Chapter 3
The Journey to Usability: A Vendor's Perspective

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Abstract To successfully utilize the full functionality of a mission-critical application such as an electronic health record (EHR), it is imperative to be flexible, intuitive, feature-rich and scalable. On a foundational level, having access to an application running with high-speed connections and fast processing speeds with an easily accessible network on a device suitable to the clinicians' choice and for the environment desired is the expectation of most users. But when it comes to usability, can the subjective become a science? Vendors, certification bodies, insurance payers, federal policy organizations and the Institute of Medicine think so, and have been working to reconcile the two-way street of adherence to training and implementation with design and workflow best practices. The additional challenge for the EHR software vendors has been the interoperability of all the components within a clinical setting to achieve optimal efficiency and results. Continued challenges grow as care coordination, quality reporting and more detailed coding lead to user options in the areas of data recognition and/or sophisticated voice recognition that capture discrete codified information. For those of us in the medical Information Technology (IT) space, ensuring that the parallel tracts of hardware, communications, networks, browsers and software applications lead to an effective EHR requires constant balance. Users must reconcile the reality of "clicks" with the need for availability of data without becoming overwhelmed. Together, the challenge of advancing mutually beneficial solutions in a highly regulated and standards-based environment has truly been monumental. This review looks at the past leading up to our current status and what is on the near and far horizon of gains in EHR usability.

Keywords History of ambulatory EHR • Usability impacted by hardware • Software • Regulations and features • Training and user engagement

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3.1 Introduction

To fully grasp the usability issues within an EHR system, you must have an under-standing of the developmental history of an EHR. There have been many changes over the past two to three decades within the United States (US) healthcare system. The Institute of Medicine (IOM) called for paperless medical records in 10 years in a publication in 1991 [13]. President George W. Bush, in the State of the Union address in January 2004, announced, "By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care. To protect the doctor patient relationship and keep good doctors doing good work; we must elimi-nate wasteful and frivolous medical lawsuits" [4], the goal being to provide every citizen in the US with a personal electronic medical record. The intensity of that effort was accelerated by President Obama in February of 2009 when he signed into law the American Restoration and Recovery Act and Health Information Technology for Economic and Clinical Health (HITECH) Act, which provided financial and technical assistance to practices implementing an EHR [2].

Since then, there has been a significant, if not dramatic, change in the develop-ment and implementation of electronic health records. For many years there was a mounting frustration for healthcare workers dealing with a paper-centric world while many other industries had learned to function efficiently and effectively in an electronic environment. This only heightened the desire for a modernized approach for complete patient management within a software application.

In the 1980s and early 1990s, the business tools used in physicians' offices on a daily basis had become highly sophisticated, but our patient clinical documentation lagged behind and still was still paper-based. Some physicians began to embrace some basic forms of electronic document capture for direct patient care. It became obvious to many that expanding to a more sophisticated system that allowed the clinical side of the practice to be as effective as the practice management was desir-able. But most clinicians had concerns as to how an EHR was going to capture all the details of a highly variable patient documentation environment.

As physicians became more exposed to other industries that were embracing internet based applications, they were developing an increased interest in having similar applications in clinical medicine. The securities and banking world led the way towards web browser-based applications; the world of clinical medicine, how-ever, was lacking that ability to modernize for a variety of reasons. So, the idea of having an internet accessible application where the practice records, both financial and clinical, were housed at a remote server and therefore out of the direct control of the practice was concerning for physicians and administrators. This was new for practices and initially a major concern because the practice would literally come to a standstill if the access stopped. Additionally, all the practice data were in the hands of someone else, which left physicians very uncomfortable. However, as more practices became comfortable with companies that offered remote applica-tions, the resistance was been much less. Currently, the trend is towards a distribu-tive network of servers or Cloud technology. If those other business institutions

could effectively deal with the security and privacy issues, then it seemed reasonable for healthcare to be able to do the same.

But to achieve a highly usable EHR application within a practice, a major basic need is having an IT workforce that understood medical practice workflow and requirements. How to get the EHR application at the point of care without interfering with the delivery of care was paramount. Early on, the networking and wireless capabilities were very limited and the cost in many ways was especially challenging for smaller practices. For some small practices, it was just cost-prohibitive to implement an EHR.

With the introduction of tablets and portable laptops, many practices saw the advantages of these tools. But these devices were bulky and heavy with a short battery life, which made them a challenge to use at the point of care. Also, their function was compromised by generally poor wireless connections within the physical plant of a practice. Many traditional paper-based practices had a physical layout that was not conducive to good wireless communications or having adequate workspace for the larger desktop computers near the exam rooms. Even when hard wired to their internet service, the internet service provider (ISP) were not reliable, requiring practices to invest in a higher-speed, more expensive T1 connection.

In addition, the software was primarily designed for desktop PC use, so having a smaller-form tablet caused more usability issues. Issues like font size, scalability and page loading over the wireless caused many users to become frustrated. So early on, only the committed, tech-savvy users embraced the new world of EHRs. Despite frustrations, these early adopters saw the advantages of the electronic health record.

Additionally, regulatory elements such as Health Insurance Portability and Accountability Act (HIPAA) were and continue to be a significant force in how an EHR potentially handles privacy and security in the protection of personal health information. And above all, patient safety is paramount in the EHR world – we need to protect, validate and act on reliable medical information to provide the utmost in patient care.

As a physician, my natural focus within my practice was to find an efficient workflow to handle the needs of my patients and at the same time provide a usable, functional document for my patient visits. Documentation requirements and needs have exploded over the last few decades. Initially the main focus of a clinical document was to provide a "note" for future reference about the patient's condition. But we all know this has been expanded to deal with coding and billing needs as well as medicolegal needs and payer audits. And now, there is an increased need for discrete data for Meaningful Use and other quality analytics. So the physician in the trenches finds himself and his staff documenting a variety of things that are not considered germane to the care of the patient.

My, and many of my colleagues', criticism of the early experience with an EHR has been that the technology did not allow me to be as efficient as I thought I was in the paper world. It has been hard for clinicians to straddle the proverbial EHR fence when adopting an EHR, still having one foot in the paper world and one foot in new the EHR world. EHRs seemed restrictive and inflexible when it came to the demands within a clinical practice. So the challenge seemed to be that an EHR had to have the

same flexibility as a paper record. That seemed reasonable until one realized that paper records had their own challenges in that not only were they bulky and disorganized, but only one person could have access to them at a time. Additionally, they often got misplaced, took up significant space and had to be maintained for at least 10 years by law, and there was a high paper/resource cost to "open" a chart on a new patient.

Despite the general frustration with EHRs over the years, many clinicians, when asked, would not return to paper. As of 2013 according to a National Center for Health Statistics (NCHS) Data Brief [8], nearly 80 % of physician practices in the US had at least a basic EHR. Acute care hospitals by 2013 have a 59 % adoption rate of a basic EHR, with 94 % being a certified EHR, according to an Office of the National Coordinator (ONC) Data Brief in May, 2014 [5].

The goal of this chapter is to explain how the components of an EHR interact to impact usability and how they have changed over time. As with most changes that occur within an industry, demand, regulations, law, and technology drive the innovation and improvements. No user wants to use, and no vendor wants to design and build, an unusable product. The over-arching desire is to have a fully functional EHR that incorporates the features needed to join the patient and providers in a comprehensive care record.

3.2 The Journey Up Until Now

So, how has usability been impacted over the years? There are multiple forces impacting the world of EHRs. Reviewing the developmental history of electronic medical records over the previous two to three decades gives us a better understanding of the complexity of the topic of usability.

When EHRs, formerly known as EMRs (electronic medical records) and before then, CPRs (computerized patient records), started gaining popularity in the early 1990s, their focus was obviously much more rudimentary than it is now. Practice management (PM) systems had existed for approximately a decade and filled a significant need for most ambulatory practices. The PM applications were growing in sophistication with the enhanced requirements for billing and claims management. The realization that the clinical side of practice was still in a paper world provided a strange dichotomy as the clinicians became more knowledgeable about computers.

The challenge has always been based on the argument that it is hard to capture the amount of variability within a clinical visit in an electronic format. However, at the same time, many ambulatory practitioners used some types of forms to capture information, and others dictated their visit encounters. As I took a more critical view of this argument, I began to realize there were many things I did in my practice that were very repetitive on a daily basis. When conditions such as the Flu or sinusitis, gallstones or a routine health visit are the concern, then a narrative can easily be repeated with relatively little variation from the previous patient with the same issue. This situation lends itself nicely to having a symptom- or diagnosis-based

template to easily compile the patients' medical history information and their current complaints along with a standard set of orders and instructions for that patient. However, for a certain percentage of patient visits, depending on the specialty, an argument can be made that there are situations in which a more detailed and complex narrative is needed to capture the nuances of the patient's problems. Many clinicians still used commercial or self-made forms, or used a set of dictation templates that their transcriptionists inserted into the documentation. Despite the documentation purists in the medical world, a ubiquitous statement in medical training was "common things happen commonly, so when you hear hoof beats, don't always think of zebras." Using this argument, many EHRs have focused on some type of template-based application for the clinical side. Build a system that allows common frequent tasks to be performed effectively and efficiently, but leave enough flexibility for the exceptions in documentation and workflow.

In the paper world, trying to get information out of the collective set of medical records in a practice was a significant, laborious challenge. Individual records had to be "pulled," then meticulously reviewed and the expectant data elements compiled in order to get a view of a group of patients. So most physicians only had a supposition of how they effectively practice on a population basis. How did their management of a diabetic patient compare to that of their peers? With an EHR, now clinicians have the ability to understand practice patterns and treatment of a population of patients. Population health management now becomes more likely in the EHR world.

More physicians could see the advantage of making the clinic side as efficient as the practice side had become. A good example of this was when a drug named Vioxx by Merck became available in May, 1999, a non-steroidal anti-inflamatory drug, Vioxx became a very popular prescription for patients with discomfort from musculo-skeletal problems, such as arthritis. There were studies, such as VIGOR, that raised concerns about the increased incidence of heart attacks and deaths directly related to the drug [10]. Greener stated that there were an estimated 88,000 heart attacks and 33,000 deaths from Vioxx [6]. Using this example, if more physicians were able to compile their information, perhaps the fact that Vioxx was a dangerous drug could have been verified earlier. In a paper-based practice, the physicians had no clear understanding of which patients were on this drug. Someone within the practice would have had to literally look through each patient's paper record to identify and verify whether the patient had received Vioxx. Now in an EHR, a report can quickly be run on those patients. This feature alone has without a doubt improved patient safety. This example only illustrates the usefulness of being able to extract valuable information out of an EHR; the challenge is still the inputting of data into a system. But this will slowly resolve as more systems are interoperable through the sharing of discrete codified data.

Additionally, outside of the office or clinic, there was no access to patient information. So, many decisions when dealing with a patient afterhours were made by memory or inadequate feedback from the patient or a relative. This was especially true when one was covering for a large number of colleagues and had never met or cared for the patients previously. Certain physicians, such as obstetricians, were

forced to have paper charts available for their near-term pregnant patients at the hospital's labor and delivery department. The potential of losing the charts or having them compromised in some way was real.

With more discrete data being accumulated, there is a perception, if not a demand from outside agencies that these data should be readily accessible to them. This has put an increasing demand on clinicians and staff to record even larger amounts of data that may not directly impact or improve patient care. The incentive payments vortex draws practices and physicians into an ever increasing requirement for advanced reporting. Grant-based programs, such as Federally Qualified Health Care (FQCH) clinics and Community Health Clinics (CHC), add another layer of demographic data collection and reporting that is usually not part of most practices' information needs. Unfortunately, there may be an unrealistic expectation that the potential availability of all these data implies some level of clinical effectiveness. So, are EHRs more uniformly able to provide clinically relevant data with which to accurately assess the effectiveness of treatment of a patient and the level of competence of medical staffs?

PM systems became the first obvious step on practices' electronic journeys. There were many data points to capture regarding demographics, insurance plan details, scheduling, coding and billing for claims. Electronic claims filing requirements made an electronic PM system mandatory for practices while the clinical side still maintained a paper record, but we still had PM needs within the paper record also. To the casual observer, it was apparent that there were two worlds in the ambulatory practices.

For the most part, employees in the front office were stationary and could easily use a desktop computer to effectively do their work. However, the clinical staffs were constantly on the move between exam and procedure rooms. They needed mobility in the computer systems that just wasn't available at that time. Additionally, there were external elements in our world: payers, legal, hospitals, medical consultants and regulatory agencies still needed or required a paper document. Communication among medical environments was all paper-based, with mail and fax as the only electronic link.

Early EMRs were focusing on documenting the visit. But it became obvious early that a computer could perform additional functions such as Evaluation and Management (E&M) coding and alerts/reminders. So within a short time it became obvious that there are multiple other needs within a clinical setting that a computer could facilitate. At the same time, hospitals were exposed to a variety of systems that allowed electronic capture of information in various departments. Inventory control was the principal need, followed by pharmacy needs and laboratory as well as clinical documentation needs. Once the hospitals entered into the era of computerized physician order entry (CPOE), the demands on the IT infrastructure increased as a result of patient care needs and safety. All of us who lived through those transitions remember the challenge of CPOE. What now came to the forefront was the development of IT shops within the acute care situations. Hospitals, as they added more modules to their software, were requiring more sophisticated IT staffs. However, in the ambulatory environment, there was a paucity of local IT companies that could help practices with their computer and network needs.

As the IT infrastructure moved from individual PCs to a local network, there became an added level of expertise that many practices did not have or did not want to develop. Many locales around the country did not have expertise in the surrounding vicinity to assist the practices in establishing a good IT strategy.

Wireless (Wi-Fi) standardization started in 1997 with the IEEE (Institute of Electrical and Electronics Engineers) version 802.11. The most common version was 802.11b, but it had limited use in clinics because bandwidth was small, so most EHR applications required more bandwidth to be useful. However, several upgraded versions were needed to get to the level at which the EHR requirements could be handled. Wireless technology started to provide the mobility and, along with the development of tablets, gave the clinician staff some workflow flexibility. With improving communications speeds and more convenient mobile devices, there was more interest in EHR adoption.

Another important need was to be able to visualize radiographic imaging outside of the radiology suite and within the ambulatory clinic. DICOM (Digital Imaging and Communications in Medicine) and PACS (Picture Archiving and Communication System) systems were developed and provided a significant advantage in handling patients' radiographic imaging. This opened the door to telemedicine, whereby radiologists could be in remote locations from where the imaging was performed and still render a specialist interpretation. Now, other areas are expanding in the telemedicine field, with online consultations with peers as well as commercial ventures in providing online medical consultation to consumers.

As most of our world has become very mobile, the demand for increased mobility in the medical world has developed. For the most part, most of the legacy EHR software was not web browser-type technology. There was a significant reliance on Remote Desk Top (RDP) for connecting clinic sites remote from the main office or for use by clinicians at home while on call; this was mostly a PC-based, DOS to VB script-type software development, which was not as compatible with the mobile environment that users wanted. There are many factors at play at this point in the journey. The rudimentary networks; weak, evolving wireless networks; and early browser-based software with early tablet hardware all had an impact on the user's experience.

Most of the practice management systems in early 1980s were DOS-based with a slow evolution to Windows-based technology. When my company approached the problem in the early 2000s, we were dealing with early browser-based functionality. It had many of the looks of a typical Internet application of the time, but lacked a lot of the functionality that Windows products were able to deliver. Users were becoming more comfortable with surfing the internet but still wanted some of the Window functionality.

It became obvious to some of us as vendors that a browser-based approach was able to provide an effective solution for the future with increased mobility to the user and increased flexibility to the practices. As more upgraded versions of Hypertext Markup Language (HTML) became available, the enhancements of capabilities increased dramatically for application. Today, many EHR applications are HTML-based, with more becoming Cloud-focused. With a more cloud-based

approach, updating applications becomes much more reasonable and timely. With less dependence on a Thick Client-based application, the hardware infrastructure for a practice becomes much more cost-effective and more flexible in the type of form factors that are available for a user. So it becomes much easier for smaller practices to keep current with the most recent version and features of their EHR product.

When looking at the path of the journey of usability over the course of the maturation of the EHR, there should be an appreciation of the multifactorial impact on the EHR development. Perhaps a train analogy would be representative of this. As the engine and caboose starts off, multiple cars get added, such as the Certification Commission for Healthcare Information Technology (CCHIT) certification, eRx, patient portal, claims eligibility, alerts and reminders, quality reporting, Meaningful Use (MU) reporting, etc. The vendors find themselves constantly trying to add a more powerful engine to pull the weight of all these "cars" so we can deliver everything in an efficient, timely fashion. In short, we want to build an application that is as perfect as can be, in which a caregiver can deliver medical care to the patient with the utmost efficiency and effectiveness and with the most value at the least cost to the payer.

3.3   The Hardware/Communications

The continued challenge for EHR vendors with a variety of hardware options is that the program have the ability to scale to size as well as deal with different device operating systems. With the different form factors increasingly available to the end-user comes the challenge for the user to find the appropriate use for their device in the current setting. Trying to use a smart phone inside a clinic when you would be looking up the results, or reading documentation or relying on point and click functionality is very difficult. However at the same time, the increasing capacities and changing size options constantly impact how vendors and users are expecting to use the device and EHR application in different environments. Improved speech technology is making voice documentation of a patient document much more effective. The smart phone's best use appears to be outside the clinic for limited functions such as coding visits for rounds in the hospital, dictating messages for the staff or memos for the chart, or eRx prescribing.

Basically there are four options for putting clinical information into an EHR – typing, handwriting recognition, point-and-click and dictation via speech recognition or transcription. Since many clinicians over the years have used dictation, there is an interest in continuing that for speed and capturing the essence of the patient encounter. The challenge with speech recognition over the years has been that it is purely speech-to-text. When the speech was translated to text, the computer systems could only store as text. When there is a need for discrete data, text alone is not a viable option. The text must be processed through a Natural Language Processing (NLP) engine. This is a reasonable option when the data can be obtained after the

fact, for instance when looking at a large number of documents and searching for certain textual elements.

The challenge is using speech recognition, and then having it run through a speech-understanding engine to produce an Extensible Markup Language (XML) document, which can be processed by different engines for evaluation and management (E&M) coding and alerts and reminders. M*Modal's speech recognition technology [7] allows speech to be rendered as a text document, but also with a CDA/XML document in the background. This functionality can make significant impact on future EHR functionally with regards to discrete data. Then a clinician can focus on the patient's management. The documentation is created by importing historical medical information and dictating the elements of the visit that are specific to the patient's complaint, compiling this into a readable document; and exporting components of the document to the super bill, laboratory test orders, prescriptions, correspondence and as responses to alerts and reminders. This will significantly enhance the usability of EHRs and the discrete data capture for clinical analytics.

Now with RFID (radio frequency identification), Bluetooth and Near Field Communication (NFC), device-to-device interoperability is becoming an emerging area in medicine. Passing medical information between devices when a patient presents to a physician's office or hospital and pulling that information into a practice EHR would be of great value in keeping medical records current and portable.

Even with the most current hardware capabilities within the clinic, network design, internet speeds, wireless speed and connectivity add another layer to the usability challenge. Wireless devices within the ambulatory space require excellent connectivity to avoid loss of critical information. Wireless routers have markedly improved over the last decade, but the demand for handling higher speeds and more bandwidth is also growing. Also, cell phone carriers are often hampered by the volume of local calls in high peak times as well as user access to cell connections. There is a movement in some areas of the country to allow the higher cellular bandwidth emergency frequencies to be open for medical use. This comes at a time when more sophisticated home healthcare is being provided with demands to have an always-on connection through which to access images and lab results when Wi-Fi connections are not feasible or available.

In the hardware world, specifically in the hand-held devices, the rapid design and functional changes over recent years have been aggressive. New and faster tablet designs are providing greater usability options for the mobile user. Much of this change has come out of the environment of human factor design and ergonomics. The computer hardware world deals with ergonomics in a very obvious way. The human-computer interface makes a huge difference in the comfort and acceptance of a user. This obviously extends to the software application used on the device.

So, the reality is that future medical practices will be limited by a variety of elements such as devices, connectivity, security, software and input issues. Although adoption of an EHR has been hindered at times as a result of these limitations, medicine has continued to move forward with EHRs. When there is a fundamental change in a well-embedded process, such as there is in medicine, there will be definite challenges of adoption and utilization.

3.4   Software Development

EHR vendors have had significant challenges in this area. With the last 20–30 years the advancement of software programs has been tremendous. As new vendors enter the EHR world utilizing the newest software languages, the older applications are challenged to keep their relevance with respect to design and look. Vendors have faced real challenges in dealing with rapidly changing software languages. Moving from client-based to browser-based software as well as cloud-based options has kept the industry on its toes. At the same time, hospitals and practices have been at the mercy of the vendors' capabilities to update their software. There are well-known applications based on MUMPS software developed out of Massachusetts General Hospital (MGH) in the mid 1960s that have been popular and are still effective. However, more user-friendly and modern designs are gaining strength and popularity.

Web browser maturity has opened up the EHR environment to move from the premise based, older code-based systems to a cloud-based, internet-connected environment. With this option comes concern over protection of PHI (patient health information) and basic security issues as a whole. More and more experience to date with cloud technology has decreased the privacy and security concerns regarding electronic health records, but hasn't completely eliminated the concern. As Microsoft became more dominant in the software world, VBScript became a more commonplace code base for healthcare applications.

Applications that can take advantage of Application Program Interfaces (APIs) are showing up on the radar in greater numbers. This expands EHR vendors' capabilities by opening up the environment for development compatible focused applications by others that can connect with the parent EHR and share information in a bi-directional way. This way, the primary application can control and certify the applications to be included in a software marketplace to fit the need of the users. The best of breed of these applications rise to the top in popularity, similarly to the way the Apple or Google stores function.

The extension of the API approach improves interoperability between EHR applications, which is a significant need in dealing with patient's medical information and portability. Interoperability has been a significant obstacle, and several approaches have been tried, including health information exchange (HIE) and health internet service provider (HISP). The Agency for Healthcare Research and Quality (AHRQ) at HHS had contracted with a group of scientists, the JASON group, which published a report in April 2014 entitled "A Robust Health Data Infrastructure" – commonly called the JASON report – with a revision November, 2014 [1].

In conjunction with the software coding world is another component related to effective use of the application. An area that has developed over the years is the environment of human factor design and ergonomics.

3.5 Usability

> What is Usability?
> Usability is the effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment. [11]

Usability has been a major issue in the EHR industry, with opinions on the topic being varied. In reality, this is no different than with any software application. Many EHR users in various roles have felt that many applications have failed to achieve the goal of a highly intuitive application that a physician and staff can implement and use to achieve the highest usability in the shortest time frame. This goes for both inpatient and ambulatory applications. There are so many different types of users with varying capabilities, training, and needs and expectations using EHRs, it is no wonder at this point in EHR development history that a complex application fails to achieve the ultimate usability goal. Regardless of whether it is a pure inpatient or an ambulatory application, or a combination of both, there are just too many variables involved in the pursuit of a "perfectly usable EHR." Despite this environment, the user expects a highly usable application that works on any device, anywhere at any time with the highest speed. This is a highly desirable goal, however it is impractical in common practice environments of the day.

When you look at the variety of medical and surgical specialties, as well as allied health specialties, there are an overwhelming number of workflows needed, not counting the different medical environments such as acute care hospitals, nursing homes, hospice, ambulatory surgical centers, clinics and more. The workflows can be highly variable, even within the same practice. So when EHR designers are working on a particular feature, for instance ePrescribing, there can be some real consistency obtained because the workflow is generally similar for most physicians writing for medications. However, when looking a feature like Tasking, there is such variability in how clinics handle passing information/tasks to each other that it becomes a huge challenge to design a facile feature that works well for everyone who touches it.

In product design, sometimes there are options in the application for a less rigid workflow, allowing some short cuts or alternate paths toward the same end. But at the same time, patient safety concerns or possible quality reporting concerns may very rigidly require a single path to completion of a task. In the transition to an EHR for seasoned physicians and other healthcare workers, the restrictions are often considered a feature of poor usability. To the EHR vendor, there is a lack of consensus on the workflow and necessary elements needed within the feature for it to be an effective tool.

To understand usability from the vendors' perspective, you need to take into account the process of software development in the healthcare space. The vast majority of EHR companies started as small, agile development shops on a mission

to build an application that would interface with a practice management application, generally built by another company. Many times, the clinical expertise had great intentions in providing subject matter expertise, but often there was some misinterpretation of the needs or workflow requirements. Then, more features were added as the demands and needs from the user community grew.

Practically, there is no uniform industry standard tool that the product team could run the application through that gave them feedback on usability. Because of this, most companies relied on the user stories to develop an application and UAT (User Acceptance Testing). The UAT generally came once the application feature was nearly complete. Experienced users, for the most part, would be asked to perform defined test-case scenarios primarily to flush out bugs in the application. This process at times would expose a suboptimal, but acceptable workflow in the users' hands. The goal of UAT was to fix bugs and get the applications into general release, and not necessarily to change the workflow, especially if it markedly impacted the release date. Unfortunately, with the best of intentions, more issues were often identified once the application came into general release, when many more different types of users started working the application in different clinical situations. Perhaps nowhere has this been more obvious than in the compressed stages of Meaningful Use. Again, usability is impacted and distracts from the user's experience with the application.

In 2009, the AHRQ published a monograph on "Electronic Health Record Usability: Interface Design Considerations" [3]. Their concerns about EHR adoption were in part focused on usability and informational design issues. Perhaps at the time of the publication, a challenge for EHR designers and developers was the lack of effective usability tools for testing as well as the inexperience of the industry in understanding workflows in both hospitals and clinics. Personal experience in this area only highlighted a translational gap between the development team and the clinicians. Often a feature or need that I thought was effectively relayed to the development team was misconstrued and potentially became an ineffective workflow. Other times, different teams worked on components of a complex workflow that when merged together became an awkward process.

In many of the earlier EHR products, the resources for the master design and architecture of a product just weren't available. Some of the products included both practice management and clinical (EHR) either as an interfaced or an integrated application. The original scope of the earlier EHR systems was primarily focused on documentation. The overall product development mindset was that of build-as-you-need-it or build-as-requested. Soon the EHR took on increased complexity because practices started to appreciate the level of integration and sophistication of features and capabilities they wanted. This soon led to many vendors having backlogs of customer-desired features. When you add the interest by the EHR user world, the governmental agencies of Centers for Medicare and Medicaid (CMS) and ONC, requirements-based groups like SureScripts and First Data Bank (FDB), and the ancillary interest groups such as Institute of Medicine (IOM), NQF and others, the demands for features and requirements on the EHR vendors becomes immense. The noise, so to speak, of the demands from so many different users, practice types and outside partnered vendors added many layers of complexity to an EHR that could not help but impact usability.

There has been no major formula for usability in the EHR industry. As the complexity and the sophistication of needs increased along with expansion of features to include patient-centric needs, the usability issues have increased with EHRs. Vendors on their own have dealt with trying to improve their usability with staffs that are designers, focus-user groups and general feedback from their users. But again, challenges surrounding feature priorities and regulatory demands often push some of the little usability items to the back of the line.

When EHRs were increasing in numbers, there were two issues starting to play out. First, each vendor was developing their approach to the EHR environment, therefore there was an inconsistency between the features and functions. Second, trying to interact with each other or with a common third party such as clinical laboratories was a challenge for vendors owing to a lack of standards. Since the federal government had a vested interest in promoting EHRs, there was move to help develop standards and certifications.

CCHIT became active as an organization granted by the ONC. More than 250 volunteers provided expertise in setting up the requirements for an EHR. The goal was to set up minimal standards for an EHR; subsequently, a certification process was set in place for vendors to obtain. In the early phases, usability was left to the design of the EHR vendor. Towards the end of CCHIT certification era, a usability score was given to applications that went through the process. Although this was a reasonable first step towards trying to emphasize usability, it really did not have an impact.

Additionally, The Healthcare Information Technology Standards Panel (HITSP) [9], a private and public collaborative, was formed to develop and harmonize standards for sharing information in the healthcare ecosystem, and was disbanded in April, 2010. Its areas of interest covered a wide range of the interoperability needs for EHR. These recommendations covered the information-handling requirements of all types of stakeholders. Again, this was all reasonable, but expanded the scope and requirements for an EHR.

The mission is to not to delve deeply into the science of usability, as far as specific testing modalities, but to give a broad understanding of all the components that impact the usability of an EHR. The areas of heuristic evaluations, UAT-User acceptance testing, cognitive walkthroughs and other modalities are well documented elsewhere along with the challenges in their utilization in the EHR industry.

The next phase of usability focus came with the Strategic IT Advanced Research Projects (SHARP) grants funding by ARRA and administered by the ONC. Fifteen million dollars in grants in four specific domains were awarded, one SHARP-C was Patient-Centered Cognitive Support, focus in areas of Clinical Decision Support and Usability centered at the University of Texas-Houston in the National Center for Cognitive Informatics and Decision Making in Healthcare, headed by Jaijie Zhang, PhD.

Some of the focus of the grant was on work by Dr. Zhang and his team of researchers from numerous universities in a usability lab, along with the development of tools for EHRs to run testing on while in development. Efforts by vendors have always had usability as a major emphasis, but many challenges have complicated these efforts over time.

There are a variety of options for usability testing. In recent years, more definitive work has been done in a variety of academic labs with a focus on how to automate testing. Traditionally, in the EHR realm, the focus was on an internal review of usability, perhaps followed by focused user testing moving on to Beta testing. A challenge for vendors has been the impossibility of testing in all of the varied environments available to users, whether thick client, thin client, multi-tenet, third party hosting, RDP or Citrix, to name a few. Many companies have tried to limit the environment to one, such as a hosted solution, but then there are challenges there. Usually it is the connection of devices that has posed the problem, most commonly scanners and printers but also clinical devices such as ECG and lab devices.

An enhanced usability lab was available to focus on workflow designs for enhanced usability in both acute care and ambulatory environments. Over the course of the project, software tools were developed specifically to help in measuring and improving usability, and are now available for the EHR vendor community. The TURF (Toward a Unified Framework) Project project was an approach to develop EHR usability guidelines and standards [14]. From this project, an application is now available for comparison testing of workflows within an EHR.

Most vendors of sophisticated, complex software applications would probably agree that usability is always a challenge. Limitations in the native software coding environment, forms factors, and operating systems, to name a few, restrict options and workflow design.

Don Norman, PhD, has been a prominent force in the world of design. His user-centered design concept has had a major impact on a variety of products and industry. He played a prominent role on the SHARP-C advisory panel. His books, <u>The Design for Everyday Things</u> and <u>The Invisible Computer</u> have been a model for any designer in all types of disciplines and fields. The tendency in many software companies is to focus more on the development side and less on the design side when it comes to usability constraints. The lack of an overall design methodology often leads to less than optimal usability features.

Trying to wrap your hands around the usability needs of an EHR user can be very challenging. Often users tend to focus on a very particular action within an EHR that is causing them angst in their daily use. When you combine this complaint with those of other users, you may see a significant variance in the issues and how users prioritize them. An action's role within a practice as well as the frequency of its use also has an impact. Sometimes usability issues center around a rarely used feature that nevertheless plays a significant role in the workflow and or patient safety.

EHR vendors certainly focus on their users' needs for features and usability. It's the challenge that comes with the turf and has its ups and downs for all EHR companies. But the real issue when thinking about usability is that it is a process that occurs over time. We tend to focus on a specific action, but it really is a process. As a feature is enhanced or matured, there are changes that can make it more usable. Usability at times is like looking at a piece of art – the person looking at it can tell you that its good or bad, but there tends to be a spectrum from good to bad. Often the vendor leaves certain features at a state or stage that needs further work. The

minimal requirements are in place, but a more mature design or added components can make the feature much more usable to the end user.

Perhaps one thing that may not come into view in the usability spectrum is training. As with any commercial software application, especially a complex EHR application, whether hospital or ambulatory, the users must have a clear understanding of the application and the feature that takes them through an effective workflow. When an experienced practice or clinical worker begins his or her exposure to a new EHR application, the issue is not his or her business or clinical capabilities. The issue is his or her willingness to learn a new system. It is easy to criticize a system which forces a user into a workflow that is different from what they are used to, particularly in a practice coming from a paper-based system. Many practices have not clearly documented their workflows, so often there is noticeable disagreement within the business or clinical areas as to how they can do "best practice" on a certain task, whether it be something like scheduling on the practice side or perhaps clinical tasking on the clinical side. So, when the implementation starts with an EHR, the trainers may have a challenge in getting the users on the same page for a particular feature. The practices that manage the change effectively become much more successful in their implementation.

3.5.1   Change Management

The one area involving the human factor that impacts all of us in our daily lives, and certainly has become a huge factor in implementing an EHR effectively, is change management. If we lived in a perfect practice world with an EHR application beyond reproach, clinicians as well as staff would still have to deal with change effectively, inside and outside of the practice walls.

When you are introducing a sophisticated application into an active practice, a couple of important points become very apparent early. First and foremost, how effective is the practice leadership in guiding their team through the change? Have they engaged the team in the necessary training and preparation well before "go-live" to ensure as successful an implementation as possible? There have been various vendor options for training both in the mechanisms of training, such as web-based, on-site, on-page training, off-site and conference type, as well as cost and mixtures of training. This only means that there is not a perfect way to train a user that sticks for every user.

Much has been written and discussed over the years about change management in different environments, but I would argue that the medical world, which is very experienced with change, is not as accepting or prepared for effective change. The resistance to change can be significant when egos, ownership and attitude come into play. In part, it could come from the attitude that anything to do with treating patients, such as a new medication regime or a procedure, is reasonable to learn about, but if it involves the business of medicine, then it is best left up to the staff to figure out.

Basic human nature has a significant impact on the success of an EHR implementation. Inquisitiveness and flexibility and an eagerness to learn, regardless of the

type of user, have a huge impact. But this is no different than in other situations, like sports teams. When practices focus on success through effective leadership, it will follow – especially in implementation.

Being part of the vendor world now, I became aware of this when two practices of the same specialty, in nearby locations with similar provider and staff numbers, went "live" on an application in the same week. They had on-site training by two experienced trainers. However, they had two different outcomes: one had embraced the change and prepared effectively and became very self-sufficient in a short time, while the other practice struggled and took much longer and felt that their experience was not good. Regardless of an EHR vendor's efforts in their design of the application features, users within a practice still require adequate training and significant understanding of their roles and tasks to get the most out of an application. Practice users must understand that there is a continuum of learning for an EHR because requirements change and features are added or enhanced all the time. Vendors have learned that once practices are on-boarded to an application, it's a must that they maintain the most current upgrade, because being orphaned on a version or not keeping up with the new features just handicaps the practice in so many ways.

This perspective on usability may be getting a little beyond what most readers would consider when speaking of usability, but it is worth mentioning. Practices, as well as any vendor in the EHR space, face this challenge. Change is inevitable, so how we handle it does impact usability in many ways. Usability in its purist sense may be at the atomic level, concerning the location of an icon, the color of a section of a page, or how to make a choice by point and click. I would argue that usability is so much broader, and involves so many things that impact the user's experience.

Change management is a challenge for vendors also, so the point is that it impacts whether the end user can effectively use the application in a meaningful way. Awareness of change is a major concern in developing an application and training its users successfully.

3.5.2   Challenges and Destination

So far the discussion has included the expected issues in any software application development with some particular needs and requirements within the healthcare space. The most challenging and somewhat unpredictable are the external forces that play an instrumental role in the impact on the doctor-patient relationship, for example the Social Security Act of 1965, two amendments to which launched Medicare and Medicaid and brought the government into the mixture as a payer. As medicine expanded its capabilities in providing more sophisticated treatments and procedures through the next decades, it also caused an increase in the cost of care. Obviously, the advancement of medicine prolongs the wellness and the health of the patient population. We are touching on this to highlight the challenge of addressing the needs in a software application of all three groups – patients, caregivers and payers.

The shift of fee-for-service model to a value-based model is certainly gaining momentum as the payers start rewarding caregivers for delivery of quality care to the patient. Pulling the providers together as a care team, as in Patient Centered Medical Home (PCMH) and Accountable Care Organization (ACO) model, or earlier quality data gathering programs like Provider Quality Reporting Initiative (PQRI) and Provider Quality Reporting System (PQRS) or the Comprehensive Primary Care Initiative (CPCI), are all attempts to communicate between the caregivers for the betterment of the patient. What this means for vendors is that a significant amount of resources, expertise and time is spent trying to stay ahead of the curve on the programs and requirements mandated by the payers. Often they are in conflict to the types of information they want. This impacts usability in two ways; first, it often changes the priority of projects that the vendor wants to include or modify in the application to enhance usability, and secondly, the requirements may require a redesign, re-factoring to potentially accommodate a small segment of caregivers.

The healthcare IT space has ballooned with a host of specialty applications that provide a specific need for the practice. So, as most of the major EHR vendors focus on core required and needed functionality, there are ancillary needs that may start off as a "nice to have," but may become "must have." Looking back, one remembers that being able to have prescription writing capability within an EMR was a "nice to have." Subsequently, alerts and reminders, followed by clinical decision support (CDS), and the feature sets have continued to explode in popularity.

CDS was interesting to me, since everyone felt the need for it, but there were so many flavors and strengths of decision support that it was hard to compare apples to oranges. Caregivers were complaining about "alert fatigue," and there was little option to stratify the alerts by role so that an individual user got the type of alerts he or she needed to care for the patient. There were attempts by different medical associations to do a best practice approach and recommend certain CDS, but those sometimes ran counter to other associations' thoughts. Also, content vendors were becoming more common with increased interest in and capabilities for connecting with an EHR. In order to facilitate pulling in medical and patient-related education, features like the "Info button" and the "blue button" became part of the EHR experience or the purpose of linking to CDS materials.

Because of the disparity of techniques and need for linking EHR and CDS-type features, there was an increasing demand from vendors to standardize the access to CDS. Certain agencies, like the NQF, have worked diligently to pull all this together. Trying to get to a universally available CDS electronic format (XML) so that content vendors can publish and EHR applications can consume CDS content is still much needed. This has become even more of a problem with Meaningful Use because of the inconsistency in the quality measures required for incentive reporting.

There has been an outcry from physicians and other healthcare workers who do not like EHRs. This is understandable when you take the whole development, scope and breadth of the EHR into consideration. Modern medicine is a complex, challenging system to work in. So many forces come into play and impact the user at the

point of care that it's not hard to be frustrated with most EHRs in their current state of functionality.

While great strides have been taken to continually improve the experience, at the same time it has been extremely challenging for vendors to "keep it between the ditches," so to speak. The vast majority of healthcare workers are in a similar position of not wanting to return to a paper medical record. There is a light at the end of the tunnel. Usability will improve across the board with newer technologies, devices and design. More systematic software organization and development processes, early coordinated User Acceptance Testing, usability tools for automated testing, and better design considerations are all becoming a necessary focus for vendors.

On the other hand, users have a responsibility to fully engage in the implementation process, train themselves on the software and learn to give constructive criticisms by working with their vendors. Practices need to have both practice management and clinical advocates in the leadership. The certification agencies and standards organizations also need to aggressively work with the vendors to accelerate work in the interoperability arena. Many of these organizations have found themselves being outrun by the needs and demands within the EHR user world.

Allowing the medical world to be part of the National Broadband Plan [12] promoted by the Federal Communications Commission (FCC) would benefit our healthcare delivery. With this expansion of broadband coverage into medical ecosystems, there could be better delivery of care into ancillary facilities such as nursing homes, remote clinic locations and home healthcare, allowing higher speeds and a higher volume of data transfer.

Hopefully, the essence of the challenges within the EHR has been captured in this chapter. Just like any ecosystem, EHRs have been impacted by myriad forces from many directions which, without a doubt, has in turn impacted usability at the point of care for the healthcare worker. The industry recognizes this, and is working diligently to improve the experience.

The future looks bright for modernizing the US healthcare information technology world, which will have a significant impact on the delivery of high-quality and good-valued medicine with improved patient safety and outcomes for our population.

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