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MODIFIED FAILURE MODE AND EFFECT ANALYSIS APPROACHING TO IMPROVE ORGANIZATION PERFORMANCE BASED ON BALDRIGE CRITERIA- A CASE STUDY OF AN ELECTRO-MEDIC INDUSTRY

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Research paper

Abstract: *Full attention is paid to quality in manufacturing; however, less effort is made to develop the organizational performance, which drives overall manufacturing quality. This research measures performance of one manufacturing company that in 2020 experienced surging in demand and experiencing barriers to social activities due to the pandemic. The evaluation was carried out using seven variables from the Malcolm Baldrige Criteria for Performance Excellence (MBCfPE) which were elaborated into 43 indicators of organizational performance. Weaknesses and strengths of organizational performance were sharpened through focus group discussions with experts and ended with a performance improvement solution with a priority rank based on risk priority numbers (RPN) of the FMEA method. The highest RPN is 567 and 432, respectively, for national standard implementation in a particular product and operational scheme during emergency conditions like the Cov-19 pandemic. This study contributes to Indonesian research that combines questionnaires and FMEA improvement analysis based on the US Baldrige criterion.*

Keywords: *Performance Excellence, Baldrige Criteria, MBCfPE, FMEA.*

1. Introduction

The industrial governance crisis due to COVID-19 has hit almost all countries, regardless of technological reliability, the sophistication of health services, or economic independence. (Ranggajati et al., 2020). According to various studies in the past year, the external aspects of the organization have greatly influenced the organization's performance, be it business in general or specifically in the industrial sector throughout 2020. (Yap, 2020), (Ahlstrom et al., 2020). External aspects that affect organizational performance include socio-economic shocks, political policies, and the environment (Amarkhil, 2019). According to the 2020 UNDP report on the actions of Asia Pacific business people, it was stated that in the period of the Cov-19

pandemic, 35% of businesses had to lay off staff, 25% postponed orders, 25% had to delay investment, 24% had to decrease wages, 18% reduce service (United Nations Development Programme, 2020). The report from Mckinsey released in early 2021 (Zurich et al., 2021) shows that the companies that have managed to survive are the companies that have succeeded in responding to changes to the challenges of the pandemic during 2020. For example, operational efficiency has decreased, and the company has taken action to cut the budget. Likewise, the use of technology has increased with better technology.

However, those reports did not provide basis of evaluation other than questionnaire. There is research gap between what had been done by the companies in respond to pandemic situation and what was background or reason for chosen actions. This gap requires approaching that put an existing or previous condition as base-line and find improvement in another way using tools that commonly being used by industries. Hence, this phenomenon is developed in this research by conducting studies and evaluating a manufacturing organization's performance during challenging periods. This research selected one organization as the research object, PT-EMB, which is a local industry that focuses on the fabrication and manufacturing of electromedical devices located in the Serpong industrial area, Banten province of Indonesia. This organization has ISO-13485 as the standard for the production quality of several types of medical devices. The company produces Oxygen Generators, which are in high demand during 2020, and the locally made ventilator.

This research is carried out for all organization sections about production, including leadership criteria, strategic planning, customer handling, operational processes, labor factors, knowledge management, and performance measurement. The method chosen is the Baldrige criteria issued by the United States, which is commonly called the Malcolm Baldrige Criteria for Performance Excellence (MBCfPE), containing seven primary variables (NIST, 2020). Large companies typically recognize Baldrige performance measurement because the criteria or variables evaluated represent the overall indicators of organizational performance. Baldrige criteria can be applied to government institutions (H. Anggara & Hasibuan, 2020; Widjajanto et al., 2020), hospitals (Sintari, 2020), education (Thompson & Blazey, 2017), and industries.

The research question in this paper is how to evaluate local business performance during the 2020 pandemic period and what to be improved. Thus, this study's objectives are described as assessing the organization's performance during the 2020 pandemic period using seven Baldrige variables and determining activities that must be improved to increase organizational performance. The baseline is Baldrige criteria version 2019-2020, but this research is intended to find performance improvement instead of performance scoring for award ranking. Data collection, interviews, and discussions were carried out from November 2020 to January 2021.

2. Literature Study

2.1 Baldrige Criteria for Performance Measurement

Baldrige method is a quality management application formally enforced in its home country, i.e., the United States. The US-Congress initiated it in 1987 as a request to Malcolm Baldrige, Commerce Department Secretary. This system was approved by the US President and outlined in the "Malcolm Baldrige National Quality Award Improvement Act of 1987" on August 20, 1987 (Vinyard, 2015). Tens of thousands of companies have adopted the Baldrige method in more than 70 countries in the world. Indonesia also adopted MBNQA and made the Indonesian Quality Award (IQA) an award for corporate performance (Widjajanto et al., 2020). Baldrige criteria consist of seven variables and are elaborated for this research into forty-three (43) indicators below Table 1.

Table 1. Baldrige Variable and Indicators

Criteria		No.	Indicator
Criteria 1	Leadership	1	Management must evaluate the company's vision and mission
		2	Evaluate consistency in vision and mission
		3	Evaluate the organization's code of ethics
		4	Improved work environment
		5	Dissemination of NEW regulations and policies
		6	Evaluate all work according to rules and policies
Criteria 2	Strategic Planning	7	Quality planning
		8	Innovative proposals
		9	Evaluation of strategic planning in day-to-day work
		10	Evaluation of the success/achievement of strategic planning
		11	Flexibility of planning changes
Criteria 3	Customer Focus	12	Evaluate the end-user / customer group
		13	Identify the needs of the customer
		14	Identify customer satisfaction and dissatisfaction
		15	Making decisions related to customer satisfaction
		16	Staff knowledge of the company's main customers
Criteria 4	Measurement, analysis, knowledge management	17	Application of performance measurement methods (KPI)
		18	Performance results as the basis for improvement or change
		19	Alignment of employee and company performance
		20	Job information for all employees
		21	Monitoring, controlling, and recording in the workplace
		22	Use of working procedures and instructions in operating equipment and tools.
		23	All employees know about the company's achievements
Criteria 5	Workforce	24	Teamwork
		25	Support for employee career advancement
		26	Employee performance appreciation
		27	Job security
		28	Evaluate employee commitment
Criteria 6 Operation al / Proc		29	Availability of materials, spare parts, and tools
		30	Evaluate the work process according to instructions

Criteria		No.	Indicator
		31	All equipment is operated using approved instructions
		32	Equipment operated by authorized personnel
		33	Evaluate the use of methods and SOPs
		34	Preparation of operational schemes to deal with emergencies such as the Covid-19 pandemic
Criteria 7	Results	35	Production targets are met
		36	Customer satisfaction is met
		37	Financial condition is maintained
		38	Compatibility of competencies with the final product
		39	Efforts to overcome obstacles
		40	Compliance with local industry regulations
		41	Application of national standard for ventilator production
		42	CSR support for the surrounding community
		43	Workplace comfort and safety

Many organizational performance appraisals have been carried out using various methods (Abdollahbeigi & Salehi, 2020). Several countries developed their version of the way by referring to standards or practices that are already popular internationally. For example, the Thai government has tools for performance measurement in their agencies and organizations that adopt ISO and MBNQA (Pengsuwan & Choonhaklai, 2019). Then there is the SIQ, namely the Swedish Institute for Quality which was developed by adopting the MBNQA (Raharjo & Eriksson, 2017). Specifically, in several Asian countries, several articles describe the performance assessment of public service organizations such as the Batu Pahat City Government Office, Malaysia (Kaliannan et al., 2014), four government institution (Custom, Immigration, Land Transport, and Mining) in Malaysia (Ali et al., 2017), Indonesian Jakarta government licensing services (H. Anggara & Hasibuan, 2020) and a performance appraisal in the local government of the United Arab Emirates written by a US researcher (Furst Bowe, 2019) as well as an article on Saudi Arabia Public Service Organization written by UK researchers (Alhaqbani, 2017).

Another study originating from Europe outlines the performance appraisal of public services, namely the Lithuanian public sector, using MBNQA, EFQM & BSC. (Balabonienė & Večerskienė, 2015), Organizations in Sweden (Eriksson et al., 2016), Public and private organizations in Sweden use SIQ (Raharjo & Eriksson, 2017) and the Mayor's Office in Greece (Tasiou, 2017). EFQM is the European Foundation for Quality Management which emerged recently after the popular MBNQA (Balabonienė & Večerskienė, 2015) and Sweden (Eriksson et al., 2016).

2.2 FMEA Method for Evaluating Organizational Performance

Failure Mode and Effect Analysis (FMEA) was first developed in the aerospace industry in the 1960s as a systematic methodology for identifying known and unknown modes of failure, including causes and consequences on the system and verifying risks associated with priority scales for corrective action. (Liu, 2016). The FMEA used in this research is classified as modified FMEA, which is developed according to a particular business organization (Huang et al., 2020). One example is a modified FMEA approach that combines multiple criteria decision making, adding a cost component to the Risk Priority Number (RPN) calculation (Lo & Liou, 2018).

Another example is the management of waste management in health institutions that also use modified FMEA (Ouyang et al., 2021) and FMEA modifications for health services (Shi et al., 2019). A study proving the relationship between risk management and organizational performance found the most important reasons for decreased performance in administrative implementation items through using the FMEA method by looking at cost and time losses (Hezla et al., 2020).

The FMEA stages are briefly described:

- Describes all operational activities,

- Compiling potential problems that could arise,

- Give the list of severity, occurrence, and detectability levels.

- Calculating the risk priority number (RPN).

- RPN = severity (S) x occurrence (O) x detectability (D)

- Compile a list of actions or actions to reduce risk according to the RPN.

The FMEA method is commonly used in industry, including electronic and medical devices. Several previous studies have shown significant results related to the use of this method. The use of FMEA is commonly used in the industry to identify possible failures in the production process. It aims to improve product quality and reliability (Hasbullah et al., 2017). Alternative repairs for each failure are priority improvements shown in the risk priority number (RPN) values (Budi Puspitasari et al., 2017). FMEA can also be combined with the Statistical Process Control (SPC) method, as carried out in a study that analyzed defects in the pulp and paper industry (Putra et al., 2020). Many practitioners use FMEA in the application of Total Productive Maintenance (TPM). A study to optimize machine maintenance using Reliability Centered Maintenance (RCM) and FMEA was conducted to evaluate the highest failures on a single type of machine with deficient availability & reliability values and did not meet production standards. The FMEA method is used to find six engine components with a high failure rate so that improvements can be made that increase the reliability value of the machine (Nugroho et al., 2020). FMEA in the electronics industry, as practiced in mobile phone manufacturing, can trace essential steps in improving the manufacturing process, resulting in reduced failures, reduced industrial costs and improved quality index, and satisfying customers. (Oliveira et al., 2019).

3. Research Method

The stages of this research were started from determining the problem, aim and objectives, develop a methodology, and identifying the organization's profile of the research object. The collection of the profile information was carried out through initial interviews. If the information regarding the profile is sufficient, then placing the performance criteria is carried out through a questionnaire. The questionnaire results will be tested to see the level of correlation and the level of reliability. In Figure 1, a research flow diagram is presented that explains the steps of this research.
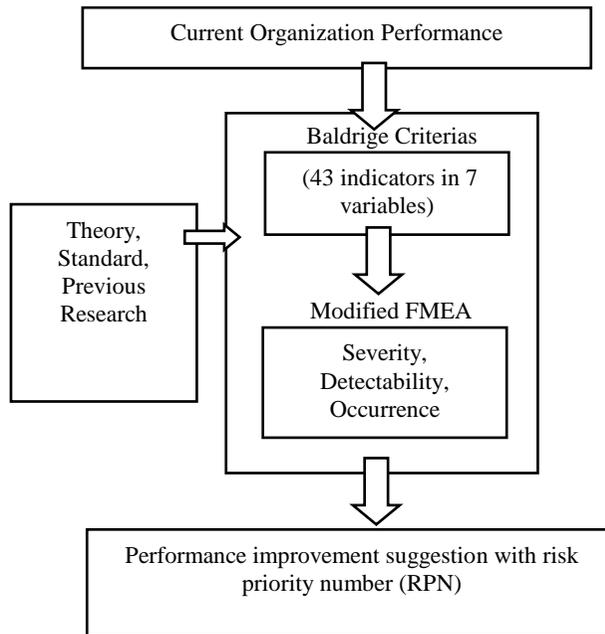
Figure 1. Research Framework

This paper's research aims to evaluate the organizational performance of a local Indonesian electro-medical equipment manufacturing company, which during the Covid-19 pandemic period received a high demand for ventilator and oxygen generator products. The challenges faced, such as social restrictions, logistical difficulties, and other obstacles, will be analyzed in depth. Evaluating the organization's performance is continued by looking for improvement opportunities to improve its organizational capabilities that can compete globally based on the Baldrige criteria used by multinational companies.

This study uses a descriptive exploratory approach using surveys, interviews, and discussions. Based on the Baldrige criteria, organizational performance appraisal produces a scoring used as a baseline as a brief description of the organization's profile. A focus group discussion (FGD) was used with experts selected based on their capabilities. That was part of the brainstorming with the FMEA approach through many performance indicators mapping the organization's condition. The empirical mapping was ranked under the severity, occurrence, and detectability category of the FMEA. The FMEA method makes it easy to adapt to actual situations and presents direct interactions between researcher, respondents, and related experts (Mzougui & El Felsoufi, 2019).

A list of questions was adopted from Baldrige examiner edition 2019/2020 (NIST, 2020) and practical samples (Yusuf, 2017) (Vinyard, 2015). Secondary data is taken from the company in log data related to fabrication activities during the Cov-19 regulation in the form of records and reports obtained that will be helpful in the analysis and determination of corrective steps. The stages in the design of

performance improvement are carried out using a modified FMEA approach with the following steps:

- Using the data obtained from Baldrige indicator list.

- Discuss FMEA to find solutions for performance by ranking priorities. The tables for severity, occurrence, and detectability modified by reference are shown in the table below.

- Evaluate and develop potential problems on severity, occurrence, detectability and calculate for respective indicators of Baldrige variables.

4. Data Result and Analysis

4.1 Baldrige Scoring Based on Questionaire

The research questionnaire was distributed to all employees, where the characteristics of the respondents were collected as well age, gender, work experience, education level, and the job position of the respondent. Item Analysis is used to check the validity and reliability of items in measuring variables. These measuring use a Likert scale as the degree of approval of a statement. The questions in the questionnaire used the Baldrige for examiner edition 2019/2020 reference (NIST, 2020). Minitab's item analysis yields the Pearson correlation and Cronbach's alpha values. The Pearson value obtained by Minitab is then compared with the value from the Pearson R critical value table, with a significance of 0.05 and df = 24; the figure is 0.388. If the calculated Pearson correlation value shows a value greater than 0.388, the data is declared valid. Item analysis was carried out to all Baldrige variables and concluded that all survey data is valid and reliable.

Baldrige score on each questionnaire variable, according to H. Anggara & Hasibuan (2020) obtained through the formula:

$$\frac{[\frac{\sum n_i w_i}{N.W} \times 100\%]}{Y} \times (\text{Standard score for each Baldrige variable}) \qquad (1)$$

n_i = number of respondent for the answer i

w_i = weight of answer i

N = total number of respondents

W = largest answer weight = 5 (Likert scale)

Y = total number of questions for each categorical variable

Calculation and recapitulation of performance scores uses common excel spreadsheets. Its summary is presented in Table 2 as a summary of total scoring. The Baldrige score for the company performance is 463.09 shown in the table. That is equal to 45.86% compared to the ideal Baldrige excellence performance. Obtained a total score of 463.09 is in the Early improvement achievement according to MBNQA award criteria. Criteria 1 until 7 description is available in Table 1 including all relevant question poin.

Table 2 Total Score Baldrige Criteria

Criteria		Score	Ideal MBNQA	Comparison (score/ideal)	Gap	Remarks
1	Leadership	58.00	120	48.33%	2.47%	Strength
2	Strategic Plan	39.44	85	46.40%	0.54%	Strength
3	Customer Focus	39.78	85	46.80%	0.94%	Strength
4	MAKM	39.10	90	43.44%	-2.41%	Weakness
5	Workforce	39.10	85	46.00%	0.14%	Strength
6	Operation	36.67	85	43.14%	-2.72%	Weakness
7	Bussines Result	211.00	450	46.89%	1.03%	Strength
Total	-	463,09	1000	45,86%	-	-

The table also states the gap value obtained from subtraction the obtained score against the average. The negative score on the gap column is classified as weakness, while the positive as strength. The lowest minus value is in criteria no.6 or the Baldrige criteria for operations. That has been labeled as weakness and will be the primary target for corrective action. In that summary, the performance that is considered weak falls also to criteria no.4 Measurement, Analysis and Knowledge Management (MAKM). The leadership or criteria no.1 is superior to the most robust criteria in this company.

4.2 FMEA FGD Result

The next step in finding a performance improvement solution is to quantify the Baldrige performance items by looking at the potential failures of this company. The qualitative performance items are evaluated using a modified FMEA by analyzing the effect of the loss on the schedule, costs, and outputs that impact either major or minor (Harman, 2020; Hezla et al., 2020). The FMEA working paper produced in this research can be classified as a preventive risk assessment method. The results are finding, prioritizing, and removing potential problems as material for improvement and lessons learned in future company activities. (Hezla et al., 2020).

Table 3 (a). Severity Level

Effect	Severity Level	Rank
Schedule	Huge impact, exceeding tolerable limits	
Total Cost	Additional expenses are very significant	$9 \sim 10$
Technical Problem	Useless output, discarded	
Schedule	Impact on schedule 10-20% of the target	
Total Cost	Additional expenses up to 20% of budget	$7 \sim 8$
Technical Problem	Output is impacted and cannot be used by the client	
Schedule	Schedule affected up to 10% of target	
Total Cost	Total expenditure costs increased up to 10%	$5 \sim 6$
Technical Problem	Outputs are impacted and require client approval	
Schedule	Schedule affected, still within tolerance	
Total Cost	Total expenses have increased within tolerance limits	$3 \sim 4$
Technical Problem	Minor impact and requires internal company approval	
	No effect for all	$1 \sim 2$

Table 3 (b). Occurrence Level

Possible Poor Performance	Probability (Occurrence)	Rank
Very high	>1 in 2	10
	1 in 3	9
High (repeatedly)	1 in 8	8
	1 in 20	7

Table 3 (c). Detectability Level

Detectability Assessment	Rank
No detection (of performance measurement) method is available that can alert enough time for corrective action	$9 \sim 10$
The detection method (of performance measurement) is unreliable or untested. The effectiveness of detection methods is not known for identifying poor performance	$7 \sim 8$
Performance detection / measurement methods are quite effective in some units / divisions / departments	$5 \sim 6$
The performance detection/measurement method has been effectively implemented in all work units	$3 \sim 4$
The performance detection method is very effective, and it is almost certain that poor performance will be detected in a sufficient time	$1 \sim 2$

In compiling the FMEA, three people were selected as an expert, the first resource person from government representative (X1 or Expert no.1), the second is an academic lecturer (X2 or Expert no.2), and the third expert is person-in-charge General Manager of the company (X3 or Expert no.3). Some references have been used to determine severity level by looking at the effects of the schedule, total costs and technical problems (Liu, 2016) (Hezla et al., 2020) elaborated in Table 3 (a). The level of occurrence and detectability is consecutively in Table 3 (b) and Table 3 (c).

The assessment begins with the information obtained from the Baldrige criteria as the basis for performance items. The points of failure are developed, which can be extracted from the situation in the company that is the object of research and evaluated for possible losses that can reduce the company's organizational performance. Focus on the three main variables of the FGD results that show weak performance. Each item in the variable is assessed severity, occurrence, and detection and calculates risk priority number (RPN). The evaluation results are in Table 4 below and sorted by RPN ranking. Indicator desciprion is available in Table 1 in previous section.

RPN = SxOxD (2)

RPN: risk priority number
S: severity rank
O: Occurrence rank
D: Detectability rank

Table 4. FMEA result with RPN ranking

Indicator ID No.	X1	X2	X3	S	X1	X2	X3	O	X1	X2	X3	D	RPN	Rank
41	9	9	9	9.00	9	9	9	9.00	7	7	7	7.00	567.0	1
34	9	9	9	9.00	8	8	8	8.00	6	6	6	6.00	432.0	2
29	8	8	8	8.00	8	9	9	8.67	6	6	6	6.00	416.0	3
22	7	7	8	7.33	7	8	8	7.67	8	7	7	7.33	412.3	4
32	7	7	8	7.33	8	8	8	8.00	5	6	6	5.67	332.4	5
31	7	8	8	7.67	8	8	8	8.00	5	5	6	5.33	327.1	6
20	7	7	8	7.33	7	7	8	7.33	5	5	6	5.33	286.8	7
33	7	8	8	7.67	7	7	8	7.33	5	5	5	5.00	281.1	8
36	7	7	8	7.33	7	8	8	7.67	5	5	5	5.00	281.1	9
35	7	8	8	7.67	7	7	7	7.00	5	5	5	5.00	268.3	10
37	7	8	8	7.67	7	7	7	7.00	5	5	5	5.00	268.3	11
40	7	7	8	7.33	7	7	7	7.00	5	5	5	5.00	256.7	12

The results obtained in the table show that the priority which has the potential to become a significant problem is the absence of a reference standard, in this case, the specific Indonesian National Standard (SNI) for ventilator products, getting the highest RPN score of 567. That is confirmed by other experts who work in certification bodies that Currently, Indonesia does not have it yet. Hence, the prototype built during the 2020 pandemic uses open-source references from research institutions (FKUI, 2020).

The subsequent finding that becomes the second priority is the availability of material needs, spare parts, and work tools with an RPN score of 416.7. The root of the problem that was successfully explored was the finding of non-standard components so that for each unit produced, different tunings and adjustments had to be done. The company confirmed the failure because the materials and parts they received were from research institutions without an independent purchasing process to find a better supply source.

The potential for performance failure, which is ranked third with an RPN score of 396, is related to the readiness of the operational scheme to face the Covid-19 pandemic emergency. The informant confirmed that the challenges faced during the pandemic were the limitation on the number of workers due to social distancing, difficulties in mobilizing to testing agencies, and logistical constraints on sensor components that still have to be imported from abroad. Potential failure in the subsequent RPN ranking is regarding teamwork cooperation, equipment operated by authorized personnel, approved work instructions and SOPs, customer satisfaction, information on work implementation for all employees, sharing information on production targets, and stable company financial performance condition, and the comfort of the working place. The availability of work guidelines is emphasized in Table 6 under several indicators, i.e., all equipment operated using approved instructions with an RPN score of 327.1 and is ranked sixth. The seventh and eighth ranks were also related to work instructions, with an RPN score of 299.9. Evaluation of the use of the method & SOP has an RPN score of 281.1.

5. Result and Discussion

5.1 Company Performance Evaluation Compare with Other Researches

This study presents two empirical studies, the first on assessing Baldrige variables in organizations using questionnaire data, which according to the literature, is a self-assessment. The second is to evaluate Baldrige performance indicators according to independent reviewers with selected sources. As such, it provides a deeper level of reliability and validity regarding assessment, perception, and reporting. The second important aspect of these studies is improving and improving the quality of performance in organizations that can be developed over time.

This research results obtained the highest Baldrige score on leadership performance, as shown in Table 5 (a) and (b). The lowest score is received on the Operational and Process performance variables. That is consistent with the results of previous research in the application of quality management in industry (Anastasiadou & Taraza, 2019; Fatima & Mahaboob, 2018; Mellat-Parast, 2015; Parast & Golmohammadi, 2019; Savov et al., 2017; Thompson & Blazey, 2017). This research found that the leadership factor is the primary driver of the quality performance of the organization. These results confirm the Baldrige concept that organization system is driven by leadership as well as senior staff, and this is the primary key to improving quality performance (Ahuja et al., 2019; Asif et al., 2019; Parast & Golmohammadi, 2019; Savov et al., 2017).

Table 5 (a) Performance criteria that needs to be improved

Priority	Based on Baldrige scoring
1st	Operational (criteria 6)
2nd	Measurement, analysis, and knowledge management (criteria 4)
3rd	Workforce (criteria 5)

Table 5 (b) Dominant Performance Criteria

Dominant	Criteria	Actual / Ideal score	(%)	Gap
The highest score	Leadership	58.00 / 120	48.33%	2.47 %
The lowest score	Operational	36.67 / 85	43.14%	-2.72 %

Table 6 below is compiled from various references related to the development of organizational performance and its significant factors. These essential factors affect organizational performance, either directly or indirectly, and positively encourage or hinder organizational performance improvement. The leadership factor is a significant factor affecting organizational performance, both positive and negative (Nandasinghe, 2020), (Parast & Golmohammadi, 2019), (Asif et al., 2019), (Ahuja et al., 2019), (Anastasiadou & Taraza, 2019), (Savov et al., 2017).

Table 6. Significant Factors for Organizational Performance in Previous Research

Description	Previous researches
Leadership factor	(Nandasinghe, 2020), (Parast & Golmohammadi, 2019), (Asif et al., 2019), (Ahuja et al., 2019), (Anastasiadou & Taraza, 2019), (Savov et al., 2017).
Training and sharing of knowledge and attention to employee intellectual property	(Kanapathipillai & Azam, 2020), (Ahmed et al., 2020), (Muwardi et al., 2020), (Mahmud et al., 2020), (Abdul Rauf et al., 2020), (Abbas et al., 2018), (Abualoush et al., 2018), (Chaudhry et al., 2017), (Puška et al., 2018)
Strategic Planning	(Kasushik & Guleria, 2020), (Chioke & Mbamalu, 2020), (Ahuja et al., 2019), (Anastasiadou & Taraza, 2019), (Dobrosavljević & Urošević, 2019)
External Organization Factor (social, politic, environment)	(Yap, 2020), (Ahlstrom et al., 2020), (Amarkhil, 2019)

One literature shows the importance of the causal relationship from the leadership factor to the information factor. The analysis is quantitatively demonstrated, proving that leadership has a vital role in information analysis and knowledge management variables. (Parast & Golmohammadi, 2019). Another study examined the relationship between leadership, quality of administration, quality of medical services, and patient satisfaction using the MBNQA criteria. Further research in hundreds of Pakistan hospitals investigated the effect of interventions on quality of medical service with relation to patient satisfaction and leadership. It obtained a positive relationship between leadership, administrative quality, medical quality, and patient satisfaction. In addition, administrative quality and medical quality were found as potential mediators in the relationship between leadership and customer satisfaction (Asif et al., 2019).

The second factor is by improving the internal work system of the organization, which is manifested by training actions, sharing knowledge between members of the organization and between departments so that the main objectives of the organization are achieved with the best collective performance and also job rotation (Sebt & Ghasemi, 2021), (Kanapathipillai & Azam, 2020), (Ahmed et al., 2020), (Muwardi et al., 2020), (Mahmud et al., 2020), (Abdul Rauf et al., 2020), (Abbas et al., 2018), (Abualoush et al., 2018), (Chaudhry et al., 2017), (Puška et al., 2018).

The third significant factor, according to the previous literature, is strategy and planning (Khan et al., 2021), (Kasushik & Guleria, 2020), (Chioke & Mbamalu, 2020), (Ahuja et al., 2019), (Anastasiadou & Taraza, 2019), (Dobrosavljević & Urošević, 2019), which in this research, it is included in the Baldrige variable number 2. However, this study did not find that variable is the dominant performance. However, strategic planning is still needed, especially the redesign of the roles and functions of each employee to adapt to the post-pandemic new normal conditions.

According to the literature, the fourth significant factor is the external influence of the organization, namely the social, environmental, or political policies imposed by the government. There are challenges in the form of Social Restrictions policies that limit the industry's movement both organizationally and in employee activities. Working conditions under pressure, restrictions on job access, and decreased employee motivation will affect organizational performance (S. A. Anggara et al., 2019). However, other research shows that managing the risks that may arise will improve the performance of the company organization (Najib et al., 2019).

The literature review also shows the importance of customer relationship management, leadership, communication, and strategic alignment as a very significant causal in implementing efficient continuous performance improvement. (Ahuja et al., 2019). As a comparison, researchers also reviewed research on evaluating organizational performance in education using the Baldrige criteria in Greece. The results of these studies prove that the main factor in their Tertiary Education System is leadership. The following variable that must be taken into account is Strategic Planning, which also has a significant effect on the successful implementation of quality (Anastasiadou & Taraza, 2019). The last article used as a reference shows that using a performance measurement system will affect organizational performance, especially helping organizations monitor performance, which ultimately leads to target achievement and gathering information and activity records that are useful for improving its performance. This system will affect various aspects of the organization, including financial and non-financial performance, employee behavior, and overall performance (Owais & Kiss, 2020).

5.2 Research Contribution to the Company

This research provides several contributions to the companies related to evaluating their performance, including leadership, strategic planning, knowledge management, customer handling, employment, operations, and production. First, this research evaluates the companies' performance using a Baldrige model, which is theoretically robust and has been widely applied in the business world. It is the first empirical performance evaluation to PT-EMB uses this kind of performance measurement. One of the critical implications of this finding is that the PT-EMB will use the Baldrige model as a self-assessment tool to improve the quality of performance further.

Table 7. List of performance indicator to be improved by PT-EMB

No	Performance variable	Performance indicator to be modified/improved	Indicator ID
1	Operational and process	Availability of materials, spare parts, and tools	29
		Preparation of operational schemes to deal with emergencies such as the Covid-19 pandemic	34
		Equipment operated by authorized personnel	32
		All equipment is operated using approved instructions	31
		Evaluate the use of methods and SOPs	33
2	Measurement, analysis, and knowledge management	Use of working procedures and instructions in operating tools	22
		Information and socialization of job task to all employees	20
3	Business results	Implementation of the national standard for ventilator product	41
		Customer satisfaction is met	36
		Production targets are met without defect	35
		Organizational financial condition is maintained	37
		Compliance with local industry regulations	40
4	Workforce	Teamwork enhancement	24

Previous research has used the Baldrige model to improve performance quality using cross-sectional surveys (Parast & Golmohammadi, 2019), and it usually follows up with SWOT analysis. Thus, the second contribution of our research is the novelty that brings up Baldrige indicator assessment via FMEA to produces suggestions for performance improvements on a priority scale. This is a contribution to academic theory as well that combines Baldrige with FMEA approach.

The third contribution of this research is to understand how to carry out comprehensive organizational performance measurements regardless of the business model and looking for loopholes to improve the quality of performance using the Baldrige approach. The improvement suggestions to the company are listed out relevant with each main criterion in Table 7.

One of the critical points of the discussion above is the absence of a specific Indonesian national standard (SNI) for the production of ventilators. Although this SNI is the government's responsibility through the National Standardization Agency for Indonesia, this does not escape its responsibility in ensuring the quality of its products. In general, the production process at this company has met the ISO-13485 quality standard (the quality standard for the medical device industry) except for the local ventilator production line, which specifically mass-produced prototypes made in Indonesia.

In addition, it is recommended that the PT-EMB involves the quality team from the planning stage, the purchasing process stage, and the material receiving stage. At the planning stage, selecting materials and determining specifications that guarantee quality should be considered. In the purchasing stage, the supplier selection must be reviewed and the technical quality specifications offered by the supplier. When receiving goods, the quality team must verify all materials are per the desired quality.

5.3 Research Limitation

This study has limitations related to social and activity restrictions due to the pandemic in the company, which causes questionnaire data collection, interviews, and discussions to be carried out in stages repeatedly—some using a paper questionnaire form and some using an online application. The same thing was done when FGD discussions with experts were conducted online using the video call facility and the online google-form application. The time limitation possessed by the five experts can be overcome by partially discussing several stages until all the results are collected, which can be made a consensus with the confirmation of the experts as a resource.

Organizational performance appraisal using the Baldrige variable in this company has never been carried out other than a performance appraisal for employees as a requirement for calculating the annual bonus and ISO13485 assessment for administrative production areas. Thus, the result cannot be compared to the previous comprehensive company performance evaluation. Other industries in Indonesia that use the Baldrige variable are only government-owned companies, hospitals, and educational institutions; hence, benchmarking cannot be carried out.

The performance evaluation was in the Cov-19 pandemic period so that company activities were only prioritized for the production of equipment for Covid-19 handling, which was carried out urgently, i.e., oxygen generators and local prototype

ventilators, and might be different from activities in normal conditions either before or after the pandemic.

6. Conclusion and Suggestion

6.1 Conclusion

The results showed that the performance of this company, when analyzed using the Baldrige variable, was at the early improvement level of achievement, with the best value performance in the leadership variable and the lowest value performance in the operational variable. It is in line with the expert's evaluation that the priority performance should be improved is the Operational variables. Apart from these variables, other variables also show weak performance indicator items, namely in the knowledge management variable, performance analysis, and measurement and outcome variables. Weak performance in the labor variable is only found in the indicator of co-worker cooperation.

This study produces solutions to improve company performance in the order of priority. In practical terms, the performance items that involve the internal company will be easily corrected. What will be difficult to implement is the availability of national standards for ventilator products. Until the time this research was compiled has not been issued by the National Standardization Agency for Indonesia.

6.2 Suggestion for Future Research

- Evaluating organizational performance using the Baldrige variable for manufacturing electro-medical devices can be a role model for similar industries, particularly in Indonesia and South East Asia. The obstacles encountered can be used as lessons learned by other researchers.
- Organizational evaluation using the Baldrige model combined with FMEA was not found in previous literature. Thus, further research is expected to be followed that will strengthen the use of these approaches.

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