

Reference Guide: (Continuous) Quality Improvement or Research?

Definition of (Continuous) Quality Improvement

Quality Improvement consists of systematic, data-guided activities to evaluate the performance of a process, program or service within an organization with the goal of designing interventions to improve that performance and/or level of consumer—patient, student or customer—satisfaction.

Steps common to QI are ‘Plan Do Study Act’:

- (1) select a quality indicator as a target for improvement;
- (2) propose a plan for improvement;
- (3) implement plan and collect data for specified time period**;
- (4) evaluate the data; and
- (5) decide to keep, modify, or end intervention without delay <https://www.ahrq.gov/cahps/quality-improvement/improvement-guide/4-approach-qi-process/index.html>.

If the steps are repeated—continuously implementing and evaluating the effects of system changes—the effort is referred to as continuous quality improvement (cQI). QI activities are usually directed by personnel with the authority to implement changes to achieve improvements.

Definition of Human Subjects Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute generalizable knowledge. Research includes collection of data through intervention or interaction with living individuals or identifiable private information about them. Such efforts are designed to benefit society in the future from knowledge gains. 45CFR46.102(e)

General Characteristics

(Continuous) Quality Improvement

Human Subjects Research

INTENT of the activity is to assess and improve established practices (i.e., usual practices) within an organization or unit.	INTENT of the activity is to generate knowledge—by generating hypotheses, testing them, & answering research questions—to develop new paradigms or untested methods, or establish standards where none are accepted.
DESIGN includes systematic monitoring to ensure all participants continue to receive standard or best evidentiary care, services, products or instruction, as applicable, during conduct of cQI activities.	DESIGN may include group comparisons, randomization, control groups, placebo. Some participants may receive non-standard or experimental tests, products or services.
SETTING of the activities undertaken is within the organization or a unit of it.	SETTING of the activities may be within or beyond the organization.
PARTICIPANTS and their data are not used as a representative sample of a broader population outside of the organization.	PARTICIPANTS and their data are selected as a representative sample of a broader population outside of the organization.
RISKS of harm to participants are not anticipated.	RISKS of harm to participants are possible.
INFORMED CONSENT is usually not required as no activity plans to provide less than standard/best practices and data collected is about the org and not participants.	INFORMED CONSENT may be required as research participation is voluntary and may involve non-standard care, products, services or instruction.

Examples

Continuous Quality Improvement

Human Subjects Research

In the Classroom:

Seeking to improve students' mastery solving complex equations, Instructor devises plan to add a group problem solving session after didactic lessons on different formulae and administers a post-test at end of each class over course of semester to assess whether students' understanding improved with the addition of group sessions. After evaluation of results demonstrates improved mastery, a decision is made to keep the customary intervention for future classes.

Instructor uses two different methods for solving quadratic equations—a.m. class taught established quadratic formula method/p.m. class taught a new/faster untested method—to determine which method is more effective/efficient to solve such equations. Post-test administered to evaluate success of methods. Instructor hypothesizes new method will be as accurate and effective and less time-consuming to solve equations.

In the Clinic:

In effort to reduce hospital-acquired (nosocomial) infection rate, hospital QI team implements checklist reflecting scientifically validated steps staff must follow when caring for patients with indwelling catheters. After implementation, QI team collects data from EMR of patients w/indwelling catheters cared for during the project cycle to determine if improvement in infection rate occurred. After data analysis, QI team further revises checklist to add info about the availability of catheter supplies and description of established hand-washing technique and distributes revised checklist. Again, QI team collects data to discern whether improvement in nosocomial infection rate occurred.

To determine which approach is more effective in reducing nosocomial infection rate, IC Dept. implements checklist reflecting scientifically validated clinical steps Unit 1 staff must follow when caring for patients with indwelling catheters. Unit 2 staff are instructed on CDC's 5-steps to proper handwashing. On Unit 3 storage/accessibility of indwelling catheter supplies is improved (supplies available in patient room rather than in unit supply closet). IC Dept. hypothesizes Unit 1 will have lowest nosocomial infection rate. At end of 3 months, the Department assesses the data to determine which of the strategies best improved the nosocomial infection rate.

In the Community:

To improve childhood vaccination rates in the community it serves, the QI team of the county Public Health Dept. analyzes vaccination rates by zip code and determines 2 areas in the county fall below the state's average rate of 71%. The team interviews clinics in the relevant zip codes and discovers well-baby clinic appointments are not routinely kept. Flyers highlighting the importance of appointments are distributed to area groceries, libraries and clinics. Team schedules to review in 3 months to determine if vaccination rates improved using flyer campaign.

To test the hypothesis that access to transportation affects compliance with well-baby clinic visits for vaccinations, the Public Health Dept. selects a random sample of families (30%) among those who regularly do not keep appointments and provides them with bus or para-transit vouchers to cover 1 year of well-baby appointments. At conclusion of voucher year, Dept. reviews appointments of families receiving vouchers versus families not receiving vouchers to determine if access to transportation impacted vaccination rates.