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A 'Green Button' For Using Aggregate Patient Data At The Point Of Care

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ABSTRACT Randomized controlled trials have traditionally been the gold standard against which all other sources of clinical evidence are measured. However, the cost of conducting these trials can be prohibitive. In addition, evidence from the trials frequently rests on narrow patient-inclusion criteria and thus may not generalize well to real clinical situations. Given the increasing availability of comprehensive clinical data in electronic health records (EHRs), some health system leaders are now advocating for a shift away from traditional trials and toward large-scale retrospective studies, which can use practice-based evidence that is generated as a by-product of clinical processes. Other thought leaders in clinical research suggest that EHRs should be used to lower the cost of trials by integrating point-of-care randomization and data capture into clinical processes. We believe that a successful learning health care system will require both approaches, and we suggest a model that resolves this escalating tension: a "green button" function within EHRs to help clinicians leverage aggregate patient data for decision making at the point of care. Giving clinicians such a tool would support patient care decisions in the absence of gold-standard evidence and would help prioritize clinical questions for which EHR-enabled randomization should be carried out. The privacy rule in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 may require revision to support this novel use of patient data.

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Randomized controlled trials are the gold standard against which all other sources of clinical evidence are measured, because these trials reduce spurious causality and bias. However, their cost can be prohibitive. In addition, it is widely acknowledged that because evidence from these trials typically rests on narrow patient-inclusion criteria, it might not generalize well to real clinical situations.[1]

The widespread adoption of electronic health records (EHRs) is creating a new source of "big data," as every clinician using an EHR generates practice-based evidence—that is, the record of routine clinical practice—as a by-product of routine clinical care. The emergence of such big data has spurred activity in a variety of research areas in both the practice of medicine[2] (such as who will be readmitted to a hospital, will incur high-cost care, or is at risk of decompensation—that is, which patients who are getting sicker and urgently need a higher level of care) and the science of medicine (such as the search for biomarkers that are predictive of disease or response to treatment).[3]

Given the increasing cost of traditional trials and the simultaneous availability of big data

from EHR systems, some health system leaders have suggested a shift away from traditional trials and toward large-scale retrospective studies.[4,5] Other research thought leaders believe that clinical registries and EHRs should be used to lower the cost of trials by integrating point-of-care randomization into clinical work flow.[6]

The argument about observational data versus randomized controlled trials may involve a false dichotomy.[7] However, no previous frameworks have effectively resolved this escalating tension. We propose a "green button" function (explained below) to help clinicians leverage aggregate patient data for decision making at the point of care, in the absence of peer-reviewed evidence. We also suggest that usage metrics can be used to prioritize resources for EHR-enabled point-of-care trials.

This novel model leverages the strength of both approaches in tandem to foster a continuous learning health care system as envisioned by the Institute of Medicine.[8] The "green button" concept is analogous to commercial applications that seek to simplify access to information by the simple click of a button icon on a computer screen. For example, the Department of Veterans Affairs and the Centers for Medicare and Medicaid Services launched "Blue Button" online tools in 2010 to simplify access to health care information for beneficiaries.[9] Before that, James Cimino and Jianhua Li developed and advocated the use of "infobuttons" to help resolve clinicians' unmet information needs.[10]

Evidence-Based Medicine

One definition of *evidence-based medicine* is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."[11] A common example is the use of clinical practice guidelines to reduce inappropriate variation and promote high-quality care. These guidelines are produced by committees of experts who sift through peer-reviewed literature and offer recommendations—based on the best available evidence—to practicing clinicians for everyday decision making.[12]

Remarkably, even in the well-studied field of cardiology, only 19 percent of published guidelines are based on randomized controlled trials.[13] Furthermore, because evidence from randomized controlled trials may not generalize well in many clinical situations, physicians are forced to rely on their best judgment instead of on quantitative analysis. Questions have been raised about the excess complexity, expense, and time required to recruit study participants, as well as the inadequate representativeness of randomized controlled trials.[1,14]

These limitations of randomized controlled trials have been well documented, and some clinical research thought leaders have suggested that EHR- or registry-enabled randomization represents a disruptive solution.[6] In a world where businesses and even political campaigns are now embracing the benefits of automated randomized experiments,[15] this approach seems not just natural but long overdue.

Randomization in health care involves ethical considerations and pragmatic realities that marketing departments and political campaigns do not confront, such as the potential for harming patients. However, there are clearly many comparative effectiveness advantages to embedding research processes in routine clinical care via integration within EHR work flows.

In 2012 the Massachusetts Veterans Epidemiology Research and Information Center, in collaboration with the Stanford Center for Innovative Study Design, set out to test the feasibility of this new method of evidence generation.[15] This first pilot of a point-of-care clinical trial, in which randomization and study processes are added to an EHR system, compared the effectiveness of two insulin regimens. Based on the early success of this pilot, it is now being expanded outside Massachusetts. By institutionalizing statistically sound and efficient learning processes, health care systems can clearly accelerate improvements in the effectiveness of care.

Another solution that has been proposed to address the limitations of randomized controlled trials is the increased use of pragmatic or practical clinical trials.[16] Practical clinical trials compare alternative interventions, study a diverse population in various practice settings, and evaluate a wide range of outcomes. The main bottlenecks in increasing the use of these trials are the lack of incentives, infrastructure, and funding for comparative effectiveness studies.

These issues are being systematically tackled via the formation of networks such as the National Patient-Centered Clinical Research Network (PCORnet),[17] created by the Patient-Centered Outcomes Research Institute (PCORI), and the NIH Collaboratory[18] from the National Institutes of Health, which aims to make clinical research easier to conduct.[19,20] PCORnet is designed to improve the national infrastructure for conducting clinical outcomes research. This network will enable a national capacity to conduct comparative effectiveness research efficiently and to learn from the health care experiences of millions of Americans. Stakeholders from health systems, clinicians, and patients participate in the network's governance and decisions about the use of the resulting data.

Currently, the clinical areas for study are selected by task forces and committees via a qualitative prioritization process. In fact, in a recent post on *Health Affairs* Blog, Joe Selby, executive director of PCORI, writes that every research study must include a plan to ensure that the research focuses on practical questions.[21] We argue that systematically tracking the use of practice-based evidence at the point of care offers a data-driven, objective, and quantitative way to prioritize the clinical areas in which better evidence is needed.

Practice-Based Evidence

Given the constraints on clinical trials, for most clinical questions the only relevant data available to aid in decision making are observational. Historically, this type of data has been administrative in nature, creating the potential for misleading interpretations of findings.[22] However, the rapid adoption of information technology is creating large new clinical data sets and argues for a reconsideration of the role that observational studies can play in evidence-based medicine, particularly in comparative effectiveness research.[23]

This approach has been used for several decades to generate hundreds of retrospective observational studies.[24–28] With the widespread adoption of EHRs as well as the increasing availability of computational methods to process unstructured information, it is increasingly possible to learn directly from practice-based evidence.[29]

Practice-based evidence can also be used in real time to improve care. We believe that the concept of leveraging information about a cohort of similar patients to support care decisions for a new patient was first described with a registry of cardiology patients at Duke University in the early 1970s. In this registry, "all data are stored in a computer information system that allows the doctor to recall the experience of patients like his new patient."[30] This "prognostigram" could be used by clinicians at Duke to quantify the outcomes of medical and surgical interventions in patients similar to their own.

Beth Israel Hospital in Boston later built a system to search a hospital's clinical database for the purposes of patient care, teaching, and research,[31] and at least one author has suggested that this approach should be systematized.[32] Scientists have created algorithms to build cohorts of similar patients.[33,34] However, it wasn't until 2011 that a group at Stanford University described using aggregate patient data from a commercial EHR system to make care decisions for an individual patient.[35]

In this case, practice-based evidence was used to assist clinical decision making in the absence of any relevant peer-reviewed literature or evidence-based clinical practice guidelines. By querying comprehensive clinical data in the EHR system to create a cohort of patients similar to a thirteen-year-old girl with lupus nephritis on the day she was admitted to the hospital, clinicians were able to recognize that she was at higher risk of clotting than patients with the same diagnosis but different lab findings. They therefore decided to give her anticoagulant therapy.

In 2012 the Institute of Medicine observed that "despite the accelerating pace of scientific discovery, the current clinical research enterprise does not sufficiently address pressing clinical questions."[8(p8)] Experts have said that this "inferential gap" exists when evidence germane to a particular clinical situation is absent, which forces clinicians and patients to make decisions that are uninformed by data.[4,5]

Creating an infrastructure for the use of practice-based evidence as a source of real-time, personalized comparative effectiveness information at the bedside is clearly a step toward a true learning health care system. Physicians believe that insufficient time is the greatest barrier to point-of-care learning and that efficiency is the most important determinant in selecting an information source.[36] We envision deploying a personalized cohort of similar patients as a "green button" solution (explained below), which could be used to support shared decision making by the clinician and the patient.

The Green Button

Recognizing that clinicians are required to make decisions in the absence of best-practice evidence every day, we propose that aggregate EHR data be leveraged for real-time, personalized comparative effectiveness information for every patient at every visit. Deploying a green "patients like mine" button[37] as a tool in the EHR would both support patient care decisions in the absence of published evidence and, as a by-product, quantify and prioritize unanswered clinical questions for EHR-enabled randomization at the point of care (see online Appendix Exhibit 1).[38]

Information about these personalized cohorts of similar patients could be drawn not just from clinical data sources but also from administrative and nontraditional data sources, such as information on pharmacy benefits, social media, and even data on shopping habits. Adding these data could enable improved assessment of longitudinal outcomes such as medication adherence and patient satisfaction.

Evidence-based medicine is about using the highest-quality evidence available while also knowing its limitations. This new approach is actually an EHR-enabled version of the well-established tenets of evidence-based practice: Use relevant data from meta-analyses or randomized controlled trials when those data are available; when they are not, use data from observational studies. Using aggregated data from local experience is clearly superior to using expert opinion alone.

Consider, for example, how the green button might be used in a learning health system that had adopted the necessary policy framework and implemented the supporting technology. Imagine that a fifty-five-year-old woman of Asian heritage known to have asthma presents to her physician with new-onset moderate hypertension. Recognizing that this patient's sex, heritage, and comorbidity are poorly represented in existing clinical guidelines, her physician queries the commercial EHR system using the green button and discovers that a large number of similar patients in a personalized cohort appear to have responded particularly well to certain classes of antihypertensive medication. Over time, this clinical question is asked frequently enough that the health system's clinical effectiveness team configures the EHR to automatically recommend randomization to one of two classes of antihypertensive medications at the point of care (see Appendix Exhibit 2).[38]

The technology needed to enable this model (including EHRs, computational capacity, and data-mining software) already exists. However, a policy framework and incentives to drive the work flows and data capture, as well as investment to deploy the necessary technology, are urgently needed to make the green button a reality.

It is also conceivable that the green button could be tied into existing guideline-based clinical decision support tools and could invoke those before proceeding to practice-based evidence. However, given the idiosyncratic nature of clinical guidelines, most of which are not yet amenable to automation, this approach might not be feasible in the near future.[39]

Operationalizing The Green Button

Another example of how the green button might be used is in development at Lucile Packard Children's Hospital Stanford, and it illustrates the technical challenges of operationalizing this model. In April 2013 the Joint Commission issued an alert about medical device alarm safety. The alert suggested that 85–99 percent of bedside alarms do not require clinical intervention.[40] Two of the five Joint Commission recommendations for addressing this issue were to have guidelines for alarm settings and to have guidelines for tailoring these settings and signaling limits for individual patients.

Lucile Packard Children's Hospital Stanford is now moving from the antiquated model of setting empirical alarm limits to a data-driven model that uses published curves for vital signs in hospitalized children.[41] For example, the old policy for setting alarm limits in the absence of a specific physician's order was based on age-based normal ranges in healthy outpatients. In contrast, the new policy reflects the normal heart rate distribution derived from thousands of hospitalized children, which we hypothesize will significantly decrease false positive alarm rates. However, this approach is still not optimal because it reflects data about children with a variety of different disorders.

The next step, which is now under development, is to move beyond using generic data from all hospitalized children to a more personalized approach. The green button in this situation will automatically generate 5 percent and 95 percent vital sign parameters using historical cohorts of similar patients during the admission process. Clinicians will be allowed to variably weigh factors such as age, weight, and diagnosis when generating the cohort.

The technical challenge of operationalizing this example is related to effectively computing patient similarity and visualizing the results in a clinically meaningful manner. This begins with defining the set of features to use and their extraction from structured and unstructured data within the EHR. This kind of phenotyping has already become fairly common.[42] Recent examples include the use of such methods for identifying breast cancer recurrence,[43] pneumonia,[44] and peripheral artery disease.[29]

The next challenge is calculating similarity thresholds. An in-depth technical discussion is beyond the scope of this article, but this challenge is amenable to computational optimization.[45]

For example, given a certain similarity threshold (say, 80 percent similarity) and a similarity metric, specific patients will be included in the cohort of similar patients. If we change the similarity metric but keep the same threshold, we get a slightly different set of patients. Now we can define the "stability" of the patient cohort as the difference between the two sets of patients. By defining "good enough" patient similarity in terms of the "stability" of the patient cohort, we can discover the threshold of similarity at which the cohort changes very little, even if when we change the similarity metric.

Ultimately, the green button will help operationalize the self-learning health care system.

The intuition is that if different metrics produce the same set of patients, then the similarity metrics are functionally equivalent. The size of the patient cohort at that optimal similarity threshold can be used to perform a power analysis to determine the reliability of the observed outcomes. Finally, with appropriate visualization as a decision support tool, the educated physician can then decide if the cohort is adequate for use in shared decision making. The green button is envisioned as a "pull" concept, with a physician choosing to click on it as needed (instead of a "push" concept, with an alert popping up to interrupt the physician). Thus, it is important to understand how physicians could be incentivized to use such a system. Given that clinical visits frequently result in unmet information needs,[46] the green button may serve as a highly personalized teaching tool for clinicians as well as patients.

We believe that tracking green-button use could even create opportunities for the maintenance-of-certification credit for board certification renewal.[47] Major disincentives would be users' perceptions of medical or legal liability, which should be dispelled by local legal review, and the potential for unintended consequences related to use of the green button. Tracking of green-button use could allow for oversight by review committees to evaluate clinician practice and minimize uninformed use.

Potential Unintended Consequences

The green button represents personalized cohorts of retrospective observational data constructed at the point of care. Thus, the limitations of this approach are best understood as the limitations of observational studies. Eliminating typical bias in observational data such as selection, information, measurement, and confounding is difficult. However, it is possible to summarize the utility of the results based on the estimated effect size; the confidence in the estimate; and clinical relevance as evidenced by effects on mortality, morbidity, or cost over time for the cohort.

For example, effect size and confidence are summarized via odds ratios (or likelihood ratios) and confidence intervals, respectively. Clinical relevance can be summarized via plots that quantify time-to-event, such as a Kaplan-Meir curve. Using such countermeasures to mitigate the unintended consequences of biases would certainly require educating the treating clinicians about these issues when reviewing results from the green button.

Other domains have undergone transitions in which complicated information traditionally used by experts—such as portfolio screening tools in finance and airline fare prediction websites—was made directly available to users. With the right tools and education, users can adapt. Even with appropriate tools, accompanying education for clinicians will be necessary for their effective use of the tools. This will integrate well with ongoing changes in medical education, which is rapidly being transformed to accommodate new technologies.[48,49]

Policy And Ethical Implications

A new policy and ethical framework will be needed to support this evolving paradigm. The development of a real-time personalized cohort for the lupus case at Stanford University was feasible because the lead author already had Institutional Review Board (IRB) approval to electronically review similar patients. Systematic implementation of real-time cohorts may require health care systems to allow any treating physician to access potentially identified data about patients who are not under his or her direct care.

These data should be deidentified if possible (that is, patient identifiers should be removed), but they may not be fully anonymized (that is, it might be possible to reidentify the data through various techniques). This may require a change in the privacy rule in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 or clarification that it is acceptable for front-line clinicians to use aggregate patient data, even if identified, for the purpose of treating a similar patient under their care. Without this clarification, conservative health system compliance officers will not allow individual clinicians to access records for patients who are not under their direct care.

It is also critical that the green button be recognized by all IRBs and the Office for Human Research Protections in the Department of Health and Human Services as a quality improvement effort instead of as a clinical research initiative. This may seem self-evident, given that the

green button is intended to be used only in situations of clinical equipoise—that is, when there is genuine uncertainty within the expert medical community about the preferred treatment.[50] However, an investigation by the Office for Human Research Protections into the IRB exemption received by University of Michigan quality improvement leaders had the detrimental effect of fundamentally altering IRB attitudes across the nation.[51] Some bioethicists continue to argue that informed consent should not be waived even in cases of clinical equipoise—a position that is incompatible with widespread implementation of either the green button or point-of-care randomization.[52]

Fortunately, the ethical foundation for such an approach was described by Ruth Faden and coauthors, who suggested that in a just health care system, patients have a moral obligation to contribute to the common purpose of improving the quality and value of clinical care in the system.[53] This framework posits that just as health professionals and organizations have an obligation to learn, patients have an obligation to contribute to, participate in, and otherwise facilitate learning. The obligation placed on patients to contribute, under limited and appropriate conditions, to learning that is integrated with their clinical care is not present in conventional accounts of either clinical ethics or research ethics, where the assumption is that no such obligation exists. Ultimately, this ethical basis will help transform the learning health care system into a self-learning health care system.

Conclusion

The US health care system fails all Americans on a daily basis. It is unacceptable that patients are routinely prescribed interventions that big data collected from EHRs may soon suggest are ineffective. Unlocking big data for use by front-line clinicians will provide personalized therapy plans and prove, through point-of-care randomization, which treatments truly work. The green button, representing real-time use of big data to create personalized cohorts of similar patients, will be a resource for both bedside decision making and the prioritization of unanswered questions for point-of-care randomization. Ultimately, the green button will help operationalize the self-learning health care system.

Donald Rubin presciently wrote in 1974: "In cases [where randomization is not feasible], it seems more reasonable to try to estimate the effects of the treatments from nonrandomized studies than to ignore these data and dream of the ideal experiment or make 'armchair' decisions without the benefit of data analysis. Using the indications from nonrandomized studies, one can, if necessary, initiate randomized experiments for those treatments that require better estimates or that look most promising."[54] In 2014 the technological capabilities are available to make these visions a reality. The question now is whether or not there is the political and sociocultural will to do so. ■

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NOTES

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37 The authors acknowledge that an application for a class 9 trademark was filed for the term *Patients Like Mine* by Epic Systems Corporation on December 29, 2011. In addition, the "patientslikemine.com" Internet domain is registered to the company PatientsLikeMe. The authors use this term to indicate a generic concept, not any specific product.
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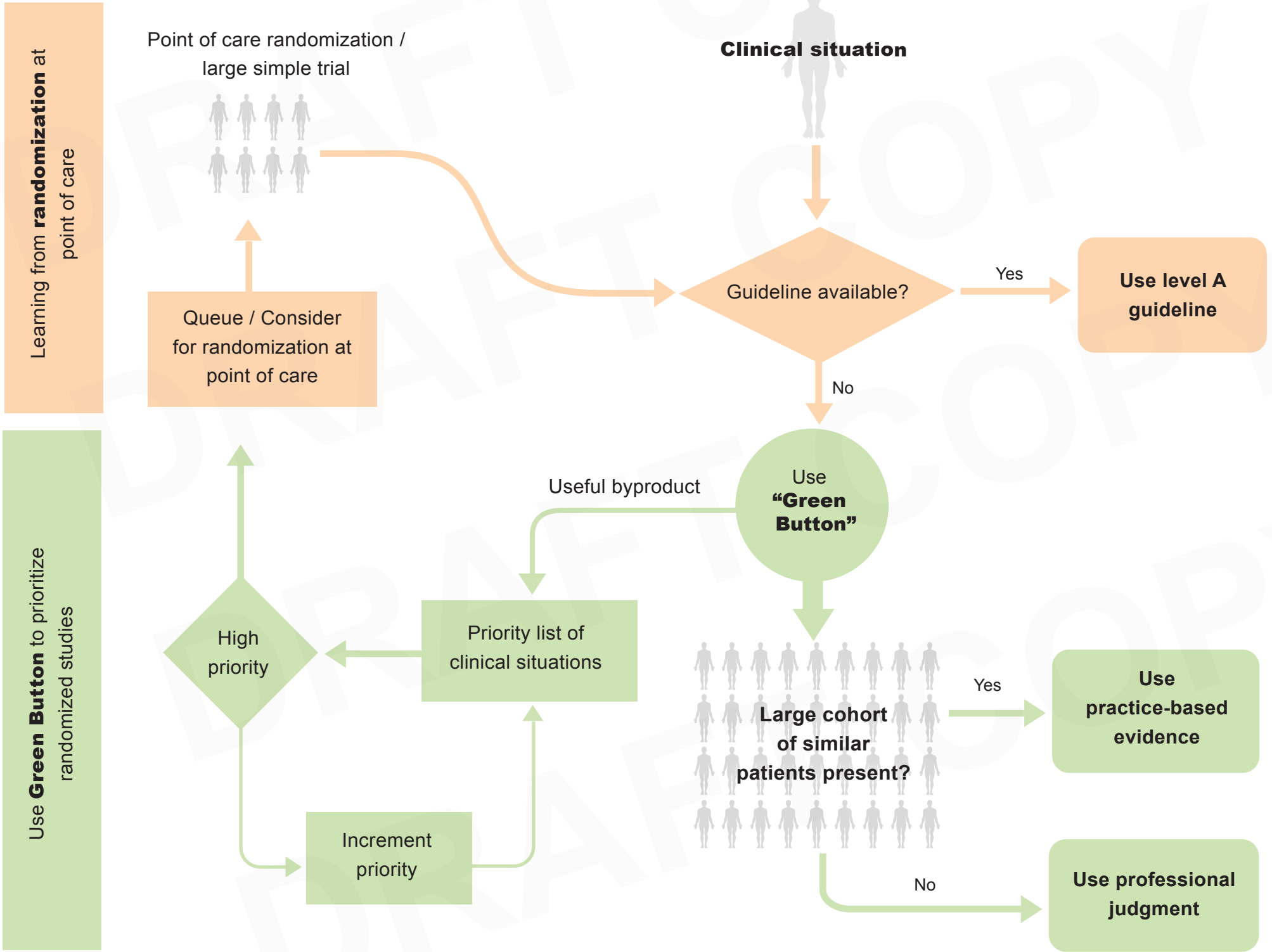
Fig 1 caption: A model showing how deploying a green "patients like mine" button as a tool in the EHR would both support patient care decisions in the absence of published evidence, and, as a by-product, quantify and prioritize unanswered clinical questions for EHR-enabled randomization at the point of care.

Fig 2 caption: An example showing the result of using the green button in a learning health system for making a personalized decision of the class of anti-hypertensives for a 55 fifty-five year old female woman of Asian heritage with asthma and new onset moderate hypertension.


Learning from **randomization** at point of care
Use **Green Button** to prioritize randomized studies
Point of care randomization / large simple trial
Clinical situation
Guideline available?
Yes
Use level A guideline
No
Queue / Consider for randomization at point of care
Use **"Green Button"**
Useful byproduct
High priority
Priority list of clinical situations
Large cohort of similar patients present?
Yes
Use practice-based evidence
Increment priority
No
Use professional judgment

Green button

My Patient

A 55 year old female of Vietnamese heritage with known asthma presents to her physician with new onset moderate hypertension

Intervention

antihypertensives

Outcome

Diastolic pressure < 90 mm Hg