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| **A. General Information** |  | |  | | | | | | |  |  | | | |  | |  | | | |  | |
| ***Project Title*** | Patient Reported Outcomes (and electronic consent) | | | | | | | | | | | | | | | | | | | | | | |
| ***Department/Division/Team:*** | **ACTION Network** | | | | | | | | | | | | | | | | | | | | | | |
| ***Population:*** | VAD Patients can be enrolled for Patient Reported Outcomes (PRO)s and can be consented using e-consent through the Tonic platform. Any heart failure patient can be consented using e-consent through the Tonic platform, but will not receive PROs. | | | | | | | | | | | | | | | | | | | | | | |
| ***Brief Project Description (AIM):*** | 1. A weekly assessment of patient symptoms and well-being, captured by the “Take ACTION Check-in” and a Visual Analog Scale (VAS). The results of these assessments can be used clinically by caregivers in real time, immediately after assessments are complete. 2. Validated longitudinal assessments of functional status, reflecting the changes before VAD, early after VAD implant, and later after VAD implant. These assessments will be captured by the PROMIS measures and the PedsQL. | | | | | | | | | | | | | | | | | | | | | | |
| ***Measures:*** | 1. Proportion of all patients on VAD who are enrolled in the PRO initiative   Missing responses when the link to measures is sent out  Incomplete survey responses  Attrition of patients/families from PRO initiative | | | | | | | | | | | | | | | | | | | | | | |
| ***Prepared By:*** | Melissa Cousino, PhD, Lindsay May, MD, Betsy Blume, MD, & Lauren Smyth, MHA | | | | | | | | | | | | | | | | | | | | | | |
| ***Date:*** | May 10, 2021, rollout to network on May 20, 2021 | | | | | | | | | | | | | | | | | | | | | | |
| **B. Project Background:** |  | |  | | | | | | |  |  | | | |  | |  | | | |  | |
| Comprehensive assessments of patient well-being (physical, social, and psychological) can help guide clinical care in both the short- and long-term. Given that there is no “gold standard” single assessment tool for young people on VAD support, ACTION will be using a combination of tools to evaluate feasibility of PRO administration and evaluate the quality and relevance of the information PROs provide for our patients.  The ACTION Patient Reported Outcomes Committee has been working on the PRO development process in partnership with Tonic Health. Process of development and pilot testing is summarized below.  1.) Parent focus groups (what is a good day, bad day/ symptom checklist)  2.) Coordinator feedback  3.) Review of pedimacs QOL experience and barriers  4.) Review of literature and all validated tools  5.) Development and compilation of measures  6.) Pilot testing for time and content at 3 sites  7.) Process iterations of parent vs patients/ text vs email vs paper etc.  8.) Weekly Tonic meeting for programming, graphics  9.) IRB amendment at 6 pilot centers completed  10.) Pilot launch for PRO initiative the week of July 20, 2020  11.) Review of incoming data, parent/patient and site feedback; edits to platform and surveys July 2020-December 2020  12.) Changes to Take ACTION survey sent to IRB and IRB approval of survey obtained March 2021 | | | | | | | | | | | | | | | | | | | | | | | |
| **C. Project Scope (and exclusions)**: | | | | | | | | | | | | | | | | | | | | | | | |
| **Inclusion**: All VAD recipients are eligible for the PRO initiative & ACTION e-consent. Any heart failure patient is eligible for ACTION e-consent. ACTION sites must have an iPad available for initial PRO completion visit. Patients must be consented for ACTION for the PRO initiative.  **Exclusion**: Lack of IRB approval for PRO initiative. Lack of consent for participation in ACTION. Non-English speaking patients and caregivers are excluded from PROs, as well as e-consent, for this initial phase (consent translation in progress).  Assessment tools will be administered to patients and/or their caregiver proxy at these intervals:   1. Time of VAD Implant: Take ACTION Check-In, Visual Analog Scale (VAS), and PROMIS 2. Weekly while on support for the first 3 weeks: Take ACTION Check-In and VAS 3. 1, 3, 6 months post-VAD implant while on support: Take ACTION Check-In, VAS, PROMIS, and at 6 months include Peds QL | | | | | | | | | | | | | | | | | | | | | | | |
| **D. High Level Timeline/Schedule:** | | | | |  |  | |  | | | | |  | | |  | |  | | | |  | |
| 1. IRB review/approval of revised Take ACTION survey – Feb 2021/March 2021 2. Integrate new ACTION ID process in Tonic – Feb/March 2021 3. Anticipated project launch for network – May 2021 (ACTION for All call 5/20/21) 4. Once we have 50 patients enrolled, we will review data – August-November 2021 | | | | | | | | | | | | | | | | | | | | | | | |
| **E. Communication & Expectations:** | | | | | |  | |  | | | | |  | | |  | |  | | | |  | |
| Sites with IRB/DUA approval will be invited to join the PRO initiative in ACTION. PROs are available for VAD patients only at this time. However, sites can use Tonic to e-consent any heart failure patient for ACTION. Teams must complete t[his project commitment survey](https://www.surveymonkey.com/r/QQSFVX7) **by 6/11/21.** Participating teams will be added to the ACTION monthly PRO Committee calls, which occur the 1st Monday of each month at 1pm ET. ***\*Your team must have at least 1 iPad available to enroll patients/caregivers into the Tonic platform.***  **PROs Workflow Expectations:**  Initial PRO Assessment: The first assessment will be performed with the assistance of the clinician, who will log in through the Tonic platform via an iPad and Tonic Health app. The patient will be consented electronically for ACTION via the Tonic App. There is also a paper consent option available for ACTION consenting. On the enrollment form for Tonic, you will input the ACTION ID for the parent and/or patient. To generate the ACTION ID, please use this REDCap to create the unique ID’s for the parent/patient: [https://redcap.link/tonicACTIONID](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fredcap.link%2FtonicACTIONID&data=04%7C01%7Cmshykova%40r1rcm.com%7Ca22cda7879e5432a617b08d9035fa89d%7C25c1df4b00ea4e3998bd5f1143c5c5df%7C0%7C0%7C637544531672150628%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=tKqIeo16i0tkxnma0t20J%2F%2B6fJUCUlm%2FpJ65TYO%2B1OU%3D&reserved=0). **Once you have the unique ID(s), return to the Tonic enrollment form to input the ID(s).**  The clinician’s email address is collected and used as their username. It will be also visible in the export file for every baseline survey collected. Tonic will also collect the patient’s name & date of birth since this information is used for consenting. In addition, Tonic will need to verify the patient’s identifiers in order to prepopulate the data if the patient/parent interrupts the survey and is returning within 24 hours, in which case the system will prepopulate the answers that have been already entered and allow them to proceed where they left off. This prepopulation expires after 24 hours so that surveys are completed with new responses each time. Clinicians will have the ability to administer surveys and those with appropriate access will have the ability to view data. Patients/caregivers will only have the ability to enter survey responses.  The clinician will enter the patient’s ACTION ID and will allow the patient/caregiver to enter their email address and/or cell phone number. They will select their preferred means of receiving the survey (either email or text). The clinician will hand the iPad over to the patient/caregiver to complete the baseline survey. After completing the initial PRO assessment in clinic/hospital by iPad, all follow-up assessments will be sent directly to patient/caregiver either by email or text (per their selection).  Ideally, the clinician should remain available in case questions or problems arise but will not assist in the completion of the questions. For patients, parents and the clinician can provide help if needed but the questions should be answered as independently as possible. Please see table below regarding who will be offered PRO surveys per age of patient.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Patient Age** | **Who Completes PROs?** | **How are PROs Completed?** | **When are PROs Completed?** | **What PROs are Completed?** | | 0-1 years old | Parent Only | Text or Email | VAD Implant  Weekly for 1st Month  1 Month Post-Implant  3 Months Post-Implant  6 Months Post-Implant | Take ACTION  Take ACTION  Take ACTION  Take ACTION  Take ACTION | | 2-4 years old | Parent Only | Text or Email | VAD Implant  Weekly for 1st Month  1 Month Post-Implant  3 Months Post-Implant  6 Months Post-Implant | Take ACTION  Take ACTION  Take ACTION  Take ACTION  Take ACTION, PedsQL | | 5-11 years old | Parent Only | Text or Email | VAD Implant  Weekly for 1st Month  1 Month Post-Implant  3 Months Post-Implant  6 Months Post-Implant | Take ACTION, PROMIS  Take ACTION  Take ACTION, PROMIS  Take ACTION, PROMIS  Take ACTION, PROMIS, PedsQL | | 12-17 years old | Patient Only OR  Parent Only OR  Both Patient and Parent | Text or Email | VAD Implant  Weekly for 1st Month  1 Month Post-Implant  3 Months Post-Implant  6 Months Post-Implant | Take ACTION, PROMIS  Take ACTION  Take ACTION, PROMIS  Take ACTION, PROMIS  Take ACTION, PROMIS, PedsQL | | 18+ years old | Patient Only | Text or Email | VAD Implant  Weekly for 1st Month  1 Month Post-Implant  3 Months Post-Implant  6 Months Post-Implant | Take ACTION, PROMIS  Take ACTION  Take ACTION, PROMIS  Take ACTION, PROMIS  Take ACTION, PROMIS, PedsQL |   At the end of the assessment, there will be several short questions for patients/caregivers such as: “Tell us about your experience with survey…” or “Was this survey length too long, too short, just right?” These questions will be asked at the end of the baseline assessment and every follow-up.  The ACTION ID, email, phone number, and preferred means of completing the survey will be asked during the baseline and will not be asked again during the follow-up assessments. Surveys will be sent automatically at the specified intervals below, with subsequent reminders if a survey link is not used within 24 hours.  Follow-Up Assessments: The first follow-up assessment will be sent 7 days after the VAD implant if the date is known (in the survey, the question is phrased as: Do you know the date of your VAD implant? / Do you know the date of your child’s VAD implant? And Please specify the date). If the date is unknown, the first follow-up will be dispatched 7 days after the baseline survey completion.  Tonic will send 1 primary notification and 1 reminder in 24 hours if the survey is not completed for the weekly surveys. For the 1-month, 3-month, and 6-month surveys, reminders will be sent at these intervals: 1 day, 4 days, and 7 days.  The survey links for the weekly assessments will be active for 3 days and the links for the monthly assessments will be active for 30 days. If the links are not used within these timeframes, they become inactive and patients won’t be able to use them to complete the assessments.  **Data Collection**  Each ACTION site PI will receive notification once new assessment data are available and will be emailed a link to log in and view results. Additional providers at each site can also be added to receive these notifications. Cincinnati Children’s Hospital, as the data coordinating center, will have the ability to view all collected data. Each site will be able to view their own patient/caregiver results and should review these data on a regular basis to ensure clinical concerns are addressed and that incomplete forms and survey issues are identified.  Tonic does not proactively notify that surveys are not complete. There are no inactivity alerts, but clinicians with data access can log in and see data and completion rates in real time via their center’s dashboard. We recommend each site identify a PRO **point person** for logging into Tonic weekly and identifying the data that should be shared with the broader clinical team. This person should also be on the study staff/IRB for your site.  **To UN-ENROLL a VAD Patient from PRO’s:**  To un-enroll or unsubscribe from Tonic, parents and/or patients will need to unsubscribe directly from the survey texts/emails. Potential reasons why one would be un-enrolled or unsubscribed from Tonic include: patient death, patient transplant, implant cancelled, patient/parent no longer desire participating in ACTION or PRO initiative. The ACTION team members can also contact Tonic (Maryna Shykova [MShykova@scisolutions.com](mailto:MShykova@scisolutions.com)) to have specific patients un-enrolled.  **Bi-Weekly Center Feedback Surveys:**  ACTION operations staff will send a short email survey to participating sites every other week to assess patient enrollment volume in Tonic and to obtain feedback and learnings from the sites. We will also be asking questions to learn about how patient PRO data may be used by sites and teams for improving patient care. | | | | | | | | | | | | | | | | | | | | | | | |
| **G. Project Risks & Mitigation**: | | | | | | | | | | | | | | | | | | | | | | | |
| **Risk** | | **Level (high/med/low)** | | | | | | | | **Mitigation and Escalation Strategy** | | | | | | | | | | | | | |
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| **F. Roles and Responsibilities** | | | |  | | |  | | | | |  | |  | | | | |  |  | | | |
| **Sponsor/Champion:** Provides overall direction on the project. | | | | | | | | | | | | | | | | | | | | | | | |
| **Name** | | | | | | | | | **Title/Role** | | | | | | | | | | | | | | |
| Angela Lorts, MD | | | | | | | | | ACTION Co-Executive Director | | | | | | | | | | | | | | |
| **Team Leader:** Leads the team and provides guidance on scope of the project. | | | | | | | | | | | | | | | | | | | | | | | |
| **Name** | | | | | | | | | **Title/Role** | | | | | | | | | | | | | | |
| Melissa Cousino, PhD | | | | | | | | | PRO Committee Co-Leader | | | | | | | | | | | | | | |
| Betsy Blume, MD | | | | | | | | | PRO Committee Co-Leader | | | | | | | | | | | | | | |
| Lindsay May, MD | | | | | | | | | PRO Committee Co-Leader | | | | | | | | | | | | | | |
| **Project Support** (**QIC/QOM/Data Analytics/Project Manager Support):** 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 | | | | | | | | | Project Manager | | | | | | | | | | | | | | |
| Paige Krack, QIC | | | | | | | | | Quality Improvement Consultant | | | | | | | | | | | | | | |
| Karina Tabar, Data Specialist | | | | | | | | | Data Management Specialist | | | | | | | | | | | | | | |
| Chloe Connelly, Data Analyst | | | | | | | | | Data Analyst | | | | | | | | | | | | | | |
| **Team Members:** Works toward the deliverables of the project. | | | | | | | | | | | | | | | | | | | | | | | |
| **Name** | | | | | | | | | **Title/Role** | | | | | | | | | | | | | | |
| PRO Committee members | | | | | | | | |  | | | | | | | | | | | | | | |
| **Family/Patient Representative:** | | | | | | | | | | | | | | | | | | | | | | | |
| Melissa McQueen and FACT | | | | | | | | |  | | | | | | | | | | | | | | |