

## QUALITY—EASY CQI

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CQI is commonly identified as a missing system during a clinical audit. It is often forgotten after the organization or site has developed and implemented in their other basic quality systems. For some groups, CQI seems overwhelming and labour intensive. Like any major initiative, the implementation of CQI requires a plan. Without a CQI plan, the initiative can be fragmented and important aspects overlooked especially in the selection process. There is no single formula or plan that applies to all organizations.

It is essential that a "roadmap" exist to manage the CQI deployment process. I once came across a man with a really big CQI plan, one which I will never forget because it was massive. His consulting group was developing the CQI plan for Canada's Health Care System. On top of the formal CQI plan report was scratched a quote *'If you don't know where you are going, it doesn't matter which road you take.'* Scarecrow, the Wizard of Oz. I do hope that in reading this article that you will understand what CQI is and that you will have a better idea of what CQI road or option you could take. If you have a simple plan, you won't likely run into lions, and tigers and bears.

**What is CQI?**

Continuous quality improvement is a concept that appears to have originated from business literature. Some older models define CQI as a management philosophy of ensuring that the needs of those who use the services and products of an organization are continually being met. CQI has evolved past that. More modern definitions define it as 'a permanent quality objective of the whole organization'. The CQI plan itself and the CQI program must be driven by the vision of the organization and the necessary resources to support same. It is vital that the CQI plan ties into the overall strategy of the organization.

Continuous and Continual Improvement are terms that are often used interchangeably. Quality practitioners do distinguish between the two:

- Continual Improvement is a broader term referring to general processes for improvement and encompassing 'discontinuous improvements that is many different approaches covering different areas
- Continuous Improvement is a subset of continual improvement with more specific focus on linear, incremental improvement within an existing process.

The principles of CQI include strong leadership, employee empowerment to address problems, and the use of visual tools such as bar charts or histograms to analyze and evaluate progress. In addition, efforts are made to achieve standards of excellence rather than minimum standards.

**Why CQI?**

- CQI promotes a corporate wide approach to quality improvement.
- It assists with the development of processes
- It establishes goals to guide, measure and track improvement
- It establishes strategies for acknowledging improvements
- It promotes compliance
- It is the necessary quality system for ISO compliance
- It is the missing link covering other quality systems

### Which Model?

There are numerous CQI models available and also a large force of organizations that sell and provide training on CQI systems. You can opt for doing it yourself or have someone come in and do it for you. It is important to plan out the project and carefully select the right CQI program for your organization.

Continuous Quality Improvement models fall into two main groups. The first group tends to focus more on reducing variation defects and cycle times. They emphasize involvement and teamwork, measuring and 'systematizing' processes. Some examples of models that fit into this first group are: Six Sigma, Lean, and Total Quality Management. The second group of models, focus on continuously assessing the results. Examples include: Deming Cycle (PDCA) or Shewhart Cycle (PDEA). The PDCA model is simple, easy to follow, and easy to implement. It is ideal for small organizations and for demonstrating how and when to use CQI.

### PDCA

The PDCA model is a four step model for carrying out change. It is depicted as a circle which has no end as the cycle should be repeated again and again until improvement and quality are achieved. The model was originally developed by both Edward Deming and Shewhart.

Plan	Identify an opportunity and plan for change
Do	Implement the change on a small scale
Check	Evaluate – use data to analyze the results of the change and determine whether or not it made a difference
Act	If the change did not work you begin the cycle again. If the change was successful, you implement it on a wider scale.



The plan–do–check–act cycle (Figure 1) is a four-step model for carrying out change.

### When to Use It

- When starting a new project
- When developing a new process, system or service
- When planning data collection and analysis in order to verify and prioritize problems or root causes
- When implementing change

Example of items for CQI comes from the activities within research organizations or sites. Quality assurance personnel perform quality system trending at appropriate intervals to identify current and emerging GCP and quality issues at all levels within the organization. They also identify issues for CQI from CAPA, root cause analysis reports, external review, audit findings, investigations or general observations. Department heads or managers prepare development plans or preliminary outlines for new projects, plans and new services, and prepare updates or progress notes on previously identified CQI issues at the departmental level. Senior Management prepares and develops plans or preliminary outlines for new corporate projects, new plans and new services and prepares updates or progress notes on previously identified CQI issues at the corporate level. Site personnel identify CQI issues in observation and practice and note them at regular staff meetings.

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**How to Start CQI**

The fastest and easiest approach is to develop your tools in advance following your plan. Start with writing a simple Standard Operating Procedure for CQI. Next, develop a form for recording the minutes. By doing this you will have an established outline, so that you do not have to write everything out. Set up a place where the minutes can be securely stored (electronically or in paper format). The QA department is a good choice of location for storage if you are an organization. It is recommended that the SOP stipulate that the minutes be for 'internal management use only.' This clause will protect your minutes from audit. There should be an additional clause that 'selected samples may be provided in the case of audit to demonstrate that that the organization has an effective CQI system'.

Example of PDCA minute taking:

- P** Ongoing documentation errors derived from CAPA root cause analysis Report 09-4Q
- D** See notes from January 10, 2010
- C** The change implemented last quarter has been evaluated. There was a 90% error reduction on the pilot forms #82 to #89.
- A** Implement the same change to forms #40 to #81 inclusive and review in 8 weeks time.

Once your procedure and tools are set up, organize monthly CQI meetings. At the site level CQI can be included as an agenda item at regular staff meetings. Ensure that there is representation from all areas of your organization at the CQI meeting. Establish a person to chair the meetings and assign someone to take the minutes. Agenda items are presented and issues are discussed using the PDCA model (refer to figure 1). For the first few meetings it is helpful to have a handout with the model on it for committee members to follow.

The last step is your issue specific plan. There are many ways to carry out a Continuous Improvement Project but most important develop a specific plan appropriate to the issue. A generic approach for CQI is described in the Appendix below. It is a sample which should suit most situations. No projects are the same and so the approach should be tailored to fit the job. If it is not a complex problem, do not make the approach complex.

CQI is an important Quality System, one that should not be missing from your quality program. There are numerous models to choose from. If you are a small organization or site with only a few personnel, select a simple model. My final advice: make a plan, chose your road carefully, take a map and talk to all the scarecrows along the way.

**Appendix 1****How to Carry out a Continuous Improvement Project**

These are the main steps once the issue has been identified and brought to the CQI committee:

**1. Set up the Project Team**

The Steering Team will have defined the terms of reference, selected the team leader and given some general directions about the composition of the Project Team.

A team is more effective than an individual for problem solving because it can draw on a wider range of experience and skills.

**2. Define the scope**

The Project Team should review the scope of the project.

The scope of the project includes the statement of the problem, a definition of the boundaries, the magnitude of improvement goals, a target date for completion and the resources available.

One of the fundamental approaches of Continuous Improvement is to look at the process “from the customer’s point of view”. The starting point should be to find out what they want.

There may be several perspectives to consider. The patient may not be the only “customer”. There may be perspectives from several parts of the treatment process, or even external to it that are important to consider. The goal should be to define those whose point of view is relevant, to find out their expectations, and to meet them.

Firstly, the team should talk to those who use the service, find out how they come about doing this, what problems they have with it and how the service can be enhanced.

The information obtained from these interviews should be analyzed to determine which aspects of the service could be improved and the extent to which the service meets the needs of those using it.

The team should then define the project goals.

The team should develop a very clear understanding of what is expected from the project. The goals should be quantified and used as a benchmark to measure any success.

**3. Understand the process**

The next step is to understand how the treatment process presently works. Before the Project Team can attempt to improve on this, it must understand how it works at present and what it is supposed to do. There are two approaches to understanding the present process. One is descriptive; the other is graphic.

**Process Description.**

A good way to understand a process is to describe it. One benefit of describing the process is that it sometimes leads to the discovery of obvious problems and solutions that can quickly be fixed. The team should ask and answer key questions:

- What does the process do?
- What are the stages of the process?
- What are the starting and finishing points?
- What are the inputs and outputs?
- Who are the providers and the users?
- Who uses the service and who pays for it?
- Are there obvious problems with the process?

### Flow Charts.

A flow chart of the process is particularly helpful in obtaining an understanding of how the process works. It provides a visual picture.

There are two types of flow charts that are particularly useful. The first is a Top Down Flow Chart and the second is a Deployment Matrix Flow Chart.

A Top Down Flow Chart shows only the essential steps in a process without detail. It focuses on the steps that provide real value. It is particularly useful in helping the team to focus their minds on those steps that must be performed in the final 'improved' process.

A Top Down Flow Chart is constructed as follows: - by first listing the main steps across the top of the page and then listing the subsidiary steps from the top down, below the main steps. The details are not recorded. For example, rework, inspection, and typing are omitted.

The flow chart provides a picture of the process that the team can work on and simplify. It allows people to focus on what should happen instead of what does happen.

Usually, most processes have evolved in an ad hoc manner. When problems occur, the process is fixed. The end result is that a simple process has evolved into something complex. A flow chart is a first step to simplification.

A Deployment Matrix Chart is another type of flow chart. This is useful because it shows who is responsible for each activity, how they fit into the flow of work and how they relate to others in accomplishing the overall job?

To construct a Deployment Matrix Flow Chart, the major steps in the process are listed vertically down the left hand side of the page and the people or work groups are listed across the top. The process is then charted to show who does what.

### 4. Plan the project

There is no 'right' way to tackle a project. There are many ways and some will work better than others. The basic plan of action will be to:

- Identify root causes
- Develop solutions
- Implement the changes
- Review the results

### 5. Determine Information Needs

Based on the project goals the team should review what information is needed to analyze the problem.

For each goal, the team should determine what information is needed to understand how well the process is working. They need to know what information is available, what is not available and how to collect the information that is not presently available.

### 6. Choose the tools for the job

There are a variety of tools that can be used, these include:

- Time Plots
- Control Charts
- Brainstorming
- Consensus Building
- Cause and Effect Diagrams
- Structure Trees
- Pareto Charts
- Six Questions

### 7. Identify the root causes

Use Brainstorming, Cause and Effect diagrams or the Structure Tree to develop a list of possible causes. Begin by defining the problem, and then generate ideas as to the cause. (In some cases this may already have been done if the issue was presented as the result of a root cause analysis done by QA.)

To get at the root cause, ask the question ‘what is the cause of the cause?’ For instance, if some sections are defective, find out why. Maybe it is due to a provider problem. Ask why again and keep asking “why?” until the team cannot think of another question to ask.

When the team has developed their opinion as to the root causes, it should verify the conclusions with data.

The team should think about why it is collecting data and what data it needs to verify the conclusions. It is easy to draw the wrong conclusions from erroneous data. Use charts and graphs to analyze the data and have the conclusions checked by others who are knowledgeable in the process.

If there are obvious root causes that can be fixed easily, then fix them straight away.

### 8. Develop solutions

The ideas for solving the problem should be evaluated against criteria to determine the best solution. The team should define the characteristics of an ideal solution and identify the criteria that must be satisfied and the criteria that are desirable, but not absolutely necessary.

Constraints to a proposed solution should be identified. A constraint is a factor that limits the selection of a particular solution. These constraints may take the form of budget limits, rules or practices that may make a solution difficult to carry out.

Each possible solution should be evaluated against the criteria for selection. The team should seek to develop a solution which comes closest to solving the root causes, remains the easiest to implement, satisfies the criteria for selection and does not impact on the constraints.

There may be occasions where the team identifies constraints that, in fact, are not real constraints. The team may find some flexibility if it pushes hard enough to have such ‘constraints’ removed.

When the team has selected the best alternative, it should obtain feedback from those who are most affected by the changes.

Depending upon the nature of the changes, it may be possible to implement these immediately. Alternatively, it may be necessary to present the recommendations to the Steering Team to obtain approval before they can be implemented.

### 9. Implement the solutions

The team should use the [Plan, Do, Check, Act](#) sequence to implement the proposed changes.

Define exactly the changes to be made. Generate a list of activities that need to be done to accomplish the objective and then decide the steps required to implement the changes.

A schedule of activities should be prepared and milestones defined so that progress can be monitored. Responsibilities for each of the action steps should be defined.

Be sure that all those who are affected by the changes are properly informed and briefed on the reasons for the changes and that they understand how the changes will take place.

It is sometimes better to implement the changes on a pilot basis rather than make a wholesale change across the board.

### 10. Review the results

Monitor the effectiveness of the changes and compare the results with the original goals of the study. Ask the following questions:

- Did the team achieve the expected benefits?
- Were there any unexpected benefits or problems?
- What can the team learn from these?

What can be done to fine tune the solution so that it can be applied on a wider basis?

### 11. Standardize the change

If the improvement project has been successful with one process, it should be refined and applied to other similar processes. One should not waste time setting up further improvement teams to re-invent the wheel.