Chapter 12

Process Indicators

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Introduction, Definitions, and Example

The organization of work by processes is a strategy well established in quality in recent times. It may seem challenging to implement this in the medical field. However, working in a process-based organization will help us establish the quality system since each process has different personnel, different procedures, different risks, controls, indicators, etc. And the interaction between those processes or sub-processes also requires particular detail.

To start with, clarification of some terms is needed because they may look similar [1, 2]:

- Process: A goal-directed, interrelated series of actions, events, or steps.
- Process control: The standardization of processes in order to produce predictable output.
- Processing: All aspects of manipulation, cryopreservation, packing, and labeling of cellular therapy products.
- Product: The easiest way to define it would be “the cells.”
- Standard operating procedure (SOP): A document that describes in detail the process or chronological steps taken to accomplish a specific task. It is also referred to as working instructions. An SOP is more specific than a policy.
- Policy: A document that defines the scope of an organization, explains how the goals of the organization will be achieved, and/or services as means by which authority can be delegated.

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Fig. 12.1 Example of a process

- **Quality:** Conformance of a product or process with pre-established specifications or standards.
- **Quality control:** A component of a quality management program that includes the activities and controls used to determine the accuracy and reliability of the establishment's personnel, equipment, reagents, and operations in the manufacturing of cellular therapy products, including testing and product release.
- **Indicators,** also referred to as key indicators or quality indicators: An indicator is a measurement done at a critical point that has to be within a defined range. If not, an action should be taken.
- **Example of a process:** The process of “baking bread” is simple and quite visual and can serve as an example (Fig. 12.1).

The process has to be validated before opening the bakery (tested to have a certain result), the equipment has to be controlled, there may be a recipe (SOP), etc.

In the process, there shall be controls to assure that the bread is almost the same every time: weight of ingredients, temperature of the oven, etc.

An indicator may be established, depending on the requirements of the clients, the controls of the product, the previous occurrences of the bakery, etc. For example, more than 95% of breads that are sold at a certain price have to weigh ≥ 500 g [4].

Process Definitions

The transplant process is extremely complicated. It can be treated as a single process with different sub-processes if all the steps are performed in a single institution, or as different processes with a close relationship in case of different entities in the same or in different institutions.

For illustrative purposes, the transplant process has been simplified (Fig. 12.2).

When a transplant program is starting in the quality and accreditation process (it is also a process) they have to work on many aspects, among them the process

Fig. 12.2 Summary of processes in a transplant program

definitions. They have to be based on the structure of the program, of the organization that hosts the program, responsible staff, etc.

Although it is not mandatory, the division in to at least clinical, collection, and processing processes can be a start. Those procedures shall have a clear interaction, whether being performed in the same or different institutions.

In the annual review, the indicators of the processes and other issues are included. A change to the processes may also be required within time and has to be carefully analyzed (risk assessment), planned, and implemented, to be further analyzed again.

Process Controls

The process controls are described in detail in the current edition of FACT-JACIE standards [1, 2].

CM8 – Marrow collection process controls include procedures, inventory, equipment, blood components, written order for collection, peripheral blood count to proceed, suitability prior to collection, anesthesia, mobilization, quality of the product, aseptic technique, pediatric donors, packing, filtration, and records.

C8 – Apheresis collection process controls include the ones seen for marrow collection (except for the different requirements for the filtration of bone marrow), plus some specific controls regarding central lines.

D8 – Processing process controls include manufacture of the product, written request, specific information for allogeneic donors, validated processing procedures, identification of critical control points, aseptic technique, microbial contamination, records, review of processing record, end points not met, more-than-minimal manipulation, blood group and antibody screen, cord blood, and sample storage.

Clinical program controls: Through all the chapter of clinical standards, a number of controls are indicated: control of airborne microbial contamination, document control, and outcome analysis (see Chap. 6). In fact, among the principal controls for the clinical unit are the ones described in the outcome analysis chapter and also performance measurements (see Chap. 9) and benchmarking.

A unit can require further controls, depending on the different procedures performed.

Process Indicators

Selection, Definition, and Range

How to choose an indicator?

As indicated in the definitions, an indicator is a measurement done in a critical point that has to be within a defined range. If not, an action should be taken. They are used to monitor the quality of the process [3, 4].

In a visual way, it is like a thermometer. If the measured value is above or below a certain level, there are no major issues, and one can continue working the same way. But if for instance the value is above that level, it is like having fever, which means that there is a problem that has to be studied and treated.

Indicators can be different among transplant programs. They have to be selected based on the risky points of the process and procedures, on the occurrences detected in the previous months or years, etc.

It is important to remember that if the indicator is not within the range, an action should be taken. For example, it is difficult to define the “number of transplants per year” as an indicator. It is a measure of the activity. An indicator requires an objective level. If you select as quality indicator “more than 100 transplants per year,” you have to think if there is any action to be performed if a year there are 90 transplants (probably not).

A way of starting would be taking into account the process controls that have been briefly reviewed before. Transplant programs do have data on those

parameters, some of them with associated occurrences or that have been shown in audits or in the risk assessment to be “difficult” or “critical.”

The parameters included in the outcome analysis are often used as indicators, for example, neutrophil above 500/ μ L at day X in $\geq 90\%$ of transplants and/or graft failure in $\leq 5\%$. The accepted level or the accepted range has to be defined according to the center experience, the literature, etc. An individual delay in engraftment in a certain patient may be studied as an occurrence and a graft failure as an adverse event. But those are the studies on individual patients. But if those cases become more and more frequent in the transplant program, a detailed review of the system and a corrective action should be implemented. In these cases, the study should include not only clinical aspects (data of the patient, lines of chemotherapy, time to recover, conditioning, etc.) but also aspects of collection and processing, for example, number of cells and potential issues affecting viability. After reviewing the potential causes, an action should be taken and analyzed at a later step.

Regarding indicators of collection, a typical example would be collections finished with the number of cells $\geq X\%$ or efficiency of collection above a certain level in a percentage of procedures. Regarding the procedure itself, depending on the program, other useful indicators would be percentage of side effects, etc.

In processing, the indicators are focused on the product: products with positive culture below a certain percentage, viability over a certain percentage, etc.

The definition of the indicator has to be clear: what are we going to measure and how [5]? The definition, the range, etc., have to be included in quality documents. The way to obtain details to do the measure can be by reviewing the patient’s clinical data or the collection or processing procedures, etc.

Persons Responsible for the Measure and Timing

Depending on the indicator and on the organization, indicators can be measured by a person directly related to the process (e.g., nurse of collection) or indirectly by the quality manager.

How often are indicators measured?

It depends on the point to measure and the urgency to take measures if the indicator deviates. They can be monitored monthly, quarterly, or, in some particular indicators, on a yearly basis.

Indicator’s Table

After defining what and how to measure, by whom, and when, it can be useful to have a summary in a table (Table 12.1). This table would be filled with the results and the actions taken. And in a quick view, you can see the evolution of the measure within time.

Table 12.1 Example of indicator's table

Indicators							
Clinical indicators							
	Title	Objective	1 st T	2 ^º T	3 ^º T	4 ^º T	Year
1	Graft failure	≤Stablished %					
2	CVC infections	≤Stablished %					
	Others						
Collection indicators							
	Title	Objective	1 st T	2 ^º T	3 ^º T	4 ^º T	Year
1	Side effects	≤Stablished %					
	Others						
Processing indicators							
	Title	Objective	1 ^º Tº	2 ^º T	3 ^º T	4 ^º Tº	Year
1	Microbial contaminations	≤Stablished %					
	Others						
Actions taken							
	Indicator deviated	Period	Action taken				

T trimester

The table may be split in clinical, collection, and processing if those units are independent. But results have to be shared with the entire program.

Actions

If the indicator falls above or below the target level, a corrective action shall be done. If an indicator is about to reach the level, a preventive action should be carried out in order to avoid reaching the dangerous level. For the development of corrective and preventive actions, see Chap. 11.

The action can be registered in the indicators panel (Table 12.1) or in the forms for occurrences. The deviation in the indicator, study of the cause, actions, etc., have to be opened and reviewed as other occurrences of the unit. The effectiveness of the actions has to be reviewed and will be seen in the following measures of the indicator.

Other Indicators

Besides the indicators seen, other key indicators may be required to monitor other aspects of the program. Indicators of the quality system itself may be required in other systems to review and keep under control particular points (e.g., corrective actions reviewed on time).

When selecting the process indicators, take into account that they have to be useful. It is not about having a long list, or indicators difficult to measure, but they have to be a practical tool to measure and improve the quality system.

Indicators Within Time

Indicators are a dynamic tool. If one gets better and better results in the point of measurement, a more demanding objective can be set.

If occurrences start to happen in a certain part of the system, or if a new issue appears on the risk assessment, a new indicator can be opened to measure it more frequently and keep it under control.

In the same way, if a previously not-controlled issue gets to be fully compliant in each patient, year after year, having an indicator may not be as useful as before. It could be considered to be closed. If occurrences in that issue are seen again, it can be started again.

Communication

The measure of the indicators is a fundamental part of the quality management system. They have to be shared in the regular quality meetings.

They have to be included also in the annual review of the system [2]. To assess if an improvement is seen, a comparison with the indicators of the previous years is also advisable.

References

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