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Steps Required to Achieve Operational Excellence (OpEx) Within Clinical Programming

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ABSTRACT

Lean, Six Sigma, Shingo, The Toyota Way and other methods under the umbrella of Operational Excellence (OpEx) have being traditionally applied to manufacturing operations. Other areas of company operations have implemented OpEx with great success: reduced cycle times, fewer quality issues and faster flow of information, as well as culture of continuous improvement. Why haven't we heard much about OpEx within Clinical Programming? Are the benefits that OpEx can deliver even of interest of Clinical Programming Operations, such as understand and exceed your customer expectations, improve quality, reduce errors, identify and drive out waste from processes, simplify your operations making them easier to manage, reduce cost, cycle-time and time-to-client etc.

This paper will cover 5 basics steps required to achieve Operational Excellence in order to manage Clinical Programming department effectively.

INTRODUCTION

WHAT IS OPERATIONAL EXCELLENCE (OPEX)?

OpEx is not very easy to define; some have a broad definition, while some others too focus in scope. And we end up with definitions that appear credible in an academic sense, such as 'Being world class', 'Being the best globally', or, 'Excellence in everything we do', but are difficult to translate into practical actions.

According to Wikipedia, "Operational Excellence is an element of organizational leadership that stresses the application of a variety of principles, systems, and tools toward the sustainable improvement of key performance metrics." From the definition, you can clearly identify the key tenets of (OpEx): focus on customer, leadership, people, process and technology, and accountability.

OpEx means focusing strategically on maximizing the value that operations deliver to your customers. Through strong leadership, the power of people, the use of industry best practice, and the application of value-add technologies, OpEx enables sustained delivery of high-quality, cost-effective services and capabilities that provide exceptional customer value.

WHY OPERATIONAL EXCELLENCE?

We embark on Operations Excellence journey because of the following reasons:

- Eliminate waste
- Improve productivity
- Improve quality
- Increase Efficiency
- Increase capacity
- Promote teamwork
- Continuous improvement culture

This paper will focus on the 5 key tenets of Operational Excellence which are: (1) focusing on the needs of the customer (2) philosophy of leadership (3) empowering employees/people (4) optimizing existing activities in the process with the use of technology (5) accountability.

CUSTOMER

A customer is the most important visitor on our premises, he is not dependent on us. We are dependent on him. He is not an interruption in our work. He is the purpose of it. He is not an outsider in our business. He is part of it. We are not doing him a favor by serving him. He is doing us a favor by giving us an opportunity to do so. ~ Mahatma Gandhi

In any organization, customer is the most important focal point and it is the same within clinical programming environment. Customers are the top of the operations excellence model because that is where they belong; they are the reason why any organization including clinical programming exists. In The Customer Rules, C. Britt Beemer and Robert L. Shook advice, “Unless the customer is the focal point of all its activities, a company is headed in the wrong direction.”

There are 2 types of customers: External customers are customer who is not directly connected to your organization e.g. Sponsor company (Pharmaceutical / Biotech) if you are CRO environment, Regulatory Authorities, etc. Internal customers is a customer who is directly connected to an organization, and is usually (but not necessarily) internal to the organization that your employees provide a service e.g. Regulatory Operations, Statistics, Medical writing etc. Internal customers are channels through which you serve your ultimate end customer (aka real customer). For example, a safety Tables & Listing will end up in CSR which will be review by Regulatory Authorities. So meeting the needs and expectations on internal customers is a prerequisite to meeting the needs and expectations of external customer.

EXPECTATIONS AND NEEDS:

“We have a 97.5% customer satisfaction rating!” Big deal.

That means 2.5% of your customers are mad and they’re telling everyone about it. And 97.5% of your customers will shop anyplace the next time they go to market for your service.

Satisfied customers will shop anyplace. LOYAL customers will fight before they switch – AND they will proactively refer people to buy from you.

The reward is a loyal customer - the consequence is a lost customer.

You need to know and understand what your customers want – not what you think they should want or what they can be talked into wanting. We need to find out exactly what the customer by asking question. For example, what output format those the customer need? Simple thing like this will save a lot of rework time. Customers’ most basic expectation:

1. Quality
2. Service
3. Value

A specific customer expectation is also known as a Critical to Quality (CTQ). CTQs are the internal critical quality parameters that relate to the wants and needs of the customer. CTQs are what’s important to the quality of the process or service to ensure the things that are important to the customer. In order words customer actually determine the quality of CP deliverable; we cannot presume to know specific customers’ expectations without asking their expectation. This will prevent a lot of time that are being spend on rework. For example, client specific output format might seems insignificant but it will lead to spending more time on the project than require on both side.

CTQs is very important and it is necessary to understand what goes in as well as what comes out. These outputs will provide important information that can be analyzed and used to improve overall customer satisfaction. There are many factors that are part of this entire process and they can be measured separately so the best possible solutions

may be reached. This will save the company both time and money. That is why critical to quality has become an essential part of customer satisfaction.

There are number of ways to quantify CTQ process performance. CTQ metrics are derived by comparing process observations against process requirement: did the process meet customer expectations, or fail to meet expectation (i.e. errors). In this case, the actual process measure is not recorded; only the count of failures, errors.

In order to determine customer requirements effectively, an active customer communication channels must establish for listening to the voice of the customer (VOC).

Voice of the customer (VOC) is the in-depth process of capturing a customer's expectations, preferences and aversions. Specifically, the Voice of the Customer is a market research technique that produces a detailed set of customer wants and needs, organized into a hierarchical structure, and then prioritized in terms of relative importance and satisfaction with current alternatives. Voice of the Customer studies typically consist of both qualitative and quantitative research steps. Example of VOS is Statistical Analysis Plan (SAP). A detail SAP will prevent a lot of time spend on rework and unsatisfied customer.

LEADERSHIP

"There is a difference between being a leader and being a boss. Both are based on authority. A boss demands blind obedience; a leader earns his authority through understanding and trust." Klaus Balkenhol

Leadership is the next important requirement for achieving Operational Excellence after customer. Leadership is considered to be the driving force behind continuous improvement. Without strong leadership, the organization goes up and down the staircase of OpEx. People need to be led, and some people are naturals at leading, while others can learn to become good leaders. Good leadership begins at the top and flow down through the organization, creating cultural values and behavioral norms that form the foundation for excellence. Effective leaders make sure that employees understand where they are going and how they are going to get there. They also ensure that everyone know the business and how to help the business be successful. To lay the foundation for excellence, leadership must be organizational clarity about the following key points:

- The business we are in and the customers we serve
- The organization mission
- The organization vision
- Strategy
- Rules of conduct
- Competitors
- Uniqueness
- Goals and objectives
- Organization and structured
- Individual roles and responsibilities
- How to measure success
- Accountability

Leadership's primary role is to create a clear vision for OpEx success and to communicate their vision clearly, consistently, and repeatedly throughout the organization. In other words, leadership must lead the effort. Their primary responsibility is to ensure that OpEx goals, objectives, and progress are properly aligned with those of the enterprise as a whole. OpEx deployment will begin with senior leadership training in the philosophy, principles, and tools they need to prepare their organizations for success.
Leadership must also be able to answer the following tough questions about their continuous improvement effort even before the beginning of the formal continuous improvement program. These questions allow employees to see where the operation is going and where they are going too. And it also create foundational thinking behind continuous improvement and Operational Excellence. Some of the questions is as follow:

1. Why do we do Continuous Improvement?
2. What is the best way to improve?
3. How do we know where to Improve?
4. What would the department look like if we did everything right?
5. Where will our Continuous Improvement Journey take us?

Leadership Organization Roadblocks

- **Internal Roadblocks** - Most organizations still have hierarchical structure known as “silos”. The functional specialist in charge of each silos tend to focus on optimizing their own functional area, often to the detriment of the organization.
- **External Roadblocks** – Most organizations do not exist as islands, there is a powerful external force that take an active interest in what happens within the organization. We deal with Food and Drug Administration (FDA) within the clinical programming environment. FDA determine type that can be use within CPO etc.
- **Individual Barriers to Change** – Perhaps the most significant change, and therefore the most difficult, is to change ourselves. It seems to be a part of human nature to resist changing oneself. By and large, we worked hard to get where we are, and our first impulse is to resist anything that threatens our current position.

Ineffective Leadership Strategies

- **Command People to act as you wish** – With this approach the senior leadership simply commands people to act as the leaders wish. The implication is that those who do not comply will be subjected to disciplinary action. The result of invoking authority is that decision-maker must constantly try to divine what the leader wants them to do in a particular situation. This leads to stagnation and confusion as everyone waits on the leader.
- **Change the rules by decree** - When rules are changed by decree the result is again confusion. What are the rules today? What will they be tomorrow? This leads again to stagnation because people don’t have the ability to plan for the future.
- **Authorize circumventing of rules** – Here the rules are allowed to stand, but exceptions are made for the leader’s “pet projects.” The result is general disrespect for and disregard of the rules, and resentment of the people who are allowed to violate rule that bind everyone else.
- **Redirect resources to the project** – Leaders may also use their command authority to redirect resources to the project. This is referring to political clout as the basis of the allocation.

Effective Leadership Strategies

- **Transform the formal organization and the organization’s culture** – The best solution is to transform the organization to one where these roadblocks no longer exist.
- **Mentoring** – A mentor can help guide the project manager through the maze of hierarchy by clarifying line of authority.
- **Identify informal leaders and enlist their support** – Mentors often know the person whose support the project really needs is not the one occupying the relevant box on the organization chart.
- **Find legitimate ways around people, procedure, resource constraints and other roadblocks** – It may be possible to get approvals or resources through means not know to the project manager.

PEOPLE

"It is a person's moral obligation and social responsibility to protect a culture that provides an honorable and dignified place in which to work." - Arthur T. Demoulas

People are the force that propels organizations towards excellence and leaders are responsible for establishing a vision and creating an environment that breeds high performance. People are the greatest asset of each organization. Values are the foundations of the operations excellence model. Establishing a foundation built on the values of trust, respect, and integrity enables leaders to create a high performance work environment and long-term employee engagement. If the trust, respect, and integrity are reinforce through leaders’ words and actions, they will serve as guidepost for employee behavior.

- Trust is difficult to earn abut very easy to lose. It is fundamental to effective leadership and high performing team. Without trust, employees have negative thoughts about leaders, peers, and subordinates. Energy is focused more on political maneuvering and self-preservation than on the initiatives that drive the success of the business.

  "The day the soldiers stop bringing you their problems is the day you stopped leading them. They have either lost confidence that you can help them or concluded that you do not care. Either case is a failure of leadership." Colin Powell

- It is through respect for one another that institution evolve. Effective leaders respect customers and their expectations, employees and their diverse opinions and approaches, and change.
- Integrity is marked by consistency, soundness and steadfastness.

Management Effectiveness

Management Effectiveness is often overlook while pursuing operations excellence. A leader's ability to communicate organizational clarity, establish foundational values, and cultivate a high-performance work environment is severely hampered if management effectiveness is absent.
Five steps toward effective management:

1. Great mangers surround themselves with great people.
2. Great managers establish clearly defined roles and responsibilities for each of their employees.
3. Great managers make their performance expectations very clear.
4. Great managers know that employee development is key to maintaining a high performance work environment and sustaining operational excellence.
5. Show that you care.

Teamwork is critical success factor to the achievement of operations excellence. Employees work together every day. Some work in isolation as freelance or contactor, but whether by email or phone, they must still work with others. A high-performance work environment cannot be archived without teamwork. Teams are made up of people, each of whom has a unique style, opinion and ego. Getting workers to set aside self-interests and work together require leadership, a goal that everyone can rally around, and an understanding of what is needed for the team to be effective.

"Teamwork is the ability to work together toward a common vision. The ability to direct individual accomplishments toward organizational objectives. It is the fuel that allows common people to attain uncommon results." --Andrew Carnegie

The intended consequence of deploying Operational Excellence is change in behavior, as well as the more obvious organizational effectiveness and efficiencies. The type of change is as follow:

1. Change the way people in the organization think: Helping people modify their perspective is a functional activity of the change agent. All change begin with individual, at a personal level. Unless the individual is willing to change his/her behavior, no real change is possible.
2. Change the norms: Norms consist of standards, models, or patterns which guide behavior in a group. All organizations have norms or expectations of their members. Change cannot occur until the organization's norm change.
3. Change the organization's systems or processes: All work is a process and quality improvement requires change at the process and system level. However, this cannot occur on a sustained basis until individuals change their behavior and organization norms are change.

PROCESS AND TECHNOLOGY

We are stuck with technology when what we really want is just stuff that works. – Douglas Adams

Process is sequence of interdependent and linked procedures which, at every stage, consume one or more resources (employee time, energy, machines, and money) to convert inputs (data, material, parts, etc.) into outputs. These outputs then serve as inputs for the next stage until a known goal or end result is reached. When we deliver services, and manage operations, we do so using processes. The quality of your service is determined not only by their design but also by the quality of the processes used to create, produce and deliver them. Operations excellence cannot be achieved without effective processes or process management.

Technology is an enabler of processes. When applied correctly, technology increases customer and operational value by improving the effectiveness and efficiency of your processes.

Processes can be grouped into three logical types: management processes, core processes, and support process. Each must be effective in order to have operations excellence.

- Management Processes guide and govern your core processes, ensuring that there is predictability in their output and performance. E.g. Business performance management, quality management.
- Core processes create customer value and are often specific to particular business unit. E.g. creating SAS macro, writing efficient programs.
- Support processes enable your management and core processes to achieve their desire intent. For example, recruiting qualify SAS programmers, regulatory compliance.

For any of these processes to be effective, they must be managed with discipline. Disciplined business process management is achieved through five fundamental practices:

1. **Process definition** –Each task that are critical to meeting all of the customers' requirement must be defined: the who, what, where, when, why, and how each and every task must be clearly documented. Process definitions should be maintained and updated when necessary. It may often be visualized as a flowchart of a sequence of activities with interleaving decision points or as a Process Matrix of a sequence of activities with relevance rules based on data in the process.
2. **Standard operating procedures** - The International Conference on Harmonisation (ICH) defines SOPs as "detailed, written instructions to achieve uniformity of the performance of a specific function". The focus of SOPs within clinical studies is always set on repeated application of unchanged processes and procedures and its documentation, hence supporting the segregation of origins, causes and effects. Essentially, they define the "how".
3. **Process change management** – To meet shifting customer demands, your service will require change. So too will the processes and procedures that produce them. If you do not document these changes, you will lose track of progress and possibly reintroduce items that were removed for a good reason. This can be achieve by using version control.
4. **Process measurement** – Data collection are necessary to monitor and improve processes over time, to ensure that desired outputs are achieved, quality standards are met, waste is minimized, and resources are utilized in an efficient, effective manner.
5. **Quality Assurance and Quality Control** – The primary objective of Quality Assurance is to guarantee that internal and external customer requirements are met or exceeded at every level of operations. The most efficient and effective method of guaranteeing quality is through prevention. Quality Control is a system of processes used to monitor variation services. Quality Control ensures that an acceptable level of consistency is maintained in process output. QC require careful monitoring, data collection, and analysis of process inputs, the process itself, and process outputs.

ACCOUNTABILITY

If you cannot measure, you cannot improve – Taguchi

Operational Excellence cannot be achieve without employing metrics and measures to drive accountability. Metrics is standards of measurement by which efficiency, performance, progress, or quality of a plan, process, or product can be assessed. Metrics used to evaluate ongoing performance in functions related to critical customer requirement are known as Key Operating Measurements (KOMs) or Key Performance Indicator (KPIs). Metrics is important because we measure as a way to understand a current problem & metrics also allow us to identify continuous improvement opportunities. Some key important points about KPIs:

- They should be based on customer requirements
- They must be tracked over time
- They should serve as catalysts for continuous improvement

Metrics & measurements can be used to answer the following question:

- Are we meeting the expectations of our customers
- How do we grow revenue
- How can we improve customer satisfaction and loyalty
- To what should we commit investment dollars and resources
- In which areas can we do better

Metrics & Measurements can also help us to:

- Separate what we think is happening from what is really happening
- Confirm or disprove preconceived ideas and theories
- Establish a baseline of performance
- See the history of the problem over time
- Measure the impact of changes on a process
- Identify and understand relationships that might help explain variation
- Control a process (monitor process performance)
- Avoid “solutions” that don’t solve the real problem

There are 2 types of metrics, qualitative and quantitative.

- Quantitative measuring in mathematical terms such as number of errors/issues, time it takes to complete a task; qualitative measuring something much less tangible including perceived quality or customer satisfaction.
- Qualitative measurements can be measured by simple observation, but are usually less precise. Deals with descriptions. Data can be observed but not measured.

The metrics must have both the qualitative & quantitative components in order to avoid having single dimensional view of the results of a specific process.

A single dimensional view may measure the output of a process without accurately measuring the outcome. The management may believe that their process is in control, when it may be from quantitative aspect, the output, when the process is actually failing to satisfy customers, the outcome. For example, a project might be completed on time (quantitative), but the customer was dissatisfied for several reason (qualitative).

CONCLUSION

A journey of a thousand miles begins with a single step - Chinese proverb

Operational Excellence is a journey not a step that requires a disciplined approach in which success, failure and progress along the journey are monitor and measure carefully. Excellence begins and ends with leadership and customers (internal/external) focus as the top priority. There are different methods under the umbrella of Operational Excellence; the most critical is to identify the right structure and follow the design of the method. There are no shortcuts, we build OpEx by following the design guidelines, by following the blueprint.

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