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Birth Defects Surveillance (BDS) System Update

Planning and Requirements Gathering Toolkit Version 2.0

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Acknowledgements

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Introduction

Purpose of this toolkit

The Birth Defects Surveillance (BDS) Planning and Requirements Gathering Toolkit is designed to provide guidance to BDS program staff in defining and documenting system requirements and needs for updating and enhancing your BDS systems. The toolkit outlines a structured framework for requirements gathering specific to BDS programs and offers established guidelines for system updates and development. This includes addressing jurisdiction-specific needs and constraints applicable to your BDS program. The structured framework and established guidelines within the toolkit ensure that all aspects of the system, whether undergoing an upgrade, new acquisition, or integration, are considered and addressed to meet the specific needs and constraints of the BDS program. Information on how to download the tools, templates and examples referenced in this toolkit can be found in the "List of tools/templates and their descriptions" section within the appendices.

Key objectives

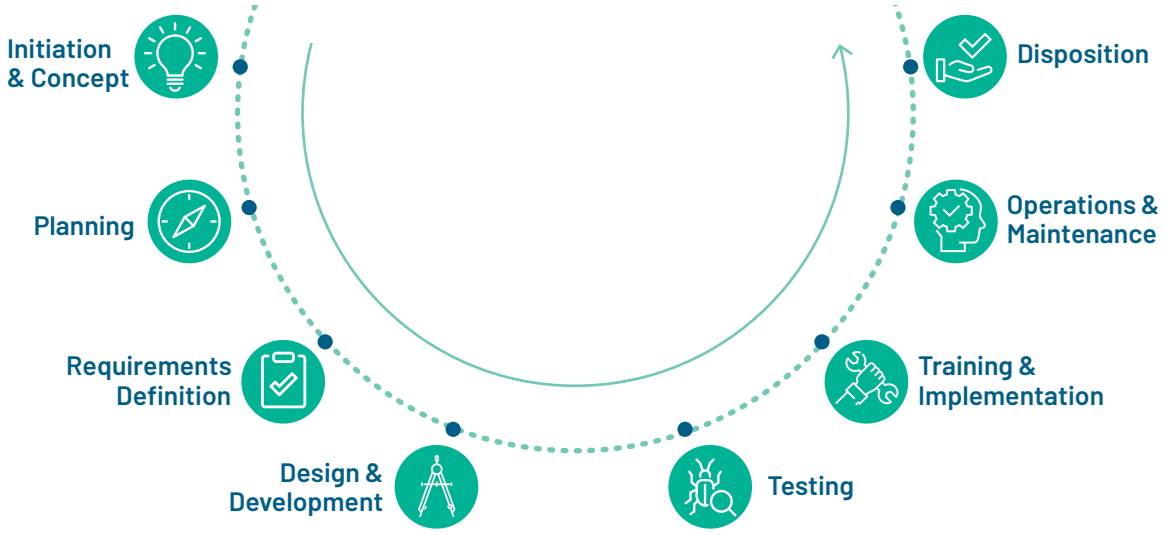
1. **Understand and apply methodologies:** Learn methodologies for gathering, articulating and documenting system requirements to effectively communicate system needs to key partners.
2. **Capacity building:** Enhance the capacity of BDS programs to define and document system requirements to support their program in transitioning to a new system or upgrading their existing systems.

What is the System Requirements Definition Process?

The requirements definition process is a critical phase in the systems development life cycle (see Figure 1) that involves gathering, documenting and managing the needs and expectations of partners for a new or updated system. This process ensures that the final system meets the intended purpose and satisfies user needs. While each step of the systems development life cycle is important, this toolkit provides guidance on the requirements definition process.

Figure 1: Systems Development Life Cycle

Taken from the Designing and Managing Public Health Information Systems: 8-Steps to Success course by the Public Health Informatics Institute (PHII)



What is a system requirement?

A system requirement is a documented representation of a system condition or capability needed by a user to perform a particular function.

Purpose of the requirements process

The primary purpose of the requirements definition process is to:

1. **Identify and capture the system needs** and expectations of partners and users.
2. **Define and document the necessary functionalities** and constraints of the system.
3. **Facilitate communication among partners** and users to ensure a clear understanding of the requirements.
4. **Establish a foundation** for system design, development, testing, and validation.

Why is requirements gathering important?

Requirements gathering is essential for successful projects—ensuring partner needs and expectations are met. Requirements gathering provides opportunities for the following key activities as part of updating or developing a system for surveillance.

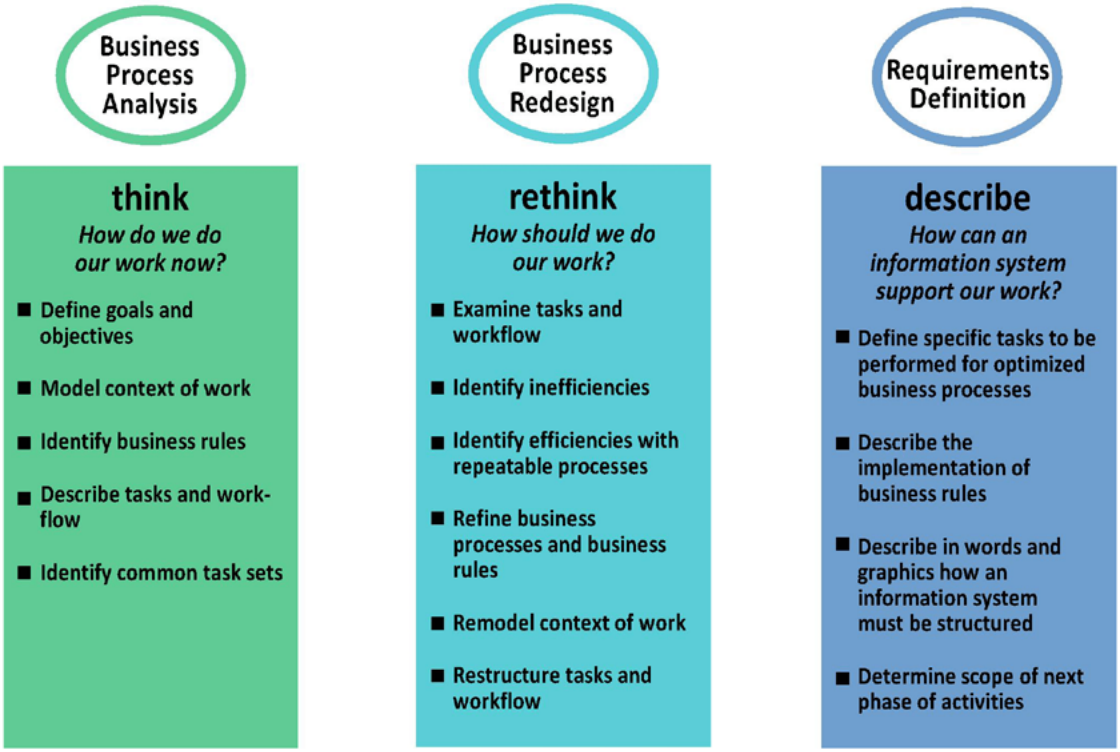
1. **Ensure partner alignment:** Engages partners to meet user needs and reduce misunderstandings.
2. **Reduce project risks:** Identifies issues early and keeps the project on track and within budget.
3. **Clarify timelines and resources:** Allows for accurate project planning and resource estimation.
4. **Facilitate collaboration:** Fosters effective relationships among program partners and internal and external data sharing partners.
5. **Enhance system functionality:** Supports the design of a scalable system integrated with other health information systems.
6. **Improve data quality and security:** Supports the adherence to best practices and regulatory standards.
7. **Support continuous improvement:** Regularly update requirements based on feedback.

What are requirements gathering methodologies?

The Public Health Informatics Institute (PHII) requirements gathering process, Collaborative Requirements Development Methodology™ (CRDM), provides a framework where participants are given tools and a process for documenting public health workflows and defining functional requirements for information systems that support those workflows. The framework navigates through three processes: business process analysis, business process redesign and requirements definition. As you follow the framework, you *think* about the current workflows, *rethink* how you may want to redesign current workflows and then *describe* how best an information system should support the new redesign.

Collaborative Requirements Development Methodology (CRDM) from PHII

Figure 2: Collaborative Requirements Development Methodology™ (CRDM)



THINK: Understanding current processes

Understanding current processes is crucial for enhancing BDS systems. Start by defining specific goals and priorities for the BDS program's data needs, aligning with the National Birth Defects Prevention Network (NBDPN) surveillance guidelines. Next, analyze current BDS processes, including data collection and reporting mechanisms as specified by state mandates or regulations. Document existing tasks, workflows and data movement and identify common task sets to recognize areas for improvement. Adding current quality control measures that are in place at this stage ensures data accuracy and consistency, laying the foundation for system enhancements.

RETHINK: Redefine current processes

Re-defining current processes is essential for optimizing BDS systems. This is an opportunity to consider new more effective, efficient and modernized ways of working. This involves examining current tasks and workflows to identify inefficiencies, such as redundant or error-prone processes in line with NBDPN standards. Consider restructuring tasks and workflows to optimize data collection, processing and reporting, ensuring the BDS program operates efficiently while complying with public health mandates.

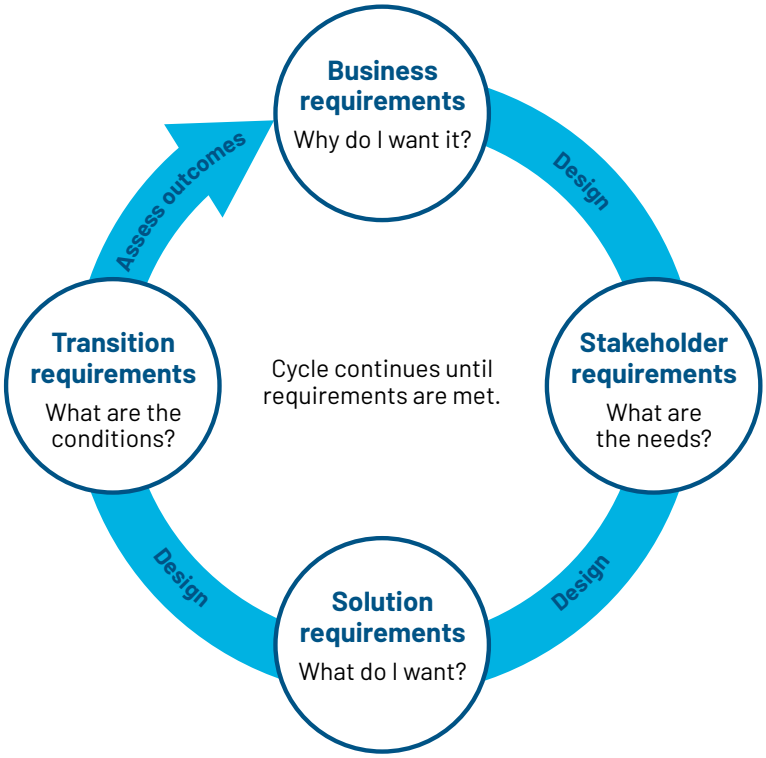
DESCRIBE: Define requirements

Defining requirements is a critical step. This toolkit will discuss more about this in the requirements gathering step by step process. However, within the CRDM methodology, this process begins with outlining tasks that align with the optimized BDS processes. Business rules are also detailed to ensure compliance and consistency across the program, referencing specific regulatory requirements as appropriate. Descriptions and visuals can also be used to illustrate the system structure to provide a clear understanding of how the system is expected to function.

Requirements Cycle

In addition to the CRDM methodology, the Requirements Cycle in Figure 3 describes an iterative flow of collecting, analyzing, documenting, and validating the requirements to achieve business goals and partner objectives. This cycle provides a slightly different take on the process of gathering requirements.

Figure 3: Requirements Cycle: A Guide to the Business Analysis Body of Knowledge



The requirements cycle encompasses defining business requirements to establish high-level objectives, partner or stakeholder requirements to identify partner needs, solution requirements to detail the solution's characteristics, and transition requirements to outline conditions for implementation. This iterative process ensures that each stage of requirements gathering is followed by system design, maintaining alignment with project goals and partner needs. Finally, the cycle includes assessing outcomes to evaluate if the requirements have been met and to identify areas for further refinement.

Business process analysis and workflow mapping

Both requirements gathering methodologies aim to complete the following activities, which will be discussed in detail later in this toolkit.

Current processes:

- **Mapping workflows:** Visualize current workflows to understand each step, partner involvement and system interactions.
- **Process analysis:** Identify bottlenecks and areas for improvement by examining workflows and collecting partner data.

Future state:

- **Envision improvements:** Propose changes to enhance efficiency and system performance.
- **Gap analysis:** Identify gaps by comparing the current state with the desired future state.

Future system requirements:

- **Detailed requirements:** Define functional and non-functional requirements for the new system.
- **Partner validation:** Ensure requirements meet user needs and organizational goals through partner engagement.

Prioritize requirements:

- **Critical versus non-critical:** Determine essential requirements for initial rollout and those for later phases.
- **Partner input:** Prioritize based on impact, feasibility and resource availability.

For additional information on the requirements definition process, refer to PHII's Collaborative Requirements Development Methodology (CRDM).

Getting started

Project planning

This toolkit emphasizes the requirements definition process. However, it is important to acknowledge that the planning period usually comes before the requirements definition process. The planning period includes defining the scope of the project, ensuring leadership buy-in and support, determining key partners, as well as exploring key objectives of the system update or development. The planning process helps to identify and mitigate problems or risks associated with the project. The outcomes from the planning process guide the subsequent steps within the system development life cycle, including the requirements development process. The following is a list of the key project planning steps with more description of these steps below.

Project planning steps

1	2	3	4	5	6	7
Leadership & resource allocation	**Identify partners**	**Assign roles & responsibilities & develop the workgroup**	**Define the scope of system upgrades/ development**	**Define the business case**	**Problem definition**	**Identify program priorities that would impact system needs**
Develop strategies for securing resources and buy-in from leadership and other key partners for updates to and maintenance of the BDS system.	Identify partners and other key individuals who will use or be impacted by the system (i.e., program/ department leadership, IT support, program staff, internal and external users, etc.).	Identify who will be part of the workgroup for the system update or development and their responsibility.	Clearly identify the expected scope for system updates.	Understand and document the business case and need for system development. This clearly developed use case will aid in gaining leadership and other key partner buy-in.*	Articulate the problems or opportunities to be addressed by the updated system.	Identify the BDS program priorities that would influence the system's development or update. Consider how the program priorities should be reflected in the needs and requirements of the system.

* Refer to Appendix for an example business use case.

Defining the workgroup and assigning roles and responsibilities

Partners and representative involvement

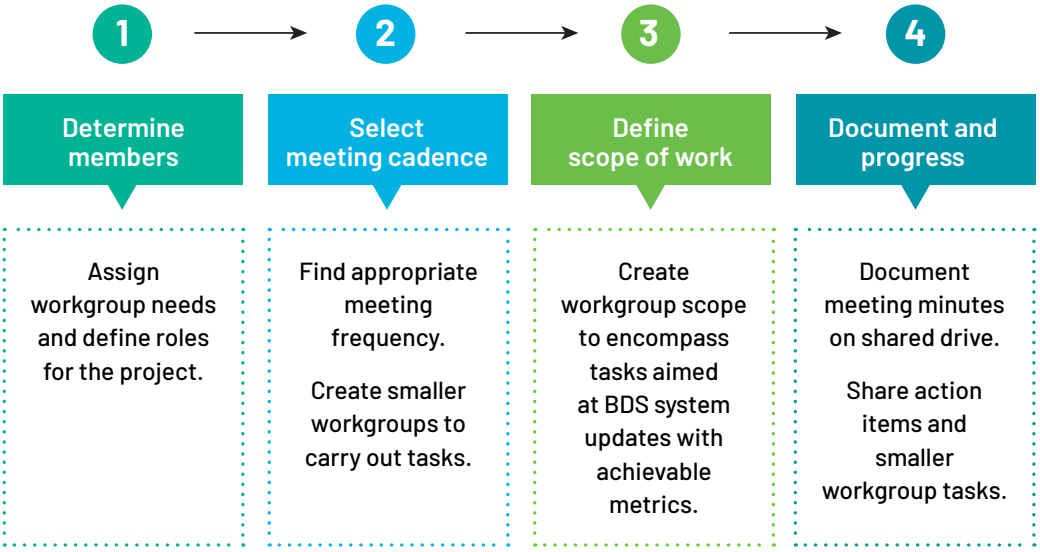
Bringing together the right partners and representatives is crucial for holistic requirements review. The Workgroup should comprise a core team who are responsible for all steps from start to finish. This team will be responsible for navigating the BDS program through the requirements definition process and engaging additional partners, including those who will participate periodically (e.g., medical record abstractors, reviewers), as needed for specific requirements gathering and validation phases. Representatives on the core team could include people from various roles in the BDS program and health department as appropriate (e.g., BDS program staff, researchers, IT staff, analysts, and other health department staff).

Partner involvement strategy

- Different members will be engaged at various stages of the requirements gathering process.
- Build the team meetings and structure. As this project kicks off, define the key players in the requirements gathering process. Then gather team resources, plan meetings and assign accountability to the project.
- Ensure representation from the IT department to address technical feasibility, integration and support considerations.
- If necessary, form smaller workgroups to maintain project momentum. Use a workgroup matrix template to organize and track these groups effectively.

Workgroup development

Figure 4: BDS System Updates Workgroup Development Example



Defining the business case

Purpose

A business case (sometimes called the value case) provides a comprehensive justification for initiating a new project. It serves multiple purposes, including obtaining leadership buy-in, securing funding, navigating policy hurdles, and gaining support for necessary changes. By clearly defining the problem and proposing a solution, a business case helps partners recognize the need for system changes and aligns goals between the health department and the IT department.

A well-constructed business case outlines quantitative benefits (e.g., decreased costs of identifying birth defects, improved efficiency) and qualitative benefits (e.g., enhanced data sharing partner satisfaction, improved data quality).

The business case will help leadership and management better understand the needs, outcomes and expected benefits of completing updates to the BDS systems.

The business case can be as complex or as simplified as the workgroup desires depending on the BDS program's needs.

Components of a business case may include:

- Executive summary
- Problem statement
- Proposed solution
- Benefits of the proposed solution
- Cost-benefit analysis
- Timeline for implementation
- Potential risks and mitigation strategies
- Recommendation

Business case example

See a business case example in Appendix: Sample business case.

Is your program prepared for a system update?

A good place to start when trying to answer whether your birth defects program is ready for a system update or development is the BDS PHII Readiness Assessment. While the Readiness Assessment focuses on interoperability and data exchange, reviewing the assessment may help your birth defects program gain an understanding of your current system and business processes, agency policies, available resources, existing partnerships, and IT considerations. The Readiness Assessment provides an approach to assess, identify and discuss information needs with internal and external partners. Starting here will give birth defects program staff a clearer understanding of success factors and the agency's current capabilities.

In addition to the Readiness Assessment, birth defects programs should review their own program and department's priorities, as some system changes are driven by external forces, such as agency data modernization initiatives, or by internal forces, such as the desire for enhanced functionality and improved efficiencies.

Requirements definition steps

Overview of the requirements definition process steps

After determining the need for system updates, documenting the business case, drafting timelines, securing leadership and partner buy-in, forming a system update workgroup, assigning responsibilities, and defining the system update scope, you are ready to identify and define requirements for a new or updated system for BDS.

What are requirements gathering methods?

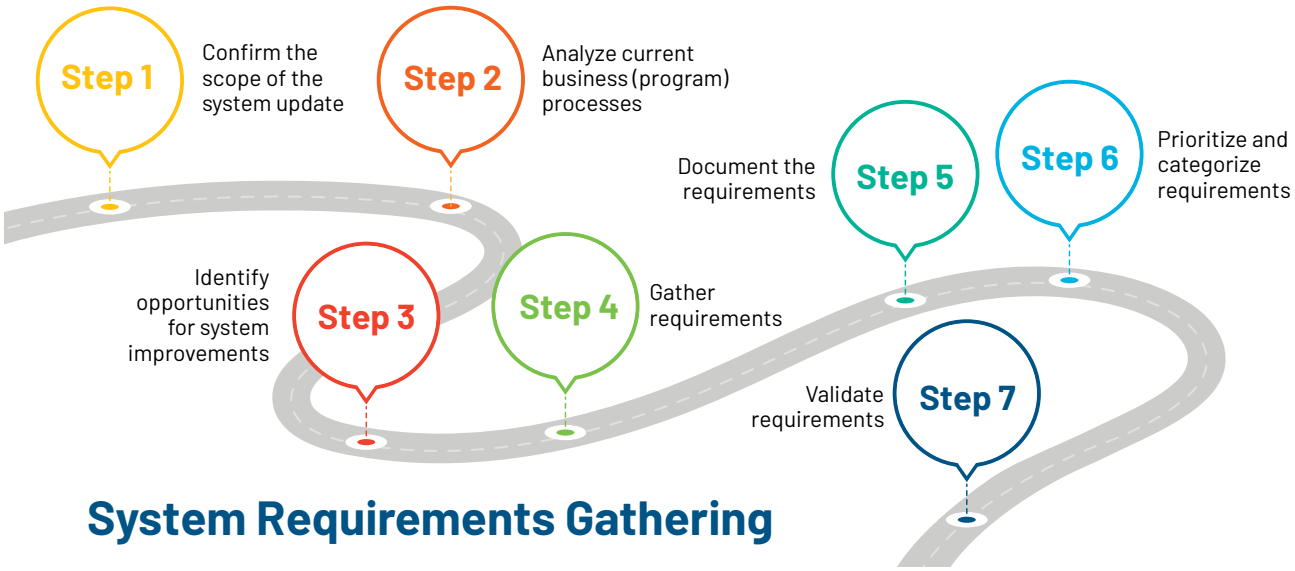
To elicit system requirements and business needs effectively, a number of methods and tools are used to identify the system needs from users and partners effectively. Different methods can be used for different purposes and lead to particular outcomes. It is recommended to use as many of these methods as possible to ensure comprehensive and accurate requirements gathering. The table below lists the requirements collection methods and the approach for which they are normally used.

Types of methods for gathering requirements from partners

Method	Description
Interviews and focus groups	Gather detailed insights and requirements on qualitative data.
Surveys and questionnaires	Collect data on user needs and system requirements.
Document analysis	Identify current system capabilities and gaps.
Workshops	Brainstorm and prioritize requirements.
Use case and workflow analysis	Identify inefficiencies and areas for improvement.
User observation	Gain insights into user interactions with the system.
Analyzing existing documents	Understand current processes, identify partners and uncover gaps or redundancies.
Joint Application Design (JAD)	Ensure accurate initial design and reduce project time.
Prototyping	Refine requirements through an iterative process.

(taken from Mamoun Eid, 2015)

Figure 5: Step-wise Requirements Gathering Process



Step 1: Confirm the scope of the system update

Understanding the scope of your system update is the first step in ensuring a successful project. For example, does your program need to update a few functions of the system, such as updating your linkage to Vital Records or is the program looking to update or develop an entirely new system? This process should be led by the system update workgroup and confirmed with leadership or other key partners.

Step 2: Analyze current business (program) processes

Gather existing business process documentation

Collecting existing documentation provides a solid foundation for understanding current processes and identifying areas for improvement.

- **Documentation sources:** Gather Standard Operating Procedures (SOPs), documented workflows, current data flows, and sources, etc. These materials will aid in reviewing requirements and determining which processes need to change or remain the same.
- **Process review:** Conduct a thorough review of the data flow process and key activities completed by BDS program staff, including any reported issues, to ensure the updated system effectively addresses these, if within the scope of the system update.

Step 3: Identify opportunities for system improvements

Based on the scope of the system update from Step 1 and the review of the current business (program) processes from Step 2, identify areas for system improvement and technology needs for the BDS program with the workgroup and other partners and users. This might involve changes to existing business processes, the addition of new processes or functionality, or the incorporation of new technology.

Step 4: Gather requirements

Use the requirements gathering methods listed in the "What are Requirements Gathering Methods" section of this toolkit to elicit ideas, needs, input, and unique system requirements from BDS program staff and other users and partners to meet the system improvement needs identified in Step 3.

Step 5: Document the requirements

Document the requirements in a format that allows for the validation, analysis and testing of each requirement. Requirements should be clear and unambiguous. Documentation of requirements typically includes functional, technical and performance requirements. These will help outline the purpose, features, functionalities and behavior of a system and provide clarity around system improvements.

For additional information on the requirements definition process refer to the BDS Business Process Analysis and System Requirements Webinar.

Requirements Gathering Checklist

Below is a checklist that can help a program as it goes through the requirements gathering process.

Step 1. Confirm the scope of the system update

- ❏ Gather system update workgroup members.
- ❏ Document the scope of the system update and why it is needed.
- ❏ Obtain buy-in from leadership.

Step 2: Analyze current business processes

- ❏ Gather standard operating procedures, documented workflows and data flows.
- ❏ Conduct a thorough review of the data flow process and key activities.
- ❏ Determine what processes need to change or remain the same.

Step 3: Identify opportunities for system improvements

- ❏ Review tasks and workflows that were documented in Step 2 and identify necessary changes.
- ❏ Identify specific functions and capabilities needed.
- ❏ Refine and document new business processes, tasks, workflows, and rules to align with enhancements.

Step 4: Gather requirements

- ❏ Schedule and conduct meetings with all involved parties to gather requirements.
- ❏ Elicit system requirements from BDS program staff and others to meet enhancement needs.
- ❏ Refer to the "What Are Requirements Gathering Methods" section of the toolkit.
- ❏ Identify technologies or systems needing integration with the new solution.
- ❏ Consider including databases, data warehouses, electronic health records (EHRs), or other specialized software.

Step 5: Document the requirements

- ❏ Document the requirements in a format that allows for the validation, analysis and testing of each requirement.
- ❏ Use clear, concise and unambiguous language in the requirements.

Step 6: Prioritize and categorize requirements

- ❏ Consider all the requirements gathered and prioritize using a structured approach such as the MoSCoW method to rank requirements with input from all partners.
- ❏ Develop a timeline that sequences requirements.
- ❏ Document prioritized and sequenced requirements.
- ❏ Conduct an iterative review of the requirements to align with project goals and expectations.

Step 7: Validate requirements

- ❏ Review program-specific needs and policies to ensure the requirements meet all regulatory requirements.
- ❏ Review the final list of requirements for accuracy.

Step 6: Prioritize and categorize requirements

To ensure a coherent and effective requirements gathering process, it is essential to prioritize and sequence requirements before moving to validation. This approach will streamline the workflow and enhance clarity for all partners involved.

Prioritize criteria

- **Mandatory requirements:** These are critical features that the system must have to meet core objectives.
- **Optional requirements:** These features enhance the system, but are not essential for initial deployment.
- **Future enhancements:** These are features that can be considered for future phases once a minimal viable product (MVP) is developed. Using a MVP approach to development can deliver a product that initially meets the high priority requirements and user needs while allowing for interactive feedback and improvements. An MVP is also a useful approach to help manage scope creep and avoid delays.
- **Impact on core objectives:** Assess how each requirement contributes to the primary goals of the BDS system and program.
- **Urgency:** Determine the time sensitivity of implementing each requirement.
- **Partner consensus:** Gather input from all partners to gauge the importance of each requirement.

Prioritization process:

- Use a structured approach such as the MoSCoW method (Must have, Should have, Could have, and Won't have) to prioritize requirements.
- Rank requirements within each category based on their criticality to the program and urgency to begin implementation. This will also help decide if certain requirements can be delayed or postponed due to other external factors and constraints.

Sequencing requirements:

- Develop a timeline that sequences the initial implementation of requirements based on their priority.
- Ensure that high-priority requirements are addressed first, followed by lower-priority items.

Documentation and communication:

- Create a detailed requirements document that outlines the prioritized and sequenced requirements.
- Communicate the prioritized list to all partners to ensure alignment and manage expectations.

Iterative review:

- Regularly review and update the prioritized requirements list based on feedback and evolving needs.
- Ensure continuous alignment with project goals and partner expectations.

Assessment and evaluation through ranking

The Project Management Institute (PMI) *Guide to Business Analysis* advocates for a structured assessment and ranking of requirements. This ensures critical needs are prioritized, guiding resource allocation and decision-making to focus on pressing issues and maximize impact. Ranking requirements involves evaluating each requirement's significance, urgency and impact, considering factors such as customer satisfaction, regulatory compliance, operational efficiency, and financial implications.

Once ranked, creating a development roadmap becomes easier, with high-priority requirements addressed first. This approach enhances efficiency by channeling resources to critical areas. Prioritizing requirements also improves communication and alignment among partners, fostering effective collaboration and reducing confusion.

This process considers benefits, costs, risks, dependencies, time sensitivity, and compliance, aiming to deliver a MVP that meets essential user needs and gathers feedback for iterative improvements.

Step 7: Validate requirements

Validation is a critical step to ensure the requirements are complete, accurate and aligned with the project's goals. During the validation process, consider the program-specific needs and policies to ensure the system meets all regulatory requirements. Take the final list of requirements back to the internal workgroup to ensure they were captured accurately and that the most critical needs are addressed for the program.

Next steps:

Once requirements are documented, it is important to communicate the findings and outcomes of the requirements gathering process. This involves distributing and confirming the final requirements with the entire workgroup, developing an implementation plan, project budgeting, and communicating with leadership and/or vendors as appropriate.

To finalize the requirements and prepare for the next phases of the project.

1. **Approval:** Secure approval for the final set of requirements from all relevant partners.
2. **Traceability:** Ensure each requirement has a unique identifier to facilitate traceability throughout the development life cycle.
3. **Communication:** Communicate the requirements clearly, especially if vendor selection is involved, whether internal or external. This step ensures that all parties understand the project's needs and expectations.

Conclusion

Summary

This BDS toolkit serves as a comprehensive guide for programs seeking to upgrade their standalone systems with enhanced capacity for integrating the BDS system into health departments or incorporating data from other systems, such as Vital Records. It provides a step-by-step approach to gathering requirements, facilitating collaboration with data sharing partners and exploring potential data exchange and sharing solutions.

The BDS toolkit addresses a wide range of needs, from simple database transitions to complex cloud-based system updates. By prioritizing requirements gathering, BDS programs can ensure their upgrades align with their goals and contribute to better public health outcomes.

In conclusion, this toolkit empowers BDS programs to navigate the complexities of system upgrades, ultimately leading to improved surveillance and better health outcomes for mothers and babies.

Appendices

Appendix: Sample business case

(to be revised by programs to reflect their circumstances)

Problem statement

The current Birth Defects Surveillance (BDS) system faces challenges related to delays in data collection and data management. Current data collection methods require the BDS program to wait X-Y months for healthcare facilities to submit potential birth defects cases to the health department. Each case must undergo a medical record review with manual data entry into the current BDS system to ensure complete and accurate data collection. As a result, the BDS is not able to complete data collection for a birth cohort until 2 years after the surveillance year. These inefficiencies in tracking birth defects increase program costs and delays in the program's ability to monitor changes in birth defects prevalence that alert the program to emerging threats. They also limit the ability to conduct outreach to impacted families to ensure they are connected with services such as the state early intervention program to promote health and wellbeing. In addition, there are evolving technical advances in reporting that can be leveraged to the BDS program. However, these would require a more robust and agile system. For instance, electronic case reporting (eCR) is evolving as a tool that can be used in BDS reporting. However, the current system cannot ingest electronic initial case reports.

Proposed solution

To improve the effectiveness and accuracy of the BDS system, the proposed solution is to integrate it with the electronic case reporting (eCR) program. For instance, integrating eCR data streams will allow for more accurate and timely birth defects data collection from health clinics to local government health departments, eventually feeding into state and federal systems such as the Centers for Disease Control and Prevention (CDC). This integration will facilitate early intervention and improved public health responses.

This integration will leverage the existing framework for reporting epidemic and non-epidemic priority diseases, leading to enhanced data accuracy, completeness, timeliness, and comprehensiveness. Currently, X% of BDS data exchange partners are enrolled in the state eCR program and Reportable Conditions Knowledge Management System (RCKMS) specifications have been released for X of the Y conditions covered by the BDS program. While eCR is not yet ready to fully replace current BDS data collection methods, the anticipated continued healthcare system onboarding and release of BD RCKMS specifications make this a viable data collection solution into the future.

Benefits

The project aims to provide several benefits, including:

a) Alignment with state data modernization initiatives

b) Improved data accuracy and timeliness of data reporting

c) Enhanced data processing and analytics capabilities

d) Compliance with state and federal reporting standards

e) Improved system scalability, sustainability and reliability

f) Efficient duplicate detection processes

g) Reduction in staff turnover through continued capacity building

h) Time savings in reporting allocation and data entry processes

i) Enhanced public health responses and outcomes

Cost-benefit analysis

The projected expenditure for the project is $X00,000 over a period of Y months, encompassing software development, data integration, staff training, and future system maintenance costs anticipated to be $X00,000 per year. The current BDS system has an annual maintenance cost of $X00,000 per year. The advantages of implementing the upgraded BDS system would be improved accuracy, completeness and timeliness of reporting data pertaining to birth defects, and long-term cost savings for both healthcare systems and the BDS program by capitalizing on investments already made by the agency and its data exchange partners. The continued utilization of the current system will result in persistent inaccuracies, misallocation of data sources, inefficient tracking of birth defects, and higher long-term costs.

Implementation plan

The project will follow an agile methodology with iterative requirements gathering and validation cycles, and regular partner reviews. Key milestones and timelines include:

1. **Initial planning and assessment:** Conduct a readiness assessment using the Birth Defects Surveillance Readiness Assessment framework provided by PHII to identify gaps and develop a tailored plan.
2. **Requirements gathering:** The following partners are engaged in requirements gathering to ensure the new system meets the BDS program, eCR program and IT needs through brainstorming sessions, design thinking workshops and focus group discussions to gather detailed requirements about the existing processes and systems.
3. **System design and development:** It is critical to design and develop the upgraded system according to the defined requirements.
4. **Testing and validation:** Conduct thorough testing and validation of the system to ensure it meets the defined requirements.
5. **Training and deployment:** Provide comprehensive training for staff and deploy the system in a phased manner.
6. **Monitoring and evaluation:** Continuously monitor the system's performance and make necessary adjustments based on feedback and evolving needs.

List of tools/templates and their descriptions

The tools and templates below can be downloaded from the BDS PHII website.

PHII BDS Readiness Assessment

Designed to help birth defects programs gain an understanding of their current system and business processes, agency policies, available resources, existing partnerships, and IT considerations to determine readiness for automated electronic data exchange using health information standards.

Requirements Checklist

Provides a one-page checklist of key tasks that should be completed as part of the requirements gathering process. This checklist can be used to ensure steps are not omitted.

References

Citations and resources

This section includes citations used in the document and additional resources.

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