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STATE OF THE ART AND SCIENCE Open-Source Health Care Software

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Software tools are yet another new technology competing for the attention of physicians. Medical software is evolving rapidly from a record-keeping tool to a communications system to a source of decision support and plays the role of a medical device or clinical service. Unlike devices and services, however, most medical software is not regulated, placing the burden of safe and effective use on the physician. Yet physicians who would hesitate to use a device or service without some understanding of how it works pay little attention to the fundamentals of their software. Perhaps this is because they feel that software technology is not under their control, but, as with other important tools, physicians influence institutional purchases and can often supplement institutional infrastructure with personal tools.

Definitions

"Open-source" and "closed-source" refer to the way that software is created and maintained. The methodologies for creation and maintenance of closed-source software, e.g., Internet Explorer, are not evident to the user. The choice between open- and closed-source software has deep implications for safety and effectiveness because software design methods are seldom peer-reviewed and software errors are not always evident.

Open-source software is like a textbook or patent in that it is available for all to see and improve. Closed-source software is secret—a black box not subject to peer review or independent improvement. As medical software becomes increasingly mission-critical, physicians should become increasingly skeptical of software secrecy and the inability to peer-review closed-source software.

Despite the obvious benefits, open-source software is still rare in medical practice because, as with music and other information-based products, it is easy to copy. Software creators will not switch to producing open-source products voluntarily because they stand to lose money by doing so. Only physicians can drive this change, and this paper describes the reasons why doing so is important to our profession and our patients.

Existing Open-Source Software in Medicine

While open-source software is still rare for doctors, there are a few examples of success. The most prominent by far is the Veterans Administration's VistA electronic health record (EHR), and a number of foreign and domestic spin-offs, including a venture-capital funded Open Vista that has been certified as satisfying

federal requirements for "meaningful use" of EHR and is therefore eligible for federal subsidy. With over 100 modules, VistA is among the most extensive EHR implementations available and includes support for inpatient care, outpatient care, and imaging.

Developed more recently, the Direct Project hosted by the Department of Health and Human Services is open-source software for secure e-mail to replace the fax as the primary means of communication between practices and even with patients. Direct Project has many unique features as a result of its noncommercial open-source design, including universal addressing that is not tied to a particular vendor or institution. Universal addressing, like modern e-mail, does not restrict communications to members of a particular exchange. This technology has been readily adopted for physician-to-physician communications by a wide range of vendors and physician organizations, including the American Academy of Family Physicians and health information exchanges in a number of states. For patients, Microsoft offers secure Direct Project inboxes along with their personal health records.

Another example of open-source software success is the OsiriX radiologist workstation. This full-featured radiology viewing and interpretation system integrates 3D and web-access features that are rarely included in commercial workstations that cost tens of thousands of dollars each. The OsiriX open-source approach encourages doctors to write their own extensions for image analysis and workflow automation. Because radiology workstations are regulated as medical devices by the FDA, a number of commercial vendors now offer FDA-registered versions of the free open-source OsiriX for a fraction of what proprietary workstations cost.

Advantages of Open Source

Open-source software offers the same benefits in medicine as it does in other fields. These include ethical advantages, access, innovation, cost, interoperability, integration, and safety.

Ethical advantages. Much has been said about the ethical advantages of "free" software in general, and it is particularly true in a profession in which the sharing of instantly available, accurate information can make the difference between life and death. As medical software begins to offer decision support, risk management, performance rating, and analytic features, physicians should not accept black boxes and secret formulas that constrain sharing and intimately affect patient care and remuneration.

Access. Open-source software reduces disparities because it is, almost without exception, free and accessible to all, domestically and around the world. Open-source software can be easily developed, adapted, and used anywhere, much as books and research papers are today, and the fiscal benefit to both developed and developing nations is obvious. In our globally interconnected world, the

dissemination of medical knowledge and best practices could be even more important than the low cost. Open-source projects such as OpenMRS are widely used to run major public health initiatives concerning HIV/AIDS, tuberculosis, and malaria.

Innovation. Open-source software promotes innovation in the same way that publication of research and methods does. It can be combined and extended in the same way that research can, which is a major reason why, once it is established in a field, it is difficult to surpass in terms of features and performance. The Firefox and WebKit (Apple Safari and Google Chrome) web browsers are examples of open-source software that has come to dominate a major category.

Ending vendor lock-in. Anyone who remembers the days when cell phone numbers were tied to carriers knows the meaning of lock-in. Changing from one proprietary electronic health record to another is expensive and disruptive and often results in information loss. Proprietary software is designed to make migration difficult. By making the cost of switching high, vendors can charge more for upgrades and support than they could if switching were easy or inexpensive. Open-source software vendors have no incentive to lock in users and, even if they did, they would be unable to prevent a service provider from altering the software to eliminate this design feature. The vendor lock-in business model also works against the adoption of standards.

Interoperability, integration, and standardization. Common terminology and effective communication, essential to medical science and public health, depend on standardization. The Framingham Study, for example, would have significantly less impact if every participating lab measured the cholesterol of its patients in a proprietary way. As physician income becomes increasingly tied to patient outcomes and dependent on coordination of care, lack of interoperability, integration, and standardization has begun to impact clinical practice. It is hardly surprising that interoperability and integration costs related to proprietary health care software are extremely high and that the true value of health care services is difficult to measure and compare.

Standardization can undermine a proprietary software vendor's ability to control the customer by making it easy to transfer essential information to another system. Standardization costs proprietary software vendors twice: first, in direct cost when they have to write the software according to somebody else's specifications (the standard), and second, in opportunity cost, when it reduces the price they can charge for upgrades lest the customer switch to a competitor. Web browsers once again offer an example, as we recall the days before open-source browsers when some web sites and applications would only work in Internet Explorer. Because proprietary vendors will drag their feet on standardization, physicians, as ethical professionals, must insist on open-source software to drive standardization that will allow objective comparison of treatment alternatives.

Support. Ongoing support for a medical device or service is clearly critical to effective practice. Proprietary software puts the physician at the mercy of the vendor, who is often more interested in acquiring new customers than serving locked-in customers. Open-source software, by definition, allows users to choose their support service provider. Unlike proprietary vendors, open-source support providers have to compete for the user's business. Open-source software also benefits from free community support. The broad ability of users to adopt and improve software creates diverse, global communities on the Internet with significant incentive to help each other.

Bug fixing and patient safety. Finally, open-source software excels where proprietary software cannot in bug fixing and patient safety. Open-source software communities have a strong incentive to publicize bugs—if only because they are a waste of time—and sophisticated users can fix the bugs themselves. Even more important, open-source software is not forced to reinvent code that has already been developed by others. The quality of proprietary software suffers greatly from the secrecy of its internal workings. Unlike a medical device or service that is subject to inspection and incremental refinement, new proprietary software from a given vendor is likely to include many of the errors and patient safety problems that other vendors have solved. Open-source software, on the other hand, mirrors typical medical research practice by reusing proven code and promoting transparency with equivalent benefits of patient safety.

Drawbacks to Open-Source Software

Investment and business issues are certainly the major drawbacks to the creation of open-source software. Rapid software development can be capital-intensive; new software categories appear as proprietary software years before open-source versions become available, and initial development can be slow to address market-driven needs. Open-source software depends on grants for research, and it can be overly academic in its design and too specific to a particular niche to have sustainable and clinically robust support communities. Because relatively few medical open-source projects currently have commercial support organizations, typical users need more sophisticated and more costly in-house support.

Summary and the Cloud Future

For all the reasons above, medicine stands to benefit as much or more from adoption of open-source software than other professions and applications. The penetration of open-source software in electronic health records will increase as the market segment matures and ethical advantages, interoperability, and patient safety become key differentiating factors. Increasingly, new cloud software services based on a combination of open-source and proprietary software will enter the market to compete with traditional proprietary software on the basis of lower cost and better support. Cloud services such as IBM's Watson, national and global in scope, will drive interoperability and consistent outcome measures at a much faster rate than proprietary software. Medical software is rapidly becoming a patient-safety issue in clinical practice, but it is not currently subject to the regulation that physicians have come to expect for their devices and ancillary services. Advocating for open-source software is one thing that every physician can do that serves both the patient, public health, and the profession.

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