=Introduction=

Health care, taken broadly, is one of the largest sectors of the world economy (in the U.S., for example, it comprises over 14% of GDP[1], more than any other sector.) Predictably, the provision of information technology designed to support health care services has also become an enormous (and growing) market. The health care information technology (HCIT) sector is distinguished by several factors:

- the fragmentation of the market among many thousands of commercial providers. To date, HCIT has no Microsoft, or even a small group of dominant corporate players;
- the high degree of involvement by public and government agencies, reflecting the critical role of the government as both a steward and a provider of health services through ongoing efforts of funding, regulation and support for standartization;
- an acute, across-the-board need for accountability and transparency while maintaining patient privacy;
- cost pressures across the sector, from the spiraling costs of developed-country healthcare systems to the inability of developing countries to afford IT systems at Western market prices;
- disproportionate cost pressures on small health care providers, who require the same level of automation as large providers but who cannot afford the fully-featured software packages offered by the larger vendors;
- a socio-economic environment in which patients are accustomed to paying for services rather than for goods;
- growing public access to medical information (e.g., on the Internet), with new forms and expectations of professional accountability for health outcomes.

Together, these factors structure a set of interesting conditions, risks, and especially opportunities for FOSS adoption, potentially greater than in any other field. Yet there are significant barriers to FOSS adoption, foremost of which are the lack of coherent government policy on FOSS, concerns about liability issues in case of system malfunctions (especially in the context of the General Public License (GPL), which offers software without warranty), and questions about the viability and applicability of FOSS business models in the field.

FOSS activity in the health field is in its infancy. This case study focuses on one of the major HCIT sub-fields—software for Electronic Medical Records (EMR)—and investigates (1) emerging open source projects in this unique health care environment; and (2) the conditions for wider adoption. Although FOSS does not yet have significant presence in the health field, conditions in the sector suggest that health care could soon become a key site for ‘vertical’ FOSS adoption, providing not only fundamental ‘horizontal’ infrastructures like operating systems and databases but also specialized applications for end-users and providers alike. To understand the full picture we should first look at the challenges facing HCIT.

=Challenges in the health care sector=

The global health care sector in general and the U.S health care system in particular are outstandingly inefficient. While increased levels of automation and advances in medical technology facilitate better treatment for disease and injury, the same cannot be said for management and clinical processes within and among health care delivery organizations, notably hospitals [2]. The clinical workflow at most provider organizations still depends on manual, paper-based systems augmented by partial automation. These lag behind the systems used by industries like banking and insurance by at least a generation. The resulting waste of resources, [3] complicated even further by workforce shortages, [4] is a significant barrier to both regulatory compliance and to improved quality of care, the two most important stated goals of health care executives. Because a large share of health care resources is devoted simply to ensuring that patient health information is accurate and available, many practitioners view better HCIT systems as an opportunity for significantly improving health services while reducing costs. Improved HCIT can also promote other functions such as a culture of self-help and community support, where patients can access their own health data and become more involved in their own care.

A standardized, reliable and secure Electronic Medical Record (EMR) system has been a central and long-standing goal of these efforts. An average person's personal medical record is comprised of hundreds or thousands of data points, drawing in information from triage systems, lab reports, radiology, x-ray and imaging equipment, pharmacies, and hand-written diagnoses from doctors, nurses and other experts. In next generation HCIT systems, these need to be combined into a secure EMR. As the American Academy of Family Physicians notes, such an electronic record system is "essential in increasing the quality of health care and improving patient safety and should contain detailed clinical notes; prescription ordering and management capability; a secure messaging system; lab and test results reporting; evidence-based health guidelines; secure and confidential patient access to health records; public health reporting and tracking system; mapping to clinical and administrative standard code sets; and the ability to interface with leading practice management software."[5]

The computerized systems that generate these growing piles of data are produced by a multitude of competing firms. Because these systems are developed independently, and because proprietary software development hides the internal workings of the software, the task of combining diverse data to a standardized, meaningful EMR is daunting. Efforts to develop industry and global standards for health care data management have been underway for some time, with limited success[6]. One major difficulty is that vendors perceive the data streams produced by their systems as potential revenue sources to be exploited by offering complementary services to their clients, rather than as elements in a diversified patient record. Consequently, most HCIT deployments involve purchasing multiple modules from the same vendor, creating vendor lock-in and making integration of systems across different institutions difficult, if not impossible.

Regulators have worked to promote HCIT development and deployment, but have not addressed the market incentives that undermine progress on standards, or identified the ways in which FOSS might alter that equation. The major regulatory act shaping HCIT development in general and EMR software design in particular is the Health Insurance Portability And Accountability Act or HIPAA for short, passed by Congress in 1996. [7] HIPAA targets a wide range of health care problems, from waste, to fraud, to abuse in health insurance and health care delivery. Among its key provisions is support for "the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information."[8] For many health care providers and insurers HIPAA implementation efforts require a focus on EMR software, including significant efforts to comply with the mandate that patient data be completely secured (e.g., behind a firewall)[9]. The challenge to HIPAA compliance arises from the diversity and complexity of HCIT systems, especially when they are expected to work together. It is often not enough to test each system component separately. A more systematic approach to security and privacy is needed.

=Leading FOSS projects in healthcare=

To date, there is no complete open source HCIT system that can solve all these problems. However, several systems have been developed in recent years that hint at FOSS's potential in the health sector. As in the proprietary HCIT market, there is significant diversity among FOSS projects. This is both a strength in terms of capacity to innovate, and a persistent challenge in a context where standardization across the field generates value. The major projects—including those described below—operate largely independently from one another. Some are the works of visionary individuals, while others are long-standing, publicly funded efforts; some focus on creating open versions of existing HCIT systems while others emphasize new IT infrastructure; some target small, local clinics while others have the country's largest hospitals or even a national infrastructure in mind. A common denominator is that they all seek to combine three traditional strengths of FOSS to address HCIT concerns: (a) cost-effectiveness (b) increased standards of security (c) modularity and ease of customization. In addition, all go beyond the traditional 'recordkeeping' tasks of EMR to integrate infrastructure and applications that can support the needs of different categories of users, working toward a model of vertical integration that can address the complexity of health care work and information flows. All stress the importance of open standards and comply with efforts by the wider healthcare community to increase the adoption of such standards.

Compared with the FOSS adoption campaigns in the server, database, and desktop arenas, where concerns about Microsoft have fairly wide resonance, the advocacy infrastructure around FOSS HCIT is thin, limited primarily to IT and health care professionals, and to a few FOSS-friendly public projects and agencies, such as the SPIRIT program within the European Commission's Fifth Framework for scientific research, the U.S. Department of Veteran Affairs, and the Centers for Medicare and Medicaid Services (CMS, which have been promoting FOSS as an element of the long-awaited U.S. national health information network). In 2000, a group of health care and informatics professionals from the U.S., Canada, and the U.K founded the Open Source Health Care Alliance (http://www.oshca.org/) to facilitate the needed networking and knowledge-sharing among FOSS developers, public health agencies, institutional users, and other interested parties. These efforts have largely focused on arranging several workshops at large HCIT conferences and facilitating online communication among project leaders.

These advocacy efforts appear to be gaining some traction, especially among categories of health providers who are most disadvantaged by the existing commercial HCIT solutions. The American Academy of Family Physicians, which represents many small medical practices, recently made a commitment to FOSS for its future electronic health records (EHR) systems. In its call for partners for its MedPlexus project, an EHR system for practices that cannot afford the multi-million dollar installations used by larger providers, the AAFP writes: "[An] open-source EHR will be designed to run on PCs, Macintosh, Linux, UNIX, Palm and PocketPC hand-held devices…Our ultimate goal is to provide an EHR that is low-cost; has a set of simple, uniform end-user interfaces; and will support a seamless, secure exchange of clinical data between health care providers, organizations, institutions and patients. The time has come to move from theory to action on this…" [12]

AAFP's goals echo those of many other FOSS health care projects, such as Debian-Med, OpenEMR, OpenVista, OSCAR, and SPIRIT. These are targeted primarily at the North-American and European health markets, though in several cases their architecture and goals have broader applicability. These projects suggest something of the diversity in the field, and illustrate some of its important dynamics.

==Debian-Med==

Debian-Med (http://www.debian.org/devel/debian-med/) is a "Custom Debian Distribution" aiming to extend Debian (a leading Linux distribution) into an operating system suited to the requirements of medical practices and research. The Debian Project is an association of individuals who have made common cause to create a free operating system. Conceived by a few developers interested in 'free software in medicine,' Debian-Med was officially started in 2002 with the official goal of creating a completely integrated, free software solution for all tasks in medical care. Debian-Med markets itself specifically as a 'free software' project and not 'open source,' reflecting its commitment to the social ambitions of FOSS. The project is in advanced stages of development, and includes packages that address all aspects of health care provisioning and research (including some aspects missing from other FOSS projects like dentistry and microbiology). The first version of Debian-Med will reportedly be included in the next stable Debian release (codename 'Sarge'.) Debian in general, and Debian-Med in particular are primarily grass-roots projects driven by individuals in the FOSS and health informatics fields.

==OpenEMR==

OpenEMR (http://www.openemr.net/) is a free, Open Source medical clinic practice management and electronic medical record application. OpenEMR is offered by a private company, the Pennington Firm, which specializes in Linux and open source software. The software is offered for free, and the company provides support and customization services. The project prides itself on being easy to install and cheap to maintain and operate—features that translate into lowered cost for its users. The software is reportedly stable, and has been embraced by several small, cost-sensitive providers. For FOSS advocates, OpenEMR illustrates that the commercial FOSS model of building a services firm can work in the health care sector. There is some possibility that it will act as a bellwether for larger players waiting to see if the FOSS model is sustainable in the field.

==OpenVista==

OpenVista (http://sourceforge.net/projects/openvista) is the open-source version of VistA—the largest integrated hospital software package in the world. Originally developed by the U.S. government's department of Veteran Affairs, VistA is used in veterans' hospitals, and has been in the public domain for years. Two separate entities have worked to expand VistA's utility and reach:

- WorldVistA (http://www.worldvista.org/), an organization founded to extend and improve VistA for use outside its original setting, notably through the development of packages for pediatrics, obstetrics, and other hospital services not present in veterans' hospitals; and
- OpenVistA, an effort to port VistA from an archaic proprietary operating system called MUMPS to Linux—and in the process reducing costs of operation. OpenVistA is supported by The Pacific Telehealth & Technology Hui[13], a joint partnership of the Department of Veterans Affairs and the Department of Defense. It is considered the most developed and robust system of its kind and has been tested in large-hospital settings.

OpenVista demonstrates a trend of open-sourcing proprietary or government funded projects as a means of attracting free developer support. By translating the software to Java and opening its code, OpenVista has been taken up by both commercial developers and the FOSS community at large. Given the challenges of keeping such a complex software system up to date, this expansion of responsibility has proved both a virtue and a necessity. OpenVista has considerable support as a possible building block of the upcoming national health information infrastructure.

==OSCAR==

OSCAR or Open Source Clinical Application & Resources (http://oscarmcmaster.org/), is a web-based integrated electronic clinical record and resources system for use in primary care. The software, the brainchild of a Canadian health care professional and visionary, was initially developed by the Department of Family Medicine at McMaster University to address the requirements of the Ontario Provincial Government's Primary Care Reform Initiative—a multimillion-dollar initiative to transform primary care in the province. OSCAR's development benefited greatly from its academic setting, which provided a context both for collaboration on design and commitment to use on the part of a range of health care professionals, technologists and end-users. This model proved successful enough to warrant OSCAR's expansion into a full-fledged EMR. As with OpenVista, OSCAR source code was eventually released for distribution in order to attract support from the development community. Project management has recently shifted to SourceForge.Net and OSCAR now enjoys contributions from developers around the world. OSCAR is used in eight facilities in Canada with several planned U.S. and international deployments. Arguably, OSCAR is the most feature-rich and stable open source software of its kind.

==SPIRIT==

SPIRIT (http://www.euspirit.org/project.php) is a virtual community and meeting place that provides resources and services to help interested parties share information about projects, and to participate in health-care-related open-source developments. SPIRIT was partially funded by the European Commission's Fifth Framework Programme, which recognized the need to accelerate the uptake of FOSS as an economically viable and effective alternative for the ailing regional health care system. Sponsored with public funds but managed by three private firms, SPIRIT aims to become a clearing-house for open-source software applications and components from both existing projects, and planned developments. Sources for software include government agencies, medical teaching institutes, and other health care providers. Services include disseminating open source research results, groupware applications, audio/video conferencing facilities, mailing lists, and web site hosting for open source health care projects. The importance of this project stems not from the impact of it activities (which are limited to date) but mainly from the fact that it is one of the only projects to have received public funding specifically to promote FOSS principles in health care.

=The politics of FOSS adoption in healthcare=

The efforts surveyed above are all in late stages of development or the early stages of deployment. Despite the promise of these projects, FOSS has a long way to go before it is fully accepted as an alternative to proprietary HCIT software. What are the obstacles to more rapid adoption?

A first barrier is legal. Although as I have argued elsewhere[14] FOSS offers an improved concept of software accountability, in the sense of an expanded capacity and willingness to solve problems, the highly-regulated, highly-litigious healthcare arena often requires strict concepts of liability. Decision makers generally seek complete prior assignment of liability in case something goes awry. FOSS projects using the GPL, especially, do not provide this assurance. Because of the collective, open-ended nature of most open source development, no single entity claims authorship of the code. There are uncertainties as to the very legal definition of an open source community and its legal liability in case of software related accidents [15]. Most FOSS licenses aim to shield developers from strict liability in such cases (although this is as yet untested in the courts). Although other licensing options exist that can accommodate legal uncertainties better than the GPL, most of the leading projects have yet to choose any of these alternative licenses. One way to change both the perception and reality of the liability problem would be for a large industry vendor to assume the risks and liabilities, offering the end-users a legal safety net that stretches beyond the standard license clauses. So far, however, only IBM has made limited gestures in this direction, and not at the level of critical applications.

A second barrier is business-driven. So far, no entity has proven that developing FOSS applications for health care is a viable business endeavor on a large scale. Although there is little doubt that FOSS can offer business opportunities in general, many of these opportunities rely on developing or repackaging reusable software infrastructure and/or selling ‘free’ software bundled with a combination of hardware and services. In health care, none of the existing large hardware and medical device vendors has exploited the possibility of leveraging FOSS for increased hardware and services sales. As mentioned above, this is due in large measure to the dominance of business models that rely on the concealment of system internals in order to sell expensive bundled solutions. In the eyes of these vendors, openness is not an opportunity but a risk. It would seem to be only a matter of time, however, before one or more of these companies recognizes the FOSS opportunity, much as IBM has done. We anticipate that large medical device companies will soon follow smaller firms in adopting the FOSS model, and begin relying on FOSS solutions to connect their devices and systems.

A third barrier is government policy toward FOSS in health care, which is largely non-existent. The absence of policy creates confusion for would-be investors in FOSS at two levels. First and foremost, does FOSS comply with the regulations of the field? Advocates claim it does, but this issue has yet to be fully explored. Second, without clear indications about the government’s investment policy in FOSS, the private sector is hesitant to foot the bill for the transition. This situation is changing, however. Following President Bush’s recent call for a ten-year plan to develop a National Health Information Network (NHIN), the Department of Health and Human Services issued a request for information (RFI). One of its questions is, “How could the NHIN be established to maintain a health information infrastructure that: a. Evolves appropriately from private investment; b. Is non-proprietary and available in the public domain…”[16] This RFI speaks directly to a potential policy that would favor FOSS in the development of national IT infrastructure. If the same considerations are maintained in the follow-on request for proposals, FOSS solutions will likely play a much larger role in the overhaul of the U.S. HCIT system. This new interest is driven largely by pressures from the Department of Veteran Affairs (VA) and the Centers for Medicare and Medicaid Services (CMS), which are considering variants of VistA and other FOSS solutions to serve their immediate HCIT needs. [17] The VA's recent report, "Approaches to Make Health Information Systems Available and Affordable to Rural and Medically Underserved Communities" [18] highlights its successful strategy to develop high-quality EHR technologies that remain in the public domain.

=Conclusion=

The projects surveyed above demonstrate that a variety of institutional and funding contexts can generate stable, reliable, secure and ready to deploy FOSS HCIT solutions. Significant barriers remain for widespread adoption of FOSS in health care but the traditional strengths of the FOSS model (low up-front costs, modularity and ease of customization, and a high degree of security) are a good match to the growing needs of the health sector. Health care remains a promising vertical market for FOSS adoption but a range of legal, business, and public policy barriers will have to be addressed. The combination of clearer public policy that valorizes FOSS, technical and economic proofs-of-concept by grass-roots projects, and shifting financial incentives for big business are arguably all working in the same direction: FOSS will play a major role in HCIT in years to come.

=Notes=

[1] OECD Health Data (2004), 1st edition (June 3, 2004).

[2] A report by Health Grades Inc. (2004). "Patient Safety in American Hospitals." Finds that each year close to 200,000 people die in the U.S. alone from potential preventable clinical errors.

[3] A study commissioned by the American Hospital Association and performed by consulting firm PricewaterhouseCoopers (2001) found that each hour of skilled nursing care results in 30 minutes of paperwork, while each hour of emergency department care generates a full hour of subsequent paperwork.

[4] For example, according to a 2002 American Hospital Association Workforce Study, 89 percent of hospital CEOs report significant workforce shortages. The shortages impact all areas of the hospital, but most prevalently affect nursing, radiology and pharmacy.

[5] American Academy of Family Physicians (2003). Press Release. "AAFP Seeks Partners to Support Open-Source Electronic Health Record Initiative," January 22, 2003 Available at http://www.aafp.org/x18356.xml

[6] Most notably a protocol called HL7 developed by Health Level Seven which is a standards developing organizations operating in the healthcare arena. Health Level Seven's domain is clinical and administrative data with a mission to provide standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services. More information available at http://www.hl7.org

[7] US Congress (1996). Public law 104–191—Aug. 21, 1996, "Health Insurance Portability and Accountability Act of 1996"

[8] Ibid, §261.

[9] HIPAA Frequently Asked Questions 2003. [Web]. United States Department of Health and Human Services 2003 [cited December 16 2003]. Available from http://answers.hhs.gov/cgi-bin/hhs.cfg/php/enduser/std_alp.php?p_sid=xPmDQ6Gg&p_lva=&p_li=&p_page=1&p_cat_lvl1=7&p_cat_lvl2=%7Eany%7E&p_search_text=&p_new_search=1.

[12] American Academy of Family Physicians (2003). Press Release. "AAFP Seeks Partners to Support Open-Source Electronic Health Record Initiative," January 22, 2003 Available at http://www.aafp.org/x18356.xml

[13] "Hui" is the Hawaiian word for partnership.

[14] David, Shay (2004). "Opening the sources of accountability" First Monday, volume 9, number 11 (November 2004) available at http://firstmonday.org/issues/issue9_11/david/index.html

[15] It is important to note that the projects described above are offered under the GPL, and not under other licenses that have dealt in numerous ways with the liability problem (e.g. the QT license)

[16] U.S. Department of Health and Human Services (2004) Request for information. "Development and Adoption of a National Health Information Network" available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2004_register&docid=DOCID:fr15n

[17] Berwin Bob, “VA drives open-source health records initiative”, Federal Computer Weekly, Nov. 22, 2004. Available at http://www.fcw.com/fcw/articles/2004/1122/news-va-11-22-04.asp

[18] U.S. Department of Veterans Affairs. (2004) Special Report "Approaches to Make Health Information Systems Available and Affordable to Rural and Medically Underserved Communities" available at http://www.os.dhhs.gov/healthit/attachment_2/attachment_2.html,