

# Using Lessons Learned from Medical Checklists to Simplify CMMI Processes

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<sup>SM</sup> CMMI is a service mark of Carnegie Mellon University.

*How big do  
think the first  
process should  
be?*



# Agenda

1. Background
2. Matching Process Complexity with Need
3. Guidelines for Creating Checklists
4. Example Service Requirements Management (REQM) Process
5. A Checklist for Checklists
6. Summary



## References

- <http://www.processgroup.com/monthlytidbits.html#tidbit8>
- <http://www.processgroup.com/monthlytidbits.html#tidbit11>

# Background

- World Health Organization Goal: **Improve surgical procedures worldwide\***.
- A **medical checklist** was created based on aviation checklists.
- **Premise**: a simple checklist can ensure that **critical steps** have not been overlooked, either due to **haste**, **forgetfulness** or **inexperience**.
- Measurements were collected from surgeries performed around the world, before and after the checklist. **Results**:
  - Major **complications** down by 36%
  - **Infections** down by ~50%
  - Patients **returned** to surgery because of **problems** down by 25%
  - **Harm** suffered from surgery (over 4,000 patients) down by 150
  - 27 fewer **deaths** (47% drop) caused from surgical complications



\*Atul Gawande, associate professor of surgery at Harvard Medical School  
*Checklist Manifesto: How to Get Things Right*

# Surgical Safety Checklist



## Before induction of anaesthesia

(with at least nurse and anaesthetist)

**Has the patient confirmed his/her identity, site, procedure, and consent?**

Yes

**Is the site marked?**

Yes  
 Not applicable

**Is the anaesthesia machine and medication check complete?**

Yes

**Is the pulse oximeter on the patient and functioning?**

Yes

**Does the patient have a:**

**Known allergy?**

No  
 Yes

**Difficult airway or aspiration risk?**

No  
 Yes, and equipment/assistance available

**Risk of >500ml blood loss (7ml/kg in children)?**

No  
 Yes, and two IVs/central access and fluids planned

## Before skin incision

(with nurse, anaesthetist and surgeon)

**Confirm all team members have introduced themselves by name and role.**

**Confirm the patient's name, procedure, and where the incision will be made.**

**Has antibiotic prophylaxis been given within the last 60 minutes?**

Yes  
 Not applicable

**Anticipated Critical Events**

**To Surgeon:**

What are the critical or non-routine steps?  
 How long will the case take?  
 What is the anticipated blood loss?

**To Anaesthetist:**

Are there any patient-specific concerns?

**To Nursing Team:**

Has sterility (including indicator results) been confirmed?  
 Are there equipment issues or any concerns?

**Is essential imaging displayed?**

Yes  
 Not applicable

## Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

**Nurse Verbally Confirms:**

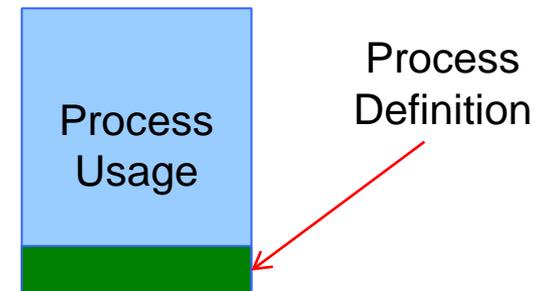
The name of the procedure  
 Completion of instrument, sponge and needle counts  
 Specimen labelling (read specimen labels aloud, including patient name)  
 Whether there are any equipment problems to be addressed

**To Surgeon, Anaesthetist and Nurse:**

What are the key concerns for recovery and management of this patient?

# Matching Process Complexity with Need

- The **time** needed to **write** a process is usually a lot less than the time spent **using** it. E.g.,
  - A **project planning** process of 1-2 pages may take a 2 days to develop and then be used numerous times.
  - A spreadsheet for **risk management** may take ½ day to develop and manage numerous risks over many years.
  - The **benefit** of using it **outweighs** the **cost** of developing it.
- **Places where a small process might be adequate:**
  - **SVC**: REQM, PP, PMC, CM, MA, OPF, OPD, OT.
  - **DEV**: OPF, OPD, PI (small DEV projects), OT
  - .... process includes all Generic Practices



# Guidelines for Creating Checklists -1

- Two main styles of checklists:
  - “**Do-Confirm**” – verify critical steps
  - “**Read-Do**” - perform given specific situations
- Select **pause points** in work flow where the completion of critical steps can be verified.
- Condense the checklist onto **one page** and use single **bullet point** sentences.
- Checklist items are **critical (high-risk)** and are not covered elsewhere.
- Run the **checklist verbally with the team** to ensure that anyone that has an issue can speak up.
- **Revise the checklist** numerous times until it is able to quickly **detect serious problems**.

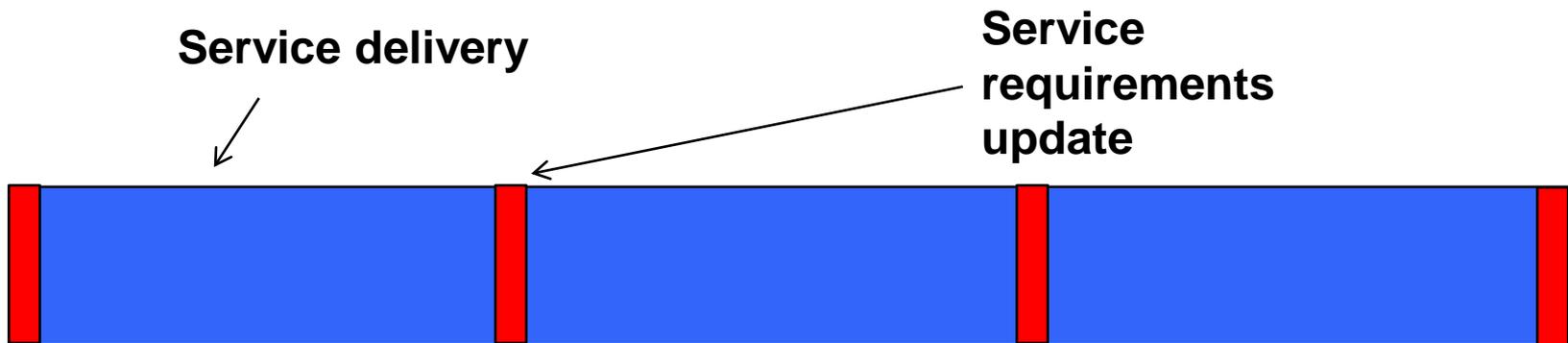
## Read-Do

### CM Process

1. List Configuration Items  
  
x, y, z
2. Establish File Naming Convention  
  
*File-x<n>.docx*
3. Establish Baseline File Structure  
  
~~~~~
4. ~~~~

# Guidelines for Creating Checklists -2

- Move implementation details as **help text or training**.
- Treat the process as “**day-to-day usage**,” not beginner.
  - This is where the majority of time will be spent.
- **Example scenario:**
  - **Service requirements** don't change much (or at all) over time.
  - REQM is **used 1 day per year** to manage the change.



# Example Service Requirements Management (REQM) Process – 1

**Purpose**: A checklist used to understand, confirm and manage changes to service requirements.

**Policy**: All service changes are managed using this checklist [gp2.1]

## **Do**

**Plan** the requirements definition/review **event** [gp2.2]:

- Date: \_\_\_\_\_
- Time / resources needed: (gp2.3) \_\_\_\_\_
- Responsibility: [gp2.4] \_\_\_\_\_
- Stakeholders [sp1.2, gp2.7]:
  - ❖ Role = Agree to services: <Name>. Commitment \_\_\_\_\_
  - ❖ Role = Provide expertise: <Name>. Commitment \_\_\_\_\_
  - ❖ Role = Team member 1: <Name>. Commitment \_\_\_\_\_
  - ❖ Role = Senior manager approval: [gp2.10] <Name>. Commitment \_\_\_\_\_

# Example Service Requirements Management Process – 2

- Discuss new and changed service requirements with stakeholders to clarify understanding: [sp1.1, 1.3, 1.5]
  - Review current service requirements
  - Review proposed changes to service requirements
  - Human resources needed to implement change: \_\_\_\_\_
  - New materials/consumables/computers needed to implement change: \_\_\_\_\_
  - Current commitments and deadlines impacted: \_\_\_\_\_
  - Added risks and mitigation actions: \_\_\_\_\_
  - Record stakeholder commitments next to name [sp1.2]
- Record major issues/actions
- Update traceability mapping [sp1.4]
  - Label service requirement 1 thru N
  - List impacted deliverables and documents for each requirement
  - State test method (e.g., peer review, test case, pilot) for each service requirement
- Save this document as service-roles-vN.doc on X drive with change history comments [gp2.6]

# Example Service Requirements Management Process – 3

## Check

- Training** has been provided to perform the steps above? [gp2.5]
  - If not, training date / time / who \_\_\_\_\_
- All process steps** above have been performed? [gp2.8]
  - Corrective actions needed/taken? \_\_\_\_\_
- Objective/independent check** done [gp2.9]:
  - Auditor name: \_\_\_\_\_
  - Audit date: \_\_\_\_\_
  - Pass / fail?: \_\_\_\_\_
  - If fail, corrective actions needed: \_\_\_\_\_
- Senior management aware** of this service requirements event, results, issues?  
[gp2.10]
  - Comments: \_\_\_\_\_

# A CHECKLIST FOR CHECKLISTS

## Development



## Drafting



## Validation

- Do you have clear, concise objectives for your checklist? 

### Is each item:



- A critical safety step and in great danger of being missed?
- Not adequately checked by other mechanisms?
- Actionable, with a specific response required for each item?
- Designed to be read aloud as a verbal check?
- One that can be affected by the use of a checklist?

### Have you considered:

- Adding items that will improve communication among team members?
- Involving all members of the team in the checklist creation process? 

### Does the Checklist:

- Utilize natural breaks in workflow (pause points)? 
- Use simple sentence structure and basic language?
- Have a title that reflects its objectives?
- Have a simple, uncluttered, and logical format?
- Fit on one page? 
- Minimize the use of color?

### Is the font:

- Sans serif?
- Upper and lower case text?
- Large enough to be read easily?
- Dark on a light background?
- Are there fewer than 10 items per pause point?
- Is the date of creation (or revision) clearly marked?

### Have you:

- Tried the checklist with front line users (either in a real or simulated situation)?
- Modified the checklist in response to repeated trials?

### Does the checklist:

- Fit the flow of work? 
- Detect errors at a time when they can still be corrected?
- Can the checklist be completed in a reasonably brief period of time?
- Have you made plans for future review and revision of the checklist?

Source: [www.projectcheck.org](http://www.projectcheck.org)

# Summary

- Processes don't have to be **voluminous** to be “complete.”
- A **checklist is adequate** for some Process Areas (and processes).
- Consider splitting processes into **2 parts**:
  - a) A **checklist** for essential steps – day-to-day usage.
  - b) **Separate training**/details/explanation.
- Use “**Do-Confirm,**” or “**Read-Do**” style.
- Refine checklist until:
  - It achieves the desired **result**.
  - It is able to quickly **detect serious problems**.

1. **Tidbit #8: *Using Checklists to Define Best Practices and Improve Performance*, Potter, N.**  
<http://www.processgroup.com/monthlytidbits.html#tidbit8>
2. **Tidbit #11: *Using Medical Checklists to Simplify CMMI Process Development - Keeping it Very Simple*, Potter, N.**  
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[www.processgroup.com/pgpostoct02.pdf](http://www.processgroup.com/pgpostoct02.pdf)
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# Acronyms

- **PP/WP:** Project / Work Planning
- **PMC/WMC:** Project / Work Monitoring & Control
- **CM:** Configuration Management
- **REQM:** Requirements Management
- **MA:** Measurement Analysis
- **OPF:** Organizational Process Focus
- **OPD:** Organizational Process Development
- **OT:** Organizational Training
- **PI:** Product Integration

## **REQM Practice definition from CMMI**

- SP 1.1 Develop an understanding with the requirements providers on the meaning of the requirements.
- SP 1.2 Obtain commitment to requirements from project participants.
- SP 1.3 Manage changes to requirements as they evolve during the project.
- SP 1.4 Maintain bidirectional traceability among requirements and work products.
- SP 1.5 Ensure that project plans and work products remain aligned with the requirements.
- GP 2.1 Establish and maintain an organizational policy for planning and performing the process.
- GP 2.2 Establish and maintain the plan for performing the process.
- GP 2.3 Provide adequate resources for performing the process, developing the work products, and providing the services of the process.
- GP 2.4 Assign responsibility and authority for performing the process, developing the work products, and providing the services of the process.
- GP 2.5 Train the people performing or supporting the process as needed.
- GP 2.6 Place selected work products of the process under appropriate levels of control.
- GP 2.7 Identify and involve the relevant stakeholders of the process as planned.
- GP 2.8 Monitor and control the process against the plan for performing the process and take appropriate corrective action.
- GP 2.9 Objectively evaluate adherence of the process and selected work products against the process description, standards, and procedures, and address noncompliance.
- GP 2.10 Review the activities, status, and results of the process with higher level management and resolve issues.