

## Remote BioMonitoring of Mothers and Newborns for Temperature Surveillance Using a Smart Wearable Sensor: Techno-Feasibility Study and Clinical Trial in Southern India

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**Abstract :** The disease burden among mothers and newborns is caused mostly by a handful of avoidable conditions occurring around the time of childbirth and within the first month following delivery. Real-time monitoring of vital parameters of mothers and neonates offers a potential opportunity to impact access as well as the quality of care in vulnerable populations. We describe the design, development and testing of an innovative wearable device for remote biomonitoring (RBM) of body temperatures in mothers and neonates in a hospital in southern India. The architecture consists of: [1] a low-cost, wearable sensor tag; [2] a gateway device for 'real-time' communication link; [3] piggy-backing on a commercial GSM communication network; and [4] an algorithm-based data analytics system. Requirements for the device were: long battery-life upto 28 days (with sampling frequency 5/hr); robustness; IP 68 hermetic sealing; and human-centric design. We undertook pre-clinical laboratory testing followed by clinical trial phases I & IIa for evaluation of safety and efficacy in the following sequence: seven healthy adult volunteers; 18 healthy mothers; and three sets of babies - 3 healthy babies; 10 stable babies in the Neonatal Intensive Care Unit (NICU) and 1 baby with hypoxic ischaemic encephalopathy (HIE). The 3-coin thickness, pebble-design sensor weighing about 8 gms was secured onto the abdomen for the baby and over the upper arm for adults. In the laboratory setting, the response-time of the sensor device to attain thermal equilibrium with the surroundings was 4 minutes vis-a-vis 3 minutes observed with a precision-grade digital thermometer used as a reference standard. The accuracy was  $\pm 0.1^{\circ}\text{C}$  of the reference standard within the temperature range of  $25-40^{\circ}\text{C}$ . The adult volunteers, aged 20 to 45 years, contributed a total of 345 hours of readings over a 7-day period and the postnatal mothers provided a total of 403 paired readings. The mean skin temperatures measured in the adults by the sensor were about  $2^{\circ}\text{C}$  lower than the axillary temperature readings (sensor =  $34.1$  vs digital =  $36.1$ ); this difference was statistically significant (t-test =  $13.8$ ;  $p < 0.001$ ). The healthy neonates provided a total of 39 paired readings; the mean difference in temperature was  $0.13^{\circ}\text{C}$  (sensor =  $36.9$  vs digital =  $36.7$ ;  $p = 0.2$ ). The neonates in the NICU provided a total of 130 paired readings. Their mean skin temperature measured by the sensor was  $0.6^{\circ}\text{C}$  lower than that measured by the radiant warmer probe (sensor =  $35.9$  vs warmer probe =  $36.5$ ;  $p < 0.001$ ). The neonate with HIE provided a total of 25 paired readings with the mean sensor reading being not different from the radiant warmer probe reading (sensor =  $33.5$  vs warmer probe =  $33.5$ ;  $p = 0.8$ ). No major adverse events were noted in both the adults and neonates; four adult volunteers reported mild sweating under the device/arm band and one volunteer developed mild skin allergy. This proof-of-concept study shows that real-time monitoring of temperatures is technically feasible and that this innovation appears to be promising in terms of both safety and accuracy (with appropriate calibration) for improved maternal and neonatal health.

**Keywords :** public health, remote biomonitoring, temperature surveillance, wearable sensors, mothers and newborns

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