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Stakeholder engagement: a key component of integrating genomic information into electronic health records

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Abstract

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Integrating genomic information into clinical care and the electronic health record can facilitate personalized medicine through genetically guided clinical decision support. Stakeholder involvement is critical to the success of these implementation efforts. Prior work on implementation of clinical information systems provides broad guidance to inform effective engagement strategies. We add to this evidence-based recommendations that are specific to issues at the intersection of genomics and the electronic health record. We describe stakeholder engagement strategies employed by the Electronic Medical Records and Genomics Network, a national consortium of US research institutions funded by the National Human Genome Research Institute to develop, disseminate, and apply approaches that combine genomic and electronic health record data. Through select examples drawn from sites of the Electronic Medical Records and Genomics Network, we illustrate a continuum of engagement strategies to inform genomic integration into commercial and homegrown electronic health records across a range of health-care settings. We frame engagement as activities to consult, involve, and partner with key stakeholder groups throughout specific phases of health information technology implementation. Our aim is to provide insights into engagement strategies to guide genomic integration based on our unique network experiences and lessons learned within the broader context of implementation research in biomedical informatics. On the basis of our collective experience, we describe key stakeholder practices, challenges, and considerations for successful genomic integration to support personalized medicine.

Keywords

electronic health records; genomics; health information technology; personalized medicine; stakeholder engagement; translational medical research

Personalized medicine holds significant promise for enhancing health care. Although some applications of genetic information have yet to be proven, others—such as pharmacogenetic testing to avoid severe adverse effects of medication or identify optimal cancer therapies, or testing for known familial cancer syndromes—are already being implemented.[1–3] As the cost of sequencing continues to decrease, whole-genome or large-panel approaches may replace current genetic-testing modalities.[4,5] Optimal use of such results will depend, in part, on the development of effective clinical decision support (CDS) tools within the electronic health record (EHR).[6,7]

Stakeholder engagement—involving those affected by changes in policy in the development of that policy—is critical for successful implementation of systems and processes that can support the use of genomic information. As Carman et al.[8] note, engagement occurs both along a continuum—from consultation and involvement to partnership and shared leadership—and at different levels within a health-care organization. In the clinical integration of genomic information, clinicians, patients, staff, scientists, policy makers, citizens, industry, and domain experts from genetics, informatics, and bioethics, and related fields all have a role to play.[6,9] Their input can address key challenges, including how to keep current with a rapidly growing knowledge base; determining the clinical implications of complex genetic results and their relative priority in patient care; and managing the privacy, security, and confidentiality of personal genomic data.

This report describes stakeholder engagement strategies used within the Electronic Medical Records and Genomics (eMERGE) Network.[10] The prior round of funding for phase I of the eMERGE Network (2007–2011) included community engagement to understand stakeholders' views about population-based genetic studies.[11–16] Now in phase II, the eMERGE Network serves as a "living laboratory" to explore the feasibility and utility of integrating genomic data into the EHR within large health-care delivery systems. Our aims

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are to contribute to the growing literature on engaging stakeholders in health information technology (HIT) implementation and to highlight issues specific to the integration of genomic information within the EHR.

ENGAGING STAKEHOLDERS IN HIT IMPLEMENTATION

The adoption and meaningful use of HIT have the potential to improve the delivery of health care by enhancing quality, efficiency, and access, and are a national priority in the United States.[17,18] Available guidance on the implementation of information systems in clinical settings points to the importance of stakeholder engagement for success.[6,19–22] Common HIT failures often trace back to social and organizational barriers in technology design and use, ineffective rollout of redesigned workflow support, lack of organizational leadership, and failure to conduct ongoing assessment of HIT as available resources evolve.[20,23] In the context of genomic integration, particular challenges include limited evidence and lack of consensus on which genetic variants are medically relevant, lack of reimbursement for genomically driven interventions, and patient and clinician burden.[2] Many of these barriers can be addressed by gaining a thorough understanding of stakeholder needs and contexts, establishing trusted leadership of "champion" clinicians,[19,21] and fostering multidisciplinary engagement[20] that reaches throughout the organization, well beyond the software vendor or IT department.[22]

The general implementation process for HIT provides numerous opportunities to address potential pitfalls through proactive stakeholder engagement in the decision, selection, preimplementation, implementation, and postimplementation phases.[19] During the decision phase, organizations must examine their needs, available resources, and potential benefits of implementing an envisioned information system. In this so-called "fuzzy front end,"[24] the aims and value of a proposed innovation are agreed upon before the start of concrete development. Organizational leadership, including clinical champions, is essential in defining vision and goals, evaluating the strength of genomic evidence, and allocating needed resources. Review of scientific evidence, policies, and suitable guidelines for genomic integration is particularly important during this phase.[2]

Once the decision has been made to move forward, the selection phase focuses on the creation or purchase of the new system or functionality. Informatics teams drive the selection of secure tools that can adapt traditional systems to new genetics-based interventions and accommodate changes in genomic knowledge bases and decision support rules.[9,25] Other tasks in this phase could include delineating the views and current practices of health professionals, flagging potential barriers and facilitators to implementation, reviewing relevant external influences (e.g., regulatory requirements, community values, or competitors' market positioning), and identifying parties whose feedback and support are critical to implementation.[26,27] Engaging patients and the local community during this phase can also shape how genomic information is made accessible in patient care.[2]

Guided by project planning and change management, core activities of the preimplementation phase focus on communication and end-user involvement in workflow redesign and testing. The informatics team must work closely with clinicians and staff to define workflow requirements, business rules, and interaction with other processes. Patients can be engaged to inform patient-facing tools and processes.[28] Applying user-centered principles helps to ensure that innovations meet their intended aims and use.[29–32] Access privileges and roles—who can do what within the system—need to be defined, as do reporting and audit requirements. In the case of genomic integration, other key contributors to this phase could include medical directors, underwriting leaders, and community relations and marketing executives.

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During the implementation phase, support and training materials must be distributed widely. Involving the people who will be affected by the change can enhance acceptability, effectiveness, and efficiency of deployment. Addressing needed refinements is particularly important with the expected initial reduction in productivity. An efficient feedback loop is critical to ensure that new resources help users understand complex genetic knowledge and its impact on health care. Careful monitoring is critical at this phase to track adherence to workflow, user satisfaction, and cost containment of genomic interventions.[2] Finally, the postimplementation phase involves continuous evaluation of system efficiency, adoption, and care outcomes, with adjustments to the system as necessary. None of these tasks can be fully addressed by the informatics team alone.[22]

Involvement of various stakeholder groups throughout the entire process is paramount for implementing any information system, including tools that integrate genomic information into the EHR. Adding genomic information into the usual clinical workflow requires multiple stakeholders to make changes in how they think and what they do. Identifying factors that could affect acceptance of new information and adoption of new processes is therefore essential. Effective engagement not only informs the design of optimal technical solutions but also supports the “soft side” of change management. Moreover, the development of tested, locally appropriate procedures for stakeholder engagement and the establishment of a cadre of advisors provide a useful organizational resource for future change efforts.

STAKEHOLDER ENGAGEMENT ACROSS THE eMERGE NETWORK

Using the broad framework of HIT implementation,[2,19] the remainder of this article describes strategies employed by eMERGE sites to involve key constituencies in the integration of genomic information into the EHR. This article does not represent a comprehensive account of the strategies of any single site; rather, it offers illustrative examples, both known engagement practices and new opportunities that arise in the genomics context, with the aim of helping other organizations design their own best practices.

The fundamental role of informatics

Implementing novel HIT is the job of biomedical informatics professionals,[33] who range from researchers, information technologists, and information systems (IS) staff to software developers, vendors, trainers, content experts, and other specialists trained in areas such as user-centered design[29–32] and implementation science.[34] These specialists form multidisciplinary teams during the selection phase to manage the overall implementation process.

Most health-care organizations have established procedures for making changes to their informatics infrastructure.[35] The Marshfield Clinic, for example, has an internal committee of IS staff and physicians that reviews and prioritizes updates for CattailsMD, its homegrown EHR. Geisinger Health System has a formal process for adding enhancements to its local implementation of EpicCare (Epic Systems, Verona, WI), a vended software solution. Quality improvement teams identify care gaps for Geisinger’s Innovation program, for which teams evaluate and prioritize care gaps, develop cases to justify particular uses, and design implementation strategies.

At Northwestern University, clinical informaticians advise on EHR implementation decisions and inform genomic integration strategies that require local customizations to EpicCare. IS staff who configure and provide daily EHR support consider the implications for ongoing maintenance. Working together, these teams reach solutions to integrate

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genomic information while maintaining active vendor involvement. Similar collaborative processes across the eMERGE Network bring informatics specialists together with other stakeholder groups to foster communication and support successful implementation.

Engaging organizational leadership

Organizational leadership shapes local policy on genomic integration by determining whether and how to proceed and provide support for the endeavor. In the case of genomic integration—in which uncertainty exists about the clinical utility of genomic results—these leaders play a key role in assessing the demand, potential benefits, and possible harms of proposed innovations. This group typically includes corporate executives, medical directors, clinician leaders, legal counsel, and marketing executives. In addition to championing the necessary vision and resources during the decision phase of implementation, continued leadership engagement is critical for encouraging adoption and allocating necessary resources for training, outreach, and sustainability.[18]

Organizations participating in eMERGE phase II, by definition, made an organizational commitment to explore the implementation of genomic medicine. As a result, site engagement with organizational leadership, particularly during the decision phase, differs from how most health-care organizations might approach the issue. However, some sites had related initiatives under way before eMERGE II began, and two experiences with leadership engagement are described below.

Personalized medicine has been championed by Vanderbilt University Medical Center leadership since 2009. For Vanderbilt's PREDICT (Pharmacogenomic Resource for Enhanced Decisions in Care and Treatment) program, early collaboration of faculty leaders from medical affairs, personalized medicine, clinical and translational research, research informatics, innovation integration, medical ethics, law, and other areas guided the design and implementation of the program and ensured that PREDICT's resource and infrastructure needs were well coordinated. Formed in 2009, PREDICT's planning team aimed to develop and implement the program in 1 year.[1] Before implementation, this leadership team reviewed clinical evidence to prioritize efforts, and it continues to evaluate the adoption and impact of PREDICT. In the absence of payer reimbursement, institutional funding has been critical for salaries, equipment costs, and genotyping. The commitment of institutional leaders across disciplines was critical for both program formation and its long-term success.

As part of eMERGE I, investigators at the Group Health Cooperative convened a 7-month consensus development panel comprising corporate executives, legal counsel, clinicians, researchers, and health plan members. Its goals were to discuss genome-scale research and the ethical, legal, and social implications of such studies; develop organizational policy recommendations; and serve as a demonstration project for similar efforts across the country. In eMERGE II, investigators served as participant–observers in an internal quality improvement process and conducted one-on-one interviews with leaders from of the clinical, information technology, and business functions within the Group Health Cooperative to learn about their needs and attitudes and to identify possible barriers and facilitators to implementation.

Engaging clinicians

Clinicians are primary users of the EHR and to a large extent drive the use of genomic information in practice. The complexity, clinical implications, and demand for genomic information make clinicians' involvement throughout multiple phases of implementation essential. In addition to providing concrete input on workflow practices, seasoned clinicians can serve as trusted champions who both promote a shared vision for genomic integration

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and address expected resistance to change.[18,20] Their input is important for understanding educational needs and concerns for practical application of genomic information in patient care. An overview of clinician engagement strategies is presented in Table 1.

Northwestern University investigators have engaged clinicians in the decision, selection, and preimplementation phases, and plan for ongoing partnership in subsequent phases of implementation. Two physician champions from general internal medicine serve on the project's planning committee, as this is the clinical area where genomic information will first be delivered. An initial survey was conducted to understand physicians' experiences and attitudes toward genomic testing. Respondents saw clinical utility as a critical factor in ordering genomic testing and utilizing genomic information. In addition, a physician-comprised Quality Improvement Committee, which works with informatics and IS staff on EHR implementation, also serves as an advisory committee for genomic integration. Over several committee meetings, discussions have centered on which variants to return, how to return results, and CDS design. The committee recommended integrating results into the current clinical workflow, ensuring that CDS is meaningful when triggered, and providing educational resources at the point of care for both physicians and patients. Future discussions will cover additional variants to return, evaluation of the process for returning results, and continued evaluation and improvement of CDS and educational resources.

During the preimplementation phase, the Mayo Clinic is using focus groups to explore the views of primary-care and subspecialty physicians. Although participants endorsed the value of pharmacogenomic testing in select cases and the use of whole-exome sequencing for cancer patients who have not responded to standard treatments, they also expressed concern about encountering genetic test results in the EHR that they could not interpret or act on. Focus group findings informed the selection of genomic variants to implement, representation of results in the EHR, and design of educational resources for clinicians.

In addition to focus groups, Marshfield Clinic partners with clinicians in software development, usability testing, and ongoing interdisciplinary meetings focused on preimplementation activities for clinical integration of pharmacogenomic information. Physician input on CDS development, data storage, "alert fatigue,"[35,36] and education is obtained through regular interdisciplinary meetings with IS staff, informatics, and pharmacy. In 2012, two focus groups were held with primary-care physicians to discuss integration of genomic data into the EHR. Participating primary-care physicians recognized the future impact of genetic information on practice and offered suggestions for genome-driven CDS to minimize alert fatigue and promote use of evidence-based guidelines. Physicians are interviewed and shadowed in the clinic to understand workflow and inform the development of prototypes, which are later user tested by physicians.

Investigators from the Group Health Cooperative and the University of Washington are engaging clinicians in the preimplementation phase through use-case development, prototype design, and usability testing. Drawing upon techniques from user-centered design,[29,30,38] investigators are collaborating with clinicians to develop pharmacogenomics use cases and design prototypes that will be used to assess the feasibility of genomic integration into clinical care. On the basis of focus groups and interviews to assess needs, investigators will further engage clinicians to specify design and workflow requirements, such as preferences for CDS content, layout, interaction, and navigation. Clinicians will be engaged in participatory design[38] of CDS prototypes for genetically guided prescribing that they will later evaluate for usability.

At Vanderbilt University, clinicians are part of a core development team with geneticists, informaticists, EHR experts, pharmacists, pharmacologists, clinical pathologists, and

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program managers. Vanderbilt's PREDICT project has been returning genotype results to clinicians and patients through the EHR since 2010.[1] Before implementing CDS in the EHR for a given drug–genome interaction, the scientific evidence and implications for CDS are vetted by both the core team and focus groups of clinicians. The Vanderbilt Pharmacy and Therapeutics Committee reviews scientific evidence for approval. If approved for implementation, PREDICT staff consults affected end users to share evidence, answer questions, and promote adoption. Currently in the postimplementation phase, investigators are surveying hundreds of clinicians about their experiences and opinions about returning genetic results to participants. The results will be used to improve communication and CDS functionality.

Engaging patients

Patients are increasingly recognized as critical partners in health-care policy[7] and HIT implementation.[2,19] Expanding upon engagement strategies employed by the eMERGE Network in phase I,[15] phase II broadened its focus to engage patients on the use of genomic information at the point of care. The social and ethical issues raised by integration of genomic information into the EHR (e.g., issues of privacy and confidentiality in the age of "big data")[39,40] make input from patients essential. Table 2 presents an overview of patient engagement strategies.

At the Marshfield Clinic, engagement with patients from the community has been a cornerstone since the decision phase of implementation.[11,13,41] Focus groups have been held to discuss the incorporation of genetic information into the EHR. One of patients' primary concerns was the possibility of genetic discrimination by insurers and employers. In follow-up, focus group participants were provided a brochure about the Genetic Information Nondiscrimination Act.[42] Similar discussions also took place with the Community Advisory Group, which provides ongoing input on deployment and evaluation of the Personalized Medicine Research Project and reviews print materials for the project, including consent forms and recruitment materials. The Marshfield Clinic has employed various consultation strategies to engage the community more generally about genomic medicine, including newsletters for study participants, community talks, and media releases that include information on genomic integration into the EHR.

The Mayo Clinic engaged patients in the early phases of implementation. In addition to exploring biobank participants' educational needs, investigators are conducting surveys and interviews with biobank participants to better understand their concerns and expectations about genomic-based medicine and placing personal genomic data in the EHR. Future engagement activities will elicit patient preferences for the delivery of genomic information via the patient portal.

Northwestern University has partnered with biobank participants and patients through ongoing advisory committees and community engagement efforts in eMERGE I.[16] In phase II, a patient advisory committee was formed to consider the implications of integrating genomic results into the EHR. During the preimplementation phase, the committee has been instrumental in the design of educational resources distributed through MyResearch, a patient research portal available through the EpicCare patient portal. The committee has also reviewed consent materials and provided feedback on privacy concerns about placing genomic data in the EHR.

At the Icahn School of Medicine, Mount Sinai's Project ENGAGE (Engaging Neighborhoods in General and Personalized Genomics Education) involves patients throughout implementation. Investigators utilize a range of methodologies to engage patients from the community in discussions about genomics, including focus groups[43] and interviews

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with low-income, ethnically diverse patients.[44] To guide implementation, a multidisciplinary team was assembled that includes racially, linguistically, and socioeconomically diverse patients and community leaders who work alongside front-line clinicians and researchers. Principles of community-based participatory research guide development of educational materials to engage diverse patients.[45] This team is actively involved in EHR integration, including the development of appropriate materials for patient and clinician portals, shared decision making at the point of care, and implementation and evaluation efforts.

Patient focus groups at Geisinger Health System have been used to inform eMERGE investigators on many issues, including use of the EHR and the MyGeisinger patient portal. Findings have informed MyGeisinger refinements, including distribution of information on research projects. Investigators are preparing to pilot test biobank consent procedures using MyGeisinger. Patient engagement in other areas has led to discussions about extending existing projects that capture patient-entered data[46] or allow patient access to provider notes[47] to genomic implementation efforts.

Vanderbilt has engaged patients through its BioVU Community Advisory Board in PREDICT.[47,49] Vanderbilt investigators conducted 10 preimplementation patient focus groups (including two in Spanish) and a survey through its patient portal, My Health at Vanderbilt, to assess patients' perceptions of pharmacogenomics and their attitudes regarding consent and return of results.[2] Vanderbilt also created PREDICT brochures for adult and pediatric populations to facilitate patient education and dialogue with providers. Vanderbilt is also integrating genomic information into patients' My Health at Vanderbilt accounts and developing a public-facing website, mydruggenome.org, to provide detailed information about drug–genome interactions for patients and providers. Recently, investigators conducted semi-structured interviews with four groups of patients who had been seen in clinics that offered PREDICT, stratified by patients who (i) had not received testing, (ii) received testing but had no resulting medication changes, (iii) had their clopidogrel dosage adjusted as a result of testing, and (iv) had changes in simvastatin. Postimplementation feedback from these groups will inform ongoing PREDICT development.

Engaging other stakeholder groups

A range of other groups can provide valuable input on integrating genomic information into the EHR. Table 3 presents several examples of the contributions these groups can make. For example, Downing et al.[6] describe roles for government, research institutions, developers of technology standards, and test developers that have the potential to generate national standards and guidelines that can facilitate implementation at the local level. Other examples include nonprofit organizations aimed at improving health-care quality and efficiency, such as the National Committee for Quality Assurance[50] and the Leapfrog Group,[51] whose policy and credentialing decisions have implications for health-care organizations' HIT priority setting. In addition, the nonprofit Health Level Seven International consists of multiple workgroups, including a Clinical Genomics Workgroup that addresses standards for the transmission and storage of genomic information in the EHR.[52]

Other groups bring diverse expertise from bioethics, social science, and other disciplines. A trend among eMERGE Network sites is the development of interdisciplinary meetings attended by specialists from a number of areas relevant to EHR integration. Similar to the "team science" approach advocated by HIT implementers,[20] Marshfield Clinic holds regular meetings on pharmacogenomics that include researchers, clinicians, and representatives from research informatics and clinic IS. At these meetings, concerns expressed by patients, providers, and the community are reviewed. As implementation has moved forward, it has

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become clear that additional stakeholders need to be involved, including researchers and clinical laboratory directors.

The social and ethical issues raised by integration of genomic information into the EHR highlight the need for input from the local community. For example, the Mayo Clinic's eMERGE I work employed a deliberative community engagement process that resulted in the creation of its Community Advisory Board.[16] Board members provide a sounding board for new policies as implementation challenges arise, such as brochures explaining the ethical complexity of returning genetic results and feedback on recruitment and consent materials for a proof-of-principle study to incorporate pharmacogenomic research findings into the EHR. A number of other sites engage community members through similar mechanisms, such as Marshfield Clinic's Community Advisory Group, Northwestern University's Community Advisory Committee, and Vanderbilt University's BioVU Community Advisory Board. By contrast, Geisinger uses community newsletters and focus groups rather than a standing community advisory board. This decision was made in response to concerns community members raised about a standing advisory board becoming "more informed" over time and potentially losing representation of the community focus and level of understanding without accompaniment of ongoing surveys and focus groups with members of the broader community.

Health-care payers also provide an important perspective. The Marshfield Clinic is one of the eMERGE sites that includes a health insurance plan, Security Health Plan. Marshfield Clinic researchers have had preliminary one-on-one discussions with plan leadership about the incorporation of genomics into clinical care. Discussion topics include nonspecificity of laboratory codes for genetic tests, noncoded laboratory results, process for approval of new diagnostics, and lack of standardized family history data that may be necessary to substantiate claims for genetic testing for rare conditions. The Marshfield Clinic is considering the electronic support needed to facilitate timely reimbursement for genomic medicine from the payer standpoint. Similar discussions are taking place at both Group Health Cooperative and Geisinger with their respective health plans.

ROADMAP FOR ENGAGEMENT: BEST PRACTICES AND CHALLENGES

We have described a range of stakeholder engagement strategies to inform the integration of genomic information into the EHR. These strategies represent a continuum of stakeholder opportunities to shape the integration across multiple phases of the implementation process. On the basis of our collective experience, we describe key challenges and considerations for successful genomic integration to support personalized medicine.

The breadth of engagement practices

Through examples from eMERGE, we demonstrate the adaptation of Carman et al.'s[8] continuum of engagement to stakeholder groups beyond patients. Numerous sites engaged organizational leadership, clinicians, and patients in consultation, such as informant interviews with leaders at the Group Health Cooperative, focus groups with clinicians at the Mayo Clinic, and interviews with patients at Mount Sinai. Involvement goes further in engaging stakeholders in defining requirements and planning implementation through advisory committees and resource development. Examples include the Group Health Cooperative's quality improvement teams, clinician engagement in software design at the Marshfield Clinic, and Vanderbilt University's community advisory board. At the partnership end of the engagement continuum, which is characterized by shared power and responsibility, we highlight Geisinger's scientific advisory board, clinicians' role in planning committees at Northwestern University, and patients as community leaders at Mount Sinai. Partnership is also exemplified at the eMERGE Network level through

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collaborations with other national entities such as the CDS Consortium[53] and the Clinical Pharmacogenetic Implementation Consortium.[54]

This breadth of engagement strategies expands upon existing recommendations provided by the broader literature on stakeholder roles in HIT implementation,[19–22] health research,[26,27] and integration of genomics into public health policy[55] and comparative effectiveness research.[56] As Carman et al.[8] note, the existence of a continuum of engagement does not imply that all organizations should aim for the higher end of the continuum for every decision. In the context of genomic integration, ongoing review of the clinical evidence by organizational leadership, medical directors, and domain experts helps the organization keep current with a rapidly growing knowledge base. Clinician input is necessary for determining the clinical implications of complex genetic results and their relative priority for patient care. Patients and community members provide essential input on managing the privacy, security, and confidentiality of personal genomic data. Although some experts recommend engaging patients affer a decision is made to implement,[18] the eMERGE Network experience suggests that early patient and community involvement provides valuable input during the decision and selection phases as well.

Other factors—stakeholder beliefs, organizational culture and practices, and social norms and policies—influence the type and depth of engagement that is appropriate and achievable.[8] Appropriate engagement activities for a delivery system with a cooperative governance model, for example, may differ substantially from those suited for use in a regional safety-net hospital.

Interdisciplinary and cross-cultural communication

Stakeholder groups may use different language, jargon, and processes, even within a single project team.[21] It is important for organizers and participants to recognize these differences, work toward clear communication, and ask questions about terms or processes that are unfamiliar. A project dictionary that provides everyday definitions for relevant clinical and informatics terms can help. Use of visuals and diagrams can also aid communication about processes or concepts that may be new to some stakeholder groups.

Extra attention should be paid to communication when working with underserved populations and non-English speakers. Investigators at Mount Sinai conducted patient interviews in Spanish and English within Project ENGAGE and ensure that consent materials are both bilingual and at or below a sixth-grade reading level. Vanderbilt University conducted some patient focus groups for the PREDICT project in Spanish. The Mayo Clinic Arizona is engaging Spanish-speaking participants in community discussions to better understand how this population views biobanking, genomic research, and personalized medicine. Communication strategies may also need to be tailored by form and frequency to different stakeholder groups. Some members of the Marshfield Clinic's Community Advisory Group lack access to the Internet, requiring alternatives to e-mail and Web resources.

Iterative collaboration across multiple phases of integration

The full integration of genomic information into clinical care will not be accomplished in one broad sweep. Implementation of genomics in the EHR will likely occur in a stepwise manner as more is understood about the clinical relevance of genomic data, how to use this information to improve patient care, and which kinds of genomic integration tools are most effective. Successful informatics development processes will include continuing opportunities for stakeholder engagement. Although many of the engagement strategies shared here focus on early phases of development, our ongoing collective work will

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incorporate more engagement activities in later phases of implementation, including usability testing of design solutions with both clinicians and patients, alpha and beta testing of deployed tools, and postdeployment evaluation.

Changes in the developing standard of care for genomic medicine will also require stakeholder input. For example, the recommendations recently published by the American College of Medical Genetics on the return of incidental findings[57] represent a major policy shift. A health-care organization using clinical whole-genome sequencing would need to convene leadership, clinician, and patient stakeholders to determine if and how these recommendations should be implemented. This would be followed by engagement with clinician and informatician teams to translate the institutional charge into an actionable implementation plan.

Although engagement is beneficial, it can be challenging to identify and recruit some stakeholder groups, such as busy clinicians and administrators. For example, O'Haire et al.[27] describe multiple barriers to stakeholder engagement in the comparative effectiveness research context: time constraints, the recruitment of a sufficient number of representatives to capture the range of views, and limited availability of certain stakeholder groups. Northwestern University, the Marshfield Clinic, and the Mayo Clinic have all experienced challenges recruiting busy physicians. These sites adapted approaches, such as scheduling time-limited activities in the evening and at the noon hour, to ensure that participants were able to engage with these critical stakeholders. Likewise, engaging representatives of diverse patient communities can be challenging, but many institutions now have experts who can help investigators overcome obstacles to engendering trust and participation.

Identifying differences in expectations, opinions, priorities, and values is an inherent part of stakeholder engagement. To move from conflicting perspectives to policy, it is important to develop a process for reconciling differences among stakeholder groups. The Marshfield Clinic includes Community Advisory Group representatives in institutional decision-making discussions. The results of these meetings are reported back to the Community Advisory Group, providing members with the opportunity to ask questions and provide additional input. Similarly, Mount Sinai has a Community-Academic Partnership Board with a dedicated genomics subcommittee that is informed of, and informs, genomic research. Another challenge is differentiating engagement for research versus practical application, which can carry different incentive structures and governing policies. Clarifying these details with all stakeholders early in the process can help reduce misaligned expectations.

CONCLUSION

Stakeholder engagement in biomedical informatics activities is critical to successful integration of genomic information into the EHR and implementation of personalized medicine. Experiences and lessons learned by the eMERGE Network present options for engaging stakeholders in all phases of the informatics development process. We hope these examples aid future implementation efforts.

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Table 1

Clinician engagement strategies by implementation phase

	Decision and selection phases	Preimplementation phase	Implementation phase	Postimplementation phase
Sample topics	• What are clinicians' attitudes toward genomic medicine and CDS? • What do they think patients' views will be? • How can clinician "champions" promote integration and facilitate trust? • What are potential barriers and facilitators to clinician adoption of genomic CDS?	• What should be the division of labor? • Who should have access to genomic information? Under what circumstances? • Where in the workflow might genomic information fit? • Which information should be "pushed," and which information should be available for users to "pull" as needed?	• How is implementation going? • What is working well and what could be improved? • Are additional training materials needed? • Are there other kinds of support that would help?	• Are clinicians using the CDS as intended? Why or why not? • What is the impact on patient care? • What additional refinements are needed? • What additional training is needed?
Sample methods	• Grand rounds or other informational presentations with question and answer • Involve interested clinicians in a standing committee on genomic medicine • Focus groups • One-to-one interviews	• Focus groups • One-to-one interviews with key informants • Design consultation • Usability testing and cognitive interviews • Shadowing and debriefing	• Brief online surveys • Shadowing and debriefing • Informal one-to-one interviews • Check-in at morning report	• Satisfaction surveys • Brief informal lunches • Shadowing and debriefing • Informal one-to-one interviews • Group reviews of system-generated data about use and adherence to CDS

Implementation stages drawn from Lorenzi et al.;[19] remainder, authors' analysis.

CDS, clinical decision support.

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Table 2

Patient engagement strategies by implementation phase

	Selection phase	Preimplementation phase	Implementation phase	Postimplementation phase
Sample topics	• What are patients' attitudes toward genomic medicine? • What are patients' concerns about privacy, security, discrimination, or insurance coverage with regard to genomic data? • What are patients' expectations regarding access—theirs and others'—to their genomic data? • What do patients think about the possibility of learning about the range of results that can be generated through sequencing?	• Which information should be provided directly to patients via Web portal or other EMR-linked tools? • What kinds of online resources should be made available to patients? • What kinds of report formats are appropriate for patient use? • What kinds of printable patient education materials might be needed within the EMR? • What should the informed consent process look like?	• How can we optimize patient engagement around genomic information? • How do patients respond to the inclusion of genomic information during the clinic visit? • Do patients want more information? Less? • Are additional patient education materials needed?	• Are patients aware that the innovation has been launched? • Does providing genomic information to patients increase satisfaction with care? • Does the integration of genomics into routine care affect relevant health behaviors? • Does the implementation of genomic medicine increase satisfaction with the patient's health plan?
Sample methods	• Informational articles in newsletters and on websites • In-clinic information: e.g., posters, brochures, kiosks • Community conversations or town hall meetings • Focus groups • Interviews • Advisory boards	• Surveys (online, telephone) • Focus groups • Usability testing • Community leaders • Participatory design of patient education and consent materials	• Launch communications: e.g., promotional materials, announcements, posters, giveaways • Postvisit surveys • Brief in-clinic interviews • Focus groups	• Periodic satisfaction surveys • Focus groups • One-to-one interviews • Feedback reports and updates via existing communication vehicles

Implementation stages drawn from Lorenzi et al.;[19] remainder, authors' analysis.

EMR, electronic medical record.

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Table 3

Contributions from other stakeholders

	Examples	Potential contributions
Quality improvement organizations	• National Committee for Quality Assurance, http://www.ncqa.org/ • The Leapfrog Group, http://www.leapfroggroup.org/ • National Quality Forum, http://www.qualityforum.org/	• Measurement standards and metrics • Quality report cards • Certification
National policy and advisory boards	• Agency for Healthcare Research and Quality, http://www.ahrq.gov/ • Institute of Medicine, http://www.iom.edu/ • US Preventive Services Task Force, http://www.uspreventiveservicestaskforce.org/ • Centers for Disease Control and Prevention, http://www.cdc.gov/ • Centers for Medicare and Medicaid Services, http://www.cms.gov/ • Evaluation of Genomic Applications in Practice and Prevention Working Group, http://www.egappreviews.org/ • Health Resources and Services Administration, http://www.hrsa.gov/ • Food and Drug Administration, http://www.fda.gov/	• Research • Evidence-based best practice recommendations • Evidence-based reviews • Coverage and reimbursement decisions
HIT policy and advisory boards	• Health Level Seven International, http://www.hl7.org/ • Clinical Decision Support Consortium, http://www.partners.org/cird/cdsc/ • Office of the National Coordinator for Health Information Technology, http://www.healthit.gov/ • Healthcare Information Technology Standards Panel, http://www.hitsp.org/ • Certification Commission for Health Information Technology, https://www.cchit.org/ • National Institute of Standards and Technology, http://www.nist.gov/	• Research • Best practice recommendations • Technology standards • Implementation incentives • EHR certification
Specialty societies	• American Society of Human Genetics, http://www.ashg.org/ • American College of Medical Genetics and Genomics, http://www.acmg.net • National Society of Genetic Counselors, http://www.nsgc.org/ • National Coalition for Health Professional Education in Genetics, http://www.nchpeg.org/ • College of American Pathologists, http://www.cap.org • Association for Molecular Pathology, http://www.amp.org/ • American Medical Informatics Association, http://www.amia.org/	• Clinical practice guidelines • Patient education materials • Policy statements • Laboratory standards and guidelines
Patient advocacy groups	• Community advisory boards • Local patient guilds and associations	• Research

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	Examples	Potential contributions
	• Disease-specific patient support organizations • Genetic Alliance, http://www.geneticalliance.org/ • Consumers Union, http://consumersunion.org/ • National Partnership for Women and Families, http://www.nationalpartnership.org/ • American Association of Retired Persons, http://www.aarp.org/	• Information on patient perspectives • Help in defining and implementing communication strategies
Health-care payers	• Specific health plans, employers, and associations • America's Health Insurance Plans, http://www.ahip.org/	• Coverage standards • Utilization review data • Relevant patient programs: case management, disease management, health promotion, and behavior change programs

EHR, electronic health record; HIT, health information technology.