eHealth Evaluation and Dissemination Research

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Abstract: This paper reviews key challenges in evaluating eHealth intervention and behavior change programs, and makes recommendations for the types of designs, measures, and methods needed to accelerate the integration of proven eHealth programs into practice. Key issues discussed include evaluation approaches that answer questions that consumers, potential adoptees, and policymakers have. These include measures of participation and representativeness at both patient and healthcare setting levels, consistency of outcomes across different subgroups, tendency of an eHealth program to ameliorate versus exacerbate health disparities, implementation and program adaptation, cost, and quality-of-life outcomes. More practical eHealth trials are needed that use rigorous but creative designs compatible with eHealth interventions and theory. These evaluations should address key dissemination issues, such as appeal, use, and robustness of eHealth programs across different subgroups, settings, conditions, outcomes, and time.
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Introduction

Although eHealth research is relatively recent,[1,2] it has produced several important efficacious interventions.[3–6] There have also been important lessons learned in eHealth assessment and research methodology.[7,8] As in most areas, however, there is a substantial gap between what is known and what is implemented in applied settings.[9,10]

The purpose of this article is to identify information that, if provided, would greatly aid those making decisions about adoption of eHealth programs. Viewed from a developer/evaluator perspective, these same actions should substantially increase the probability of successful program dissemination.

Perspective

This section covers fundamental "context" type questions—information about the who, what, when, where, and how of eHealth programs. In terms of who participates in eHealth programs, one of the earliest concerns about eHealth has been the "digital divide." When Internet applications first became available there was a pattern, frequently seen with other innovations[11] in which earlier adoptees tended to be highly educated, young, white males.[12,13] This pattern has become more complex over the years, and now some subgroups such as racial minorities and older adults are now among the fastest growing groups of new Internet users.[12,13] To-day, eHealth digital divide issues include amount of participation across users at different levels of health literacy, computer experience, and types of connections to the Internet.

eHealth developers can take two important actions to address digital divide issues. First, they can develop applications with digital divide issues in mind, rather than pushing "whatever the technology will bear." Second, they can be much more systematic about documenting who uses (and does not use) eHealth programs. These key user participation issues are summarized in Table 1. The question "who is invited—and who is not invited" can be addressed by clearly specifying both inclusion and exclusion criteria. Often underserved populations can be unintentionally left out of interventions by requirements, such as requiring high-speed Internet connectivity to participate.

Other papers have addressed issues of participation and survey response rates in eHealth,[2,14,15] but issues of representativeness have been less well articulated. There are two basic approaches to addressing representativeness in intervention studies. The preferable option is to compare characteristics of participants to persons declining to participate. Although involving institutional review board and Health Insurance Portability and Accountability Act of 1996 (HIPAA) complexities, it is possible in many cases to either (1) obtain responses on a few key characteristics from nonrespondents after explaining the importance of such information,[16] or (2) to obtain deidentified information on nonparticipants from administrative databases maintained by organizations such as health plans or worksites.[17]

The second approach is to utilize existing databases to compare eHealth participants to those in the same

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Table 1. Key user participation and representativeness issues

Who gets invited and who comes? (Digital-divide stereotypes)
— Specify both eligibility and exclusion criteria
— What percent of those invited participate?
— What are the characteristics of participants?
  Compare to:
    (1) Nonparticipants or
    (2) Representative sample(s)[a] on following key factors:
        (a) race, ethnicity, and socioeconomic status
        (b) computer experience
        (c) health literacy
— What are barriers to patient participation in this context?

[a]It is often possible to use sources such as the Behavioral Risk Factor Survey, the HINTS,[20] census data, or other appropriate administrative aggregate data sources as appropriate.
HINTS, health information national trends survey.

neighborhood, community, state, or nation. Although the choice of database obviously needs to be determined by the question, frequently useful sources include the Behavioral Risk Factor Survey, the health information national trends survey (HINTS),[18] census data, and an increasing number of Geographic Information System (GIS)–based databases. GIS databases provide information by location on factors such as proximity and density of parks and recreation facilities, fast-food restaurants, liquor stores, as well as crime statistics and other information.

There are, of course, respondent burden issues that preclude collection of voluminous characteristics from participants, let alone nonparticipants. (Keeping careful records of recruitment results and use of existing databases do not increase respondent burden, however). Table 1 summarizes participation and representative issues that are especially relevant for eHealth research. In particular, an understanding of the reach of eHealth programs among persons of different levels of health literacy and numeracy is needed. Recent summaries have documented the powerful relationship of health literacy to health status, patient–provider interaction, and a host of other variables, even after controlling for sociodemographic factors.[19,20] Recent validation of brief assessments of health literacy[21] make collection of health literacy data more feasible.

Practical eHealth Studies

The majority of evidence-based healthcare procedures fail to translate into practice.[22,23] Part of the reason for this failure to translate is because of the research methods most often used to evaluate interventions. In particular, typical designs do not address external validity concerns or provide information relevant to policymakers or to those considering program adoption.[24–26] To address this issue, Tunis et al.[24] have proposed criteria for "practical clinical trials," which can also be applied to design "practical eHealth trials." There are four key characteristics of practical trials (Table 2). They study representative patients, are conducted in multiple settings, employ as controls reasonable alternative intervention choices rather than no treatment or "usual care," and report on outcomes relevant to clinicians, potential adoptees, and policymakers.[24]

Tunis et al.[24] stress that it is important to collect multiple outcomes, and measures important to decision makers. eHealth investigations could accelerate translation if more studies would collect the types of measures discussed below.[24,26,27] A comprehensive, yet feasible package would include measures of behavior change, biological changes, cost, and quality of life (and/or potential negative outcomes).

In the past, it has been difficult to have such practical trials funded by study sections. This was because reviewers commonly evaluated such studies again criteria for efficacy studies or did not understand the challenges of translational research. This situation is changing somewhat with the establishment of the "R18" grant mechanism for translation research and recent multi-institute requests for applications on dissemination and implementation research (e.g., PAR-06-521 and NIMH 82-SEDR) that have their own study sections.

Behavior Change

Because the intent of many eHealth interventions is to assist users in changing their health behaviors (e.g., exercise more, stop smoking, take medication regularly), it is important to directly assess behavior change. It is not sufficient to simply measure knowledge or biological outcomes, and assume that behavior change occurs.[27,28] Although there are usually linkages among these measures, knowing what happened on one outcome does not necessarily permit inference about results on other domains.

Table 2. Key elements of "practical clinical trials" recommended for eHealth

Controlled experimental evaluations that include:
● Representative patients—especially on health disparity-related factors
● Multiple settings—chosen to represent broad cross-section of potential adopting sites
● "Standard of care" or other alternative treatments for comparison conditions (not just usual care or no treatment)
● Outcomes include measures relevant to clinicians and decision makers
    — Behavior change measures (at multiple levels, if relevant)
    — Quality of life and/or potential negative impacts
    — Cost and where feasible, economic outcomes
    — Biological outcomes related to study aims

One of the challenges to collecting behavioral outcome measures has been the length of assessments required. Two relatively recent developments have combined to change this situation. First, investigators have developed brief forms of measures that perform almost as well as longer forms.[29–31] When the primary purpose is to assess intervention effects, the most relevant criterion for selecting a measure is its sensitivity to change: it does not necessarily need to have extraordinarily high levels of internal consistency (often obtained by having lengthy surveys). Glasgow et al.[30] have recently recommended measures for dietary change, physical activity, risky drinking, and smoking that should be sufficiently sensitive, yet brief enough to be employed in eHealth interventions requiring brief measures. The other recent development is computer adaptive testing (CAT).[32] CAT procedures make it possible to accurately determine a given person's standing on a domain while only administering a fraction of the total number of items in a battery, by judicious selection of items having different distributional characteristics. There are numerous projects underway utilizing CAT procedures, including the Patient-Reported Outcomes Measurement Information System (PROMIS) project,[32] which should produce broadly applicable results related to quality of life.

Other issues in behavioral assessment include the measurement of implementation of behavioral strategies that are recommended in eHealth programs. For example, to what extent did participants log onto the website each week, decrease their fast food consumption or TV watching? The two most common methods of assessing these intermediate behaviors are through unobtrusive, automated measures of website engagement and participant self-monitoring.

Cost and Economic Measures

One of the greatest needs for advancing eHealth is for more systematic collection of economic measures. Comprehensive economic analyses that determine outcomes such as cost–benefit or cost offsets[33,34] require considerable time and expertise, and may be beyond the scope of many eHealth projects. However, it should be feasible for almost all eHealth projects to collect measures of intervention costs, and to estimate what Meenan et al.[35] have called replication costs, which estimate what it would cost to deliver the intervention in other settings. Until more is known about the costs and cost effectiveness of eHealth interventions, it is unreasonable to expect decision or policymakers to adopt such programs without such information. One caveat regarding economic measures is that "costs are not costs are not costs." Thus, potential adoptees may want to see a breakout of costs by category, because many have different budgets for upfront versus gradually accrued costs, for equipment or software versus personnel costs, fixed costs versus per participant costs, and so forth.

Quality of Life and Potential Adverse Effects

There are multiple reasons to recommend collection of quality-of-life measures. The first is that well-validated, quality-of-life measures provide a common metric on which to compare interventions for different problems and different behaviors. Several authors have argued that improving quality of life is the ultimate goal of health care.[36,37] Especially if quality of life can be converted to quality-adjusted life years,[34] it provides a convenient and widely understood metric for comparing diverse programs. There are now several well-validated, brief quality-of-life measures, such as the World Health Organization (WHO)-5[38] and the Centers for Disease Control and Prevention (CDC) Healthy Days measures[39] that are sensitive to change and appropriate for diverse cultural groups.

Quality-of-life measures can also evaluate whether an eHealth program inadvertently creates adverse outcomes or unintended consequences. It is now apparent that many healthcare interventions have created unintended adverse consequences.[40] The eHealth field should not repeat the same mistakes other fields have made in assuming that because programs were well intended, that they could not cause harm. Quality-of-life measures can assess whether an intervention does more harm than good. It may be difficult to believe that visiting an eHealth website could produce negative outcomes. However, given limited time and the competing demands faced by both patients and healthcare providers,[41,42] devoting greater attention to one health risk factor may mean doing less of some other valuable activity. eHealth programs, especially those not collecting quality-of-life measures, may want to collect measures of nontargeted health behaviors or of Health Plan Employer Data and Information Set (HEDIS) items[43] to ensure that quality of care in nontargeted areas are not adversely affected.

Qualitative Measures

Qualitative measures can be very helpful at several different phases of eHealth research. They are important during development and formative evaluation to design programs that appeal to and are understandable to intended users. They are useful in helping to understand quantitative results, such as why potential users decline to participate or why they do not remain engaged over time. Finally, qualitative measures can be very helpful in understanding contextual issues.

Summarizing this section, practical eHealth studies should assess the representativeness of both patients and settings (e.g., clinics, worksites) that participate, employ comparison conditions that include alternative interventions (especially if one wants to claim that their
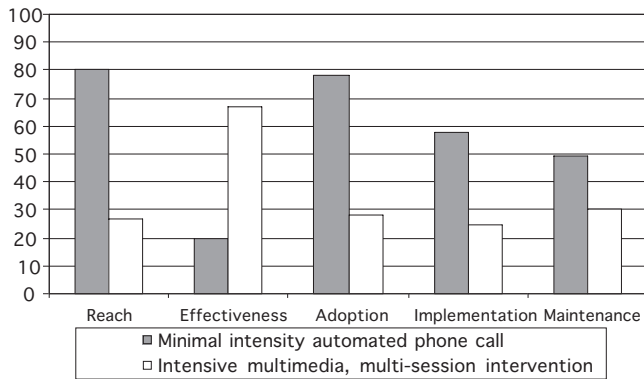
Figure 1. Pattern of results across RE-AIM dimensions for two types of eHealth programs

program is superior to existing programs), collect a broad range of measures (Table 2), and present results in a way that is understandable to decision makers that one wants to influence.[24,25]

Evaluation Frameworks

For eHealth developers who wish to have their program widely adopted, there is much to be said for following a translation framework throughout the planning, implementation, analysis, reporting, and refinement of their product. It is beyond the scope of this paper to discuss the relative advantages of the different frameworks,[11,44–46] but almost all are influenced by the pioneering work of Rogers's diffusion of innovations model,[11] and of Green and Kreuter's PRECEDE-PROCEED model.[44]

This paper discusses implications and recommendations that follow from the RE-AIM framework.[46,47] RE-AIM is an acronym that stands for Reach (participation rate and representativeness of participants); Effectiveness (on both primary outcomes and quality-of-life/negative consequences); Adoption (participation rate and representativeness among settings and staff implementing a program); Implementation or consistency of program delivery, and Maintenance or sustainability at both patient and setting levels (www.re-aim.org). Each dimension is important for determining the eventual population-based impact of a program, and different eHealth technologies likely have different patterns of results across these five dimensions.[47,48] As shown in Figure 1, a simple automated telephone call encouraging users to take a one time preventive action (e.g., go for cancer screening) will likely have high reach, be widely adopted by many organizations, but by itself have limited effectiveness. In contrast, a more intensive, multimedia, multisession lifestyle change eHealth intervention that requires users to return repeated times (and is more expensive) would likely have lower reach, might be adopted by fewer organizations (both because of cost and complexity), but will

likely be more effective for those users who do persevere.

Different decision makers may wish to emphasize one RE-AIM dimension over others or to make adoption decisions based on the dimension(s) that is most important to their organization. However, it would be helpful to have a composite index to summarize the public health impact of different programs. Table 3 presents some of the newer RE-AIM metrics[49] for this purpose. At the individual user level, overall program impact may best be conceptualized as a product of the Reach of a program multiplied by its Effectiveness.[50,51] Reach is a function of both the participation rate and the representativeness of those users on characteristics such as those in Table 1.

Effectiveness is a function of multiple components, including: (1) the median effect size on primary outcome(s) for a given program (effect size serves as a common metric across diverse content areas); (2) adjusted for any adverse impacts on quality of life or other outcomes; and (3) differential impact across population subgroups, with special reference to impact across groups identified in health disparities research.[19] Table 3 illustrates how a composite Individual Level Impact metric can be calculated from the combination of such Reach and Effectiveness indices.[49]

Most decisions are influenced not only by the overall impact of an eHealth product, but also by its cost. Therefore, based on reasoning by Green and Kreuter,[44] an "Efficiency Index" is calculated as the cost of an eHealth intervention divided by its composite Individual Impact score. Use of this index in studies of different eHealth interventions involves calculation of the incremental cost of an eHealth intervention relative to a comparison program, divided by its incremental Individual Level Impact compared to the other program.

Table 3. RE-AIM summary composite indices that combine multiple dimensions

(1) Individual Level Impact (RE) = Reach × Composite Effectiveness
    (a) Reach = [Participation rate – Median $ES_{differential\ characteristics}$]
    (b) Composite Effectiveness = [Median $ES_{key\ outcomes}$ – Median $ES_{negative\ outcomes/QOL}$ – Median $ES_{differential\ impact}$]

(2) $\text{Efficiency} = \dfrac{\text{Cost of Intervention (over control)}}{[\text{Reach} \times \text{Composite Effectiveness}]}$

(3) Setting Level Impact (AI) = Adoption × Implementation
    (a) Adoption = [Setting Participation Rate – Median $ES_{differential\ setting\ characteristics}$]
    (b) Implementation = [Overall Median Implementation Rate across Components – $ES_{differential\ implementation}$]

The RE-AIM framework considers results not only at the individual level, but also at the organizational level. Setting level impact is determined by the number and types of organizations that adopt the product. The Summary Setting Level Impact score is calculated by multiplying Adoption times Implementation, parallel to the Reach times Effectiveness score at the individual level (Table 3). Adoption is a function of both the participation rate among settings as well as the representativeness of these settings (e.g., do low resource organizations and rural settings participate in equal rates to other settings?). Setting Level Implementation is a composite variable that reflects both the median level of implementation of different components of an intervention, and consistency of delivery across different settings.

Implications

There are several implications from the RE-AIM framework for future eHealth research. The first is that representativeness is important at multiple levels—patient, clinician/healthcare team, and organizational setting. Although representativeness has been largely ignored at the setting level,[9] it is just as important as patient level representativeness.

Second, contextual factors and moderating variables are important determinants of intervention outcomes. Program effectiveness often varies across settings and subgroups of users, and we need to report on such contextual effects. One recommended method for inquiry is the "focal point" approach of Rakowski and Breslau,[52] which emphasizes conceptualizing program effects as a joint function of person, problem, setting, and context.

The final "take-home" message from the RE-AIM framework, is to remember the "three Rs" of translation and dissemination research: representativeness, robustness, and replicability. Representativeness has been covered above, but the other Rs deserve further comment. Robustness, or generalization of effects, is important from health disparities, methodologic, and program understanding perspectives. It concerns the extent to which program results are similar across different patient subgroups, clinicians, settings, and other factors. For more detail, see classic texts by Cronbach et al.,[53] who refer to generalizability across persons, time, measures, situations, and program modifications, and on research design by Shadish, Cook, and Campbell.[54]

Replicability refers to whether the results of a program can be duplicated in settings in addition to those in which they are originally reported. Replication is an important, but often underemphasized criteria for strength of evidence.[55] It also helps to ensure that findings are not restricted to a unique context or setting.

In summary, it is recommended that future eHealth research focus on identifying programs that: (1) **reach** large and representative numbers of users, especially those who are most in need; (2) are widely **adopted** across settings, especially those having fewer resources; (3) are consistently **implemented** and do not require staff with high levels of expertise; and (4) produce **robust**, **replicable**, and **long-lasting effects**, and minimal negative impacts, at reasonable **costs**.

Evaluation Challenges and Recommendations

The reader may be thinking, "well, these issues are worth considering, but is it really feasible to integrate all of them into a typical study, and without a huge budget?" The answer, fortunately, is yes: it is possible. Many of the evaluation recommendations, such as specifying denominators of settings and patients approached, tracking costs, collecting automated measures of user engagement, and analyzing representativeness and robustness require few financial resources and do not involve any patient burden. They can be addressed by simply doing a systematic job of keeping project records. Other issues such as assessing patient quality of life and nontargeted behaviors do require additions to typical assessment batteries. The payoff from the ability to answer questions critical to decision makers should be well worth the added items required, especially now that brief, validated scales are available.

There are also an increasing number of studies[56–60] that provide good models by including the majority of these translation topics. Recently, the grantees of the Robert Wood Johnson Foundation–funded eHealth Initiatives (www.hetinitiative.org) agreed to collect common behavior change and quality-of-life measures across projects.

It would be naïve to assert that there are not substantial challenges remaining to getting eHealth programs more widely adopted. However, by taking a consumer perspective—both from the viewpoint of the end-user, and from that of relevant stakeholders (e.g., health plan manager, medical chief, corporate human resources executive)—the eHealth field should be able to substantially decrease the gap between research and practice.

Research Recommendations

This paper concludes with four specific recommendations to accelerate the integration of eHealth knowledge into practice.

1. Venture outside of our research "silos." Most eHealth promotion and medical research has been restricted to narrowly defined questions. Most projects address only one illness or health condition or one target behavior, using a single intervention modality in a single setting, and evaluate outcomes on a single

primary dependent variable. By greatly simplifying the context and eliminating or controlling "potential confounding variables," such approaches can enhance internal validity.[54] However, they do so at the expense of decreased external validity and reduced relevance to real-world settings.[61]

What most organizations interested in eHealth programs need is interventions that work across different illnesses, for multiple risk factors, that produce beneficial outcomes on multiple variables, and that work across different setting conditions for a wide variety of population subgroups. In particular, primary care settings which are faced with multiple competing demands[41] cannot afford to have different programs for asthmatic smokers, overweight diabetes patients, and hypertensive older adults. Future eHealth programs will need to address more than one isolated problem for one specific group to be competitive.

2. Investigate the role of human support. Seldom are the amount, type, and timing of human interaction specified in eHealth reports, despite the fact that this could be one of the most important contextual factors. An eHealth program may work quite differently when introduced by one's primary care physician or nurse, when access is provided to a content expert (e.g., eHealth coach), and when one has contact with persons in a similar situation to oneself than in the absence of these elements. The few studies available on this issue suggest that the addition of electronic eHealth coaches can significantly enhance outcomes.[5,6]

Specific research questions related to interpersonal contact in eHealth include investigation of the level, timing, and types of health professional contacts that best facilitate change; the effects of peer support (e.g., chat rooms, bulletin boards) on both process and outcomes; and the impact of lay health coaches (e.g., Senior Net volunteers).

3. Use experimental designs and reporting criteria that fit the eHealth questions being addressed. If eHealth is considered to be interactive, user-centered, dynamic, and evolving, our designs need to be capable of evaluating such properties. This does not mean that eHealth evaluations should not be well controlled or address threats to interpretation. It does mean that a classic drug trial randomized controlled trial-type design is not automatically the best approach for all eHealth questions. Instead, greater use of optimization procedures and fractional factorial designs,[62] adaptive designs, and interrupted time-series designs[54] should be considered more often. Particularly needed are evaluation methods that capture how eHealth interventions evolve over time[45] and the impact of these iterations. For example, keeping users engaged in Internet-based programs over time appears to be a common challenge across intervention areas.[48,58] To retain users, it is likely necessary to provide fresh material over time, and consumer-centric eHealth programs often

Table 4. Recommendations for future eHealth research to facilitate translation

- Think like and involve your target audience from the beginning—both patients and stakeholders
- Focus on the denominators (all those eligible at the levels of settings, clinicians, and patients) and program reach—not just the numerators of those participating
- Plan for generalization and adaptation—don't just hope for it
- eHealth is contextual—customize to fit local settings and document it

change content over time based upon user responses. Research designs and reporting practices should address these issues.[45]

4. Follow translation and diffusion models. These models include Rogers[11] diffusion of innovation theory, the PRECEDE-PROCEED model that outlines principles of patient and community-centered research,[44] and the RE-AIM model that focuses attention on both individual and setting level factors critical for public health impact[47,63] (www.re-aim.org). Other promising frameworks for eHealth developers to consider include the CURRES (cost effective, useful, realistic, robust, evolving, and sustainable) approach of Rotherham-Borus and colleagues[45] and models of practical clinical and behavioral trials.[25,26]

Conclusion

Great progress has been made in eHealth, and as evidenced by the papers in this issue, a lot has been learned in a relatively short period of time. However, to better understand the potential for and public health impact of eHealth programs, several changes are recommended in the development and evaluation of eHealth programs (Table 4).

A common theme throughout the NIH 2005 eHealth Research Meeting, on which this series of papers is based, was the importance of taking a user-centered approach to development, including usability testing. It would advance dissemination if this same user-centered approach was also applied at the setting level to integrate the perspective of stakeholders and potential adopting organizations. Inclusion of these decision makers early in the process of developing interventions, and in the design of evaluation methods so that they answer questions important to translation, is needed.

Another cross-cutting issue is the need to report information on **denominators** in eHealth research. By denominators, I mean the populations from which the sample of settings, health professionals, and patients in a given study are drawn.[9,27] By reporting only on the numerator of number of participants, critical information about the uptake of eHealth innovations is lost. To address issues related to "the digital divide," health

literacy, and public health impact, such denominator information is essential.

eHealth research needs to plan for generalization and adaptation. There is a long history of interventions being designed for and tested in only a single type of setting. Developers are then surprised when decision makers in other settings do not adopt their "proven intervention." Potential adoptees want to know how a product addresses issues in their setting. Generalization—be it across settings, subgroups, behaviors, conditions or time—must be planned for—it does not occur spontaneously.

Finally, eHealth applications are contextual. They need to fit into a given setting with all of its supports, competing demands, constraints, policies, and customs. Reports of eHealth products need to better describe these contexts and how the product has been adapted to fit these settings. In conclusion, eHealth is complex, contextual, evolving, and has effects at multiple levels. The designs and measures for eHealth research need to have these same characteristics.

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