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Using the Collaborative Requirements Development Methodology to Build Laboratory Capacity for Timely Diagnosis During the Zika Epidemic in Puerto Rico

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Abstract

Introduction: In 2016, Puerto Rico became the focal point of the Zika epidemic, with more than 36 000 laboratory-confirmed cases before August. The Puerto Rico Department of Health (PRDH) responded by providing tests to symptomatic and asymptomatic pregnant women. The increased demand for Zika testing placed unprecedented strain on the laboratory capacity and information management processes used within the PRDH. The PRDH recognized the need to have an updated informatics system that securely manages, stores, and transmits digital data. The Centers for Disease Control and Prevention funded the Public Health Informatics Institute to collaborate with the PRDH to assess and improve the informatics capability to respond to the ongoing Zika virus transmission in Puerto Rico.

Approach: The team employed a 4-component approach to assess the informatics system and improve the information management processes for laboratory testing and reporting of arboviral diseases (Zika, chikungunya, and dengue). The method consisted of a (1) needs assessment, (2) business process analysis and requirements definition, (3) vendor analysis, and (4) solution implementation.

Results: The needs assessment determined that the PRDH's procedures for arbovirus testing and reporting were highly complex and paper-based and thus did not maximize the use of existing technology. The solution was to build a Web portal. The business process analysis yielded information to create a map of the flow of specimens, an arbovirus context diagram, and more than 200 requirements. The requirements identified in this process guided the design and creation of the Web portal.

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Discussion: This report describes the process to build a Web portal to enhance laboratory testing and electronic reporting of Zika cases during the 2016 epidemic in Puerto Rico. We demonstrate the utility of applying the Collaborative Requirements Development Methodology, a proven informatics method, to the development of a Web portal for managing arboviruses in a health department.

Keywords

capacity building; laboratories; public health informatics; Puerto Rico; Zika

On December 31, 2015, the Puerto Rico Department of Health (PRDH) reported the first locally acquired case of Zika virus infection in the United States.[1] In response, the PRDH provided tests to symptomatic and asymptomatic pregnant women at the initiation of prenatal care and during the second and third trimesters. Puerto Rico became the focal point of the Zika epidemic, and by the end of 2016, there were 35 395 confirmed cases of Zika.[2] Although the incidence began to decline by April 2017, and the PRDH declared the end of the Zika epidemic on the island, there were more than 36000 laboratory-confirmed and presumptive Zika cases.[3,4]

The pathogenicity and consequences of Zika virus infection are well documented elsewhere.[5,6] The Zika virus is most commonly spread by the bite of an infected mosquito, but it can also be transmitted sexually and by a pregnant woman to her developing fetus.[7,8] In general, most people infected with Zika virus do not develop symptoms or develop only mild symptoms that typically resolve within several days to a week. However, Zika infection during pregnancy can cause microcephaly in developing fetuses.[6,9] It also can lead to congenital Zika syndrome in babies, a pattern of birth defects that includes brain abnormalities, vision problems, hearing loss, and problems moving limbs.[9,10]

In February 2016, the Centers for Disease Control and Prevention (CDC) issued recommendations that all symptomatic and asymptomatic pregnant women in regions with ongoing Zika virus transmission be tested for infection at the initiation of prenatal care and during the second trimester.[10] The PRDH immediately adopted these recommendations and released administrative orders notifying health care providers and insurance companies of their responsibilities regarding screening for Zika virus and ensuring appropriate prenatal care for those pregnant women who test positive for the virus. In October 2016, the PRDH modified the testing guidance and added an additional requirement for third trimester testing.[11]

The Zika epidemic and resulting increase in the need for Zika testing and reporting placed unprecedented strain on the PRDH's laboratory capacity and information management processes. At the onset of the Zika epidemic, testing and reporting for arboviral (arthropod-borne) diseases (eg, Zika, dengue, chikungunya) were highly complex, paper-based, time-consuming processes that involved numerous entities, information needs, information handlers, and data exchanges. In response, the PRDH implemented several new processes designed to manage the surge in Zika-related clinical samples. The new process improved validation of samples and implementation of appropriate laboratory testing, prioritization for high-risk groups, and improved efficiency of specimen transport between medical clinics

and laboratories.[12] Although these new processes helped alleviate some of the challenges related to the increased demand for Zika testing and reporting, the PRDH and the CDC recognized the need to strengthen the health department's overall capacity to conduct timely and efficient laboratory testing and secure reporting of laboratory results for arboviral diseases, including Zika. In October 2016, a cooperative agreement from the CDC provided funds to the Public Health Informatics Institute (PHII) to collaborate with the PRDH to support the public health response to arbovirus transmission, epidemiology, and informatics efforts in Puerto Rico. This report describes the process to design and build a Web portal to enhance the PRDH's laboratory testing and electronic reporting of arboviruses using the PHII's facilitated collaborative method Collaborative Requirements Development Methodology (CRDM).

Approach

The PRDH's existing informatics system was assessed for strengths and weaknesses, which provided solutions to improve data collection,data sharing between systems, and data management for more efficient processing of laboratory test orders and result reporting for arboviral diseases endemic to Puerto Rico. A team from the PHII consisting of 4 informatics specialists implemented a validated 4-step method consisting of a needs assessment, business process analysis and requirements definition, vendor analysis, and solution implementation (Figure 1).[13]

Needs assessment

The needs assessment qualitatively described processes required for Zika surveillance, testing, collection and storage of data, and dissemination of results. The team provided the PRDH's information technology (IT) team a questionnaire that assessed Zika specimen collection, logistical resources, system, database, and the information flow process. In October 2016, the team conducted a site visit to complete the needs assessment with the PRDH and the CDC in San Juan, Puerto Rico. During the site visit, the team conducted structured interviews with 4 PRDH representatives to obtain additional details of the logistical procedures in the health department and documented internal and external information flow processes related to laboratory testing of arbovirus specimens. Key informant interviews were conducted with those involved in the Zika testing process, including the PRDH Receiving Laboratory, the Biological and Chemical Emergencies Laboratory, and the CDC Dengue Branch Laboratory. In addition, the team attended an incident management meeting to understand the strategies in place for Zika response and visited the PRDH data entry and processing center to understand the final steps in processing laboratory results and documenting epidemiological information. At the end of the site visit, the PHII and the PRDH analyzed and summarized qualitative data from the initial receipt of a Zika specimen through the reporting process. Data were depicted to visualize the entire Zika laboratory information flow (see Supplemental Digital Content Figure 2, available at http://links.lww.com/JPHMP/A630).

Business process analysis and requirements definition

Business process analysis is an approach to identify how to increase the efficiency and effectiveness of a process to better achieve its end goal. For more than 2 decades, the PHII has conducted business process analysis to reveal how public health work is accomplished and strengthen public health systems. These types of analyses have been successfully implemented to define a local health department's business process goals, objectives, triggers, inputs/outputs, business process rules, and outcomes.[13] As part of its approach to business process analysis, the PHII used CRDM to qualitatively identify existing processes, create task flows, refine processes, and develop requirements for public health information systems (Figure 2).[13] The CRDM provides both a framework for comprehensively mapping how an organization is already conducting its work and a method for identifying improvements and changes.[14]

In April 2017, the PHII implemented the principles of CRDM to identify the PRDH's current business processes, goals, and objectives related to testing and reporting of arboviral diseases, including Zika. During a 2-day workshop held in Puerto Rico on May 2017, the PHII worked with 12 participants from the PRDH and 1 local health care provider to map key business processes for submitting and processing electronic orders for laboratory testing related to arbovirus diseases, securing electronic laboratory test reporting, and managing provider contact information. These data served to develop and validate business process matrices, task flow diagrams, and functional requirements that were necessary to provide support for the development and implementation of an information management Web portal that aimed to improve the timeliness and efficiency of laboratory testing and reporting of arboviral diseases.

Vendor analysis

The processes listed previously and the resulting data informed the identification and selection of qualified vendors. Vendors were expected to collaborate with the IT team (Oficina De BioSeguridad) at the PRDH to design and develop a Web portal and to provide training for the PRDH staff in the development and management of the portal. The team conducted a comprehensive vendor analysis by researching existing technical software trainers who met the requirements for the PRDH's IT and informatics training needs. In July 2017, the team completed an environmental scan of existing IT development and training vendors based on the functional requirements and technical training needs collected during the CRDM and business process analysis workshop with the PRDH. A request for information was developed to contact and request additional information from vendors who were identified as having expertise in supporting IT software development using hypertext markup language, Health Level Seven (HL7), and Structured Query Language (SQL).

Based on the requirements identified during the CRDM and business process analysis workshop, the team developed a vendor requirements matrix, using information from the vendor responses to the request for information to complete the matrix for each vendor (see Supplemental Digital Content Table 1, available at http://links.lww.com/JPHMP/A631, for an example of the vendor requirements matrix). The team used the matrices to assess each vendor based on the extent to which it met (fully, partially, or not at all)

specific requirements within the following domains: general system requirements, ordering laboratory tests, retrieving laboratory test results, managing provider information, processing laboratory test orders, and performing laboratory testing.

Solution development and implementation

The team facilitated the development and implementation of the solution; team members supported the PRDH in working with the internal PRDH BioSeguridad IT team members and local qualified software developers to develop a Web-based platform, the PRDH BioPortal. The purpose of this Web portal is to improve the timeliness and efficiency of the overall laboratory test process through the provision of a secure electronic method of ordering laboratory tests and sending test results to the providers. The Web portal also includes features that support necessary administrative functions, such as user registration, login, password reset, and provider lookup. All the documentation and information related to the technology used for the development of the PRDH BioPortal are detailed and maintained in GitHub, an online development platform that allows users to host and review code,manage projects,and collaboratively build software. Throughout the process of developing the PRDH BioPortal, the team continued to work closely with the PRDH to provide the technical assistance necessary to fully implement the BioPortal.

Key Findings

Documenting a complex process

The needs analysis revealed that PRDH's approach to Zika testing and reporting was a highly complex, paper-based process that involved numerous entities, information needs, information handlers, and data exchanges. Health care providers ordered tests for Zika and submitted specimens to the PRDH from patients with clinical suspicion of Zika, chikungunya, or dengue virus infection, and each specimen was accompanied by an arbovirus case investigation form. Zika samples were sorted at the point of receipt by priority, based on the number of days between the onset of illness and specimen collection. Specimens were also sorted by whether they were obtained from a symptomatic pregnant woman, an asymptomatic pregnant woman, an infant, or all others. Once the specimens were sorted, they were transported to the laboratories for testing, with all specimens from asymptomatic pregnant women tested at the CDC Dengue Branch Laboratory and all other specimens tested at the Biological and Chemical Emergencies Laboratory. A testing algorithm provided information on which tests should be performed on the basis of details surrounding each specimen. In some cases, multiple tests were required before a final testing determination could be made (see Supplemental Digital Content Figure 2, available at http://links.lww.com/JPHMP/A630).

In addition, the needs analysis revealed several other challenges and opportunities related to Zika response management. The PRDH recognized the opportunity to improve the timeliness of laboratory reporting by working with the Puerto Rico Health Information Network to electronically send laboratory results to providers. However, the Puerto Rico Health Information Network's capacity level and timing for enhancing capacity were not well aligned with the immediate need of the Zika response team to securely exchange

confidential laboratory results between laboratories and providers. For example, the PRDH initiated efforts to establish a data use agreement to enable the sharing of electronic laboratory results via HL7 messaging with the Biological and Chemical Emergencies Laboratory, but at that time, the CDC Dengue Branch Laboratory did not have the ability to support HL7 messaging. Because infrastructure did not exist to enable the PRDH to transmit confidential patient data in a secure electronic manner back to the provider or the laboratory, Zika responses were delayed. Notably, the lapsed time from receipt of Zika specimen to mailing of laboratory results to providers had decreased from approximately 25 days at the start of the Zika epidemic to approximately 15 days at the time of the needs assessment. However, all stakeholders recognized the critical need to further improve the timeliness of laboratory testing and reporting. Ultimately, the findings of the needs assessment underscored an urgent need to rapidly design, develop, and deploy an information system for Puerto Rico that would allow for the secure electronic file transfer of Zika test results from all Zika testing laboratories to health care providers.

Business processes of Zika testing

Public Health Informatics Institute, with assistance from the PRDH's informatics and laboratory staff, created and reviewed business process matrices (for an example of a matrix, see Table 1) that led to recommendations to redesign and improve the efficiency of the process. Specifically, the business process analysis revealed several challenges in the execution of 4 major processes: arbovirus laboratory test ordering, distributing laboratory test result(s), retrieving laboratory test results, and provider information management. For example, during the processing of laboratory test orders, the PRDH staff had to review each order manually for accuracy and completeness. If an order was identified as inaccurate or incomplete, the PRDH staff were required to contact the provider to gather the necessary data. There were also challenges related to incomplete provider addresses and other types of provider data, which required the PRDH staff to contact providers to obtain the missing data. The team made the recommendation to redesign the 4 major processes and provided written suggestions to improve the efficiency of Zika testing and reporting.

Data from the business process analysis and collaborative requirements definition process indicated that a Web portal would be the optimal solution to support Zika test ordering, provider management, and secure electronic exchange of patient information between laboratories and providers. The context diagram of the specimen logistics and information flow for Zika testing (Figure 3) was used as the framework for the development of more than 200 system functional requirements for the portal. Briefly, it was agreed that the Web portal would be designed to allow providers to access the portal using account credentials, submit laboratory test orders, and view test results for their patients. Providers who wished to submit laboratory test orders or retrieve laboratory test results would be required to create and maintain a complete and accurate provider account within the PRDH Web portal. The matrices and diagrams created using CRDM and business process analysis were also used by the PRDH to prioritize functional requirements and to inform the technical vendor selection process.

Identifying and selecting qualified vendors

The environmental scan of existing IT development and training vendors produced a list of 13 vendors who met the PRDH's functional and training requirements. The PHII sent a request for information to each of the 13 vendors and received responses from 6 vendors. Based on the review of vendor proposals, and supported by the use of the vendor requirements matrix, 1 vendor was selected to develop the front end of the PRDH arbovirus Web portal and 2 other vendors were selected to conduct HL7 and SQL training sessions in Spanish and on-site with the PRDH staff.

In addition to informing the selection of vendors, the vendor analysis process yielded other positive outcomes. By participating in the vendor analysis process, the PRDH gained knowledge and experience that should be helpful in future activities that involve identifying and selecting vendors to support other public health goals and objectives. The PRDH can adapt the tools used in the vendor analysis, including the environmental scan document and vendor requirements matrix, for future use. The PRDH is also now aware of numerous vendors who have been prescreened through the vendor analysis process to ensure that they meet their technical programming and training requirements.

Implementing a solution

The long-term solutions were to create the PRDH Web portal, develop capacity of the PRDH IT team and personnel to use the portal, and understand the software. The team provided training to the PRDH staff on hypertext markup language, SQL, and HL7 in Spanish. The PRDH team learned how to customize and configure the Web portal, which will increase the sustainability of the informatics system by empowering them to perform routine maintenance. The PHII and the IT team collaboratively created the Web portal, hosted it on a server, and performed quality control on the 4 processes. Hurricane Maria (2017) prevented the completion of the project. Consequently, the next phase will be to document the portal's informatics standards, the PRDH's internal security requirements, and interoperability with the CDC's systems. The Web portal is expected to enhance the efficiency of arbovirus laboratory test ordering, improve the timeliness of test reporting, and support secure electronic communication with providers.

Discussion and Conclusion

Key challenges

Unfortunately, the destruction caused by Hurricane Maria in September 2017 led to a prolonged recovery effort in Puerto Rico that significantly delayed the work and affected the timeline to develop and test the Web portal's 4 processes: arbovirus laboratory test ordering, distributing laboratory test results, retrieving laboratory test results, and provider information management. Although the team eventually completed the 4 processes, members responded to the unexpected delays resulting from Hurricane Maria by prioritizing 2 processes over the others: electronic laboratory reporting and secure exchange of confidential laboratory results. These priorities were met by conducting training to advance the technical skills of the PRDH staff, both in HL7 and in SQL, and designing the Web

site to interact with more than 3 systems to electronically provide laboratory results of Zika, chikungunya, or dengue to providers.

In addition, throughout the course of this project, the team considered that the PRDH has limited resources, which would require any resulting solutions to be as efficient as possible in order to maximize the staff time and materials invested in managing them. In keeping with this goal, the PHII provided the PRDH with CRDM training to build the PRDH capacity and ensure that the PRDH could remain fully autonomous in the future in maintaining and sustaining the system. An additional barrier that sprang from this activity was securing a trainer who met all requirements around language, location, and technical skill set; securing a sufficiently skilled trainer with Spanish language skills who was based in Puerto Rico proved to be a challenge.

Additional discussion and summary

This case study documented a 4-step process to design and develop an information system that will allow for the secure electronic file transfer of Zika test results from all Zikatesting laboratories to health care providers. Although the PRDH's Zika testing and reporting were complex and mostly paper-based, the PHII determined that the goals identified in the business process analysis and the development of a functional Web portal could be completed in 1 year.

When possible, the PRDH's effective business processes and workflows were left in place, and only inefficient processes were redesigned. For example, there was a complete redesign of processes for transitioning the arbovirus case investigation form from a hard copy paper to an electronic version. The most notable results were the detailed information from the business processes, map of the flow of specimen testing information from health department to provider, arbovirus Web portal context diagram, and more than 200 requirements. Health departments can use this information to improve or redesign their Web sites.

Health departments across the country are slowly progressing toward having optimal informatics systems that securely manage, store, and transmit digital data.[15] A critical component to an informatics-savvy health department is a competent workforce. The advantage of our approach was the collaboration of experts in information systems design with key stakeholders at the department of public health, the CDC, and laboratories, which resulted in data that were jointly reviewed and analyzed. Learning opportunities across the continuum of development reinforced the IT team's knowledge and skills. For example, the context diagram of the specimen logistics and information flow for Zika testing provided an opportunity for the PRDH staff to understand their own business processes. The PRDH team experienced additional learning through direct participation in the creation of the framework for the Web portal and the development of more than 200 functional requirements.

This report details the approach used to enhance laboratory testing and reporting related to the Zika epidemic in Puerto Rico and clearly demonstrates the utility of applying proven informatics methods to the development of a laboratory reporting system, even in the midst of a rapidly moving infectious disease outbreak. By thoroughly but quickly analyzing existing reporting practices and then systematically identifying the true "business

requirements" of the public health authorities who needed laboratory data to guide their epidemic control measures, the PHII and the PRDH were able to design a technologically appropriate solution unique to the health department's goal to improve the timeliness of laboratory testing and reporting for arbovirus diseases in Puerto Rico.

The utility of the 4-step approach, processes, and tools described in this report is not limited to arbovirus diseases or applicable only to emerging infectious diseases. Rather, this report highlights an approach that can be used more broadly by public health practitioners at the local, state, or national level to understand and improve a wide variety of public health practices. According to "Public Health 3.0: A Call to Action to Create a 21st Century Public Health Infrastructure," it is time for a "major upgrade" to infrastructure and 1 component of the upgrade is "technology, tools, and data that matter."[16] The approach and tools described in this report can be used by public health agencies and practitioners to ensure that they have the technology, tools, and data to support such an upgrade and effectively address future public health challenges.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Implications for Policy & Practice

- CRDM provides a framework to help public health practitioners think about current business processes or workflows, gain understanding into all aspects of the current process, rethink or redesign business processes, and define the requirements of information systems that can support improved business processes.
- Mapping key business processes provides the opportunity to identify inefficiencies, bottlenecks, gaps, and opportunities for improvement in current and future processes.
- To maximize the limited resources that most local and state health departments are working with, it is critical to leverage existing institutional knowledge by collaboratively developing functional requirements with all key stakeholders. In doing so, an agency can build capacity by developing an information system that is most likely to support more efficient processes.
- A thorough vendor analysis of existing solutions is an important step in meeting the collaboratively developed functional requirements.

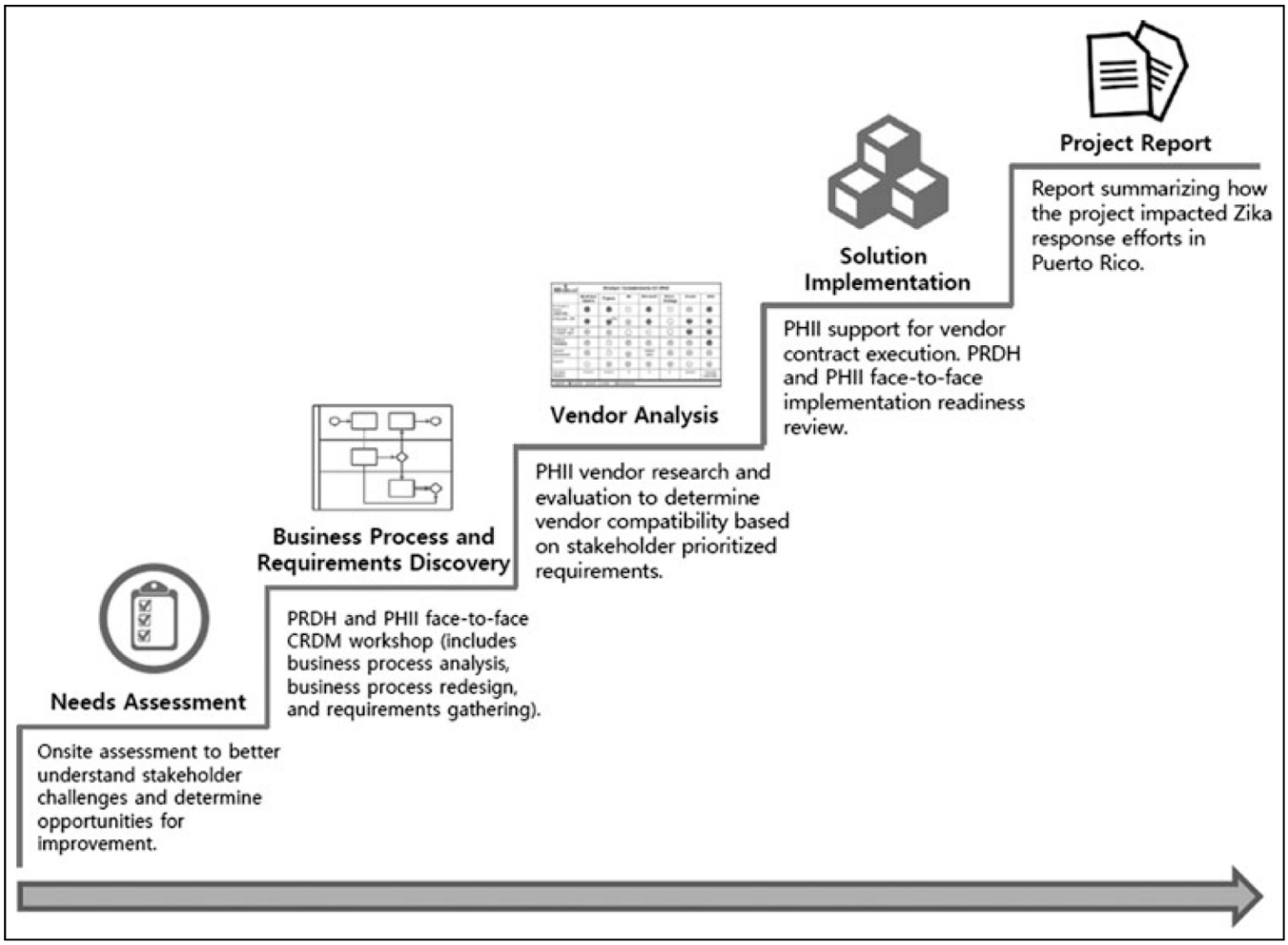

FIGURE 1.
Approach
Abbreviations: CRDM, Collaborative Requirements Development Methodology; PHII, Public Health Informatics Institute; PRDH, Puerto Rico Department of Health.

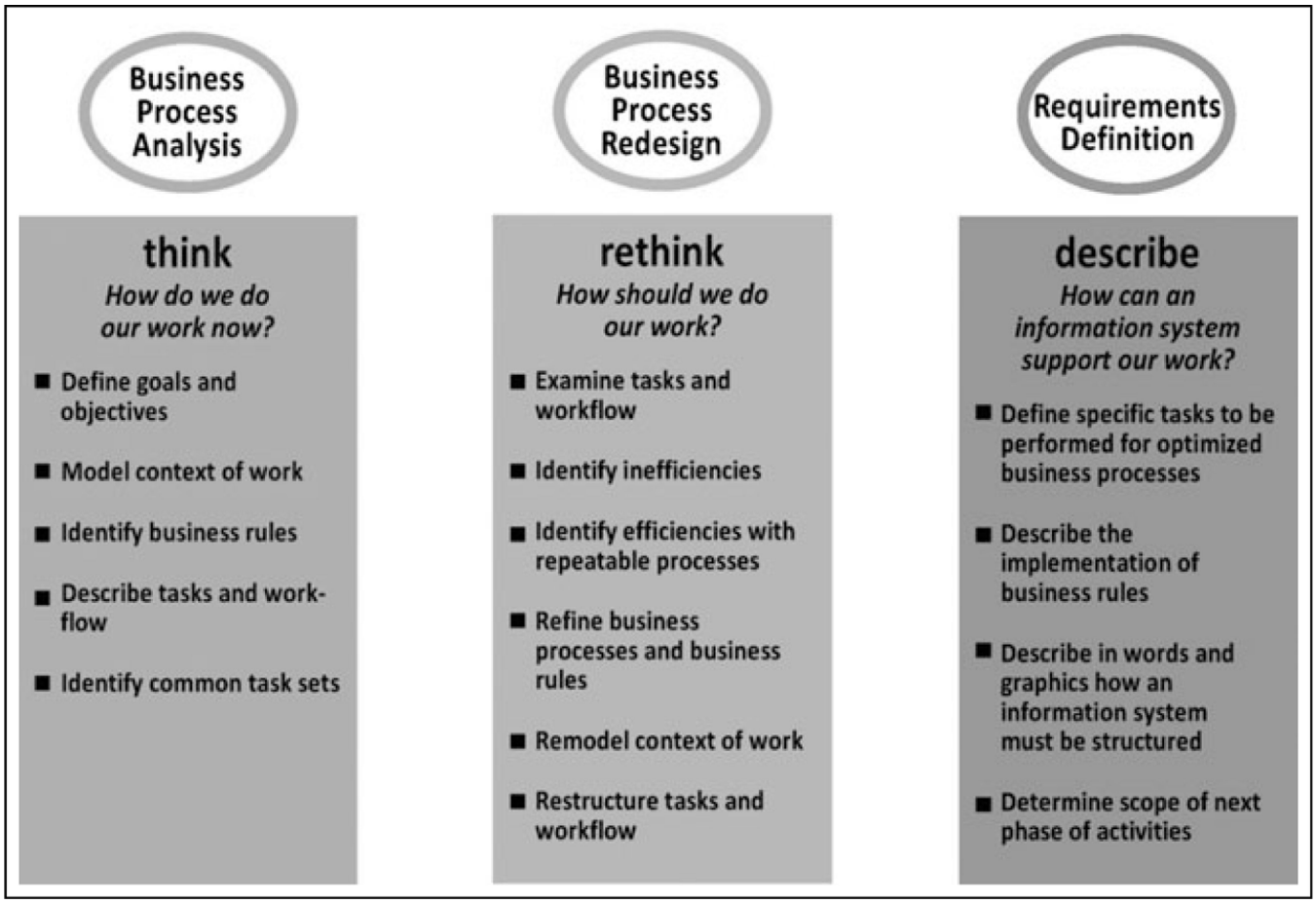

FIGURE 2.
Collaborative Requirements Development Methodology

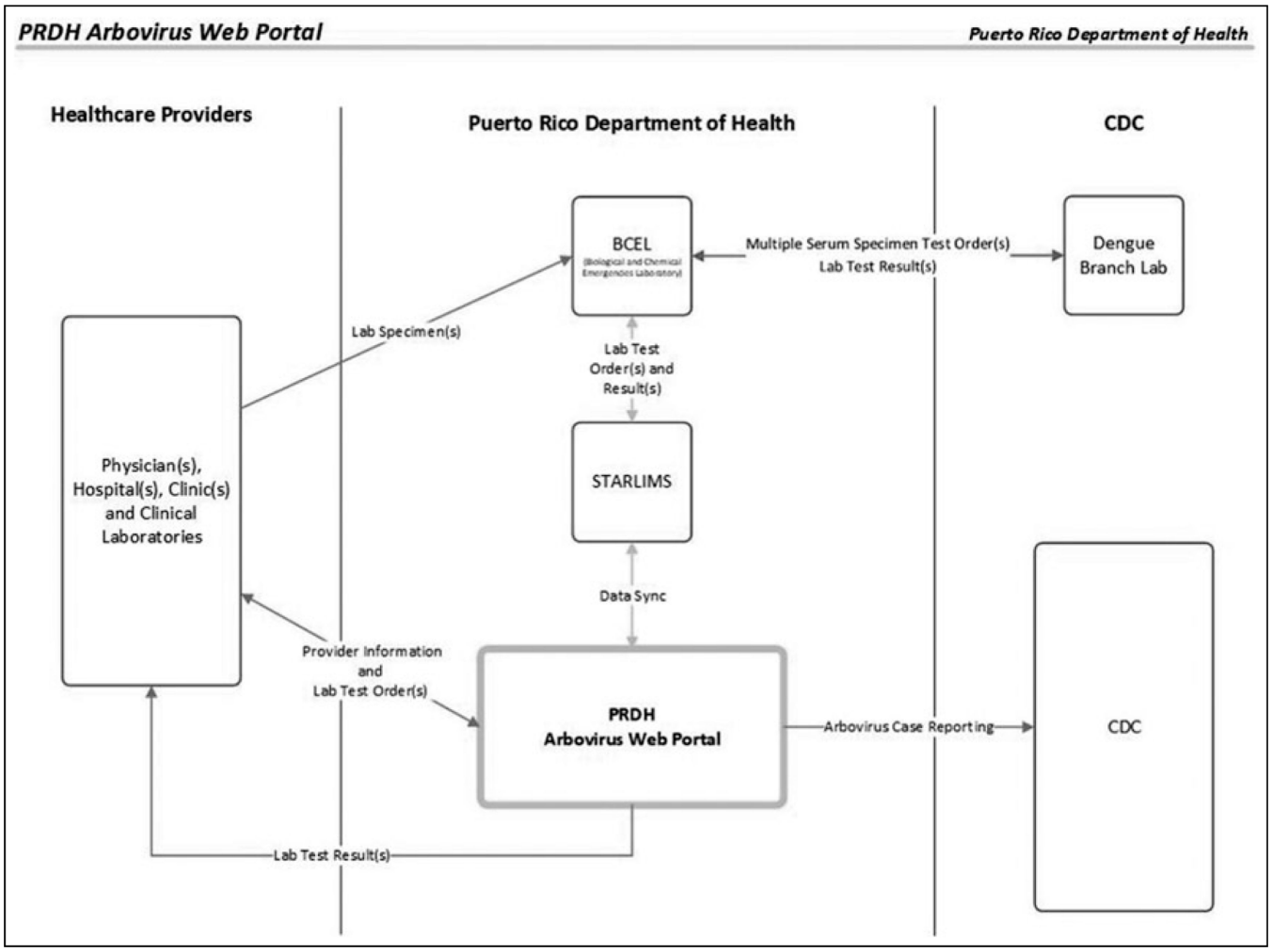

FIGURE 3.

Context Diagram

Abbreviations: CDC, Centers for Disease Control and Prevention; PRDH, Puerto Rico Department of Health.

TABLE 1

Business Processes of Arbovirus Laboratory Test Ordering

Objectives	Business Rules	Triggers	Task Set	Inputs	Outputs	Measurable Outcomes
To request an arbovirus laboratory test To receive laboratory test order(s) To confirm patient cases of arbovirus diseases	Puerto Rico Department of Health policies and procedure(s) HIPAA regulation(s) Health Information Exchange policies HITECH regulation Laboratory and clinical guideline(s)	Patient has symptoms associated with any arbovirus disease Patient needs arbovirus laboratory test Clinic walk-in/patient request Physician refers patient	1. Patient visits health provider 2. Examine patient 3. ACIF test required? 4. Partially fill out ACIF document 5. Take sample(s) 6. Attach ACIF to sample(s) 7. Submit laboratory test 8. Receive ACIF document and samnle(s)	Patient identifiable information (eg, first name, last name, birth date, etc) Patient address Patient medical condition/ symptom(s) Provider/clinical laboratory contact information Sample(s) collection date	Conducted laboratory test ACIF document and patient sample(s)	Number of arbovirus laboratory test order submission(s) Number of arbovirus tests ordered in a specific time frame Number of types of tests ordered by provider(s)

Abbreviations: ACIF, arbovirus case investigation form; HIPAA, Health Insurance Portability and Accountability Act; HITECH, The Health Information Technology for Economic and Clinical Health Act.

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