Plan-Do-Study-Act Cycles Applied to a Longitudinal Research Protocol in a Family Medicine Residency

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BACKGROUND AND OBJECTIVES: Barriers to research in family medicine are common. Resident studies are at risk of remaining incomplete. This report describes a process improvement (PI) to optimize survey data collection in a longitudinal research protocol led by family medicine residents. The protocol subject to the process improvement sought to evaluate maternal outcomes in group prenatal care vs traditional care. In the months preceding the PI, the resident researchers noted many surveys were not completed in their intended timeframe or were missing, threatening study validity. We describe a practical case example of the use of a PI tool to resident-led research.

METHODS: The residents applied three plan-do-study-act (PDSA) cycles over 8 months. Throughout the cycles, we solicited barriers and proposed solutions from the research team. Process measures included percentage of surveys completed within 2 weeks of the deadline ("on-time" response rate), and percentage of surveys completed overall.

RESULTS: A secure, shared survey tracker was created and optimized during three PDSA cycles to calculate and track survey deadlines automatically upon enrollment in the study. Automated colored flags appeared for due or overdue surveys. On-time response rates did not improve. Overall response rates did improve meaningfully from 57% (19 of 33 eligible) to 84% (16 of 19 eligible).

CONCLUSIONS: The PDSA cycles improved survey response rates in this research protocol. This intervention incurred no cost, was easily implemented, and was impactful. Other research teams can apply this PI tool to barriers in their research processes with minimal risk and cost.

Research involvement in residency promotes the practice of evidence-based medicine, lifelong learning, and continued participation in research.[1] Despite these benefits, family medicine residents are relatively unlikely to participate in research.[2-4] Barriers include a lack of interest, time, mentorship, and skills.[5,-8] Residents are more likely to perform research limited to a single time point (particularly case reports) and are unlikely to undertake longitudinal, hypothesis-driven projects.[3,9] Studies are at risk of being abandoned and remaining incomplete.[2,10] We describe a practical case example of using a process improvement (PI) tool to facilitate resident-led research.

As residents, we led a longitudinal, survey-based, prospective cohort research protocol designed to evaluate group prenatal care (CenteringPregnancy). Survey instruments assessing patient satisfaction, incidence of depression and anxiety, breastfeeding practices, and breastfeeding attitudes were administered at five specific time points across 13 months of follow-up. During the study, we noted that many surveys were not being completed during their intended time frame or were missing entirely. We feared that the response rate was low enough to threaten study validity, and therefore intervened immediately.

Process improvement (PI) tools have been adopted in residency settings to achieve clinical change.[11-14] There is a limited body of literature describing application of process improvement concepts to improve research processes.[15,16] We applied a PI tool, the Plan-Do-Study-Act (PDSA) cycle, to maximize survey responses in our low-resource setting. The PDSA cycle is commonly used in family medicine residencies.[13,14,17-19] It starts with a specific, measurable, achievable, relevant,

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and time-limited (SMART) objective.[20] The process involves continuous cycles of incremental change, assessment of progress toward the objective, and reflection on lessons learned.[20,21]

Methods

The research team was led by three family medicine residents. The PDSA cycles were not funded and incurred no monetary cost, but did require dedication of nonprotected time by research coordinators, research assistants, faculty mentors, and the resident team leaders (Table 1).

At three intervals over 8 months of the study, PDSA cycles were implemented to improve the survey response rate (Table 2). The resident leaders met with the research coordinator and assistants to solicit barriers and proposed solutions biweekly. We developed objectives following the SMART format. Interventions were chosen by consensus, based on feasibility and impact. An early intervention of the first PDSA cycle involved creation of a shared survey completion tracker. Process measures informed by this tracker included "on-time" response rates and overall response rates. On-time responses were defined by the number of participants who were eligible to complete a survey during the PDSA cycle and completed that survey within 2 weeks of the deadline. This measure was chosen by the research team to raise visibility and prioritize follow-up for those subjects. Survey deadlines were defined by the research protocol: 30 weeks gestation, 6 weeks, 4 months, and 6 months postpartum. Overall response rates were defined by the number of participants who were eligible to complete a survey during the time period of PDSA cycle and completed that survey at any point before the end of the PDSA cycle, even if outside the on-time window. PDSA cycles were process driven and did not require alterations to the existing research

Table 1: Details of Roles and Responsibilities of the Research Team (Prior to PDSA Cycles)

Research Assistant (2-4 people)			
Research Project Responsibilities	**Organizational Role**	**Protected Time for Research**	**Estimated Time Spent**
• Consent patients into study • Distribute and receive survey instruments • Score survey instruments and enter data	Medical technician*	0-4 hours per week**	8-12 hours per week***
Research Coordinator (1 person)			
Research Project Responsibilities	**Organizational Role**	**Protected Time for Research**	**Estimated Time Spent**
• Consent patients into study • Track subjects due for survey instruments, alert research assistants to give subjects surveys at scheduled appointments	Clinical nurse	None	10-14 hours per week
Lead Investigators (3 people)			
Research Project Responsibilities	**Organizational Role**	**Protected Time for Research**	**Estimated Time Spent**
• Study design • IRB approval and continuation reports • Recruit and train research assistants/coordinators, maintain human subjects research training records for all personnel • Optimize study recruitment • Oversee processes of subject consent, data collection, maintain confidentiality	Resident physician	None	4-12 hours per week
Faculty Mentors (2-3 people)			
Research Project Responsibilities	**Organizational Role**	**Protected Time for Research**	**Estimated Time Spent**
• Assist and mentor lead investigators in study design, recruitment, and troubleshooting of data collection	Faculty physician	None	As needed, but not more than 2-4 hours/month

* Equivalent to medical assistant

** Protected time is noted for all personnel in this role combined.

*** Estimated time is noted for all personnel in this role combined.

Table 2: Details of Three PDSA Cycles Conducted by Research Team, July 2016-February 2017

PDSA 1: July–October 2016			
Plan	**Do**	**Study**	**Act**
Barriers: • Incomplete data collection* Goals: • Establish a tracked deadline for 100% of all surveys • Complete 100% of 30-week surveys on-time	• Biweekly meetings with research technicians • Establish shared participant tracking system on password protected, secure network drive using Excel	• 72 out of 92 (74%) of future surveys had established deadlines in the shared system. • 5 of 11 (45%) 30-week surveys returned "on-time" • 11 of 11 (100%) 30- week surveys returned overall	• Technicians were not using automatic formulas to establish survey deadlines, which was cumbersome. • Shared tracker helped increase visibility of upcoming surveys • Goals were not realistic.
PDSA 2: October–December 2016			
Plan	**Do**	**Study**	**Act**
Barriers: • Need more efficient way to track deadlines • Need to expand to postpartum survey sets Goals: • Establish deadlines for 100% of all surveys • Complete 60% of all surveys on time	• Automated survey deadlines using Excel formulas • Automated color-coded flags appear in shared tracker for due and overdue surveys	• 100% of surveys have documented deadlines (automatic) • 10 of 33 surveys (30%) returned on time" • 19 of 33 (57%) returned overall	• No longer need to track whether deadlines are established due to automation • Less on time completion in the postpartum period. Study patients often seen at other clinics in the facility, rather than in the family medicine residency clinic
PDSA 3: January–February 2017			
Plan	**Do**	**Study**	**Act**
Barriers: • High research staff turnover during this cycle • All resident leaders off-site Goals: • Complete 50% of surveys on time completion • Complete 70% overall survey completion	Multiple changes had been made in the last few months with anticipated high staff turnover. No new changes were made during this PDSA cycle test run of previously made changes.	7 of 19 (37%) returned on time 16 of 19 (84%) returned overall	More beneficial to delay further changes during this time of transition, allowing the current system to be more consistently adopted.

* Informally noted by resident leaders—no baseline data collected before intervention

protocol approved by the institutional review board.

Results

Details of the iterative process changes and the resultant changes in survey response rates are outlined in Table 2 and Figure 1. Notably, survey response rates in PDSA cycle 1 were tracked only for the participants eligible to complete the 30-week gestation surveys. This served to pilot the tracking tool. Response rates were determined for surveys at all time points for cycles 2 and 3.

Discussion

This project aimed to increase survey response rates using PDSA cycles. The PDSA cycle yielded a meaningful improvement from 57% to 84% overall survey responses. While the on-time response rate minimally improved, the overarching goal of the PI was to maximize survey responses in a resource-limited setting.

There were several limitations evident in this project. The scope of the PI was limited to a single research team. No baseline data for survey response rates was collected since we felt it was imperative to address the response rate problem immediately. The PDSA cycle has limited utility in research conducted at a single time point—the longitudinal nature of our protocol allowed us the opportunity to address unanticipated barriers. We did not assess whether gains made from the PDSA cycles

Figure 1: Survey Response Rates at Conclusion of Each PDSA
Cycle for All Combined Survey Time Points, Including 30 Weeks'
Gestation, 6 Weeks, 4 Months, and 6 Months Postpartum

PDSA cycle 1 data not pictured—only 30 weeks' gestation survey response rates were measured
during the initial cycle.
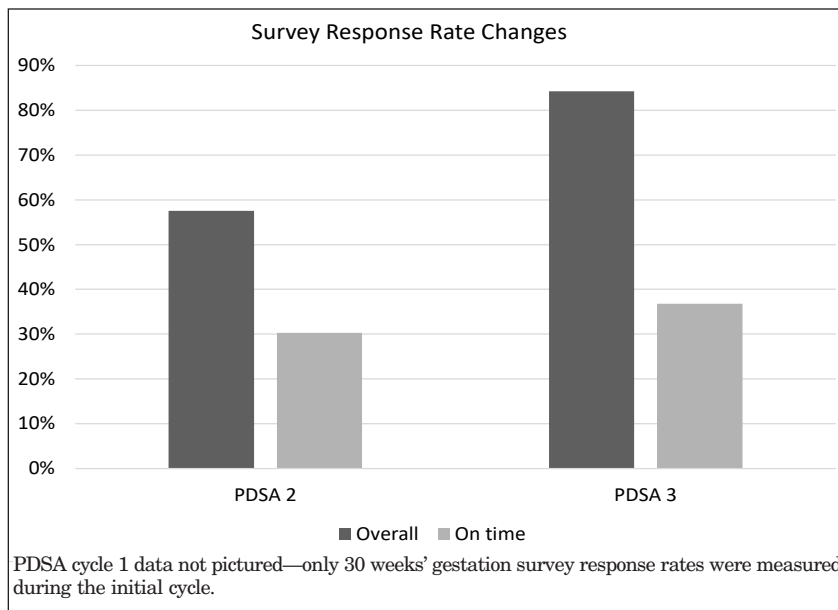
were sustainable, which would be an important area for future inquiry.

Additional next steps would include replication by other teams, and application of the PDSA cycle to other barriers in the research environment, such as subject recruitment, team turnover, or data collection and processing. It is uncertain based on this single example whether systematic application of PDSA cycles by academic research institutions would help increase resident participation in research or help ensure completion of resident research projects. However, it is reasonable to expect that improving research processes could facilitate resident involvement in research. This is a key area for future inquiry.

While this PI was not designed or evaluated as a curricular intervention, we noted an opportunity to develop an educational model to help learners develop a deeper understanding of the goals and conduct of both PI projects and research studies. By applying the conceptual learning in the same realm, we noted one key difference between PI and research tasks. The hypothesis-driven research study followed a predetermined protocol, while the PI

experience involved adopting incremental changes quickly, benefitting or suffering as a result. Unanticipated barriers hindered research but were exactly what PI was designed to address. Similarities also emerged. We needed to answer a question that was measurable, to collect data as completely and correctly as possible, and to work within a team. Notably, we simultaneously accomplished the process improvement and scholarly activity requirements required of residents by ACGME.[22]

Overall, this serves as an important proof of concept that other research teams could adapt to fit their own needs. Our research team was limited both in funds to hire dedicated personnel and in protected research time for our clinical personnel. We needed to optimize our processes to get the best possible result in a less-than-ideal environment. Our situation is not unique; research resources are relatively scarce in family medicine. PDSA cycles enabled us to overcome unanticipated research barriers in a way that incurred no monetary cost, added minimal additional time, and was impactful. Family medicine researchers will benefit from adopting

this strategy for their research challenges.

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