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An experimental approach to total quality management in the context of Industry 4.0

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by

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CONTENTS

1. INTRODUCTION, OBJECTIVES

Industry 4.0 refers to the new technological development that occurred at the industrial production systems. It evolved as a result of integrating the Internet of Things, Cyber-Physical Systems, Big-Data, Artificial Intelligence, and Cloud Computing in the industrial systems. This integration aided new capabilities to achieve higher levels of business excellence, efficiency, and effectiveness. total quality management (TQM) is a managerial approach to achieve outstanding business excellence. There are several approaches to apply TQM principles in any organization. Industry 4.0 could be utilized as a key enabler for TQM especially by integrating its techniques with the TQM best practices.

In this research work, the role of Industry 4.0 in developing total quality management (TQM) practices is discussed through two approaches; theoretical and experimental. The theoretical approach included a comprehensive review of the features and technologies of Industry 4.0. Such a review is followed by exploring the ISO 9000:2015 standards family as a TQM commonly adopted strategy. These TQM practices are discussed in the context of Industry 4.0. Hence, how industry 4.0 will influence the implementation of TQM principles. Moreover, an integrated Industry 4.0 – quality management based system is suggested where Industry 4.0 features and technologies are integrated into the traditional quality management system (QMS) functions.

On the other hand, the experimental approach assessed the impact of integrating one of the Industry 4.0 technologies, namely machine learning techniques with one of the TQM practices, namely process monitoring and improvement. In this experimental approach, machine learning is utilized to enhance failure mode and effects analysis (FMEA) as a process and product quality assurance technique. This experimental approach is conducted in partnership with an agricultural machinery manufacturing company in Hungary, namely CLAAS Hungária Kft (CLH).

In conclusion, the impact of Industry 4.0 on improving TQM practices is examined in a real-case example. The results of this research work are theoretical including the Industry 4.0 - QM based system, which is important nowadays to respond to such a development in the practices of quality management, and experimental which are resulted from applying machine learning methods on developing a quality management method which is FMEA. The objectives of this research can be described as follow:

- To identify an interface where Industry 4.0 can support the most critical practices of total quality management such as the seven TQM principles as in ISO 9000:2015 standard in addition to quality control and quality assurance.
- To identify the set of qualitative and quantitative performance indicators for the TQM best implementation practices aligned with Industry 4.0 features and technologies. Accordingly propose their relevant measurement methods tools by using suggested Industry 4.0 features and technologies.
- To suggest a comprehensive Industry 4.0 – quality management-based system and to examine the actuality of such a system or part of it through a scientific partnership with an industrial company in Hungary.
- To examine the impact of Industry 4.0 technologies on one of the TQM common practices such as “process monitoring”. Hence: enhancing FMEA using auto-machine learning.

2. MATERIALS AND METHODS

In this chapter, the used materials and methods for the theoretical analysis and experimental investigation are discussed concerning TQM practices jointly with Industry 4.0 features and technologies. The industrial cooperation that is made with an industrial company in Hungary to apply machine learning methods including data collection, pre-processing, analysis and machine learning modeling.

2.1. Total quality management in the context of Industry 4.0

Industry 4.0 offered many capabilities for quality management practices, the technological advancement provided new techniques to ensure the quality of the products, new inspection tools, new early failure detection and prediction methods, and self-adaptation and self-adjustment possibilities. These techniques enabled the production facility to re-adjust its production plans to respond to customers' requirements, fluctuating demand, and avoiding machine failure or downtime. Table 1 summarizes the contribution of Industry 4.0 features and technologies on the implementation of TQM principles according to ISO 9000: 2015 standards, quality control, and quality assurance.

Table 1. TQM and Industry 4.0 interaction summary

TQM principles	Quality objectives	Industry 4.0 contributions
Customer Focus	• Improved customer satisfaction & loyalty, • growth in customers' base, • improved organization's reputation.	• Improved responsiveness due to collaboration technologies and the integration of different service units. Moreover, utilizing Big-Data analysis using AI techniques such as ML and robotics, • customized product/customer due to dynamic individualized production systems and integration, • smart prediction of market demand due to prediction techniques of Big-Data analysis.
Leadership	• Unity of purpose among the organization, • aligned strategies, policies, processes and resources, • effective communication between all administrative levels.	• Smart allocation of resources using CPS, • high coordination among all levels of the organization due to integration feature, • effective evaluation for results due to Big-Data analysis and integration among the value chain.
Engagement of people	• Increased peoples' motivation, • increasing innovative ideas, • enhanced people satisfaction, • self-evaluation and self-improvement culture.	• Improved communication and collaboration due to connectivity and collaboration features, • facilitating innovation and sharing of ideas due to the future prediction by Big-Data analysis.

Process approach	• Identify key processes and points of improvements, • optimized performance and effective process management, • manage processes, and interrelations, as well as dependencies.	• Transparent, interconnected, dynamic processes due to utilization and integration of smart prediction and analysis tools, • self-learning and early failure prediction due to AI prediction-based systems, • less downtime, early maintenance prediction due to AI and ML applications.
Improvement	• Responsive systems to customer requirements, • enhanced ability to react to the development of processes, products and market needs, • support drivers for innovation.	• Active interaction with dynamic market requirements due to collaboration and integration features, • instant re-configuration of production processes to respond to improvement requests due to the utilization of CPS, • motivating for change environment due to instant Big-Data analysis.
Evidence-based decision making	• Clear decision-making process, • data availability and clarity, • effective past decisions, • analyze and evaluate data using suitable methods and tools.	• Rich information and analytics dashboards about production, machines, and markets due to Big-Data analysis, • early evidence detection to correct or support decisions due to AI and ML applications, • factual decision making based on Big-Data analysis, AI, and ML techniques.
Relationship management	• Stakeholders are identified and suitable communication tools to each are known, • stakeholders are satisfied, and their feedback is considered, • suppliers are responding to materials requests on time and at the required quality, • the supply chain is stable and no downtime due to lack of supply.	• Easy identification and communication tools due to integration features and collaboration technologies, • the ability to hire segmentation of stakeholders based on priorities by using Big-Data analysis and AI techniques, • stronger collaboration with providers and partners to encourage continuous improvements.
Quality control	• Ensuring high-quality products free of defects and conformed to design, • the fulfilment of customers. needs, • utilizing inspection and statistical quality control tools.	• Real-time quality control activities including inspection and defected products exclusion by using smart monitoring and analysis tools such as sensors, 3D cameras and deep learning techniques, • instant product quality inspection by

		using smart monitoring and analysis tools such as sensors, 3D cameras and deep learning techniques, • lower cost of quality due to less defective production and instant process adjustment using CPS.
Quality assurance	• Standardized processes and production procedures, • ensure process quality in order to produce quality products. • minimize process variation and deviations.	• Process monitoring and early deviation prediction by using smart monitoring and analysis tools such as sensors, 3D cameras and deep learning techniques, • self-process adaption and self-adjustment by utilizing CPS, • overall integration with other stakeholders such as suppliers and maintenance management by utilizing collaboration and interconnectivity features.

2.2. Developing the relevant key performance indicators

In order to assess the effectiveness and efficiency of integrating Industry 4.0 on TQM principles, a set of key performance indicators is suggested for every TQM principle or practice. Moreover, it is important to select suitable assessment tools by which data is being gathered, and effective data analysis and evaluation methods. Consequently, it is important how the results will be presented to relevant people at their respective locations.

In conclusion, the suggested KPIs to assess the impact of Industry 4.0 on TQM practices are presented in section 3.2. The identification of the KPIs is subjected to the seven TQM practices, quality assurance and quality control performance indicators.

2.3. Developing an integrated Industry 4.0 - quality management based system

The development of the proposed system is carried out by integrating the Industry 4.0 features and technologies with all the functions of the QMS. For example, integrating Industry 4.0 collaboration feature in gathering customers' requirements through different channels, and translate these requirements into working orders which are managed by the QMS.

Plan-do-check-act (PDCA) cycle is also backed by Industry 4.0 technologies. For example, an optimum production including efficient processes and operations planning is reached by utilizing CPS (Plan). Where new production scenarios are translated into actual production plans (Do). The performance of the system is measured and evaluated (Check) using data gathering and analysis techniques such as Big-Data and AI. Further enhancement and system adjustment are suggested and re-planned by CPS (Act).

2.4. An experimental approach to TQM in the context of Industry 4.0

CLAAS Hungary Kft (CLH) was contacted in order to find a cooperation opportunity to examine the experimental part of this research work. CLH, established in 1997, is a subsidiary company of CLAAS Group in Germany. However, the experimental work can't examine all parts of the QMS.

Therefore, a single quality management method is selected based on a careful overview of current quality management practices and the discussion with the partner company to find a mutual interest in such a single activity. As shown in Fig. 1, the main activity of CLH today is the production of various types of feeding houses, cutting bars, maize, and sunflower adapters, development and production of cutting bars trailers, and the development of new agricultural and other machinery equipment.

Fig. 1. Sample of devices manufactured at the subsidiary company subject of this study
Source: (https://www.claashungaria.hu/)

CLH's quality staff has developed dedicated "Quality Checklists" for every product, process, or manufacturing phase. These quality checklists are developed based on the FMEA documents and are being used at the quality gates on the shop floor in order to ensure that common failure causes are avoided. Moreover, this process aims to ensure that critical device components are installed and configured at the optimal conformance to design. However, FMEA documents are prepared during the product design phase and can be changed once the serial production is initiated. Meanwhile, further failures can be detected at the final assembly phase. Therefore, these quality checklists are needed to be dynamic, updatable and responsive to critical quality issues that are reported during or after the production.

This work is focusing on a single device that consists of the combine harvester feeder house as shown in Fig. 2. The feeder house is a device that is attached to the combine harvester to facilitate the control of the cutting head and the flow of crops from the cutting head to the combine harvester. The device consists of several complex systems such as mechanical, hydraulic, electrical, and electronic systems. This device is wholly manufactured in the subsidiary company in Hungary and dispatched to be assembled to the combine harvester at the mother company in Germany.

Failures or defects which are observed during assembly or reported by end-users are gathered daily through the global ERP system of the company. After that, this information is extracted, manually reviewed, and evaluated by an experienced quality management team. This evaluation process aims at analyzing the failure root cause(s) and consequently taking the needed correction actions in order to maintain profitability and high-quality production. The company uses an internally customized FMEA technique to evaluate reported claims by obtaining RPN for every claim according to FMEA documents. The method which is used here aims at generating an RPN value for every claim on a scale from 1 to 300 points, where 300 is the highest priority number.

Fig. 2. CLAAS combine harvester feeding house
Source: (https://www.claashungaria.hu/)

RPN in CLH is obtained based on three major factors namely severity, occurrence, and impact. The relationship between these three elements is illustrated in Fig. 3. Severity, or gravity as named by the company's internal manuals, represents the risk consequences of the claim on the final customer/ operator (F1.1). It also includes the safety impact on the internal operator at further manufacturing processes (F1.2) and the cost of resolving this issue (F1.3). The weight of this factor ranges between 1 to 10 points, where 1 is the lowest severity and 10 is the highest. In the meanwhile, occurrence represents the number of incidents a specific claim has been witnessed in a specific period (F2.1). The weighting scale of this factor is also 1-10, where 10 is the highest. Impact is weighted by a scale of 3 points from 1 to 3. Impact represents the repair efforts, time (F3.1), the overall impact of the claim on the reputation and image of the company (F3.2), and repetition of the same work (F3.3). Moreover, Equation (1) shows the multiplication of the three factors values that result in an RPN value between 1 and 300 points. An RPN value above 160 points is classified at a very high priority, while, a value between 100 and 160 points is classified as a high priority. Medium priority is noted if the RPN value is in the range of 35-100, while low priority is noted if the RPN value is less than 35:

$$RPN = Severity \times Occurrence \times Impact. \tag{1}$$

According to the RPN value of every claim, the quality team decides the next handling steps. Further steps could be tracing root cause(s) and ensuring the elimination of such cause(s) and/or updating the quality checklists to ensure further failures will not repeat in the future. Early and fast processing of quality issues is translated to a lower quality cost and will positively enhance the general business performance. Moreover, standardization of the evaluation process and consistency of the process is vital to guarantee consistent RPN results every time.

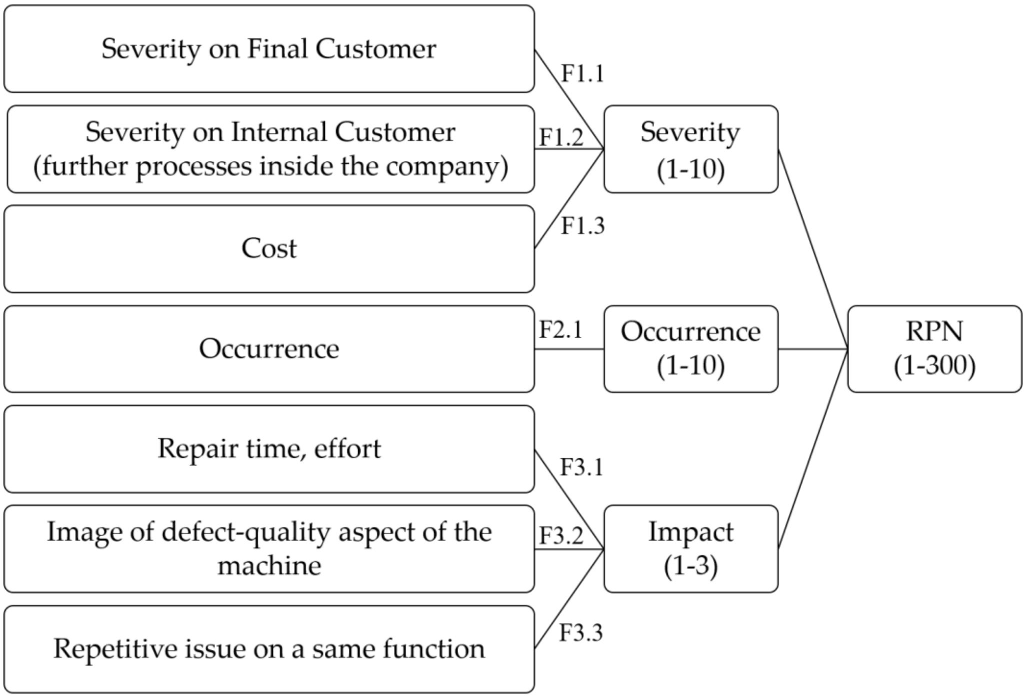


Fig. 3. Factors affecting claim ranking and the weight of every factor

In this experimental work, supervised machine learning technology is suggested to replace human intervention in processing, evaluating, and categorizing claims. The current flow of claims from involved parties is illustrated in Fig. 4. In this figure, claims from internal company quality product audit (Product audit claims) and issues that were detected during assembly (Cross company claims) are pipelined in the company's ERP system and human intervention is important at one point to evaluate claims manually. Every claim is evaluated and assigned an RPN value from 1 to 300 points.

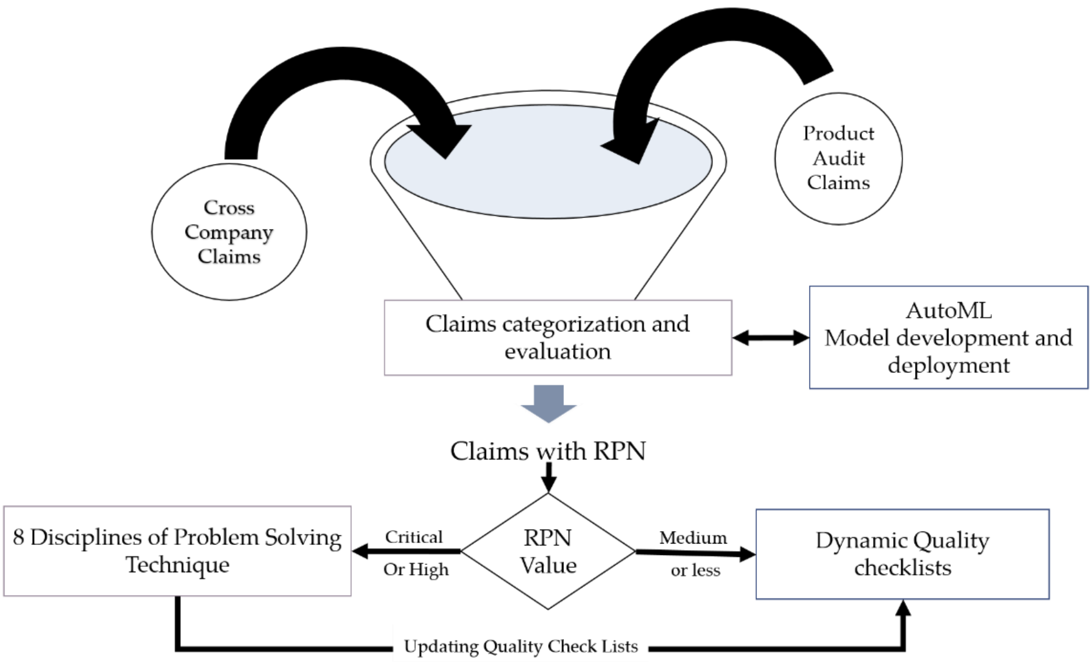


Fig. 4. The flow of internal quality audit and cross-company claims to quality management

Accordingly, a dataset that contains one-year data of claims is extracted from the ERP system of the company. This data is concerning the selected device only (the feeder house shown in Fig. 2). Firstly, to ensure the accuracy of the developed models, the data was prepared and validated using a specially developed platform. At this stage, the evaluation is made manually by experienced quality engineers to obtain the three RPN elements (severity, occurrence, and impact) and to define the root cause and the source manufacturing process (such as cutting, bending, welding, painting, assembly, etc.). The evaluation process depends here on the experience of the quality team and based on the internal FMEA procedure for every failure mode. After that, the updated dataset is used for models' training and to develop four machine learning models that are deployed to predict an RPN value for future failure claims and classify its root cause instantly without further human intervention.

Table 2 summarizes the input features types and roles in the models. Whereas this dataset is used to develop the machine learning models. 46 cases are excluded from the training process because of missing critical details such as claim textual description and the root cause input. Moreover, scales (8-10) in Severity and (7-10) in occurrence had an insufficient number of claims (less than 50 cases) for every element, these records are excluded too. The reason behind that, AutoML platform cannot run the training with less than 50 cases per class. Therefore, the dataset is copied three times, and classes with less than 50 readings are eliminated. Finally, 1343, 1269, 1355, and 1309 claims are used for models training of severity, occurrence, impact, and category respectively. 141, 156, 131, and 134 claims are used as validation samples for every developed model for severity, occurrence, impact, and category respectively.

Table 2. Dataset input features for the machine learning model

Data Type	Number of inputs	Labels	Brief summary
Textual Text	5	Claim description, root cause, machine type, and description, and remediation action made.	• This data is written in natural language by the labors or engineers at the German company, explains the failure, its root cause, the part involved, and the remediation action made. • It will help to recognize the failure mode, its root cause, and its technical solution.
Categorial Data	10	Machine code and name, damage name and code, initial criticality assessment, component type, and reporter information.	• Contains data about the device affected, the damage category, and its criticality • It will help to identify reoccurrence of similar failure, evaluate its importance, and define the location at which it was detected.
Numeric Data	7	Different costs data, number of affected devices.	This data will help to evaluate the consequences of this failure in terms of labor cost, transportation, material cost, and any extra costs.
Timestamp	1	Date and time of the report.	This data shows the frequency of a similar claim in a specific period.

2.5. Machine learning models development

The proposed solution aims at developing an automatic claim ranking system to replace human intervention based on developing four machine learning models that can read, analyze, evaluate, and assign relevant RPN values for every processed claim. In order to do so, the dataset which is evaluated in the first stage is used to train the model. Afterward, the model will be deployed to evaluate new claims based on the experience gained by the training data. Fig. 5 elaborates on the process of models' development, its inputs, and outputs. The first step in models' training is to pre-process the input data, feature selection, and data types. The auto machine learning tool resulted in four models that will be able to predict four independent values by which three of them will be multiplied to calculate an RPN value (as in Eq. 1). The fourth decides the source manufacturing process of the same claim.

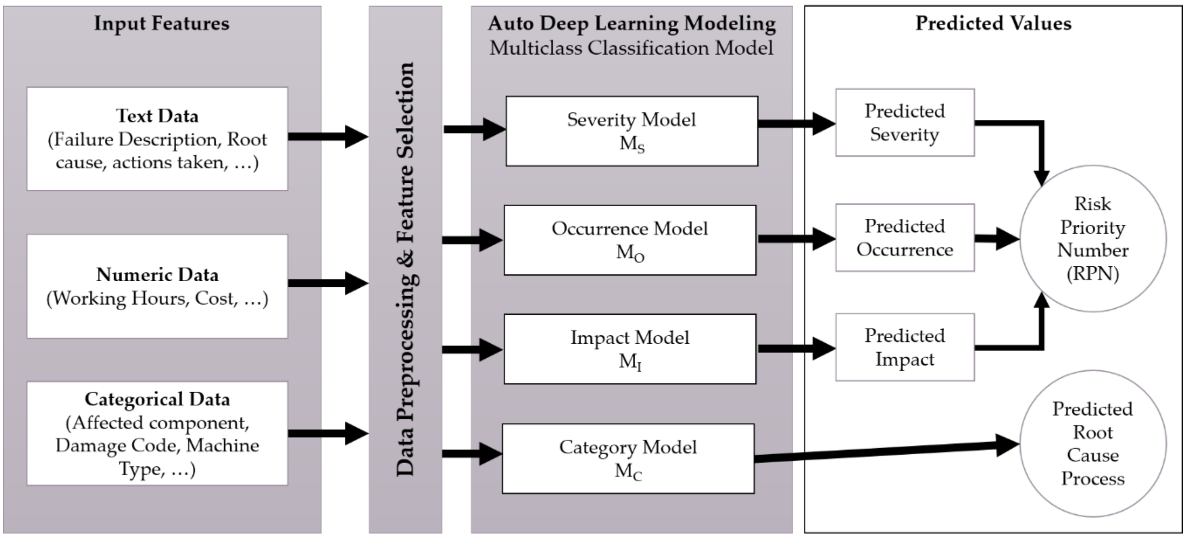


Fig. 5. Development of a machine learning model

Multiclass classification technique is applied to develop four machine learning models, while the suitable algorithm is automatically developed by Google AutoML. Google AutoML is developed to help researchers in handling large data and building high accuracy models with the least coding experience and resource consumption. The datasets are uploaded, the input features are defined, and targeted elements are selected. The prepared datasets are analyzed to obtain three independent models that can evaluate every claim to predict three independent values for severity, occurrence, and impact, from which an RPN can be calculated by applying Eq. 1. Additionally, a fourth model (for claim category) is obtained to identify the manufacturing process which caused this failure to occur. The manufacturing process could be cutting, bending, welding, painting, assembly, packaging, and transportation. The aim of the fourth model could be extended in the future to include more specific processes such as welding machine 1, assemblyline 2 and so on. odels obtained after training.

As the AutoML platform is a cloud system, then the consumption processing can be measured by node hour. The training process consumed 0.944, 1.105, 0.86, and 1.111 node hours for severity, occurrence, impact, and category respectively. Every node hour includes the use of 92 n1-standard-4 equivalent machines in parallel, where a single n1-standard-4 machine operates 4 virtual CPUs and 16 GB of RAM memory.

3. RESULTS

The present chapter displays the most important achieved results and their discussion.

3.1. Total Quality Management – Industry 4.0 interface

As concluded in the previous discussions, Industry 4.0 can serve the successful implementation of the seven TQM principles as in ISO 9000:2015 standards family. Therefore, the first result of this research work is the interface where the impact of Industry 4.0 on TQM can be defined clearly. Fig. 6 represent the interaction interface between Industry 4.0 features and technologies and TQM practices according to ISO 9000:2015 standards family, quality control, and quality assurance.

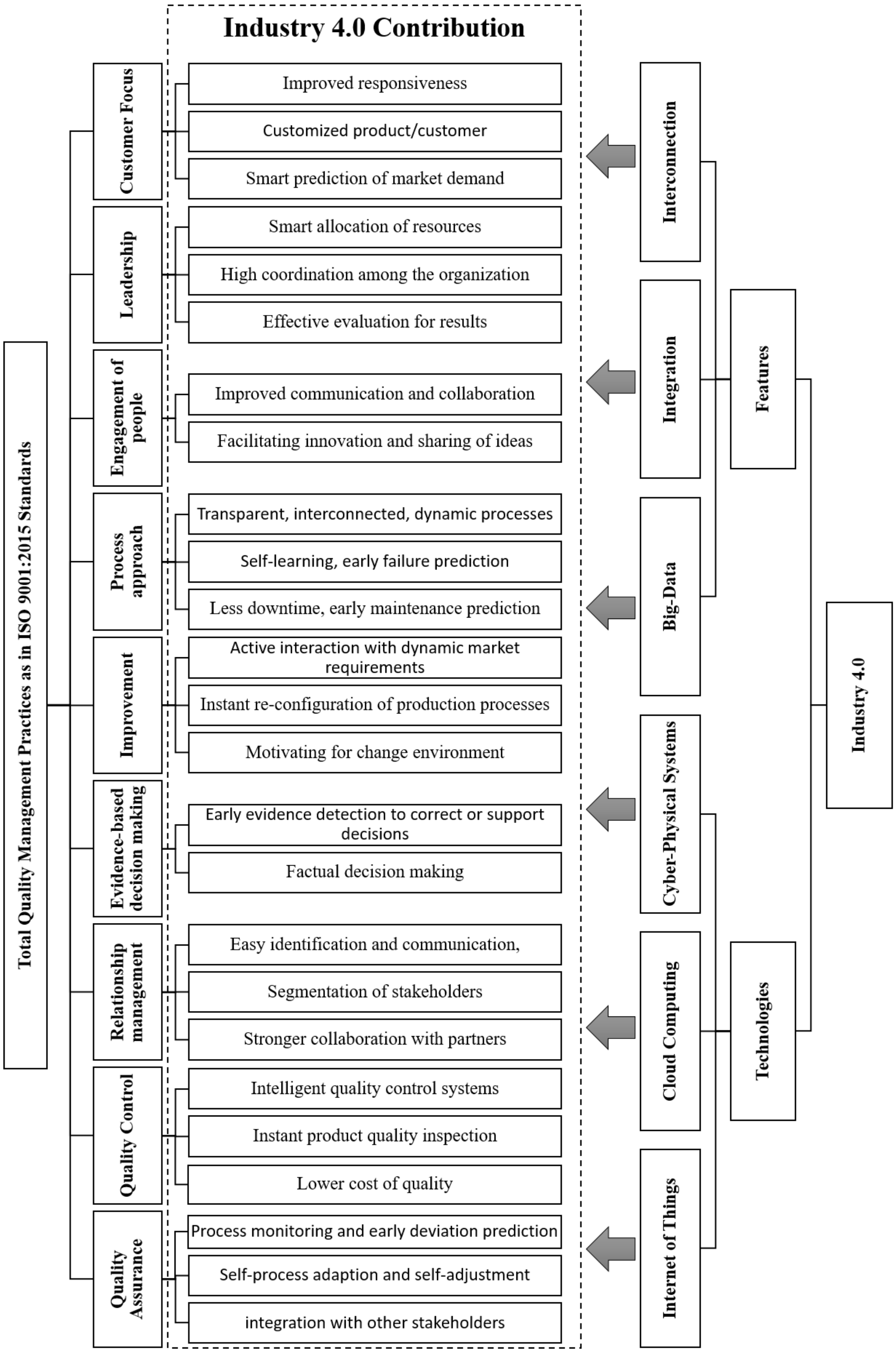


Fig. 6. Total quality management in the context of Industry 4.0

3.2. Identified sets of qualitative and quantitative measures

As the interface between TQM and Industry 4.0 is well defined, the impact of Industry 4.0 on the implementation of TQM shall be measured and evaluated. As mentioned earlier, the impact of Industry 4.0 on TQM practices can be assessed by comparing quality performance indicators before and after implementing Industry 4.0 technologies and features.

Therefore, Table 3 lists the suggested set of indicators as identified by ISO 9000:2015 requirements document and as suggested by other literature. The indicators are followed by their relevant suggested means of measurement which are suggested in the context of Industry 4.0.

Table 3. Set of indicators to measure Industry 4.0 impact on Total Quality Management

TQM Principles	Indicators for measurement	Means of Measurement
Customer Focus	• Customer satisfaction, retention & loyalty, • number of claims, • growth in market share, • improvement of organization reputation.	• IoT, Wi-Fi and Big-Data techniques as the data gathering and analyzing tools, • social media, analysis of customers feedback using AI techniques, • CRM & ERP systems.
Leadership	• Effectiveness of meeting quality objectives, • coordination and collaboration efficiency among organization’s units, • operational effectiveness.	• Real-time resources monitoring and automatic regulation and reallocation, • system monitoring dashboards, ERP systems.
Engagement of people	• Improvement in employees’ satisfaction, • growth of innovative ideas, • improvement of self-evaluation and self-improvement culture.	• HR management systems, • ERP system, • statistical data from production.
Process approach	• Productivity increase, • improvement in lead time, • downtime due to poor process management, • improvement in production costs.	• ERP system (integrated with customers and suppliers), • sensors and actuators within the production process, • process-related Big-Data analysis, • Internet of Things (machines data), • maintenance management system.
Improvement	• Responsiveness to customer or market requirements/needs (time to react), • cost of poor quality, • defects rate.	• ERP system and CRM system, • Big-Data themes, • customers feedback.
Evidence-based decision making	• Clear decision-making process, • data availability and clarity, • past decisions effectiveness, • data-driven decisions.	• Big-Data analysis, • CRM system, • ERP system.
Relationship management	• Stakeholders satisfaction, • suppliers efficiency, • supply chain stability.	• ERP system (integrated with customers and suppliers), • sensors and actuators within the production process, • process-related Big-Data analysis, • Internet of Things (machines data).

Quality Control	• Cost of quality, • defective rates, • customer claims.	• CPS and ERP dashboards, • CRM systems.
Quality Assurance	• Cost of quality, • rework and scrap, • maintenance efficiency, • downtime and system failure.	• Smart maintenance management systems, • ERP system.

3.3. Development of a theoretical updated QMS in the context of Industry 4.0

Quality management has never been as smart as when utilizing Industry 4.0 features. Fig. 7. illustrates the integration of Industry 4.0 technologies in the manufacturing value chain. It represents the flow of information, data, and operational orders from and to the production level. Information is streamed from the customers and markets to the Big-Data, where it is analyzed by AI and machine learning technologies and transferred to the production systems as production orders containing instruction, specifications, and volumes. The production system transfers the received orders automatically from the ERP to the CPS to simulate and implement the optimum production schemes. At this point, process re-adjustment may occur based on the new production orders. During the production, sensors are transferring data via the necessary interface to the Big-Data and ERP systems, this data includes row-material requests, maintenance requests, and production analysis. Any unplanned changes occurring during the production are analyzed instantly, and responses are sent automatically to relevant stakeholders.

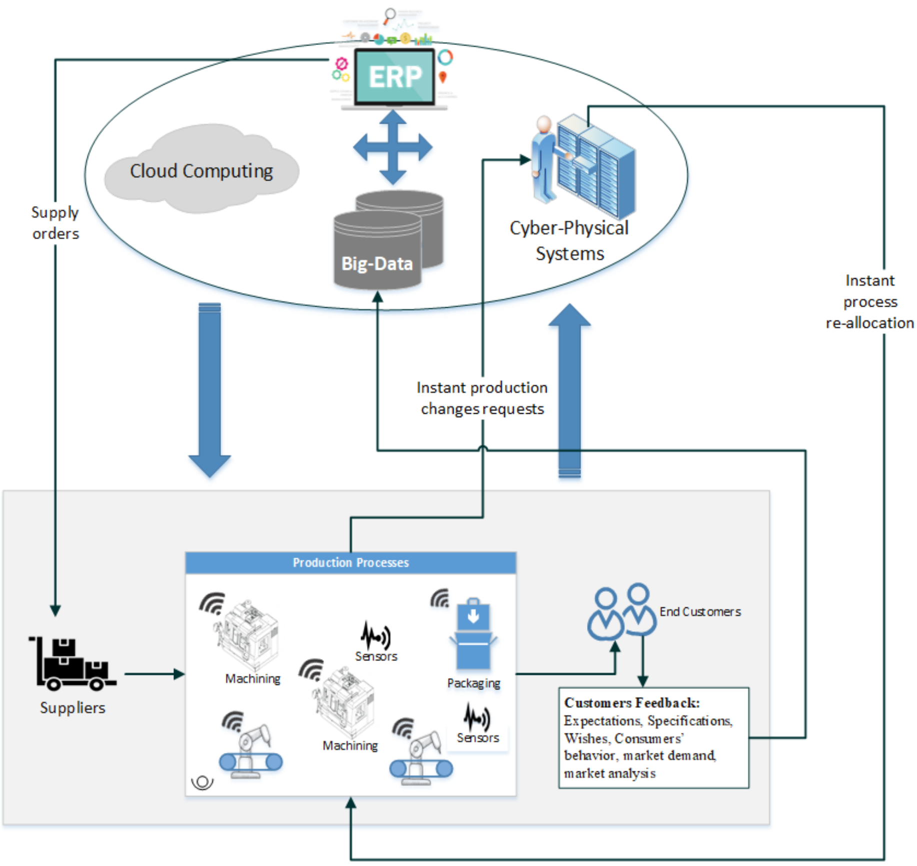


Fig. 7. Integration of Industry 4.0 technologies in the value chain

From a quality management perspective, sensors and in-process quality inspection devices are sending real-time data to the global Big-Data systems. Consequently, this data is processed locally at the machine smart system, which enables the machine to suggest or make decisions at the micro-level. Accordingly, the global Big-Data system analyses data at the macro level, making proper decisions to avoid defects, system failure, or downtime. Production is optimized by applying lean manufacturing, and supply chain management techniques.

The production system is managed by the ERP and CPS by analyzing the current production schemes, arrange production priorities, and allocate resources. The real-time quality inspection ensures that quality requirements are being fulfilled, and any causes of process deviation or production failures are avoided or eliminated.

An Industry 4.0 – QMS will enhance production and provide confidence that all quality requirements are fulfilled and total quality management practices are all realized. Within such a system, the cost of quality is minimized, as defective products are early detected, and process deviations are corrected. Communication with the end customer is effective and the production system is responsive to market demand.

In conclusion, the general framework is developed. This general framework is used as a basic system for further development during the experimental part of this research. A quality management system is a general approach of how every company is progressing its daily processes and activities with the objective of maintaining and enhancing quality. Thus, each company has its customized quality management system.

A general theoretical model for integrating Industry 4.0 technologies and features with the quality management system is illustrated in Fig 8. In this suggested model, the PDCA cycle and quality management system functions such as planning, support and operation, performance evaluation, improvement, and leadership are integrated with Industry 4.0 features. Industry 4.0 technologies are connected (connectivity) at every point of the quality management system starting by customers and closed by the main objective of quality management which is customer satisfaction (Integration). Customers' requirements and feedback are gathered and analyzed using Big-Data and AI technologies using (Big-Data analysis) and translated to requirements and specifications (inputs). Such an activity could be made via cloud computing technologies to improve effectiveness and enhance performance. In the meanwhile, the cyber-physical systems are controlling the physical manufacturing system according to the dynamic changes that are occurring from a quality management perspective. Failures in products or processes are reported directly and analyzed, decisions are made, and correction actions are executed.

Within an integrated Industry 4.0 – QMS, customers' expectations, market analysis, are directly communicated to the production systems, products' quality is controlled and assured using smart sensors and failure investigation analysis. Machines are connected, smart, able to predict, plan, and operate under different circumstances. Production schemes are flexible and dynamic due to hiring cyber-physical systems, where customized products can be produced without production delay. Suppliers are instantly notified about inventory consumption and can fulfill demand just in time. ERP systems can plan activities and handle orders and other business activities. Quality cost is at its minimum due to smart failure detection and early prediction. All the business units are performing as one integrated unit, where every business unit is aware and can participate positively in the entire system.

Within such scenarios, implications of Industry 4.0 are expected to reach an outstanding level of business excellence, effectiveness, and efficiency, and at the end a successful implementation of total quality management principles.

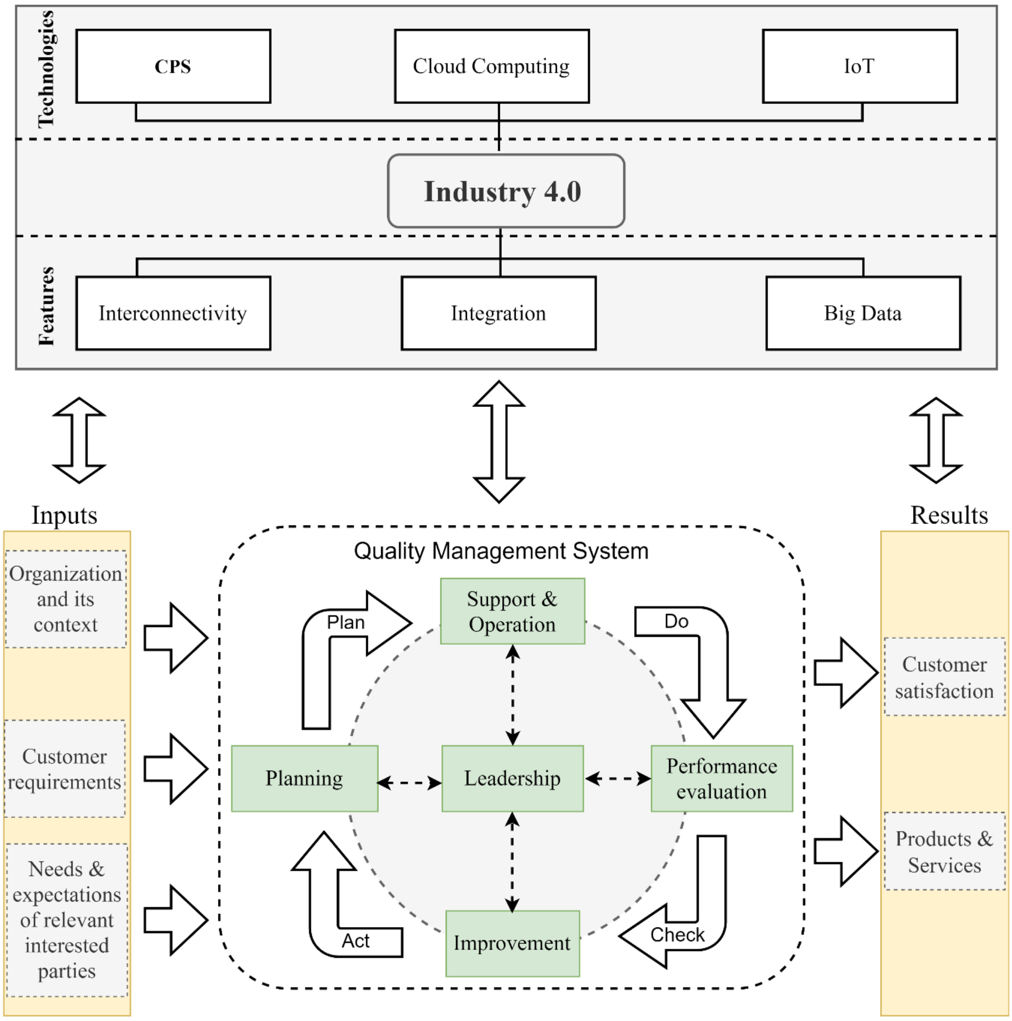


Fig 8. General QMS framework integrated with Industry 4.0 features and technologies (Upgraded from Abildgaard, 2018; ISO, 2015b)

3.4. Utilizing auto-machine learning to enhance FMEA

As discussed earlier, multiclass classification is used as an experimental method to develop a novel approach to enhance failure mode and effects analysis and the generation of RPN. This is done by developing four machine learning models using auto-machine learning.

A dataset that includes a one-year registry of 1532 failures with their description, severity, occurrence, and impact is used to develop four models to predict the values of severity, occurrence, and impact. In meanwhile, the resulted models are evaluated using 9.50%, 10.95%, 8.82%, and 9.29% of the dataset respectively. Evaluation results show that the proposed models have high accuracy whereas the average value of precision, recall, and F1 score are in the range of (86.6-93.2) %, (67.9-87.9) %, (0.892-0.765) respectively. The proposed work helps in carrying out FMEA in a more efficient way as compared to the conventional techniques.

Based on that, the aim of this research work is to examine a novel optimization approach applied to FMEA and RPN by classifying failures according to updated FMEA documents and generating the RPN automatically without human intervention.

Evaluation of the results according to the proposed FMEA method

The resulted trained models are evaluated according to evaluation metrics used in classification supervised machine learning techniques. Table 4 summarizes the training evaluation results and accuracy metrics for four classification models of severity (M_s), occurrence (M_o), impact (M_i), and category (M_c). The evaluation sample was automatically truncated and tested by the AutoML platform.

The evaluation metrics show relatively high-quality models, with different levels of precision for each model. The area under the precision-recall curve (AUC-PR) and the area under the receiver operating characteristic curve (AUC-ROC) is close to 1, which indicates high-quality classification models. Moreover, the models' precision rates which represent the correct predictions in the validate sample compared to the actual true values in the same sample are 93.2%, 87.6%, 89.9%, and 86.6% for M_s, M_o, M_i, and M_c respectively, which indicates that the models predicted correctly the classes of the validation sample for every model. The acceptance of such rates is accepted here given the size of the dataset and the quality of data. In a normal situation, the rates are evaluated based on the company's quality policy, the type of case being evaluated, and the identified quality objectives of the company.

Moreover, the true positive rates (recall) which represent the correct predictions of the validation sample compared to the total validation sample are 68.1%, 67.9%, 88.5%, and 76.9% for M_s, M_o, M_i, and M_c respectively. However, the F1 score values are 0.787, 0.765, 0.892, and 0.814 for M_s, M_o, M_i, and M_c respectively. Such values for the F1 score convey a balance between the precision and recall rates. For this problem, such values for precision, recall, and F1 scores are acceptable and represent relatively high-quality machine learning models.

Table 4. Evaluation summary for the four models

Dataset targeted value	Validation Sample	Score threshold	Precision	TPR (Recall)	F1 score	AUC (PR)	AUC (ROC)
Severity (M_s)	141 test rows	0.5	93.2% (96/103)	68.1% (96/141)	0.787	0.895	0.970
Occurrence (M_o)	156 test rows	0.5	87.6% (106/121)	67.9% (106/156)	0.765	0.871	0.955
Impact (M_i)	131 test rows	0.5	89.9% (116/129)	88.5% (116/131)	0.892	0.954	0.973
Category (M_c)	134 test rows	0.5	86.6% (103/119)	76.9% (103/134)	0.814	0.877	0.972

The evaluation metrics are not limited to the general metrics as in Table 4 detailed metrics are used in order to provide closer evaluation for the performance of the model. Every model is evaluated by applying the resulted models on the test set. As mentioned earlier, the test sets are approximately 10% of every dataset. Other useful metrics are discussed in detail as follows:

Models' evaluation according to confusion metrics

The confusion matrices in Tables 5-8 show that the concentration of the true predictions is at the diagonal cells of all models. However, both models M_s and M_o show higher confusion for predicted labels against true labels, in contrast to M_i and M_c models where higher concentration is shown at the diagonal cells. This is highly connected with the data volume and will be improved when a larger volume of data is used for model upgrading. Moreover, Table 6 shows greater confusion in class 2 diagonal cells. The value 48% represents a shortcoming in predicting this class in the M_o model. An extended or an enhanced dataset could improve the prediction of the model at this class and other classes in other tables.

Table 5. Confusion matrix for the model of severity (M_s)

	Predicted labels							
	Class	1	2	3	4	5	6	7
True labels	1	95%	5%	-	-	-	-	-
	2	-	89%	7%	-	4%	-	-
	3	-	7%	60%	13%	13%	-	7%
	4	-	17%	3%	67%	3%	7%	3%
	5	-	20%	13%	-	60%	7%	-
	6	-	-	-	-	12%	88%	-
	7	-	-	22%	-	11%	-	67%

Table 6. Confusion matrix for the model of occurrence (M_o)

	Predicted labels						
	Class	1	2	3	4	5	6
True labels	1	81%	6%	3%	9%	-	-
	2	14%	48%	14%	10%	10%	5%
	3	-	7%	87%	4%	2%	-
	4	-	9%	9%	78%	4%	-
	5	-	-	13%	-	73%	13%
	6	-	-	5%	-	5%	90%

Table 7. Confusion matrix for the model of impact (Mi)

	Predicted labels			
	Class	1	2	3
True labels	1	97%	3%	-
	2	18%	80%	2%
	3	-	33%	67%

Table 8. Confusion matrix for the model of category prediction (M_c)

	Predicted labels							
Class	A	B	C	D	E	F	G	H
A	95%	-	-	-	-	-	5%	-
B	14%	86%	-	-	-	-	-	-
C	-	-	71%	-	-	8%	13%	8%
D	-	-	-	83%	-	-	17%	-
E	-	-	-	-	86%	-	14%	-
F	-	-	25%	-	-	63%	13%	-
G	5%	10%	-	-	-	2%	83%	-
H	-	-	-	-	-	-	-	100%

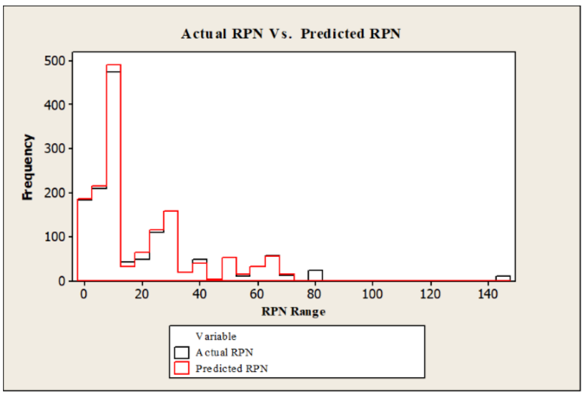
True labels

Evaluation of predicted RPN value against the original dataset RPN

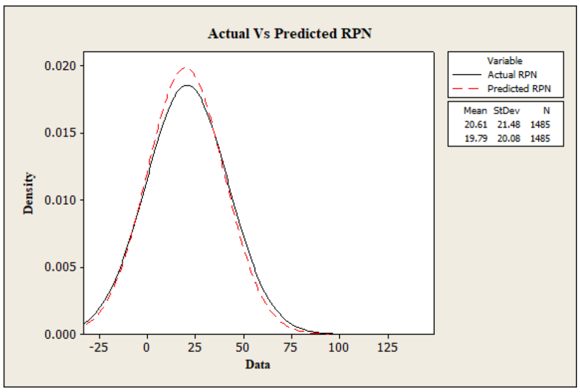
Another approach to evaluate the developed models is to examine the RPN in the original dataset (actual RPN) against the RPN which is resulted from applying equation 1 to the three predicted elements, call it (predicted RPN).

Fig. 9a compares the two RPN frequency histograms (Actual vs. Predicted) for the overall dataset. The histograms show a high overlapping of results between the two RPN values. In the meanwhile,

Fig. 9b represents the probability density function for both actual and predicted RPN values. The graph shows a very slight error magnitude between the two bell shapes, which also supports the hypothesis that the implemented approach is a high degree of conformity. Similarly, applying statistical accuracy measurements between actual and predicted values, resulted in a mean absolute error of 3.86 and a root-mean-squared error of 12.76 which both represent acceptable accuracy of predicted against actual. However, the histogram in 9a shows a shortage in predicting higher RPN values when the multiplication result is higher than 80 (the values larger than 140 in the histogram is a clear example). The reason behind this weakness is due to a lack of data at high classes for severity and occurrence in the training dataset. Such weakness can be resolved by providing a larger dataset for model training.



a. Frequency histogram



b. Probability density function

Fig. 9. Models evaluation by comparing actual Vs. predicted RPN values

4. NEW SCIENTIFIC RESULTS

In this section the unique scientific results investigated in my study are shown as follows:

1. Identifying Total Quality Management - Industry 4.0 interaction interface

Based on the intensive literature analysis on TQM practices and Industry 4.0 features and technologies, a clear interface describing the relationship between TQM and Industry 4.0 is identified. Hence, the main goal of this study is fulfilled; to define the impact of Industry 4.0 on TQM common practices.

In this study, TQM principles as defined by the ISO 9000:2015 standards family are discussed from the perspective that one or more of the Industry 4.0 features and technologies are anticipated to support the successful implementation and optimization of one or more of the TQM principles.

The research work concluded that Industry 4.0 is a key enabler toward the successful implementation of total quality management practices and the proposed interface is illustrated clearly in Fig. 6. The novelty of this result is that it has never been discussed precisely and comprehensively before, although it was discussed on an individualized approach.

2. Identified sets of qualitative and quantitative measures

Along with the identification of Industry 4.0 - TQM interface, it is important to measure and assess the impact of Industry 4.0 on every single item of the TQM principles. Therefore, this study successfully developed the relevant set of performance indicators for each one of the seven TQM principles, quality control, and quality assurance practices, and suggested the performance indicators along with their respective measurement methods (see Table 3).

For example, customer focus is one of the TQM principles as defined by ISO 9000:2015 principles. As a result of utilizing Industry 4.0 features and technologies, enhanced customer satisfaction and loyalty is expected. Such satisfaction is resulted due to the enhanced response time, improved communication, and the ability to afford individualized and customized products.

Consequently, the enhancement that occurred to customer satisfaction due to the application of Industry 4.0 must be measured and evaluated. These measures are identified in this research work. Moreover, the research work suggested utilizing Industry 4.0 technologies like Big-Data, ERP and CRM systems to gather data that could be used for impact evaluation. Such data is customer retention, sales growth, market share, and social media comments and insights.

This data could be gathered and analyzed using machine learning methods and natural language processing where natural language can be rendered on dashboards in the form of useful knowledge for the company leadership.

3. Suggesting an updated quality management system (QMS) – Industry 4.0 integrated model

In this result, a traditional QMS model is adopted as a basic QMS that can be upgraded to become an Industry 4.0 - QM integrated system. The proposed new model is illustrated in Fig. 8. where the major functions of the QMS are integrated with Industry 4.0 features and technologies.

Customers are integrated into the quality management system using the Industry 4.0 features and technologies. Therefore, their requirements and feedback along with their satisfaction measures are communicated to the QMS plan-do-check-act cycle very efficiently. Such information is transformed into useful knowledge and transmitted to the management which can utilize Industry

4.0 technologies such as CPS to re-plan and optimize the resources management and maintain the continuous improvement strategy. An example of the specific integration of Industry 4.0 features and technologies with the production value chain is illustrated in Fig. 7.

4. Suggesting a novel approach to enhance FEMA and the generation of RPN

In this novel approach, a cloud solution namely auto-machine learning (Google AutoML) is used to automate one of the quality management methods which is failure mode and effects analysis. The development of such an analysis was conducted in partnership with an agricultural machinery manufacturing company located in Hungary. In previous scenarios, quality issues were reported from the mother company in German to the company in Hungary. An expert engineer was responsible to review and evaluate every one of these claims. According to the evaluation result and the value of RPN, further actions are decided. Such a process was costly from many perspectives; the time and effort consumed, cost of quality, and above all, its human-based nature.

The adopted novel methodology is developed based on the accumulated previous decisions extracted from archived data. AutoML is used to develop an automatic cloud service where the flow of claims is evaluated in the cloud and the final evaluation result for RPN is processed instantly, suggesting a recommendation for quality engineers on how to handle important claims.

The resulted models minimized the time needed to process a set of claims containing 361 claims from three working hours to 15 computing minutes. Consequently, the results are processed automatically on the cloud without consuming any other resources on the location of the company. Therefore, the resulted approach is cost-effective and efficient in terms of accuracy. Similarly, such a solution can be applied to other fields such as analyzing customers' feedback. It is very common to deploy machine learning models to suggest solutions or operating instructions to frequent complaints by customers.

5. Provide an efficient web-based platform to automate FMEA process

During this research work, a web-based platform was developed to manually evaluate the claims needed for data training. Later, after developing the machine learning models, the models were integrated into the platform, so the platform is used as an interface to evaluate new claims. As a result of such integration, the platform displays the evaluation results as recommendations to quality engineers.

Moreover, the platform is extended to conclude the top 10 quality issues instantly and list them on a separate screen according to their manufacturing process. Therefore, top issues per the manufacturing process are displayed at the manufacturing shop floor, which will directly transfer the claims to their respective sources.

5. CONCLUSIONS AND SUGGESTIONS

It is obvious that Industry 4.0 has a great potential to enhance total quality management practices. TQM practices are backed by capabilities offered by Industry 4.0 features and technologies. The following are the main contribution offered by Industry 4.0 to such enhancement, as concluded from this research work:

- Developing real-time monitoring and efficient failure prediction systems.
- Application of in-process intelligent quality assurance systems which enabled inspection for the entire production.
- Data analysis and visualization of information that facilitated factual decision making.
- Enhanced integration of the production systems, from suppliers to the end customer, which minimized product lead time, increased responsiveness, and improved customer satisfaction.
- Optimized lean production systems, and the ability to produce customized products for different customers' demands.
- Optimizing supply chain and logistics management strategies.
- Provided bases for the successful implementation of TQM practices.
- Minimizing the cost of quality due to early defect detection (quality control) and early elimination of defects' causes (quality assurance).
- Reliable, smart, dynamic planning techniques due to rich decision supporting systems and visual information provided by ERP, Big-Data, and CPS.

All the above-mentioned implications of Industry 4.0 on production systems influenced the quality management strategies and obtained new methodologies for quality control, quality assurance, and total quality management. However, future research could contribute more to find new implications and examine the impact of Industry 4.0 in further quantitative methods.

Industry 4.0 provided a stone rock support for a successful implementation of TQM principles. This research work highlighted the zone where TQM can benefit from Industry 4.0 features. A wider perspective as suggested by this research work to integrate Industry 4.0 features with TQM practices where Interconnectivity, Integration, and Big-Data can enhance the implementation of quality management practices.

This research work matched the possibilities offered by Industry 4.0 to support the implementation of TQM from theoretical and experimental approaches. Accordingly, the experimental approach concluded that Industry 4.0 can support any of the TQM methods and practices. An industrial partnership is made with a leading agricultural machinery manufacturing company in Hungary. After two years of cooperation, this research work successfully implemented a novel approach to improve the FMEA process by using an AutoML based method.

The suggested application of Industry 4.0 features and technologies such as cloud computing, machine learning, and integration, improved the performance of a single quality management method namely FMEA. Such an application can be extended to other quality management methods and could be implemented to cover other products and processes.

The main goal of this research work is to discuss TQM in the context of Industry 4.0 and to provide evidence from real life on the proposed model.

6. SUMMARY

AN EXPERIMENTAL APPROACH TO TOTAL QUALITY MANAGEMENT IN THE CONTEXT OF INDUSTRY 4.0

This research work is conducted through two approaches, theoretical and experimental. In the theoretical approach, total quality management major practices as in ISO 9000:2015 standards were investigated in the context of Industry 4.0 technologies and features. An intensive literature review is made to define the interface where TQM practices could be served by the features and technologies of Industry 4.0. Afterward, an upgraded Industry 4.0 based QMS is suggested, where all tasks and responsibility of a QMS is linked to Industry 4.0 features and technologies. Accordingly, as the link between Industry 4.0 and TQM/QMS is established, there is a need to evaluate the impact of such a link. This study suggested a set of indicators along with its respective measurement tools by which the performance of an Industry 4.0 – QMS based system can be measured and evaluated.

On the other hand, such a model must be examined to provide experimental evidence that Industry 4.0 technologies can support TQM methods. Here comes the experimental approach of this study; auto-machine learning was utilized to optimize FMEA handling by automatically identifying the failure mode, obtain its RPN and identify the manufacturing process related to the root cause of the issue. Three multiclass-classification machine learning models were developed to predict values for the RPN three elements namely severity, occurrence, and impact. A fourth multiclass-classification model was developed to classify failures to their root cause process. The models' evaluation indicated relatively high accuracy models that can be deployed and integrated to enhance the company's ERP system.

One of the features of the selected AutoML platform is its simple integration through the API, which is offered on the cloud. Such technology performs efficiently for large applications at the macro level of the factory. Utilizing such a solution enhanced the capabilities of the quality management team to handle any volume of claims data under high flow velocity. Such a solution allowed the quality team to focus on other strategic issues and enhanced the team's performance and results.

The benefits of such technology do not end by this, but also could be furtherly extended to link claims and defects to the relevant manufacturing machine and operator. Once a claim is reported to the quality management it will be processed by the deployed model and instantly will be communicated to the relevant operators or managers and deeper to the shop floor in the factory.

In conclusion, this study supported the theoretical approach with the experimental one. In this experiment, one effective Industry 4.0 tool is used which is machine learning, executed on the cloud, which is Google cloud AutoML platform, to automate a single TQM method which is failure mode and effects analysis (FMEA) and its respective evaluation metric risk priority number (RPN). This experiment is conducted in partnership with an industrial partner from the agricultural machinery industry and is implemented in cooperation with the quality management office at the company.

7. THE MOST IMPORTANT PUBLICATIONS RELATED TO THE THESIS

Refereed papers in foreign languages:

1. **Sader S.**, Husti I., Daróczi M. (2017). Suggested indicators to measure the impact of Industry 4.0 on total quality management. International scientific journal: Industry 4.0. Vol. 2 No. 6, pp. 298–301. ISSN (Print) 2535-0153. ISSN (Online) 2535-0161, https://stumejournals.com/journals/i4/2017/6/298/pdf
2. **Sader S.**, Husti I., Daroczi M. (2019). Quality management practices in the era of Industry 4.0. Zeszyty Naukowe Politechniki Częstochowskiej Zarządzanie, Vol. 35, No. 1, pp. 117-126. ISSN 2083-1560, https://doi.org/10.17512/znpcz.2019.3.10
3. **Sader S.**, Husti I., Daróczi M. (2019). Industry 4.0 as a key enabler toward successful implementation of total quality management practices. Periodica polytechnica social and management sciences, Vol. 27 No. 2, pp. 131-140. https://doi.org/10.3311/PPso.12675 (Scopus: Q2)
4. **Sader S.**, Husti I., Daróczi M. (2020). Enhancing failure mode and effects analysis using auto-machine learning: A case study of the agricultural machinery industry. Processes, 8(2), p. 1-16. https://doi.org/10.3390/pr8020224 (IF: 1.963*, Scopus: Q2)
5. **Sader S.**, Husti I., Daróczi M. (2020). Introducing “Quality 4.0”: A survey for definitions, features, technologies, applications, challenges, and future research areas. Total Quality Management & Business Excellence. (Under review, submitted: 04. 01. 2020)

Refereed papers in Hungarian language:

6. Husti I., Daróczi M. és **Sader S.** (2017): A minőségügy új kihívásai az „Ipar 4.0” tükrében, Magyar Minőség Társaság, November 2017, Vol. XXVI, No.11, 23-41 o., ISSN 1789-5510 (Online). ISSN 1789-5502

International conference proceedings:

7. **Sader S.**, Husti I., Daróczi M. (2018): Integrating Industry 4.0 features with quality management practices, Proceedings of the 8th International conference on management 2018, "Leadership, Innovativeness and Entrepreneurship in a Sustainable Economy", Częstochowa University of Technology, Poland, Faculty of Management, June 7-8. 2018, pp. 533-538. ISBN 978-83-65951-28-1
8. **Sader S.**, Husti I., Daróczi M. (2017): Total quality management in the context of Industry 4.0, Proceedings of Synergy international conferences - Engineering, agriculture and green industry innovation, Gödöllő, Hungary, October 16-19. 2017, pp. 7-16. ISBN 978-963-269-680-5.
9. **Sader S.**, Husti I., Daróczi M. (2017): Suggested indicators to measure the impact of Industry 4.0 on total quality management, International scientific conference (Industry 4.0), Borovets, Bulgaria, December 13-16, 2017, pp. 230-233. ISSN (Print): 2535-0153, ISSN (Online): 2535-0161.

7. The most important publications related to the thesis

International conference abstracts:

10. **Sader, S.** (2019). Utilizing machine learning technologies to process customers claims automatically. Synergy international conferences - Engineering, agriculture and green industry innovation, Gödöllő, Hungary, November 4-6, 2019. Szent István University Faculty of Mechanical Engineering, (2019) p. 20. ISBN 978-963-269-854-0
11. **Sader S.**, Husti I., Daróczi M. (2019): Introducing "Quality 4.0" practices, 9^{th} International conference on management 2019, "People, Planet and Profit: Sustainable business and society", Szent István University Gödöllő, Hungary, 13-14th June 2019. ISBN 978-963-269-836-6