Applying the Plan-Do-Study-Act (PDSA) Approach in Pragmatic Research with Safety Net Health Centers

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BACKGROUND

The ***Plan-Do-Study-Act*** (PDSA) cycle is a commonly used improvement process in health care settings. ***Strategies and Opportunities to STOP Colon Cancer in Priority Populations*** (STOP CRC) recently used this process to optimize the implementation of an automated cancer screening outreach program as part of standard health care.

The PDSA process enabled clinics to actively participate in the integration of a research-based intervention into everyday care processes.

The PDSA cycle may also prove useful in supporting the adaptation and implementation of research-based interventions.

SOURCES OF SUPPORT

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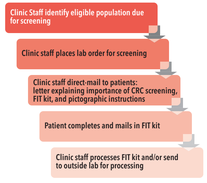
METHODS

Design:

- Cluster-randomized trial
- Test of direct-mail FIT offering
- 26 clinics/8 FQHCs
- Clinics received structured presentations on applying PDSA's to improve implementation

Clinic Workflow

Center leaders submitted PDSA plans and delivered reports via webinar at the project's advisory board.



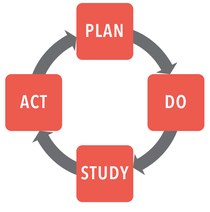
Description of PDSA Work with Clinics

The PDSA cycle helps introduce a new program into a complex environment, such as primary care. An improvement process, may identify:

- the need for a workflow that can improve efficiency (e.g., calling patients with invalid addresses) or training (e.g., best practices for recording historical colonoscopies)
- additional intervention components to improve effectiveness or reach (e.g., clinic posters that show how to do the test)

PDSA Cycle for Quality Improvement

1. **PLAN:** each clinic identified the question they wanted to ask, and determined what data they needed to collect and by whom
2. **DO:** carry out the change or activity and collect the data
3. **STUDY:** the data collected
4. **ACT:** identify next steps or further PDSA cycles



RESULTS

Common benefits of using PDSA cycles in pragmatic research were that it provided a structure for staff to focus on improving the program and it allowed staff to test the change they wanted to see. A commonly reported challenge was measuring the success of the PDSA process with the available electronic medical record tools.

PDSA Topics and Plans

Health Center (HC) No.	PDSA Aim Statement	Initial Plan
CORRECT WORKFLOW AND STAFFING		
HC 1	Create standardized process for CRC screening.	Test staffing models for mailing FIT kits. By June 1, 2015, have a standard workflow to increase percentage of patients screened for CRC.
HC 2	Develop standard work for printing letters and mailing kits that can be sustained by support staff within teams. (~100 mailings per month).	Test scenarios for using alternative staffing models (like the front desk staff) and temporary staff to prepare and mail FIT kits.
HC 3	Compare return rates from kits distributed in-clinic vs. kits mailed, and shorten the look-back period for mailed kits from 1 year to 3 months.	Pilot-test pre-visit planning to improve capture of CRC screening data in the medical record.
INCREASE RETURN RATE		
HC 4	Improve the rate of FIT kit returns.	Test the mailing of the introductory letter with and without FIT and assess results for patients enrolled or not enrolled in the patient portal.
HC 5	Determine whether a second reminder via phone call will increase the rate of FIT kit returns.	Test phone reminders.
HC 6	Improve the rate of FIT kit returns.	Test the use of metered return mailing versus of drop off at the clinic.
HC 7	Improve the rate of FIT kit returns.	Test the mailing of FIT 1-2 weeks prior to scheduled clinic visit.
INCREASE ACCURACY OF FIT COLLECTION		
HC 8	Resolve the issue that many completed FIT kits cannot be processed because the patient omitted the date(s) of collection to the kit label.	Improve materials to prompt patents to write the date of collection on the kit label.

SAMPLES OF RESULTS:

Correct Workflow and Staffing: Health Center 2

Clinic staff examined whether the number of letters and FIT kits sent to patients could be boosted by using staff at the front desk rather than lab technicians or clinical staff. Local university students working at Health Center 2 provided staff education about the importance of CRC screening and use of FIT testing, created a flyer as a patient education tool, and helped create better workflow design.

> "*We chose to see how we were going to transition this work to the clinical staff... because at the time of starting the PDSA we had this backlog of work, and I [as project lead] had no way of knowing how we were going to be able to give this to the clinical team, which is where I thought it belonged. I also knew that I had some nursing students coming and colorectal cancer screening was something they wanted to work on. And so I thought this was a great opportunity to figure that out. So that's why I chose it.*" – Clinic Project Lead

Increase Return Rate: Health Center 4

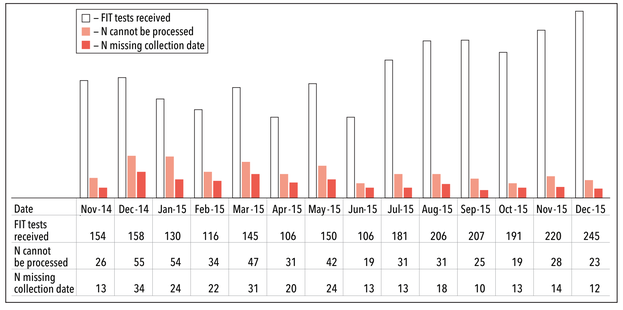
	Pre-PDSA		Post-PDSA	
Site	N	% Returned	N	% Returned
Clinic 1	568	18.5	421	23.0
Clinic 2	144	25.0	311	23.5
Total	*712*	*19.8*	*732*	*23.2*

Pre-PDSA: separately mailed introduction letter and FIT kit
Post-PDSA: a combined introduction letter and FIT kit

> "*...We didn't really know if the patients weren't returning the kits because they'd never opened the intro letter, or vice versa. And so if we mailed it all together then they don't have to find the first piece of mail that we sent them that reminds them why they're getting a second piece of mail.*" – Operations Manager

Increase Accuracy of FIT Collection: Health Center 8, completed FIT kits unable to be processed

Health Center 8 staff chose to enhance their patient outreach materials to improve FIT collection accuracy. Staff highlighted in yellow the sentence in the introduction letter that instructed patients to write the collection date for each collected sample. They also developed a new FIT kit insert that included a graphical image of where to write the collection dates. They tracked the monthly number of kits that were returned improperly completed and the number with omitted collection dates during two 7-month time periods (November 2014 through May 2015 and June 2015 through December 2015). They found that the average number of test cards with missing collection dates dropped from 24.0 to 13.3 and the average number of overall samples that were improperly collected dropped from 41.3 to 25.1



Date	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15	Oct-15	Nov-15	Dec-15
FIT tests received	154	158	130	116	145	106	150	106	181	206	207	191	220	245
N cannot be processed	26	55	54	34	47	31	42	19	31	31	25	19	28	23
N missing collection date	13	34	24	22	31	20	24	13	13	18	10	13	14	12

> "*We had a very large percentage of returned samples coming back without the collection date on the label — if they didn't have a collection date we had to toss them. So we had to figure out a way to teach patients the importance of that and make sure that it was done.*" – Clinic Project Lead

CONCLUSION

All interview participants found their PDSA activity for STOP CRC beneficial. Primarily, participants found it helped them focus on the planning and organizing necessary to implement tasks pertaining to workflow, staffing, and resources for the program.

> "*There were still some unknowns and so it focused me in writing out what our problems actually were… so having it all down in one document really helped focus the project and [we] know what to work on next.*" – Operations manager

PDSA cycles could be a novel method for dealing with the complexity of implementation. At the heart of the PDSA method is the ability to break things down and focus on making small, measurable changes. Understanding how the PDSA process can be applied to pragmatic trials and the reaction of clinic staff to their use may help clinics integrate evidence-based interventions into their everyday care processes.

- Given our emphasis on implementation (vs. effectiveness) the PDSA approach was well suited for our study but may not be appropriate for all.

Ongoing questions:

- Is the best time to implement a PDSA process during the initial intervention (as in prior research) or months into the process (as we did)?
- The standard PDSA cycle involves multiple iterations but we asked clinics to just do one cycle for the study, which may have affected what project each clinic chose. How can multiple iterations be used in research?

REFERENCES

1. Greene SM, Reid RJ, Larson EB. Implementing the learning health system: from concept to action. Annals of internal medicine. 2012;157(3):207-10. Epub 2012/08/08.
2. Luce BR, Kramer JM, Goodman SN, Connor JT, Tunis S, Whicher D, et al. Rethinking randomized clinical trials for comparative effectiveness research: the need for transformational change. Annals of internal medicine. 2009;151(3):206-9. Epub 2009/07/02.
3. Califf RM, Sanderson I, Miranda ML. The future of cardiovascular clinical research: informatics, clinical investigators, and community engagement. JAMA : the journal of the American Medical Association. 2012;308(17):1747-8. Epub 2012/11/03.
4. Green LW. Making research relevant: if it is an evidence-based practice, where's the practice-based evidence? Family practice. 2008;25 Suppl 1:i20-4. Epub 2008/09/17.
5. Chalkidou K, Tunis S, Whicher D, Fowler R, Zwarenstein M. The role for pragmatic randomized controlled trials (pRCTs) in comparative effectiveness research. Clinical trials. 2012;9(4):436-46. Epub 2012/07/04.
6. Nallamothu BK, Hayward RA, Bates ER. Beyond the randomized clinical trial: the role of effectiveness studies in evaluating cardiovascular therapies. Circulation. 2008;118(12):1294-303. Epub 2008/09/17.