I. Summary
There is growing consensus that in order to confront the challenges of high cost and variable quality, the health care system must determine which activities contribute to patients’ health and which are costly but unnecessary. In order for health systems to engage in such learning, they must report outcomes both internally and externally so that health care delivery activities can be correlated with outcomes. The outcomes that are most essential to report are those that matter most to patients. These include not only traditionally measured outcomes such as mortality, but also patient reported outcomes (PRO), such as functional status, mental health, and the ability to perform activities of daily living. The ability of electronic health records (EHRs) to display outcome measurements and patient generated health data (PGHD) as part of clinical documentation is critical to such reporting and learning and is, therefore, critical for the foundation of the evolving healthcare system.

Though much of the value from patient reported outcome measures (PROMs) comes from lessons at the system level drawn from aggregated data, its collection by patients and providers depends on PRO being useful on the individual level. The collection of PRO and PGHD is challenging since it requires the involvement of both the patient to provide responses and either a clinician or a technology system to record responses. To make this effort from all parties worthwhile, PGHD must be actionable. To be actionable, PGHD must be captured in the EHR, since increasing demands on workflow have meant that only information that is captured in the EHR can be expected to be consistently actionable.

In short, the ability of the health care system to learn is dependent upon the capture of PROMs in aggregate, which in turn depends on individual PRO collection, which relies on the ability of the EHR to display PRO so that they are actionable. Meaningful Use standards
that encouraged the incorporation of PRO into the EHR would significantly catalyze the adoption of PRO.

Several aspects of the manner in which PRO are incorporated into the EHR can enhance the ability of such systems to improve care:

1. **PRO must feed into coded fields in the EHR.** Coded fields allow for alerts and decision support on an individual patient level and data aggregation and analysis on a system level. Tablets, smart phones, and web-based systems will increasingly be the tools used to collect PGHD. This will make incorporation into clinical documentation significantly easier, provided there are fields in place in EHRs to display such data.

2. **PGHD can enter the EHR without provider verification** if two conditions are met: A. Any critical values trigger alerts that are sent to providers for acknowledgment; and B. PGHD that appears in the EHR is clearly demarcated as patient generated. This strategy is superior to that of having clinicians “accept” incoming PGHD, which then becomes an indistinguishable part of the medical record.

3. **Patients’ view of their PRO reports should be identical to providers’ view.** PRO reports have a potentially high value when used as tool for discussion between patients and providers. Looking at a report together, a patient and provider can discuss discrepancies perceptions of the patient’s status, engage in goal-setting, and make more informed shared medical decisions.

4. **PRO can be a tool to coordinate care across providers and across the continuum of care from acute care to home.** Once PRO are in coded fields in the EHR, functionality can be developed to use PRO to coordinate care across providers and throughout the continuum of care. The most appropriate clinician to respond to a particular patient reported problem may not be the one that the patient is currently seeing. Automated systems can nonetheless ensure that the most appropriate clinician sees a critical value. Similarly, a patient at home may not seek care, but may require further intervention. Electronic capture of data and transmission to the most appropriate clinician promotes the care of patients whether they are presenting for care or not.

PROMs and PGHD are vital components of quality improvement and cost reduction in health care. Policy at the national level that facilitates the frequent and uncomplicated reporting of PRO and PGHD into coded fields within EHRs would significantly enable such quality improvement and cost reduction.

II. **Background**

Partners HealthCare (Partners), an organization that includes Massachusetts General Hospital (MGH) and Brigham and Women’s Hospital (BWH), launched its effort to institute PROMs in 2011. With the ultimate goal of having patients report outcomes across all clinical conditions and care sites, Partners launched the first phase of the initiative for patients with diabetes and patients undergoing cardiac surgery at select clinics at BWH and MGH. We
have partnered with Quality Data Management, Inc. (QDM) to help administer and report PROMs. In 2013, we are expanding clinical conditions to include stroke, acute myocardial infarction, and urology and clinical sites to include non-academic medical centers.

Partners’ PRO tools include both a set of questions common to all conditions and condition-specific questions. The common questions include the PROMIS-10 Global Health instrument, which provides both physical and mental health scores, and an overall health utility question. To determine the condition-specific questions, a group of physician and non-physician experts from across the continuum of care at Partners is convened to determine which patient reported outcomes are most relevant to care for the condition in question.

The process of collecting PRO is described in detail in Appendix A: Collecting Patient Reported Outcomes. Briefly, patients who fit a given condition and who visit a given clinic are listed on the opening page of an iPad app. A clinic staff member selects the patient’s name from the list and hands the iPad to the patient. The patient uses the touch screen to enter the PRO and also to select a follow up modality including the web-based patient portal or telephone. The patient is contacted by this modality at the appropriate time interval. This technology backbone is captured in Figure 1.

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1 Patient Reported Outcomes Measurement Information System (PROMIS), funded by the National Institutes of Health (NIH), is a system of highly reliable, valid, flexible, precise, and responsive assessment tools that measure patient-reported health status.
PRO are automatically tabulated into a *Snapshot*™ report that is instantaneously reported to the patient on the iPad and sent to the patient via the electronic patient portal and to the clinical care team via the EHR. An example of the *Snapshot* is shown below in Figure 2. In addition to recording individualized data in the *Snapshot*, Partners collects aggregate data by clinic, condition, and patient subpopulation and analyzes the data for variability.
III. Goals of Patient Reported Outcomes

Partners has described five goals for the Patient Reported Outcomes Initiative:

1. To use PRO to improve the care of individual patients through better monitoring and improved responsiveness.
2. To use population-level data to set patient expectations and improve joint medical decision-making.
3. To use aggregate data as the basis for internal comparative effectiveness research.
4. To publically report outcome measures in order to demonstrate quality and value.
5. To orient care toward outcomes that matter to patients, creating a health system that learns

1. To use PRO to improve the care of individual patients through better monitoring and improved responsiveness.

Asking a particular set of well-validated questions and delivering the responses to clinicians at regular intervals has the potential to improve care. There are three primary ways that this can be achieved:

A. Systematically asking the relevant questions.
Currently, clinicians do not systematically ask questions about many of the outcomes that matter to patients, or, if they do, the relevant information may not be given to the appropriate member of the care team.

Healthcare professionals gather information through multiple modalities. Often this means gauging a patient’s mental health by their affect or gauging their functional status by their ability to walk into the exam room. More rigorous methods of verbally assessing many of these outcomes would be too time consuming for a clinician to engage in with each patient. PRO ensures that these important outcomes are captured systematically for all patients without additional time requirements for the clinician.

B. Delivering the answers to the right provider.
Often, one member of the care team might obtain information to which they are not best suited to respond. For example, depression following heart surgery is very common. However, a surgeon who determines that a patient is depressed is much less suited to treat the patient than a primary care doctor or better yet a mental health professional with this information. Patient reported outcomes have the ability to make the relevant outcomes readily available to the team member best suited to respond.
C. Monitoring patients whether or not they present to the healthcare system.
Currently, healthcare practitioners monitor patients almost exclusively when they are at a point of care. Conversely, the system Partners has designed can take a Snapshot when the patient is in the clinic, at rehab, or at home, either by phone or using Patient Gateway. As we move toward population management where we care for all of our patients rather than just those who present for care, this multimodal data collection system will be invaluable.

2. To use population-level data to set patient expectations and improve joint medical decision-making.

Patient-centered care requires that patients have the right information to make informed decisions about care options. The healthcare system currently lacks a robust method of setting patient expectations. At the present anecdotal experience of clinicians or clinical trial data that more closely reflect study populations than actual patient populations, are the only means for setting any kind of patient expectations.

By aggregating PRO for a given condition or treatment option and providing this aggregate data to patients and providers, we can begin to educate patients about what outcomes they can likely expect along the very metrics that they care most about.

3. To use aggregate data as the basis for internal comparative effectiveness research.

There is significant variability in most aspects of patient care, even for narrowly defined conditions. This variability exists between institutions, between providers, and even for the same provider among their patients. Often there are no data to explain these variations, as clinical trials for these often subtle differences in care are not feasible.

It may be challenging to determine the statistical significance of differences in PRO between subpopulations, since it is impossible to control for certain extraneous variables. However, examining differences in these outcomes among institutions, providers, and treatment methods may provide the basis for further comparative effectiveness research.

4. To publically report outcome measures in order to demonstrate quality and value.

Partners anticipates reporting outcomes to demonstrate quality to patients, to compare with other institutions, and to measure value for payers.

   A. Patients

   Few institutions are collecting PRO in the United States today. Partners’ ability to demonstrate performance on outcomes that matter to patients is a powerful signal to patients that we are achieving the results that they are interested in.
B. Other health care providers

As patients and payers examine differences between institutions, it has been difficult to find metrics that are both relevant and able to differentiate good institutions from mediocre ones. Many of those metrics, such as mortality, are often more a function of the state of the art of medicine rather than of differences in quality of care at particular institutions. PRO, on the other hand, may be significantly different between institutions. Once reported by multiple institutions, PRO may be useful for differentiating institutions on the basis of quality. It may also benefit to learn best practices between health care institutions.

C. Value

In general, outcome measures that matter to patients can be compared to costs in order to determine the value of care that is being delivered, where value is defined as outcomes divided by cost. Though there may be disagreement about whether lowering cost or improving outcomes is more important, there is broad agreement that improving value is a worthwhile goal.

5. To orient care toward outcomes that matter to patients, creating a health system that learns.

Healthcare institutions, and organizations of all types, orient their improvements toward the metrics that they measure. Currently, institutions typically measure mortality, readmissions, and length of stay, among other common metrics. Mortality is important, but is difficult to improve upon given that it is very similar at all US hospitals and is affected more by the current state of the art of medicine than the quality of individual institutions. Readmissions and length of stay metrics can be used to improve care, but while patients care about these areas, they are not often the most important metrics to patients. Most patients would rather spend extra time in the hospital if it would mean that they felt better after they leave.

Patient reported outcomes are an effort to truly capture outcomes that matter to patients. Many outcomes measured are consistent across conditions, such as physical function and mental health, as, regardless of their condition, patients want to be able to perform their daily activities easily and to be free from sadness or anxiety. For other outcomes, condition-specific measures are important. (e.g. patients undergoing knee surgery are likely to be most concerned about their ability to walk and their pain.)

By analyzing differences in outcomes across a health system, the system can learn which activities contribute most to patients’ health. For instance, analysts can identify positive and negative outliers for a given procedure. They can then investigate the causes of that variability and generate best practices. Furthermore, it is possible that only certain populations benefit from a given treatment. The analysis of patient reported outcomes can elucidate these hidden drivers of clinical outcomes. Systematically incorporating these outcomes and the process of analysis into a health care system converts that system into one that is perpetually learning how to improve care.
IV. The Role of Clinical Documentation

A New Paradigm of Documentation

The current system of clinical documentation is based on two historical facts:

1. The patient’s chart was a physical folder that could only be populated by serial paper “notes” that were added sequentially.

2. In a fee-for-service system, payers require proof in the form of “notes” documenting services rendered before they will provide reimbursement for those services.

Both of these facts are becoming less relevant. EHRs are becoming universal, largely due to Meaningful Use standards. In outpatient clinical medicine today, elements not in the EHR such as paper documents and imaging disks are barely considered part of the clinical record for all practical purposes, since one can never be sure whether these elements will be accessible to providers or at other locations. In response, clinicians who want paper elements to remain part of the record will scan the document or upload images. This illustrates the degree to which the EHR has become the dominant component of clinical documentation to the exclusion of non-electronic material.

Additionally, although most health care is still provided in a fee-for-service environment, health care is shifting toward episode-based or population-based metrics for reimbursement. In this environment, documentation of the activities performed at a single encounter is less relevant to payers than the results achieved at the end of an entire episode for acute care or over a period of time for a chronic disease or primary care population.

Liberation from the requirement that clinical documentation be based on notes can allow us to examine the truly important elements of clinical documentation:

A. An up-to-date and accurate representation of the current state of a patient. This includes the diagnoses and problems which a patient suffers; static features such as demographics, family history, and genetic predispositions; and dynamic features such as medications, allergies, laboratory and radiology findings, patient reported outcomes, vital signs and physical exam findings. In addition, this current state includes the members of the care team and the plan of care currently being executed.

B. Trends of relevant information. Changes over time in some of the dynamic features listed above are relevant to care. This is most obvious for laboratory or radiology findings, but is also critical for medication lists and physical and patient-reported findings.

C. A narrative of clinical reasoning, when appropriate. One important aspect of clinical documentation not available in the two categories above is the reasoning behind decisions made at a given encounter. Clinical documentation needs to capture this
reasoning in series in a way similar to the current “Assessment and Plan” section of notes.

Clinical documentation that recognizes these important elements can take a different form than current records. One way to capture these elements would be to have an electronic patient dashboard that includes the static and dynamic features above in coded fields. Clicking on a dynamic feature would yield a time trend of that element. The dashboard could also include a sidebar with a dated running narrative of assessments and plans.

In this paradigm, documentation becomes much less time intensive, redundant, and cumbersome. Static elements remain present without having to be re-entered. Changes in the patient’s condition are more apparent when dynamic elements are entered or visualized in the context of a trend rather than entered de novo. The running narrative allows members of the care team to quickly understand the clinical course to date without resorting to the investigation often required when sifting through multiple discrete notes. All of this serves to promote efficiency and quality of care.

While not all the elements above are relevant to documentation of PRO, many of the same principles were utilized in the method of reporting PRO in the EHR at Partners. At any one time, there is one Snapshot of PRO in the EHR. This Snapshot captures the current state of the patient’s PRO in a visual analog display. Time trends of these elements are displayed graphically adjacent to the current state. The decision aids at the bottom of the Snapshot display an assessment of each PRO with reference to previous assessments (e.g. “Your mental health has gotten worse since your last Snapshot. We would like to help find out what has changed. You may be showing signs and symptoms of depression. You should talk to your care team about these signs and symptoms. Your care team may refer you to one of our mental health staff.”). When a patient enters a subsequent set of PRO, the previous Snapshot is replaced by the new one, with the older data now incorporated into the time trends of the current Snapshot.

The Role of Clinical Documentation in a Team

As the size of teams required to care for patients has increased, EHRs have become the predominant means of coordination among team members. As health care is evolving, so is the notion of the clinical team. The team now includes the primary care physician and often multiple specialists. Even within primary care, non-physicians, including nurses, physician assistants, pharmacists, medical assistants, physical and occupational therapists, care coordinators, and administrative assistants, are essential contributors to patient care. In this new environment, no single individual has sole ownership of the patient record or the expertise to populate all the relevant information.

When one team member sees a patient, it has become necessary for her to review the contributions of the other team members. For example, when a patient has a stroke, the patient’s PCP may need to review a neurologist’s detailed examination and a community resource specialist’s notes about supervised day programs in the area to help the patient and
her family make the right medical decisions. Currently this information sharing is accomplished by reviewing discrete notes, but in the future a careful review of the patient dashboard plus the running narrative sidebar may allow this to occur even more effectively and efficiently. While in some settings, including some Patient Centered Medical Homes (PCMHs), clinicians have the opportunity to discuss patients formally in huddles or informally due to colocation, in most instances care is still provided across space and time. When clinicians cannot discuss patients in person, it is the EHR that allows coordinated, multi-disciplinary care to occur.

One of Partners’ goals is to use PRO to improve the care of individual patients through better monitoring and improved responsiveness. As stated above, this is accomplished in part by delivering the PRO to the team member best suited to respond to them. Because the PRO becomes part of a coded field in the EHR, logic is incorporated into the reporting mechanism that ensures that the appropriate clinician sees the relevant PRO. In the example of cardiac surgery given above, a patient’s newly developed depression is caught by the PRO tool in the cardiac surgeon’s office six weeks after surgery even if the patient has not sought help for depression. While the surgeon may not be equipped to respond to this, the system immediately generates an alert that goes simultaneously to the PCP and the associated practice mental health professional who can then take the appropriate steps to ensure the patient receives care. In addition to better care for the patient by addressing his depression, this smart reporting also provides the patient his best shot of a favorable surgical outcome, as depressed patients often have less favorable outcomes after cardiac surgery. This is one example of how Partners’ initiative uses clinical documentation in the EHR to achieve higher quality care that is better coordinated across the clinical team.

Patient Access to Clinical Documentation

Though there has been resistance in the past to giving patients access to their EHR, patients are the most important member of the care team and, as such, would be best served by sharing the same information as their providers. There have been multiple studies showing that increased patient engagement is associated with better outcomes. Similarly, studies show, and most providers can attest to, large discrepancies between what patients understands at the moment of the encounter and what they retain over time. Allowing an increasingly medically-savvy population to review the facts and clinical reasoning behind their care will likely lead to more engagement and superior outcomes. This may not always be as simple as leaving the patient unaware of these details, but it is almost certainly better for the patient, both purely for the sake of transparency and for improved clinical care.

One important caveat is that some clinical information is difficult to interpret. It is important that patients not be exposed to certain clinical information before a clinician has had the opportunity to discuss it with the patient. A simple example of this is a pathology report

showing metastatic cancer. Before a patient views this information at their home, it would likely be prudent to have the patient meet with a clinician who can explain the significance of the diagnosis and the treatment options. This can easily be accomplished by restricting certain types of information until it is “released” by providers. Alternatively, one pilot at Children’s Hospital Boston releases all clinical information to inpatients at noon daily, so providers know they must address any potentially distressing results before then.

The Partners PRO initiative has insisted that the patient and the provider see identical Snapshot reports. This has improved communication between patients and providers. Results have come up that are surprising to clinicians; patients often have a poorer view of their own health. Having a common report to work off has led to fruitful conversations about why there is a discrepancy between the provider’s and the patient’s view of the patient’s health.

The Role of Device and Mobile Technology in Clinical Documentation

Technology enables documentation to occur as a part of care delivery rather than in parallel or in addition. Currently, significant inefficiencies are incurred when patients fill out paper forms. As noted above, paper forms are often ignored unless they are scanned into the EHR. Even scanned forms miss the opportunity to input data into coded fields, resulting in the loss of the ability to have decision support around this data, the ability to trend information for an individual patient, and the ability to aggregate the information of multiple patients.

Tablets, such as the iPads used in Partners’ initiative, allow information to be documented at the same time as it is collected. Software programming creates a standard report based on answers, including decision aids based on multiple points of branching logic. Furthermore, rules governing the flow of information based on certain values in coded fields can be used to send information to the appropriate clinician. The initiative’s web-based patient portal allows this same functionality. Smart phones hold the promise of taking this phenomenon to new heights, letting patients begin to become routinely engaged in their own health care.

Handling Patient Generated Data

PGHD is most appropriately incorporated into the EHR when accurately flagged in the record as patient-generated, and, if so flagged, does not need to be routinely verified or acknowledged by a provider. There are increasingly diverse data streams converging in the patient records. Clinicians currently assume that most sources entering data are relatively reliable. Many physicians and health data professionals are concerned, however, that PGHD may be particularly vulnerable to inaccuracy and therefore require verification. Furthermore, many are concerned that clinically dire results may be reported and therefore require acknowledgement. For this reason, many experts advocate that clinicians should have to “accept” PGHD into the EHR. By accepting the data, both the verification and acknowledgement are presumably fulfilled.
The primary problem with this strategy is that once this data is accepted into the EHR, it is untraceable, meaning a future provider cannot tell that this information was patient generated. If PGHD is indeed more likely to be inaccurate, then it would make more sense to maintain a designation in the EHR that clearly identified PGHD as patient-generated in perpetuity. Clinicians would then no longer have to verify this information. It should also be noted that in most cases clinicians would not be able to verify the accuracy of much PGHD anyway.

In terms of acknowledgment, all data in the increasing torrent of information flowing into the EHR is potentially of immediate clinical significance. It would be impossible, however, to demand that providers sift through all this information for their growing panels of patients. Even if it were possible, as volume increased, providers would likely begin to become desensitized to the process of accepting information and less able to catch potentially relevant clinical information. Instead, if information is electronically entered into coded fields, decision support and other information engines in the EHR can alert the appropriate clinician with the appropriate level of urgency in response to potentially significant incoming data.

V. Conclusion

The single most important step that the HIT Policy Committee could take is to encourage the reporting of PRO in the EHR through Meaningful Use standards. Clinical documentation is a critical component of health care activities and must actively evolve to suit the changing needs of health care. The Health Information Technology Policy Committee has demonstrated vision in developing past stages of Meaningful Use standards that have catalyzed this evolution. There are several strategies enumerated throughout this testimony to describe how PRO can best be incorporated into the EHR. Ultimately, however, it is simply the incorporation of PRO into the EHR that will enhance the ability of health systems to collect PRO broadly. By facilitating the broad adoption and internal, and ultimately public, reporting of outcomes including patient reported outcomes, the HIT Policy Committee would enable health systems and the health care system writ large to learn from its activities how best to deliver health care.
VI. Appendix A: Collecting Patient Reported Outcomes

The process of collecting PRO at Partners is as follows:

1. Patients with the given clinical condition are identified by certain clinical information (e.g. diabetics are identified if they have had a HgA1c score of more than seven and/or “Diabetes” listed on their Problem List).
2. This list of patients is automatically cross-referenced with the clinical scheduling system to find which patients have appointments on any given day.
3. A tablet (iPad) in the control of the clinic administrative staff is populated using this system to show the list of patients eligible for PRO.
4. When the patient checks in for her appointment, the staff clicks on the name of the patient on the tablet and hands the tablet to the patient.
5. A brief animation explains PRO to the patient and provides instructions for use.
6. The patient answers 16-21 questions on the iPad touch screen.
   a. All patients receive the general questions: PROMIS global health-10 and a health utility question.
   b. Patients also receive condition-specific questions (e.g. questions related to chest pain and shortness of breath for those undergoing cardiac surgery).
   c. The patient chooses a method for subsequent PROMs reporting. Current choices include email using Patient Gateway (Partners’ electronic patient portal) or phone using interactive voice response (IVR). A smart phone app for iPhone and Android may be available as an option soon.
7. The patient returns the iPad to the staff.
8. A Snapshot© report is generated by QDM in real time.
   a. The PROMIS global health-10 questions are used to compute a Physical Health score and a Mental Health score. The health utility score is also reported.
   b. The condition-specific questions are reported in various ways (e.g. an aggregate symptom score).
   c. Both the patient’s most recent scores and her trend for each score over time are reported. A range is provided based on population data as a reference for each score and time point.
9. The Snapshot report is available to the patient on Patient Gateway immediately.
10. A link is generated in Partners’ EHR called “Patient Reported Outcomes” and displays the identical Snapshot report to any provider who clicks on the link.
11. At the designated time interval (e.g. every six months), QDM uses the method designated by the - either through Patient Gateway or by phone - to contact the patient and collect PRO.

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