Assessing Risk in the Kaiser Permanente Clinical Technology Program

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About the Authors

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The Kaiser Permanente Clinical Technology (KP ClinTech) program consists of 10 autonomous healthcare technology management (HTM) teams across the enterprise's seven geographic regions, as well as a relatively new national leadership team. Although the organizational reporting relationships and budget resources vary across regions, the KP ClinTech program is on a journey to function as a unified service: One ClinTech (Figure 1). The national team provides vision and strategic direction and facilitates the consensus process necessary to address the challenges of variation in process, procedure, and performance. The regional operations teams work to fulfill the vision and strategy.

In late 2012, Kaiser Permanente (KP) introduced an integrated risk management (IRM) program to address the increasing complexity in the healthcare industry and regulatory environments. Healthcare reform, individual state involvement, and tight budgets further complicated efforts to assess and manage the enterprise's risk. The IRM program provided a more efficient and effective way for leadership, operations, and risk management units to come together to identify requirements for operational processes, apply common criteria to prioritize risks related to those processes, and implement coordinated risk assurance activities for priority risks.

In late 2013, the decision was made to sponsor an initiative to implement IRM within the KP ClinTech program. The expenditure of resources required to move forward with the initiative was justified by the interregional process design and reconciliation activities, as well as the magnitude of risks associated with implementation, use, and support of medical technologies. Of note, Technology Management Solutions (Trumbull, CT) was selected to carry out the first phase of the IRM process.

Objectives

The primary focus of this programmatic risk assessment project was to evaluate technology management issues throughout the entire medical technology life cycle, with emphasis on the role of the KP ClinTech program.

The specific types of risks to be assessed included:

- **Risks to patient and staff safety.** Safety risks are of paramount concern. Assessing risk is fundamental for any healthcare organization but especially important for HTM programs that are charged with responsibility for the safety and effectiveness of medical equipment.
- **Regulatory and compliance risks.** Healthcare delivery is a highly regulated enterprise, and therefore, maintaining complete and ongoing compliance is essential. This is particularly challenging for an organization like KP that operates across the country in multiple jurisdictions.
- **Financial risks.** Every organization must consider risks to financial stability and cost-effective technology.
- **Reputational risks.** Similarly, every organiza-

tion must protect its hard-won reputation for quality and service.

- **Operational and liability risks.** A variety of risks arise from business operations in a litigious environment. Prudence dictates careful consideration.

Although every risk assessment project must be open to recognizing any type of risk encountered, beginning each project with a consensus on the types of risk that are of greatest concern to the organization is important. The list for this project was based on both historical experience and anticipated developments in healthcare delivery.

Risk Assessment Process

All of the parameters for designing the project were specified at the outset. With strong support and cooperation from KP staff, an online survey was distributed to personnel with knowledge and interest in clinical technology issues. In addition, more than 40 telephone interviews were conducted among more than 200 individuals. The primary intent of this effort was to draw open-ended commentary from as many people as possible. As the project proceeded and common themes were identified, additional interviews were conducted with staff who had exhibited strong interest and expertise.

To complement this work, numerous documents, including previous assessments, current and proposed policies and procedures, and available performance data, were reviewed. Site visits and additional interviews in four KP regions (Mid-Atlantic States, Southern California, Northern California, and Northwest) also were conducted. Because of the hands-on nature of HTM, observing the program in action was important.

The work was organized to cover all phases of the clinical technology life cycle. Figure 2 shows the model developed by the KP National Clinical Technology Committee. Our review was based on recognized guidelines for healthcare technology (Table 1).

Observations

We observed variations across regions regarding the extent to which the KP ClinTech program was routinely involved in all phases of the medical technology life cycle. This is consistent with the observation made by many in the HTM community that healthcare organizations vary widely in how effectively

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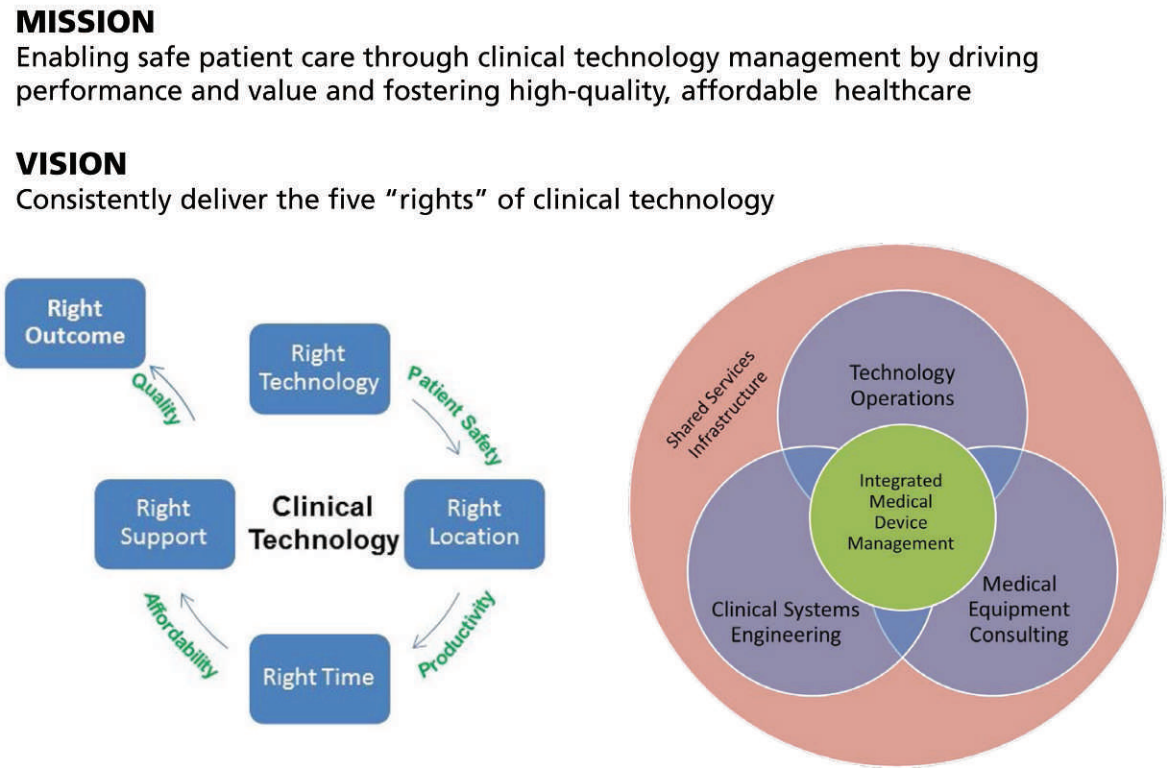

Figure 1. The One ClinTech initiative

HTM expertise is incorporated into the medical technology assessment and planning processes.

Because KP regions have a long history of relative independence from each other, attention was given to regional variations in practice that might influence the effectiveness of the KP ClinTech program. For example, we found that the operational definition of "clinical technology" itself varied, with different regions having different definitions of the types of medical equipment included in the KP ClinTech program scope. As other healthcare organizations plan similar risk assessment projects, identifying broad categories of risk that merit special attention because of historical, cultural, or other factors unique to each organization is important.

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Each potential risk identified was categorized according to risk type and risk effect. Risk type (i.e., safety, cost, compliance) helped focus attention on the operational issues that could be affected. Risk effect (i.e., business, regulatory) further focused attention on how potential risks should be understood and addressed. Each potential risk also was categorized by one or more life-cycle phases to which it was most applicable.

For example, regional variation in the level of involvement of clinical technology in the technology assessment process was categorized as follows:

- **Risk type.** Primarily cost and safety risks through, for example, lack of standardization, but also potentially a compliance risk relative to Joint Commission standards.
- **Risk effect.** Primarily a business risk.
- **Life-cycle phase.** Primarily related to the assessment and plan, design, and budget phases.

Additional categorizations of particular interest to KP were made to help identify, for example, the specific components of the organization that would be tasked with addressing each potential risk. Each healthcare organiza-

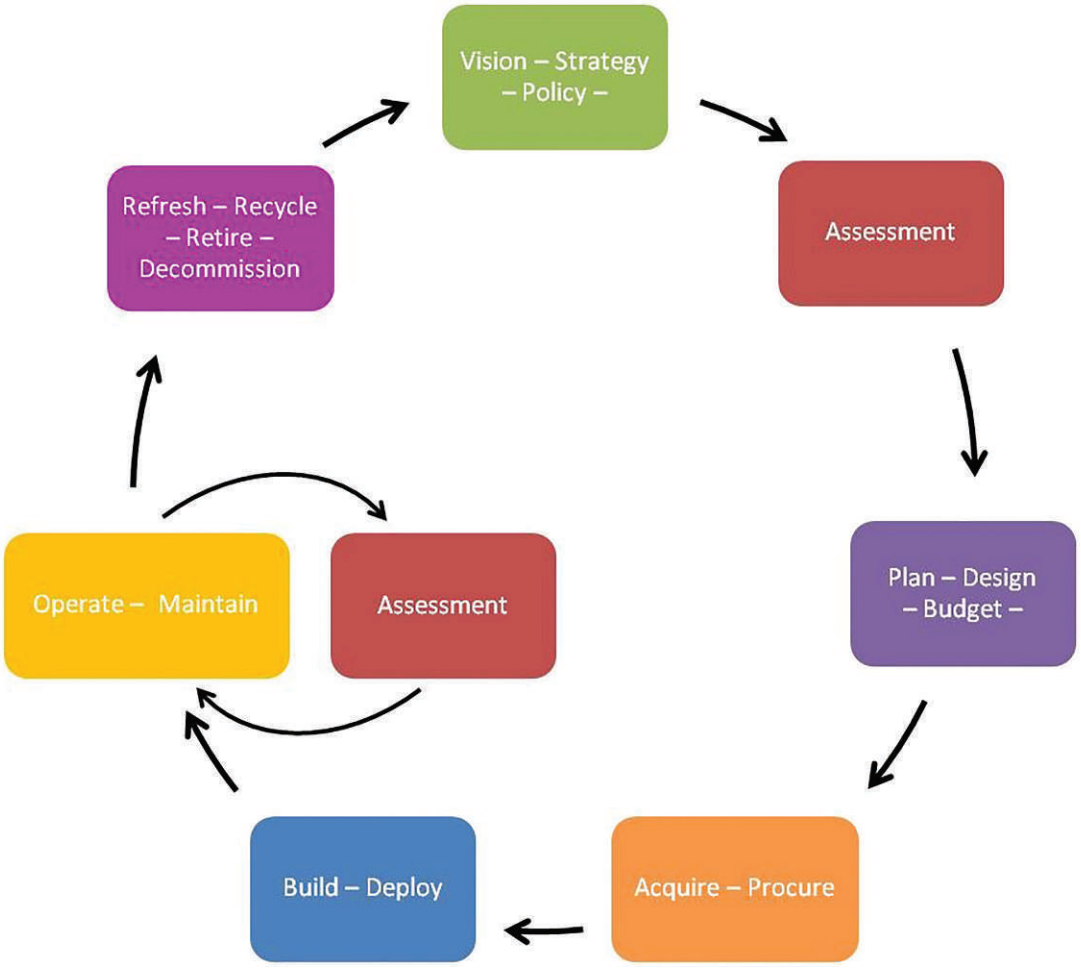

Figure 2. Medical technology life cycle

tion must undertake a similar risk assessment project to recognize its unique characteristics and design its project accordingly. Careful planning in this regard will increase the value of the project in terms of interpreting the findings and improving organizational performance.

The next step was to apply the KP IRM model (Figure 3), in order to assess the impact and likelihood of each potential risk. In this model, the impact dimension considers the consequences or degree of threat of disruption to our mission, strategic objectives, and operational processes. The likelihood dimension identifies the chance that the risk event will occur, taking into account current controls, processes, systems, and management practices. The combination of these two factors produces an overall risk rating that ranges from very low to very high.

After sorting the potential risks by risk rating and focusing on the most important issues, we were left with a list of more than two dozen risks that were regarded as deserving further attention. Based on discussions with KP leaders, these risks were grouped into five partially overlapping groups (i.e., critical risk areas), as follows:

1. **Scope of clinical technology services.** For the purposes of this project, the issue of scope was broken into four questions: 1) What technologies should be included in the KP ClinTech program scope? 2) What phases of the technology life cycle should be addressed? 3) What care settings should be covered? 4) What services are provided within these dimensions?
2. **Computerized maintenance management system (CMMS).** This risk area included a range of issues to be considered in developing systemwide software for the KP ClinTech program. KP had previously completed a CMMS requirements assessment that informed our review. Our recommendations primarily focused on the ability of the currently deployed CMMS and related software to meet the system's needs.
3. **Regional variation.** Various issues related to differences across KP regions were included in this risk area. We identified, for example, regional variations in staffing levels, policies and procedures, scope of services, and other operational issues.
4. **Life cycle management for medical technologies.** Closely related to the scope issue outlined above, this risk area included issues regarding comprehensive support across the entire medical technology life cycle. For

Programmatic Risk Assessment: Critical Factors For Success

- Secure support from administration in terms of scope, objectives, schedule, and available resources
- Incorporate risk management expertise and risk assessment methodologies
- Identify organization-specific issues and concerns
- Design the process to be followed, including decision points for review and possible refocusing
- Draft the project report and use it for discussion with key stakeholders
- Complete the report and use it as a basis for action

National Fire Protection Association (www.nfpa.org)
• NFPA 99 (2012), *Health Care Facilities Code* • NFPA 70 (2014), *National Electrical Code*
Association for the Advancement of Medical Instrumentation (www.aami.org)
• ANSI/AAMI EQ56:2013, *Recommended practice for a medical equipment management program* • ANSI/AAMI/IEC 80001-1:2010, *Application of risk management for IT networks incorporating medical devices—Part 1: Roles, responsibilities and activities*
The Joint Commission (www.jointcommission.org)
• 2014, *Comprehensive Accreditation Manual for Hospitals* • 2014, *Comprehensive Accreditation Manual for Ambulatory Care* • 2014, *Comprehensive Accreditation Manual for Behavioral Health Care Organizations*
Other Accreditation Programs
• College of American Pathologists (www.cap.org) • Accreditation Association for Ambulatory Health Care (www.aaahc.org)
Centers for Medicare and Medicaid Services (www.cms.gov)
• CMS Hospital Conditions of Participation (42 CFR Part 482) • Health Insurance Portability and Accountability Act (45 CFR Part 164)
Food and Drug Administration (www.fda.gov)
• Medical Device Reporting (21 CFR Part 803)
California Department of Public Health (www.cdph.ca.gov)
• California Code of Regulations—Title 22

Table 1. Guidance documents used in the project

Impact	Likelihood: Remote	Unlikely	Possible	Likely	Almost certain
Catastrophic	High	High	Very high	Very high	Very high
Significant	Medium	Medium	High	Very high	Very high
Moderate	Low	Low	Medium	High	High
Limited	Very low	Very low	Low	Medium	Medium
Minimal	Very low	Very low	Very low	Low	Low

Figure 3. Kaiser Permanente integrated risk management model

example, we identified a need for consistently applying a total cost of ownership analysis in the equipment planning process.

5. **Role of national clinical technology team.** This risk area addressed internal organizational and financial relationships among the various components of the KP ClinTech program. We recommended streamlining the process for handling hazard alerts and recalls by giving the national team a central role in handling medical equipment alerts and recalls.

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Finally, for each of these critical risk areas, we carried out a gap analysis that identified KP's current performance relative to the state of the art in HTM. All of these findings, along with recommendations for addressing them, were included in a written report and follow-up discussions with KP leaders. This was an iterative process designed to deliver an actionable report that would support efforts to continually improve the KP ClinTech program. Pragmatism and feasibility were characteristics on which KP insisted from the beginning, and we believe they are essential for achieving genuine performance improvement.

Going Forward

After completion of the first phase of the IRM process, the KP ClinTech program has continued this effort in collaboration with the National Compliance, Ethics, and Integrity Office and the National Facilities Services Compliance Office. Detailed and prioritized initiatives have been defined in alignment with existing work streams. A specific aspect of the highly prioritized hazard alert and recall management process has been singled out as the pilot project to demonstrate the remediation component of the IRM process. This pilot work includes representatives from KP's National Product Safety team, national and regional risk management units, and the clinical technology national and regional teams.

All of the risk categories and initiatives are under further review within KP and will be prioritized for synchronization with other work planned for 2015. This includes enterprisewide implementation of standardized KP ClinTech program processes defined in 2013–14: On-Boarding New Medical Equipment and Clinical Systems; Preventive (Planned) Maintenance; Corrective Maintenance; Hazard Alert and Recall Management; Equipment-Triggered Incident Investigation; and Decommissioning. All of this work is encompassed in and supported by the long-range strategic initiative to migrate the KP ClinTech program to the KP shared services operating model. ■