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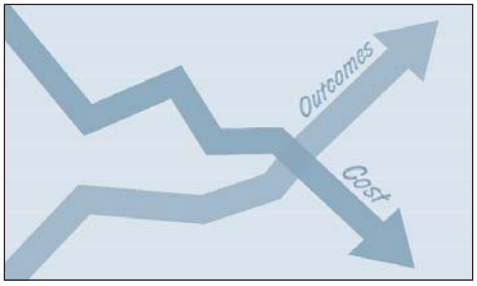

Innovation Series 2010

Reducing Costs Through the Appropriate Use of Specialty Services

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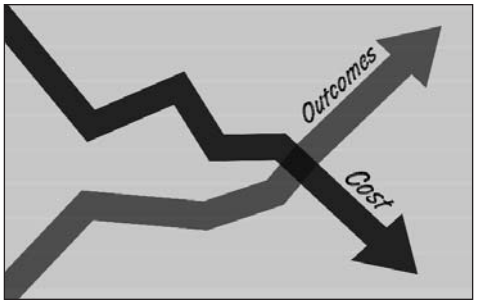

Innovation Series 2010

Reducing Costs Through the Appropriate Use of Specialty Services

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Executive Summary

For more than 20 years, evolving research has demonstrated overuse, misuse, and underuse of clinical services in American health care.[1,2] It has been estimated that by correcting these deviations from optimal care as much as 30 percent of health care costs, or approximately $700 billion, could be eliminated without reducing quality.[2] The latter stipulation is crucial: done appropriately, cutting such costs would not be arbitrary but guided by clinical knowledge into areas where reductions in costs would maintain or improve quality. Fewer patients would be exposed unnecessarily to risk of harms. In this sense, costs become an indicator for potential areas of clinical "mismatch" of services, or "overuse."[3]

Eliminating this overuse offers a huge potential opportunity to help in the pursuit of universal coverage without rationing health care.[4] Methods for such reductions already exist in the US health care system, since certain regions of the country have demonstrably lower costs with the same or even higher quality than high-cost regions.[1,2] However, despite knowledge of variation in practice since at least 1938, progress in addressing it has been slow and costs continue to escalate.[5]

This white paper describes efforts by the Institute for Healthcare Improvement (IHI) to find ways to reduce overuse, with a focus on specialty services, a significant source of expense in the US health care system. Examples of success in identifying and reducing overuse without apparent negative impact on quality, and without using techniques experienced as coercive by physicians, are explored. Given the plethora of specialties and procedures, the object of IHI's work in this area has been to identify approaches that could be applied across many specialties, procedures, and types of organizations.

Several major themes emerged from these explorations:

- Most physicians are driven by doing what is right for the patient and are not aware of possible overuse in their own practices.
- Patterns of overuse generally develop where there is medical uncertainty due to lack of definitive scientific evidence for standards.
- In successful efforts to reduce overuse, physicians are engaged as the experts and as partners in identifying and interpreting variation data without prejudgment of the meaning of high or low utilization or focusing on outliers (e.g., high utilizers).
- Despite medical uncertainty, there are multiple examples of the emergence of consensus standards for subgroups of patients from physician discussions about variation which result in substantial reductions in utilization. Explicit local development or adaptation of standards appears to be important for sustainable reductions in utilization.
- Payment incentives that drive utilization are a barrier, but not necessarily a make-or-break determinant of whether specific areas of overuse in specialty care can be addressed successfully. Both fee-for-service and salaried physicians have participated in successful efforts to reduce overuse. A major determinant of success is choosing a clinical topic area for intervention (e.g., low pack pain or post-menopausal bleeding), as a result of taking into consideration multiple driving forces and barriers when addressing potential areas of overuse.

Based on these major themes, IHI developed a framework to address overuse in specialty services. The framework includes approaches that will be familiar to those who develop and implement protocols, guidelines, and standards.[6,7,8,9] The framework focuses on developing standards within the context of a broader, overall priority of changing professional culture to recognize and address overuse. Clinical areas in which there is overuse generally lack definitive evidence, strong consensus, or answers about the "right" level of utilization.[10] In this context, we do not believe that telling physicians what will be worked on, when, and how will work very well. Consequently, the major emphasis is on collaborative engagement with physicians and other key stakeholders in the choice of clinical topic areas, and then on testing whether standard development will be feasible and lead to meaningful clinical and financial results. Testing keeps commitments provisional until the readiness of the culture for change, the scope of change relative to costs of execution, and other factors can be assessed.

The IHI Framework for Appropriate Use of Specialty Services has six steps:

Step 1. Opportunity Search and Engagement of Physicians, Patients, and Key Stakeholders
Step 2. Define a Standard (Consensus Criteria)
Step 3. Discernment
Step 4. Evaluation of Discernment
Step 5. Additional Interventions
Step 6. Execution (Implement Standards)

The key elements of the framework include the following:

- Identify opportunities for reducing overuse locally, based on local driving and restraining forces, to determine what is clinically and financially feasible and meaningful.
- Use variation data to engage physicians in positive inquiry about practice and to prioritize specific opportunities for reducing overuse, in contradistinction to creating an environment of needing to justify decisions.
- After selecting an opportunity, develop standards locally with an emphasis on consensus identification of one or more subgroups of patients for which application of a standard of care is feasible and practical ("usual patient streams"), as opposed to patient subgroups that require customization of care ("special patient streams").
- Through prospectively testing the standard, determine the willingness and ability of physicians to apply it. Estimate the volume of the "usual patient stream" to predict the benefits of implementation. Information from testing, including lack of sufficient volume, may lead to revision of the standard or a shift to another area of opportunity.
- Engage physicians and all stakeholders in the care system in process improvement to achieve sustainable change.

These steps constitute a *theory* of what will work to reduce certain patterns of overuse in specialty services. The framework requires proactive and intentional testing. It does not explicitly define a design and sequence of changes to address all the dimensions of overuse such as patient expectations, patient engagement in decision making, payment incentives, medical-legal issues, etc., that will be needed for broader, comprehensive change. This does not mean these additional issues are ignored; they must be taken into consideration and addressed appropriately. However, the goal of the framework is to achieve cultural change by carefully selecting improvements and standards that will work best in local circumstances. Selective, smaller-scale efforts to reduce overuse can still result in meaningful reductions in cost and improvement of the clinical value of care, and will prepare the local culture for broader changes in the future.

Background

This white paper describes a framework to enhance the appropriate use of specialty services, which is currently being tested. The initial intention is to focus on opportunities for reducing "overuse" of specialty services. Overuse is defined as clinical care that appears to be excessively utilized given the known tradeoffs between its costs plus potential harms versus the potential benefits. In contrast, "underuse" is the failure to provide a service when benefits clearly outweigh potential harms, and "misuse" is care that is inappropriate or leads to preventable harms.[1,2]

Overuse has huge impact in our health care system. In the US, it is estimated that as much as 30 percent of health care costs, or approximately $700 billion, could be eliminated without reducing quality.[2] Both the National Priorities Partnership (NPP) of the National Quality Forum and the New England Health Institute (NEHI) have systematically reviewed and prioritized areas of overuse.[1,2] Some of the specialty procedures, but not all, that might be a focus of a local improvement effort are in the NPP list under the headings "unwarranted diagnostic procedures" (e.g., lumbar spine magnetic resonance imaging prior to conservative therapy [without red flags], cardiac computed tomography, and endoscopy) and "unwarranted procedures" (e.g., spine surgery, knee or hip replacement, and hysterectomy).

The Institute for Healthcare Improvement (IHI) has developed a framework for the appropriate use of specialty services through consultations with multiple experts and organizations. Not surprisingly, terms such as "overuse" and "unwarranted" were often perceived quite negatively, especially by physicians. Physicians may feel that they are blamed for ordering tests for financial gain. However, among those consulted, there was widespread agreement that, except in a few egregious examples, physicians make choices about interventions with the best interests of the patient in mind. There was also widespread agreement that payment incentives such as fee-for-service are a strong driver of overutilization. How can these observations be reconciled: that physicians act with integrity, that there is a significant amount of overuse of specialty services, and that payment incentives are a strong influence?

For more than 20 years, research on variation in physician practice has suggested the answers. Recently, this research has moved to the forefront of the national debate on health care reform, partly thanks to Dr. Atul Gawande's article in *The New Yorker,* "The Cost Conundrum."[11] It is reputed that President Obama made this article required reading in his Administration.[12]

Dr. Gawande describes his investigation of medical care in two cities in Texas located a few hundred miles apart, one with $14,834 per year of expense per Medicare patient and the other with $7,901 per year, based on 2006 data. Similar expense data has been determined for Medicare patients by *The Dartmouth Atlas* for 306 Hospital Referral Regions across the US.[13] Variations in costs are quite large across regions in the country. However, as with the two cities in Texas, higher spending regions do not necessarily have better quality of care and may even have worse quality than lower-spending regions.[14,15] High utilization is not predominantly explained by differences in illness rates, patient preferences, fees, or other population factors.[14,15] What this means is that "geography is destiny"[16] — the same patient with the same symptoms is more likely to receive a potentially unnecessary, inappropriate, or non-productive intervention, depending on *where* the care occurs.

How can such wide variation in utilization develop, even in the context of similar payment incentives such as fee-for-service? Part of the explanation has to do with evidence. In those areas of clinical medicine supported by strong evidence, the more common gap in care is underuse.[10] Examples are the prescription of beta-blockers after myocardial infarction and mammography for women 50 to 69 years of age. The development and implementation of evidence-based guidelines has been a key method for addressing underuse.[17]

In contrast, while not true for every procedure, it appears that overuse generally occurs for procedures not supported by strong evidence.[1,2,10] There are no "right" answers about the optimal indications or the "right" level of utilization for such procedures.[18] This inherent uncertainty leads to variation and vulnerability to additional local influences, which move thresholds for intervention lower. Such influences include how a physician was trained, local supply of services, payment incentives, medical-legal concerns, patient expectations for services, whether a medical practice owns its own diagnostic equipment, primary care patterns of ordering diagnostic tests, and primary care referral rates to specialists.[10]

Patient values and preferences are also a key factor in overuse in "preference-sensitive" procedures, where tradeoffs between benefits and risks are not clear cut and only the patient can determine what is most preferred.[10] Examples include back surgery, hysterectomy, or knee and hip replacement. Multiple studies have shown significant gaps in patient involvement in decision making in both primary and specialty care.[19,20] In randomized controlled trials, specially designed decision aids for patients have been shown to improve patient knowledge and involvement in decisions, and to reduce the utilization of several major elective surgeries.[21,22] However, integration of patients' values and preferences in decisions and use of decision aids have not spread rapidly.[5] Involving patients in

medical decisions is a change in practice culture from the traditional reliance on physician opinion to determine medical necessity.[22,23]

For the most part, physicians are unaware of overuse in their own practices or the factors that lead to it. Assumptions are that science drives application of criteria for interventions and that physicians practice similarly to each other. "In the end," as Dr. David Eddy has stated, "given all the uncertainties, incentives, and heuristics....if it is admitted that the uncertainty surrounding the use of a procedure is great, and that there is no way to identify for certain what is best or to prove that any particular action is right or wrong..." then physicians will do what feels safest and most comfortable. A physician who follows what appears to be accepted based on training or the way others practice is safe from criticism. The result is significant regional variation in medical practice.[24]

Examples of Reducing Costs Through the Appropriate Use of Specialty Services

Given the plethora of interacting causes and the underlying skewed financial incentives, fixing the problem of overuse is complex. In July 2009, the Institute for Healthcare Improvement and its partner organizations invited health care leaders from a select group of high-performing regions of the US, as identified using *Dartmouth Atlas* data and defined criteria, to share their experiences at a gathering in Washington, DC. Called *How Do They Do That?™ Low-Cost, High-Quality Health Care in America,* the meeting brought together teams from ten high-performing regions to explore openly the local, regional, and national factors — including culture, financing, infrastructures, and more — that contribute to their ability to deliver high-quality care at lower cost.[12]

Four key ingredients in the high-performing regions are leadership, altering financial incentives, measurement and feedback, and engagement of communities. A prominent overarching finding was that "culture" matters: lower-spending communities develop a culture of collaboration and restraint which provides a "force" against the damaging tendencies of the health care system. The pathways to changing community culture, organizational culture, and professional culture remain to be defined.[25]

As IHI scanned the literature and talked with organizations to identify examples of reduced costs through the appropriate use of specialty services, we did not find what we believed were definitive conclusions, based on strong evidence, about one best approach to improvement. We did, however, recognize that changing professional culture was at the core of the approach. Lacking a clear implementation design, IHI developed a theory of what will work to reduce overuse in specialty services by identifying the most promising change ideas from case examples and the literature, and by incorporating improvement methodology to implement these changes. The resulting framework includes a sequence of steps to guide intervention. The framework is a *theory* of the elements needed to reduce costs through the appropriate use of specialty services. The framework is not based on one particular specialty or procedure or organizational structure or context.

As a theory, the framework needs to be tested and refined based on shared learning. IHI continues to seek input from experts and organizations as to the relevance and power of the ideas. What we know without a doubt is that there are some powerful ideas in the framework. We also know that elements of the framework very likely will need revision. Shared learning through applying a common sequence of steps will more quickly advance our knowledge.

The three selected case examples that follow, one from the literature and two from IHI's direct explorations with organizations, are examples of successful interventions that encouraged us to pursue development of a framework for reducing costs through appropriate use of specialty services in the face of barriers such as lack of payment reform.

There are multiple such examples and they are not new. For instance, in the late 1960s, Dr. John Wennberg discovered that the rate of tonsillectomies in children age 15 and younger in the town of Middlebury, Vermont, was 7 percent while in Morrisville, just two hours away, the rate was 70 percent, without any apparent differences in the populations. After Dr. Wennberg reviewed the data with the Morrisville physicians, this group introduced a system for obtaining second opinions and reduced tonsillectomies by two-thirds over five years.[26]

Palo Alto Medical Foundation

The Palo Alto Medical Foundation, headquartered in Palo Alto, California, is a multicenter, multidisciplinary group practice with 850 primary care physicians and specialists covering 250,000 to 300,000 patients, 70 percent of whom are preferred provider organization (PPO) or fee-for-service and 30 percent of whom are capitated. They have established a method for engaging specialists in a process of inquiry about variation in their data for costs in specified subgroups of patients and use of procedures. The Foundation approaches the physicians as the experts and avoids labeling data as "good" or "bad." Some specialty groups have responded quickly — for example, the ear, nose, and throat (ENT) physicians in one group created consensus "best practice" criteria for the use of nasal endoscopy for chronic sinusitis and saved $250,000 within eight months. After eight months, there was still considerable variation in utilization across providers, but nearly all had achieved some reduction in utilization.

Maine Medical Assessment Foundation[18]

Through the support of the Maine Medical Assessment Foundation, a study group of specialists in obstetrics and gynecology in the state of Maine was brought together to examine variation data on hysterectomies in the state. One hospital service area had a rate of 67 percent of women reaching age 65 who had received hysterectomies, while another had a rate of 33 percent. After discussion of the implications and meaning of the data, the group decided that higher rates were likely not appropriate. The Foundation disseminated the data and findings through the state. Within eight years, the rate

of hysterectomies in the high-utilization areas dropped to nearly the state average, which was close to 33 percent.

HealthPartners

HealthPartners, headquartered in Minneapolis, Minnesota, is the largest consumer-governed, nonprofit health care organization in the nation, providing care, coverage, research, and education to 1.25 million members and caring for over 500,000 patients in their HealthPartners care delivery system, which includes 70 clinics and three hospitals. They experienced growth in high-technology diagnostic imaging (e.g., CT, MRI, and PET scans) that was approaching 20 percent per year. Through a collaborative process that involved the Institute for Clinical Systems Integration (ICSI) and others in the Minneapolis community, they incorporated appropriateness criteria for radiologic tests into the electronic medical record as a reminder to primary care doctors. Doctors refer to the criteria at the time of decision making, but they are not prevented from ordering any imaging test. The growth of high-end imaging has dramatically slowed, from 20 percent to a flat rate.

The IHI Framework for Appropriate Use of Specialty Services

The IHI Framework for Appropriate Use of Specialty Services has six steps, described in detail below:

Step 1. Opportunity Search and Engagement of Physicians, Patients, and Key Stakeholders
Step 2. Define a Standard (Consensus Criteria)
Step 3. Discernment
Step 4. Evaluation of Discernment
Step 5. Additional Interventions
Step 6. Execution (Implement Standards)

Principles and Assumptions about the Framework

Change Professional Practice Culture

Development of the framework resulted in a primary focus on changing professional practice culture through the engagement of physicians in developing and implementing practice standards. The framework derives partly from known principles and methods of guideline or protocol development.[6,7,8,9,17] Changing professional culture includes nonjudgmental styles of engagement, choosing the right opportunities based on local circumstances, surfacing and questioning underlying assumptions about practice, and providing mechanisms to test changes.

The framework is not meant as a comprehensive pathway for changing health care that explicitly defines a design and sequence to address such issues as payment incentives, engaging patients and families in decision making, use of decision aids, and other important considerations. But this does not mean that the framework ignores these issues. They have to be taken into consideration and addressed appropriately when choosing opportunities and implementing interventions to reduce overuse and cost. The goal of the framework is to achieve cultural change by carefully selecting improvements and standards that will work best in local circumstances. Selective, smaller-scale efforts to reduce overuse can still result in meaningful reductions in cost and improvement of the clinical value of care, and will prepare the local culture for broader changes in the future.

An equally important approach to developing standards for physicians is to increase patient involvement in decision making through use of patient decision aids that improve shared decision making. Such decision aids are specially developed tools to enhance decision quality through clarifying patient values and preferences. Randomized controlled trials have demonstrated that use of such aids increases patient knowledge and participation in decisions, and reduces utilization of procedures without impacting quality.[21] Use of decision aids takes time, equipment, funds, and staffing; the optimal support and training required for their effective use are not yet well defined.[21,22,23] Shared decision making itself is a significant cultural change for physicians. To help define the best pathway for integration of decision aids into care, multiple organizations are systematically testing methods of implementation.[27,28]

Both enhancing the appropriateness of physician decision making and engaging patients in decisions are keys to reducing overuse. The best pathways for each approach have not yet been defined, and it is unclear if it is most efficient to test changes simultaneously in each area or in sequence. Currently, we have observed that approaches (i.e., simultaneous or sequential development) vary depending on local culture and resources for improvement. While emphasizing appropriateness criteria or standards for physicians, the framework also reference ways to ensure appropriate engagement of patients.

Use a Sequential Testing Approach

We recommend testing changes in a specific area by proceeding through the steps in the framework with a relatively small group of patients, physicians, and locations for a defined time period (e.g., one to three physicians in two practices, for a series of patients, over six weeks). The physicians involved are ideally those "early adopters" who were engaged in standard development. At the same time, communication with the broader group of physicians needs to be transparent and appropriately integrated as the work proceeds. Such a testing approach should help determine the willingness and ability of physicians to define and apply a standard for a subgroup of patients and predict the impact of the changes prior to devoting resources for full implementation. Testing on a small scale also allows refinement of the changes before spreading improvements more widely.

Engage Multiple Disciplines

The framework currently places considerable emphasis on physicians because physicians still exert major control over the use of specialty resources; however, this reality in no way diminishes the importance of engaging other clinical and administrative team members. Successful improvement requires teamwork and participation by multiple disciplines.

Consider Organizational Size and Configuration

The framework was not designed with a specific organizational configuration or size in mind; ideally, it will be tested in a large variety of settings. It is difficult to predict how specific barriers in the local context might affect application of the framework. For example, large organizations might have more infrastructure to support change; however, large size could also make it harder to gain consensus around standards.

Integrate the Science of Improvement

The framework needs to be applied in conjunction with the basic principles of quality improvement, including using and learning from sequential small tests of change; applying the principles of change management; and implementing the principles of sustainability and spread.[29]

Steps in the Framework

Step 1. Opportunity Search and Engagement of Physicians, Patients, and Key Stakeholders

Components

- Search for and prioritize opportunities for reducing high or escalating costs while maintaining or improving quality, reducing exposure to risk of harms, and sustaining or improving health outcomes.
- Choose a clinical topic area that will be the focus of your improvement efforts and determine a key point in the pathway of care for applying a standard.
- Engage physicians through nonjudgmental, collaborative dialogue to interpret variation data.
- Engage patients and additional key stakeholders (e.g., health plans, payers, financial officers) for input and decision making at each step of the framework.

Example

An administrator of clinical delivery services in a multidisciplinary group practice that includes both fee-for-service and managed care (i.e., capitated) patients reviews internal data and finds escalating utilization of CT and MRI scans, particularly for low back pain. The administrator shares this information with the medical director of the physician group, who is also a primary care physician.

The medical director agrees that more focused investigation of CT and MRI utilization in the practice offers a potentially large opportunity to reduce costs and unnecessary exposure to radiation. They decide to focus on both the large volume of ordering in primary care and the use of imaging in orthopedic surgery. The medical director approaches the orthopedic surgery department head, who agrees that variation across many different tests and procedures in that department exists and needs to be understood. A specific focus on use of imaging in patients with back pain is a relatively uncontroversial place to start. The medical director engages six primary care physicians in her practice group, and the team begins to test the framework.

Background and Additional Guidance

Define and Choose Opportunities

Costs are an important indicator for prioritizing opportunities to reduce overuse of specialty services. Using costs as a driver to reduce overuse is particularly important because specific quality indicators such as primary or intermediate health outcomes are generally hard to come by in areas of overuse. At the same time, physician judgment about the likely areas of overuse needs to be integrated with cost and variation data.

When costs are prominently involved, change management can be difficult. Past experiences of arbitrary cost cutting can create negative perceptions of improvement initiatives. Organizations addressing overuse of specialty services often describe initiatives in terms of their clinical value, cost effectiveness, or appropriateness. Costs, appropriateness, quality, and patient experience outcomes are part of a value "equation."

The various payment incentives are a factor for choosing a successful focus for improvement, but this factor is not a make-or-break determinant of success. Reductions in costs have been successfully achieved in fee-for-service situations. Also, even organizations with primarily capitated financing and salaried physicians experience escalating utilization, as well as variation across practices.[30]

Thus, reducing overuse of specialty services requires the consideration of multiple factors, including the state of relationships with all key stakeholders, the structure and relationships within local practices, data and information technology resources, the presence of physician opinion leaders, the likelihood of achieving consensus criteria, and prior experience in reducing overuse of services. Considering all of these factors related to feasibility and scope of potential impact helps prioritize opportunities for reducing potential overuse.

For example, in IHI's explorations in this area, more than one organization mentioned that focusing on cardiac diagnostic imaging in a community dominated by private cardiology practices that have their own CT and MRI scanners would not be a fruitful place to begin addressing the appropriate use of such services because the barriers were too significant. Examples of clinical

topic areas where physician buy-in, consensus standards, and reductions have seemed more readily achieved despite payment barriers include use of nasal endoscopy by ENT specialists in chronic sinusitis, arthroscopy by orthopedic surgeons in shoulder bursitis, diagnostic imaging by primary care in acute low back pain, or hysterosocopy by obstetricians-gynecologists in post-menopausal bleeding.

Determining the key points at which physicians make decisions about whether or not to use a specific procedure can help focus improvement efforts for reducing potential overuse in primary or specialty care. For example, a standard might be applied for referral of patients with a given condition to a specialty service, to primary care decisions about patients' direct use of specialty services such as imaging, and/or to use of procedures by specialists themselves. Another possible approach is to develop the multiple standards, measures, and processes that are needed to cover an entire pathway of care (e.g., the diagnosis, adjunctive medical treatment, intervention, and follow-up in percutaneous coronary interventions).[31]

Use Multiple Data Sources to Identify Opportunities

Organizations can use multiple methods to identify areas of high or escalating cost and high variation, including episode treatment group methodologies,[32] per capita cost analysis, *Dartmouth Atlas* data, and health plan and internal data. Episode treatment group methods, which are currently proprietary, use algorithmic techniques combined with electronic data to aggregate costs from the beginning to end of episodes of care for patients with similar conditions.[32] Areas of high cost can then be identified. The absence of such analytic tools does not appear to be a significant handicap because an organization can determine costs according to diagnostic groups and drill down into its billing data. The emphasis is to use all billing data and not just subsegments, such as capitated or Medicare patients only, to identify specialty services in which there may be potential overuse.

Clinical judgment is just as important as cost in order to avoid arbitrary cost cutting. Organizations will need to refer to the scientific literature as well as internal and external experience to identify, from a clinical perspective, specialty services with high utilization and/or high or escalating costs that may need closer investigation for potential overuse.

Use Variation Data and Collaborative Dialogue to Engage Physicians

Engaging physicians in a collaborative dialogue using data on practice variation is at the heart of addressing the appropriate use of specialty services. Variation data call into question assumptions about practice, such as the assumption that all physicians practice similarly. Conversations with physicians are most effective when they are engaged as the experts to understand what the variation might mean. Variation data should be presented without prejudgment of high or low utilization. The main goal is to change practice culture — to generate sufficient question about current

practice to lead to agreement by the physicians to test the development and application of a standard of care. The goal is not to focus on outliers or justify levels of utilization for each physician. Such conversations typically require a series of meetings. Physicians will question data and ask for further analysis. Those organizations IHI talked with found that variation in practice remains, no matter how data is analyzed.

Consider Developing Criteria for Prioritizing Opportunity Areas

Such criteria could include:

- Measurability
- Scope of impact (e.g., population size, clinical outcomes, financial)
- Potential to reduce unnecessary harms to patients
- Ease of implementation
- Availability of local physician opinion leaders
- Ease of establishing a consensus standard in a subgroup of patients

Consider Ways to Engage Patients

- Invite selected patients to participate in the improvement work as part of the key stakeholder group.
- Test changes (e.g., a standard that is developed) with patients to ascertain their understanding and buy-in.
- Obtain the patient perspective through use of surveys, case stories, and interviews.
- Map the patient journey.[33]
- Integrate decisions aids into the pathway of care.

Key Questions to Answer in This Step

- How will you display variation data and create a nonjudgmental environment in order to engage physicians?
- When and how will you involve each of the key stakeholders, including patients?
- How will you know you have enough engagement to move forward?
- What is the added value and purpose of each iteration of additional data analysis?
- What will be the size and scope of initial testing (i.e., how many physicians in which practices and for what patients, and how many standards)?

Step 2. Define a Standard (Consensus Criteria)

Components

- Define the elements to consider in developing a consensus decision on a standard or criteria.
- Guide the stakeholders to consensus, starting with patient subgroups for which clinical care needs are similar and relatively predictable, and for which standardization is likely to be practical. These are "usual patient streams" as opposed to "special patient streams," which have less predictable, more unique needs that require customization of care.
- Design additional support for clinical decision making as needed (see Step 5. Additional Interventions below).
- Document explicitly the evidence, opinions, and projected outcomes that were considered in creating the standard. Set a date for updating the standard.

Example

The administrator, medical director, and orthopedic surgeon review the available guidelines and selected literature on use of imaging in patients with back pain. While they do not find definitive criteria for when to do imaging, they decide that most physicians agree that imaging studies could be delayed for at least a month after presentation, provided the patient showed no signs of systemic or neurologic disease. The medical director seeks input from five colleagues and the orthopedic surgeon also gets input from five colleagues, and they achieve agreement on a standard. The primary care group feels that they need the support of patient educational materials to meet patient demands for imaging. They create a one-page brochure with the assistance of several members of the orthopedic surgery and radiology staff, as well as from nursing staff representatives from those specialties. Three patients who come into the primary care clinic for back pain are asked to review the brochure and give feedback, which leads to revisions.

Background and Additional Guidance

In IHI's experience, the clinical literature on addressing overuse and our interviews with organizations did not always explicitly identify whether or how physicians were involved in developing a standard. This can leave the impression that use of peer awareness and peer pressure through sharing utilization data alone can be effective in reducing overuse. We found a few organizations that share variation data as the primary, if not sole, approach in addressing overuse.

More commonly, we found that a consensus standard along with a variety of implementation methods were elements of sustainable reductions of overuse. For example, Maine Medical Assessment Foundation found that "while…feedback and peer pressure can strongly influence the behavior of physicians, we also learned that when consensus cannot be reached, variations recur."[34] Also, using one method of practice change such as audit and feedback in isolation has not been found as effective as the use of multifaceted approaches, including guideline development, academic detailing,

reminders and alerts embedded into the process of care, etc.[8,17] As a result, the IHI Framework for Appropriate Use of Specialty Services encourages development of a standard along with additional strategies for execution to ensure the standard is applied at the time of decision making.

A detailed discussion of the development of consensus standards is beyond the scope of this paper. Professional societies have published appropriateness of care criteria that can be useful when developing standards. However, the predominant lack of definitive evidence,[35] concern about bias on guidelines panels, and other barriers[17,36] make it difficult to depend solely on criteria developed external to the organization that is creating the standard. Local adaptation may be necessary. In such circumstances, inclusion of multiple outcomes from different stakeholder viewpoints (e.g., costs, benefits, risk of harms, patient experience) in standards development can help balance important concerns.[37] Ultimately, if aforementioned barriers can be overcome in the future, national standards would be helpful in reducing burdens of development locally and perhaps reduce variation regionally.

Certain technical aspects of creating standards need to be considered such as:

- Consulting guideline and evidence-grading manuals and resources to determine the approach that will be used.[7,8,9,38,39,40]
- Basing the standard on consideration of multiple outcomes, including estimates of clinical, utilization, patient experience, and cost impact, wherever feasible.[37]
- Integrating the viewpoints of key stakeholders (e.g., payers, health plans, patients).
- Finding and engaging physician opinion leaders who are aligned with the framework approach to help assess the issues and facilitate development of a reasonable standard based on the state of the science and prevailing opinion within a given local specialty.

Examples of standards agreed upon locally include:

- Back pain: Delay imaging for one month in uncomplicated acute low back pain.
- Post-menopausal bleeding (PMB): Women with spontaneous PMB should not receive hysteroscopy until after primary evaluation with endometrial biopsy or transvaginal sonography (TVS) to measure the thickness of the endometrial echo complex (EEC).

Elements to guide reaching consensus on a standard include:

- Scientific evidence and expert opinion on the benefits and harms
- Guidelines or criteria developed by professional societies or other organizations
- Cost reduction potential
- Incentives
- Patient perspectives
- The “usual patient stream” can be identified by consensus
- Feasibility and costs of implementation

Key Questions to Answer in This Step

- How will it be determined if objections to proposed standards raised by physicians are reasonable and based on evidence?
- From which key stakeholders is it vital to get input and buy-in?
- How will you determine patient, nursing, and other staff reactions to the standard?
- Can the physicians and stakeholders define a subgroup of patients ("usual patient stream") for whom a standard is feasible and practical to apply?
- Is the volume of the "usual patient stream" likely to be large enough to justify expenditure of resources for broader implementation?
- Will additional interventions be necessary?

Step 3. Discernment

Components

- Discernment refers to the physician's decision about whether or not a standard applies to an individual patient.
- The doctor will refer to the standard at the time of decision making (discernment) and determine "yes" or "no" (i.e., does the standard apply?). There is no pressure to have a certain volume of "yes" or "no" answers — that is, there is no pressure to avoid utilization of a given procedure. Adding documentation of the rationale for "no" responses can provide valuable information for improvement, as long as the goal is learning and not judgment or pressuring physicians to make a particular decision.
- Determine if support is needed to make discernment easy to remember and document (e.g., progress note template with the standard written at the top and a check box for "yes" or "no"). At this stage, such implementation design is *temporary* in order to evaluate the application of the standard in Step 4 (Evaluation of Discernment). In the last step of the framework (Step 6. Execution), permanent implementation design is established.

Example

The six primary care physicians agree to test the standard with patients presenting with back pain for the next six weeks. They decide to develop a temporary special progress note form. The administrator will ensure that all exam rooms have copies of this form. The orthopedic surgeon (the opinion leader) and another colleague test the standard with their patients during the same time period.

Background and Additional Guidance

Many practicing physicians are likely to be familiar with external requirements to document when a patient is not getting a core recommended intervention or is receiving an intervention despite a standard that advises against it. Documentation of the rationale when a physician decides the standard does not apply is not required as part of the framework, and documentation may be viewed negatively and might interfere with the testing standard. However, payment and measurement for external purposes may require documentation and it can be useful in the event of litigation claiming that a physician did not follow the standard of care. Organizations should use their own judgment to determine whether or not it is desirable to document the rationale for "no" responses, based on local culture and requirements.

Key Questions to Answer in This Step

- Has any defensiveness or resistance to using the standard surfaced among the physicians?
- Do other members of the clinical team need to be involved to make this standard work?
- Should the response of patients to application of the standard be tested?
- What will be the expected volume of patients for whom the standard might be applied and over what time period? Will this be practical for measurement during testing?
- How will the physicians remember or be prompted to determine if the standard applies when needed?

Step 4. Evaluation of Discernment

Components

- Determine the rate at which physicians refer to the standard at the time of decision making.
- Predict what utilization reduction goals can be achieved. Consider revising the standard or shifting to a different opportunity area if the goals do not appear to be of "sufficient size" to warrant investment of resources for formal implementation or execution of the standard.
- Where there is large variation in physician behavior around the standard (e.g., high rates of "no" for some doctors), carry out further explorations to determine causes and opportunities for improvement.

Example

An analyst reviews 30 records for the primary care physicians for the previous six weeks. There is clear discernment (i.e., the "yes" or "no" decision as to whether or not the standard applies to a given patient) recorded in 28 out of 30 patients presenting with back pain. Of the 28 patients, all but four patients met the criteria defined in the standard and did not receive imaging studies. This was substantially higher than the previous performance of this clinic and higher than the organizational average. The team decides to expand testing to another clinic. The physicians agree to review and

discuss the four patients who received imaging (i.e., those for whom the standard was determined not to apply). The orthopedic surgeon and his colleague have a total of 20 patients with back pain for whom they applied the standard. They were surprised to find that the standard applied in 75 percent of these patients since they thought, prior to the test, that their practices included a much greater proportion of complicated cases than primary care.

Background and Additional Guidance

Complete the evaluation of discernment using a sample, such as the next 30 to 50 patients, and project what might be achieved in utilization reduction for the larger population of patients. If the projection seems small relative to potential investment of resources for implementation or expectations, the optimal solution at this point may not be to pursue physician outliers or high utilizers. It might be more appropriate to consider changing the standard, if that is clinically appropriate, or selecting a different opportunity area.

For example, the criterion for imaging in back pain might be a one-month "watchful waiting" period. If only 5 percent or less of patients received "watchful waiting" (i.e., do not receive imaging) based on the standard, additional criteria might need to be considered, such as "all patients receive self-management support or referral to physical therapy."

Approaching physician outliers or high utilizers as a means of addressing overuse might increase the risk of negatively impacting the local culture, and may put a burden on limited administrative and leadership resources. This does not mean, however, that organizations should never focus on physician outliers or high utilizers. A thoughtful, respectful approach that is informed by current levels of overutilization, compared to other physician groups, and the current practice culture is recommended.

The following are factors to consider when determining "sufficient volume" in terms of utilization reduction:

- In initial efforts to reduce overuse of specialty services, the primary goal is to engage physicians in changing practice; reducing large utilization "volume" and reducing costs are less overriding concerns.
- Consider the overall business case for changing practice, including such factors as the potential cost savings, health outcomes benefits for patients, and costs of implementation of a standard. An organization can benefit as much or more from implementing several small- to moderate-impact changes that reduce overuse than from implementing one large-impact change.

Key Questions to Answer in This Step

- How will you sample the patients?
- What is the level of satisfaction and buy-in of doctors, patients, nurses, and other staff?
- How do you extrapolate the results to overall progress toward a final goal?
- How will you scale up this work to reach more physicians?
- When and how will you engage individual physicians who are outliers in utilization in a way that minimizes negative impact on the practice culture — and actually leads to positive "teachable moments"?
- How will you determine what constitutes a "sufficient volume" in terms of reduction of utilization as a result of application of the standard?

Step 5. Additional Interventions

Components

Determine if additional interventions are necessary in order to support implementation of the standard such as:

- Discussions with individual physicians as identified by variation data
- Patient educational tools
- Decision aids for patients[27,28]
- Additional decision support for physicians (e.g., diagnostic tools, appropriate interventions if the patient does not receive a given procedure, etc.)
- Primary care and specialty care service agreements to define referral criteria, availability for consultation, etc.

Example

As more primary care practices test the standard, it becomes clear that a more formal pathway for diagnosing and treating back pain is needed. The organization creates this pathway with input from primary care, orthopedics, and radiology. Criteria are developed for referral from primary care to orthopedics. Orthopedics establishes a system for on-demand consultation.

Key Questions to Answer in This Step

- How will you determine if additional interventions are needed?
- How will you design the process of care to integrate the interventions efficiently and reliably?

Step 6. Execution (Implement Standards)

Components

- Design and improve processes for efficiency, reliability, and sustainability, including ongoing measurement and feedback.
- Spread the new standard or consensus criteria and implementation design to additional practices or clinics.

Example

An "alert" box is included at the top of the form used to order imaging that reminds physicians about the criteria for imaging tests for back pain. An automatic reminder is planned once the electronic medical record is implemented. Imaging utilization data for back pain are reported for all clinics on a monthly basis, unblinded by clinic. At the clinic level, the data for individual physicians is unblinded. Performance agreements for administrators and clinic physician leads include a negotiated target for imaging for back pain patients.

Background and Additional Guidance

Up to this point, the main objective has been to test the willingness and ability of physicians to apply the standard, the potential impact on utilization, and additional interventions that may be needed in order to support application of the standard. In this final step of the framework, it is important to determine the implementation design necessary to ensure sustainability of application of the standard and accompanying reductions in utilization.

For sustainability, a multifaceted approach is often needed, including local physician engagement in developing or adapting standards or criteria, decision support embedded into the workflow, and other information technology support.[8,17] Leveraging health information technology[17] to support decision making at appropriate points in the care process has been identified as crucial, although the number of reminders and alerts physicians have to contend with is an implementation challenge that needs to be addressed.

At the same time, some organizations we interviewed contended that specialty practice is different from primary care and inpatient care, where there has been the most experience with these multifaceted approaches. One position is that once specialists buy in to a standard, further reminders may not be needed to sustain lower utilization levels for some procedures.

Therefore, testing must take into account these uncertainties about what is required for sustainability in specialty practice environments. In general, in health care the experience has been that awareness through education and training alone do not usually achieve a high degree of process reliability

because of inherent flaws in process design and human factors such as stress, complexity, fatigue, and limitations of memory. Reliability principles create a hierarchy for implementation methods such as training, performance feedback, standing orders, reminders and alerts, and other design approaches that then lead to increasing levels of process reliability. These principles have been adapted by IHI in inpatient settings[38] and appear promising in outpatient primary care settings.[41]

Key Questions to Answer in This Step

- What change ideas will you implement to improve sustainability of the standard?
- How will you scale up implementation of the standard to reach more physicians, clinics, etc.?
- How will you capture problems that develop during spread of the standard, to determine if redesign is needed?
- What additional structures, tools, and processes are needed for implementation and spread?
- What will the information technology needs be to support spread and sustainability?

Limitations of the Framework

- The framework does not currently provide a method for the design and implementation of patient decision aids, or other innovative approaches to involve patients in decision making. One application of the framework might include establishing a standard for using a decision aid at a specific time point in the pathway of care for a particular condition.
- Measurement is not fully defined in this white paper. Determination of reductions in cost or utilization, for instance, could be supplemented by measures to determine if there are unintended consequences of implementation of a standard. For example, Palo Alto Medical Foundation allergists were concerned that reducing the use of skin testing could lead to inadequate interventions and patient inconvenience due to increased need for follow-up visits. Subsequent studies found that reducing skin testing did not increase the number of follow-up visits.
- The benefits and costs are not yet clear for creating a series of standards and protocols that cover an entire pathway of care, including work-up, diagnosis, treatment, additional medical interventions, and follow-up.[31] The business case for such an approach may vary according to condition.
- We anticipate other limitations will be discovered through testing.

Summary

The IHI Framework for Appropriate Use of Specialty Services primarily focuses on changing professional practice culture by engaging physicians in developing and implementing practice standards that will work best in local circumstances to reduce high or escalating costs, reduce exposure to risk of harms, sustain or improve health outcomes, and improve the patient experience. The framework derives partly from known principles and methods of guideline or protocol development. It is not meant as a comprehensive pathway that explicitly defines a design and sequence to address such issues as payment incentives and engaging patients in decision making, among other important considerations, but the framework does take these issues into consideration. Even with a more specific focus on standards for physicians, IHI's review of case examples suggests strongly that this approach can achieve substantial gains for some clinical topic areas and procedures. And, it will lay the groundwork for a shift in practice culture that can support more comprehensive change in the future.

Continued testing of the framework by organizations that are willing to share what they learn is needed. In addition, patient expectations, patient engagement in decision making, payment incentives, medical-legal issues, and other dimensions of overuse still need to be considered for broader, more comprehensive change. Given the plethora of specialties and procedures, the object of IHI's work in this area is to identify approaches that can be applied across many specialties, procedures, and types of organizations.

Conclusion

It is difficult for individual physicians or physician groups to recognize variations in their practices that indicate possible overuse of specialty services unless they engage support from the broader health care system. Even when physicians identify where changes are needed, systems must be redesigned to support change and make it sustainable. Addressing overuse is the work of everyone involved in health care. Neither the health care system nor patients can afford to wait to start testing methods for changing practice. As David Eddy stated in 1984:

> "There is no doubt that uncertainty about the consequences of different medical activities can harm both the quality and cost of medical practice. It is also true, however, that most of the simplifications and heuristics point in one direction, toward overutilization. When this happens the price is paid in terms of inconvenience, pain, distress, days in the hospital, unnecessary risks, and money…The problems that exist today are not the fault of any individuals; the fault lies with the profession and society as a whole for not developing the traditions and methods to assess medical practices. Today the problem is bad; five years from now, if not improved, it will be a tragedy."[24]

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