



Target Product Profile

Flow Splitter - Respiratory Support

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Note to the reader

Because of the richness of the discussion, and in an attempt to keep this report simple and readable, this report aims to convey the themes addressed in each session, rather than attempting to provide a chronological summary of the dialogue.

Disclaimer: The TPPs do not replace or supersede any existing UNICEF TPPs. The TPPs do not constitute tender specifications, nor is UNICEF bound to tender or procure products that arise as a result of these TPPs. UNICEF may require regulatory approval and proof of compliance to quality management and product-specific international standards for tendering purposes.

INTRODUCTION

At birth, a baby's lungs must transition from fetal to neonatal life in three key ways:

- I. fluid in the lungs must be absorbed and replaced with air,
- 2. lungs must expand fully and regular breathing must be established, and
- 3. pulmonary blood flow is increased.

When these three things do not happen, a baby will have respiratory distress. Respiratory distress syndrome (RDS) is when there is deficiency of surfactant that is needed to prevent alveolar collapse; this is especially common in premature newborns.

Oxygen provision is important in the care of newborn infants because many conditions that affect babies in the first days of life can result in low levels of oxygen in the body. Hypoxemia, or low levels of oxygen in the blood, is a life-threatening condition that results in increased mortality and morbidity. Prematurity and respiratory distress syndrome (surfactant deficiency), pneumonia and other severe infections, asphyxia, and difficulties in the transition from fetal to neonatal life can all result in hypoxemia. Yet, despite its importance in acute severe illnesses, hypoxemia is often not well recognized or managed in settings where resources are limited. It is therefore important for health workers to know the clinical signs that suggest the presence of hypoxemia and how supplemental oxygen can appropriately be used as an essential lifesaving treatment [1].

A flow splitter allows the output of a concentrator or other oxygen source to be split between multiple patients while independently monitoring and adjusting each flow rate. Each of the outputs should measure from 0-2 liters per minute (LPM or L/min) and should have the same FiO2 as the source gas it is attached to. Please see below for further considerations.

When using an oxygen concentrator or oxygen with neonates, low flow is critical in order to avoid preventable disability including retinopathy of prematurity (ROP) and chronic lung disease. A significant number of preventable childhood blindness due to ROP in low- and middle-income countries (LMIC) has been documented [2,3]. Importantly, this is observed in children at higher birthweights and gestational ages than children in high-income settings, suggesting an association with rapid expansion of neonatal care, perhaps without adequate attention to the quality of care or harms of oxygen administration. Neonatal units seeking to provide comprehensive care should consider the procurement of splitters and flow meters with precision adjustment at a minimum of 0.1 - 0.125 L/min. As health facilities advance, introduction of microcalibrated flow meters with precision finer than 0.1 L/min or oxygen blenders should be considered [4].

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DEVELOPING A TARGET PRODUCT PROFILE

Overview

Manufacturers need Target Product Profiles (TPPs) at an early stage in the medical device and diagnostic development process. These TPPs help inform the ideal targets and specifications and align with the needs of end users. TPPs outline the most important performance and operational characteristics as well as pricing. In the TPPs to follow, the term "Minimal" is used to refer to the lowest acceptable output for a characteristic and "Optimal" is used to refer to the ideal target for a characteristic. The Optimal and Minimal characteristics define a range. Products should meet at least all of the Minimal characteristics and preferably as many of the Optimal characteristics as possible. TPPs should also specify the goal to be met (e.g. to initiate treatment), the target population, the level of implementation in the healthcare system and the intended end users.

For the NEST360° Newborn Care in Low-Resource Settings Target Product Profiles, an initial set of TPPs were developed listing a proposed set of performance and operational characteristics for 16 product categories. The development timeline envisioned in the TPPs was four years, although some commercially available technologies may fit some of the criteria already. For several of the characteristics, only limited evidence was available and further expert advice was sought from additional stakeholders.

Delphi-Like Process

To obtain this expert advice and to further develop the TPPs, a Delphi-like process was used to facilitate consensus building among stakeholders. The initial TPPs were sent to a more comprehensive set of stakeholders including clinicians, implementers, representatives from Ministry of Health, advocacy organizations, international agencies, academic and technical researchers and members of industry. In total, 103 stakeholders from 22 countries participated in the TPP development process via survey.

17 respondents participated in the Delphi-like survey for the Flow Splitter.

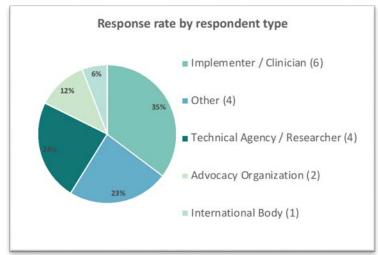
Survey respondents were requested to provide a statement on their level of agreement with each of the proposed characteristics for each TPP. Agreement was scored on a Likert scale ranging from I to 5 (I=disagree, 2=mostly disagree, 3= neither agree nor disagree, 4=mostly agree, 5=fully agree) with an option to opt out with the selection of "Other - Do not have the expertise to comment". If participants did not agree with the characteristic (i.e., selected 3 or below) they were asked to provide an explanation with comments. Participants who agreed with the statements could also provide comments however were not explicitly asked. In total, over 1,780 comments were reviewed and summarized in this report.

For each characteristic in each product category, a percentage agreement was calculated for both the Minimal and Optimal requirements. The percentage agreement was calculated as the ratio of the sum of number of respondents who selected 4 and 5, to the sum of numbers of respondents who gave any score (from 1 to 5 where 5=fully agree, 4=mostly agree, 3=neither agree nor disagree, 2=mostly disagree and 1=disagree). Consensus for the survey characteristics was pre-specified at greater than 50% of respondents providing a score of at least 4 on the Likert scale.

A classic Delphi process requires at least two rounds of survey ahead of an in-person meeting. Initially, two rounds of the survey were planned, but since 50% consensus for most characteristics was reached after the first round survey, a second round survey was not initiated. Survey results are detailed by characteristic in the individual product category sections.

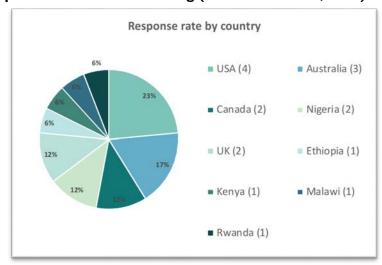
In total, over 180 organizations/individuals were asked to participate in this Delphi-like survey process, of whom 103 (see Appendix A) responded (response rate, 56%). Survey respondents were asked to self-disclose their affiliation.

Figure 1: Summary of organizational affiliation for Flow Splitter TPP from Delphi-like Survey prior to Consensus Meeting (data as of Oct 25, 2019)



Respondent type	Percentage
Implementer / Clinician (6)	35%
Other (4)	24%
Technical Agency / Researcher (4)	24%
Advocacy Organization (2)	12%
International Body (1)	6%

Figure 2: Summary of response rate by country for Flow Splitter TPP from Delphi-like Survey prior to Consensus Meeting (data as of Oct 25, 2019)



Country	Percentage
USA (4)	24%
Australia (3)	18%
Canada (2)	12%
Nigeria (2)	12%
UK (2)	12%
Ethiopia (1)	6%
Kenya (1)	6%
Malawi (1)	6%
Rwanda (1)	6%

Consensus Meeting

On November 20 - 22, 2019 over 69 stakeholders gathered in Stellenbosch, South Africa to focus on building further consensus on areas of discrepancy in opinion within the 16 TPPs. More specifically, characteristics on which fewer than 75% of the respondents agreed, or on which a distinct subgroup disagreed, were discussed. Consensus Meeting moderators presented the results and comments from characteristics with <75% agreement from the Delphi-like survey, the moderators then solicited additional feedback on each characteristic with <75% agreement from the Consensus Meeting participants, and then a proposed change to the TPP characteristic was discussed amongst Consensus Meeting participants. In some cases, Consensus Meeting participants nearly universally agreed on proposed changes. In other cases, Consensus Meeting participants failed to reach 75% consensus on proposed changes. If consensus was not achieved after two votes on proposed changes, meeting participants agreed to move forward and the disagreement is noted in this report.

Methodology for Mentimeter Voting Results: Certain proposed changes to TPP characteristics, for which a distinct subgroup disagreed, were anonymously voted on using Mentimeter.com to determine the overall level of agreement and disagreement amongst the Consensus Meeting participants. The Mentimeter Voting Results are presented throughout this report in three distinct categories:

- I. Overall vote – Includes all Consensus Meeting participants who voted on Mentimeter.com. To eliminate the possibility of duplicate votes, all respondents were asked to enter their name (to be viewed only by the report authors) and blank (potentially duplicate votes) were eliminated from the overall vote.
- II. Clinicians – Includes all Consensus Meeting participants who voted on Mentimeter.com and who designated themselves as a Clinician on Mentimeter.com.
- III. Excluding involvement with product development - Includes all Consensus Meeting participants who voted on Mentimeter.com minus those who indicated on a Declaration of Interest form that they are 'currently or have been involved in the development of a candidate technology or product' specific to the Product Category being voted on.

Of the 133 stakeholders that were invited to the meeting, 69 participants were able to attend. Participants comprised country representatives, stakeholders from technical and funding agencies, researchers, implementers and civil society organizations, and representatives from companies working on newborn care technologies (see Appendix B for the Consensus Meeting Participant List). An overview of the discussion for Oxygen Concentrator and final consensus achieved is included in this report. Most characteristics discussed are presented in this report, however, overarching characteristics that applied to all product categories were discussed in unison and are included in the NEST360° Newborn Care in Low-Resource Settings Target Product Profiles. These characteristics are: Target Operator; Target Population; Target Setting; Quality Management; Regulation; User Manual/Instructions; Warranty; Power Source; Battery; Voltage; Power Consumption.

Flow Splitter

FINAL TPP - FLOW SPLITTER

Final target product profile for Flow Splitter						
Characteristic	Optimal	Minimal				
SCOPE						
Intended Use	To allow multiple patients to receive individually adjusted flow rates from a single source of oxygen					
Target Operator	For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians					
Target Population	Neonates (born at any gestational age a	and require ongoing care)				
Target Setting	Hospitals in low-resource settings, but, may be used in health facilities based on country guidelines	Hospitals in low-resource settings				
SAFETY AND STANDARDS						
Quality Management	ISO 13485:2016 Medical devices – Quality management systems Requirements for regulatory purposes					
Regulation	At least one of: CE marking, approved by US FDA or another stringent regulatory body of a founding member of IMDRF (e.g., Japan or Australia or Canada)					
TECHNICAL CHARACTERISTICS						
Air Flow per Patient	0-2 L/min					
Flow Control	Each patient has individually controlled flow rate					
Number of Outputs	5	2				
Indication	Each flow rate has a visual indicator					
PURCHASING CONSIDERATIONS						
Instrument Pricing	<\$100 ex-works <\$600 ex-works					
TRAINING AND MAINTENANCE						
Maintenance	No/minimal maintenance					

¹ There was not 75% voting agreement on the Minimal characteristic. Please refer to the TPP Report discussion for additional detail.

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Consensus Meeting Summary: Flow Splitter

To arrive at the final TPP for Flow Splitter, we conducted a pre-meeting survey to prioritize the items for discussion at the Consensus Meeting for characteristics that achieved below 75% agreement in the survey results. An overview of the discussion at the Consensus Meeting of these characteristics is included below.

Instrument Pricing

- There was disagreement on the Minimal characteristic for instrument pricing as it was dependent on the number of splitters included in the device. Participants noted that there is a wide range of commercial products available ranging in price from \$80 \$600. Accuracy implications remain a key concern for neonatal use. Product developers noted that ISO and CE Mark certification will require that Flow Splitter covers 30-40% accuracy, however, this may increase the price to the \$600 mark with 5 ranges included. Therefore, a tradeoff exists in the current market whereby a cost reduction would be at the expense of accuracy. One basic work-around discussed at the hospital level was to utilize an oxygen monitor which can cost around \$150 but may be used for multiple use-cases.
- Minimal: <\$600 ex-works
 - Overall Vote 82% Agree (n = 22)
 - Clinicians 79% Agree (n = 14)
 - Excluding involvement with product development 82% Agree (n = 22)

Broad Themes and Considerations

At the Consensus Meeting, the following additional themes emerged and are summarized below:

Instrument Pricing

In order to provide a consistent measure of pricing, the ex-works price is included in the TPPs. Participants highlighted that ex-works pricing is not a true measure of landed cost and is often vastly understated to what a procurement agent will pay. One participant from an international NGO noted that there is a "minimum 30% mark-up on the ex-works price." The rationale for using the ex-works price is that it is a reliable measure that can be used for consistent comparison across geographies since distributor markups vary by country and geography.

Utility Requirements

A significant portion of the discussion was devoted to deliberating on how equipment can be designed to work in health facilities with limited electrical infrastructure. Designing the equipment for low-resource conditions often requires back-up batteries which adds to the expense of the technology, as well as the size of the equipment which can pose a challenge in crowded newborn wards. Some participants noted that rather than designing equipment for these facilities with limited electrical infrastructure, to consider whether a broader investment in electrical infrastructure would be a better use of funds. This inherent tradeoff was discussed multiple times when electrical characteristics were discussed.

Additionally, there were a variety of characteristics in the initial survey that related to Utility Requirements (i.e., electricity and power) that varied slightly in title across the TPPs. During the TPP Consensus Meeting, participants agreed that all characteristics relating to Utility Requirements (includes Back-up Battery; Battery Power; Batteries; Voltage; Power Requirement; Maximum Power Consumption; Response During Power Outage; Surge Protection, Electrical Plug) be reviewed and harmonized following the TPP meeting across the product categories. These characteristics have since been reviewed and harmonized into four distinct characteristics (Power Source, Battery, Voltage, and Power Consumption) in the final TPPs.

- **Power Source** This defines the desired power source for the device and can be broken down into the following categories:
 - o Mains power device must be plugged into a mains power source for use
 - Mains with battery backup device must be plugged into a mains power source for use, however, in the case of a power failure, the device has a battery backup that can last a specified period of time
 - Mains with rechargeable battery device has a rechargeable battery that operates both when the
 device is charged by a mains power source, or, when the device is plugged in (e.g., a mobile
 phone)

- o Battery is disposable and replaceable
- No power required (i.e., disposable device)
- Battery This includes the length of time the rechargeable or disposable battery should function
- Voltage This specifies the preferred voltage conversion if the Power Source utilizes Mains Power. Note that for certain technologies (i.e., Bilirubinometer, Glucometer, Hemoglobinometer, pH monitor, and Pulse Oximeter), the Voltage characteristic is included in reference to the rechargeable battery charger requirements. For example, while the Optimal Voltage characteristic is "None" (i.e., no charging is necessary), the Minimal Voltage characteristic should conform to "the voltage and frequency of the purchasing country's local power grid (e.g., 110-120 VAC at 60 Hz or 220-240 VAC at 50 Hz)" to ensure that the charger for the battery is compliant.
- **Power Consumption** This specifies the maximum Watts of electricity that the device should consume

Ideally, all devices should be developed to withstand power surges and voltage spikes.

Note that comments received in the Pre-Meeting survey report highlighted the importance of the correct frequency in electrical plugs. It was noted that a universal adaptor would not safely support the conversion of 60Hz equipment to 50Hz and that a machine relying on this method could fail in a short period of time (applicable to Oxygen Concentrator, Warming Crib, Radiant Warmer).

Delphi-like Survey: Flow Splitter

Delphi-like survey results for Flow Splitter TPP prior to Consensus Meeting (data as of Oct 25, 2019)

	Optimal		Minimal		
Characteristic	Optimal requirement	% agreement (n size)	Minimal requirement	% agreement (n size)	Collated comments from Delphi-like survey
Intended Use	Optimal: To allow multiple patients to receive individually adjusted flow rates from a single oxygen source.	94% n = 17	Minimal: Same as Optimal.	94% n = 16	Recommended for neonatal and low flow oxygen as per interagency oxygen therapy guide Preference for low-pressure piping and a separate flow meter beside each bed rather than a flow splitter and having the flow meters far from the patients
Target Operator	Optimal: For use in low- and middle-income countries by a wide variety of clinicians, including nurses, clinical officers, and pediatricians.	100% n = 16	Minimal: Same as Optimal	100% n = 15	0 comments
Target Population	Optimal: Neonates (<28 days)	94% n = 16	Minimal: Same as Optimal.	93% n = 15	Theme: Broaden Age Range For sick and small newborns likely need different precision of flow adjustment but same over all flow range

	Optimal		Minir	mal	
					as you need for infants; Change to 6 months of age Any child requiring oxygen
Target Setting	Optimal: Hospitals in low-resource settings	100% n = 13	Minimal: Same as Optimal.	100% n = 12	Theme: Broaden Target Setting Optimally, it would be good to have a flow splitter for transport / referrals Optimal should be health centres (primary)
International Standard	Optimal: ISO 13485:2016 Medical devices – Quality management systems Requirements for regulatory purposes.	100% n = 8	Minimal: Same as Optimal.	100% n = 7	2 comments
Regulation	Optimal: CE marking or US FDA Clearance	83% n = 12	Minimal: Same as Optimal.	82% n = 11	6 comments as summarized below Theme: Add more flexibility v. irrelevance of characteristic Consider additional 'or' options: Other Stringent Regulatory Authorities – Japan or Australia or Canada Consider regulatory bodies of Low- and Middle-Income Countries
Air Flow per Patient	Optimal: 0-2 L/min	81% n = 16	Minimal: Same as Optimal.	93% n = 15	5 comments as summarized below Theme: Confusion as to total Air Flow per patient versus capacity of total Flow Splitter • 3-5 flow meters and max total of 10 LPM Theme: Want more than 2 L/min (for older children) • 3 L/min • 5 L/min Theme: Confusion as to role of Flow Splitter versus Flow Meter on Oxygen Concentrator TPP • Add resolution in increments on .25 LPM
Flow Control	Optimal: Each patient has individually controlled flow rate.	94% n = 16	Minimal: Same as Optimal.	93% n = 15	3 comments

	Optimal		Mini	mal	
Number of Outputs (corrected from 'Pressure')	Optimal: 5	94% n = 16	Minimal: 2	100% n = 15	6 comments as summarized below Theme: Consider a range vs. an absolute Optimal: >2 Minimal: At least 2
Indication	Optimal: Each flow rate has a visual indicator.	100% n = 16	Minimal: Same as Optimal.	100% n = 15	0 comments
Maintenance	Optimal: No/minimal maintenance.	87% n = 15	Minimal: Same as Optimal.	87% n = 15	4 comments as summarized below Routine cleaning with regularly available cleaning products Need to add Inlet filter to Optimal Preference for ability to replace individual flow meters
Instrument Pricing	Optimal: <\$100 ex-works	93% n = 15	Minimal: <\$600 ex-works	64% n = 14	6 comments as summarized below Theme: Specify capacity of splitter (e.g. \$600 for 5 user splitter) Theme: Range of prices suggested for Minimal

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APPENDICES

Appendix A: Delphi-like Survey Respondent Organizational Designation

3rd Stone Design

Abuja University Teaching Hospital

Alex Ekwueme Federal University Teaching Hospital Abakaliki

Baylor College of Medicine

BC Children's Hospital

Burnet Institute

CCBRT Dar es Salaam

CENETEC-Salud

Center for Public Health and Development (CPHD)

Children's Hospital of Philadelphia

Christian Medical College, Vellore

Clinton Health Access Initiative

College of Medicine, University of Lagos

College of Medicine, University of Malawi

Dartmouth

Day One Health

Diamedica UK Ltd

D-Rev

Egerton University - Nakuru County Referral Hospital

ETH Zurich

Fishtail Consulting

FREO2 Foundation Australia

Global Strategies

Hawassa University

Independent Biomedical Engineer

Institute for Healthcare Improvement

intelms.com

Kamuzu Central Hospital

Kamuzu College of Nursing

Kemri-Wellcome Trust

Kenya Paediatric Association

Komfo Anokye Teaching Hospital

Malawi-Liverpool Wellcome Trust

Mama Lucy Hospital

Masimo

Mbarara University of Science and Technology

McGill University Health Centre

McMaster University

Medecins Sans Frontieres

Mediquip Global Limited

Ministry of Health, Senegal

mOm Incubators

MRC Gambia at LSHTM

Muhimbili National Hospital

Muhimbili University of Health and Allied Sciences (MUHAS)

Neopenda

No designation listed (10)

Pediatric and Child Health Association in Malawi

Pumwani Hospital
Queen Elizabeth Central Hospital
Rice 360 Institute for Global Health
Royal Children's Hospital and Centre for International Child Health (University of Melbourne)
Save The Children
Texas Children's Hospital
The University of Queensland
UCSF and London School of Hygiene & Tropical Medicine
UNICEF
University of Alabama at Birmingham
University of British Columbia
University of Global Health Equity
University of Maiduguri Teaching Hospital, Maiduguri
University of Nairobi
UNTH, Enugu

Appendix B: Consensus Meeting Participation

Albert Manasyan (University of Alabama Birmingham)

Anna Worm

Antke Zuechner (CCBRT)

Audrey Chepkemoi (Moi Teaching and Referral Hospital)

Bentry Tembo (Kamuzu Central Hospital)

Bev Bradley (UNICEF)

Casey Trubo (D-Rev)

Chishamiso Mudenyanga (Clinton Health Access Initiative)

Danica Kumara (3rd Stone Design)

Daniel Wald (D-Rev)

Edith Gicheha (Kenya Pediatric Research Consortium)

Emily Ciccone (University of North Carolina - Chapel Hill)

Emmie Mbale (PACHA)

Grace Irimu (University of Nairobi)

Guy Dumont (The University of British Columbia)

Helga Naburi (Muhimbili National Hospital)

Jeffrey Pernica (McMaster University)

John Appiah (Kumfo Anokye Teaching Hospital)

Jonathan Strysko (Children's Hospital of Philidelphia/Princess Marina Hospital)

Joy Lawn (London School of Hygiene and Tropical Medicine)

Lincetto Ornella (WHO)

Liz Molyneux (College of Medicine, Malawi)

Lizel Lloyd (Stellenbosch University)

Mamiki Chise

Marc Myszkowski

Maria Oden (Rice University)

Martha Franklin Mkony (Muhimbili National Hospital)

Martha Gartley (Clinton Health Access Initiative)

Mary Waiyego (Pumwani Maternity Hospital)

Matthew Khoory (mOm Incubators)

Melissa Medvedev (University of California, San Francisco; London School of Hygiene and Tropical Medicine)

Msandeni Chiume (Kamuzu Central Hospital)

Naomi Spotswood (Burnet Institute)

Norman Lufesi (Ministry of Health Malawi)

Pascal Lavoie (University of British Columbia)

Queen Dube (College of Medicine, Malawi)

Rachel Mbuthia (GE Healthcare)

Rebecca Richards-Kortum (Rice University)

Rhoda Chifisi (Kamuzu Central Hospital)

Rita Owino (GE Healthcare)

Robert Moshiro (Muhimbili National Hospital)

Ronald Mbwasi (Kilimanjaro Christian Medical Centre)

Sam Akech (KEMRI-Wellcome Trust Research Programme)

Sara Liaghati-Mobarhan (Rice University)

Sona Shah (Neopenda)

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Appendix C: Abbreviations

°C Degrees Celsius

bCPAP

bpm

Beats per minute / Breaths per minute

CE Mark

Conformité Européenne – certification mark

 $\begin{array}{cc} cm & Centimeters \\ cm^2 & Centimeter squared \end{array}$

CRP C-reactive protein
CPAP Continuous positive airway pressure
DHS Demographic and health survey

DHS Demographic and health survey
FDA Food and Drug Administration
HIS Health information system

Hz Hertz

IMR Infant mortality rate

ISO International Standards Organization

IV Intravenous

KMC Kangaroo Mother Care

kg Kilogram

LPM Liters per minute
LRS Low-resource settings
MCH Maternal and child health
MDG Millennium Development Goal

Mg/dL Milligrams per deciliter
mL/hr Milliliters per hour
mmol/L Millimoles per liter
µmol/L Micromoles per liter
MMR Maternal mortality rate

MNCH Maternal, newborn, and child health

MNH Maternal and neonatal health

nm Nanometer

NMR Neonatal mortality rate

PCT Procalcitonin

PEEP Positive end-expiratory pressure

PR Pulse rate

RDS Respiratory distress syndrome
ROP Retinopathy of prematurity
SpO2 Peripheral saturation of oxygen
SDG Sustainable Development Goal

TFR Total fertility rate
U5MR Under-5 mortality rate

UNFPA United Nations Population Fund

USAID U.S. Agency for International Development

uW Micro Watts W Watt

WHO World Health Organization