CSHP 2015 TOOL KIT (OBJECTIVE 4.7): ONE DOSE AT A TIME: IMPLEMENTING A UNIT-DOSE MEDICATION MANAGEMENT SYSTEM

Developing the Project Plan

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Introduction

The process for approving projects varies from one organization to another; it is typically complex, and multiple reviews and sign-offs are usually required.

It is important to have an understanding of the organization's processes, as well as the political and financial environment, and that the plan reflects the organization's process. Key stakeholders (e.g., the project sponsor, senior leaders) should be asked to provide sign-off for the project plan, before funds and other resources are released and the project is initiated. That sign-off usually takes the form of a project charter.

The development of a thorough plan requires effort and knowledge of what to expect to occur during implementation. The plan does not need to be perfect; in fact it will not be. It is important that the plan be prepared with sufficient detail to guide implementation yet be revised from time to time, adjusting to changing circumstances.

Developing the Project Charter

Purpose of Project Charter

A project charter is a document by which the project sponsor formally authorizes a project,¹ usually following the review of a business case. It is created so that everyone with a stake in the project's success can reach agreement on the following fundamental characteristics of the project:

- why the project is being conducted
- the objectives and scope of the project
- what results the project will deliver
- how and through whom the project will deliver those results
- how the project will be managed

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The project charter comes into effect after the project has received approval and funding to proceed.

The project manager creates the initial draft of the project charter. The primary audience for the project charter includes, but is not limited to, the following stakeholders:

- project sponsor: must review, approve, and accept the charter, including approving the definition of project and how it will be managed
- members of the project team: must understand their respective roles, the deliverables they will be producing, and the project management procedures under which they will work
- health organization staff: must manage or follow (depending on their role and responsibilities) the new procedures upon completion of the project
- other departments and stakeholders as appropriate (e.g., nursing, physicians, materiel management, other clinics or departments affected by changes in pharmacy packaging or stocking procedures): must understand how their work will change after implementation

Once accepted, the project charter defines the "contract" between the project sponsor and the project manager. The project charter is a "living document" that will be revised to reflect any changes to the project, ensuring that it continues to reflect a valid definition of the "contract".

Components of Project Charter

The project charter should consist of the following elements,² at a minimum.

Overview of Project

The project charter should include an overview, which is the executive summary of the project. The overview includes the following information about the project:

• the reason for carrying out the project;

The project charter

- defines the "contract" between the project sponsor ar the project manager
- is revised to reflect changes to the project



- the intended solution (and possibly any potential solutions that have been discarded);
- the intended solution (and possibly any potential solutions that have been discarded);
- the scope of the project and exclusions;
- the risks associated with the project, as well as the risks of not proceeding;
- the names of the project manager and sponsor and other members of the project team;
- the required resources;
- the time frame of the project;
- a summary of any constraints (see below); and
- a description of what will mark successful completion of the project should also be

Goals of Project

included.

To ensure project success, a statement of deliverables, including what will be achieved through the project and a timeline for these achievements, is required. This statement, which serves as a goal, may include interim deliverables, along with the complete list of goals and objectives for the project.

The following are examples of specific objectives that could be included in the project charter for implementation of a unit-dose system: interface automatic tablet counting and packaging (ATC) machine to pharmacy information system by X date; convert nursing units to ATC packaging over Y months.

Statement of Scope

The scope of the project consists of all items that are considered to be covered by the project. For instance, a unit-dose project might encompass all solid oral doses and selected oral liquids and rectal products. The locations that will be affected by the project should also be specified.

The scope should align with the goals of the project (e.g., a project goal might be that 99% of solid oral doses are packaged in unit-of-use packaging for 90% of inpatients).



Statement of scope





Statement of Out-of-Scope Items

In addition to specifically stating what the project will do, it is important that the charter describe what the project will not do. All items that are potentially related to the project but that will not be addressed by the project (e.g., the project might not include the unit-dose packaging of oral liquid antacids, or the use of automated dispensing cabinets as a delivery option) should be listed in the out-of-scope statement, along with any specific items or issues that may arise from the exclusion.

Milestones

The significant events such as phases, decision points should be summarized in this section, giving the reader a high-level schedule for the project.

Deliverables

The deliverables of the project include all anticipated outcomes. Deliverables may take the form of policies, procedures, manuals, educational sessions, hardware, software, and physical products.

Impact Analysis

The impact analysis looks at all areas and processes that will be affected by the project. The analysis will help provide an informed opinion in identifying the factors required for successful implementation of the project. For a unit-dose project, the impact analysis should consider the effects of implementation on both pharmacy and patient care (primarily nursing). These effects may include needs for additional pharmacy staff for packaging or delivery, a process for interim dose delivery, and nursing education, as well as consideration of the budgetary implications of the new unit-dose system.

Critical Success Factors (Dependencies)

After determining the project's goals, analysis is required to determine what factors are critical to the project in meeting the goals. These factors may be internal and/or external to the organization and may include the number of staff required to work on the project, the specific types of hardware and software that may need to be purchased, other specific budgetary expenditures, and educational activities.





Constraints

Constraints are those resources (human, financial, or other) or issues that may restrict or otherwise affect the project manager and project team in achieving the project goals. For example, the need for an educational presentation to nurses may be considered a critical factor for success, but an inability to get nurses to the session on time may represent a constraint.

Project Team

A successful project team or task force should consist of a project sponsor from the executive team, a steering (or oversight) committee, a project manager, and an implementation team. The sponsor, the project manager, and some members of the working team may be included on the steering committee.

The roles, responsibilities, and reporting relationship of each position on the project team, should be clearly defined. In particular, the issues that will require input from the steering committee and approval of the project sponsor should be clearly stated. For larger projects, a project organization chart may be used to demonstrate the reporting and working relationships between project members. Some project members may be required to perform certain specific tasks or may be required only at specific points in the project (e.g., an information technology technician may be required when creating the interface between the ATC packager and pharmacy software, but not for other steps of the project).

The chart on the following page shows one possible organizational structure, including membership and responsibilities, to ensure appropriate use of resources.





	Member(s)	Responsibilities
Executive	 Hospital executive (e.g., Vice President) 	Provides leadership and support for the project
Steering Committee	Project sponsor: an executive responsible for the overall project deliverables; usually a	Provides overall direction and guidance for the project
	member of the senior leadership team (e.g., vice president)	Ensures that stakeholders' interests are taken into consideration
	 Project champion: person responsible for promoting the project from conception to 	Resolves issues that arise during the project
	completion and approval	Reviews and approves deliverables and changes
	 Project manager: person responsible for ensuring that the project is completed on time, on budget, and to the agreed- upon specifications. 	to the project
	Pharmacy manager(s)	Provides expert advice to
Project Team	 Nursing manager(s) 	the project manager and guides working groups
	 Pharmacist or pharmacy technician 	through completion of their tasks
	Nursing staff	Is involved in planning,
	 Representative of professional practice department (if one exists) 	monitoring, controlling, and ensuring success of the project
	 Representative of information technology or clinical informatics department 	 Refers issues and risks to steering team when they cannot be resolved within the project team or task
	Representative of finance or decision support department	force
	 Representative of building and facilities maintenance department 	
	 Change management expert (if available) 	
	Others may be added but team size should be under 10 to ensure effectiveness.	



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	Member(s)	Responsibilities
Working	Examples include: Pharmacy and nursing 	Deliver all interim and final deliverables
Group	 Procurement 	 Report to the project team or task force
	Information technology and clinical informatics	through a designated team lead
	Communications and change management	
	Building and facilities maintenance, planning, space allocation	

Project Management



Project management describes how the project manager and other members of the project team will ensure the project is implemented, producing the desired outcomes. Items to include in information about project management will be the reporting structure (e.g., to whom, how often, and in what format progress reports will be made), issue management (how unforeseen issues will be handled, including which issues will be sent to the steering committee or project sponsor for resolution), scope management (how requests for adjusting the scope of the project will be handled), management of changes in business processes (how the project will be integrated into existing processes within the hospital or health region), communication management (how often and in what format stakeholders will be updated on progress), management of hand-off or project closure (how the project will be transitioned into the normal operating processes of the pharmacy, hospital, or health region and what celebrations will be planned at the conclusion of the project).

Revision log

As noted above, the project charter is a "living document" and may be revised as the project moves forward. Diligent use of a revision log for the charter will aid in determining the progress of the project, as well as when and why changes to the original project



occurred and how these changes may affect the project's success.

Charter sign-off

As noted above, the project charter is a "contract" between the project sponsor and the project manager, determining both the resources available to the project and the deliverables expected. Sign-off on the original charter and any revisions indicates acceptance by both the project sponsor and the project manager.

Creating the Detailed Implementation Plan

Building on the project charter, establish a plan that will guide the implementation of the new system.

The following section is based on the publication, by Haughey, entitled "Project Smart 2000–2010: project planning: a step by step guide."³

The plan should include the following elements:³

Draft of the project schedule

The project schedule should include the goal(s) of the project and the project deliverables, both drawn from the project charter.

The following activities should be undertaken when preparing the schedule.

- Prepare the overall schedule according to the time frame of the project, as per the project charter.
- 2. Estimate a date for each deliverable.
- 3. Establish milestones and estimate target dates to achieve these milestones.
- For each deliverable, create a list of subdeliverables and related tasks to meet the goals; specify when and how each item must be delivered and task completed.
- 5. Identify the following for each task:
 - a. the number of hours or days required to complete the task; and





- b. the staff responsible for each task (see human resources plan, below).
- 6. Determine more accurate delivery dates, and update the deliverables section of the plan as needed. A Gantt chart is a useful tool to chart the project schedule and deliverables.

Development of supporting plans

Supporting plans for human resources, communications, issues, and downtime can be included in the project plan. Examples of what to include in the plans are provided below. Also, refer to the Appendix: Tips or Tools to Address Common Barriers and Other Challenges for more information about issues that can arise and suggestions on how to address them.

Human resources plan

- Describe the number and cadres of personnel required to carry out the process.
- Identify the individuals, and describe their roles and responsibilities.
- Identify when the personnel will be needed and for how long.
- Determine their availability and whether backfilling of their regular positions is required.

Communications plan

- Determine who needs to be kept informed about the project and how such communication will be accomplished (usually a weekly, biweekly, or monthly progress report).
- In each progress report, describe how work on the project is progressing, the milestones that have been achieved, and what is planned for the next phase.

Issues plan

- Create a plan to deal with any problems that may be identified by stakeholders and other people involved in the project.
- The plan should allow for potential solutions to be discussed and implemented.





Downtime plan

Have a backup plan in case of technology failures.

Selection of performance indicators

Performance indicators should be chosen to assess the effectiveness of the unit-dose distribution system. Specifically, the indicators should reflect the issues that were the impetus for the change, and the goals and expected benefits of the unit-dose project. For samples of performance indicators, please see the section on <u>Checking Performance</u>.

Creation of a testing environment

A testing environment should be created to validate all assumptions, testing all functions of any interfaces between the unit dose system and other related systems, to ensure that all parts of the unit-dose system are working as anticipated. The plan should include the resolution of any issues or problems before the system operates in a live environment.

Developing an adequate testing environment entails the following tasks:

- Establish testing plans and procedures.
- Determine who will do the testing.
- Determine the equipment required for the testing environment.
- Develop a plan for ongoing testing as new programs and enhancements are added to the system.

Appendix: Tips or Tools to Address Common Barriers and Other Challenges

Planning for and implementing a unit-dose drug distribution system is not without its challenges. The type and extent of challenges experienced by an organization as it transitions to a unit-dose drug distribution system will likely vary among organizations. However, there will likely be some common issues. The following table is based on the







experience of organizations and highlights the types of challenges experienced and offers tips, tools and advice for preventing or responding to the challenge.

POTENTIAL BARRIERS or CHALLENGES	TIP or TOOL	ADVICE
Resistance to change (staff)	Develop or adopt a change management model	Create a sense of urgency, engage the team, demonstrate short-term wins, communicate, and do not give up! Adapt change management tools to fit the situation (See the Additional Resources section of <u>Soliciting the Organization for Support</u>)
	Develop posters	
	Host regular meetings	Encourage feedback and a sense among front- line staff that they are being listened to and that their observations are valued
	Develop collaborative team work	
	Establish pharmacy and nursing groups	This should include representatives of users of the proposed unit-dose system (e.g., pharmacy technicians, nurses), so they feel they are being listened to and their suggestions will be implemented if consensus indicates they will be effective.
	Assign project champions	
	Provide on-going support	Provide support. There will be lots of questions, concerns and suggestions during the first few weeks of implementation, but the system should be periodically re-examined on a regular basis to ensure goals of efficiency, effectiveness and safety are being met.
Meeting training requirements	Use simulation set up	To alleviate anxiety about the new system, set up a simulation as a "show and tell" so that everyone has a chance to see what the process will look like and to ask questions.
	Develop super users	Identify at least one person per shift who can answer questions and solve problems
	Provide one on one training	Provide such training only if needed for specialized activities. Otherwise, training can be presented in small-group sessions.
	Develop a manual	A process manual should be available to all staff, with a segment for each job activity, so





POTENTIAL BARRIERS or CHALLENGES	TIP or TOOL	ADVICE
		that everyone can see the responsibilities of all staff members.
	Develop "cheat" sheets	
Developing a workable process flow	Provide and accept feedback	Feedback should be encouraged and acted upon, if appropriate. If no action is taken, the reason should be explained.
	Encourage collaborative environment	Everyone should be encouraged to offer suggestions to show front-line staff that they have a stake in the success of the project and to forestall frustrations (and potential attempts as sabotage or subversion).
	Create a problem log	A problem log may be useful in getting a sense of recurrent problems that may require a change in procedure and/or processes.
Addressing problems with the technology	Create an online problem log	A problem log may be useful in getting a sense of the frequency of recurrent problems with equipment or interfaces.
	Record and respond to common complaints (frequently asked questions)	
	Request assistance and training from vendor	
	Develop or adopt a change management model	
Working with dual processes during transition	Parallel system will be necessary if the whole site is not being converted to the unit-dose system all at once	The period of overlap should be as short as possible to minimize the inefficiency of running 2 systems side by side.
Addressing interface issues (vendors, IT)	Test interfaces before program is implemented	Any segments of the system that rely on interfaces must be thoroughly tested and running well before the program is implemented.
Dealing with supply-related	Work closely with the manufacturer/ supplier to ensure	Monitor supply levels to avoid stock-out. Be aware of the differences between supplies





POTENTIAL BARRIERS or CHALLENGES	TIP or TOOL	ADVICE
issues (drugs, supplies for unit dose system, etc.)	consistent supply chain	(e.g., labeling, packaging materials) and any additional work to adjust the system to a new supply, if needed.
Lack of standardized bar coding	Early in project, consider how bar coding will be used so that strategic decisions can be made for future use	Anticipate issues that might arise with regards to the decisions whether to implement bar coding. Refer to the <u>Canadian Pharmaceutical Bar-</u> <u>coding Project.</u>
	Decide how the bar coding will be done (e.g., created in house)	
	Consider how bar coding will be used for bedside medication verification	
Handling various controlled substances (e.g., narcotics, controlled drugs)	Continue to provide in multi-dose packaging	Controlled substances will likely continue to be supplied in a multi-dose fashion (using "blister cards") as a means to meet the requirements for security and accountability of these products.
Cross- contamination of highly allergenic products e.g., beta- lactams	Frequently clean packaging equipment Consider segregating the packaging of these substances, using a different method to package	All unit-dose packaging equipment must be thoroughly cleaned and inspected before packaging a different drug to prevent exposing a person to a highly allergenic product (e.g., penicillin) through cross-contamination and to ensure that mislabeling does not occur.
Staff exposure to hazardous pharmaceuticals	Label as hazardous substance or as chemotherapeutic (as relevant)	 Hazardous products should be labeled to prevent nurses and other staff from being exposed to such product inadvertently. Refer publications that guide the safe handling of these substances. The following are examples of such papers: <u>Prevention Guide - Safe Handling of Hazardous Drugs</u>. Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales (ASSTSAS); (2008). Working Committee on the Safe Handling of



POTENTIAL BARRIERS or CHALLENGES	TIP or TOOL	ADVICE
		 Hazardous Drugs. [Printed in French and English] <u>National Institute for Occupational Safety</u> and Health (NIOSH) Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. National Institute for Occupational Safety and Health; (2004). <u>NIOSH List of Antineoplastic and Other</u> Hazardous Drugs in Healthcare Settings 2012.
Maintaining the cold chain	Use reminder notices to direct proper drug selection and handling	Items requiring refrigeration will not fit into the typical unit dose cart system. A reminder card may be placed in the patient's medication drawer directing the nurse to retrieve the product from the ward fridge.
Storing bulky products	Use reminder notices to direct proper drug selection and handling	Reminder cards may be placed in the patient's medication drawer directing the nurse to the location where these products are stored.



Literature Cited

- 1. Treasury Board of Canada Secretariat. Project Charter Guide. Ottawa (ON); 2008 [cited 2011Dec21]. Available from <u>http://www.tbs-sct.gc.ca/emf-</u> <u>cag/project-</u> <u>projet/documentation-</u> <u>documentation/guide-</u> <u>guide/guide-guide00-eng.asp</u>
- 2. Treasury Board of Canada Secretariat. Project Charter Template. Ottawa (ON); 2008 [cited 2011Dec21]. Available from <u>http://www.tbs-</u> <u>sct.gc.ca/emf-cag/project-</u> <u>projet/documentation-</u> <u>documentation/template-</u> <u>modele/template-modele00-</u> <u>eng.asp</u>
- Haughey D. Project Smart 2000– 2010. Project planning a step by step guide. Project Smart. (UK); [no date]. Available from: <u>http://www.projectsmart.co.uk/p</u> roject-planning-step-by-step.html

Additional Resources:

<u>Sample mini-project charter</u> (Regina Qu'Appelle Health Region, Saskatchewan)

<u>Project Charter Management Plan</u> <u>Template</u> (Regina Qu'Appelle Health Region, Saskatchewan)

<u>Project Charter Template</u> (Royal Victoria Regional Health Centre, Barrie, Ontario)

