American Council for Technology | Industry Advisory Council

VistA Modernization Report

Legacy to Leadership

May 4, 2010

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American Council for Technology-Industry Advisory Council

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VistA Modernization Working Group

In response to a request from the U.S. Department of Veterans Affairs (VA), the Industry Advisory Council (IAC), chartered a working group on October 20, 2009 composed of experienced healthcare and information technology professionals selected from IAC member companies. Their charter was to respond to this request to assist the VA in understanding the issues associated with the modernization of its Veterans Information Systems and Technology Architecture (VistA) and make recommendations as to how the VA might proceed in modernizing VistA. The working group was composed of a single member from 42 member companies, representing the diversity of the government IT industry and was chaired by Ed Meagher, former Deputy Assistant Secretary for Information Technology, Department of Veterans Affairs. This working group was empanelled under operating principles and guidelines as established by the IAC Board of Directors and in accordance with the IAC Code of Conduct. Specifically and most importantly the individual members of the working group as well as the companies they work for agreed that:

- Government IT issues drive the agenda
- All activities will be ethical, open, and transparent
- All activities will be objective, fair and vendor/technology independent
- Lobbying and business development are prohibited

The working group took this to mean that they were not representing their companies while working on this project but were in fact professionally representing their industry and personally representing all veterans, citizens and other stakeholders. The working group conducted all of its deliberations under a consensus model and this report is presented on behalf of the entire membership of the working group.

Acknowledgements

The Working Group would like to acknowledge the dozens of individuals within the VA that spent many hours helping us understand VistA, as it exists today as well as the history and background of how it began and was developed over the years. We would like to thank the dozens of individuals and groups in private industry, the medical community as well as the Open Source community for their willingness to provide us guidance, instruction, and feedback as we built our understanding of the possible choices available. We would also like to thank the leadership and staff of the American Council for Technology and the Industry Advisory Council for the opportunity to participate in this important initiative, for their support during the process and for their trust that we would fulfill our responsibilities. There are too many individuals and organizations to list individually but to all who assisted us your contribution is known and acknowledged.

Disclaimer

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VistA Modernization Working Group Charter

IAC was chartered by the Department of Veterans Affairs (VA) to assess the issues, challenges and opportunities associated with modernizing the current legacy VistA system and make recommendations to address these issues and challenges and take advantage of the opportunities presented. The group was specifically asked to respond to the following series of thematic questions:

1. Is VistA a system that could be deployed to a wider community? If yes, what is the most appropriate deployment model: open source code; cloud computing; business process/methodology; other?

2. If VistA is deployed and used by other government agencies or private sector entities, what organizational and management structure should be developed? Possible questions include:

    a. Which organization(s) should have responsibility for maintaining the system?
    b. Should VistA be established as a national standard? What are the implications of this action?

3. What is an appropriate strategy for modernizing VistA and transitioning it to a more current and innovative architecture? The strategy should result in an appropriate, creative and agile acquisition and development plan. (NOTE: The project will establish the general guidance and principles for this strategy and will not be involved in matters pertaining to any actual acquisition.)

4. What are the opportunities and impact of modernizing and deploying VistA upon private industry, the healthcare community and other key groups?

5. Based on the above, what principles and best practices should be documented and distributed for use by other government agencies considering similar issues?

As part of the assessment, IAC was asked to consider whether there are principles or strategies that would be applicable to other legacy systems currently operated by the government such as those driving Social Security and Medicare.

VistA Modernization Background

VistA has been developed and managed by the VA over the last 25 years and is used throughout the VA's 153 Medical Centers and 768 VA Outpatient Clinics across the country serving almost eight million veterans. In addition, the US Indian Health Service and commercial and public hospital systems in several states and foreign countries have adopted versions of VistA.

VistA is generally recognized as the most completely integrated healthcare information system in existence(Longman, 2007). VistA currently provides each veteran a completely digital medical record that has improved quality, patient safety, patient and provider satisfaction and lowered costs and may have value for the entire national healthcare community. However, as one of the government's oldest legacy information technology systems, VistA must be updated and modernized in order for the VA to continue to meet the needs of the veteran community and to enable the private sector to take advantage of the breadth of healthcare applications included under the mantle of VistA.

VistA Modernization Working Group Approach

The VistA modernization working group decided to divide its available time into three roughly equal segments. The first segment was devoted to informing and educating ourselves as a group. The entire working group met at least weekly to receive briefings and ask questions of VA and private sector experts. The working group collected and analyzed hundreds of available documents, reports, and studies. The entire working group made a field trip to the Washington, D.C. Veterans Administration Medical Center and received an in depth set of presentations by senior hospital administrators and VistA managers and working staff. The working group was allowed to view VistA in operation in a clinical setting and speak to clinicians, developers, and support staff. At the conclusion of this period the entire VistA working group participated in an all-day, off-site working session to review what had been learned and plan the next phases.

The second segment was devoted to analyzing the information and knowledge the working group had assembled and to decide what additional information and analysis was required. It was decided to divide the whole working group into several subcommittees to focus on identified issues that needed more study and analysis. These subcommittees consisted of:

- Executive Committee

- Subcommittee on Alternatives
  - The Alternatives subcommittee was asked to look across the various subcommittees and identify alternative approaches, analyze those alternatives, and ensure that all viable alternative approaches were adequately considered and analyzed.

- Subcommittee on Modernization and Architecture
  - The Modernization and Architecture subcommittee was asked to identify and analyze the modernization and architectural approach associated with the overall working group's recommendation. Areas of consideration included open source techniques to leverage innovation within and outside of the traditional OI&T environment. These included clinicians, large and small public health information technology organizations such as Military Health and the Indian Health Service, as well as large commercial health informatics systems providers. Additionally, the group included open source developers associated with World VistA as well as two motivated developers in a garage who want to get involved in or help advance healthcare IT – respectively.

- Subcommittee on Models and Extensions
  - The Models and Extensions subcommittee was asked to understand the assessments of the working groups and to apply these to the real world environment at the VA.

- Subcommittee on Deployment Models
  - The Deployment Models subcommittee was asked to explore the various options for deploying a large scale, complex system and identify the pros and cons associated with each approach.

- Subcommittee on Governance
  - The Governance Models subcommittee was asked to identify and rationalize the various approaches to

governance for the recommended deployment models. In addition, the Governance Models Subcommittee was charged with identification of open source licensing alternatives and recommendations.

- Subcommittee on Opportunities and Impacts
  - The Opportunities and Impacts subcommittee was asked to examine, analyze and recommend areas of opportunity for transacting distinct innovation within health Information Technology (HIT), Electronic Health Records (EHR's) and other healthcare delivery processes and identify their high-potential impacts or results of modernizing and deploying VistA within the public-private sector healthcare communities, markets and other key groups.

- Subcommittee on Terms and Definitions
  - The Terms and Definitions subcommittee was asked to develop a complete set of relevant terms and clear definitions that will ensure that the entire working group shares a common understanding of the issues under discussion.

- Subcommittee on Reports and Presentations
  - The Reports and Presentations subcommittee was asked to assisting the other subcommittees in the preparation and presentation of their reports so that they are clear and consistent. Additionally, they were responsible for version control of drafts and the development of the final report and presentation produced by the VistA Working Group.

During this period more focused briefings and discussions were held to clarify the working group's thinking and to begin the process of coming to conclusions about the working group's recommendations. The various subcommittees and the entire committee met at least weekly. The working group conducted a second all-day off-site working session where a high level narrative of the working group's findings was presented and discussed. After several rounds of revisions and amendments, the working group endorsed the approach and directed the subcommittees to focus on this set of recommendations.

The third segment was devoted to the task of answering the questions that were posed by the VA, creating a set of recommendations, and drafting the final report. A great deal of time and effort was expended to ensure that the recommendations and the report were consensus-based and represented the best advice the information technology community could provide.

VistA Modernization Working Group Executive Summary

The Industry Advisory Council (IAC) of the American Council for Technology (ACT) was asked by the Department of Veterans Affairs (VA) to form a working group representing a broad cross section of the Information Technology (IT) community that supports the Federal government. The VA asked IAC to provide answers to several specific questions and to provide specific recommendations to the Department that represents the IT Community's best advice on how to modernize VA's legacy health information system, the Veterans Information Systems and Technology Architecture (VistA).

In response, the Industry Advisory Council (IAC) chartered a working group on October 20, 2009 composed of 42 experienced healthcare and information technology professionals selected from among the 540 IAC member companies. The working group was comprised of experienced IT professionals from small to very large companies with backgrounds in technical disciplines, management, healthcare and marketing.

The working group agreed to represent their industry and not their companies and to provide their guidance and advice as citizens and IT professionals. The group met at least weekly and held 3 all day off site sessions. The group conducted research on the issues by interviewing and questioning dozens of experts within the VA and spoke with an equal number of industry and subject matter experts. The working group adopted a consensus based decision-making model and delivered the following recommendations **unanimously.**

- The working group recommends that the VA commit to and announce a plan to move to an open source, open standards model for the reengineering of the next generation of VistA (VistA 2.0). This action should be a strategic policy for the VA.

- The working group recommends that the current VistA application be placed on an aggressive program of stabilization, with limited tactical upgrades and enhancements driven only by patient safety and other mandated requirements

- The working group recommends that the VA contract with an appropriate Federally Funded Research and Development Center (FFRDC) to provide a detailed set of technical specifications for the development of a VistA 2.0 Open Source Core Ecosystem (Figure 1). Use of the term ecosystem by the working group refers to "the entirety of hardware, software, and networks that drives the delivery of VistA 2.0 products and services."These technical specifications should describe the following components

    - Open Source, Open Standards Operating environment

    - Open Source, Open Standards Application Development Environment

    - Sand Box Application Development Environment and based on the following set of high level characteristics to ensure that this ecosystem is optimized for

        - High performance,
        - Security and identity management
        - Scalability

    This operating environment must provide a scalable, segmented, open source, open standards environment that will provide the following components

    - Operating environment
    - Security services
    - Identity management
    - Database functions
    - Application programming interfaces
    - Data structures and terminology
    - Rules development and enforcement
    - Test and certification environment

    This ecosystem must also natively support

- A structured open source application development environment that will provide the following common services
  - Trusted and approved application development tools, datasets, test cases, and test, simulation and certification services
- A "sand box" application development environment that will provide the following common services
  - Application development datasets, test cases, test, and simulation services

- The working group recommends that the VA contract with an appropriate FFRDC to build and deliver a fully functioning prototype based on the technical specifications developed by the initial FFRDC for the Open Source Core Ecosystem consisting of the
  - Open Source, Open Standards Operating environment
  - Open Source, Open Standards Application Development Environment
  - Sand Box Application Development Environment

- The working group recommends that the VA contract with an appropriate FFRDC to provide an appropriate business model, bylaws, operating principles and organizational blueprint for an independent, not-for-profit Open Source Foundation to manage, operate and maintain the VistA 2.0 Open Source Core Ecosystem, based on the recommendations provided by the Governance subcommittee in this report

- The working group recommends that based on the recommendations provided by the FFRDC tasked with providing an appropriate business model, bylaws, operating principles and organizational blueprint for an independent, not-for-profit Open Source Foundation that the VA charter and initially fund an independent, not-for-profit, Open Source

foundation to manage, operate and maintain the VistA 2.0 Open Source, Open standards Core Ecosystem, Open Source Application Development Environment, and Sand Box Application Development Environment

- The working group recommends that the VA contract with an appropriate FFRDC to provide the functional decomposition of the current VistA Application Suite to deliver a state of the art
    - set of functional and design specifications of current application functionality
    - set of functional and design specifications for required application functionality
    - set of functional and design specifications for additional application functionality
- The working group recommends that the VA determine what application functionality it wants to develop/acquire for the VistA 2.0 Open Source Core Ecosystem using
    - internal in-house application development resources
    - external commercial application development resources
    - Commercially available (i.e., commercial-off-the-shelf [COTS]) products
    - Open source application development resources
- The working group recommends that the VA develop a master schedule for the acquisition of these applications and functional capabilities
- The working group recommends that the VA develop and acquire the applications and capabilities based on the VistA 2.0 Open Source, Open Standards Ecosystem that meet its requirements and develop a plan and schedule for concurrent operations and migration from VistA to VistA 2.0

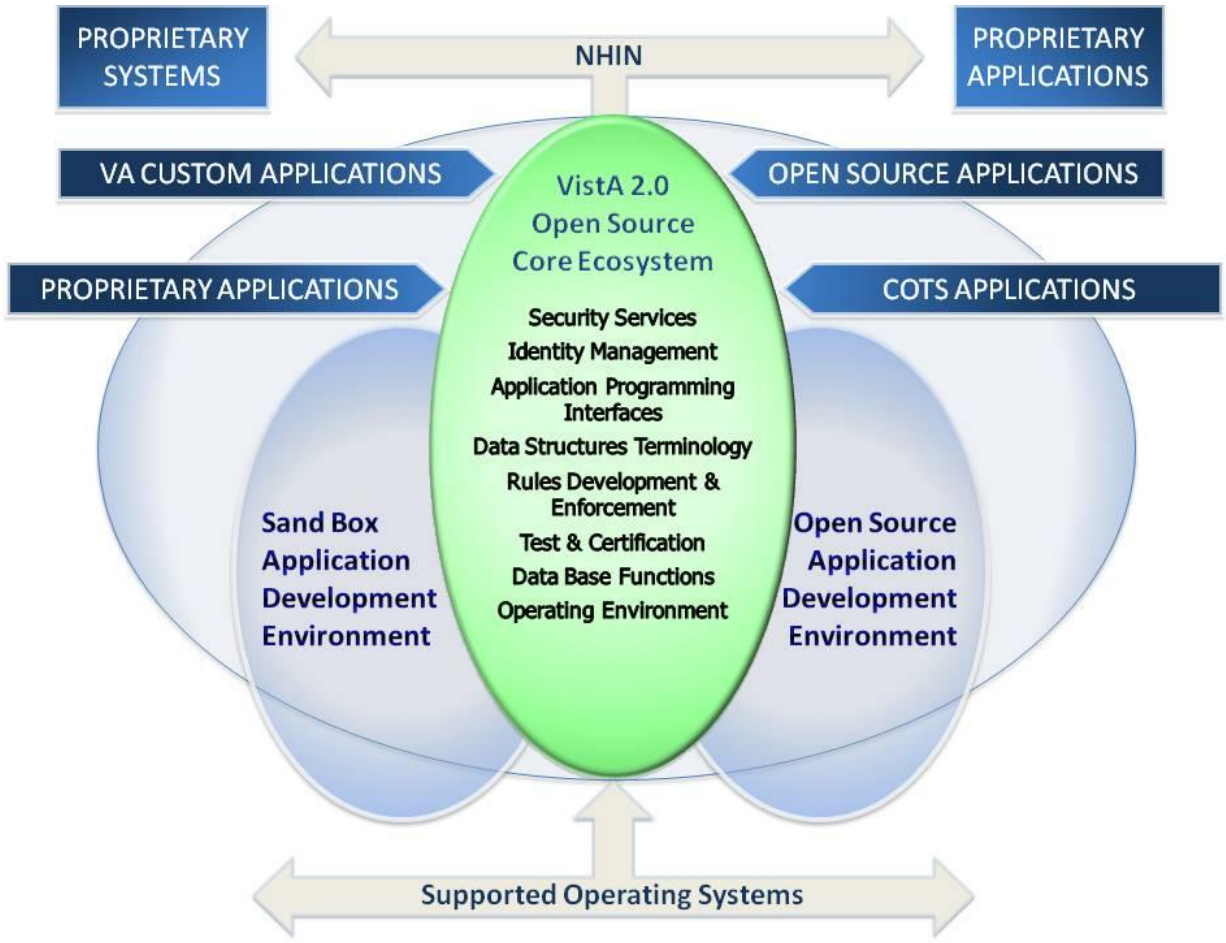

Figure 1: VistA 2.0 "Egg" Diagram

VistA Modernization Working Group Responses to Specific Questions Posed

One of the objectives of this project was to provide VA with an industry-based, community-wide response to a set of specific questions. The working group provides the following short responses to each question posed. More detailed responses are provided in the working group's recommendations and the information provided in the subcommittee recommendations.

Is VistA a system that could be deployed to a wider community? If

yes, what is the most appropriate deployment model: open source code; cloud computing; business process/methodology; other?[1]

VistA is currently deployed to a small community of public, private and international users outside of the VA. However, because it is very difficult to operate and expensive to modify it has not had a much wider adoption. We recommend that VistA be used as a functional specification and be completely reengineered within the VistA 2.0 Open-source, Open-standards Ecosystem as recommended by this working group so that a much wider community can adopt and extend it more readily.

If VistA is deployed and used by other government agencies or private sector entities, what organizational and management structure should be developed? Possible questions include:

Which organization(s) should have responsibility for maintaining the system?

We recommend that VA "sponsor an open-source community" to promote the continued development and extension of VistA 2.0 functionality and associated business rules.

Should VistA be established as a national standard? What are the implications of this action?

Given the resources that VA has expended to date and can bring to bear in the future on this issue, VistA 2.0 should be offered up as the international standard information system for medical centers. Not only would this result in huge financial savings in the healthcare community, but VistA 2.0 would provide huge advances in evidence based medicine, medical research and data standardization and portability.

What is an appropriate strategy for modernizing VistA and transitioning it to a more current and innovative architecture?
The strategy should result in an appropriate, creative and agile acquisition and development plan. (NOTE: The project will establish the general guidance and principles for this strategy and will not be involved in matters pertaining to any actual acquisition.)

VistA should not be “modernized” in the sense of upgrading and updating current VistA in a traditional evolutionary model. VistA should be “reengineered” into VistA 2.0 in the sense of creating a new, open-source, open standards ecosystem within which the proven functional capabilities of VistA can be replicated, modernized and enhanced in a sustainable, scalable, and secure environment.

What are the opportunities and impact of modernizing and deploying VistA upon private industry, the healthcare community and other key groups?

The national and international healthcare communities desperately want and need an appropriate, consistent and dependable “guide-star” architecture, development environment, and reusable components within a fair, open, and collaborative community. While this report focuses on solving VA’s challenges, we feel obligated to at least mention that this system has larger Federal, national and even international implications.

Based on the above, what principles and best practices should be documented and distributed for use by other government agencies considering similar issues?

The lessons learned from the efforts of the VistA Modernization Project are applicable and appropriate for other government agencies facing similar issues. Many older, large-scale government legacy software systems are serving adequately at the current time but are in need of modernization and/or re-engineering. This working group has developed a series of processes and principles that have been documented and can be directly applied to other Departments and Agencies of the Federal Government.

VistA Modernization Working Group Recommendations

The working group recommends a “reengineering approach” to the modernization of current VistA where reengineering encompasses the following understandings.

Replicate (screen by screen; interface by interface if reasonable) the functionality of the existing VistA (legacy) system using:

- contemporary technology and agile development processes
- modern open systems architecture
- reusable components and/or COTS components and applications

Harvest everything of value from current state VistA, including:

- Data models
- Business processes
- Test cases
- Workflows
- Performance metrics
- User or even system level documentation
- Training materials

Have as a first order goal the replication of current, acceptable VistA capability and refrain from adding new functionality until the legacy system has been decommissioned, but plan for new functionality as VistA 2.0 is being designed and architected.

Assume that every line of code in the reengineered VistA 2.0 system will be replaced with many fewer lines of much more maintainable and malleable code that can last a few decades but be upgraded, modified, and enhanced easily.

The reengineering of the legacy VistA system recommended in this report should **not** be confused with the reengineering of the business processes of an organization!

The Working Group Recommendations

- The working group recommends that the VA commit to and

announce as a matter of strategic policy a plan to move to an open source, open standards model for the reengineering of the next generation of VistA (Vista 2.0) to include the core ecosystem as well as those components built by the VA, for the VA, or by the open source community.

- Current VistA should be placed on an aggressive program of stabilization with limited tactical upgrades and enhancements driven by patient safety and other mandated requirements

- The working group recommends that the VA contract with an appropriate Federally Funded Research and Development Center (FFRDC) to provide a detailed set of technical specifications for the development of a VistA 2.0 Open Source Core Ecosystem (Figure 1). Use of the term ecosystem by the working group refers to "the entirety of hardware, software, and networks that drives the delivery of VistA 2.0 products and services." These technical specifications should describe the following components

    - Open Source, Open Standards Operating environment
    - Open Source, Open Standards Application Development Environment
    - Sand Box Application Development Environment

  and based on the following set of high level characteristics to ensure that this ecosystem is optimized for

    - High performance,
    - Security and identity management
    - Scalability

  This ecosystem must provide a scalable, segmented, open source, open standards environment that will provide the following

    - Operating environment
    - Security services

- Identity management
- Database functions
- Application programming interfaces
- Data structures and terminology
- Latencies or service levels associated with capability or service invocation
- Rules development and enforcement
- Test and certification environment

This operating environment must also natively support

- A structured open source application development environment that will provide the following
  - Trusted and approved application development tools, data definitions with sample de-identified datasets, test cases, and test harnesses for simulation and possible self certification or at a minimum unit test
- A "sand box" application development environment that will provide the following
  - Application development datasets, test cases, test, and simulation services

- The working group recommends that the VA contract with an appropriate FFRDC to build and deliver a fully functioning prototype based on the technical specifications developed by the initial FFRDC for the Open Source Core Ecosystem consisting of the
  - Open Source, Open Standards Operating environment
  - Open Source, Open Standards Application

Development Environment

- Sand Box Application Development Environment

- The working group recommends that the VA establish effective governance for the VistA 2.0 Open Source Core Ecosystem as quickly as possible. This governance should be based on the recommendations provided by the FFRDC tasked with providing an appropriate business model, bylaws, operating principles and organizational blueprint for an independent, not-for-profit Open Source Foundation. The working group recommends that the VA charter and initially fund an independent, not-for-profit, Open Source foundation to manage, operate and maintain the VistA 2.0. The three most feasible approaches to establishing Governance for the VistA 2.0 platform, and the open source applications that will be written to operate on it, are

    - Establish a new entity to carry out the governance of VistA 2.0

    - Select an existing open source organization with existing charters, license agreements, and operational procedures, that would adopt the principles provided by the recommending FFRDC and provide an immediate starting point for VistA 2.0 governance

    - Have an FFRDC provide governance directly based on the principles provided by the recommending FFRDC

- The working group recommends that the VA contract with an appropriate FFRDC to provide the functional decomposition of the current VistA Application Suite to deliver a state of the art

    - set of functional and design specifications of current application functionality

    - set of functional and design specifications for required application functionality

    - set of functional and design specifications for additional application functionality

- The working group recommends that the VA determine what application functionality it wants to develop/acquire for the VistA 2.0 Open Source Core Ecosystem using
    - internal in-house application development resources
    - external commercial application development resources
    - Commercially available (COTS) products
    - Open source application development resources
- The working group recommends that the VA develop a master schedule for the acquisition of these applications and functional capabilities
- The working group recommends that the VA develop and acquire the applications and capabilities based on the VistA 2.0 Open Source, Open Standards Ecosystem that meet its requirements and develop a plan and schedule for concurrent operations and migration from VistA to VistA 2.0

Alternatives- Executive Summary

The Alternatives subcommittee was asked to "think outside the box" and make sure that the working group had thought through all the reasonable alternatives for radically improving VistA within VA. Twenty alternatives were suggested and analyzed by the alternatives subcommittee and then by the entire working group. Six of these alternatives were considered to be the most practical. With further discussion and anlaysis, the subcommittee concluded that each of these 6 alternatives could be categorized as being either:

- Improve and restructure what already exists or
- Reengineer VistA in order to completely replace the current system.

The subcommittee recommends the reengineering approach be undertaken by harvesting as much useful functionality, business rules, screen designs, and data models from VistA as possible.

Assumptions

VA has access to adequate resources to fund any reasonable alternative.

VA needs are given priority by this working group as compared to other stakeholders such as DoD, commercial healthcare, etc. Solving VA's problem is large enough challenge, we have not attempted to consider all the issues related to IHS, DoD, DoS, HHS, or commercial interests. However, the desirability of leveraging VA resources and investments to support the U.S. national agenda to implement electronic health records was a consideration.

The VA does not need to build the best electronic medical record system in the world. However, it must operate the best one.

We assume that the current VistA system cannot survive as is indefinitely. Not only will it become increasingly obsolete in comparison to alternatives, but its current architecture and design cannot safely support significant changes and upgrades.

When it was first built, VistA was ahead of its time. It enabled the VA to move from being the worst to the best large-scale healthcare provider in the U.S. However, since its implementation, the U.S. commercial healthcare market has made significant strides to bring functional tools to the market. Meanwhile, the pace of change and innovation in VistA has slowed significantly, partially due to deliberate cessation of enhancements while VistA's intended replacement system (HealtheVet) was under development. Commercial products are beginning to outstrip VistA in functionality, capability, and reliability. In addition, the number of people who understand how to maintain and enhance the current VistA application is dwindling. Therefore, a solution should be implemented and deployed in the next 5 years.

Analysis Process

The Alternatives subcommittee began with an extended brainstorming session to identify as many different approaches to solving the problem of how to get to a replacement system. This list of about 16 alternatives was then shared with the entire working group which resulted in four more entries on the list.
The list of 20 alternatives along with a short description of each is provided below:

	Alternative	Description
1	X Prize	Launch a giant challenge to industry with an associated giant prize to the winner; e.g., $100m to the first company that can replicate the functionality of several key VistA applications or some such carefully considered and measurable challenge
2	Angel Ventures	Provide relatively small amounts of money ($100's of thousands) to entrepreneurs to see if they can spawn new companies replicating important chunks of the VistA functionality
3	Big Bake Off	Launch a competition with a relatively small number of entrants (<10) which is pared down to two or three rather quickly until a single winner is announced -- not unlike what DoD does when acquiring new aircraft
4	Big Bang Modernization	Have a competition to select a single team to "modernize VistA" using traditional requirements, design, and development methods
5	Oregon Experiment	Replicate the process used to improve the University of Oregon infrastructure; it involved dividing the budget into three categories (mega, medium size, and tiny) each of which was asked to replicate successful "patterns" that seem to have worked well there in the past
6	Buy COTS	Accept the fact that COTS vendors are not producing products that will satisfy most of VA needs; So buy the best and build only the rest
7	Cope and Hope	This was the title given by a senior VA leader to the current development process; so this is a business as usual approach
8	Adopt AHLTA	DoD has been much more successful in getting a set of vendors to build functionality in a hurry; so why not just adopt what DoD has done and move out from there…
9	ARPA	The Advanced Research Projects Agency (now DARPA -- Defense) has been successful in DoD for more than 40 years doing very leading edge research -- sometimes with considerable pay-offs; sometimes not
10	FFRDC	Create a Federal Funded Research and Development Center (FFRDC) to foster the research, design and development of new functionality for VA
11	Structured Open Source	Discover or create a mechanism to much more aggressively participate and even lead the open source community in the development of innovative new systems and applications

12	Manhattan Project	In four years, the Federal government managed to assemble a massive team of 130,000 scientists, engineers, construction workers, and military experts to design, develop, test, and deploy radically new "technology". Can or should a similar approach be taken with VistA?
13	NSF/NIH	National Science Foundation/National Institute of Health: these agencies fund fundamental research -- some of which is already related to healthcare IT; maybe we should just radically increase their budgets and see what happens
14	Stock Market for Ideas	Maybe we should look for completely new ways to get a lot more well informed, deeply involved users and innovators involved in this process; one such idea is to create a "stock market for new ideas" where a large collection of people (say 1,000) are each issued 1 million dollars to invest in new ideas by buying and selling "idea stocks"; the result is a near instantaneous quantifiable list of new ideas that might be funded
15	Skunk Works	The Air Force has had considerable success in the design and development of radically new aircraft by simply giving the task to a small, select team of very well funded experts working in "relative seclusion" -- sometimes "total seclusion"
16	Stumble Forward	Make small changes to what we already have and reduce expenditures
17	Healthcare IT Extension Service	Maybe there is a way to create geographically dispersed research centers co-located with universities doing related work in Healthcare IT
18	"Toucan"	There is considerable precedent in the software industry to suggest that really big innovations or breakthroughs come from two person teams -- one of whom is highly technical; the other understands the needs of the users and is likely one him or herself. Since many of the VistA applications were actually built this way, why not do what has proven to work in the past
19	Reengineer VistA	Use VistA as a functional specification and replicate its external functionality using the latest available and appropriate technologies -- quite different from a modernization project which tries to do everything that people want, but have never managed to build before
20	Evolutionary Modernization	Maybe it is possible to modernize "chunks of VistA" without trying to take on the whole system; how these large independently designed and developed chunks might fit together is to be determined

Table1 – List of Alternatives Considered by Working Group

Observations and The working group then took these 20 alternatives and did a variety

of evaluations which included:

- Extent of Research
- Financial Risk
- Technical Risk
- Governance Complexity
- Number of Partners Involved
- Annual Costs
- Degree of Control
- Source of Funding
- Time to See Benefit
- Estimated Return on Investment

From these 20 alternatives, 6 were deemed most practical, valuable, and viable. Those six were:

- Structured Open Source
- Two Can (aka Toucan)
- Stumble Forward
- Reengineer VistA
- Big Bake Off
- Buy COTS

As we analyzed these six alternatives we noticed that they boiled down to the two basic options described below:

(1) Restructure the existing VistA system, piece by piece, into a more modular and well-behaved application while still using it. ("Changing the tires while the car is still on the road.") and

(2) Build a replacement system reusing the business processes, workflow, screen designs, and data models from VistA. This reengineered system must be done using a contemporary architecture which is more structured and properly componentized (with components being provided from internal VA development, external development by paid contractors, project grants, the open source community, or commercial off-the-shelf products).

Both options carry a significant level of risk. The working group recommends the second option because it will provide a sufficiently malleable base upon which much needed enhancements and

improvements can be made over the next few decades. But the subcommittee recognizes that many involved will consider the first option to be a faster and safer approach in spite of ten years of data to the contrary. Reengineering projects, unlike modernization projects, have a very high success rate, even for large legacy reengineering projects.

Transition to any new system will require operating both VistA and the new system in parallel for a period of time. Planning for this transition must begin on day one and is recognized to be one of the largest challenges in designing and developing a reengineered system.

Therefore, the current VistA should be replaced with a new system that supports interoperable "plug-and-play" of increasingly advanced system components and modules, putting it on a new foundation that supports future evolutionary enhancements. This conclusion seems relatively straightforward and generated little controversy within the broader working group. However, the more difficult question is what is the appropriate path to take to reach that objective.

While not chartered to propose such a path, the subcommittee had detailed discussions regarding various approaches. We were convinced that when an appropriate architecture, a sufficient set of development tools, and enough open source components become available many individuals, small companies, large companies, and other organizations will be keenly interested in contributing software, time, and effort to completing the reengineering effort.

Recommendation of the Subcommittee on Alternatives

A Vision for 2020.The current VistA should be replaced with a new system that supports interoperable "plug-and-play" of increasingly advanced system components and modules, putting it on a new foundation that supports future evolutionary enhancements. By having a combination of contracted software components, open source components, and COTS software will give the VA maximum flexibility to choose the best of breed. The result will be a state of the art, medical application development environment with a comprehensive suite of extensible components and functional applications provided by VA, entrepreneurs, university researchers, commercial medical and non-medical software products companies, national health services, etc. with a superset of the functionality in today's VistA system.

How might we get there?

To get there, we believe VA must reengineer VistA, then extend and expand it as required with the support of a new open source ecosystem launched by VA, to augment its existing acquisition approaches of internal development, contracted development, and COTS acquisition.Evaluation of the sources for potential alternatives would be based upon functionality, extensibility, security, quality, etc.

The ecosystem's goals should be two fold. In the short-term it should drive the architectural and reengineering efforts of the existing system, while progressing towards a day when it becomes the 'upstream' provider of software to the VA.

We recommend replacing all the code in VistA while retaining the required functionality (business processes, workflow, information on screens, data model, etc.). The most important aspect of the new system is the development of an architecture which includes identification of well-behaved ways for the modules to communicate with one another. It should be redesigned, reengineered, reimplemented, appropriately documented, fully tested, and progressively deployed. It should also support local VA configuration, while still retaining a single code base which is managed under strict configuration control.

Modernization and Architecture- Executive Summary

The Modernization and Architecture Subcommittee first investigated the historical successes and less than fruitful approaches to modernizing VistA or adding enhanced capabilities to the VistA environment. Based on informal question and answer sessions with those involved in sustaining, enhancing and evolving the current VistA environment, the subcommittee explored the possibilities and potential for continued incrementally evolution of the environment through improved interface definition, data definitions and service level definition (logical modularization). This approach was discussed with the entire working group at length and the working group as a whole decided that the reengineering of current state VistA to an open source, open architecture environment, dubbed VistA 2.0, was the desired and optimal path. To achieve this target state, the development of a reference model is required consisting of the following:

- Core Services derived from an analysis of the capabilities of the VistA kernel and the requirements of future state VistA 2.0

- A documented Open Source Architecture (similar to logical modularization, includes interface definitions and data definitions with required response times or service levels)

- An Open Source Software Development Kit (SDK) including a recollection of accepted open source development tools and some limited number of exemplar medical applications outside of the core of Vista 2.0 to show developers acceptable approaches on how to invoke capabilities of the core from outside of the core.

- Standardized data model

- Standardized interfaces

- Use of open source tools

The reference model, consisting of the core with sample applications outside of the core, should be built on and for a modular, scalable hardware platform which should be optimized for performance, security and identity management, and scalability. The notional high level representation of the reference model is depicted below in figure 2. The exact approach is left up to the developing body – the Federally Funded Research & Development Center (FFRDC) as detailed in the sections on Governance and Deployment.

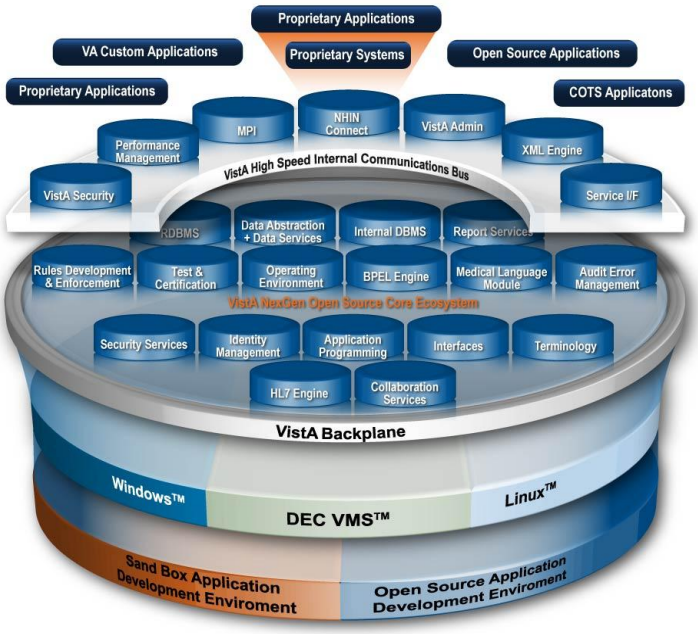

Figure 2 – High-Level reference model representation

As the core of VistA 2.0 is developed, VistA, as it exists today, should be prepared to coexist with Vista 2.0 as the capabilities become available by aggressively moving towards stabilization – freezing the current capabilities while only addressing patient safety issues and defining the logical interfaces, data definitions and services levels associated with the application environment allowing for logically invoked functions on a modular level via the use of an application broker. This parallel path enables the ultimate release of open source capabilities in an open architecture is depicted in figure 3 below and allows for a seamless transition to the user community

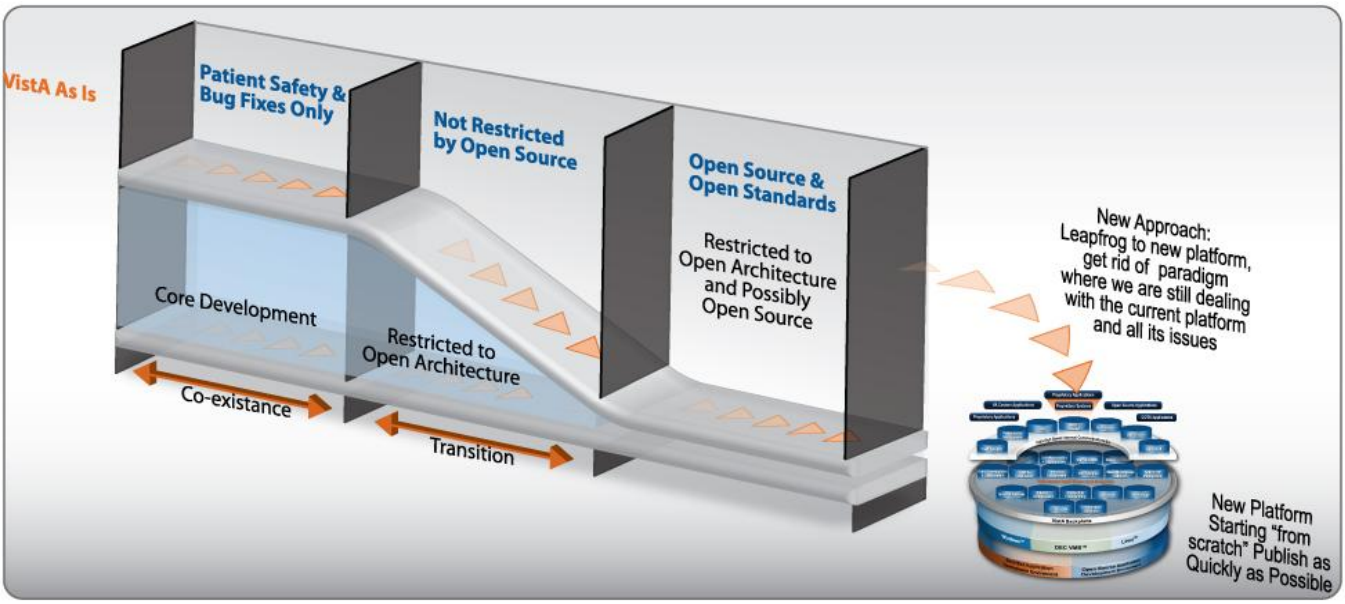

Figure 3 – The Path to VistA 2.0

Assumptions

- "Innovation" and "Open source" are the main drivers for VistA modernization. Other important drivers are the lack of consistent architecture, inflexibility of the current system, maintenance costs, performance issues, security issues, scalability and availability issues.
- Restated as individual assumptions:
    - For clinical reasons, VA needs to increase the rate of innovation in VistA
    - The current VistA architecture greatly increases the total cost of ownership
    - Current maintenance costs, while not necessarily onerous to the VA, could be better utilized to provide new innovation and functionality
    - Availability and scalability of current VistA needs improvement
- VA is looking for a VistA 2.0 system that facilitates innovation.
- An Open Source environment is a strategic goal of the VA

- Development activities for Vista 2.0 must be accomplished in synchrony with stabilization and limited patient safety related enhancements to current VistA

- It is acceptable to develop a new system from scratch as long as the core business processes are preserved

- VA will support the base "standard" VistA 2.0 core ecosystem and accept/certify software from other implementers as long as it is developed in the VistA 2.0 ecosystem and tests and certifies in that environment.

- The target state vision for VistA 2.0 modernization and its proposed architecture is a long term strategy

- The use of COTS products together with Open source products (wherever applicable) is acceptable as long as the COTS products align with the VA EA framework and adhere to the common interfaces specified within core VistA 2.0

- The recommendations should take into consideration all development communities including VA, open source communities and other commercial vendors.

Analysis Process

The Modernization and Architecture Subcommittee adopted industry best practice analysis techniques and processes to address the complex task of VistA modernization. The process consisted of:

- Gaining an understanding of the existing VistA environment
- Gathering information on gaps and issues
- Determining modernization goals
- Developing architecture principles and guidelines to aid decision making
- Evaluating options
- Developing recommendations.

Information was gathered from a variety of sources and perspectives. The team conducted interviews and had working sessions with sources, within the VA, as well as external sources:

- Clinical User perspectives (VA DC Medical Center staff)
- Architect perspectives (Legacy Architecture)

- Engineer perspectives (Interagency Sharing)
- VA OI&T Management (Office of the Assistant Secretary)
- OED (Legacy Product Services)
- FOIA VistA implementers.

The Current State

From the Clinical User perspective, "VistA, as currently implemented at the Department of Veterans Affairs, is the most comprehensive, large scale, integrated healthcare information system in the world. It successfully supports more of the specific functional requirements of its extensive user base than any other large scale system."

Yet from the IT perspective, we find a different perspective that includes words like *brittle, complex maintenance, complex operations, complex deployment, code that is not well structured, difficult to test, difficult to integrate, and inability to support current and emerging technologies.* The IT perspective is validated by the organization's inability to deliver substantial new functionality for the last few years.

Gaps and Issues

During each interview/meeting, the team identified known/perceived gaps and issues. The gaps and issues are summarized in Table 2:

Gaps and Issues	Perspective	Impacts
New functionality takes too long to deliver.	Clinical User	Product Delivery
Integration of new technologies takes too long.	Clinical User	Product Delivery Innovation
VistA perceived as brittle – it breaks it does not bend.	Clinical User	Performance
COTS does not integrate well with VistA.	Clinical User	Product Delivery
Roll and Scroll users less happy than CPRS users.	Clinical User	Usability
Easy to get data in, hard to get data out.	Clinical User Engineer	Performance Innovation
Semantic interoperability among multiple VistA implementations.	Clinical User Architect	Usability

Gaps and Issues	Perspective	Impacts
Heterogeneous technology mix makes maintenance, installation and operations difficult.	Engineer Operations	Product Delivery Innovation
Product complexity and unstructured code.	Engineer Architect	Product Delivery Innovation
Dated technologies impact innovation and maintenance and operations.	Engineer Architect Operations	Product Delivery Innovation
Local ability to customize impacts stability	Engineer Architect	Product Delivery

Table 2 – Gaps and Issues Identified by Subcommittee on Modernization and Architecture

Modernization Goals

With the assistance of the various stakeholders, the team created a set of goals for the modernization of VistA (not prioritized).

- Enhance "innovation" and improve the flexibility of the system so that new features/functions can be delivered in a timely manner
- Improve the ability to incorporate enhancements and performance of the product
- Increase the ease and rate of technology and functional innovation
- Make the data more accessible for reporting and analysis
- Maintain clinician end user involvement in requirements identification, application design and user acceptance
- Reduce the costs associated with operations and sustainment

As is seen in both the gaps and the goals, there are multiple, often competing, concepts. Recognizing this, the team developed a number of architectural principles to guide decision making for modernization.

Recommendations Subcommittee on Modernization and Architecture

The subcommittee recommends the development of a reference model based on open source technologies with a documented open architecture for VistA 2.0 which should include:

- Core Services derived from an analysis of the capabilities of the VistA kernel and the requirements of future state VistA 2.0
- A documented Open Source Architecture (similar to logical modularization, includes interface definitions and data definitions with required response times or service levels)
- An Open Source Software Development Kit (SDK) including a recollection of accepted open source development tools and some limited number of exemplar medical applications outside of the core of Vista 2.0 to show developers acceptable approaches on how to invoke capabilities of the core from outside of the core.
- Standardized data model
- Standardized interfaces
- Use of open source tools

Models and Extensions- Executive Summary

The mission of the Models and Extensions Subcommittee was to understand the recommendations of our colleagues and their respective teams, yet make sure the outcome could achieve what the VA is trying to accomplish.

Assumptions

Aligned with the mission, we used the assumptions made by the working group and the other subcommittees.

Analysis Process

The Models and Extensions subcommittee met weekly to discuss the draft recommendations document. Several members of this team sat in on the other team's weekly meetings, to keep current on the processes and recommendations that were being formulated. This team attended all of the off-sites, also to understand the VA's perspective on this project. Research was done to understand the current state of affairs at the VA, how to implement change in an organization of this size, and some of the real life experience from

the team members was also brought into play. Several of the team members have assisted in implementations around VA and its facilities in the past.

Observations and Outcomes

The VA has numerous challenges ahead. We agree with the recommendations of the various subcommittees and believe we have also given them some ideas on how to have the recommendations succeed in an Open Source, fluid and complex environment. We believe one of the biggest challenges the VA will have around the Vista Project will be a culture change in the overall way they procure software, incent the Open Source communities to participate, and speed development of this mission critical application and infrastructure. We hope that the Executive Level stakeholders at the VA will embrace the ideas and recommendations that these subcommittees have put forth.

Recommendation of the Subcommittee on Models and Extensions

The Models and Extensions subcommittee approached this task by understanding what we were modeling would reflect the real world of an enterprise wide, mission critical application. This would include all aspects from the software development to the cultural changes that could come about. Our recommendations attempt to reflect real users and business concerns.

Cultural Barriers, Innovation Risks

Timing

The VistA Working Group has decided on a recommendation of the establishment of an Open Source Foundation (OSF) dedicated to the development of VistA 2.0. The timing of the OSF implementation is of significance. The OSF must make available components of ***value*** to the community, including the VA as soon as possible. The VA must contribute viable, working core code as the foundation of the VistA 2.0 OSF. This foundation code will be a key event that will show the members and potential members of the community that the Open Source venue is meeting its goals and will be establishing a community in which they will want to participate. At the same time, the VA stakeholder's expectations for meaningful and productive enhancement and improvements to current VistA applications must be met with timely availability of value as soon as possible after establishment of the OSF. The design of the OSF will take the needs for early delivery into account in order to maximize participation and probability of success.

Community

The concept of OSF in Government is not new. Several currently exist with a variety of missions expressed in their founding charters and various degrees of vitality. One measure of the success of OSF's is the robustness of their “ecosystem”. There are potentially disparate driving interests of community members that culminate in a single thriving Open Source community.

In this case, we define the ecosystem as the contributing members of the foundation. Each member of the foundation will have significant motivation for participation – typically each member in equal standing. In the case of the VistA OSF recommendation, we have assessed several areas of interest that stand to make the VistA OSF ecosystem a vibrant community. There are several unique drivers that stand to contribute to this end.

The single biggest driver will be the development funding provided by the VA. The process of a Government agency providing funding for a non-profit OSF organization is not new. One practiced means of providing this application development funding is through a grants program. Another alternative may be a direct funded RFP process where foundation members compete for the opportunity to develop modules, applications, or components. Both processes involve a fair and equitable decision making process of soliciting, evaluating and committing funds for each particular piece.

With many modules, applications and components needed, these requirements, over time will be many and varied and will be plenty to keep vigorous community attention. Potential interested members of the community include companies in the medical software applications market, smaller entrepreneurial businesses, university research teams, and pure software and systems development companies.

A second motivator of the OSF community is access to the code itself, the OSF’s intellectual property. Each member of the OSF is entitled to the OSF VistA products subject to the terms of the license agreement. The terms of the license agreement are as established in the OSF charter. The specific license terms are to be determined with the setup and establishment of the OSF and as recommended by the FFRDC given that mission. There will be many OSF members, whether they actually develop code or not, that will be

keenly interested in securing the VistA core and application software. Typically, the companies in this market will be involved in a variety of businesses including that of Value Added Resellers that might supplement, combine services and package derivative products for sale. The viability of this market has already been established.

A third motivator of the community is the availability of VA's test data. With the appropriate redactions for privacy &security, and protection and separation of the development environment by the OSF, there is significant research value in the VA's data. Various researchers throughout the country have already shown keen interest in the rich and voluminous information collected by the VA for many years. The potential to learn from the unique nature of VA's long-term relationship with its patients is remarkable.

Innovation

There are several elements of the Open Source recommendation that foster real innovation. The Sandbox development environment can provide the means for innovative members of the OSF community to brainstorm and prototype a wide variety of potential capability without constraint. The Sandbox innovation can be fueled by incentive programs sponsored by the OSF or VA that would involve compensation for the best and brightest solutions. A second method that has the potential to foster significant innovation involves a process for cultivating third-party development of ***plug-in*** applications. This method mirrors the Google apps approach, where based on published standards, API's and in this case perhaps Sandbox availability, third-parties develop their own mini-applications that can then be sold in a marketplace. This marketplace may be VA or it may be the commercial medical software and systems markets – perhaps even directly to the veterans themselves.

Culture

Are there significant cultural barriers? Anytime changes are made in an organization, there are impacts to Agency culture. At the point that these changes become a barrier, the momentum moving forward with strategic change may be slowed. The concept of VA being an active and responsible member of and OSF community, participating in governance, operations, funding, testing and fielding applications that come from and OSF source all reflect new operating procedures. These processes will not be an abrupt step transition, but will be a more gradual ramp to establish and implement efficient and effective operation in this new environment. The VA personnel are not new to their overarching mission. With a careful picture drawn of the advantages of the OSF development to the larger community including VA and hospitals outside of the VA,

states and municipalities, foreign countries, and other stakeholders, they will see the significance of their investment moving forward. The foundational culture of caring for VA patients, and now perhaps patients within a larger community, will not change.

Business Model – Developing New Applications

Grants, contract awards, innovation prizes and even donations from member companies make up the wide variety of mechanisms within an Open Source construct that can generate valuable application code, modules and useful development or production utilities. Success is what drives each of these areas. There is a win-win perspective for each of these cases and in an active development community, the opportunities for success and the resulting successes are clearly visible. A diverse economic model with multiple mechanisms to drive innovation and development will yield the greatest results for all participants.

Open Source

The Open Source Community is alive and well. President Obama's commitment to this mode of development resonates in his goal for Open and Transparent Government. There are numerous commercial companies embracing this concept, as they develop new products and tools to work within an OS environment. Web 2.0 creation is also a key component. People in everyday life are used to applications that are interactive, visual and easy to navigate. This has created an expectation that the business applications used must follow the same guidelines. This has created a drive for the development communities to share their creations, develop new and innovative applications, and assist all with the overall view of sharing information. Dashboards, report cards, scorecards, etc. are all very prevalent in Federal agencies today.

The challenge that the VA may have is how to harness this innovative community to create specific applications around patient centric care. This draft addresses some ideas to have this community participate in the VA programs.

VistA & VistA 2.0

- The current recommendation is that VistA and VistA 2.0 run in parallel for a period of time. This will require an investment in 2 areas-
    - first to keep the current system up and running under an aggressive program of stabilization with limited tactical upgrades and enhancements driven by patient safety and other mandated requirements

- substantial investment in developing the VistA 2.0.

As there is a wealth of discoveries around new medical applications and processes, and this information must find its way to the VA. The VA must commit to being open to researching and understanding what might be available in the commercial world, while maintaining the highest level of care and ensuring patient safety.

Before VistA 2.0 can be successful, the VA must involve the current VA community as stakeholders in the success of VistA 2.0. This may require a cultural shift and it is imperative that the stakeholders view themselves as agents of change, while not sacrificing their day to day commitments.

Process to bring in New Applications

The current paradigm of VistA software development must evolve into a structured application development approach that is defined by strict governance and change management. Well-defined processes will need to be developed for bringing new applications into the structured Open Source application development environment. A governing body must be ready to enforce rules and guidelines as they are established and set timelines for releases, upgrades, and maintenance tasks. Testing and certification entities must be established and engaged to maintain quality control. The Sandbox, though "unstructured" in nature, will need to be maintained by a dedicated entity. The key to success will be in maintaining a healthy application development process, utilizing tools such as social media to drive innovation and motivation.

Program Control and Oversight

The importance of program control and oversight in the Open Source application development environment cannot be overstated. The pros and cons of both internal and external governing bodies will need to be weighed carefully. Who will have the ultimate control over the Open Source application development environment? A well-defined approval process will be an integral part of the overall application development strategy and must be applied consistently across development organizations of all sizes.

The security and privacy of personal health information is a common thread across all electronic health record (her) systems, in both the public and private healthcare sectors. Who will address security needs across systems and applications in the VistA 2.0 environment? This will be one of the first challenges faced by

stakeholders of the new VistA ecosystem.

Risk, Threats and Barriers

The introduction of a VistA Open Source ecosystem into the current EHR marketplace may pose a threat to clinicians and vendors already carving a niche in this space. It is fair to assume that many stakeholders outside of the VA would not welcome this new marketplace competitor, as it may have economic implications. For example, physicians and hospitals in rural communities with limited resources would likely choose a robust Open Source EHR solution as opposed to a costly proprietary system.

Other risks to the VA may include: 1) the financial commitment required to modernize VistA and 2) the time commitment required to develop VistA 2.0 on a modern platform.

The mitigation of these risks will be a crucial component of the successful evolution of VistA 2.0.

Deployment Models - Executive Summary

The Deployment Models subcommittee considered several key aspects in an effort to identify the best suited and optimal approach for the deploying VistA 2.0 within the VA and external organizations. These aspects included –

- Logical and Physical Deployment models
- Systems Development Life-Cycle related Deployment Activities
- Deployment Pillars - Integrated System Characteristics such as Reliability/Availability, Maintainability/Support, Scalability, Extensibility and Interoperability
- Deployment Environments – An Innovation Sandbox including computing environments/reference models for development, test, integration, release and production

Given the size and complexity of the Department of Veterans Affairs and its implications for the VistA 2.0 system based on an open-source approach and architecture, it is imperative that deployment activities be built around five pillars - ***Reliability/Availability, Maintainability/Support, Scalability, Extensibility and Interoperability***. The foundational model to best support these pillars is accomplished most efficiently through a Centralized Model for logical deployment of applications. It is recommended that the ***Centralized model*** be enabled by the appropriate physical model based on cloud computing and service orientation. Regardless of the

system architecture and governance framework, a VistA 2.0 system based on an open architecture and open-source software will be capable of being deployed via a variety of Logical and Physical models.

In addition to the deployment model, the choice of a ***Systems Development Life-Cycle (SDLC)*** is critical to successfully implement and deploy VistA 2.0, based on an open architecture. While there are several traditional SDLC methodologies to choose from, large and complex organizations like the VA often define and customize their own version(s) of the SDLC methodology to best meet their needs. A flexible approach to the SDLC such as Agile methodologies in the VA environment would potentially be the most successful with the appropriate governance framework put into place.

It is recommended that ***open-source based Development, Test, Integration and Release environments*** be established to foster Class III type innovation from organizations external to the VA. To ensure a successful deployment and sustainment of the VistA 2.0 solution careful considerations should be provided to the development of a comprehensive Deployment Roadmap with a well-defined end result, Disaster Recovery and Continuity of Operations Planning (COOP) capabilities required, and the FOIA and Patch release processes for delivery and deployment of VistA 2.0 software in an open-source environment.

Assumptions

- Changes to deployment or redeployment of the current VistA environment (Cache) is outside the scope of the subcommittee's considerations.
- Deployment considerations related to various business models that may be utilized to provide VistA to a wider audience are outside the scope of the subcommittee's recommendations.
- Deployment models best suited to meet the VA's mission may not match the deployment needs (dictated by technical and/or business constraints) of organizations external to the VA.

Analysis Process

In addition to participating in the weekly working group calls, the Deployment Models subcommittee actively engaged in

brainstorming activities and discussions with other subcommittees including Models and Architecture, Governance, and Opportunities and Impacts. Given the downstream nature of the deployment activities within the systems lifecycle, such participation provided the opportunity to learn and share key insights with these groups and ensure a coherent overall approach and recommendations.

The following deployment related aspects were analyzed and considered in light of the proposed open-source approach to VistA 2.0–

- Logical and Physical Deployment models
- Deployment Activities – SDLC-related
- Deployment Pillars - Integrated System Characteristics
- Deployment Environments – Innovation Sandbox

Observations and Outcomes

- Regardless of the Models or Architecture selected, VistA 2.0 will be capable of being deployed via a variety of Logical and Physical models.

- No loss of current capability to deploy in a variety of physical and logical models

Recommendation of the Subcommittee on Deployment Models

- It is recommended that VistA 2.0 be deployed using a Centralized logical model enabled by the appropriate XaaS model for the VA or another organization adopting the open-source VistA software.

- Deploy VistA 2.0 using physical and logical model which best suits specific mission need

- Establish Open Source Application Development, Test, and Evaluation environment

- Create an Innovation Sandbox for External to VA contribution and enhance Class III type innovation within the open-source ecosystem

- Provide careful considerations to the following for a successful deployment of a modernized VistA solution:

- Developing a comprehensive Deployment Roadmap with a well-defined end result.

- Disaster Recovery and Continuity of Operations Planning (COOP) capabilities required.

- FOIA and Patch release processes for delivery and deployment of VistA 2.0 software in an open-source environment.

Governance- Executive Summary

Credible and effective governance is just as important to the success of the VistA 2.0 platform as the technology decisions that will be made.

The working group recommends that the VAcontract with an appropriate FFRDC to establish or identify an external entity to provide governance for the VistA 2.0 platform and for the applications that it makes available as open source.
The working group recommends that the VA establish Governance as quickly as possible after VA makes a commitment to an open source approach.

The working group recommends that the VA work with the governing entity to identify (from existing licenses) those licenses which will help create and maintain a vibrant "eco-system" of open source and proprietary applications built around the VistA 2.0 platform

Assumptions

- VA will make a highly visible public commitment to an Open Source approach to the VistA 2.0. VA will include a timeline for initial activities to demonstrate commitment and create urgency.

- VA will create or sponsor a VistA 2.0 platform version 1.0 and an associated tool set, and make it available as open source.

- VA will publish Application Programming Interface specifications, which will allow development of medical applications for use of VA.

- VA will develop (internally or by contract) a significant set of critical VistA applications to run on the VistA 2.0 platform, and make those applications available as open source. VA will have

to provide functional specifications and performance requirements to ensure these applications meet its needs.

- Any applications internally developed by VA, or custom developed by VA, will be made available as open source.

Analysis Process

In order to meet this objective, the Subcommittee gathered information on the current VistA system and Open Source alternatives through research of publicly available books and articles; interviews with industry experts, including Mr. Mike Milinkovich from the Eclipse Foundation and Skip McGaughey from Open Health Tools. The Subcommittee also conducted specific research on various license types currently in use in the open source community. Governance Subcommittee members participated in all ACT-IAC VistA Working Group current systems analysis, demonstrations, and knowledge sharing sessions, as well as other subcommittee meetings and proceedings (Modernization & Architecture, Deployment Models, and Executive Subcommittees). The team met weekly to review progress and status and next steps.

Observations and Outcomes

Why would VA make the VistA 2.0 platform and a suite of applications associated available as open source? There are two primary two reasons. First, the VA would derive benefits including cost savings and infusion of innovation from the open source community. The VA will be sharing the cost of software debugging, maintenance and improvement with a community of users. As the number of users increases, so does the number of institutions and individuals who are invested in improving the software. Furthermore, it is reasonable to assume others will develop innovative ideas and applications on the VistA 2.0 platform, which VA can consider using. In current VA terminology, "Class III" software can be developed outside VA as well as inside VA. Secondly, a widely used VistA 2.0 platform offers potential benefits to the entire healthcare industry. It would greatly enable interoperability, which would benefit individual patients and the healthcare industry. Applications written on the VistA 2.0 platform, and certified as adhering to its standards and definitions, will be inherently interoperable, or could be made interoperable with a minimum of effort. Additionally, a viable VistA 2.0 platform available as open source, along with a significant suite of applications, both open source and proprietary, could hasten adoption of electronic health records across the country.

Establishing Governance

If VA is to make the VistA 2.0 platform available as open source, along with a compelling set of development tools, frameworks and a significant suite of applications, it must consider how this software will be governed.

Why does open source software need governance? Governance ensures that the software is distributed and maintained in accordance with the licensing for the software. Effective governance ensures that the product is maintained and improved to meet the needs of the user community. Effective governance keeps the software from "splitting" – that is it prevents the development of competing and incompatible versions of the same software. Maintaining a "gold standard" version of open source software benefits the entire user community by increasing operational efficiency and effectiveness, accelerating the rate of improvement, and reducing operational costs.

What are the attributes of effective governance? Effective governance brings together all major users and stakeholders, and meets their collective needs. No one user benefits at the expense of other users. A governing body or entity would

a. Establish a well defined set of membership and governance processes, essentially a set of rules and procedures that stakeholders agree to. This assures that all stakeholders play by the same rules and are following the same processes, helps avoid conflict, and provides processes for dealing with the conflict when it inevitably occurs.

b. Bring together and enlarge the stakeholder community. Establish a neutral and effective forum for discussion and work to benefit the entire community, built upon trust and effective communication.

c. Establish a set of rules, processes, and practices that are part of the software development and improvement process. This assures that for clinical applications, "life critical quality characteristics" are followed and are replicable.

d. Maintain the reference model or "Gold Standard" version of the VistA 2.0 platform and open source software

written against it. Help the community decide what suggested improvements or changes are adopted, and help resolve technical issues. Distribute and license the software.

e. Create and maintain a vibrant ecosystem centered on VistA 2.0. This would help with aftermarket products and services (education, training, partner programs etc.) as well as deployment offerings to assist with implementations.

f. Create and maintain a development environment, regression test environment, and a self certification environment for applications for the VistA 2.0 platform.

Governance should be established as quickly as possible. The working group recommends that the VA establish governance for the VistA 2.0 platform as quickly as possible. Governance is necessary for the community to come together, and the governing body will help assemble the community. VA will need to balance four essential attributes around establishing governance. They are:

- Speed - speed at which effective governance can be established
- Effectiveness – degree to which the governing body can meet the requirements of effective governance described above
- Credibility – that is, acceptance of the governing body by internal and external stakeholders
- Influence– the degree to which the VA can maintain necessary and appropriate influence and guidance over the VistA 2.0 platform

Speed. VA will want to ensure that effective governance is established as quickly as possible. Many issues will arise as soon as VA begins to develop the VistA 2.0 platform. The governing body should be working from the beginning to attract stakeholders, help resolve issues and establish its approach to the wide range of governance issues and functions.

Effectiveness. Governance must be effective for an open source strategy to be successful. Membership rules, governance processes and software standards must all be in place and seen as fair, reasonable, even handed and designed to promote the interests of the entire community.

Credibility. The governing body must be seen as highly credible by potential and actual stakeholders. Reputation, previous work, existing membership and projects, and stature of its leadership are all key issues. Credibility does not necessarily come easily or quickly. Slowly building credibility over time would not be the preferred approach.

Influence. VA will have a fundamental interest in ensuring that the VistA 2.0 platform, as it is developed and maintained, is always highly useable by and acceptable to the VA. As envisioned, VA will have a robust suite of mission critical applications working on top of this platform. VA will want to ensure that it is always using a version of the platform compatible with the open source version. If the platform VA uses ever diverges or "splits" from the open source platform, the benefits of open source will be lost to VA. Therefore, VA will have to be assured that the governing body always sees VA as a major stakeholder, and that as decisions are made, VA's interests will always be protected, consistent with the interests of the broader open source community.

How will the VA Establish Governance*?*

As indicated above, VA must establish effective governance as quickly as possible. How will VA do this? The three most feasible approaches to establishing Governance for the VistA 2.0 platform, and the open source applications that will be written to operate on it, are

- Establish a new entity to carry out governance, based on the business model, bylaws, operating principles and organizational blueprint for an independent, not-for-profit Open Source Foundation as provided by the recommending FFRDC

- Select an existing open source organization with existing charters, license agreements, and operational procedures, that are in concert with the business model, bylaws, operating principles and organizational blueprint for an

independent, not-for-profit Open Source Foundation as provided by the recommending FFRDC which would provide an immediate starting point for VistA 2.0 governance

- Have an FFRDC provide governance directly in concert with the business model, bylaws, operating principles and organizational blueprint for an independent, not-for-profit Open Source Foundation as provided by the recommending FFRDC

VA will need to carefully weigh the approach it takes to establishing effective governance. **Credible and effective governance is just as important to the success of the VistA 2.0 platform as the technology decisions that will be made. Therefore, the approach taken toward establishing governance should be given thesame level of consideration, to help ensure the highest probability of success.** Each of the three approaches has pros and cons, which are discussed below.

Establish new entity to carry out governance. VA could establish a new entity to govern open source VistA 2.0, possibly with help from an FFRDC to accomplish this very quickly. While an organization could be established quickly, two issues would need to be addressed. One, could the organization establish effective and credible leadership, working capital and a reasonable business plan, all necessary to ensure long term viability? Two, would a new organization have sufficient credibility to attract stakeholders? The stature and experience of the leadership of the new organization would be critical.

Select an existing organization. Another approach would be to select an existing organization to provide governance. One would look for an existing organization that is currently providing governance to open source software, knows the existing community of VistA stakeholders, would be seen as credible by the stakeholder community, and would be able to attract additional stakeholders. This could be done through an existing membership or through an acquisition process.

Direct FFRDC governance. VA could task an FFRDC with providing governance over open source VistA 2.0. FFRDC's are generally not-for profit, operate in the public interest, and provide objective and independent advice and action. An FFRDC could in theory provide credible and effective governance for open source

VistA 2.0. The question would be whether the FFRDC would know the stakeholder community, could attract additional stakeholders into the community, and would be seen as fair, credible and sufficiently independent from VA to govern in the interests of the wider community.

Membership. If VA is a member of an organization that governs open source software, and sees that organization as a viable candidate to govern open source VistA 2.0, it could simply designate that organization as the governing organization. This has the benefit both of speed, and ensuring VA at the end of the day has the governing body it thinks will be most effective.

Acquisition. Another approach would be to follow an acquisition process. That is, VA would issue a RFP and invite organizations to offer proposals. VA would select from the proposals submitted, based on experience governing open source software, current membership and business model, ability to attract a broader community of stakeholders, the financial and other resources offered, and the cost of the services being offered. This approach would offer all interested parties the ability to compete for designation as the governing body, and might therefore be seen as "fair" by those interested parties. VA might also encourage them to consider partnering. However, this approach has some potentially serious drawbacks. Some highly viable governing entities might determine that they cannot participate in an RFP-type process. Therefore, effective and definitive market research would have to be undertaken before this approach could be considered. Furthermore, one could question whether this approach could be sufficiently rapid to meet VA's needs, and whether VA would end up with a desired outcome at the end of the process. Once undertaken, an acquisition approach could well be very difficult to abandon, and so should be pursued only if VA is convinced it will be quick enough to meet VA's needs, and will yield an effective outcome.

No matter what approach is taken, The working group recommends that the VA be aware that one or more existing organizations or entities might well see themselves as ideally suited to provide the governance VA is looking for. If these entities are not chosen, they are likely to question both the decision made, and the process VA followed to achieve the decision. No matter what approach is taken, VA must be prepared to articulate sound reasons for the approach taken, and why at the end of the day it creates or chooses one

particular governing body.

VA Role in Governance

If VA is to derive the expected benefits from placing the VistA 2.0 platform and associated applications into the open source community, VA will need to take a highly visible and active role in the activities of the governance entity – that is, in the ongoing improvement of the VistA 2.0 platform, and in the ongoing maintenance development of any open source applications running on the VistA 2.0 platform. By actively participating, the VA will ensure that improvements to the platform and applications are made on an ongoing basis. VA's active involvement and support will demonstrate its commitment to the platform and to the open source business model. This will encourage additional users, which will in turn stimulate additional applications, both open source and proprietary. This will benefit VA, in that maintenance and improvements will not be made solely at VA's expense, and will happen at a very rapid pace.

VA will need to provide financial support

VA's contributions will almost certainly include financial support. As part of its active participation in governance activities, VA will need to support the governing entity financially as well as with its active participation and support. Governing services are not free. Different open source governance organizations have a variety of business models. Examples include dues as a requirement for membership, funding to support development or governance of specific products, and external funding – a foundation model. The level and type of financial support VA will need to contribute will largely be a function of the governing body it selects or establishes. But in any case, VA must be prepared to provide the financial support required, along with the broader community of stakeholders.

VA Internal Governance

VA already manages a complex governance process for over 150 deployed instances of the current VistA system. The current set of processes and tools is continually evolving. VA is moving toward a centralized baseline management of the VistA 'gold standard' version that is used in its VA Medical Centers (VAMC's).

Moving to an Open Source solution will increase the complexity of the VA's existing governance and will require senior-level resource support to serve as the VA's official liaison to the VistA 2.0 open source governance organization and the open source VistA 2.0

community in general.

In the current environment, the VA releases VistA through a FOIA process but does not need to be concerned with changes that are being made to that software among the community of users who are consuming this version and extending it. This community must react to any changes VA makes and releases, again through the FOIA process.

When the Open Source model is adopted, the VA becomes one of many stakeholders in an Open Source community that is a consumer of the Open Source VistA 2.0 software. Granted, the VA will be a heavily leveraged and arguably the most important stakeholder, as the VA will be the sponsor and primary contributor of the VistA 2.0 "Core Platform" into the Open Source community. Nonetheless, the "ownership" of the core open source solution becomes external to the VA – an entire community of others with a vested interest in both consuming and contributing to the software. Therefore the VA must establish within the Office of Information and Technology (OI&T) a senior level liaison to the VistA 2.0 Open Source Software (OSS) Community. Figure 4 below is a very high level depiction of how the VA will interact through this Liaison office with the Open Source community and within the VA to manage the VistA 2.0 baselines as they change.

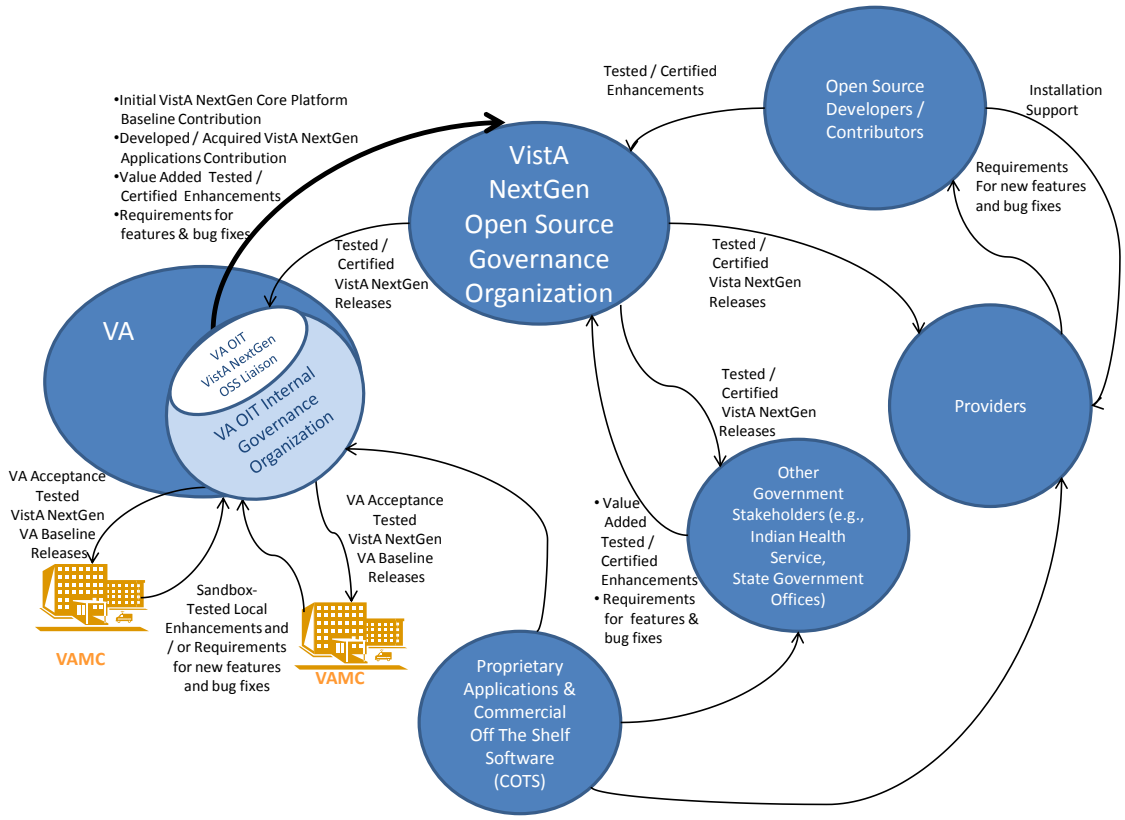

Figure 4 – VA Interaction with Open Source Community and within the VA

As discussed previously, the VA will need to ensure that there are no significant changes implemented within the VA that would cause divergence from the open source version of VistA 2.0. VA's OIT organization will work to ensure that all changes implemented locally are tested at a minimum in the Open Source Organization's 'sandbox' environment and VA's own internal testing environment to ensure that these changes will be compatible with VistA 2.0 and successfully certify to be part of the VistA 2.0 baseline. The VA will work through the governance process to release the value-added changes that have been incorporated into the VA baseline back into the open source community. The VA's OIT VistA 2.0 OSS Liaison will be responsible for establishing and executing the processes necessary to meet this objective. It is also reasonable to expect that this Liaison office will represent the VA's interest at events and discussion groups among the Open Source community and serve as the VA representative participating in the overall governance process for the VistA 2.0 Open Source Governance organization.

Licensing

Open source Governance and Open source licensing are twin concepts that are linked together. In US there are hundreds of open source initiatives being conducted successfully. There are a number of license types championed by various foundations. Some examples of the foundations are Open Source, Free Software Foundation (FSF), Mozilla, Linux, etc.

In general software licenses are either:

. **Proprietary Software**: This license type is used by commercial vendors, such as Microsoft, Oracle etc. The software is licensed for use by a commercial vendor, where a user is permitted to use the software for a fee, but the software is protected (by trade secret, copyright, etc.), and is provided without source code. The user cannot modify, or re-distribute the software without additional special agreements and associated licenses. Examples of proprietary software are the Microsoft Office suite, Oracle Data Base Management system (DBMS) etc. Note that some proprietary software is made available in source code form for free, but additional fees and agreements are required if commercially deployed -- aka proprietary open source.

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. **Open Source Software**: Open Source Software is software for which the underlying code, also called source code is available to the users so that they may read it, make changes to it, and build new versions of the software incorporating their changes. There are many types of Open Source Software, mainly differing in the licensing term under which (altered) copies of the source code may (or must be) redistributed. In some open source licenses, the redistribution must be done under the same license as the original, while in other license types the redistribution may be done under different licensing arrangements.

There are a plethora of open source license types, developed by many organizations and authors. The open source software in general falls under three categories depending upon whether (1) one is allowed to link the open source software with a software that has different license, essentially meaning that the user is

allowed to link the original software with another software module only if the linked software can also be licensed under the same terms and conditions as that of the original software or (2) allowed to redistribute the software with a different license. There may be other subtle differences.

- Restrictive Open Source Software: The characteristics of open source software are that it is distributed with source code, along with its binary, and a user is Free to use, Free to modify/change, Free to distribute, free to redistribute after making changes to the source, but under same licensing agreement. The examples of these licenses are Free Software Foundation's (FSF) General Public License V1 (GPLv1), GPLv2, and GPLv3. Redistribution (1) must occur under GPL, with no additional license conditions, (2) Redistribution must also include "source code" and (3) Redistribution must include a copy of the GPL, so that users are aware of their rights to use, copy, modify and distribute, and so that anyone engaged in redistribution is also aware of the conditions under which redistribution is permitted. Essentially the user has to disclose the source code of any software that has been developed if he chooses to redistribute the software. Furthermore the software should be issued under same license agreement as the original.

- Less restrictive Open Source software: It is similar to above, except it allows a user to link this software with the code which has different license, make changes to the software, and redistribute the software under same license. In this license type the licensee is not forced to disclose the source code. Some examples of this licensing arrangement are FSF's Lesser GPLv1, LGPLv2, and LGPLv3, and Eclipse Foundations' Eclipse Public License (EPL). Other example is Open Software License (OSL) v3.

- Non-restrictive License: In this license type user can link the software with this license to other software with different license, make changes to the code, and redistribute the modified software under different license. Essentially the user is not forced to distribute the source code of the modified software, and he can issue the

software under a different software license if he so desires. An example of this license type is Berkley System Distribution (BSD) authored by Regents of the University of California.

For a description of different license types see Appendix 1. The table below identifies and compares some License types that are frequently used.

License	Approved By	Link from a code with different License?	Release changes under different License	Redistribution of the code with changes	Compatible with GPL v3	Authored by
GNU GPL V3	(FSF), OSI	No (Proprietary S/W cannot be linked)	No	Only if the derivative is GNU GPL	Yes	FSF
GNU LGPL V3	FSF, OSI	Yes (since the S/W that is linked is not considered a derivative work)	No	Only if the derivative is GNU LGPL or GNU GPL	Yes	FSF
GNU AGPL	FSF, OSI	No	No	Yes, Only if the derivative is GNU LGPL or GNU GPL	No	FSF
BSD License (Original)	FSF, OSI	Yes	Yes	Yes	No	Regents of the Univ Of California
Modified BSD	FSF, OSI	Yes	Yes	Yes	Yes	?
MIT License	FSF, OSI	Yes	Yes	Yes	Yes	MIT
Apache License Vs 2	FSF, OSI	Yes	Yes	Yes	Yes	Apache Foundation
Common Public License	FSF, OSI	Yes	No	Yes under CPL	No	IBM
Eclipse Public License-	FSF, OSI	Yes	No	Yes Under EPL	No	Eclipse Foundation
Mozilla Public License (Version 1.1)	FSF, OSI	Yes			No	Mozilla Foundation

Table 3 – Frequently Used Licensing Types

A proper selection of license types will strengthen the commercial ecosystem as well as open source community for health related applications development. The selection of one or more license types would be based on the ability to foster open source development and a vibrant open source community based on the VistA 2.0 Platform and tool set. And, at the same time, the ability to foster an equally vibrant commercial or proprietary ecosystem based on the 2.0 VistA Platform and tool set. Ideally, users of the 2.0 VistA Platform would have a wide array of both open source and commercial applications from which to choose. This choice would provide a strong incentive to adopt the 2.0 VistA Platform. In turn, wide spread adoption would encourage the development of additional applications. The capability to incorporate Commercial Off The Shelf (COTS) software in conjunction with open source VistA 2.0 platform version 1.0 is a critical component of the vibrant ecosystem envisioned. This will allow the VA and the broader community using the VistA 2.0 Platform to quickly implement new applications. This requires that the open source license allows linking with proprietary commercial software. The actual licenses adopted should be a decision made by the governing entity (which presumably has intellectual property expertise and experience) in close consultation with VA and other existing and potential stakeholders, consistent with the objectives described above. Examples of this type of license would include Apache License Version 2, Common Public License, Eclipse Public License, and Mozilla Public License (Version 1.1).

Recommendation of the Subcommittee on Governance Models

(1) The subcommittee recommends that the VAcontract with an appropriate FFRDC to establish or identify an external entity to provide governance for the VistA 2.0 platform and for the applications that it makes available as open source. Such governance should encourage and maintain active participation by a wide range of stakeholders.

(2) The subcommittee recommends that the VA establish Governance as quickly as possible after VA makes a commitment to an open source approach.

(3) The subcommittee recommends that the VA take a highly visible and active role in the activities of the governance entity, in the ongoing development of the VistA 2.0 platform, and in the ongoing development of any open source applications running on the VistA 2.0 platform.

(4) The subcommittee recommends that the VA establish rigorous internal governance of its instantiation of the VistA 2.0 platform and applications. The working group recommends that the VA not implement any changes that would cause divergence from the open source version of the VistA 2.0 platform.

(5) The subcommittee recommends that the VA work with the governing entity to identify (from existing licenses) those licenses which will help create and maintain a vibrant "eco-system" of open source and proprietary applications built around the VistA 2.0 platform. Developing new or "VA specific" licenses is strongly discouraged.

(6) Governance of the VistA 2.0 platform should be tightly controlled after it is released into open source, with significant VA input into improvements.

Opportunities and Impacts- Executive Summary

It has been determined by the Open Source VistA Subcommittee on Opportunities and Impacts that there are significant advantages in making VistA 2.0 available to a broader community that could include both government and non-government entities.

The vast majority of the opportunities and impacts identified by the Opportunities and Impacts subcommittee are positive and desirable.

The potential benefits of VistA 2.0 as described in this report far outweigh any potential negative impacts.

Opportunities and impacts related to sharing Open Source VistA 2.0 resources are widespread and include the VA, advanced biomedical entities and multiple public and private health communities and IT communities of practice. Key opportunities include:

1. Revolutionized patient-centric health delivery processes;

2. Interface of health prevention practices with consumer-centric behaviors;

3. Closer integration of evidence-based science in healthcare and health IT that will increase value to other participants or industries related to the healthcare arena; and

4. Value-based accountability and enhanced returns-on-investment (ROI) from Open Source VistA 2.0 implementations

Through collaboration, open solutions and innovation, and the applied strategies and tactics of mutual health IT sharing arrangements revolutionary advancements can be imagined in the areas of

- Semantic Interoperability Systems, Natural Language Processing and Web Technologies.
- Genetic and Genomic Information Systems.
- Nano-technology and Nano-medicine.
- Personal Health Records – Next Generation Web 3.0 Portals and Technologies.
- HealthGrid.
- Healthcare Everywhere – Anytime.

The next generation Ecosystem of Open Source VistA 2.0, can rapidly accelerate the widespread adoption of electronic health records aligned with the nation's goals.

Sharing Open Source VistA 2.0 widely within the U.S. and around the globe will create a "center of gravity" for innovative technologies that can reform and transforming healthcare in America and worldwide.

In conclusion, Open Source VistA 2.0 has the potential to be a game changing advance in the delivery and enhancement of healthcare at the VA, other governmental agencies, public and private sector healthcare delivery systems, research and development entities as well as healthcare organizations worldwide. While the opportunities for transforming healthcare delivery are maturing Open Source VistA 2.0 can serve as a catalyst, incubator, test environment and delivery platform for health communities worldwide. Adopting an open source model for VistA 2.0 will

position the VA to create opportunities for advanced IT development, impact the communities that are transforming healthcare delivery in the 21st Century, take advantage of open source benefits and regain market leadership.

Assumptions

Our effort is not to predict the future, but to point in the direction of what is possible through a stronger, revitalized commitment to share a next generation Open Source VistA 2.0 with healthcare professionals to help accelerate the adoption of EHR's and improve quality healthcare delivery.

The subcommittee assumes the acceleration of EHR adoption through Open Source VistA 2.0 will lead to improved internal and external information sharing for the VA. In turn, the enhancement of information sharing will lead to improved quality of care for Veterans.

Opportunities for sharing VistA with the biomedical science community may lead to the discovery of efficient clinical pathways, advanced medical technology to prevent illness and suffering, hasten healing and wellness, and help to shape the next generation of healthcare delivery.

Relative to Open Source VistA, interfacing with external health IT domains and systems, e.g., genetic and genomic information systems, creates a number of potential constraints that the subcommittee recognizes will require the ongoing attention of the VA CIO and the Administration. These constraints could accelerate or decelerate adoption.

For example, if a major healthcare organization had a security breach and thousands of medical records of veterans or wounded warriors were compromised, this would reinforce current public concerns about privacy and security of EHR's and decelerate the process. Adoption, however, could be accelerated by events similar to Hurricane Katrina or a major bioterrorism event. It is safe to conclude that most Americans, and many people throughout the world, will eventually have EHR's and PHR's – the only question is when.

Even without a major security breach, there are numerous factors that can impact adoption, constraints such as: complexity, lack of

interoperability, high costs of EHR's installation, and significant change in delivery processes in medical practices and other healthcare settings. The Open Source VistA EHR and Ecosystem could contribute to enhancing or reducing risks relative to such existing conditions.

Analysis Process

The subcommittee explored a broad landscape of the different leading innovations in health IT to guide its analysis. The technique of conducting a web based environmental scan of the literature within health IT, biomedical technology and medical informatics was applied. The process of vetting information was conducted through the contributions of invited subject matter experts most familiar with VistA and open source culture and practices. The result was an efficient analysis of both primary sources, i.e., literature reviews, and secondary resources, i.e., interviews directly with VistA experts in the field. Analyses were recorded and shared with the full working group.

Observations and Outcomes

The Open Source VistA, 20/20 vision and model that the working group articulated will provide a significant step toward the solutions required for an intelligent, empowered and participatory approach to health information technology, improving the costs associated with EHR's and speeding the adoption of EHR's overall. The high-potential opportunities and impacts are already being realized on a limited basis as evidenced by: The Veterans Health Administration, Kaiser Permanente, WorldVistA, OpenHealthTools, different consortiums of small, agile companies and innovators dedicated to services of Open Source VistA implementation, and the abundance of Federal Government agencies like DoD, NIST, DOE, HHS, IHS, etc. are actively deploying Free and Open Source Software solutions and leading development initiatives.

Moreover, there have been more the 50 VistA implementations across the public-private sectors in the U.S. and internationally, for example, sites include: West Virginia Bureau for Behavior Health and Health Facilities, Virginia Lakeview Healthcare Systems, University of Hawaii Department of Geriatric Medicine, and Egypt's Cairo National Cancer Institute.

The distribution of VistA implementations is illustrated in Figure 5.

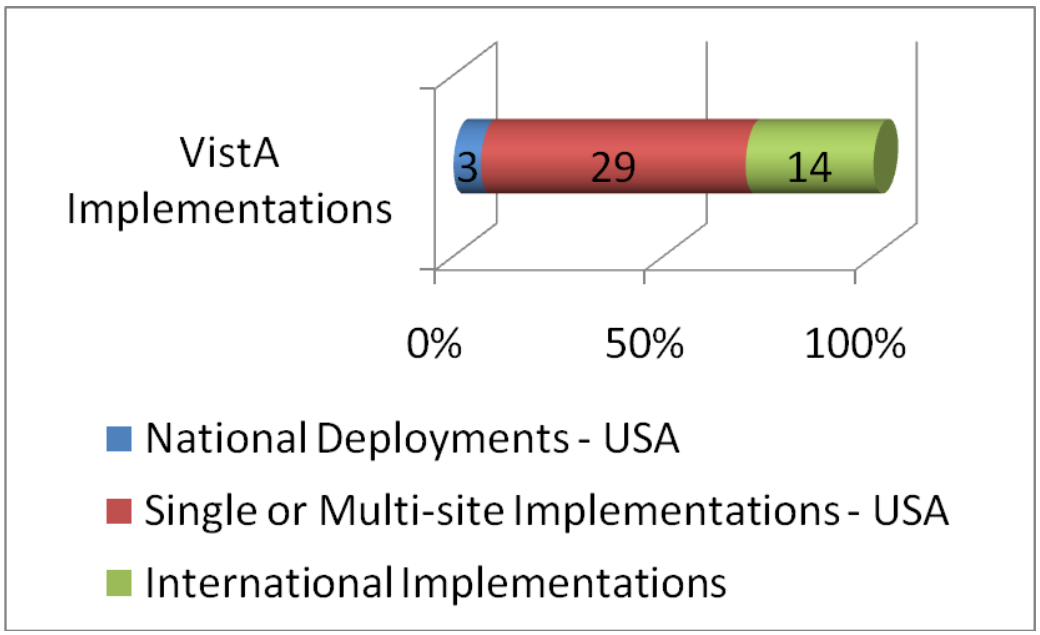

Figure 5- Distributions of VistA Implementations

Following are key observations and benefits that will be realized from taking advantage of the opportunities and harnessing the impacts of the Open Source VistA Ecosystem.

Observations/Benefits of Open Source Solutions

a) Significantly lower and quantifiable Total Cost of Ownership (TCO)- when comparing Open Source VistA Software against proprietary vendor solutions in key software product categories – business, clinical, technical.

b) Enhanced security and interoperability (e.g., meeting HIPAA, NHIN, HITSP, HL7 and other standards) relative to many of the proprietary commercial software products.

c) Continuing growing weight of global public and private support around Open Source VistA Software products and solutions- including collaborative organizations like Open Source Development Labs, WorldVistA, Free Software Foundation, Open EMR, Open HRE, and Open Health Tools.

d) Rapidly growing number of OSS implementations and success stories in government and the healthcare

arena– many federal, state, local governments, international and private sector healthcare facilities are all using OSS solutions that represent high-potential sharing opportunities.

e) Evolving federal trends, mandates, and executive recommendation - e.g., DOD OSS policy, the President's Information Technology Advisory Council - 2000, HHS and ONC initiatives, the Presidential mandate for widespread use of EHR systems, the breakthrough implementation of an Open Source VistA EHR in West Virginia as a model promoted by CMS Medicaid for other states, and many other instances where use of Open Source Software and next generation Open Source VistA solutions are suggested.

f) Extensive growth in Open Source Software availability, and functionality in many technical and functional areas, e.g., genetic and genomics, Internet2 and HealthGrid.

g) Potential improvement in system performance and reliability (including process change, impact from distinct innovation and quality outcomes) when using next generation open source solutions, based on comparable workloads in a growing number of application areas.

h) Reduction in ongoing staff support and costs- i.e., new software, patches, and other ongoing maintenance and support tasks.

The categories, below, represent the 'opportunities and impacts' that will facilitate distinctive innovations within the VA and among its external public-private sector partners:

OPPORTUNITIES	IMPACTS
Semantic Interoperability Systems and Web Technologies	• Semantics and EHR's will drive the future of interoperability supporting accurate content and situational timing for open source VistA 2.0
	• Application of semantic technology to the medical domain will provide IT systems with the ability to better understand terms and concepts as data is transmitted from one system to another

Open Source VistA 2.0 Impact Acceleration of PHR's	• Rise of PHR systems will play a key role in the evolution to a more holistic, integrated person-centered healthcare system • Numerous collaborative projects
Genomic Information Systems	• Intense collaboration between public and private sector organizations • Use of standards and open source solutions to accelerate the integration of computerized patient records with genomic biorepositories, bioinformaticists will allow the development of sophisticated applications that will truly transform healthcare delivery in the 21st century
Nanotechnology/ Nanomedicine	• Nanomedicine deals with comprehensive monitoring, control, construction, repair, defense and improvement of human biological systems at the molecular level using engineered nanostructures and nanodevices • Early nanomedicine applications include: focused pharmaceutical delivery systems; "laboratories on a chip" that perform multiple medical tests invitro or invivo; health related imaging nanodevices; nanosurgical tools; and nanotechnology implants and tissue scaffolds. Currently available health-related products using nanotechnology include burn and wound dressings, water filtration, a dental-bonding agent, and sunscreens and cosmetics.
Healthcare@Everywhere in the 21st Century	The Following are specific opportunities of innovation technologies that should be supported through Open Source VistA next generation: Smart eHealth; Record Systems; eHealth Advisors (eHAL); Complementary and Alternative Medicine (CAM); Genetic Information Systems &BioRepositories; Wearable Intelligence Technology Systems (WITS); and eHealthcare&Telehealth; Robotics; and Standardization.

Table 4 – List of Opportunities and Impacts

Recommendation and Conclusions of the Subcommittee on Opportunities and Impacts

In summary, the subcommittee validated the VA's interests in implementing Open Source VistA and advanced IT solutions that would help them deal with the major challenges facing them. The exemplary areas of advanced information technology presented in this report provide high potential resources for VA to collaborate, share, and add value to the transformation of healthcare, especially in caring for and aiding the lives of millions of wounded warriors, veterans, their families and communities.

The VA must lead the way with the Open Source VistA Ecosystem, providing the industry with the tools to transform healthcare. Likewise, the VA must harness the innovations made by public-private sector partners working within the modernized Open Source VistA Ecosystem, by disseminating them freely across the Veterans Health Administration network providers and among its patients and families, and affiliated institutions from the private sector.

A robust open source market for EHR systems is maturing and gaining momentum in commercial and public sector healthcare communities around the world. Organizations including public health, small and rural providers, hospitals systems and clinics, veterans and their families and wounded warriors are well positioned to take advantage of the numerous opportunities that will truly transform healthcare delivery in the 21st century. Recommendations presented in this report should prove helpful in developing the justification for investment in these new systems.

Appendix I- References and Supporting Material

Executive Summary:

Longman, P. *Best Care Anywhere*. PoliPoinPress, LLC. Sausalito, CA. 2007

Modernization and Architecture:

Architectural Principles

Architecture principles provide a framework for making decisions when making trade-offs becomes necessary. Each principle contains a rationale (why the principle exists) and a set of implications (things that must be done to implement the principle). The modernization and architecture subcommittee have adopted the following principles:

1) First do no harm from the clinical perspective
   a) Rationale: VistA is a superior product that provides best of breed services for Veterans, care providers and healthcare administrators; its functionality and performance should not be compromised.
   b) Implications: Changes to VistA must be carefully planned and expertly executed to avoid compromising Veterans healthcare. From a clinical perspective, evolution is better than revolution.

2) Implement systems and services with low coupling
   a) Rationale: Current brittleness in VistA can be traced to the high degree of tight coupling among various components. Complexity in maintenance and improvements is also traceable to tight coupling. De-coupling systems and services improves agility of maintenance and reduces failures due to brittle structure
   b) Implications: Architectural boundaries must be identified and protected. Tight coupling (e.g. RPC and embedded services) will have to be taken apart and re-structured

3) Maintain and increase cohesion
   a) Rationale: The Electronic Health Record and the Virtual Lifetime Electronic Record represent a highly cohesive information base for VistA. Interoperability among medical

facilities depends on a high level of semantic interoperability. This has been partially compromised by the high level of customization supported by VistA.

b) Implications: The degree of customization (especially where data is concerned) must be managed more closely; especially where the information is shared. The ability to customize information must be viewed in the context of being shared globally. Dynamic semantic translation technology needs to be explored.

4) Maintain lowest possible total cost of ownership
   a) Rationale: Open Source keeps cost of ownership low and allows VA to maintain control of the upgrade path. The total cost of ownership, when development activities are included is increasing and becoming an inhibitor to provisioning of new features
   b) Implications: To manage the cost of ownership, VA needs to control development costs as well. An Open Source environment for VistA could contribute to an overall lower cost of development to VA. This also has significant organizational implications to the VA. However, COTS can lower the total cost of ownership (e.g. transaction managers, services busses, reporting engines, data base management) are better purchased than built

5) Surround and bound VistA modules – get control of the interfaces (logical partitioning)
   a) Rationale: Brittleness in operations and agility in software maintenance can be overcome through tight management of stable interfaces, contract based specifications and decoupling of interfaces
   b) Implications: Service contracts need to be explicitly established and managed. Interfaces need to be stable. Protocols need to be concise, minimal and stable. Interfaces not adhering to the contract need to be removed (e.g. rogue interfaces). Decoupling of modules needs to be aware of performance requirements.

6) Commoditization of the hardware environment
   a) Rationale: VistA's common services operating environment (e.g. DEC Alpha) is dated and represents a high risk to future innovation. The operating environment must be upgraded to support commodity hardware and operating

systems. This will allow the VistA environment to become standardized and to support current and emerging technologies (e.g. Grid, Cloud, etc.)

b) Implications: the VistA modernization activities must address common services architecture and technology if VistA 2.0 is to be viable in the long term.

7) Commoditization of software services – buy or build
   a) Rationale: The VA has built many features and functions (which must now be maintained) and which are readily available either through open source or COTS. The current Core, while increasing flexibility, it greatly increases development cost and generally provides less features than many commercial products
   b) Implications: A SWOT analysis of each VistA common service/package should be conducted to determine what capabilities or collection of combined capabilities should survive. Architects have to consider best-of-breed versus best-fit when considering the architecture for the new services within the Core. Vendor dependence and "lock-in" become major risks even in the case of open source tool selection and needs to be managed. Not all open source and COTS products support a common set of services which is a major consideration as the VA may choose to incorporate proprietary components to address VA specific needs.

8) Automate Performance Monitoring and Reporting
   a) Rationale: VistA's is perceived to be a high performing system (for data reads). Moving towards an open, standards based services environment has risks. Performance monitoring and reporting should be built into the environment and be automatic, customizable and manageable at the interface level
   b) Implications: Meaningful and high-impact performance variables must be identified and a framework developed to measure and report on these variables should be instantiated. Most modules will have to be upgraded to support monitoring and reporting.

Adopting these architectural principles, regardless of which formal modernization path is taken, will promote innovation and the ability to accept innovation from multiple sources. Working in conjunction

with the Alternatives Subcommittee, the M&A Subcommittee has evaluated the proposed alternatives and has compared and contrasted their relative architectural merits.

The benefits of such an inclusive approach as outlined in the executive summary offer the ability to promote both innovation and parallel development:

- From within the Office of Information & Technology (OI&T),
- Amongst the field such as clinicians who are technology savvy or clinicians coupled with information technology professionals – traditionally known as Class 3 Development, as well as

Developers outside of the VA who want to contribute or leverage upon the environment.

Evaluation of the Options

First, we must recognize that doing anything to VistA is a high risk proposition that has the potential to put patient safety at risk. Second, it is apparent that the clinical functionality must be protected. The evidence leads the subcommittee to conclude that much of the problem lies within the architecture of the VistA Common Services. Prudence mandates that we deal with high-risk architecture and modernization decisions early. Several competing options have been evaluated:

1) Get control of the interfaces – Mumps© provided one the most flexible interface mechanisms of its day (but by no means unique in that aspect); this is both a blessing and a curse. Through "rogue" interfaces, it has become impossible to maintain common business rules or common data standards. Access to common services must be tightly controlled; the VA must offer a tightly controlled, but rich set of standard interfaces. The subcommittee will use the term logical partitioning for this option. Without controlling the interfaces and the data standards, maintenance, innovation, performance and interoperability will continue to be elusive.

2) Decouple the existing clinical modules from the common services. The subcommittee uses the term physical decoupling for this option. Once the clinical functionality is decoupled from

both the common services as well as other clinical modules, maintenance, testing and stability should dramatically increase.

3) Modernize the Common Services and kernel as a complete package (not evolutionary). The subcommittee terms this the iPhone option. The VA needs a standardized, stable, modern platform on which to build the VistA 2.0 ecosystem. With a superior platform that exposes a rich set of functionality through stable interfaces; the VA positions the platform for innovation. We would like to believe that with this option, the VA too can tell the clinicians "there is an app for that."

4) VistA 2.0 should be standards based; that is to say any set of services that adhere to VistA standards (esp. service and data contracts) should be acceptable to the VistA community. This implies that both open source and COTS products could be used to fulfill any functional requirement.

5) VistA 2.0 should become an open source product. If the VA is serious about innovation; it needs to establish a wider community of developers. Open Source is one mechanism through which this can be achieved. This path, however cannot compromise on option 1.

6) The VA should not build those things that it can obtain (open source or purchase) (subject to 1 and 4 above).

7) The VA should supply a software development kit (SDK) to allow all developers to access common services through the stable, controlled interfaces – this will allow "class 3" software to peacefully coexist within the ecosystem.

8) The VistA ecosystem should migrate to "commodity" hardware that is current and viable.

9) The VistA ecosystem should migrate to "commodity" software development technologies to increase the availability of development resources.

10) Produce a baseline architecture and ensure strict adherence to the same for VistA development and deployment.

11) Standardize the interfaces and provide guidelines for

development of new interfaces

12) Produce a standard data model and data exchange guidelines between VistA and other internal/external systems

13) Standardize “services” and publish the services so that the development community not only aware of the existing services but can build new services using the existing ones

14) The VA should develop and implement a robust performance management and monitoring capability at the interface level. VistA should degrade gracefully as opposed to just failing.

Clearly, the Clinical Users like what they have, and they want more, and they want it now. OI&T, at the same time, wants to maintain VistA as the preeminent clinical system in the world, support rapid innovation, improve functional delivery times and protect this national asset. The subcommittee has conducted a robust debate surrounding these options. We have applied the architectural principles as required to develop a consistent set of recommendations.

Observations and Outcomes

Parallel development without an architectural guide is virtually impossible. There are many open source models (OpenLDAP, JBoss, OpenSolaris, Apache, BSD) that have solved these challenges and gained wide spread acceptance within the public and private sector development communities. To achieve the goals outlined in the aforementioned section and to support OI&T, Class 3 and external development, VistA 2.0 should be derived from a terminal release VistA code base. This will allow the migration to begin. VistA 2.0 open sourced components should be snapshots of the latest VistA 2.0 release under development by OI&T. Future versions of VistA will be based on technology from the VistA 2.0 project. This will allow the VA to expand the developer and user community around VistA 2.0. This can be used to gather input to solve the Mumps© challenge and begin the logical partitioning process for the standard interfaces.

An initial recommendation would be to open source the newly partitioned interfaces of the VistA code base. The VistA 2.0 code base should be released under a common development and

distribution license agreement approved and governed by the VA. One important item which needs to be addressed is what elements get open sourced and what elements don't. There will be system code that should not be open sourced and can be made available only as pre-compiled binary files. This system code is considered to be part of the VistA "core" code base elements which are essential to ensuring the integrity of the composite application and are critical to providing the heath care requirements of the VA. OI&T should plan and expertly execute these core components. Decoupling clinical modules from common services, interface standardization, etc., can be handled through these same processes.

Standardization and migration to commonly used software development and hardware platforms can be handled through a community advisory board comprising of VA personnel and open source community members. This will create constitution for the open source project, provide feedback loop into and out of VistA 2.0 and provide a governance body which ensures the clinical functionality is protected. The community advisory board will also provide a forum for a collaborative, consensus based development, a practical software licensing and validation model, and an aspiration to create high quality software that continues the tradition of the VA being a world class leader in this area. When undertaking standards based development and supporting an open source community, standards cannot withhold any detail necessary for interoperable implementation. As flaws are inevitable in this type of project, it is critical that a process is defined for fixing flaws identified during implementation and interoperability testing. This process needs incorporate any changes into a revised version or superseding release candidate.

The VistA 2.0 program must include source code and must allow distribution in source code as well as compiled form. VistA 2.0 will have components of its architecture that are not distributed with source code as mentioned above. The VA will have a well-publicized means of obtaining the source code for no more than a reasonable reproduction cost preferably or downloading via the Internet without charge. The source code must be the preferred form in which a programmer would modify the program.

Adhering to and utilizing the observations and outcomes surrounding architectural guidance will allow the VA to expand upon general educational and advocacy surrounding Veterans healthcare

and to execute the VistA 2.0 mission.

Deployment Models:

Logical and Physical Deployment Models

Logical deployment models span a continuum from a centralized to a decentralized model as depicted in Figure 6.

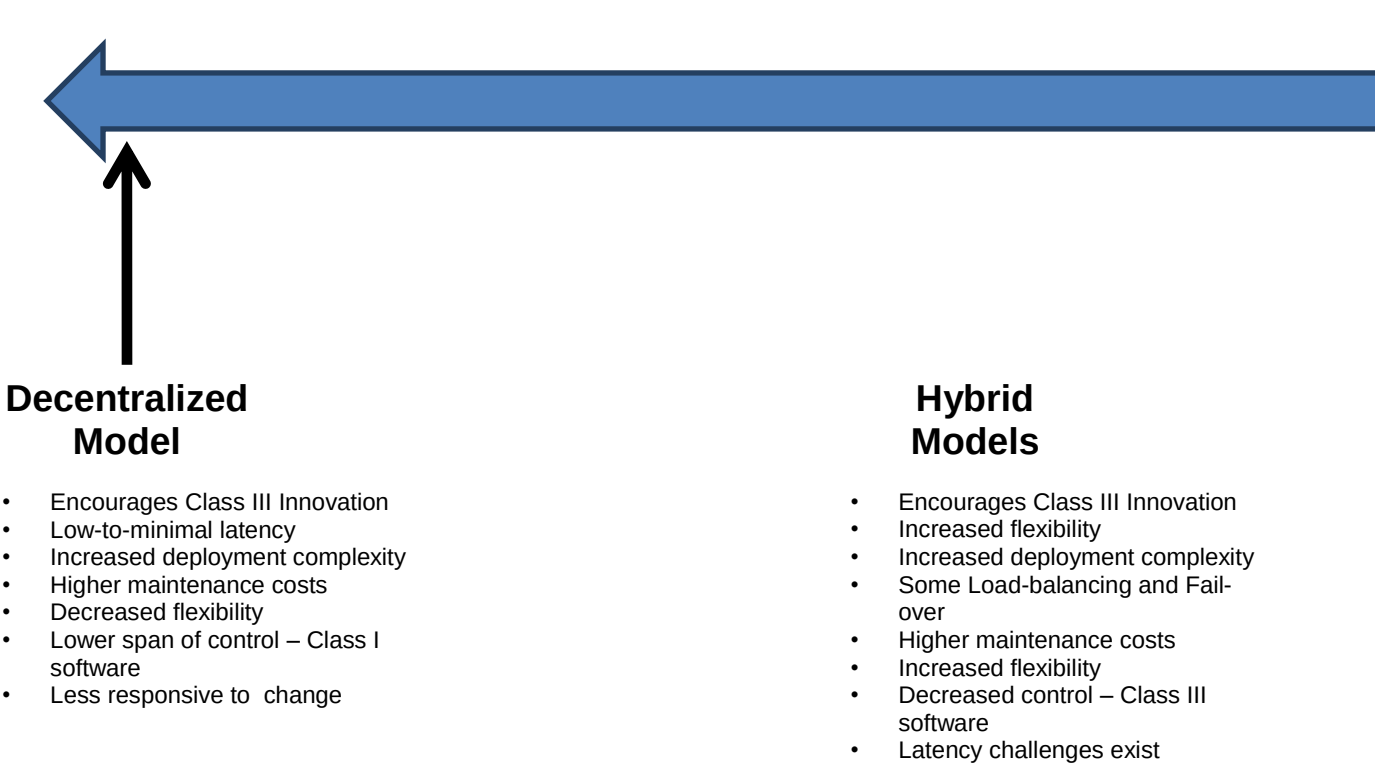

Figure 6 – Deployment Continuum

- ***Centralized Model*** – All system functions are deployed centrally (two or more data centers). The only system component required locally (user's laptop/PDA/workstation) is a web browser that is loaded when the application executes. High Availability is achieved through redundancy and replication of data. When the primary data center fails, a back-up site automatically takes the load. Availability is typically a feature of the system architecture that can be enhanced after initial deployment to include multiple failover

sites or load balancing. Employing a centralized model provides an improved change control capability and eliminates any non-uniformity of software applications within the organization. This alternative requires no software components in the VA Medical Centers or private hospitals participating in the modernized VistA system. There may be some exceptions to this based on the local provider needs for additional capabilities not provided by VistA.

- ***Decentralized Model*** – A version/copy of the VistA 2.0 system will be deployed at each VA Medical Center or provider site. Alternatively, a single instance could be setup a collection of sites belonging to service a specific region. As in the centralized model, the only VistA component required by a user is a web browser that is loaded when the application runs. A central database will house VistA-wide metadata in addition to information aggregates for MI and Administrative purposes. A local database will be used to store some data locally. Connectivity to a central data center/hub is required to exchange information (transaction-based) between medical facilities in real-time and synchronize data between the local and central databases. If a locally deployed instance fails, the site(s) using that system would fail-over to a backup instance within the local deployment context. Advanced capabilities involving fail-over to a centralized instance on-demand could be accomplished through virtualization and comprehensive configuration management.

- ***Hybrid Model*** – All system capabilities are implemented as re-usable and stand-alone/orchestrated services. Services are deployed centrally or locally (regionally) based on level of re-usability. The application including the VistA user interface is built and deployed centrally and invokes centralized or local services to accomplish all business processes. Services deployed centrally will be deployed with fail-over and load-balancing capabilities similar to the centralized model (multiple data centers). Services deployed locally (or regionally) will be managed as in the decentralized model from a fail-over/load-balancing perspective. A Service Bus, in cooperation with rules-based decision support and monitoring tools will provide invocation and orchestration services. For example, invocation could be

based on a service level requirement, history of response time performance, security constraints, service availability, or other similar factors. In this model, services are not directly invoked by the VistA client/presentation layer. For example, even though a service might reside in close proximity physically (locally or regionally deployed service), to a particular application instance, it is virtually invoked from the centrally deployed VistA instance.

Physical deployment models – Traditional models comprise of a combination of computing hardware and software installed and configured to host business applications such as VistA. As cloud computing and virtualization technologies mature, the XaaS model is increasingly becoming commonplace. The 'X' in XaaS takes form of 'I' for Infrastructure, 'P' for Platform and 'S' for Software with several business and technical advantages including cost savings, ease of maintenance and deployment, flexibility and integrated security.

- ***Infrastructure as a Service (IaaS)*** – Refers to the delivery of computer infrastructure (typically a platform virtualization environment) as a service. Rather than purchasing servers, software, data center space or network equipment, computing resources are acquired on-demand as a fully outsourced service. The service is typically billed on a utility computing basis and amount of resources consumed (and therefore the cost) will typically reflect the level of activity.

- ***Platform as a Service (PaaS)*** **–** Refers to the delivery of a computing platform and solution stack as a service. It often goes further than IaaS with the provision of a software development platform in addition to hardware resources. It facilitates deployment of applications without the cost and complexity of buying and managing the underlying hardware and software layers, providing all of the facilities required to support the complete life cycle of building and delivering web applications and services entirely available from the Internet.

- ***Software as a Service (SaaS)*** **–** Refers to a model of software deployment whereby a provider licenses an application to customers for use as a service on demand. SaaS software vendors may host the application on their own web servers or download the application to the

consumer device, disabling it after use or after the on-demand contract expires.

Figure 7 illustrates how several combinations of physical models can be leveraged to deploy VistA 2.0 using a Centralized logical model.

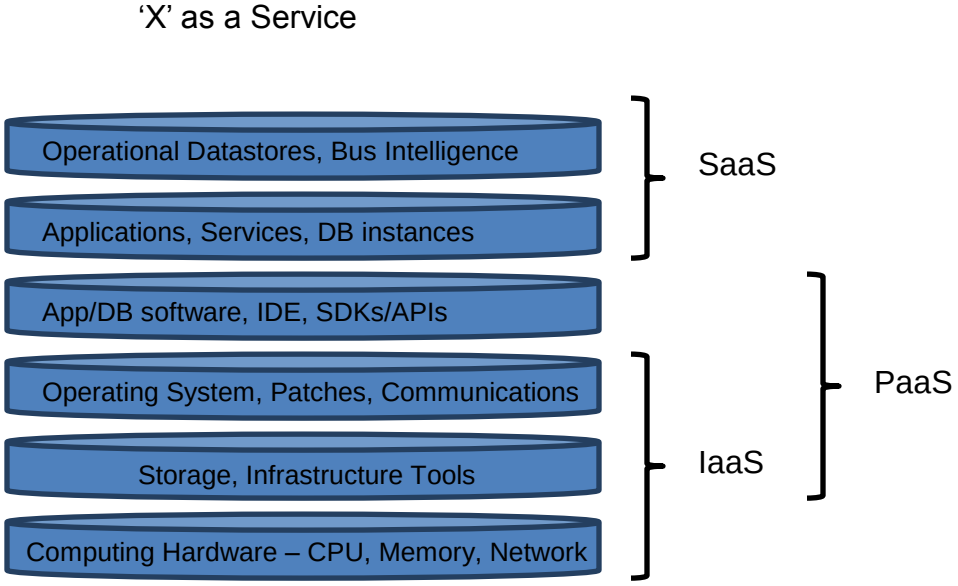

Figure 7 –Combination of Physical Models Leveraged to Deploy VistA 2.0 using a Centralized Model

Deployment Activities

Careful consideration should be provided to the following Deployment Activities regardless of the specific Model or Architecture that is adopted for the "VistA 2.0". To accommodate the various 'end user' communities, large Health Centers, regional Hospitals, or small Clinics and Doctor's Offices a variety of logical, physical, and business models may be required without sacrificing any loss of current functionality. The determination of whether to deploy a logical or physical model will depend upon which model best suits the specific mission needs and targeted end users. The following Deployment Activities should be considered:

Release - The release activity follows from the completed development process. It includes all the operations to prepare a system for assembly and transfer to the customer site. Therefore, through a site survey, it must determine the resources required to operate at the customer site, prepare a requirements definition document and collect information for carrying out subsequent activities of deployment process through the implementation plan. It

is this chain of artifacts upon which delivery acceptance will be based that define a successful delivery of the release.

Install and Activate - Activation is the activity of starting up the executable component of software. For a simple system, it involves establishing some form of command for execution. For complex systems, it should make all the supporting systems ready to use. This can be achieved using configuration control software such as Subversion that can maintain the software based for various types of installations, and provision from the Internet. As the configuration changes, the changes can also be provisioned to the client.

In larger software deployments, the working copy of the software might be installed on a production server in a production environment. Other versions of the deployed software may be installed in a test environment, development environment and disaster recovery environment. The install and activate process should include the following:

- Identify each component of the application
- Identify the deployment steps of each component(s)
- Identify the implementation/installation process for each component (order)
- Identify testing of each component deployment step (Validation that the implementation/installation step completed successfully)

Critical Components - Identification of components that are critical to the application. These are the identified items/steps/components that are of a critical nature for proper functionality of the application without major restrictions or outages. These are to be identified and noted as critical components.

Test - Testing should include both unit testing of all components comprising of the solution or systems. Performance testing should be completed to validate production load. Each phase of testing should follow test plans designed from the solution requirements and developed during the analysis and design phase prior to deployment (both application and security). Testing should be completed both during the implementation process as well as after the security/lockdown process is completed.

Testing is but a stage in the deployment's configuration. Subversion may also be used to support testing, and when testing

is successful, the same system settings may be used to deploy the release.

Feedback Loop - Once in production, a Feedback Loop should be implemented as a method to retrieve end user feedback and develop future requirements for subsequent versions of the solution. This feedback should occur within an Issue Tracking system. The working group recommends that the VA consider an Open Source Issue Tracking package that can track issues as well as desired refinements and processes to resolve issues. Without such a system, issues are passed through word of mouth and take longer to fix. This system should be accessible by all relevant stakeholders in the solution including developers, managers, information officers, operations, and security personnel.

Change Control - Change Control processes and procedures are required to assure dependable and positive impacts are felt during adaptations, upgrades, and updates. This includes a multi-step process called a Change Control System that identifies, reviews, discusses, and plans the implementation of any changes that may affect the configuration of a deployed production system.

Knowledge Transfer - Knowledge Transfer is a vital step to the success of any significant systems implementation. This step allows for the introduction of technology and the processes that support the maintenance of that technology to the team chartered with operating that system throughout the system's lifespan. This knowledge transfer should include some form of formal training on any open source products as well as less formal training on the specific implementation of those technologies in the production deployment. The deliverables for this activity should also include complete systems documentation and operational manuals. The use of Web 2.0 based tools that support user comments and the discussion of problems is highly effective.

Deactivate - Deactivation is the inverse of activation, and refers to shutting down and removing executing components of a system. Deactivation is often required to perform other deployment activities, e.g., a software system may need to be deactivated before an update can be performed. The practice of removing infrequently used or obsolete systems from service is often referred to as application retirement or application decommissioning. Before “software” is deactivated, an analysis should be performed to

determine the consequences that may be experienced from deactivation.

Adapt - The adaptation activity is also a process to modify a software system that has been previously installed. It differs from updating in that adaptations are initiated by local events such as changing the environment of customer site, while updating is mostly started from remote software producer. In many cases, as software is adapted, it tends to out-perform itself and be used in new and interesting ways for which it was not originally intended. Open Source software adaptation is part of the culture and ongoing life-cycle of the software.

Update and Upgrades - The update process replaces an earlier version of all or part of a software system with a newer release.

Built-In - Mechanisms for installing updates are built into some software systems. Automation of these update processes ranges from fully automatic to user initiated and controlled. Norton Internet Security is an example of a system with a semi-automatic method for retrieving and installing updates to both the antivirus definitions and other components of the system. Other software products provide query mechanisms for determining when updates are available.

Version Tracking - Version tracking systems help the user find and install updates to software systems installed on PCs and local networks. Web based version tracking systems notify the user when updates are available for software systems installed on a local system. For example: VersionTracker Pro checks software versions on a user's computer and then queries its database to see if any updates are available. Such version trackers can work with the Subversion system to get updates as they become available.

Local version tracking system notifies the user when updates are available for software systems installed on a local system. For example: Software Catalog stores version and other information for each software package installed on a local system. One click of a button launches a browser window to the upgrade web page for the application, including auto-filling of the user name and password for sites that require a login.

Browser based version tracking systems notify the user when

updates are available for software packages installed on a local system. For example: wfx-Versions are a Firefox extension which helps the user find the current version number of any program listed on the web.

Uninstall – Un-installation is the inverse of installation. It is a removal of a system that is no longer required. It also involves some reconfiguration of other software systems in order to remove the uninstalled system's files, registry, and dependencies

Retire - Ultimately, a software system is marked as obsolete and support by the producers is withdrawn. It is the end of the life cycle of a software product and requires a retirement date for application. The choice of a ***Systems Development Life-Cycle (SDLC)*** is critical to successfully implement and deploy VistA 2.0 based on an open architecture. While there are several traditional SDLC methodologies to choose from, large and complex organizations like the VA often define and customize their own version(s) of the SDLC methodology to best meet their needs. Table 5 illustrates the key SDLC methodologies and their pros and cons.

Methodology & Criteria	Advantages	Disadvantages
Waterfall **Budget: High** **Time: Long Term** **Functionality: Static**	➢ Clearly defined stages ➢ Assures delivery of initial requirements ➢ Well documented process and results	➢ Lack of measurable progress within stages ➢ Cannot accommodate changing requirements ➢ Resistant to time and/or budget compression
Incremental **Budget: High** **Time: Short Term** **Functionality: Static** **or** **Budget: Low** **Time: Long Term** **Functionality: Static**	➢ Early and periodic results ➢ Measurable progress ➢ Supports parallel development efforts	➢ Demands increased management attention ➢ Can increase resource requirements ➢ No support for changing requirements
Evolutionary **Budget: Low** **Time: Long Term** **Functionality: Dynamic**	➢ Supports changing requirements ➢ Minimizes time to Initial Operating Capability (IOC) ➢ Achieves economies of scale for enhancements	➢ Increases management complexity ➢ IOC only partially satisfies requirements and is not complete functionality ➢ Risk of not knowing when to end the project

Methodology & Criteria	Advantages	Disadvantages
Spiral **Budget: High** **Time: Long Term** **Functionality: Dynamic**	➢ Supports changing requirements ➢ Allows for extensive use of prototypes ➢ More accurately captures requirements	➢ Increased management complexity ➢ Defers production capability to end of the SDLC ➢ Risk of not knowing when to end the project
RAD (Rapid Application Development) **Budget: High** **Time: Short Term** **Functionality: Dynamic**	➢ Minimizes time to delivery ➢ Accommodates changing requirements ➢ Measurable progress	➢ Increases management complexity ➢ Drives costs forward in the SDLC ➢ Can increase resource requirements
Agile/Scrum (Roger mentioned that the VA is currently pretty happy with results and sees this as the future of SDLC at the VA)	➢ Provides more insight to the development/configuration work being completed and allows for risk management at a more granular level. ➢ Allows for more collaboration and adaptation to changing business needs - avoids "Paralysis - Analysis".	➢ Requires more IT governance oversight, leading to the need for more management / PMO resources (i.e. money). ➢ An investment committee will need to ask themselves - will the additional investment of process oversight and management return better rewards? What will be the impact to deployment timelines? What's the expected cost savings in the end, due to risks being mitigated?

Table 5 – Selecting an SDLC Framework

The Veterans Affairs typically utilizes a waterfall/iterative approach to SDLC. Today, the typical VA project defines the following high-level phases:

- Concept Definition (Phase 0)
- Requirements Development (Phase 1)
- System Design and Prototype (Phase 2)
- System Development and Testing (Phase 3)
- System Deployment (Phase 4)
- System Operation (Phase 5)

Each phase has a specific purpose, entry and exit criteria, and other special considerations.

Recently, the VA has found success with the adoption of Agile methodologies. The open-source approach recommended to implement VistA 2.0 will spur innovation both within the VA and the healthcare community. Continual integration with such innovations requires organizational practices to align with incremental bursts of development, configuration and deployment in addition to risk management at a more granular level. Agile methods allow for more collaboration and adaptation to changing business needs.

It is recommended that the VA continue to be flexible with the framework chosen per type of deployment to meet the needs of the end user. This may change based on deployment within the VA vs. private hospitals, or dependent on the modules of VistA being implemented and the source of the solution (e.g., internal VA module vs. open-source module vs. COTS module). A flexible approach to the SDLC in the VA environment would potentially be the most successful; assuming, the appropriate governance model (i.e., PMO resources) is put into place.

Deployment Pillars

The size and complexity of the Department of Veterans Affairs and the requisite implications for the VistA 2.0 system are best illustrated by building deployment activities around five pillars. These pillars are identified as; ***Reliability/Availability, Maintainability/Support, Scalability, Extensibility and Interoperability***. The foundational model to best support these pillars is accomplished most efficiently through a Centralized Model for deployment of applications. This Centralized Model is already well underway at the Department of Veterans Affairs through the National Data Center Program with the co-location and consolidation of VistA.

Healthcare is predicated on the efficient interaction between the patient and the caregiver. With over 150 medical centers and over 6,000,000 visits annually the reliability and availability of the VistA applications is of critical importance to providing care for the veterans and dependents. The centralized model; be it through cloud computing, Application Service Provider (ASP), or virtualized client-server, must have performance metrics associated with the applications before and after the consolidation efforts to understand the physician and veterans experience. These performance measurements can help develop the necessary baselines and Service Level Agreements to quantify performance improvements with the consolidation of VistA apps. This information also enables

the Office of Information Technology (OIT) to strive to continuously improve the delivery of service through historical information to enable troubleshooting and triage of applications.

The past experience of the VA highlights that trying to support a separate instance of VistA at each Medical Center (MC) results in an unsustainable economic model for maintenance and resources necessary to maintain the hundreds of VistA instances. The centralization and consolidation of VistA will result in a significant cost savings for maintenance and time spent in applying patches and/or new version of the multiple applications. If VistA is to continue to be the Electronic Health Record (EHR) application that provides the most comprehensive medical information for VA physicians and veterans then the Maintainability/Supportability pillar inevitably leads to further consolidation.

The current efforts of consolidation in the VA and moving to a more cloud based approach will increase the Scalability of the apps to meet the increasing number of veterans using the system. Under a typical client server approach to scalability the applications very quickly reach an untenably complex infrastructure that continues to add risk to delivering care to the Veteran. While the limitations of physical scalability resulted in the consolidation of VistA into several data centers the interoperability of the applications has become even more important. With Veterans receiving as much as 75% of their care through non VA hospitals the ability to exchange information with private entities has resulted in many new mandates around interoperability. These interoperability requirements are best addressed through a Service Oriented Architecture based on standards and certifications that enable the secure cross domain exchange of electronic protected information and/or personally identifiable information.

As the needs of the Veterans evolve it is also necessary that the systems that contribute to care are able to evolve in a similar manner. Therefore, the Extensibility of the VistA 2.0 application must be taken into considering when deploying to the enterprise. In addition to distributing the apps in a centralized manner the development environment must accommodate both open source and COTS based applications. The open source nature of the deployment model enables the integration of the “next great” application and follows the Apple model that has proven successful in driving innovation in the public arena.

The adherence to the five pillars listed above can help ensure greater adoption by the caregivers in the Department of Veterans Affairs. Though the history of VistA has been problematic from the Information Technology and support perspective it has proven to be a big success with physicians providing care to Veterans. Most of the positive commentary about the VistA system stresses the ease of use and comprehensive nature of the system. These are key attributes that must be enhanced in any new system and not impacted by any deployment model. The more transparent and non-disruptive the new system is the greater the chance of adoption by the VA's fiercest critics; the caregivers.

Deployment Environment- Innovation Sandbox

The size and complexity of the Department of Veterans Affairs and the requisite implications for the VistA 2.0 system are best illustrated by building deployment activities around five pillars. These pillars are identified as; ***Reliability/Availability, Maintainability/Support, Scalability, Extensibility and Interoperability***. The foundational model to best support these pillars is accomplished most efficiently through a Centralized Model for deployment of applications. This Centralized Model is already well underway at the Department of Veterans Affairs through the National Data Center Program with the co-location and consolidation of VistA.

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Governance:

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Opportunities and Impacts:

Mission Statement
Examining the Ways to Improve Healthcare through Open Source VistA 2.0 and Identifying the potential Opportunities and Impacts of VistA 2.0 implementation

Daniel Johnson, MD wrote in, "Medical Enterprises and Open Source," "The history of the medical community's discovery of the importance of sharing discoveries is a paradigm for what has been more recently developing in the free software or open source community."

The Open Source VistA Working group and Subcommittee on Opportunities and Impacts endorses the strategy of Collaboration, Open Solutions and Innovation in order to succeed with the transformation of VistA to VistA 2.0. Our findings represent our most realistic appreciation of potential opportunities and potential impacts of Open Source VistA 2.0.

A premise of the subcommittee is that the VA can lead the nation's healthcare industry in transforming healthcare delivery and quality of care through sharing VistA 2.0 as Free Open Source Software. Open Source VistA 2.0 will create a robust model for accelerating change, reducing medical errors and improving quality in the U.S. and other countries' healthcare systems.

The subcommittee focused on identifying innovative ways ("opportunities and impacts") that VistA can be modernized and deployed as VistA 2.0 in collaboration with the 'public-private sector' healthcare communities and other key groups. The opportunities for

vigorously sharing VistA 2.0 with biomedical science to discover efficient clinical pathways, advanced medical technology to prevent illness and suffering, and hastening healing and wellness will help generate significant new outcomes, systems, tools and applications.

The question we asked ourselves is, by 2020, how can Open Source VistA 2.0 serving as a Gold Standard Health Information System (HIS) and Electronic Health Record (EHR) be used to facilitate advancements in healthcare?

The subcommittee's mission is to recommend these converging, advanced information technology routes toward transformation through sharing and collaboration.

It is assumed that by freely sharing and constant communication the knowledge and applied creative power of team members in healthcare organizations nationally and internationally can improve processes and transform healthcare outcomes. VistA 2.0 will accelerate collaboration, encourage open solutions and innovation across the U.S. and around the globe.

The key strategy of collaboration requires VA's rapid movement to mutually engaging sharing behaviors, supporting new open horizons of software development that should be more readily practiced between the VA and the public-private sector that will involve sharing and disseminating VistA as an open source ecosystem platform.

The result will be unprecedented benefits of measurable cost-effectiveness and returns-on-investment of medical and scientific knowledge, capabilities and resources to healthcare leaders, patients and consumers, allowing them to save time and money across the many health and medical industry tiers and markets.

Approach

Listening to Subject Matter Experts and Observing Best Practices

The open source market and open solutions strategy and tactics are growing modestly and can be stimulated to grow rapidly across different markets. The opportunity is for the VA to lead the modernization and deployment of VistA 2.0, especially for public

hospitals and clinics, providers in rural and underserved areas and individual and small medical practices in order to implement the meaningful use of EHR's. In accordance with the HITECH Act and requirements for adopting EHR's, these providers are least likely to be able to afford the costs of traditional proprietary EHR's and most likely to benefit from the availability of a next generation Open Source VistA 2.0 ecosystem.

The subcommittee approach to identifying opportunities and impacts with modernizing and deploying VistA 2.0 was to go directly to the people and organizations which would benefit the most from an open source EHR and open solutions. Key contributing factors for this demand for an Open Source VistA 2.0 ecosystem are the growing awareness of the benefits of open source as less costly, innovations in the power of IT that will transform healthcare delivery, increased functionality, increasing adoption, and the ability of Open Source VistA 2.0 to operate at the enterprise or Health Information Exchange (HIE) level. The increased functionality has resulted from high-profile alliance and coalitions among advanced IT communities of practice both in the U.S. and internationally.

In summary, the subcommittee's approach is outlined as follows:

- Conferred and agreed to survey of key articles, reports and activities important to demonstrating the high potential methods, techniques and beneficial outcomes related to sharing VistA.
- Identified and interviewed subject matter experts from the government, industry and non-profit sectors, approximately 20 including subcommittee and working group level engagements.
- Developed "Opportunities and Impacts Guidance Questions and Answers," providing a foundation for justification and rationale supporting the line of analysis and recommendations regarding VA's sharing advanced IT innovations between the public and private sectors.
- Conducted extensive market research and environmental scan of key targeted articles, literature and communities of practice related to health IT open source methods, communications and innovation.
- Facilitated discussion driven by the Open Source VistA Working group's chartered priorities to establish insight to current and future deployments of VistA Open Source and other EHR

systems.

- Identified high potential collaboration opportunities and impacts within biomedical domains for integrating Open Source VistA in the public-private sector healthcare communities, markets and other interested groups.
- Gained consensus of conclusions and recommendations through presentation and discussion with the Open Source VistA Working group.

- **Semantic Interoperability Systems, Semantic Web Technologies and Open Source VistA**

The set of technologies associated with semantics and ontologies in healthcare are, relatively speaking, still in their infancy or early childhood. While there are high expectations, only modest progress has occurred to date.

The VA's creation of Open Source VistA Ecosystem leading partnerships between major technology vendors such as commercial database companies and large scale integrators, working in collaboration on public-private sector EHR projects, will help break through some of the existing major barriers.

With the ease of posting structured lists on the Internet, and with Extended Markup Language (XML) as an emerging standard for such lists, it is likely that the next decade will witness an explosion of medical ontologies generating faster transactions, more accurate and timely knowledge with less cost available in the public domain.

- **Communities of Practice**

Exemplary Market Opportunities and ImpactsSemantic Interoperability Systems, Semantic Web Technologies and Open Source VistA:

- ProteinOntology http://proteinontology.info/
- WordNet Semantic Lexicon http://en.wikipedia.org/wiki/WordNet
- Foundational Model of Anatomy (FMA Ontology) http://sig.biostr.washington.edu/projects/fm/AboutFM.html
- Systems Biology Ontology (SBO) http://www.ebi.ac.uk/sbo/
- General Ontology for Linguistic Description (GOLD) http://www.linguistics-ontology.org/gold.html
- Gene Ontologyhttp://sourceforge.net/projects/geneontology/

- Center for Clinical Translation Sciences (CCTS) at the University of Texas Health Science Center at Houston; CCTS utilizes Semantic Web technologies not only for integrating, repurposing and classification of multi-source clinical data, but also to construct a distributed environment for information sharing, and collaboration online with security and privacy of personal data. *See* *http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2646248*

- **Genomic Information Systems and Open Source VistA**

Over the next decade, a great goal for genomics will be to transform knowledge about the human genome into improvements in clinical practice. For a number of years we have collected information on many of the known genomic information systems initiatives and have been monitoring their progress. Numerous federal agencies and private clinical research enterprises engaged in developing genomic information systems are embracing collaborative ventures and open source solutions.

The role of "open" computing and "open" standards will be to support global collaboration between public and private healthcare organizations in this arena, and VA's leadership is critical. Collaborating within this community of genetic researchers, biomedical drug developers and clinicians is essential if substantial progress is to be made over the near term.

In the 2004 Annual Report of Recommendations the of the Veterans Health Administration, Health IT Sharing (HITS) Program, the HITS staff recommended that the VA should begin the exploration for sharing information technology between the DOD and VA for the purpose of integrating genetic and genomic data from military service members with VistA Computerized Patient Record System. These efforts should be expanded through Open Source VistA.

Communities of Practice – Exemplary Market Opportunities and Impacts: Genomic Information Systems and Open Source VistA:

- **Armed Forces Repository of Specimen Samples for the Identification of Remains (AFRSSIR)** -

http://www.afip.org/Departments/oafme/dna/afrssir/
The Armed Forces Repository provides reference material for DNA analysis to assist in the remains identification process.

- **BLAST** - http://www.ncbi.nlm.nih.gov/BLAST/
  BLAST is a set of Open Source Genomic software applications and databases produced by the National Center for Biotechnology Information (NCBI) and others.
- **DOE Genomes** - http://www.doegenomes.org/
  Genome programs of the U.S. Department of Energy.
- **Genetic Computer Language/Genomic Messaging System** - http://www.haifa.il.ibm.com/projects/software/imr/gms.html

- **Nanotechnology, Nanomedicine and Open Source VistA**

The challenge for interested healthcare organizations is to help governments to formulate long-term strategies that promote the cost effective development of nanotechnology that meets as many needs as possible, especially with regards to healthcare. Early involvement by healthcare provider organizations will prove useful in providing guidance about funding efforts to link nanotechnology solutions to Open Source VistA systems.

Major long-term cost-benefits related to investments in nanotechnology for VA and healthcare include:

- Significant investment must be made over time before achieving major benefits.
- Potential for radical advances in the VA involving medical diagnosis and treatment of such debilitating illnesses as PTSD/TBI, diabetes, heart disease and cancer are high.
- Powerful capabilities built into future health IT systems between VA and the private sector will utilize nanotechnology.
- Improvements in personal health information and personal care products will be driven by evidence-based data at the minute level of biomedical science.
- Early involvement and investment by the VA with Open Source VistA should lead the way ahead following standards and resulting with robust interoperability.

The evolution of nanotechnology will likely involve extensive testing of solutions coupled with consideration of the social and ethical consequences of deploying them. "Like any powerful new technology", says National Science Foundation (NSF) Director Rita

Colwell, "nanotech also has the potential for unintended consequences - which is precisely why we can't allow the societal implications to be an afterthought." In March 2005, a European Commission was launched to promote international dialogue on the social, ethical and legal benefits and potential impacts of nanotechnology.

Other challenges or issues that need to be addressed by the VA through the Open Source VistA Ecosystem include the need for standards, overcoming legal barriers, collaborative research, development of interfaces to health information systems, patient safety, and interoperability to name just a few. Cheaper and higher performing nanotechnology solutions, combined with convenience and greater functionality, will revolutionize healthcare in the coming decade(s) and will change the daily business practices of healthcare organizations and how they provide patient care.

Communities of Practice – Exemplary Market Opportunities and Impacts Nanotechnology, Nanomedicine& Open Source VistA:

- The U.S. Army Institute of Soldier Nanotechnologies (http://web.mit.edu/isn/)
- Employing nanoengineered molecules called "nanolipoblockers" as frontline infantry against harmful cholesterol - is showing promise starting in earlier laboratory studies at Rutgers and The State University of New Jersey. See http://www.physorg.com/news66485379.html
- Nanotechnology and Occupational Health - http://www.cdc.gov/niosh/topics/nanotech/
- NIOSH is the leading federal agency conducting research and providing guidance on the occupational safety and health implications and applications of nanotechnology.
- NASA can share technologies enable nano-sized particles to warn of early developing cancer and genetic diseases. http://science.nasa.gov/science-news/science-at-nasa/2004/28oct_nanosensors/

- **HealthGrid and Open Source VistA**

By 2020, public health information systems in the United States, such as disease registries, will be integrated into grids linked by the

National Health Information Network (NHIN) that will utilize the Next Generation Internet (NGI) or Internet2.

There are a number of ways that grids can potentially be used with Open Source VistA systems over the coming years.

- **(1) *computational grids*** can be used to solve large-scale research problems in healthcare effecting veterans with PTSD/TBI using the unused power of computer workstations of EHR systems in healthcare provider organizations;
- **2) *data grids*** can be established that don't share computing power but instead provide a standardized way to securely exchange patient data internally and externally from EHR systems for data mining and decision support impacting VA's clinical research and development;
- **(3) *collaborative grids*** can be built that let geographically dispersed users share medical information and work together on complex cases using patient data sets and clinical images maintained in EHR systems of multiple healthcare provider organizations benefiting VA's and the private sector's next generation Open Source VistA software development, clinical data systems requirements, and revolutionary practices of medical specialization and consulting for micro-orthopedic surgery, neurosurgery, telemedicine and other advanced technology intensive operations.

Communities of Practice – Exemplary Market Opportunities and Impacts Health Grid & Open Source VistA

Organizations: & Grids:

- Open Grid Forum (OGF) - www.ogf.org
- Globes Alliance - www.globus.org
- HealthGrid.Org - www.healthgrid.org/en.html
- BIRN - www.nbirn.net
- caBIGhttps://cabig.nci.nih.gov/
- DoD Telemedicine and Advanced Technology Research Center (TATRC)
  The methodology for this Integrated Research Team is the pairing of biomedical and Grid expertise, to underscore the point that biomedical research can be accelerated and enhanced through collaborative and cooperative arrangements, and the VA and Open source VistA presents the best opportunity for Health Grid advancement

in a medical setting.
http://www.tatrc.org/website_healthgrid05/index.html

- **Personal Health Records (PHR's) and eHealth, Everywhere-Anytime**

We are seeing a major sea change at work. Smartphones, health apps, implantable technologies, wearable systems and other mobile solutions are going to bring about changes we may find hard to imagine. This is a real movement. Cerner, CPSI, Eclipsys, Epic, GE Healthcare, McKesson, Meditech and Siemens have all been steadily expanding their footprints in the mobile health information technology space.

In order for the VA to stay timely and remain as a leader with consumer demands, it becomes imperative to modernize through Open Source VistA collaboration and sharing with Mobile *e*Health using new applications and tools ready to assume the functions of PHR's.

We are seeing a major sea change at work. Smartphones, health apps, implantable technologies, wearable systems and other mobile solutions are going to bring about changes we may find hard to imagine. This is a real movement. As mobile phones and other mobile devices become part of everyday life, people become better equipped to respond to emergencies, consult with peers and health professionals about health issues as they arise, and access health services that are increasingly being delivered through mobile phone based systems.

Our soldiers and wounded warriors are accustomed to using the advanced Web apps and tools delivered and operated through cell devises and virtual reality games.

These new mobile applications, bypassing the fixed-line solutions, are creating new pathways for sharing health-related information. Mobile technologies will contribute significantly to the revolution in healthcare over the coming decade and will change the daily business practices of healthcare organizations and enhance how they provide patient care. They will also start to be used and dramatically impact the lives of everyday citizens and wounded warriors. The Open Source VistA Ecosystem can become the public-private sector's go-to place to

promulgate the design, development and dissemination of Mobile *e*Health IT supporting PHR's.

Communities of Practice – Exemplary Market Opportunities and Impacts
Mobile *e*Health and PHR's

These are some PHR-oriented apps and tools representative of how Open Source VistA can be used to advance innovation based on the VA's foundational architecture:

- Epocrates Rx: http://www.epocrates.com/products/rx/
- DoctorCalc: http://doctorcalc.com/
- MedicTouch is the developer of the first cellular wearable health and wellness devices that allows users to monitor their pulse, view the results in a high-resolution screen on a Java technology-enabled mobile phone, and transmit the data to a Java compliant server. www.medictouch.com/news
- TrixieTracker can help track a baby's health needs to be shared with physicians.
- http://www.apple.com/webapps/utilities/trixietracker.html

Appendix II- Terms and Definitions

Application Programming Interface (API)– is an interface implemented by a software program to enable its interaction with other software. It is similar to the way the user interface facilitates interaction between humans and computers. APIs are implemented by applications, libraries and operating systems to determine the vocabulary and calling conventions. The programmer should employ it to use their services. It may include specifications for routines, data structures, object classes, and protocols used to communicate between the consumer and implementer of the API

Class III Software –Inside VA's VistA, Class III software is locally developed, supported and installed software. This is as opposed to mandatory or "Class I" software, which is developed and supported centrally. Class III software allows individual VA Medical Centers to develop applications for their own use, and is an important source of innovation. In some cases, Class III software has been of sufficient value to be converted to Class I software – that is, adopted for use system-wide, and centrally supported.

Federally Funded Research and Development Center (**FFRDC)** -

A Federally Funded Research and Development Center (FFRDC) is a unique organization that assists the United States government with scientific research and analysis, development and acquisition, and/or systems engineering and integration. FFRDC's address long-term problems of considerable complexity, analyze technical questions with a high degree of objectivity, and provide creative and cost-effective solutions to government problems. FFRDC's are administered in accordance with U.S Code of Federal Regulations, Title 48, Part 35, Section 35.017 by universities and corporations. For the most up to date master list of every FFRDC, please view the following website: http://www.nsf.gov/statistics/ffrdclist/start.cfm

Open Source Software [License]–Open Source Software is software for which the underlying code, also called source code is available to the users so that they may read it, make changes to it, and build new versions of the software incorporating their changes. There are many types of Open Source Software, mainly differing in the licensing term under which (altered) copies of the source code may (or must be) redistributed. In some open source licenses, the redistribution must be done under the same license as the original, while in other license types the redistribution may be done under different licensing arrangements.

Proprietary Software [License]This license type is used by commercial vendors, such as Microsoft, Oracle etc. The software is licensed for use by a commercial vendor, where a user is permitted to use the software for a fee, but the software is protected (by trade secret, copyright, etc.), and is provided without source code. The user cannot modify, or re-distribute the software without additional special agreements and associated licenses. Examples of proprietary software are the Microsoft Office suite, Oracle Data Base Management system (DBMS) etc.. Note that some proprietary software is made available in source code form for free, but additional fees and agreements are required if commercially deployed -- aka proprietary open source.

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* Robert Lantz's participation ceased on 4/1/2010 due to the Working Group Rule that only one member per company can participate. Further questions regarding VistA Working Group Participation can be addressed to IAC.