

United States General Accounting Office

Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

June 2004

COMPUTER-BASED PATIENT RECORDS

VA and DOD Efforts to Exchange Health Data Could Benefit from Improved Planning and Project Management





Highlights of GAO-04-687, a report to the Subcommittee on Oversight and Investigations, House Committee on Veterans' Affairs

Why GAO Did This Study

A critical element of the Department of Veterans Affairs' (VA) information technology program is its continuing work with the Department of Defense (DOD) to achieve the ability to exchange patient health care information and create electronic medical records for use by veterans, active-duty military personnel, and their health care providers.

This report provides an assessment of the departments' recent progress toward achieving an electronic two-way exchange of health care data, along with recommendations based on GAO's work.

What GAO Recommends

To help ensure progress by the departments in achieving the twoway exchange of health information. GAO recommends that the Secretaries of Veterans Affairs and Defense develop an architecture for the systems' electronic interface, establish a project management structure that designates a lead decision-making entity, and create and implement a coordinated project plan for developing the interface between the departments' health information systems. In commenting on a draft of this report, the departments agreed with our recommendations and identified actions planned or undertaken to address them.

www.gao.gov/cgi-bin/getrpt?GAO-04-687.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Linda D. Koontz at (202) 512-6240 or koontzl@gao.gov.

COMPUTER-BASED PATIENT RECORDS

VA and DOD Efforts to Exchange Health Data Could Benefit from Improved Planning and Project Management

What GAO Found

While VA and DOD continue to move forward in agreeing to and adopting standards for clinical data, they have made little progress since last winter toward defining how they intend to achieve an electronic medical record based on the two-way exchange of patient health data. The departments continue to face significant challenges in achieving this capability.

- VA and DOD lack an explicit architecture—a blueprint—that provides details on what specific technologies will be used to achieve the electronic medical record by the end of 2005.
- The departments have not fully implemented a project management structure that establishes lead decision-making authority and ensures the necessary day-to-day guidance of and accountability for their investment in and implementation of this project.
- They are operating without a project management plan describing the specific responsibilities of each department in developing, testing, and deploying the electronic interface.

In seeking to provide a two-way exchange of health information between their separate health information systems, VA and DOD have chosen a complex and challenging approach—one that necessitates the highest levels of project discipline. Yet critical project components are currently lacking. As such, the departments risk investing in a capability that could fall short of what is expected and what is needed. Until a clear approach and sound planning are made integral parts of this initiative, concerns about exactly what capabilities VA and DOD will achieve—and when—will remain.

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United States General Accounting Office Washington, DC 20548

June 7, 2004

The Honorable Steve Buyer Chairman, Subcommittee on Oversight and Investigations Committee on Veterans' Affairs House of Representatives

Dear Mr. Chairman:

As you know, the Departments of Veterans Affairs (VA) and Defense (DOD) are currently pursuing the ability to exchange patient health care data and create an electronic medical record for veterans and active-duty military personnel. While in military status and later as veterans, many patients tend to be highly mobile and may have health records residing at multiple medical facilities within and outside of the United States. Having readily accessible medical data on these individuals is important to providing high-quality health care to them and to adjudicating any disability claims that they may have. This goal of having electronic medical records that display all available clinical information in each department's health information system is a positive and necessary step. However, as we have previously reported,¹ the lack of progress the departments have made in accomplishing this two-way exchange of health care data raises doubts as to when and to what extent a true electronic medical record will be achieved.

As requested, our objective was to assess VA's and DOD's recent progress toward achieving an electronic two-way exchange of health care data. In conducting our work, we analyzed key documentation supporting VA's and DOD's strategy for developing and implementing the two-way electronic exchange of health data. In addition, we reviewed documentation to identify the costs incurred by VA and DOD in developing technology to support the sharing of health data, including costs for the

¹U.S. General Accounting Office, *Computer-Based Patient Records: Sound Planning and Project Management Are Needed to Achieve a Two-Way Exchange of VA and DOD Health Data*, GAO-04-402T (Washington, D.C.: March 17, 2004) and *Computer-Based Patient Records: Short-Term Progress Made*, but Much Work Remains to Achieve a Two-Way Data Exchange Between VA and DOD Health Systems, GAO-04-271T (Washington, D.C.: November 19, 2003).

Government Computer-Based Patient Record/Federal Health Information Exchange (GCPR/FHIE) initiatives, DOD's Composite Health Care System II, and VA's Health<u>e</u>Vet VistA. We did not audit the reported costs, and thus, cannot attest to their accuracy or completeness. We supplemented our analyses with interviews of VA and DOD officials responsible for key decisions and actions on the initiatives. Our work was performed at VA and DOD offices located in the Washington, D.C., area in accordance with generally accepted government auditing standards, from December 2003 to May of this year.

Results in Brief

While VA and DOD have continued to define data standards that are essential to facilitating the exchange of data, they have made little progress toward defining just how they intend to achieve the two-way exchange of patient health data between their two health information systems currently under development. Although VA officials recognize the importance of having an architecture that describes in detail how they plan to develop an electronic interface between those systems, they acknowledge that the departments' efforts continue to be guided by a less specific, high-level strategy that has been in place since September 2002. Compounding the challenge and uncertainties of developing the electronic interface is that VA and DOD have not fully established a project management structure to ensure the necessary day-to-day guidance of and accountability for the departments' investment in and implementation of this capability. Although maintaining that they were collaborating on this initiative through a joint working group and receiving oversight from executive-level councils, neither department has the authority to make final project decisions binding on the other. Further, the departments are operating without a project management plan describing the specific responsibilities of VA and DOD in developing, testing, and deploying the interface. In the absence of an explicit architecture and critical project management, VA and DOD are progressing slowly in their development of the interface and their limited progress to date calls into question the departments' ability to begin exchanging patient health information by their targeted date of the end of 2005.

Given the implications that readily accessible medical data can have for improving the quality of health care and disability claims processing for military members and veterans, we are recommending that the Secretaries of Veterans Affairs and Defense take a number of actions to improve the likelihood of successfully achieving the two-way exchange of medical data. In commenting on a draft of this report, the Secretary of Veterans Affairs and DOD's Interagency Program Integration and External Liaison for Health Affairs agreed with the report's recommendations. In their comments, they provided information on actions planned or undertaken to improve program management.

Background

Since 1998 VA and DOD have been trying to achieve the capability to share patient health care data electronically. The original effort—the government computer-based patient record (GCPR) project—included the Indian Health Service (IHS) and was envisioned as an electronic interface that would allow physicians and other authorized users at VA, DOD, and IHS health facilities to access data from any of the other agencies' health information systems. The interface was expected to compile requested patient information in a virtual record that could be displayed on a user's computer screen.

Our prior reviews of the GCPR project determined that the lack of a lead entity, clear mission, and detailed planning to achieve that mission made it difficult to monitor progress, identify project risks, and develop appropriate contingency plans. Accordingly, reporting on this project² in April 2001 and again in June 2002, we made several recommendations to help strengthen the management and oversight of GCPR. Specifically, in 2001 we recommended that the participating agencies (1) designate a lead entity with final decision-making authority and establish a clear line of authority for the GCPR project, and (2) create comprehensive and coordinated plans that included an agreed-upon mission and clear goals, objectives, and performance measures, to ensure that the agencies could share comprehensive, meaningful, accurate, and secure patient health care data. In 2002, we recommended that the participating agencies revise the original goals and objectives of the project to align with their current strategy, commit the executive support necessary to adequately manage the project, and ensure that it followed sound project management principles. VA and DOD took specific measures in response to our recommendations for enhancing overall management and accountability of the project.

²U.S. General Accounting Office, Veterans Affairs: Sustained Management Attention Is Key to Achieving Information Technology Results, GAO-02-703 (Washington, D.C.: June 12, 2002) and Computer-Based Patient Records: Better Planning and Oversight By VA, DOD, and IHS Would Enhance Health Data Sharing, GAO-01-459 (Washington, D.C.: April 30, 2001).

By July 2002, VA and DOD had revised their strategy and had made some progress toward electronically sharing patient health data. The two departments had renamed the project the Federal Health Information Exchange (FHIE) program and, consistent with our prior recommendation, had finalized a memorandum of agreement designating VA as the lead entity for implementing the program. This agreement also established FHIE as a joint effort that would allow the exchange of health care information in two phases. The first phase, completed in mid-July 2002, enabled the one-way transfer of data from DOD's existing health information system to a separate database that VA clinicians could access. A second phase, finalized this past March, completed VA's and DOD's efforts to add to the base of patient health information available to VA clinicians via this one-way sharing capability. The departments reported total GCPR/FHIE costs of about \$85 million through fiscal year 2003.

The revised strategy also envisioned the pursuit of a longer term, two-way exchange of health information between DOD and VA.³ Known as Health<u>@</u>People (Federal), this initiative is premised upon the departments' development of a common health information architecture comprising standardized data, communications, security, and high-performance health information systems. The joint effort is expected to result in the secured sharing of health data required by VA's and DOD's health care providers between systems that each department is currently developing—DOD's Composite Health Care System (CHCS) II and VA's Health<u>@</u>Vet VistA.

DOD began developing CHCS II in 1997 and has completed the development of its associated clinical data repository—a key component for the planned electronic interface. The department expects to complete deployment of all of its major system capabilities by September 2008.⁴ It reported expenditures of about \$464 million for the system through fiscal year 2003. VA began work on Health<u>e</u>Vet VistA and its associated health data repository in 2001, and expects to complete all six initiatives

³IHS, was not included in FHIE, but was expected to assume a role in the longer-term project—Health<u>e</u>People (Federal).

⁴DOD's CHCS II capabilities are being deployed in blocks. Block 1 provides a graphical user interface for clinical outpatient processes; block 2 supports general dentistry; block 3 provides pharmacy, laboratory, radiology, and immunizations capabilities; block 4 provides inpatient and scheduling capabilities; and block 5 will provide additional capabilities as defined.

comprising this system in 2012.⁵ VA reported spending about \$120 million on Health<u>e</u>Vet VistA through fiscal year 2003.

Under the HealthePeople (Federal) initiative, VA and DOD envision that, upon entering military service, a health record for the service member will be created and stored in DOD's CHCS II clinical data repository. The record will be updated as the service member receives medical care. When the individual separates from active duty and, if eligible, seeks medical care at a VA facility, VA will then create a medical record for the individual, which will be stored in its health data repository. Upon viewing the medical record, the VA clinician would be alerted and provided access to the individual's clinical information residing in DOD's repository. In the same manner, when a veteran seeks medical care at a military treatment facility, the attending DOD clinician would be alerted and provided with access to the health information in VA's repository. According to the departments, this planned approach would make virtual medical records displaying all available patient health information from the two repositories accessible to both departments' clinicians. VA officials have stated that they anticipate being able to exchange some degree of health information through an interface of their health data repository with DOD's clinical data repository by the end of calendar year 2005.

⁵The six initiatives that make up Health<u>e</u>Vet VistA are health data repository, billing replacement, laboratory, pharmacy, imaging, and appointment scheduling replacement.

The Two-Way Exchange Could Benefit from Improved Planning and Project Management	 While VA and DOD are making progress in agreeing to and adopting standards for clinical data,⁶ they continue to face significant challenges in providing a virtual medical record based on the two-way exchange of data as part of their Health@People (Federal) initiative. Specifically, VA and DOD do not have an explicit architecture that provides details on what specific technologies they will use to achieve the exchange capability; a fully established project management structure that will ensure the necessary day-to-day guidance of and accountability for the departments' investment in and implementation of the exchange; and
	• a project management plan describing the specific responsibilities of each department in developing, testing, and deploying the interface and addressing security requirements.
System Architecture Not Developed	VA's and DOD's ability to exchange data between their separate health information systems is crucial to achieving the goals of Health@People (Federal). Yet, successfully sharing health data between the departments via a secure electronic interface between each of their data repositories can be complex and challenging, and depends significantly on the departments' having a clearly articulated architecture, or blueprint, defining how specific technologies will be used to achieve the interface. Developing, maintaining, and using an architecture is a best practice in engineering information systems and other technological solutions. An architecture would articulate, for example, the system requirements and design specifications, database descriptions, and software descriptions that define the manner in which the departments will electronically store, update, and transmit their data.
	disparate systems. The Institute of Medicine's Committee on Data Standards for Patient Safety has reported the lack of common data standards as a key factor preventing information sharing within the health care industry. VA and DOD, along with the Department of Health and Human Services, have been active participants in the Consolidated Health Informatics initiative. As part of this initiative, the Secretary of Health

Department of Health and Human Services, have been active participants in the Consolidated Health Informatics initiative. As part of this initiative, the Secretary of Health and Human Services announced in early May the adoption of 15 new standards to enable the exchange of health information.

just what they will be able to exchange by the end of 2005—their projected date for having this capability operational. While VA officials stated that they recognize the importance of a clearly defined architecture, they acknowledged that the departments' actions were continuing to be driven by the less specific, high-level strategy that has been in place since September 2002.

Officials in both departments stated that a planned pharmacy prototype initiative, begun this past March in response to requirements of the National Defense Authorization Act of 2003,⁷ would assist them in defining the electronic interface technology needed to exchange patient health information. The act mandated that VA and DOD develop a real-time interface, data exchange, and capability to check prescription drug data for outpatients by October 1, 2004. In late February, VA hired a contractor to develop the planned prototype but the departments had not yet fully determined the approach or requirements for it. DOD officials stated that the contractor was expected to more fully define the technical requirements for the prototype. In late April, the departments reported approval of the contractor's requirements and technical design for the prototype.

While the pharmacy prototype may help define a technical solution for the two-way exchange of health information between the two departments' existing systems, there is no assurance that this same solution can be used to interface the new systems under development. Because the departments' new health information systems—major components of Health@People (Federal)—are scheduled for completion over the next 4 to 9 years, the prototype may only test the ability to exchange data in VA's and DOD's existing health systems. Thus, given the uncertainties regarding what capabilities the pharmacy prototype will demonstrate, it is difficult to predict how or whether the prototype initiative will contribute to defining the architecture and technological solution for the two-way exchange of patient health information for the Health@People (Federal) initiative.

⁷Sec. 724 of the act mandates that the Secretaries of Veterans Affairs and Defense seek to ensure that, on or before October 1, 2004, the two departments' pharmacy data systems are interoperable for VA and DOD beneficiaries by achieving real-time interface, data exchange, and checking of prescription drug data of outpatients, and using national standards for the exchange of outpatient medication information. The act further states that if the specified interoperability is not achieved by that date, the Secretary of Veterans Affairs shall adopt DOD's Pharmacy Data Transaction System for VA's use.

Fully Established Project Management Structure Not in Place

Industry best practices and information technology project management principles stress the importance of accountability and sound planning for any project, particularly an interagency effort of the magnitude and complexity of Health@People (Federal). Based on our past work, we have found that a project management structure should establish relationships between managing entities with each entity's roles and responsibilities clearly articulated.⁸ Further, it is important to establish final decision-making authority with one entity.

However, VA and DOD have not fully established a project management structure that will ensure the necessary day-to-day guidance of and accountability for the departments' investment in and implementation of the two-way capability. According to officials in both departments a joint working group and oversight by the Joint Executive Council and VA/DOD Health Executive Council has provided the collaboration necessary for Health<u>e</u>People (Federal).⁹ However, this oversight by the executive councils is at a very high level, occurs either bimonthly or quarterly, and encompasses all of the joint coordination and sharing efforts for health services and resources. Since a lead entity has not been designated, neither department has had the authority to make final project decisions binding on the other. Further, the roles and responsibilities for each department have not been clearly articulated. Without a clearly defined project management structure, accountability and a means to monitor progress are difficult to establish.

In early March, VA officials stated that the departments had designated a program manager for the planned pharmacy prototype and were establishing roles and responsibilities for managing the joint initiative to develop an electronic interface. Just this month, officials from both departments told us that this individual would be the program manager for the electronic interface. However, they had not yet designated a lead entity

⁸GAO-01-459.

⁹The Joint Executive Council is comprised of the Deputy Secretary of Veterans Affairs, the Under Secretary of Defense for Personnel and Readiness, and the cochairs of joint councils on health, benefits, and capital planning. The council meets on a quarterly basis to recommend strategic direction of joint coordination and sharing efforts. The VA/DOD Health Executive Council is comprised of senior leaders from VA and DOD, who work to institutionalize sharing and collaboration of health services and resources. The council is cochaired by the VA Under Secretary for Health and DOD Assistant Secretary of Defense for Health Affairs, and meets on a bimonthly basis.

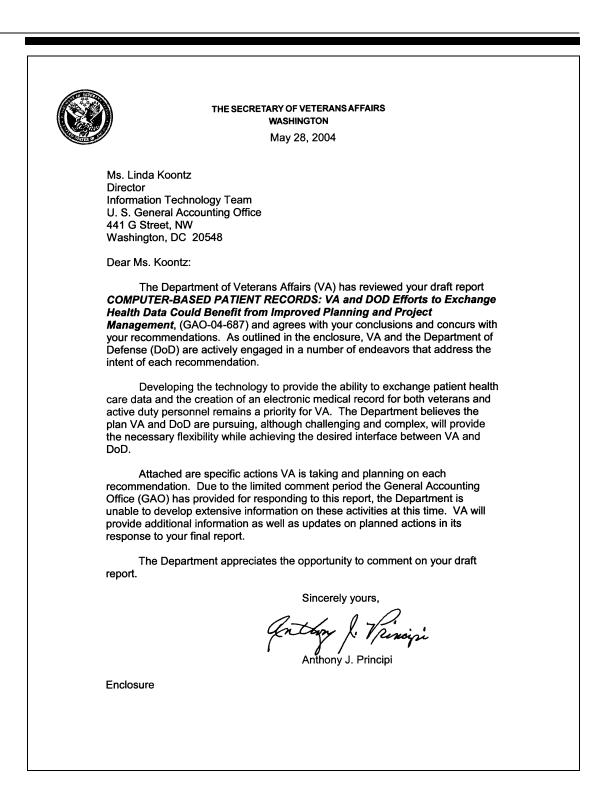
	or provided documentation for the project management structure or their roles and responsibilities for the Health <u>e</u> People (Federal) initiative.
Project Management Plan Lacking	An equally important component necessary for guiding the development of the electronic interface is a project management plan. Information technology project management principles and industry best practices ¹⁰ emphasize that a project management plan is needed to define the technical and managerial processes necessary to satisfy project requirements. Specifically, the plan should include, among other things, the authority and responsibility of each organizational unit; a work breakdown structure for all of the tasks to be performed in developing, testing, and deploying the software, along with schedules associated with the tasks; and a security policy.
	However, the departments are currently operating without a project management plan for Health@People (Federal) that describes the specific responsibilities of each department in developing, testing, and deploying the interface and addressing security requirements. This month, officials from both departments stated that a pharmacy prototype project management plan that includes a work breakdown structure and schedule was developed in mid-March. They further stated that a work group that reports to the integrated project team has been given responsibility for the development of security and information assurance provisions. While these actions should prove useful in guiding the development of the prototype, they do not address the larger issue of how the departments will develop and implement an interface to exchange health care information between their systems by 2005.
	Without a project management plan, VA and DOD lack assurance that they can successfully develop and implement an electronic interface and the associated capability for exchanging health information within the time frames that they have established. VA and DOD officials stated that they have begun discussions to establish an overall project plan.
Conclusions	Achieving an electronic interface that will enable VA and DOD to exchange patient medical records is an important goal, with substantial

¹⁰Institute of Electrical and Electronics Engineers, *IEEE/EIA Guide for Information Technology* (IEEE/EIA 12207.1 - 1997), April 1998.

	implications for improving the quality of health care and disability claims processing for the nation's military members and veterans. In seeking a virtual medical record based on the two-way exchange of data between their separate health information systems, VA and DOD have chosen a complex and challenging approach that necessitates the highest levels of project discipline, including a well-defined architecture for describing the interface for a common health information exchange; an established project management structure to guide the investment in and implementation of this electronic capability; and a project management plan that defines the technical and managerial processes necessary to satisfy project requirements. These critical components are currently lacking; thus, the departments risk investing in a capability that could fall short of expectations. The continued absence of these components elevates concerns about exactly what capabilities VA and DOD will achieve—and when.
Recommendations for Executive Action	To encourage significant progress on achieving the two-way exchange of health information, we recommend that the Secretaries of Veterans Affairs and Defense instruct the Acting Chief Information Officer for Health and the Chief Information Officer for the Military Health System, respectively, to
•	develop an architecture for the electronic interface between their health systems that includes system requirements, design specifications, and software descriptions;
•	select a lead entity with final decision-making authority for the initiative;
•	establish a project management structure to provide day-to-day guidance of and accountability for their investments in and implementation of the interface capability; and
•	create and implement a comprehensive and coordinated project management plan for the electronic interface that defines the technical and managerial processes necessary to satisfy project requirements and includes (1) the authority and responsibility of each organizational unit; (2) a work breakdown structure for all of the tasks to be performed in developing, testing, and implementing the software, along with schedules associated with the tasks; and (3) a security policy.

Agency Comments	The Secretary of Veterans Affairs provided written comments on a draft of this report and we received comments via e-mail from DOD's Interagency Program Integration and External Liaison for Health Affairs; both concurred with the recommendations. Each department's comments are reprinted in their entirety as appendixes I and II, respectively. In their comments, the officials also provided information on actions taken or underway that, in their view, address our recommendations.
	We are sending copies of this report to the Secretaries of Veterans Affairs and Defense and to the Director, Office of Management and Budget. Copies will also be available at no charge on GAO's Web site at www.gao.gov.
	Should you have any question on matters contained in this report, please contact me at (202) 512-6240, or Barbara Oliver, Assistant Director, at (202) 512-9396. We can also be reached by e-mail at koontzl@gao.gov and oliverb@gao.gov, respectively. Other key contributors to this report were Michael P. Fruitman, Valerie C. Melvin, J. Michael Resser, and Eric L. Trout.
	Sincerely yours, Linda & Koontz
	Linda D. Koontz Director, Information Management Issues

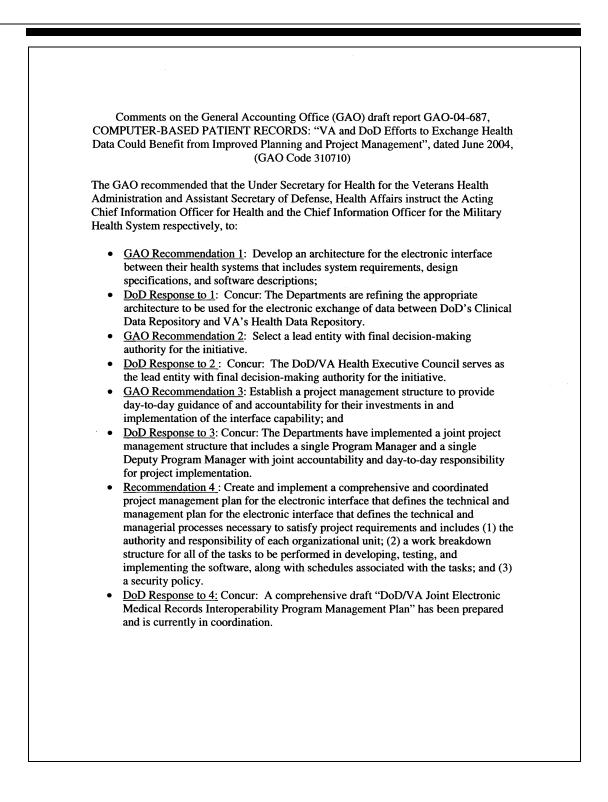
Appendix I: Comments from the Secretary of Veterans Affairs



Enclo The Department of Veterans Affairs (VA) Comments on the General Accounting Office's (GAO) Draft Report: COMPUTER-BASED PATIENT RECORDS: VA and DOD Efforts to Exchange Health Data Could Benefit from Improved Planning and Project Management (GAO-04-687) GAO recommends that the Secretaries of Veterans Affairs and Defense instruct the Acting Chief Information Officer for Health a the Chief Information Officer for the Military Health System respectively to: Develop on excitations of the electronic interface betw	
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Defense instruct the Acting Chief Information Officer for Health a the Chief Information Officer for the Military Health System respectively to:	nd
Develop on eachitecture for the electronic interface both	
 Develop an architecture for the electronic interface between their health systems that includes system requirements design specifications, and software descriptions. 	
<u>Concur</u> – The Departments are actively engaged in several activities that relation development of a final architecture for the electronic interface between the agencies' health information systems. VA and DoD expect to have developed final architecture by the 1 st Quarter, FY 2005. The Departments anticipate that the current work to develop a pharmacy prototype to demonstrate the bi- directional exchange of pharmacy data will provide important technical information, and have significant impact on the final definition of an architecture	d the at
 Select a lead entity with final decision-making authority the initiative. 	for
<u>Concur</u> – The Veterans Health Administration (VHA) Acting Under Secretary Health and DoD's Assistant Secretary of Defense for Health Affairs, have ag that the VA/DoD Health Executive Council (HEC) will continue to serve as th lead entity with final decision-making authority for the initiative. Co-chaired b the Assistant Secretary of Defense Health Affairs and the Under Secretary for Health the HEC is an executive body that provides single and final decision making authority for the initiative.	reed ∋ y
 Establish a project management structure to provide da to-day guidance of and accountability for their investme in and implementation of the interface capability. 	
<u>Concur</u> – The Departments have implemented a joint project management structure that includes a single Program Manager from VA and a single Depu Program Manager from DoD. This structure ensures joint accountability and to-day responsibility for project implementation. VA provided formal	
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	Enclosure
	The Department of Veterans Affairs (VA) Comments on the General Accounting Office's (GAO) Draft Report: COMPUTER-BASED PATIENT RECORDS: VA and DOD Efforts to Exchange Health Data Could Benefit from Improved Planning and Project Management (GAO-04-687) (Continued)
do pa	cumentation of this project management structure and the appointments as rt of its response to GAO's document request on May 14, 2004.
	 Create and implement a comprehensive and coordinated project management plan for the electronic interface that defines the technical and managerial processes necessary to satisfy project requirements and includes (1) the authority and responsibility of each organizational unit; (2) a work breakdown structure for all of the tasks to be performed in developing, testing, and implementing the software, along with schedules associated with the tasks; and (3) a security policy.
Jo Pla do of an pla co co to rec Pri	oncur – The Departments have developed a comprehensive draft "DoD/VA int Electronic Medical Records (JEMR) Interoperability Program Management an" that updates the previously provided project management plan. This draft iccument is in coordination between the Departments. VA anticipates approval this plan in June 2004. As part of its response to GAO's document request d in earlier responses, VA provided GAO with an initial project management an and GANTT chart/work breakdown structure for the high-level tasks that mprise the work to achieve interoperability. A final security policy will be mpleted once the final technical architecture is identified. It is current practice ensure that all patient data exchanges are done in compliance with all gulatory and congressional privacy and security mandates, including the ivacy Act and the Privacy Regulations contained within the Health Insurance ortability and Accountability Act.
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Appendix II: Comments from the Director, Interagency Program Integration & External Liaison for Health Affairs



GAO's Mission	The General Accounting Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.		
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