaligned donor and national financing cycles:** A frequent tension exists between donor project-based cycles (prioritizing rapid, short-term impact) and national fiscal sustainability (requiring long-term domestic absorption of costs).
- **Price-focused procurement incentives:** Tendering based primarily on lowest price, without sufficient weight on quality and lifecycle costs, can discourage investment in high-quality, durable products and equipment.

5.1.4 Regulatory and quality systems

Regulatory and quality systems determine whether newborn medicines, devices and clinical services are safe, effective and suitable for use. National authorization, quality assurance, facility licensing, professional regulation, post-market surveillance and clinical governance all influence which interventions can be procured, introduced and sustained. Product assessment and specifications also need to consider suitability for low-resource settings, including durability, ease of use, environmental operating conditions, energy requirements, availability of components and local maintenance capacity. Key bottlenecks include:

- **Limited quality-assured supply base:** Limited number of quality-assured suppliers for specialized MNH products.
- **Slow and weakly enforced product registration:** Slow registration timelines (6 months to 4 years); weak enforcement against substandard or falsified medicines circulating in-country.
- **Nascent pharmacovigilance systems:** Pharmacovigilance systems are often nascent and poorly understood by frontline workers; limited facility-level monitoring.

5.1.5 Demand generation, community engagement and advocacy

Family and community engagement shapes whether families recognize newborn danger signs, seek care early and continue using available services, and whether newborn survival receives sustained public and political attention. Families and communities are partners in care, not only recipients or sources of demand: respectful communication, caregiver participation, kangaroo mother care, zero separation, peer support, community linkages and financial protection all influence care-seeking, adherence and continuity after discharge. Trust is shaped by the actual experience of care, and community feedback, parent groups, professional networks, civil society

and legislative oversight can strengthen accountability for service quality, product availability and budget execution. Key bottlenecks include:

- **Trust deficit and bias:** Families often avoid facilities due to a lack of trust, fear of detention for non-payment or cultural preferences for traditional remedies, limiting the impact of available products and services.
- **Siloed advocacy:** MNH advocacy is often siloed from other sectors like climate adaptation or social protection, missing opportunities to address the "five Es" (Equity, Economics, Environment, Education, Emergencies).
- **Weak misinformation and digital engagement strategies:** Strategies to manage misinformation, engage influencers and monitor public sentiment in real time are often limited. Coordination with social media platforms is often weak, leading to fragmented messaging, rapid spread of harmful advice and missed opportunities to promote trusted newborn care information.

5.1.6 Service delivery capacity and systems readiness



Service delivery capacity and system readiness determine whether lifesaving newborn interventions can be delivered safely, consistently and at scale. This function spans the continuum from community and primary care to district and referral hospitals, including inpatient care, kangaroo mother care, stabilization, referral and post-discharge follow-up, and brings together the workforce, infrastructure, equipment, referral systems and operational management that translate policies, financing and procurement into functioning services. It also depends on data, measurement and shared learning: routine data need to connect service readiness, product availability and functionality, quality of care and newborn outcomes, supporting planning and quality improvement at facility and district level, and budgeting, procurement and accountability nationally. Non-state providers, including faith-based and private facilities, deliver a substantial share of newborn care in many high-burden countries. Key bottlenecks include:

- **Routine data systems face multiple constraints:** Systems rely on aggregate reporting that limits linkage between outcomes and specific interventions, often exclude private and faith-based providers from national reporting, and omit key indicators for high-impact interventions. Parallel quality and audit processes increase workload for overstretched managers, while fragmented digital platforms and weak interoperability reduce visibility across financing, supply and service delivery systems.
- **Unclear accountability and readiness gaps:** Many facilities lack clearly defined authority and accountability for advanced resuscitation, continuous provision of oxygen and safe early initiation of CPAP with blended oxygen and transitional stabilization, resulting in inconsistent implementation of life-saving practices. Workforce shortages and limited specialized neonatal skills weaken the ability of teams to provide continuous, high-quality care, especially during the critical minutes after birth. Referral and transport arrangements are often not well linked to facility readiness,

leading to delays in stabilization and continuity of care. Supply systems do not always prioritize essential therapies such as caffeine citrate, reflecting weak integration between clinical protocols and procurement decisions. At the same time, policies promoting practices like immediate kangaroo mother care and zero separation are not consistently translated into operational standards, supervision and infrastructure design, reducing their practical impact at the point of care.

- **Product-focused rather than integrated planning:** Small and sick newborns frequently need multiple interventions delivered together, and product-specific initiatives may have limited impact where they are not linked to staffing, infrastructure, infection prevention, safe oxygen, thermal and feeding support, kangaroo mother care (KMC/iKMC), zero separation, maternal services, referral, data and follow-up.

5.2 Implications for action

Across the six components, the most significant constraints arise less from the absence of evidence, products or institutions than from weak connections between functions: from guidance to operational implementation, from budgets to timely financing, from procurement to functional access, from individual products to integrated care, from regulation to continuous quality assurance, and from projects to national ownership and scale. Addressing them requires a small number of shifts in how these functions connect. These shifts frame the recommendations in Section 6, which set out specific actions by product archetype, service delivery platform and component of the pathway.

- **From guidance to operational implementation:** Global recommendations and technical guidance need to be translated systematically into national plans, clinical protocols, essential medicines and equipment lists, target product profiles, procurement specifications, training and facility workflows, with implementation research treated as an integral part of the pathway rather than a follow-on activity.
- **From product delivery to functional access:** Success should be judged not only by whether products have been delivered, but also by whether they are functional, maintained and appropriately used at the point of care. This places lifecycle costs, maintenance and functionality data at the center of procurement and investment decisions.
- **From approved budgets to predictable financing:** Priorities set in policy need to be matched by timely disbursement and explicit provision for the recurrent costs of care, including workforce, consumables, maintenance, referral and data, while protecting families from out-of-pocket costs.
- **From individual products to integrated care:** Planning and investment organized around integrated packages of care and defined levels of care, rather than single products, can reduce fragmentation and make better use of shared staff, infrastructure and supplies.
- **From registration to continuous quality assurance:** Regulation, procurement and facility reporting need to operate as a connected system, so that product failures,

adverse events and equipment downtime inform corrective action and future purchasing.

- **From fragmented data to shared learning:** Connecting information on stock, equipment functionality, service readiness, quality of care and newborn outcomes through national systems can support forecasting, accountability and improvement, and shared learning across countries.
- **From pilots to national ownership:** Demonstration programs should plan for transition into national policy, financing, procurement and workforce systems from the outset, with regional and global support aligned behind country-defined priorities.

Moving from demonstration programs to sustainable scale-up requires early planning for integration into national policy, financing, procurement and workforce systems, with regional and global support aligned behind country-defined priorities. Making these shifts does not require stakeholder roles to be prescribed through a single global framework. Rather, countries and partners can organize collaboration around clearly defined access and delivery problems. For each priority problem, the relevant stakeholders can identify the functions required, locate the points of failure, clarify decision rights and accountabilities, and align financing, technical support and learning around shared outcomes.

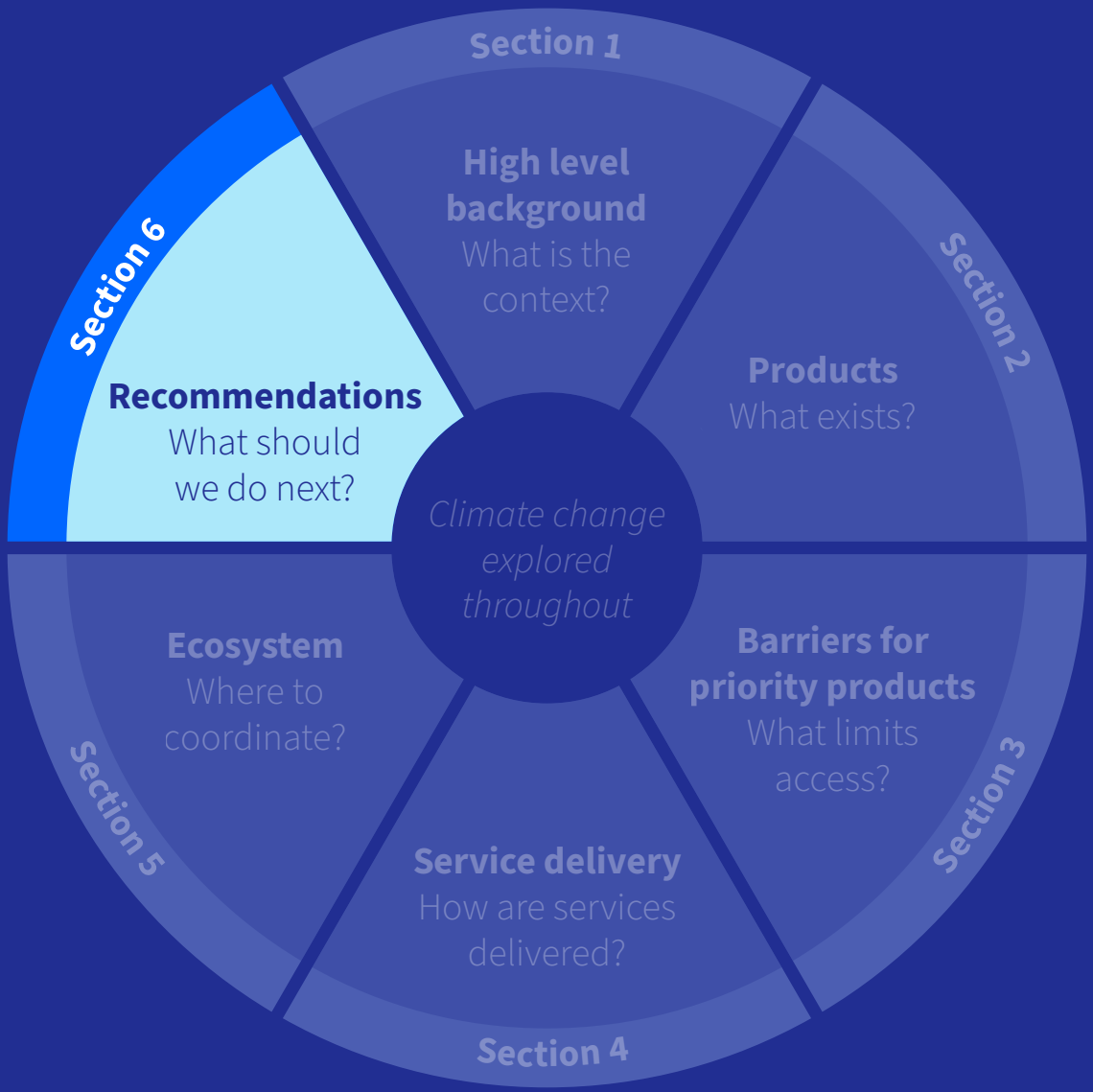
Box 5.1: Climate resilience across the SSNC ecosystem

Climate change increases the need to strengthen the resilience of the systems, markets and service-delivery platforms that support SSNC. Climate considerations cut across the functions described above and should be incorporated into planning rather than treated as a separate institutional responsibility.

- **National and subnational planning should build resilience into SSNC scale-up.** Planning should consider resilient electricity, oxygen infrastructure, water and cooling, transport, cold-chain capacity, emergency preparedness and continuity of essential newborn services during climate-related shocks.
- **Procurement and investment decisions should prioritize resilience alongside access.** Product specifications, procurement and investment decisions should account for durability, energy efficiency, backup power, heat, humidity, dust exposure, supply disruption and maintenance capacity in climate-vulnerable settings.
- **Products should be designed and tested for real operating conditions.** Technologies should be tested under realistic environmental and operating conditions, including extreme heat, humidity, dust exposure and unstable electricity, with transparent information on energy requirements, consumables, maintenance and expected performance.
- **Service-delivery models need contingency arrangements.** Service-delivery models and referral networks should include contingency arrangements for floods, extreme heat, power disruption, transport interruption and interruptions to oxygen or other critical supplies.
- **Evidence and guidance should incorporate climate resilience.** Research, evidence and guidance should increasingly incorporate climate resilience, environmental operating conditions and continuity of care into product evaluation, implementation frameworks and quality standards.

6. Recommendations

What should we do next?



Section summary

Reducing preventable newborn mortality and improving outcomes for SSNs will require more than the introduction of new products and technologies. While many high-impact interventions already exist, persistent barriers related to product access, service delivery, financing, procurement, regulation, workforce capacity and health system readiness continue to limit their adoption and sustainable scale-up in LMICs. Addressing these challenges requires coordinated action across the innovation-to-impact pathway.

Key takeaways

Six headline recommendations emerge from this landscape. Successful implementation will require strong country ownership, alignment with national priorities and engagement of local stakeholders across government, professional associations, communities and the private sector, with particular attention to populations facing the greatest barriers to quality newborn care, including those in rural, remote, humanitarian and underserved settings.

- **Build and scale functional Level 2 newborn care platforms:** Level 2 care is the primary delivery platform for most priority products. Expand equitable access to a comprehensive Level 2 package, supported by the infrastructure, workforce, equipment, referral systems and recurrent financing needed to sustain quality care.
- **Deliver integrated respiratory care packages rather than standalone products:** Bubble CPAP, pulse oximetry, safe oxygen delivery and blending, surfactant, caffeine citrate and antenatal corticosteroids have the greatest impact when introduced as a bundle, with oxygen sources, consumables, maintenance and trained providers planned and procured together.
- **Prioritize access to proven interventions over discovery of new interventions:** Many high-impact products already exist but remain underutilized. Focus investment on the affordability, operational models, service readiness and implementation evidence needed to bring them into routine use, while supporting targeted development of LMIC-appropriate products where clear gaps remain.
- **Strengthen market shaping and sustainable access mechanisms:** Use pooled procurement, demand aggregation, quality-assured supplier panels, regulatory reliance and value-based procurement to improve affordability, supply security and long-term functionality, backed by ring-fenced domestic financing for recurrent costs.
- **Organize care around zero separation and family-centered care:** Deliver Level 2 interventions alongside immediate kangaroo mother care wherever clinically feasible, design new devices to be KMC-compatible, and recognize parents and caregivers as essential partners in care.
- **Improve coordination and accountability across the innovation-to-access pathway:** Align guidance, financing, procurement, regulation and service delivery behind costed national plans, and strengthen data systems, routine monitoring and accountability mechanisms to track progress and guide continuous improvement.

The recommendations in this section are organized into four complementary sections that build upon one another. Collectively, the recommendations in this section, based on data previously considered and sourced in the document, aim to support more coordinated, country-driven and sustainable approaches to improving survival, health and developmental outcomes for SSNs worldwide.

- **Recommendations for Priority Products** focus on the products and interventions with high potential to improve newborn outcomes and the actions needed to overcome barriers to their adoption and scale-up.
- **Recommendations for Service Delivery** focus on the models of care, workforce, infrastructure, referral systems and quality improvement approaches needed to deliver these products and interventions effectively.
- **Recommendations Across the Pathway** address the broader ecosystem conditions required for sustainable scale-up, including financing, market shaping, procurement, regulation, policy, advocacy and health system strengthening.
- **Recommendations for Implementation Research** identify priority evidence gaps and learning needs to accelerate adoption, strengthen implementation and inform future investments.

6.1 Recommendations for priority products

The products and interventions highlighted in this report represent some of the most promising opportunities to improve survival and long-term outcomes for SSNs. However, many remain underutilized due to barriers that extend beyond product availability, including affordability challenges, weak maintenance systems, provider capability gaps, limited market incentives and the absence of products appropriately designed for district-level settings. This section focuses on the actions needed to overcome the primary barriers preventing these products from achieving greater impact at scale. Recommendations are organized by product archetype based on the principal challenge limiting access and uptake, reflecting the market access framework introduced in Section 3. For each archetype, cross-cutting recommendations are presented first, followed by product-specific recommendations where additional actions are needed. While it is useful to consider recommendations for individual priority products, we must emphasize that, as noted in Section 3.4, a meaningful portfolio of products along with appropriate service delivery is needed to drive reductions in mortality and morbidity, as in the preterm respiratory care bundle described there. With that caveat, we provide recommendations by archetype below. Furthermore, across all archetypes, product-focused actions should be implemented alongside investments in the service delivery systems required for effective use, including workforce capacity, referral networks, quality improvement and sustainable financing.

Key

Archetype 1 | Archetype 2 | Archetype 3 | Archetype 4

Cross-cutting recommendations by archetype

Archetype	Cross-cutting recommendations
Strengthen operational models for improved uptime Products: pulse oximeters, bubble CPAP and LED phototherapy	**1.1 Drive a bundles mindset in procurement and management of equipment:** Isolated devices have limited impact, but the right combination of devices, when present with necessary consumables, can save lives. Bubble CPAP, pulse oximetry and technologies that enable safe oxygen delivery and blending should be viewed as part of a respiratory care bundle that also includes a reliable oxygen source, oxygen distribution infrastructure, monitoring and maintenance systems.
	1.2 Address consumables / spares supply chain and interoperability issues: Neonatal probes for pulse oximeters and nasal prongs, masks, interface connectors, filters and circuits for bubble CPAP are critical consumables. The supply chain for these consumables and spares needs to be improved to avoid stock-outs. Consumables are often designed to work only with specific equipment, which can create dependencies and limit supply options. There is a need to push standardization and interoperability of consumables.
	1.3 Foster multi-use and disinfection protocols: The reality of many LMIC settings is that consumables and equipment intended for single use are often reused. Additional operational research is needed to understand product durability, safe reuse practices and the impact of repeated reprocessing on performance and infection risk. Existing disinfection and reprocessing guidance should be adapted and operationalized within resource-constrained settings to support safe implementation.
	1.4 Drive equipment rationalization and quality assurance: A combination of fragmented procurement and parallel donation programs has contributed to a highly heterogeneous equipment landscape across LMIC facilities, complicating standardization, maintenance and workforce training. Countries should seek to rationalize equipment portfolios based on local needs while maintaining appropriate market competition. Such efforts also provide an opportunity to increase uptake of quality-assured devices. Given the number of poor-quality devices in several newborn technology categories, continued efforts to evaluate, identify, procure and promote quality-assured technologies remain important.
	1.5 Drive use of service contracts, maintenance budgets and leases with uptime guarantees: Building on the equipment management measures described earlier, countries may need targeted technical support to put them into practice: costing and ring-fencing recurrent maintenance budgets, negotiating service agreements and warranties at the point of procurement, and holding vendors to agreed response times. Funders and procurers can also help test and refine uptime-based models for LMIC settings, in which a vendor is paid for a working service rather than for equipment alone (for example, leases with uptime guarantees), and share lessons on cost, performance and scalability.

Archetype	Cross-cutting recommendations
	1.6 Invest in biomedical engineering capabilities and equipment monitoring systems/predictive maintenance: Biomedical engineering capacity remains a persistent gap in many LMICs and limits the value of the maintenance and monitoring approaches. Governments and partners should consider investing in building, training and retaining this workforce across health areas rather than in disease-specific silos. Equipment monitoring and predictive maintenance can then be scaled as a practical tool for these teams, with low-cost options such as digital equipment registries linked to maintenance and procurement planning, and evaluated for effectiveness and affordability in LMIC facilities.
Find LMIC-appropriate product or administration  Products: sepsis diagnostics, injectable antibiotics and surfactants	**2.1 Support R&D through philanthropic capital (grants and blended finance):** Newborn innovation is not a commercially attractive area, especially those focused on LMIC-driven challenges. At the same time, validation studies are complicated and expensive; studies with neonatal subjects are inherently challenging. Such studies will require philanthropic support as noted above. Philanthropic capital will be required to stimulate development and commercialization of new products. Some of this capital may be traditional grant capital, but other options also exist. Blended finance instruments such as advance market commitments (price/volume guarantees) may be used to incentivize efforts from start-ups, larger firms and academics.
	2.2 New product development should ensure KMC/iKMC compatibility where possible: KMC/iKMC relies on prolonged continuous skin-to-skin contact with the caregiver, so devices should be designed, where feasible, to allow care to continue without interrupting skin-to-skin contact or requiring the device to be detached or repositioned. Devices that require separation of the mother–baby dyad create a direct trade-off between two evidence-based interventions. Designing for compatibility through wireless or long-lead sensors, lightweight and body-worn form factors, tolerance of caregiver movement and secure fixation that remains in place during movement between cot and chest can remove this trade-off and protect KMC adherence in practice.
Overcome health systems barriers  Products: antenatal corticosteroids and bag-valve-masks	**3.1 Strengthen provider competencies through low-dose, high-frequency training and technology-enabled learning:** Expand competency-based training approaches that combine frequent, short simulation sessions, mentorship, supportive supervision and continuous skills assessment. Leverage digital and virtual learning platforms, such as ENC Now!, remote telementoring and peer-learning networks, to extend training and specialist support to providers in underserved settings. Integrate simulation technologies and real-time performance feedback tools, such as NeoNatalie Live and the Augmented Infant Resuscitator (AIR), to improve resuscitation skills, reinforce correct technique and support ongoing competency assessment. Explore AI-enabled learning, adaptive simulations and digital decision-support tools to further personalize training and strengthen provider confidence and clinical decision-making.

Archetype	Cross-cutting recommendations
Make product affordable ✚ Products: Caffeine citrate	No cross-cutting recommendations for this archetype; see product-specific recommendations below. It should be noted that affordability has been highlighted as a secondary concern in some of the other products (e.g. surfactant).

Product-specific recommendations

Product	Product-specific recommendations
Pulse oximeter ●	**Strengthen safe oxygen delivery through pulse oximetry and oxygen blending in Level 2 facilities:** Ensure routine pulse oximetry monitoring to guide oxygen administration and titration of blended oxygen to appropriate neonatal saturation targets. Low-dose, high-frequency training and supportive supervision should reinforce provider competencies in adjusting oxygen delivery to prevent hypoxemia and hyperoxia.
	Evaluate need for pulse oximetry at Level 1 facilities: Previous efforts in driving pulse oximeter use in Level 1 facilities (e.g. Unitaid's TIMCI project) have highlighted that pulse oximetry alone may have limited impact in the absence of strong referral systems and adequate quality of care. In the context of limited budgets, demonstrated benefits (e.g. strong referral mechanisms already in place) will need to be documented to make the case for increasing use of pulse oximetry in level 1 facilities.
	Monitor the case for multi-modal devices: Although the cost of multi-modal devices (that go beyond peripheral oxygen saturation (SpO2) measurement) has come down, they are still more expensive than traditional pulse oximeters. This cost-benefit ratio of procuring multi-modal devices needs to improve to justify investments, in case of new procurement. Moreover, experts point to the higher potential impact of a multimodal device failing, which may render multiple measurements unavailable in such times including the critical SpO2 measurement. (expert input, 2026)
Bubble CPAP ●	**Invest in provider skills and confidence, and in data-driven quality improvement programs to realize full potential of technology:** Experts have emphasized that provision of functioning equipment in facilities is only the first step; building provider skills and confidence in safe oxygen administration requires sustained investment. Both delayed oxygen provision and inappropriate oxygen use can contribute to poor outcomes, undermining confidence and discouraging adoption. Data-driven quality improvement initiatives, mentorship programs and supportive supervision can help providers develop the skills needed to safely deliver oxygen and respiratory care and troubleshoot challenges as they arise. Continued support to governments and stakeholders will be needed to realize the full potential of these life-saving interventions.

Product	Product-specific recommendations
	Invest in public goods to help purchasers procure the right CPAP: Choosing the right combination of the CPAP, oxygen source and other equipment for a given context is non-trivial. There is a need for purchaser education efforts which may be done through creation of public goods such as procurement guides, guideline updates and technical assistance to governments.
LED phototherapy ●	**Increase access to light meters and testing consumables using market shaping:** As noted previously, phototherapy quality suffers because irradiance meters are rarely used, and their cost could be reduced through market shaping. Bilirubin testing is also underused: transcutaneous meters are expensive to buy, and serum testing depends on costly consumables, which could likewise benefit from market shaping. These efforts should be paired with provider training so that treatment quality is monitored.
	Explore addition of low-cost solar solutions to complement traditional LED phototherapy: These emerging solutions are eco-friendly and can often offer useful daytime backup in times when a high number of patients are present or during power outages.
Sepsis diagnostics ▲	**Focus on development and validation of host response biomarker-based tests:** Given WHO's target product profile focused on a rapid PoC test, host-response biomarker tests appear most promising currently, with several groups working towards such tests. Validation studies are required to be conducted for such biomarkers.
	Reduce prices of existing tests (CRP, PCT) through market shaping: As a secondary approach, market shaping efforts may be undertaken to make currently available tests cheaper. These tests (although not stand-alone tests for sepsis) require repeated samples for their utility, and current pricing makes their use prohibitively expensive. Such tests are based on mature technologies and generally have diversified manufacturing, which points to feasibility of market shaping efforts. Moreover, these tests also have a broader utility beyond neonatal sepsis.
Injectable antibiotics for sepsis ▲	**Invest in trials for novel antibiotics and novel combinations:** Trials such as the NeoSep trial are promising for the field, and further investments in this area are needed.
	Map resistance profiles in LMICs and potentially adapt treatment guidelines: Mapping the typical resistance profiles at a regional level can also better direct treatment decisions. Many doctors already prescribe treatments different from the WHO standard, acknowledging resistance. However, more solid evidence based on local patterns can support countries to contextualize guidelines.

Product	Product-specific recommendations
	Invest in quality-assured African production of priority antibiotics: Challenges around stock-outs and quality issues around antibiotics were noted previously. While many antibiotics are low-cost commodities, they are essential medicines with large, predictable demand across African health systems. Strategic investment in quality-assured regional production could strengthen supply security, reduce dependence on imports for selected high-volume products, and improve access to reliable antibiotics during supply disruptions. Note that investments in sterile injectable manufacturing will be required for the medicines under discussion here.
	Explore need for supporting pediatric formulations: As noted in Section 3, adult-dose packages are commonly used in hospitals, requiring providers to calculate and provide appropriate dosage, which is an error-prone process. Further assessment is needed to determine whether investment in neonatal- and pediatric-appropriate formulations would address key implementation barriers and improve delivery of neonatal sepsis care in LMIC settings.
	Invest in prevention at the same time: Treatment advances will be outpaced by resistance unless matched by investment in preventing infection in the first place. Infection prevention and control in maternity and neonatal wards, hand hygiene and environmental cleaning, chlorhexidine cord care, clean birth practices and the water, sanitation and staffing that make them possible. These measures reduce the exposure that drives both sepsis incidence and antibiotic pressure, and are typically far cheaper per case averted than any new antibiotic.
Surfactants ▲	**Invest in aerosolized delivery for the long-term:** If successfully developed and introduced, aerosolized surfactant delivery could expand access to surfactant therapy in Level 2 facilities by simplifying administration and reducing reliance on specialized procedural skills. While promising, experts suggest these products remain at least 5–7 years from broad market availability. WHO has developed a target product profile to guide product development in this area.
	Invest in easier delivery mechanisms for the short-term: As discussed previously, LMA-based surfactant administration using the SALSA technique has demonstrated operational feasibility in Level 2 settings and may enable broader access to surfactant therapy without requiring advanced intubation skills. Successful introduction will require investment in provider training, mentorship and implementation support.
	Drive market shaping efforts: Surfactants remain unaffordable for many LMIC facilities, including most Level 3 units. Opportunities may exist to improve affordability through market-shaping interventions such as demand aggregation, pooled procurement, increased market competition, and other approaches that lower prices and improve supply security. These efforts could be pursued in parallel with introduction of simplified administration approaches such as SALSA.

Product	Product-specific recommendations
Antenatal corticosteroids ◆	**Explore technology-enabled gestational assessment tools:** Several experts in the field spoke to the promise of the AI-enabled POCUS to help determine gestational age and help providers make confident decisions to administer antenatal corticosteroids. Given high costs of such devices, cost-benefit analyzes as well as operational assessments will determine whether this solution is appropriate in LMIC contexts. In settings where POCUS devices are already present, the case for AI-enabled gestational age calculation is easier to make.
	Strengthen facilities to meet conditions for ACS use: WHO recommendation for use is conditional on the presence of appropriate infrastructure for neonate and mother. Without adequate facility strengthening to meet WHO conditions, the benefits of ACS may not be fully realized.
Bag-Valve-Mask ◆	**Invest in improved devices or those that provide real-time feedback of resuscitation:** Complementary to training efforts, investments may be made in bag-mask devices with improved usability and seal performance, as well as technologies that provide real-time feedback during resuscitation. These innovations may help improve resuscitation quality, support skills retention and strengthen provider confidence.
	Standardize sterilization techniques for reuse: Reusable devices require proper sterilization prior to use. See recommendation 1.3 above on need for sterilization/ disinfection protocols.
Caffeine citrate ✚	**Improve affordability through market shaping:** Affordability challenges can be addressed through a combination of strategies, including increasing market competition, aggregating and pooling demand to negotiate better prices, improving pricing transparency across the supply chain and reducing costs introduced through procurement, distribution and facility-level markups. Optimizing product presentations and pack sizes for LMIC contexts may also help reduce wastage and improve value.
	Invest in provider awareness and education: Despite superior efficacy and safety profiles, caffeine citrate remains underutilized in some settings due to continued reliance on more familiar alternatives. Strengthening provider awareness through clinical guidelines, training and integration into routine newborn care programs may help accelerate adoption alongside affordability interventions.
	Packaging: For caffeine citrate, efforts are underway to discover optimal packaging for LMIC contexts to reduce costs as well as wastage. Explore how different caffeine citrate presentations influence affordability, availability, procurement and wastage across LMIC settings.

6.2 Recommendations for service delivery

Improving access to priority products is a critical first step, but product availability alone is insufficient to improve newborn outcomes. Achieving impact at scale requires service delivery models that ensure newborns can access the right interventions, at the right time, in the right setting, delivered by appropriately trained health workers.

6.2.1 Build Level 2 newborn care platforms around zero separation

Current status: Level 2 newborn care represents the primary delivery platform for many of the products and interventions highlighted in this report, including respiratory support, oxygen therapy, feeding support, infection management and monitoring technologies. Important foundations already exist. The EWENE agenda has elevated Level 2 newborn care as a global priority, while the WHO–UNICEF Model of Care for Small and/or Sick Newborns provides a framework for delivering and scaling integrated, high-quality care. Several countries have demonstrated scalable district-level models. Expanding access to Level 2 newborn care requires financing models that support not only capital investments, but also the recurrent costs required to sustain service delivery. Several countries have begun incorporating newborn care into broader UHC reforms, and investment planning and costing efforts are underway in several settings. Multiple newborn health programs have also demonstrated the importance of pairing technology introduction with investments in service readiness, mentorship and quality improvement.

Priority area	Recommendation
Expand and strengthen Level 2 newborn care services	1.1 Deliver Level 2 interventions as an integrated package of care organized around zero separation and iKMC, with mothers and newborns cared for together wherever clinically feasible. For eligible preterm and low-birthweight newborns, iKMC provides a foundation for this model, with interventions such as CPAP, feeding support, phototherapy and infection management delivered alongside skin-to-skin care rather than requiring routine separation. 1.2 Prioritize expansion of equitable access to this comprehensive Level 2 package while ensuring facilities have the infrastructure, workforce, equipment and referral systems needed to provide quality care. 1.3 Focus future investments on adapting and expanding these approaches within national health systems.
Promote equitable access to SSNC	2.1 Prioritize expansion of Level 2 services in underserved districts and populations, informed by burden, service availability and geographic access. 2.2 Complement strategic service placement with strengthened referral and transport systems and targeted measures to reduce geographic, financial and social barriers to accessing quality newborn care.

Priority area	Recommendation
Strengthen financing mechanisms for sustainable newborn care delivery	3.1 Integrate newborn care into national health financing strategies, UHC benefit packages and insurance schemes, with dedicated financing for workforce, consumables, oxygen systems, maintenance, quality improvement, referral systems and post-discharge follow-up. 3.2 Orient future financing models increasingly towards long-term service delivery sustainability rather than one-time commodity or equipment investments.
Invest in service readiness as a prerequisite for product introduction and scale-up	4.1 Accompany decisions about introducing new products with assessments of facility readiness, including workforce capacity, infrastructure, oxygen availability, power reliability, supply chains, maintenance systems and data systems. 4.2 Align product adoption strategies with broader efforts to strengthen health system capacity rather than implementing them as stand-alone initiatives. 4.3 Make pairing technology introduction with investments in service readiness, mentorship and quality improvement standard practice for future newborn product introduction efforts.

6.2.2 Deliver integrated, high-quality care

Current status: WHO's standards for quality maternal and newborn care, the EWENE agenda and national newborn care strategies increasingly promote integrated service delivery approaches. WHO's recommendations on immediate kangaroo mother care and growing global efforts around family-centered neurodevelopmental care provide a strong foundation for action, and several countries are already integrating these approaches into newborn care guidelines and facility redesign efforts. Many newborns require timely identification, stabilization, referral and follow-up across multiple levels of care. Country experience has also demonstrated the value of strengthening referral pathways alongside facility-based newborn care investments.

Priority area	Recommendation
Adopt integrated service delivery models that support comprehensive care for SSNs	1.1 Introduce products as part of coordinated care packages rather than through siloed implementation approaches. 1.2 Support integrated models that combine respiratory support, nutrition, infection prevention and management, diagnostics, developmental care and follow-up services across the continuum of care. 1.3 Use future investments to accelerate operationalization and scale of these models at district level.

Priority area	Recommendation
Embed family-centered care and kangaroo mother care within routine newborn services	2.1 Design service delivery models that recognize parents and caregivers as essential partners in care. 2.2 Direct investments in facility design, workforce training and quality improvement initiatives to support family participation, kangaroo mother care, breastfeeding, caregiver education and post-discharge support. 2.3 Ensure facilities provide adequate space, sanitation, food and rest areas for mothers and caregivers to enable their sustained presence and participation in newborn care.
Strengthen referral networks and care pathways across levels of the health system	3.1 Strengthen referral systems including stabilization and care during transport, transport mechanisms, communication pathways and post-discharge follow-up services to ensure continuity of care and reduce avoidable delays. 3.2 Treat referral readiness as a core component of newborn care delivery in future scale-up efforts.

6.2.3 Build capacity for continuous improvement and scale

Current status: Scaling priority products will require sustained investments in training, mentorship, supportive supervision and workforce planning, and expanding access must be accompanied by efforts to improve quality and safety. Competency-based training and mentorship models are increasingly available, and quality improvement approaches have been successfully integrated into newborn care programs in many settings. However, these approaches are not yet consistently institutionalized within national workforce strategies, preservice education systems and routine health system management.

Priority area	Recommendation
Strengthen the health workforce required to deliver specialized newborn care	1.1 Build multidisciplinary teams with competencies in newborn bedside care, respiratory care, feeding support, infection management and quality improvement. 1.2 Institutionalize competency-based training and mentorship models within national workforce strategies and preservice education systems.
Integrate quality improvement into newborn service delivery	2.1 Strengthen routine measurement, clinical governance, audit and feedback mechanisms, supportive supervision and quality improvement collaboratives to ensure products and interventions are used appropriately and effectively. 2.2 Embed quality improvement within routine health system management rather than project-specific initiatives.

6.2.4 Commit to a costed, long-term national plan

Current status: Sustainable scale-up of SSNC requires national leadership, long-term financing and coordinated investment across the ten components of care described in Section 4.2. While some countries have integrated newborn care into broader UHC reforms, implementation remains fragmented and reliant on short-term funding. Costed national plans with dedicated budgets and clear accountability are essential to ensure investments translate into sustainable, high-quality newborn care.

Priority area	Recommendation
Develop and finance a long-term national plan for SSNC scale-up	1.1 Develop a costed five-year national plan for the systematic scale-up of SSNC, supported by a dedicated budget line, and advance all ten components of the SSNC model of care simultaneously rather than in isolation. 1.2 Build national plans on these foundations and link them to the ring-fenced budget lines and costing approaches described in Section 6.3.3, with clear targets, timelines and accountability for each component.

Together, these recommendations emphasize that sustainable improvements in newborn outcomes depend not only on expanding access to high-impact products, but also on strengthening the service delivery platforms, financing mechanisms, workforce and quality systems required to ensure those products can be delivered effectively and equitably at scale.

6.3 Recommendations across the pathway

Strengthening products and service delivery models is essential, but neither can achieve sustainable impact at scale without a supportive enabling environment. Financing constraints, fragmented procurement systems, regulatory barriers, weak market incentives, limited coordination and insufficient country ownership continue to slow the adoption and scale-up of high-impact newborn health interventions. The recommendations in this section focus on the ecosystem conditions required to translate effective products and service delivery models into sustained population-level impact. They address cross-cutting challenges that span the innovation-to-impact pathway, including financing, market shaping, procurement, policy and regulatory systems, advocacy and health system strengthening. While many of these barriers affect individual products, they are often systemic in nature and require coordinated action across multiple stakeholders and sectors. Together, these recommendations aim to create the conditions needed for sustainable scale-up by strengthening the systems, markets, policies and partnerships that enable high-quality newborn care to reach all who need it.

6.3.1 Innovation and normative guidance

Current status: Global momentum around SSNC has accelerated through WHO quality-of-care standards, the WHO/UNICEF model for scaling SSNC, EWENE targets, expanded Level 2 care frameworks, and growing investment in newborn technologies and service delivery models. However, the landscape shows that innovation continues to outpace operational guidance and country adoption. Many evidence-based interventions remain underutilized or concentrated in tertiary facilities because implementation guidance, regulatory pathways and operational adoption mechanisms for district-level LMIC settings remain weak or fragmented.

Priority area	Recommendation
Accelerate translation of global guidance into national adoption Despite expanding WHO guidance and EWENE priorities, major delays persist between normative recommendation, national registration, procurement readiness, country-level dissemination and routine clinical implementation. These delays are particularly significant for newer newborn interventions and contribute to uneven adoption across high-burden LMIC settings.	1.1 Develop time-sequenced Access Roadmaps linked to implementation guidance that synchronize regulatory, procurement, financing and clinical adoption processes. 1.2 Expand collaborative registration and regulatory reliance mechanisms to accelerate national approval of WHO-prequalified or SRA-approved newborn products. 1.3 Establish structured South-South knowledge-sharing and Solution Transfer platforms to accelerate adaptation of proven implementation approaches across LMIC settings.
Shift implementation research leadership and financing towards LMIC settings The landscape repeatedly demonstrates that implementation barriers, rather than lack of clinical efficacy, are the primary constraint to scale for many newborn interventions. However, implementation research remains severely underfunded relative to pre-clinical and product development research.	2.1 Increase direct financing for LMIC-led implementation research focused on district-level newborn care delivery, operational feasibility and integrated service models. See Section 6.4 on Implementation Research Priorities for more details. 2.2 Require implementation and delivery evidence generation as part of large-scale newborn product introduction and market-shaping initiatives. 2.3 Support and expand existing multicountry implementation learning platforms, including ANA and ANN, to evaluate adaptation of newborn innovations across different health system contexts.

Priority area	Recommendation
Strengthen unified global advocacy and political prioritization for newborn care Despite increasing technical consensus around SSNC priorities, maternal and newborn health advocacy remains fragmented relative to more vertically coordinated global health agendas. This fragmentation weakens visibility within financing, policy and national planning processes.	3.1 Strengthen coordinated advocacy and communication that builds on existing global initiatives, including EWENE, to support consistent messaging and sustained political visibility for maternal and newborn health. 3.2 Strengthen alignment between newborn survival, stillbirth prevention, maternal health, disability and UHC advocacy agendas. 3.3 Expand country-level advocacy capacity to support inclusion of SSNC priorities within national financing and UHC agendas.

6.3.2 Supply chain

Current status: Despite major progress in expanding the availability of newborn commodities and technologies, access to SSNC interventions remains constrained by fragmented procurement systems, weak maintenance capacity, limited forecasting visibility and inconsistent financing for recurrent operational costs. The landscape demonstrates that product availability alone is insufficient to ensure access: functionality, consumables, spare parts, after-sales service and reliable distribution systems are equally critical determinants of whether life-saving interventions remain consistently available at district level. These challenges are particularly acute for device-dependent interventions requiring oxygen ecosystems, biomedical support and ongoing consumable supply chains.

Priority area	Recommendation
Strengthen predictable financing and procurement systems for newborn commodities Without dedicated financing and aligned procurement systems, newborn commodities and equipment are frequently deprioritized relative to high-volume general medicines and broader health system needs. This contributes to inconsistent product availability, delayed procurement cycles and weak incentives for manufacturers to sustain supply.	1.1 Strengthen health financing reforms and increase dedicated funding for MNH to support predictable financing for essential commodities and services. Reliable funding helps stabilize supply chains, enable longer-term procurement planning and strengthen supplier confidence in newborn health markets. 1.2 Expand pooled procurement, coordinated forecasting and long-term purchasing agreements for priority newborn medicines, diagnostics and technologies. 1.3 Align newborn commodity financing with EWENE implementation priorities, country-level MNCH strategies and service readiness plans.

Priority area	Recommendation
Transition from standalone device procurement to integrated service delivery models Many advanced newborn technologies – including bubble CPAP, oxygen systems and phototherapy devices – become non-functional shortly after deployment because procurement processes fail to include consumables, spare parts, biomedical engineering support and maintenance contracts. As a result, large proportions of equipment in LMIC settings remain partially functional or entirely unusable.	2.1 Institutionalize care bundles and equipment–service bundling models that integrate consumables, training, maintenance, spare parts and after-sales service into initial procurement agreements. 2.2 Develop standardized procurement specifications and interoperability standards for oxygen and respiratory care ecosystems. 2.3 Expand district-level biomedical engineering capacity and preventative maintenance systems to improve equipment uptime and functionality.
Improve visibility and data systems for forecasting and supply chain management Weak facility-level consumption data, fragmented LMIS, and limited digital integration undermine quantification and forecasting accuracy and contribute to simultaneous stockouts and overstocks across newborn commodities and consumables. Many national systems also lack visibility into equipment functionality and utilization at district level.	3.1 Expand adoption of integrated electronic LMIS (eLMIS) platforms, MNH commodity dashboards and digitized facility-level reporting systems to improve visibility into newborn commodity consumption and stock levels. 3.2 Use AI-enabled forecasting and predictive analytics to improve procurement planning, inventory management and stock redistribution across newborn supply chains. 3.3 Integrate newborn commodity utilization, equipment functionality and service readiness indicators into national health information systems and electronic medical records platforms.

6.3.3 Financing and resource allocation

Current status: Financing for SSNC remains heavily fragmented, short-term and insufficiently aligned with the operational realities of district-level service delivery. While many countries include maternal and newborn health priorities within national strategies and donor-supported plans, major bottlenecks persist in budget execution, domestic resource allocation and long-term financing for recurrent costs such as consumables, maintenance, workforce and after-sales service. The landscape also highlights a persistent mismatch between donor project cycles focused on rapid results and the sustained financing required to operationalize integrated newborn care systems at scale.

Priority area	Recommendation
Strengthen budget execution and direct financing for newborn care systems Even when maternal and newborn health financing is approved within national budgets, delays between budget approval and disbursement can prevent funds from reaching procurement and facility levels in time, contributing to artificial stockouts and interruptions in service delivery.	1.1 Establish permanent, ring-fenced national budget lines for maternal and newborn health commodities, equipment and services to protect financing from being deprioritized relative to other health expenditures. 1.2 Expand fiscal decentralization and Direct Health Facility Financing (DHFF) approaches that enable facilities to procure essential newborn commodities locally when central supply chains fail. 1.3 Strengthen innovative financing approaches, including matching fund models and revolving drug funds, to improve predictability and sustainability of newborn commodity financing.
Align external financing with long-term national sustainability Externally funded project cycles focused on demonstrating results within short timeframes are not always aligned with the long-term fiscal commitments required to sustain district-level newborn care systems. This can result in successful pilots that cannot be absorbed into domestic financing structures.	2.1 Expand co-financing and matching fund mechanisms that incentivize governments to increase domestic investment in newborn care systems. 2.2 Deploy activity-based investment cases using device planning and costing tools to develop evidence-based and financially credible funding requests. Demonstrating the economic value of newborn health investments, including evidence from Tanzania showing returns of US$7–12 for every US$1 invested, can help secure sustained government financing and political commitment. 2.3 Ensure that high-impact SSN care interventions are explicitly costed, financed and monitored within national investment cases, MNCH strategies and UHC financing mechanisms, including dedicated provision for recurrent costs, workforce requirements, equipment maintenance and service readiness.
Transition from lowest-price procurement to value-based financing and procurement models. Procurement systems that prioritize the lowest upfront purchase price frequently incentivize acquisition of lower-quality products while excluding maintenance, training, consumables and service agreements. This contributes to high rates of equipment failure, low-quality products and undermines long-term functionality of newborn care technologies.	3.1 Establish quality-assured supplier panels that limit procurement to vetted manufacturers meeting WHO prequalification or equivalent regulatory standards. 3.2 Coordinate aggregated demand forecasting and volume guarantees across countries and regions to improve market predictability and incentivize manufacturer investment in high-quality newborn product lines. 3.3 Expand “as-a-service” financing models, including OaaS, that shift maintenance and uptime responsibility to vendors while reducing capital expenditure burdens on facilities.

6.3.4 Regulatory and quality systems

Current status: Regulatory and quality assurance systems for maternal and newborn health products remain fragmented and uneven across many LMIC settings, contributing to delayed market entry, limited availability of quality-assured products, and continued circulation of substandard or poorly maintained technologies. Registration timelines for specialized newborn products can extend from months to several years, while pharmacovigilance and post-market surveillance systems often remain weak at facility level. At the same time, limited local manufacturing capacity, shortages of spare parts and restrictive servicing arrangements undermine long-term reliability and maintainability of critical newborn technologies.

Priority area	Recommendation
Expand availability of quality-assured newborn products A limited number of quality-assured suppliers currently exist for many specialized maternal and newborn health commodities and technologies, constraining competition, increasing prices and limiting procurement options for national programs.	1.1 Provide technical assistance to regional and national manufacturers to support achievement of WHO PQ status and compliance with international quality standards. 1.2 Strengthen regional manufacturing ecosystems and regulatory harmonization initiatives to improve availability of quality-assured newborn products across LMIC markets.
Accelerate regulatory approval and strengthen enforcement systems Long registration timelines and inconsistent regulatory enforcement delay access to life-saving newborn products while allowing substandard and falsified products to remain in circulation.	2.1 Strengthen regulatory enforcement capacity to identify and remove substandard and falsified newborn medicines and devices from national markets. 2.2 Expand use of GS1 barcoding and traceability technologies to improve supply chain visibility and facilitate rapid identification and removal of poor-quality products.
Strengthen post-market surveillance and maintainability of newborn technologies Weak pharmacovigilance systems, limited facility-level monitoring, and restricted access to spare parts and servicing contribute to poor equipment functionality and unreliable long-term performance of newborn technologies.	3.1 Strengthen pharmacovigilance and post-market surveillance systems for newborn medicines, diagnostics and devices, including facility-level reporting mechanisms and frontline worker training. 3.2 Support LMIC-based research and development for newborn technologies designed for local operating conditions, including accessible spare parts and open maintenance systems.

6.3.5 Demand generation, community engagement and advocacy

Current status: Demand for maternal and newborn health services remains heavily influenced by trust, affordability, cultural norms and perceptions of quality of care. Even where life-saving newborn commodities and services are available, families may delay or avoid seeking care because of fear of financial hardship, prior negative experiences including disrespectful care and provider abuse, mistrust of facilities or preference for traditional providers. At the same time, maternal and newborn health advocacy remains fragmented across sectors and stakeholders, while digital misinformation and weak communication systems increasingly shape care-seeking behaviours. The landscape highlights the importance of positioning caregivers and communities not as passive recipients of care, but as central actors in newborn survival and long-term health outcomes.

Priority area	Recommendation
Rebuild trust in newborn care services through respectful, family-centered care Trust deficits between communities and health systems continue to undermine timely care-seeking and sustained utilization of maternal and newborn health services. Financial barriers, fear of detention for non-payment and poor patient experiences further weaken confidence in facility-based care.	1.1 Strengthen respectful, family-centered care models and enforce policies prohibiting detention for non-payment to improve trust in newborn care services. 1.2 Engage community leaders, traditional providers, parent support groups, and caregivers in culturally sensitive outreach and referral strategies. 1.3 Expand social protection mechanisms – including fee waivers, emergency transport schemes, insurance coverage and community-based financing approaches – to reduce financial barriers to care-seeking. 1.4 Institutionalize routine measurement of patient experience, trust and caregiver engagement within newborn quality-of-care systems.
Integrate maternal and newborn health into broader cross-sector development agendas Maternal and newborn health advocacy often remains siloed from related sectors such as climate adaptation, education, social protection and emergency preparedness, limiting opportunities to address the broader social and environmental determinants shaping newborn outcomes.	2.1 Establish cross-sector coordination platforms and joint planning mechanisms linking maternal and newborn health with climate, education, nutrition, social protection and emergency preparedness agendas. 2.2 Integrate newborn indicators and service delivery considerations into broader social protection programs, disaster preparedness plans and community resilience initiatives. 2.3 Align financing, data systems and accountability mechanisms across sectors to strengthen coordinated support for vulnerable mothers and newborns.

Priority area	Recommendation
Strengthen digital communication, misinformation management and public engagement Coordinated strategies to monitor misinformation, engage trusted influencers and respond rapidly to harmful or inaccurate newborn health information circulating online and within communities are often limited.	3.1 Establish formal partnerships between health authorities and social media platforms to promote verified newborn health information, amplify trusted voices and flag misinformation. 3.2 Invest in digital listening tools, analytics platforms and sentiment monitoring systems to support early identification of misinformation and targeted public communication responses. 3.3 Train health workers, community leaders, youth influencers and parent networks in responsible digital engagement and risk communication. 3.4 Integrate digital communication and misinformation response strategies into national maternal and newborn health communication and emergency preparedness plans.

6.3.6 Service delivery capacity and system readiness

Current status: Many LMIC health systems continue to face major constraints in delivering reliable, high-quality care for SSNs at district level. Routine data systems often lack visibility into intervention-specific outcomes, equipment functionality, referral performance and service readiness, while fragmented digital systems and parallel reporting processes limit accountability and timely decision-making. At the facility level, workforce shortages, inconsistent neonatal competencies, weak referral coordination and limited operationalization of standardized care pathways contribute to delays in stabilization and inconsistent implementation of life-saving interventions. The landscape repeatedly highlights that mortality reductions depend less on isolated technologies and more on the reliability and coordination of integrated newborn care systems.

Priority area	Recommendation
Strengthen data-driven planning, accountability and service readiness monitoring Fragmented routine data systems and weak interoperability across supply, financing and service delivery platforms reduce visibility into facility readiness and limit the ability of managers to identify and respond to bottlenecks in newborn care delivery.	1.1 Expand routine collection and use of service readiness, quality and neonatal outcome data – including staffing levels, equipment functionality, referral times, bed occupancy and key neonatal outcomes – to identify gaps, strengthen facility-level planning and accountability, and inform continuous improvement. 1.2 Integrate digital dashboards, decision-support tools and interoperable reporting systems into routine newborn care management processes. 1.3 Align routine monitoring, neonatal outcome review, supervision and quality improvement systems to reduce parallel reporting burdens and enable data to be routinely used to identify implementation gaps and improve care.
Strengthen integrated newborn care delivery, workforce capacity and referral readiness Many facilities lack clearly defined authority, standardized operational pathways and sufficient workforce capacity to consistently deliver high-impact newborn interventions, including advanced resuscitation, early CPAP initiation, thermal care and stabilization during referral and transport.	2.1 Establish standardized newborn care bundles that integrate resuscitation, CPAP, thermal care, early kangaroo mother care, provision of safe oxygen, lifesaving respiratory medications and stabilization into coordinated operational care pathways. 2.2 Expand competency-based pre-service and in-service neonatal training, team-based simulation, mentorship and supportive supervision programs such as low-dose high-frequency models to strengthen district-level workforce capacity and clinical confidence. 2.3 Integrate neonatal workforce planning into national staffing strategies and establish retention mechanisms that reduce routine rotation from specialized newborn care units. 2.4 Strengthen referral stabilization protocols and integrate transport teams into clinical governance systems to improve continuity of care during transfer between facilities.

Priority area	Recommendation
Align operational systems, financing and supervision with high-impact newborn care delivery Weak alignment between clinical protocols, procurement systems, financing decisions and supervision structures undermines consistent implementation of evidence-based newborn care practices and contributes to interruptions in availability of essential therapies and equipment.	3.1 Align procurement and financing decisions with standardized clinical care packages to ensure reliable availability of essential newborn therapies, consumables and equipment. 3.2 Embed performance indicators for high-impact newborn interventions into routine supervision, quality improvement and accountability systems. 3.3 Operationalize policies supporting immediate kangaroo mother care (iKMC), zero separation and family-centered care through facility design standards, staffing models and supervision systems. 3.4 Include training, mentorship, supervision and equipment maintenance costs within recurrent government budgets to improve long-term sustainability of newborn care services.

6.4 Implementation research priorities

Strengthening products, service delivery models and enabling ecosystem conditions is essential for improving newborn outcomes at scale. However, important questions remain regarding how best to introduce, finance, deliver and sustain high-impact interventions in diverse LMIC contexts. Many of the barriers identified throughout this report are not primarily questions of clinical efficacy, but of implementation, i.e. understanding what works, for whom, under what conditions and why.

The priorities in this section focus on generating the evidence needed to accelerate the translation of innovation into impact. They address key uncertainties across the innovation-to-impact pathway, including product introduction, service delivery, financing, regulatory systems, community engagement and health system readiness. By strengthening implementation learning and generating actionable evidence for policymakers, funders, implementers and manufacturers, these research priorities can help shorten the time between innovation, adoption and large-scale impact while supporting more effective and sustainable newborn care programs.

MNH pathway	Priority research question	Rationale	Key evidence gap
 **Innovation and normative guidance**	**1. Prioritizing high-impact SSN care packages:** How can existing health systems and mortality impact modelling approaches be leveraged and expanded to identify the highest-impact intervention packages for SSNs and the bottlenecks that most constrain their delivery?	Recent modelling supported by Unitaid has demonstrated how health system bottlenecks influence effective coverage and mortality impact across maternal, newborn and child health interventions. Similar approaches could be applied to additional SSN conditions and intervention packages, including respiratory distress syndrome, neonatal infection, jaundice, hypothermia, feeding support and post-discharge care.	The relative impact of different SSN intervention packages, the bottlenecks that most limit effective coverage and whether combining interventions across a care pathway produces greater gains than introducing individual interventions alone.
 **Supply chain**	**2. Optimizing oxygen ecosystems for newborn care:** What oxygen ecosystem package–including oxygen source, power backup, pulse oximetry, air-oxygen blending, consumables, maintenance systems, and biomedical support–delivers the highest reliability and safest neonatal outcomes?	Oxygen is one of the most important but system-dependent interventions in newborn care. Investments frequently focus on individual products rather than the broader ecosystem required for safe delivery.	The optimal combination of products, infrastructure, maintenance and service-delivery components required to ensure reliable and safe oxygen access for newborns.
 **Financing and resource allocation**	**3. Sustainable financing models for specialized newborn care:** Which financing and provider-payment mechanisms most effectively support recurrent costs for newborn commodities, oxygen systems, equipment maintenance and specialized newborn services within UHC programs?	Many SSNC investments focus on capital procurement while recurrent costs remain underfunded, contributing to equipment downtime, stock-outs and service disruptions.	Which financing approaches are most effective at sustaining long-term SSNC readiness and service quality.

MNH pathway	Priority research question	Rationale	Key evidence gap
Regulatory and quality assurance systems	**4. Accelerating access to quality-assured newborn commodities:** What regulatory reliance, collaborative registration and quality assurance approaches are most effective in accelerating the introduction and sustained availability of quality-assured newborn products such as caffeine citrate and surfactant in LMIC markets?	Several high-impact newborn products remain unavailable or inconsistently available despite strong clinical evidence and inclusion in global guidance.	Which regulatory and quality assurance approaches most effectively reduce time to market, improve supplier participation and sustain availability of quality-assured newborn products.
Demand generation, community engagement and advocacy	**5. Home-based caffeine citrate for high-risk preterm infants:** Can continuation of caffeine citrate after discharge safely reduce post-discharge mortality, morbidity and readmissions among selected preterm infants at risk of ongoing apnea?	As survival improves, a growing proportion of mortality occurs after discharge. Few interventions specifically address this period of risk among vulnerable preterm infants. Successful implementation would depend on caregiver acceptance, adherence, follow-up and community-based support systems.	The feasibility, safety, acceptability and impact of home-based caffeine citrate administration, including caregiver-led delivery and follow-up models.
Service delivery capacity and system readiness	**6. Integrated respiratory care bundles across the continuum of care:** Does implementation of a standardized respiratory care bundle–including antenatal corticosteroids (ACS), caffeine citrate, CPAP, surfactant, oxygen management, monitoring, and referral–improve survival and disability-free outcomes compared with introducing interventions independently?	Similar to the E-MOTIVE trial for postpartum hemorrhage, evidence is needed to determine whether coordinated implementation of a respiratory package achieves greater impact than deployment of individual interventions alone.	Whether bundled respiratory care can accelerate reductions in mortality and morbidity among preterm and small newborns compared with standalone interventions.

MNH pathway	Priority research question	Rationale	Key evidence gap
	7. Delivery-room respiratory stabilization for preterm newborns: Does initiation of CPAP with or without caffeine citrate in the delivery room, provided by clinicians trained in advanced neonatal resuscitation, improve stabilization and outcomes among preterm newborns prior to transfer to newborn care units?	Respiratory support is often delayed until admission to a neonatal care unit. Earlier stabilization at the point of birth may reduce deterioration during the critical transition period and improve downstream outcomes.	The feasibility, effectiveness and optimal implementation model for initiating CPAP and caffeine citrate immediately after birth before transfer to higher levels of care.
	8. Simplified respiratory resuscitation and support at Level 2 facilities: Can simplified respiratory technologies and approaches–including laryngeal mask airways (LMAs), T-piece resuscitators and simplified surfactant administration approaches–improve newborn stabilization and respiratory outcomes at Level 2 facilities?	Many Level 2 facilities lack access to advanced neonatal expertise and equipment. Simplified approaches may expand access to quality respiratory care while strengthening referral pathways.	Which respiratory support and resuscitation approaches can be safely and effectively decentralized to Level 2 facilities.
	9. AI-enabled ultrasound to improve ACS targeting and respiratory outcomes: Does AI-enabled ultrasound improve the accuracy of antenatal corticosteroid administration and downstream newborn outcomes through more accurate gestational age assessment and identification of women at risk of preterm birth?	Accurate gestational age assessment remains a major barrier to appropriate ACS use in many low-resource settings. While AI-enabled ultrasound has demonstrated promise for gestational age estimation, it remains unclear whether this translates into improved clinical decision-making, more appropriate ACS administration, improved referral decisions and better respiratory outcomes among preterm newborns.	The effect of AI-enabled ultrasound on provider decision-making, ACS targeting, referral practices, and respiratory outcomes for preterm and small newborns.

7. Conclusion

Despite substantial progress in child survival, neonatal mortality remains a persistent global challenge, with small and sick newborns bearing a disproportionate burden. This landscape demonstrates that many of the medicines, diagnostics and devices needed to prevent and manage the leading causes of newborn mortality and morbidity already exist and are supported by global guidance. Yet access to these interventions remains inequitable, particularly in low- and middle-income countries (LMICs), where barriers to availability, affordability, quality, functionality and appropriate use continue to limit their impact.

By examining 98 interventions, priority product market access barriers, service delivery models and the broader innovation-to-access pathway, this landscape provides an evidence-informed resource for a range of stakeholders. Governments and national programs can use the findings to identify product access gaps and inform national planning, procurement and service delivery priorities. Funders and development partners can identify opportunities for targeted investments, market shaping and coordinated support, while manufacturers, innovators and regulatory authorities can use the findings to inform product development, quality assurance and market entry. Implementing partners and researchers can draw on the identified gaps and priorities to guide implementation strategies, evidence generation and sustainable scale-up. Together, these applications can support more coordinated, country-led action to improve equitable access to quality newborn care.

Three interconnected priorities for action

Together with the analysis of service delivery models and the broader innovation-to-access pathway, these findings highlight **three interconnected priorities** for accelerating access to quality SSNC. Together, these priorities bring the six headline recommendations presented in Section 6 into a single agenda for action:

1. **Close product access gaps through differentiated strategies.** The landscape demonstrates that improving access requires approaches tailored to the barriers affecting different products. These findings reinforce that no single product access strategy will be sufficient. For many interventions, the principal challenge is no longer establishing what works, but ensuring that proven solutions become consistently available, affordable and usable at scale, supported by stronger market-shaping efforts and sustainable access mechanisms. Investments must respond to the specific barriers limiting product introduction, availability, adoption and sustained use, while promoting quality assurance, affordability and market sustainability. For established devices such as continuous positive airway pressure (CPAP), phototherapy and pulse oximeters, the priority is to move beyond procurement toward lifecycle management that ensures equipment remains functional and supported by reliable maintenance and consumables. For surfactants, sepsis diagnostics and injectable antibiotics,

where clear product gaps remain, opportunities exist to accelerate the targeted development and evaluation of products and administration approaches appropriate for LMIC settings. Other interventions, including antenatal corticosteroids and bag-valve-mask ventilation, require stronger provider competencies and clinical decision-making, while caffeine citrate highlights opportunities for market shaping, demand aggregation and improved affordability. Across product categories, greater attention is also needed to ensuring reliable access in climate-vulnerable, conflict-affected and humanitarian settings, where infrastructure limitations, disrupted supply chains, unreliable power and reduced maintenance capacity can further constrain product availability, functionality and sustained use.

2. **Strengthen Level 2 newborn care as the platform for effective product use.** Level 2 newborn care represents a critical opportunity to expand access to high-impact interventions for SSNs. However, the availability of medicines, diagnostics and devices alone does not ensure improved outcomes. Their effectiveness depends on skilled providers, appropriate infrastructure, reliable supplies, maintenance systems and the capacity to deliver coordinated, high-quality clinical care. *Building and scaling functional Level 2 newborn care platforms* is therefore essential. *Integrated respiratory care packages, rather than standalone products*, require coordinated access to CPAP, safe oxygen, pulse oximetry, caffeine citrate and, where appropriate, surfactant, alongside thermal care, monitoring and referral capabilities. These interventions must be delivered within care organized around *zero separation and family-centered care*, supporting kangaroo mother care and continuity of care and recognizing parents and caregivers as essential partners in care. Strengthening Level 2 platforms provides an opportunity to align product investments with workforce capacity, service readiness and sustainable delivery models, ensuring that effective technologies translate into improved newborn survival and health outcomes.

3. **Align investments and partnerships across the innovation-to-access pathway.** The landscape identifies persistent fragmentation across product development, normative guidance, regulatory approval, procurement, financing, service delivery and sustained use. Addressing these gaps requires stronger *coordination and accountability* among governments, manufacturers, regulatory authorities, funders, implementing partners, health care providers and communities. Priority actions include aligning guidance, financing, procurement, regulation and service delivery behind costed national plans, accelerating regulatory reliance and harmonization, strengthening forecasting and procurement systems, promoting quality-assured and context-appropriate products, adopting financing approaches that account for recurrent costs and long-term functionality, and strengthening data systems and routine monitoring to track progress and guide continuous improvement. Greater alignment between product innovation, market-shaping investments and country implementation priorities can help reduce duplication, improve market predictability and accelerate equitable access. Implementation research can further inform how innovations and interventions are introduced, delivered and sustainably scaled across different settings.

Looking ahead

Accelerating progress in newborn survival will require a shift from investing in individual products toward ensuring equitable, sustainable access to integrated packages of effective, quality-assured medicines, diagnostics and devices. This means addressing product-specific barriers while strengthening the service delivery capabilities and partnerships needed to support their appropriate and sustained use. By bringing together evidence on products, markets, service delivery and the innovation-to-access pathway, this landscape provides a foundation for more targeted investment, informed prioritization and coordinated action. The opportunity now is to translate what is already known, available and achievable into reliable access to high-quality care for every small and sick newborn who needs it.



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