A novel digital health approach to improving global pediatric sepsis care in Bangladesh using wearable technology and machine learning

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(I’ve copy-pasted text and images from the article in every slide except for the last slide)

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Introduction

- Sepsis, defined as life-threatening organ dysfunction caused by a dysregulated host response to infection, is the **leading cause of child mortality worldwide**
- **Management of septic children is challenging** even for experienced clinicians, as children often have dynamic and subtle physiologic changes which indicate worsening sepsis
- While clinical scoring systems have been used largely in HICs, these scores are often **not feasible to operationalize in LMICs** due to their reliance on regular laboratory tests, clinical assessments from experienced HCWs, and relatively cumbersome calculations
- **Innovative digital technologies hold great potential** to overcome some of the greatest barriers to improving sepsis care.

Objectives

1) determine the feasibility of using a **wireless, wearable device for continuous remote vital sign monitoring** in children with sepsis

2) **develop a clinical diagnostic model** using primarily wearable device data to predict advanced sepsis (infection with organ dysfunction) among children in Bangladesh

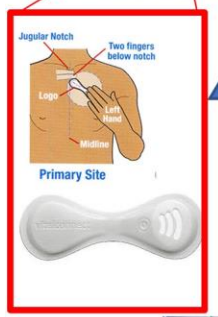
Real-time monitoring of vital sign and ECG data from the wearable is displayed on smartphone

Transmission of data to Cloud for remote monitoring and data processing

Wearable device attached to patient which continuously transmits data to smartphone

Data entered into clinical diagnostic model for advanced sepsis

Machine learning models output risk of advanced sepsis and prediction of mortality

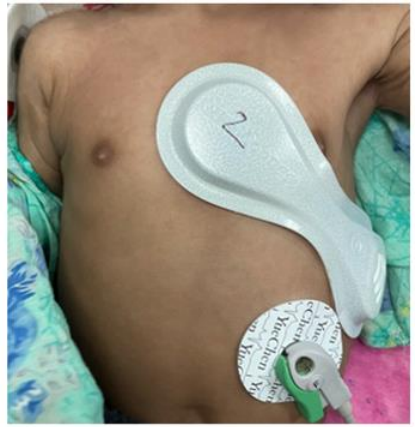


Customized alert system notifies clinicians of signs of patient decompensation

Methods: Study Design & Patients

- This was a **prospective, observational study of children with suspected sepsis** between two months (prematurity-corrected) to 17 years of age who were admitted to the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b) Dhaka Hospital Intensive Care Unit (ICU) from February–December 2022
- After patient enrollment, **study staff collected demographic and clinical data on all patients**. **Laboratory testing and clinical assessments** were also done routinely during admission. Using these data, a **pSOFA score** was calculated to determine the stage of sepsis.
- Staff then applied a **VitalPatch** (VitalConnect, Inc., San Jose, CA), a medical grade wearable biosensor device, to the patient's torso.
- The device **continuously transmitted the following data**: single-lead ECG signal, three-dimensional accelerometer, uncalibrated skin temperature
- Patients enrolled in the study received **routine care for sepsis**

A



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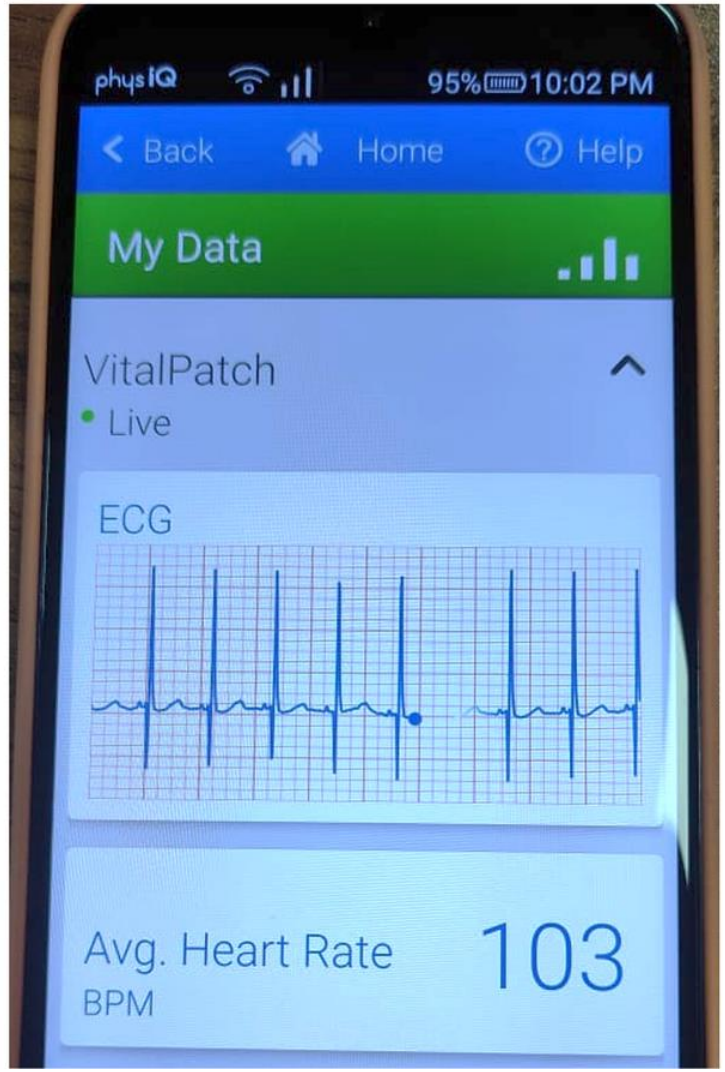
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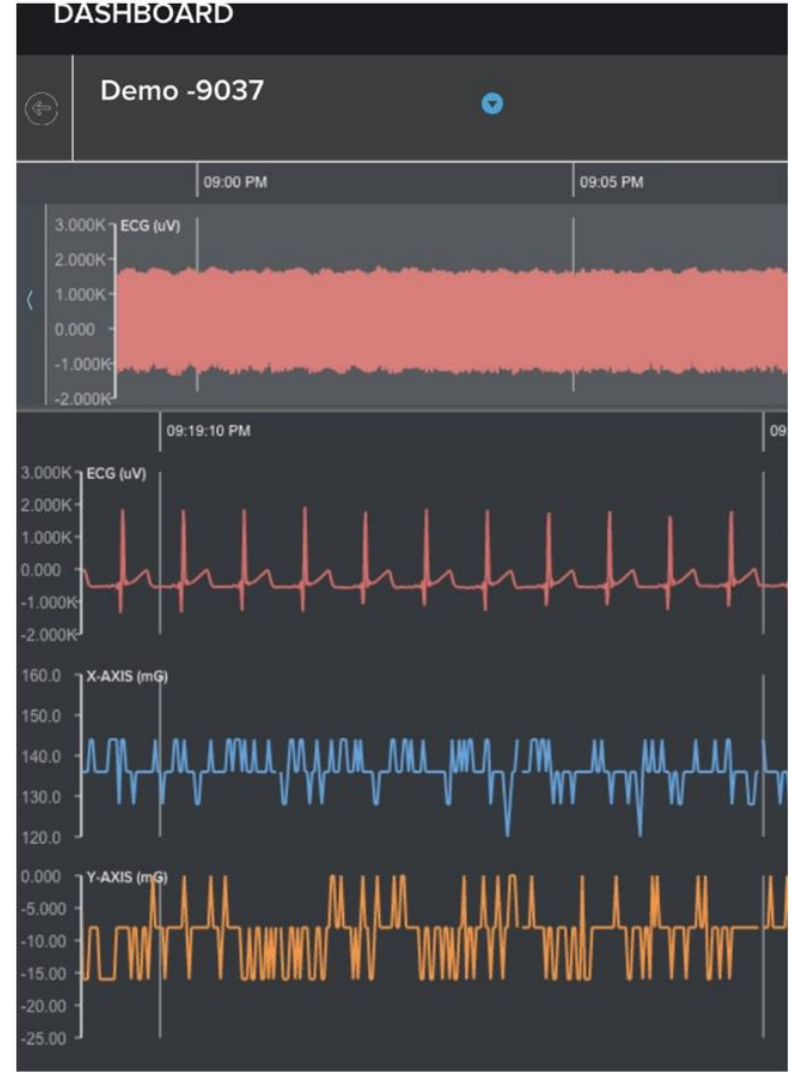
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Methods: Measurements

- The primary outcome of interest was the **development of advanced sepsis defined as pSOFA score > 8** (indicative of organ dysfunction and/or septic shock)
- To **assess feasibility**, data was collected for each patient (e.g. % of patients successfully transmitting data, % of patients monitored for the entirety of their ICU stay)
- To assess the ability of the system to support real-time, remote physiologic monitoring in a real-world clinical setting, vital signs collected using the smartphone-linked wearable device were **compared to manual vital signs obtained by a research nurse (considered the gold standard in this setting).**

Methods: Model Development

- Three candidate models were developed using Ridge regression
    - **Model A.** All features from the table (i.e., wearable device and manually collected features)
    - **Model B.** Best correlated features (all features which explained at least 4% of the outcome variation from Model A)
    - **Model C.** Best correlated features collected from the wearable device (no manually collected data)
- The ability of the best performing model to detect advanced sepsis was compared to physician diagnoses

Manual Features	Age (months), sex, presence of diarrhea, capillary refill*, peripheral edema, jaundice, delayed skin pinch, sunken eyes, pupillary reaction, general appearance, malnutrition (using mid-upper arm circumference [MUAC] or body mass index), weight (kg), height (cm), mean arterial pressure, SpO2: FiO2
Wearable Device (VitalPatch)–Derived Features	Mean and standard deviation (SD): worst (most extreme) respiratory rate, heart rate, heart rate variability, skin temperature, core temperature, and activity† Percent of time in the "danger" (red) zone for heart rate, respiratory rate, skin temperature, and core temperature using age-specific thresholds based on the modified pediatric early warning score (MPEWS) thresholds [18].

* A measure of peripheral perfusion

† Activity is a measure of movement as sensed by the VitalPatch triaxial accelerometer. It is the standard deviation of the 3D acceleration sensor data magnitude in 30-second windows, calculated every 5-seconds. The 5-second results are then averaged to produce minute values of "Activity".

Note: Mean, SD, and worst vital sign variables were calculated from a one-hour period surrounding the time that study staff collected the laboratory tests and performed the clinical assessments used to calculate the pSOFA score.

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Results: Patients

- A total of **100 children** were enrolled of whom 41% were female with mean age of 15.4 (SD 29.6) months.
- In-hospital mortality was 24%
- Nearly half (46%) of patients were also diagnosed with **severe acute malnutrition** during their hospitalization
- The **median admission pSOFA** score was 5
- Using the data collected twice-daily for each child during their ICU stay, we were able to calculate 417 pSOFA scores, out of which the **rate of the primary outcome (pSOFA > 8) was 21%** (88/417)

Characteristic	n (%) (N = 100)
Age (months)*	8 [5–18]
Sex	
Female	41 (41)
Male	59 (59)
Duration of Current Illness (days)*	4 [2–6.25]
Referred from another medical facility	
Yes	21 (21)
No	79 (79)
Past Medical History^	
None Known	84 (84)
Developmental Disability	5 (5)
Cerebral Palsy	5 (5)
Heart Disease (non-cyanotic)	2 (2)
Premature Birth	2 (2)
Epilepsy	1 (1)
Cleft Palate	1 (1)
Monthly Household Income (Taka / $USD)	Tk 15,000 [10,000–20,000] / $137 [91–182]
Years of Mothers' Education†*	6.5 [5–9.25]
Preliminary Source(s) of Sepsis^	
Gastrointestinal / Diarrheal	98 (98)
Respiratory / Pneumonia	54 (54)
Central Nervous System / Meningitis	15 (15)
Genitourinary	2 (2)
Bloodstream	2 (2)
Other / Unknown	1 (1)
Severe Acute Malnutrition	
Yes	46 (46)
No	54 (54)
Admission pSOFA Score	5 [3–7]
Hospital Length-of-Stay (days)*	6 [4–9.75]
In-Hospital Mortality	
Lived	76 (76)
Died	24 (24)

*Median [IQR = interquartile range]

†Mother or primary female caregiver

^ Multiple selections allowed therefore numbers do not sum to 100%

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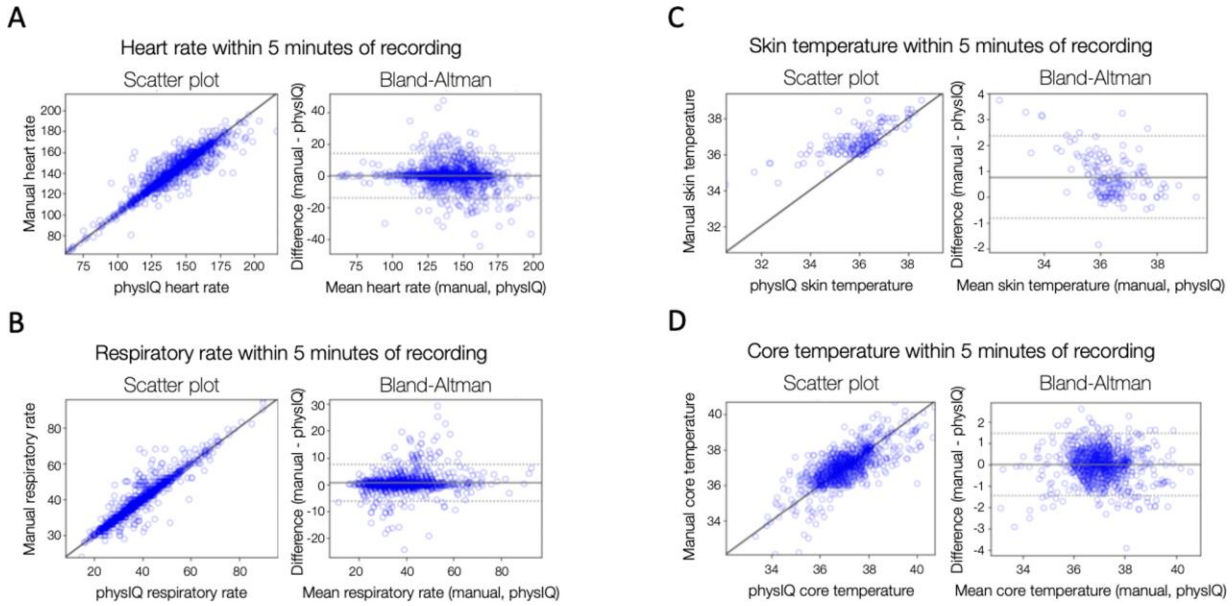
Results: Data Quality

- Patients were **monitored for an average of 52.5 hours** (2.2 days) with the wearable device, with a median of > 99% “high quality” data capture over each patient’s study enrollment period.

- Wearable device-collected vital signs were compared to manual vital signs collected by experienced study nurses using Pearson’s correlation and Bland-Altman plots

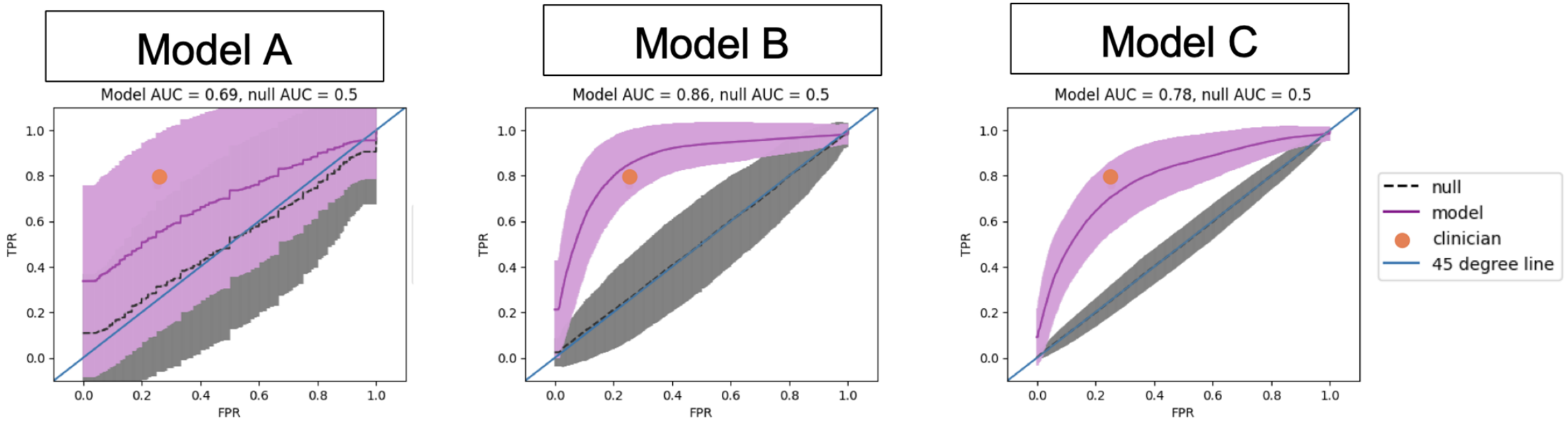
- **Correlation was excellent for heart rate and respiratory rate.** Correlation was less robust but still acceptable for core temperature and skin temperature.



Results: Models

- Of the three candidate models developed, Model B had the best discriminatory ability to detect pSOFA > 8 with AUC of 0.86, indicating excellent discriminatory ability

- Model B included the following features: mean arterial pressure (MAP), worst (highest or lowest) HR, SD of the RR, SpO2:FiO2, mean HR, worst RR.



Results: Models

- **Model B was more sensitive compared to clinicians in diagnosing advanced sepsis** (mean model sensitivity = 0.83; clinician sensitivity = 0.76; $p < 0.001$), while equally specific (model and clinician specificity = 0.75)

- Additionally, **Model B detected advanced sepsis significantly earlier than the clinicians' diagnosis** (model mean = 4.22 versus clinician mean = 6.26 hours after wearable device placement, $p < 0.001$).

	Clinicians	Model B	Significance **(p<0.05)
False positive rate	0.25	0.25	t(988) = -0.90, p = 0.37
Sensitivity	0.76	0.83	t(988) = 15.55, p < 0.001**
Specificity	0.75	0.75	t(988) = 1.26, p = 0.21
Accuracy	0.75	0.76	t(988) = 4.64,p < 0.001**
F1 score	0.45	0.53	t(988) = 13.05, p < 0.001**

https://doi.org/10.1371/journal.pdig.0000634.t004

Results: Feasibility

- After the training period, research staff were **able to successfully integrate use of the wearable mobile device** monitoring system seamlessly into routine clinical activities.

- Patients routinely received procedures such as radiographs, ultrasounds, intubation and mechanical ventilation, and standard telemetry monitoring **without significant issues in data capture using the wearable monitoring system.**

- **Internet connectivity issues were infrequent** (less than once per month on average during the course of patient enrollment) with use of 3/4G mobile network for nearly all data transmission.

- Additionally, during periods of poor connectivity, due to redundancy allowing for data storage on the wearable device itself for up to 18 hours**, there was no data loss** during brief periods of poor connectivity.

Discussion Questions

- Can wearable devices play a significant role in capturing data in low resource settings? Are there barriers to use other than those which were mentioned in this study?
- What opportunities does real-time monitoring of symptoms present in terms of early diagnosis?
- What are potential barriers and opportunities associated with adopting machine-learning models for diagnosis in low resource settings?