OPEN ACCESS

Newborn care technology investments for LMIC settings: a CPAP approach

Bolanle Aishat Kasali ,[1] Anisha Gururaj,[2] Maneesh Batra[3,4]

[1]Maternal, Newborn and Child Health Discovery and Tools, Global Health Division, Bill and Melinda Gates Foundation, Seattle, Washington, USA
[2]Maternal, Newborn and Child Health Discovery and Tools, Bill and Melinda Gates Foundation, Seattle, Washington, USA
[3]Division of Neonatology, Seattle Children's Hospital, Seattle, Washington, USA
[4]Department of Pediatrics, Division of Neonatology, University of Washington School of Medicine, Seattle, Washington, USA

Correspondence to
Dr Bolanle Aishat Kasali, Maternal, Newborn and Child Health Discovery & Tools, Global Health Division, Bill and Melinda Gates Foundation, Seattle, WA 98119, USA; Aisha.kasali@gatesfoundation.org

Accepted 18 February 2021
Published Online First 7 April 2021

To cite: Kasali BA, Gururaj A, Batra M. *BMJ Innov* 2021;**7**:519–522.

Globally, it is estimated that 15 million babies are born prematurely each year. Approximately one million of these newborns die due to complications of preterm birth, and these deaths occur disproportionately in low/middle-income countries (LMICs).[1] Respiratory distress syndrome (RDS) is a common cause of death among those born preterm, and continuous positive airway pressure (CPAP) has been established as an effective therapy for reducing mortality and morbidity from RDS among preterm neonates.[2] Unfortunately, the high cost of conventional CPAP devices has limited its availability in low-resource settings.[3] To fill this gap, multiple low-cost, effective and safe CPAP devices have emerged, although this space remains an area for active innovation and development. In this paper, we focus on the use of the target product profile (TPP) as a tool for aligning innovators and other stakeholders for product innovation. As a funding organisation, we are invested in the implementation of technology products that improve health outcomes at scale. We have observed the presence of multiple CPAP products without clear alignment on the key features and specifications, nor the systemic and delivery factors required for successful implementation.[4] This has resulted in a major barrier to large scale uptake and implementation of CPAP devices for the treatment of RDS in preterm infants in LMICs.

Newborn technology design for respiratory distress can be done in a purposeful way. While clinical guidelines and recommendations on the clinical use of CPAP for newborn care are available, there is insufficient guidance to align innovators, investors and other stakeholders developing new product prototypes. The WHO (2015) issued a recommendation on the use of CPAP for the treatment of preterm newborns with RDS immediately on diagnosis. It includes provision of blended oxygen, monitoring of oxygen saturation and cardiorespiratory status, and use in facilities that can provide quality care to support newborns,[5] as well as guidance on the core components of a home-made, or improvised bubble CPAP device.[6] The recently released WHO standards for improving care for small and sick newborns also established CPAP as a treatment for newborns diagnosed with respiratory distress.[7] In addition to this, we believe further guidance should be provided to innovators to guide technical design specifications and key considerations requisite for CPAP implementation in low-resource settings. This is critical to identifying where further innovation is needed, as well as to align the community on effective use of CPAP across geographies and health systems to ensure sustainable impact. The TPP may be a useful tool to create this alignment and guide stakeholders who are keen to innovate in this space.

In the last decade, the global health development sector has increasingly adopted the use of TPPs in product development for public health priority diseases in low-resource settings.[8] The TPP is a strategic planning tool that defines the minimum and optimistic criteria or characteristics for a product to meet the needs of its target users or population.[8] Establishing a TPP is useful for setting priorities to inform technology conceptualisation for public good.[9] Furthermore, it articulates the intent and critical attributes of a product to guide research and development goals., It is vital for innovators to consider developing their own TPP or using publicly available TPPs when developing their product as a benchmark for consideration of all relevant product attributes. For example, UNICEF in collaboration with NEST 360 have developed

TPPs for 16 different key newborn product categories, including CPAP.[10]

For funders, investors and programme implementers to better understand and segment the commercial landscape a TPP can help to identify where there may be gaps and barriers in the products needed to drive scale and global impact. For example, with CPAP, using a TPP framework can help organise the product landscape into archetypes which may serve competing or complementary roles across a health system. It provides strategic insights to optimise and guide CPAP product innovation while ensuring access, affordability and equity, and provides clarity on the critical attributes that are needed to tackle global health challenges especially in resource-limited settings. We assessed seven different devices across three geographies including Sub-Saharan Africa, South Asia and North America. The three main archetypes of CPAP products we have observed are described by features in table 1. They include (1) low-cost, unbundled CPAP consisting of improvised or home-made bubble CPAP, or improvised bubble CPAP with enhanced components (eg, oxygen blender), (2) medium cost, integrated or

Table 1 Continuous positive airway pressure (CPAP) product archetype comparison

	Low-cost, unbundled CPAP devices			
Features	**Improvised/home-made CPAP**	**Improvised CPAP with enhanced components**	**Medium cost, bundled CPAP**	**High cost, bundled CPAP**
Intended use	Initial treatment of newborns with respiratory distress			
CPAP generator	Yes	Yes	Yes	Yes
Air flow	Requires external air flow source	Requires external air flow source	Generates own air flow source	Requires external air flow source
Oxygen source	Requires external oxygen and/or air source	Requires external oxygen and/or air source	Requires external oxygen source, but has integrated air source	Requires external oxygen and/or air source
Oxygen blender	No	Yes, but not all	Yes, some may measure FiO_2	Yes, can measure FiO_2
Oxygen saturation/FiO_2 measurement	Requires pulse oximetry to monitor saturation but no FiO_2 regulation available	Requires pulse oximetry to monitor saturation and regulate FiO_2 level	May require pulse oximetry to monitor saturation Some devices allow FiO_2 to be set directly without manual calculations by user *One device is known to have an integrated pulse oximeter	Requires pulse oximetry to monitor saturation, FiO_2 may be set directly without manual calculations by user *One device is known to have an integrated pulse oximeter
Humidification	Relies on ambient humidity	Relies on ambient humidity; passive humidification	May rely on ambient or have passive or active heated humidification	Heated humidification system
Patient interface	Any nasal prongs	Any nasal prongs	May use custom-made or standard Hudson prongs	May use custom-made or standard Hudson prongs
Tubing or circuit limbs	Standard wide bore tubing, inspiratory and expiratory circuit	Standard wide bore tubing, inspiratory and expiratory circuit	May use custom-made or Standard wide bore tubing, inspiratory and expiratory circuit *One device is known to have controlled heated inspiratory circuit	Insulated tubing and heated breathing circuit
Internal performance monitoring	No internal performance monitoring system: bubbling of water in CPAP generator chamber may be used as an indicator	No internal performance monitoring system: bubbling of water in CPAP generator chamber may be used as an indicator	May include audio/visual alarm notification system	May include audio/visual alarm notification system
Power and battery	Does not require electricity except used with oxygen concentrator	Does not require electricity except used with oxygen concentrator	Requires electricity, may include backup battery,	Requires electricity
Cost	US$1–4. Does not include cost of O_2 concentrator and other consumables	US$100–200. Does not include cost of O_2 concentrator	US$1000–2000. May or may not include cost of consumables	US$3000–6000
Regulatory approval	N/A	CE mark possible	CE mark	CE mark
Product Examples		(i)VAYU CPAP (ii)PATH (KIWOKO) CPAP	1. Pumani (NEST) CPAP 2. Equalise Health (D-REV) nCPAP 3. Polite CPAP	1. Fisher-Paykel bubble CPAP 2. Dolphin MTTS

*This was not intended as an exhaustive list of examples of continuous positive airway pressure (CPAP) products. The authors do not endorse or critique any of the listed products but only highlight them for illustrative purposes.

bundled CPAP devices, and (3) high-cost, integrated or bundled bubble CPAP devices.

These range of options might suggest that needs in this space are fulfilled; however, it is important to consider how each of the different categories of devices are suited for different segments within a health system. For example, depending on available resources, funding and support for newborn care in a given health system—a facility with consistent supply of wall oxygen and existing pulse oximetry monitoring tools may benefit from the use of improvised devices with oxygen blender; however, another facility may need an integrated device due to inconsistent availability of piped oxygen, lower patient to nursing ratio and vital signs monitoring. In another scenario, facilities may need to supplement occupied automated or commercial devices with the use of improvised devices when patient demand outweighs supply of devices. This may lead to decisions regarding which babies should receive treatment from a specific device and brings to light the ethical considerations that healthcare workers in this situation face daily.[11]

In addition to product specific technical requirements, understanding barriers and facilitators of widespread use and implementation of the device need to be carefully considered and addressed. For example, the presence of limited bedside personnel and understaffing of neonatal units may preclude the ability of health staff to rigorously monitor each infant on CPAP, as well as limit the amount of time available for trainings.[4] This emphasises the need to design products that are integrated with automated capabilities and intuitive user interfaces, require minimal maintenance and are universally compatible with available consumables. Also, the availability of different types of devices may inadvertently limit utilisation and scale up due to the need to train staff on the set up, use and maintenance of varying devices in settings that are chronically understaffed.[4]

Furthermore, affordability is of utmost importance for market penetration and scalability in settings where the cost of devices remains out of reach.[12] Total costs include more than the device itself, but also the costs of maintenance, wrap-around support, training, consumables and health worker time. Innovators need to factor in these additional costs when establishing target device cost per unit as it has dire implications on sustainability and long-term use.

To drive investment considerations, understanding of the drivers of healthcare worker behaviour, systemic issues that limit implementation such as availability of oxygen and constant supply of electricity,[13] health ministry prioritisation of newborn health including flow of funds and procurement process for newborn care packages across the health system or facility level, tradeoff between needs such as purchasing essential medicines and supplies versus tools and devices, procurer choice of which CPAP device to purchase based on perceived value proposition of the device. All of these affect the design and ultimate uptake of CPAP and ancillary newborn care technologies and are necessary prerequisites when considering investments in a new product.

Other key factors to be considered include the commercialisation and distribution plan; current distribution channels for newborn care equipment are fragmented, with limited interests from commercial manufacturers and distributors to engage in the space due to smaller market size, low profit margins and high requirements for maintenance support. Leveraging existing distribution networks by partnering with local manufacturers and/or regional distributors for commercialisation is critical for scale. Having all these components in place is necessary to drive substantial investments in new product development. Investments in newborn care technology could help save millions of newborns around the world. Fortunately, the newborn technology space is rapidly improving, and the criteria set in the TPP on the product, such as cost, ease-of-use and target population or use case could play a pivotal role in effecting impact at scale. We propose the widespread use of a global health TPP when considering product innovation in newborn care technology, using CPAP as an example. We also emphasise the need to consider local systemic factors including affordability, health worker training, procurement policies, as well as scale and commercialisation strategy during product development. These factors are important for driving further investments towards maximal impact for newborn care in LMIC settings.

Twitter Bolanle Aishat Kasali @Aisha Kasali

Contributors BAK conceptualised and codesigned the study, drafted the initial manuscript and reviewed and revised the manuscript. All authors codesigned, coordinated and critically reviewed the manuscript for important intellectual content. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Funding This work was supported by Bill and Melinda Gates Foundation.

Competing interests BAK and AG have no competing interests to disclose. MB is involved in the development of the PATH (KIWOKO) CPAP device: one of the CPAP product examples listed in table 1.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD
Bolanle Aishat Kasali http://orcid.org/0000-0003-4525-893X

REFERENCES

1 Lawn JE, Kinney MV, Belizan JM, *et al*. Born too soon: accelerating actions for prevention and care of 15 million

newborns born too soon. *Reprod Health* 2013;10 Suppl 1:S6.
2 Thukral A, Sankar MJ, Chandrasekaran A, *et al*. Efficacy and safety of CPAP in low- and middle-income countries. *J Perinatol* 2016;36 Suppl 1:S21–8.
3 Dewez JE, van den Broek N. Continuous positive airway pressure (CPAP) to treat respiratory distress in newborns in low- and middle-income countries. *Trop Doct* 2017;47:19–22.
4 Kinshella M-LW, Walker CR, Hiwa T, *et al*. Barriers and facilitators to implementing bubble CPAP to improve neonatal health in sub-Saharan Africa: a systematic review. *Public Health Rev* 2020;41:6.
5 WHO Library Cataloguing-in-Publication Data. *Who recommendations on interventions to improve preterm birth outcomes*. World Health Organization, 2015. ISBN: 978 92 4 150898 8.
6 WHO Library Cataloguing-in-Publication Data. *Oxygen therapy for children: a manual for healthcare workers*. World Health Organization, 2016. ISBN: 978 92 4 154955 4.
7 World Health Organization. *Standards for improving quality of care for small and sick newborns in health facilities*. Geneva: World Health Organization, 2020.
8 Terry RF, Plasència A, Reeder JC. Analysis of the Health Product Profile Directory - a new tool to inform priority-setting in global public health. *Health Res Policy Syst* 2019;17:97.
9 Brooks A, Nunes JK, Garnett A, *et al*. Aligning new interventions with developing country health systems: target product profiles, presentation, and clinical trial design. *Glob Public Health* 2012;7:931–45.
10 UNICEF. Nest 360. target product profiles for newborn care in low-resource settings (v1.2) consensus meeting report, 2020. Available: https://www.unicef.org/supply/sites/unicef.org.supply/files/2020-04/TPP-newborn-care-final-report-v1-2.pdf
11 Ntigurirwa P, Mellor K, Langer D, *et al*. A health partnership to reduce neonatal mortality in four hospitals in Rwanda. *Global Health* 2017;13:28.
12 Kawaza K, Machen HE, Brown J, *et al*. Efficacy of a low-cost bubble CPAP system in treatment of respiratory distress in a neonatal ward in Malawi. *PLoS One* 2014;9:e86327.
13 Aneji C, Hartman T, Olutunde O, *et al*. Implementing bubble continuous positive airway pressure in a lower middle-income country: a Nigerian experience. *Pan Afr Med J* 2020;37:10.