Chapter 7
Clinical Workflow Analysis, Process Redesign, and Quality Improvement

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Learning Objectives

By the end of the chapter, the reader should be able to: (1) apply appropriate tools and techniques for analyzing workflow in a health setting using; (2) appraise the value of process re-engineering and its application to improve health care processes; (3) describe quality improvement tools available for use in clinical settings; (4)

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discuss the role of workflow in clinical decision making, design and implementations of health IT and organizational design.

Core Content

The following core competencies are covered in this chapter:

- Characterize, evaluate, and refine clinical processes
- Understand how business processes influence health care delivery and the flow of data among the major domains of the health system
- Apply methods of workflow analysis
- Appraise quality improvement and re-engineering principles and practices

Key Terms

Workflow analysis, process redesign, quality improvement, lean, six sigma, visualization, qualitative approaches, quantitative approaches

Case Vignette

Background

City Hospital (CH) is a community hospital in the United States. Physicians at the hospital include both employed physicians and physicians in private practice. The majority of hospitalists and primary care physicians are employed, while the majority of specialists are not. In the midst of an EHR implementation, the implementation team is reviewing the clinical workflow with the hope of improving patient safety in conjunction with the EHR deployment. Some units are on the new EHR, some are on old department-specific ones and some are entirely on paper. Each unit has its own processes, partially due to the documentation systems, and partially due to unit-specific culture.

Situation

Mr. Smith's wife drove him to the Emergency Department (ED) of CH in the middle of the night because he was complaining of shortness of breath and arm pain. Upon arrival to the ED, the triage nurse put his information into the registration system, settled the patient in a room and called the ED physician. The ED physician took a history and physical and documented results in the ED system. The unit clerk was directed to place a consult for a cardiologist. The cardiologist ordered tests and examined Mr. Smith. After initial testing, the cardiologist called the interventional cardiologist at home and they agreed that the patient should go immediately to the interventional cardiology unit for angioplasty and possible stent placement. The interventional cardiologist told the cardiologist he would meet the patient at the unit.

The cardiologist informed the ED staff that the patient was going to the interventional unit immediately. The ED staff nurse called the interventional cardiology unit, but it was after hours and closed. The ED staff nurse then consulted the cardiologist, who called the hospital operator and asked her to call the interventional cardiology unit team on call. This on call team consisted of nurses and scrub techs from the unit who staff the unit during the day. They take turns taking call for emergencies.

Upon arrival, the on call staff called the ED to ask about the patient. After a brief hold, the nurse obtained the patient's last name, identified the patient in the registration system, and started gathering information and inputting it into the interventional cardiology unit system. As she was doing this, the interventional cardiologist and scrub tech arrived. After being briefed by the interventional cardiologist, she called the ED and told them to bring the patient over.

The ED staff printed out information from their chart, put it on the patient's stretcher and transported the patient to the interventional cardiology unit. There upon arrival, the ED and unit staff conferred about Mr. Smith then proceeded to take the patient to the procedure room. Typically, patients are taken to a holding room for an examination beforehand, but this did not occur in the interest of time. Pre-procedure documentation was done and a brief history taken.

Mr. Smith was allergic to one of the common medications (unfractionated heparin) given in the interventional cardiology unit. However, this was not known to the staff of the interventional unit. It was documented in the ED, but not in the interventional cardiology system. The patient was given this medication and had an adverse reaction. Ultimately, the interventional cardiologist was not able to complete the procedure and the patient died. The CH administration are in the midst of conducting a detailed analysis of why this occurred and ways that EHR implementation can help prevent future events.

Introduction

The case vignette at the beginning of the chapter presents how workflow and processes can breakdown in a typical clinical setting. What are the places where communication broke down? How can systems and processes accommodate those breakdowns? What kinds of quality improvement efforts would improve processes? Where were there delays in the process? Why did these occur? Answers to these questions are related to workflow and processes, which affect patient outcomes and organizational performance. Workflow and processes are also related to design and implementation of health information technologies, communication, interruptions, hand-offs and coordination of care.

Process redesign and quality improvement efforts aim to make the delivery of care more effective and efficient by changing the steps in the delivery of care. This chapter begins with a definition of workflow and description of related frameworks. Then we describe tools and techniques to capture, visualize and analyze workflow in health care settings. Afterwards, we discussed several quality improvement approaches to improve quality of care.

What Is Workflow?

Workflow has been examined as a phenomenon and as a concept. Workflow as a phenomenon can be defined as the flow of work through space and time [1]. Workflow as a concept refers to the procedural aspect of a work system [2, 3]. Either way, workflow focuses on temporal properties (e.g. unfolding of work activities over time). Temporal properties are important because they provide tools and information to users at key moments of activities or enable the user to overview the work process. Other than temporal properties activities, actors [4], information [4], other resources (e.g. technology, materials) [5, 6] are important building blocks of workflow. Moreover, organizational infrastructure such as rules, policies, [7] and the external environment [6] are important factors that affect workflow.

One of the intermediate aims of clinical workflow studies is to model "true work" in health settings. Models are a simplified version of a complex system. Health care is "hyper complex" when it is compared with other domains [8, 9]. Modeling is an appropriate strategy to make complex systems more comprehendible because of the explanatory power of models [10]. However, it is important that workflow models accurately show the essential components and functions of the work that is under investigation.

Because of the comprehensive scope and complexity of workflow, multilevel perspectives are needed in understanding workflow [3, 11, 12]. One possible multilevel workflow approach can be describing the scope from lower to higher levels. For example, cognitive, individual, organizational and inter-organizational workflow can be the focus of describing the scope of work. Cognitive workflow focuses on the collection of cerebral activities such as sensation, perception, decision-making and response-execution [12]. Individual workflow refers to the collection of physical and mental activities by a single individual (physician, nurse, respiratory therapist etc.). Organizational workflow can be defined as a structured and measured set of activities designed to produce a specified output for a particular customer or market [6, 13]. Inter-organizational workflow occurs when activities to produce a specific output takes place in multiple organizational context. For example, if a patient with a diagnosis of asthma is seen in an ED for a breathing problem, a summary of the visit should be communicated to the patient's primary care office. This is essential to the flow of communication and patient management when modifying therapy by one set of providers to another. In health care delivery settings, the output or outcome is better health status for patients, lower costs, efficiency of care delivery and patient satisfaction.

Workflow studies are more likely be reliable and valid when applicable theories, models and frameworks from disciplines such as health informatics, human factors engineering, cognitive science, organizational behavior are utilized. Theories, models and frameworks provide validated pathways to link observed phenomena with foundational knowledge, thus enhancing efficiency and generalizability [14]. We will provide a summary of four approaches to workflow that were developed within the informatics community.

Pervasive and Specific Levels of Workflow

Unertl et al. [7] proposes that a model has two levels of workflow, *pervasive* and *specific*. The *pervasive* level includes three components that apply to workflow: context, temporal factors and aggregate (actors and actions) factors. The *specific* level is composed of: the people performing the actions (actors); the physical and virtual tools the actors are using (artifacts); details of the actions being performed (actions); description of the actions (characteristics) and the end products of the actions (outcomes) (Fig. 7.1).

Workflow as Collection of Individuals' Routines

Malhotra et al. [4] suggested the development of a workflow in care delivery settings by combining routines of individuals (e.g. nurses, residents and attendings). They also discussed the requirement of "a framework to temporally relate and

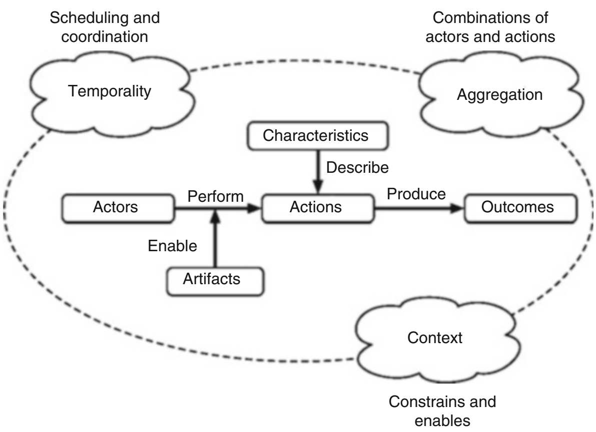

Fig. 7.1 Workflow elements model

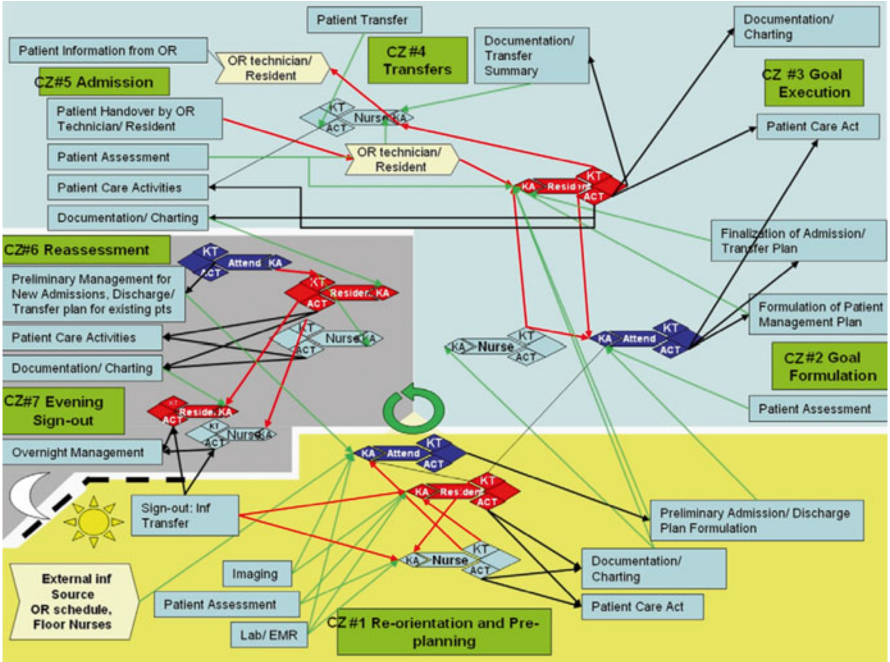

Fig. 7.2 Workflow in an intensive care unit (Reproduced from Malhotra et al. [4] with permission from Academic Press)

identify activities" for representing workflow. For that purpose, they set up conceptual zones (i.e. activity groups) in a way that the zones show the temporal relationship of the activities with each other. In this model, they delineated the workflow into different activities during the day shift and then clustered them based on the critical nature or temporal relevance into seven critical zones (CZ) (Fig. 7.2). This model reflects cognitive, individual and organizational workflows together.

Patient-Oriented Workflow

Ozkaynak et al. suggested a patient-oriented workflow approach. In a patient-oriented workflow, the patient is the nucleus of the care episode; the gravitational pull of the patient attracts, binds, and choreographs the essential elements of workflow [15]. Patient-oriented workflow models provide the "true flow of the work" [16] by including activities performed by multiple individuals and capturing the cooperative nature of health-related work in the care of a patient. In institutional environments, patient-oriented workflow models traditionally capture the work of multiple staff members. Extending patient-oriented workflow to the study of health-related activities in the home and community environment can capture the work of the patient, informal caregivers and "care partners" [17].

Organizational Routines

Organizational Routines framework examines workflow as a set of tasks and associated resources including people, systems and equipment, needed to reach a particular goal [18]. While some workflows are explicitly codified, others are tacit. These tacit workflows are operationalized through routines, or repetitive patterns of action [19]. Routines allow “actors” to know what to expect from others and can help bridge spatial, temporal and professional lines.

Routines can be studied as a whole, in parts or studied in tandem with how they change [20]. Regardless of how routines are studied, they have two different aspects: *ostensive* and *performative* [19]. The *ostensive* aspect of the routine is the “ideal-type”, or how the routine should occur. This aspect of a routine can be determined by asking the actor “how do you do x?” or by reviewing policies and procedures. When developing process models, the ostensive aspect of the routine is what is being modeled. Individual performances of the routine might vary from the ostensive routine. The *performative* aspect of the routine [19] outlines how the routine occurs in actual practice i.e. the “real world”.

Studying both the ostensive and performative aspects of a routine is necessary to understand workflow because the two aspects may differ. Ostensive routines are a guide for routines in practice. Ostensive and performative aspects of routines can differ for several reasons. Sometimes, there are changes from the norm in the environment or in the patient. Other times, the way that actors conceptualize the routine and the way that it occurs in practice differ [21]. This might occur for a number of reasons including, actors being unaware of each other’s role in the routine, the processes being tacit, or because it is difficult to fully describe the routine. Some unintended consequences of these differences include adverse events or inefficiencies [18]. In other cases, the tension between the ideal-type (ostensive) and routine in practice (performative), may lead to organizational change [20].

These four workflow approaches can guide workflow studies. However, each approach has a different focus and purposes. “Pervasive and specific levels of workflow” approach provides a holistic approach that includes various building blocks of workflow. “Workflow as a collection of individual routines” approach shows how various clinicians’ routines intersect with each other. Patient-oriented workflow suggests individual patients (as opposed to clinician) as the foci of workflow. Organizational routines focus on repetitive patterns that allow a care delivery settings accomplish its goals. Researchers and practitioners can choice to utilize any of these four frameworks depending on their needs and objectives.

The comprehensive examination of workflow may require interdisciplinary expertise including industrial engineering, human factors, sociology, psychology and organizational theory, combined with domain knowledge as well as perspectives of stakeholders such as patients. Therefore, a workflow study starts with establishing a team with complementary skills. A missing expertise can lead to incomplete modeling of workflow or incomplete interpretation of it. Xie et al. [22] examined multi-stakeholder collaboration in the redesign of family-centered rounds process which involved four human factors engineering researchers, three attending physicians, a parent, a medical administrator, two nurse managers, two nurses and two residents. Each participant's contribution was essential for the redesign. For example, the parent participant provided feedback and gathered feedback from other parents. Researchers played an important role in the collaboration process within the team. Clinicians and hospital management provided their perspective during the redesign.

Methods to Develop a Better Understanding of Workflow

Healthcare-related workflow is complex and highly adaptive; any single approach to studying workflow is likely to capture only a small fraction of this complexity. A wide range of methods are useful for capturing workflow data, including qualitative, quantitative, and mixed methods. No single "right" approach to studying workflow exists. Selection of method is dependent on underlying theoretical frameworks, research questions, project aims, available resources, contextual constraints, to name a few.

Qualitative Approaches

Qualitative study designs for workflow research are typically more open-ended and iterative in nature than study designs using quantitative methods. Qualitative methods are more suited towards generating hypotheses rather than testing them.

Observation, or *naturalistic observation*, is the systematic study of behavior and activities in context. When studying healthcare workflow, context refers to locations where work is occurring, such as an ambulatory clinic, ED, or hospital unit. Subjects for naturalistic observation could include anyone participating in the workflow of interest such as nurses, physicians, patients and their caregivers, administrative staff, and ancillary professionals. During naturalistic observation sessions, a researcher shadows a subject as the subject participates in routine work activities. The researcher may focus on specific activities during these sessions, such as observing how a subject interacts with technology. Researchers conducting naturalistic observations typically record free text notes, which are later transcribed and analyzed.

Two methods that are particularly useful as supplements to naturalistic observation are **artifact collection** and **spatial analysis**. Artifacts are any items an individual uses in work activities. Examples of **artifacts collected** with health information technology include: paper forms, sticky notes, print-outs from electronic health records (or other technology systems), lists of contact information, and written descriptions of procedures. The heavy use of artifacts can be an indicator of workarounds and gaps between existing technology systems and user needs. **Spatial analysis** involves studying the physical environment in which work is occurring. This method can involve photographing the work environment, drawing sketches of physical space, or obtaining blueprints of the environment. Spatial analysis can assist with uncovering how the physical space constrains and enables workflow. For example, the spatial layout of an exam room can create barriers between computer use and physician-patient interaction that directly impact workflow.

The use of interviews is also a well-established method for workflow data collection. Interviews are often used in combination with *naturalistic observation*. For example, informal interviews can be conducted during observation periods, to clarify observed behavior and to understand the rationale behind specific actions. Interviews can also take on a more formal structure, with one or more researchers interviewing either an individual or a group, using a semi-structured interview approach. Semi-structured interview instruments provide a common set of questions for all subjects, but allow the flexibility to add or alter questions based on the subject's response. Focus groups could be considered a type of group interview, with several subjects asked to respond to questions. Group interviews have limitations related to the potential for dominant personalities to steer the discussion without including other perspectives and related to difficulty sharing potentially sensitive information in a group setting. Participatory design workshops could be considered a more active type of group interview, with participants asked to contribute to design of an experience or technology.

An emerging trend in healthcare workflow research (particularly with respect to qualitative methods) is the study of the activities that patients engage in while managing their health. New methods will likely be needed to assist in this type of workflow research outside the boundaries of traditional healthcare contexts. Methods that have shown promise for understanding patient workflow include journals recorded by patients about their health management activities, photo diaries of health related artifacts, and walkthroughs of homes. Significant work is needed to continue refining methods to study patient health management workflow outside of the traditional health care setting.

Quantitative Approaches

While naturalistic observation is considered a qualitative method, structured approaches to observation may be considered a more quantitative method. Early approaches in this regard emerged from industrial settings, through the time-motion study concepts developed by Frederick Winslow Taylor, Frank Gilbreth, and Lillian Gilbreth [23, 24]. The time-motion study approach seeks to quantify the amount of time and effort involved in completing specific work activities, through structured observation involving collection of temporal data. Researchers studying healthcare workflow have adapted these concepts to the study of more complex work in healthcare. Other structured approaches to observation have included structured data collection instruments to quantify the observed behavior [25–27].

Various approaches related to Human Factors Engineering [28] have also proved useful in collecting data about workflow. Approaches such as "think-aloud" protocols [29, 30], have individuals describe each step of their activities. For example, an individual could describe each part of an electronic health record as they access it and why they are selecting specific functions. Other useful human factors approaches include studying individual and team workflow during scenarios in simulated clinical environments.

Surveys and questionnaires have also shown promise for study of workflow. Several standardized survey instruments including the NASA-TLX [31] and System Engineering Initiative for Patient Safety [32] have demonstrated an understanding of workload and task allocation.

An area of workflow methodology still under development is the use of data extracted from health information technology systems. In theory, information recorded through routine use of technology such as electronic health records and electronic scheduling and registration systems could assist researchers in understanding aspects of clinical workflow. Much work remains however, to further develop and refine software extraction.

Visualizing Workflow

In general, visualization supports researchers and practitioners by providing cognitive support through exploiting advantages of human perception, such as parallel visual processing, and compensating for cognitive deficiencies, such as limited working memory [33]. Specifically, visualizing workflow facilitates examining patterns and variations in practice. In this chapter we will discuss four different visualization techniques.

Process Map/Flow (Process) Charts

Although in this chapter the terms flow (process) chart and process maps will be used interchangeably, there is slight difference in these terms. The actual diagram is the flowchart while process mapping involves the creation of the diagram. The overarching goal of a process map is to graphically represent a set of associated processes [34]. The idea of process mapping is not new. It was described in the early 1920s [24] as "*a device for visualizing a process as a means of improving*." Every detail of a process is more or less affected by every other detail; therefore the entire process must be presented in such a form that it can be visualized all at once before any changes are made in any of its subdivisions. In any subdivision of the process under examination, any changes made without due consideration of all the decisions and motions that precede and follow that subdivision will often be found unsuitable to the ultimate plan of operation. Moreover, creating a process map is an iterative process. Key stakeholders should be involved in the review and subsequent reviews until consensus is reached that the process has been correctly and completely mapped.

Creating a process map entails the use of symbols, as shown in Fig. 7.3.

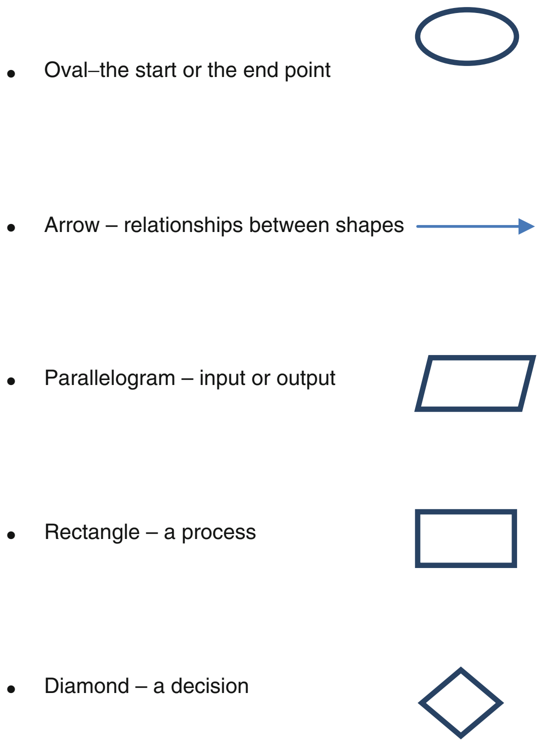

Fig. 7.3 The five basic symbols of a process map

Data Flow Diagrams

A data flow diagram is defined as "a graphical representation of the flow of data through a system." This includes what information is exchanged but it does not show when or in what sequence the information is exchanged. As such the data flow diagram differs from a flowchart diagram. Sharp and McDermott [34] explain that "on a data flow diagram, a data flow line between the steps indicates that data produced by the originating step is used by the receiving step". It is not recommended to merge a data flow diagram and a process map. A merged diagram can become highly complex resulting in a loss of explicit detail visualized in individual diagrams.

Like the process map, creating a data flow diagram involves the use of symbols (**see** Fig. 7.4) [35]:

Spaghetti Diagrams

Spaghetti diagrams (Fig. 7.5) are a visual illustration of the work unit running through a process including the flow sequence of the information. It documents the functional dependencies and responsibilities for each step in the process. The name

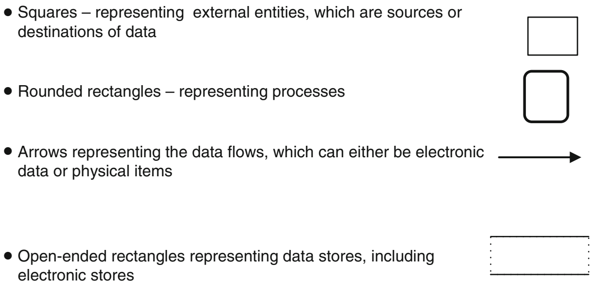

Fig. 7.4 The four major symbols of a data-flow diagram

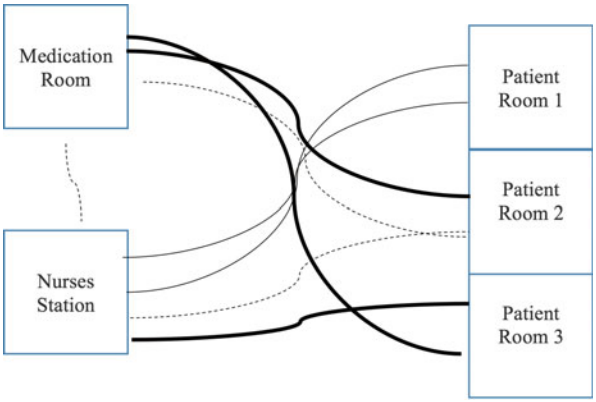

Fig. 7.5 An example of a spaghetti diagram that shows the movement of three nurses in a clinical setting. The type of line (*regular*, *thick* and *dashed*) shows the movements of a nurse in a pre defined time frame

"spaghetti diagram" is derived from the representations that often resemble a plate of spaghetti. The diagrams record the current state for specific paths through a process. The spaghetti diagram helps determine the efficiency of a space, by making it easier to identify wasted motion. Through spaghetti diagramming it is easier to quantify the impact of a layout on a process over time.

A spaghetti diagram can be created by

- Diagramming a layout of the physical facility.
- Indicating what task is completed, at what step, as well as the person or department involved in each step.
- Documenting the time to move from one step to the next.
- Documenting the travel time and distance from the map into a table and calculating the opportunity to shorten the distance.

Like other diagrams, spaghetti diagrams use symbols. However, the notation is not as extensive as many other diagrams. Spaghetti diagrams rely on the use of lines. The lines are often squiggly rather than straight, color coded to visualize the various workflows (Fig. 7.5).

Swimlane Diagrams

Another visualization of workflow is the swimlane diagram. A swimlane diagram looks much like a swimming pool that has been divided into swim lanes. In a swimlane diagram, each actor is assigned to a lane. Swimlane diagrams are meant to visualize a complete process from start to finish and to show what is done, by whom, and in what sequence as well as dependency and time [34]. An actor can be either a person, a group, or another process. All the work performed by an actor will be visualized in their specific swimlane. Each lane will visually depict the steps and decisions for a specific process performed by an actor. The swimlane can be depicted either horizontally or vertically.

Swimlane diagrams can depict different types of work flow [34]:

- Sequential a simple, orderly step by step workflow
- Conditional in which a decision is involved and determines the subsequent workflow
- Parallel in which one step is followed by two or more steps, each of which stands alone

Visualizing a swimlane diagram relies on the symbols shown in Fig. 7.6.

Today, various software applications can be used to create these four diagrams (process map/flow charts, data flow, spaghetti and swimlane diagrams. For example, Microsoft (i.e. Visio) offers applications with features and functionality for drawing and inserting shapes in the creation of these diagrams.

Examining Workflow Through Advanced Statistical Modeling

As data collection methods advance and more data are available to examine workflow, sophisticated quantitative data analysis techniques that are powered for large sample sizes, become possible. Quantitative data analysis techniques are useful because they can establish statistical relationship between process and outcome variables. In this chapter we describe three quantitative techniques; (1) Markov Chains, (2) Petri-nets, and (3) Discrete Event Simulation. We selected these techniques from among many available models in operations research because these techniques (1) represent workflow graphically and (2) have strong mathematical foundations. The main disadvantage common to all such models is that they are time consuming to apply.

Markov Chains: A Markov Chain (MC) is a stochastic (random) process that is characterized by a set of discrete states and transitions between these states [36, 37]. The simplest form of the Markov Chain can be defined as a triplet (Q, A, π), where Q is the number of states, A is the matrix of transition probabilities, and π is the

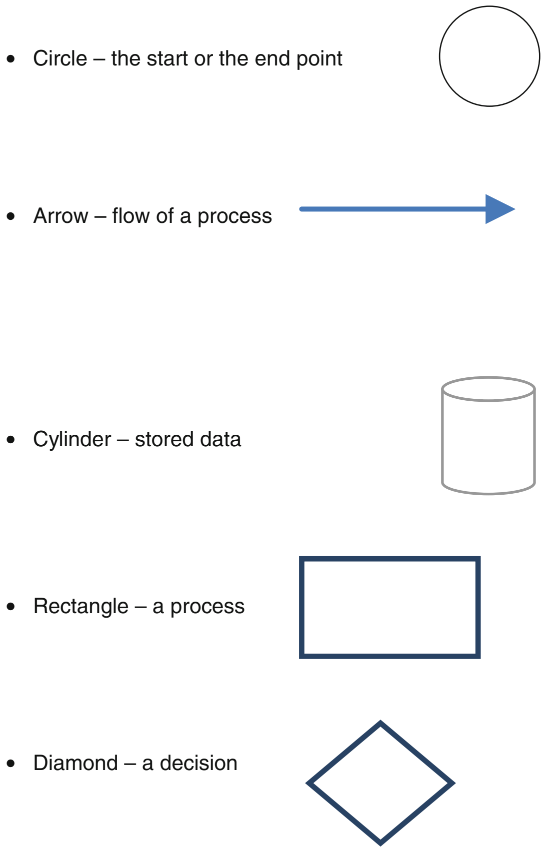

Fig. 7.6 The symbols that comprise a swimlane diagram

initial distribution accounting for the probability of being in one state at time t = 0 [38]. In modeling workflow, **Q** is a set of patient care events (e.g. triage started, physician assessment), **A** is a matrix of probabilities associated with transition from one of these patient care events to another. Finally, **π** is the probability of being in the initial patient care event. MC is a probabilistic modeling method used for temporal sequence analysis [39, 40]. MC has been shown to work with simulated data [41] and has the potential for analyzing data in-situ [42] such as modeling workflow patterns quantitatively. The goal of the analysis is to identify MCs that represent sequences of high-probability clinical actions, or in MC terminology, chains of states.

Petri-Nets: A Petri-Net (Fig. 7.7) is a directed bipartite graph, in which the nodes represent transitions (i.e. discrete events that may occur), places (i.e. conditions), and directed arcs (that describe which places are pre- and post-conditions for which transitions) [43, 44]. Petri-Nets model workflow by focusing on cases. Cases (or instances) are the objects, which need to be handled by the workflow. The object that is being processed highlighted instead of the subjects who process the object. Examples of cases are insurance claims and patients. The actual state of the system

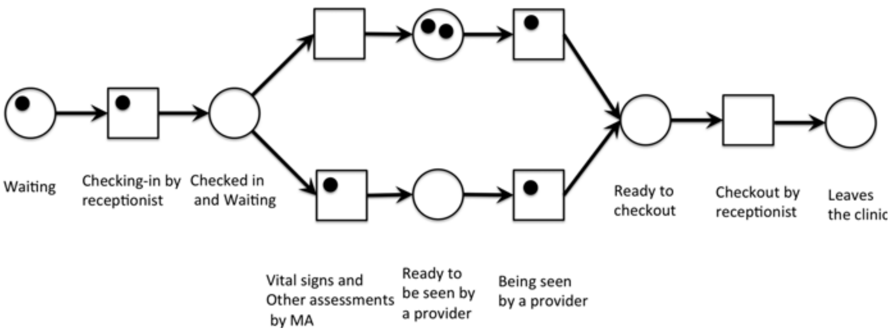

Fig. 7.7 An example of a Petri-net diagram showing the position of patients and caregivers in a clinic setting

is determined by the tokens (represented by filled circles), which are passed from place to place, undergoing transformations as they go. The Petri-Net in Fig. 7.7 shows seven tokens (i.e. seven patients). The diagram depicts the stage of the seven patients in a clinic setting. In this example, one patient is waiting in the first position, while the receptionist is checking in another patient. In this system there are two providers and each has a medical assistant (MA). The upper leg of the diagram shows the activities of one provider-MA dyad where the MA is idle, one patient is with the provider and other two patients are waiting for the provider. In the lower leg, the MA is with a patient and another patient is with another provider.

Discrete Event Simulation (**DES**): DES refers to codifying the behavior of a complex system as an ordered sequence of events. It imitates the "real world" operations of a system over time using queuing theory. The inputs of a DES are statistical distributions for the behaviors of the system elements such as arrival rate of patients and service (encounter) time of clinicians. Simulation is useful to illustrate how the performance of multiple events affect each other and the overall performance of the delivery of care. One advantage of DES is that it allows testing the performance of a planned intervention in a care delivery settings. The results will inform changes to the intervention before implementing any changes. For example Zhou et al. [45] used simulation to estimate the impact of the electronic health record with various levels of interoperability on day-to-day tasks in primary care settings. Once data is collected to run a DES, a wide range of software packages can be used to process the data and simulate the care delivery setting. Hoot et al. [46] used DES to forecast overcrowding in EDs.

Selecting Appropriate Methods

Multiple considerations go into selection of methods for understanding workflow. Research questions and study aims should drive the selection of methods. Quantitative methods are generally most appropriate for answering questions related to frequency of events or actions, amount of usage of a technology system, and workflow-related metrics. Qualitative methods are typically better suited for study aims related to; underlying reasons for workflow choices, rationale for usage or non-usage of technology, and impact of technology on collaboration and teamwork.

The complexity of workflow demands the application of multiple methods to gain a deep and accurate understanding of workflow. Applying a single research method to a workflow research question will rarely result in a comprehensive understanding of workflow. Whether the selected methods are qualitative, quantitative, or mixed methods, by combining methods, gaps in the understanding of workflow can be filled unlike when a single method is applied.

A critical consideration when designing a workflow study is consideration of the unit of analysis and the study boundaries. Depending on the study aims, the unit of analysis can range from a subset of roles within a work group (e.g. nurses within a single clinic), a specific work group of various sizes (e.g. staff, nurses, physicians, and other healthcare team members within a single hospital unit), different groups within one organization (e.g. emergency department and inpatient unit within the same hospital), or multiple organizations (e.g. health information exchange among different hospitals).

Because work crosses many boundaries, once the unit of analysis is established, the boundaries of the study also need to be considered. For example, when studying workflow related to care coordination for individuals with diabetes, will a study focus on workflow within a clinic or will it also consider the individual's home/community? Will aspects of workflow that cross into environments like schools or community pharmacies be included in the data collection and analysis? Clearly accounting for study boundaries is an important aspect of the study design, and aids in establishing study transparency.

A final consideration when selecting methods for the study of workflow involves balancing available resources against project aims. Methods such as observation and one-on-one interviews yield a wealth of data, but also require a significant investment in time and personnel. Methods such as extraction of workflow data from health information technology (HIT) require appropriate technological resources and training on analysis. Workflow studies need to consider what methods contribute to the understanding of workflow, and identify whether adequate resources are available to meet the requirements of specific methods.

Process Redesign

Process redesign opportunities arise due to performance gaps as well as changes in technology, physical space, or personnel. Process performance can be examined in terms of clinical outcomes, patient satisfaction, or operational measures such as utilization and patient waiting time. Gaps in performance may be identified based on complaints, comparison with similar processes in other units or organizations, or identified as part of a culture of continuous improvement. As more data is collected

Table 7.1 Ten steps of process redesign as suggested by Karsh and Alper [49]

Step-1: Decide what system will be the subject of the analysis
Step-2: Produce a preliminary workflow map
Step-3: Use the preliminary workflow map to determine who should be represented on the team that will carry out the analysis
Step-4: Conducts an initial scan of the system with the team
Step-5: Put boundaries on the system under study
Step-6: Performance expectations for each step determined
Step-7: Formal data collection to revise and update the workflow map. Gauge the current performance of the system, and determine baseline measures that will be used to evaluate the effectiveness of the redesign
Step-8: Analysis of the data
Step-9: Once hazards (i.e., causes of failure modes or variances) have been identified, control strategies should be developed
Step-10: Analyzing redesign ideas. Deciding on a redesign idea, pilot testing and implementation

and analyzed in IT systems, new measures can be tracked, yielding additional opportunities and ideas for process redesigns. For example, by collecting data across different organizational units, Kaiser Permanente discovered that sepsis was the leading preventable cause of mortality. This set forth the development of new clinical guidelines to standardize care, resulting in significant quality improvements [47].

Changes to the building blocks of a process include; tasks, people, the physical environment, and information and other technologies, create the opportunity and often a need for process redesign. For example, a move to a new clinic space may be designed to support group visits for patients with a common chronic disease or improve access by providing more examination rooms for additional providers. New information technologies (e.g. EHR, mobile applications) are currently a key driver to the process of change. Because EHR systems encode specific workflows (e.g. specifying what information needs to be recorded and in what order), those implementing such systems need to work with providers to ensure consistency with best practice. In addition, EHR systems support new capabilities, such as the ability to track and support all patients with specific chronic conditions or to give providers access to patient data anytime, anywhere [48]. Patient portals and mobile applications often seek to engage patients more in their health. This means that processes need to be redesigned to support this engagement.

Three process redesign frameworks will be described: (1) System Analysis [49]; (2) Sociotechnical Principles for Redesign [50]; (3) Systems Engineering Initiative for Patient Safety (SEIPS) [51]. These frameworks overlap with each other but also have different focuses.

Karsh and Alper [49] suggest a ten step work system analysis (Table 7.1). This analysis is based on systems engineering principles. Clegg [50] proposed 19 principles of redesign based on sociotechnical principles (Table 7.2). SEIPS model highlights five components of work system and the interplay among them (Fig. 7.8).

Applying systematic approaches to process redesign increase the likelihood that desired goals will be achieved. These guidelines can mitigate the following common problems that

Table 7.2 Nineteen principles of redesign by Clegg [50]

1. Design is systemic
2. Values and mindsets are central to design
3. Design involves making choices
4. Design should reflect the needs of the business, its users and their managers
5. Design is an extended social process
6. Design is socially shaped
7. Design is contingent
8. Core processes should be integrated
9. Design entails multiple task allocations between and amongst humans and machines
10. System components should be congruent
11. Systems should be simple in design and make problems visible
12. Problems should be controlled at source
13. The means of undertaking tasks should be flexibly specified
14. Design practice is itself a sociotechnical system
15. Systems and their design should be owned by their managers and users
16. Evaluation is an essential aspect of design
17. Design involves multidisciplinary education
18. Resources and support are required for design
19. System design involves political processes

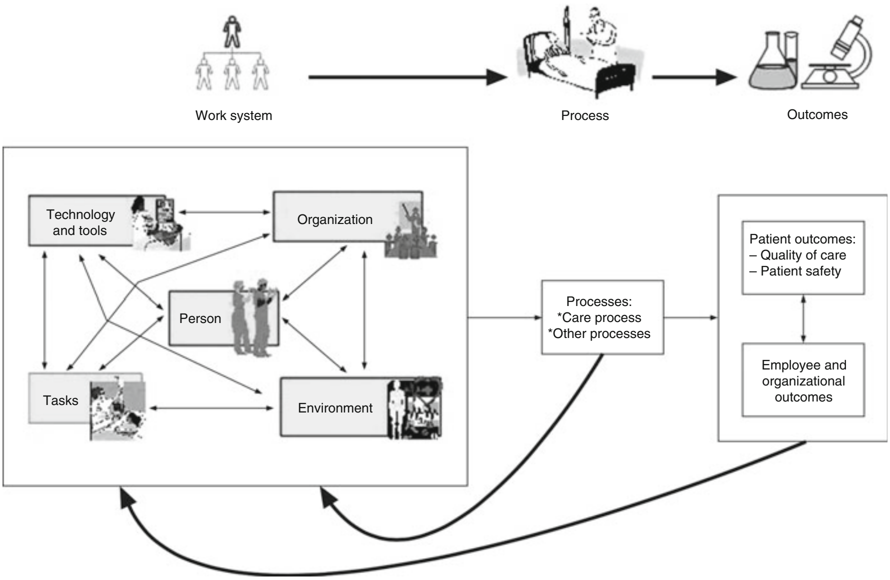

Fig. 7.8 The Software Engineering Initiative for Patient Safety (SEIPS) model

can occur. First, the solutions implemented may not address the real cause of a process issue. Second, the scope of the change may not be significant enough to achieve the desired goals, or so broad as to be unwieldy or outside the control of those seeking to make the change [52]. Third, efforts at redesign (which often focus primarily on tasks and activities), may not address the need to redesign roles and incentives or provide sufficient infrastructural support [52]. In particular, the resources provided for implementation may not consider ongoing investments needed to sustain a new process, such as the need for additional training or refining a new EHR feature. Finally, process redesign requires the commitment of leadership. They must recognize participants and support the time and effort to develop a redesign, and be willing to implement suggested changes. Lack of leadership commitment is often cited as a critical element of implementation failure. Several process redesign and quality improvement approaches have been used to address these problems.

Quality Improvement in Health Care

Quality improvement (QI) is a continuous approach for enhancing process delivery and performance, and is used extensively in healthcare. Quality in health care has been defined as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” [53]. In 2001, the Institute of Medicine outlined six aspects of the healthcare system that could be improved to create a higher quality system, including safety, effectiveness (defined as providing services based on scientific knowledge and refraining from providing services that are not likely to add benefit), patient-centeredness, timeliness, efficiency, and equitability [54].

Defined in this context, quality improvement encompasses not only clinical outcomes but also patient satisfaction and access to care. Donabedian [55] theorized a three-part approach to quality assessment and improvement, suggesting that (1) an appropriate structure (the attributes of the setting in which care occurs) increases the likelihood that (2) good processes for giving and receiving care will yield (3) better outcomes. Workflow and process redesign efforts, which seek to create the structure and processes that improve performance, build an understanding of the relationship between process and outcomes, and thus support quality assessment and improvement. Informatics and process interventions can reinforce one another, creating new capabilities that can yield better outcomes.

Important Quality Improvement Frameworks

Several different models of quality improvement are used in healthcare settings. They share some common features including; iterative cycles of improvement, use of quality tools (such as flow charts or other visual process descriptions), active engagement of frontline staff, and the need for leadership commitment [56].

Plan-Do-Check-Act

One of the most popular methods used to guide cycles of quality improvement in clinical settings is a Plan-Do-Check Act (PDCA) or a Plan-Do-Study-Act (PDSA) approach. Also known as a Deming Cycle or the Deming Wheel, named after W. Edwards Deming, a leader in the field of quality improvement. As with all QI methods, the PDSA cycle encourages a methodical approach that emphasizes understanding issues before jumping to potential solutions [57]. In the "Plan" phase, a problem is identified and potential solutions are developed. For example, a solution might involve a change in process design. Fishbone diagrams, also cause-and-effect diagrams might be used as a starting point to understand how potential system elements (e.g., personnel, technology, environment, methods) might contribute to the problem. In the "Do" phase, a pilot testing of a solution may be carried out. During the "Study" or "Check" phase, the proposed change is undertaken to determine if it has been successful. In this step, qualitative and quantitative evidence is gathered to evaluate the change. In the final "Act" phase, the proposed solution is either adopted into routine work, abandoned, or adjusted (following which it goes through another PDSA cycle).

While the PDSA cycle forms a foundation for continuous quality improvement, it is focused on testing changes and is more effective embedded in an infrastructure that ensures that important problems are addressed and quality improvement efforts are sustained. As an example, the PDSA cycle is one component of the model for improvement [58], but a second component requires understanding the overall aim for the project and defining how a "successful" change will be determined. Other studies have found that one PDSA cycle is often used in isolation [59], rather than in a sequence of iterative cycles, and that sustaining and spreading changes is difficult. Quality improvement methods such as Lean and Six Sigma also build from and use PDSA cycle, but include additional philosophies and structures that support problem definition, measurement, and sustainability. Table 7.3 compares the Lean and Six Sigma approaches, which are described in more detail below.

Lean Methods

Lean is a QI strategy that emphasizes value and process from a customer perspective, respect for people, and continuous improvement [56, 60]. The **Lean** philosophy, as well as its supporting principles, originated with Toyota automotive industry [61]. These principles have been employed extensively to improve process performance in a variety of industries, and include: (1) identifying the value a process provides; (2) mapping the value stream, or the set of activities and tasks making up the process; (3) improving process flow, by eliminating activities that do not add value, standardizing work, or removing disruptions from the process (such as an error, which must be reworked); (4) creating pull, so that the process produces what is needed by the customer when it is needed; and (5) achieving perfection, by continuously improving the process [61].

The use of **Lean** in healthcare settings has grown dramatically in the past 5 years, and it is one of the most widely used QI models in the US. **Lean** is used in healthcare both as a strategy for improvement across the entire organization, as well as an effective approach for supporting the implementation of specific practices and activities within a practice setting [62]. Several healthcare organizations have used **Lean** to achieve significant operational improvements, including Thedacare, Virginia Mason, Cleveland Clinic, and Intermountian Healthcare [63, 64]. At Thedacare, Touissant and Berry [65] augmented traditional **Lean** philosophies to include unity of purpose, or tying the goals of individual projects to broader organizational goals and visual management

Lean includes a diverse range of tools that are used to implement the underlying principles. These tools include methods that support process design as well as management approaches that provide infrastructure for ongoing improvement. One commonly used tool is an A3, or A3 problem-solving [57, 66]. A3 is a plan for solving an identified problem and a structure for moving through continuous improvement cycles (PDSA cycles) to achieve a desired goal (Table 7.3).

Table 7.3 Lean and six sigma comparison

	Lean	Six sigma
Goal	Eliminate waste, improve flow	Reduce variation, eliminate defects
Methodology	A3 problem-solving, which involves: 1. Defining the problem or gap in performance 2. Understanding the current process 3. Determining the root causes of the problem 4. Developing actions to address root causes 5. Implementing the plan 6. Collecting follow-up data Steps 2–6 are carried out as a series of cycles until the desired target is met	DMAIC Problem-Solving: D – Define M – Measure A – Analyze I – Improve C – Control
Underlying Principles	Define value and the value-stream, eliminate or reduce activities that hinder process flow, pull work through a process based on customer demand, seek perfection	Six sigma emphasizes continuous improvement, but is also a toolkit and a measure of quality Figures and numbers are valued
Tools and Methods	Process mapping, spaghetti diagrams, identifying seven types of wastes, 5S (workplace organization), root cause analysis/fishbone diagrams, results boards	Similar tools as lean, but emphasizing more statistical and quantitative approaches such as statistical process control and failure modes and effects analysis (FMEA)
Infrastructure	Kaizen events – a short-term event that brings stakeholders together to understand root causes and develop responses Lean management system – a management approach that focuses on alignment with organizational goals and understanding the daily work of frontline staff	Dedicated improvement team, with black and green belt personnel trained in six sigma methods to support project

The A3 problem-solving process is often facilitated through workshops that bring together relevant stakeholders to understand a problem and generate solutions. These are called *Kaizen* events or rapid process improvement workshops (RPIWs) [67].

Other tools support specific problem-solving steps. For example, *value-stream mapping* or other process mapping approaches can be used to identify the specific activities in a process, to understand how each contributes to providing value [68]. Often both the current state of the process and a desired future state are mapped. As solutions are tested and measured, a *results board* is updated to display the outcomes in a prominent location. To support sustainability and a culture of continuous improvement, **Lean** also includes specific management activities, such as *Gemba walks*, which involve going to see the actual process and understand issues by talking with those who do the work. Daily *huddles*, which are short meetings that often occur in front of a results board, which bring staff together to keep them up to date on the activities of their work area and enable them to raise and address issues as they occur, preventing larger problems from developing [57]. Tools such as fishbone diagrams that were developed in the context of other QI approaches are also commonly used.

Six Sigma

As with Lean, Six Sigma has elements that are focused on problem-solving at the project level, as well as infrastructural elements that support sustaining a QI effort and ensuring an impact on organizational performance. In terms of infrastructure, Six Sigma programs include rigorous training for Six Sigma practitioners, called Green Belts and Black Belts, who support project teams engaged in QI efforts [57]. Teams include a champion, who sponsors the project and ensures there is management support and commitment for projects.

At the project level, problem-solving is guided by a process that involves [57] five phases or stages:

1. Define – spell out the goal of the project and determine who will be part of the project team
2. Measure – collect data to determine how the process or system is currently operating
3. Analyze – examine the data to understand what underlying factors may influence measures and current process performance
4. Improve – based on the analysis, develop potential solutions and test them, which is often done using a PDSA cycle, measuring improvements and comparing them to the baseline performance captured in the Measure phase
5. Control – implement changes and monitor them to ensure that they are sustained.

In a Six Sigma project, QI tools such as process mapping are often employed, but the Green Belts or Black Belt assigned to the project also has the knowledge to design more sophisticated experiments to test and analyze results. Many healthcare organizations combine elements of Lean and Six Sigma, creating Lean Six Sigma programs to promote and support QI efforts.

Important Components of Quality Improvement

The biggest opportunity to improve patient outcomes in the near future will probably come not from discovering new treatments, but from learning how to deliver existing therapies more effectively [69, 70]. Therefore improving quality is a critical aim for most health care delivery organizations and they initiate quality improvement studies using various approaches, which may yield different levels of success [71]. The unique features of organizations make it impossible to develop prescriptive rules for success [71]. However there are five principles common to successful projects: (1) Participation and teamwork, (2) Leadership, (3) Being data driven/data monitoring and dashboards, (4) Focus on value-added activities and (5) Embrace continuous improvement.

Emerging Trends

We identified three important emerging trends that will be central to workflow, process redesign and quality improvement. The first trend is the availability of big data for workflow studies [72, 73]. Electronic health records (EHR), electronic medication administration records and Radio-frequency identification technologies allow data to be stored for every patient. As a result, detailed data can be generated and obtained for very large sample sizes at a reasonable cost. The second emerging trend is examining workflow in non-traditional health settings such as the home and community [74]. As more health activities are conducted in the home and community settings, a better understanding is needed of how these settings and traditional care settings (hospital and clinics) are connected to each other. The third emerging trend is visual analytics and its contribution to workflow studies and process redesign [75]. Visual analytics can assist in identifying patterns and variations of workflow even in very complex situations [76].

Furthermore, an important trend in health care delivery that is related to workflow research is to identify potential patients at risk using data analytics. EMS and other paramedical personnel (community paramedics) are being deployed to find these patients and intervene. Therefore, hospital admissions can be prevented by actively managing these patients as outpatients [77].

Summary

Workflow can be defined as defined as the flow of work through space and time. It is a key component of the design and implementation of health informatics interventions; because a misfit between workflow and the intervention will lead to inefficiencies and potential patient safety concerns. To better understand the term workflow, we provided a survey of methodologies to capture and analyze workflow. These methodologies include qualitative, quantitative, visualization and statistical approaches. We further provided a survey of process redesign, which included three process redesign frameworks. At the end of the chapter, we presented a survey of quality improvement in health care with three frameworks for performing quality improvement.

Application Exercise/Questions for Discussion

1. Please describe how a data diagram could have prevented the communication breakdowns in the case study?
2. Please describe the difference between a process map and a data flow diagram. How do they each impact the study of workflow?
3. What is the difference between the ostensive and performative aspects of routines? How do these differences impact workflow?
4. What kinds of workflow questions are suited to study qualitatively versus quantitatively?

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