Chapter 10
Indicators for Measuring Changeover Activities: Operationalization of 4Ps model of Changeovers

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ABSTRACT

At present, the manufacturing industries require the implementation of more efficient and flexible fabrication processes to offer high-quality products. The changeover methodologies can be used to reduce the setup times, allowing the industries to be more competitive. The application of changeover methodologies is mainly influenced by the 4Ps model, which is composed of organizational and design factors, such as people, practices, product, and processes. However, this model is not useful in determining the relationship between each one of the Ps and the changeover activities. In this chapter, the authors have developed an exhaustive review of the references to establish the indicators to design an instrument composed of 79 items and divided into the five constructs of the 4P model, which was statistically validated using the Kendall W indicator and the Cronbach´s alpha indicator.

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INTRODUCTION

Currently, in the industry, several factors such as the growing demand from markets and customers which demand higher quality products, have influenced the way by which organizations use their personnel, facilities, and administrative and production systems and be capable to respond to the need of manufacturing flexibility in relation to the variety of products and production volume at profitable costs. Recently Chabowski et al. (2016) detected through an analysis of causes, that a production line, does not reach the established required standards mainly because of changeover activities. Therefore, one of the key factors that allows an industry to be more productive is the reduction of build-up production times, achieved through the implementation of changeover methodologies. The literature reports that a significant number of companies have implemented the SMED methodology (Single Minute Exchange of Die) or its variations, combining it with lean manufacturing methodologies. However, in those reports are not consider the factors and variables that intervene in the production systems deployment, so the results are often not optimal. Researchers have to consider that the design and organizational factors play an important role because they are the basis of operational and administrative decisions within the companies. The production variables are identify and controlled flexibility and efficiency inside and outside the organization.

Reik et al. (2006), present a model of rapid changeover that considers organizational and design factors to support increased capacity and flexibility in manufacturing processes and thus respond timely to the customer's needs. This Theoretical Model shows the relation of positive influence and correlations between four factors: Product, Process, Human Resource (People) and Work Methods (Practice) and is called the model of the 4P's. In this model, the rapid changeover activities are understand as essential tasks such as disassembly, assembly, adjustments, and validation, involved in the production process and its accomplishment improves efficiency and facilities availability. On the other hand, the Process and Product factors are present at the initial stage of the productive processes and are directly relate to machine designs, use of tools, manufacturing systems, and products, and all the factors that can contribute to flexibility, simplify, through eliminating or adding elements that contribute to the capacity and stability of each system run. "People" and "Practices" factors are relate to the industry functioning, as they organize and use their resources to achieve greater profitability and competitiveness. Van Goubergen et al. (2002), suggest that the assignment of employees with specific skills and abilities influences the performance of their responsibilities and the provided resources.

As is shown, the model presents a great option to support the efficiency of changeover implementation. However, because this model is theoretical, the 4P factors cannot be explain just with these concepts, it requires the definition of measurable and observable variables and so to determine the degree of relationship that each of the P's has with the activities of the rapid changeover. In order to make sense of the 4P's model, a review has been realize from which variables were obtained and used to design an instrument of 79 items.

This chapter deals with the operationalization of the variables and the design and validation of an instrument that allows measuring for rapid changeover activities. The operationalization consisted of a descriptive analysis of each identified variable described through indicators. Then the measurement scale was define. From the described analysis, an instrument composed of 79 items was formulate. Each item gives six options to respond based on a Likert scale and represents each indicator. Finally, to obtain higher reliability of the gathered information is addressed the content validation and instrument reliability. The instrument was submit to the appreciation of six maintenance professionals to validate its

content. The judges evaluated through a test the content validation of each instrument giving a relevance of 94%. The agreement of the experts was estimated using a Kendall hypothesis test (Olmos Rueda & Mas Torelló, 2018) obtaining a p-value of 0.029, indicating an acceptable relation between the judge's agreement and the relevance of the items. Additionally, Changeover activities were execute to estimate the reliability of the instrument, by a pilot run of 31 respondents from industries in the Tijuana, Baja California region. The reliability test was apply using the Cronbach alpha (α), whose coefficient values oscillate 0 to 1. The value closest to one indicates the highest degree of reliability of the instrument. In this analysis, we obtained a coefficient of 0.97 by the statistical software SPSS version 25. Therefore the instrument is reliable and feasible to apply it in the industry of the Baja California region and to test the relationships and correlations of the Reik's and 4P's model.

CONTINUOUS IMPROVEMENT TECHNIQUES IN THE MANUFACTURING INDUSTRY

Changeover Methodology

A changeover it is define as the set of activities executed to set up the materials and equipment necessary to manufacture a product having the quality and speed required (Reik, 2006). In Figure 1, is show the sequence of the changeover activities. The process starts when the manufacturing period of product "A" falls to zero. Then the "set up" period is execute, during this period all the accessories and equipment necessary to manufacture the product B, are install. Finally, starts the "run up" period, which lasts until the quality and production rates desired are reach again. Also, in Figure 1, shows the production losses during "set up" and "run up" periods.

Changeover activities are an essential tool of modern industries (Mileham, et al., 1999) to improve changeover times and at the same time increase the variety of products, and small volumes; they contribute to short time interventions that become economically viable.

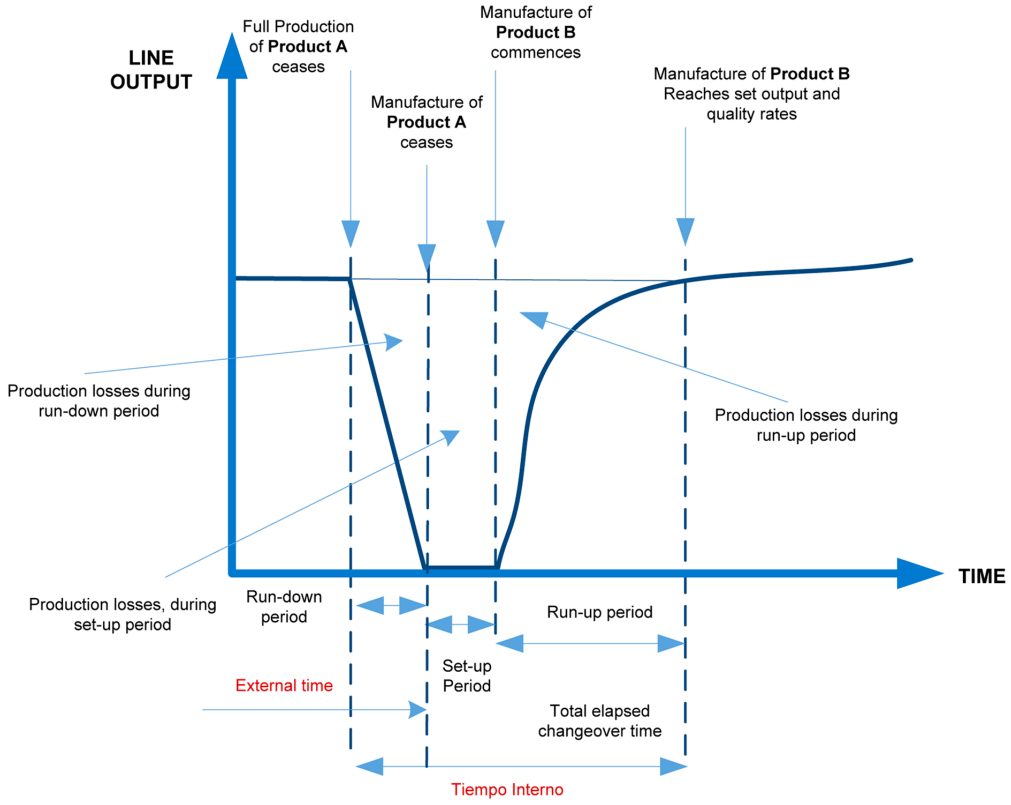
4P's Model

On the other hand, Reik et al. (2006) presents a model of rapid changes that consider organizational and design factors to support the increase of capacity and flexibility in manufacturing processes to respond timely to the customer's needs (Reik et al., 2007). This Theoretical Model integrates, in turn, factors of Product design, Process Design, Human Resource (People) and Work Methods (Practice) and is known as the 4P's model as shown in Figure 2.

4P's model shows a positive influence and correlations between the constructs to solve the problem of the changeover activities effectiveness. However, to explain each P in the model is required the definition of measurable and observable variables. Figure 3, is shows the procedure for confirming factor analysis and establish the related hypotheses.

This chapter shows the first results for the validation of the model, which consists in the design and validation of a measurement instrument (Questionnaire) for data collection in the manufacturing sector in the state of Baja California, Mexico.

Figure 1. Shows the components of changeover process (Reik, et al., 2006)

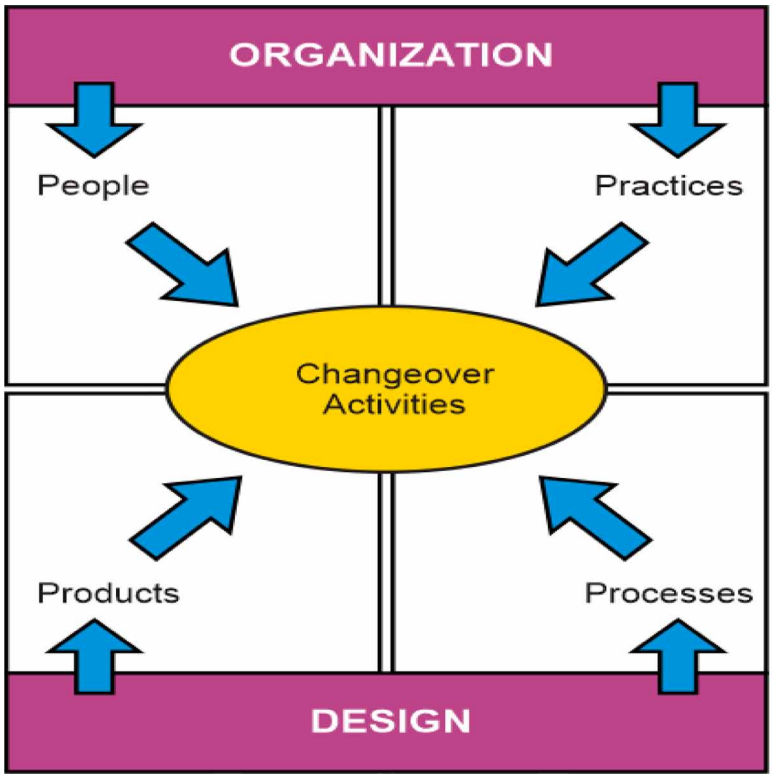


OPERATIONALIZATION OF 4P'S MODEL METHODOLOGY

Resources

1) Electronic databases. The first step consisted of an extensive review through several electronic databases and Journals such as IEEE, Elsevier, and Springer, among others; throwing 37 papers related to the analysis and applications of changeover methodologies. 73% of studied papers were published less than 5 years ago, and the others correspond to relevant references for the study.
2) Measurement instrument (Questionnaire): this step consisted on the instrument design from the review of the literature and the descriptive analysis of the variables that will be developed later, consisting of 79 items in 5 constructs: Changeover, processes, products, people, and practices.
3) Statistical programs. For the data processing and instrument, validation is used the software: *Statistical Package for the Social Sciences* (SPSS) version 25.

Figure 2. 4P's Theoretical Model for changeover activities (Reik et al., Part 2, 2006)

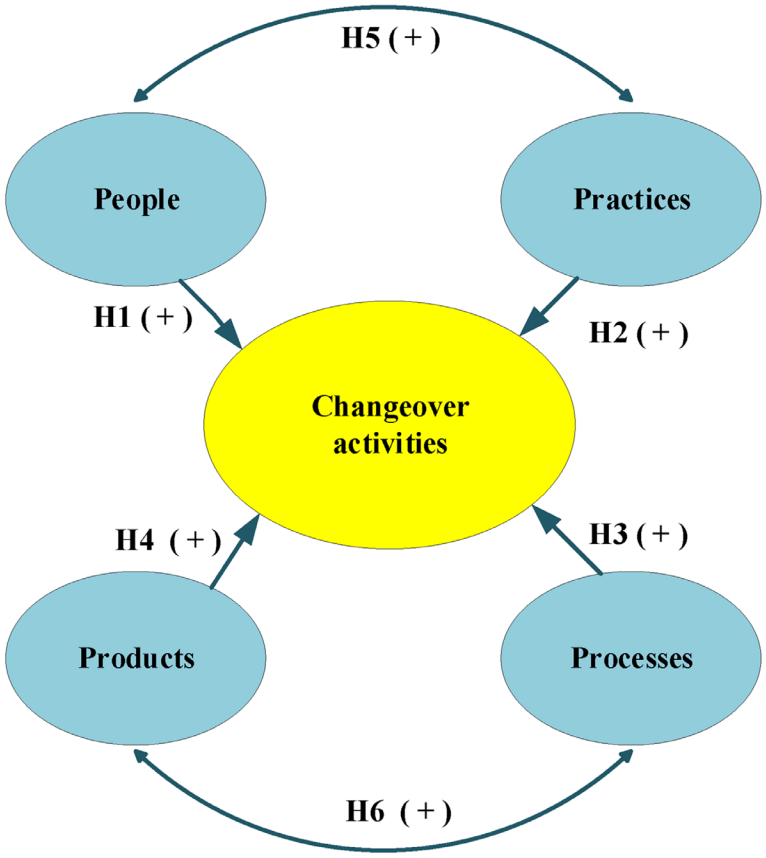


Methods

The initial model consists of 4 constructs, and a fifth construct was considered to identify the activities that make up the rapid changes and to evaluate the weights that they have on this construct, in the second stage of this investigation.0

1) **Variables Collection for each construct**. To identify the observable variables of five constructs and the changeover activities, 37 papers were select. Firstly, the variables that the authors highlighted as relevant in the application of rapid change methodologies were list using a matrix supported by Excel software. Then, all variables were group in each of the constructs empirically. Finally, were calculated the frequency and repetition percentage of each variable.
2) **Descriptive analysis of the variables (Operationalization)**. A descriptive analysis of the observable variables was realized for the characterization of the Theoretical 4P's model, considering the following 4 phases. (Cauas, 2015):
    - Representation of the concept of the latent variable (Construct). The construct is theoretically define, to be more understandable the relationship they have with the model.
    - Specification of each concept. The dimensions are recognize, being understand as the operative variables of the new model.
    - Selection of indicators. In this step, the observable indicators of the variables were select, now statistical methods can be apply.

Figure 3. Theoretical model of 4P's and their relationships. This model explains the six hypothetical positive relations for the efficient deployment of changeover activities.



- Index: In this step, the criteria for measuring the indicators are establish, to determine their presence or absence, the respondent could choose between six options based on a Likert scale, from "totally disagree" to "totally agree".
- Design of the measuring instrument (Questionnaire). From the descriptive analysis of the variables, a questionnaire is formulate, composed of 79 questions divided into the 5 sections. A question was ask per indicator affirmatively, giving six options to answers according to the Lickert scale.
- Validation of the instrument. An analysis of the data validity and reliability of the questionnaire was develop to obtain higher reliability of the information gathered in the questionnaire. Data validation consisted of an evaluation of relevance of the items raised in the instrument, each indicator was evaluated using a scale from 1 to 6 points depending on the items relevance, where 1 is totally in disagreement, 2 strongly disagrees, 3 disagrees, 4 agrees, 5 strongly agrees, and 6 totally agrees, then, the relevance of the instrument was calculated using the following equation:

Relevance of the instrument = (Total Favorable Answers (4, 5, 6)) / (Total responses of the instrument)

In addition to these results, the reliability of the expert assessment was estimate through a statistical match test known as the Kendall's W Model. This model establishes that the following criteria must be met, W> 0 and the test statistic p-value <0.05 to obtain a matching value. This test is performed at a 95% reliability (Olmos & Mas, 2018) (Escobar & Cuervo, 2008), and it seeks to reject the null hypothesis, which states that there is no agreement among the evaluators. To test the reliability of the instrument a pilot run of 31 respondents from companies in the region was carried out, carrying out activities of rapid changes and the Cronbach alpha statistical test (α) was applied in SPSS, whose coefficient oscillates between 0 to 1, where the value closest to 1 is excellent, with $\alpha \geq 0.7$ being acceptable (Gómez et al., 2019).

VARIABLE IDENTIFICATION

Seven operational variables were identify in the construction of the changeover activities from the 37 papers selected for the factor's analysis.

Changeover Activities

Table 1 shows the variables of the changeover activities construct, which are essential tasks in the product changes and their execution are part of the efficiency of the change period, as it can be see, most of the authors highlight the separation of external and internal activities, adjustments and validation and control.

According to Reik, et al.(2006). In the 4P's model, these are affected by organizational and design factors. In the following section is described the operationalization of each construct.

Design Factors

It is necessary for the products designers and productive team to identify the variables involved in the changes of products to consider them from the early stages of design and contribute to efficiency in the production processes (Wiendahl, et al., 2007) also improves flexibility and production capacity and provides higher stability in product runs (McIntosh et al., 2000). These are considered instruments, tools,

Table 1. Variables of the changeover construct

Variable	Repetition rate	Repetition (%)
Adjustments	18	49
Assembly	15	41
Change planning	16	43
Disassembly	15	41
Mounting	16	43
Separation of internal and external activities	25	68
Validation and control	17	46

and products design, and production practices to improve the capacity for changeover (Reik, et al., part 2, 2006), allowing to simplify, eliminate or add elements to make model changes more efficient (Sugai et al., 2007). Table 2 shows the results of the analysis for the process construct, it can be observed that the variables with higher repetition rate and influence in changeover activities according to the authors are the "standardization", "exclusive tools of a manufacturer", "processes of changes manuals" and the "elements of settings used".

Regarding the evaluation of the "Product" construct, it has been find that the indicators more repetitive are "lot size", "cost price" and "quality specifications", as shown in table 3.

Organizational Factors

To be more productive, profitable and competitive, companies have to be committed to the effective use of resources and deploy the best practices, while maintaining a company-wide continuous improvement strategy. McIntosh, et al. (1996), analyze the works developed by Shigeo Shingo and determine that 36% of the difficulties in the changeover methodologies implementation are relate to aspects of an organizational type. Among the organizational factors, for instance, Van Goubergen, et al. (2002) reports that people performance depends mainly on their abilities and skills, as well as the use of the resources required to do the job. Table 4 presents more factors related to the construct "People".

Regarding the evaluation of the "Practice" construct, it has been found that the most frequent indicator are "organizational structure", "use of continuous improvement tools" and "Procedures tracking", as shows table 5.

Table 2. Construct "process" variables

Variable	Repetition rate	Repetition (%)	Variable	Repetition rate	Repetition (%)
Access to the machine or tools	18	49	Manual Process	19	51
Adjustment elements	19	51	Manufacturer's tools	26	70
Automation	11	30	Measurement (Times, losses, failures)	15	41
Cleaning	9	24	Modular Fixing System	3	8
Decreased effort	15	41	Monitoring equipment/ Scrap detection	9	24
Dependent task	3	8	Simplification	13	35
Driving	13	35	Standarization	30	81
Easily identify the pieces (color, engraving)	7	19	Subjection	4	11
Fast release devices	11	30	Systems tolerant to variation	3	8
Handling	9	24	Tools location	18	49
Lightweight materials	4	11	Transport of tools	16	43
Machine lines	4	11	Try and error systems	6	16
Maintenance	12	32	Universality	4	11

Table 3. Construct "product" variables

Variable	Repetition rate	Repetition (%)
Cost/price	14	38
Lot size	16	43
Product documentation	3	8
Quality specifications	12	32
Sizes variety	6	16
Standard product characteristics	8	22

Table 4. Construct "people" variables

Variable	Repetition rate	Repetition (%)
Commitment	9	24
Culture	5	14
Number of line workers	16	43
People's skills	21	57
Physical effort	4	11
Responsible for improvement projects	14	38
Specialization	14	38
Tasks quality	12	32
Teamwork (motivation, communication, leadership)	23	62
Training	27	73

Table 5. Construct "practice" variables

Variable	Repetition rate	Repetition (%)
Balance of workload	9	24
Company goals	7	19
Documented procedures	10	27
Environmental conditions	2	5
Organizational structure	28	76
Procedures tracking	11	30
Security	5	14
Supervision	13	35
Use of continuous improvement tools	18	49
Work sequence	9	24

Variable Operationalization

Because of this research, the following operationalization tables were obtain including the definition and characteristics of each indicator, as well as the scale used to measure them. Table 6 shows the operationalization and definitions corresponding to the changeover activities construct. It can be observed that the changeover activities construct is affected by 7 central activities described through a corresponding indicator.

The process construct is one of the most complex due to the number of activities and variables involved, in this research was find to be describe by 26 main activities, as is shown in table 7. This table presents the activities arranged alphabetically, a definition of each variable and how they can be measure.

The product construct is mainly influence by customer's specifications, standard characteristics and product cost as can be observed in table 8.

The People construct involves several activities related to social development such as motivation, commitment, leadership and communication; also, it must be consider the physical effort, employee's skills, specialization and training. In table 9, are show the activities studied in relation to people construct.

Table 6. Operationalization of the "changeover activities" construct

Variable	Definition	Indicator	Scale
Assembly	Parts that are coupled together or in several combinations to form the main component to produce product B.	Assembly time of the elements for the new product manufacture.	Interval
Disassembly	Includes the disintegration-useful parts linked to the last batch of product A, that is not required to manufacture a product B.	Time spent in dismantling or changing the elements unnecessary to fabricate a new product.	Interval
Mounting	It refers to the installation of the components in the machine or production equipment.	Installation time given to the clarity in the activities of location, orientation, temperature, speed, movements, cleaning, purging, etc.	Interval
Preparation: Planning the change	It is about ensuring that all the pieces, materials, utensils, etc. Are where they should be and prepared to work properly	Production Programs strategically planned and organized production. Control of external activities that have started in a timely manner.	Interval
Separation of activities in internals and externals	It refers to the classification of internal activities, which are the ones that require the team to be stop, affecting the productive time of the team. In addition, the external activities, which can be done with the machine in production, since they are executed outside the operation of the machine, not affecting the productive times.	Existence of classification and analysis of internal and external operations for the optimization of the changeover time	Interval
Settings / configuration	They are successive approximations for the achievement of manufacturing of the first pieces of product B.	Clearly in the criteria of adjustments in the process, to obtain the first good piece of product B.	Interval
Validation and control	They correspond to all the measurements and calibrations that must be carried out to begin the manufacture of product B, such as: centering, dimension adjustments, temperature measurements, pressure measurements, etc.	Existence of a validation and control of the set of adjusted values, as well as tests, quality controls and indicators of the set up.	Interval

The management of people is a key factor for achieving the goals of the organization, for which clear and well-structured work practices are required, in table 10 and efficiency in their activities.

MEASUREMENT INSTRUMENT DESIGN

Once the 5 constructs were operationalized, the measurement instrument was designed (questionnaire), being structured with 79 items, these items were written as affirmative statements, with the purpose that the research subject gave their degree of agreement or disagreement to the statement. For the measurement, a Likert scale of six categories (1 to 6) was used, where the value of 6 means totally in agreement and 1 totally disagrees. The constructs were construct in the following way:

- Construct "Activities of rapid changes", which refers to those tasks necessary to make the change, is integrated by 8 items.
- Construct "Processes", corresponding to a design factor, which refers to the technical and operative conditions of the machines, tools and production systems, was integrated into 26 items.

Table 7. Operationalization of the "process" construct

Variable	Definition	Indicators	Scale
Automation	Implementation of technologies and intelligent systems to manipulate, operate and control the equipment in the changeover. To exclude human activities that require greater effort or risks to the operators.	Change times in automated change processes.	Interval
Cleaning	Includes all the actions taken to keep organized and clean the workplace, equipment, machinery or tools. For example: remove oil, lubricants or dust; disinfect, sweep, vacuum and others.	Cleaning control of equipment, tools and work area.	Interval
Dependent tasks	Those tasks that depend on others to be performed	Independent tasks are performed which facilitate the simultaneous work between operators to speed up the change.	Interval
Adjustments elements	Accessories that assure dimensional requirements in the assembly of two pieces that adjust independently of their shape.	The equipment uses elements of adjustment such as single turn screws, one movement or combined methods, torque tools, washers, etc.	Interval
Equipment or tools access	The path taken from point A to point B to transport everything is required to perform the tasks of change.	It means clean access for transportation and equipment handling to make product changes.	Interval
Error proof systems	The mechanism that prevents human errors in processes from becoming defects. Fault-free mechanism (poka-yoke).	Error test systems (poka-yoke) are use to prevent errors and guarantee quality and security in activities of change.	Interval
Fastening devices	Devices with the purpose of keeping two or more elements tied to facilitate tasks.	Use fastening devices to keep objects fixed with minimum effort.	Interval
Handling	Refers to facility of modifications and withdraw of tools, pieces or equipment after being employ.	Use few change components.	Interval
Identification of pieces (color, engraving)	Refers to the easiness to recognize or differentiate necessary elements in the change. Normally they are classified or identified by color, finishing, etc.	Elements are classify and identify. Through visual inspection, you can know if there are the materials or tools necessary to carry out the change.	Interval
Materials light weighting	Refers to the use of low-density materials in modern molding design technologies, as well as in the manufacturing materials, in order to facilitate transport, handling, assembly, disassembly and maintenance that ensure accuracy and mechanical properties in production, that is, without sacrificing the quality parameters of the final product.	Lightweight materials are using in molds and equipment to facilitate the installation, transport and maintenance.	Interval
Location tools	Physical place where tools, parts or accessories are located for the changeover activities.	Control and organization of tools, parts and accessories necessaries to perform the tasks of the machine and/or equipment.	Interval
Machine lines	Structure where the equipment interconnects and share functional relations in the manufacturing process of a good, affecting in the times of change.	Production process configuration such as workshop, work centers, production in line, modular manufacturing, continuous manufacturing, etc.	Interval
Maintenance	Set of activities developed with the objective of ensure that any asset (machinery, instrument, etc.) continues to perform the desired functions.	There are maintenance plans and controls for equipment and tools	Interval

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Table 7. Continued

Variable	Definition	Indicators	Scale
Manipulation	Refers to the actions taken by persons to alter or modify equipment, tools or others, needed to start-up of the productive processes.	Mechanisms and controls to assure and keep the precision in replacement parts and to guarantee the product quality.	Interval
Manual process	Set of activities developed manually by operators through traditional tools in a process of change.	Change times in manual activities.	Interval
Manufacturer´s tools	Tools and accessories that are property of the equipment manufacturers and cannot be replace or manipulate without its control.	Available equipment to handle accessories and tools that are exclusive of the manufacturer.	Interval
Measurement (Times, losses, failures)	Process by which a set of data is generated to evaluate objectively the performance of the tasks of change, for example: change times, wastes due to quality, quantity of failures, stoppages, etc.	Measurement and monitoring of indicators such as times of changes and resources used to start up the new product.	Interval
Minimize the effort	Requirement of the design to minimize movements, transportations and physical efforts by the operator when making a change in order to avoid accidents or work injuries.	Identification of complex and unsecure elements in the processes of change.	Interval
Modular fixing system	System that facilitate fixation of pieces, working material for a better manipulation, increase precision in assembly of product B.	Modular fixation systems are used to facilitate the assembly of machine parts.	Interval
Monitoring equipment/Scrap detection	Devices installed in strategic zones of the process that allow the record or detection of failures by means of sensors to supervise tasks in the process and avoid equipment faults or waste.	Failure control and waste separation and control.	Interval
Quick release devices	Devices that allow coupling or uncoupling of components in a simpler and safer way.	Quick release devices that facilitate change activities are present.	Interval
Simplification	Action of making the task easier.	a) Few mechanisms to perform activities of change exists and whole pieces' change or pipe connections are not necessary. b) Tools have few accessories and minimum manual tools are using in activities of change.	Interval
Standardization	Unification of components, tools, materials and others that are used in different processes in order to save money and time in the tasks of change.	Standardization of parts, tools, components, etc.	Interval
Tool Transportation	They are special elements for loading, used for the transportation of material, molds and tools, easily and safely to the work place, for example: Pallet Jack, cranes, forklifts, accessories carts, etc.	It has special transport elements to move materials and tools, such as Pallet Jack, portable cranes, accessories cart and transporters.	Interval
Universality	Attribute that allows tools, accessories, fixtures and pieces to be the same for all the processes.	Use of universal parts, tools and fixtures in different processes	Interval
Variation tolerant systems	System or equipment capable to work with more than one product model, adapting to their dimensions, weight, etc.	Identify equipment that can handle different product configuration.	Interval

Table 8. Operationalization of the "Product" construct

Variable	Definition	Characteristics	Scale
Lot Size	Refers to the quantity of pieces or products that are processed in the production system, which is fundamental for resource planning and influences the time and cost of configuration.	The size of lot affects the times of changeover activities.	Interval
Product Documentation	Documents including product details and their manufacture, as well as plans, drawings, work routs, materials, costs, manufacturing time, among others.	Clear product specifications (plans, drawings), which facilitate model changes.	Interval
Variety of sizes	Products differ in sizes but are part of the same family of products. Product A is of different size than product B. Is consider a minor configuration when the piece is part of the same family.	The unitary volume of the product (size) influences changeover activities.	Interval
Quality specifications	They are the technical specifications of the products, services and manufacturing processes to meet the client needs. These parameters are monitor along the manufacturing process.	a) The product quality specifications affect the times of rapid changes b) The different configurations of the products have an effect in the times of rapid changes.	Interval
Standard characteristics of product	They are the characteristics or attributes of the products and are link to client specifications. Managing different product implies more time in the process of change, starting with the acquisition of the materials, preparing the equipment in a specific way, documentation, storing and saving all the previous product components, etc.	a) The characteristics of the product (components, dimensions, forms, functions, parameters) influence in the times of rapid changes. b) The variety of products have an effect in the times of rapid changes.	Interval
Product cost	Investment on the manufacturing of the product, which is composed of the cost of labor, materials and indirect costs (amortization of machinery, indirect labor, fuel, etc.).	Perform improvement actions to reduce manufacturing costs of products.	Interval

- Construct "Product", the other P of Design, which have to do with the conditions and characteristics of the product in the impact of the activities of rapid changes, was integrated by 7 items.
- Construct "People", which is part of the factors of the organization, and refers to the indicators that have to do with the human factor, 17 items integrated this.
- 21 items formed construct "Practice", second P of the organization, which corresponds to the practices performed by the company for the achievement of improvement projects.
- Finally, a block of general questions was add such as company sector, hierarchical position, size of the company, among others, with the purpose of carrying out a descriptive study to determine areas of opportunity in the different sectors. The designed measurement instrument is aim at the personnel of the companies that are involved in the activities of model changes.

Pilot Test

A pilot test was carried out in manufacturing companies in the Tijuana Baja California region, which carry out rapid change activities, this was carried out through a non-probabilistic sample, since the application of the instrument depended on the accessibility of the company, in the following table 11, It shows the distribution of the 31 surveys applied, the company turns, the number of surveys applied and the percentage of participation that was taken from each industrial sector.

Table 9. Operationalization of the "people" construct

Variable	Definition	Indicators	Scale
Commitment	Capacity that a person has to become aware of the importance that exists in fulfilling something previously agreed before.	The personnel in charge of carrying out the activities is committed and understands clearly the importance of carrying out the activity in the shortest time.	Interval
Number of operators	Persons assigned to the management and control of operational parameters in the production process. This assignment arises from an analysis of operations.	The number of people involved in rapid change activities is enough to achieve efficiency in times of change	Interval
People's skills	The skill or ability that a person must carry out and successfully, a certain activity or work.	a) The team in charge of model changes has professional skills and experience. b) People involved in rapid change activities have the capacity and willingness to perform various tasks in the processes of change (poly functionality).	Interval
Physical effort	Activity in which, in response to the demands of a task, the operator sets up a series of resources / capacities / abilities, etc. in order to satisfy the requirements that are required.	The workload of the people involved in the team is adequate.	Interval
Quality of the tasks	Efforts made by people to meet the characteristics required in the team, product or organization, efficiently and productive.	a) The quality with which the individual tasks are perform in the sequence of activities of the changeover influences the time in which the team is available to run the model without generating waste and fulfilling the requirements. b) The workers' culture (values, beliefs, customs, knowledge, etc.) have a positive influence on the quality of tasks, teamwork and motivation.	Interval
Responsible for improvement projects	The leader in continuous improvement projects, who actively participates with the people to achieve productivity and efficiency of the processes.	The person responsible for directing, managing or administering rapid change projects collaborate in planning, monitoring, resource management, supervision, coordination of personnel, generate statistics, solve incidents and problems and communicate results efficiently.	Interval
Specialization	It refers to the extensive knowledge that a person has of a specific topic or work, which implies limitations for the change of roles or support with multiple tasks.	Identify people with more specialization in the performance of tasks.	Interval
Teamwork (motivation, communication, leadership)	It is the union of two or more people, who share efforts, attitudes, skills and knowledge in the work to achieve a common goal, requires leadership and effective communication. An efficient and harmonious union increases motivation and retains talent in the company.	a) The staff works in, sharing knowledge and skills, which is reflect in the reduction of time of tasks and greater efficiency of work. b) Staff motivation positive impact on the performance of activities of rapid change, mainly in the quality of their work. c) The verbal, written and visual communication between the people involved in the activities of rapid changes is an important factor for the accomplishment of the tasks. d) The leadership of those responsible for rapid change projects motivate people and clarify the objectives for a favorable performance.	Interval
Training	These labor education activities prepare the worker, with the purpose of being able to develop a position or function within an organization, with greater efficiency.	a) The people involved in implementing the changeover have a training program to handle the equipment and use tools. b) All those involved in the implementation of changeover know the process of product changes. c) The persons in charge of changeover know the operation and maintenance of the tools and equipment.	Interval

Table 10. Operationalization of the practice construct

Variable	Definition	Indicators	Scale
Organizational structure	It is the way in which each member of an organization takes a role in the activities that are done to achieve the goals and objectives set. This structure allows establishing rules of action, allocation of resources, efficiency in tasks and measuring the performance of the organization, for the improvement of technical and administrative processes.	a) There is a clear organizational structure that allows each person know their role and responsibilities. b) Top management supports the implementation of rapid change projects. c) There is a specific area or group for the continuous improvement of the company's processes, and from there the problems and the reduction of equipment times are consider and addressed.	Interval
Processes documented	It is the detailed documentation of the activities developed in a work environment; they represent the action guides and avoid operational errors, such as factors of time, effort, security, among others.	a) The company has a culture of quality assurance and documents have their operational processes. b) Every improvement actions are document and the procedure of the task is update. c) The times of the tasks or activities have been identify, documented, assigned and measured, which facilitates the development and avoids errors. d) There are controls for measuring and controlling incidents, readjustments, failures, etc., which facilitates process improvement actions.	Interval
Supervision	Set of activities (assessment, guidance, advice, monitoring, inspection, etc.) that a person exercises in relation to others, over which he has some authority within the organization.	The responsible person directs, manages, collaborates, follows up, guides, coordinates the staff, generates statistics, solves problems and communicates the results efficiently.	Interval
Procedures tracking	Set of actions to verify the correct execution of the activities, previously documented, so that they can be measured and take appropriate actions to the process. The staff follows systematically the tasks contained in the documents.	S and follow procedures in the order and sequence indicated in tasks change.	Interval
Work sequence	It consists of activities that are executed together with the time (hours) / priorities and other dependencies that determine the order of the process.	a) Identify the activities / tasks that have immediate origin. b) There is a procedure to change the daily production plan so as not to affect the resources of the company.	Interval
Use of tools for continuous improvement	These tools are useful to look for weak points in the processes, products or services developed. Some focus on identifying the areas of improvement with the highest priority, to minimize time and make the necessary changes.	a) In the process of improvement, tools are used for the analysis of how 5 whys, Pareto diagrams, cause-effect diagrams, PDCA cycle, and control charts, among others that help to identify areas of opportunity in change activities. b) Complementary techniques are used to improve processes such as 5's, Poke Yoke, Just in Time, TPM, Kanban, DMAIC, Value Chain Mapping, Standardized Work, Kaizen, among others that support the efficiency of change times. c) The implementation of several methodologies of continuous improvement at the same time drive the activities of rapid change.	Interval

continues on following page

Table 10. Continued

Variable	Definition	Indicators	Scale
Environment	Are the conditions present in the environment where the product or service provision is obtain that influence the motivation, satisfaction and quality of the tasks?	Identify the best conditions for the work environment.	Interval
Objectives of the company	It refers to the goals that a company aims to achieve in a given period of time and with the resources available.	a) There are strategic objectives to reduce change times, increase the availability of the machine or equipment and reduce costs related to exchange activities. b) There are established objectives to reduce waste caused by rapid change activities. c) There is financial support for the implementation of improvements in the equipment, tools, work area, etc. that simplifies and improves the quality	Interval
Security	It is a set of techniques and procedures applied in the labor areas, in order to minimize or eliminate the risks derived from the work.	a) Availability of protective equipment for the safety of the personnel that performs the tasks. b) Only the tools, materials and means of control established to make the change are used.	Interval
Balance of workload	It is the amount of responsibility or tasks assigned to an area or staff, which must be relate to the capacity and number of activities to be developed, to achieve efficiency and a favorable work environment.	The roles of people who participate in rapid change activities are assign according to their experience, knowledge and skills, which allows for greater results in the process.	Interval

Table 11. Participation of types of companies in the pilot test

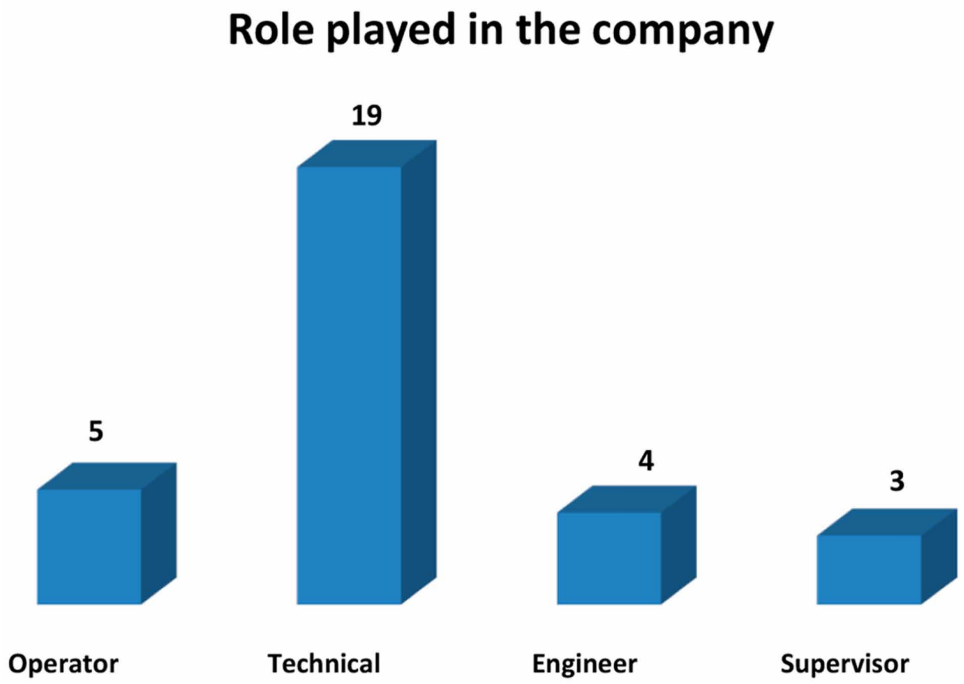
Industrial Sector	Surveyed	% participation
Medical	7	23%
Aeroespace	6	16%
Alimentary	2	6%
Electronics	3	10%
Metalworking	8	26%
Automotive	4	19%
Total	**31**	**100%**

The subject of study within the company was select as that person who was relate to the change process, considering in the analysis managers, engineers, technicians, supervisors and operators, since all of them have influence with the variables that are analyze in questionnaire. In this pilot, 61.29% was represent by responses from technicians, who have a greater impact on the product startup process as shown in figure 4.

Validation of the Instrument

The measurement instrument is presented to 2 types of analysis to measure its performance, the first call, the duration of the content and a second reliability of the instrument.

Figure 4. Distribution of respondent results according to the role in the change process



The validity of content. It consisted in an evaluation of the importance of the elements raised in the instrument by 6 experienced judges, with more than 10 years of experience in the activities of changes in the manufacture industry of the region, where it was evaluated with an escalation from 1 to 6 points the relevance of the questions. In the following figure 5, you can see the scores given by each evaluator to each of the questions, clearly noting that the majority is above 4 points.

The total answers that obtained a score greater than or equal to 4 points were count, with the objective of calculating the total relevance of the measurement instrument, obtaining a total relevance of 94.93%, according to equation 1. What we can conclude, that the evaluators consider the questions contained in the questionnaire relevant

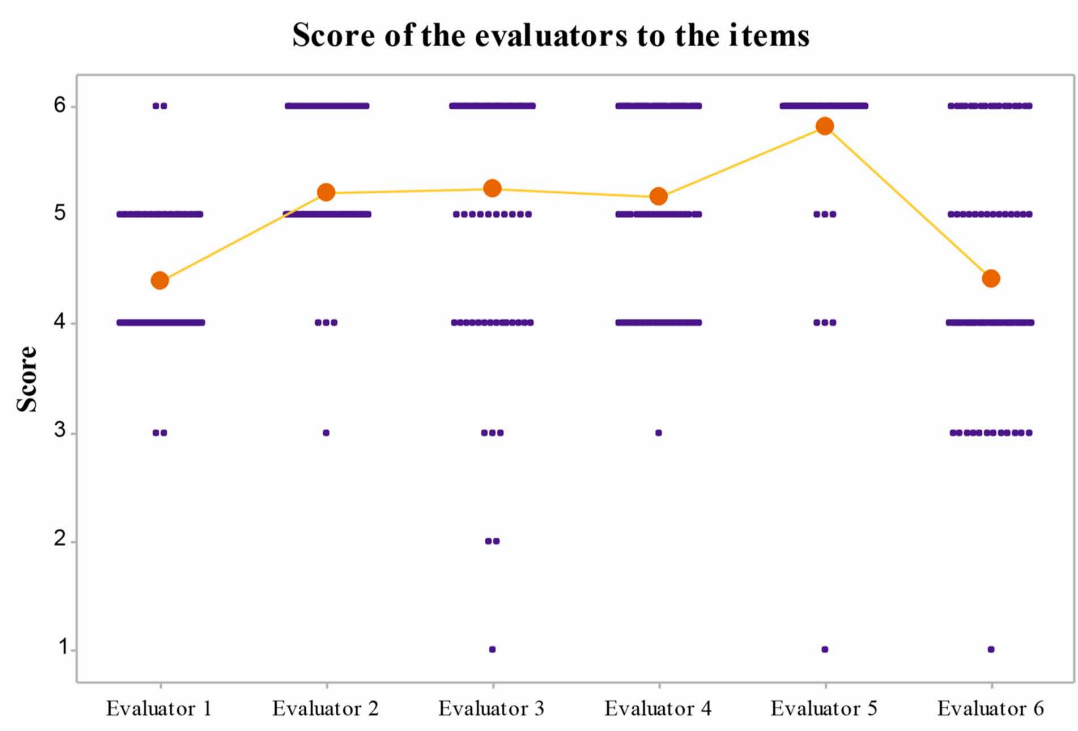
$$Relevance\ of\ the\ instrument = \frac{450}{474} = 0.9493 \times 100 = 94.93\% \quad (1)$$

To give more confidence to the design of the instrument, an agreement of expert judgment was analyze, through the Kendall test, which contrasts two statistical hypotheses with a 95% reliability. The hypotheses are evaluate by the P-value. Where values below 0.05 provide strong evidence to reject the null hypothesis and consequently accept the alternate, together with this we obtain the coefficient of W of Kendall that measures the strength of the agreement (W> 0) closest to 1 greater concordance.

Expert Judgment Concordance Hypothesis:

H_0, There is no significant agreement among the evaluators regarding the items contained in the 4Ps measurement instrument for changeovers.

Figure 5. Score of the evaluators to the questionnaire items



H_A, There is a significant agreement among the evaluators in relation to the items contained in the 4Ps measurement instrument for changeovers.

Table 12, is shows a P value of 0.029, indicating that there is enough statistical evidence to reject the null hypothesis (H_0) and conclude through the alternative hypothesis (HA), that there is a significant agreement between the evaluators in relation to the questions contained in the instrument with a weight of W = 0.2208

Reliability of the Instrument. From the data obtained in the pilot test, in SPSS the reliability of the instrument was analyze through the Cronbach alpha statistic, resulting in a value of 0.974 with the 79 items analyzed. What the instrument is quite consistent to measure the 4Ps of rapid change activities. Gómez, et al., (2019), mentions that the closer the Cronbach coefficient is to 1, the more reliable the instrument is, being acceptable greater than 0.7. The following table 13 shows the Cronbach coefficients by construct, being reliable to gather information to validate the hypotheses of the model of the 4Ps, defined in Figure 2.

Table 12. Kendall concordance indicators of changeover instrument

W	Chi-square	Freedom degrees	P-Value
0.220807	103.338	78	0.029

Table 13. Reliability indicators by construct of the 4Ps model

Construct	Cronbach Alpha
Changeover activities	0.872
Process	0.934
Product	0.763
People	0.910
Practice	0.934

CONCLUSION

The needs of the productive sectors to be more efficient in the application of methodologies to improve their processes, is increasingly necessary. With more demanding markets, a modern manufacturing is required that involves the manufacture of small lots and a great variety of product models; this implies that the times of changes have to be shorter and, to the same extent, reduce the costs associated with them, so. Therefore, it is necessary to know the relative effect of the factors that influence these activities. Design factors and organizational factors play an important role because they are the basis of operational and administrative decisions within the company, as Reik proposes in its model of the 4Ps. As a result, this article shows the design of a measurement instrument, based on the operationalization of each of the P's so that, in this way, improvement strategies are made to reduce the model change times.

The results presented correspond to the first stage of the research project, which is the design and validation of the measuring instrument for rapid change activities, as seen in the results of the evaluations, the instrument is relevant for changeover experts and complies Kendall's statistical hypothesis of agreement, in addition to having internal reliability, which was demonstrated with the Cronbach's alpha of 0.974 when conducting the pilot test in the industrial sector of Baja California. In the following stages of this project, the instrument will be applied to a sample of at least 300 people, and the statistical hypotheses of relations of the Reik model will be demonstrated, by means of a confirmatory analysis with the technique of structural equations.

FUTURE RESEARCH DIRECTIONS

In the future work, the validation of the statistical 4P's Changeover Model, the use of Structural Equations to find the relationships and the weights of each hour will be presented. The changeover activities, which will be a contribution to the theoretical model of Reik and a useful tool for continuous improvement for companies in the region.

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