


Enhancing communication and social engagement among clinicians and research teams to improve reliability of research recruitment

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ABSTRACT

The success of rare disease research relies heavily on robust partnerships with clinicians to help identify new patients and collect samples. Many studies for paediatric rheumatic diseases requiring pretreatment samples have suffered from slow enrolment rates due to the low incidence of disease and relative urgency to treat. Therefore, timely identification of all potentially eligible patients is crucial. The objective of this project was to apply quality improvement methods to increase the frequency and timeliness of identification of eligible patients with new paediatric rheumatic diagnoses to approach for research studies. A retrospective chart review was undertaken in our paediatric rheumatology clinic to measure the number of eligible patients identified for potential research recruitment between missed recruitment opportunities. Improvement methodology was used to integrate standardised communication between clinicians and the research team into clinic workflow, to leverage social feedback as positive reinforcement for good communication and to measure change in response to the interventions. The number of eligible patients identified between missed recruitment opportunities increased from every 0–1 patient to every 14 patients during the project period, corresponding to an increase in the overall identification rate from 32% to 91% of all eligible patients. Quality improvement methods can be used to successfully integrate research recruitment into routine clinical care and accelerate advances necessary to improve health outcomes.

PROBLEM

Prospective clinical and translational research studies are critical for improving outcomes in rare diseases, and their quality and execution are contingent on meeting target subject enrolment rates. Paediatric rheumatology is a field in which the studied conditions are either rare or uncommon, and slow enrolment rates pose a major challenge to conducting research. Additionally, pretreatment enrolment and biospecimen collection are crucial for novel breakthroughs, further necessitating timely identification of eligible subjects.

The Division of Pediatric Rheumatology is based at the Children's Hospital of Philadelphia, a tertiary academic centre with a broad referral base. As one of the largest paediatric rheumatology practices in the USA, our centre is actively engaged in recruiting patients for both provider-initiated and multisite collaborative studies. An estimated 15–20 studies are enrolling at any given time, all of which are coordinated by the Rheumatology Research Core (RRC). The RRC is composed of research assistants (RAs), a lead coordinator and the clinical research director. In May 2017, the RRC recognised that studies requiring enrolment of newly diagnosed patients and collection of pretreatment biospecimens suffered from the poorest enrolment rates, and several opportunities to approach eligible patients had been missed. At the time, our centre was actively enrolling incident cases of polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis and inflammatory bowel disease-associated arthritis. Approach and recruitment were dependent on individual clinicians identifying potentially eligible patients at the time of diagnosis and alerting the RRC. While busy clinic schedules and competing demands were acknowledged barriers to timely recognition of research-eligible patients, our team believed that system and process improvements could help integrate timely research recruitment into established clinic workflow. The overall aim was to increase the number of research-eligible patients identified between each missed recruitment opportunity from an average of 0–1 patient to at least 5 in our paediatric rheumatology clinic.

BACKGROUND

Innovative research is one of the most important means of improving health outcomes for children and is of particular importance in



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fields such as paediatric rheumatology, where there is a relative paucity of robust evidence to guide clinical practice.^{1 2} Inadequate enrolment rates remain significant barriers to conducting research in children. Of 152 paediatric studies registered on ClinicalTrials.gov that terminated between 2000 and 2010, 83 (55%) identified poor recruitment or administrative barriers as their reason for terminating the study.³ In addition to the intrinsic challenge of studying diseases with low incidence, increasingly busy schedules and administrative burdens can overwhelm clinicians' cognitive capacity to recognise patient research opportunities.⁴ Although some studies address patient and physician-based barriers to recruitment, very few do so in the context of integrating paediatric research into general clinic flow using quality improvement methodology.

In rare disease research, potentially eligible subjects are infrequently encountered, and therefore high reliability in the recruitment system is critical to ensure that every potential subject is appropriately identified. To successfully recruit patients for incident study designs and pretreatment sample collection, there needs to be timely communication between the clinicians making the diagnosis and the research team. Examples from patient safety literature have demonstrated that team huddles can improve reliability in healthcare systems by enhancing communication between providers, develop relationships among providers and increase situational awareness among the entire team.^{5 6} Other strategies to engage providers include incentive programme, which are demonstrated to yield performance gains in the workplace and have been increasingly applied to healthcare.⁷ Lessons learnt from patient safety literature and behavioural economics may be particularly applicable to rare disease research recruitment.

MEASUREMENT

We initially planned to track the monthly proportion of new research-eligible patients successfully identified to the RRC for recruitment. However, given the low frequency of new diagnoses, we chose an alternative outcome measure of number of eligible patients identified for recruitment between each missed recruitment opportunity (goal: ≥ 5 patients, approximating an 83% success rate). Missed opportunities were determined by manual chart audits of all new patient visits by one of the five rheumatology fellows-in-training, all of whom received education on the active division-wide research studies. Clinicians were only responsible for identifying patients with research-eligible new diagnoses and communicating them to an RA, who ultimately determined eligibility for specific studies and approached the patients. The RAs routinely entered all patients with a research-eligible diagnosis in a screening log at the time of identification, regardless of eligibility. A separate enrolment log was used to track eligibility, approach and enrolment. As a result, the RRC was able to determine whether communication occurred

by comparing the chart audits to their screening logs, and patients did not need to be approached by the RRC to be included in the outcome measure. As secondary outcome measures, we tracked the proportion of eligible patients successfully enrolled in at least one study and the proportion who successfully provided a biospecimen. Process measures included the percentage of all half-day clinic sessions for which preclinic communication between the clinician and the RRC was documented. All clinics with at least one scheduled new patient were included.

Baseline measurement

During the preimplementation period from July 2017 to October 2017, manual chart review of 138 half-day clinic sessions revealed 19 patients with a research-eligible new diagnosis. Only 6 (32%) had been successfully identified to the RRC at the time of diagnosis, all of whom were subsequently enrolled in at least one study. Only 2 (11%) of the 19 eligible patients provided a pretreatment biospecimen. The average number of eligible patients between missed opportunities for recruitment during the preimplementation period was 0.5.

DESIGN

The quality improvement team consisted of one rheumatology attending physician, five rheumatology fellows-in-training and two RRC representatives. The Division of Rheumatology Clinical Research Director served as an executive sponsor. We followed the Standards for Quality Improvement Reporting Excellence (SQUIRE) Guidelines for reporting our quality improvement work.⁸

High-level process mapping was used to understand the recruitment workflow and identify areas of potential weakness. We used a fishbone diagram to brainstorm potential causes of recruitment misses. After further analysis and classification of the 13 prior misses into areas where the process broke down, we used a Pareto chart to identify the most common cause of recruitment failure, which was inconsistent identification of and communication about research-eligible patients by the clinician at the time of diagnosis. Therefore, we focused our interventions on two themes: (1) standardising communication between physicians and research staff and (2) increasing social incentives for identification of research-eligible patients.

Potential interventions were appraised based on probable impact and ease of implementation using a Possible-Implement-Challenge-Kill (PICK) chart. Considering perspectives of both research staff and clinicians, the team chose interventions in the 'Implement' category felt to be most feasible and effective in the context of the rheumatology clinic. We settled on preclinic huddles between clinicians and RAs, which minimised the burden on clinicians to remember, which studies were enrolling, and allowed the RAs to triage potential new subjects without the medical knowledge otherwise needed to review charts. The face-to-face communication also had the advantage of increasing situational awareness. As a social incentive

for good catches, we chose email distribution of amusing photograph acknowledgements because it was rapid, low cost and had the potential to increase interest and awareness of ongoing studies across the entire division.

STRATEGY

Plan, do, study, act (PDSA) cycles were employed to test the interventions and evaluate their impact. Our improvement team met monthly to review process and outcome measures. Team members audited the charts for every new patient visit (approximately 30 charts per week) on a monthly basis to continuously evaluate the impact of our interventions. Process and outcome metric data were tracked using run charts and G-charts, respectively, and later analysed using statistical process control methods. G-chart control limits were calculated using the baseline preintervention data from July 2017 to October 2017.

PDSA I

Preclinic huddle

In January 2018, we implemented a preclinic huddle between the clinician and the RRC. The RRC independently identified an RA responsible for initiating the huddle immediately prior to each clinician's half-day clinic session. The RA was instructed to engage in a brief, unstructured review and discussion of each scheduled new patient with the intent of identifying those who might be research-eligible. Following the huddle, the clinician initialled a paper calendar to document huddle completion. We initially hypothesised that posting the calendar next to the master schedule would remind clinicians to perform the huddle prior to their first patient encounter.

The process measure was preclinic huddle completion rate, defined as the percentage of half-day clinic sessions with documentation of a preclinic huddle (goal: 50%).

Clinician recognition

In the same PDSA cycle, we implemented division-wide recognition of clinicians who successfully identified a patient with a new research-eligible diagnosis and communicated with the RRC. For each success, the RRC sent a humorous email to all clinicians, nurses, RAs and administrative staff, acknowledging the clinician's contribution to a particular study. We hypothesised that the email acknowledgement would serve as a positive social incentive by generating friendly competition between clinicians and would also increase awareness about ongoing research studies across the division.

PDSA II

Because of higher-than-expected uptake, a second iteration starting in June 2018 focused on standardising the content reviewed during the preclinic huddle. We created a set of semistructured questions (online supplementary appendix 1) in a REDCap tool to ensure continued high-quality but focused discussions. Transitioning documentation of huddles to REDCap-enabled tablets also facilitated tracking completion rates more easily and accurately.

RESULTS

Outcomes

From January 2018 through December 2018, a total of 744 rheumatology clinic half-day sessions took place. During the first PDSA cycle, we met special cause variation and exceeded our goal of at least five successfully identified patients between misses (figure 1). By month 6, we reached 14 successfully identified patients without any misses. The first missed event postintervention occurred during PDSA cycle II, which on further review was felt to be due to a misunderstanding of study criteria. The improvement was sustained for the remainder of the observation period with no additional misses to date. In total, 29/32 (91%) patients with a research-eligible new diagnosis were identified to the study team, 25/32 (78%) were successfully enrolled into at least one study and 17/32 (53%) provided a biospecimen (table 1).

Process measures

During PDSA cycle I, the percentage of clinic sessions during which a preclinic huddle was completed consistently exceeded our goal of 50%. Completion rates were 58%, 64% and 68% in January, February and March 2018, respectively (figure 2). The huddle completion rate improved even further to 98% after transitioning to the REDCap tool in PDSA cycle II and has been sustained since our goal for this process measure was met.

Balancing measures

Huddles took a median of 2 min to complete (IQR (1–2)). Only 1/9 providers surveyed after implementation felt that huddles interrupted their workflow. Providers reported spending 15–30 min on average prereviewing charts, of whom 6/9 reported no change from their routine practice, while 3/9 reported a 15 min increase in time spent prereviewing charts.

Contextual factors

There were several contextual factors that facilitated the success of the intervention. First, the physical proximity of the provider workroom and the RRC office facilitated the

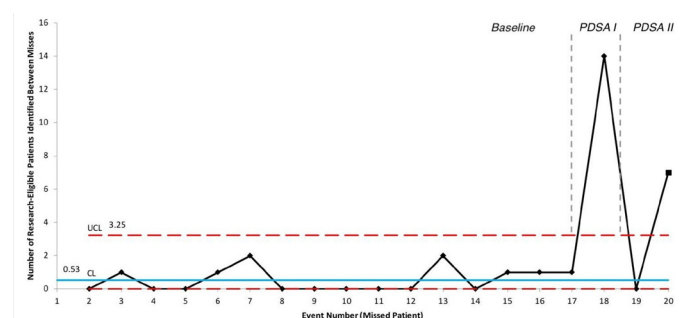


Figure 1 G-chart displaying number of patients with research-eligible diagnoses successfully identified to the Rheumatology Research Core between each missed patient, at baseline and during subsequent tests of change. Upper and lower confidence limits of the baseline measurement are also shown. PDSA, plan, do, study, act.

Table 1 Percentage of patients with an eligible new diagnosis successfully identified and enrolled in a research study preimplementation and postimplementation

	Preimplementation	PDSA I (preclinic huddle, positive feedback)	PDSA II (standardised huddle tool)
Total number of clinic sessions, N	138	274	470
Eligible patients, n	19	12	20
Eligible patients identified at time of diagnosis, n (%)	6 (32)	12 (100)	17 (85)
Patients successfully enrolled, n (%)	6 (32)	10 (83)	15 (75)
Consented for biospecimen collection, n (%)	2 (11)	7 (58)	10 (50)

PDSA, plan, do, study, act.

huddles. Second, clinic sessions start at approximately the same time in the morning and afternoon, so a single RA was able to huddle with multiple providers in succession. Third, the RAs function as a core unit that runs multiple studies simultaneously, allowing for flexibility to dedicate one RA to huddles each day.

One of the potential barriers was reliance on providers to prereview charts before clinic. While the huddles themselves were brief, some providers reported an increase in time spent prereviewing charts, and therefore, our approach may be more challenging to implement in settings where providers do not routinely review charts.

Additional observations

We observed that huddles enhanced overall communication between the research team and clinicians and improved the efficiency of research recruitment. In addition, positive feedback provided a social incentive for providers, improving providers' and trainees' engagement in research. Some unexpected benefits included an increase in division morale created by the amusing pictures used for positive feedback and a greater awareness of eligibility criteria for ongoing research projects.

Some of the challenges faced included the time-consuming nature of retroactive screening to measure the outcome and small number of eligible patients. In addition, despite improvement in identification of eligible subjects, the RRC faced additional challenges obtaining

biospecimens due to laboratory insurance capitation and patients' or families' refusal of additional venipuncture.

LESSONS AND LIMITATIONS

We achieved our goal of reducing missed opportunities to identify research-eligible patients by implementing a sustainable system to enhance multidisciplinary communication between clinicians and research teams and increase overall engagement through positive social incentives. To our knowledge, this is the first purposeful application of improvement methodology to better integrate research recruitment into clinical practice as a manner of improving future health outcomes. This project has direct relevance to clinicians, researchers, patients and families. A key lesson learnt was that involving each of the stakeholders (including fellow physicians, attending physicians and members of the research team) from inception through completion helped to garner support for the PDSA cycles and ensure sustainability of the intervention going forward.

Our team identified suitable moments for structured communication between clinicians and research staff, which aided proactively identifying research-eligible patients and reducing missed opportunities to obtain time-sensitive samples. The intervention utilised existing staff and required no investment in terms of formal training or materials. Therefore, preclinic huddles as a form of structured communication represent a minimal opportunity cost for clinicians and research staff alike. Similar strategies have been employed with success in the patient safety literature to support high reliability.^{5 6 9 10} In the context of our rheumatology clinic, team huddles served to enhance reliability of the timely identification of research-eligible patients, resulting in increased enrolment rates.

In addition to structured communication, we implemented a second approach to increase provider engagement in research recruitment using a social incentive. While many studies have focused on financial incentives to drive improvement in provider performance,⁷ well-designed non-financial incentives based on internal transparency can be equally, if not more effective.¹¹ We chose to

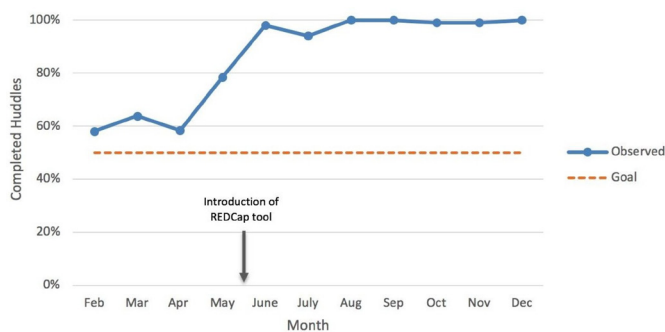


Figure 2 Run chart of the completion rate for preclinic huddles between clinicians and the research team, expressed as a percentage of half-day clinics per month.

circulate only positive feedback for 'good catches' among the division rather than publicising misses, which created friendly competition, built camaraderie and helped maintain awareness of the different ongoing research studies.

There are wide-ranging impacts stemming from our simple intervention. Increasing identification rates, even without increasing the consent rate among patients approached, resulted in significantly increased enrolment rates. Our patient population benefits from the valuable knowledge gained through clinical studies and the promotion of rare disease research. Unintended benefits for our clinical division included increased total reimbursement for study participation in some cases, as well as a heightened profile in national collaborative efforts. There may also be other indirect benefits of engagement of clinicians in research, such as improvements in overall healthcare performance, which warrants further study.¹²

With respect to the limitations of our approach, we restricted our outcome measure to include studies that were open for the duration of the project, and it is unclear whether introducing new studies with different inclusion criteria would have an impact on the outcome measure. Ideally, this possibility will be explored in the future. In addition, our work did not seek to address the yield of approaching patients for sample collection. While the majority of patients approached were successfully enrolled in a registry study, only half consented to biospecimen collection. We were able to document reasons why patients/families decline to provide research samples, including health system issues such as laboratory capitation and desire to avoid extra venipuncture. Lastly, the generalisability of our approach may be limited by our clinic space and staffing model, especially the presence of a core team of RAs with flexible roles.

CONCLUSION

In summary, our project team identified that poor communication between clinicians and research staff and lack of situational awareness regarding ongoing research studies were major barriers to meeting target enrolment rates. Poor enrolment rates have threatened many paediatric studies, particularly studies involving rare or uncommon diseases. We have demonstrated significant improvement in our timely identification of research-eligible patients with minimal financial cost or disruption of clinic workflow by using improvement methodology to diagnose the problems in our research recruitment process and develop strategies for enhancing structured communication and social engagement. In order to sustain our improvements when staff turnover occurs, further work is currently underway to ensure that the onboarding process for future research staff and clinicians includes training in the implemented strategies.

This project underscores the importance of frequent, clear and standardised communication in the identification of research-eligible patients, as well as provider engagement in research. Next steps include evaluating whether improvement methodology can be applied to

enhance clinician-to-patient communication to increase participation rates among patients approached for studies that require biospecimen collection.

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