Developing Wearable Technology to Measure and Promote Kangaroo Mother Care

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1. Clinical Problem: Neonatal health is a prominent area of focus among clinicians and researchers worldwide. Immense resources are invested in addressing the medical needs of neonates. These medical needs vary across countries depending on demographics, socioeconomic factors, and access to resources. India and the United States are currently facing different yet parallel neonatal crises. India bears the highest burden of neonatal deaths worldwide and has high rates of prematurity and low birth weight, while the United States struggles with an opioid epidemic that results in newborns who are born with Neonatal Abstinence Syndrome (NAS). Preterm and low birth weight infants along with newborns with NAS experience dysregulation and instability of the autonomic nervous system that lead neonates in both groups to stay in the Neonatal Intensive Care Unit (NICU). Emerging evidence shows that Kangaroo Mother Care (KMC), continuous skin-to-skin contact between the neonate and an adult, is an effective intervention for preventing neonatal mortality (section 1.1) as well as rehabilitating neonates with NAS (section 1.2).

However, there is a dearth of quantitative data in the literature surrounding the physiologic benefits of KMC and optimal implementation of KMC among these two groups of neonatal patients. Currently, the only mechanism for quantitatively recording KMC practices requires a healthcare worker to document observed frequency and duration of KMC. This time consuming activity constrains already overburdened healthcare workers in the NICU. Alternatively, a lack of proper documentation of KMC practices can result in a loss of valuable data needed to track clinical practices and enforce accountability. Unlike pharmacologic interventions, KMC requires active participation from neonates’ parents. In the context of their child’s frailty, parents may need assistance and reassurance that they are administering KMC properly. Moreover, current guidelines recommend “initiating KMC as early and for as long as possible.” These nebulous indications may cause confusion and cast KMC as an unscientific remedy. This application to develop an innovative wearable technology to measure and promote KMC is informed by preliminary work of our research team (section 2.2). We believe that the use of a medical device to investigate the impact of KMC on newborn physiology will kick start new research programs that increase KMC acceptance among clinicians, enhance parental self-efficacy for KMC administration, and lead to widespread diffusion of KMC in real world settings.

1.1 Neonatal Mortality in India
Every year worldwide, nearly three million children die during the neonatal period, the first four weeks of life. India is at the epicenter of this tragedy, accounting for one-third of all neonatal mortalities. India has the highest number of neonates born preterm or weighing less than 2,500 grams in comparison to the rest of the world. Kangaroo Mother Care refers to a combination of interventions that include early initiation of prolonged skin-to-skin contact between the neonate and an adult, as well as exclusive and frequent breastfeeding. It is estimated that Kangaroo mother care (KMC) can prevent a higher portion of preterm and low birth weight neonates from dying over the next ten years (48%) than corticosteroid administration (41%), proper antibiotics (9%), neonatal resuscitation (7%) and thermal care provision (16%). Unlike neonatal resuscitation, corticosteroid and antibiotic administration, KMC administration does not require advanced medical training. However, the promise of KMC to reduce neonatal mortality in India is unfulfilled due to suboptimal implementation.

1.2 Neonate Abstinence Syndrome in United States
Neonate Abstinence Syndrome (NAS) refers to a drug withdrawal syndrome that is common among newborns who are born to mothers who used opiates during pregnancy. Affected newborns can develop symptoms of withdrawal such as tremors, poor feeding, vomiting, and increased muscle tone. The Finnegan scoring system is commonly used to assess severity of withdrawal. Infants who are diagnosed with NAS are admitted to the NICU. Opioids are the mainstay treatment for withdrawal symptoms and the newborn stays in the NICU for several weeks until symptoms resolve and the medication is subsequently slowly weaned. The diagnosis of NAS is associated with an eight-fold increase in the NICU stay and more than 20-fold increase in the healthcare cost in U.S. Three separate case studies of KMC for newborns suffering from NAS (Finnegan score > 8) reported a drop in Finnegan score of 6 to 9 units after KMC administration. Nevertheless, KMC is not routinely recommended to parents as a key component of the treatment plan.

2. Research Team and Preliminary Work: This application is supported by a 5+ year collaboration between UMMS and Charutar Arogya Mandal, a tertiary care academic medical center in rural western India.

2.1 Research Team
Our multidisciplinary research team includes investigators with expertise in global child health, pediatrics, and epidemiology. Dr. Fahey and Mr. Soni have led design, implementation, and publication of several community-based studies in India under the mentorship of Drs. Allison and Nimblekar. Two of the investigators (Drs. Nimblekar and Rhein) head the NICUs at their respective institutions. Both have well-established protocols for facilitating KMC in their respective NICU and they...
have vested interest in advancing KMC research and clinical practice.

2.2 Barriers for widespread KMC implementation in NICU
In a study of nearly 700 neonates admitted to CAM NICU from 2010 through 2014, we found that KMC practices were improved by active involvement of a physician champion. Further follow-up about the mechanisms suggested that there are barriers for broader implementation at the provider and patient levels. Recent scholarship from implementation scientists, including a study by our group from earlier this year, has identified key steps necessary for broad implementation of KMC: 1) improving KMC surveillance in clinical settings, 2) generating a feedback mechanism to enhance parental self-efficacy for providing KMC, and 3) developing standardized KMC guidelines.

3. Study Goals: We envision a medical device made of conductive synthetic polymers printed on a wearable compression belt (Figure 1) that can 1) automatically record skin-to-skin contact between the neonate and the parent, 2) provide real-time feedback to parents about the appropriate administration of KMC, and 3) record physiological data (i.e. temperature, heart-rate variability) from the neonate. Smartwear technology offers an elegant solution for capturing various physiological measurements from newborns in a safe, non-invasive, and comfortable manner (Table 1).

Table 1: Desirable attributes of the PROMOTE-KMC device based on existing technologies

<table>
<thead>
<tr>
<th>Innovation</th>
<th>Details</th>
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<tr>
<td>Scalable</td>
<td>Embedded conductive polymers using screen-printing techniques allow for mass production. Fabric technology can allow for the device to be washed</td>
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<tr>
<td>KMC recording</td>
<td>Changes in impedance across the belt during skin-to-skin contact allows for accurate recording of KMC practice</td>
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<td>Heart Rate</td>
<td>Screen-printed sensors can collect an ECG signal, from which heart rate &amp; rhythm can be determined</td>
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<tr>
<td>Resp. Rate</td>
<td>Changes in thoracic impedance in response to breathing can be used to estimate respiratory rate</td>
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<td>Temperature</td>
<td>An infrared thermometer can record skin-surface temperature without touching the skin</td>
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<td>Sympathetic activity</td>
<td>Algorithm-based spectral analysis of electrodermal activity in eccrine glands (dispersed across the torso of the neonate) allow for consistent measurement of autonomic tone</td>
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<td>Position</td>
<td>Accelerometers embedded in the compression belt can provide positional information</td>
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<td>Safety</td>
<td>Adjustable compression belt is safe because it does not use any medical adhesives, which are uncomfortable and often result in skin stripping, tears, and blisters</td>
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<td>Data management</td>
<td>Data can be wirelessly transmitted using Bluetooth technology to a smartphone, where it is stored and displayed in an app in a parental and provider mode</td>
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3.1 List of potential collaborators
We envision collaborating with Dr. Deepak Ganesan and his team in the “Mobile and Sensor Systems” division at UMass Amherst. Members of our team met with Dr. Ganesan and his team following the 2017 annual CCTS research retreat to discuss possible opportunities for collaboration. He has expressed excitement for pursuing this collaboration utilizing their advances in smartwear technology to address this clinical problem and develop potential solutions.

4. Impact and Future Steps
At present, a portable medical device designed to seamlessly capture this data across a variety of physical environments is not available. A medical device that can achieve these goals can transform the field neonatology research and clinical practice. The “big data” generated from this device can elucidate the mechanisms of action for KMC. Feedback from the device can help parents track their KMC practices, increase their self-efficacy, and allow healthcare providers to set goals. For example, many studies have shown that continuous glucose monitoring is associated with improved HbA1c control and fewer hypoglycemic episodes. Therefore, this device can also guide KMC administration in clinical settings. Development of this device will also provide a stepping stool for seeking extramural funding to 1) assess the feasibility of using the these devices to facilitate home-based KMC and allow for early discharge of neonates suffering from NAS, 2) perform a randomized clustered trial to assess the effect of the device use in hospitals and at home to improve child growth and reduce neonatal mortality, and 3) develop clinical guidelines that indicate minimum KMC duration required to improve health outcomes across varying high-risk neonate groups. Ultimately, we anticipate this device becoming a mainstay in NICU clinical practice to guide KMC and monitor newborn physiology.
References


