



Preventive Ethics

Addressing Ethics Quality Gaps on a Systems Level

Second Edition



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on a Systems Level

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IntegratedEthics

Improving Ethics Quality in Health Care

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This document and other IntegratedEthics[®] materials are available online through the website of the National Center for Ethics in Health Care.

VA employees should access the site via the intranet at <http://vaww.ethics.va.gov/IntegratedEthics>.

Others should access the site via the Internet at <http://www.ethics.va.gov/IntegratedEthics>.

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Executive Summary

Preventive Ethics: Addressing Ethics Quality Gaps on a Systems Level describes preventive ethics (PE), one of the three core functions of IntegratedEthics® (IE), a comprehensive and systematic approach to ethics in health care developed by the National Center for Ethics in Health Care (NCEHC) at the Department of Veterans Affairs. It was designed as a primer, initially to be read in its entirety by everyone engaged in PE, including leaders responsible for overseeing the PE function. This revised edition includes substantial new material and refinements that have been incorporated into the PE function since the original edition was released in 2007.

Part I: Introduction to Preventive Ethics in Health Care

Part I provides an overview of PE, explains why it is necessary to have a PE team, and reviews the critical factors necessary for a successful PE function.

What is preventive ethics?

For the purposes of this document, *preventive ethics* is defined as “activities performed by an individual or group on behalf of a health care organization to identify, prioritize, and address systemic ethics quality gaps.” An *ethics issue* is an ethics quality gap that results from poorly performing, unreliable, or ill-defined systems and processes that can arise anywhere in a health care organization. The overall goal of PE is to *measurably improve ethics quality by identifying, prioritizing, and addressing ethics quality gaps on a systems level*.

Model for preventive ethics

As designated by facility leadership, PE activities are carried out by a PE team led by a preventive ethics coordinator. The coordinator disseminates information about the PE function to leadership and staff, manages a log of ethics issues, and collaborates with the IntegratedEthics council (or other ethics leadership body) and other stakeholders to determine which ethics issues are appropriate for a quality improvement (QI) approach and should be addressed.

In addition to the coordinator, the PE team typically includes one or more core members who participate in an ongoing way and one or more ad hoc members who have subject matter expertise relevant to the particular ethics issue being addressed. The coordinator ensures that the team carefully defines the ethics quality gaps using the ISSUES approach (see below) and incorporates other QI tools or methods such as Plan, Do, Study, Act (PDSA) or Lean Six Sigma as appropriate. In addition, the coordinator is responsible for developing member proficiencies.

Optimally, the PE team is a subgroup of the IE council. Alternatively, PE activities might be performed by a subgroup of the facility’s quality management (QM) program, or by a separate organizational ethics committee. Wherever PE is located administratively, the IE program officer works with the PE coordinator to ensure ongoing integration of PE within the IE program. At health care organizations, needs also arise for maintaining and revising

ethics policies and addressing ethics-related external review standards. Such maintenance activities fall under the purview of the IE program and may be addressed in a variety of ways, including by the PE function. However, ethics QI is where PE teams should spend most of their time.

Proficiencies required for preventive ethics

To be able to address ethics quality gaps at a systems level through a QI approach, every PE team should include or have access to individuals who have proficiencies in several areas such as QI, ethics expertise and knowledge, or relevant organizational environment(s).

Critical success factors for preventive ethics

To provide an effective mechanism for advancing the goals of PE, the PE function must have the following:

- Integration
- Leadership support
- Expertise
- Staff time
- Resources
- Access
- Accountability
- Organizational learning
- Evaluation

Because all these factors are critical for the success of PE teams, each should be addressed in *policy*.

Part II: ISSUES — A Step-by-Step Approach to Preventive Ethics

Part II describes in detail a practical, systematic process for addressing ethics issues on a systems level through a QI approach.

The ISSUES approach

The ISSUES approach provides step-by-step guidance to help PE teams improve the systems and processes that influence ethics practices in a facility. Based on established principles and methods of QI, the ISSUES steps are designed to standardize the process of PE throughout a health care system. By using the ISSUES approach, PE teams can focus improvement efforts on closing ethics quality gaps to achieve ethics quality in health care.

Tools for preventive ethics

In addition to this primer, a wide range of tools (e.g., print, video, and electronic media) are available to teach core PE concepts, support management of the function, and conduct specific aspects of the QI cycles. In addition, the *Preventive Ethics: Beyond the Basics* workshop provides advanced training in select aspects of the ISSUES approach. This training, along with other practical tools, are available on the NCEHC website, <http://vaww.ethics.va.gov/integratedethics/pec.asp> or <http://www.ethics.va.gov/integratedethics/pec.asp>.

The ISSUES Approach

Identify an issue

- Be proactive in identifying ethics issues
- Assess whether the issue suggests an ethics quality gap
- Clarify each issue by listing the improvement goal
- Prioritize the issues and select one

Study the issue

- Diagram the process behind the relevant practice
- Describe best ethics practice using ethical standards
- Describe current ethics practice using quantifiable information
- Refine the improvement goal to reflect the ethics quality gap

Select a strategy

- Identify the major cause(s) of the ethics quality gap
- Identify change strategies to address the cause(s) of the ethics quality gap
- Select one or more strategies for small-scale testing

Undertake a plan

- Plan how to carry out the small-scale test of the strategy to narrow the gap
- Plan how to evaluate if the strategy narrowed the gap
- Execute the small-scale test

Evaluate and adjust

- Check the execution and the results of the small-scale test
- Adjust as necessary
- Evaluate your ISSUES process

Sustain and spread

- Sustain the improvement
- Continue monitoring
- Spread the improvement
- Disseminate the improvement

Part I:

Introduction to Preventive Ethics in Health Care

What Is Preventive Ethics in Health Care?

In the IntegratedEthics® (IE) model, **preventive ethics** (PE) describes activities performed by an individual or group on behalf of a health care organization to identify, prioritize, and address systemic ethics quality gaps.

What is an ethics issue?

An ethics issue is an ethics quality gap that results from poorly performing, unreliable, or ill-defined systems and processes that can arise anywhere in a health care organization. PE targets these poorly performing systems and processes to ensure that practices in a health care organization are consistent with ethical standards. For example:

Patients should be offered the opportunity to complete an advance directive. If many are not, that constitutes an ethics issue. PE would address this gap by focusing on the systems and processes that are intended to ensure that patients are offered the opportunity to complete an advance directive. Once these systems and processes have been improved, patients will more reliably be offered the opportunity to complete an advance directive, consistent with prevailing ethical standards.

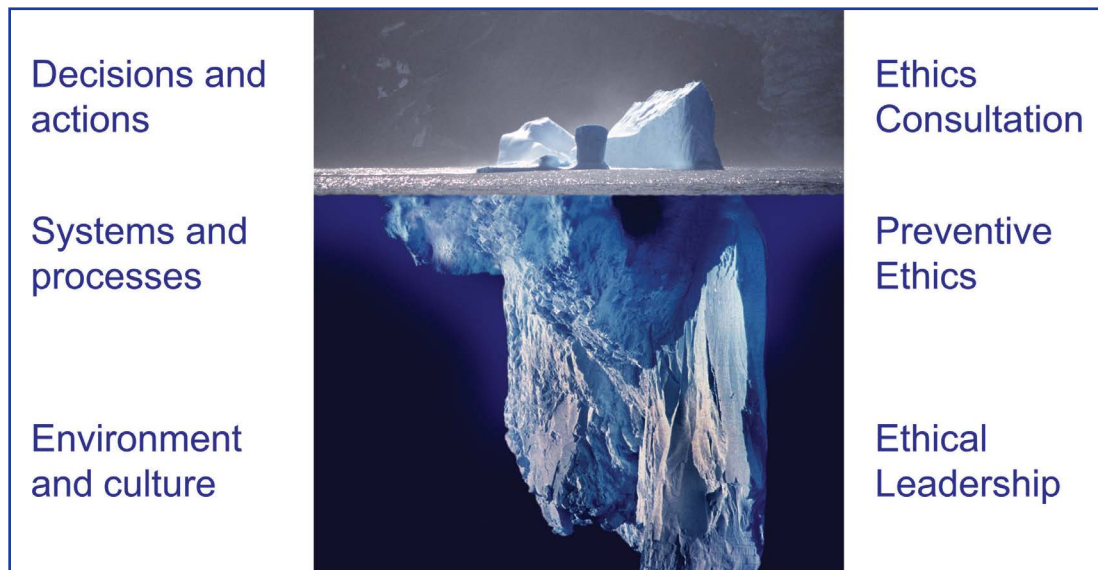
Conceptually, PE targets one core aspect of *ethics quality*. Ethics quality means that practices throughout an organization are consistent with widely accepted standards, norms, or expectations for a health care organization and its staff — as set out in statutes and policies, organizational mission and values statements, codes of ethics, professional guidelines, consensus statements, and position papers. The image of an iceberg helps to illustrate the concept of these three levels of ethics quality in health care (see Figure 1). PE addresses ethics quality at the middle layer, that of systems and processes. (For more information about the IE model for ethics quality, see Fox et al.¹)

Looking at this level of systems and processes, an ethics quality gap is the difference between what *is* (current ethics practices) versus what *ought to be* (best ethics practices). *Best ethics practices* refers to ideal practices established on the basis of widely accepted standards, norms, or expectations for the organization and its staff. When *current ethics practices* deviate from *best ethics practices*, a measurable *ethics quality gap* results. Ethics issues tend to be complex and typically require study to accurately describe the current workflow process, ethics quality gap, and underlying causes of the gap. Identifying, prioritizing, quantifying, and addressing these ethics quality gaps at the level of systems and processes is the role of PE (see Figure 2).

Notably, PE isn't restricted to ethics issues in clinical care; it's relevant to a whole host of

issues that can arise anywhere in a health care organization. For instance, it might be used to address ethics quality gaps in human resources practices, fiscal management, or protection of research subjects.

Figure 1. The Three Levels of Ethics Quality in Health Care



The goal of preventive ethics

The overall goal of PE is to *measurably improve ethics quality by identifying, prioritizing, and addressing ethics quality gaps on a systems level*. Thus, the central focus of PE is to reduce unjustifiable variation in ethical practices, thereby improving overall *ethics quality* within an institution.

To accomplish this, PE applies the principles and practices of quality improvement (QI) to address ethics quality gaps at the level of an organization's systems and processes. QI principles are incorporated into the ISSUES approach, which provides a framework for clearly defining and operationalizing the ethics quality gap that will be the focus for improvement. PE, like other systematic QI approaches, reduces variation by identifying and intervening on aspects of an organization's systems and processes that contribute to and sustain ethics quality gaps. The ISSUES approach incorporates principles and tools used in a range of QI methods as illustrated in Figure 3. Notably, all methods address a gap in practice, and apply the same or similar QI tools to identify causes and test strategies for identifying the best interventions for implementation on a broader scale.

Interventions undertaken as part of PE QI may include:

- redesigning work processes to better support ethical practices;
- implementing checklists, reminders, and decision support;
- developing specific protocols to promote ethical practices;
- and redesigning incentive or reward systems to motivate practice in accordance with ethics standards.

Figure 2. Ethics Quality Gap

Ethics Quality Gap =

The difference between:

What is

(right now, i.e., current ethics practice)

Versus

What ought to be

(ideally speaking, i.e., best ethics practices)

A brief history of preventive ethics

The term “preventive ethics,” first introduced in the bioethics literature in 1993,² was used to describe “explicit, critical reflection on the institutional factors that influence patient care.” Historically, efforts to improve all ethics practices in health care have focused on the three traditional functions of an ethics committee: education, policy development, and consultation on individual patient cases. In recent years, however, there has been growing recognition of how organizational factors (such as employee socialization, environmental pressures, and care system relationships) influence ethics practices and the importance of systems thinking.³ PE thus captures this growing awareness of the organizational dimension of ethics in health care.

Efforts to apply systems thinking specifically to ethics in health care have become commonplace. Health care facilities are reporting on their experience with implementing a “performance-improvement organizational ethics role.”⁴ Today, many agree that “the most exciting prospects for ethics committees and consultants involve integrating them into the QI culture of health care organizations.”⁵

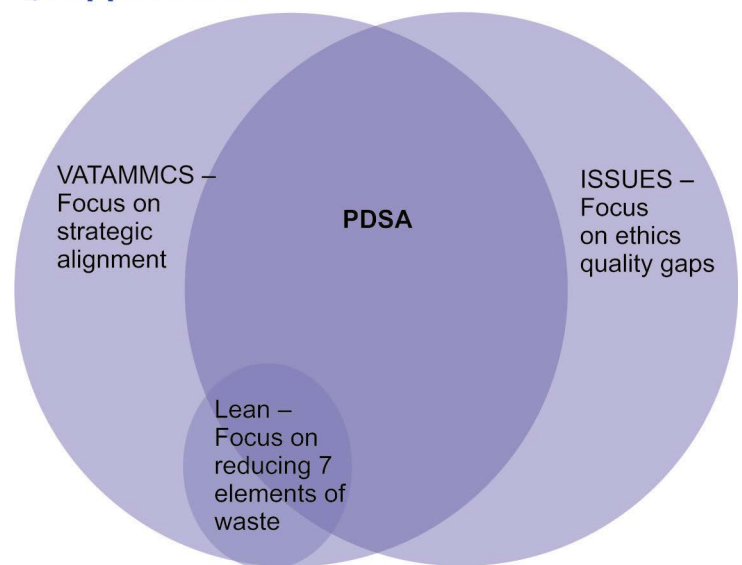
Preventive ethics in the Integrated Ethics model

As the largest health care system in the country, Department of Veterans Affairs (VA) has been uniquely situated to translate its real-life experience into “how to” guidance on PE. IE establishes a conceptual framework for PE, and tangible structures and methods to operationalize the concept. Fundamental to IE and PE activities is the concept that ethics is integral to health care quality. A health care provider who fails to meet established ethical standards is not delivering high quality care — even if the standards that relate to other dimensions of health care quality, such as technical or service quality, are met. At the same time, a failure to meet minimum quality standards raises ethical concerns. Thus, health care ethics and health care quality cannot be separated.

Three key assumptions informed the development of PE within the IE model. The first assumption is that *preventive ethics is necessary because ethics consultation is reactive and not well suited to address systems-level obstacles to ethical practices*. While ethics consultants engage in ethical analysis to answer a specific ethics question, PE is oriented to understanding why the *best ethics practice* (i.e., the ethical practice standard) is not consistently occurring and applying systems-level solutions to proactively improve practice. For example:

An ethics consultation service documented repeated consults related to values conflicts between clinicians and surrogates regarding medical treatment decisions for patients who lack decision-making capacity. Using a QI approach, the PE team determined that the causes of these recurrent consults included process issues with (a) making timely identification of surrogate decision makers, (b) ensuring that surrogate

Figure 3. PDSA Is an Integral Part of QI Approaches



decision makers understood their role with respect to making treatment decisions, or (c) priming clinicians to engage surrogates early and often in care planning. By addressing these three processes and standardizing each as part of routine operations, consultation requests for this type of conflict decreased dramatically.

The second assumption is that *ethical practices within organizations are powerfully influenced by the organization's systems and processes*. Consequently, PE aims to improve these systems and processes so that strong ethical practices become reflexive or inevitable. The third assumption is that *ethical practices in health care can be operationalized, measured, and continually improved*.⁶

Since 2008, VA PE teams have completed over 1,800 improvement cycles to close ethics quality gaps through implementation of improved processes around topics such as protecting the confidential and private information of patients, increasing transparency of hiring decisions to ensure fairness in hiring, ensuring adherence to informed consent requirements for HIV screening tests, ensuring that patients who leave against medical advice have equitable access to the outpatient continuum of care, and expanding inclusion of health care staff in budget allocation discussions and decisions.

Other organizations outside VA are taking on aspects of the model, including Kaiser Permanente. In recent years, Kaiser's clinical ethicists have been involved in multiple ethics quality projects that have focused on improving advance care planning throughout the continuum of care, creating an approach to managing requests for non-beneficial treatment, improving informed consent for vulnerable populations, addressing moral distress among staff, improving debriefing after codes, and improving processes for ensuring quality care in complicated patient situations in the acute care setting.⁷

How Is Preventive Ethics Performed?

The need for dedicated structures and processes

Ideally, all clinical and non-clinical staff in a health care organization should be involved in identifying, prioritizing, and quantifying ethics quality gaps on a systems level. As a practical matter, however, the PE function needs to be associated with specific organizational structures and processes.* In other words, it should have a clearly delineated *home* within the organization's formal structure to avoid reproducing common problems with traditional ethics programs that have frequently operated in silos, without the benefit of oversight, accountability, leadership support, and/or access to needed resources.¹ Optimally, PE is a subfunction of the IE council (the ethics leadership body). In VA, each medical center is required by national policy⁸ to have a PE team that is led and managed by a PE coordinator.

* Throughout this primer there are references to models and structures (i.e., IntegratedEthics, preventive ethics, the ISSUES approach, the IE council) that have been developed to meet specific VA needs and requirements. Non-VA facilities adopting all or part of the preventive ethics approach or IE model may need to modify these programs or establish other reporting structures than those described here to fit their specific organizational contexts.

To be effective, every PE team should have:

- someone to coordinate the function (i.e., a PE coordinator);
- core team members;
- and a specific, systematic quality improvement approach that addresses identified ethics quality gaps.

The IE council is responsible for establishing and monitoring PE performance and quality improvement goals, allocating appropriate and adequate resources, reviewing and prioritizing ethics issues identified by the PE team, and advising the PE coordinator regarding action plans for managing identified ethics issues. To maximize effectiveness, the coordinator typically is a member of and reports regularly to the council.

Through the council, PE receives leadership support to realize its goals. This support is important because change processes often require resource commitments such as release time for the PE team, participation of numerous staff from different service lines or departments, and other resources needed to implement the change strategy. Leaders can determine priorities for ethics improvement projects and make sure that PE activities are aligned with the organization's strategic plan.

Alternatively, PE activities might be performed by a subgroup of the facility's quality management (QM) program, or by a separate organizational ethics committee. Wherever PE is located administratively, the IntegratedEthics program officer (IEPO) works with the PE coordinator and, as a representative on the IE council, ensures ongoing integration of PE within the IE program.

In networked organizations with multiple facilities, PE teams should also be linked through a regional coordinating body, such as a regional IntegratedEthics advisory board.¹ A PE subcommittee of the advisory board can bring together the PE coordinators from multiple facilities for mutual support, identify ethics issues that cross facility boundaries, share strong practices and ways to surmount hurdles encountered during specific improvement cycles, and educate others relevant to the performance of PE activities. (See Figure 4 for organizational charts that detail facility- and network-level program structures for IntegratedEthics that were developed in VA.)

Preventive ethics coordinator and team responsibilities

The primary responsibilities of the PE coordinator include:

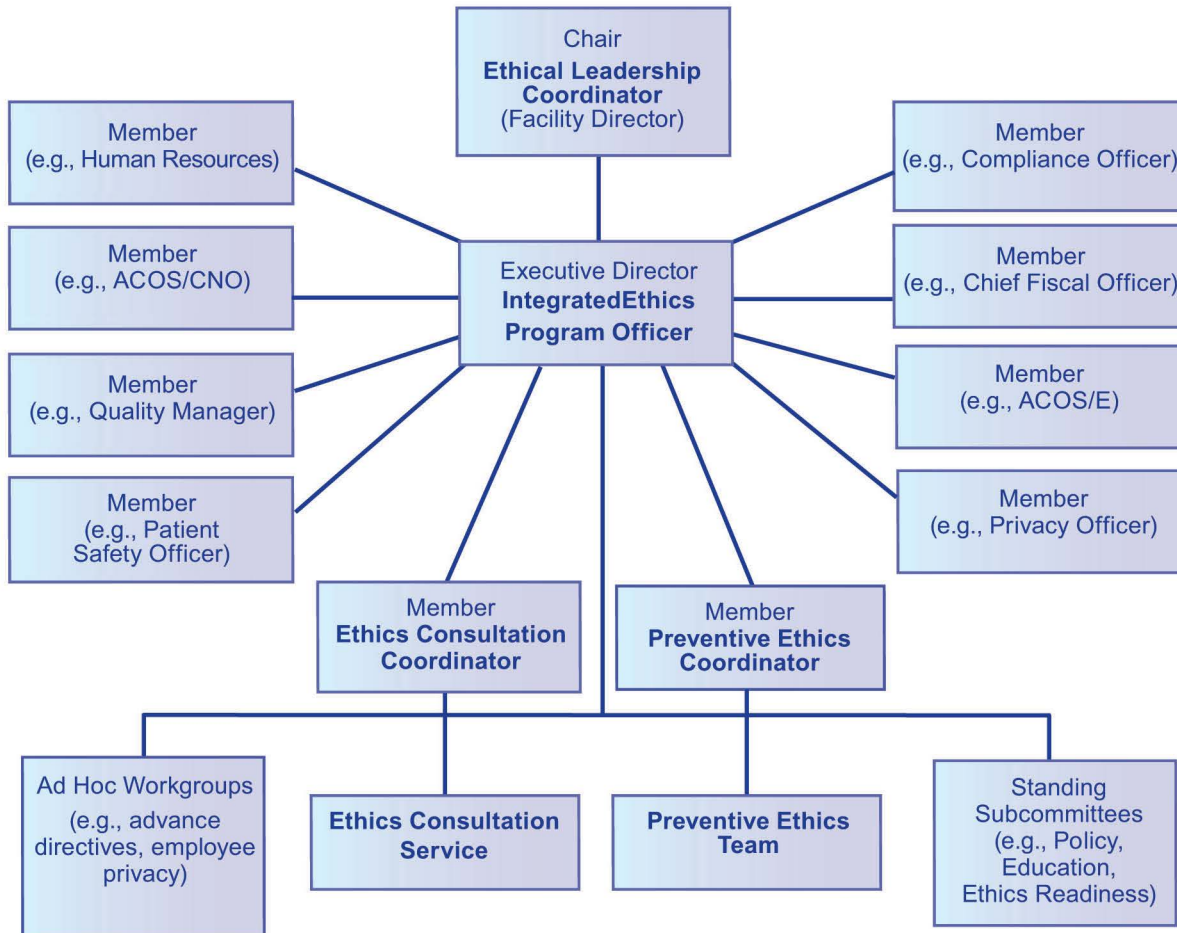
- maintaining an active PE function;
- ensuring that facility leadership and staff are aware of the PE function and know how to request assistance with ethics issues that may be amenable to a PE approach;
- making recommendations for assignment of individuals to the core PE team;
- recruiting staff who possess specific content or process expertise to serve as ad hoc team members to complete an ethics QI cycle;
- familiarizing themselves with PE training materials;
- managing the PE log of ethics issues;
- providing timely notification to the IE council regarding ethics issues that are controversial, lack a clear and authoritative ethical standard to guide improvement, or require leadership input before addressing the issue through a QI approach;

Tip:

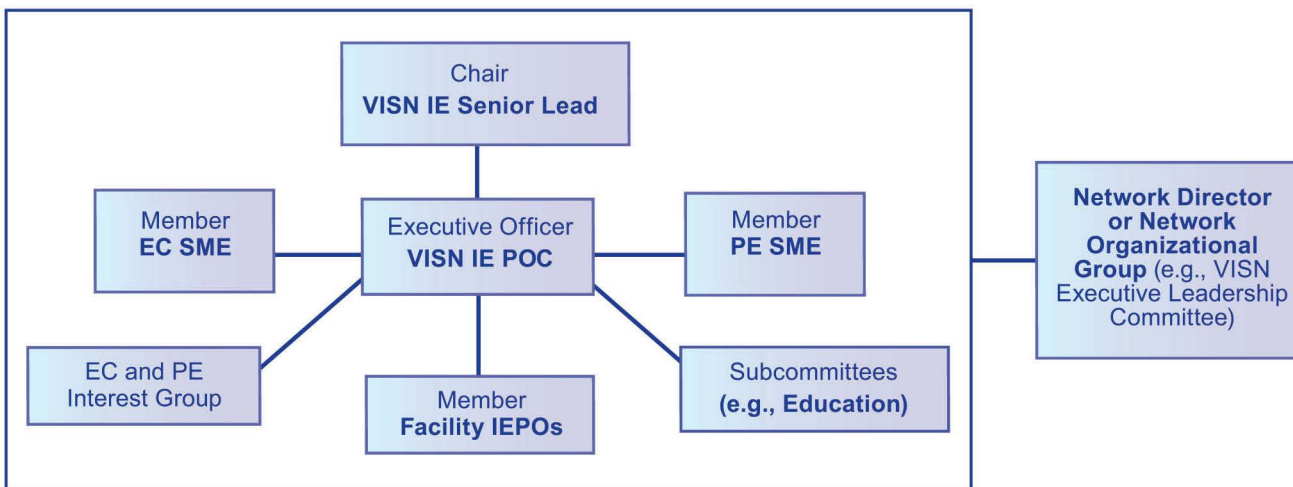
To build a strong team and be optimally effective using the ISSUES approach, a PE team must regularly perform improvement cycles. Accordingly, in VA, PE teams are expected to be continuously working on improvement cycles.

Figure 4. IntegratedEthics Program Structure

IE Council: Facility-Level IE Structural Element



IE Advisory Board: VISN-Level IE Structural Element



- determining which issues are appropriate for a PE approach (i.e., represent an ethics quality gap rather than a technical or service quality gap) and explaining the reasoning for those not appropriate to the program, service, or resource that owns the issue;
- developing the proficiencies of the PE team;
- contributing to the identification of crosscutting ethics issues (i.e., ethics issues that cut across units, services, or entire facilities) and bringing them to the attention of the IE council;
- and evaluating the PE function for ongoing developmental and improvement opportunities.⁸

Led by the PE coordinator, the PE team is responsible for:

- identifying ethics issues amenable to a QI approach and prioritizing among them;
- addressing ethics quality gaps in health care ethics domains using ISSUES or a similar QI approach (see Appendix 1 for a listing of the IntegratedEthics Health Care Ethics Domains and Topics);
- promoting PE programmatic goals;
- and ensuring continuing professional development in PE proficiencies.⁸

In any organization, to be successful, PE requires an effective leader and champion for the function, resourcefulness, effort to apply objective measurement thinking to ethical practices, strong leadership connections, high levels of teamwork, and specialized knowledge of ethics quality improvement methods and processes.⁸

Organizing preventive ethics

In many health care organizations, the PE function is responsible for two types of activities that address systemic ethics issues: (a) QI cycles and (b) maintenance activities. However, these activities require different skills and methods and thus may be carried out by different individuals. In fact, depending on local realities, resources, and history, facilities can assign responsibility for the ethics QI and ethics maintenance components of the PE function in different ways within the organization's hierarchy, with the IE council providing broad oversight and coordination.

The primary purpose of the PE team, managed by the PE coordinator, is to address identified ethics quality gaps that require an intensive QI approach. Improvement cycles are best carried out by small, dynamic workgroups that include one or more core team members and one or more ad hoc members who have process or subject matter expertise in the particular ethics issue being addressed. The core team members should be carefully selected to ensure they have the proficiencies needed for QI cycles (see discussion of proficiencies below).

Maintenance activities include ensuring facility readiness regarding ethics-related accreditation standards, policies, and procedures; reviewing and participating in the development of ethics-related policies; ensuring that appropriate communication and education materials are available to all employees; and coordinating ethics-related activities throughout the facility.

To manage maintenance activities, the council may require the expertise and participation of the PE team in addition to other council members. Maintenance activities are best carried out by standing committees, such as a subgroup of the IE council (e.g., ethics policy subgroup, ethics education subgroup, ethics accreditation subgroup) or by a subgroup of the PE team, whose members have developed specialized knowledge and skills over time. However, they can also be handled by ad hoc committees that have been specifically convened to address an identified task, such as designing education based on staff survey results.

Bringing ethics QI cycles and ethics maintenance activities together under a PE umbrella does, however, help to ensure that they are effectively coordinated and systems thinking is applied to all components. Ethics maintenance activities can also benefit from a QI approach that targets specific needs. For example:

Rather than continuing to administer the same education programs that may have been developed to meet earlier needs, QI can inspire the adoption of stronger educational approaches that address current identified ethics quality gaps (e.g., clinical staff have significant misconceptions about the appropriate use of life-sustaining treatment), set specific goals (e.g., 80 percent of clinical staff will complete the training and score at least 70 on the post-test), and then evaluate the effectiveness of the activities in meeting those goals. A QI mindset is similarly useful for ensuring that the facility maintains accreditation readiness with respect to ethics standards.

At the same time, the broad institutional perspective and special skills of those who carry out ethics maintenance activities can inform and enhance the work of those who carry out ethics QI cycles.

Identifying members of the preventive ethics core team

Each facility should designate a specific PE coordinator to be responsible for directing its PE function, managing all PE activities, and collaborating with the facility's IEPO. Each facility also needs a core team who collectively possesses the proficiencies outlined on page 16 for a successful PE team and who are trained in the principles and practices of PE. Team size may vary, depending on the organization's size and level of complexity, and the number and range of ethics issues prioritized by the team and leadership. Because they may need to address ethics issues across the full range of health care ethics domains, these teams should not entirely comprise clinical staff but should include, for instance, members from other organizational functions, such as finance, human resources, or information systems management.⁶ Improvement teams are more likely to succeed if team members complement one another's strengths and weaknesses, respect one another's contributions, and have previous experience working together as a team.⁹ As mentioned above, ad hoc members should then be added as needed on a project-by-project basis. They are typically selected because they are process owners, or bring needed content or process expertise.

It's important that the core team members work together regularly to develop their collective knowledge and skill at performing PE activities. As discussed further below, it is essential to assign at least one core member who has QM or systems redesign knowledge and expertise to each improvement project. Having a small but nimble core of trained individuals can also allow the organization to handle multiple ethics issues concurrently by establishing separate workgroups that include ad hoc members who are knowledgeable about the specific ethics issue the workgroup is addressing. For example:

If the PE core team establishes a workgroup to address a systemic ethics issue in human resources, it would be vital to include an ad hoc member with knowledge of relevant human resource processes. If relevant expertise isn't included, it's unlikely the core team will succeed in narrowing the ethics quality gap. In fact, it's actually more likely that the gap between current practice and best practice will widen.¹⁰

What Proficiencies Are Required to Perform Preventive Ethics?

Certain baseline skills are essential to enable members of the PE team to address ethics quality gaps at a systems level. Specifically, every PE team should include individuals who have proficiency in the following areas:

- QI principles and practices;
- basic statistical literacy (ability to find, collect, interpret, and display data);
- ethics expertise, including knowledge of internal and external ethical standards and common ethics topics and concepts;
- broad knowledge of the health care system;
- knowledge of relevant organizational environment(s), including how to get things done in that environment;
- project management skills;
- familiarity with change strategies beyond policy development and education;
- and ability to communicate comfortably and effectively with the organization's leadership.⁶

Tip:

PE teams and ethics consultation services within a facility can share expertise as well as complement each other's work when a PE representative is a standing member of the ethics consultation service, and vice versa.

Few (if any) individuals possess all of these types of knowledge and skills. But if the PE function is to succeed, all must be available either through the skill sets of the core PE team or through collaboration with others who have relevant expertise. The team should actively seek input, including ethics expertise, from other parts of the IE program including the facility ethics consultation service and other programs or offices, such as compliance and business integrity, and quality management.

What Are the Critical Success Factors for Preventive Ethics?

To be effective, the PE function requires adequate integration, leadership support, expertise, staff time, and resources. Critical success factors also include access, accountability, organizational learning, and evaluation. Because all of these factors are critical to the success of PE and many require support from leadership and others within the facility, program structures and practices to achieve these factors should be set out in policy.

Integration

The IntegratedEthics program promotes and supports collegial relationships through the structure of the IE council. The council brings together leaders from key offices and

programs, including coordinators of the three core IntegratedEthics functions — ethics consultation, PE, and ethical leadership — to coordinate ethics-related activities across the organization.¹

To carry out its role effectively, each function in an IntegratedEthics program must have regular contact with the other functions through established channels. This will ensure that all functions benefit from one another's expertise and activities. The PE team should collaborate regularly with the ethics consultation service to identify recurring consultation topics that might appropriately be addressed through a PE approach. For example:

The ethics consultation service might identify that there was a 50 percent increase in consults from the Intensive Care Unit, where there is a lack of timely identification of surrogate decision makers causing a delay in treatment planning for patients with life-limiting diseases. The PE team would address the systemic cause and improve timely identification of surrogate decision makers, reducing the consultation service's work load, but more importantly, ensuring that patients' wishes and preferences for care and treatment are honored. Likewise, the consultation service may benefit from the expertise of the PE team to help the service assess its activities and continuously improve.

The PE team should look for opportunities to share activities and skills, and to work to achieve mutual goals with other departments and services. Since PE is in essence a QI activity (albeit with a focus on ethics quality — not technical or service quality — and is managed by the IE council), it's particularly important for the PE team to establish close working relationships with QM and others within the organization that apply improvement methodology. The PE team's QI representative, for instance, could be a QM staff member, or a member of the QM staff could be designated as the PE coordinator. In addition to providing required expertise to the PE team, this person can update the service on PE activities, and advise and educate QM staff on ethical aspects of quality problems. By developing this relationship, ethical aspects can be addressed in all QI projects even when the project is not under the direct purview of the PE program.

Leadership support

Explicit leadership support is essential if the goals of PE are to be realized. Ultimately, leaders are responsible for the success of all programs, and PE is no exception. Leaders establish organizational priorities and allocate resources to support those priorities.

Unless leaders support — and are perceived to support — the PE function in a facility, the function cannot succeed. The PE coordinator should engage leadership to address

Tip:

In VA, the responsibilities of all IntegratedEthics roles and leadership committees — as well as those of leadership for supporting these roles and committees — are described in VHA Handbook 1004.06, *IntegratedEthics*. Facilities are also offered an authoritative template for drafting a local facility policy that aligns with the national Handbook.⁸

Tip:

In health care organizations that are organized into regions, facility PE programs can integrate their efforts to reduce ethics quality gaps across the region. For instance, VA regional programs have taken on crosscutting projects such as creating common policies related to use of home oxygen for patients who smoke and/or practices for patients with service animals. These projects can be addressed through improvement cycles and also ongoing maintenance activities.

PE management and advocate as needed to achieve a fully integrated and effective PE function.

Leaders at all levels and throughout the organization demonstrate support of PE by:

- understanding the scope and role of PE;
- referring appropriate ethics issues to the PE team;
- and encouraging others to refer ethics issues to the PE team.⁸

Leaders who supervise employees who are members of the core PE team should:

- include responsibilities for PE in staff performance plans;
- dedicate time for PE staff to complete their work;
- and recognize staff for their PE activities.⁸

Finally, leaders at the executive leadership and mid-manager levels can ensure a strong PE function by:

- providing resources or removing obstacles to performing PE improvement activities;
- keeping up to date on the activities of PE;
- regularly updating staff on those activities;
- ensuring that critical success factors are in place as described in this section;
- promoting organizational learning by encouraging dissemination of completed improvement projects;
- prioritizing among PE projects;
- connecting PE projects with organizational strategic priorities and projects;
- addressing or providing information regarding ethics-related aspects of other QM projects;
- providing formal opportunities to share PE storyboards;
- and promoting spread of strategies that improve ethics quality.⁸

Tip:

The PE coordinator might work with leadership to establish a leadership development program that engages trainees to complete ISSUES cycles as *capstone* exercises. Such initiatives will accomplish a dual purpose: develop QI expertise and improve processes for managing ethics.

Expertise

Leaders of health care facilities and those who are responsible for PE should ensure that the PE core team has the expertise to perform the role. Selection of the right PE coordinator is pivotal to the success of the function. At a minimum, the coordinator should be proficient in QI methods. If the coordinator does not have this expertise, a core team member must. The coordinator should also be a capable manager who can identify relevant issues, assign responsibility, delegate authority to team members, and establish clear lines of accountability. He or she should have sufficient stature in the organization to communicate effectively and persuasively with senior leaders and should have a strong working knowledge of how to get things done. The coordinator must be skilled in motivating both the core team and ad hoc members who are involved in addressing particular issues.

The PE coordinator must determine whom to recommend as core members to the IE council. To ensure success of the function, these core members also need specific knowledge and skills as outlined above. Perhaps most important are the principles and methods of QI and systems redesign. The ability to communicate with patients and families or to interpret a patient's health record isn't essential, but skill at *getting things done* at an organizational level is. Thus some individuals with an interest in ethics may be well suited for both ethics consultation and PE, while others may be best equipped to perform only one of the two functions.

For individual projects, the coordinator should select two kinds of experts as ad hoc members of the team:

- process experts — those with specific hands-on knowledge of the systems and processes that result in the ethics quality gap (e.g., the local process of documenting informed consent);
- and content experts — those with deep knowledge of the ethics issue and the ethical practice the team is aiming to improve (e.g., the ethical standard and best practice regarding informed consent for medical treatments and procedures).

Tip:

The PE coordinator can generate enthusiasm and build capacity within the core team by routinely assessing members' skills and providing training to address identified gaps. This approach will also build capacity within the team to ensure its ongoing success.

Staff time

PE should not be viewed as an optional activity but as an essential part of health care operations. As such, the PE function requires adequate staff time to perform its responsibilities. PE activities can be time consuming, and individuals responsible for this function (including ad hoc members) need dedicated time to do their work. In a given facility, the time required for PE will vary depending on the number and type of issues addressed. Although some narrowly focused issues can be resolved with a simple process intervention (e.g., with a checklist), complex ethics issues will typically require dozens of person-hours, over a period of weeks or months.

For members of the core team, PE activities should be included in their performance plans, and team members should establish a clear understanding with their supervisor(s) of how much time this activity involves. Facility policy should also support the provision of protected time for PE team members to perform their work.

Resources

Individuals performing PE activities also must have ready access to resources, such as clerical or data entry support, library materials, and ongoing training. The facility library may provide access to a good selection of QI texts and journals. In addition, many useful QI resources are available online, so access to the Internet is essential. Core members of PE teams that aren't subgroups of QM may also wish to investigate what resources and tools are available through the facility's QM program. Over time, the PE team may find that its work is facilitated by QI software or use of spreadsheets or relational databases to manage QI cycles.

Tip:

VA policy requires that facility directors ensure that the PE coordinator has adequate resources to manage PE teams and that team members receive protected time to perform their role effectively, thereby empowering coordinators and the IE council to negotiate with leaders and supervisors for sufficient staff time and resources for PE activities.⁸



The National Center for Ethics in Health Care has developed a variety of resources and materials to help support preventive ethics. See: <http://vaww.ethics.va.gov/integratedethics/pec.asp> or <http://www.ethics.va.gov/integratedethics/pec.asp>.

Access

The PE team learns about systemic ethics issues from its own ongoing monitoring and input from institutional sources, including the IE council, the facility ethics consultation service, senior leaders, service and program heads, human resources personnel, compliance and business integrity officers, privacy officers, patient advocates, quality and risk management groups, and individual staff. The PE team should educate these groups about what it does and how to refer issues to the team for consideration.

Developing a referral network takes time and commitment — a one-time presentation, for instance, to a meeting of senior leaders isn't sufficient. Establishing routine communication is crucial to developing and maintaining a vibrant referral network. Participation by the PE coordinator in the IE council will help to establish relationships and ensure regular communications with programs and offices across the institution. The PE team should also consider routinely getting on the agenda at key meetings to market PE. Potential referral sources will want to know what the team can do for them — and a powerful source of persuasion will be sharing outcomes of successfully completed ISSUES cycles.

Frontline staff across the organization can be a rich source of potential ethics quality gaps. Supervisors and managers — from clinical services to the business office to human resources to maintenance — should encourage staff to proactively identify potential ethics issues with a possible ethics quality gap so managers can refer them to the PE team. If

Tip:

To locate issues, PE teams should target data sources, such as external reviews, that are most likely to address the ethics component in various practices. For example, a review by The Joint Commission could identify a process issue with advance care planning. Another strong practice is to include key stakeholders (such as patient advocates) on the core PE team who have regular access to employee and patient perceptions in the course of their work.

the PE team observes that ethics issues are being referred from all areas of the organization (e.g., main facility, community-based outpatient clinics, and business and clinical departments) and levels (e.g., frontline staff, top leadership, patients, and families), it can be confident that it has successfully spread awareness of PE across the organization.

The PE team shouldn't rely only on referrals to identify ethics quality issues. The team should seek out the most pressing issues from the virtually unlimited supply of QI opportunities to be found in any health care organization.

However, a PE team shouldn't be expected to act on every identified issue. Good stewardship requires that PE teams exclude issues that are outside the scope of PE or that can be addressed more effectively and efficiently by a different

approach or organizational unit. Prioritizing among the various ethics issues that need attention and addressing the highest priority issues first will be discussed further as part of Step 1 of the ISSUES approach ("Identify an issue") in Section II.

Tip:

A PE team led by a program or department head (e.g., QM) can utilize support from a program assistant to keep minutes and other records for the team.

Accountability

Like any other important health care function, PE must have a clear system of accountability. Day-to-day responsibility for PE should rest with a designated individual, the PE coordinator. In the IE model, this individual is accountable to the IE program officer. The program officer, in turn, is accountable to the chair of the IE council, who is a member of the facility's top leadership (e.g., the facility director).

The IE council provides oversight of PE. Specifically, it is responsible for establishing specific goals, structures, processes, and performance expectations for the IE program. The council also enables organizational leaders to monitor the function's operations, successes, and failures and whether it is accomplishing its goals. For example:

The council might ask the PE coordinator to present regular updates or to develop written reports on a quarterly or annual basis. Similar reports, when distributed more broadly to facility staff, serve as a useful reminder of the existence, availability, and value of PE. Regional coordinating bodies (i.e., the regional IE advisory board) should clearly express accountability expectations in policy, charters, or similar documentation.

Tip:

When the IE council is involved early in prioritizing and selecting issues, and regularly reviews project updates, it can provide ongoing support and monitoring, and remove barriers.

Organizational learning

It's also important for PE teams to contribute to organizational learning by sharing their knowledge and experience with others in the organization.¹¹ PE teams use a storyboard worksheet to record information during the steps of an ISSUES cycle. They then document completed cycles on a standardized ISSUES summary template.



See <http://vaww.ethics.va.gov/integratedethics/pec.asp> or <http://www.ethics.va.gov/integratedethics/pec.asp> for blank storyboard worksheets and summary templates and for filled-in samples. For an example of a completed summary, see Appendix 6. Using an easy-to-read column format, Appendix 7 provides other examples of ethics issues from different domains that have been addressed using the ISSUES approach.

These tools are intended to guide the PE team in their work, and, equally importantly, to facilitate disseminating information across the facility in a transparent and timely way. A standardized ISSUES summary template handout can be used to inform facility staff during group discussions. A PE ISSUES storyboard can be reworked into a newsletter article that summarizes an important ethics quality gap. When an ISSUES cycle finds that practice is compromised because staff doesn't understand a policy, the PE team can create Frequently Asked Questions and post them on a website. Such efforts enhance staff knowledge and the credibility and visibility of PE.

Ideally, as the PE function matures, the core team will be able to nurture spin-off teams at the service or unit level.

Tip:

Learning from other sites' projects has the potential to improve organizational learning. VA conducted a focused national QI project to improve practices for informed consent for HIV testing. The program collected national and regional data from the electronic health record and offered focused support to all facilities (the community of practice). Using a sharing site, facilities throughout the VA community accessed documents showing current strategies and results.

Working with small, unit-level teams can extend PE well beyond what the core team by itself could ever accomplish.

In regional organizations with multiple facilities, PE teams can use an online document-sharing site to create an accessible library of PE summaries. Such sharing promotes rapid exchange of organizational knowledge, lessons learned, and strong practices for improving ethics quality throughout the organization. PE teams can also learn about the innovative and successful improvement efforts of other facilities through regional meetings, conferences, and information shared by the regional office. Regional offices can take the initiative in promoting coordinated efforts to address crosscutting issues that are affecting numerous facilities within their regions.

Evaluation

Evaluation is an important strategy to improve the process of PE (i.e., how it is being implemented) as well as its impact (i.e., how PE benefits patients and other stakeholders in the facility). Evaluation is defined as “ongoing, systematic assessment of the operation and/or impact of the program compared with explicit or implicit standards as a means to contribute to continuous improvement of the program.”¹² Evaluation efforts need not be burdensome or costly.

This primer establishes explicit standards for PE against which actual practices may be compared. For instance, the critical success factors identified in this section should be assessed systematically:

- *Integration* — Is the PE function well integrated with other components of the organization?
- *Leadership support* — Is the PE function sufficiently supported by leadership?
- *Expertise* — Do individuals performing PE activities have the required knowledge and skills?
- *Dedicated staff time* — Do they have adequate time to perform PE effectively?
- *Resources* — Do they have ready access to the resources they need?
- *Access* — Do staff know when and how to refer issues to the PE team?
- *Accountability* — Is there clear accountability for PE within the facility’s reporting hierarchy? Does the PE team keep leaders apprised of its activities?
- *Organizational learning* — Is the PE team effectively disseminating its experience and findings?
- *Evaluation* — Does the PE team continuously improve its quality through systematic assessment?
- *Policy* — Are the structure, function, and processes of PE formalized in institutional policy?

The PE team should assess whether ethics issues are addressed in accordance with the approach outlined in Part II, “ISSUES: A Step-by-Step Approach to Preventive Ethics” or a similar QI approach.

The team should also determine whether it is meeting its professed goals. For instance, does the team effectively identify, prioritize, and address ethics quality gaps? Does it develop practical solutions that lead to measurable improvements in ethical practices and the overall quality of care? Use of the IntegratedEthics Facility Workbook¹³ and other IE tools can help identify gaps in an existing PE function, such as whether the PE

function is well integrated with the other core functions of IE and with other ethics-related activities.



The Glossary provides short definitions of the workbook and self-assessment tool. See <http://vaww.ethics.va.gov/integratedethics/pec.asp> or <http://www.ethics.va.gov/integratedethics/pec.asp>.

The PE team should also develop annual objectives for the function and evaluate progress on these. The plan should include associated action plans to meet the objectives, measurable results to be achieved, and specific time frames for each. Annual plans can provide the team with a tactical blueprint to grow PE within the organization.



See <http://vaww.ethics.va.gov/integratedethics/pec.asp> or <http://www.ethics.va.gov/integratedethics/pec.asp> for an array of PE tools and resources to help teams implement PE and measure progress.

Policy

The structure, function, and process of PE should be formalized in institutional policy. At a minimum, this policy should address the following topics:

- definition of PE;
- goals of PE;
- who will perform PE;
- what activities fall within the mandate of PE;
- what role the IE council will play in the management of PE;
- what role leadership will play in the support of PE;
- how visibility of PE will be built in the organization;
- how issues will be identified, prioritized, and addressed;
- how PE activities will be performed;
- how PE activities will be documented;
- how team proficiencies will be developed;
- and how the quality of PE will be assessed and developed.

VHA Handbook 1004.06, *IntegratedEthics*⁸ provides national guidance for VA facilities and includes a model for local policy.

Part II:

ISSUES: A Step-by-Step Approach to Preventive Ethics

This section describes the ISSUES approach, a systematic, step-by-step process developed by VA's National Center for Ethics in Health Care for reducing ethics quality gaps. This approach involves six steps:

I

IDENTIFY an Issue

*Be proactive in identifying ethics issues
Assess whether the issue suggests an ethics quality gap
Clarify each issue by listing the improvement goal
Prioritize the issues and select one*

S

STUDY the Issue

*Diagram the process behind the relevant practice
Describe best ethics practice using ethical standards
Describe current ethics practice using quantifiable information
Refine the improvement goal to reflect the ethics quality gap*

S

SELECT a Strategy

*Identify the major cause(s) of the ethics quality gap
Identify change strategies to address the cause(s) of the ethics quality gap
Select one or more strategies for small-scale testing*

U

UNDERTAKE a Plan

*Plan how to carry out the small-scale test of the strategy to narrow the gap
Plan how to evaluate if the strategy narrowed the gap
Execute the small-scale test*

E

EVALUATE and Adjust

*Check the execution and the results of the small-scale test
Adjust as necessary
Evaluate your ISSUES process*

S

SUSTAIN and Spread

*Sustain the improvement
Continue monitoring
Spread the improvement
Disseminate the improvement*

The ISSUES Approach

Preventive ethics employs a systematic, step-by-step process improvement approach called ISSUES. ISSUES includes the following major steps that will be discussed in detail below: **I**dentify an issue, **S**tudy the issue, **S**elect a strategy, **U**ndertake a plan, **E**valuate and adjust, and **S**ustain and spread.

Step 1: Identify an Issue

As defined in Part I (page 8), an ethics issue is an ethics quality gap that results from poorly performing, unreliable, or ill-defined systems and processes that can arise anywhere in a health care organization. The specific aim of the PE function is to produce measurable improvements in the organization's ethics practices by implementing systems-level changes that reduce disparities between current ethics practices and best ethics practices.

The first step in the ISSUES approach sounds deceptively simple, but it is critical and often the most difficult to execute successfully. In this step, the team must identify a list of potential ethics issues, exclude those that are not appropriate for the ISSUES approach, and then select a high priority ethics issue for further study and work.

IDENTIFY an Issue

*Be proactive in identifying ethics issues
Assess whether the issue suggests an ethics quality gap
Clarify each issue by listing the improvement goal
Prioritize the issues and select one*

Be proactive in identifying ethics issues

Using an IntegratedEthics tracking tool developed specifically for this purpose, the PE team should proactively gather and maintain a list of candidate ethics issues that warrant consideration. To find out about issues that might be appropriate for a PE approach, the team should look to the IE council, senior management, service and program heads, the ethics consultation service, quality and risk management groups, human resources personnel, compliance and business integrity officers, privacy officers, patient advocates, and individual staff. *The PE team should establish regular contacts and lines of communication with these groups and check in with them frequently.*

IntegratedEthics council. The IE council, whose members represent a cross-section of institutional leadership, is an important source of information about potential ethics issues for the PE team. Ethics issues will come to the attention of the council not only through its members, but also through referrals from elsewhere in the organization and through the council's role in analyzing the results of the IntegratedEthics Facility Workbook¹³ and IntegratedEthics Staff Survey.¹⁴

Service and program heads. Service chiefs, program coordinators, and other heads of clinical and nonclinical divisions who aren't members of the IE council can also be good sources of information about ethics issues that arise in their respective areas. For example:

A member of the PE team might learn from the chief of risk management that concerns have been raised about the reliability of the process for ensuring that medical errors are communicated to patients, or about the process for ensuring that oral informed consent for HIV screening is documented in the health record.

Ethics consultation service. The ethics consultation service, especially, should be one of the first stops for identifying ethics issues that are amenable to a quality improvement (QI) approach. An active ethics consultation service is likely to know the ethical challenges commonly faced by patients and staff. The PE coordinator should meet routinely with the ethics consultation service or, as discussed earlier, include the ethics consultation coordinator as a core member of the PE team to facilitate ongoing identification and discussion of potential ethics issues from recent consultation activities.

Quality management (QM) staff. Quality managers are often uniquely knowledgeable about systems-level ethics issues. For example:

A quality manager might become aware of problems with inconsistent documentation of informed consent for particular tests or diagnostic procedures and enlist the PE team to address them. In addition, the QM program collects and summarizes data that may point to ethics quality gaps.

Other sources. New PE teams should also plan on contacting key committees and polling staff regarding perceptions of ethics issues in the organization and within individual work units. They can elicit ethics issues by using open-ended questions such as, “What types of ethics issues do you encounter in your setting?” “How often does this [ethics issue] happen?” “Do you think there are things (i.e., system or process changes) we could do to prevent the ethics issue from recurring — or to at least improve the situation?” or “What would you suggest to improve the situation?”

To identify ethics issues for its list, the PE team should also regularly review other information sources, such as:

- accreditation reviews;
- sentinel event reports;
- patient satisfaction and employee feedback surveys (e.g., IntegratedEthics Staff Survey¹⁴);
- employee and patient complaints;
- investigations by the Office of Inspector General, Office of Medical Inspector, licensing boards, or similar agencies;
- congressional or media inquiries;
- and employee exit interviews.

Involving staff members who can best interpret this information will help ensure that the PE team attains an accurate understanding of the data.

Assess whether the issue suggests an ethics quality gap

There are many opportunities to improve ethics quality, but not all issues are appropriate for a comprehensive QI approach such as ISSUES. Good stewardship requires that PE teams exclude issues that are outside the scope of PE or that can be addressed more effectively and

Tip:

In VA, all ethics consultations are documented in ECWeb, a Web-based electronic tracking tool.¹ Because this tool categorizes all completed ethics consultations by Domains of Ethics in Health Care (e.g., Shared Decision Making) and topics under those Domains (e.g., Advance Care Planning), it enables efficient identification of frequently recurring problem-prone processes that are associated with ethics quality gaps. (See Appendix 1 for a listing of the Domains and topics.)

efficiently by a different approach or organizational unit. But how do PE teams accomplish this central task of identifying appropriate ethics issues? VA's National Center for Ethics in Health Care has designed a screening tool that enables PE teams to (a) document potential ethics issues, (b) screen potential ethics issues, and (c) determine if a candidate issue likely possesses an ethics quality gap appropriate for a comprehensive improvement approach.

The team should complete the "Choosing Issues for PE: Worksheet" (see Appendix 2) and "Choosing Issues for PE: Tracking Tool" (see Figure 5) for each issue it is considering. (For a full-size, fillable version of the tool, see Appendix 3.) The worksheet leads the team through a set of questions/criteria for identifying appropriate ethics improvement projects, and the tracking tool enables the team to document their decision-making rationale for all issues they are considering. Taken together, the worksheet and tracking tool provide a record of issues considered by the PE team, and can be used to explain decisions about *appropriateness* in a rational and organized manner to senior leaders and the IE council.



See <http://vaww.ethics.va.gov/integratedethics/pec.asp> or <http://www.ethics.va.gov/integratedethics/pec.asp> for the most recent versions of these prioritization and tracking materials.

Figure 5. Choosing Issues for PE: Tracking Tool

Appropriateness for PE												Priority for PE ISSUES Approach							
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Date Issue Came to Attention of PE (mm/dd/yy)	Source of Issue (1-2 words)	Possible Ethics Issue (who, what, where, when, how much or how often)	Immediate Action Req'd (Y/N/U)	Simple Problem/Obsvious Solution (Y/N)	Other Program Responsible for This Issue (Y/N/U)	Ethics Quality Gap				Preliminary Improvement Goal	Appropriate for PE (Y/N/U)	Alignment with Strategic Goals (L/M/H)	Impact on Patient and/or Employee (L/M/H)	Volume of Scope or Effect (L/M/H)	Resources Req'd to Improve (L/M/H)	Likelihood of Success (L/M/H)	Refer for Ethics Leadership Approval (Y/N)		
						Best Ethics Practice		Current Ethics Practice											
						Ethics Domain	Ethics Topic	Practice Inconsistent with Ethical Standards or Expectations (Y/N/U)	Data Available (Y/N/U)										

Y= Yes; N=No; U=Unsure

L=Low, M=Medium, H=High

The first three screening questions are intended to allow the PE team to quickly exclude those issues that are likely to be outside the purview of PE.

- Does the issue require urgent and immediate action by leadership?
 - PE is not a crisis management function. Ethics issues could be reviewed after crisis intervention has been completed.
- Is the issue simple with an obvious solution?
 - If yes, apply the solution!
- Is there another program or service that is responsible for the issue?
 - If another program or service has oversight responsibility, then the PE team should consult with that program.

The next set of questions/criteria is critical to allow the PE team to distinguish between an ethics quality gap and a technical or service gap. If the issue does not suggest an ethics quality gap, it is not appropriate for PE and should be referred to the appropriate program or service. PE teams should ask:

- Is there an ethics domain related to the issue?
- Is there an ethics topic related to the issue?
- Is there an ethical standard related to this issue, and is the practice inconsistent with this standard?

The tool, “Domains of Ethics in Health Care,” provides a simple framework for determining if a potential ethics issue can be accurately categorized into a recognized domain and topic area (see Appendix 1).

If the PE team concludes that there is an ethics dimension to the issue based on affirmative responses to the questions above, they must then ask whether there is measurable data available (or readily collected) to quantify the gap between best and current ethics practice. Novice PE teams sometimes take up an ethics issue without considering that after testing a strategy to bring about change, they will need to demonstrate improvement in measureable terms. If the ethics quality gap cannot be measured, then it is not appropriate for a comprehensive improvement approach. That being said, measurement of improvement need not be complicated. Often it is as simple as counting something and expressing it as a number or a percentage. A simple case example illustrates this:

The nurse manager in cardiac rehab called the PE team to ask for its help in addressing an ethics quality gap. He talked to all 25 of his present caseload of patients and found that only five had an advance directive and the remainder did not recall being offered information or assistance with completing an advance directive. In other words, 20 percent of patients are offered information or assistance with completing an advance directive.

If, after applying these criteria the PE team determines that an issue really isn’t appropriate for the ISSUES approach, the team should get back to the program or service that is the process owner for the issue, explain the reasoning for its decision, and help the program or service consider other avenues for assistance. Members can also ask their ethics program leadership to assist with this process as needed.

It’s important to remember that for an ethics issue to be appropriate for the ISSUES approach, there must be a gap between current ethics practice and best ethics practice. If team members use the tools and focus on identifying the ethics quality gap, they will have a greater chance of not taking on vague and ill-defined organizational problems (i.e., “institutional messes”) in which the gap between current ethics practice and best ethics practice cannot be clearly described.

Determining the appropriateness of issues and categorizing them can also help the team highlight the types of issues that have been addressed either disproportionately or not sufficiently. For instance, if the tracking tool lists issues across all domains but the team has focused on only one or two domains (e.g., issues relating to Shared Decision Making with Patients or Ethical Practices in the Everyday Workplace) and not yet addressed an issue that has been identified in others — say, Patient Privacy and Confidentiality or Professionalism in Patient Care — then the team can explore and try to understand why the imbalance exists in order to develop a plan to address the imbalance.

Finally, as noted above, categorizing issues will be useful for reporting progress to others such as senior leaders and the IE council.

Clarify each issue by listing the improvement goal

Next, for each ethics issue, the team should draft a preliminary improvement goal. At this stage, the goal is a general statement of the desired outcome of the improvement and, if possible, a direction of change.

For example, an ethics issue presented to a PE team was:

A recent accreditation review of health records found that only a few patient requests for assistance with completing an advance directive were followed up by clinic staff. A preliminary improvement goal for this issue could be, “Increase assistance to primary care patients who request help with completing an advance directive.” Further study will then be required to fully define the ethics quality gap and complete a refined improvement goal.

A common mistake that less experienced PE teams can make is to state the preliminary improvement goal in terms of improvement *strategies* instead of improvement *outcomes*. For instance, in the example above, if the goal were stated as “Increase education to staff about advance directives,” it would identify a strategy to bring about change through training or education, but not the desired outcome of increasing assistance to patients who want to complete an advance directive. In other words, this goal states what activity will be undertaken to bring about change (strategy), but not what change the activity is expected to accomplish (improvement goal/outcome).

Specifying a preliminary improvement goal is important for several reasons. First, it requires the team to clarify the meaning of ill-defined concepts or ambiguous terms and helps to ensure that everyone is talking about the same aspect of the ethics issue in question. Second, if the issue was initially defined too broadly, stating a specific improvement goal will help the team focus more narrowly and define the issue in more manageable and measurable terms. Finally, specifying a concrete goal also helps to ensure that the team operates in an efficient, practical, problem-solving mode.

Once the team has specified the preliminary improvement goal, it should assign a shorthand working title that succinctly conveys both the ethics issue and the improvement goal. For instance, for the improvement goal “Increase assistance to primary care patients who request help with completing an advance directive,” a good working title might be “Shared Decision Making: Completing Advance Directives.” The preliminary improvement goal and working title should be recorded on the tracking tool.

Prioritize the issues and select one

After identifying ethics issues that are appropriate for a comprehensive QI approach and specifying the preliminary improvement goal, the team should prioritize and decide which issue(s) should be recommended to the IE council or appropriate organizational leader for final approval.

Because time and resources are limited, the team should select an issue for which the improvement effort is likely to have a real impact on the facility’s ethical practices. To ensure that high-priority ethics issues don’t languish, PE teams should routinely review the tracking tool. A related tool, “Applying Prioritization Criteria to Each Ethics Issue: Worksheet,” guides teams through a systematic, efficient process that applies consistent criteria to all ethics issues (see Appendix 4). Teams can use the worksheet to document the discussion behind each ranking, which is especially useful when presenting the team’s overall rankings and recommendations to leadership and the council.

Although the worksheet identifies prioritization criteria, an organization may augment this initial listing with organization-specific criteria to contextually prioritize potential ethics improvement projects.

The criteria on the tool are:

- alignment with strategic goals — To what extent does addressing the ethics issue align with the organization's and ethics program strategic priorities?
- level of risk — What level of risk does the ethics issue pose to the organization if left unaddressed?
- impact on patient and/or employee — What level of impact will addressing the ethics issue have on patient and/or employee satisfaction?
- volume or scope of effects — If this ethics issue is addressed, how many people, units, etc., will be impacted by the resulting quality improvement in ethics quality?
- resources required to improve — How substantial are the resources required to improve ethics quality for this specific ethics issue? Is the anticipated outcome sufficient to justify this expenditure?
- likelihood of success — How likely is it that the PE team can succeed in tackling the ethics issue and achieving the desired outcome?
- refer to leadership for approval — Following consideration of preceding criteria, should the ethics issue be referred to leadership for approval to proceed?

Once the team has reached agreement on the ethics issue(s) to be addressed through the ISSUES approach, these recommendations should be reviewed and discussed with the IE council. Sometimes, leadership may have additional information and/or a more in-depth understanding of the organization's priorities, which may lead to reprioritizing the order of ethics issues or changing the team's approach.

Not every appropriate ethics issue can be addressed by the PE team. Organizational leaders or ethics leadership (such as that provided by the council) should help decide what to do with unaddressed ethics issues. In some instances, the ethics issue will remain a priority but can be addressed at a later date. These issues should stay in the queue and on the tracking tool.

In other instances, leadership may address at least some aspect of the ethics issue using a different approach — for example, by assigning another component of the ethics program to lead the charge or delegating the ethics issue to another program or department. In other cases, it may be appropriate to collaborate with a systems redesign or QI group to address the ethics issue; in such occurrences, the PE team would take a supportive or consultative rather than primary role.

Alternatively, the prioritization process might reveal that the ethics issue is of such low priority it does not warrant further action by the PE team or may be better addressed by the team that identified the issue.

As the team completes the review with leadership and decisions are made on what ethics issues will be addressed, the PE team should close the loop and communicate their decisions and rationale to others who need to understand the team's selection process.

Step 2: Study the Issue

The second step in the ISSUES approach is to study the ethics issue selected in Step 1. This involves learning about how the issue manifests itself and describing the gap between current ethics practice and best ethics practice.

S

STUDY the Issue

Diagram the process behind the relevant practice
Describe best ethics practice using ethical standards
Describe current ethics practice using quantifiable information
Refine the improvement goal to reflect the ethics quality gap

Diagram the process behind the relevant practice

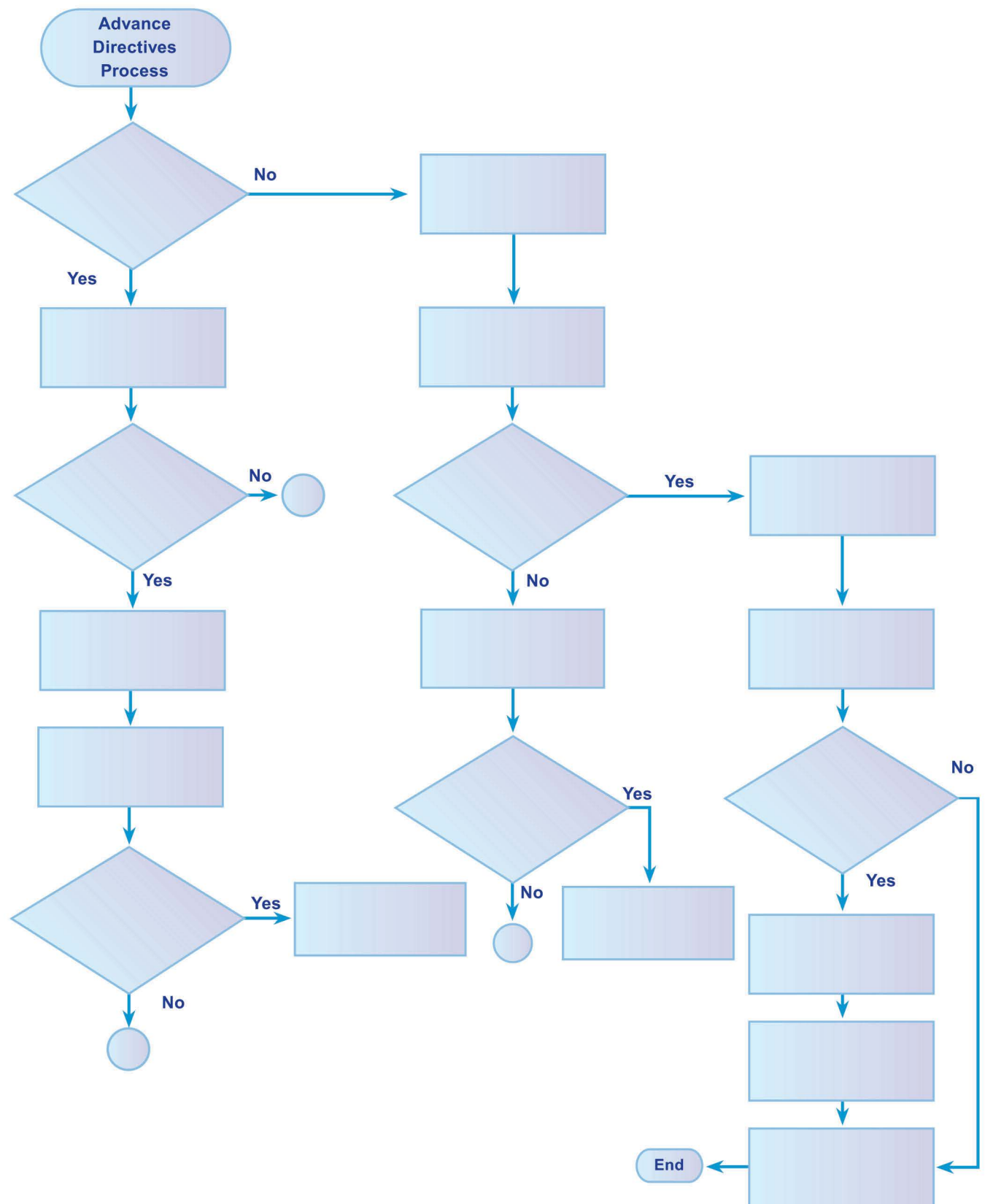
The PE team should begin by constructing a process flow diagram that illustrates how the selected ethics issue manifests in the local setting (see Figure 6). This requires gathering information from key sources to develop a detailed understanding of the process behind the relevant practice. PE teams may find it helpful to briefly describe the system or process they will be diagramming to ensure that everyone is on the same page; for instance, “we are diagramming the process of identifying surrogate decision makers in the ICU for patients who lack decision-making capacity.” Understanding how the process actually works is a crucial step, as it helps the team clarify the scope of the issue, identify potential leverage points for change, and generate ideas for measuring improvement.

Most processes are complex and the different people involved may perceive the process very differently. Stakeholders who are affected by a process may see it differently from individuals who carry it out. Often these latter individuals are familiar with aspects that directly involve their work but lack a comprehensive sense of the process. Therefore, except for very simple processes, PE teams generally must access multiple sources of information to ensure that their description of the process is accurate and complete. For example:

The team is gathering information about the process for ensuring that informed consent for HIV testing is obtained and documented in the health record. To construct a sufficiently detailed diagram of the process, the team may want to include information from clinicians who order HIV tests and are expected to obtain and document informed consent, staff who perform patient education, staff who administer the test, and possibly even patients who have been tested.

Whenever possible, information about a given process should be collected from the people who are most directly involved. Including such process experts from start to finish is important to fully understand all aspects of the process. Further, these experts can help identify process improvement opportunities. Methods for gathering information include conducting group discussions (or formal focus groups), directly observing the practice, talking to individuals one-on-one, and/or involving them in team meetings to construct the flow diagram. Ideally, individuals with direct knowledge and experience of the process under study should be included as ad hoc members of the workgroup exploring the ethics issue.

Figure 6. Flow Diagram



The PE team should ensure that staff do not feel threatened by information-gathering activities. Teams should take their cue from the field of patient safety and always explain clearly at the outset that they're committed to addressing ethics issues through process improvement, and not looking for individuals to blame. In addition, the PE team should safeguard the data it collects, especially data that is in any way identifiable. The team should take the same precautions it would take to protect other types of QI data.¹⁵

Questions that are potentially useful in understanding and diagramming a process include:

- What are the scope and boundaries of the practice?
- What is the actual flow of the process behind the practice?
- Who is involved in each step of the process? What are their roles?
- Who else is directly or indirectly affected by the practice?
- How do the steps relate to each other?
- Does everyone generally approach the practice in the same fashion, or does each person, service, or unit do it differently?
- Is the practice documented?
- Do existing standards (e.g., policies or standard operating procedures) define how the practice should be performed?
- Do staff members adhere to those standards?
- Do staff have workarounds to bypass current standards?
- Are there unwritten rules that conflict with the formal standards?
- What really happens on a day-to-day basis?

With information from various sources in hand, the team should draw and label a process flow diagram — a visual representation of the actual flow or sequence of events in a particular process. A variety of process flow diagram formats can be used. Diagramming a complex process accurately and efficiently may require multiple meetings with process experts. Although this may seem time-consuming, in the end it's the most reliable method of developing a process flow diagram. *Completing a flow diagram is most helpful for uncovering contributing causes, such as unnecessary complexity, redundancies, and places in the process where simplification and standardization may be possible.* The flow diagram will be further explored in Step 3: Select a Strategy.

Describe best ethics practice using ethical standards

Next, it's important for the PE team to describe best ethics practice as part of defining the ethics quality gap in order to establish a clear picture of how the status quo needs to be changed. Recall that measurably improving ethical practices depends on the ability to *identify, describe, and quantify* the ethics quality gap. An ethics quality gap is the "disparity between current ethics practice and best ethics practice" where best ethics practice refers to an ideal practice established on the basis of widely accepted standards, norms, or expectations for the organization and its staff. For example:

Hospital policy requires staff to offer patients information about advance directives during the admission process. Excepted from this policy are patients who are admitted on an emergency basis and those who lack decision-making capacity.

Based on this standard, the best ethics practice could be described as follows:

All patients should be given information about advance directives during the admission process except for patients who are admitted on an emergency basis or who lack decision-making capacity. The current ethics practice was determined based on a chart review of the past 50 admissions: Only 60 percent of the patients who were supposed to be given information about advance directives were actually given this information.

Without a clear understanding of this gap, a well-meaning team may inadvertently weaken rather than strengthen ethical practices within their institution. From our previous example, a team may start to focus on increasing the number of advance directives on file versus the number of patients being offered information on completing an advance directive. Completing an advance directive is a voluntary activity so focusing on increasing the number of completed advance directives may have the unintended consequence of having staff unduly pressure patients to complete the form.

To fully describe the ethics quality gap, the PE team must be able to perform the following steps:

1. identify appropriate sources for ethical standard(s);
2. describe the ethical standard(s), including any *exclusions* to the standard;
3. draft an operational definition of *best ethics practice* based on ethical standard(s), exclusions to the standard, and details of the specific ethics issue;
4. and quantify current ethics practice as a baseline against which to compare the impact of subsequent improvement efforts.

The first three steps are required to describe best ethics practice. The fourth step is required to *quantify current ethics practice* and will be addressed in the next section. The ethics quality gap is the difference between the best ethics practice and the current ethics practice. From these steps, the refined improvement goal, which aims to narrow the gap, can be developed. This provides the team with clarity on the process to be improved.

One of the most challenging aspects of describing an ethics quality gap is to identify one or more appropriate ethical standards from sources of ethical standards that can inform the operational definition of the best ethics practice. Common sources of these standards include:

- accreditation standards;
- consensus statements or position papers from professional societies;
- executive directives and other senior management guidance;
- organizational policies;
- precedents from case law;
- professional codes of ethics;
- and statutes, laws, or regulations.

In addition, the team may find it valuable to undertake a literature review, talk to subject matter experts, and/or consult with their ethics consultation service to identify the ethical standard(s) that apply to the specific ethics issue.

Once ethical standard(s) are identified, the team should critically assess each standard on its validity and currency. No standard should be adopted uncritically, because ethics thinking often evolves over time, and policies or other sources of ethical standards may not be updated frequently enough to keep pace.

To assess possible ethical standards for describing best ethics practice, the team should consider how the standard was developed. Was there a rigorous development process by subject matter experts, including those with ethics expertise? a comprehensive literature review? input from a broad range of stakeholders? consensus building? careful writing and editing? a defined approval process?

A standard based on a rigorous development process would generally be considered highly authoritative and a strong basis for describing *best ethics practice*. Sometimes, one source for the ethical standard is sufficient because it is so authoritative that it trumps all other potentially conflicting or even complementary sources of ethical standards. For example, in a government health care system, there would be no need to consult additional sources if a particular ethical practice were required by a national policy or federal law. On the other hand, a local policy developed by a particular facility in that organization might not be sufficient as a single source of an ethical standard if that local policy is trumped by federal law, or if consensus statements or professional codes of ethics suggest that the local policy does not reflect current ethics thinking.

Tip:

Occasionally, local policy misinterprets the original sources on which it was based. When a local policy is being considered as an authoritative standard, the PE team should refer back to the local policy's source document. If a discrepancy is uncovered, the source document should be considered the standard for the best ethics practice. This information can be located in the references to the local policy.

Figure 7. Evaluating Sources of Ethical Standards

The use of subject matter experts and ethics consultants and/or members of the leadership body may help PE teams to complete a comprehensive review of the sources of ethical standards and develop a clear understanding of the ethical standard. Additionally, the team should use caution when describing the ethical standard such that they are not:

Interpreting a standard too narrowly: For example, if a policy requires signature consent for a given procedure, it would be a mistake to assume that consent would necessarily need to be obtained on paper when, under the policy, it would also be permissible to obtain a signature electronically.

Interpreting a standard too broadly: For example, it would be a mistake to expect that every patient will be asked about advance directives upon admission to the hospital since there will be exclusions (e.g., some patients arrive unconscious).

Failing to take into account local considerations: For example, it might be a mistake to apply a standard established for a 24/7 hospital setting to a contract community-based outpatient clinic.

Adopting a standard based on common practices: For example, when no internal written standard exists, it would be a mistake to adopt a standard based only on common practices that may or may not be ethically desirable. Checking with subject matter experts in ethics can help PE teams avoid the possible trap that "because everyone is doing it, it is right."

Additional examples of highly authoritative sources would be professional codes of ethics and legal standards. In contrast, a published article expressing the opinions of one or more individuals or a policy that was developed by a particular group without a rigorous development process would not be highly authoritative sources.

If the PE team cannot find a sole source for a standard that is so authoritative that it trumps all other sources, then it is necessary to review multiple sources, and assess how authoritative they are. During this review, the team must determine if the descriptions of the ethical standards are consistent. If not, then the team may need to involve subject matter experts and/or the ethics consultation service

to clarify or interpret ethical standards. (For further information on evaluating sources of ethical standards, see Figure 7.)

In some cases, the PE team may be unable to identify a widely accepted ethical standard on which to base a description of best ethics practice. When this occurs, a novice team may be tempted to take on the task of developing a *de novo* standard. However, this is not generally advisable for three reasons: (a) establishment of a new ethical standard often requires sophisticated ethical analysis, which may be best accomplished by an ethics consultation service; (b) for complex or controversial ethics issues, standard development is best accomplished through a rigorous and inclusive deliberative process; teams are not generally set up or staffed to oversee such a process; and (c) ethical standards will need leadership authority for approval in order for an ethical standard to be established.

Therefore, when PE teams cannot identify a widely accepted ethical standard for an ethics issue, they should generally refer the issue to a decision-making body within their organization that has the authority to determine what the standard should be for the organization, and whether a written articulation of the standard (e.g., in a formal policy or executive directive) is warranted (see Figure 8).

An exception is that, in some cases, even though a particular ethical practice is not formally documented in a written standard, the ethical norms that apply to the practice are straightforward and widely accepted.

For example, if the PE team discovers that staff have expressed serious concerns about the fairness of recent resource allocation decisions, it could establish an ethical standard

Figure 8. When There Is No Appropriate Ethical Standard

Here is an example of the steps the PE team at a hypothetical facility took when it could not identify an appropriate ethical standard for an ethics issue that had been brought to its attention:

The chief medical officer asked the PE team to take a look at an ethics issue in the emergency department involving residents and medical students practicing intubation on newly deceased patients. Newly deceased patients were thought to provide a training advantage over mannequins. In a small number of deaths, the next of kin were asked whether they would provide consent for students to practice the procedure but, most of the time, consent was not obtained.

The PE team could find no institutional standards that applied to this issue, and a review of available literature showed that not all medical associations agreed that consent from the next of kin was required.

The team also contacted the ethics consultation service for help identifying and interpreting existing standards and found out that there was not a highly authoritative source for an ethical standard relating to this issue, but there were various non-authoritative sources with conflicting standards. Next, they called the local university hospital and some of its affiliates and found that practices varied, even within the same institution. The PE team called the chief medical officer to outline their findings and have leadership determine what should be the institutional practice standard. The team explained further that an institutional practice standard was required before an improvement process could be initiated.

The PE team in this situation was wise, knowing that an inclusive, deliberative process was required to develop an ethical standard for this controversial practice and that this issue needed to be referred back to leadership in order for an ethical standard to be established.

that management should communicate the reasoning behind those decisions, especially the important ones.

In these instances, the PE team, in consultation with stakeholders, may draft for review and approval by leadership its own ethical standard describing the widely accepted norm and proceed with process improvement on that basis. In the process, teams should be sure to check in with leadership and those in the institution who have ethics expertise to validate that the ethical standard coheres with both internal norms developed by the organization and applicable external norms.

Once the ethical standard is determined, the PE team is ready to draft its **operational description** of best ethics practice based on the ethical standard(s) and the specific ethics issue. A well-written description contains:

- the word should (what practice should occur);
- the action that is supposed to happen;
- the party responsible for doing or being involved in the action, if specified in the standard (e.g., done by whom or applied to whom);
- and the exclusions to the ethical standard, if any.

For example:

Nursing staff on an acute care medical floor report that they are having an increasingly difficult time persuading physicians to round on dying patients waiting to be discharged to another care setting — and that patients continue to ask when the doctor will visit and wonder why the doctor has stopped coming every day. Policy requires that all patients on the acute medical floor should be seen daily by the physician.

Tip:

In a well-crafted policy, the exclusions to the policy are specified. But because a PE team cannot be sure that written standards reflect important exclusions, it should always ask, “Are there circumstances or people to whom the practice described in this standard would not apply?”

Figure 9 displays the ethical standard source, description (with exclusions), and best ethics practice for this example. Defining circumstances and people to whom the standard does not apply will also be important when collecting data on current ethics practice. These exclusions should not be included in data collected to determine current ethics practice.

Describe current ethics practices using quantifiable information

After the best ethics practice has been operationally defined, the PE team needs to quantify current ethics practice so that the team can determine how much the current ethics practice departs from the ethical standard. Collecting baseline data that accurately describes current ethics practice is an essential step in defining the ethics quality gap. Without such data, teams will be unable to set a measurable improvement goal, let alone assess whether any changes result in improvement.

When data are collected on current ethics practice it is important to identify who or what *counts* for purposes of measurement. To do this, the PE team might start by asking, “What information should be collected to evaluate if the standard (best ethics practice) is being met?” Next, the team should fully define the denominator and numerator for the ethical practice being measured. The denominator is the population of interest for which the ethical standard applies (after patients or instances that qualify as exclusions to the standard have been removed). The numerator is the total number of cases in the population of interest that meet the standard.

Figure 9. Best Ethics Practice Example

1. Ethics Issue	2. Ethical Standard Source(s)	3. Ethical Standard Description(s) with Exclusions	4. Best Ethics Practice “Should”
Nursing staff on the acute care medical floor have reported that they are having an increasingly difficult time persuading physicians to round on dying patients waiting to be discharged to another care setting—and that patients continue to ask when the doctor will be in to visit and wonder why the doctor has stopped coming every day.	American Medical Association Statement on End-of-Life Care Facility Policy on Management of Information	Patients should be able to trust that their physician will continue to care for them when dying. If a physician must transfer the patient in order to provide quality care, that physician should make every reasonable effort to continue to visit the patient with regularity, and institutional systems should try to accommodate this. Facility policy states that patients should receive the same care by all treating providers, and patients on acute care floors should be seen daily. Exclusion(s): Patient does not wish to have his/her physician round on a daily basis.	Physicians <i>should</i> continue to round daily on dying medicine patients that are waiting to be discharged to another care setting unless [Patient does not wish to have his/her physician round on a daily basis].

For example:

The quality manager for surgical services found multiple instances in which harmful adverse events that should have been disclosed to patients were not. The denominator might be the total number of adverse events that caused harm to patients on surgical services. The numerator then is the number of adverse events that caused harm that were disclosed to patients. Say that there were 100 adverse events (denominator) and 50 of those adverse events were disclosed to patients (numerator); then current ethics practice would be 50 percent of adverse events that caused harm to patients were disclosed.

In addition to specifying the metric (i.e., numerator and denominator) that will be used to assess current ethics practice, the PE team must select appropriate data collection methods, and understand the four core elements of an effective data collection plan:

- method(s);
- sampling;

- time frame;
- and task definition and assignment.

To use resources efficiently, the team should keep data collection efforts simple and targeted, selecting measures that will provide practical, actionable information with a modest investment of time and effort. The plan does not have to entail complicated measures, demanding data collection efforts, or a large number of occurrences that would yield statistically significant conclusions. Sampling should be encouraged when a data set is large and cumbersome. Ethics practices can often be measured simply by comparing the number of occurrences of a particular practice before and after an improvement strategy has been implemented.

Data to measure baseline practice can come from a variety of sources through various methods. (See Appendix 5, Comparison Chart: Data Collection Methods.) The table in Appendix 5 presents the common data collection methods used to measure current ethics practice. No one method is better than another; they each have strengths and weaknesses. When determining which methods to use for data collection, teams have to use their best judgment in correlating those strengths and weaknesses with the particular ethics practice they aim to improve. The best data collection method is the one that provides data that best matches the practice the PE team is interested in measuring — and does so with the least amount of burden to the team. Here are some key points to consider:

- Maintain the focus on the best ethics practice (i.e., the measure must anchor to the best ethics practice).
- Keep data collection efforts simple and targeted (i.e., this is not research).
- Use sampling to provide just enough data to illustrate the current ethics practice and show improvement. (For additional guidance, see The Joint Commission's recommendations for a sampling methodology in Figure 10.)

Figure 10. The Joint Commission (TJC) Sampling Methodology¹⁶

- For a denominator of 30 or fewer, you would review all 30.
- For 30–100, you would review 30.
- For 101–500, you would review 50.
- Above 500, you would review 70.

The PE team should focus on the issue at hand and resist the temptation to turn data gathering into a larger review that explores related topics of interest. Improvement efforts stall when teams begin expanding the focus of the improvement opportunity too broadly.

Refine the improvement goal to reflect the ethics quality gap

Once the ethics quality gap is clearly described, the team's task is to integrate specific details of the ethics quality gap into a refined improvement goal that aims to narrow the gap between current and best ethics practices, and also specifies the achievable (target) improvement goal for this cycle.

To simplify the process, the team can use a formula (see Figure 11) that includes the following elements:

- the direction of change (increase or decrease by percentage or number);
- a concise statement of the ethics practice, with exclusions following the word *unless*;

Tip:

As the team defines the current ethics practice for the issue, *anchor* the operational statement for best ethics practice by posting it in the room or, if working virtually, in a shared electronic workspace.

Figure 11. Formula for Refined Improvement Goal

<hr/>	
Direction of Change (increase or decrease by % or number)	
<hr/>	
Ethics Practice*	
<hr/>	
From <hr/>	To <hr/>
Current Ethics Practice	Achievable Goal
By <hr/>	
Time Frame (quarter or more specific, if required)	
*EXCLUSIONS:	
Refined Improvement Goal:	
<i>Increase the % of</i> <hr/>	
Direction of Change (increase or decrease by % or number)	
<hr/>	
<i>Primary care patients who receive requested assistance with completing an advance directive.</i>	
Ethics Practice*	
<hr/>	
From <hr/>	To <hr/>
10% Current Ethics Practice	90% Achievable Goal
By <hr/>	
3rd quarter, 20XX Time Frame (quarter or more specific, if required)	
*EXCLUSIONS: <i>Patients who change their minds about their request for assistance, who withdraw from the health care system, or who now lack decision-making capacity.</i>	

- specification of current ethics practice expressed as a percentage or number;
- specification of achievable goal expressed as a percentage or number;
- and the time frame for the goal to be met.

For example, if the ethics issue is that patients who leave against medical advice are denied medications, and the preliminary goal was to increase the percentage of patients who receive medications after leaving against medical advice, then the refined improvement goal would be:

Increase the percentage of patients who receive medications after leaving against medical advice from 10 percent to 95 percent by third quarter fiscal year (FY) 20XX.

In this refined improvement goal, 10 percent is the baseline data for current ethics practice, 95 percent is the achievable goal, and third quarter FY 20XX is the time frame for goal attainment.

How should the PE team establish the achievable improvement goal? How much improvement over current ethics practice is expected? PE teams can ask a series of questions that will help them set an appropriate target:

- Is there a performance requirement for the ethics practice that is the focal point of improvement, such as an accreditation standard? If so, that goal should be adopted.
- Is there benchmark or comparative data available? Benchmark information can be both internal and external to the organization.
- How serious is the ethics quality gap? Can even one occurrence of the practice be tolerated? For instance, it would be intolerable to experiment on even one human subject without his or her informed consent.
- What factors in the current environment will impact goal setting? Are there constraints in the local environment or factors that might support a more robust improvement target?
- What goal might challenge the team? What amount of improvement would make the team feel proud of its efforts and want to share the accomplishment publicly? A stretch or challenge goal can counteract the tendency to “just do that much and no more.”

By the end of this step, the PE team should be able to focus on a specific improvement goal that is clearly defined, manageable, and measurable. In the example of an ethics issue involving a current ethics practice where adverse events that cause harm to patients are disclosed to patients 50 percent of the time, the policy benchmark is that all events that cause harm would be disclosed. Based on a review of literature, the benchmark in comparative institutions is between 95 and 100 percent. However, in terms of seriousness, it would be intolerable not to disclose events to patients that have caused them harm. When looking at factors that impact the goal, leadership and risk management should support disclosing adverse events that cause harm. Accordingly, an appropriate challenge goal that would make the team proud should involve meeting the benchmark. So, in this case, the achievable goal should be near 100 percent.

Step 3: Select a Strategy

With a clear understanding of the ethics quality gap, the team should next work to determine the major and contributing causes of the ethics quality gap, select those causes that contribute most to the particular gap, and identify change strategies to address them.

S

SELECT a Strategy

*Identify the major cause(s) of the ethics quality gap
Identify change strategies to address the cause(s) of the ethics quality gap
Select one or more strategies for small-scale testing*

Identify the major cause(s) of the ethics quality gap

A major cause is one believed by the expert team to *contribute most* to the ethics quality gap.¹⁷ To identify major causes, it is essential to include your process experts (i.e., those

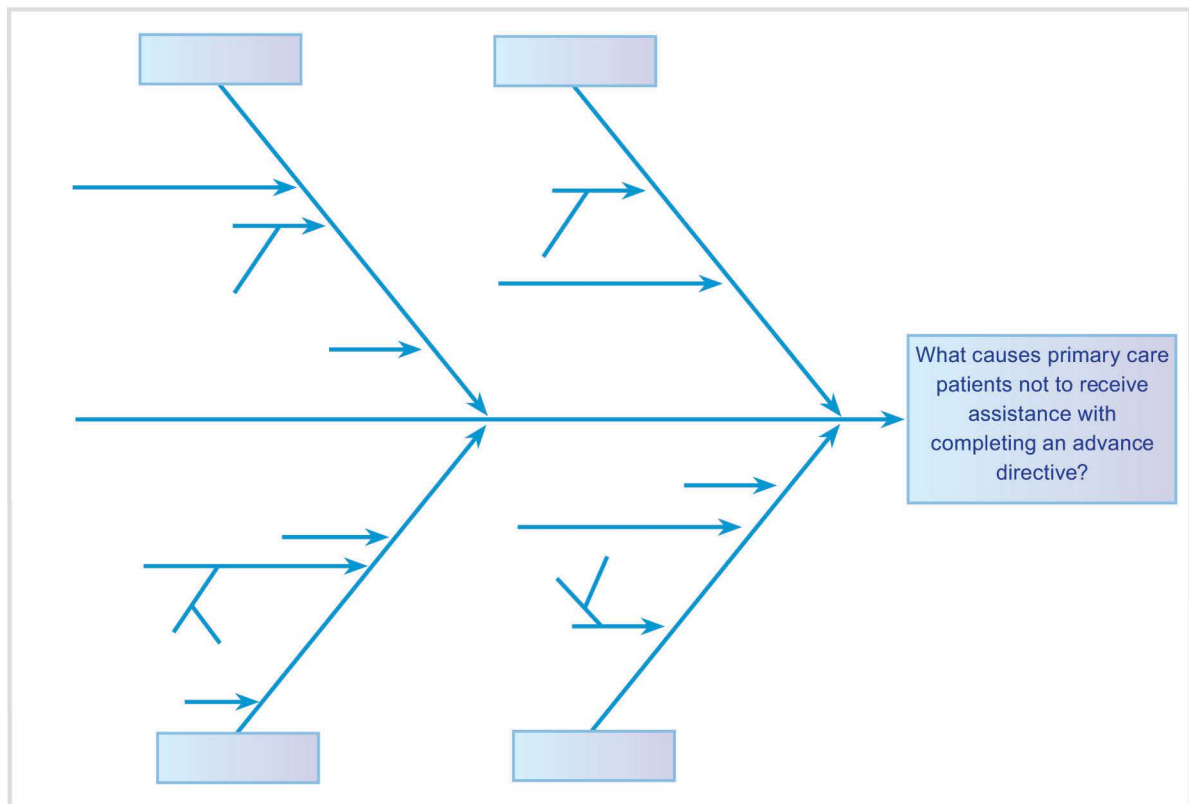
with hands-on knowledge of the processes that result in the ethics quality gap) and content experts (i.e., those with deep knowledge of the ethics issue and the ethical practice the team is aiming to improve). Often times, teams will use a cause-and-effect diagram (such as the fishbone diagram in Figure 12) to organize identified causes. The diagram allows the team to categorize similar causes on a “bone” of the fish. The head of the fish has a *cause question* to keep the team focused on the targeted ethics practice. The *cause question* begins with, “what causes...” and then can be easily derived from the description of the current ethics practice. For instance, suppose this practice is that “computers are routinely left unattended with personal health information visible on the screen.” The cause question would be, “What causes computers to be routinely left unattended with patients’ personal health information visible on the screen?”

Two useful approaches to identify major causes of an ethics quality gap are to direct the expert team to (a) brainstorm causes using the cause question and (b) review the process flow diagram for unnecessary complexity, redundancies, and places where simplification and standardization may be possible.

It’s also important to remember that most effects (ethics quality gaps) come from relatively few causes. According to the Pareto Principle,¹⁸ 80 percent of poor quality results from 20 percent of possible causes. Thus the PE team should take care to separate the “vital few” from the “trivial many”¹⁹ among possible causes of an ethics quality gap. Using the 5 Whys concept²⁰ may help the team pinpoint the vital few contributing causes versus the “trivial many.”

After the team has identified a cause, it can then ask “Why?” to see if it has determined the true root cause (see Figure 13). Although the method is called 5 *Whys*, the number of times the team asks why will vary. The intent is to ask why until reaching the root cause. When the team does this exercise with several causes, often the answers they generate will assist

Figure 12. Cause-and-Effect Diagram



in highlighting the cause that needs an improvement strategy. Other times, the team may decide to multi-vote on causes to narrow down the list and identify which cause needs to be addressed first.²¹

Identify change strategies to address the cause(s) of the ethics quality gap

Figure 13: Using the “5 Whys” to Discover the Root Cause of an Ethics Quality Gap

One of the top causes for outpatients not receiving assistance with completing an advance directive is that the requests are not being received by a social worker.

1. Why was the request not received by the social worker?

Answer: Because the unit clerk sends requests to the social work department’s general fax number.

2. Why is the request sent to the social work department’s general fax number?

Answer: Because policy indicates that is where to send the information.

3. Why does the policy indicate that all requests be sent to the social work office?

Answer: Social work coverage for primary care is through multiple social workers. There is not one specific social worker assigned to primary care.

4. Why are there not designated social workers assigned to primary care?

Answer: Workload does not support a specific designated social worker so coverage is provided when a clerk finds someone who is available.

The “root cause” of this ethics quality gap is that no specific social worker is assigned to primary care. In this example, only four whys were needed to arrive at the root cause.

Once the PE team has identified the major causes of the ethics quality gap, the team should consider which change strategies are likely to narrow the gap between best ethics practice and current ethics practice in a measurable and meaningful way. Team members should remain open to a wide range of possibilities and strive to think creatively, going beyond familiar strategies such as education and policy formation, which alone are unlikely to create sustainable change. The change strategy should address the cause of the ethics quality gap. One of the more common pitfalls in strategy selection is that the change strategy is not sufficiently related to the cause of the gap to make a difference. Consider an ethics issue where staff members with ethical concerns were not reporting their concerns so that they could be addressed. The team determined through focus groups that staff did not know about the Web reporting process despite the link for reporting being located on the home page. However, if the team pursued providing education only to service leaders, this strategy may not reach all staff. A better strategy would be to develop brochures for

use in providing routine ongoing marketing of the Web reporting process through regularly scheduled meetings such as town halls or staff meetings.

Select one or more strategies for small-scale testing

Depending on the ethics issue being addressed, the PE team may develop variable strategies, with some being relatively simple and others more complex. For example, some ethics issues can be resolved simply by refining the communication loop between one group and another, while others may require multiple strategies or a multi-faceted plan to improve the ethics practice. When the team discovers that more than one strategy will be required, multiple improvement cycles may be needed.

To determine which strategy or strategies should be selected for small-scale testing, the team should:

1. match strategy with cause,
2. assess strategy strength,
3. and then assess strategy impact/effect.

A change strategy that will result in improvement may be self-evident when matched with the cause. For example:

One issue that PE teams have addressed is that food products stored in a common refrigerator were being labeled with personally identifiable information. The identified cause was that the label maker was programmed to include the personally identifiable information. Reprogramming the label maker to not include that information was a simple and strong strategy that corresponded directly to the cause of the gap and eliminated the ethics issue.

When selecting a strategy, teams need to recognize that some strategies are much more likely than others to narrow the gap between current and best ethics practice. Some interventions are inherently stronger — or weaker — than others in terms of the probability that they will bring about sustained change in a particular practice.²¹ Weak strategies used alone are unlikely to substantially impact the ethics quality gap in the short run and most certainly will not result in sustained change. Stronger strategies tend to ensure that those involved in the practice will find it easier to “do the right thing” in the process. For instance, if a computer screen with personally identifiable information goes into sleep mode after 30 seconds of inactivity, employees will find it easier to not leave this information up on the screen since it is almost done for them. Figure 14, “Strength Levels of Change Strategies,” maps common strategies to three levels of strategy effectiveness (stronger, intermediate, weaker).²²

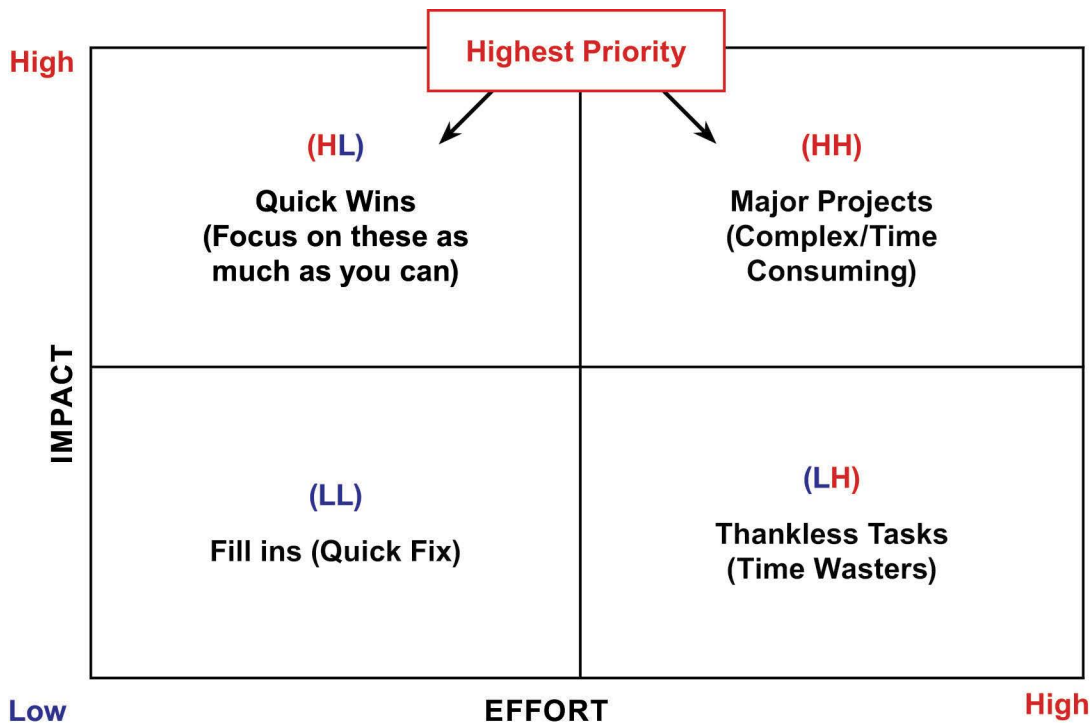
Figure 14. Strength Levels of Change Strategies

Stronger	Intermediate	Weaker
Architectural/plant changes New devices with usability testing Forcing functions Simplify the process Standardize the process Tangible involvement or action by leadership	Checklist or cognitive aid Enhanced communication Redundancy Reduce distractions Software enhancements and modifications Eliminate sameness (look alike, sound alike)	Policy development Education Double checks Warnings or warning labels Additional study or analysis

PE teams should resist the temptation to default to the usual fixes — such as an education program or new policy — without considering the full range of options available. They should always consider whether weaker strategies should be accompanied by stronger systems or process changes that are more likely to produce sustainable changes. To achieve the most impact, select intermediate or stronger change strategies whenever feasible, or combine weaker with stronger or intermediate strategies. Use the Impact/Effort Grid (Figure 15) to assess each strategy for those likely to significantly impact the identified causes of the ethics quality gap with an economy of effort.

However, PE teams should also not be overly ambitious in trying to implement several strategies at once or developing an overly comprehensive plan. Immediately undertaking modest strategies involving low effort can help to ensure that the group maintains momentum rather than becoming overwhelmed by the large scope of more complex strategies. Also, testing multiple modest strategies in a limited area before trying to complete a grand plan could incrementally improve the process over time, because these strategies may prove to be more effective than initially believed. A simple test for what might be manageable is to ask, “What can we do next Tuesday?”²³ Strategies should also be tested to minimize disruption to the organization. Those found to improve practice can be spread (as applicable) to the rest of the organization. This approach can reduce frustration the team might encounter if a larger-scale improvement strategy fails to work, and ultimately makes better use of team time and resources.²⁴

Figure 15. Impact/Effort Grid



Place each improvement strategy in the quadrant that best reflects the impact expected and the effort it would require.

Working on strategies that address multiple different causes simultaneously can be problematic. Changes made in the early stages of a process can affect future aspects of the process. If a team is working on multiple approaches, those changes could work at cross purposes, making it more difficult to determine if improvement has occurred and potentially limiting the effectiveness of each intervention. To the extent possible, teams should focus on one clearly defined strategy or a group of closely related strategies focused on a specific portion of the process.

It's also important to consider the full range of potential consequences — positive and negative, intended and unintended. Some strategies could substantially reduce the ethics

quality gap but, at the same time, create other problems that erode or even outweigh the benefits of the improvement. For example:

A strategy to require all patients to sign a form indicating that they understand their rights could increase the likelihood that patients will actually be given information about their rights, but at the same time increase the workload of clerks who must scan these documents into the medical record, and perhaps increase the backlog of other documents that must also be scanned into the system, such as release of information forms. Or efforts to prevent overbilling patients by designing a new data entry form could lead to confusion and more errors if the new form too closely resembles an existing form used for other purposes.

The PE team should further consider whether a proposed strategy may itself be ethically problematic. For example, strategies shouldn't impose disproportionate burdens on vulnerable patient populations, such as homeless patients, or on staff members who have limited ability to challenge the hierarchy, such as billing clerks or nursing assistants. For each potential strategy, teams should look for ways to ensure that those affected by the change process, patients and staff alike, are protected from potential physical, psychological, social, or financial harms. For example, data collection and analysis procedures should adhere to regulations governing patient privacy and security. Accordingly, teams should collect only the minimum amount of personally identifiable health information needed to track the change process.

Tip:

When considering each strategy, teams should discuss not only the short-term impact on those who are immediately involved, but also the potential downstream effects on other groups or processes. Whenever possible, the team should monitor such secondary effects.

Step 4: Undertake a Plan

Once the PE team has identified the most promising strategy (or set of closely related strategies) for narrowing the gap between current ethics practice and best ethics practice, the next step is to develop a specific plan for carrying out and evaluating the strategy, and then executing the plan. This means that the PE team must design and implement a small-scale test to see if the strategy successfully improves ethics quality.²⁵

U

UNDERTAKE a Plan

Plan how to carry out the small-scale test of the strategy to narrow the gap
Plan how to evaluate if the strategy narrowed the gap
Execute the small-scale test

Plan how to carry out the small-scale test of the strategy to narrow the gap

The PE team must first determine what steps are needed to design a small-scale test of the strategy and who should be involved. Small-scale testing is necessary to determine

whether the strategy results in improvement and narrows the gap between current and best ethics practice.²⁴ Typically, a testing plan should include the following:

- the question the test is designed to answer;
- where the test will occur;
- data collection methods;
- sample and number of data points to be collected;
- and who is responsible for which aspects of the small-scale test, including data analysis.

In some cases, the core team might execute the plan itself; in others, the team will need to put together a special workgroup or recruit additional individuals to perform specific tasks. Teams must identify who needs to be informed about the testing plan (e.g., frontline process owners) to ensure that people are not blindsided by changes in their area. When feasible, the team should enlist the help of frontline staff, some of whom may have already helped in prior stages of the ISSUES process.

Second, the team should identify what location will be used for testing the strategy. Teams should focus on areas that have already been involved with identifying and designing the improvement strategy as they are more likely to assist in testing the strategy. As mentioned above, completing small-scale testing will prevent large disruptions to the organization and ensure that successful improvement is possible before spreading to other areas within the organization. Because not all improvement ventures are successful, testing is important to minimize negative impacts to the organization.

Lastly, and equally important, the team must anticipate barriers to implementing the testing plan and address them head on. The team should also proactively identify staff whose support is essential for successful implementation. For example, a change process that involves social work and nursing processes will be easier to advance if social work and nursing leadership communicate their support of the test to their respective staffs.

Plan how to evaluate if the strategy narrowed the gap

Any plan for evaluating the strategy should include two types of measures: measures to assess execution (whether the strategy was executed as planned) and measures to assess effectiveness (whether the strategy narrowed the gap between current and best ethics practice — i.e., was the achievable goal met?). For example:

Say the refined improvement goal is to increase the percentage of patients who receive assistance (after requesting it) with completing an advance directive from 60 percent to 90 percent by the fourth quarter. The selected strategy to ensure that patient requests are followed up is to develop a monthly social work call schedule. The execution measure(s) could be as simple as (a) checking if a monthly call schedule was developed, (b) establishing whether there is a process for communicating the call schedule to responsible social workers, and (c) validating that the social workers received the call schedule. Clearly, if these activities are not undertaken, the strategy will not succeed — and not because the strategy is flawed but because it wasn't executed properly.

The effectiveness measure assesses whether the refined improvement goal was achieved. If, in the advance directive example, the small-scale test revealed that, following implementation of a social work call schedule, 95 percent of requests for

assistance with advance directives were followed up, results clearly suggest a highly effective strategy!

Execute the small-scale test

To execute the small-scale test, the PE team should spell out each task in detail, assign each task to a specific person, and establish explicit deadlines. Someone from the team should be appointed to oversee and monitor execution. This person should follow up to ensure that tasks are being implemented and, if the plan is not proceeding according to schedule, determine why, troubleshoot, offer advice, reassign tasks, convene a team meeting, or make other adjustments as necessary. If the team encounters barriers that they are not able to sufficiently address, it may need to elicit support from leadership.

The team should also appoint someone to monitor results in real time as the plan is executed, in case mid-course changes are needed. Ideally, this person should have experience in collecting and analyzing data through the methods proposed, whether qualitative or quantitative. Regular monitoring can help to identify whether small adjustments to the strategy are necessary or whether implementation needs to be cut short because the intervention is resulting in unintended consequences. Depending on the nature of the project, it may be necessary to make mid-course corrections daily as teams gain insight into what works (and what doesn't) and how the strategy can be perfected to better achieve the intended improvement goal.

Tip:

For many improvement projects, small-scale testing will help the team make changes in ways that are less threatening to process owners and will determine quickly if the change strategy is likely to lead to the improvement sought. If a key staff member appears resistant to change, the team should attempt to get the person's buy-in by engaging him or her in the improvement process. When they are involved in implementing change, the biggest detractors can become the staunchest supporters.

Step 5: Evaluate and Adjust

After the strategy is executed, the PE team should evaluate the execution and results, and follow up accordingly.



EVALUATE and Adjust

*Check the execution and the results of the small-scale test
Adjust as necessary
Evaluate your ISSUES process*

Check the execution and the results of the small-scale test

The PE team should review information about the execution and results to determine whether (a) the strategy succeeded in narrowing the ethics quality gap; (b) the strategy

should be made permanent and disseminated more broadly within the unit, service, or facility; and (c) whether adjustments to the strategy are needed in order to achieve the improvement goal.

Teams should ask:

- Was the strategy executed as planned? If not, why not? Did this make a difference in the results?
- Did the strategy achieve the improvement goal? Did it improve the practice as intended? Did it narrow the ethics quality gap? If not, why not?
- Is the strategy having other positive or negative effects?
- What are the next steps?

PE teams can evaluate the strategy by asking:

How much did the strategy close the gap between current ethics practice and the achievable goal?

Then members fill in the blanks with the data collected:

From _____(n/%) to _____(n/%)
(Current ethics practice) (Achievable goal)

For an overall improvement of _____(n/%)

As noted earlier, it is important to assess whether the strategy was executed as planned in order to know, when a strategy does not achieve its intended results, whether the strategy itself is faulty or if a sound strategy was executed poorly. For example, an important component of the strategy may not have proceeded according to plan because there was a breakdown in communication or a crucial member of the staff was on sick leave. In such cases, the strategy shouldn't be abandoned but rather revisited and executed according to the plan. Only then will the team be able to assess how effective it is in narrowing the ethics quality gap.

In other cases, the strategy may have been executed according to plan but did not achieve its intended effect on the ethics quality gap. For example:

To increase the number of instances where oral consent for HIV testing was documented in the medical record, one team educated providers in a primary care clinic. But the measurement showed only a slight improvement in the number of tests that were accompanied by this documentation. Upon further review, providers indicated they forgot to document the oral consent despite the training.

The strategy was weak because it did not fully address process issues. A more effective strategy would not have required providers to remember to do the documentation; rather, it would have automated or otherwise facilitated the process. And, in some cases, even when a strategy is successful in narrowing the gap, it may have unintended secondary effects that make it unacceptable. It is important for the team to consider unintended effects from improvement efforts and complete small-scale testing to evaluate all impacts of the improvement strategy. For example:

A team that was working on improving the documentation of oral consent for HIV testing was concerned that testing rates could decline due to providers' perception of documentation as an increased burden. To monitor for this

unintended consequence, the team also monitored testing rates over the course of the cycle.

Adjust as necessary

Depending on the results achieved, the PE team may decide to implement the process change permanently, modify the original strategy and conduct another test, or look at a different strategy to achieve the same improvement goal. The team would choose between the following options:

- adopt: implement strategy as is;
- adapt: modify strategy and retest;
- abandon: drop strategy;
- or another: select a different strategy to try.

If the strategy worked to narrow the ethics quality gap, the team should determine whether the improvement was sufficient to declare victory and move on. In general, if a small-scale test indicates that the strategy achieves the improvement goal or otherwise improves the process without causing adverse consequences in other parts of the system, the process change should be implemented more broadly.

Evaluate your ISSUES process

Finally, at the end of each cycle, the PE team should step back and evaluate its own performance and how the ISSUES process contributed to the aim of continuous improvement. This self-evaluation can take several forms. At a minimum, the team should complete a critical internal review by retrospectively analyzing the ISSUES cycle and systematically comparing what actually occurred against the approach suggested in this primer. Discussion should focus on lessons learned and opportunities for improvement.

Ideally, the PE team should seek input from other participants in the change process to determine how it could have been improved to better meet the needs of those experiencing the change. Feedback from supervisors or peers who were aware of the improvement effort but not directly involved can also be valuable. Presenting the results of the improvement to the IE council or other leadership groups can be a learning experience for PE team members and others alike. Such group reviews can help the team outline lessons that can be applied to future cycles as well.

PE teams that wish to further challenge themselves may want to explore opportunities to receive external peer and/or expert review. For instance, teams might arrange discussions with local quality management teams, another facility's ethics program, or a university affiliate.

Step 6: Sustain and Spread

Once it's been determined that a given strategy was successful in narrowing the ethics quality gap, work is needed to sustain the improvement, monitor results on an ongoing basis, implement the improvement more broadly, and disseminate results to leadership.



SUSTAIN and Spread

Sustain the improvement
Continue monitoring
Spread the improvement
Disseminate the improvement

Sustain the improvement

Producing lasting changes in practice can be very difficult. To increase the chances that improvements will endure, PE teams should systematically integrate process changes into standard operating procedures rather than rely on specific individuals to sustain them. For example:

If the service chief of a particular department takes another job, the process changes that were implemented during his or her tenure should continue seamlessly. If they don't, it is likely that the process was not sufficiently integrated into day-to-day operations. Sustaining improvement requires careful planning that extends beyond regular monitoring.

Continue monitoring

To support ongoing implementation of a new process, there needs to be a plan for monitoring the new process with feedback to the individuals involved. Teams need to actively plan who will monitor the process, how frequently monitoring will occur, and to whom the results will be reported. If the issue is *owned* by the PE team, the team might be involved in the ongoing monitoring but, more often, the process or content owners from the team will identify who can continue the monitoring.

Initially, the monitoring should be fairly frequent to keep the process active. Once the process has been effectively sustained for a longer period of time, monitoring can occur less often. For instance, after initially monitoring the process monthly for six months (or other appropriate amount of time), process or content owners can discuss decreasing the frequency to quarterly.

Ideally, results of monitoring should be reported to individuals involved in the process and to an entity with oversight responsibility. This oversight entity will usually include leadership that is empowered to address issues related to ongoing sustainability of the process or any unanticipated issues that may arise.

Spread the improvement

Once a given intervention has proven effective, it should be implemented more widely (e.g., across additional units, settings, facilities, networks, or the entire system). The target of dissemination will depend on the scope and boundaries of the practice, the effectiveness of the change, and an understanding of who might benefit from broader application of the change. The PE team should also recognize that groups outside its facility may find value in its findings if QI information for that topic is limited. However, as each setting has unique

features that must also be taken into account, improvements may need to be refined to enable large-scale adoption. For example:

A strategy to improve a process in primary care may not work exactly the same in a specialty care clinic. Similarly, a strategy designed for the intensive care unit might not work exactly the same in a rehabilitation setting. Accordingly, the team will need to identify issues and possibly test variations to the original strategies to meet different needs.

Spreading an improvement is not likely to be successful unless the spread is done gradually, and with careful planning. It is advisable to pilot the improvement to a slightly larger and more variable group of settings. By targeting the next testing to such groups, the team can evaluate the impact different aspects of the setting may have on the process, and determine where strategies may need to be altered slightly.

Once the pilots in the different areas have been completed, the PE team can pursue spreading to areas outside of the pilots. To complete this spread, the team should share results from the pilots to *whet the appetite* of those whom the improvement will impact in these other areas. Early adopters will need to assist in the spread of the improvement.

Disseminate the improvement

The PE team should disseminate its results to management, those involved in the improvement process, and others who could learn from the process, including those who might want to adopt the improvement in their area. The IE council is the primary forum for sharing results with facility leaders, and the team should also take advantage of available communications channels supported by the IE program to disseminate its results. It may also be valuable to share any *false starts* — efforts that didn't go far enough or that had unanticipated consequences — so that future improvement teams are aware of such possibilities. Teams may, in fact, find that interventions that were less effective elsewhere may suit the particular characteristics and circumstances of their local setting.

By sharing the improvement broadly, the PE team raises awareness of ethics issues, changes to ethics practices, and the team's QI focus. Inserting articles in newsletters, posting on websites, holding town hall-type meetings, and presenting posters at quality and other informational fairs are all ways that the team can broadcast their efforts and successes throughout the organization.

The Preventive Ethics ISSUES Summary (Appendix 6) can help with these efforts.



See <http://vaww.ethics.va.gov/integratedethics/pec.asp> or <http://www.ethics.va.gov/integratedethics/pec.asp> for the Summary template. The PE team can also demonstrate long-term results by tracking and reporting completed issues using the “Choosing Issues for PE: Tracking Tool” (Appendix 3).

Conclusion

Ethics quality is inextricably linked to quality health care. Too often, however, ethics is thought of narrowly in terms of decisions and actions by individual employees, health care teams, administrators, or other staff. This perspective overlooks how organizational systems and processes can drive practices in a way that creates ethics quality gaps. That is, by focusing narrowly on ethical concerns in particular circumstances, we fail to understand the impact of systemic issues on ethics quality in health care and, in consequence, the potential to improve ethics quality by addressing ethics issues at a systems level.

PE provides a new way to identify, prioritize, and address ethics issues on a systems level. The ISSUES approach is specifically designed to help improve those systems and processes that influence ethical practices in a health care organization that aren't adequately addressed either through traditional ethics committees or traditional quality improvement approaches.

Specifically, the ISSUES approach helps PE teams to proactively identify and prioritize ethics issues, define the ethics quality gap between current ethics practice and best ethics practice, identify the cause(s) of the gap, and develop practical strategies to narrow the gap. It follows through with systematic implementation, evaluation, and follow-up to ensure that PE activities achieve the desired results.

By offering an innovative method and practical tools to improve ethics quality, ISSUES builds on VA's experience as a leader in health care QM. Together with ethics consultation and ethical leadership (the other core functions of an IE program), PE helps promote ethical practices throughout the health care organization.

Appendix 1. Domains of Ethics in Health Care

Domains of Ethics in Health Care

Shared decision making with patients (how well the organization promotes collaborative decision making between clinicians and patients).

- Decision-making capacity (ability of the patient to make his/her own health care decisions)
- Informed consent process (providing information to the patient or surrogate, ensuring that the decision is voluntary, and documenting the decision. Note: informed consent for research should be coded under Ethical Practices in Research)
- Surrogate decision making (selection, role, and responsibilities of the person authorized to make health care decisions for the patient)
- Advance care planning (statements made by a patient with decision-making capacity regarding health care decisions in the event they lose capacity in the future)
- Limits to patient choice (questions relating to choice of care setting, choice of provider, demands for unconventional treatment, etc.)
- Other (topics about shared decision making with patients that do not fit in the categories listed above)

Ethical practices in end-of-life care (how well the organization addresses ethical aspects of caring for patients near the end of life).

- Cardiopulmonary resuscitation (CPR) (withholding or stopping resuscitation in the event of cardiopulmonary arrest, including DNAR/ DNR orders)
- Life-sustaining treatments (questions relating to the initiation, limitation, or discontinuation of artificially administered fluid or nutrition, mechanical ventilation, dialysis, surgery, antibiotics, etc.)
- Medical futility (a clinician's judgment that a therapy will be of no benefit to a patient and that it should not be offered or should be withdrawn)
- Hastening death (intentionally or unintentionally, e.g., questions relating to euthanasia, assisted suicide, or the doctrine of double effect)
- Death and post-mortem issues (determination of death, organ donation, autopsy, disposition of body or tissue, etc.)
- Other (topics about ethical practices in end-of-life care that do not fit in the categories listed above)

Ethical practices at the beginning of life (how well the organization promotes ethical practices with respect to preconception, conception, pregnancy, and the perinatal period).

- Preconception and conception (questions relating to assessment of reproductive capacity, cryobanking of sperm, ova, and embryos, fertility medications, assisted reproductive technologies, preconception sex selection, gestational surrogacy, etc.)
- Pregnancy (questions relating to genetic testing and diagnosis, the balance between the health of the mother and the fetus, forced interventions during pregnancy, etc.)
- Peri-natal period (questions relating to labor-inducing drugs, elective cesareans, extraordinary medical interventions for premature infants, peri-natal care at the threshold of viability, etc.)
- Other (topics about ethical practices at the beginning of life that do not fit in the categories listed above)

Patient privacy and confidentiality (how well the organization protects patient privacy and confidentiality).

- Privacy (protecting individuals' interests in maintaining personal space free of unwanted intrusions and in controlling data about themselves)
- Confidentiality (nondisclosure of information obtained as part of the clinician-patient relationship)
- Other (topics about patient privacy and confidentiality that do not fit in the categories listed above)

Professionalism in patient care (how well the organization fosters behavior appropriate for health care professionals).

- Conflicts of interest (situations that may compromise the clinician's fiduciary duty to patients, including inappropriate business or personal relationships. Note: financial conflicts of interest relating to the government employee's duty to the public should be coded under Ethical Practices in Government Service; conflicts of interest relating to the researcher's duty to research should be coded under Ethical Practices in Research)
- Truth telling (open and honest communication with patients, including disclosing bad news, adverse events, etc. Note: truth telling related to informed consent should be coded under Shared Decision Making with Patients; truth telling relating to leadership, human resources, or business integrity should be coded under Ethical Practices in Business and Management; truth telling relating to communications with the public should be coded under Ethical Practices in Government Service; truth telling among staff should be coded under Ethical Practices in the Everyday Workplace)
- Challenging clinical relationships (staff management of relationships with patients and/or their family and loved ones who present challenging or disruptive behaviors, requests, or demands. Note: challenging requests, demands, and choices related to treatments and procedures should be coded under Shared Decision-Making with Patients)
- Respect for diverse cultural/religious perspectives (clinician interactions with patients and/or their family and loved ones of different ethnicity, religion, sexual orientation, gender, age, etc.)
- Respect in interprofessional relationships (recognition and respect for unique cultures, values, roles, and expertise of other health care professionals; development of cooperative and trusting relationships across professionals)
- Other (topics about professionalism in patient care that do not fit in the categories listed above)

Ethical practices in resource allocation (how well the organization demonstrates fairness in allocating resources across programs, services and patients).

- Systems level/macroallocation (questions relating to fairness in allocating resources across programs and services)
- Individual level/microallocation (questions relating to fairness in allocating resources to individual patients or staff)
- Other (topics about ethical practices in resource allocation that do not fit in the categories listed above)

Ethical practices in business and management (how well the organization promotes high ethical standards in its business and management practices).

- Leadership (behaviors of leaders in support of an ethical environment and culture)
- Human resources (questions relating to the fairness of supervisory management of employees)
- Business integrity (questions relating to support for the oversight of business processes, compliance with legal and ethical standards, and promotion of business quality and integrity)
- Other (topics about ethical practices in business and management that do not fit in the categories listed above)

Ethical practices in research (how well the organization ensures that its employees follow ethical standards that apply to research practices)

- Research integrity (questions about the conduct of research and reporting of results)
- Societal value (questions about the value of research to the advancement of science and to society at large)
- Risks and benefits for human subjects research (questions about adequate protections of human subjects and the appropriate balance of risks and benefits)
- Selection of human subjects (questions about equitable recruitment and selection, including for vulnerable populations, etc.)
- Informed consent for human subjects (questions about providing information to research participants/others, ensuring that the decision is voluntary, participation incentives, approach to documentation, etc. Note: informed consent for clinical care should be coded under Shared Decision-Making)
- Privacy and confidentiality for human subjects (questions about the protection and disclosure of personal information of research subjects)
- Other (topics about ethical practices in research that do not fit in the categories listed above)

Ethical practices in the everyday workplace (how well the organization supports ethical behavior in everyday interactions in the workplace).

- Respect and dignity (employee privacy, personal safety, respect for diversity, respectful behavior toward others, etc.)
- Ethical climate (openness to ethics discussion, perceived pressure to engage in unethical conduct, etc.)
- Other (topics about ethical practices in the everyday workplace that do not fit in the categories listed above)

Ethical practices in government service (how well the organization fosters behavior appropriate for government employees).

- Government ethics rules and laws (ethics rules, regulations, policies, or standards of conduct that apply to federal government employees, e.g., bribery, nepotism, gift and travel rules)
- Other (topics about ethical practices in government service that do not fit in the category listed above)

Appendix 2. Choosing Issues for PE: Worksheet

This worksheet should be completed for each issue referred for PE. Answers should then be transferred to **Choosing Issues for PE: Tracking Tool**. Together, the worksheet and tracking tool provide a record of issues referred for PE, and can be used to explain decisions about “appropriateness” in a rational and organized manner to the ethics leadership body or other leaders.

APPROPRIATENESS FOR AN ISSUES APPROACH

1. Date that the issue came to the attention of the PE team?

2. What is the source of the issue?

3. Describe the possible ethics issue.

Provide a description of the issue: who, what, where, when, how much or how often?

► “Red Flag” Questions ◀

4. Does this issue require immediate attention or urgent action by leadership?

Does the issue involve a situation that includes, for example, risk of harm to patients or staff; wilful disregard of law or policy, intentionally unsafe acts or unaddressed personnel issues?

Yes	STOP Refer to ethics leadership body or other leaders.
No	Move to the next element for assessing appropriateness.
Unsure	STOP Assess whether immediate action is required.
Explain:	

5. Does this issue represent a simple problem with an obvious solution?

Yes	STOP This issue does not require ISSUES to improve. Just Do It!
No	Proceed to the next element for assessing appropriateness.
Explain:	

6. Other program or service responsible for this issue

Does another program or service have oversight responsibilities for the issue? Does this issue involve a clinical, business, or research process that another office “owns” or is directly responsible for?

Yes	STOP Contact the program or service that has oversight responsibility or that “owns” the process.
No	Move to the next element for assessing appropriateness.
Unsure	STOP Determine whether another program has oversight responsibilities or “owns” the process.
Explain:	

► **Best Ethics Practice** ◀

7. Is there an ethics domain related to this issue? (For a listing of the ethics domains and topics, please refer to the IntegratedEthics website at <http://www.ethics.va.gov> or <http://vaww.ethics.va.gov>)

Yes ☐ No ☐

If yes, Domain:	
If no, STOP	If the PE team cannot, at a minimum, identify an ethics domain, then the issue probably does not suggest an ethics quality gap but, rather, a technical or service gap.
Comment:	

8. Is there an Ethics Topic related to this issue?

Yes ☐ No ☐

NOTE: If your issue does not appear to fit any of the Ethics Topics listed under the Ethics Domain, designate “Other,” which is the last sub-category under each Ethics Domain, and briefly describe the topic in the space provided.

If yes, Topic:	
If no, fill in “Other”	
Comment:	

- 9. Is the PE team certain that the practice described in the ethics issue is inconsistent with prevailing ethical standards, norms, or expectations?**

Yes ☐ No ☐ Unsure ☐

Can the team identify specific and widely accepted ethical standards (e.g., policy, professional codes of ethics, accreditation standards), norms, or expectations for the practice?

Resp.	(√)	Next step
Yes		Identify or describe the ethical standard, norm, or expectation and whether the practice is inconsistent with
No		STOP The issue may not be appropriate for ISSUES
Unsure		STOP Consult with ethics program leadership or the ethics consultation service to clarify if the practice is inconsistent with ethical standards, norms, or expectations.
Explain:		

Select the standards below that are related to this issue, and cite their sources, if known.
(Choose all that apply.)

Common Sources of Ethical Standards	Check (✓)	Source of Ethical Standard (e.g., VHA Handbook 1004.01 <i>Informed Consent for Clinical Treatments and Procedures</i>)
Accreditation standards		
Consensus statements or white papers from professional societies		
Executive directives or other senior management guidance		
Organizational policies		
Precedents from case law		
Professional codes of ethics		
Statutes		
Other — describe source		

NOTE: If the PE team can identify an ethics domain and ethics topic, then the issue, at least on its face, suggests an ethics quality gap. If the team is able to identify an ethical standard that relates to the issue, the case for appropriateness is even more persuasive.

► **Current Ethics Practice** ◀

10. Is there measurable data (i.e., qualitative or quantitative information that can be counted or expressed as a number or percent) about current practice?

Resp.	(✓)	Next step
Yes		Proceed to Q. 12.
No		Proceed to Q. 11.
Unsure		STOP Determine whether data on current practice is available and then proceed to Q. 11.
<p>Explain:</p>		

11. If you don't have measurable data about current practice, is it easily collected?

Resp.	(√)	Next step
Yes		Proceed to Q. 12.
No		STOP This issue may be outside the scope of what the PE team can address.
Unsure		STOP Determine whether data about current practice can be easily collected.
Explain:		

NOTE: If data on current practice is available or easily collected, the issue can be referred for PE Prioritization.

12. Describe the preliminary improvement goal (i.e., the desired outcome of the improvement process, including the direction of change).

13. Is this issue appropriate for ISSUES?

Resp.	(√)	Next step
Yes		Proceed to prioritization of ethics issue.
No		Close feedback loop, communicate rationale to source of issue.
Unsure		Bring to the ethics leadership body.

Now you will move on to Prioritization for a PE ISSUES approach.

Prioritization for a PE ISSUES Approach

All ethics issues that were assessed as appropriate for an ISSUES approach now need to be prioritized. This portion of the handout is intended to:

1. Guide you through a systematic process for prioritization, using a rating scale of High (H), Medium (M), and Low (L)
2. Ensure that consistent criteria are applied to all ethics issues
3. Help you determine which ethics issues should be recommended to your ethics leadership body (e.g., in VHA, the IntegratedEthics Council) for approval to move forward

PE teams and ethics leadership teams may add to these criteria if something of local importance is missing.

14. Alignment with Strategic Goals

To what extent does addressing the ethics issue align with the organization's strategic goals, priorities, or initiatives, including the ethics programs?

NOTE: As a rule of thumb, strategic priorities represent values that are important to the organization, and typically, leaders support activities that advance these priorities. If you aren't sure what your organization's strategic priorities are, your organization's senior and middle managers should be able to help you identify them.

Alignment with Strategic Goals, Priorities, or Initiatives:	High / Med / Low <i>circle one</i>
Rationale for Rating:	

15. Level of Risk

What level of risk does the ethics issue pose to the organization if left unaddressed?

NOTE: Risks to the organization can take many forms including legal exposure; financial exposure; loss of reputation; and loss of trust by patients, staff, the organization's board of directors, third-party payers, or the public. In VHA, public accountability is ensured through Congress.

Level of Risk:	High / Med / Low <i>circle one</i>
Rationale for Rating:	

16. Impact on Patient and/or Employee

What level of impact will addressing the ethics issue have on patient and/or employee satisfaction?

NOTE: Prioritization should be given to resolving ethics issues that benefit patients or employees directly, thereby improving their experiences and overall satisfaction.

Level of Impact on Patient and/or Employee Satisfaction:	High / Med / Low <i>circle one</i>
Rationale for Rating:	

17. Volume or Scope of Effect

If this ethics issue is addressed, how many people, units, etc., will be impacted by the resulting quality improvements? Would you consider this scope to be high, medium, or low?

NOTE: In general, a broader scope of effect is necessary to justify a comprehensive improvement effort.

Volume/Scope of Effect:	High / Med / Low <i>circle one</i>
Rationale for Rating:	

18. Resources Required to Improve

How substantial are the resources required to improve ethics quality for this specific ethics issue? Is the anticipated outcome sufficient to justify the expenditure of resources?

NOTE: Many highly significant ethics issues can be addressed economically—and in general these are the types of ethics quality gaps PE is set up to address.

Level of Resource Required to Improve:	High / Med / Low <i>circle one</i>
Rationale for Rating:	

19. Likelihood of Success

How likely is it that the PE team can succeed in tackling this ethics issue and achieving the desired outcome within the desired time frame?

NOTE: If the PE team believes the chance of success is remote, the project should not be undertaken unless the barriers to achieving the desired outcome are removed. This may require leadership involvement to assist in removing barriers, negotiate time frames, or decide whether more resources can be brought to bear to achieve the outcome.

Likelihood of Success:	High / Med / Low <i>circle one</i>
Rationale for Rating:	

20. Refer for Ethics Leadership Approval

Should the ethics issue be referred to the ethics leadership body (e.g., in VHA, the IE Council) for approval to move forward?

Resp.	(√)	Next Step
Yes		The PE team has judged that the ethics issue is a high priority and will recommend that it be addressed using an ISSUES approach.
No		Close feedback loop, communicate rationale to source of ethics issue.
Unsure		Bring to the ethics leadership body and share concerns.

Appendix 3. Choosing Issues for PE: Tracking Tool

Choosing Issues for PE: Tracking Tool (See reverse side for brief column descriptions.)

Note: Columns 14-20 contain fillable boxes that allow you to change headings, if you wish.

Appropriateness for PE										Priority for PE ISSUES Approach										
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	
Date Issue Came to Attention of PE (mm/dd/yy)	Source of Issue (1-2 words)	Possible Ethics Issue (who, what, where, when, how much or how often)	Immediate Action Req'd (Y/N/U)	Simple Problem/Obvious Solution (Y/N)	Other Program Responsible for This Issue (Y/N/U)	Ethics Quality Gap		Ethics Topic	Practice Inconsistent with Ethical Standards, Norms, or Expectations (Y/N/U)	Data Available (Y/N/U)	If Data Unavailable, Easily Collected (Y/N/U)	Preliminary Improvement Goal	Appropriate for PE (Y/N/U)	Alignment with Strategic Goals (L/M/H)	Level of Risk (L/M/H)	Impact on Patient and/or Employee (L/M/H)	Volume of Scope or Effect (L/M/H)	Resources Req'd to Improve (L/M/H)	Likelihood of Success (L/M/H)	Refer for Ethics Leadership Approval (Y/N)
						Best Ethics Practice	Current Ethics Practice													

L=Low, M=Medium, H=High

Y= Yes; N=No; U=Unsure

Column Descriptions

1. **Date Issue Came to Attention of PE:** Enter the appropriate month, day, and year that you learned about the issue. **(mm/dd/yy)**
2. **Source of Issue:** Answers could include a member of the ethics team, as well as a service line or department leader. **(1 or 2 words)**
3. **Possible Ethics Issue:** Provide a description of details relating to the issue, including who, what, where, when, how much, or how often. **(3–5 sentences)**
4. **Immediate Action Required?:** Does the issue require immediate attention or urgent action by leadership? If Yes, STOP this assessment process and refer the issue to line management or leadership. If Unsure, assess whether immediate action is required before proceeding to the next question. **(Yes/No/Unsure)**
5. **Simple Problem/Obvious Solution:** Does this issue represent a simple problem whose solution is apparent? If Yes, STOP the assessment. The issue does not require an ISSUES approach to improve. **(Yes/No)**
6. **Other Program or Service Responsible:** Does another program or service have oversight responsibilities for the issue? If Yes, contact the appropriate program or service to determine if collaboration would be the best approach to address this issue. If Unsure, determine whether another program has oversight responsibilities or “owns” the process. **(Yes/No/Unsure)**
7. **Ethics Domain:** Refer to IntegratedEthics Website for listing of domains and topics at <http://www.ethics.va.gov> or <http://vaww.ethics.va.gov>
8. **Ethics Topic:** Refer to IntegratedEthics Website for listing of domains and topics at <http://www.ethics.va.gov> or <http://vaww.ethics.va.gov>
9. **Practice Is Inconsistent with Widely Accepted Ethical Standards, Norms, or Expectations:**
Is the PE team certain that the practice described in the ethics issue is inconsistent with prevailing ethical standards, norms, or expectations? Can you identify specific and widely accepted ethical standards (e.g., policy, professional codes of ethics, accreditation standards), norms, or expectations for the practice? Without a clear practice standard, an ISSUES approach may not be appropriate. If Unsure, consult with the ethics leadership team. **(Yes/No/Unsure)**
10. **Data Available:** Do you have measurable data about current or baseline practice i.e., qualitative or quantitative information you can count or express as a number or percentage, about your current practice? If Unsure, determine whether measurable data on current practice are available before proceeding to the next question. **(Yes/No/Unsure)**
11. **If Data Unavailable, Easily Collected:** Could you easily gather measurable data about current or baseline practice? If No, the issue may be outside the scope of what the PE team can address. If Unsure, determine whether data can be easily collected before proceeding to the next question. **(Yes/No/Unsure)**
12. **Preliminary Improvement Goal:** Describe the desired outcome of the improvement process (e.g., increase disclosure of adverse events that cause harm to patients or personal representative).
13. **Appropriate for PE:** If you can develop a preliminary improvement goal based on answers for questions 7–11, then answer yes to 13 and proceed to prioritization. If Unsure, bring the issue to leadership. **(Yes/No/Unsure)**
14. **Alignment with Strategic Goals:** To what extent does addressing the ethics issue align with the organization’s and ethics program’s strategic priorities? **(Low/Medium/High)**
15. **Level of Risk:** What level of risk does the ethics issue pose to the organization if left unaddressed? **(Low/Medium/High)**

16. **Impact on Patient and/or Employee:** What level of impact will addressing the ethics issue have on patient and/or employee satisfaction? (**Low/Medium/High**)
17. **Volume or Scope of Effect:** If this ethics issue is addressed, how many people, units, etc., will be impacted by the resulting improvement in ethics quality? (**Low/Medium/High**)
18. **Resources and Time Required to Improve:** How substantial are the resources and time required to improve ethics quality for this specific ethics issue? Is the anticipated outcome sufficient to justify this expenditure? (**Low/Medium/High**)
19. **Likelihood of Success:** How likely is it that the PE team can succeed in tackling the ethics issue and achieving the desired outcome? (**Low/Medium/High**)
20. **Refer to Leadership Body:** Should the issue be referred to leadership for final approval? If Unsure, bring to the leadership body. (**Yes/No/Unsure**)

Appendix 4. Applying Prioritization Criteria to Each Ethics Issue: Worksheet

1. In the chart that follows, rate each ethics issue “low,” “medium,” or “high,” or “yes,” “no,” or “unsure” with respect to the 7 prioritization criteria.
2. Based on the ratings, give each issue an overall prioritization ranking in the Final Rankings chart at the end of the handout, with “1” for the highest priority down to “5” for the lowest priority. Use your best judgment to balance the ratings. For example, if an issue receives high ratings on most criteria but a low rating for required resources, it could still be ranked as a high priority.

This process (and completed chart) will be useful in choosing the top two issues to recommend to the ethics leadership body for carrying forward in an ISSUES approach, and for helping leadership understand why these ethics issues are being recommended.

* L = low; M = medium; H = high

3	14	15	16	17	18	19	20	21
Possible Ethics Issue (who, what, where, when, how much, or how often)	Alignment with Strategic Goals (L/M/H)*	Level of Risk (L/M/H)	Impact on Patient and/ Employee (L/M/H)	Volume or Scope of Ef- fect (L/M/H)	Resources Req'd to Im- prove (L/M/H)	Likelihood of Success (L/M/H)	Time Sensitive (Y/N)	Refer for Leadership Approval (Y/N)
	To what extent does addressing the ethics issue align with the organization's strategic goals, priorities, or ini- tiatives, including those of the local or regional ethics programs? NOTE: Strategic priorities repre- sent values that are important to the organization and, typically, leaders support activities that advance these priorities.	What level of risk does the ethics issue pose to the or- ganization if left unaddressed? NOTE: Risks to the organization can take many forms including legal exposure; financial expo- sure; loss of reputation; and loss of trust by patients, staff, the organiza- tion's board of directors, third- party payers, or the public.	What level of impact will addressing the ethics issue have on patient and/ employee satisfaction? NOTE: Priori- tization should be given to resolving ethics issues that ben- efit patients or employees di- rectly, thereby improving their experiences and overall satisfaction.	If this ethics issue is ad- dressed, how many people, units, etc., will be impacted by the result- ing quality improvements? Would you consider this scope to be high, medium, or low? NOTE: In gen- eral, a broader scope of effect is necessary to justify a comprehensive improvement effort.	How substantial are the resources required to improve ethics quality for this specific ethics issue? Is the an- ticipated outcome sufficient to justify the expenditure of resources? NOTE: Many highly significant ethics issues can be addressed ec- onomically—and in general these are the types of ethics quality gaps PE is set up to address.	How likely is it that the PE team can succeed in tackling this ethics issue and achieving the desired outcome? NOTE: If the PE team believes the chance of suc- cess is remote, the project should not be undertaken unless the bar- riers to achiev- ing the desired outcome are removed.	Is this is- sue time sensitive, i.e., does it have a deadline? NOTE: Pri- ority should be given to those items with a specific end date that is within the next 12 months.	Should the issue be referred to leadership for final approval to move forward? If Unsure, bring to the leader- ship body.
EI#1: There have been long-standing complaints from inpatient nursing staff that do-not-resuscitate (DNR) orders written by medical residents are not reviewed and signed off on by the attending physician within 24 hours—thus allowing the DNR order to expire. Nursing staff noted that if a code was called on a patient whose DNR order expired, staff could inadver- tently attempt to resuscitate a patient who did not wish to be resuscitated.	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	Y/N: Rationale:	Y/N: Rationale:

3	14	15	16	17	18	19	20	21
Possible Ethics Issue (who, what, where, when, how much, or how often)	Alignment with Strategic Goals (L/M/H)*	Level of Risk (L/M/H)	Impact on Patient and/ Employee (L/M/H)	Volume or Scope of Effect (L/M/H)	Resources Req'd to Improve (L/M/H)	Likelihood of Success (L/M/H)	Time Sensitive (Y/N)	Refer for Leadership Approval (Y/N)
EI #2: A recent accreditation review of primary care health records found that only a few patient requests for assistance with completing an advance directive were followed up on by clinic staff.	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	Y/N: Rationale:	Y/N: Rationale:
EI #3: Informed consent for endoscopy procedures are being obtained from patients after they are "gowned, placed on a gurney, and with sedating drugs on board."	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	Y/N: Rationale:	Y/N: Rationale:
EI #4: The quality manager for surgical services found a number of instances where adverse events that have caused harm that should have been disclosed to patients or personal representatives were not disclosed.	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	Y/N: Rationale:	Y/N: Rationale:

3	14	15	16	17	18	19	20	21
Possible Ethics Issue (who, what, where, when, how much, or how often)	Alignment with Strategic Goals (L/M/H)*	Level of Risk (L/M/H)	Impact on Patient and/or Employee (L/M/H)	Volume or Scope of Effect (L/M/H)	Resources Req'd to Improve (L/M/H)	Likelihood of Success (L/M/H)	Time Sensitive (Y/N)	Refer for Leadership Approval (Y/N)
EI #5: A chart review found that patients discharged from the institution against medical advice (AMA) were frequently discharged without prescriptions or follow-up clinic appointments, and previously scheduled appointments were automatically cancelled. An informal punitive culture towards AMA patients among attending and resident physicians reinforced and sustained this practice despite patient and staff complaints.	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	L/M/H: Rationale:	Y/N: Rationale:	Y/N: Rationale:

Final Rankings

Ethics Issue	1-5**
EI #1: DNR Orders Not Reviewed Within 24 Hours	
EI #2: Advance Directives	
EI #3: Informed Consent	
EI #4: Adverse Events Not Disclosed	
EI #5: Discharged Patients with Little Follow-Up	
** Ethics issues that are ranked #1 and #2 will be recommended to the ethics leadership body for approval.	

Appendix 5. Comparison Chart: Data Collection Methods

Method	Strengths (+)	Weaknesses (-)
Existing Data (Health or other record)	<ul style="list-style-type: none"> + Available + Inexpensive + Metric already determined + Commonly used in health care + Most health care staff are experienced in finding and extracting data from health record 	<ul style="list-style-type: none"> - Sometimes off the mark (collected for a different purpose) - Uncertainty about representativeness of data - Variability in the consistency of clinicians' documentation in medical records - Data depends on reliable documentation process
Observations	<ul style="list-style-type: none"> + Direct measurement + Objective + Able to obtain qualitative information after observation period + Contextualized + Most health care staff already experienced in "observing" 	<ul style="list-style-type: none"> - Time limited (possible problems with representativeness) - Hawthorne effect (social desirability) - Requires development of "observations checklist" to define what observers will be looking for - Possible reliability problems if more than one observer
Interviews: Telephone	<ul style="list-style-type: none"> + Able to obtain a large sample + Able to obtain complete data + Able to ask about personal information, i.e., knowledge of respondent 	<ul style="list-style-type: none"> - Requires development of a set of interview questions and probes - Possible barriers due to language and/or hearing challenges - Hawthorne effect (social desirability bias) - Training requirements for interviewer(s)
Interviews: Face-to-face	<ul style="list-style-type: none"> + Able to collect complete data + Knowledge of respondent + Controlled environment + Good response rate 	<ul style="list-style-type: none"> - Hawthorne effect (social desirability bias) - Training requirements for interviewer(s) - Challenge with sensitive questions
Focus Groups (6-8 individuals)	<ul style="list-style-type: none"> + Obtains brush stroke information + Affirms/refutes ideas easily + Synergy (new ideas) may occur in the group process 	<ul style="list-style-type: none"> - Obtains brush stroke information - May not be representative - Need skilled facilitator - Role, levels of authority, gender, etc., may affect openness - Threats include domination of air time, side-tracking

Method	Strengths (+)	Weaknesses (-)
Surveys: Mail	<ul style="list-style-type: none"> + Standardized + Able to obtain data from a large number of respondents + No need for interviewers + Convenient for respondents + Allows for anonymity with sensitive questions 	<ul style="list-style-type: none"> - Needs cognitive testing to minimize the risk of participants misinterpreting the meaning of the questions - Fear about lack of confidentiality - Lower response rates may threaten representativeness - Risk of incomplete data - Reading and language barriers - Uncertainty about who is responding - Respondent may consult other sources (e.g., Internet, colleagues) before responding; however, this may not be a bad thing if you are looking for facts, not opinions which sometimes may be required
Surveys: Internet	<ul style="list-style-type: none"> + Able to obtain data on large numbers of respondents + No need for interviewers + Less expensive + Convenient for respondents + Speedy + Able to have automated data entry and results reporting (e.g., aggregated statistics) 	<ul style="list-style-type: none"> - Needs cognitive testing to minimize the risk of participants misinterpreting the meaning of the questions - Non-response bias - Often requires knowledge of the Web - Requires computer literacy - Barriers may exist pertaining to language and physical disabilities - Respondent may consult other sources (e.g., Internet, colleagues) before responding; however, this may not be a bad thing if you are looking for facts, not opinions

Appendix 6. Example: Preventive Ethics ISSUES Summary

Preventive Ethics (PE) ISSUES Summary

Directions: The purpose of PE ISSUES summary tool is to provide a concise snapshot of a completed ISSUES cycle. One tool should be completed for each completed PE ISSUES cycle. Full descriptions for each element and example provided at end of the form.

VISN number _____ Facility number and name _____ FY Completed _____

Point of contact (email or phone) _____

Domain _____ Shared Decision Making _____ Topic _____ Advance Care Planning _____ Source of Issue _____ Accreditation Review _____

Element	Description
1 Ethics Issue Provide a description of the details relating to the issue, including who, what, where, when, how much or how often	A recent accreditation review of primary care health records found that only a few patient requests for assistance with completing an advance directive were followed up on by clinic staff.
2 Ethical Standard Source List the widely accepted sources of ethical standard(s) that describe the ethical practice that ought to be happening, i.e., what people <i>should</i> be doing.	VHA Handbook 1004.2 <i>Advance Care Planning and Management of Advance Directives</i>

	Element	Description
3	Ethical Standard Description Describe the ethical standard, including any exclusions to the standard. To describe the ethical standard, provide the section of the standard that describes (or at least approximates) what the expected practice or behavior <i>should</i> be.	VHA Handbook states that additional information about advance directives and/or assistance in completing the forms must be provided for all patients who request this service. Exclusions: Patients who change their minds about their requests for assistance, who withdraw from the health care system, or who now lack decision-making capacity.
4	Best Ethics Practice “Should” Draft an operational definition of best ethics practice based on the ethical standard(s) and the specific ethics issue	Primary care patients who request assistance with completing an advance directive <i>should</i> receive it [unless patients change their minds about their requests for assistance, withdraw from the health care system, or now lack decision-making capacity].
5	Current Ethics Practice Metric Describe the numerator and denominator for this issue.	Numerator: The number of primary care patients provided with assistance as measured by a completed note template Denominator: Total number of primary care patients who requested assistance with completing an advance directive

	Element	Description
6	Current Ethics Practice “is” Results of the data collection defined in the metric and a summary statement that provides how often a practice is occurring. XX% of (practice that is the focus).	Current ethics practice was determined based on a review of 30 primary care patient health records. Currently, 10% of primary care patients who have a documented request for assistance with completing an advance directive receive it.
7	Refined Improvement Goal Using the formula for writing an effective improvement goal.	<u>Increase/Decrease (n or %)</u> of primary care patients who receive requested assistance with completing an advance directive. From <u>30%</u> to <u>90%</u> by <u>Q4, 20XX</u> . (Date) (Current ethics practice) (Achievable Goal) (Ethics practice)
8	Strategies to Address Major Cause of EQG For each of the one to three major causes, list the strategies that are most likely to eliminate or modify that cause and contribute to improved practice.	Major Cause <u>Lack of clarity in consult process within Social Work</u> Strategies <u>Develop coverage schedule for primary care clinics</u> Major Cause <u>Variation in information provided to patient</u> Strategies <u>Develop training tools for all staff to use with patients and/or families</u>

Element	Description
9	<p>Measurable Results Using the metric defined under current ethics practice, show how much the strategy closed the gap between current ethics practice and the achievable goal listed in the refined improvement goal.</p> <p>Results from a small test of changing in the Orange clinic showed an increased % of patients who received requested assistance with completing an advance directive to 94% by Q4 20XX.</p> <p>Was goal met? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Will another cycle be pursued for this issue? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p>
10	<p>Sustain and/or Spread Indicate how often the improvement will be monitored. If spreading the improvement, specify where and when the strategy will be spread.</p> <p>Monitoring Daily <input type="checkbox"/> Weekly <input checked="" type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Annually <input type="checkbox"/> Who <input type="checkbox"/></p> <p>Spread (facility or VISN) Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>N/A – goal not met <input type="checkbox"/></p>

1. **Ethics Issue:** Provide a description of the details relating to the issue, including who, what, where, when, how much or how often. **Example:** A recent accreditation review of primary health records found that only a few patient requests for assistance with completing an advance directive were followed up on by clinic staff.
2. **Ethical Standard Source:** List the widely accepted sources of ethical standard(s) that describe the ethical practice that *ought* to be happening, i.e., what people *should* be doing. Types of ethical standards include: statutes, laws or regulations, precedents from case law, accreditation standards, institutional policies, executive directives or other senior management guidance, consensus statements or white papers from professional societies, codes of ethics, widely accepted ethical norm or other (please provide document source). **Example:** VHA Handbook 1004.2 *Advance Care Planning and Management of Advance Directives*.
3. **Ethical Standard Description:** Describe the ethical standard, including any exclusions to the standard. To describe the ethical standard, provide the section of the standard that describes (or at least approximates) what the expected practice or behavior *should* be. By exclusions, we mean situations or groups of individuals to whom the standard does not apply. **Example:** VHA Handbook states that additional information about advance directives and/or assistance in completing the forms must be provided for all patients who request this service. Exclusions include: patients who change their mind about their requests for assistance, withdraw from the health care system or who now lack decision-making capacity.
4. **Best Ethics Practice “Should”:** Draft an operational definition of best ethics practice based on the ethical standard(s) and the specific ethics issue. Base statement on standard description, exclusions and details of the ethics issue. A well written best ethics practice statement includes 1) the word *should*, 2) the specific practice that *should* occur, 3) describes who is responsible for the practice (done by whom), 4) describes to whom the practice applies, and, includes the word unless, followed by the identified exclusions. **Example:** Primary care patients who request assistance with completing an advance directive *should* receive it [unless the patient changes their mind about their requests for assistance, withdraw from the health care system or who now lack decision-making capacity].
5. **Current Ethics Practice Metric:** Describe the numerator and denominator for this issue. The denominator describes the population of interest which is based on the ethical standard and exclusions to the standard as applied to the specific ethics issue. The numerator describes the number of cases or instances within our population of interest that meet the standard. **Example:** Numerator = the number of primary care patients provided with assistance as measured by a note template completed by a social worker or someone equally trained. Denominator = total number of primary care patients [minus exclusions] who requested assistance with completing an advance directive.
6. **Current Ethics Practice “Is”:** Results of the data collection defined in the metric and a summary statement that provides how often a practice is occurring. XX% of (practice that is the focus). **Example:** 3/30 or 10%. 10% of primary care patients who had a documented request for assistance with completing an advance directive received it.
7. **Refined Improvement Goal:** Using the formula for writing an effective improvement goal. Increase or decrease the number or percent of (insert ethical practice) from (insert current ethics practice) number or percent to achievable goal number or percent by time frame (insert quarter and FY or month and FY). **Example:** Increase the % of primary care patients who receive requested assistance with completing an advance directive from 10% to 90% by Q4, FYXX.
8. **Strategies to Address top 2-3 Major Causes of the Ethic Quality Gap (EQG):** For each of the one to three major causes, list the strategies that are most likely to eliminate or modify that cause and contribute to improved practice. **Example:** One cause of primary care patients not receiving assistance with completing advance directives is that no one is assigned to provide that assistance. One strategy to address that cause is to identify which clinical staff will be responsible for responding to patient requests.
9. **Results:** Using the metric defined under current ethics practice, show how much the strategy closed the gap between current ethics practice and the achievable goal listed in the refined improvement goal. **Example:** Strategy improved % of primary care patients who received assistance with completing an advance directive from 10% to 96%. Overall improvement of 86%.
10. **Sustain and Spread:** Indicate how often the improvement will be monitored. If spreading the improvement, specify where and when the strategy will be spread.

Appendix 7. Example: Ethics Issues Addressed Using Preventive Ethics

Here are three more examples of ethics issues that have been addressed using the ISSUES approach. For easier viewing and to conserve space, the results are presented in columns that correspond to each section of the preventive ethics ISSUES Summary tool.

DOMAIN: Professionalism in Patient Care — Truth Telling								
1. Ethics Issue	2. Ethical Standard Source(s)	3. Ethical Standard Description(s) with Exclusions	4. Best Ethics Practice "Should"	5. Metric	6. Current Ethics Practice "Is"	7. Refined Improvement Goal	8. Strategies to Address Major Causes of EQG	9. Measurable Results
The quality manager for surgical services found a number of instances in which adverse events that should have been disclosed to patients or personal representatives were not disclosed.	VHA Handbook 2008-002 <i>Disclosure of Adverse Events to Patients</i>	Patients or personal representatives must be informed of the occurrence of any adverse event that has resulted in harm to the patient. Exclusion(s): Patient is deceased, incapacitated, or otherwise unable to take part in the process, and there is no personal representative.	Adverse events that cause harm to patients on surgical services <i>should</i> be disclosed to the patient or personal representative.	Numerator: Number of adverse events that caused harm to patients that were disclosed to patients or personal representatives Denominator: Total number of adverse events that caused harm to patients on surgical services Method: Review of patient health records Sample size: 100% Time frame: Past 6 months	Current practice was determined by identifying all adverse events that caused harm to patients on surgical services over the past 6 months through a review of incident reports. The health records of these patients were reviewed for a disclosure note. Currently, 65% of adverse events that cause harm to patients on surgical services are being disclosed to patients or personal representatives.	Increase the % of adverse events that cause harm to patients on surgical services that are disclosed to the patient or personal representative from 65% to 95% by Q4, 20XX.	Cause: There is not a mechanism to alert Risk Management (RM) about potential and actual harm events. Strategy: Developed automatic notification to RM Cause: Staff are not aware of template Strategy: Staff education	The % of adverse events that cause harm to patients on surgical services that were disclosed to the patient or personal representative improved from 65% to 98%.

DOMAIN: Ethical Practices in End-of-Life Care — Other								
1. Ethics Issue	2. Ethical Standard Source(s)	3. Ethical Standard Description(s) with Exclusions	4. Best Ethics Practice “Should”	5. Metric	6. Current Ethics Practice “Is”	7. Refined Improvement Goal	8. Strategies to Address Major Causes of EQG	9. Measurable Results
Nursing staff on the medical floor have reported that they are having an increasingly difficult time persuading physicians to round on dying patients waiting to be discharged to another care setting — and that patients continue to ask when the doctor will be in to visit and wonder why the doctor has stopped coming every day.	American Medical Association Statement on End-of-Life Care Medical Staff By-laws and Rules	Patients should be able to trust that their physician will continue to care for them when dying. If a physician must transfer the patient in order to provide quality care, that physician should make every reasonable effort to continue to visit the patient with regularity until transfer occurs, and institutional systems should try to accommodate this. Bylaws state that patients should receive the same care by all treating providers, and patients should be seen daily. Exclusion(s): Patients who do not wish to have their physician round on a daily basis.	Physicians <i>should</i> continue to round daily on dying medicine patients that are waiting to be discharged to another care setting.	Numerator: Number of dying patients who were visited daily by a physician while waiting to be discharged to another care setting Denominator: Total number of dying patients waiting to be discharged to another care setting Method: Observation Sample size: 20 patients Time frame for data collection: 5 days	Current practice was determined by a retrospective health record review of 5 medicine patients per physician awaiting discharge to another care setting. Currently, 30% of physicians round on dying patients at least once per day while the patient is waiting to be discharged to another care setting.	Increase the number of physicians who round on dying patients on a daily basis from 3 to 10 by Q4, 20XX.	Cause: No mechanism to relay information on transfer status of transfer patients to physicians Strategy: Revised daily huddle agenda items to include discussion of transfer patients and expected time of transfer Cause: Lack of awareness regarding changes in daily huddle agenda Strategy: Staff education	The number of physicians who round on dying patients on a daily basis improved from 3 to 10.

DOMAIN: Integrated Ethics Program—Integrated Ethics Structure and Processes								
1. Ethics Issue	2. Ethical Standard Source(s)	3. Ethical Standard Description(s) with Exclusions	4. Best Ethics Practice “Should”	5. Metric	6. Current Ethics Practice “Is”	7. Refined Improvement Goal	8. Strategies to Address Major Causes of EQG	9. Measurable Results
The ethics consultation service’s annual report found that none of its consultations were about ethical concerns affecting non-clinical staff.	Integrated Ethics Program Requirements	Just as Integrated Ethics addresses all three levels of ethics quality, it also deals with the full range of ethical concerns (e.g., clinical, business and organizational ethics concerns) that commonly arise in health care — not just clinical concerns.	Ethics consultation should address ethical concerns affecting non-clinical staff.	Number of ethical concerns affecting non-clinical staff referred to the consultation service Numerator: Number of consultations affecting non-clinical staff Denominator: Number of consultations Method: Pull data from ECWeb repository of all consultations requested Sample size: 100% of consultations Time frame for data collection: Quarterly	0/10 consultations affected non-clinical staff over the last year.	Increase the number of ethical concerns referred to the consultation service that affect non-clinical staff from 0% to 20% by Q4, 20XX.	Cause: Non-clinical staff unable to locate Web-based link to request a consultation Strategies: • Relocated Web-based tool link to facility’s homepage to make it easier to locate • Trained and certified service chiefs in the use of the Web-based tool • Developed an electronic guide, including screenshots, on the consultation referral process for use by service chiefs and staff • Provided training to non-clinical staff in use of the Web-based tool through staff meetings	Increased the number of ethical concerns referred to the consultation service that affect non-clinical staff from 0% to 28%.

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Achievable goal: A specific improvement goal for an ISSUES cycle that is clearly defined, manageable, and measurable, taking into account the following: (a) performance requirements for the ethics practice, (b) benchmark or comparative data, (c) seriousness of the gap, (d) environmental factors, and (e) team capacity and motivation to handle stretch goals.

Best ethics practice: An ideal practice established on the basis of widely accepted standards, norms, or expectations for the organization and its staff.

Cause-and-effect diagram: A tool for systematically analyzing a process and the factors that contribute to it; one example is a “fishbone” diagram.

Current ethics practice: How a process or practice is actually being carried out in real-world settings, which may deviate from best ethics practice. A key step in the ISSUES approach is to quantify current ethics practice so it can be used as a baseline against which to compare the impact of subsequent improvement efforts.

Decision-making capacity: Ability of the patient to make his or her own health care decisions. Clinical determination of decision-making capacity should be made by an appropriately trained health care practitioner.

Ethical leadership: Activities on the part of leaders to foster an environment and culture that support ethical practices throughout the organization. These include demonstrating that ethics is a priority, communicating clear expectations for ethical practice, practicing ethical decision making, and supporting a facility’s local ethics program.

Ethical practices in health care: Decisions or actions that are consistent with widely accepted ethics standards, norms, or expectations for a health care organization and its staff. *Note that in this context, “ethical” conveys a value judgment—i.e., that a practice is good or desirable;* often, however, “ethical” is used simply to mean “of or relating to ethics,” as in the phrase “ethical analysis” referring to analysis that uses ethical principles or theories.

Ethics: The discipline that considers what is right or what should be done in the face of uncertainty or conflict about values. Ethics involves making reflective judgments about the optimal decision or action among ethically justifiable options.

Ethics consultation in health care: The activities performed by an individual or group on behalf of a health care organization to help patients, providers, and/or other parties resolve *ethical concerns* in a health care setting. These activities typically involve consulting about active clinical cases (ethics case consultation), but also include analyzing prior clinical case or hypothetical scenarios, reviewing documents from an ethics perspective, clarifying ethics-related policy, and/or responding to ethical concerns in other contexts not immediately related to patient care. Ethics consultation may be performed by an individual ethics consultant, a team of ethics consultants, or an ethics committee.

Ethics consultation service: A mechanism in a health care organization that performs ethics consultation and manages ethics consultation-related activities.

Ethics issue: An ethics quality gap that results from poorly performing, unreliable, or ill-defined systems and processes that can arise anywhere in a health care organization. Ethics issues tend to be complex, and typically require study to accurately describe the current workflow process, ethics quality gap, and underlying causes of the gap.

Ethics quality: Practices throughout the organization are consistent with widely accepted standards, norms, or expectations for a health care organization and its staff. Ethics quality encompasses individual and organizational practices at the level of decisions and actions, systems and processes, and environment and culture.

Ethics quality gap: The difference between what *is* (current ethics practice) versus what *ought to be* (best ethics practice). When *current ethics practice* deviates from *best ethics practice*, a measurable *ethics quality gap* results.

Focus group: A research methodology that employs facilitator-led discussions to elicit opinions and responses about a defined subject or issue from a small group of participants representative of a broader population.

IntegratedEthics advisory board: Ethics leadership body that implements IE across a region and supports the regional director's oversight of IE deployment and integration throughout all facilities in the region.⁸

IntegratedEthics council: Facility-level ethics leadership body that includes leaders from key offices and programs across the facility, including coordinators of the three core IE functions (ethics consultation, preventive ethics, and ethical leadership), to coordinate ethics-related activities across the organization. Examples of responsibilities include establishing and monitoring preventive ethics performance and quality improvement goals; ensuring facility readiness regarding ethics-related accreditation standards, policies, and procedures; reviewing and participating in the development of ethics-related policies; and coordinating ethics-related activities throughout the facility.

IntegratedEthics Facility Workbook: A self-report instrument used to assess the structures and functions of a facility's IE program and determine the extent to which it is comprehensive, systematic, broadly deployed, and integrated. The tool identifies strengths and opportunities for improvement.¹³

IntegratedEthics program: A local mechanism in a health care organization that improves ethics quality at the levels of decisions and actions, systems and processes, and environment and culture through three core functions: *ethics consultation*, *preventive ethics*, and *ethical leadership*.

IntegratedEthics Staff Survey: A tool to assess employees' perceptions of ethical practices and ethics culture.¹⁴

ISSUES approach: A systematic, step-by-step process developed by VA's National Center for Ethics in Health Care for reducing *ethics quality gaps*.

Key informants: Representatives of groups affected by a particular issue, or individuals who have specialized knowledge of the issue or are likely to be involved in implementing improvement strategies for that issue.

National Center for Ethics in Health Care (NCEHC): VA's authoritative resource for addressing complex ethics issues that arise in patient care, health care management, and research. NCEHC developed and launched the IE program in 2007 as a comprehensive approach to managing ethics in health care organizations. NCEHC's websites include information about the IE program: <http://vaww.ethics.va.gov/integratedethics/pec.asp> (accessible only within the VA firewall) or <http://www.ethics.va.gov/integratedethics/pec.asp> (external website).

Preventive ethics: Activities performed by an individual or group on behalf of a health care organization to identify, prioritize, and address systemic *ethics quality gaps*.

Preventive ethics coordinator: Manages and maintains an active preventive ethics function. Responsibilities include working with the IE council on prioritizing ethics issues, making recommendations for assignment of individuals to the core preventive ethics team, recruiting staff who possess specific content or process expertise to work on ISSUES cycles; managing the preventive ethics log of ethics issues, and selecting and addressing ethics quality gaps using the ISSUES approach.

Preventive ethics team: Individuals assigned to address identified systemic ethics quality gaps.

Preliminary improvement goal: A general statement of the desired outcome of the improvement and, if possible, a direction of change developed after an ethics issue has been identified but before the ethics quality gap has been fully quantified. Helps the preventive ethics team focus more narrowly and define the issue in more manageable and measurable terms.

Process flow diagram: A visual representation of the actual flow or sequence of events in a process that any product or service follows.²⁶



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