Rising T1DE Report

Remote Patient Monitoring

RISING T1DE
ALLIANCE

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Rising T1DE Report:

Remote Patient Monitoring Intervention

Children's Mercy Diabetes Center - 2022

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BACKGROUND: USING REMOTE PATIENT MONITORING TO DECREASE A1C IN AT-RISK YOUTH WITH T1D

WHO WE ARE

The Rising T1DE Alliance was formed in collaboration between Children's Mercy Kansas City, the Joslin Diabetes Center, Nemours Children's Health, and Cyft, Inc. Its creation was supported through a grant from The Leona M. and Harry B. Hemsley Charitable Trust to Children's Mercy Kansas City. The Alliance seeks to accelerate innovations in clinical care by 1) incorporating the voices of persons with diabetes (PWDs) and their caregivers; 2) getting in front of health problems by predicting outcomes whenever possible; 3) using the Model for Improvement to rapidly discover process improvements and novel interventions that improve outcomes; 4) understanding the barriers, facilitators, and cost effectiveness of each interventional approach; and 5) disseminating this know-how broadly to other care systems.

HOW TO USE THIS RISING T1DE REPORT

A Rising T1DE Report is a document that provides a brief and practical update on the things we've tried within the Rising T1DE Alliance to improve care, and what we're learning as we go. Diabetes care teams seeking to improve outcomes in their center by implementing Remote Patient Monitoring (RPM) are likely to benefit most from this Report. It is best used in combination with other Quality Improvement tools, including a clinic-specific change package, and skills and experience with quality improvement methodologies.

Considerations when determining your center's readiness to implement change:

- Strategic alignment with institutional vision and goals
- Team readiness/desire for change
- Organizational willingness to try small tests of change (PDSA cycles); adopt what works, adapt where needed, and not be afraid to abandon interventions that don't work
- Having a well-defined SMART (specific, measurable, achievable, realistic, time-bound) Aim
- Personnel with skills to map existing clinical processes, identify challenges and opportunities
- Personnel with analytic capabilities to measure and display data over time and to find trends
- Infrastructure to share successful interventions with eligible clinic populations and sustain over time

THE PROBLEM WE'RE TRYING TO SOLVE

The majority of youth with type 1 diabetes do not achieve targets for glycemic control, raising the risk for future micro- and macro- vascular complications. Evidence suggests that suboptimal control early in the course of disease has an irrevocable impact on this risk (viz. the metabolic memory hypothesis).

Data from the T1D Exchange has also shown that youth in the US collectively exhibit deterioration in glycemic control from age 8-18 years old (Figure 1), with glycemic control only slowly improving from age 18-30 years old (Miller et al., 2015). Additional evidence suggests that among youth in multiple areas of the world (i.e., the U.S., Europe and Australia), about 18-22% of youth account for most of the rise in HbA1c that is observed; furthermore, one can predict which youth are more likely to experience a rising trajectory of HbA1c (Figure 2; Clements et al., 2019).

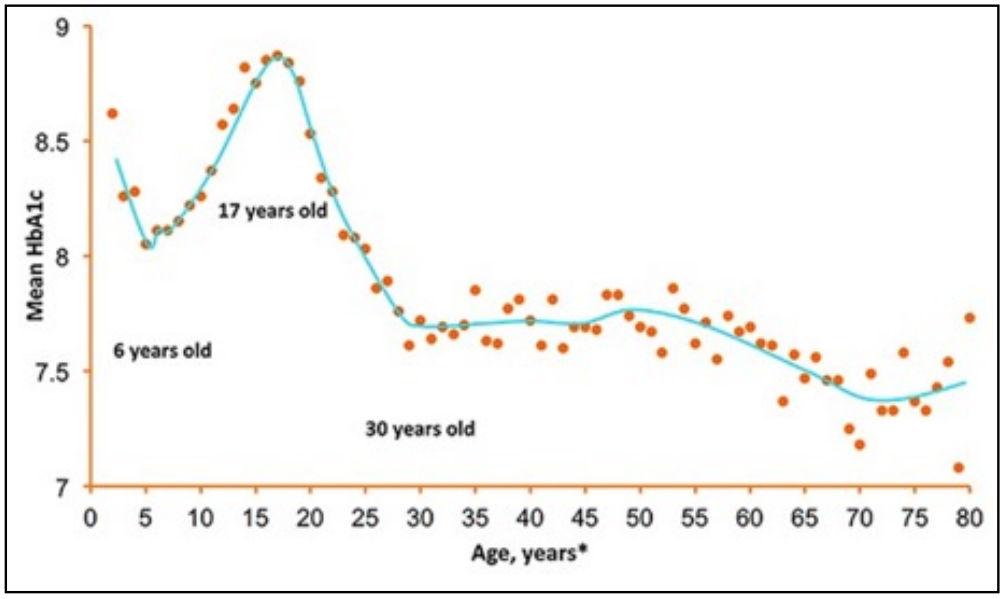
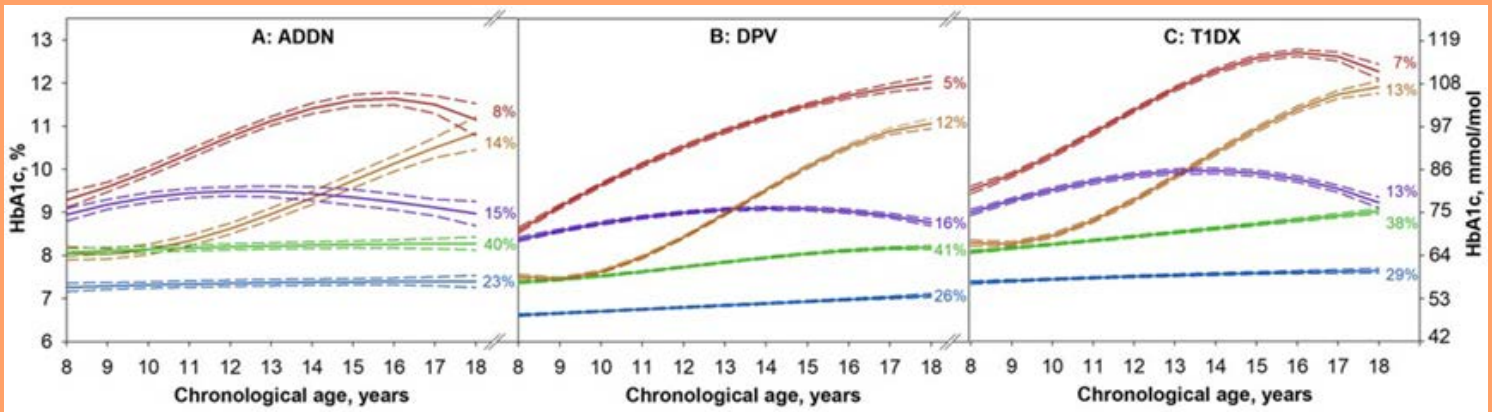


Figure 1. Glycemic Control Across the Lifespan. Youth between ages 8 and 18 years demonstrate considerable rise in HbA1c, and the recovery to an improved, more stable level occurs between ages 18-30. Target HbA1c is <7.0%

Figure 2. Trajectory of HbA1c



	Number patients	Number of measurements										
		8	9	10	11	12	13	14	15	16	17	18
ADDN	1132	986	1041	1097	1099	1094	946	831	694	538	380	206
DPV	8929	8929	8693	8656	8657	8627	7748	6872	5983	5155	4138	2535
T1DX	5836	5161	5452	5706	5690	5702	5123	4539	3915	3304	2571	1633

The blue trajectory is labeled *low stable* HbA1c, the green pattern as *intermediate stable* HbA1c, the purple curve as *high stable* HbA1c, the orange pattern as *intermediate increasing* HbA1c, and the red trajectory as *high increasing* HbA1c. Approximately 20% of youth experience deteriorating in glycemic control from age 8-18, and specific factors can predict which youth will experience deterioration.

WHY REMOTE PATIENT MONITORING?

- There is an emerging evidence base surrounding the use of remote patient monitoring (RPM) methods to control blood glucose and manage diabetes. For example, the Diabetes Control and Complications Trial (DCCT) was a landmark trial that demonstrated that people with Type 1 Diabetes who kept their blood glucose levels as close to normal as safely possible, had fewer diabetes-related health problems and complications after 6.5 years, compared to those who used a conventional treatment. In addition to a more rigorous insulin regimen, the treatment group also met with their healthcare team more frequently – monthly, compared to every 3 months in the control group. Moreover, treatment group subjects were instructed to self- monitor their blood glucose levels at least 4 times a day. Our remote patient monitoring program integrates these same strategies of frequent contact with our team and self-monitoring of blood glucose in order to help improve A1c levels.

- Optimal glycemic control (measured by HbA1c) is important to prevent or mitigate potential long-term complications of the disease. Despite evidence that frequent contact with a diabetes care team (nurses, dietitians, Certified Diabetes Care and Education Specialists (CDCES), advanced practice professionals, and physicians) improves glycemic control, most youth with type 1 diabetes (T1D) do not achieve the recommended four in-person diabetes clinic visits per year. Fewer visits are associated with worse glycemic control; in one study, youth who missed >2 appointments per year were less likely to meet ADA HbA1c targets and experienced a 1% increase in HbA1c (Fortin et. al, 2016).

- There is evidence that downloading and reviewing diabetes device data (glucometer, insulin pump, continuous glucose monitors) frequently at home is associated with a 0.8% decrease in HbA1c for children with T1D (Wong et. Al, 2015). Despite the evidence, few families actually download or review data regularly (Beck, 2015), although the number is increasing as the number of devices that automatically stream data into data into cloud data systems is increasing.

WHAT IS REQUIRED FOR RPM?

RPM is defined as "collection and interpretation of physiologic date (e.g. blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time." In 2018, new codes allowed providers to earn reimbursement for initial setup of RPM services and bill for initial setup, monitoring and up to 20-40 minutes of interaction per month. Patients must provide consent to participate in an RPM program, and are eligible for RPM billing codes if they share data from at least 16 days per calendar month from a device that meets the definition of a medical device. Healthcare providers and other qualified healthcare professionals may provide RPM services. Clinic staff can be supervised by a billing provider to perform setup and management of an RPM patient.

HOW DOES RPM COMPARE TO CHRONIC CARE MANAGEMENT (CCM) AND REMOTE THERAPEUTIC MANAGEMENT (RTM)?

CCM has some similarities to RPM services, but they vary significantly with regard to patient eligibility as well as reporting requirements. CCM services require at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with several specific elements required. CCM's complex requirements coupled with limited uptake has allowed RPM to provide new opportunities for providers to expand their services when embracing new digital and device technologies. Remote therapeutic monitoring is a relatively new offering that is currently limited to respiratory and musculoskeletal conditions; it allows monitoring based on patient-reported outcomes. If expanded, it will offer broader use cases and applications for patient care. RPM codes are classified as evaluation and management codes while RTM codes are general medicine codes. Currently, therapists and psychologists can bill for RTM, but not RPM .

IS RPM GAINING TRACTION IN THE MARKETPLACE?

Many RPM companies have formed in the past several years. Most operate as "virtual-only" clinics that do not communicate with the patient's current medical home. These companies are now competing for patients served by regional healthcare systems. If healthcare systems do not respond to this market trend, they are at risk of losing a segment of the market, while persons with diabetes may find it confusing to navigate a new, more complex medical ecosystem with multiple independent and disconnected care delivery formats.

BUT WILL FAMILIES SHARE DATA BETWEEN CLINIC VISITS?

Knowing that increased face-to-face contact with patients and increased device data review both have positive effects on glycemic control, we present here, a novel method to identify the highest risk patients and interventions to increase contact using a Direct-to-Consumer telehealth. While evidence has shown that few families download or review blood sugar data routinely at home, it was our experience that families in our clinics welcomed the opportunity to do so with routine guidance as detailed in this package. We developed a tool to facilitate downloading device data at home prior to telehealth visits, and after utilizing it, more patients downloaded or shared their data. In total, at-home device downloads increased by 10.3% in three months. Ultimately, of the targeted population who were reached by phone, 73% opted into the RPM telehealth intervention visits.

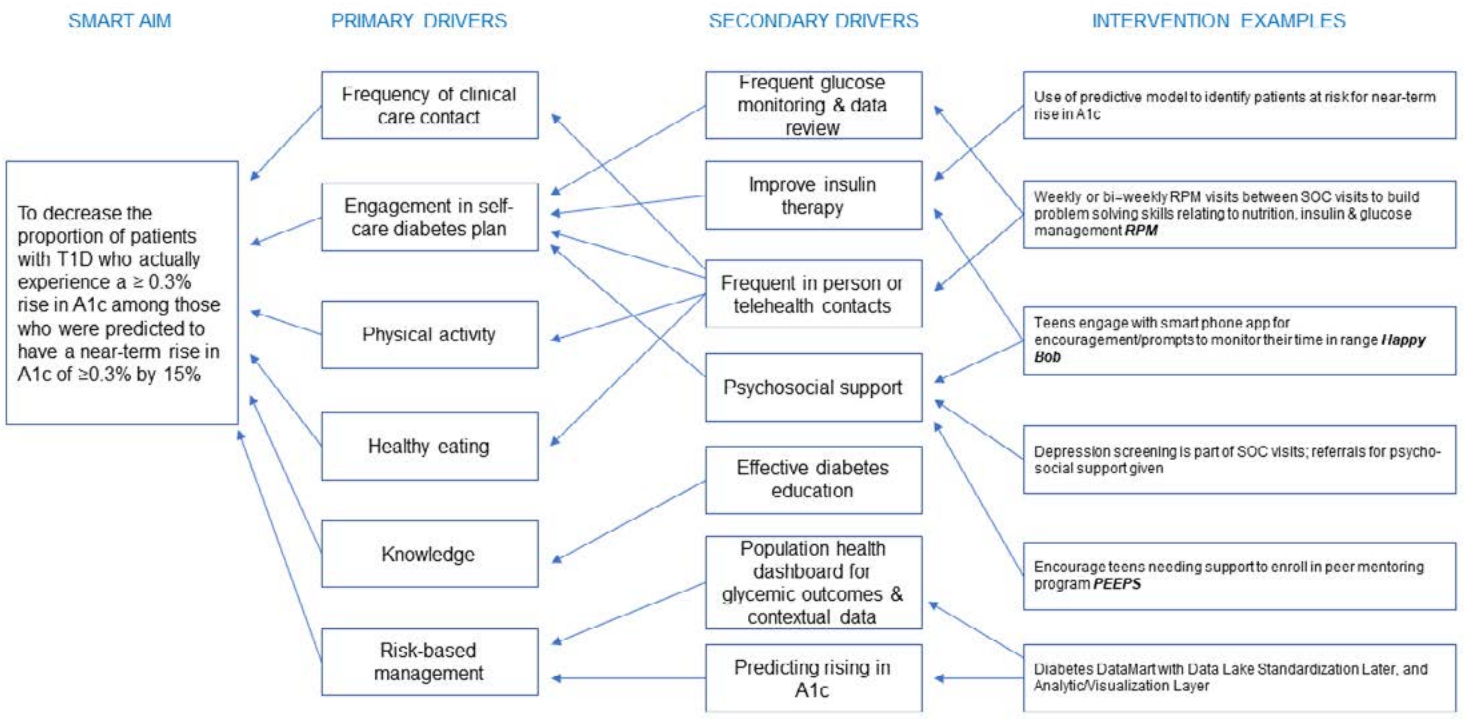
SETTING FOR THIS LEARNING

The Diabetes Center	Interdisciplinary Team		
• The Diabetes Center was the first pediatric program in the U.S. to be accredited by the American Diabetes Association. Approximately 56% of patients with diabetes have private insurance, 40% carry public insurance, and 3.5% are self-pay. • 26 pediatric endocrinologists • 4 Nurse Practitioners • 14 CDCES nurse and dietician FTEs • Over 100 staff members specialized in endocrine disorders and diabetes prevention, treatment and research • Serves ~ 2,400 youth and young adults with Types 1 and 2 Diabetes • Approximately 300 newly diagnosed patients annually	**The team includes**: • 2 Advanced practice nurses • 3 Fellows • 4 Social workers • 2 Clinical Psychologists	**Intervention Team**: • 5 Physicians • Began with 6 CDCES nurse & dietician FTEs, now have 8 • 6 Asst. Research Coordinators • 1 Data Analyst • 1 Data Scientist • 1 Research Scientist	**Lead Physicians** • Mark Clements MD, PhD maclements@cmh.edu • Ryan McDonough DO rjmcdonough@cmh.edu **Site Coordinator** • Emily DeWit eldewit@cmh.edu

ADAPTING & SCALING TO FIT YOUR CENTER

While we tested Remote Patient Monitoring in a large academic diabetes center, the approach presented in this report is adaptable and scalable and can be implemented in diabetes centers of all sizes with all levels of support. Interventions that worked for us may not work for you. And that's okay! If it's not working for your center, you can adopt, adapt, or abandon in favor of new change ideas as you see fit. To have the greatest chance for success, you'll want to consider implementing Remote Patient Monitoring as a small "tests of change" that will help you help define if the intervention is ready to adopt, adapt, or abandon before you commit large fiscal or human capital. Targeting small groups of high-risk but high-impact patients may result in an impressive measurable change. Yet even small improvements can and should be used to help justify growth of these interventions.

SMART AIM AND KEY DRIVER DIAGRAM



DEFINING YOUR POPULATION FOR INTERVENTION

WE DEFINED OUR POPULATION IN A UNIQUE WAY

We decided to predict which patients would experience a rise in hemoglobin A1c in the next 90 days using advanced machine learning and artificial intelligence. It takes some data science resources to develop those predictions and implement them. Our models utilize big data from our EHR that are supplied to a partner with the knowledge and infrastructure to digest and analyze mass quantities of health record data, so it's important to note that our predictions may not be achievable by everyone. However, our method of prediction is just one way of doing this. That does not, and should not, limit a center's interest in implementing RPM, which can be applied to any at-risk population defined in any way. If you want to learn more about predicting hemoglobin A1c, reach out! We'd love to talk with you.

DEFINING YOUR POPULATION

Your center can define a high-risk population using any number of alternative (and simpler) methods. Those able to engage AML/AI models are encouraged to do so, but for those who don't have access to these advanced analytics, this is absolutely doable by other means! We suggest defining your population by leaning on existing lists of patients with the highest HbA1c, those lost-to-follow up, those frequently admitted for DKA, etc.

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REMOTE PATIENT MONITORING (RPM)

RESOURCES AND REQUIREMENTS

SCREENING PROCESS AND CLINICAL ALGORITHMS

We opted to intervene on individuals who were seen in clinic the prior week and who were predicted to experience a rise in HbA1c of 0.3% or greater in the next 90 days; this threshold was selected because it reflects the widely accepted minimum clinically significant difference in HbA1c from measurement to measurement. If you can run a report from your EMR, your center can use any identification approach to define your target population for intervention.

Start by asking:

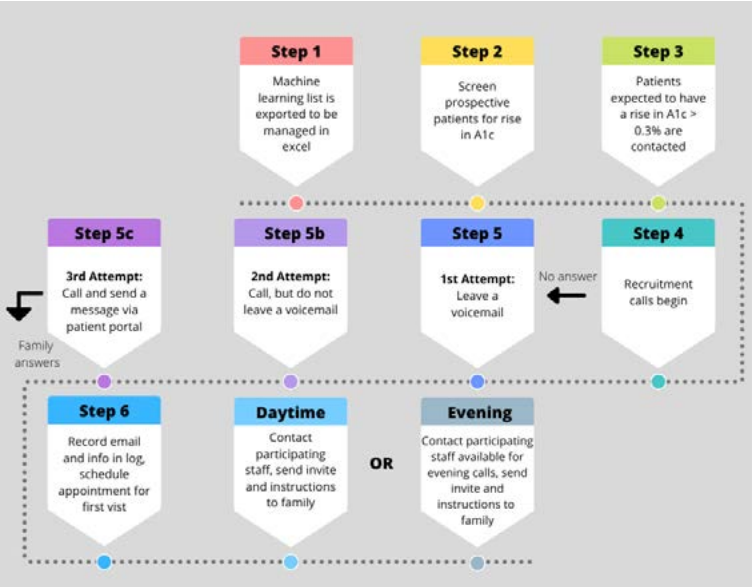
- What outcome are we trying to improve?
- How do we want to define the highest risk population?
- What is our threshold for high-risk versus not-so-high risk?
- Should this be defined by our resources and capacity?

Your population should be feasible for you to identify in a population health report from your EMR. You should also consider collecting additional information in that report that will help your team manage the work. These data may include the patient's most recent clinic date, basic information about the encounter, most recent HbA1c, SMBG vs. CGM usage, insulin pump vs MDI usage, etc.

During recruitment, patients and their families are approached for inclusion in this quality improvement initiative by phone outreach. (Recruitment methods were changed during the COVID-19 pandemic to accommodate fewer in-person clinic visits). Patients may also be approached using a patient portal message.

To participate in the RPM intervention, a minimum technology requirement exists, since RPM requires the digital sharing of sensor data measuring a physiologic signal. Families need to have reliable access to a home computer or mobile phone with high-speed internet to be included in the intervention; however, telephone calls can also be used to complete these visits. If able, communications technology (e.g., laptop or tablet computer) can be loaned to families to aid in this intervention. The figure below represents the sequence of steps that are taken, from recruitment of patients to their enrollment.

WHAT DO I DO IF THE SAME PATIENTS KEEP SHOWING UP ON MY RISK REPORT?



We recommend having a protocol in place for how to handle this. Patients who appear on our weekly lists multiple times are approached again if they have not completed the intervention, were previously unable to be reached, were lost to follow-up or had completed the intervention over three months prior. Those that declined previously are not re-approached within 12 months.

INTERVENTION TEAM

Providers and diabetes team members receive a series of training sessions at team meetings, and receive booster training on an ad hoc basis. During these sessions, encounters from both the provider and patient/family perspective are demonstrated with role play examples. Members may also train by shadowing recruitment and intervention calls.

Task	Individual(s)	Description
Recruitment phone calls	QI work team	• Provide participants/parents with information regarding the intervention • About 15 minutes per patient depending on answered phone call or not
Scheduling	QI work team	• Connect the patient and the clinician based on schedule availability • Scheduling appointments for the interventionalist and set up the electronic • Coordinate communication with the interventionalist and patient/family. • 10-15 minutes spent per patient to document scheduled visits and send out appropriate invites/ documents to corresponding interventionist and family
Intervention Visit	CDEs and Physicians	• Visits are conducted using Microsoft Teams • Interventionist meets with the family to discuss immediate concerns as well as a variety of content outlined in the intervention manual • Visit time spent with the patient should last no longer than 15-20 minutes
Satisfaction surveys to participating families	QI work team	• Work team members send a survey link to families who have completed at least 1 RPM • Survey feed- back is used to inform changes to the process. • Less than 5 minutes per patient spent sending satisfaction surveys.

COMMUNICATION TOOLS

RECRUITMENT

Initial communication from the diabetes team to patients/parents is completed via a recruitment call over the telephone. A phone script is used to ensure that each family is given a consistent description of RPM and is given an opportunity to ask questions. If a family chooses to participate via video visit, their email address is confirmed so they can receive an invitation to connect to the telehealth software (N.B. we have used both Microsoft Teams and Teledoc), instructions for using the platform for the visit, as well as a link to instructions for uploading diabetes device data or connecting their devices to a data streaming service connected to our professional accounts prior to any visits. If a family chooses to participate via telephone, their contact number is confirmed, as well as an email address where they will receive an RPM visit reminder with date/time, and the link to uploading instructions.

SCHEDULING

The staff member identifies the family's availability for the first RPM call, then recruits an available interventionist from the pool of trained staff. An appointment is set in the appropriate scheduling tool and shared with both the family and the staff member.

DURING VISITS

The preferred mode of communication between the interventionists and patients is a video conferencing platform. This platform's video chat function allows for a visual experience and level of interaction that can't be achieved by solely using the phone. This lets the interventionist not only speak to the patient and family, but see and assess any visible issues, much like in-clinic visits. Video visits allow for direct observation of BG checks, insulin dosing, pump site health, device use proficiency and an overview of the living situation of the participant. While video conferencing is preferred, patients who request audio-only phone calls are accommodated so that there are no technology barriers to participation.

Once patients and their family have agreed to participate, a member of the Diabetes Team assists them in installing the appropriate mobile phone applications for improved real-time data sharing, or computer applications to support data uploads before visits. Instructions on how to join a virtual visit are given to the family and they are provided contact information in case they have additional questions or need help with joining the meeting.

Additional reminder phone calls or written communications may take place; written communications are conducted through our EHR Patient Portal. Any concerns brought up during screening and recruitment are relayed to the interventionist to address, and visits are tailored to the needs of the patient. However, a menu of topics is used to guide these personalized discussions.

Abbott LibreView, Dexcom Clarity, Glooko, Medtronic Carelink, and Tandem t:connect are some platforms used for patients and parents to share their CGM, glucometer, or insulin delivery device data with the interventionist.

Fig. 2: (Visit Discussion Topics table)

Topic – PRN/On Demand Visit	Concern	Suggested Discussion/Remedy
BG/Pattern Review	Download	• Download and/or Review streamed data from Abbott LibreView, Dexcom Clarity, Glooko, Medtronic Carelink and Tandem t:connect as needed • Encourage family to download before calling • Walk patient/family through using the downloading systems for future success • Goal formation
	Insulin Regimen	• Review & verify current insulin regimen with patient/family
	Adjustments to Regimen	• Encourage family to identify patterns • Encourage family to make suggestions on insulin regimen changes • MDI: Guide patient through calculation examples PRN • CSII: Guide patient/family through pump setting change
	Monitoring	• Review current recommended BG monitoring recs • Importance of BG monitoring • Encourage routine download and review of BGs
Prescription Refills	Insulin	• Have patient show current Rx (allow correct Rx to be sent to the correct pharmacy) • Discuss when refills are truly needed (when RF = 0) • Authorize Rx's only with enough refills to get to next IP visit (to encourage attendance)
	BG Testing Supplies	• Have patient show current Rx (allow correct Rx to be sent to the correct pharmacy) • Discuss when refills are truly needed (when RF = 0) • Review Prior Auth process and expectations • Authorize Rx's for 12 months
	Pumps & CGMs	• Discuss how to request refills through traditional means • Discuss Prior Auth process and expectations

Topic – PRN/On Demand Visit	Concern	Suggested Discussion/Remedy
Urgent Management	Ketones	• Indication for checking • Discuss results (consider having family show you color on strip) • Discuss routine treatment and monitoring for Neg/Sm/Trace • Discuss routine treatment for Mod/Large • Insulin: Confirm dose, and witness correction dose administration • CSII: Watch pump site change
	Nausea/Vomiting	• Review routine sick day management • Witness BG and Ketone check (have patient show results to provider) • Assess for s/sx of DKA • Refer to Physician or ER as needed
	Hypoglycemia	• Assess patient • Review 15/15 rule with family • Review Glucagon administration (in the event it became necessary) • Escalate to 911 as needed
School (future iterations may include School RN directly communicating with team using RPM)	Concerns at School	• Collect concerns, review 504 and IEP as common tools for success at schools • Consider referral to CMH SW • Provide updated school orders (discuss use of portal to obtain orders

VISIT DOCUMENTATION

Each RPM visit is documented using a dedicated electronic health record template that captures the topics discussed and goals set. These clinical notes are entered into the patient's electronic medical record. All prescriptions, letters of medical necessity and prior authorizations are also documented, as is consistent with our standard workflows. Interventionists schedule the next RPM visit with the family before ending the current visit. This information is relayed to the QI work team who tracks this in an electronic data capture system.

THE DIABETES TEAM

We recommend spending some time selecting the tools you will use to drive your team's communications and collaboration approach. Our QI work team opted to use a Microsoft Teams channel dedicated to this project to preserve and internally communicate all related documentation, including patient recruitment logs and participation records. This serves as our "knowledge sharing commons". Emails and virtual meetings are the main platforms the Diabetes Team uses to communicate with each other and to schedule appointments. Shared calendars, documents, and spreadsheets also enable everyone to keep up to date and communicate rapidly and efficiently.

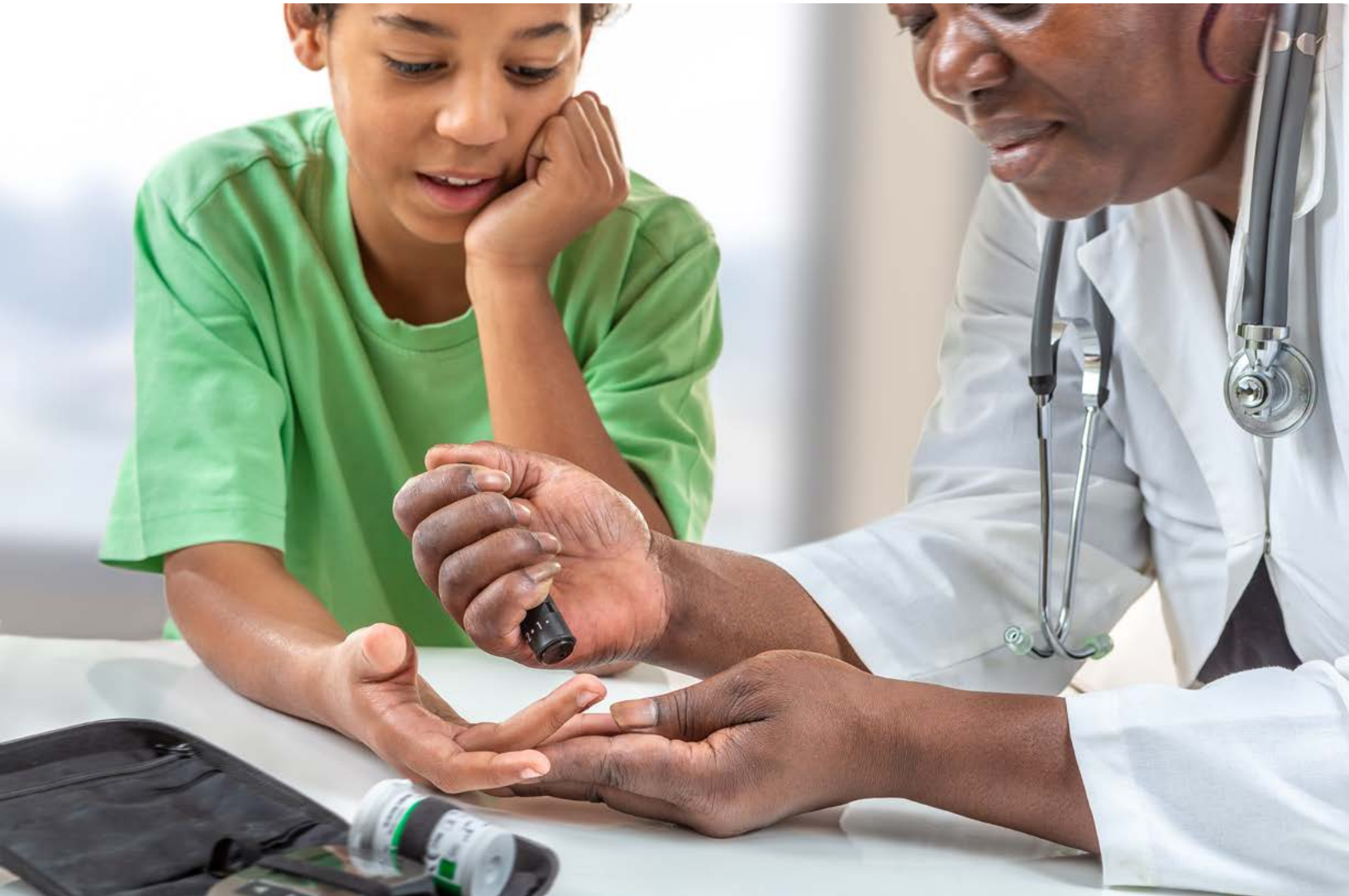
PLAN-DO-STUDY-ACT CYCLES FOR RPM INTERVENTION:

The following table summarizes the PDSA cycles we tested at our large, academic diabetes center. This table should provide perspective on the focus, scope, and frequency with which we implemented "ideas for change" as we scaled our implementation of RPM. We recognize that your capacity for testing change ideas may be different than ours, but key considerations for all centers include:

- Keeping a pulse on the patient experience through the collection of qualitative data
- Developing a clear communication plan for conducting & documenting visits and training additional staff to sustain efforts
- Routinely reviewing data to determine whether to adopt, adapt, or abandon your test of change

PDSA Cycle	Test of Change	Aim	Lessons Learned/Recommendations
1 1/1/2020	RPM Satisfaction Survey sent to families who completed at least 1 visit	Collect family feedback to share with interventionists and inform future iterations	Families indicated they valued having the same interventionist for each RPM visit. We met this request moving forward.
2 3/1/2020	Interventionist feedback survey given to all interventionists	Collect qualitative data from interventionists to improve process & inform future iterations	Streamline communication – feedback suggested CDCES reschedule cancelled appointments & schedule subsequent visits. This helped avoid back & forth communication triangle between QI team, patient, & interventionist. Fewer families were lost to follow-up.
3 3/25/2020	RPM calls scheduled via Microsoft Teams. Developed written instructions for families using Teams platform	Give families multiple platform options for visits	Clear written instructions were helpful. Some families still prefer phone calls, especially for those with limited access to quality internet connection.
4 4/20/2020	Revised the team's RPM documentation Template (EMR) to include platform type, discussion topics, and goals to match the RPM manual	Match EMR template to the manual for consistency and tracking purposes	Made documentation and families' education consistent. Template also prompted interventionists to schedule next visit and help patients set goals.
5 6/1/2020	Contact families who were not reached by phone through a portal message	Increase the percent of RPM eligible families who are reached to offer the intervention.	Additional point of contact with families we were unable to reach by phone. While the response rate from portal messages is not very high, it gave families an additional opportunity to participate and method to reach us.
6 7/6/2020	First interventionist trained in expansion city (Wichita, KS)	First interventionist offering RPM to patients at Wichita location (on Mondays)	

PDSA Cycle	Test of Change	Aim	Lessons Learned/Recommendations
7 11/1/2020	Offered RPM to patients whose primary language is not English. CM-approved Spanish-speaking interventionists identified and available.	Include high-risk, non-English speaking families in RPM.	Expanded capacity (engaged Spanish speaking interventionists) to meet needs of patients. Institution-wide language services department should be engaged in this work when non-English speaking families qualify for this support.
8 2/1/2021	Training video developed for interventionists, which includes a mock-RPM visit and overview of documentation process.	New interventionists can be trained quickly.	Shadowing an RPM visit was trialed, but unsuccessful due to scheduling conflicts. Training video offered more time convenience, allowed for continuous recruitment of interventionists, and answered most frequently asked questions.
9 2/16/2021	Appointments added to CM Teleteams (shared calendar among clinic staff and QI team)	Streamline process of scheduling appointments and communicating information.	Streamlined patient-interventionist communication and made appointment scheduling easier.



OUTCOMES OF RPM INTERVENTION

In the cohort of 69 patients who participated in RPM, we collected demographic information as well as A1c metrics. The patients receiving RPM were generally representative of the overall clinic population, although fewer participants spoke Spanish and a larger proportion were female. The majority of participants used multiple daily injections as a mode of insulin delivery and were on a CGM.

Satisfaction surveys indicated that 86% of families either agreed or strongly agreed that the telehealth visits helped them improve their skills managing diabetes. When asked for comments or suggestions about their experience with the intervention, one parent remarked, “Our child has a great relationship with her doctors and nurses which makes appointments run smoothly and no stress.”

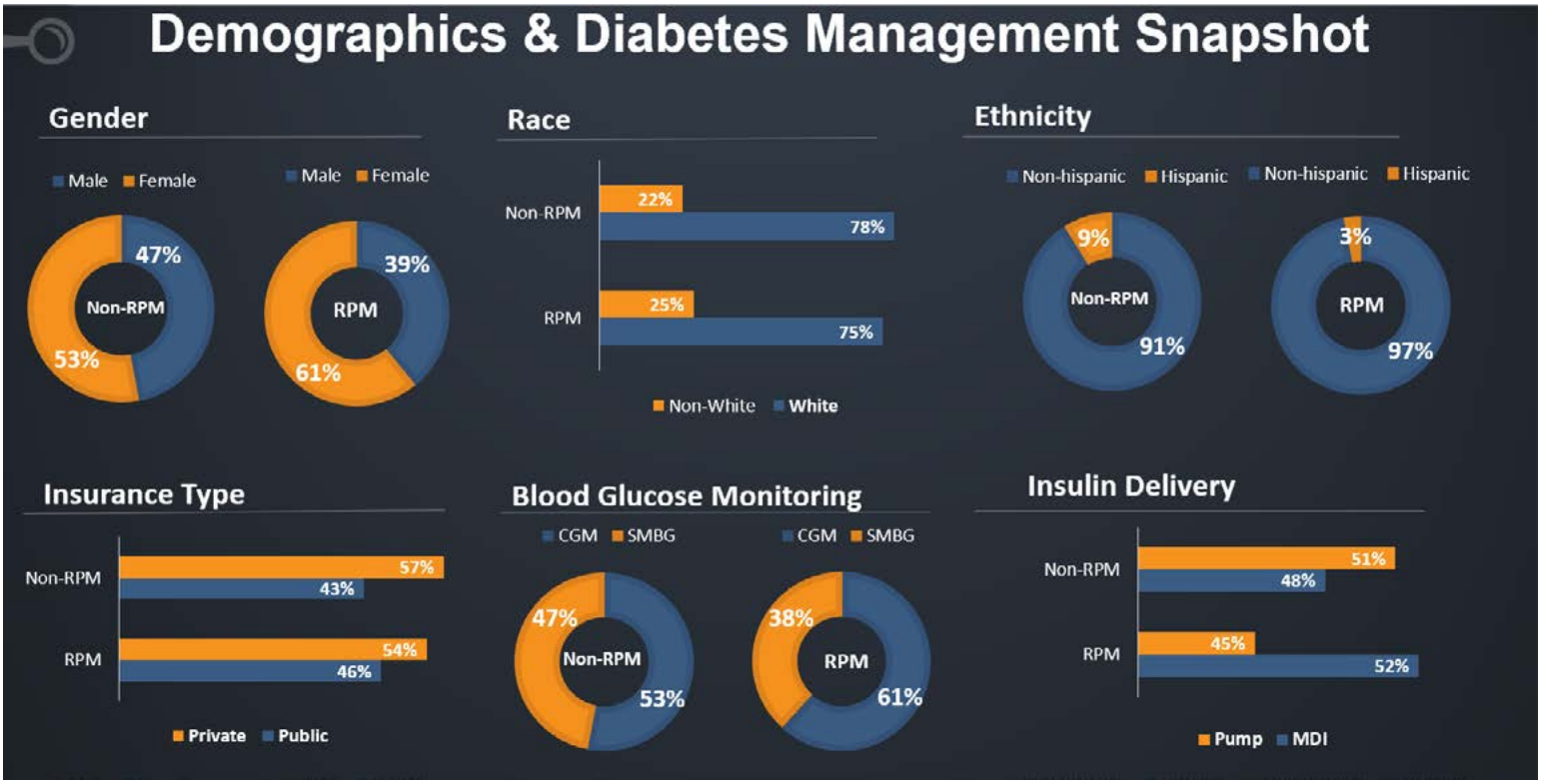
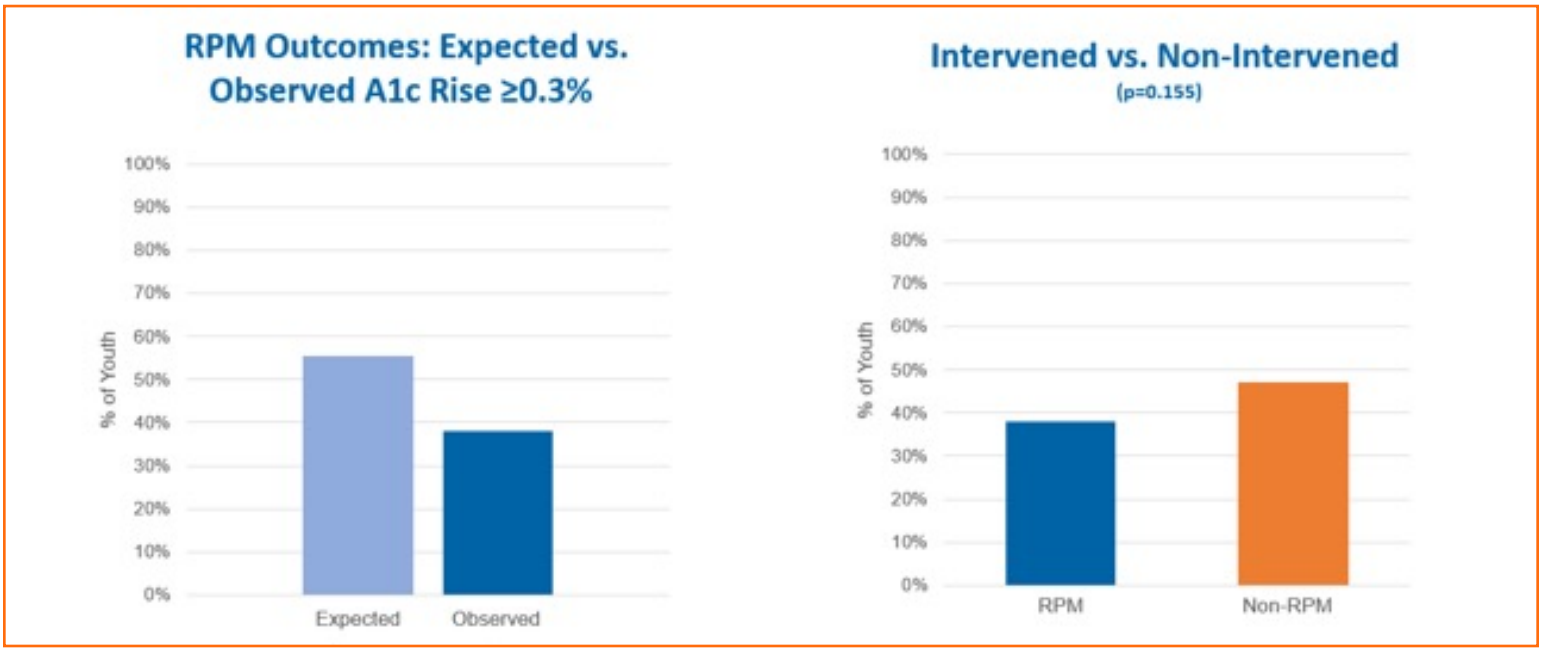


Figure 3: Proportion with A1c Rise >0.3% (3mmol/mol)



CASE STUDY

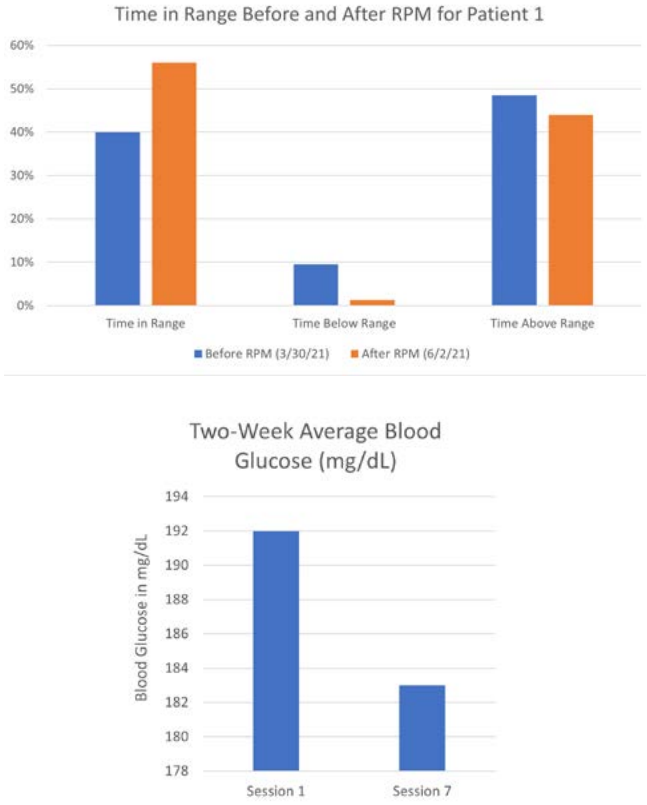
A young adolescent patient with T1D has shown great improvements since starting this intervention. She joins her RPM visits with her mother, who had this to say regarding the visits:

> "The weekly one-on-one check-ins is [sic] a good idea for helping get my daughter's diabetes under control. She is not having anywhere near the highs and lows she has been having for months! This is better than the three-month tweaking we have been doing when she goes to her regular doctor appt. We appreciate the nurse we are currently working with. Since she also has type 1 as well I think it helps my daughter feel better because they can relate to one another on how this feels. We appreciate the flexibility of these sessions and that they have been relaxing. My daughter has been a lot more comfortable with these appointments"

The CDCES she has been working with also echoes those sentiments.

> "I really enjoy working with them. She has really grown since we started. She was taken off her pump at her appointment prior to starting RPM because of safety concerns. She then after a couple weeks showed that she was willing to safely put in the work to use the pump. We try to meet every week, or every other week and they have shown vast improvements. She is talking more than she did, so she is becoming more comfortable but more importantly even since their very 1st appointment she has increased her time in range to 50% from 40%. Decreased her lows by 9% and also decreased her very high numbers by 8%. Her overall average has come down from 192 with SD of 98 to 183 SD 83. They may seem like minimal changes from an outsider's perspective, but she has grown considerably, and praise is certainly due to her"

Figure 4: Average glucose and time in, below, and above range before and after RPM intervention for Case Study Patient



Helpful Resources

- Appendix A - Sample Script
- Appendix B - QI Tools
- Appendix C - QI Training Videos

SAMPLE SCRIPT

"Hi, my name is ___ & I'm calling from the Diabetes Center at CM. May I please speak to the parent of ____? I'm contacting you on behalf of Dr. _____ (attending physician) at the Children's Mercy Diabetes Center.

The Diabetes Center is working to improve how we deliver care & target patient needs. To do that, we've used some fancy math to predict which of our young people with diabetes may experience a Rise in A1c over the next few months. It's similar to the approaches used by meteorologists to predict the weather. Your child has been identified on this list, so we would like to offer you some extra support for a few months. Would you like to hear about the new program we are making freely available through the Diabetes Center?

- Great! These calls are like "mini check-in" visits that happen between your regular standard of care visits. They are used to review pump/cgm data, make changes to insulin regimen, ask questions about sick day management, or address any concerns you may have about your child's diabetes care.
- Sessions are 15-20 minutes and scheduled every 2 weeks plus additional sessions can be scheduled if you think it would be helpful.
- Sessions can be done by phone or using Microsoft Teams (preferred option).
- Diabetes Center staff member will request that you download pump/cgm data BEFORE sessions
- Educator or provider will determine best course of action based on the downloaded data and conversation with you and your child.

The availability of diabetes educators & providers is usually between 8:30 -4:30 on weekdays. There are limited providers that can take calls after business hours. What is your general availability? Can you please verify your email address to send you the link to the invite? Are you comfortable with downloading your pump/CGM data?"

B

QI TOOOLS

QI Essentials Toolkit:
Driver Diagram

A driver diagram is a visual display of a team's theory of what "drives," or contributes to, the achievement of a project aim. This clear picture of a team's shared view is a useful tool for communicating to a range of stakeholders where a team is testing and working.

A driver diagram shows the relationship between the overall **aim** of the project, the **primary drivers** (sometimes called "key drivers") that contribute directly to achieving the aim, the **secondary drivers** that are components of the primary drivers, and **specific change ideas to test** for each secondary driver.

Primary drivers are the most important influencers on the aim, and you will have only a few (we recommend 2 to 5); secondary drivers are influencers on (or natural subsections of) the primary drivers, and you may have many. As you identify each driver, establish a way to measure it.

Remember: It's unlikely that a single individual has a clear view of an entire complex system. When developing a driver diagram, enlist the help of team members who are familiar with different aspects of the system under review.

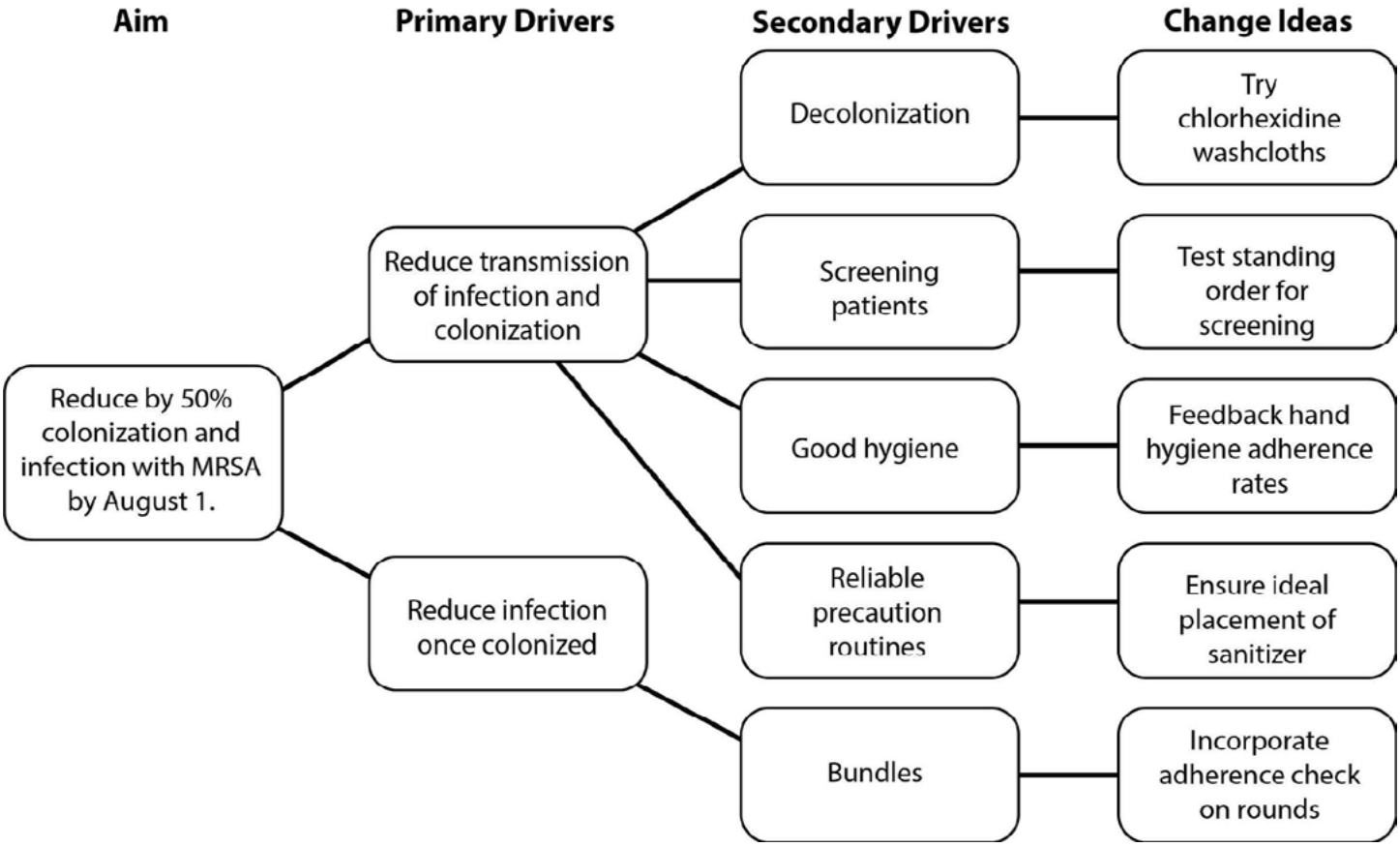
IHI's QI Essentials Toolkit includes the tools and templates you need to launch and manage a successful improvement project. Each of the nine tools in the toolkit includes a short description, instructions, an example, and a blank template. NOTE: Before filling out the template, first save the file on your computer. Then open and use that version of the tool. Otherwise, your changes will not be saved.

- Cause and Effect Diagram
- **Driver Diagram**
- Failure Modes and Effects Analysis (FMEA)
- Flowchart
- Histogram
- Pareto Chart
- PDSA Worksheet
- Project Planning Form
- Run Chart & Control Chart
- Scatter Diagram

Instructions

1) On the left, list the project aim (what will be improved, by how much, for whom, and by when) and draw a box around it.
2) To the right of the aim, list a few "primary drivers" — the most significant high-level influencers on the aim you've identified. Draw a box around each of the primary drivers, and draw lines to connect the primary drivers to the aim.
3) To the right of each primary driver, list as many "secondary drivers" that influence the primary driver as you can think of. Draw a box around each secondary driver, and draw lines to connect the secondary drivers to the primary drivers. Note: Secondary drivers can connect to more than one primary driver.
    - Tip: To show strong relationships, use solid lines; to show weaker relationships, use dotted lines.
4) To the right of each secondary driver, list specific change ideas you will test to influence the secondary driver. Note: Change ideas can connect to more than one secondary driver.

Example: Driver Diagram



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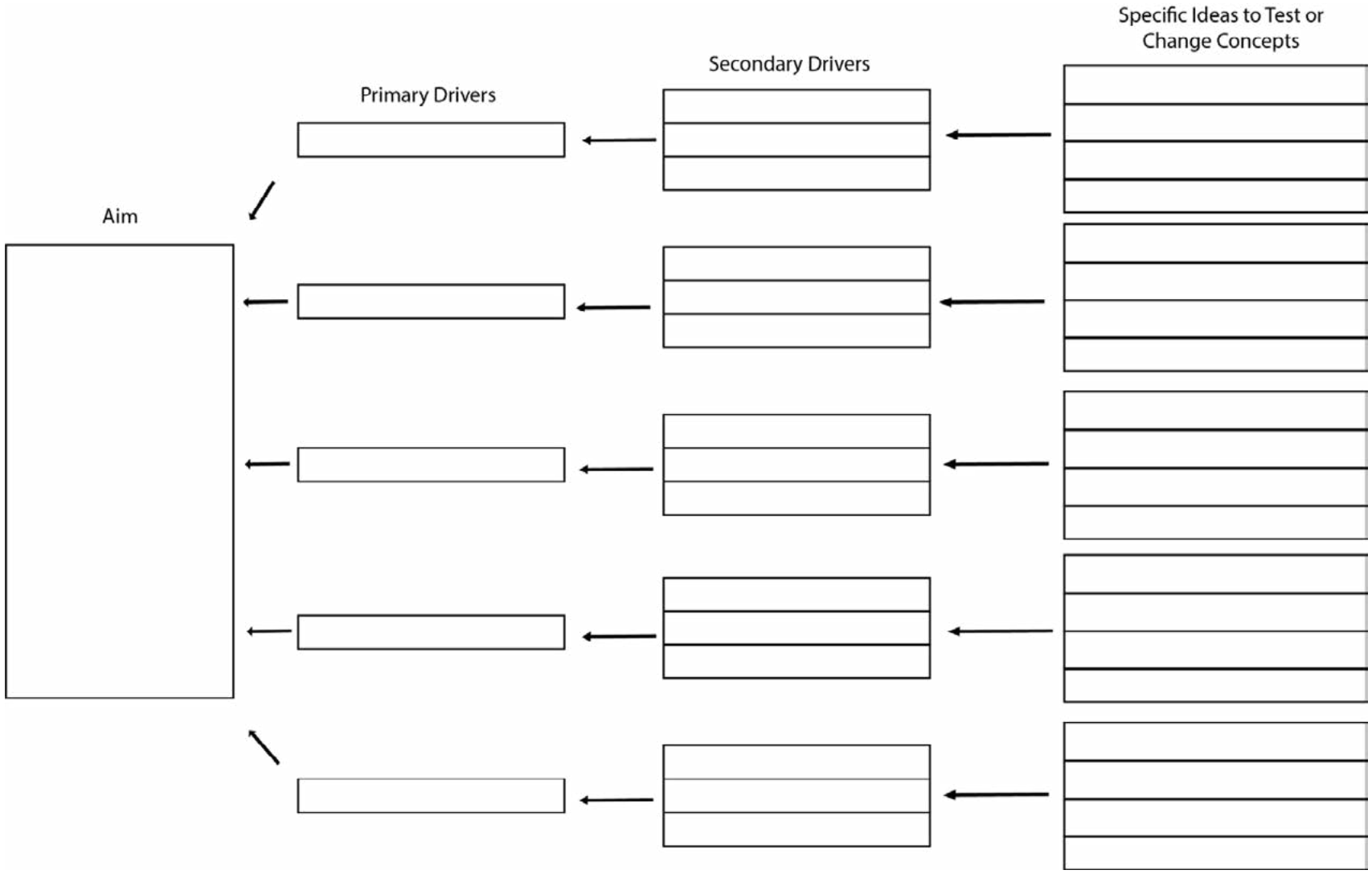
Template: Driver Diagram



Children's Mercy

Framework for Problem Solving: Asking the Right Questions

Developed by Lory Harte, PharmD, CPHQ

Focus:	Owner:	Date:	Approved:
A3 Team:		Sponsor:	Coach:

1. Clarify the Problem: Critical to understand the problem in order to solve it

- What is the actual problem?
- What is the desired state or target condition?
- What is the current state or condition?

Describe the gap between the current performance and what you hope to achieve by understanding the perspective of all involved in the problem. Identify one or more key measures in order to quantify the gap.
Tools: Complete set of Measures, Data Collection, Best Practice, Voice of the Customer

2. Break Down the Problem: To focus efforts on largest contributor of the problem

- What factors contribute to the identified gap?
- What barriers are encountered?
- Which factors or barriers contribute more than others?
- What characteristics of the population might relate?
- What subpopulations are impacted?
- Which steps in the process are creating waste?
- Who? What? When? Where? How much?

Narrow the problem by identifying and quantifying each factor that contributes. Focus on the problem from a systems perspective. Go and observe the process, people, and place.
Tools: Process Flow Map, Fault Tree, Pareto Diagram

3. Set a Target: Critical to help the team focus on a reasonable and attainable goal

- What are we trying to accomplish? How much? By when?
- What drivers are associated with a successful outcome/target?

Create an aim statement that is specific, measurable, actionable, relevant, and time bound. Incorporate the perspective of the patient or customer. Consider realistic and inspirational targets. Understand the rationale for the target.

4. Identify Root Cause: To identify, understand, and prioritize the underlying factor(s) that are contributing or causing the gap

- What happened?
- Why did it happen?
- Can the causes be drilled down by asking why 5 times?
- What factors contribute to the problem more than others?
- What can be done so it doesn't happen again?

Graphically display the factors contributing to the problem. Look for proximate and root causes. Identify correlations and possible causation. Eliminate unlikely causes. Observe.
Tools: Fishbone Diagram, 5 Whys, Pareto Diagram

5. Develop and Implement Countermeasures: To focus change efforts on the things most likely to yield improvement

- What changes can we make that will result in improvement?
- How can we prioritize the ideas?
- Will the countermeasure address the root cause(s)?
- Can / should we test it on a small scale?
- How will we implement?
- What actions are needed? (what, when, who?)

Brainstorm system-level ideas and rank by feasibility and reliability. Recognize the alignment between the countermeasure and the performance mode it will address. Test the countermeasures in iterative PDSA cycles. Consider short term and long term countermeasures. Visually display the drivers and countermeasures in a diagram.
Tools: Brainstorming, Affinity Diagram, Driver Diagram, PDSA

6. Check Results and Process: To determine if the countermeasures were implemented as intended and produced the expected results

- Did the countermeasure lead to improvement?
- How do we know if it's normal variation or improvement?
- How do we confirm that the process is still working?
- Has the root of the problem been resolved?
- Are there any new problems/unintended consequences to address?

Confirm the countermeasure resulted in improvement. Display data in time series. Understand the difference between common cause and special cause variation.
Tools: Run Chart, Control Chart, Confirmation Checklist, Rounding to Influence

7. Standardize and Follow Up: To ensure that an improvement has been embedded into practice and that any abnormalities are made visible when they occur

- Why do we need to standardize?
- Is the Target the new standard?
- Is it clear when things are normal versus abnormal?
- How do we ensure sustainable improvement?
- How can we impact other areas by sharing what we learned?

Utilize the daily management system to confirm sustainability of the improvement. Replicate or spread to other areas. Share what you learned.
Tools: Standard Work, Confirmation Checklist, Confirmation Rounds, Rounding to Influence, Leader Standard Work, Huddle Boards, Methods, Control Plan

References: Sobek II, D. K., & Smalley, A. (2008). *Understanding A3 thinking: a critical component of Toyota's PDCA management system*. Productivity Press.
Langley, G. J., Moen, R. D., Nolan, K. M., Nolan, T. W., Norman, C. L., & Provost, L. P. (2009). *The improvement guide: a practical approach to enhancing organizational performance*. John Wiley & Sons.
Optimizing Root Cause Analysis and Organizational Learning Foundation Education and Training [Pamphlet]. (2006). HPI, LLC.

IMPROVEMENT ACADEMY

QI Essentials Toolkit:

Cause and Effect Diagram

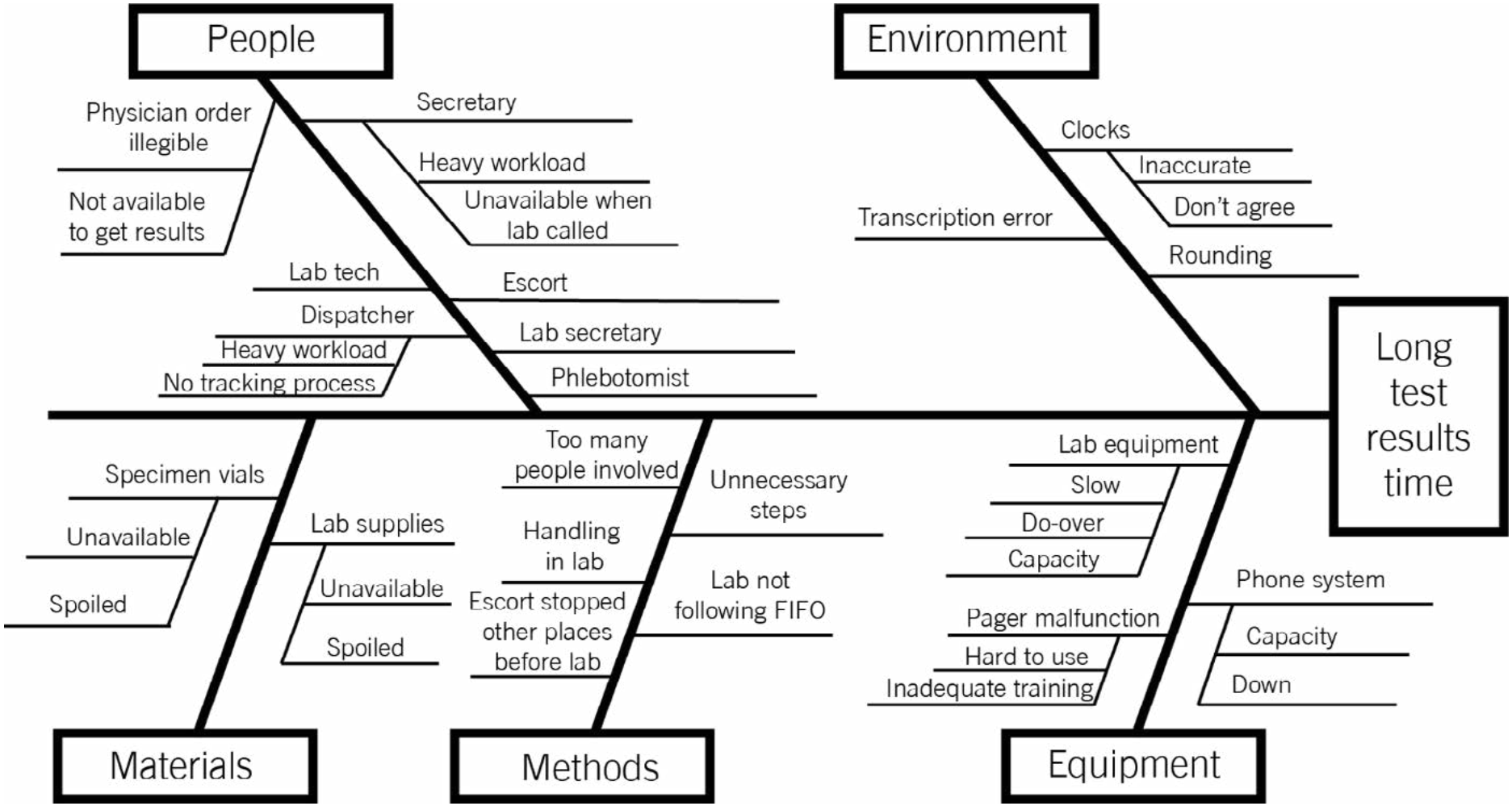
A common challenge for improvement teams is determining what changes they can test to improve a process. A cause and effect diagram is an organizational tool that helps teams explore and display the many causes contributing to a certain effect or outcome. It graphically displays the relationship of the causes to the effect and to each other, helping teams identify areas for improvement.

The cause and effect diagram is also known as an Ishikawa diagram, for its creator, or a fishbone diagram, for its resemblance to the bones of a fish. Teams list and group causes under the categories of Materials, Methods, Equipment, Environment, and People.

Instructions

1) Write the effect you wish to influence in a box on the right-hand side of the page.
2) Draw a horizontal line across the page to the left, starting at the box you just drew.
3) Decide on five or six categories of causes for the effect. The standard categories in a classic cause and effect diagram are Materials, Methods, Equipment, Environment, and People.
4) Draw diagonal lines above and below the horizontal line to create "fishbones," and label each line at the end with one of the categories you have chosen. Draw a box around each label.
5) For each category, generate a list of the causes that contribute to the effect. List the causes by drawing "branch bones." As necessary, draw additional branch bones from the causes to show sub-causes.
    - Tip: Develop the causes by asking "Why?" until you have reached a useful level of detail — that is, when the cause is specific enough to be able to test a change and measure its effects.

Example: Cause and Effect Diagram

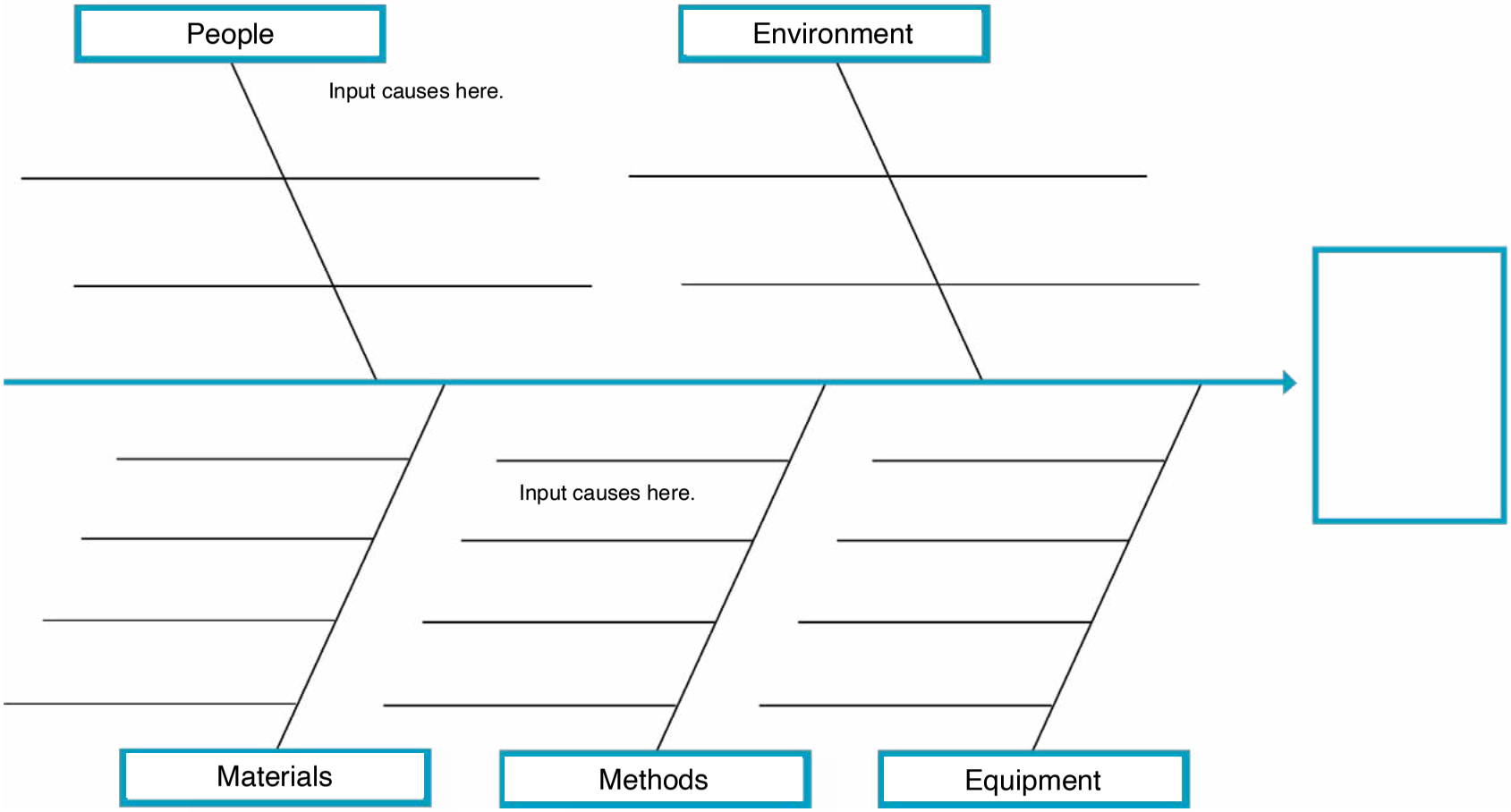


Before filling out this template, first save the file on your computer. Then open and use that version of the tool. Otherwise, your changes will not be saved.

Template: Cause and Effect Diagram

Team: _____ **Project:** _____

1) Input the effect you'd like to influence.
2) Input categories of causes for the effect (or keep the classic five).
3) Input causes within each category.



QI Essentials Toolkit:

PDSA Worksheet

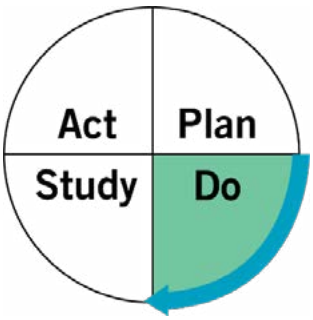
The Plan-Do-Study-Act (PDSA) cycle is a useful tool for documenting a test of change. Running a PDSA cycle is another way of saying testing a change — you develop a plan to test the change (Plan), carry out the test (Do), observe, analyze, and learn from the test (Study), and determine what modifications, if any, to make for the next cycle (Act).

Fill out one PDSA worksheet for each change you test. In most improvement projects, teams will test several different changes, and each change may go through several PDSA cycles as you continue to learn. Keep a file (either electronic or hard copy) of all PDSA cycles for all the changes your team tests.

Instructions

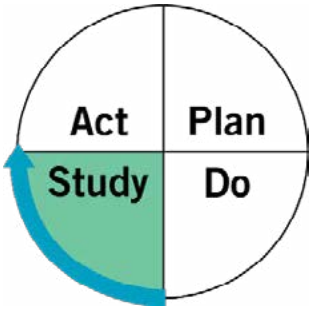
Plan: Plan the test, including a plan for collecting data.

- State the question you want to answer and make a prediction about what you think will happen.
- Develop a plan to test the change. (Who? What? When? Where?)
- Identify what data you will need to collect.



Do: Run the test on a small scale.

- Carry out the test.
- Document problems and unexpected observations.
- Collect and begin to analyze the data.



Study: Analyze the results and compare them to your predictions.

- Complete, as a team, if possible, your analysis of the data.
- Compare the data to your prediction.
- Summarize and reflect on what you learned.

Act: Based on what you learned from the test, make a plan for your next step.

- Adapt (make modifications and run another test), adopt (test the change on a larger scale), or abandon (don't do another test on this change idea).
- Prepare a plan for the next PDSA.

Example: PDSA Worksheet

Objective: Test using Teach-Back (a closed-loop communication model, in which the recipient of information repeats the information back to the speaker) with a small group of patients, in hopes of improving patients' understanding of their care plans.

1. Plan: Plan the test, including a plan for collecting data.

Questions and predictions:

- How much more time will it take to use Teach-Back with patients? It will take more time at first (5 to 10 minutes per patient), but we will start to learn better communication skills and get more efficient.
- Will it be worthwhile? The extra time will feel worthwhile (and possibly prevent future rework).
- What will we do if the act of "teaching back" reveals a patient didn't understand the care plan? If a patient is not able to explain his or her care plan, we will need to explain it again, perhaps in a different way.

Who, what, where, when:

On Monday, each resident will test using Teach-Back with the last patient of the day.

Plan for collecting data:

Each resident will write a brief paragraph about their experience using Teach-Back with the last patient.

2. Do: Run the test on a small scale.

Describe what happened. What data did you collect? What observations did you make?

Three residents attempted Teach-Back at the end of the day on Monday. Two residents did not find anything they needed to ask patients to Teach-Back. Jane found that her patient did not understand the medication schedule for her child. They were able to review it again and, at the end, Jane was confident the mother was going to be able to give the medication as indicated.

3. Study: Analyze the results and compare them to your predictions.

Summarize and reflect on what you learned:

- Prediction: It will take more time at first (5 to 10 minutes per patient), but we will start to learn better communication skills and get more efficient. *Result: Using Teach-Back took about 5 minutes per patient.*
- Prediction: The extra time will feel worthwhile (and possibly prevent future rework). *Result: Jane felt the time she invested in using Teach-Back significantly improved the care experience.*
- Prediction: If a patient is not able to explain his or her care plan, we will need to explain it again, perhaps in a different way. *Result: After a second review of the medication orders, the patient was able to Teach-Back the instructions successfully.*

In addition to the team confirming all three predictions, Jane realized the medication information sheets she had been handing out to parents weren't as clear as she thought. She realized these should be re-written — maybe with the input of some parents.

4. Act: Based on what you learned from the test, make a plan for your next step.

Determine what modifications you should make — adapt, adopt, or abandon:

Jane is planning to use Teach-Back any time she prescribes medication. Although it may take more time, she now understands the importance. The other residents are going to work on using Teach-Back specifically for medications for the next week.

They would like to pull together a team to work on some of the medication information sheets with parent input, but they are first going to gather more information through more interactions in the coming days.

Before filling out the template, first save the file on your computer. Then open and use that version of the tool. Otherwise, your changes will not be saved.

Template: PDSA Worksheet

Objective:

1. Plan: Plan the test, including a plan for collecting data.

Questions and predictions:

-
-

Who, what, where, when:

Plan for collecting data:

2. Do: Run the test on a small scale.

Describe what happened. What data did you collect? What observations did you make?

3. Study: Analyze the results and compare them to your predictions.

Summarize and reflect on what you learned:

4. Act: Based on what you learned from the test, make a plan for your next step.

Determine what modifications you should make — adapt, adopt, or abandon:

QI Essentials Toolkit:

Run Chart & Control Chart

A **run chart** is a graph of data over time. It is a simple and effective tool to help you determine whether the changes you are making are leading to improvement.

Run charts help improvement teams formulate aims by depicting how well (or poorly) a process is performing, understand the value of a particular change, and begin to distinguish between common and special causes of variation.

Common-cause variation is the natural or expected variation inherent in a process. Special-cause variation arises because of specific circumstances that are not inherent in the process.

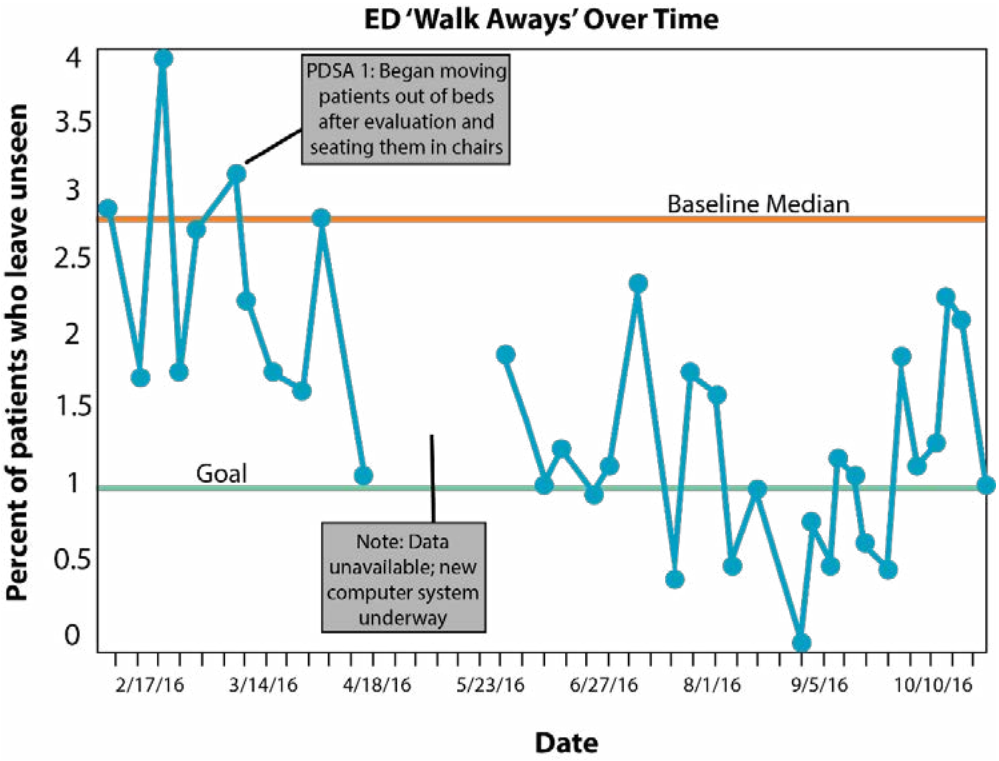
A **control chart**, which includes an upper control limit (UCL) and a lower control limit (LCL), goes further to help teams distinguish between common and special causes of variation within a process. Use a control chart when you have more than 15 data points and want more insight into your data.

Control charts help improvement teams identify special-cause variation in a process, identify early signs of success in an improvement project, and monitor a process to ensure it is holding the gains from a quality improvement effort.

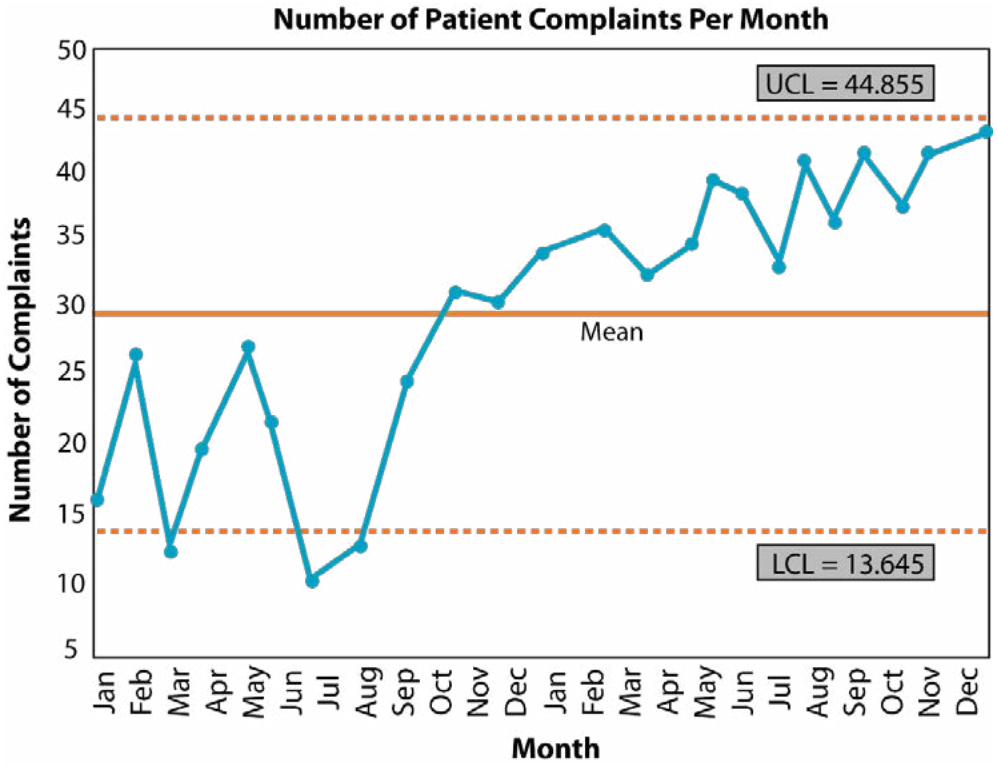
Instructions

1) Obtain a set of data points in their natural time sequence.
2) Draw the vertical and horizontal axes, leaving room on all sides to title and label the graph.
3) Label the vertical (Y) axis with the name of the value being measured (e.g., Percent of Births by C-section, Number of Days to Third Next Available Appointment, etc.).
4) Label the horizontal (X) axis with the unit of time or sequence in which the numbers were collected (e.g., April, May, June, etc., or Quarter 1, Quarter 2, etc.).
5) Determine the scale of the vertical axis. The scale should extend from a number 20 percent larger than the largest value to a number 20 percent smaller than the smallest value. Label the axis in equal intervals between these two numbers.
6) Plot the data values in the sequence in which they occurred.
7) Draw lines to connect the data points on the graph.
8) Calculate the median (the data point half way between the highest and the lowest data point) of the plotted numbers and draw the line on the graph.
    - Note: For a control chart, complete these two steps:
        a) Instead of calculating the median, calculate the mean or control limit (the average) of the plotted numbers and draw the line on the graph.
        b) Calculate and then draw upper and lower control limits that correspond to +/- 3 sigma limits from the mean. (We recommend doing this in Microsoft Excel or another software program.)
9) Title the chart, and note the goal line and the sample size.
10) Annotate the chart, indicating when tests of change were initiated, so that it is easy to see the effect of changes on the measure. Also indicate any external events that may have affected the performance of the process.

Example: Run Chart



Example: Control Chart



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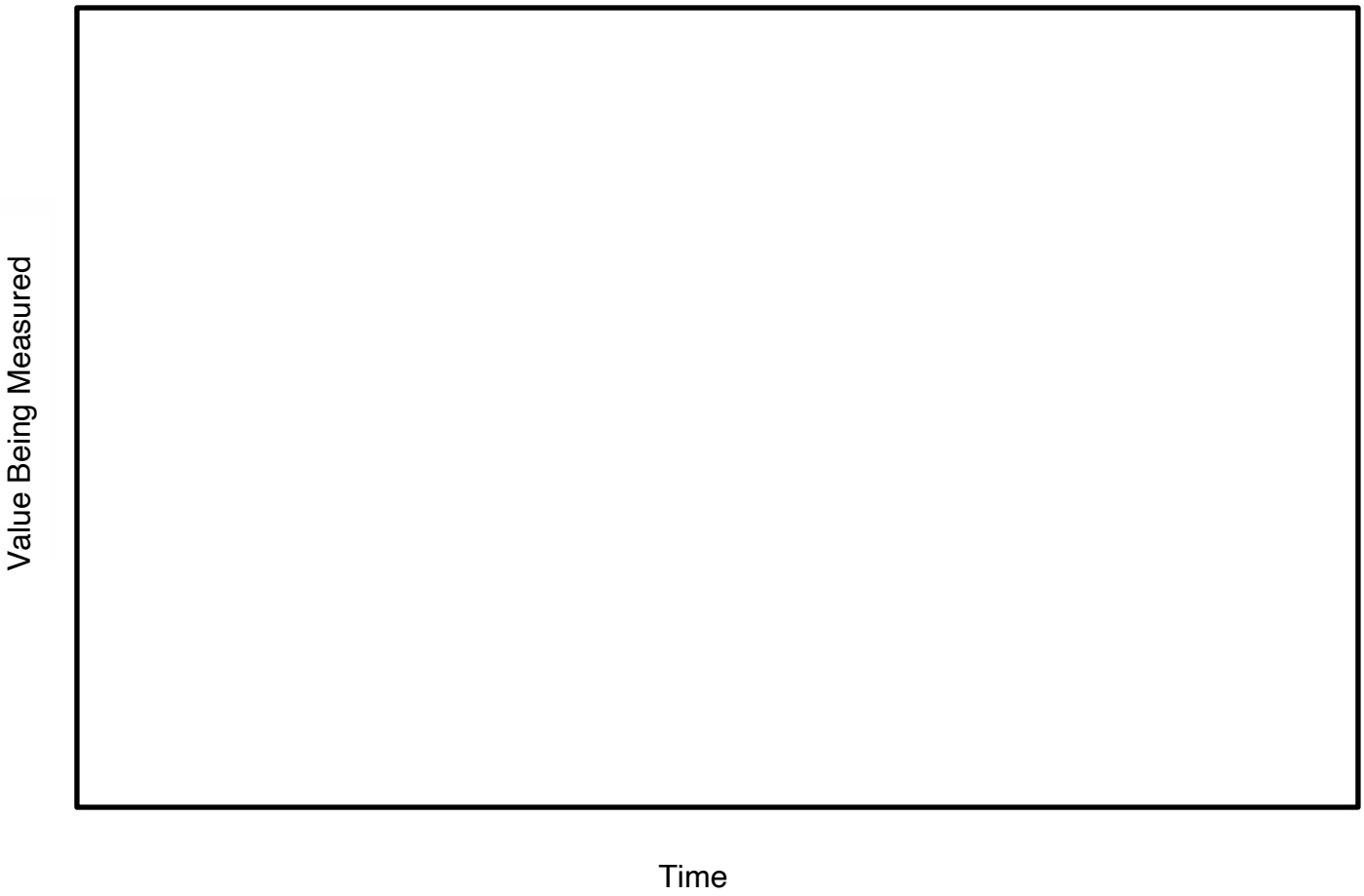
Template: Run Chart or Control Chart



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QUALITY IMPROVMENT TRAINING VIDEOS

Here are some quick videos that will give you a brief overview and some training in quality improvement basics. If you are interested in more in-depth training, get connected through IHI or the T1D Exchange.

Training Videos:

- 5 Whys: Finding the Root Cause: https://youtu.be/3QOy1DyTFJY
- Driver Diagrams
  - Driver Diagrams: https://youtu.be/A2491BJcyXA
  - How do you Use a Driver Diagram? https://youtu.be/yfcE_Q-IRFg
- An overview of the Failure Modes and Effects Analysis (FMEA): https://youtu.be/PIEzR5uhqnw
- The IHI Global Trigger Tool for Measuring Adverse Events https://youtu.be/19iWhQjb3DQ
- PDSA Cycles
  - PDSA Cycles part 1: https://youtu.be/_-ceS9Ta820
  - PDSA Cycles part 2: https://youtu.be/eYoJxjmv_QI

More Tools and Overview Videos from IHI:

- Patient Safety Essentials Toolkit (and how to use the worksheets): https://youtu.be/GyBJms7EXDQ
- IHI's QI Essentials Toolkit https://youtu.be/r-3jveJ-uBA
- The science of Improvement - on a Whiteboard!
  - Deming's system of profound knowledge pt. 1: https://youtu.be/xKv--YA8XJE
  - Deming's system of profound knowledge pt. 2: https://youtu.be/STTwZGNvLmM
  - The model for Improvement part 1: https://youtu.be/SCYghxtioIY
  - The model for Improvement part 2: https://youtu.be/6MIUqdulNwQ
  - Run Charts part 1: https://youtu.be/YQd1QoMHYwU
  - Run Charts Part 2: https://youtu.be/8e38RCU8-uA
  - Static vs. Dynamic Data: https://youtu.be/UJqvC_uo63M
  - Flowcharts Part 1: https://youtu.be/tq7dQVaTbcc
  - Flowcharts Part 2: https://youtu.be/yFtV0-gm9nk
  - Control Charts Part 1: https://youtu.be/9kmblj5zRtA
  - Control Charts Part 2: https://youtu.be/lQ3woMr822U
  - Family of Measures: https://youtu.be/uow7mzrFif4
  - Cause and Effect Diagram: https://youtu.be/387chd8p54c
  - Divergent and Convergent Thinking: https://youtu.be/CUcyBgxR9js
  - Force Field Analysis: https://youtu.be/oEcLloCF0Uo
  - Pareto Analysis: https://youtu.be/zbDRH2ASyqQ

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