

A. General Information	
<b>Project Title &amp; Project #:</b>	Wearables in pediatric heart failure and ventricular assist devices
<b>Department/Division/Team:</b>	Heart Failure
<b>Population:</b>	<p>Patients between <b>≥12-19</b> years old and not in the ICU:</p> <p>1) With acute decompensated heart failure and enrolled in ADHF ACTION study (Definitions (from ACTION): <i>Heart failure – A clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection. Cardinal symptoms include breathing difficulty, feeding intolerance, or other symptoms leading to decreased activity. Acute decompensated heart failure – Heart failure severe enough to warrant hospitalization.</i></p> <p>2) Supported with ventricular assist device and enrolled in ACTION VAD registry</p>
<b>Brief Project Description (AIM):</b>	<p><b>PRIMARY Aim: To evaluate the feasibility of collecting physiologic and activity data from pediatric patients with severe heart failure and VAD using a smart watch application.</b></p> <p><b>SECONDARY AIM: To describe the physiologic and activity data of pediatric heart failure and VAD patients as measured by the Apple Watch.</b></p>
<b>Measures:</b>	<p><b>Initial cohort will be followed for 3 months.</b></p> <p><b>Apple Watch app will collect:</b> Steps covered, distance walked/ran, resting energy burned, number of times fallen, active energy burned, exercise time, stand hours, resting heart rate (HR), walking HR average, HR variability, timeInBed, timeAsleep, respiratory rate while asleep, number and duration of patient-initiated ‘Workouts’ on the watch.</p> <p><b>Prompt patient to perform the following tasks:</b></p> <ul style="list-style-type: none"> <li>• ECG reading once/week</li> <li>• 6-minute walk test once/month</li> <li>• Patient entered weight (in lbs or kg) every other day</li> </ul> <p><b>To correlate with characteristic and event data from:</b> <b>ACTION ADHF project forms</b></p> <p><b>ACTION VAD registry forms</b></p>
<b>Prepared By:</b>	David Peng and Kevin Hall
<b>Date:</b>	September 8, 2022
B. Project Background:	
<p>Pediatric heart failure is a significant, burdensome, and complex condition associated with high morbidity and mortality. The estimated incidence of heart failure is 0.9-7.4 per 100,000 children.<sup>1</sup> Each year in the United States, tens of thousands of children are admitted for heart failure with an in-hospital mortality of 7%.<sup>2,3</sup> In children with congenital heart disease admitted with severe heart failure requiring at least intravenous inotropes, in-hospital mortality climbs to 26%.<sup>4</sup> For the sickest children on the waiting list for a heart transplant, 22% will die before a donor organ becomes available.<sup>5</sup> Managing end-stage heart failure in children is particularly challenging due to the paucity of pediatric-specific</p>	

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data and evidence. There are limited tools and scoring systems available to monitor and assess disease severity and functional status in pediatric heart failure.<sup>6, 7</sup> Traditional practice is driven by brief, infrequent encounters and imprecise, biased recall that may not accurately or wholly reflect a patient’s clinical status, trajectory, and risk. In order to improve quality of life and outcomes, it is important to better understand and characterize children in heart failure and in the hopes of earlier identification of, and intervention for, children at high or worsening risk of decompensation.

Adult heart failure studies have demonstrated that digital biomarkers from wearable or implantable sensor technologies may help identify patients at greater risk, predict clinical decompensation, and prevent heart failure exacerbations.<sup>8-10</sup> In adult heart failure patients, physical inactivity is associated with higher all-cause mortality and exercise-based cardiac rehabilitation may reduce hospital admissions and improve health-related quality of life.<sup>11, 12</sup> The ability to accurately, regularly, and closely monitor a child’s physiologic and activity data may improve the assessment of the child’s health status, adequacy of therapies, and identify areas of potential intervention and improvement.

Wearable technologies have rapidly advanced in recent years. On-person devices of reasonable cost and portability are now able to capture a significant amount of physiologic and activity data and may facilitate interventions, presenting opportunities to improve care in heart failure.<sup>13, 14</sup> However, we do not yet know if and how the technology can be optimally adopted and utilized in children with heart failure. We propose a novel prospective, observational, multi-center cohort study using a custom, pediatric-designed smart watch (Apple Watch) application to demonstrate feasibility and collect actionable biometric health data of children with severe heart failure being evaluated for or listed for heart transplant.

### C. Project Scope (and exclusions):

- Subjects between ≥12-19 years old with acute decompensated heart failure
- Capable of managing/wearing smart phone and wrist sensor.
- Watch requires pairing to patient or parent iPhone (personally owned)
- Project will first be piloted at ~5-10 centers in good standing with ACTION

### D. High-Level Timeline/Schedule:

- 1<sup>st</sup> quarter 2022 – Develop and test app with BTC
- 2<sup>nd</sup> quarter 2022 – Meet with pilot centers to refine project and requirements
- 3<sup>rd</sup> quarter 2022 – Launch pilot project
- 4<sup>th</sup> quarter 2022 – Evaluate initial feasibility and review preliminary data

### E. Communication & Expectations:

ACTION sites will be invited to participate in the pilot portion of this study. Baseline and follow up clinical variables will be entered by sites into REDCap and linked to Apple Watch Data by the DCC.

### F. Project Risks & Mitigation:

Risk	Level (high/med/low)	Mitigation and Escalation Strategy
Workload burden for staff	med	Simplify data collection on tool and minimize required data entry
Technical challenges of using and collecting patient data using Apple Watch	High	Team members and select patients will test-use app and the app will be refined before launching pilot. One of the main specific aims is testing the feasibility of using an Apple Watch in our patient population.

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G. Roles and Responsibilities	
<b>Sponsor/Champion:</b> Provides overall direction on the project.	
Name	Title/Role
David Peng	MD/ ACTION leader
E Kevin Hall	MD/ ACTION Leader
Angela Lorts	MD/ ACTION leader
David Rosenthal	MD/ ACTION Leader
<b>Team Leader:</b> Leads the team and provides guidance on scope of the project.	
Name	Title/Role
Farhan Zafar	DCC leader
Kyle Werling	DCC leader
E Kevin Hall	Team leader
<b>Project Support (QIC/QOM/Data Analytics/Project Manager Support):</b> Leads in the planning & development of the project; manages the project to scope and/or provides data analysis and reporting expertise for the project.	
Name	Title/Role
Lauren Smyth	MHA/ Program Manager
<b>Team Members:</b> Works toward the deliverables of the project.	
BTC – app development	
TBD	
<b>Family/Patient Representative:</b>	
Name	Title/Role
TBD	

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