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Managing the Tensions Between National Standardization vs. Regional Localization of Clinical Content and Templates

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Abstract

The deployment of sophisticated software tools and electronic health records offers many new opportunities and challenges to support care delivery. One of the key opportunities is to enhance the quality of care with evidence-based medicine (EBM). One of the key challenges is to embed EBM in tools that directly facilitate the process of documentation and care delivery.
Since clinicians typically have the option of using free text for most of their documentation, the tools that provide embedded EBM must be at least as efficient as free text. There are many requirements that must be met in order to effectively embed EBM within clinical content tools and enhance both the usability and the actual use of such tools and clinical content: (1) Facilitate the documentation process; (2) Facilitate the care delivery process, e.g. make order entry faster; (3) Contain recommendations that are highly relevant to the clinical context of an encounter; (4) Aid in the capture of discrete coded data.
Support for local variation is often key to meeting these objectives and becomes a central factor in helping clinicians shift from unstructured free text, to the use of these tools, which support the delivery of EBM.
This document describes the central tension between the objective of national standardization and delivery of EBM and the need for regional localization of clinical content. This tension must be thoughtfully managed to maximize the quality of care delivery and associated workflow practices. The key elements of legitimate local variation that must be recognized in order to achieve these goals are described in this document, and the key principles for managing the tensions between generalization and localization are identified.

Keywords:

Practice Guidelines; Information Systems; Decision Support Systems, Clinical; Medical Records Systems, Computerized.

Introduction

Kaiser Permanente (KP) is the largest not-for-profit health maintenance organization in the United States, serving 8.4 million members across the country. An integrated health delivery system, KP organizes and provides or coordinates members' care, including preventive care such as well-baby and prenatal care, immunizations, and screening diagnostics; hospital and medical services; and pharmacy services. Over 11,000 Permanente Medical Group physicians and tens of thousands of allied health professionals contribute to KP's care delivery.

The Kaiser Permanente HealthConnect program is a multi-year initiative focused on the national deployment of a highly sophisticated and integrated information management and delivery system. The goal of KP HealthConnect is to deliver on the KP Promise of quality, caring, convenient and affordable care for our members. KP HealthConnect integrates the clinical record with appointments, registration and billing to deliver improvements in care delivery and cost savings across the organization. Patients, physicians and other authorized health care staff have immediate secure access to complete, up-to-the-minute medical records, including test/lab results, prescriptions, and other ancillary data regardless of time or location. Immediate access to best medical practice recommendations within the proper contexts in the applications helps streamline patient care processes and improve health outcomes. KP HealthConnect is rolling out nationally to all KP facilities over the next several years.

The deployment of sophisticated software tools offers many new opportunities and challenges to support care delivery. One of the key opportunities is to enhance the quality of care with evidence-based medicine (EBM) and care delivery processes. One of the key challenges is to embed EBM in tools that directly facilitate the process of documentation and care delivery[1-3]. The virtues of standardizing clinical practice and care delivery processes are well described in numerous publications, well understood by clinicians, and are fully embraced in the clinical content authoring process within KP.

There are however a number of realities that warrant support of local variation. In most cases these local variations do not reflect differences in the EBM components, but reflect local variations in such factors as the composition of the care delivery team or differences in local regulations or resources.

Since clinicians have the option of using free text for most of their documentation, the tools that provide embedded EBM must be at least as efficient as free text. There are many requirements that must be met in order to effectively embed EBM within clinical content tools and enhance both the usability and the actual use of such tools and clinical content. The tools and clinical content must achieve one or more of the following objectives: (1) Facilitate the documentation process; (2) Facilitate the care delivery process, e.g. make order entry faster; (3) Contain recom-

mendations that are highly relevant to the clinical context of an encounter; (4) Aid in the capture of discrete coded data.

Support for local variation is often key to meeting these objectives and becomes a central factor in helping clinicians shift from unstructured free text, to the use of these tools, which support the delivery of EBM.

This document describes the central tension between the objective of national standardization and delivery of EBM and the need for regional localization of clinical content. Among those people experienced in authoring and using this type of content within systems, it is a universal experience that this tension is real and must be thoughtfully managed to maximize the quality of care delivery and associated workflow practices. The key elements of legitimate local variation that must be recognized in order to achieve these goals are described in this document, and the key principles for managing the tensions between generalization and localization are identified.

Background

Statement of the Problem

Since the initial research of John Wennberg in the late 1970's that showed large variation in medical practice in six New England States[4], dozens of subsequent articles have further documented large variations in care in nearly every geographic area and specialty. Reasons for this variation have included severity of illness, insurance coverage, patient income, patient education, patient health beliefs, access to care, resource availability, and provider preferences. Adverse effects on both quality of care and cost of care have been well-documented results of this variation when it is unjustified.

There is a central tension between "global generalization vs. local specialization" that is not unique to clinical content or to Kaiser Permanente. Managing this inherent tension is a responsibility of the clinical content oversight process that is central to the success of the whole process and key to reducing unnecessary variation in practice.

There are however variations in local context that justify some localization of clinical content, and these legitimate variations are elaborated below. The purpose of this document is to elaborate the business drivers for both a) standardization, and b) localization, so that we can use a principled and systematic approach for managing both the standardization and localization processes. The key business challenge is to enhance quality and efficiency of the care delivery enterprise while supporting the needs for efficient documentation tools and processes.

Definition of Clinical Content

Clinical content is the form in which rules, guidelines, and EBM are surfaced to clinicians within an application. Clinical content includes but is not limited to the following elements: Data entry templates and questionnaires, orderable items (lab, pharmacy, radiology, etc.), patient instructions, selection lists, libraries of diagrams for graphic documentation, flow sheets and reports, synonyms and preference lists, health maintenance reminders, automated alerts - such as drug-drug and drug-allergy alerts, patient instructions and links to knowledge sources.

Brief History of The Debate within KP

KP has a long history of at times frustrated efforts to reduce unnecessary variation. One central basis of this frustration resides in the relative scarcity of incontrovertible evidence that supports a particular practice or process. It is not a coincidence that the development of evidence-based guidelines themselves has been frustrated by this same paucity of solid evidence. It should be noted, however, that with increasing numbers of good-quality studies published in the medical literature, there is a growing body of evidence to guide practice in many areas of medicine. This document is not intended to address the issue of availability of generally accepted evidence. The focus of this document is on managing the requirements for both standardization and for localization *within that evidence constraint*. After five years of outstanding work, there now exist many national KP Clinical Practice Guidelines that advance our capabilities for evidence-based medicine, but there remain many more areas for which national guidelines do not yet exist.

One of the reasons that prior efforts for standardization have had high overhead is the many well intentioned but naive attempts to deny that there are indeed appropriate reasons for local variations in practices and processes. Unless these localization requirements are understood and respected, and unless there are systematic principles for and a commitment to managing localization, the efforts to achieve standardization at a national or even a regional level will continue to suffer from these well-intentioned but naive directives. In the spirit of successful practices we need to elaborate and re-validate the rationale for localization and the principles that guide the processes of standardization vis-à-vis localization.

There are two key elements necessary to understand and manage the tension:

1. The business drivers that warrant standardization at a national level; and
2. The rationale and criteria for acceptable and appropriate local variations.

Key Objectives and Design Points for Authoring Clinical Content

The creation of clinical content must support several key objectives and design points:

- Facilitate the documentation process and thereby enhance the care experience for both clinicians and members.
- Support the consistent implementation of evidence-based clinical practice.
- Support the consistent implementation of evidence-based care delivery processes.
- Support the capture of discrete coded data that are useful for both real-time decision support and for analytic purposes. Analysis in turn supports the advancement of evidence-based care practice and processes[5].
- Creation of coherent, comprehensive, searchable, and usable libraries of clinical content that are coordinated

with the objective of reducing the overhead for maintaining those libraries.

These five objectives are not always complementary, and often lead to direct conflicts. A common example of such a conflict is that capturing discrete data for analysis is sometimes less efficient that entering free text.

Business Drivers for Enterprise-wide Standardization of Content

Business drivers that support enterprise-wide standardization of content include:

- Support consistent definition and delivery of EBM across the entire enterprise.
- Support reimbursement by the Centers for Medicare & Medicaid Services (CMS) and 3rd party payors through consistent documentation.
- Support analysis of outcomes through consistent data representations in clinical content that facilitates aggregation of data at a national level. Types of outcomes include clinical quality, functional status, utilization, and financial.
- Reduce overhead for clinical content development and maintenance by optimizing the reusability of content in all regions and reducing the need for additional resources for localization of content within regions.
- Limit the total volume of clinical content (i.e. one national copy vs. a local variant copy for each region), thus facilitating search, manageability, and performance of clinical content.
- Enhance our capability to develop better evidence for best practices.
- Accrediting agencies, regulatory bodies, and the public will force both a review and an explanation of any differences in both recommendations and practices across the enterprise (aka Victa-Olsen).
- Increase clarity around successful practices and decrease liability from care delivered using successful practices.

Business Drivers for Localization of Content

In many types of clinical content there is an alternative to use free text rather than templates. Generally speaking, users will use whatever provides the most efficient documentation. It is therefore imperative that the structured clinical content be sufficiently relevant to a local context that it is no less efficient to use than free text. To the extent that any systematic differences exist in different local contexts, these types of clinical content must reflect those differences in order to enhance their usability, and hence their actual usage, and thereby the delivery of optimum care. If standardized content does not reflect legitimate local needs, there will be reduced usage of the pre-defined content, thereby defeating the basic purpose of developing clinical content. Local variations in templates are warranted to support the following legitimate and prevalent variations in local context:

- Local variations in scope of practice, e.g. legally defined variations in privileges granted to different provider types in different states.
- Local variations in the availability of orderable drugs and procedures, e.g. pharmacy formulary and locally available lab and radiology services.
- Local variations in delivery system configurations, e.g. variations in the provider mix within an individual care delivery team or larger operational unit naturally leads to different workflows that must be supported with content that reflects the local provider mix.
- Local variations in member populations (genetic pool variations). Simple Bayesian principles warrant adjustments to algorithms and thresholds based on age, ethnic, and environmental exposure profiles of a given population, e.g. there are significant differences in prevalence of and comorbidities associated with diabetes in different ethnic populations. Similar populations will likely act similarly in our different regions. Thus, the variation will be population-specific rather than region-specific.
- Local variations in geographic environments (environmental variations). Simple Bayesian principles warrant adjustments to algorithms and thresholds based on geographic variations in disease prevalence (some endemic and some epidemic), e.g. higher prevalence of coccidiomycosis in Southern California, histoplasmosis in Ohio, SARS in local outbreaks, etc.
- Local variations in interpretations of evidence where sufficient evidence does not exist. Different locales continue to apply different "standards of evidence" to evaluate the evidence base for a given practice. This variation may diminish over time, but it remains a reality at this time. If we migrate to the adoption of a shared methodology for assessing the clinical evidence even in the absence of a nationally produced guideline, the variability among regional guidelines should diminish.
- Supports analysis of two acceptable variations for a given practice with insufficient evidence to distinguish the two practices. This approach allows for systematic models to analyze outcomes and determine if one of these practices is superior to the other. (The statistical constraints and limitations to this approach notwithstanding, there is value in this approach if carefully managed and interpreted[7].).
- Supports localization required to address resource availability and constraints: Local differences exist between locales and within locales with respect to the availability of specific services, e.g. shortages of dermatologists, radiologists, endoscopists, diabetes case managers, PET scanners, etc. As one example, the availability of trained endoscopists affects how aggressively a locale can pursue outreach efforts for screening sigmoidoscopies and colonoscopies. If there is a surplus of such resources, the thresholds for outreach could be lowered, whereas if there is a resource constraint or a significant backlog of demand, the thresholds need to be raised. Failing to

address these local variations in resource availability can result in either a failure to comply with stated guidelines or failure to exceed a "national standard" where superior resources are available. In some cases, exceeding the national standard based on available resources may be desirable (e.g. screening colonoscopies), and in other cases undesirable (e.g. screening prostate-specific antigen levels on anyone over 30).

Principles for Managing Standardization vs. Localization

Optimization of the above business drivers leads to the following set of principles for managing standardization vs. localization:

- There is a need for enterprise-wide consensus regarding the key business drivers guiding clinical content creation.
- All else equal, we strive for program wide consistency and standardization.
- When there is good evidence, the clinical content should be determined by and consistent with that evidence.
- When the evidence is considered insufficient to support a definitive recommendation, the content should generally take a conservative approach. For example, if the evidence is insufficient to determine the value of, say, screening for some condition, the content should not affirmatively promote screening, even if physicians "feel" that screening is good.
- Where a local variation is thought to be necessary, the justification for the local variation should be described.
- It is inescapable and in many cases desirable that content will be developed and tested locally before it is identified as a good candidate for "promotion" to national content status. This local content should be continually sought out and where appropriate, promoted to national clinical content.
- Processes and tools should be built that facilitate the adherence to these principles at both the national and local levels. These tools need to enable localized content to be updated as changes to national content occur.
- Local bodies responsible for localization of national content need to recognize and adhere to these principles.
- A periodic review of these principles should be conducted, and course corrections should be suggested where appropriate. Principles are derived from business drivers and technical constraints, which can change over time.
- It will be important to identify areas of local variation that appear not to be supported by available evidence and highlight these opportunities for standardization to the appropriate national entity.
- It is essential that the content development process support distributed development opportunities within locales. The effectiveness of much of the clinical content cannot be determined without actually testing it in operations. It is safer and more efficient in many cases to test new content in a subset of users before introducing it into national clinical content.
- Clinical content will use discrete coded data elements in every instance where it either supports or does not impede the workflow and documentation process. In some exceptional cases where capture of discrete data is critical, policy decisions will support the use of discrete data despite some modest additional overhead for documentation.

Conclusion

We've made considerable progress with electronic health records. HL7 communication protocols foster greater semantic interoperability. There has been substantial progress made in the domain coverage and standardization of medical terminology, along with the ability to exploit that terminology in ways that are clinician-acceptable and that provide powerful options for data analysis and reporting[8]. The ability to maintain medical terminology at the national level, while localizing it within particular contexts has become nearly fully automated. Meanwhile, the growth of EBM and the successful deployment of that EBM in applications continue to mature. Deployment of that content in a way that is acceptable to clinicians and leads to the capture of more discrete data and more consistent data will benefit from widespread understanding and adherence to these principles.

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