DEVELOPING AND IMPLEMENTING A COLORECTAL CANCER AMBULATORY SAFETY NET

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Contents

Foreword

Delays and errors in cancer diagnoses pose significant patient safety risks and can have devastating effects for patients and their families. In many cases, these errors can be attributed to failures in communication and breakdowns in the loop-closure process — a patient receives an abnormal test result, but the necessary follow up is not completed, and a potential cancer diagnosis is missed.

Ambulatory safety nets help provide a safeguard against these errors. They allow health systems to efficiently identify patients in need of follow up through a registry and connect them to the care they need using patient navigators. When successful, safety nets offer a reliable, effective, and person-centered approach to connecting patients to the right care at the right time. Success, however, hinges on a coordinated implementation process that embraces continuous learning.

In July of 2021, CRICO and Ariadne Labs convened this working group to develop recommendations on how health systems can effectively implement these life-saving programs in the context of colorectal cancer screening. Our multidisciplinary group includes representatives from Atrius Health; Beth Israel Lahey Health, including Beth Israel Deaconess Medical Center and BILH Primary Care; Cambridge Health Alliance; Mass General Brigham, including Brigham and Women's Hospital and Massachusetts General Hospital; along with patient advocates who have offered perspectives on the patient care experience.

Using our collective expertise, we have identified 14 core components for developing and implementing an ambulatory safety net. The following guide builds on the Patient Safety Adoption Framework, in which culture and context are central to the implementation process. The recommendations included in this guide are a starting point for successful implementation and will need to be adapted to the unique context of each organization to support its strategic goals. We hope our work can help health system leaders in implementing an ambulatory safety net that meets the needs of their system.

By closing gaps that jeopardize patient safety through diagnostic error, ambulatory safety nets offer a critical opportunity to save patient lives.

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Introduction

Overview of Ambulatory Safety Nets (ASNs)

Failures in closing the loop in ambulatory care are a significant source of diagnostic error and can have devastating consequences in patients' lives, including but not limited to late or missed diagnosis with serious outcomes, decreased trust in the healthcare system, and avoidance of further medical care in the future.[1]

An ambulatory safety net (ASN) provides a backup system for following up on abnormal test results when the standard follow-up process fails. ASNs function by leveraging electronic health record (EHR) fields to create a registry of patients with abnormal results outside of the follow-up window. The ASN team, typically including a patient navigator, contacts these patients and helps facilitate follow up for the patients. Many different types of ASNs have been successfully implemented, including follow up of cancer screening tests (lung, prostate, breast, cervical, colorectal), drug level monitoring, kidney disease, post-splenectomy immunizations, suicidal ideation, and medication safety.

ASNs are high-reliability, person-centered programs that improve the patient and caregiver experience. The health system also benefits from ASNs by reducing stress related to diagnostic error, thereby improving provider well-being and retention, and by redesigning workflows, thereby identifying inefficiencies and waste in the system. There is a strong business case for ASNs with cost-effectiveness of the program well below ranges justifiable from a societal perspective (Appendix A). The business case is based on adding revenue from procedures, office visits, and surgery resulting from follow-up studies and cost savings through reduction of the total medical expenditure of late-stage cancer diagnoses and malpractice cases.

Finally there is a strong social case for ASNs: "the benefit to the individual (patient) or to society of improved health status and productivity, regardless of cost."[2] It is simply the right thing to do to ensure that patients are aware of their results and to help them get the follow up they need.

1.Prentice JC, Bell SK, Thomas EJ, Schneider EC, Weingart SN, Weissman JS, Schlesinger MJ. Association of open communication and the emotional and behavioural impact of medical error on patients and families: state-wide cross-sectional survey. BMJ Qual Saf. 2020 Nov;29(11):883-894. doi: 10.1136/bmjqs-2019-010367. Epub 2020 Jan 20. PMID: 31959717.
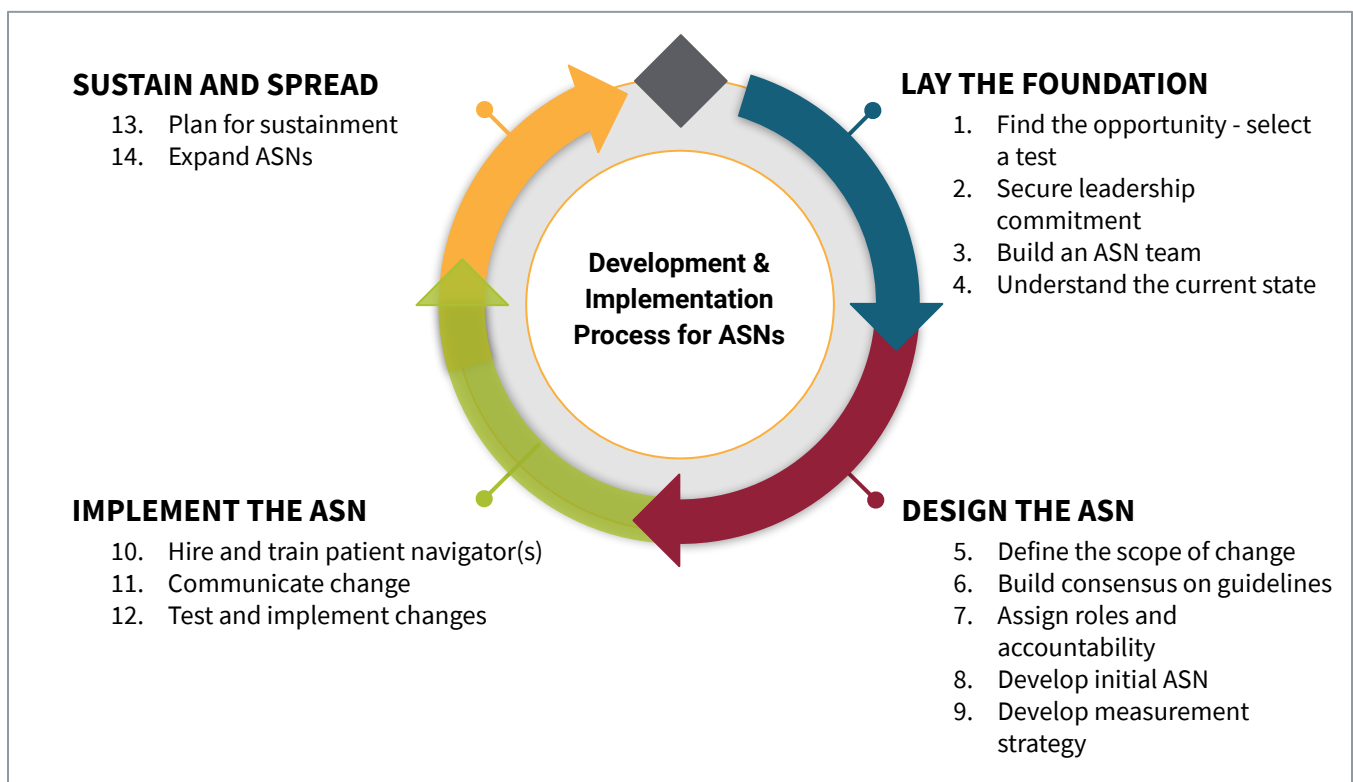2.Leatherman S, Berwick D, Iles D, Lewin LS, Davidoff F, Nolan T, Bisognano M. The business case for quality: case studies and an analysis. Health Aff (Millwood). 2003 Mar-Apr;22(2):17-30. doi: 10.1377/hlthaff.22.2.17. PMID: 12674405.

Introduction (cont.)

Development & Implementation Process for Ambulatory Safety Nets

In July and August 2021, a working group comprising of representatives from Atrius Health; Beth Israel Lahey Health, including Beth Israel Deaconess Medical Center and BILH Primary Care; Cambridge Health Alliance; Mass General Brigham, including Brigham and Women's Hospital and Massachusetts General Hospital; and patient and family advocates collaborated to reach consensus on the four phases and 14 core components of developing and implementing an ASN (Figure 1).

FIGURE 1

SUSTAIN AND SPREAD
13. Plan for sustainment
14. Expand ASNs

LAY THE FOUNDATION
1. Find the opportunity - select a test
2. Secure leadership commitment
3. Build an ASN team
4. Understand the current state

Development & Implementation Process for ASNs

IMPLEMENT THE ASN
10. Hire and train patient navigator(s)
11. Communicate change
12. Test and implement changes

DESIGN THE ASN
5. Define the scope of change
6. Build consensus on guidelines
7. Assign roles and accountability
8. Develop initial ASN
9. Develop measurement strategy

The working group included subject matter experts in ASNs, primary care, medical subspecialties, measurement, and patient safety. The working group combined their expertises to map relevant stakeholders and their roles, to develop actionable steps, and to capture recommendations, best practices, and examples for each of the 14 core components of the development and implementation of ASNs. The 14 core components presented in this guide remain consistent regardless of an ASNs focus, though action steps within each component may require some adaptation to the unique needs and structures of individual systems and sites.

Introduction (cont.)

How to Use this Guide

This guide uses colorectal cancer and the follow up of abnormal at-home screening tests or delays in interval colonoscopy (when a colonoscopy is recommended sooner than the standard screening interval) to illustrate the four phases and 14 components of ASN development and implementation. Of the four most commonly missed cancers (prostate, breast, lung, colorectal), colorectal cancer has the highest rate of delays in ordering diagnostic tests and obtaining referrals for treatment.[3] Missed and delayed colorectal cancer remains a significant malpractice risk: a review of malpractice cases from 2007-2016 found 447 colorectal cancer claims, with 86% occurring in an ambulatory setting, resulting in a total of $117 million in incurred losses.[4]

The foundation of this guide is The Patient Safety Adoption Framework & Guidance (Figure 2) developed by CRICO and Ariadne Labs. At the core of this framework is context, including organizational culture. Context is crucial to a successful implementation and can be assessed using the Implementation Readiness Checklist (Appendix B). These readiness questions can help teams identify institutional strengths and gaps that influence implementation success prior to ASN implementation.

Figure 2: The Patient Safety Adoption Framework
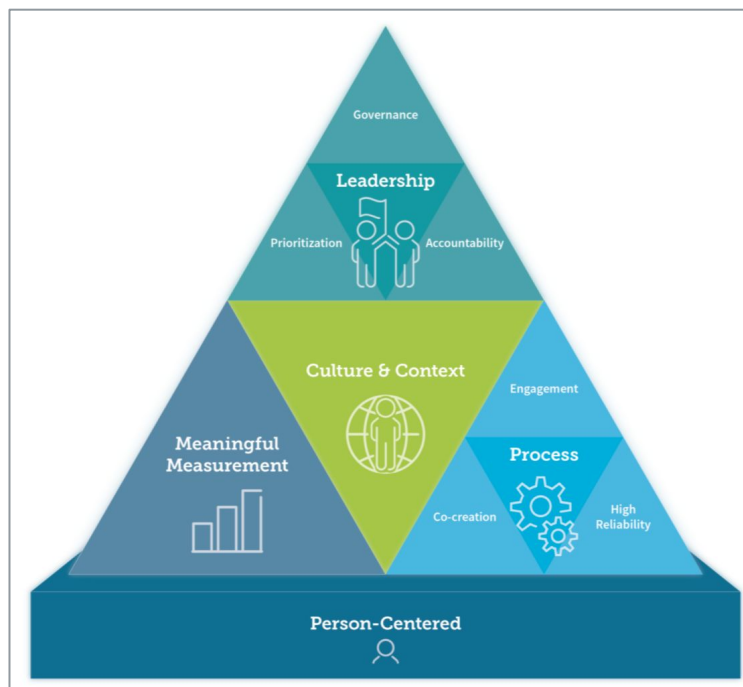
3. Aaronson EL, Quinn GR, Wong CI, Murray AM, Petty CR, Einbinder J, Schiff GD. Missed diagnosis of cancer in primary care: Insights from malpractice claims data. J Healthc Risk Manag. 2019 Oct;39(2):19-29. doi: 10.1002/jhrm.21385. Epub 2019 Jul 23. PMID: 31338938.
4. CRICO. CBS Data Across Four Types of Cancer. Internal report.
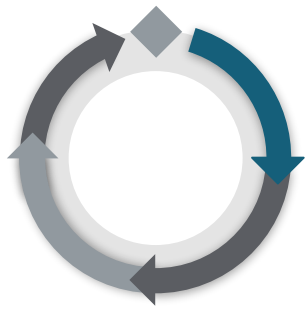
Lay the Foundation

CORE COMPONENTS

1. Find the opportunity - select a test.
2. Secure leadership commitment.
3. Build an ASN team.
4. Understand the current state.

Creating a firm foundation by making sure the right people are involved and supportive is essential to a successful ASN. Involving senior leadership in the process of selecting a test then securing their commitment to implementation are the first steps in developing an ASN. Leaders build the will for change and create accountability structures. The next step is building a strong ASN team, which is necessary to carry the work forward and to collaborate with stakeholders to develop the ASN.

The final step in this phase is understanding the current process in place for test result follow up and the readiness for implementation at your organization. If this is not the first ASN implemented at your organization, Step 2 and Step 3 may already be completed. Reviewing this section may highlight additional considerations and provide an opportunity to make adjustments.

The Patient Safety Adoption Framework in this section:

Leadership

Governance is part of the process of selecting the test and gaining approval for necessary resources in Step 1.

Accountability through the use of metrics is included in Step 2.

Prioritization of resources to support the ASN by leadership is in Step 2 and Step 3.

Context is assessed in Step 4, referencing the readiness checklist that accompanies the framework.

Meaningful measurement and its role is established with senior leadership in Step 2.

Process

Co-creation through partnering with subject matter experts for the selection of the test (Step 1) and through regular meetings with patient and family advisors (Step 2).

High reliability of current processes is assessed in Step 4.

Engagement of senior leadership and leaders in affected departments is the focus of Step 2, and stakeholders are engaged for reviewing the current workflow in Step 4.

Person-centered is reflected in Step 4 by evaluating how patients are contacted and move through the system.
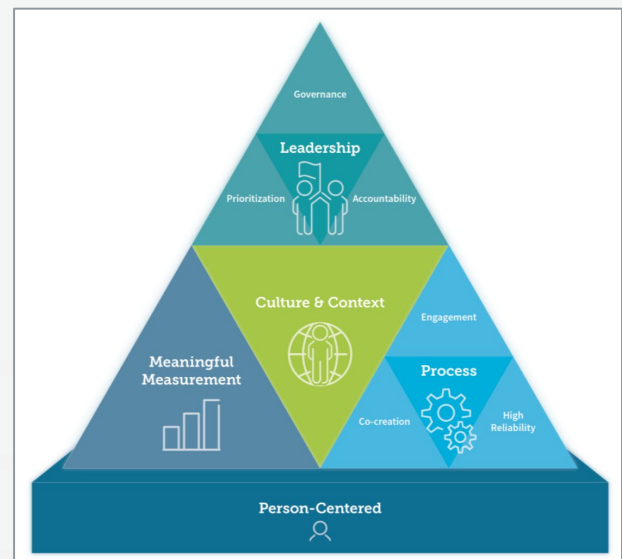
Find the opportunity - select a test

OBJECTIVE

> Identify an area of focus and specific test(s) for the ASN.
> Gain agreement on the selected focus and test(s) from senior leadership.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Board of directors, senior administrative leadership, medical director, director of quality, finance	Approve area of focus, ongoing monitoring, and funding; prioritize the ASN and communicate its importance to others; board of directors ensures reporting as part of the annual report; appreciate the business and quality of care aspects of implementation of an ASN
Medical team: Medical providers, subject matter experts, nurses and other clinical team members	Provide input on the area of focus based on clinical expertise, clinical practice guidelines, and local practice
Quality and Safety: Risk management	Provide data on safety events and malpractice cases and information on internal quality improvement priorities
Information Services: EHR systems analyst, data analyst, registry specialist	Provide subject matter expertise on registry development

ACTION STEPS

The ASN medical director, chief medical officer, and chief quality officer identify potential areas of focus. Review local quality improvement priorities, recent safety events, medical malpractice cases, organizational priorities, and evidence based recommendations from clinical guidelines or high quality studies.

Review the recommended areas of focus with a panel of subject matter experts and senior leadership. Subject matter experts should include those with expertise in the identified clinical areas, in ASN development, and in registry development.

Share the recommended area of focus and the associated test(s) that will be included in the ASN with the board of directors and senior leadership for approval.

Secure leadership commitment

2

OBJECTIVE
> Communicate the benefits of the ASN with leadership.
> Set expectations for resources, the role of leadership, and metrics.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Board of directors, senior administrative leadership, medical director, director of quality, finance, departmental leadership	Agree on providing support and removing barriers, the prioritization of the ASN

ACTION STEPS

Secure priority support for ASN initiative from senior leadership and the board of directors.	**TIP:** Use the business case (Appendix A) to communicate the value of ASNs.

Secure interest and buy-in from the departments and people who will be actively engaged in ASN development, implementation, and operation (e.g. Primary Care, Gastroenterology).

Obtain preliminary commitment from leadership on the allocation of resources (funds, people, time) for ASN development and implementation. This includes funding for patient navigator(s), project manager, medical director, and IS resources to develop registries.

Agree on the role of metrics and reporting in driving accountability. Examples include > Make ASN metrics part of system-level internal performance framework (See Step 9: Develop measurement strategy). > Consider developing a standardized ROI calculation/metric. > Track patient equity metrics. > Once implemented, consider funding the team contingent on performance against metrics.	**TIP:** For more on establishing accountability review the accountability domain in the Patient Safety Adoption Framework and Guidance.

Schedule regular meetings with key departments and teams:
> Weekly updates with the administrative director or operational leader for primary care and/or gastroenterology.
> Quarterly meetings to share progress against operational goals and opportunities for institutional improvements with the Patient Family Advisory Council (PFAC) Steering Committee.

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Build an ASN team*

3

OBJECTIVE

> Establish team roles and responsibilities.

> Hire and train ASN team members.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Senior administrative leadership, medical director, director of quality, finance, departmental leadership	Select key stakeholders to popular the ASN team; approve budget and allocations

ACTION STEPS

Create a governance structure to support and oversee the design and implementation of the ASN. Consider the following model.

> **ASN Team**: Core team members who are responsible for the day-to-day activities of the ASN, including patient navigation, coordination with specialists, maintenance of the ASN, and strategic decisions for future ASN development.

> **Working Group:** Individuals who are critical for the design and testing of an ASN, including clinical subject matter experts (e.g. gastroenterology), operations (e.g. scheduling), patient advisors, and EHR/IT specialists.

> **Steering Committee:** Key stakeholders who are critical to the success of the ASN, including senior leadership, quality and safety, ambulatory care, ancillary services, etc.

TIP: Each step of the Intervention Guidebook offers recommendations on how to engage each stakeholder.

Steering Committee

Working Group

ASN Team

* This step is most relevant when the first ASN is being designed and implemented. For subsequent ASNs, a team will NOT need to be built but the existing team may need to be updated or reconfigured

4. Build an ASN team (cont.)

Secure the appropriate funding to recruit and hire individuals for the ASN team. The allocations listed below are based on an organization with 1-3 million ambulatory visits per year and 1-4 ASNs (active or in development).*

The team at a minimum includes:

> **ASN medical director** (0.20 - 0.35 FTE) - They are responsible for ASN program and guidelines review and provide clinical input and legitimacy. Ideally, this person has experience in quality improvement and informatics. The range of their allocation varies based on the number of ASNs they are overseeing.

> **ASN project manager** (1.0 FTE) - They are responsible for overseeing the project, assisting with the project timeline and deliverables, and communicating with stakeholders. They gather information about the existing workflows and necessary data for the measures.

> **ASN patient navigator** (1.0 FTE) - This person is usually hired later, and details about their role are outlined in Step 10. They conduct chart review and communicate directly with patients.

> The project manager may also work directly as a patient navigator depending on need or may take on some of the responsibilities of the patient navigator while the ASN is starting out and before the patient navigator is hired.

Appendix C contains details on the calculation of these allocations.

Establish methods for team communication, scheduling meetings, and developing the project plan.

Understand the current state

4

OBJECTIVE

Develop a detailed understanding of the current process, including

> Guidelines used,
> Departments and people involved, and
> Current performance on key metrics.

STAKEHOLDERS TO ENGAGE	PURPOSE
Medical team: Primary care providers, gastroenterologists, nurses, medical assistants and other clinical team members	Review current practice; prepare for the process of achieving consensus regarding how the ASN will interface with current workflow
Patient Advisors	Review how a patient moves through the system and current methods of patient communication
Administrative: Referrals manager, scheduling department (GI, PCP), gastroenterology operations	Provide information on workflows (scheduling, referrals, patient communication); identify existing barriers to timely follow-up; evaluate current staffing resources and responsibilities of team members to determine how project tasks could be allocated across the GI team
Information Services: EHR systems analyst	Provide information on how results are entered into EHR and existing registries within EHR
Ancillary Services: Lab manager, pathology	Provide information on how at-home screening tests are processed and how pathology reports are entered into EHR (interval)
Quality and Safety: Quality department (department and system level), population health	Review guidelines and current practice; provide access to patient safety event reports and malpractice cases; provide information on any existing workflows to address CRC screening rates; provide access to currently collected measures related to CRC screening and follow up; assist in data collection and support reporting.

4. Understand the current state (cont.)

ACTION STEPS

Make a detailed list of stakeholders to engage during this step. Schedule one-on-one meetings or arrange for a small group meeting to review existing guidelines, workflows, and follow-up criteria with all stakeholders.

TIP: Look for individuals who are enthusiastic and engaged as potential champions. They can even be added to the working group developed during the previous step.

FOR INTERVAL COLONOSCOPY ONLY

Review current guidelines and variations in medical practice. Examples include

> GI interval colonoscopy recommendations (internal and external)

> The utility of ranges for follow up (ex: 5-7 years)

FOR AT-HOME SCREENING/FIT ONLY

Review current guidelines and variations in medical practice. Examples include

> Provider's acceptance and use of noninvasive screening

> Use of at home testing and whether all positive tests requires colonoscopy

Review and understand current reporting of results, including how at-home screenings are captured. For example, cologuard results may not be in a discrete field within the EHR, making it difficult to query.

Review existing workflows in several areas:

> Receiving results, fields of EHR, who accesses results, and scheduling follow-up.

>> Consider how internal and external reports are routed (at home testing).

>> Consider how follow up time frame is documented (interval colonoscopy).

> Patient communication from scheduling to results notification, including scheduling follow-up testing.

TIP: While assessing current communication practices, note patient and provider communication preferences, which will help in future steps.

Review existing measures, such as

> Rates of CRC screening and follow up

> Related malpractice cases specific to your facility

> Related patient safety events

> Patient satisfaction, provider satisfaction/burn-out

Evaluate the organization's context and readiness for implementation by conducting a formal context assessment.

TIP: A context assessment (Implementation Readiness Checklist) is available in The Patient Safety Adoption Framework & Guidance and in Appendix B.

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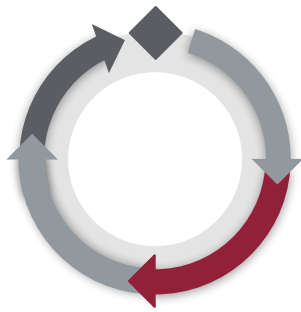
Design the ASN

CORE COMPONENTS

5. Define the scope of change.
6. Build consensus on guidelines.
7. Assign roles & accountability.
8. Develop initial ASN.
9. Develop measurement strategy.

This section contains the steps to design the ASN. It starts with defining the scope of the ASN, followed by gaining agreement on guidelines, redesigning workflows, building the registry, and selecting measures that will demonstrate change. The content in these steps is specific to colorectal cancer ASNs; however, the objectives for each step remain the same for the design of any ASN.

This section also contains design considerations for facilities seeking to customize aspects of the ASN based on their resources, patient volume, and the interoperability of EHR systems.

The Patient Safety Adoption Framework in this section:

Leadership is included in each step as key stakeholders for approval of the scope of change, budget, guidelines, updated workflow, and measures.

> **Accountability** of each step of the updated workflow is the focus of Step 7.
>
> **Prioritization** of resources to support the ASN by leadership is in Step 8.

Context is an important consideration when determining the scope of change in Step 5.

Meaningful measurement is the focus of Step 9: selection of the measures to demonstrate meaningful change.

Process

> **Co-creation** through partnering with patient and family advisors to determine the best methods for patient communication (Step 8).
>
> **High reliability** is captured in the design of the registry, by automating as much as possible and by having a back-up owner for each stage of the workflow (Step 7,8).
>
> **Engagement** of stakeholders occurs throughout the design process and is especially important for input and agreement on the guidelines (Step 6).

Person-centered is incorporated in communication around patient preferences (Step 8) and in the focus on workflow and measurement from the patients' perspective (Step 7,9).

Define the scope of change

5
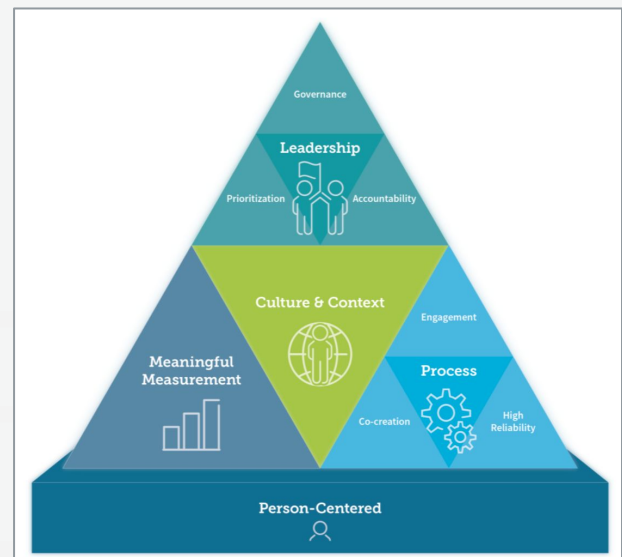
OBJECTIVE

> Determine timeline, budget, and human resource allocations for design and implementation.
> Develop project aim.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Medical director, director of quality, finance	Provide approval of available resources (financial, human resources), budget and timeline; consult on alignment of aim with organization wide initiatives
Medical team: Primary care providers, gastroenterologists, nurses	Advise on ASN focus and the feasibility of desired aim; provide data on current volume of screening and colonoscopies needed
Patient Advisor	Give guidance on aim and focus of the ASN
Administrative: Gastroenterology operations, primary care operations	Share information on patient volume and practice size when defining the scope of the ASN
Information Services: EHR Systems Analyst, data analyst, registry specialist	Provide input on feasibility of cross functionality of EHR for system level implementation
Quality and Safety: Quality department (department and system level), population health	Allow data access for determining potential patient volume in ASN; provide input on availability of population health support; provide input on alignment of the aim with other quality initiatives

5. Define the scope of change (cont.)

Review the selected test or procedure from Step 1. Narrow or expand the focus based on the information collected in the previous step and on the available resources.

Define the scope of the ASN in several areas:

> **If the ASN will be system level, hospital level, or practice level**

> **Which practices will be included** -- interval colonoscopy can be contained to GI, or for at-home screening, it can be confined to primary care; however, this limitation depends on local agreements and practice sites (assessed in the previous step).

> **The affiliation of patients and practices** that will be included in the ASN.

> **The limits of the ASN** -- if at-home screening or interval colonoscopy needs to be standardized, consider standardizing before implementing the ASN, or determine building consistency of screening criteria or interval follow up into the ASN.

TIP: Plan with your end goal in mind. If you choose to start at a practice level, but the goal is systems level, consider how the ASN would function at the various levels throughout the ASN design phase.

TIP: It is best to start small and demonstrate success. This may mean beginning with one colorectal test (i.e. interval screening) among gastroenterologists at one site (with everyone on the same EHR).

Assess what resources are needed and what is available. Create a projected budget for implementation and sustainment of the ASN. Resources needed:

> **Allocated time** for core team and information services specialist, patient navigator(s), scheduling support

> > Recommended minimum allocations for sites with 1-3 million ambulatory visits per year and 1-4 ASNs (active or in development):

> > > Medical Director (0.20-0.35 FTE)

> > > Project Manager/Coordinator (1.0 FTE)

> > > Patient Navigator (1.0 FTE)

> > > Information services specialist with experience building registries (0.15-0.5 FTE during build phase and 0.1-0.05 FTE during the maintenance phase)

> > When determining allocations, consider the anticipated number of patients in the ASNs. Estimate this number by evaluating the volume of at-home screening ordered yearly or the volume of colonoscopies performed at the facility. Additionally, consider performing chart review for missed follow up to roughly determine how often follow up is missed.

> > As the ASN expands and new ASNs are added the staffing allocations will need to be reassessed. This may require a higher allocation to the medical director or the addition of another patient navigator or project manager depending on local needs and patient volume.

> **Office space** with a phone, computer, and supplies for mailing letters to patients

5. Define the scope of change (cont.)

Review steps in this guide, and develop a timeline for ASN design and implementation. The timeline will vary based on the facility size, scope of ASN, and resources.

Present the projected budget, resource requirements, and timeline to senior leadership for discussion and approval.

Create a project aim (goal):

> Review information from Step 3 for any recognized gaps.

> Example aim: *Within a year, we will reduce harm by implementing a colorectal cancer ambulatory safety net that ensures all patients with abnormal test results get the follow up they need when, where, and how they need it.*

> Develop and get consensus on the aim from the implementation team and key stakeholders.

TIP: Effective aims are SMART (Specific, Meaningful, Actionable, Relevant, Time-bound).

Build consensus on guidelines

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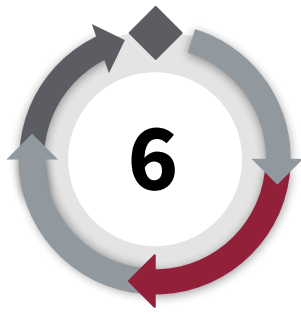
OBJECTIVE

> Review guidelines with key stakeholders.

> Customize areas of the guidelines as needed.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Medical director, director of quality	Provide approval on final guidelines
Medical team: Primary care providers, gastroenterologists, nurses	Contribute expertise on national guidelines and current practice; provide input on ASN guidelines
Information Services: EHR systems analyst, data analyst, registry specialist	Determine feasibility of data capture, analysis, provide information on existing/available EHR fields
Quality and Safety: Quality department (department and system level), population health	Give access to data and provide input on special populations
Ancillary Services: Lab manager, pathology	Determine feasibility of accessing results and cross-functionality between EHR and results

6. Build consensus on guidelines (cont.)

Review national guidelines (e.g. USPSTF) for any changes to appropriate follow up of abnormal results.

Review recommended guidelines for at-home testing and interval colonoscopy ASNs (see next page).

Consider the following when customizing the guidelines:

> Create clear follow-up criteria to avoid variations in medical practice. For example, colonoscopy interval might be documented as 7-10 years. Criteria for ASN must be specific (e.g. 7 years).

> Define unreachable patients by reviewing your organization's policy on contacting patients with test results. It is recommended that a patient outreach should use multiple methods of communication (phone calls, letters, patient portal), multiple times (at least 2 phone calls so a voicemail can be left), over a period of months. All communication should be standardized and documented. From a malpractice risk mitigation standpoint it is imperative to follow the organizational policy and document outreach attempts in compliance with that policy.

> Account for the average lag time between abnormal test result and follow up.

> Determine appropriate next steps for patients who have changed their care providers, had a change in insurance, or prefer a non-affiliated practice for follow up.

> Decide whether patients with inconclusive and/or incomplete at-home screening test results are included in the ASN.
> *Recommendation:* Patients with an *inconclusive* test result should be included in the ASN as they have completed their screening test, but the result is unknown and therefore a follow-up action is required. Patients with an *incomplete* test result should be followed up by primary care as they have not yet had an initial screening test.

> Consider adding special patient populations to the exclusion criteria. This may be groups that are already followed closely and are unlikely to benefit from the ASN, such as patients with inflammatory bowel disease, Lynch syndrome, or familial adenomatous polyposis. Exclusions can also include groups for whom screening recommendations aren't as strong, such as people >75 years old.

TIP: Developing a system to periodically review and revise guidelines and to communicate these changes to information services for necessary changes to the registry is an important part of the sustain phase (Step 14).

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6. Build consensus on guidelines (cont.)

RECOMMENDED CRITERIA

AT-HOME TESTING (FIT/COLOGUARD):

Inclusion criteria:

> Patients who have a positive or inconclusive FIT or Cologuard result within the past 2 years

Exclusion criteria:

> GI for consult or scope since result (lag time = 6 months)

> Order for a GI consult or scope (lag time = 1 month)

> Patient deceased

> Intervention not clinically indicated (e.g. hospice)

> Patient declined through shared-decision making with provider

Closure criteria:

> Completed flexible sigmoidoscopy

> Patient declined (conversation and reason documented in EHR)

> Intervention not clinically indicated

> Patient unreachable (contact attempted using multiple methods, multiple times, over a multi-month period per institution policy)

INTERVAL COLONOSCOPY:

Inclusion criteria:

> Diagnostic or surveillance colonoscopy completed at affiliated practice location/hospital

> Pathology obtained from colonoscopy

> Flag (such as Epic health modifier) in the EHR indicating that colonoscopy was overdue (colonoscopy is not completed 6 months after the due date of the patient's recommended colonoscopy)

Exclusion criteria:

> No longer indicated (e.g. hospice)

> Patient deceased

> Patient declined through shared-decision making with provider

Closure criteria:

> Patient sought out of network care (e.g. preference, insurance changes)

> Patient declined (conversation and reason documented in EHR)

> Patient moved

> No longer indicated, GI provider updated medical record

> Patient unreachable (contact attempted using multiple methods, multiple times, over a multi-month period per institution policy)

Assign roles and accountability

7

OBJECTIVE

> Create new workflows and assign ownership at each step.
> Define roles and responsibilities.

STAKEHOLDERS TO ENGAGE	PURPOSE
Medical team: Primary care providers, gastroenterologists, nurses	Provide input on their roles and responsibilities with EHR fields and ownership of results
Patient Advisors	Advise on how patients move through the system and potential improvements in the workflow for patient interactions
Administrative: Referrals manager, scheduling department (GI, PCP), patient navigators, gastroenterology operations, primary care operations	Review feasibility of new workflow; provide input on roles and responsibilities; approve any staffing resources incorporated into the new workflow
Information Services: EHR systems analyst, data analyst, registry specialist	Advise on how reports can be generated and tracked and the recommended frequency of retrieving reports
Ancillary Services: Lab manager, pathology, social worker	Determine feasibility of test processing and access to results in EHR; provide resources for anticipated barriers and input on communication pathways (social worker)
Quality and Safety: Quality department (department and system level), population health	Review and approve new workflows

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7. Assign roles and accountability (cont.)

ACTION STEPS	
Review information from Steps 4, 5, and 6, and create a new workflow that encompasses the entire ASN. Evaluate the current process for any bottlenecks associated with elements of scheduling and patient follow up that are labor intensive. Utilize technological solutions to improve the overall process and increase efficiency.	**TIP:** Use workflow process mapping to create a visual. See this [resource](#) for more information.
Determine who will own each step of the new process. Consider the following steps and recommendations for ownership:	**TIP:** To increase efficiency, allow the project manager or patient navigator to order the colonoscopy in the EHR on behalf of the ordering provider.
> Update the registry monthly by adding new patients who meet the inclusion criteria — *Recommendation:* ASN project manager	
> Reviewing patient charts to ensure the patient still requires follow-up care — *Recommendation:* ASN patient navigator	
> Enter the patients who require follow up into an ASN database — *Recommendation:* ASN patient navigator	
> Communicating with patients — *Recommendation:* ASN patient navigator with assistance from endoscopy scheduling. Patients will be more comfortable having the first point of contact coming from a practice they are familiar with. Coordinate with endoscopy and primary care office if needed.	
> Helping patients overcome barriers to care (e.g. transportation, insurance) — *Recommendation:* ASN patient navigator connects patient with necessary resources depending on the barrier. This may include connecting them to social work. In such cases, social work communicates to ASN [project coordinator or patient navigator & PCP/GI] when barrier is removed to schedule appropriate follow up.	
> Documenting external colonoscopy results within EHR — *Recommendation:* ASN project manager, patient navigator, or referral coordinator obtains gastroenterology consult note or colonoscopy report from outside health systems.	
> Ordering appropriate follow-up tests (colonoscopy) — *Recommendations:* > At-home screening: Ordering provider of at-home screening > Interval colonoscopy: Prior GI provider. If GI is external or no longer at institution, default to PCP as ordering provider	

7. Assign roles and accountability (cont.)

ACTION STEPS

FOR INTERVAL COLONOSCOPY ONLY

> Updating family and personal histories in the EHR to determine patient risk profiles

Recommendation: GI for internal colonoscopy, PCP for external colonoscopy

> Updating recommended EHR data field that "flags" timing of next colonoscopy (e.g. Epic health modifier field)

Recommendation: GI provider updates after the patient has a colonoscopy based on their risk factors, colonoscopy findings, and pathology results.

ASN project manager or patient navigator emails PCP to update the field for patients who receive testing out of network

### FOR AT-HOME SCREENING/FIT ONLY

> Following up with patients who have an incomplete test result

Recommendation: Determine if the population health department addresses incomplete tests; if so, follow up on incomplete tests should reside in population health.

Recommendation: If there is no population health protocol for follow up of incomplete tests, then organizations should explore that potential improvement in conjunction with population health.

Determine the role of the patient in results follow up and scheduling. Ensure that these expectations are communicated to patients and include how patients can expect results to be communicated and what actions they need to take based on this information.

TIP: Collaborate with primary care, gastroenterology, and patient advisors closely during this step.

Determine "back-up" system for each listed task and responsibility to ensure system does not become person dependent.

List each role that is identified in the new workflow and their responsibilities. Share this list and the workflow with relevant stakeholders for input and approval if needed.

Develop initial ASN

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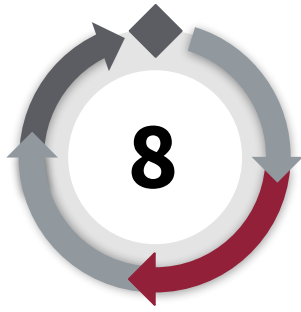
OBJECTIVE
> Build and test the ASN registry.
> Develop standardized tools and follow-up documentation for ASN team.
> Solidify strategy for patient tracking and staffing.
> Confirm workflow and modify as needed.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Medical director, director of quality	Prioritize resources to build the registry and staffing
Medical team: Primary care providers, gastroenterologists, nurses, medical assistants and other clinical team members	Approve final workflow modifications, provide input on standardized tools
Patient Advisors	Provide insight into patient tracking, develop patient communications
Administrative: Referrals manager, scheduling department (GI, PCP), gastroenterology operations, primary care operations	Approve final workflow modifications, assist with patient tracking; advise on staffing requirements
Information Services: EHR systems analyst, data analyst, registry specialist	Build and test the registry
Ancillary Services: Lab manager, pathology	Review cross capability of importing results to EHR
Quality and Safety: Quality department (department and system level), population health	Approve final workflow modifications; provide input in measurement strategy; prioritize staffing allocations

8. Develop initial ASN (cont.)

ACTION STEPS

Build and test registry:

> Identify an information services (IS) specialist with experience building registries and familiarity with the local EHR and natural language processing. Partner them with a clinician with informatics experience to collaborate on building the registry.

> Communicate the desired requirements based on the guidelines from Step 6 with the IS specialist.

> Build and test the registry by comparing registry results with manual chart review. Refine the registry until it reaches an acceptable level of sensitivity and specificity. Each site should consider staffing capacity and time requirements for manual chart review during development. If there is limited time for manual chart review, consider making the registry more specific.

> Determine how you will remove people from the registry once they have fulfilled the closure criteria, so they don't keep coming up each time the registry is run. Discuss options to build in ways to automate their removal with the IS specialist.

> Build in feedback loops between the ASN team and the IS specialist to constantly refine the registry based on patterns discovered during chart review and changes to the guidelines.

> Determine if any changes will be needed in the way clinicians interact with the EHR to make sure the EHR fields used by the registry are accurately populated (e.g. negative lab results for at-home screening, health modifier field for interval colonoscopy)

TIP: Start working with the IS specialist early; building registries require a large time commitment.

TIP: Automated removal of people from the registry may be difficult with information in open text fields, such as when the patient declines based on shared decision making, so consider the feasibility of building an additional flag in the record for these patients to exclude them from the registry in the future.

TIP: Consider offering training sessions and reminders for any changes clinicians must make to how they enter information into the EHR. Start this process early, and consistently provide feedback.

Mechanism for contacting and tracking patients:

> Develop necessary databases, spreadsheets, or other documentation that will be required to track patients in the ASN.

> Determine how to update patient contact information or access their most up to date information for any changes.

> Determine if and how you will connect with your organization's patient portal. If you are following up with patients via the portal, ensure all team members have the appropriate access level.

TIP: Reach out to your population health department to review how they track patients to see if some of this tracking work is already being done by population health and how you can access that information.

TIP: To create a highly reliable system, automate as much as possible.

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8. Develop initial ASN (cont.)

Explore the use of text message based patient communication with IS. This offers the benefit of reaching more patients with less effort from the patient navigator and the possibility of translating messages to the patients native language. Creating automated messages that allow the patient to directly connect with colonoscopy scheduling or confirm receipt of the message offers convenience for the patient and reassurance to the ASN that the message reached the patient.

Confirm workflow.

> Review workflow mapped out in the previous step, and make any modifications that are needed.

> Add registry-specific steps to the workflow, such as frequency of running the registry and the process of ongoing registry feedback and refinement.

> Ensure appropriate roles have access to areas of the EHR, database, and/or patient portal as defined by Step 7.

Solidify staffing requirements. Ensure the ASN team has appropriate allocations by evaluating team members' allocated time for the ASN. Discuss with senior leadership if more time is required.

Develop standardized processes for

> Chart review.

> Documenting outreach attempts and communication with patients in the EHR.

> Patients unreachable with the initial outreach processes.
  Recommendation: Patient is defined as unreachable after multiple methods of communication (phone calls, letters, patient portal), multiple times (at least 2 phone calls so a voicemail can be left), over a period of months. All communication must be standardized and documented.

> Communicating with limited-English-speaking patients (e.g. accessing interpreter services).

Develop standardized follow-up emails, letters, and phone call templates with patient advisors.
When developing materials, consider

> Health literacy,

> Patient education and awareness,

> Non-English-Speaking or English as a second language.

Define standardized criteria for

> When the ASN [project coordinator/manager/patient navigator] should contact the ASN medical director.

> When the patient navigator should contact the ordering provider. Examples may include discrepancy in the follow-up date listed in structured EHR field (e.g. Epic health modifier) versus in chart review. Patient navigator may contact ordering provider for clarification.

Develop measurement strategy

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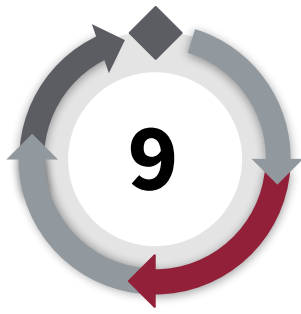
OBJECTIVE

> Select measures to assess whether the changes are resulting in improvement.

> Develop methods to collect and review measures.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Medical director, director of quality	Approve measure selection; develop schedule to review measures
Medical team: Primary care providers, gastroenterologists, nurses, medical assistants, and other clinical team members	Provide insight into what are clinically meaningful measures
Patient Advisors	Provide insight into what measures are meaningful to patients
Administrative: Referrals manager, scheduling department (GI, PCP)	Give access to sources of data for measures
Information Services: EHR systems analyst, data analyst, registry specialist	Identify data sources and feasibility of collecting the data required for the measures
Quality and Safety: Quality department (department and system level), population health	Approve measure selection; identify data sources through quality measures that are already collected

9. Develop measurement strategy (cont.)

Select measures based on the aim.

> Select a small set of useful measures that are meaningful and relatively easy to collect (e.g. already being collected).

> Select data that can be displayed using run charts to see the story in the data over time.

> Define each measure, include the target population (inclusion and exclusion criteria), and predict a timeframe for how long it will take to see a change in the measure.

> Classify the desired change and possible measures using the Donabedian model of quality measures (structure, process, outcome) as well as balancing measures.

> Review recommended measures, and select a small set to be collected and tracked (see below).

TIP: Balancing measures assess for unintended consequences (positive or negative) as a result of the changes.

Develop measurement strategy.

> Determine sources of data and set up a monitoring system.

> Decide how often measures will be collected.

> Identify leaders and other stakeholders who need access to data and updates on measures.

> Determine a process for the continued monitoring of data to assure that improvements are sustained and to take action on patterns indicating negative trends.

9. Develop measurement strategy (cont.)

| RECOMMENDED MEASURE	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT STRATEGY	INTERPRETATION
Structure Measures (Frequency = one time or as needed)			
S1 (Optional) Positive predictive value of the registry (ASN)	N: number of patients who had a delay in follow-up testing (were appropriate for the ASN after chart review)	Data collected at each facility from chart review (N) and ASN registry (D).	If positive predictive value is <80%, then consider doing manual chart review on a subset of patients and refine the registry. Consider doing this measure occasionally to check registry functionality.
	D: total number of patients who were identified through the electronic registry as potentially having a delay in follow-up testing		
S2 Fields built into the database/ registry	Data points: see inclusion and exclusion criteria per test	Data collected at each facility from ASN registry.	
Process Measures (Frequency = monthly)			
P1 Proportion of patients in ASN successfully contacted	N: patients in ASN successfully contacted	Data collected at each facility from ASN registry.	If O1 if not achieved, utilize this measure to determine where in the process breakdown is occurring.
	D: total number of patients in the ASN		
P2 Proportion of patients in the ASN with a colonoscopy scheduled	N: patients in ASN with a colonoscopy scheduled	Data collected at each facility from administrative record system (N) and ASN registry (D).	If O1 if not achieved, utilize this measure to determine where in the process breakdown is occurring.
	D: total number of patients in the ASN		
P3 Patient factors that may limit colonoscopy completion	Data points: Patient to call back, patient wants to reschedule, insurance change, patient unable to have colonoscopy, unable to reach patient, out of network, patient moved, patient deceased	Data is collected at each facility from clinical records systems.	Utilize this measure to improve patient access to care.

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9. Develop measurement strategy (cont.)

RECOMMENDED MEASURE	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT STRATEGY	INTERPRETATION
Outcome Measure (Frequency = monthly)			
O1 Proportion of eligible patients in ASN who receive appropriate follow up	N: Number of eligible patients who have completed follow-up care > At home: 6 months > Interval: 1-year: 6 months 3 years or more: 1 year D: total number of eligible patients in ASN	Data is collected at each facility from clinical records systems (numerator) and ASN registry (denominator).	Goal is to ensure patients receive the appropriate follow-up care within an acceptable timeframe. If there is a decrease in this measure, then consider improving process measures and patient navigation approaches.
Balancing Measures (Frequency = quarterly)			
B1 Delay in routine screening with influx of volume from ASN	Data point 1: Date patient is due for screening colonoscopy (among entire population) Data point 2: Date patient received screening colonoscopy (among entire population)	Data collected from each organizations GI/endoscopy center.	Goal is for no change in time for routine screening. If it is taking longer for patients to get screened, consider other factors besides ASN (e.g. COVID). If trend continues work with leadership and GI department.
B2 Delay in high-risk screening with influx of volume from ASN	Data point 1: Date high-risk patient is due for screening colonoscopy (among entire population) Data point 2: Date high-risk patient received screening colonoscopy (among entire population)	Data collected from each organizations GI/endoscopy center	Goal is for no change in time for high risk screening. If it is taking longer for patients to get screened, consider other factors besides ASN (e.g. COVID). If trend continues work with leadership and GI department.

9. Develop measurement strategy (cont.)

RECOMMENDED MEASURE	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT STRATEGY	INTERPRETATION
Balancing Measures (Frequency = quarterly) (cont.)			
B3 No-show rate for everyone vs. those from ASN	N: Number of patients in the ASN who are scheduled for a colonoscopy and do not show for the appointment. D: Total number of patients in the ASN who are scheduled for a colonoscopy	Data collected from each organizations GI/endoscopy center	ASN patients have the support of patient navigators and therefore should have the same no-show rate, or lower than, the general population, If no show rate is higher, consider ways to improve navigation process.
B4 Size of ASN	Data point 1: Total number of patients in ASN	Data collected from ASN registry.	Goal is that there is stability in the size of patients captured in the ASN over time. This measures is likely to see a lot of variability at the beginning of the project as new processes are put in place. For example, the new recommendation to begin initial colorectal cancer screening at age 45 may lead to a drastic increase in the size of the ASN. Over time, if there are large changes - increases or decreases - consider looking upstream for breakdowns in care.

9. Develop measurement strategy (cont.)

RECOMMENDED MEASURE	NUMERATOR (N)/ DENOMINATOR (D)	MEASUREMENT STRATEGY	INTERPRETATION
Assessing Long-term impact (Frequency = semi-annual)			
Number of patients in ASN diagnosed with adenoma or neoplasm	Total number of safety net patients with a diagnosis of adenoma or neoplasm.	Data is collected at each facility from clinical records systems and ASN registry.	This number is expected to be low and is not a reflection of the quality of the ASN. The outcome measure (O1) is of the utmost importance. This measure provides an additional descriptor on the ASN and provides an example of patients who benefit from the ASN.
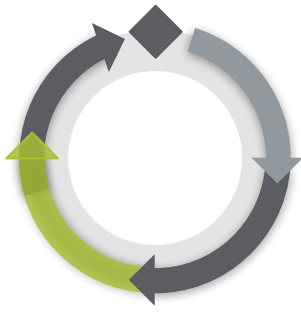
Implement the ASN

This section outlines the steps for the final preparation and implementation of the ASN designed in the previous phase. Implementation includes solidifying the ASN team with the addition of a patient navigator and informing and promoting the ASN through communication to leadership, providers, and patients. The final step is testing the ASN using PDSA cycles to continually refine the process.

The Patient Safety Adoption Framework in this section:

Leadership support through the approval of hiring the patient navigator (Step 10) and public commitment to the ASN (Step 11).

> **Prioritization** of resources to support the ASN with staffing (Step 10) and when addressing challenges encountered in Step 12.

Culture that supports continuous improvement is necessary for Step 12.

Meaningful measurement is part of the PDSA cycles that are used in Step 12.

Process

> **Co-creation** through partnering with patient and family advisors when developing communications to patients about the ASN and through collaborating with clinicians for feedback on the ASN (Step 11).

> **Engagement** of leadership, clinicians, and patients when communicating and seeking feedback about the ASN (Step 11).

Person-centered is central to the patient navigator role detailed in Step 10.

Hire and train patient navigator(s)

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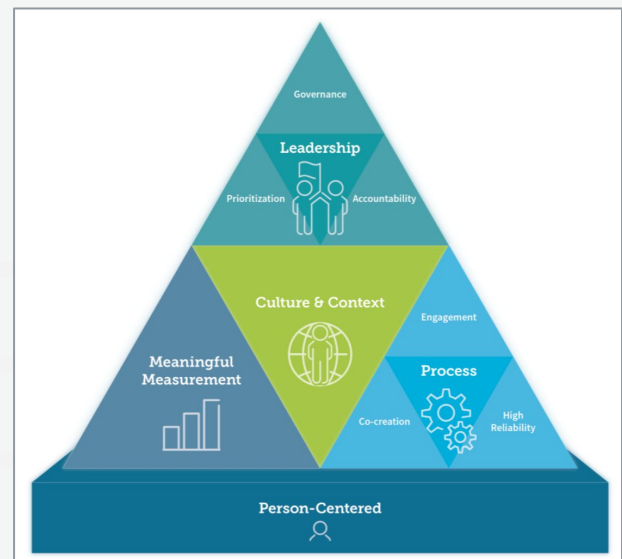
OBJECTIVE

> Recruit and hire a patient navigator, if needed.
> Onboard and train the person who will be in the patient navigator role.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Medical director, director of quality	Approve administrative and EHR access
Medical team: Primary care providers, gastroenterologists, nurses, medical assistants, and other clinical team members	Participate in clinical training and mentorship
Patient Advisors	Provide a resource for questions related to health literacy and methods of communication; bring awareness to existing cultural and environmental barriers for patients
Administrative: Referrals manager, scheduling department (GI, PCP), gastroenterology operations, primary care operations	Train patient navigator on electronic systems for scheduling and referrals; provide consistency on messaging to patients; approve administrative access to scheduling; verify methods to contact patients; consistency on methods of documentation and communication between teams
Information Services: EHR trainer	Train patient navigator on EHR systems

10. Hire and train patient navigator(s) (cont.)

Recruit and hire a patient navigator.

> Recruit and hire someone who will be in direct contact with patients. *This guide refers to this role as a patient navigator, but depending on available resources, patient contact may be the responsibility of the project manager.* This position can be filled by someone with a medical license or certification (RN, LPN, MA) or by someone with no official medical background, such as a community health worker.

TIP: Community health workers offer the benefit of having close connections within the community, of tailoring communication with the patients in a way that is culturally competent, and of saving costs.

> Qualifications for the ideal patient navigator include

> > Education and experience

> > > High school diploma or GED required, bachelor's degree in health sciences preferred

> > > Healthcare experience and understanding of medical terminology preferred

> > > Strong computer skills required; familiarity with healthcare information systems preferred

> > > Bilingual preferred (assess local patient population to determine languages that would be most helpful)

> > Personal characteristics and skills

> > > Strong communication skills with an ability to explain things in a way everyone can understand

> > > Ability to show maturity, empathy, and professionalism while effectively responding to sensitive issues

> > > Strong interpersonal skills

> > > Commitment to patient advocacy, patient safety, and care coordination with the ability to champion issues and identify the appropriate resources

> > > Cultural and structural competence

> > > Substantial knowledge of community resources

> > > Strong organization skills with excellent time management, the ability to multitask, and attention to detail

> > > Ability to be flexible and adapt when priorities change

> Define the scope of the position based on workflow redesign (Step 6, 7).

> > To reduce barriers for patients, consider giving the patient navigator capabilities to directly schedule colonoscopies and having a standing order from the medical director for a colonoscopy based on set criteria.

Review the ASN patient navigator core competencies (Appendix D) with the patient navigator to clarify their role.

TIP: Adapt these competencies as needed for your organization. These can also be used to guide training and annual employee reviews.

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10. Hire and train patient navigator(s) (cont.)

Onboard and train the patient navigator in the following areas.

> Local facility orientation

> EHR training, including conducting a chart review, ordering/referring and documenting communication in the medical record.

> Communicating with patients through the patient portal.

> Clinical context of care for the suggested intervention (i.e. why do these patients need colonoscopy?), procedure logistics/details (i.e. what should the patient expect in completing bowel prep or colonoscopy?)

> Communication networks and workflow specific to the facility

> Specifics related to the ASN (purpose, how it functions, roles)

> Communicating with patients and how to manage their concerns

> Local resources to help patients overcome barriers (e.g. transportation, insurance liaison)

> Health literacy

> Patient Family Centered Care

> Equity informed care and diversity and inclusion training

> Motivational interviewing (optional)

Establish a support structure for the patient navigator.

> Introduce them to patient and family advisors at your organization

> Assign a clinical mentor, like the ASN medical director, who can be a resource for clinical questions or concerns. Ensure that the patient navigator has a clear chain of command for escalating clinical issues.

> Introduce them to online patient navigator networks, such as the Patient Navigator Network, which brings together oncology patient navigators from the Dana-Farber/Harvard Cancer Center (DF/HCC) institutions.

> Connect them with key people they will be working with to coordinate care (e.g. social worker, scheduling, nursing staff).

Evaluate additional ways that the patient navigator can address health equity such as providing access to interpreter services, understanding common barriers to care, and contacting patients during non-traditional hours.

Communicate change

OBJECTIVE
> Engage clinicians, staff, and patients about the ASN.
> Generate interest in and enthusiasm for the ASN.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Medical director, director of quality	Provide a public endorsement of the ASN; support communication efforts
Medical team: Primary care providers, gastroenterologists, nurses	Actively engage with the ASN team and provide feedback
Patient Advisors	Advise on messaging and method of communicating with patients, especially patients who are difficult to reach
Administrative: Referrals manager, scheduling department (GI, PCP)	Actively engage with the ASN team and provide feedback
Ancillary Services: Lab manager, pathology, social work, community health partners	Actively engage with the ASN team and provide feedback
Quality and Safety: Population health	Advise on methods of patient outreach

11. Communicate change (cont.)

Share information about the ASN with leadership and with providers and staff who will be affected by the ASN. When communicating, include the following content.

> A general overview of the ASN and how they may be contacted by a member of the ASN team:

> **Example for providers:** *An Ambulatory Safety Net (ASN) is a system set up to catch abnormal results that have not had subsequent follow up and to coordinate the appropriate resulting care. The ASN is not meant to replace the current process of abnormal result follow up but acts as a "back-up" to ensure that all patients are notified of abnormal results and receive the necessary follow up. The ASN is run by a centralized team that tracks abnormal results and contacts patients to assist in arranging appropriate care. You and your patients may be contacted by someone from the ASN team to help determine whether or not follow up is needed based on chart review.*

> How the ASN benefits the organization and patients. If possible, share (de-identified) patient stories or safety events that illustrate the importance of the ASN.

> How the ASN benefits providers by reducing stress and administrative/clerical burden

> Changes to the workflow, including changes to EHR fields or current methods of follow up

> The start date, scope of the ASN (populations/tests included), and an estimated number of patients that can benefit from the ASN.

> Answers to common questions and where to find more information.

> A point of contact (the ASN project manager) and the best way to reach them for any questions, concerns, or feedback.

TIP: Specifically ask providers to share their feedback and then revise the ASN as needed.

Communicate using multiple methods including existing departmental meetings, intranet home page, organization newsletter, and email.

Engage with senior leadership to discuss ways they can support communications with providers and staff. Public commitment at leadership meetings and through organization-wide email sends a powerful message about the importance of the ASN.

TIP: Sending emails should not be the only method because emails are often discarded without being read thoroughly. When sending email, keep the message short, include a link for additional information, and write a concise subject line.

11. Communicate change (cont.)

Partner with primary care and/or gastroenterology on patient education efforts about the importance of colonoscopy for positive at-home testing or for those at increased risk based on their last colonoscopy.

TIP: Examples of educational materials for patients can be found at The American College of Gastroenterology and UCLA Health.

> Instead of striving to inform all patients about the existence of an ASN, emphasis should be placed on the importance of follow up when they are with the provider. This education can be reinforced by the patient navigator when they contact patients. Providing written information can be helpful when the patient needs to contemplate receiving the follow-up colonoscopy. The patient navigator can send the link for materials from the organization to the patient and then re-contact them to further discuss the educational material.

Test and implement changes

12

OBJECTIVE

> Understand the role of Plan-Do-Study-Act (PDSA) cycles in testing and implementation.

> Apply PDSA cycles to turn ideas into action and to connect action to learning.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Medical director, director of quality, senior leadership	Provide support during testing and implementation
Medical team: Primary care providers, gastroenterologists, nurses, medical assistants, and other clinical team members	Participate in the changes being tested; provide feedback
Patient Advisors	Participate in the changes in patient communication being tested; provide feedback
Quality and Safety: Quality department (department and system level), population health	Provide support for testing, implementation, and data collection
Information Services: EHR systems analyst, data analyst, registry specialist	Participate in the changes being tested; refine the registry; provide feedback
Administrative: Referrals manager, scheduling department (GI, PCP)	Participate in the changes being tested; provide feedback

ACTION STEPS

Use PDSA cycles to test and learn about the process and systems changes before implementing them.

> Start testing on a small scale (e.g. one practice, internal colonoscopy results only, FIT testing only) and use that learning to gradually scale up the conditions and the scope of the test. Progress to implementation when you have a high degree of belief in the changes, the cost of failure is low (not just money but safety, momentum, etc.), and everyone is ready to make the change. By starting small and testing quickly, an idea can be rapidly tested and then expanded upon.

> Plan multiple tests that can occur simultaneously in rapid fashion to accelerate learning.

TIP: A prediction is a critical part of the PDSA cycle. Comparing the prediction to what actually happens contributes to learning about the system.

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12. Test and implement changes (cont.)

ACTION STEPS

Select and prioritize changes to test for the ASN. Consider the following major areas that would benefit from testing.

> Refinement of registry

> Changes to workflow

> Contacting patients

> Scheduling patients

> Methods to track patients

TIP: Keep track of successful strategies for contacting patients (eg. time of calls, phone vs. text vs. email). Tracking these strategies may improve the patient navigator's ability to contact patients.

TIP: Test changes that occur at the beginning of a sequence first and involve staff who are most affected in prioritizing the change ideas.

Continue testing cycles for any changes that are made. Consider testing things such as new job descriptions, training programs, and methods of communication throughout the system.

Monitor select data as you are testing and implementing to know if what you are testing is or isn't resulting in improvement. Use statistical process control charts (run charts) to see if the changes are resulting in improvement in real time. Be sure to annotate the charts with the changes you are testing and implementing.

TIP: The data at the PDSA level is different from the overarching metrics. For example, if you are testing having the patient navigator schedule ASN patients for follow-up care compared to the specialists office, the PDSA measure is if the navigator had the ability to schedule. The overarching metric would be the percent of patients getting to their follow-up appointment.

Plan communication with all staff and pertinent stakeholders to inform them of progress toward aims, to celebrate successes, and to increase buy-in and interest in the work.
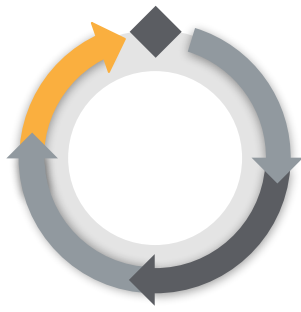
Sustain and Spread

CORE COMPONENTS
14. Plan for sustainment.
15. Expand ASNs.

Once changes have been tested and implemented into the everyday work flow, organizations must plan to sustain the improvement and to expand to other parts of the system. The purpose of this section is to guide organizations through planning to maintain the gains made from implementing their ASNs and thinking through spreading ASNs to other specialty areas, units, or hospitals within their systems or expanding to other areas of focus or tests.

The Patient Safety Adoption Framework in this section:

Leadership

Accountability of the long term management of the ASN is addressed in Step 13.

Prioritization of sustaining the ASN through continued support and resources in (Step 13).

Culture of safety and the promotion of a just culture through accountability is required for sustaining the ASN in Step 13.

Meaningful measurement through developing the long term measurement plan in Step 13.

Process

High reliability is reinforced through the standardization of processes in Step 13.

Engagement of stakeholders and leaders when determining the plan for expansion in Step 14.

Person-centered through the continued focus on patient communication in Step 13.

Plan for sustainment

13
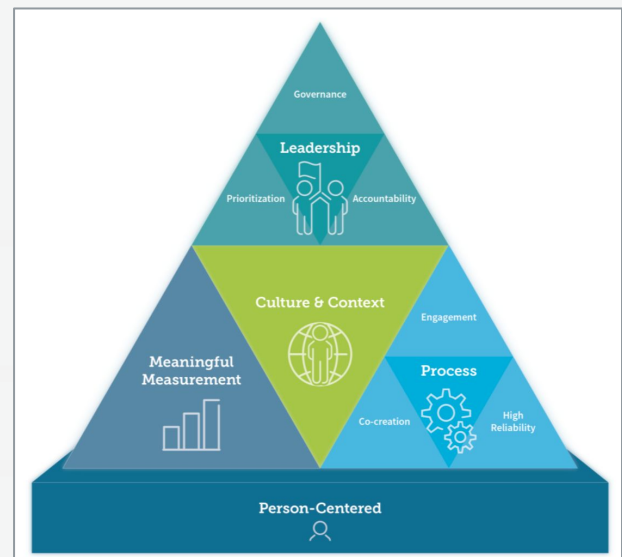
OBJECTIVE

> Develop a plan for long term sustainment of the ASN.
> Optimize the resources that have been invested during the testing and implementation phase.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Medical director, senior leadership, director of quality	Provide the resources necessary to sustain the ASN; receive periodic updates on key metrics
Medical team: Primary care providers, gastroenterologists, nurses, medical assistants, and other clinical team members	Raise issues that occur to the ASN team; provide ongoing feedback; review changes in guidelines
Patient Advisors	Receive periodic updates; advise on ways to continuously improve patient experience
Information Services: EHR systems analyst, data analyst, registry specialist	Update registry periodically; maintain communication with ASN team for changes to EHR

13. Plan for sustainment (cont.)

ACTION STEPS	
Develop a long-term plan for measurement. Determine what you will continue to measure, what you will stop measuring, and how you will address any negative signals in the data.	**TIP:** Appendix E contains a sustainability worksheet designed to help you plan.
Assign ownership of the new system. Consider who will be accountable to maintaining different aspects of the ASN, including > Changes to screening guidelines > Changes to documentation or lab result reporting > Maintenance of the registry and EHR updates > Responding to changes in workflow that affect the ASN > Updating methods of communication to patients	**TIP:** Guidelines for the registry should be reviewed and updated at least once a year. **TIP:** Updating the fields of the registry should occur on an annual basis to improve the quality and efficiency of the ASN.

Update job descriptions for accountability.

> Ensure new employees' job descriptions include information about and necessary training for the ASN.

> Update current employees' job descriptions to include their ASN responsibilities.

Embed the changes into current practice. Review workflow changes, and improve processes that have not become standardized, embedded elements in the system to prevent a return to the old way of working. For example, ensure that communication to patients about the ASN (see Step 11) is part of standard care.

Expand ASNs

14

OBJECTIVE

> Determine readiness for expanding ASNs.
> Develop plan for spreading ASNs beyond the initial location and/or areas of focus.

STAKEHOLDERS TO ENGAGE	PURPOSE
Leadership: Medical director, senior leadership, director of quality	Provide oversight and support; connect the work to strategic initiatives; allocate resources
Medical team: Primary care providers, gastroenterologists, nurses, medical assistants, and other clinical team members	Advise on plan for spread and future opportunities for the ASN
Quality and Safety: Quality department (department and system level), population health	Provide support on the strategy to spread; align with other quality improvement initiatives

14. Expand ASNs (cont.)

ACTION STEPS

Assess the stability of the existing ASN(s). Expansion should only be considered once existing ASNs are stable, reliable, and have a sustainability plan in place.

Assign an executive sponsor and project manager.

> The executive sponsor role should include playing an active part in developing the expansion plan, offering assistance in overcoming barriers, helping others understand the importance of the initiative, and keeping the executive team aware of progress.

> The project manager should oversee the development, execution, and revision of the expansion; connect adopters to others who can assist them; share important issues with appropriate leaders; manage the expanding knowledge base; report on progress; and organize and lead the team.

Source: Langley J, Nolan K, Nolan T, Norman, C, Provost L. The Improvement Guide. San Francisco: Jossey-Bass 1996.

Consider the ASN team's availability. Led by the core team members of the medical director and project manager, the expansion team is an important structure to guide and support the work. Ensure both team members have the time available to commit to developing and implementing a new ASN while also maintaining all current ASNs.

Assess organizational readiness for the expansion of ASNs.

> Consider other major organizational priorities and/or contextual factors when determining when to spread.

> Review the business case (Appendix A) and the required financial support for expansion.

> Consider the necessary resources required, including the need for more staff allocations as the size of the ASN increases. Revisit these questions when you repeat the ASN implementation cycle.

TIP: Refer to Spread Planner to assess readiness for spread.

Begin the ASN cycle again, starting with Step 1, "find the opportunity - select a test."

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Appendix A: ASN Business case

Estimated staffing cost of the program: *Salary estimates from NIH and Glassdoor.com*

Role on Project (*Examples*)	Annual Base Salary ($)	Annual Effort	Salary Support	Fringe Rate (%)	Total Personnel Costs Requested
Medical Director	$199,300	20%	$39,860	31%	**$52,216**
Project Manager/ Coordinator	$67,000	100%	$67,000	35%	**$90,450**
Patient Navigator	$44,500	100%	$44,500	35%	**$60,075**
IT specialist*	$80,000	5%	$4,000	35%	**$5,400**
During maintenance phase			**A. Subtotal Personnel Cost**		**$208,141**

Cost per patient touched by ASN (assuming 500 patients/year): $416

In our research on ASN's, we observed a range of resources and costs.. For the purpose of ease and summary, we are including the average costs based on the average staffing and salaries observed in the literature for a ASN managing 500 patients per year

Estimated added revenue:

> Fee-for-service programs documented positive contribution margin of patient navigation for CRC screening due to recovery of colonoscopy procedures. The net revenue associated with increased colonoscopy volume exceeded the program cost per additional colonoscopy, and this yielded a net financial benefit.[1,2,3] Colonoscopy reimbursement from Medicare is $582 for ambulatory surgical centers and $992 for hospital outpatient departments.[4] There may be additional added revenue for pathology and surgical procedures.

> Global capitation programs documented costs savings due to earlier detection of cancer and lower the total medical expenditure from late stage diagnosis or from cancer prevention from early removal of adenomas.[5,6]

Cost-effectiveness (of patient navigators for CRC):

Incremental Cost Effectiveness Ratio (ICER) per Quality Adjusted Life Year (QALY) for patient navigation for CRC (ICER comparing patient navigator to no patient navigator): **Average $3400 per QALY gained.**[1,3,5,7,8,9]
The threshold to be cost effective at societal and payer level is less than $100,000.[10]

Other benefits:

> Prevention of costly malpractice claims for missed and delayed cancer diagnosis
> Improved patient experience and enhanced trust in the healthcare system
> Improved provider satisfaction and well-being which can improve employee retention
> Increase productivity and efficiency during the workflow redesign
> Prevention of damage to reputation of the health organization from missed results
> Prevention of "second victim phenomenon" in clinicians who are involved in medical errors and unexpected patient harm.[11]

Appendix A: ASN Business case

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Appendix B: Implementation Readiness Checklist

These questions can also be found in The Patient Safety Implementation Adoption Framework & Guidance

LEADERSHIP

Leader	Leader with a frontline role	Frontline	Implementation		Agree	Disagree	Don't Know
				GOVERNANCE			
■		▲		There is a clear goal for [intervention name]			
	◆	▲		I know who to go to on my clinical team when I need something for patient care.			
				ACCOUNTABILITY			
■				Staff will have the supplies, medicines and equipment they need to be able to do [intervention name]			
■				In general, leaders are held accountable for the success of practice changes.			
■				In general, staff are held accountable (formally or informally) for doing practice changes.			
			◉	The implementation team for [intervention name] has a leader who moves the work forward.			
			◉	The implementation team meets at frequent intervals to discuss progress towards goals.			
	◆	▲		I am clear about my role on my clinical team.			
				PRIORITIZATION			
■		▲		The problem being addressed by [intervention name] is one of our top priorities.			
■				[Intervention name] aligns with other goals we are working toward in our organization.			
■				We do not have other changes underway or planned that will compete with [intervention name] for resources, time or personnel.			
■				Staffing issues (turnover, too few staff) will not impact implementation of [intervention name].			
■				I will prioritize my time for [intervention name].			
■				Staff will have dedicated time to work on implementing [intervention name].			
■				Staff will have dedicated time to participate in training for [intervention name].			
■				A staff member will have dedicated time to support the implementation team with administrative tasks for [intervention name].			
			◉	I have enough time to work on implementing [intervention name].			
		▲		I typically receive the help I need when our [unit] implements a change.			

CULTURE AND CONTEXT

Leader	Leader with a frontline role	Frontline	Implementation		Agree	Disagree	Don't Know
				CULTURE			
■		▲		In the past, I have seen *doctors* in our *[unit]* take the lead on promoting changes to improve patient care.			
■		▲		In the past, I have seen *nurses* in our *[unit]* take the lead on promoting changes to improve patient care.			
■		▲		In our *[unit]*, staff in the *same* role work well together.			
■		▲		In our *[unit]*, staff in *different* roles work well together.			
■				Our leaders stick with practice changes through the ups and downs of implementation.			
■		▲		I am comfortable asking for help at work.			
■		▲		I am comfortable speaking up when I have a concern at work.			
	◆	▲		In our *[unit]*, my clinical team works well together.			
	◆	▲		Members of my clinical team share key information as it becomes available.			
	◆	▲		Members of my clinical team listen to each other.			
				CONTEXT			
■				Staff have the skills and knowledge needed to do *[intervention name]*.			

PROCESS

Leader	Leader with a frontline role	Frontline	Implementation		Agree	Disagree	Don't Know
				CO-CREATION			
		▲		Leaders in our *[unit]* ask me for my input.			
				HIGH RELIABILITY			
■				Staffing issues (turnover, too few staff) will not impact implementation of *[intervention name]*.			
■				When we introduce changes they become part of the usual way we do our work.			
■				I make sure that staff receive the help they need when our [unit] implements a change.			
			◉	The implementation team has a plan for how to implement *[intervention name]*.			
			◉	The staffing on our implementation team has not changed.			
				ENGAGEMENT			
■				I know why we are introducing *[intervention name]*.			
■				*[Intervention name]* is the right solution to address the problem.			
■		▲		Senior leadership is committed to *[intervention name]*.			
■		▲		Our [unit] leadership is committed to *[intervention name]*.			
■				I am committed to *[intervention name]*.			
■		▲		I can identify *doctors* in our *[unit]* who will take the lead on promoting *[intervention name]*.			
■		▲		I can identify *nurses* in our *[unit]* who will take the lead on promoting *[intervention name]*.			

MEANINGFUL MEASUREMENT

Leader	Leader with a frontline role	Frontline	Implementation		Agree	Disagree	Don't Know
■		▲		I am able to view our *[unit]*'s patient outcome data (for example, total number of falls or infections, vaccination rates, patient feedback).			
■		▲		We use our *[unit]*'s patient outcome data (for example, total number of falls or infections, vaccination rates, patient feedback) to change how we provide patient care.			
■		▲		In general, our *[unit]* collects data about patient outcomes (for example, total number of falls or infections, vaccination rates, patient feedback).			

PERSON-CENTERED CARE

Leader	Leader with a frontline role	Frontline	Implementation		Agree	Disagree	Don't Know
■		▲		I would feel safe receiving care in my *[unit]* as a patient.			
■		▲		Our *[unit]* has the bandwidth to take on a patient improvement project at this time.			
■		▲		There are systems or processes in place to ensure that patients are empowered in their care and engaged in the planning of their health systems.			
■				We collect patient-reported outcome measures, including perceptions of care.			
■		▲		There are defined standards for person-centered care that are built into quality assurance programs and are monitored and acted upon.			
■		▲		Leaders and staff receive training in person-centered care.			
■				Health literacy and cultural competency are considered in all initiatives, and educational support is provided for patients to make informed decisions about their care.			

Appendix C: ASN staffing

Staffing allocations for ASNs that have been developed and implemented:
These allocations were averaged to give the range of recommended staffing allocations in this guide.

Atrius Health

> 2.3 million ambulatory visits/year
> 4 active ASNs
> 0.1 FTE Medical Director
> 1.0 FTE Project manager/ Patient navigator

Brigham & Women's Hospital

> 2.5 million ambulatory visits/year
> 4 active ASNs
> 0.35 Medical director
> 1.0 FTE Project manager
> 1.0 FTE Project coordinator
> 0.5 FTE Patient Navigator

Kaiser Permanente Southern California (Integrated health system)

> 12 million ambulatory visits/year
> 27 active ASNs
> 1.0 FTE Medical director
> 5.0 FTE RNs/LPNs with advanced analytic experience (1:2.4 million ambulatory visits/year)

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Appendix D: ASN Patient Navigator Core Competencies

Adapted from: [Core Competencies for Oncology Nurse Navigators](#) and [Oncology Nurse Core Competencies](#)

ACTION STEPS

1. Patient care

1.1 Identifies potential and realized barriers to care (e.g., transportation, child care, elder care, housing, language, culture, literacy, role disparity, psychosocial, employment, financial, insurance) and facilitates referrals as appropriate to mitigate barriers.

1.2 Facilitates individualized care within the context of functional status, cultural consideration, health literacy, and psychosocial, and spiritual needs for patients, families, and caregivers.

1.3 Empowers patients and families to self-advocate and communicate their needs.

1.4 Assesses educational needs of patients, families, and caregivers by taking into consideration barriers to care (e.g., literacy, language, cultural influences, comorbidities).

1.5 Provides anticipatory guidance and manages expectations in cancer screening and its potential outcomes.

2. Knowledge for practice

2.1 Demonstrate basic knowledge of healthcare systems, medical terminology and evidence behind cancer screening.

2.2 Demonstrate familiarity with the process of scheduling and the process of receiving cancer screening (e.g. bowel prep instructions, post-colonoscopy instructions).

3. Interpersonal and communication skills

3.1 Acts as a liaison between the patients, families, and caregivers and the providers to optimize outcomes.

3.2 Advocates for patients to promote patient-centered care that includes shared decision making.

3.3 Ensures that communication is culturally sensitive and appropriate for identified level of health literacy.

4. Professionalism

4.1 Ensures timely documentation of conversations with patients and patient outreach.

4.2 Adheres to established regulations concerning patient information and privacy.

4.3 Participates in the tracking and monitoring of metrics and outcomes, in collaboration with administration, to document and evaluate outcomes of the ASN program.

4.4 Establishes and maintains professional role boundaries with patients, caregivers, and the multidisciplinary care team in collaboration with manager, as defined by job description.

5. Interprofessional collaboration

5.1 Develops knowledge of available local and community resources and establishes relationships with the providers of these services.

5.2 Facilitates communication among members of the multidisciplinary care team and patient to prevent fragmented or delayed care that could adversely affect patient outcomes.

Appendix E: Sustainability Worksheet

*Adapted from the IHI sustainability worksheet www.ihi.org/resources/Pages/Tools/Sustainability-Planning-Worksheet.aspx

MEASUREMENT

What will we measure? What will we stop measuring?

How will we address downtrending or negative measurements?

ACCOUNTABILITY

Who will own the new work? Are they familiar with the initiative?

COMMUNICATION AND SUPPORT

How will we communicate any changes?

How can we support individuals? How can we collect feedback and answer questions?

How can we train individuals?

HIGH-RELIABILITY

How will we make it hard to do the wrong thing and easy to do the right thing?

How will we standardize the process?

Is there a way to embed the initiative in the current workflow?