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Document: Use Case
Course: INFO-B641 Business of HI
Date: 24 October 2013

Patients First
Use Case – Lab Test Results: To the patient!

Summary

Patients First (PF) is a healthcare organization based in the state of Missouri, United States. As their name suggests, their mission is to be a consumer-centered provider of healthcare within their region of service. PF has rapidly adopted the Electronic Health Record (EHR), and has specified that one Meaningful Use (MU) criteria they wish to fulfill is electronic patient notification of laboratory results. Therefore, we build a use case that is centered upon this goal. Obtaining this use case would be easy for an organization such as PF, as proper IT adoption protocols and consumer-centered attitudes were prime consideration in their EHR implementation. The use case is then extended into a value case by potential downstream benefits, and a case explored in more detail is that of increased patient knowledge with respect to patient conditions; the value case argued is therefore is a measurable improvement in patient outcomes; indeed, we find in the literature that increased patient knowledge of a patient's own health condition has been demonstrated to lead to better patient outcomes. Lastly, these outcomes may be measured by disorder-specific scales, empirical laboratory value changes, and patient surveying. Should these values not be available (as is the current case), Monte Carlo simulation is used in order to provide simulated values of measurable patient outcome improvement.

Background: Patients First, Adoption, & MU

Patients First (PF) is a consumer-centered health organization that by nature would strongly benefit from any steps that enhance the knowledge, health, and well being of its patients (Patients First, 2011). Their own description (as per MU example submission to the Department of Health and Human Services [DHHS]; DHHS 2010-2013) does not mention financial stakeholders as primary targets in their decision to adopt EHRs. In the late 2000s, PF adopted NextGen and NextMD, both of which are electronic health systems. NextMD allowed for reporting of patient lab test results in particular; results are delivered not just to the patient's treating physician, but also the patient him or herself.

In terms of EHR adoption, PF chose expert users that they believed were highly influential in the clinic's social hierarchy (Patients First, 2011) as points of introduction for NextGen/NextMD implementations. Research by Mirriahi et al (2012) on the adoption of technology indicates that people of high centrality (i.e., influence) are the best "nodes" at which to introduce novel technologies. Therefore, in construction of our use case, we may thus assume that Patients First has used an ideal introductory method and that bottlenecks in their system will not exist at the point of novel IT introduction.

MU criteria (Patients First, 2011) suggest that amongst other things, "patient-specific education resources", "provide[ing] clinical summaries", and "[supporting] access to information" are goals of MU programs. Patient notification of laboratory results primarily supports the latter criterion, although laboratory results may be considered a part of the clinical summary and perhaps even patient education, depending upon the nature of the visit and patient's condition, respectively. Nonetheless, we approach the notion of lab result notification as an issue that pertains to open patient access of personal health information.

However, it is very important to note that PF claims that it has very little access to back-end aspects of its EHR system (Patients First, 2011). Back-end aspects would include admin panel views of databases, the ability to create new views for data representation (beyond the views that NextGen and NextMD already offer), and potential abilities to detect patient usage of the system. PF has specifically cited issues with the latter criteria (Patients First, 2011). However, in construction of this use case, we shall have to request that PF find a method by which they can access the latter *two* criteria (i.e., creation of new representation views and detection of patient EHR usage and views).

Literature In-Depth: Benefits of notifying patients

It would not be appropriate to discuss the merits and drawbacks of this use case without discussing the direct and downstream benefits of patient notification. The academic literature also supports patient notification as beneficial to patient health; however, patient notification in context has been found to be somewhat more difficult. Given that PF is a patient-centered organization, PF should understand the benefits their system may provide.

Notification of *authorities* in the case of disease outbreaks is commonplace in the health informatics (HI) field in clinical subfields ranging from infectious disease (Kelly et al, 2013) to adverse reactions to blood transfusions (Pedrosa et al, 2013). However, notification of patients as to their laboratory test results may be less frequent, and health systems have started increasing direct notification to patients; it is the opinion of Singh et al (2013) that one onus of EHRs is indeed to notify patients of all laboratory test results, with a focus on abnormal results. "Failure to notify patients" (Singh et al, p. 727) is cited as a major issue in EHRs, strengthening the case for notification of patients. Singh further

suggests that timely patient notification of test results (particularly abnormal ones) should be used in the evaluation of an EHR system (p. 727). Lawton & Skjoet (2011) also found that informing patients of laboratory results also had a further wellness benefit; specifically, proper reporting of laboratory results in a manner understandable to patients resulted in a reduction of adverse drug reactions (ADRs); however in Lawton & Skjoet's study, an electronic delivery system did not perform as well as its paper counterpart due to its use of unfamiliar terminology.

Therefore, we will need to turn to Topac & Stoicu-Tivadar's (2013) vision of "patient empowerment" (p. 454). Topac & Stoicu-Tivadar found that patient knowledge (and therefore empowerment) was increased by the translation of medical terms into "lay knowledge" (language that could be understood by patients) (p. 454). Such a system showed efficacy in increasing general medical knowledge amongst the lay population; a system such as the one proposed could have dramatic impact on patients with conditions if (unlike with Lawton & Skjoet's e-System) laboratory results are reported in a context familiar to patients.

Lastly, it is important to note that patient well-being has been positively correlated with patient knowledge empowerment; without noting this idea, the proposed use case is not of value. Lee, Bridges, & Shockney (2008) found that cancer patients were able to make the wisest decisions regarding their own care when shown the maximum amount of relevant information, and Tenforde at al (2012) found that the usage of the EHR by patients did not correlate to improved well being unless usage was widespread; we could interpret this observation as an issue with adoption of the technology in question.

Use Case Description

We shall assume that an external laboratory performs testing, and that the EHR system (EHRS) is in place already. We assume the fairly ordinary trigger of the doctor suspecting that the patient may have an illness (or an existing illness that is getting worse), and that this laboratory result will confirm the physician's suspicions (and educate the patient). The research by Singh (2013), Lawton & Skjoet (2011), and Topac & Stoicu-Trivadar (2013) all suggest that proper implementation of the representation of patient laboratory test results to the patient him or herself has a great possibility of enhancing health outcomes. In order to avoid the issues encountered in Lawton & Skjoet's 2011 study and in line with the opinions of Topac & Stoicu-Trivadar (2013), we add to the use case the suggestion that context be given as part of lab test result delivery in order to maximize value and transform this use case into a true use-value case that promotes patient participation and increases patient knowledge, ultimately creating benefits for patient health.

More importantly, however, this use case requires that PF have knowledge of and access to the back-end of their system, which they do not (more information regarding this issue is available in the literature review and at the Patients First case study site listed in the references section). PF does indeed have to gain access to this particular end of their systems (or create accessory systems that can do so) in order to fulfill most of the use case as presented.

This use case is diagrammed at the bottom of this section; the appendix contains our impression of a sample patient-centered result format. However, it must be noted that PF may have to take the step of surveying its users as to their level of medical terminology

familiarity; the posted example assumes that the patient is generally unfamiliar with the jargon that can often be found in laboratory test results.

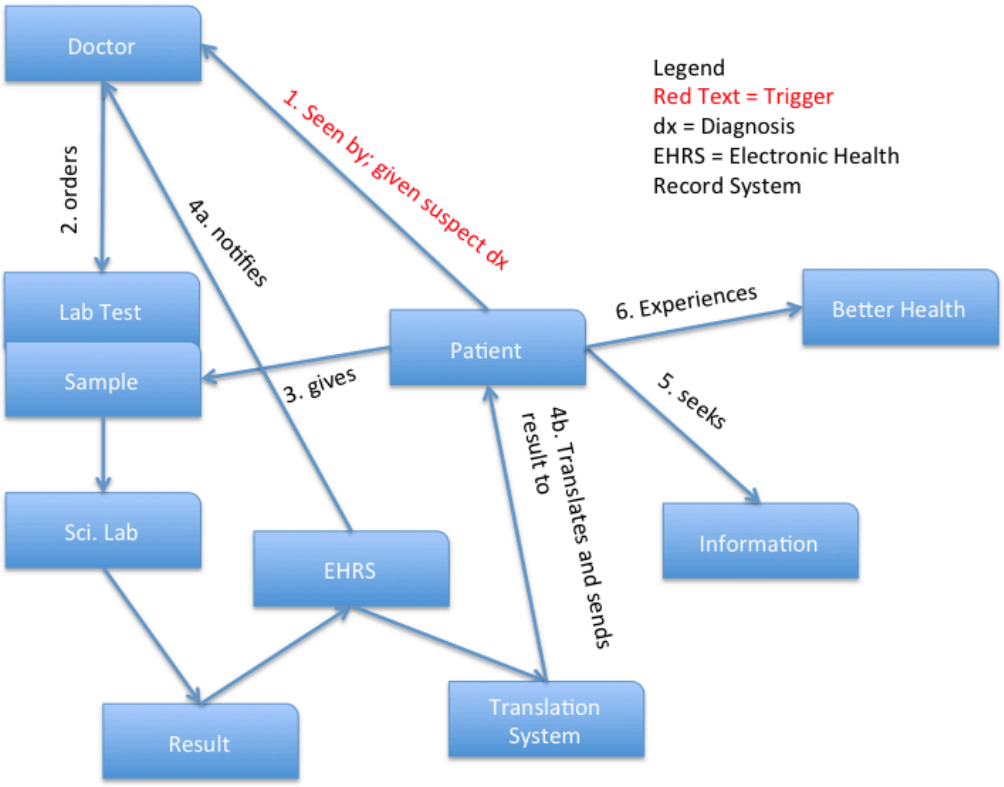

Figure. Use case master diagram. The output of the translation system is available in the appendix of this paper.

Use Case Metrics

It is obvious that PF will wish to judge the clinical utility of reporting of lab results to their patients. While there are of course many instruments to judge utility of the reporting of lab results to authorities, there are few to judge utility of reporting these same results to patients. Lawton & Skjoet (2011) observed ratings from a pre-written, disorder-specific wellness scale, as well as objective wellness measures. Tenforde et al (2012) suggest an

actual laboratory numerical value metric (in their use case, improvements in Hb-A1C were measured in diabetic EHR users). Because there exists no consensus on the proper way to measure efficacy of a use/value case as specific as the one presented, it is recommended to PF that a combination of disorder-specific rating scales, empirical test improvements (provided that serial test results are compatible!), and direct user surveying as to their personal opinions regarding relevancy of lab data are all suggested as potential outcome measures.

More specifically, PF may wish to use a paired t-test in order to evaluate efficacy in improvement of patient laboratory values. We first consider the case of a value such as A1c, where there is an ideal goal and patients can be deliberately tested in a controlled fashion. Paired t-testing of values in a controlled experiment would be conducted as such:

1. (Day 1): The patient's blood sample is taken and an A1c level is determined.
2. (When A1c result is available): The system logs are checked for the first time the patient gains access to his or her laboratory test result value; then the number of days from test result availability to first patient observation of value should be calculated.
3. (Day 90): The patient's blood sample is taken again for A1c.
4. (When second A1c result is available): For each patient, A1c result is observed.
5. The values from each patient are then paired and a t-test run to see if an improvement (in our case, decrease in lab value) was observed at alpha = 0.05.

It is also important to note that in step (2) of above, we recorded the time to the patient's checking his or her own test result value. The rationale for having done so is to extend the

research performed by Tenforde et al (2012). PF should then perform a linear regression with the following evaluands observed:

- Change in A1c for each patient
- Days to checking own EMR for initial A1c result. If the EMR is not checked, we assign a value of 90 to the patient's delay in checking their own result.

Linear regression is done between the above two evaluands using a method such as Pearson coefficient correlation. If the data are observed to fit a reasonably tight form of line (as opposed to space), but the observed line is curved and R-squared in the linear fashion is not significant, we can then entertain a curvilinear regression with the same ideal R-squared.

It is important to know that correlation is never the same as causation. However, most statisticians allow for sufficient guess (at a 95% confidence level) of causation if *both* t-test p-value ≤ 0.05 *and* Pearson coefficient squared ≥ 0.95 (in any type of regression) occurs. Furthermore, the specific type of regression (e.g. linear, power, logarithmic, sigmoidal, etc.) assists in determining the specific type of causation (Kutner, Nachtsheim, & Neter, 2004).

Simulation of Use Case Metric Results

In order to simulate the type of data such an experiment may produce, we utilize a Monte Carlo simulation. These simulations provide numbers among any distribution that is programmed by the user and are widely used in fields ranging from pharmacoeconomics (Ademi et al., 2013) to determining the biological fate of cancer cells (Marcu & Harriss-Phillips, 2012). A random (z-normal) distribution is assumed for the first set of A1c values obtained, and then to force some sort of change in the post-observational distribution, we use a linear distribution in the simulation for that variable, in essence assuming that the

mean value departs a central tendency and then spreads to either side in a linear-type distribution, which for this case, we manipulate with a downhill slope, expecting some improvement in overall A1c trends. Therefore, we have the two classical equations:

$$z(A1c) = (\frac{A1c}{SD(A1c)}) \text{ and } y(A1c) = mx + b$$

Z represents the initial random distribution of A1c, and y represents the new linear distribution expected with the patient being able to see his or her records. In the former equation, *SD(A1c)* is the standard deviation of the whole of patients' A1c values. Furthermore, it is important to note that the improvement in A1c for any given individual is by nature $z - y$. Using these two assumptions, we construct a Monte Carlo simulation and then perform both t-testing and linear regression between the old values and new values.

After performing t-testing between these two sets of obtained variables, if significant decrease in A1c is determined, we then observe (virtually) the number of days it took for any patient to retrieve his or her result. The user running the simulation may wish to assume that the result was observed in a z-normal distribution from 1 day (first day of availability) and 100 days (with day values over 90 being categorized at 90 days), creating a median observation of 50 days, although a linear distribution of information seeking time may also be used; it is important to note that literature neither supports nor confirms the superiority of either of these distributions.

Discussion; Final Recommendations

We defend this particular use case as not just a stated use as per PF, but also as a case of increased value in terms of patient health. As PF is patient-centered, patient health outcomes are their primary targeted evaluand in system evaluation. The academic literature is rich in support for PF's use case of delivering laboratory results to the patients; furthermore, the potential exists for extension of this use case to a value case.

We recommend PF to continue pursuing the introduction of IT innovations to individuals of high centrality, including well-respected physicians and staff. Continued use of a cultural structure that has already been correlated with high levels of IT adoption in PF's own institution (and not to mention external academic research) and will have a lasting positive impact for downstream use cases (such as the one studied in this report). In Tenforde's (2012) study, improved IT adoption protocols as already used by PF may have in fact allowed a very similar electronic to-patient lab result reporting system to flourish rather than only partially succeed.

As for the use case itself, we of course define it as the patient receiving his or her own laboratory test results, but endeavor to turn this event into a true value case. Foremost, due to PF's strongly patient-oriented culture, patient information access (such as that to lab results) is strongly recommended. A true value case itself, however, may not be made until the patient is informed of laboratory results in context (in particular, with terminology familiar to the patient). However, if the patient is empowered in this manner, improved patient health outcomes are likely to result.

Preliminary results for this use case could be obtained by a Monte Carlo type simulation, which randomly assigns values to evaluands (e.g. patient portal utilization vs. some measure of health). Such results may be analyzed by linear regression and/or t-test to

discover any trends between adoption and potential health habits. However, such an approach should be used with caution, as there is a paucity of literature on using Monte Carlo simulations for such use cases.

Lastly, a post-adoption surveillance system is encouraged. While the implementation process was carried out in 2011, no public data exist on PF's particular use case and it is thus unknown if PF is carrying out metrics (or any other sort of surveillance) for their adoption program. Implementation of metrics for surveillance (as mentioned in this document's metrics section) is therefore highly encouraged. In order to adopt metrics for measuring value in this use case, furthermore, some creativity will be required, as the NextMD and NextGen systems do not have default capabilities in terms of creating new context for reporting to patients their own records and monitoring patient usage of these reports.

Appendix: Patient-facing lab test result screen (author's conception)

Example: Contextualized Lab Result Report (for Patient)
Author's Conceptualization (May NOT contain accurate medical information)

NextNP – Your Laboratory Test Results
Patient: Josephson, John P. (M / 39)

Diagnosis: Diabetes, Type II, Mature onset of young

Panel: Diabetic fasting, A1c & FBG

Date of Sample: October 24 2013

Result 1
Test: Hb-A1c (Hemoglobin A1c)
Purpose: Hb-A1c (also known as A1c for short) is a long-term estimation of your blood glucose over about the past three (3) months.
Result: 6.8%
A time series is available for this result. See how your values have changed over time and what this means!

Result 2
Test: Fasting Blood Glucose (FBG)
Purpose: FBG is a measure of your blood's sugar (glucose) content at the time the sample was drawn.
Result: 130 mg/dL (HIGH)

What these results mean: Individuals such as yourself with Mature onset diabetes of the young (MODY) should strive to keep an A1c of below 7.0%. Your result implies that you have been keeping good control of your blood sugar levels. However, even those with diabetes are best keeping their fasting blood glucose (FBG) below 120 mg/dL at any given point in time. It is possible that your sugar control has not been well the past day or two, or that you did not fast appropriately (you may not consume any calories for 12 hours pre-test). Nonetheless, your A1c level of 6.8% shows that you have generally been taking good care of your condition.

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