AHRQ Grant Final Progress Report

TITLE PAGE

Title of Project: Ambulatory Pediatric Patient Safety Learning Lab: Pursuing Safe Healthcare at Home

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STRUCTURED ABSTRACT

Purpose: The objective of this research is to improve management of pediatric chronic conditions in the clinic and home settings. We aim to reduce the two most egregious harms in this setting — medication errors and treatment delays — in two common conditions.

Scope: Most healthcare is provided in the clinic and home, however, where few intervention studies exist. We chose to focus on two populations in this study: children with autism and children with type 1 diabetes (T1D).

Methods: A transdisciplinary team of parents, safety researchers, and clinicians employed process mapping, with data collected through in-home medication review, medication administration observation, parent surveys, simulations, and failure modes and effects analysis (FMEA). Interventions were created with input from design day activities and included an online insulin calculator, simulation scripts, and an antipsychotic medication monitoring questionnaire.

Results: Eight (57%) of the 14 children with T1D who had home visits and chart reviews experienced 18 errors (31 per 100 medications) detected during the home visit or chart review. Seven (78%) of the nine children with ASD who had home visits and chart reviews experienced eight errors detected during the home visit or chart review. FMEA output included process maps, which demonstrated opportunities for interventions. Workflows to improve safety in both conditions were created and implemented (simulations in T1D and eVisit questionnaires in autism).

Key Words:
- Patient Safety
- Patient Harm
- Diabetes Mellitus, Type 1
- Autism Spectrum Disorder

PURPOSE

Our long-term goal is to implement successful interventions for pediatric chronic disease management across the SPS network. The objective of this research is to improve management of pediatric chronic conditions in the clinic and home settings. We have identified three key opportunities to reduce the two most egregious harms in this setting — medication errors and treatment delays — in two common conditions.

We aim to:
1. Redesign processes for adjustment of medication dosing based on clinical information gathered by the patient/family to prevent medication errors. (This will be studied in T1D.)
2. Create processes for patient/family medication monitoring and communication with clinic to prevent adverse drug events. (This will be studied in children with ASD on antipsychotics.)
3. Design a workflow to plan for, detect, and prompt management of serious illness among children with chronic conditions at home. (This will be studied with both T1D and ASD.)

This study is a collaboration between human factors experts (Dr. Tosha Wetterneck); design experts from Mad*Pow; and parent, a clinician, and research experts from Cincinnati Children's. The overarching goal of the study is to redesign systems of care and coordination between the clinic and home to eliminate harm due to healthcare to children with autism spectrum disorder and type 1 diabetes in the outpatient setting. The proposed study follows the stages of problem analysis, design, intervention development, evaluation in the simulation center, and implementation in the clinical setting.

SCOPE

Background

After almost two decades, the US is beginning to realize improvements in the safety of healthcare for hospitalized patients. The vast majority of healthcare is provided in the clinic and home, however, where few intervention studies exist. At home, two in five children with chronic disease have a medication error.[1,2] Of these, 3.6% are injured due to these errors — the same rate as hospitalized children.[3] Among the 165,000 children with type 1 diabetes (T1D) nationally, 20% have poor glycemic control.[4,5] The leading cause of death before age 30 among individuals with T1D is acute complications (e.g., severe hypoglycemia, diabetic ketoacidosis (DKA)), and 5% of deaths are attributable to "dead-in-bed" syndrome (sudden unexplained death in young people with T1D).[6] Over 1 million children have autism spectrum disorder (ASD). Of these, 64% are on psychotropic medications, including 40% on antipsychotic medications and 36% on polypharmacy. Though the risk of diabetes is increased four-fold in children on antipsychotic medications, most (62%) are not screened.[7] Children are especially vulnerable to preventable harm caused by healthcare for many reasons, including weight-based medication dosing, handoffs between caregivers, and their limited ability to communicate evolving symptoms.

Table 1. Definitions.

Medication error: Defined by AHRQ as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer."[8] Errors occur during drug ordering, dispensing, preparation, administering, and monitoring.
Adverse drug event: An injury resulting from medication use.
Treatment delay: Defined by The Joint Commission as when a patient fails to get an ordered treatment or clinical visit in the time frame in which it was supposed to be delivered.[9] Treatment delay may result in injury or death.

Little information is available regarding the contribution of the healthcare system to errors in the home setting. Coordination between caregivers in the ambulatory setting is highly complex and fragmented. For example, poison control centers receive one phone call every 8 minutes about a pediatric medication overdose at home, most commonly due to duplicate doses administered erroneously by two different caregivers.[10] Coordination between home and clinic is also problematic. Telephone triage nurses, for example, miss symptoms of serious illness 64% of the time.[11] The field of ambulatory pediatric patient safety is wide open: interventions have not been widely tested, and health systems have not undertaken systematic redesign to improve patient safety.

Setting and Context

Cincinnati Children's Hospital Medical Center, a pediatric academic health center, has 1.5 million outpatient visits a year. The Diabetes Center, which sees over 2000 patients, is staffed by endocrinologists, nurses, certified diabetes care and education specialists, social workers, and psychologists. The Developmental Behavioral Pediatrics medical clinic has 2113 children with ASD. This clinic is composed of board-certified developmental-behavioral pediatricians, nurse practitioners, fellows, nurses, medical assistants, child life specialists, and social workers. Psychotropic medications are prescribed and managed by developmental pediatricians, with referrals to mental health after repeated failures. Epic (Verona, WI) is the electronic health record (EHR) system, and patients have access to MyChart, Epic's patient portal.

Participants

This study is on treatment delays and medication errors among children with chronic conditions in the outpatient setting and home. We chose to focus on two populations in this study: children with autism and children with type 1 diabetes. Both populations use medications with a narrow therapeutic window — in which both overdoses and underdoses are dangerous. Both groups are at risk for emergent medical and behavioral issues that quickly escalate at home in the setting of treatment delay. Diagnosis and treatment in ASD are particularly difficult, because many of these patients are non-verbal.

Incidence/Prevalence

Nearly half of all Americans, 133 million people, suffer from a chronic condition.[12] One in four American children, approximately 15 million children, have a chronic condition. Given these statistics, it is not surprising that Americans take a lot of medications. One billion medications are prescribed annually in the US.[13] Half of Americans took one prescription medication in the last month.[13] Over half of children took one or medicines in the past week.[14] Chronic disease care and daily medication use are ubiquitous in American lives. As model populations, this study focuses on children with autism and on children with type 1 diabetes. There are 1.6 million Americans with type 1 diabetes, of which 187,000 are younger than 20[15]; 5.4 million adults and 1.1 million children in the US have ASD.[16] However, the vast majority of patient safety research focuses on hospitalized patients.

Existing literature indicates that medication safety and treatment delay are critical areas in outpatient care where harm is occurring. [1,10,17,18] Pediatric outpatient medication errors are common and dangerous. Over half of children took one or more medicines in the past week.[14] There are 63,358 calls annually to poison control centers, or one phone call every 8 minutes, about a pediatric medication overdose at home. The most common reason is duplicate doses administered by two different caregivers.[10] In children with leukemia, errors occurred in one in 10 oral chemotherapy medications studied.[19] Children with epilepsy have 2.5 times the risk of healthy children of accidental prescription medicine poisoning.[20] Our group found that 40% of children with chronic conditions have a medication error at home — with a rate of preventable adverse drug events similar to that of hospitalized children.[2] An editorial about this study called for improved scaffolding to support families caring for children at home.[21]

Treatment delays in children are dangerous and understudied. Diagnostic delay, including treatment delay, is a relatively new defined quality gap described by the IOM report and other landmark works.[22] This is the most common reason for pediatric malpractice lawsuits.[18] Although the rate of malpractice claims is relatively low for pediatricians, the percent of lawsuits resulting in over $1 million in payout higher than for other disciplines — presumably because preventable serious injury or death in a child is so egregious. Failure to provide patients with clear follow-up instructions and poor communications between providers are root causes of harms associated with treatment delay.[18] Much of this communication takes place over the telephone. In a systematic review, telephone triage was safe in 92% of daytime calls but only 46% of high-risk calls.[11]

Insulin misuse at home and treatment delays can be fatal in T1D. **Less than half of children with T1D have optimal glycemic control, and approximately 33,000 (20%) have poor glycemic control.[4,5]** T1D is an auto-immune condition that results in complete insulin deficiency. Management requires frequent monitoring of blood glucose levels, multiple daily administrations of insulin bolus doses based upon carbohydrate intake and blood sugar, adjustment of doses during illness, and routine co-management with the diabetes care team. Carbohydrate intake and activity levels are hard to predict in children, and symptoms of high or low blood sugars are frequently missed.[23] **The leading cause of death before age 30 among individuals with childhood-onset T1D is acute complications (e.g., severe hypoglycemia, DKA), and 5% of deaths are attributable to "dead-in-bed" syndrome (sudden unexplained death in young people with T1D).[6]** In one study, one in four teens with T1D made dangerous insulin dosing errors.[24]

Polypharmacy and abysmal monitoring of antipsychotics put children with ASD at risk for both acute and lifelong complications. Sixty-four percent of children with ASD use psychotropic medication (atypical antipsychotic, stimulants, antidepressant, and sleep aids) for treatment of behavioral challenges and comorbid mental health diagnoses, and 35% use more than one such medication.[25] Atypical antipsychotics, in particular, are associated with adverse events, including acute dystonia, akathisia, tardive dyskinesia, hyperlipidemia, weight gain, and hyperglycemia.[26] The use of antipsychotic medications results in an increased risk of diabetes[27] and hyperlipidemia. Despite this risk, Dr. Walsh (Co-PI) found in a recent PCORI-funded study at 10 children's hospitals that only 38% of the 7600 children on antipsychotics received recommended annual screening for high cholesterol and diabetes.

Ambulatory patient safety is challenged by fragmented locations of care — including clinic, pharmacies, and home — that impedes coordination and communication. Although the patient is the recipient of care in the inpatient setting, in the ambulatory setting, the patient and family are the agents of care. However, patients rarely receive adequate direction or supervision when learning care tasks.[28] The vast majority of ambulatory care is provided at home, not in clinic. In the words of Justin Masterson (parent Co-I), whose daughter has T1D:

> "*The 8 hours a year that a parent/patient with T1D spends interacting with their diabetes clinic represents less than one tenth of one percent of the time they spend taking care of their diabetes. What would we change if we embraced the reality that diabetes clinics do not care for patients — they support and empower those who do?"*

METHODS (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)
The study methods align with the stages of problem analysis, design, intervention development. Evaluation was performed in the simulation center (T1D), and implementation was performed in the clinical setting (ASD).

Study Design.
A transdisciplinary team of parents, safety researchers, and clinicians employed Systems Engineering Initiative for Patient Safety (SEIPS)-based process mapping, with data collected through in-home medication review, medication administration observation, parent surveys, staff surveys, and focus groups informing a failure modes and effects analysis (FMEA). The SEIPS model was selected due to its safety-centeredness and scientific rigor (its validity, acceptance, and commonality in the patient safety community and literature). Our study team includes clinicians, parents, and researchers providing expertise in human factors, pediatric ambulatory patient safety, informatics, and patient care. A design firm, Mad*Pow, provided consultation throughout the study. Our focus on ambulatory patient safety was well aligned with hospital priorities, and the priorities of health system leaders in quality and ambulatory care drove study aims. Collaborating with parents and clinicians, we focused on medication errors and treatment delays germane to ambulatory T1D and ASD care.

Recruitment. Patients aged 0-17 years with T1D or ASD were recruited by a research assistant for participation in the study. Patients and families were recruited during clinic visits and clinic staff in person or by email. Clinic staff participants gave verbal consent for observation and written informed consent for interviews. All patient participants gave written informed consent. Any current patient of the Diabetes Center with a diagnosis of type 1 diabetes or of the Developmental Behavioral Clinic with autism on a psychotropic medication was eligible to participate. Participants were recruited by provider referral, as well as postal mail and email flyers. Participation was voluntary. Verbal consent to participate was obtained either in person or over the phone. Written consent for video recording of the simulation was obtained via REDCap (Vanderbilt University, Nashville, TN). All participants who completed a simulation session received $50 compensation in the form of a reloadable debit card (ClinCard). This study was approved by our institution's review board prior to enrollment.

Demographics. Demographics were collected by patient report and included patient characteristics (e.g., age, race/ethnicity, insurance, highest education) and characteristics of their health and healthcare (e.g., whether the individual with T1D was on injection or pump therapy). The baseline therapy of the person(s) with T1D was characterized as (1) multiple daily injections (MDI) and self-monitoring of blood glucose (SMBG); (2) MDI and CGM; (3) continuous insulin pump and SMBG; and (4) continuous insulin pump and CGM.

Data Sources/Collection: Problem analysis
For problem analysis, parents participated in in-home medication reviews and observation of administration, interviews, and chart review. We also conducted staff interviews and in-clinic observations. Finally, parents and staff participated in failure modes and effects analyses.

In-home medication reviews, observations, surveys, and post-visit chart reviews. A trained nurse conducted the home visits and observed medication dosing and administration, reviewed medications, interviewed the parent or guardian, and evaluated medical records specifically on outcomes 1 month following the visit. The nurse also administered the Problem Recognition in Illness Self-Management survey and the Newest Vital Sign health literacy survey.[29,30]

Home visit procedures. In preparation for the visit, the nurse reviewed the medical record to identify all current medications and doses. In the home, she exampled all medication bottles and interviewed caregivers, discussing each medication's current dose and frequency, indications, problems with the medication (e.g., dispensing errors in the past), and missed doses in the last week. She also identified whether all the medications were at home or if there were any medications at home that were not listed on the EHR list. We developed the SEIPS 2.0 framework home visit observation tool, including recording field notes on home medication use processes and behaviors and tools used.[31,32] She identified errors by comparing the medication prescription to the bottle label and how families reported medication usage and administration. The inter-observer reliability for the detection of errors was excellent (K=0.89).[31]

After the home visit, the nurse used established methods to review all components of the patient's ambulatory medical record for the subsequent month.[33] Using standardized forms in REDCap, the nurse recorded information about potential errors. Errors were identified as a medication dose that differed by 10% or more from the correct dose. [34]

Error adjudication*.* Two physicians independently determined if an error occurred and its severity (clinically trivial, potential for injury but did not injure, and injury; severity: significant, serious, life-threatening), focusing on insulin-specific safety considerations. Inter-rater reliability for error occurrence was 100%. [2,35,36] Inter-rater reliability for error occurrence was 100%. The K was 0.62 on whether the errors resulted in injury or had the potential for severe injury.

Failure Mode and Effects Analysis (FMEA). FMEA is a systemic team-based approach that aims to understand how a process can fail and formulate interventions to redesign the process. [37] FMEAs with parents and clinic staff were employed to deliver a comprehensive understanding of potential failures and a varied range of solutions. The two FMEAs performed focused on (1) "a change in insulin dose due to abnormal glucoses at home" (medication error) and (2) "management of a sick child with T1D at home" (treatment delay). The study team taught the FMEA method to participants using real-world examples, simple language, and written materials at a third-grade reading level. Participants outlined the process, brainstormed failure modes, and suggested modes for each step in the process. In order to prioritize failure modes, we calculated risk priority numbers by multiplying participant Likert scale ratings of frequency of occurrence, the likelihood of detection, and clinician ratings of severity for each failure mode[37,38] The group suggested potential interventions for failure modes with the highest risk of priority numbers.

Measures/Analysis. We summarized demographics and error rates using descriptive statistics. For the PRISM survey, items with mean scores >2 were counted as self-management barriers.[29] Scores for the Newest Vital Sign survey were calculated and reported as 0-1, 2-3, and 4-6.[39] SEIPS-based process mapping were used to understand and examine the diabetes home care processes. This method utilizes swim lane process mapping. Each process step outlines the system elements of people, tasks, tools and technologies, organization and environmental components, and notes barriers and facilitators. Process maps were created using OmniGraffle Pro™ software (The Omni Group, Seattle, WA).

Conceptual Design and Solutioning.
We held our virtual design days on two days, a week apart, in July 2020. Participants included clinic staff and parents as well as senior leaders. At the design day, we iterated through exercises to brainstorm; then we down-selected some candidate interventions.

We initially sorted our idea space into eight solution categories: education materials at home, group messaging between caregivers, asynchronous group support, text-based dosing reminders, text-based status checks, clinic process modifications, cloud-based data sharing from glucose monitors, and an app that counts carbs using photos.

Intervention development – T1D

Given the input from the Design Day and the constraints of our grant period and resources, the team settled on focusing on two of the eight solution categories: sick day home care guidelines and text-based status checks. After gathering inspirational materials, including those from our parent experts, the team created prototypes around visual-driven sick day home care guidelines for T1D and created a 'chatbot' dialog flow for closed-loop communication.

We complete end-user design on the interventions and iterated through several versions of the prototypes with the project team and alpha testers. We completed formal end-user design activities with parents and clinic staff and finalized intervention artifacts in collaboration with Mad*Pow, clinicians, parents, and our human factors expert. Final artifacts included (1) a Just in Time visual tool to guide parents through the home care of sick children with type 1 diabetes (available for phones, web access, or paper); (2) a web-based ketone correction calculator for parents of sick children with type 1 diabetes; (3) a set of simulation scripts and activities for endocrine clinic physicians or diabetes educators and parents of children with type 1 diabetes to teach sick day care; (4) a chat-bot design for status checks to follow up with parents calling the clinic about sick children with T1D to find out how the child was doing after the phone call with clinic and after changes to medication dosing; and (5) simulation scripts and associated evaluation plans.

Development of web-based medication supports, including ketone calculator

During interactions with patients and families, it became apparent that, during times of illness, there were challenges with corrective dosing of insulin to accommodate the presence of ketones. Patients and families had a difficult time remembering the steps and calculations of this infrequent process. In response, we created a web-based tool (#2 above) that included the design content from earlier project activities and a ketone calculator. The tool was readily accessible via the intranet and was deployed in our simulation sessions.

Development of simulation sessions

Our multi-step process included (a) development of performance-based, scripted sick day scenarios, (b) selection and training of content experts within T1D care as simulation facilitators, (c) piloting and iterative revision of chosen scenarios, (d) selection of a video conferencing platform with recording ability, and (e) implementation of the simulation sessions via the Microsoft Teams communication platform (Microsoft Corporation, Redmond, WA). Multiple platforms were reviewed, and two were assessed in pilot sessions.

A team composed of endocrinologists, a simulation expert, a diabetes educator, and a number of parents scripted event-based sick day scenarios. Scenarios replicated the realistic, but complex, decision making required to manage hypo- and hyperglycemia as well as ketonuria for a child with T1D who may have a serious illness in the home environment. Five scenarios were created at increasing levels of complexity/severity for patients with T1D who used either insulin injections or a continuous insulin pump. We chose five scenarios to be representative of common triage calls placed to the Diabetes Center. Scenarios were scripted on a one-page flowsheet to allow for inclusion of trigger/critical events and targeted responses organized by most desired, less desired, and incorrect processes (see Figure 1). Multiple rounds of discussion and revision amongst the development group led to the creation of scenarios used in pilot sessions.

The simulation expert trained three facilitators, a diabetes educator, and two endocrinologists in medical simulation-based facilitation and debriefing. Facilitator training consisted of (a) review of a slide deck focused on debriefing of medical simulations and review of two articles, (b) a 2-hour workshop focused on facilitation, and (c) feedback on facilitation after each of the pilot simulation sessions. The training emphasized providing a psychologically safe environment for participants, the use of experiential learning, and the identification and closure of performance gaps through focused debriefing. We performed five pilot sessions (one for each scenario) and iteratively revised the scenarios.

Final simulation sessions were audio and video recorded via Microsoft Teams and conducted with caregivers of children, or young adults with, T1D. Sessions were 60 to 90 minutes in duration. We used block randomization to randomize participants to numbered scenarios in blocks of three and then assigned participants a numbered simulation at random. All participants received Scenario 1 to familiarize them with the simulation process, followed by a combination of Scenarios 2-5. Scenarios were led by a diabetes educator (lead facilitator) and modified in response to the participant's stated actions, similar to semi-structured interviewing. A second co-facilitator and physician acted as a record keeper and provided quality assurance to make sure all intended questions were asked and all outcomes were covered. A structured introduction was developed to help introduce the simulation process and concept of psychological safety to the participants. Participants were invited to collect any materials or supplies they would typically use for diabetes sick day management. For each scenario, facilitators recorded several performance goals, such as glucose and urine ketone checks or activation of emergency medical services (EMS), when indicated. To further identify performance gaps, the following questions were asked as part of the structured debriefing: what went well, what was easy for you, what was challenging, and what would you do differently?

Evaluation of Simulation Sessions. The primary outcome was performance of the participant during the three simulated scenarios they received, which was assessed using the process described below. Performance objectives were categorized into 1) knowledge elements, 2) skill elements and 3) critical thinking. Critical thinking and problem-solving are needed to recognize clinical deterioration and understand when to reach out for help as well as respond to changes in glucose and ketone status. A secondary outcome was the availability of key diabetes management supplies in the home setting. A recording tool was developed to describe, categorize, and quantify most desired, least desired, and incorrect processes. This tool was created based off the simulation scenario script/flowsheet. As part of simulation debriefing, qualitative participant feedback was collected. Learner satisfaction was examined via participant experience, appreciation, and perceived benefits of the simulations. Field notes were taken on any technical issues that hindered our ability to perform simulations and feedback collected from participants on any difficulties they had with the platform.

Measures/Analysis*.* Quantitative data were tabulated and analyzed using descriptive frequencies. Qualitative data were recorded and evaluated for common themes. Inter-rater reliability was calculated using percent agreement on whether an incorrect process occurred. For simulations in T1D, scenarios were assessed by task/activity, and categorized as most desired, less desired, and incorrect processes.

Intervention Development - Autism Spectrum Disorder

We sought to develop parent education materials that address key aspects of patient safety emerging from PSLL parent/staff interviews and home observations. Themes that emerged included the high cognitive burden experienced by caregivers of children with ASD, especially when their child has escalation or crisis of challenging behaviors. In this setting, if a caregivers cannot get their child to take a particular oral medication, they are more apt to feel distressed and not confident in medication helping their child, leading them to stop it. Sensory processing differences factor prominently in what oral formulation a child with ASD will tolerate or even how to get them to take it. Therefore, we devised written and visual support tailored to giving a child with ASD different formulations of medication (pill, capsule, liquid, ODT).

We identified individuals with content expertise and clinical experience in prescribing and administering psychotropic medication to children with ASD (Jennifer Ehrhardt, MD, and two RNs from DDBP clinic who are also parents of children with DD). We conducted a review of publicly available parent education materials related to medication administration for children with ASD, with limited such materials identified. We then developed content, including 1) a Medication Plan for when your child is taking atypical antipsychotic medication (How will I know it is working? What are the side effects? When should I contact clinic team and how?) and 2) formulation-specific guidance, including giving a child with ASD an oral medication by pill, capsule, liquid, ODT. We identified family member through DDBP's Family Advisory Counsel and additional clinic team members (RNs, nurse practitioners) to review and give feedback on this content. We then worked with design firm Mad*Pow to take this content and present it visually in a way that is easy to understand for caregivers. We took this product back to family member and clinic team to view and give feedback on.

Implementation and Evaluation – ASD

The work, learnings, and ASD intervention materials developed from this project were then used as the core material in a larger quality improvement project (through the Intermediate Improvement Science Series – I2S2) at Cincinnati Children's Hospital. The project, "Psychotropic medication management: Optimizing parent/clinic communication and ongoing care," focused on improving communications between the home- and the clinic-based care team. In partnership with a APRN and RN, a separate FMEA was conducted that focused on communication (and potential failures) between parent and clinic from the time of an in-person visit where a psychotropic medication was started or changed to the next visit. A pareto chart of failure modes related to ineffective communication was created, as was a key driver diagram based on the SMART aim of "Increasing the proportion of patients who have psychotropic medication management touchpoint within 1 month of starting or adjusting dose of medication from 20% to 60% by July 2023." The main outcome measure was the proportion of time communications between parent and clinic that took place after a psychotropic medication started or changed, occurring within 1 month following visit. Several PDSAs were conducted in the clinic setting with the partner APRN and three RNs. The interventions were adapted, including establishing a personalized communication plan with patient/family (ask for preference of phone or MyChart, specific timing ([e.g. 2 weeks from visit], use delayed staff message in EPIC to trigger RN to enact communication plan) and other adaptations to improve the closed-loop communication. An eVisit template in the EHR was established and used for families who preferred that method of communication. The process is outlined below:

- Patient has visit with MD/APRN at which atypical antipsychotic is started or dose adjusted.
- MD/APRN explains to family that we would like to check in with them in *** weeks (e.g., 2 weeks). This communication helps us know if medication has been effective for child's behaviors, if child has side effects, or If parent has problems getting child to take medicine. The care team can make medicine adjustments if needed.
    - The care team explains to family that they will schedule child for eVisit *** weeks from now.
    - If family is not signed up for MyChart, they offer to sign them up. Currently, MyChart enrollment in the clinic is over 80%.
    - If family indicates they do not want to or cannot use MyChart, they are offered to have a RN make a phone call in same timeframe.
- MD/APRN places order in Epic for eVisit and identifies "delivery date" (e.g., 2 weeks from now).
- On delivery date, family receives email alerting them to eVisit in MyChart.
- Family completes questions and eVisit.
- MD/APRN receives eVisit in their Epic message inbox. Based on information shared by family, the care team continues the medication or makes an appropriate change. They can have MyChart message exchange with family around medication changes they are recommending.
    - If medication change made, MD/APRN decides if should have another eVisit or FU. At time of previous visit, they advised family to schedule FU visit, in addition to eVisit.
- If the plan is for the RN to call the family, they make the call, asking same questions as those in eVisit, and route response to MD/APRN as phone encounter. MD/APRN responds and RN calls family back with their recommendations.

The primary outcome measure of the quality improvement study increased the proportion of timely follow-up from a baseline value of 20% of visits to 60% of visits.

RESULTS (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Principal Findings

- Over half of the T1D patients involved in our home-visit study population had errors, at a rate of 31 per 100 medications.
- The errors in both conditions were heterogenous, with a wide variety of causes/etiologies.
- FMEAs demonstrated a large burden of monitoring for effectiveness and safety falls on the families and patients, with a potential to shift some of that burden to the clinic-based teams through better communication (and closed-loop) pathways.

- Simulations are an effective way to assess patient/family knowledge and reinforce common illness scenarios and correct actions.
- There are currently no effective tools to detect diagnostic safety in the home, tools that focus on the patient and family as the diagnostician.
- Even patients and families who know their insulin treatment plan well do not recall all the additional steps to take when ill or normal treatment plans are not working (e.g., ketone management in T1D).
- Families of patients with autism have a difficulty distinguishing between adverse effects of medications and behavioral variations/escalations associated with ASD.

Outcomes

The following is a sample of our outcomes and results. Full data and more examples are present in our publications and artifacts.

Study Demographics

From March to December 2019, we performed 14 home visits and two FMEAs (eight parents, four clinic staff). The 14 children with T1D in the study were 4 -17 years old and took 59 medications at home (Table 1). Half of the parents (n=7) reported that they had previously given the same medicine or missed a dose in the home due to errors in communication between in-home caregivers (e.g., two parents).

Table 1. Demographics of home visits

	T1D home visit patients (N=14)	ASD home visit patients (N=9)	Simulation participants (N=12)
Medications n, median, (min, max)	59, 4, (1-7)	n/a	n/a
Parent of 1 child with diabetes, n (%)	n/a	n/a	8 (57%)
Parent of 2 children with diabetes, n (%)	n/a	n/a	2 (17%)
Adult participant with diabetes, n (%)	n/a	n/a	2 (17%)
Female n (%)	5 (36%)	7 (78%)	11 (92%)
Race n (%) White/Caucasian Black or African American Hispanic Multiple races	 9 (64%) 5 (36%) n/a n/a	 n/a n/a n/a n/a	 8 (67%) 2 (17%) 1 (8%) 1 (8%)
Private Insurance n (%)	8 (57%)	5 (56%)	7 (58%)
Public Insurance n (%)	6 (43%)	4 (44%)	5 (42%)
Children with multiple Individuals administering meds n (%)	12 (86%)	n/a	n/a
Primary person responsible administering child's meds n (%) Mom Dad Child (self-administration)	 8 (57%) 0 (0%) 6 (43%)	n/a	n/a
Use support tools (i.e., calendar) to manage child's medications n (%)	14 (100%)	n/a	n/a
Time since Diagnosis (Years) Mean Median Range	 n/a n/a n/a	 6.2 years 6.5 years 11 years	 n/a n/a n/a
Has Additional Diagnoses n (%)	n/a	9 (100%)	n/a
Participating in other Clinical Trial n (%)	n/a	2 (22%)	n/a
Has Allergies n (%)	n/a	4 (44%)	n/a

n/a = Not applicable

Errors Detected

Eight (57%) of the 14 children with T1D who had home visits and chart reviews experienced 18 errors (31 per 100 medications) detected during the home visit or chart review (Table 2). Of these, four errors were harmful, and 13 had the potential to harm the child but did not. All four errors with harm were separate incidents that occurred for two patients with comorbid mental health issues. Two injuries required emergency department (ED) visits for severe hypoglycemia and lethargy, for which the child did not receive glucagon or any oral carbohydrates at home for rescue therapy. Two others were repeated failures to administer insulin at home properly.

Seven (78%) of the nine children with ASD who had home visits and chart reviews experienced eight errors detected during the home visit or chart review (Table 2). Of these, none were harmful, and seven had the potential to harm the child but did not. One dispensing error and two administration errors involved psychotropic medications.

Table 2. Medication Errors identified among 14 children with T1D and nine children with ASD using in-home medication review, observation of administration, caregiver interview, and chart review.

Error type	Example
Treatment delay/Omission (N=2 T1D)	Child received insulin but did not eat in the morning. Parent drove the child to the hospital when the glucose was low; did not use glucagon or food because did not know to do ***Error with potential for harm; life threatening***
Not checking ketones at home (N=1)	During the home visit, a child had a glucose over 400 but did not check ketones, even after being reminded by the nurse to do so ***Error with potential for harm; serious***
Not checking sugars at home (N=1)	School nurse called the clinic because glucose range from 50-380; no one at home is checking glucose at all ***Error with potential for harm; serious***
Medication under dose or missed doses (N=7 T1D insulin, N=2 ASD)	Adolescent misses putting his glucose or carb count in the pump for a bolus, and lets his pump run out of insulin, changing only with the next meal ***Error with potential for harm; serious***
Wrong technique (N=5 T1D)	Parent administered insulin pen but removed the pen immediately while pen was still dispensing the dose, causing some of the insulin to be on the skin ***Error with potential for injury; significant***
Expired medication (N=2 T1D, 3 ASD)	Family only had expired glucagon at home ***Error with potential for injury, life-threatening***
Pharmacy Dispensing (N=1 ASD	Dose of escitalopram was changed but the pharmacy dispensed the old dose. The mother was giving the correct dose. ***Error with potential for injury***
Administration (N=1 ASD)	Child missed a dose of Adderall XR before school. ***Error with potential for injury***
Prescribing (N=1 ASD)	Child was prescribed an age-appropriate dose of cetirizine ***Clinically trivial error***

Findings from FMEAs and Process Mapping

We produced FMEA diagrams with failure modes and errors mapped to the process affected. A sample SEIPS-based FMEA diagram is shown below for the high-risk process, "Management of a Sick Child with T1D at Home" in Figure 1 and for “Contacting the clinic about worsening behaviors for child with ASD” in Figure 2.

Bright red symbols indicate the highest risk failure modes. Table 3 shows the highest risk failure modes and suggested interventions for each FMEA.

Figure 1: Management of a Sick Child with T1D at Home

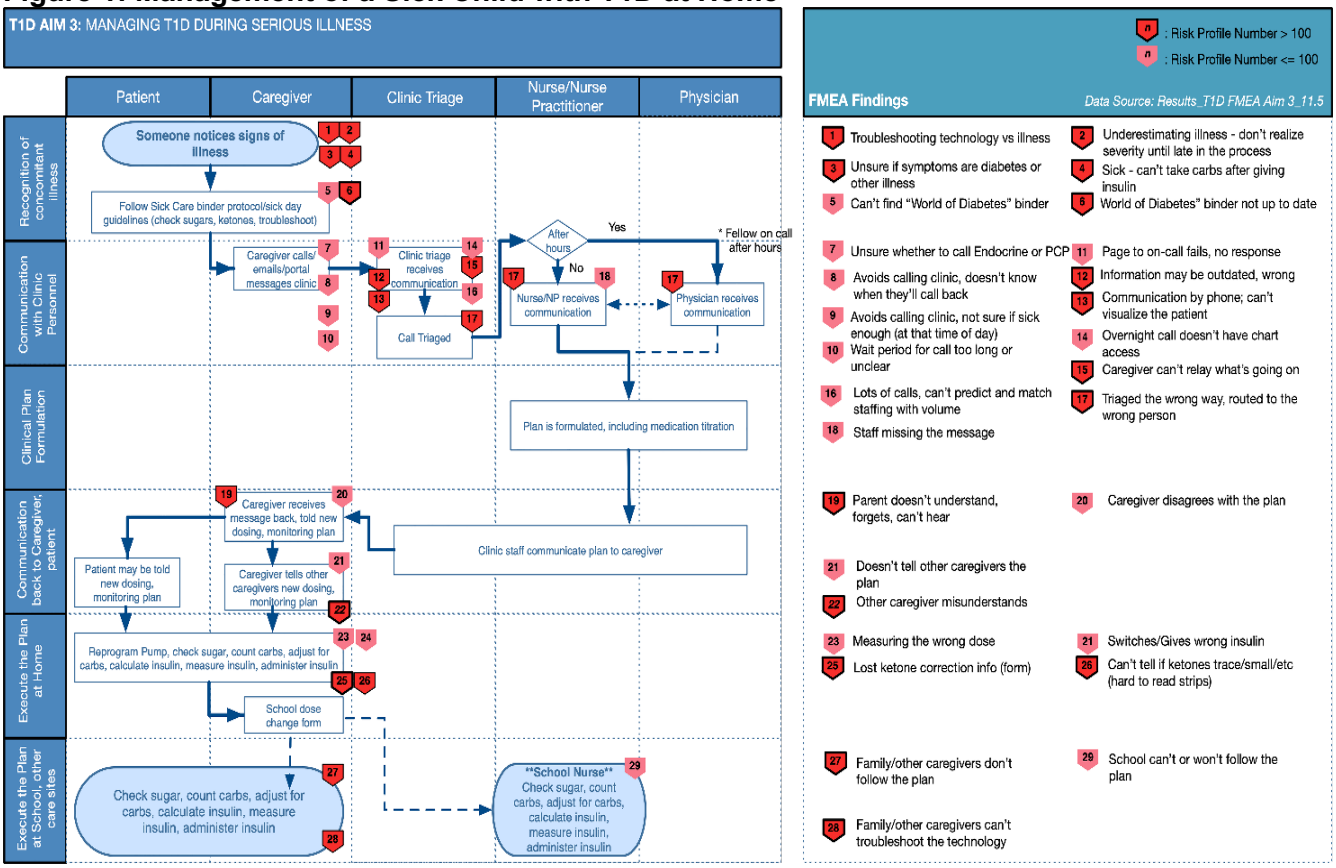


Figure 2: Contacting the clinic about worsening behaviors for child with ASD

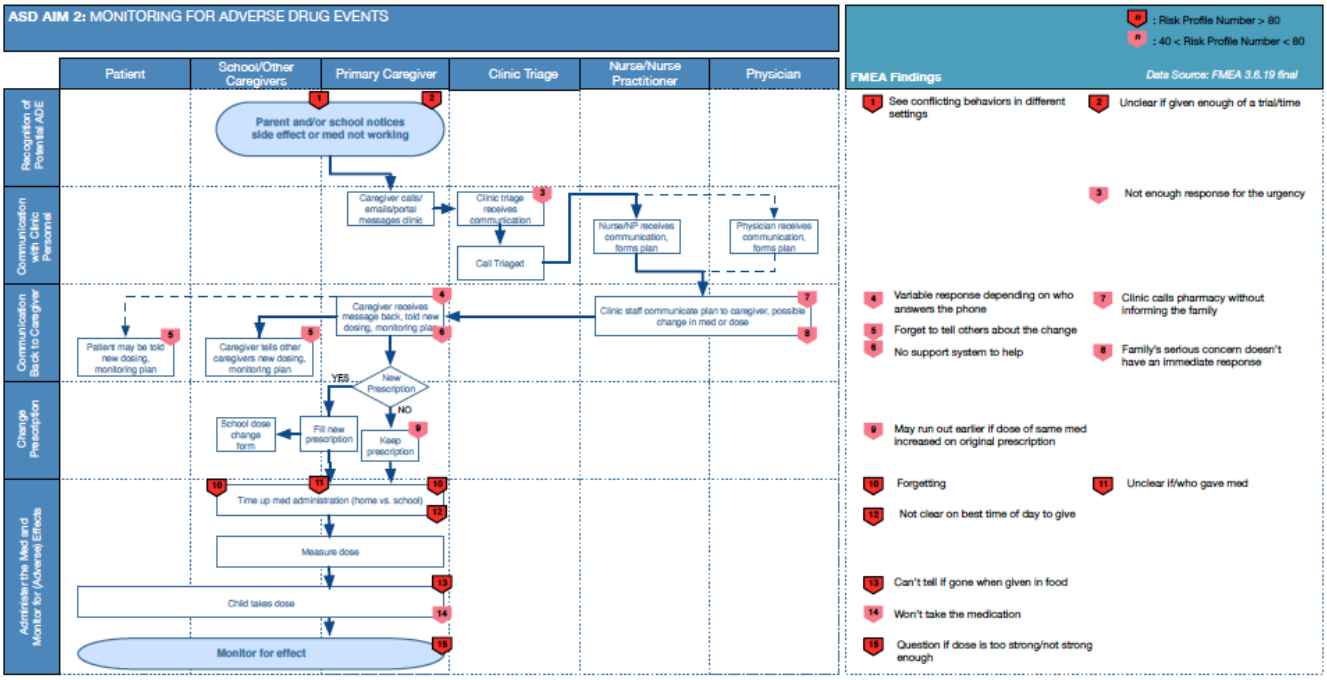


Table 3. Highest-risk failures identified by eight parents and four clinic staff in separate failure modes and effects analyses (FMEAs). Failure modes were layered onto the SEIPS-based process maps.

Process steps	Failure Mode	Intervention
FMEA* #1. A change in insulin dose due to abnormal glucoses at home		
Caregiver/patient notices frequent abnormal glucoses	No one is checking glucoses	Highly visible, prominent paper at home or app for recording glucoses
	Does not notice that the glucoses are abnormal	
	Adolescent patient forgets to tell anyone about the abnormal glucoses	
	When asked, adolescent doesn't tell the truth about the glucose levels to caregiver because she/he does not want to deal with it	
Caregiver contacts clinic	Correct information not relayed from parent to clinic	Tools (e.g., handout, on hold message) that prep families for information needed, template for info needed, personal relationship with caregiver
	Clinic is not open, after hours, weekends and unable to get through to someone	Extend clinic hours, periodic after hour visits
FMEA #2. Management of a sick child with T1D at home		
Caregiver notes signs of illness	Overwhelming difficulty determining whether technology or illness as cause of symptoms and calling clinic while child is sick (e.g., actively vomiting)	Simple just-in-time algorithm/ process map that walks caregiver through troubleshooting, when to call (digital and paper-based options)
	Caregiver does not notice the illness until the child has gotten much worse later in the process, e.g., a home-based diagnostic delay	A more active process for families and patients to engage in when patients first get sick, to help them understand how ill the patient is, if it's T1D or something else (or both), etc.
	Unsure if sick (is it diabetes, or something else)	Parents suggested a peer consultant service
Clinic receives information from clinic about what to do	Information may be outdated (patient worsened while the clinic was processing and responding to original call from home)	A more active process for families and patients to engage in when patients first get sick, to help them understand how ill the patient is, if it's T1D or something else (or both), etc.
Administer insulin	Can not tell if ketones are trace/small/etc. (hard to read)	Use blood ketone meters
Discussion between triage nurse and nurse practitioner	Caregiver unable to clearly explain what's going on or misses important information	A hold message or written handout/template of information needed when talking to clinic
Caregiver tells other caregivers about plan	The caregiver forgets to tell the other caregiver, or the other caregiver misunderstands and does not follow instructions (at home hand-off)	Visual, written information sent from clinic to home about management plan after phone call for caregiver to share with other caregivers
FMEA #3. Contacting the clinic about worsening behaviors for child with ASD		

Communicating information to nurse or physician	There were variations on how the physician managed the clinic each day	Communication around standard management for common issues
Caregiver/school observes escalating behaviors	Caregivers try to endure the worsening behaviors	Increase access to behavior therapy, better behavioral resources. Outline clear behavioral goals for medication interventions & process for behavior escalation at home on after visit summary
Caregivers instructed on how to monitor and identify problems and when and who to contact with problems	Caregivers were not provided a comprehensive set of tools and instructions	Standardize written materials for families around how to handle worsening behaviors at home, including who to contact

*FMEA: Failure Modes and Effects Analysis

Other Design Outputs - Interventions

Several chat-bot scripts for automated follow-up for T1D patients were created, including one for medication adjustments and one for checking in with patients for clinical status updates. Both scripts were created to facilitate timely, closed-looped communications that are scalable. An example is shown below in Figure 3.

Figure 3: Chat-bot language flow draft for future implementation. This method could be used to automatically check-in with patients and families, to conveniently close the loop on clinical follow-ups and status updates.

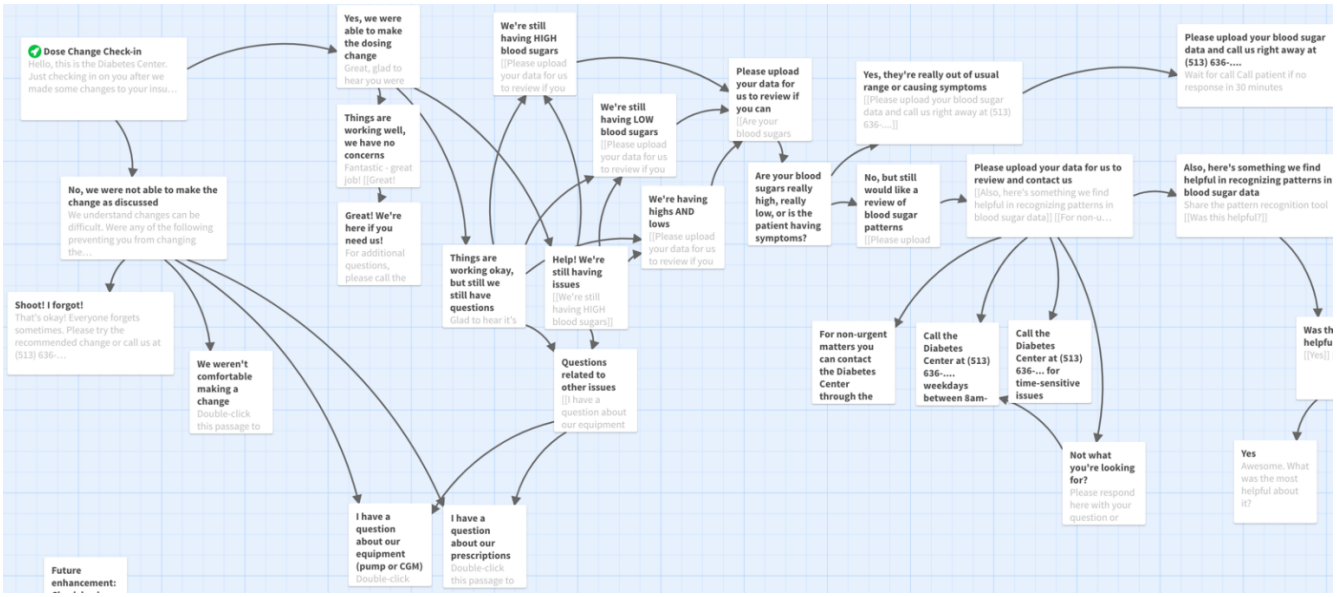
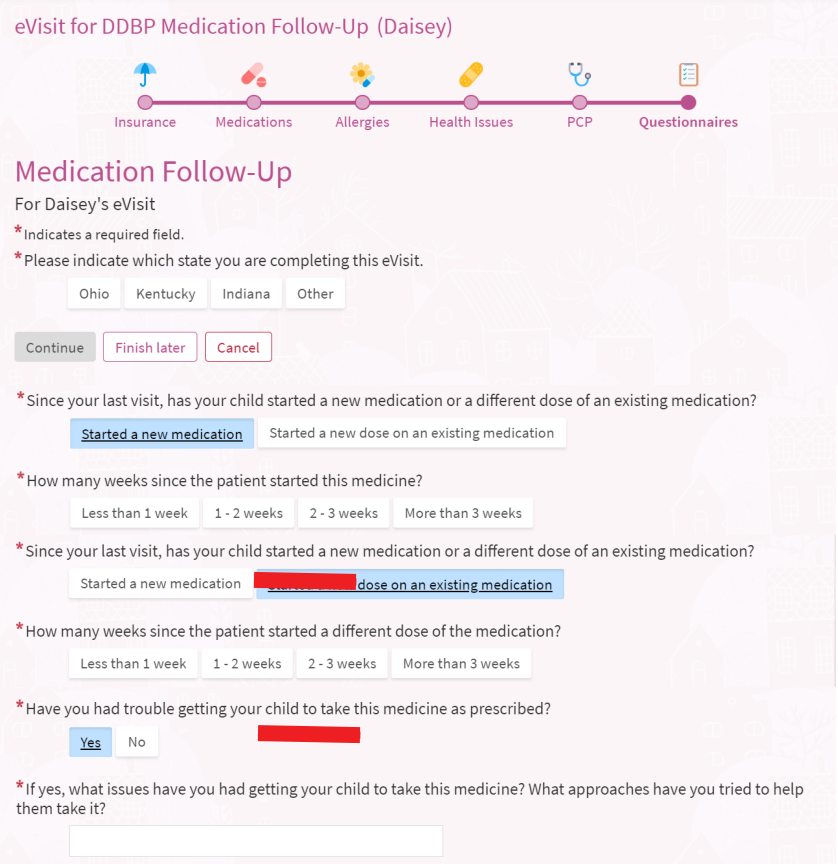


Figure 4: ASD Medication Follow-Up eVisit Questionnaire. This screenshot shows the first several patient-reported outcomes collected as part of the closed-loop communication quality improvement project in ASD. The actual questionnaire is much longer and incorporates more medication safety and administration questions.



T1D Simulation Study Results

Two blocks of six randomized and scored simulation sessions were conducted from March 2022 - March 2023. All participants were able to verbalize the need to increase oral intake of fluids when ketones are present. Consistent knowledge deficits involved when and how much insulin to give when ketones are present (42%) as well as the what the upper glucose limit was for either glucometer or CGM. The most common error participants made was management of ketones (Table 3). Despite most participants being familiar with insulin pump therapy, pump site malfunction was not consistently suspected when ketones were present. Surprisingly, a third of participants (33%) did not have the Diabetes Center triage phone number either entered in the "Contacts" of their mobile phone or readily accessible.

Table 3. Type and Frequency of Errors in Simulated Sick Day Scenarios

Error type	**# with error**
Insulin dosing error, *n* (%)	3 (25)
Technology error, *n* (%)	2 (17)
Ketone management error, *n* (%)	5 (42)
Treatment delay error	0

Due to the free response nature of simulation, participants were able to describe actions that they would perform for each scenario and explain their rationale. Participants also brought up additional actions as well as errors that were not included in the scenario process map(s).

After completing the introductory sick day scenario (Scenario 1), participants trended toward improvement in the final simulation, with more desired processes scored (Table 4). Eight of the 12 participants (67%) made no incorrect processes (Table 4) at all during the final scenario presented.

Table 4. Simulation Participant Actions by Scenario

Participant actions						
	Total	Scenario 1 (n=11)	Scenario 2 (n=6)	Scenario 3 (n=6)	Scenario 4 (n=6)	Scenario 5 (n=6)
Most desired	19.5 (11-30)	7 (3-12)	5.5 (3-7)	9 (5-12)	8 (7-9)	5.5 (3-9)
Less desired	4 (0-6)	1 (0-2)	0 (0-7)	0.5 (0-3)	1.5 (0-4)	0.5 (0-2)
Incorrect	0 (0-2)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-1)	0 (0-0)

*Data are expressed as median with range in parentheses.

Secondary Outcomes – real-world assessments accompanying simulation scenarios

Participants were asked about having "back up" supplies for MDI therapy and SMBG in case of pump and/or CGM malfunction, respectively (Table 5). Multiple participants with pump users in the home denied having spare basal insulin at home. One mother stated, "Some people just rely on the pump so much, I know I do." Of those who had a glucometer available (83%), not all had test strips. Most participants did not know the expiration date of their glucometer (67%) test strips, and of those with urine ketone strips (83%), 40% were expired. One participant did not have emergency glucagon rescue available, which prompted facilitators to send a renewed prescription. Half of participants also did not have the institution's handbook for T1D management, including sick day guidelines, which is distributed to all patients at diagnosis.

As simulations required participants to join via Microsoft Teams and view shared content on either a computer or phone screen, technical issues were assessed. We observed variation in use of different devices (e.g., mobile phone versus computer), disruption of service and connectivity, and setting (e.g., home vs car). Most technical issues were able to be overcome and simulation sessions could be completed. The most notable example was person who was moving/had major social challenges.

Discussion

We set out to study and improve chronic care management across two conditions, type 1 diabetes and autism spectrum disorder, through a patient/family engagement in user-centered design. Each condition has differing characteristics, with one key differentiator being the amount of reliance on objective versus subjective data to maximize the safety and effectiveness of high-risk medications. This monitoring is largely done by the patients and families in an outpatient setting, and the assessment of disease status and escalation of care depends even more on them to bring issues to the attention of their healthcare providers. We know from prior studies that the rates of errors in this setting and context is high. In previously published case studies of insulin administration errors, most errors were in administration at home.[40] The objectives of this project were meant to study and address these issues.

Rates of errors were indeed found to be high, and, like many other safety studies, the causes and failure modes were many and heterogenous. The knowledge and skillsets of patients and families dealing with these conditions varied greatly, which signals a personalized approach to providing care and communications is necessary. Even highly knowledgeable and experience patients with T1D, for instance, were found to not be able to recall how to adjust their insulin dosing when they were ill and had tested positive for ketones. This is partially due to the infrequent occurrence of this physiologic state for most patients, and the complexity of the additional steps needed to adjust their already complex regimen and treatment plan.

Through co-collaboration sessions with families of patients with both conditions, we identified drafted SEIPS-based process maps, recognized and prioritized key failure modes and ultimately brought their, and many others', experiences and knowledge to design sessions.

Through these sessions, we identified key interventions that would address some of these issues directly and that fit within the constraints of our project period and resources. Ultimately, this led to the creation of numerous high-yield artifacts (digital content and tools) that served as both educational/training tools, as well as utilities to implement in both simulation environments (T1D) and the real-world (ASD). It also led to the creation of some tools to implement in future projects tailored and resourced appropriately to study their effects (chat-bot dialogs for follow-up status checks).

The creation of the simulation scenarios, coupled with the online tools, allowed us to create an entire framework for simultaneously assessing the knowledge of patients and the safety of their current processes. The simulation framework also provided an evaluation tool, which highlighted, in real-time, opportunities for the patients to improve their knowledge. This framework is now being incorporated into the routine educational programs at Cincinnati Children's Hospital and can be further built upon and disseminated in many ways. In addition, the FMEAs and process maps provide the team with tools to further study the safety and opportunity at each step of several processes.

On the ASD side of the project, we have created numerous artifacts as well, targeted toward safety aspects (how to detect adverse effects and when to contact healthcare providers) as well as effective administration of different formulations of medications in a sensory-specific population. The knowledge and tools created as part of the original scope of the grant were used to implement a quality improvement project whose aim was to improve the percentage of timely follow-ups with patient families after the initiation or adjustment of dose of an antipsychotic medication. Early analysis of the initial project shows a three-fold increase in closed-loop communication, from 20% contact within 1 month of change to 60% after the implementation of the program and iteration through several PDSA cycles.

Regardless of the condition studied, this project facilitated a much deeper and richer understanding of the different types of errors and failure modes as well as opportunities to improve the care of our patients where it is occurring – in the home setting. We continue to operationalize and iterate on our current findings and have several follow-up lines of inquiry and implementation in mind.

Conclusions

Using SEIPs-based process mapping informed by multimodal methods to identify medication errors and treatment delays in children with T1D, we found errors were common. A significant burden of care exists at home for families of children with T1D; additional support from the healthcare system is needed to prevent errors. Better support for managing acute illness-associated hypo or hyperglycemia at home and more seamless communication between families at home and the diabetes clinic are areas rich in potentially high-yield interventions. Such solutions, co-produced with patients, families, and clinicians, can potentially improve the safety and quality of outpatient pediatric T1D developed by families at home.

Significance

Medication errors are common in the home setting, and care providers must recognize and adjust treatments to keep their children safe. This includes acute illness or exacerbation of chronic conditions as well as adverse effects of the medications. Most communication with the healthcare system for escalations is incumbent on the patient or family, and most systems are not convenient or personalized. Creating educational and more effective communication tools and processes has the potential for improving both the safety and effectiveness of, as well as satisfaction with, the care our current healthcare systems provide.

Impact

Potential Impact

Nearly half of all Americans, 133 million people, suffer from a chronic condition.[12] One in four American children, approximately 15 million children, have a chronic condition. Given these statistics, it is not surprising that Americans take a lot of medications. One billion medications are prescribed annually in the US.[13] Half of Americans took one prescription medication in the last month.[13] Over half of children took one or medicines in the past week.[14] Chronic disease care and daily medication use is a ubiquitous part of American lives. As model populations, this study focuses on children with autism and on children with types 1 diabetes.

There are 1.6 million Americans with type 1 diabetes, of which 187,000 are younger than 20; 5.4 million adults and 1.1 million children in the US have ASD.[16,41] However, the vast majority of patient safety research focuses on hospitalized patients.

Improvement of Clinical Processes

- (T1D) Team members are now working to make the materials and interventions created from this project part of the normal training and education process for new-onset diabetes, after a significant clinical event (hospitalization for diabetic ketoacidosis) and for assessments during routine clinical visits.
- (ASD) Study team members used this project as a springboard for an extensive clinic-wide quality improvement effort to help families safely use antipsychotics at home, monitor for improved behavior, and monitor for adverse events as part of a mentored improvement science course.

Education/Training

- Extensive training and experience of endocrinologists (including clinic leaders), nurses, and diabetes educators in patient safety, embedded research, and use of simulation to improve patients safety
- Extensive training in human factors engineering and patient safety for developmental pediatrician and quality improvement leader.
- Additional training for staff of the autism clinic in medication safety
- Presentation at national meetings by several junior members of our study team, with senior authorship by clinician members of our team

List of Publications and Products

Conference Poster and Lectures

Kirkendall ES, Brady PW, Ehrhardt J, Ruddy RM, Corathers SD, Wetterneck TB, Walsh KE. Redesigning Communication and Care for Children with Type 1 Diabetes or Autism Spectrum Disorder, and their Families. Platform presentation at: Human Factors and Ergonomics in Health Care International Symposium. April, 2021; Online.

Nelson H, Corathers SD, Brady PW, Kirkendall ES, Ruddy RM, Wetterneck TB, Walsh KE. Ambulatory Patient Safety Learning Lab: Failure modes and effects analysis for management of type 1 diabetes during illness. Poster session presented at: International Society for Pediatric and Adolescent Diabetes (ISPAD) Annual Conference. October, 2021; Online.

Geis G. Applying Principles from Simulation Learning Labs to Diabetes Sick Day Management. Grand Round Lecture presented at: Cincinnati Children's Hospital Medical Center, Division of Endocrinology. February, 2024; Cincinnati, OH.

Fox C, Nelson H, Geis G, Smith E, Walsh KE, Brady PW, Kirkendall ES, Corathers, SD. Simulation as a Tool To Improve the Effectiveness of Diabetes Sick Day Education. Poster session presented at: Association of Diabetes Care and Education Specialists; August, 2023; Houston, TX.

Journal Articles

Kirkendall ES, Brady PW, Corathers SD, Ruddy RM, Fox C, Nelson H, Wetterneck TB, Rodgers I, Walsh KE. Safer Type 1 Diabetes Care at Home: SEIPS-based Process Mapping with Parents and Clinicians. Pediatr Qual Saf. 2023 May/Jun;8(3):e649. doi: 10.1097/pq9.0000000000000649.

Brady PW, Ruddy RM, Ehrhardt J, Corathers SD, Kirkendall ES, Walsh KE. Assessing the SaferDx Tool ® in the Understanding of Ambulatory System Design Changes for Type 1 Diabetes and Autism Spectrum Disorder in Pediatrics. In progress.

Nelson H, Fox C, Corathers SD, Kirkendall ES, Walsh KE. Novel Use of Simulation in Pediatric Type 1 Diabetes Sick Day Education for Patients and Caregivers. In progress.

Electronic Resources and Tools

Pediatric Patient Safety Learning Lab. Managing Type 1 Diabetes: Ketone Correction Calculator. [Internet]. Available from: http://psll-t1d.azurewebsites.net/. Accessed 2024 Jan 17.

Pediatric Patient Safety Learning Lab. Managing Type 1 Diabetes: What To Do When Your Child Is Sick. [Internet]. Available from: http://psll-t1d.azurewebsites.net/. Accessed 2024 Jan 17.

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Ambulatory Patient Safety Learning Lab. Type of Medicine Capsule You Open and Sprinkle. 2023.

Ambulatory Patient Safety Learning Lab. Type of Medicine Liquid. 2023.

Ambulatory Patient Safety Learning Lab. Type of Medicine Pill You Can Crush. 2023.

Ambulatory Patient Safety Learning Lab. Type of Medicine Medical Plan. 2023.

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