Cardiology in the Young

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Mobile health monitoring of children with CHDs

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Original Article

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Abstract

Background: Mobile health has been shown to improve quality, access, and efficiency of health care in select populations. We sought to evaluate the benefits of mobile health monitoring using the KidsHeart app in an infant CHD population. *Methods:* We reviewed data submitted to KidsHeart from parents of infants discharged following intervention for high-risk CHD lesions including subjects status post stage 1 single ventricle palliation, ductal stent or surgical shunt, pulmonary artery band, or right ventricular outflow tract stent. We report on the benefits of a novel mobile health red flag scoring system, mobile health growth/feed tracking, and longitudinal neurodevelopmental outcomes tracking. *Results:* A total of 69 CHD subjects (63% male, 41% non-white, median age 28 days [interquartile range 20, 75 days]) were included with median mobile health follow-up of 137 days (56, 190). During the analytic window, subjects submitted 5700 mobile health red flag notifications including 245 violations (mean [standard deviation] 3 ± 3.96 per participant) with 80% (55/69) of subjects submitting at least one violation. Violations precipitated 116 interventions including hospital admission in 34 (29%) with trans-catheter evaluation in 15 (13%) of those. Growth data ($n = 2543$ daily weights) were submitted by 63/69 (91%) subjects and precipitated 31 feed changes in 23 participants. Sixty-eight percent of subjects with age >2 months submitted at least one complete neurodevelopment questionnaire. *Conclusion:* In our initial experience, mobile health monitoring using the KidsHeart app enhanced interstage monitoring permitting earlier intervention, allowed for remote tracking of growth feeding, and provided a means for tracking longitudinal neurodevelopmental outcomes.

Introduction

Mobile health (mHealth) encompasses "a spectrum of digital technologies that leverage mobile devices, wearables, and applications to support the achievement of health objectives".[1] In its most idealised form, mHealth promises a paradigm shift from reactive to proactive care by empowering patients and their families to actively engage in their own health. In a meta-analysis of 34 studies, mHealth technologies were associated with improved care delivery, access to care, quality of care, and enhanced technical performance, accuracy, and efficacy of workers.[2]

Currently, there is little data on the role of mHealth in children with heart disease. Childhood heart diseases are often high-risk conditions, and more frequent mHealth monitoring could meaningfully augment care delivery. As an additional benefit, mHealth allows improved tracking of longitudinal outcomes and could fill an unmet need. In a 2007 report on outcome measures of paediatric cardiac diseases, Jacobs et al. concluded that "analysis of outcomes must move beyond mortality, and encompass longer term follow up, including cardiac and non-cardiac morbidities, and importantly, those morbidities impacting health related quality of life".[3]

There are currently only a few examples in the literature of mHealth/telehealth monitoring in CHD.[4–8] Given the potential of mHealth to augment care, and the unmet need/need for improvement in longitudinal outcome tracking in childhood heart disease, we developed the KidsHeart mHealth application to track family-reported outcomes in patients with high-risk heart disease following neonatal heart surgery. The KidsHeart platform collects longitudinal outcomes with measures including vital signs, weight gain, medication compliance, and incidence/severity of red flag symptom events, and it delivers age-appropriate neuro-developmental surveys. Here, we report initial feasibility, participant response rates, and the clinical and research utility of the KidsHeart mHealth platform.

Materials and methods

The KidsHeart app (Figure 1) was developed with parent input via a series of focus groups. Focus groups included six female participants ages 32 through 39 (75% identifying as white, 25% as

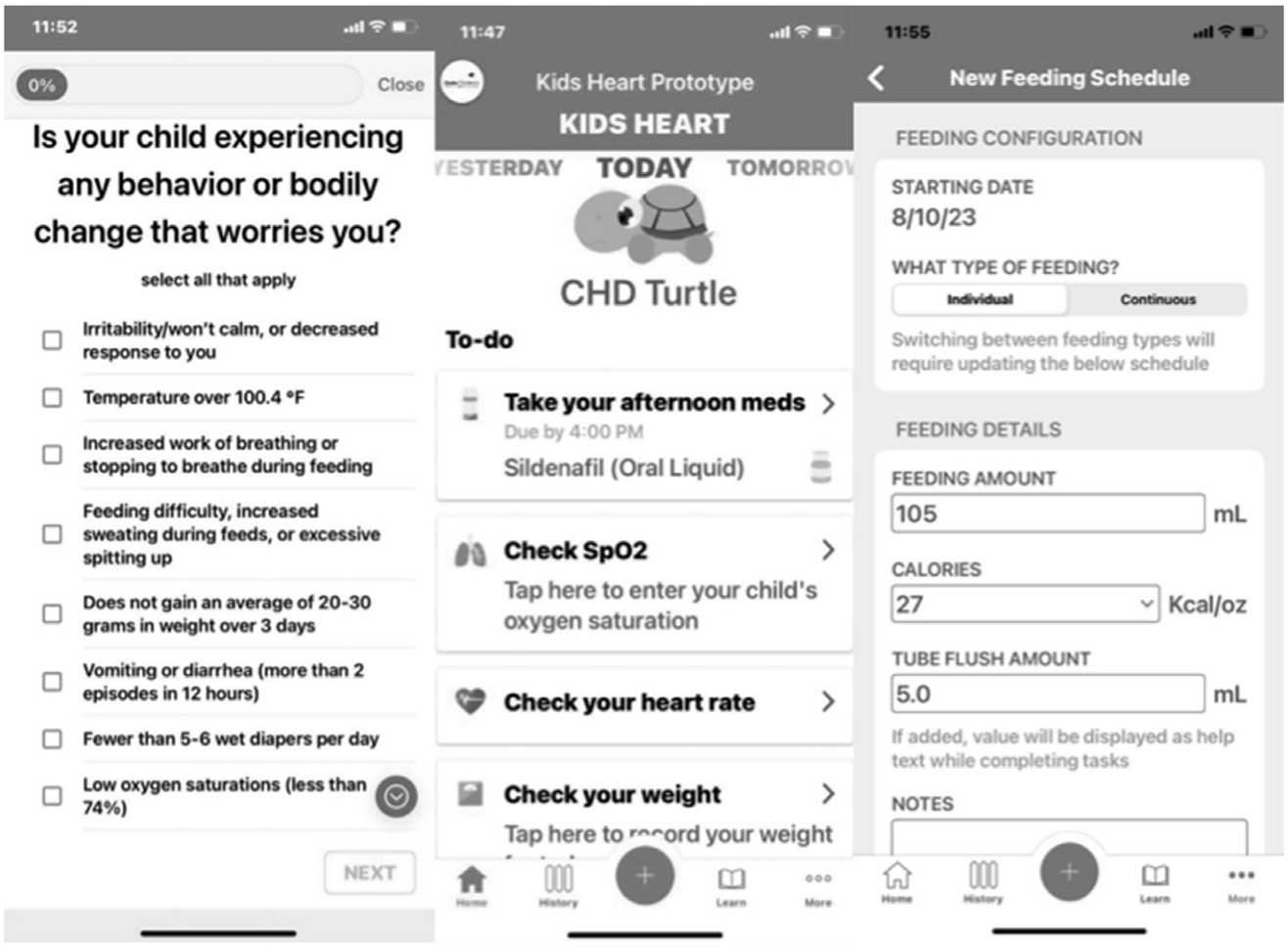

Figure 1. Images of KidsHeart app interface.

black, one hispanic ethnicity). A focus group summary and full-text comments about it are included in the on-line supplement. The KidsHeart app was developed on the Pattern Health™ mobile app platform (Pattern Health Technologies, Inc., Durham, NC). Features include educational materials in both video and PDF modalities, customisable centre information (e.g. clinic locations, contact information, provider names), a diagnostic summary, and a chat feature accessible to both parents and providers. Parents were encouraged to input daily growth and feeding data, vital signs (oxygen saturations and heart rates), and medication compliance. They can track progress using the app's graphical features and receive rewards and reminders via the app to encourage appropriate data submission. One of the design objectives of the KidsHeart app was that it would augment home monitoring of the high-risk infants including single ventricle patients in the "interstage" period. However, the app was intended to augment and not replace traditional home monitoring protocols. Therefore, all patients continued with regularly scheduled out-patient cardiology appointments as well as traditional primary care follow-up.

The KidsHeart app incorporates two longitudinal survey mechanisms, a red flag monitoring survey and a neurodevelopmental survey. The red flag monitoring survey is a custom-designed single ventricle red flag questionnaire that we developed for remote interstage monitoring. The questionnaire is delivered to parents daily and is scored on a scale from 1 to 30 based on symptom severity (Table 1). The scoring system was designed by our investigative team with input from content experts and sought to evaluate a spectrum of clinical concerns that might indicate early clinical deterioration. Any questionnaire with a red flag event (any score above 0) triggered an alert to the care team. Parents were then contacted directly to further evaluate symptoms and to triage needs. One of the aims of this study was to assess and validate this red flag scoring system's ability to accurately triage severity of interventions based on the score. The neurodevelopmental survey is the "Survey of Well-being of Young Children™", a parent-report instrument for remote neurodevelopment assessment.[9] The Survey of Well-being of Young Children is a validated survey of neurodevelopmental progression[10] and was chosen for its quality and because it is used in our Primary Paediatric Clinics. The Survey of Well-being of Young Children™ is automatically delivered via the KidsHeart app to parents at 2, 4, 6, 9, 12, and 18 months. In response to an abnormal Survey of Well-being of Young Children survey, families are contacted to schedule more in-depth neuro-developmental assessment and families are referred to local resources (psychologic, speech, and occupational therapies, etc.) when indicated. Survey of Well-being of Young Children data are summarised in this manuscript as a proof of principle that

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Table 1. Red flag scoring system

Points	Red flag symptom
0	No red flag symptoms
1	Feeding pump or pulse oximeter problems
2	Does not gain an average of 20–30 g in weight over 3 days
3	Vomiting or diarrhoea (>2 episodes in 12h)
3	Feeding difficulty (increased sweating or excessive spit ups)
4	Low o2 sats
4	Irritable/won't calm down OR lethargy/decreased responsiveness
4	Temperature > 100.4
4	Fewer than 5–6 wet diapers
5	Increased work of breathing or stop breathing while feeding

neurodevelopmental surveys can be delivered remotely to families; however, because comprehensive evaluation of neurodevelopment requires longer-term follow-up, we have deferred more comprehensive analysis of the impact of Survey of Well-being of Young Children surveys on neurodevelopmental outcomes.

The KidsHeart app was first tested by a small number of collaborators and then rolled out to patient groups for this initial pilot study with the opportunity to make further adjustments if needed in the future based on findings. For the purposes of this pilot study, parents of children admitted for a birth hospitalisation and fulfilling any of the following diagnostic criteria were eligible for inclusion: (1) any single ventricle heart disease status post stage 1 palliation, (2) biventricular CHD status post ductal stent or surgical shunt, (3) biventricular CHD status post pulmonary artery band, and (4) biventricular CHDs with right ventricular outflow tract stent. Parents were approached for study participation following transition from the paediatric cardiac ICU to our step-down unit. They were given access to the app via the care team and provided digital consent upon downloading the app. Parents were allowed to enter data into the app during the remainder of their in-patient stay to allow for troubleshooting and teaching. Our objectives for this analysis were to report on initial feasibility, participant response rates, and the clinical and research utility of the KidsHeart mHealth platform. We collected demographic data from the app-enrolled study population and assessed both the clinical and longitudinal outcomes tracking utility of red flag monitoring, growth/feeding monitoring, and neurodevelopmental surveys. To assess red flag monitoring, we evaluated four key intervention types collected via review of the electronic medical record: (1) any adjustment to the child's feeding or medication regimen, (2) any non-elective out-patient or emergency department evaluation, (3) any unplanned admission, and (4) any unplanned admission with cardiac intervention (trans-catheter). With respect to the neurodevelopmental assessments, long-term neurodevelopmental outcomes data are not yet compiled; therefore, analyses focus on the initial feasibility of mHealth neurodevelopmental surveying. All KidsHeart data were prospectively collected, and data presented in this manuscript cover the 18-month period spanning from 04-01-2021 to 09-30-2023, though data collection is ongoing. Study data were downloaded from the on-line tracking platform into a study database and combined with data collected manually from the electronic health record.

Table 2. Demographics

Median age at enrolment (IQR)	28 days (20, 75)
Male gender, *n* (%)	44/69 (63%)
Race, *n* (%)	
White	42/69 (61%)
African American	21/69 (30%)
American Indian	2/69 (3%)
Asian	1/69 (1%)
Other	3/69 (4%)
Hispanic ethnicity	10/69 (14%)
Diagnostic subgroup, *n* (%)	
Single ventricle	29/69 (42%)
2V systemic to pulmonary artery shunt	22/69 (32%)
2V pulmonary artery band	12/69 (17%)
2V right ventricular outflow tract stent	6/69 (9%)

IQR = interquartile range.

Statistical analysis

Descriptive statistics, including *n* (%), median (interquartile range), and mean (standard deviation) where appropriate, were used to describe cohort characteristics and study outcomes. *T*-tests were used to compare red flag severity scores by intervention and to evaluate weight gain documented via app versus the electronic medical record. A two-tailed p value <0.05 was considered statistically significant.

Results

Study population

A total of 72 participants (63% male, 41% non-white) consented to study participation. Of these, 3 were excluded from analysis after transitioning care to other centres. Table 2 summarises patient demographic and diagnostic information. Median (interquartile range) length of mHealth follow-up at the time of data lock was 137 days (56, 190) with 100% of enrolled participants submitting some longitudinal follow-up data following birth hospital discharge; 90% ($n = 28$) of those status post stage II palliation continued to submit data through the time of their stage II hospitalisation.

Remote red flag monitoring and interstage interventions

A total of 5700 red flag surveys were completed (82.6 ± 71.5 per participant) (Figure 2). Of these, 245 represented red flag violations (any score >0). Red flag violations were submitted by 80% (55/69) of enrolled subjects (average 3.0 ± 3.96 red flag violations per participant). Survey scores ranged from 0 to 15 with a median per-patient highest severity score of 4 (interquartile range 2, 5). During the study analytic window, 219 interventions were performed in the study cohort with 53% (116/219) of all interventions initiated following a remote, mHealth red flag monitoring violation. Interventions precipitated by these violations are summarised in Figure 3 and included hospital admission in 34 (29%) with 15 (13%) of the admissions including trans-catheter evaluation. Higher-level interventions (out-patient/emergency department evaluation or hospitalisation/intervention) had significantly higher

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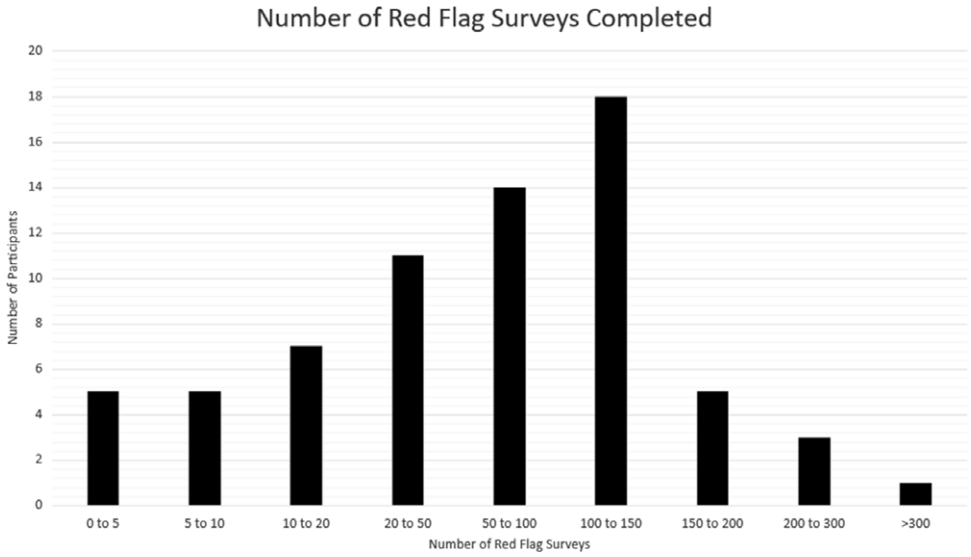

Figure 2. Number of red flag surveys submitted by participants.

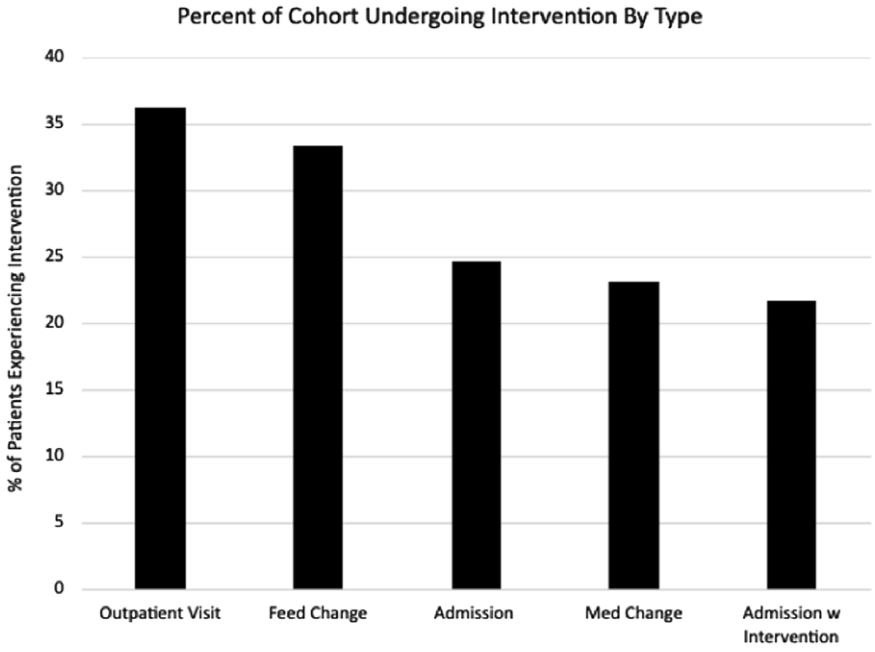

Figure 3. Percent of patients in cohort undergoing intervention by type. (For the purposes of this figure, admissions and admissions with interventions represent mutually exclusive groups; thereby, any admission with a transcatheter intervention is not also represented within the admission group).

red flag scores when compared to red flag submission without intervention or with lower-level (medication or feeding change) interventions (3.1 ± 1.4 vs. 4.9 ± 2.8 respectively, $p < 0.0001$). Our response rates were analysed for those who had completed the interstage period (i.e. had completed their second stage intervention surgery). Daily compliance with app survey response was 65 ± 38 % of daily responses with nearly half of participants responding >70% of the time. There were five deaths (6.9%), all in interstage (pre-stage II surgery) single ventricle patients. Of these five deaths, one was a "classic interstage death" with the patient presenting to the emergency department in extremis with failed resuscitation. This patient had not submitted any red flag surveys in the 7 days preceding death. The remaining four deaths occurred during in-patient re-admissions, all of >2 months duration. None presented in extremis although two of the four were admitted in response to red flag events received via the KidsHeart app.

Remote feeding and growth tracking

Growth/feeding data were digitally submitted by 63/69 (91%) patients with a total of 5253 weight data points submitted by all patients (76.1 ± 67.24 submitted weights per patient). Median daily weight gain was 18 g/day (12, 20) and was the same as chart-documented weight gain obtained from clinic visits (but with more frequent monitoring via the app). Daily weight gain was not statistically different for those using the app ($n = 63$) compared to those that did not ($n = 6$), although numbers are too small for accurate comparison. Home app-monitoring precipitated 31 feed

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changes in 23 participants, which included addition or subtraction of fortifiers (formula caloric content, mct oil, etc.), adjustment of feed volumes, and changes in formula.

Remote neurodevelopmental tracking

Neurodevelopmental questionnaires were provided at age-appropriate intervals. At the time of data lock, 68% of app-enrolled subjects with age >2 months had submitted at least one complete developmental questionnaire.

Discussion

We report our experience using the KidsHeart mHealth app to monitor for high-risk "red flag" violations, to track feeding and growth, and to evaluate longitudinal outcomes. In this pilot analysis, patient engagement was good with most patients submitting daily red flag scores and daily weights/feeding data. More than half of all interstage interventions were precipitated by an app-generated red flag notification. In addition, we remotely tracked interstage weight gain and intervened with app-precipitated feeding and nutrition changes in more than a third of all enrolled participants. Finally, mHealth proved a useful means for tracking longitudinal post-discharge outcomes such as neurodevelopmental scores.

Mobile health improves both access to care and quality of care[2] and has been shown to offer clinical impact across multiple populations.[2,11–17] MHealth may be especially valuable for rare diseases and conditions, such as children with CHDs, where care is primarily delivered at regional referral centres. An estimated 25% of CHD patients live >100 miles from their surgical centre.[18] Although more intensive monitoring improves outcomes in these patients,[7] geographic isolation can be a major impediment. In other paediatric patient populations with complex medical needs, mHealth improves caregiver involvement and our experiences were similar with 100% of enrolled subjects submitting post-discharge data via the app.[19]

Our data add to a growing body of pilot data demonstrating the value of mHealth technology for interstage monitoring in children with single ventricle heart disease.[20–23] The interstage period represents the time between the first and second stage of single ventricle surgical palliation. During this high-risk period, intensive surveillance monitoring significantly decreases the incidence of interstage mortality and other poor outcomes.[24–29] Our work expands this literature by performing interstage monitoring digitally as well as the addition of longitudinal remote neurodevelopmental tracking. Although we did not rely solely on mHealth interstage monitoring and continued our standard interstage monitoring programmes, over half of our interstage interventions were precipitated by an mHealth alert. These interventions included 34 hospital admissions with 15 of these leading to trans-catheter evaluation. These interventions' clinical acuity suggests that our mHealth monitoring is not simply leading to increased detection of non-significant concerns. Our red flag monitoring checklist was custom designed for the KidsHeart app. While prior interstage monitoring studies have provided reasons to contact the medical team[22] or a list of action plans,[24] our red flag daily questionnaires automated the process to facilitate prompt intervention with an associated severity score. Our data validates the checklist with higher scores associated with higher acuity interventions.

Optimal feeding and growth are similarly important during the interstage period in patients with CHD. A meta-analysis including >1,400 pre-stage II single ventricle patients showed, on average, reduction of >1 z-score in both and weight during the interstage period.[30] Growth concerns adversely impact both neurodevelopment and surgical outcomes,[31] and the Joint Council on Congenital Heart Disease Quality Improvement Task Force highlighted optimising nutritional status as a key target for high-risk neonates.[32] In our pilot data, weight trajectory was measured reliably compared to EMR-documented growth but with more frequent monitoring, more data points, and automated notifications when weight gain is not meeting goals (20–30 g per day). This allows earlier intervention with more than one third of our patient population receiving feeding adjustments following an app notification. It also allowed for closer weight and feeding monitoring during the formula shortage.

Finally, our pilot data demonstrate a proof of principle that mHealth can function as a useful means for tracking longitudinal post-discharge outcomes. This is an unmet need in CHD care which has historically relied on robust in-patient registries yet lacks data on the longer-term post-discharge outcomes that matter most to families. In our analysis, 100% of KidsHeart app study participants submitted post-discharge data, thereby verifying vital status and providing information on important longitudinal outcomes such as growth and neurodevelopment. Our KidsHeart app incorporates a unique patient identifier that, in theory, can be used to link back to existing registry data, thereby providing a rich data source for longitudinal outcomes analyses.

There are important limitations to this analysis. As a pilot study, the sample size is small and overall duration of app usage relatively low. Our data was not intended to be directly compared to current standard of care but rather to augment existing care models. Moreover, we have limited data on longer-term neurodevelopment and growth outcomes which are needed to accurately validate the utility of mHealth neurodevelopmental surveys and feeding interventions. The KidsHeart app will continue to enrol permitting these analyses to be completed in the future. While mHealth offers an opportunity for equity of access to health resources in remote communities, there are limitations to this as well, including socio-economic barriers that may impact feasibility.[33]

In conclusion, the KidsHeart app pilot data demonstrates the utility of mHealth in CHD population and augments the clinical benefits of remote monitoring with success in red flag monitoring and subsequent implementation of interventions, growth monitoring, and longitudinal outcomes assessment. In terms of future directions, we aim to collect more robust and longer-term neurodevelopmental outcomes and to validate these data with standardised neurodevelopmental assessments. We intend to assess socio-economic barriers to mHealth monitoring and to develop a linkage methodology allowing mHealth longitudinal outcomes to be linked back to existing registry data. Accomplishing these goals will extend the value of mHealth technology by supporting research as well as clinical care.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S1047951124026222.

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Author 4 declares no competing interests.
Author 5 declares no competing interests.
Author 6 declares no competing interests.
Author 7, Kevin Hill, is a consultant for Actelion Pharmaceuticals.

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