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An integrated diagnostic device for neonatal sepsis and childhood pneumonia

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Globally, among the 5.6 million annual under-5 child deaths, roughly 1.28 million die due to pneumonia and neonatal sepsis.[1] Neonatal sepsis is difficult to differentiate clinically, therefore, WHO classifies infants 0-59 days of age (young infants) who have fever (>38°C), hypothermia or low body temperature (<35.5°C), fast breathing (≥60 breaths per minute), severe chest indrawing, not feeding well, convulsions, and no spontaneous movements as *possible serious bacterial infection* (PSBI).[2] Neonates with PSBI are at high risk of mortality, which can be prevented by early diagnosis and by prompt and effective treatment with antibiotic. While pneumonia kills approximately 935,000 children <5 years of age each year,[3] the mortality risk becomes higher when pneumonic child has also hypoxemia (defined as oxygen saturation rate, SPO_2, <90%)[4] and remains without oxygen therapy. Pulse oximetry can measure hypoxemia, by measuring oxygen saturate (SPO_2), non-invasively to identify young children in need of oxygen, yet it is currently not routinely available in hospital outpatient clinics and non-existent in peripheral health facilities or at community levels in resource-limited settings.

The WHO's IMCI guideline necessitates counting respiration, measuring temperature and using pulse oximeter (PO) to determine oxygen saturation (SpO2) in order to identify very sick children, including neonates (with fast breathing, and/or fever and/or hypothermia, and/or SpO2<90%) and refer them to a hospital for immediate treatment. Furthermore, the IMCI guidelines recommend immediate referral to a hospital for management of PSBI in neonates and young infants (0-59 days). These guidelines for management of fast breathing and serious infection in newborns clearly highlight the necessity for an integrated diagnostic tool which can be used at point-of-care by community health workers (CHWs) as well as facility health workers for accurate assessment of fast breathing, temperature and SpO_2, leading to appropriate diagnosis and treatment decisions.

Current tools for measuring respiratory rate include UNICEF's Acute Respiratory Infection (ARI) timer and other timing devices.[5] These methods have proven difficult to use, are not reliable, and result in miscounting of the child's breaths, ultimately leading to false assumptions and misdiagnosis. Across all methods, the worker needs to watch the child's chest and belly for respiration count. The main challenge of current POs is that different probes are required to cover varying age groups. Having multiple probes not only increases costs but requires high maintenance and can lead to user error. Currently there is no readily available PO with a universal probe on the market. The lack of long-lasting thermometers is another issue leading to subjective and unreliable temperature assessments.

In response to UNICEF's call for innovation of pneumonia diagnostic, our research team developed the Children's Automated Respiration Monitor (ChARM). The device is placed around the child's belly and automatically measures respiratory rate and classifies fast breathing according to WHO guidelines. The technology is based on the Intellivue cableless monitor which includes 3D accelerometry and signal processing of respiration-based biomechanics, launched in 2014 for adults and since then tailored for infants and children.[6] An intuitive user interface for ChARM has already been iteratively designed for ease-of-use and acceptance and has been evaluated in Kenya in 2016. The ChARM device is now expanded into an integrated device by adding unique peripheral capillary oxygen saturation (SpO_2) probe, pulse rate sensor and infra-red temperature sensor. This new integrated device compensates for motion artifacts and has a reusable universal probe that accommodates all ages <5 years to provide accurate SpO_2 measurement. This diagnostic device will be rechargeable via the grid and its operation time with one time charging will depend on its use. We expect it to be needing recharge after a few days (maybe a week) of normal use (~10 measurements/day). The device will be made dust and water resistant to withstand the environmental conditions in rural areas, but also ensure long-term use of 3 to 5 years.

We have proposed an innovation of expanded version of ChARM with added technology as a point-of-care diagnostic device which will assess its validity to accurately measure key vital signs (SpO2, temperature and respiration rate) among neonates, infants and children <5 years and will also conduct an assessment of usability, feasibility and acceptability of the device at health facility and community levels.

The potential public health impacts from our innovation include: i) this point-of-care diagnostic device will increase adherence to WHO's IMCI guideline for diagnosing sepsis and pneumonia among children, including newborns and young infants. ii) More accurate diagnosis will reduce burden of unnecessary use of antibiotic and thus will help reducing antibiotic resistance.

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References

1. United Nations Inter-agency Group for Child Mortality Estimation (UN IGME). Levels and Trends in Child Mortality: Report 2017. Available from: http://www.childmortality.org/files_v21/download/IGME%20report%202017%20child%20mortality%20final.pdf
2. WHO. IMCI Chart Booklet. 2014. Available from: http://apps.who.int/iris/bitstream/10665/104772/16/9789241506823_Chartbook_eng.pdf
3. Ginsburg AS, Delarosa J, Brunette W, et al. mPneumonia: Development of an Innovative mHealth Application for Diagnosing and Treating Childhood Pneumonia and Other Childhood Illnesses in Low-Resource Settings. PLoS One 2015;10:e0139625.
4. Lazzerini M, Sonego M, Pellegrin MC. Hypoxaemia as a Mortality Risk Factor in Acute Lower Respiratory Infections in Children in Low and Middle-Income Countries: Systematic Review and Meta-Analysis. PLoS One 2015;10:e0136166.
5. UNICEF. Innovation: Acute Respiratory Infection Diagnostic Aid (ARIDA). Available from: https://www.unicef.org/innovation/innovation_81722.html
6. Philips. Delivering clear information at point-of-care: Patient monitoring. Available from: http://www.healthcare.philips.com/main/products/patient_monitoring/products/intellivue_cableless/

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