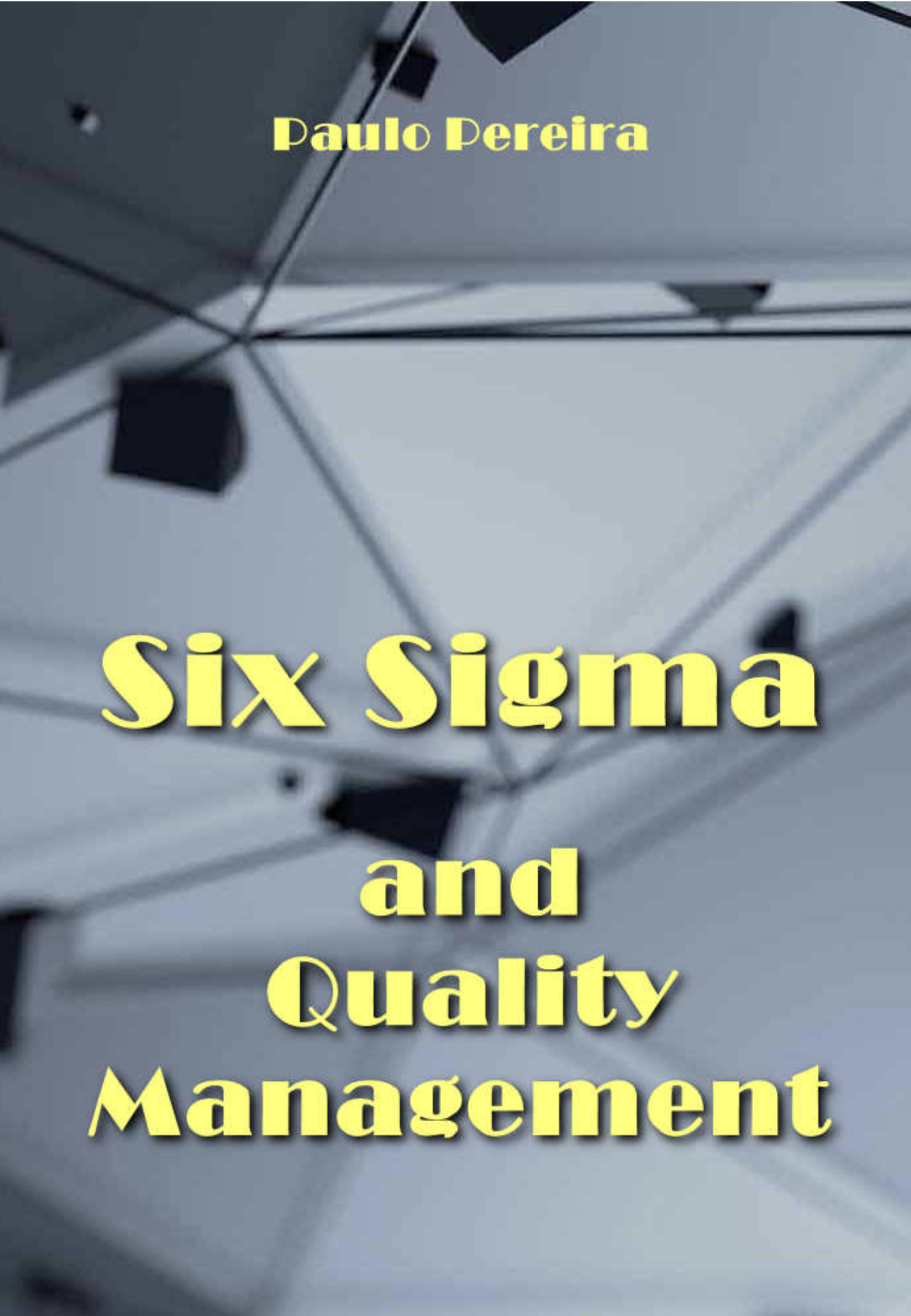
Paulo Pereira
Six Sigma
and
Quality
Management

Chapter 1

Total Quality Management of Research Articles in Electrical Engineering

Monika Verma, Mini Sreejeth and Madhusudan Singh

Abstract

Recently, the quality management of research articles (RA) has cherished an era of remarkable growth and conglomeration. It is because the qualitative approach has become an established and valued approach among varietal areas and contexts. The quality of RA is precisely based on the clarity of the illustration of the aims. Previously, the categorical analysis of RA has been restricted to the format of writing the article following Introduction-Process-Testing-Conclusion (IPTC) or Introduction-Methodology-Result-Discussion (IMRD) standards. But the wholesome strategy of Total Quality Management (TQM) of RA has not been demonstrated from the core in the discipline of Electrical Engineering (EE). The research question, sample, control of staggering variables, research designs, criteria measures, data analysis, ethics, discussions, references are the critical collectibles (CCs) on what matters to the readers of RA. The macrostructures of EE-RA, features of each sector of EE RA, section headlines, extension of description and prominent aspects were analyzed for hundred RA from fifteen journals of EE. These features are compared with respect to all the CCs. This chapter helps to recognize the necessary inputs for TQM implementation with different proactive journals of EE to improve the quality of RA.

Keywords: electrical engineering, critical collectibles, research articles, total quality management, survey

1. Introduction

The research articles (RA) may have excellent process of analysis management and tools to ensure strength of the study. However, analysis management alone cannot ensure the readers' satisfaction. Total Quality Management (TQM) is an approach to not only ensure high quality of an experimental and developmental research but to accomplish the higher levels of readers' satisfaction.

To keep up the relevant level of quality of any research, all the features and tasks of RA are needed to be monitored. The strategy of TQM involves the target of achieving pre-defined benchmark standards of quality through the formulation of policy, planning, assurance and control of quality advancement.

The macrostructure of RA in science stream has been described by Harmon in [1]. The Introduction-Methodology-Result-Discussion (IMRD) standard had been set for describing the experimental kind of research. However, this standard was found to be incompetent for engineering stream [2]. Harmon also categorized engineering RA into theoretical and developmental standards. The overall TQM implementation in developmental or theoretical RA of engineering stream seem to receive slight attention, even though articles related to engineering stream typically contributes towards the development or advancement of novel solution to a particular problem [3]. A different macrostructure standard named as, Introduction-Process-Testing-Conclusion (IPTC), has been recently claimed to the prototypical standard for RA related to EE [4].

The subfields or sectors of EE are related to fields of computer engineering, power engineering, signal processing, photovoltaic cells, system engineering, telecommunications, radio-frequency engineering, instrumentation, optics, electronics and photonics. Most of these fields observes the overlapping with other engineering sectors. There are thousands of RA pertaining explicitly to EE subfields. From the point of view of themes of EE, the topics are categorized into electromagnetism, physical laws, control engineering, electronics, power engineering, electric vehicles, signal processing, instrumentation and telecommunication.

This chapter analyzes hundred RA in fifteen journals of EE to acknowledge their quality check with respect to CC measures of TQM. The distinctive aspects about the different approaches addressed for implementation of TQM are also described. The chapter is organized in the form of sections, given as follows. The 'literature survey' section presents that the RA from all fields of EE in almost all the journals are peer-reviewed. The 'research methodology' section presents the complexity of analyzing the representative corpus of articles in EE and the techniques used in this work. The 'analysis results and remarks' section shows that although the quality management is executed through very transparent approach while analyzing an article but from the point of view of reviewers and readers of articles in EE, this task is somewhat subjective. It also represents that how the quality assessment approach has evolved over the years and the discussion of pedagogical implications respectively, followed up by a comprehensive conclusion.

2. Literature survey

There are various genres that are perceived within the field of engineering [5]. However, this research concentrates on the full length RA in one or two step peer-reviewed journal. A significant amount of work has been reported in literature related to the framework of genre analysis.

The New Rhetoric variant of genre analysis is a kind of inter-disciplinary field technique used for introducing broad way of argumentation of classical canons of rhetoric, which are structure of content (arrangement), language (style), background (memory), what to say (invention) and delivery (presentation).

The Systematic Functional Linguistic (SFL), originally designed by M. Halliday, uses the idea of developing analytical categories of language. According to SFL, language is the means of social parole system. SFL provides a convenient tool to analyze RA by emphasizing the functional base of structure of language.

Another variant of genre analysis is English for Specific Purpose (ESP) [6]. Generally, it refers to the subset of the language learning in accordance to the enhancement of vocabulary or the skills of the author of the articles.

The above mentioned variants of genre analysis are few important measures used for carrying out the review process of an article. The articles following the ESP custom are first reviewed in this section. Through the survey, it is demonstrated that the earlier RA are first examined on the basis of macrostructure. Then, it is researched that the field of electrical engineering is considered as that of applied science, due to which the wholesome strategy of TQM implementation may have prevented.

Using the analysis done by Harmon, through diversity in engineering RA, it was found out that the articles are mostly 'experimental' exhibiting a certain confined structure. Such structures include heading (i.e., title and/or subtitle), abstract, introduction, methodology, experimental specifics, results, explanation, conclusion, acknowledgements and references. The quality check of the articles used to be done on the basis of research work done and the explanation of the basic theory associated to the work. However, it is found that only macrostructure cannot be always enough for maintaining the quality management of the RA.

In applied linguistic [7–8], the secondary RA commonly consist of non-standard headings of the subsections. Such headings or titles of the sections in an article can be one of the distinguishing features in different fields. The RA, following IMRD structure, consists of deductive or hypothetical procedures of science. Whereas, those articles, which follow the IPTC structure, demonstrate the problem solving techniques of science [9]. In the field of information systems or computer science, the RA are structured in the form of one add-on section or replacement of the 'methodology' section by a new heading called 'algorithm' or 'application' or 'implementation process, system or program' [10].

In [11], by examining RA related to thirty-nine disciplines, Lin et al. discovered seven variants of IMRD macrostructure for each discipline of engineering disciplines. The modeling of ESP scholars' adopting the canonical IMRD structure, results in rise of the limitations of the related analyses [11] which degrades quality of corresponding RA. Lin et al. defined the RA which contain "empirical design", "research and data design", "experimental" or "the study" types of variants in Heading method are called experimental papers. However, few from such papers fit the description of adoption of such macrostructure. It is because the data results of few RA establish actual variability. This is justified by distinguishing 'experimental' RA from 'review' and 'theoretical' RA. So, the quality of macrostructure needs to be subdivided into separate categories depending upon the quality of content rather than their headings in RA.

The discipline of engineering is spoken of as a lone field while the researchers divide science into multiple fields. For instance, the British Academic Written English (BAWE) corpus exhibit different branches of science but at university level, it lacks in distinguishing various fields of engineering [12]. The field of engineering is stated as a lone field by Kanoksilapatham, with subfields of biomedical, software and civil [13]. The fields of biochemistry and microbiology are distinguished as distinct fields. In this chapter, the typical specialties belonging to a particular academic field are treated as 'sub fields' within a field. Due to the presumption that the engineering is one gigantic field, the researchers are led to assume that all RA are similar in quality. Maswana et al. has stated that engineering appears to be an undivided field concerned with the production of profitable artifacts obtained by applying scientific principles [14]. However, there is a diversity in the features of engineering RA. They consist of wide range of articles containing mathematical simulations, prototypical experiments, review experiments and observational experiments as revealed from the diverse representation of the results.

3. Restriction of TQM studies to RA

The level of significance of total quality management (TQM) has grown with rapid pace lately. The concept of TQM is seen as a phenomenon essential to attain competitiveness. The researchers correlate the TQM concept with success of an industry [15–17]. Few researchers claim that TQM is just a fad of management by pointing out the failure stories of implementation of TQM [18–20]. There are many inter-related reasons of having different outlooks of TQM. For example, disagreements among founders of TQM, similarities of the concept with other management tools, unclear interpretations and hypothetical definitions of TQM. Therefore, the problems associated to TQM are needed to be addressed. The relevant techniques, tools and values as a wholesome management system are also described.

A. Disagreements among founder

Deming, one of the renowned quality founders, has considered the term TQM to be just a lingo and meaningless word [21]. In [22], William L. et al. stated the concept of quality to be the consequence of a process rather than being a process itself. Juran has been critic of the fact that the term TQM is being tumbling down without defining it properly. The actions included in TQM are actually listed in criteria associated to the reputed Baldrige Award [23]. This reluctance to accept the term TQM seems confusing to the researchers.

B. Unclear interpretations and hypothetical definitions of TQM

The definitions of TQM has been unclear or misinterpreted in literature. The formulations can be seen like "culture of..", "philosophy of..", "approach for..", and "business strategy of.." etc. The respective descriptions of hypothetical definitions is found in literature [24–27]. The definition presented in ISO 8402; 'quality management and assurance' has also been found to be vague [28]. It says, "TQM is centered on quality, and it is a management technique of an organization. It involves participation of all members of organization and aims towards long-run success path through consumer's satisfaction. In this way, it is advantageous to all members as well as to the society." The development and perception of the term TQM over the years from philosophy to culture has been one of the reasons for confusions and the usage of various terms in its definitions. The term philosophy is base of the concept and culture is the required state. This desired state can be attained only when the clear description of philosophy is realized. The explanation of strategy used to realize the philosophy is given in [29]. Another reason of unclear interpretation can be that most of the literature has been penned by consultants and the academia has not been much interested in knowing about what 'TQM' actually is.

C. Similarities of TQM with other management tools

There exists some consensus about what TQM actually means. There has been various similar terms in literature, for instance, total quality control (TQC) [30–31], company-wise quality control [32], total quality improvement [33], and strategic quality improvement [34].

4. Methodology

The articles published from 1 January, 2021 to 31 December, 2021 are studied through cross-sectional survey. The survey comprised of all articles, consisting of self-administered problems, as their dominant methodology and has been published in any of the fifteen journals related to EE, given in **Table 1**.

It is important that the implementation of TQM needs to be peered as a system. The techniques and associated tools support the core values of the articles. The process management technique establishes process orientation. Here, by 'cross sectional survey', it is meant that the data of RA has been collected one time and not repeatedly over a time period. The top publishers are considered for necessary population based categorization. And the satisfaction score (in %), based on the Transparency and Openness Promotion (TOP) guidelines, has been used as the associated statistical technique to present the survey in tabular form as per the quality assessment.

First seven journals were listed as the top EE practice journals, using InCites Journal Citation Report (JCR) published by Clarivate Plc for the year 2021, on the basis of the recent impact factor. Furthermore, the remaining journals are selected based on their representations of significant EE subfields like PD, VLSI etc. and/or organizations like IET, Elsevier etc. The leaflets of each issue of the journal published within this study has been searched manually by two independent investigators for identifying RA satisfying the criteria.

A COMPENDEX search has been conducted to confirm the screening of all relevant RA published in the corresponding journals. The elimination criteria included RA using participant-observation kind interview techniques, market survey, additional qualitative investigation techniques, analysis using combined quantitative/

Acronym	Journal title	Publisher
EC	*Energy Conversion	IEEE
IE	*Industrial Electronics	IEEE
CAD-ICS	*Computer-Aided Design of Integrated Circuits and Systems	IEEE
SG	*Smart Grid	IEEE
MTT	*Microwave Theory and Techniques	IEEE
C	*Communications	IEEE
PA-MI	*Pattern Recognition and Machine Intelligence	IEEE
CC	Computer Communications	Elsevier
ESA	Expert Systems with Applications	Elsevier
PD	*Power Delivery	IEEE
EPSR	Electric Power Systems Research	Elsevier
MAP	IET Microwaves, Antennas and Propagation	IET
VLSI	*Very Large Scale Integration Systems	IEEE
JSSC	*Journal of Solid State Circuits	IEEE
PR	Pattern Recognition	Elsevier

**IEEE Transactions on....*

Table 1.
EE journals and corresponding acronyms used in this study.

qualitative techniques, RA unavailable in complete text or RA in languages other than English.

The evaluation of each RA has been carried out using preceding publication, a checklist tool developed by RA experts. This checklist consists of 8 transportable standards from Transparency and Openness Promotion (TOP) guidelines, that are: (1) data transparency, (2) citation standards, (3) material transparency, (4) analytical approach transparency, (5) analysis plan preregistration, (6) study preregistration, (7) design & analysis transparency and (8) replication. Four investigators participated in an initial test of the prescribed checklist by examining four pre-determined articles that were involved in final survey. The checklist standards were either removed or modified on the basis of consensus. The standards were removed because of the lower chances of its application to EE articles. The standard removed from the checklist was 'study preregistration'. So, the list consisting of remaining standards is referred as the final checklist. Each item in the checklist is weighted as 1 point, as seen in **Table 2**.

Checklist Standards	**Description**	**Satisfaction score, *n* (in %)**
1	Data transparency	
	• Background statistical details provided	100 (100%)
	• Sample frame and population of survey provided	90 (90%)
	• Financial inducement provided	28 (28%)
	• Techniques to handle absent data provided	8 (8%)
2	Citation standards	
	• Mode of communication provided	89 (89%)
	• Illustration of who addressed inherent participant	25 (25%)
3	Material transparency	
	• Research tool explained	90 (90%)
	• Pre-testing techniques reported	41 (41%)
	• Psychometric characteristics reported	7 (7%)
4	Analytical approach transparency	
	• Purpose of study is explicitly reported	96 (96%)
5	Analysis plan preregistration	
	• Background particulars reported	100 (100%)
	• Problem formulation provided	45 (45%)
6	Design & analysis transparency	
	• Reliability and validity provided	31 (31%)
	• Objectives are addressed through results	99 (99%)
	• Techniques for data analysis explained	8 (8%)
7	Replication	
	• All responses and respondents are reported	59 (59%)
	• Originality and strengths of research explained	16 (16%)

Table 2.
Satisfaction score of checklist standards in all-inclusive RA (100).

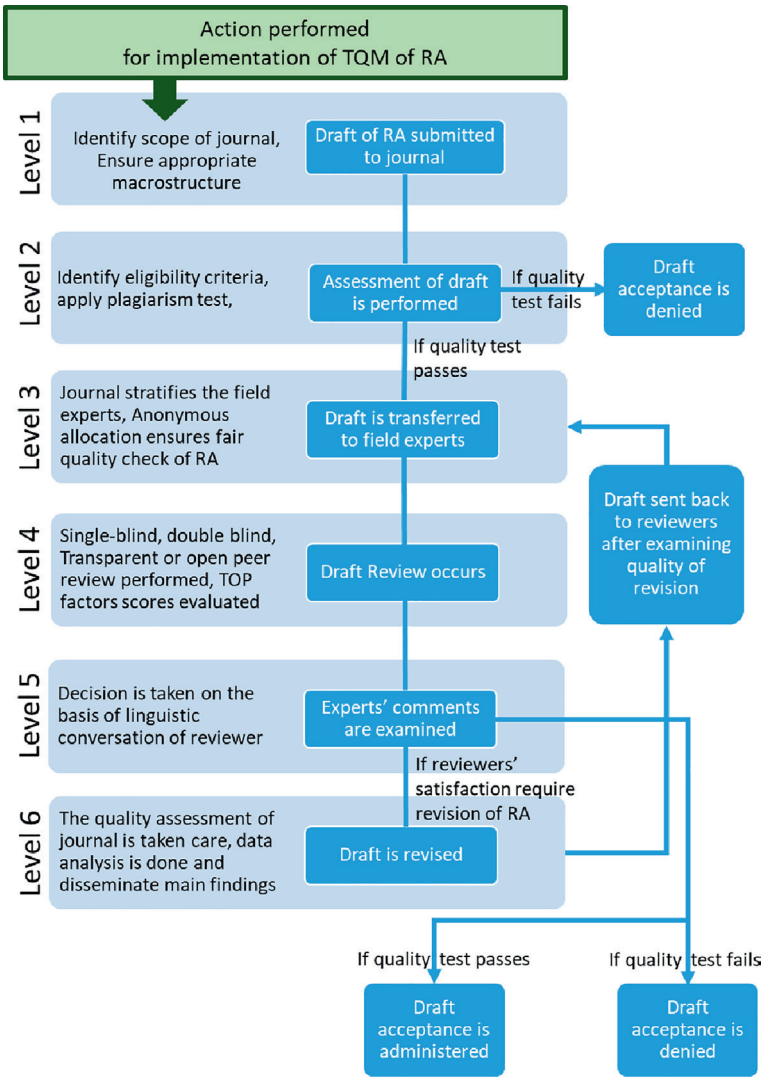

Figure 1.
Implementation of TQM process for quality check of RA.

The following critical collectibles (CCs) has been observed in various articles; research problem, specimen or sample, design technique, control of variables, methodology, analysis process, discussions, ethics and references. The quality management of RA is controlled by a process followed by the corresponding journal. The TQM implementation is directly associated with the concept of the peer review process of a journal, as represented in **Figure 1**. The implementation of TQM for quality check of RA occurs in six levels. Level 1 is administered by the author who is submitting the draft of RA to a journal. The scope of the journal is identified and corresponding macrostructure is followed. Level 2 to Level 5 are administered by the editors/technical editors and field experts of the journal. If quality test of Level 2, that involves eligibility test and plagiarism test, is passed, the field experts are anonymously communicated for examination of the article's quality and possible improvement in the product (RA) (Level 3 to Level 5).

As per the assessment of reviewers' comments, Level 6 of TQM is addressed. If the quality test of article at Level 5 fails, draft acceptance is denied. Otherwise, the quality improvement is carried out ensuring the maintenance of core values of the journal reputation. The dissemination of dominant discoveries is carried out by authors of RA using data analysis tools. Then the process repeats from Level 3 onwards till the final decision of quality test is not communicated.

5. Results

A total of 192 articles were tested for eligibility assessment, out of which 100 articles (52%) utilized quality research as fundamental technique. Out of remaining hundred RA, 62 (62%) used the IMRD format and 38 (38%) used IPTC as the prime representation, including 13 RA from IE, 9 RA from ESA & VLSI each, 11 RA from EPSR, 12 RA from PD, 10 RA from EC, 8 RA from CAD-ICS, 7 RA from MTT, 5 RA from SG & MAP each, 4 RA from JSSC, 3 RA from C, 2 RA from PA-MI and 1 RA from CC & PR each. The primary reasons for exclusion of RA are lack of quality research methodology as the fundamental technique. The critical points denoting the exclusion of RA are represented in **Figure 2**.

The computation of average outline score, out of 7, was performed for RA published in EE literature, by assigning 1 point for each checklist standard. The overall average outline score was 4 ± 2 (2–6). As stated from **Table 2**, the proportion of satisfaction score is obtained by each article as per the checklist standards. The most concurrence areas covered almost 70%, including: statistical details regarding background of research; sample frame & population of survey; mode of communication; research tool; pre-testing techniques; purpose of study; background particulars; formulation of problem; reliability & validity; objectives are addressed through results; reporting of all response and respondents. The RA that reported at the most 30% of checklist standards included: techniques to handle absent data; illustration of who addressed inherent participant; psychometric characteristics; techniques for data analysis; originality and strength of research. The average outline score of journal are

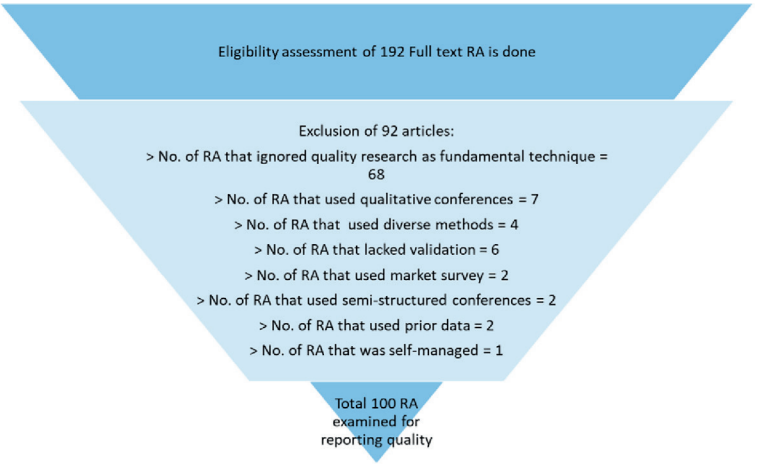

Figure 2.
Screening test and exclusion test of RA.

Journal	Outline score	Journal	Outline score
EC (10)	4.9	ESA (9)	4.2
IE (13)	3.2	PD (12)	3.5
CAD-ICS (8)	5.4	EPSR (11)	2.9
SG (5)	2.8	MAP (5)	2.8
MTT (7)	3.6	VLSI (9)	4.8
C (3)	3.1	JSSC (4)	5.8
PA-MI (2)	4.6	PR (1)	2.7
CC (1)	5.2		

Table 3.
Outline score of EE journal.

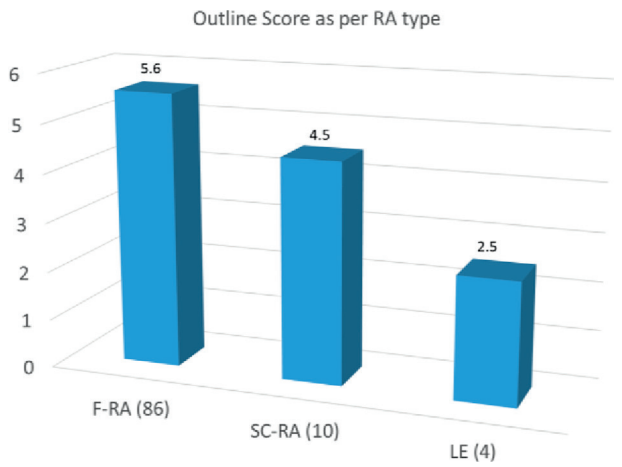

Figure 3.
Score with respect to type of RA publication; F-RA = full research article; SC-RA = short communication research article; LE = letter to editor.

provided in **Table 3**. The highest score has been 5.8 out of 7 for JSSC, 5.4 for CAD-ICS, 5.2 for CC. The outline score with respect to the type of RA is shown in **Figure 3**.

The outline score of 5.6 is obtained by full research article, while short communication type RA had 4.5 and letter to editor had 2.5. **Figure 4** presents the average outline score of RA based on the type of the author. The articles authored by research scholars and graduates of EE has the highest outline score of 5.5 and 4.9 (out of 7) respectively. Whereas EE faculty and Scientists secures almost similar score of ~3.7. the lowest score of 2.7 is obtained by Non-EE category of authors of RA.

6. Discussion on findings and limitations of study

The quality assessment of RA in this chapter established that the research published in leading EE-journals scored reasonably on a recognized platform designed for sequential estimation of quality research outline. The obtained results were

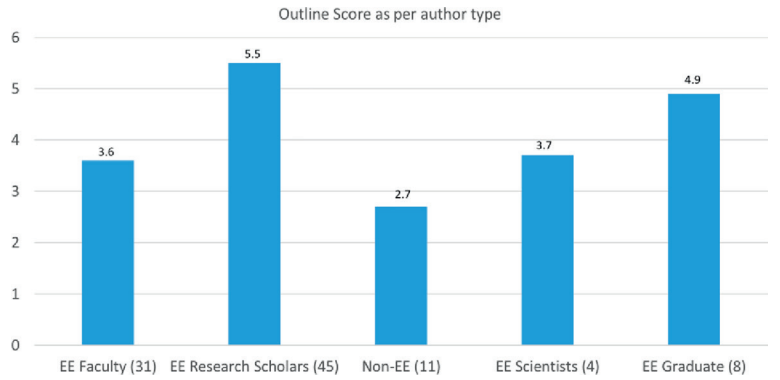

Figure 4.
Score with respect to type of author of corresponding RA.

found to be equivalent across various journals, and author types, when observed excluding the LE type.

This chapter also reveals the different areas that seemed to be associated with lesser scores on recognized platform. On the contrary to the field experts' recommendations, the full problem formulation should not be included in appendix section of RA. Due to this, the reader's satisfaction stage of the TQM gets affected and the end users of the articles become unable to re-use the information about the questionnaire to notify their intrinsic research work. The absence of psychometric properties and validity also arises the credibility or reliability questions of the research work. This chapter recognized certain opportunities for quality improvement with respect to reporting analysis results, that involves risk assessment for undemonstrative error and differentiation between non-responders and responders, and in addition, description of handling absent data and partial reactions.

This study provides the key finding provided the rate of response, on an average, was extremely varying among various EE journals. This may be due to the diverse nature of population which refers to a particular RA in corresponding journal. For instance, an EE research scholar, the most educated population in EC, is more suitable for responding to stimulus as compared to Non-EE population. The areas that report durability included techniques of data analysis, transparency of research limitations, and clarity in report presentation.

This study reflects an equivalent study that was conducted to compute the sample of journals in medical field [35], predominantly for ensuring transparency. This prior study found fundamental areas for possible improvement and reported a recognized platform for former testing and governing reliability and validity. This study provides moderately high performance in former aspect and moderately low performance in latter aspect among EE journals. It is suggested that researchers, who gets engaged in writing RA in EE field for the first time, should cautiously assess Bennett's tool before planning their research study and writing article for publication. This may be advantageous for EE journals to integrate such tools into peer-review instructions to the author, for elevating the quality of RA published in EE journals.

The assessment done by independent investigators for quality management of each RA utilized the standard evaluation platform and systematic techniques for identifying relevant articles. However, there have been certain limitations to our study. For example, with the data collected for only one recent full year, the inclusion

of RA may have missed all RA to different categories of RA. Also, various checklist standards such as identification of who addressed possible field experts, techniques for handling absent data etc. may be of subjective nature. The buildup of score sheets of such standards required the maintenance of consensus between investigators. The opportunity, to inspect for rating the reliability due to going through a vigorous agreement process before going for survey of RA in EE, has been missing. Few article types (like LE), journals (like SG, PR) and types of author (like EE graduates, EE scholars, residents) were not representable. Due to this, the analysis results may not be in generalized form included in the corresponding category. Also, since only first author was categorized, this may represent the absence of the impact of remaining authors' team with respect to the reporting exercise.

7. Conclusion

The RA published in EE literature scored reasonably on a recognized platform consisting of publishing instruments for appraisal of articles in systematic way. The results were found to be homogeneous, in general, across various author types and journal types. The limited form of representation in specific categorization gives rise to limitations to the study. The areas in which the quality of RA can be improved included providing data about psychometric characteristics of existing research tools, validity and reliability of new research tools, possibility for non-responsive errors, differentiation between defendants and non-defendants, and delivering the handling techniques of RA in case the data and responses are missing from RA.

Acknowledgements

This research was supported by Project and Research Laboratory of Electrical Engineering Department in Delhi Technological University, New Delhi, India.

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Chapter 2

A Renewed Perspective on Lean Six Sigma in Healthcare – People and Performance

Relinde J. de Koeijer, Jaap Paauwe, Mathilde M.H. Strating and Robbert Huijsman

Abstract

The Lean Six Sigma (LSS) approach has taken a central role in healthcare quality management, and many studies report positive effects of the method on performance of healthcare organizations. However, LSS in healthcare is also unbalanced because the human side of the method is undervalued. A more balanced application of LSS in healthcare includes an interrelated approach of both "soft" and "hard" LSS practices, broad perspective on employee well-being, "soft" HR approach related to LSS, and "soft" climate for LSS. This leads to a renewed perspective on LSS in healthcare that considers both people and performance and where the interplay between "hard" and "soft" factors is addressed.

Keywords: lean, six sigma, healthcare, performance, employee well-being, HRM, climate

1. Introduction

In the past 20 years, since the Institute of Medicine [1] defined the concept of quality of care, it has become increasingly clear that healthcare is a clashing vessel of values. Values such as good quality of care and safe and accessible care are important. But also, effective and efficient care because healthcare must also remain affordable. The Covid-19 pandemic has highlighted the struggle with bringing the different values together within healthcare systems across the globe [2]. Changed circumstances lead to different value trade-offs. For example, during the coronavirus crisis we started to look differently at lean approaches to organizing care, using as few supplies as possible (also called just-in-time management) [3]. Other existing issues were put on edge by the crisis. For example, Covid-19 did not create the healthcare staffing shortage, but the impact is worsened because of it, visible in current high levels of burnout among healthcare professionals [4]. In addition, consider the challenges of access to healthcare services and of enhancing the quality of care and patient safety while reducing costs [5]. These existing challenges, amplified during the Covid-19 pandemic, emphasize

the importance of operations management for healthcare for years to come. Moreover, it demands a renewed perspective on commonly applied operations management methodologies in healthcare, such as Lean Six Sigma (LSS), which integrates values regarding people and performance. In this chapter, in which we, among other things, use PhD work done before [6], we will start with a short history of LSS in healthcare, followed by identifying gaps in the application of this method based on current literature, leading to proposed renewed perspective on LSS, the scientific and managerial relevance of this perspective, and a research agenda for the upcoming years.

2. A brief history of lean six sigma in healthcare

The LSS approach has taken a central role in healthcare quality management. LSS follows a long history of system management and quality improvement, starting at the beginning of the twentieth century through mass production affected by among others, Henry Ford, followed by the Toyota Production System (TPS) in the Japanese automotive industry and adopted as Lean Management (LM) in the Western world since 1980 [7]. Around the same time that LM was embraced, many large companies, including Motorola and General Electric, implemented Six Sigma (SS) with a focus on reducing errors and minimizing variability [8]. LSS as a combination of Lean Management and Six Sigma is seen as the most effective process improvement that it is widely implemented in the top performing organizations [9], also in healthcare settings [2, 10]. Although the integration of Lean Management and Six Sigma is still relatively rare in healthcare [11], more and more studies report positive effect of LSS on outcomes. For example, Bhat et al. [12] explore the successful deployment of LSS in the Indian healthcare sector and found improvements in patient registration cycle time and reductions in average waiting time, queue length, and staff utilization. Antony et al. [13] report the use of LSS in reducing medication errors in the Norwegian public healthcare context. The Mayo Clinic Rochester in the USA increased their process efficiency and financial performance by applying LSS [14]. A recent study by De Koeijer et al. [15] shows strong positive effects of LSS on internal process and financial performance in university hospitals in the Netherlands. These studies illustrate that in healthcare, LSS is commonly applied with the aim to improve process efficiency, thereby improving quality and reducing costs [7]. Given these positive reports of LSS and given the ever-increasing costs in healthcare, it is very likely that the application of LSS will grow rapidly in healthcare. However, the Covid-19 pandemic has taught us that a narrow focus on specific values of care, such as safety and efficiency, can lead to neglect of other crucial values of care, such as humanity and taking care of healthcare personnel. And this risk is also apparent for LSS. In the next paragraph, we will discuss why LSS, in its current form, is likely to be insufficiently equipped to tackle the multifaceted challenges that healthcare systems are facing, including rising costs, growing expectations from patients, demographic changes, and growing burn-out rates among healthcare professionals.

3. Lean six sigma in healthcare: unbalanced?

From the beginning, criticism has been part of LSS in healthcare. Some researchers and practitioners object to the notion of industrialized healthcare delivery. They argue that tensions may arise between the need to demonstrate efficiency and achieve performance targets (derived from governmental financial pressure) and the need

to invest time and resources in continuous improvement. Moreover, some state that with these increasing administrative burdens and productivity targets, the intrinsic motivation of healthcare employees is suffering [16]. LSS is controversial from the perspective of employees. Proponents argue that healthcare organizations that embrace LSS to improve performance can simultaneously foster employee well-being. Opponents, however, say that LSS leads to higher performance yet lower employee well-being. LSS is not a neutral and value-free activity, and the debate about relationship between LSS and employee well-being is crucial in the light of the workforce shortage in healthcare combined with current high levels of burn-out among healthcare professionals. One of the explanations for this ongoing debate could be that LSS, in its current form, is unbalanced in several ways.

First, the application of LSS in healthcare is accompanied with a heavy focus on tools and techniques at the expense of the human side [17]. The LSS toolbox that healthcare organizations deploy tends to be filled with "hard" LSS practices focusing on process improvements. Henrique and Filho [18] state in their systematic review that the most common techniques used in healthcare are VSM, Standardization of Work, and Visual Management. Also, LSS practices such as "focus on metrics" (the use of quantitative metrics to measure quality and process performance and to set improvement goals) and "process management" (e.g., statistical process control and error-proof process design) illustrate the dominant "hard" focus of LSS practices. Due to this single-minded focus on process improvement, LSS initiatives risk being perceived as cost-cutting efforts at odds with the values of healthcare and therefore risk the withdrawal of staff and potential resistance. Moreover, the outcomes of healthcare organizations depend, on the one hand, on routine and standardized processes and, on the other hand, on employees with the right customer mindset and ability to anticipate changing demands from their customers [15]. "Hard" and "soft" LSS practices should thus go hand in hand: a singular focus on a "hard" approach to optimizing processes neglects the human factor, while a one-dimensional focus on a "soft" approach complicates the attainment of performance outcomes. Therefore, this chapter contains a balanced interrelated approach of LSS practices in healthcare (see **Table 1**) that consists of both "hard" practices, which are focused on practices for improving processes (quality information, process management, structured improvement procedure, focus on metrics) and "soft" practices aimed at employees and relationships (top management support, customer relationship, and supplier relationship). This interrelated approach of LSS makes it possible to empirically examining the effects of multiple dimensions on outcomes.

Second, although many healthcare organizations state that both efficiency and employee goals are drivers for applying LSS, the conceptualization of employee goals is very limited compared with efficiency and quality targets [7, 19, 20]. Where recent research in healthcare agrees on two core performance dimensions of LSS: internal process and financial, employee well-being is poorly defined. For example, a study by Niemeijer et al. [21] of almost 300 LSS projects in Dutch hospitals describes concrete aims of LSS initiatives regarding reducing costs, improving safety, and increasing revenue; however, employees' outcomes are not characterized. And when employee goals are mentioned in studies on LSS, this is mostly done in terms of workers satisfaction [22, 23]. It is important to create a more balanced perspective of employee well-being, since there is no agreement on the effect—positive, negative, or nonexistent—of LSS on employee well-being [24]. For example, studies by Graban [25], Stamatis [26], and Collar et al. [27] mention improved levels of commitment and satisfaction related to LSS initiatives. However, a large study by the Saskatchewan Union of Nurses [28]

LSS practices that are part of the systems approach	Description	Special aspects in a healthcare setting
Top management support	Top management accepts responsibility for quality, creates and communicates a vision focused on quality and encourages and participates in quality improvement efforts.	Managers and physicians together form top management.
Customer relationship	Customer needs and expectations are regularly surveyed. Customer satisfaction is measured. There is a close contact with key customers.	Customers are not only patients, but also family members, caregivers, decision-makers and insurers.
Quality information	Timely collected quality data are available to managers and employees, and must be used for improvement.	Delivering care is a complex process. Collecting accurate and reliable information is a challenge.
Focus on metrics	Quantitative metrics are used to measure process performance and quality performance, and set improvement goals. Business-level performance measures and customer expectations are integrated with process-level performance measures.	
Process management	Statistical process control and preventive maintenance are applied. Managers and employees make efforts to maintain clean shop floors and meet schedules. There is an emphasis on mistake-proof process design.	Safety and hygiene are crucial in a patient environment. A clean working environment and well maintained devices are a requirement.
Structured improvement procedure	There is an emphasis on following a standardized procedure in planning and conducting improvement initiatives. Teams apply the appropriate quality management tools and techniques.	Professionals are trained to act with autonomy. Too much emphasis on standardization could evoke resistance.
Supplier relationship	A small number of suppliers are selected on the basis of quality and involved in product development and quality improvement. The organization provides suppliers with training and technical assistance.	There are many areas of knowledge and practice. In general, each specialty has preference for certain suppliers and assortments.

Table 1.
LSS interrelated systems approach of both "hard" and "soft" practices.

Well-being components	Description	Special aspects in a healthcare setting
Health	The physical or health dimension encompasses indicators related to employee health, such as workload, job strain and need for recovery.	Healthcare professionals perceive increased demands and expectations from customers.
Happiness	The psychological or happiness dimension refers to subjective experiences of employees, i.e. their psychological well-being, for example job satisfaction and unit commitment.	Professionals highly value performing rewarding work.
Trusting relationships	The relationship dimension of employee well-being focuses on the quality of trusting relationships between employees and their employer and colleagues.	The hierarchical structure impacts the relations between employees and their employer and colleagues.

Table 2.
Employee well-being.

showed that LSS had an overall negative effect on worker satisfaction, and studies by Angelis et al. [29] and White et al. [30] discuss negative effects of LSS on worker commitment. Reviews of studies that focus on trusting relationships and health effects of LSS report mainly negative effects [31]. Since most healthcare organizations claim that employee goals are part of the LSS approach, it is wise to define these goals to determine the effect—positive, negative, or nonexistent—of LSS on employee well-being. A broad perspective on employee well-being supports healthcare organizations in monitoring these goals, and based on recent literature [15, 32], this chapter contains the following balanced conceptualization of employee well-being, related to LSS, which includes three components: happiness (satisfaction and commitment), trust, and health (workload and need for recovery) (see **Table 2**).

4. The human side of lean six sigma in healthcare – HRM and climate

Although employees' issues related to LSS are substantial, since LSS in healthcare commonly focuses on organizational challenges that have to do with work (re)design in a complex and dynamic environment, the attention for management of employees is limited. LSS initiatives are a result of collective efforts and require engaging a multitude of actors (e.g., clinicians, nurses, and administrators) and LSS project members operate as "liaison officers" between professional groups, between organizational "layers," and between the internal and external worlds of the healthcare organization. To fulfill their role successfully, LSS project members need specific abilities, motivation, and opportunities. Also, given potential conflicts of interest between different stakeholders, management decisions are needed to shape employment relationships that are aimed at achieving specific (LSS) goals. The employees' issues as described above show the importance of strategic Human Resource Management (HRM) related to LSS; however, especially in healthcare HRM is still considered as a more operational or tactical concept within the larger framework of LSS [33]. For example, Antony et al. [34], and Honda et al. [35] state that training is crucial when implementing LSS. Buestan et al. [36] and Ahmed et al. [37] argue that successful implementation of LSS depends on the participation of healthcare staff. While these separate HR practices are indeed relevant, there is a need for a more coherent, and strategic perspective on HRM that is in sync with LSS. For example, cross-functional teams could help to generate ideas for science-based, systematic quality initiatives [38]. Performance appraisal and rewards could also function as morale boosters and encourage employee engagement [9, 39, 40]. In addition, training and development are crucial to getting skilled and motivated people to work on LSS projects [41, 42]. Employee participation and engagement in decision-making and problem-solving can also help inspire commitment to organizational excellence [43]. If LSS can be imagined as a dance within healthcare organizations, then HRM is its matching dance partner and together they make sure that the dance is balanced on "hard" and "soft" issues. Therefore, this chapter provides a more balanced union between LSS and HRM by including a separate strategic HRM approach (see **Table 3**). By constructing LSS and HRM separately, it provides an approach that does justice to both perspectives [15], and it supports investigating effects and relationships of these two approaches combined and separately.

In addition, the narrow focus on the "hard" side of LSS has led healthcare to neglect activities that encourage employees to develop shared perceptions of LSS. These shared perceptions are important for the internalization of LSS interventions [44]. For the effects of LSS to become visible and measurable, a process of

HR practices that are part of the systems approach	Description	Special aspects in a healthcare setting
Participation and job design	Employees are involved in quality decisions and have the opportunity to take responsibility for their own tasks.	Professionals are trained to act with autonomy. They are, together with their colleagues, responsible for delivering quality of care.
Training and development	Both managers and employees receive training on quality management. There are opportunities to develop new skills and knowledge.	Professionals are highly trained individuals with a specific expertise. Performing tasks or development outside their area of expertise is unusual.
Performance appraisal and rewards	Employees receive feedback on quality performance of their team and are rewarded for quality improvement.	Quality of care is highly appreciated and rewarded in healthcare organizations.
Team working and autonomy	Teams are formed to solve problems. Teams are encouraged to try to solve their problems as much as possible.	Health care is usually provided by multidisciplinary teams of professionals and support services.
Employment security	Employees have an employment contract that offers job security.	Increasing expenditures create pressure on organizations.
Work-life balance	Employees have the possibility to work flexible hours and arrange their work schedule.	Consumers are increasingly putting higher demands and expectations on healthcare professionals. Therefore, it is challenging to balance the needs of work and life for professionals.

Table 3.
HRM systems approach.

routinization must take place in which professionals adopt these new work practices and adapt their existing organizational routines accordingly. However, there is a dearth of research investigating the organizational patterns (routines) that LSS implementation may enable [13]. Adopting LSS in such a way that it becomes a permanent part of the organization's daily routine can be described as internalization [45]. New routines cannot be sustained in a setting that does not support and enable their performance, however. For example, unless the LSS climate reflects employees' belief in the real value of LSS for their organization, there is a significant risk that LSS will never be internalized [46]. This risk is particularly acute in healthcare because healthcare professionals fear that adopting LSS will lead to over-standardization [47] and that LSS redirects clinical practice away from patient care toward more administrative and management tasks [48]. Shared perceptions support employees in their drive to sustain quality improvement initiatives [49] and in their commitment to accomplishing organizational excellence [43, 50]. Creating a climate for LSS that reflects positive shared perceptions of employees about LSS practices and their commitment to them is therefore crucial to the internalization of LSS [45]. Climate is consistently conceptualized as employees' shared perceptions about the nature of their organization in terms of events, policies, practices, and procedures [51, 52]. Internally, climate is often considered actionable, i.e., management can try to shape climate to pursue organizational goals and influence performance [53, 54]. Many scholars of operations management have attempted to define a climate for LSS, most of them by drawing on the experience

of organizations that have implemented LSS successfully [55]. Bhat et al. [2] argue that an integrated LSS strategy ensures a climate of continual improvement in the healthcare setting. Goodridge et al. [56] state that LSS seeks to create an environment in which mistakes are opportunities for learning, with consistent application of no-blame approaches to mistakes and errors. Ambekar and Hudnurkar [57] claim that people with a positive attitude and critical-thinking capability innovate and ideate solutions. While researchers agree that a successful LSS implementation will aim to achieve climate change and succeed, they fail to agree on the specific characteristics of such a climate for LSS. This chapter highlights a "soft" climate for LSS that reflects employees' perceptions regarding the extent to which the organization emphasizes specific LSS values, goals, expected behaviors, and contributions at work, related to quality, innovation, and efficiency [15, 58].

5. A renewed perspective on lean six sigma in healthcare: people and performance

In the above paragraphs, we discussed different lines of thought on supporting a more balanced application of LSS in healthcare: by embracing an interrelated approach of both "soft" and "hard" LSS practices, by adopting a broad perspective on employee well-being and by developing the human side of LSS in healthcare by constructing a "soft" HR approach related to LSS, and by adapting a "soft" climate for LSS. This brings us a renewed perspective on LSS in healthcare that considers both people and performance and where the interplay between "hard" and "soft" factors is addressed, contrary to earlier research [59].

When focusing on the interplay between "soft" and "hard" factors, there are a few relationships that need to be considered. For example, it is important not to pick and choose from the LSS toolbox [60, 61], healthcare organizations may benefit the most from LSS, when applied as a systems approach of LSS practices. Also, the relationship between LSS, performance, and employee well-being is worth discussing. Healthcare organizations that adopt LSS to improve organizational performance may assume based on the more classical view (see **Figure 1a**) that LSS will also benefit or at least not harm employees. However, recent research [6] shows that the situation might be more complex and that LSS is suitable for improving performance and

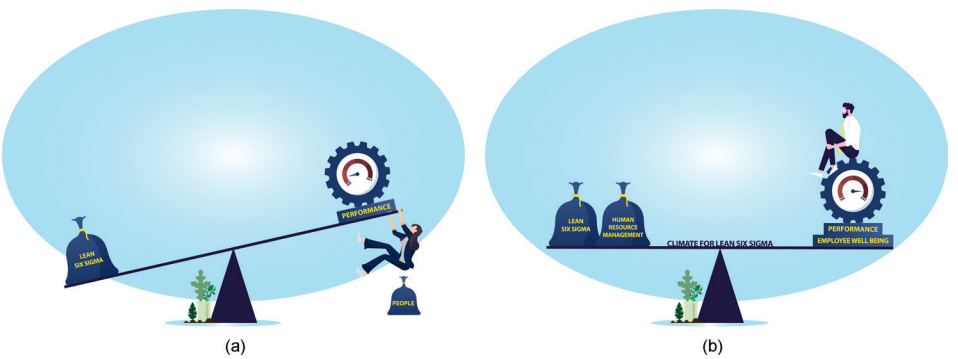

Figure 1.
a: Classic view on LSS in healthcare. b: Renewed perspective on LSS in healthcare: People and performance.

unsuitable for increasing employee well-being. In fact, they show that performance and well-being are at odds with each other: when well-being increases, performance decreases and vice versa. This may lead to a new perspective on the ongoing discussion whether LSS positively or negatively impacts employees. In this chapter, we argue that LSS is simply not designed to improve employee well-being. Although this may seem obvious, systematic reviews by D'Andreamatteo et al. [23] and Moraros et al. [22] mention both efficiency and employee goals as drivers for applying LSS in healthcare organizations. However, the driver for improving employee well-being is not visible in the way LSS is designed: especially in healthcare LSS is often applied as a set of "hard" practices, concerning tools and techniques for improving processes. Therefore, our renewed perspective on LSS in healthcare reserved a special place for HRM (see **Figure 1b**). Not only does research show that HRM is essential to improve employee well-being [15, 62], previous studies have confirmed that HRM plays a vital role in shaping climate and thereby internalizing LSS [63]. HRM is crucial for creating shared perceptions among employees and, consequently, a climate for LSS [6]. In this context, HRM can be seen as a signaling system that constantly sends messages to employees stressing the attitudes and behaviors desired within the organization. For example, hospital management can use HR practices to create a desired climate where LSS initiatives take root by communicating to employees that quality improvement is important, that improvement initiatives and innovative behavior are expected and rewarded, and that attaining organizational excellence is encouraged [43, 50]. Where LSS practices are more generic, HR practices are developed specifically for employees. For example, quality management training can be tailored to specific employee groups and their educational backgrounds. Following this line of thinking, it can be said that HRM boosts employee engagement and involvement in continuous quality improvement [43, 64]. Finally, by adapting a climate for LSS, employee well-being is improved [15]. Given the ambition of hospitals to maintain higher standards of both organizational performance and employee well-being, it is crucial that hospitals that adopt LSS should also foster a climate for LSS by combining LSS and HRM, thereby internalizing LSS. Employees interpret management activities as indicative of organizational support and care and reciprocate accordingly with commitment, satisfaction, and trust [65]. In that sense, healthcare employees may experience HRM as a form of recognition and concern, creating a climate for LSS and affecting their well-being.

Summarizing, with the renewed and balanced perspective on LSS in healthcare that encompassed people and performance (see **Figure 1b**), healthcare organizations can create mutual gains and sustainable outcomes for both the organization and employees. With this renewed perspective, healthcare organizations can face multifaceted challenges related to both performance (for example rising costs and growing expectations from patients) and people (for example retaining highly dedicated and competent employees and growing burn-out rates among healthcare professionals).

6. Managerial and practical implications

Many healthcare organizations that struggle with both challenging efficiency targets as well as increasing personnel shortages have tried to find one cure for all their problems by embracing LSS. However, despite promising (sales) stories about LSS, for example, that it leads to happy employees who have more time for the work they are passionate about, this chapter shows that LSS in healthcare is unbalanced. The heavy

focus on tools and techniques at the expense of the human side, the poorly conceptualization of employee goals, the limited attention for management of employees, and a climate for LSS may lead to suboptimal results, which will not be conducive to establishing a fully-fledged quality philosophy [43]. One could argue that LSS should be used for those processes where the financial pressure is high. But the danger is that LSS will become a concept that is not that attractive for healthcare professionals, since performance will not be at the core of their profession. How can a healthcare organization stay financially sustainable and deliver good quality without happy, healthy, and trusting employees? The systematic review by Hall et al. [66], for example, shows that low levels of well-being of healthcare workers are correlated with poorer patient safety. Fortunately, from a management perspective, we see that adopting a balanced approach of both "soft" and "hard" LSS and HR practices allows healthcare organizations to capitalize on their synergies for internalizing LSS, performance, and employee well-being. Management can use HRM to shape a climate for LSS conducive to the pursuit of organizational goals and the well-being of employees. Therefore, healthcare organizations should involve their HR departments right from the start when introducing LSS programs to ensure that a HRM systems approach is in place. In many healthcare organizations, HRM—unlike LSS—is a consistent component, covering all employees. There is a fundamental different pace of HRM and LSS. Where LSS in healthcare is focused on improving short-term efficiency through short-cycle improvement projects [67, 68], HRM is present constantly. HR practices are practical and can be tailored to specific employee groups and their educational backgrounds. For example, HR practices such as teamwork, participation, and training involve employees at different levels in continuous quality improvement. Management can use these HRM practices to create a desired climate in which LSS initiatives can take root. It is important that managers are consistent in communicating to employees what is valued and considered important in the organization and the kind of behaviors and attitudes that are expected and rewarded [69, 70]. For example, they should emphasize the importance of continuous improvement and of achieving quality outcomes and discuss with employees how they can contribute in practical terms.

It is vital for healthcare executives to acknowledge the fundamental dichotomy between the process-oriented tasks required to provide health services and human factors [71]. Where most literature on LSS so far has argued for the inclusion of HR practices in an LSS systems approach, this chapter enlightens that LSS and HRM should be viewed as two different things. Separating LSS and HRM could be an opportunity for healthcare organizations, since a critical challenge that faces LSS implementation is a lack of belief that it will work [14]. Employees might perceive LSS as something new and be hesitant to embrace the method [72], also due to the increasing internal and external pressure to work more efficiently. When the resistance to apply LSS is growing, healthcare organizations can be flexible in reframing the method, while at the same time can be tenacious in applying HRM systems approach. This conclusion also has impact on the positioning of LSS in healthcare organizations. As LSS is meant to continuously improve performance and not employee well-being, it makes much more sense to make LSS part of the quality and safety department. HRM departments have a separate and equal important task to continuously foster the health, happiness, and trusting relationships of the employees of their healthcare organizations. Still, LSS and HRM require constant alignment and should be managed integrally. In practice, this could mean that when healthcare executives share the "why" of LSS within the organization, they should emphasize both performance improvements and higher levels of employee well-being. Another recommendation

is to monitor progress in LSS integrally by focusing not only on the number of LSS initiatives and their progress but also on the happiness, health, and trusting relationships of employees, and by explicitly including performance indicators in the "LSS dashboard." In addition, since direct supervisors play a prominent role in transmitting values and climate [73], they should actively support their employees with a balanced approach that incorporates both "hard" and "soft" factors into the improvement process [74]. For example, appraisal interviews should not only focus on "hard" key performance indicators, but also on improvement efforts and more narrative input. This may also mean that employee productivity would temporarily decline to allow time for improvement projects or quality training.

Concluding, in recent years, a great deal has been invested in LSS in healthcare: belts have been trained, improvement teams have been formed, and LSS improvement approaches have been widely embraced. This chapter demonstrates an optimistic view about LSS in healthcare, if applied balanced and with a focus on people and performance (see **Figure 1b**). With this renewed perspective, where HRM is strategically aligned with the goals of LSS, healthcare organizations can create mutual gains and sustainable outcomes for both the organization and employees.

7. Agenda for future research

To acquire a deeper understanding of the causal relationships in our renewed perspective on LSS, future research should apply a longitudinal and intervention design (including control settings). Such research could, for example, examine a potential spiraling positive or negative effect, i.e., that the more LSS in combination with HRM is adopted, the more LSS is internalized and the more performance and employee well-being improve, and vice versa. Longitudinal research could also verify whether the relationships as discussed in this chapter, for example, between LSS and performance, HRM, climate, and well-being, are cause-and-effect relationships.

In addition, it is interesting to investigate whether the renewed perspective on LSS is generic for different types of healthcare organizations (e.g., hospitals, elderly, and disabled care) or that a specification for each subsector is needed. Also, the current inpatient and specialty-oriented view of healthcare professionals will develop into more disease path- and care chain focused ways of working, in (regional) teams with common integral responsibility for each other's functioning [75]. Therefore, it is interesting to conduct future research into multidisciplinary teams, consisting of healthcare professionals from different healthcare institutions that work together on LSS initiatives.

Finally, we need a broader definition of performance in relation to LSS, as well as a more comprehensive set of performance measures. The definition of performance related to LSS, namely "value for customers while optimizing resources" [76] could benefit from a more contemporary and healthcare-specific clarification. Recent debates have focused on how performance in healthcare should be defined and measured [77]. For example, is performance about costs, efficiency (e.g., shorter waiting times, improved utilization), customer satisfaction, quality, health-related outcomes, or all of the foregoing [78, 79]? In light of these recent debates, we argue that the definition of performance in relation to LSS should be updated and clarified specifically in the context of healthcare. In addition to this chapter setting out a wide range of perceived improvements (e.g., internal processes, customer satisfaction, and financial results), we propose incorporating objective outcome measures into any future research.

8. Conclusion

The LSS approach has taken a central role in healthcare quality management, and many studies report positive effects of the method on performance of healthcare organizations. However, LSS in healthcare is also unbalanced in several ways. First, the application of LSS in healthcare is accompanied with a heavy focus on tools and techniques at the expense of the human side. Second, although many healthcare organizations state that both efficiency and employee goals are drivers for applying LSS, the conceptualization of employee goals is very limited compared with efficiency and quality targets. In this chapter we discuss different lines of thought on supporting a more balanced application of LSS in healthcare: by embracing an interrelated approach of both "soft" and "hard" LSS practices, by adopting a broad perspective on employee well-being and by developing the human side of LSS in healthcare by constructing a "soft" HR approach related to LSS, and by adapting a "soft" climate for LSS. This brings us a renewed perspective on LSS in healthcare that considers both people and performance and where the interplay between "hard" and "soft" factors is addressed, contrary to earlier research [59]. With the renewed and balanced perspective on LSS in healthcare that encompassed people and performance (see **Figure 1b**), healthcare organizations can create mutual gains and sustainable outcomes for both the organization and employees.

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Chapter 3

Integrated Lean Safety Model to Develop Organizational Safety Culture

Pal Pandi Ammavasi, Kallarpiran Arumugam and Anbu Meenakshi Sundram

Abstract

The basic purpose of any business organization is to operate it with minimum risks and accidents. These contexts maintain safety culture in the organization in order to improve performance. The integration of Lean and Six Sigma along with existing safety practice may build a more effective safety culture, which may engage the entire workforce proactively seeking a healthy and hassle-free work environment considerably and notably reducing risks and accidents and mitigate the stress of workforce. This prompted the present authors to develop an integrated Lean Safety Management model (ILSM) for improving safety in workplaces. ILSM is an integration of Lean Thinking, Six-Sigma (DMAIC) and Behaviour Based Safety Management. The purpose of this chapter is to bring out the salient features of ILSM through SMILE approach and its credibility in meeting out the needs of the stakeholders regarding industrial safety and occupational health aspect.

Keywords: safety culture, behavioral based safety, lean six sigma, ILSM model, SMILE Approach

1. Introduction

Though, the concept of industrial safety is widely practiced in Western and few other developed countries, its predominant presence in India is yet to be seen except the manufacturing industries having foreign collaborations and some large manufacturing industries having well defined inclusive infrastructure. The chemical and cement industries are very much vulnerable to the risks of accidents. The health of employees is at risk as they are exposed to dangerous chemical activities and exhumation of dusts. This prone to severe health hazards in employees at long run. Therefore, safety is inclusively concerned with the employees as well as the workplace. The malfunctioning of machineries in the workplace may cause accidents. The leakages of chemicals or oil, in case of chemical and oil industries have direct adverse impact on employee's safety. It could be seen that few big Indian construction industries have taken the advantages of the safety concept in their workplace but not in full fledged manner. "Safety has been defined as a condition where nothing goes wrong or

a condition where the number of occurrence of accident, risk of injury, loss and danger to persons, property and environment is acceptably small" [1]. Rene [2] has pointed out that technical breakdown and human errors cause unsafe situation. The safety is considered to be very important in the sense that reducing risk of accidents and avoiding careless handling of machineries may pay a good dividend in terms of performance excellence and financial benefits to the organization. Besides, it helps boost the morale and activate the positive motivation among the employees. Safety is very much concerned with employees' health and incepts care on their family in all welfare aspects. Further, it is very essential that creating and maintaining a safe working environment ensures high health levels among the workers, protecting the workers from the risk of accidents, illness or discomfort in the workplace and increase the efficiency of wok processes, improves employee perceptions of their working environment and leads to higher recruitment attractiveness [3]. The above context clearly emphasizes the safety concept in manufacturing and services organizations give more importance to the employees than the machineries. In the context of importance given to employees, their behavior and attitude form base in implementing safety culture in organization. To keep the safety culture permanent and perennial in organization, it is very important to induct the safety culture among the employees by transforming their behavior and attitude. This thought of imbibing the importance and benefit of safety among employees lead to the concept of "Behavioral Based Safety (BBS)" management for maintaining safe work environment in organization. The both lean thinking and BBS concept helps proliferate safety in organization by eliminating the unwanted and non value added activities and streamlining the processes in all aspects. Lean Thinking and Six Sigma (DMAIC Methodology) are viewed as formidable strategic weapons to succeed in performance excellence. Therefore, the authors felt the need of an appropriate comprehensive integrated lean safety model (ILSM) to ensure safety practices and enrich safety and health performance in the industry by reducing the risk of accidents. Since, ILSM is a practice of accident prevention system; the authors suggest that the top management must initiate holistic implementation of ILSM to attain safety culture sustainability in the organizations.

1.1 Objectives

Following are few important objectives for this study

1. To understand the importance of Safety Concept in different types of organizations.
2. To evaluate how safety culture could be infiltrate among employees.
3. To understand the role of human components as a base to carry out safety activities in organization and its importance to keep organization accidents free and hazard free.
4. In the context stated in the third objective, to study how far (the) Behavioral Based Safety management system could be aligned with Lean and Six Sigma.
5. To integrate Lean and Six Sigma with BBS (and) to develop a new conceptual model.

2. Review of literature

The Review of Literature has been presented in eight major sections. The first section would bring out the studies related to safety, the second section has been marked to review studies on culture, in the third section, the authors try to highlight the studies on safety culture, the fourth one detail about BBS, the fifth and the sixth describe factors attributing to workplace accidents and benefits of BBS respectively. The Seventh and the eighth sections highlight the linkage of Lean and Six-Sigma with BBS.

- Safety

"Safety has been defined as a condition where nothing goes wrong or a condition where the number of occurrence of accident, risk of injury, loss and danger to persons, property and environment is acceptably small" [1]. Rene [2] has pointed out that technical breakdown and human errors cause unsafe situation.

- Culture

Culture is the product of the interaction between human psychological, work behavioral, and organization situational [4]. According to Reason [5], culture is the 'engine' that drives the organization towards the goal of sustaining the maximum resistance towards hazards. Organizational cultures are rooted within community expectations and intersect with national cultures [6].

- Safety Culture

Safety culture in the organizational set up includes the 'health' as an important one. Therefore, in most of the literature it has been referred as 'Health and Safety' (H&S) culture. Accordingly, based on Hale and Hovden [7] who in their study classified H&S in three ages, Hudson [8] has suggested following three stages in the evolution of H&S culture. In the first stage, Technology was given importance (technical age), then in second stage, more emphasize has been given on H&S management systems (human factors' age) and in the third the H&S is seen through cultural aspect (safety culture age). Reason [5] suggests that 'an abiding concern for failure' would be the key component of a good safety culture. Therefore, organizations having good safety culture are sensitive and responsive to signals of danger.

Before going into detail discussion, understanding the definitions of SC is more important. The cultural drivers of Health and Safety comprises of social forces within organizations that shape organizational members' assumptions, beliefs, values and actions [9]. Few of the identified important factors of SC are; management [10], individual and behavioral [4], Worker's knowledge on safety. In this regard, the stakeholder role in safety culture and safety performance has been discussed by Althaqafi and Abunar [11]. A broad thinking is that the social forces are the main cultural drivers which shape organizational members' assumptions, beliefs, values and actions [9]. In line with the social phenomenon, Richter and Koch [12] define safety culture as the shared and learned meanings, experiences and interpretations of work and safety-expressed particularly symbolically – which guide peoples' actions towards risk, accidents and prevention.

- Levels of SC

Hudson [8] has identified five levels in SC namely, Pathological-unless we experienced we will not think and cares about safety; Reactive-safety is important in the sense that when we do a lot every time we have to meet an accident; calculative-there is system in place to manage all hazards; Proactive-trying to anticipate safety problems before they arise and generative-health and safety show how the business is going on. According to theory of SC, following four levels have been identified that are; physical culture, institutional culture, behavior culture and spiritual culture. Further it has been defined as "the sharing of safety values, attitudes, ethics and code of conduct" (State Administration of Work Safety, 2009 [a & b]).
SC being an important part of organization management system, it improves the quality and operation mode of safety management level which could prevent major accidents, reduce accident rates and improve safety performance.

- Behavioral Based Safety (BBS) Management

Employee awareness of safety plays crucial role in maintaining safety standards in organizations. Poor awareness of safety indicates a poor safety climate which decreases the health and safety of employees. Behavioral Based Safety (BBS) is a process within which employees of organizations have been enveloped to follow the safety procedures in their work situation where by to learn more on safe and unsafe activities towards transformation of their behavior and attitude to avoid unsafe work environment, loss of life, get injured and loss of time and financial remuneration. Therefore, BBS focuses on what people do, analyses why they do it and then applies a research supported interventional strategy to improve what people to do. It is an approach based on human behavior used to prevent workplace injuries. BBS is one of the approaches to make employees to aware safety in workplace to improve safety performance and decrease the number of accident cases at the workplace and incorporated with safety management system towards safety and health performances and improvements [13] and is not a program, but an integrated management "process" [14]. The important role of human components in organizations accelerates the risk of accidents wherein, the attitude and behavior of workers have to be carefully considered at the workplace to avoid the untoward incidents. In this exercise, the organization has the compelling responsibility and the duty to make the worker to understand to work safe in the safe environment. Therefore, it is the behavior and the attitude of the worker to follow the norms of the safety in workplace. So, organization should come forward to instill among workers the positive behavior towards safety and has the responsibility to activate and motivate the worker to abide to the strategic plans and related training programs of organization. This is otherwise called as the behavior based safety management. The sustenance of the safety systems management is possible only when the BBS has been transformed to be a culture of the organization, since it wholly relied on human resources.

- Factors Attributing to Workplace Accidents

Cox has defined BBS as the intervention that focused on people and Connor suggested to develop a list of human factors that influence workplace safety. The workplace accidents are caused by unsafe behavior [15] and unsafe act [16], unsafe working conditions and false acts, inadequate safety performance, improper

housekeeping, low tool maintenance, supervisory fault [17] and unsafe act or unsafe conditions. Any act that deviates from generally recognized safe procedure laid down to do the job may be considered as unsafe act [18]. In spite of organizations having well managed safety management with good safety policy, significant accidents occur [19] and this may be due to unsafe or careless employees which can easily be resolved by closely monitoring and changing the behaviors of workers [20].

- Lean Thinking Aligning with Safety Management System

Lean Manufacturing (LM) is a business concept; its goal is to minimize processing time, resources and other activities in the manufacturing process and by eliminating wastages to achieve performance excellence and sustainability. The 5S process (Sort, Set in order, Sweep, Standardize, and Sustain) is the basis for an effective lean implementation. The 5S process is a structured program to systematically achieve total organization, neatness, cleanliness, standardization and discipline in the workplace [21]. LM process gives importance to the worker safety by informing, empowering the workers to be active with knowledge, skills and create opportunity to act safely in the workplace in order to eliminate or reduce hazards or risk of accidents.

Anvari et al. [22] have attempted to evaluate an approach aligning Lean Manufacturing with Safety Management Systems and tried to establish relationship between them. In compliance with the above, the above authors have talked about the 6th S that is Safety along with the existing 5S of Lean Manufacturing since safety strategies are considered crucial to world-class competitiveness. Because, the 6S process simplifies the work environment, reduces waste and non-value activities while improving quality of efficiency and safety [22]. The 5S were drawn from Toyota Management System (TMS) and the 6th S has been added by Universal Coordinated Time to emphasize safety in the workplace [23]. The 6th gets prominence since; it is the first method the companies often implement before implementation of Lean process because it serves as the foundation of future continual improvement effort [24]. When safety (6S) is aligned with the Five Ss it creates a culture of continual improvement and employee engagement that is essential for successful implementation of Lean. The 6S helps other lean methods such as cellular manufacturing, one-piece flow and JIT production for easy implementation. In the context stated above, 6S that is Safety can strongly be considered as one of the tools of LM. It strongly enables for employees and enables people to be free of aggravations that hinder their work and it acts as a positive way to involve people in improving their own work settings [25]. Health and Safety hazards in organization are created due to employees de-motivation, lack of or unclearly defined working procedure and tasks, lack of control, lack of instruction or appropriate training, unsafe worker behavior, low management commitment to safety, no consensus on what Safety Management System (SMS) exactly is and on corresponding scope [26] all those could be controlled by LM process. The errors of total productive maintenance (one of the LM component) contribute to accidents in complex systems [27]. Sourin et al. (have) found the relationship between the Lean tool Poka-Yoke and SMS. Fernandez et al. and Bottani et al., [28] have suggested that creation of all types of hazards controlled in LM environments. It could be concluded that there is a perfect correlation and relationship between all the SMS policies and practices and the LM/6S. It could be concluded that all the dimensions of safety culture are used in LM [29]. Increasing diffusion between organizations in respect of Safety Management Systems have been felt by Bottani et al. [28] this is because of the major shortcoming in most of the safety

culture models due to lack of integration [15]. Therefore, Fernandez-Muniz et al. [30] suggest that safety must be integrated into all the organization's decisions and actions, and the prevention must be more organizational and strategic than material, since human component plays an important role in the causal chain of workplace accidents. When two or more systems are integrated into one model, the level of compatibility increases resulting potential tangible and intangible gains with added value to the organization [31]. Several authors for example, Karapetrovic and Jonker, [32]; Beckmerhagen et al. [33]; Jergensen et al. [34] and Rebelo et al. [35] have extensively studied the integration of Safety with other management systems (like various quality and environmental management systems) for efficient management and excellent performance of organizations.

Following the efforts taken by the above mentioned authors, the present authors have developed a new conceptual model like ILSM and established SMILE approach in behavior based safety system.

- Six Sigma Aligning with Safety Management System

Rehman and Ateekh-ur-Rehman [36] have evolved the possibility of managing safety through Sig Sigma approach and found that the DMAIC approach was effective in reducing the safety hazards. Kehinde et al. [37] have conducted a study in a food processing industry on managing safety using Six Sigma Technique. The Sigma level of safety was estimated using DMAIC method. Further, Failure Mode Effect Analysis (FMEA) was used and the Risk Priority Number (RPN) for various departments was also calculated. This study helped to contain safety hazards at present and in future. Stricoff and Seymour [38], Bahadir and Ivan [39], and Ng et al. [40] have endorsed the above findings.

2.1 Gap

Safety Management System (SMS) is familiar with all types of industries in countries abroad. BBS is one of the safety concepts in SMS. The Indian scenario is seemed to be different, particularly, in Southern most part of India that is Tamil Nadu, the Safety practice industries still yet to be taken off. It was observed from field visit that few big industries of various types around Chennai, the capital of Tamil Nadu follow few elements of SMS but not in full. Particularly, the lean oriented BBS concept in most of the industries in India, particularly in Tamil Nadu is still to be practiced. The reason being, the negligence of organizations to adapt lean oriented BBS concept and the less interest of employees to understand the salient features of the system and failed to understand that despite giving benefits to the organization, it forms basis for the health and welfare of the workers. Further, very few literatures are available on industries with regard to implementation of BBS in associate with Lean Six Sigma.

2.2 Reasons and need

The industries are looking forward to achieve financial benefits through increasing performance. This could be achieved by the relentless contribution of workers. Therefore, workers should be given a healthy and accident free work environment. This warrants change of behavior and attitude. Thus the organizations must keep workers more informative of the work environment and to make them aware of their responsibility in discharging the task in a prescribed way of operation. The holistic

implementation of BBS may help organizations to successfully face challenges from similar organizations and the national and international market volatilization.

2.3 The main focus of the study

This study may help to maintain safe work conditions through principled practice of discipline through BBS practice among employers and employees. This cultivates the safety culture in order to reap benefits like, reduction of cost of product in all aspects, eliminate cost of worker's compensation claims and to reduce costs related to employee medical leave and absenteeism.

3. The proposed model

On extensive deliberations about the integration of Lean, Six Sigma (DMAIC) and BBS, the authors have developed the following SMILE approach in working environment and new conceptual model to be implemented in organizations for attaining safety culture. The robust implementation of lean oriented BBS (SMILE approach) and integrated lean safety model in an organization may definitely help harvest good benefits in terms of accidents free organization, performance excellence and huge financial benefits (**Figure 1**) (**Table 1**).

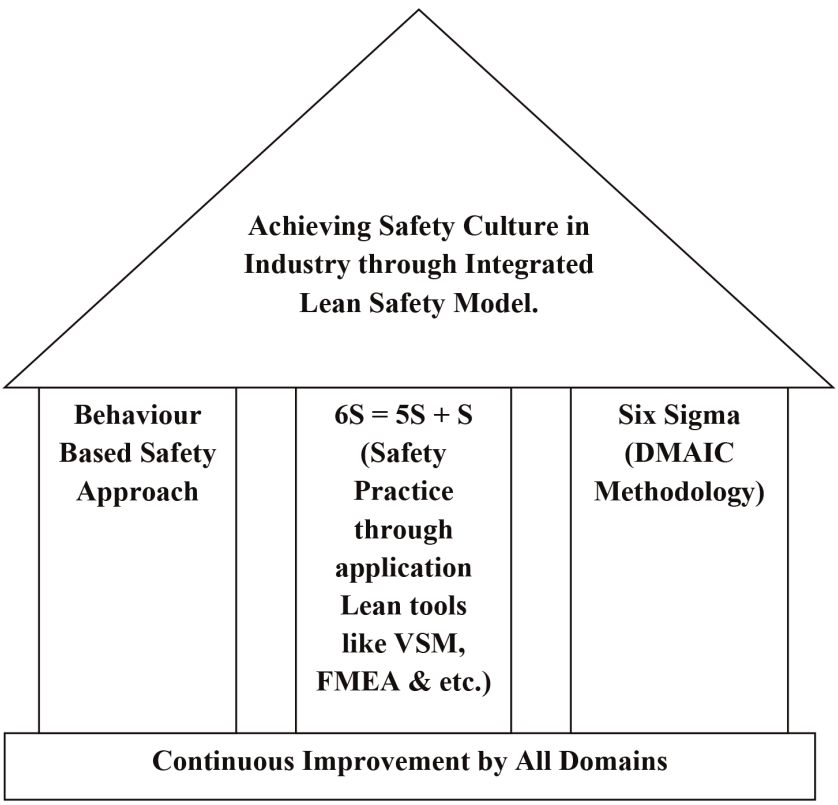

Figure 1.
A conceptual model of safety culture environment.

S – Select	• Initially BBS coach is selected to conduct the observation regarding employees' work practice in the industry environment. • The BBS coach after observation selects the safe and unsafe behavioral practices of the employees within the workplace / plant as per framed checklist.
M – Mentor	• If unsafe behavior is carried out, immediately corrective actions are suggested by the coach in an appropriate manner. • If the employee rectify at risk behavior (unsafe) practice while performing the operations, he will be appreciated by the coach. • Further the observer (BBS coach) offers constructive feedback to the employees for their consistent performance.
I – Implement	• Brainstorming sessions are carried out to emphasis the need of safe practices and are to be implemented in all aspects without any hesitation.
L – Lean	• Observer initiating Lean Six Sigma Based BBS approach. Lean Thinking means eliminating the wastes (unnecessary activities) by streamline the process in a structured way of practicing working behaviors consciously during productive hours as per safety act & rule. • The project team (Six-Sigma team) must be formed to solve the safety related problems in the industry through DMAIC approach.
E - Evaluate	• The improved safe practices are evaluated as per safety act & rule. • The scope of existing improved behavior is discussed with steering committee members for continuous improvement of working environments (Zero injuries / Accidents to be achieved) i.e. maintaining safety culture.

Table 1.
SMILE approach - lean oriented behavior based safety system.

4. Findings and discussion

Various past studies have brought out the importance of implementing Safety Management System in manufacturing, construction and related organizations. The studies have also underlined several benefits like, keeping and improving employee's health and welfare, changing behavior and attitude of employees towards positive and safe work environment and thus motivating them to work in risk and accident free environment. Therefore, the organizations could reap financial benefits by reducing compensation paid to employees due to accidents, improve quality and production due to increased performance excellence, and could stand out as unbeatable competitor in the market. The Six Sigma technique also reduces the process output variation to six standard deviation which lies between the mean and the nearest specification limit to 3.4 defections per million opportunities. Peter et al. [41] have stressed the need of Six Sigma for continuous improvement in the workplace.

The integration of various managements systems with SMS further fillip to the Safety processes in organizations. The basic and the main concept of Lean is the reduction of space, time, manufacturing processes and other non-value added activities, resources and the various types of wastes. The 5S tool of Lean has been structured to systematically achieve total organization, neatness, cleanliness, standardization and discipline in the workplace [21] which result the reduction of risk of accidents through safer and more efficient productive operation. Stricoff and Seymour [38] have suggested that Six Sigma could be applied for the purpose of organizational safety. Staryarsky and Whitfield [42] have identified few constraints in applying Six Sigma in manufacturing organization towards "World Class" safety performance. In spite of the constraints, several authors have studied the utilization of Six Sigma in various

types of organizations, for example, ship Management and safety [39]; to explore injury rate of an international waste disposals firm [41] and reduce hazards among cargo handlers working in cargo container [40].

5. Conclusion

Especially manufacturing and construction industry have become an important sectors in promoting economic growth. However, the accident cases in the manufacturing sector and construction industries are always higher than other sectors. In order to reduce the accident cases, safety culture is the long term solution that creates consistent patterns of safety behaviors, beliefs and values in the organization by practice of effective leadership support, management commitment (Management must be sensitive towards safety issues and committed to challenge unsafe behaviors without fail) and effective safety management system. Safety has a significant role in industrial organizations. Lean is built on the central idea of reducing or eliminating wastes from the system. Since accidents are fundamentally a waste, lean inherently includes safety concerns within its scope.

The conclusion arrived here at is purely a hypothetical based on a number of related studies by various authors and according to their findings. Anvai et al. [22] have found the perfect relationship between lean management and safety management system and most of the attributes of lean management positively and significantly correlated with the SMS process. Several authors have stressed the employee awareness of safety has been considered to be an important in quality outcome in the organizations [43] because poor awareness would result in poor safety climate which would be detrimental to the employee as well as organization. The safety concept is mainly and wholly related to human component. Therefore, it is very important a change in the behavior and attitude of worker to be instituted for a complete transformation in the safety concept to be followed in organization. Therefore, the safety culture should be given equal attention like other important elements such as quality and productivity. Safety Culture could be attained through effective implementation of SMILE approach and integrated lean safety model in industry. The authors suggest that top management (safety monitoring authority committee) must initiate practice of ILSM with support of 'SMILE' approach to reduce the occurrences of accidents in all aspects of the company by sustainable safety culture.

5.1 Implementation

Though, different approaches in implementation of BBS process could be observed from various studies, those were mainly based on case study approach. Faridha et al. [19] after reviewing various studies by Killimett [44], Wirth et al., [45], Geller [46], DePasquale and Geller [47] and Smith, have seen a common and consistent approach which has been included in the following four steps as suggested by Dejoy [20] and Krause et al. [48]. Step 1 Identify critical safety behavior that contributes to injuries and losses; Step 2 Observation over sometime period of identified behavior; Step 3 Reinforcement is applied to increase desired behavior and Step 4 Findings and Feedback on the performance is presented for continuous improvement. The White Paper published by SoBran-Bio Science suggests the following four steps for implementation. Those are; establish a need for change, create a plan of action, plan for implementation and put energy into implementation and sustainability. The robust

implementation of Lean oriented BBS (SMILE approach) and Integrated Lean Safety Model in an organization may definitely help harvest good benefits in terms of accidents free organization, performance excellence and huge financial benefits.

6. Implications

Implications can be classified into two. One is theoretically impacted and another one is practically experienced. The paucity of studies on lean six sigma oriented behavior based safety management under Indian environment could be fulfilled with this endeavor. In practical, this paper may feed some useful information on the importance of safety aspects in various types of industries which are very much prone to all types of risks. The present model may be an eye opener to those industries which are still in early stage of implementing safety procedure and for the industries still not yet been implemented. Those types of industries vulnerable to different types of risks, accidents and social ill-health may recoup their industries process with risks and accidents free with the help of this model and thus could achieve performance excellence.

6.1 Limitations and scope for future studies

This study is purely a theoretical one based on the findings of various research studies done by different authors in different environment and different types of industries. The present conceptual model developed based on new approach called 'SMILE'. This new model needs empirical validation to confirm its authenticity. This paper has been developed having taken in mind the Indian industrial environment. However, universal applications of this approach may give greater dividend to all types of industries that are prone to risks, accidents, since the nucleus of this study centered on 'Safety Culture' which is an universal entity.

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Chapter 4

The Lean Approach in Waste Management – A Case Study

Roberta Pinna and Giovanni Senes

Abstract

This work presents a manufacturing case study focused on reducing waste in a corrugated paperboard packaging company located in Italy. Corrugated paperboard is the primary material used in transporting, distributing, and storing many products, particularly food productions. The project started in September 2020 with the aim of identifying the causes of some waste along the production process and the conse-quent planning of actions to reduce them. This project was implemented following the logic of lean manufacturing through the use of the PDCA (Plan-Do-Check-Act) methodology. The quality control tools for continuous improvement of the manu-facturing process are used. The results achieved by the plant are significant in terms of economic and environmental sustainability. From an economic point of view,
the measures implemented have allowed the plant to achieve, in the period between September 2020 and March 2021, a decrease from 10% to 9% of the percentage of the waste with a cost reduction approximately of € 17,000 for each of the first three months of 2021. From an environmental point of view, waste reduction is one of the objectives underlying the sustainability strategy adopted by the company, which has long been committed to the responsible management of its production processes to reduce its environmental impact.

Keywords: lean production, PDCA, waste reduction, continuous improvement tools, sustainability

1. Introduction

Four years after the adoption of the 2030 Agenda by the 193 member countries of the United Nations, including Italy, there is a growing awareness worldwide of the need for an integrated approach to address complex economic, social, *and* environmental challenges in order to shift to a sustainable development model. The sustainability approach, a set of principles, tools, and practices oriented toward sustainable development, is progressively establishing as a new paradigm in the activities and processes management of all organizations [1]. In particular, among the factors that more than others have given a strong impetus in the direction of a profound change in the management models and tools adopted, the joint search for efficiency, effectiveness, and sustainability represents the most significant. In fact, organizations that

develop sustainable strategies may have a competitive advantage in terms of higher productivity, better products, and considerable cost savings [2]. In literature, there is a consensus that sustainable development involves improvements in different aspects, such as energy consumption, reduction of emissions to air, water, and soil, environmental impacts of the products, reduction of waste and better efficiency in the use of rawmaterial, health and worker safety [3–5], and the implementation of lean or Six Sigma approach in the business organizations can improve productivity and environmental sustainability.

In the manufacturing sector, as well as in the cardboard packaging production sector, the management of waste and the efficiency in the use of raw materials represent one of the most critical situations that companies have to manage. The corrugated cardboard production sector, with almost 7 billion m^2 of produced area, 150 thousand employees, and almost 500 plants in Europe, has become over the last decades the most requested material in the production of eco-friendly and robust packaging to contain, protect and transport. Thanks to its recyclability and biodegradability, it has fostered the birth of green packaging industry, whose main prerogative is the reduction of environmental impact. In Italy, the sector is worth about 4 billion euros and counts on a supply chain that employs 15 thousand people for an annual production that in 2018 exceeded 7 billion m^2 (an increase of 3.62% compared to 2017). According to the Italian Corrugated Cardboard Manufacturers Group (GIFCO), this is a sector that records continuous growth thanks also to the push of e-commerce. Italy is the second European producer of corrugated cardboard used in packaging after Germany, followed by France and Great Britain. In the last decade, corrugated paperboard companies are under pressure in order to improve productivity and quality while reducing costs. In addition, the need to promote the long-term sustainability of the natural resource, such as wood fiber, which is the single largest input to the manufacturing of paper products, become strategic the efficient use of renewable natural resources, thus reducing waste and improving the circularity of the manufacturing processes. Today, corrugated boxes are made from a high percentage of recycled paper, such as corrugated boxes, cartons, or newspapers. The re-use of such items means corrugated offers a number of environmental benefits. In other words, the adoption of a sustainable strategy allows more efficient use of resources, better cost results, and reduces adverse impacts on people and the environment. There are several methods that facilitate sustainable practices, one of these is lean production [6–10]. It is a methodology that aims at maximum efficiency through eliminating all those activities with no added value and that are a source of waste and costs.

The objective of the present study carried out in a corrugated cardboard industrial company, was to implement a lean production system based on the PDCA (Plan-Do-Check-Act) method to identify and reduce wastes in the production process of the firm. The orientation toward sustainability has become one of the cardinal principles of company policy, for this, it is important to become more efficient in the use of resources through a reduction of the waste in the production process; thus, enabling the increase of economic benefits. This has led the company to make a strong commitment to improve the environmental impact of all its plants and promote the sustainability of the company for the benefit of future generations. For this reason, since 2020 the management of the company has implemented a lean production approach, with the aim to reduce waste by 0.75% in 2021. To achieve the proposed objectives, a methodology based on the PDCA cycle was implemented.

2

2. Lean production and waste management in manufacturing

The term *Lean production* was coined by researchers in the International Motor Vehicle Program at the Massachusetts Institute of Technology to describe the way in which production operations were organized at the Toyota Motor Company in Japan during the 1980s. The goal of lean production is doing the same number of outputs by reducing the number of inputs, through the elimination of waste in order to give customers what they want and satisfying their expectations. In other words, this management approach allows for improving the operational efficiency, quality, and flexibility through the elimination of waste [7, 10]. The elimination of waste is the primary goal of any lean system. The term waste or *muda* is anything that consumes resources without creating value for the customer. Studies conducted in the manufacturing sector [11–13] have confirmed the existence of seven types of waste (**Table 1**) and how they negatively impact time, cost, and product quality. In particular, with specific reference to defects, some research [14, 15] has shown that these represent the main cause of damage or bad quality of products. In this case, bad quality or defects do not only result in customer dissatisfaction, but also in waste due to additional costs and time to repair the defect, resulting in a slowdown in production and increasing lead time. In the manufacturing sector, as well as in the cardboard packaging manufacturing sector, the presence of defects in raw materials are one of the most critical situations that companies in this sector must manage. Waiting time is another particularly important type of waste. For example, employees are not doing their work, as they are unproductively waiting for the elimination of the defect and restarting the machine.

Over the years the lean production model has been refined, taking on other designations as well, such as lean organization, lean manufacturing, lean service, lean office, lean enterprise, and even lean thinking, indicating its nature as an industrial "philosophy" that inspires essentially all methods and techniques. Numerous studies [16–20] have demonstrated the effectiveness of this approach in terms of cost reduction, improved quality, and flexibility through the elimination of all non-value-added activities and waste.

2.1 Continuous improvement and PDCA cycle

Implementation of lean production may be facilitated by the use of quality tools, among which the Plan-Do-Check-Act (PDCA) method can be applied to the implementation of waste reduction programs and sustainable management strategies. This methodology initially was developed in 1930 by Walter A. Shewhart. However, it was William Edward Deming who developed this method with the purpose of providing a tool for product quality control [2, 21]. It quickly became an industry, a useful tool that can support the development of process improvements at the organizational level [22]. This cycle is a sequence of actions necessary not only for pursuing the goal of continuous improvement but also for solving quality-related problems and implementing new solutions. Some authors [23] show that continuous improvement tools, such as PDCA, are often used in change management processes, in the implementation phases of new solutions, or when a new process has to be designed. Thanks to its versatility, this tool can be used successfully in any company and in any sector of activity, such as health and education sectors. The Deming cycle is divided into four phases:

Waste	Definition	Some causes
Overproduction	Producing more than what is needed or producing faster than what is needed.	• volume incentives (sales, pay, purchasing) • high-capacity equipment • line imbalance; poor scheduling/shiftingpoor production planning
Process wastes	Non-value-added man/machine processing.	Organizational inefficiencies Low machine performanceInadequate equipment or tools
Transport	Unnecessary material/tools movement.	Poor route planning • complex material flows • poor layout • disorganized workplace
Waiting	All waiting times that are "not strictly necessary" to the product manufacturing cycle.	Unsynchronized processes; • inflexible workforce • unscheduled machine downtime • long set-up • material shortage or delay
Inventory	Excessive process inventories excessive raw material inventories	Over-production • long lead times • local optimization • large minimum order quantities • high rework rate • lack of material requisition and issuance standards
Motion	Unnecessary movement and motions of worker.	poor layout and housekeeping • disorganized workplace and storage locations • unclear, non-standardized work instructions • unclear process and materials flow
Defects	Processing due to the production of defects processing due to rework or repair of defects materials used due to defect and rework	• unclear customer specifications • incapable processes • lack of process control • unskilled personnel • departmental rather than total quality • incapable suppliers

Table 1.
Seven types of waste.

- PLAN: The purpose of this phase is the analysis of the current situation in order to understand the nature of the problem and the development of actions for solving the problem.

- DO: In this phase, the action plan was implemented.

- CHECK: After the application of the action plan, the results of the actions are analyzed. In this phase, it is important to compare the new situation to the old, verifying if there were improvements.

4

- ACT: At this phase, the new actions will be standardized, and identify other opportunities for improvement.

Numerous studies conducted in different industrial contexts [24–27] show that different applications of PDCA methodology have been implemented with positive results in terms of reduction of waste and costs, as well as improving the quality of processes and products. Some authors [28] investigated how to reduce defects that minimize the rework rate through the PDCA methodology. In another work [29] the PDCA cycle was used for continuous quality improvement in a dairy laboratory. The results showed a significant reduction from the initial 368 to 85 samples of contaminated UHT milk. This reduction resulted in an increase in efficiency from 68.02% to 74.06% and ineffectiveness from 88.95% to 96.85%. So, the PDCA methodology allowed a reduction in the incidence of errors, making the processes more efficient. The effective implementation of PDCA requires the use of appropriate techniques and tools that can support each of the phases of the cycle, especially in the problem analysis and in the definition of the actions that must be implemented. The seven basic tools are flowcharts, control charts, histograms, Pareto analysis, Fishbone diagram, check sheet, and scatter diagram. Through the synergistic use of these tools and techniques, it is possible to identify the problems that are at the origin of the waste, select the main one, show the relationships between different variables, search for all potential causes, and then get to select the real ones. Numerous researches [30–35] have confirmed the effectiveness of quality tools in continuous improvement projects. In addition to the seven basic quality tools, some authors [2, 15, 36] also mention the following main ones: Six sigma, the 5S method, A3, failure mode analysis and effects (FMEA), quality function deployment (QFD), single-minute exchange of die (SMED).

3. The case study

This study was conducted in a large multinational company producers of fiber-based packaging and pulp. In Italy, this organization has four plants responsible for the production of corrugated boxes, offering customized packaging solutions for fruit and vegetables, poultry, and industrial segments. The research was carried out in an Italian plant responsible for the production of corrugated packaging solutions for agricultural, consumer goods, and industrial applications. This plant occupies an area of 30,000 m^2 and employs about 170 people, with an annual production capacity of 150 million m^2 of cardboard. The flow of materials goes through the following unit:

1. Raw materials warehouse where the paper reels, after quality control, are stored in two separate warehouses.

2. Corrugator unit: the first step is to create sheets of corrugated cardboard; this takes place in the corrugator department. With an area of about 2500 m^2, it employs a line equipped with machines that perform different functions during the process, such as preheating the paper, corrugating it, gluing the various layers of the final sheet of cardboard, dehumidifying it, cutting the continuous strips of cardboard, etc. In this department is also considered the pulping department in which there is a machine that macerates the waste paper to be then sold in order to make a minimum profit from the production waste.

3. Wip unit: it represents the intermediate unit between the corrugator and the cardboard box machine. In this unit with the sheets of cardboard are sorted in the seven lines of the box factory unit.

4. Box factory unit: it is an area of about 6500 m^2 with seven production lines, dedicated to the production of cardboard boxes.

3.1 Methodology

Since 2020 the management of the company has implemented a lean production approach, with the aim to reduce waste by 0.75% in 2021. To achieve the proposed objectives, a methodology based on the PDCA cycle was implemented. In the first phase, data collections were carried out weekly in order to quantify the forms of waste. At the same time, the flow diagrams of the various processes under analysis were created with the aim of highlighting those that have occurred in a higher amount [37]. Based on these data, through Pareto chart and Fishbone diagram, it was possible to identify the main causes of waste. In this way, opportunities for improvement were identified [15, 28]. In the second phase, based on the analysis carried out in the previous step, improvement opportunities were implemented. Subsequently, during the third phase, the results of each action implemented were evaluated. Finally, in the fourth phase, on the basis of the evaluation carried out previously, the new measures were standardized.

3.2 Results and discussions

3.2.1 Results of phase PLAN

In this phase, the current situation of the waste in the different production unit was identified through the manageable waste KPI (MW KPI). In order to identify all forms of waste, it was necessary to analyze the overall production process, from the paper reels arrived at the plant, until they were shipped to the final customer. To do this, a flowchart of each department was developed. At this stage, it was important to engage the employees in order to understand exactly where, when and under what conditions the problem occurred. In addition, direct observation of the tools and machinery used in the production process it was important in order to identify problems and defects. During the various meetings with improvement groups, it was decided to focus on the corrugator cardboard manufacturing line where the largest amount of waste was generated. A corrugator cardboard machine is a set of machines designed to bring together three, five, or seven sheets of paper to form single, double, or triple wall board in a continuous process. In order to identify the most frequent causes of waste, the Pareto diagram was used (**Figure 1**).

Pareto diagram highlighted that the most important causes of waste in the corrugator cardboard manufacturing line were the downtime, peel, and paper residual around the core of the roll. The analysis of MW KPI pointed out that the high number of defective cardboard boxes was due to the frequent downtime of the corrugator, which had suffered a productivity decrease in recent years. This important type of waste was caused by defects and blocks recurring in the corrugator machine. The results in **Figure 2** show that the main causes of downtime of the machine were paper breaking and blocks.

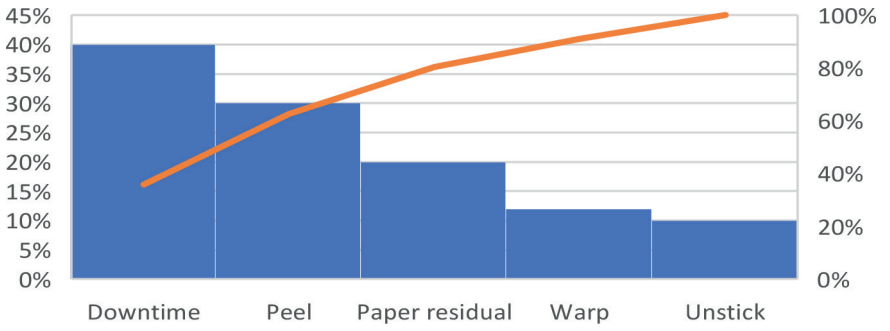

Figure 1.
Pareto diagram—causes of waste.

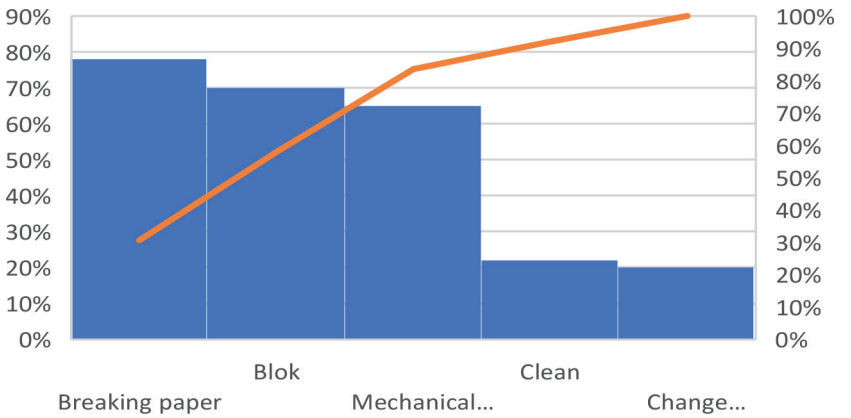

Figure 2.
Pareto diagram—causes of downtime.

To analyze the causes of this phenomenon, the Ishikawa diagram was used. This tool is a result of brainstorming of the working team of the corrugator department, consisting of employees of the Ondulator Department, manufacturing manager, and process improvement manager. As a result, of brainstorming, it emerged that breaking paper was mainly due to mistakes made by employees during the creation of the couplings. Indeed, the breaking paper was caused by wrong operations, wrongs in paper reel peels, paper reel wrong, uncontrolled paper reel, and damaged paper reel.

The same analysis has been made for the block machine. The team identified three main groups of causes: method, machine, and people (see **Figure 3**). In the "machine" group, the main cause was the incorrect adjustment of belts, causing their premature wear.

The next group of causes "Method" and "People" specified causes, such as lack of right scheduling interventions, failure reporting, incorrect frequency of lubrication activities, and wrong procedure

After identifying the causes which might have affected the problems, the improvement continuous team, through continuous interaction with the employees of the corrugator unit, identified potential solutions, based on the cost-effectiveness of the solution, its effectiveness, reliability, and technical complexity. With reference to each solution, the person responsible for the action itself, the deadline, and goals were then identified.

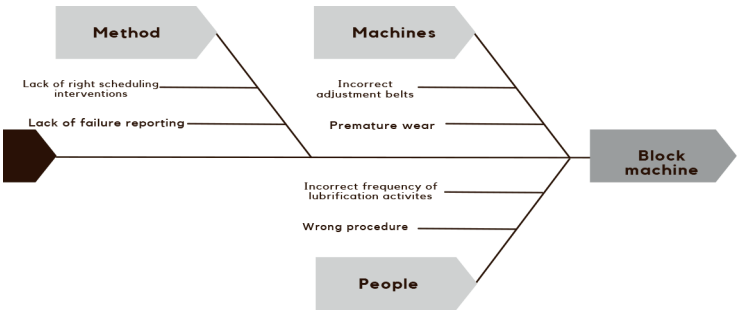

Figure 3.
Ishikawa diagram.

3.2.2 Results of phase DO

The aim of this phase is to implement the action plan in order to make changes and eliminate the causes of problems in the production process. Among the implemented improvements were the following:

- Root cause analysis, with the aim to obtain a large amount of data in order to understand what happened, how, and why. In this way, it has been possible to show which section of the machine deteriorated most frequently, and how often were these problems occurring.
- Implementation of new breakdown reporting.
- Improvement of maintenance activity end and its planning.
- Employees empowerment through sharing of key indicators related to the number of wrong couplings and downtime of the line.
- Training meetings.

3.2.3 Results of phase check

At this phase, the results of the implementation of actions for each type of problem are analyzed. It is necessary to ask whether the problems identified in phase 1 have disappeared, or at least diminished. This activity, with a view to continuous improvement, was very important because it is possible to highlight any deviations from the planned objective, and it is possible to identify other opportunities for improvement.

Regarding the breaking paper, **Figure 4** shows a decrease in downtime after the implementation of the actions planned.

3.2.4 Results of phase act

Based on the findings of the check analysis and verified the sustainability and effectiveness of the implemented actions, it was necessary to proceed with standardization of improvement. Standardization is a key element in the lean approach, as

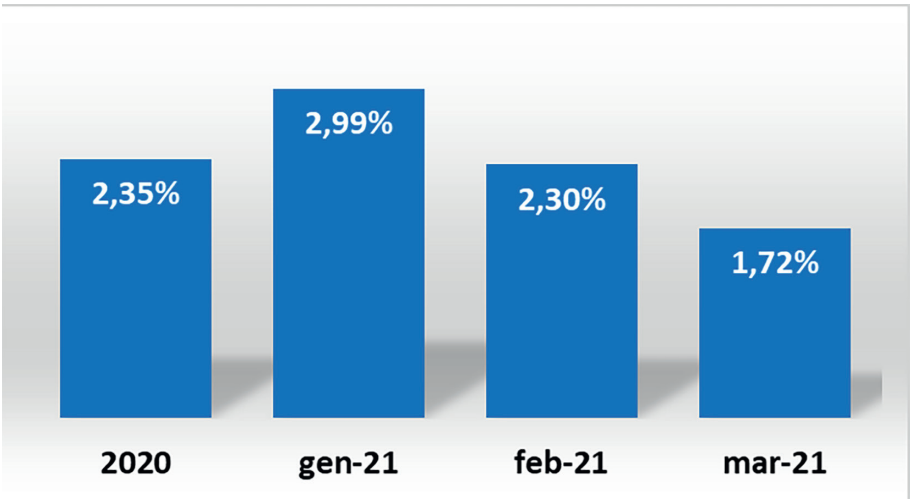

Figure 4.
Downtime for breaking paper after the implementation of the action plan.

standards define best practices for process implementation. What was tried within a single team, what was tried in a single process, the change that was made in a single machine, all of this must be extended to become the new standard to be followed and becomes the basis for subsequent further improvements. Since the purpose of the standard is to enable activities to be carried out without error and waste, it must contain a precise description of the sequence of activities and how these activities should be carried out correctly in order not to generate waste.

4. Conclusion

Lean management is nowadays one of the most dominating management approach, both in industrial and service environments. One of the reasons for such success is its simplicity. The whole concept is based on a common-sense idea of so-called "waste." Removing it is the very essence of Lean Management. The measures implemented in the Italian plant in the period between September 2020 and March 2021 have allowed sto significantly reduce waste and costs. The waste associated with breaking paper and blocks were reduced from 10% to 9%, with a cost reduction of 17.000 euros. This is an important achievement considering that the company's competitive position depends on many factors, including price, cost, product, and service quality. In addition, the implementation of the lean methodology has enabled the company to make the overall corrugated cardboard production process more efficient through better organization of the work. This means that in order to improve the process and reduce waste, it is necessary to encourage employees to analyze the problems and identify the opportunities for improvement. The plant's achievements are also particularly important in terms of sustainability. In fact, waste reduction is one of the goals underlying the sustainability strategy adopted by the company, which has long been committed to the responsible management of its production processes in order to reduce their environmental impact. Environmental protection and responsible production practices are two fundamental aspects of the company's way of operating.

For this reason, the efficient use of paper in the corrugated board production process and the consequent reduction of wastes represent important goals for the company and which are, therefore, continuously monitored.

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Chapter 5

Internal Audit

Aijaz Panhwar, Ateeq Rehman Memon, Azhar Naeem, Aftab Kandhro, Syed Zainulibad, Sofia Qaisar and Awais Panhwar

Abstract

The internal audit is an efficient, free, and documented procedure for gathering audit evidence and objectively evaluating it to ascertain the extent to which the audit criteria are fulfilled. The internal audit is very effective tool not only to judge the level meeting the needed requirements but also to improve the Quality Management System of the organization and great impact for the improvement of the performance of testing laboratories, inspection, certification agencies, and can play vital role for the strengthening of any organization. Internal Audit is a major way out to read through to gain guarantee that the organization is actually doing what it says is doing. During the internal audits in accordance with any of the required check, an auditor makes sure that the actions taken to meet the quality objectives of the organization are appropriate, and management system is in compliance with the relevant standard/check. Nowadays, quality is important in business and industrial world as it is actually the value addition. The organization must have a quality system in place to guarantee that the product or service being offered is of a high enough calibers to satisfy the needs of the clients.

Keywords: audit, certification, effectiveness, horizontal audit, inspection, internal audit, improvement, testing laboratories, vertical audit

1. Introduction

Internal audit is a very important step in quality management as well as an aspect for effective improvement tool. ISO 19011 [1] is a standard that details the auditing process for management systems. This is the manual by which the auditors are instructed and expected to be in agreement, but it also serves as a useful manual for conducting internal audits of management systems. According to this standard, an internal audit is one that is carried out by or on behalf of the business to evaluate its management system. In essence, it means that you have a choice between hiring someone from outside and using your own staff to conduct an internal audit. Internal audit has a great impact for improvement of the performance of testing laboratories, inspection, certification agencies, and metrology organization Hamza [2]. Different ISO/IEC standards cover almost all aspects of inspection, certification, and laboratory management. A laboratory certification boosts an organization's performance through improved laboratory procedure control, which in turn raises its potential

owing to higher customer satisfaction. Internal auditing is done to evaluate both the organization's overall performance and the effectiveness of its quality management system. The internal audits show adherence to the planned arrangements, such as the implementation and upkeep of the QMS and associated processes. A management system auditor's job is to obtain unbiased proof of performance and conformance in order to assess how well the management system and its processes are operating. Internal audits serve as a method to guarantee that the quality management system is functioning properly by assessing process compliance, evaluating performance, and identifying processes that need improvement. System is still fully operational and ready for external audits. Internal audits, often known as "first-party audits," are carried out by the company in order to assess compliance with a set of requirements that may be derived from standards. Seven key categories should be included on the audit checklist, such as assessing the company's compliance with organizational context, leadership, planning, support, operation, performance evaluation, and improvement. Every 3 years, certification audits are usually carried out. Following certification, the registrar will conduct surveillance audits at regular intervals to make sure the auditee is still adhering to the QMS and ISO requirements. In an internal audit conducted in accordance with ISO 9001, an appointed auditor evaluates the organization's procedures and quality management system in accordance with the criteria set out by the most recent version of the standard. The insufficient use of quality control and control systems inside the organizations are the major reasons that lead to an inaccurate/misleading result.

1.1 Internal audit

To review the compliance of the system or to analyze/find the gaps in the system, to overcome the weaknesses before external audit, or to compare the achievements of the defined objectives.

1.2 Purpose of internal audit

The purpose of internal audit is to confirm that the practical implementation complies with the accrediting standard, the management system requirements, and other requirements such as local, state, federal, and international laws, etc. The primary goal of the audit is to generate a judgment about the data in the report as a whole, not to find every possible inconsistency. This translates to the fact that, despite the fact that auditors keep an eye out for any indications of potential material fraud, it is impossible to guarantee that frauds will be found [3].

1.3 Objectives of internal audit

The objective of an auditor during an audit is to verify compliance, controlling all organizational activities strictly is one of an internal audit's key objectives. Management is responsible for ensuring the accuracy of the company's financial records and the effectiveness of its operations. To ascertain both, conduct an internal audit. Controlling all organizational activities strictly is one of an internal audit's key objectives. Management is responsible for ensuring the accuracy of the company's financial records and the effectiveness of its operations. An internal audit helps to determine both. The internal audit function works from within and serves as a guardian of the integrity and accountability of the organization, examining financial

reporting, protecting against fraud, error and risk, and providing objective assurance that the company is complying with the regulations and standards it should. The objective of an internal audit is to advance and improve an organization's operational processes. An organization's current Quality Management System (QMS) is evaluated by a quality management system audit to determine whether it complies with organization policies, contractual obligations, and legal requirements.

1.4 External audit

The most frequent third-party audit is the certification audit carried out by the certifying organizations. The external audit is an audit carried out by a second party or third party on his own behalf or on behalf of another company. The difference between internal and external audit can also be understood in the following way: the findings of an internal audit will only be used within your organization, whereas those of an external audit, or third-party audit, can be used publicly as well. For instance, if an organization chooses to undergo a certification audit and receives a certificate, this certificate is a public document, meaning it will frequently be shown to others.

1.5 Difference between internal audit and external audit

Internal audit evaluates risks and issues connected to business procedures, whereas external audit focuses on the all activities' records and provides an opinion on the organization's improvement statements. While external auditors typically do a single annual audit, internal auditors conduct audits throughout the year.

1.6 The importance of an audit

The audit is an important as it provides credibility to a set of statements and gives the stakeholders confidence that the system reports are true and fair. It can also help to improve an organization's internal controls and systems. Internal Audit would pay close attention to any organizational changes that might have an influence on risk management. Organizational ethics, managerial reorganizations, financial requirements, resource limitations, technology/internet/E-business, consolidations/alliances, and legislative/regulatory imperatives are just a few examples of these adjustments that may occur. Internal audits are necessary if you want assurance that your business is accomplishing its primary objectives. Internal audits will help you get there if you want to save your company time and money and keep everything running smoothly. Internal audits are essential if you want to defend your business against fraud and stop fraudulent behavior.

1.7 Internal audit focus

A company's risk appetite, risk detection and mitigation techniques, and risk communication and monitoring protocols are all examined through internal audit. One of the primary functions is to guarantee that risks have been adequately defined and evaluated. Internal audit is tasked with independently attesting to the effectiveness of a company's risk management, governance, and internal control systems. The objective of an internal audit is to advance and improve an organization's operational processes. Evaluation of the effectiveness of the organization's quality management

system and overall performance are the objectives of the internal ISO 9001 audit. An organization's present quality management system (QMS) is evaluated to see if it conforms to corporate standards, contractual responsibilities, and legal requirements.

1.8 Types of internal audit

- Financial/controls audits
- Compliance audits
- Operational audits
- Construction audits
- Integrated audits
- Information systems audits
- Special investigations
- Follow-up audits and validation testing

1.9 Scope of internal audit

The scope of internal audit within an organization is wide and can include many issues such as operational efficiency, Quality Management System compliance, financial reporting reliability, fraud prevention and investigation, asset protection, and regulatory compliance.

1.10 Stages of internal audit

Internal audit performs a warranty audit in a five-step process that includes

- Selection
- Plan
- Perform fieldwork
- Report results
- Follow-up of corrective action plans

1.11 Benefits of internal audit

Audits are used to obtain factual information for management system, unbiased management information, to improve communication and motivation. These audits are further used to identify the areas of risk, opportunities, and need of trainings. This supports to assess performance and equipment status. Internal audits offer management and the board of directors a further benefit by allowing process weaknesses to be found and fixed before external audits. Internal audits have the responsibility

of independently confirming the efficiency of an organization's risk management, governance, and internal control systems.

1.12 Risk assessment

There is very important role of internal audit in development or progress of any organization. Risk is the likelihood that a circumstance or course of action will have a negative impact on the entity or activity that is the subject of the audit. The organization can use a risk assessment to prioritize audit projects according to the level of potential risk, determine the nature, timing, and scope of internal audit procedures in direct relation to the level of risk, and develop a plan for carrying out internal audit projects in a risk-based manner. Prior audit findings, the entity's strategic plan, and its financial statements are reviewed as part of the risk assessment process. Department heads and process owners are also interviewed with an emphasis on "what may go wrong" scenarios.

1.13 Role of internal audit

Internal audits will outline the steps you need to take and how to conduct them if you want to lower risks to your business' operations, finances, cyber security, and other areas of concern. You need routine internal audits if you want to be sure your organization is abiding by the rules, regulations, and standards that are relevant to it and if you also want to save money and time when external auditors check your compliance. After defining management's responsibility for internal controls and how internal audit might contribute to management fulfilling this obligation, let us examine some specific benefits that an internal audit function might provide to an organization and its management. Internal audit provides "reports" to management or the board directly rather than through an outside agency or adversarial body; it also improves the "control environment" of the organization. It increases responsibility within the organization by spotting redundancy in operational and control procedures and making suggestions to boost the efficacy and efficiency of procedures. It serves as an Early Warning System, allowing flaws to be discovered and corrected promptly. As a result, management would have a support system, risk manager, controls specialist, efficiency expert, partner for problem-solving, and safety net. There are so many advantages for businesses that we could write a book about effective internal audits. It suffices to remark that, aside from the expense of hiring an auditor, these highly skilled, accredited specialists are not cheap; there are not really any drawbacks. Additionally, automating allows you to cut expenditures.

2. Methodology

2.1 Audit techniques

2.1.1 Horizontal audit

It is a normal audit from start to end, e.g., clause-by-clause audit; it is also called systematic audit. Mostly audit conducted is horizontal. It also can be said the detailed examination of a specific element in the quality system. In this system auditor can assess that does the quality system meet the requirements in the required standards or as per other requirement documents. It is also compliance between written procedures and praxis [4].

2.1.2 Vertical audit

A vertical audit is a check of implementation of the quality system. Audit in depth considered in any one clause. In this type an auditor starts with a report (inspection, testing, certification, and calibration) and traces all registration related to this item all the way back to the contract with the customer. It means top to bottom approach. Start with a contract and follow all registration related to the inspection all the way to the inspection report, bottom to top. The vertical audit gives a good overview of the implementation of the management system. Evaluation of the work flow and many requirement elements in the standards/required document at the same time. Vertical audit often reveals systematic weaknesses [4].

2.2 Methods during audit

a. Horizontal approach

b. Vertical approach

c. Review of documentation and records

d. Interview and discussions

e. Observation of inspections

2.3 Important steps in planning of the internal audit

Planning the Audit Schedule; Planning the Process Audit; Conducting the Audit; Reporting on the Audit; and Follow-up on Issues or Improvements Found. Auditing is a science with increasing importance in the last years [5]. Internal auditing is performed by a professional with specific scientific and professional background for technical and non-technical organizations, who is an employee of the audited company [6]. A managerial control activity is important for the evaluation of performance, nonconformities elimination, and ISO standards compliance is the important feature of the audit [7, 8]. As per data most organizations are not interested to be beneficiary from the internal audit process, to improve the system [9]. Alic and Rusjan [7]; Panhwar et al. [4] have discussed that internal audits are an improvement tool.

2.4 Effects of internal audit

The effects of internal audit help management to keep proper control of the assets, activities, and responsibilities. Internal audit gives confidence to management on the working of its system. There is biggest impact of internal audit on testing, calibration, and medical laboratories. As we know that testing laboratories are very important as per nature of work, these are directly relevant with our life. The huge investment on these laboratories is another aspect. To maintain the temperature is essential requirement, and ambient temperature is basic requirement (23 + −2°C) because temperature for the concerned test in laboratories is very important. Almost comfort environment is considered 25 + −5°C, if temperature is not mentioned in related method. In textile testing laboratories to maintain relative humidity is important; in

other words, to maintain the temperature, relative humidity, to qualify in Proficiency Testing (PT), are effects of internal audit. Another benefit of proficiency testing is to validation methods, using in the laboratory.

2.5 Internal audit as an improvement

Additionally, internal audit reviews to lower product flaws and enhance quality controls are also included. Customers will be less likely to complain, productivity will increase, costs will drop, and profitability will rise. Internal auditors help businesses discover important risk issues. This enables the business to recognize present shortcomings and anticipate potential future issues. It also enables a business to pinpoint ineffective procedures and controls and presents a chance for improvement, aids in asset protection and lowers the risk of fraud, increases operational efficiency, and boosts financial stability and integrity, ensuring adherence to legislative requirements and the law. Compliance hazards are a simply type of risk that internal audit analyzes to assess how well the company's risk management procedures are working. Compliance needs to be audited as a management function, usually via internal audit. Internal audit examines recent occurrences, whereas compliance must be involved prior to the creation of a new product, service, or agreement. Internal audit is in charge of the company's overall risk management, whereas compliance is in charge of the three major risks of reputational, regulatory, and legal nature.

3. Strengths of internal auditor

Characteristics leading internal auditors possess

- Great communication skills
- Unyielding curiosity
- Technological savvy
- Ability to work independently and on a team
- Drive to be life-long learners
- Integrity and courage

3.1 Levels of quality

The levels of quality that the authors talk about are:

- Acceptable quality
- Appropriate quality
- Aspirational quality

3.2 Skills and characteristics of an auditor

It is wish of majority of the people to be an auditor but not everyone can be a good auditor. Auditor should hold good communication and interpersonal skills, intelligent, good listener, good analytical skills with ability to assess the data and determine how it is related to the audit criteria, command over standards, regulations, audit techniques, as well as management skills. Auditor should check the compliance as per objective evidence, audit should be documented if found any irregularity. Audit in depth in any one clause, this audit type is necessary to find out the system errors. Auditor should be open-minded and mature, to communicate well, good listener, possess sound judgment with analytical skills; to understand the knowledge of conducting assessment, be updated regarding the latest relevant polices, have the skill to complete the tasks within time limits. Must be able to distinguish crucial and essential points, be able to perceive situation and can understand the role of individuals within organizations.

3.3 Principals for a good auditor

i. Honesty

ii. Integrity

iii. Impartiality

iv. Good listener

v. No talkative

vi. No leading questions

vii. Positive

viii. Open-minded

ix. Punctual

3.4 Responsibility of lead auditor

The Lead auditor has to lead the team members, be able to support and guide the technical experts, can conduct introductory/opening as well as final/closing meeting. Have command on assessment process, planning, and preparing the audit and reports. It is prime responsibility of the lead auditor to assess the management system against required standards, have competence to review technical activities being evaluated by the team. The decision regarding the grading of the non-conformities, decision on time frame for corrective actions, and finally recommendations for grant of Certification lies with the lead auditor. The Lead auditor be able to make learn to his team about to conduct audit within time and manners, to collect the required/necessary information by effective ways, e.g., interview, listening, observation, review of the documents and records. Overall Lead Auditor should be firm in his opinion despite pressure to change the objective evidences and loyal to the policies/rules/

regulations. There is another prime responsibly of the auditor is to provide comfort environment to his team members as well as auditee during the audit.

3.5 Auditor should avoid

The internal auditors should not take audit as a hunting of non-conformities, no act the role as police, and no criticize on system or individuals. No sharing of experience and examples of other bodies. The auditor should not show himself as a champion of the expertise or Jack of all trades. Auditor must not pretend that he has understood something that he does not. Auditor should remain neutral, positive, and avoid the dropping out at eleventh hour. During the audit the role of an auditor should be cooperative, never place the examples of auditor's own organization, job, or environment.

3.6 Code of conduct for auditor

3.6.1 Impartiality

Evaluate impartiality toward the conformity/inspection/certification, to be assessed, and inform the organization on which behalf audit is being conducted.

3.6.2 Confidentiality

Keep information about assessed organization strictly confidential.

3.6.3 Loyalty

Auditor must remain loyal to the organization utilizing the services and must avoid about any consultancy to the auditee.

3.6.4 Positive

Auditor must keep positive and professional attitude during the audit.

3.7 Questions in internal audit

The internal auditor should use/ask easy questions but must have control over the question (limit/number of questions). The auditor must avoid questions based on Yes or No, Leading questions on assumption basis, multiple questions, means question upon question without complete listening of first reply, provocative question, and any question without any meaning or meaningless questions. An auditor can ask questions with the help of seven best words such as what, why, When, When, How, Where, and Who, and the last/seventh word is SHOW ME. An auditor should start with general questions, continue into details if necessary. Distinguish between essential and unessential elements. Control the interview so that can collect the needed information. Planned aspects be assessed and auditor be polite and flexible for new solutions, and never think that (auditor) knows the best.

The following questions may be raised during the audit:

- What do you do with...?
- Why do you...?

- How often do you,,,?
- How did you make...?
- Where do you keep...?
- Where do you find information about...?
- Who has the responsibility for...?
- Can you tell me about...?
- When do you see...?

3.8 Questioning techniques: types of questions

The internal Auditor may use some or all of the following questioning techniques.

Hypothetical
Let us suppose that...
I do not understand
Can you explain it again please...
Systematic
OK, you have done this, this and this, what is next ...?
Silent
Many people find silence uncomfortable, and will offer information.
Obvious
Ask the obvious question and hear a pin drop!
Unasked
Analyze the evidence out load, the auditee will interrupt with more information.
Inverse
Good for "resentful" auditee; e.g. do you have all the cooperation you need to do your job? Breaks the barriers.
Composition
OK. So the instruction says a, but you do b.....

3.9 Internal audit procedure

The inspection/certification/conformity assessment bodies shall have a procedure to ensure that the organizations have structure, time table, responsibilities, auditor's qualification, training of personal and technical requirements for utilization of an internal auditor for the audit. The auditor must be aware of independence of the auditor, reporting requirements and information of the outcome and follow-up activities.

3.10 Training and approval of the auditors

The selection of internal auditors is also an important aspect of the audit. Before selection and approval of the auditors, it is necessary to evaluate the auditor in terms of education, external and internal trainings especially during recent years. The knowledge and command of the standard include relevant audit techniques. The

auditors can be selected following the rule "Right person, Right Job, on Right time" from the organization, sister organization, part-time auditor, combination of above; but an auditor should be dedicated, committed, and having command over related standard.

3.11 Internal audit plan

The proper plan of internal audit is mandatory and according to the requirement of the standard all areas must be included. The plan of internal audit be given as planned activity well in time.

3.12 Internal audit's structure

Following are the parts of the structure of internal audit. Such as Agenda of the internal audit, opening meeting, check lists, closing meeting, report writing (activity audited, findings, nonconformance, and recommendations for improvements), and follow-up audits.

3.13 Systematic approach plan

PDCA: Plan, Do, Check, Act.

3.14 Why audit reports

To find facts during audit of the organization, an informative report should and must be written clear and there must be no ambiguity in findings of internal audit. The raw data sheet is an essential document to report the facts found during the audit and be attached as evidence. Every sentence of the internal audit report should be no ambiguity and use 3 Cs: Clean, Concise, Complete.

3.15 ISO-19011 audit principles

ISO 19011 [1] is defined as a standard that provides guidelines for auditing management systems. This standard provides guidance on managing the audit program, audit principles, and the evaluation of the person responsible for managing the audit program. There are seven principles that need to be incorporated into an audit program to make auditing an effective tool for your organization and to make the collected data accurate and useful. These principles help you draw relevant, consistent, and useful audit conclusions. All audit members are expected to follow these principles during the audit process.

Integrity: The integrity of inner auditors establishes belief and affords the premise for reliability at the judgment. Auditors want to be ethical, honest, and responsible. If you aren't able to audit a procedure, because of a loss of understanding, then you definitely want to stop. Audits want to be completed impartially to cause them to truthful and unbiased. Remember, you are auditing to affirm conformity you are not digging for errors.

Fair presentation: Audit findings, audit conclusions, and audit reviews must replicate truthfully, objective, timely, clear, entire, and as it should be the audit sports performed. The audit wishes to file the truth, as it should be and objectively. Any audit statements want to be primarily based totally on verifiable data and now no longer

at the opinion of the auditor. Audit reporting wishes to be timely, clear, and entire in order that the data may be acted upon if necessary. If there's a trouble in a procedure, this wishes to be said virtually all through the audit procedure, now no longer not noted all through the audit and simplest pronounced within side the audit file.

Professional approach: Auditors have to exercise due care according with the significance of the mission they carry out and feature the self-assurance for the audit consumer and different involved parties. Making affordable judgments primarily based totally at the significance of the mission is essential. If you are auditing a crucial function, searching deeper and taking extra samples is a great manner of making sure which you test thoroughly.

Confidentiality: Internal auditors appreciate the fee and possession of statistics they obtain and do now no longer divulge statistics without suitable authority except there's a criminal or expert responsibility to do so.

Impartial/Independence: Auditors must be unbiased of the hobby being audited anywhere practicable and must in all instances act in a way this is loose from bias and war of interest.

Evidence primarily based totally approach: Internal auditors observe knowledge, skills, and revel in had to gather the proof and have to have basic evidenced primarily based totally approach. Similar to truthful presentation, the auditor wishes to have verifiable data to lower back up their audit findings and conclusions. These data basically come from facts of the procedure; however, they also can be statements of truth through informed employees or observations of sports. If there's no proof of non-conformity, then non-conformity must now no longer be raised.

Risk primarily based totally approach: Considering dangers and possibilities within side the audit is critical to make sure which you recognition on extensive matters. Remember the two sorts of dangers that want to be addressed the dangers that the audit targets will now no longer be met, and the threat that the audit will adversely have an effect on the procedure being audited.

Culturally sensitive: Respect for the lifestyle of the auditee is vital for an auditor to efficaciously discover the statistics they want to decide if the deliberate preparations for the procedure are met.

Collaborative: Even though audits are completed independently, the general audit is frequently completed as a team, and the auditor will want to collaborate with that team, and the auditee's employees, to get the activity completed.

3.16 Types of non-conformances

It is responsibility of the assessor's in consultation with the technical assessors (if relevant). International guideline is available [10] on grading of non-conformances exist. The non-conformity may write after completely investigation/digging of clause.

Observation: If there is a minor gap in compliance as per requirement and there is a single instance that does not lead to destruction is given as "Observation" in result of audit.

Very Serious (Major): Systematic and/or extensive problem that may or definitely threaten the results and hence threaten the credibility of Conformity Assessment/Certification is considered as "very Serious" Non-Conformance.

Very serious non-conformance must be corrected as soon as possible without wastage of time.

Essential (Minor): An essential non-acceptable single incident or a continuous problem (systematic) that must be addressed and corrected in a timely manner but does not have a destruction threat to the system.

Non-Conformities: Despite above grading of non-conformities, following are also considered non-conformity, if no follow-up of Management Review Committee (MRC) and violation of own procedures.

Note: If assessors are assessing as a team, then many single event non-conformities raised by different assessors/auditors can be combined to a systematic non-conformity. Avoid those non-conformances regarding direct to analyst of do not write name of any analyst in nonconformity. Nonconformity may write after completely investigation/digging of the clause.

3.17 Difference between evaluation, audit, and assessment

There is no much difference in the evaluation, audit, and assessment activities, but there is a difference between names of performing audit and auditee.

3.17.1 Evaluation

It is process to evaluation (audit) of an Accreditation body of the member country, the evaluators are nominated/Selected by International Laboratory Accreditation Council (ILAC) from different member countries. Evaluators can evaluate only accreditation bodies. Almost there is one accreditation body in one country, in some cases more than bodies are working simultaneously.

3.17.2 Audit

It is same process, but name is different called auditor. Auditor can audit only certification and inspection bodies.

3.17.3 Assessment

This term is used for assessment (audit) of conformity assessment bodies (CAB) such as testing and calibration laboratories.

4. Discussion and conclusion

Audit/Assessment is important in monitoring the effectiveness of the implementation of the standard or some specific requirements in the organization/laboratory/inspection/certification body/quality management system. Both external and internal audits yield useful information; however, internal audit is the major and detailed activity having a complete overview of all activities with ample time. Audits are used to identify problems in the organization, in order to improve processes and procedures. An outcome of audit/assessment is lead toward the improvement by finding root causes of problems and taking corrective actions. Internal audits be conducted

on regular basis as per plan that will definitely provide information for continual improvement. Findings of the internal audits may become opportunities for improvement if taken positively. Internal audit is a mandatory activity for all ISO standards. Internal audit is a well-thought-out, world-class format for planning and performing process audits. It can help to ensure that the process implemented is consistent and effective for the required outcome.

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Chapter 6

Problems of Improving the Quality Management System of a University in the Era of Big Data (Experience of Professional Training of Railway Engineers)

Zhanna Maslova and Ilona Khitarova

Abstract

The application of the analytical approach to quality management in higher education bodies is particularly relevant. The problems of formation, implementation, and practical use of quality management system in higher education have not yet been sufficiently reflected in the studies of foreign and domestic specialists, although there are a large number of publications on the formation and implementation of quality management systems in industrial production conditions. The publication intends to consider the main triad of education quality components: conditions, process, and result of educational activity. The quality of education is presented as a system functionally related to all parameters and a measurable characteristic of the function-ing of an educational organization. The quality of such functioning is represented as a degree of implementation of the main goal, which consists of achieving a given (normative) level of students' preparedness and providing the basis for sustainable development. As an illustration to the theoretical provisions, the experience of imple-mentation and certification of quality management system in the leading technical university of Russia is considered, recommendations on the development of strategic and operational management documents in the implementation and practical use of quality management system in the university are given.

Keywords: quality management system, higher education, strategic management, operational management, quality objectives, model, education market, Big data, statistics, data sets

1. Introduction

Global processes taking place in the society are inevitably reflected in the state of education. Economic, social, and environmental challenges in modern society, the

formation of innovative orientation of the economy, integration into the world set new priorities and tasks for the system of higher education, among which the most urgent is the task of ensuring the quality of training specialists. At present, education is in the first place among the factors of human development. The importance of knowledge in the economic development of the countries of the world is increasing rapidly, ahead of the importance of the means of production and natural resources. When calculating the rating of countries according to the Human Capital Index, an important factor is investment in people through quality health care, education, skills, and jobs. The health and education components included in the Index are used in combination, which, judging by the data of empirical studies conducted at the microeconomic level, reflects their contribution to the level of productivity and accumulation of public goods. The quality of education plays a key role. The report states that "the governments of many states allocate a significant share of their budgets to education and health, but often public services fail to form human capital because of their poor quality, as the bureaucratic apparatus proves unable or not motivated to convert sound policies into effective programs" [1].

Thus, to a large extent, the economic success of the state is determined by its educational system and the education of its citizens. This circumstance has led to an awareness in developed countries of the role of education in society, the need for its priority development, and the development of new methods and tools for quality management.

The publication deals with quality management in higher education in the era of Big Data. Big Data is not just a large amount of information. We are talking about unstructured data. It is a huge and chaotic flow of information from different sources, which raises the problem of processing and ordering information. Thanks to data analysis, it is possible to predict the behavior of large groups of people. Big data allows not only to know in advance what representatives of a particular audience will choose, but also to predict how this choice will change over time. Big Data is, on the one hand, a set of technologies, tools, methods, and approaches designed to solve the problem of processing large volumes of data, and on the other hand, it is a volume of data that cannot be processed conventionally, that is, by traditional methods. The strongest factor in expanding the range of applications of Big Data is the Internet.

The usual field of application of Big Data is marketing. By analyzing the data, companies study what principles guide the consumer's choice of product or service. As a result, marketers model the behavior of the potential consumer and launch an appropriate advertising campaign. For education, an important feature of Big Data is the ability to analyze different parameters and modeling.

"Big data has been a popular research problem across different academic disciplines. Although this problem has been treated mainly for advancing and innovating technological development [2], organizations and business communities are continuously exploring different aspects, perspectives and contextual specifics to find or explore benefits and value adding for improving practices" [3]. According to statistics, the introduction and use of analytics and work with big data are not just effective, its use can decide the outcome of competition in the market. In September 2014, Accenture published the results of a major study called "Big Success from Big Data" [4]. Correspondents surveyed 1,000 company directors from seven different industries. Ninety-two percent of respondents expressed satisfaction with the end results of Big Data implementation and its impact on their business, 89% called activity analytics a very important component in setting up business processes. A GE (General Electric) study titled "Industrial Internet Insights Report" [5] was conducted by the company in 2015. Ninety percent of respondents from various industries assured: Big Data is in the

top 3 leading areas for their businesses. Eighty-four percent of respondents believe the use of analytics has the potential to displace competing businesses from the marketplace within 1–3 years. According to Proficient Market Insights, "the global Industrial Internet of Things (IIoT) market size is projected to reach US$ 78400 million by 2028, from US$ 57040 million in 2021, at a CAGR of 4.2% during 2022-2028" [6].

Sources of Big Data in education are, first of all, message streams from social communities, statistics sites. Application of Big Data in higher education is possible primarily in the analysis of documents and modeling of educational processes. Big Data technologies imply working with huge arrays of information. There is no universal method of Big Data processing, but there is a possibility of using various methods, so it is important to use specific tools for specific strategic decisions.

According to the provisions of ISO 9000 standards, the quality management system (QMS) must be thoroughly documented. Documentation makes the system "visible" not only to its developers, but also to users and reviewers. It is only possible to prove that the QMS complies with the established requirements when the system is presented in a documented form. Otherwise, it can be argued that there is no quality system. ISO 9001 establishes the criteria for a quality management system and is the only standard in its series that can be certified to (although it is not a mandatory requirement). It can be used by any organization, regardless of its size and field of activity. Accordingly, this research is based on the analysis of documentation and the method of modeling. In the quality management system the main features of the engineering component of the methodology of organizational design are well traced, in particular, its concepts of the system environment, management, and organizational changes. At industrial enterprises, the introduction and implementation of the process approach are seen as a way to improve the effectiveness of the quality management system.

The problem to be solved in improving the quality management system in the educational organization is the partial elaboration of documents. Part of the QMS documents is stipulated in the standard, another part is implied. Therefore, the structure of the quality management system has a "constant" component defined by the standard and a "variable" component, which depends on the specific organization.

2. QMS in the system of higher education in Russia

In modern education system, quality is understood as compliance with the standards. The requirements and recommendations of international ISO 9000 Series of Quality Standards are widely used as a basis for the formation and implementation of quality management systems (QMS). The international standards of ISO 9000 series include requirements and recommendations that provide methods for monitoring, measuring, analyzing, and improving all QMS processes. The implementation and subsequent continuous improvement of the QMS require not only understanding and vision of its development prospects, but also the use of objective methods of measurement (including statistical) to assess the effectiveness and efficiency of both the QMS of the university as a whole and its individual processes. The potential stakeholders in the ISO standards are consumers, society, suppliers, owners (shareholders), and personnel of the organization, which corresponds to the quality management principles formulated in the ISO 9000 Standards.

Problems of formation, implementation, certification, and practical use of QMS, its subsystems and mechanisms in universities, have not yet found a sufficiently

complete reflection in the studies of foreign and domestic experts. Most publications are devoted to the problems of quality in the QMS of industrial production organizations.

Ph. Crosby, one of the well-known experts in the field of quality, studying the issues of value assessment of quality, expressed the famous aphorism: "Quality is still free" [7]. It follows that the manufacturer does not have to pay for quality, but for its presence, which must be the subject of constant monitoring and analysis. E. Deming wrote: "The consumer is the most important link in the production line. Quality must be aimed at satisfying his needs, present and future" [8]. Eventually transformed into the process of satisfying the needs of existing and potential customers, at the current stage of business development quality is naturally formalized in the principles of Total Quality Management – TQM and acts in its new understanding as a measure of balancing the expectations of all stakeholders. There is a difficulty in direct application of TQM principles in the formation of QMS of higher education institution.

Currently, educational organizations use the following basic principles of the well-known system of total quality management (TQM) [9]:

- active quality management by the administration of the educational organization;
- organization of the activities based on the requests of employers and reactions of society;
- selection of strategies and policies in the field of quality, aimed at continuous improvement and achievement of results, providing stable operation of the educational organization;
- creation of quality systems, taking into account the recommendations of international ISO 9000 Series of Quality Standards, supplemented by the experience of the best educational organizations;
- continuous professional development of the staff and its involvement in the work to improve the quality of educational services provided;
- provision of necessary resources with minimal stocks and rational use of them;
- information and analytical support of the work in the field of quality;
- effective management of all processes taking place in the university;
- implementing of certification of educational services and quality systems, tracking and compliance with current legislation in the field of quality.

The participation of university units in the implementation of macro processes of quality management system is as follows (**Figure 1**):

The university receives information, capital, human resources, and materials from the environment. These components are called inputs. In the transformation process, the educational institution processes these inputs, converting them into products or services, which are outputs of the organization that it brings out into the environment.

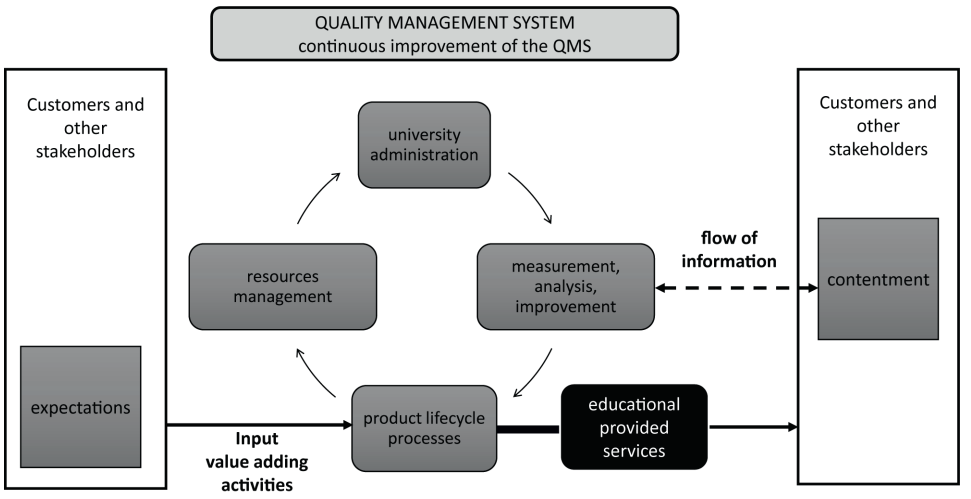

Figure 1.
Macro processes of quality management system at the university.

In Russian higher education, the participation of management in the development of quality management system should be emphasized. The rector of the university decides on the expediency of the preparation, implementation, and subsequent certification of the quality management system. The rector appoints a quality management representative, who will be the project manager of the quality management system preparation for certification. The quality management representative, top management, and consultants jointly determine the list of subdivisions involved in the work, and by the Rector's order, form the Quality Council, which includes (ex officio) the heads of administration all departments involved in the preparation of the quality management system departments involved in preparing the quality management system for certification. The Quality Council is chaired by the Rector.

3. The problem of assessing the quality of education

One of the main tasks of higher education is to ensure the quality of specialists. The problem of the quality of education has always existed. Now it has become extremely acute not only in Russia, but all over the world. At the same time, there are no clear criteria for the concept of "quality of education."

The education system in the Russian Federation is considered as a service that meets the educational needs of the population. In accordance with the Russian Federation Law "On Education" (Article 2), "education is a single purposeful process of education and training, which is a socially important benefit and is implemented in the interests of the individual, family, society and the state, as well as the totality of the acquired knowledge, abilities, skills, values, activity experience and competence of a certain volume and complexity for the purposes of the intellectual, spiritual, moral, creative, physical and/or professional development of an individual, meeting his educational needs, and, as a result, the quality of education" [10]. In Russian higher education, the quality of specialists training is connected mainly with the implementation of State Educational Standards of higher professional education,

state regulation of higher education institutions. An educational standard is a set of mandatory requirements for higher education.

Educational programs of a particular cycle of subjects determine the content of education of the corresponding level and orientation and are divided into two major groups by their intended purpose: general education and professional. Basic educational programs are designed to ensure the achievement of such a level, which corresponds to the state educational standard. State Educational Standards of higher professional education determine the educational minimum content of the main educational programs, the maximum educational load of students, the requirements for the level of training of graduates. These standards are established by the state authorities (management) and act as a basis for objective assessment of the level of education and qualification of graduates, regardless of the form of education. Orientation of some universities only on State Educational Standards of higher professional education as a guarantee of quality assurance has two drawbacks: the false idea that quality can be achieved by inspection; neglecting the needs of the educational market (standards do not keep pace with changes in employers' requirements).

In the State Educational Standards, the model of training specialists is personally oriented. The quality of the result of training programs is determined by two blocks of parameters that characterize the knowledge accumulated in a particular academic area and acquired competencies, including the personal development of students (critical thinking, general development).

The education system objectively operates on the following markets: the segment of the market of educational services, providing satisfaction of the needs of citizens in education and training; the segment of the labor market, providing satisfaction of the needs of employers and professionals; the segment of the market of intellectual goods, providing satisfaction of consumers (customers) in new knowledge, technologies, and knowledge-intensive products. The results of the activity of higher education institutions are manifested in several types, namely: services of educational character; scientific and technical products; integrated products based on scientific and technical products and educational services; educational and methodological developments.

3.1 Approaches to assessing the quality of educational services

There are two approaches to assessing the quality of educational services. Assessment of consumer properties of services (quality as value) is determined by active involvement of all stakeholders (students, faculty, corporate partners, etc.) in quality assurance processes at all levels of its management (the USA, Germany, Taiwan, Philippines). At the same time, quality control and assessment are either the priority of state structures or government-funded structures (Germany, the United Kingdom), or are based on internal process of control and self-regulation and external, expert quality assessment (the USA, Taiwan, the Philippines) [11].

The second approach is characterized by a wide range of powers of the state in ensuring the quality of educational services. The composition and quality of educational programs are determined and regulated by the state. The control and evaluation of education quality are centralized (France, Russia, Kazakhstan). In accordance with this, the quality of education in the context of the quality of the result of the educational process is considered as "compliance of the level of knowledge of students and graduates to the standards," on the one hand, and the needs of the market, on the other hand. The parity of state and market interests in the field of quality is provided

by the state standards through the system of elective courses, the composition and content of which are determined by the university independently.

The system of higher education in Russia has a more developed external quality assessment, focused on standards and performance indicators. The main elements of this system are standardization and procedures for licensing, attestation, and accreditation, as well as a comprehensive assessment of educational institutions as a whole and individual specialties based on the rating system. All of these procedures involve an internal review. One of the undesirable consequences of external control in education is the tendency to block information that lowers the grade. This leads to the loss of credibility of the entire system of management information.

The starting point of quality management system formation is to build a "model" of a university graduate as a set of certain personal professional qualities, the development of which should be aimed at the educational process: its content, teaching methods, forms of organization, methods of monitoring and evaluation of students' knowledge. The quality management system in higher education institution as a whole consists of the quality management of each type of university activities (educational, scientific, educational-methodological, educational, administrative-economic, etc.).

The analysis of different models of quality management systems has shown that the technological solutions of quality management in an educational organization should be focused on:

- elaboration of the mission, policy, and development strategy of the educational organization;
- creation of a new dynamic organizational management structure, including the definition of the components of this structure and their position in relation to each other, the establishment of interconnection of components, and ensuring the implementation of "development" strategy and interaction;
- transition from the subordinate principle of management organization to the dominance of horizontal coordination type organization, uniting equal and independent components on the basis of self-organization and self-development;
- the optimal combination of functional and linear quality management structures with a situational approach to management;
- ensuring the integrity of management functions within the management cycle;
- targeting of control actions, definition of objects and subjects of management, clear delimitation of powers, rights, duties, and responsibilities of the subjects of management;
- strengthening elements of monitoring, analysis, and evaluation of the results of the educational process, the construction of sound criteria and evaluation indicators;
- combination of different types of material and social motivation, as well as volitional management, organizational impact;
- economic, educational, organizational, and administrative, psychological and pedagogical methods of management.

3.2 Development of quality systems in higher education organizations

There are two main ways to create quality systems in higher education institutions. The first is the development of a unique model of quality management system on the example of a particular institution, partly universal and applicable to other organizations. The second way is the use of universal principles of modern quality management systems used in different spheres of human activity. The third way is the integrated process of building a unique quality management system in education using TQM principles and the requirements of international ISO standards.

The top management should bring to the attention of the staff the following provision: in order to manage the quality of the process, it is necessary to be able to measure its effectiveness and efficiency. In addition, the management of the university should ensure that the management representative prepares a report on the functioning of the QMS and the need to improve it. This report should be used as input for management's analysis. It usually includes the following information [12]: the status of actions based on previous management reviews; changes in external and internal factors; information on the QMS performance and results, including various trends (customer satisfaction; feedback from stakeholders; extent to which quality objectives have been achieved; nonconformance and corrective actions; monitoring and measurement results; audit results; external supplier results); adequacy of resources; effectiveness of actions taken in relation to risks and opportunities; opportunities for improvement.

Methods should be developed to measure (evaluate) the performance of each process. Senior management should ensure that the results of analysis are used to assess:

- the conformity of products and services (results of processes of educational services and other categories of university products);
- the degree of customer satisfaction; c) performance and effectiveness of the QMS; d) the success of planning;
- the effectiveness of actions taken in relation to risks and opportunities;
- results of external suppliers (including the expected number of high school graduates and secondary vocational school graduates);
- needs for improvement of the QMS.

The quality of the results of the activity of higher educational institutions (HEIs) should be provided through quality management of the main working processes of HEIs. It is reasonable to distinguish three groups of processes: basic processes, management processes, and supporting processes. Taking into account these requirements, it is possible to recommend to distinguish the formation of educational program of professional education and organization of educational process among the main processes of educational activity of university. Each of the abovementioned processes should include subprocesses, which should take into account the general requirements for the formation and organization of educational process, as well as the specifics of the university. In turn, these processes can also be decomposed.

Quality management processes at universities (HEIs) should include, first of all, those processes that are regulated by mandatory procedures in accordance with ISO 9001:2015 "Quality management system. Requirements" [12]. These include: QMS

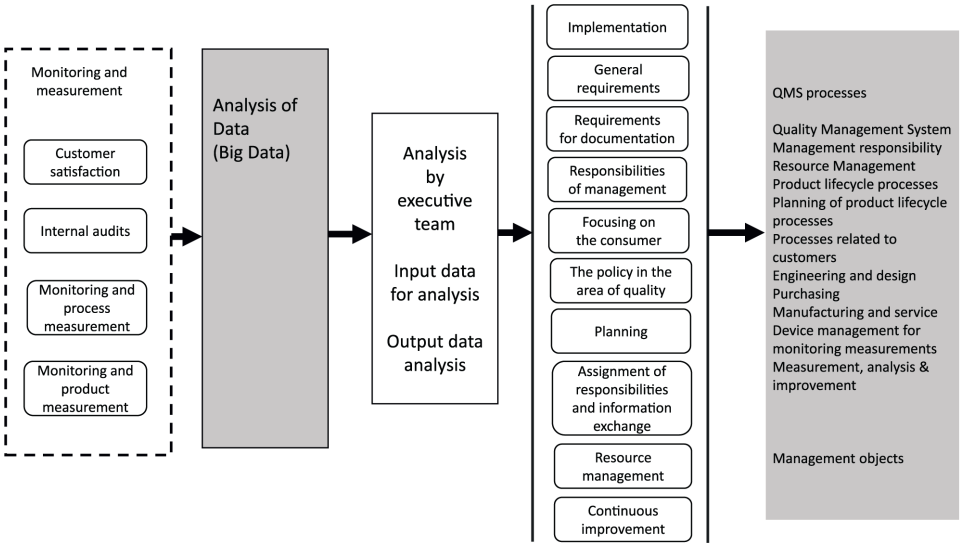

Figure 2.
Quality management processes at universities that should be under analysis.

documentation management, quality data management (records), internal audit, management of nonconforming products, corrective and preventive actions. In addition, it is also necessary to provide for a number of other processes, such as development and updating of quality policy and objectives, quality planning, quality analysis by management, etc. (**Figure 2**).

It is claimed in some research that all of the dimensions of e-services quality have had an impact on student satisfaction for ease of use [3].

To characterize the quality of education, certain indicators are introduced, which can be divided into three enlarged groups: indicators of investment in education, indicators of the quality of processes, and indicators of the quality of results. The indicators of the first group include information on financial, material, and technical, personnel, information and methodological support, etc. The indicators of the second group—process quality indicators—are identified on the basis of information

In order to be able to use the information obtained in the process of improving the quality of education, it is necessary to combine all the indicators that characterize the educational system "at the input," "in the process," and "at the output," to establish the nature of the observed relationships and then, based on the analysis done, to outline a strategy to improve the quality of the output results.

There are indicators of the third group, they include the results of the assessment of the quality of training and value orientation of students, as well as information about their career development after the completion of a certain educational stage.

To assess the effectiveness of the educational institution, the indicators affecting the learning outcomes can be divided into:

- indicators of the capacity of the organization or the area of activity under study; static indicators of performance and effectiveness achieved to date.

Processing of the results of education quality assessment can be carried out using special statistical methods of regression and correlation analysis, specific techniques

recommended by ISO 9000 Series of Quality Standards. The method of multilevel models is also used to assess the effectiveness and efficiency of the organization or a separate direction.

After determining the indicators that characterize the quality of the educational process, it is necessary to design the process of quality analysis (monitoring, information processing, and evaluation). The process of self-analysis and self-assessment is extremely useful, which is not so simple and requires considerable expense. It is extremely important to conduct self-analysis of an educational organization and be able to compare its results with the opinion of independent external experts.

The organization must identify the processes required for the quality management system and establish the sequence of these processes and their interaction.

With the introduction of big data analysis in the quality management system of universities, it is effective to consider the concepts of "risks" and "opportunities" as two independent and independent indicators. In this case, it is characteristic to tie "risks" to unfavorable events, and "opportunities" to favorable ones. The indicator "opportunities" should be considered separately from the indicator "risks."

The system of Hazard Analysis and Critical Control Points (HACCP) provides for the application of risk assessments using a combination of two indicators, the first of which is called "probabilities of hazard realization" and the second – "severity of consequences from the realization of the hazard" [13].

By analogy with HACCP, it is proposed to use the following approach: when assessing the indicator "possibility" (P) using a combination of two indicators:

1. Experts make a point estimate of the first indicator – "probability of realization of potential improvement" (PI) based on four possible assessment options in the form of points: 1 – practically equal to zero; 2 – low (probability of realization not more than 40%); 3 – medium (probability of realization 40...85%); 4 – high (probability of realization 85...100%);

2. Experts carry out point estimation of the second indicator – "significance of positive consequences of the supposed improvement" (SI). Here also four variants of this consequence estimation are possible (in the form of points given below): 1 – very small (the effect of improvement is insignificant); 2 – small (costs are recouped in 3 – 7 years); 3 – significant (costs are recouped in 1 – 3 years); 4 – large (costs are recouped faster than 1 year);

3. The boundary of permissible values of indicator "possibilities" on the qualitative diagram coordinates in the form of "probability of realization of potential improvement" (PI) and "significance of positive consequences of supposed improvement" (SI) as it is indicated in **Figure 3**;

4. For each considered case of using the indicator "possibility" (improvement), a point is plotted on the diagram with the coordinates of PI and SI, the values of which were evaluated as indicated above. If the point lies on the border or above – the assessed option of improvement of activity in QMS is characterized by a high value of the "possibility" and should be considered by the management of the division or organization for the use of the available opportunity. If the point lies below the border, then the value of the indicator of "possibility" is small in magnitude, and the considered option of improvement of activity is unpromising for planning and implementation of the project aimed at use of the available situation. Thus,

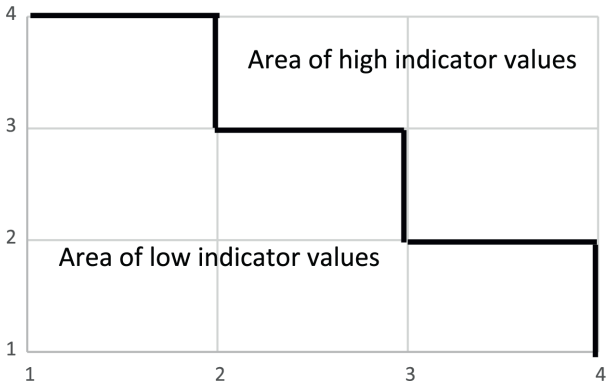

Figure 3.
Sphere of opportunity distribution.

the indicator "possibility" (improvement) is represented by a point (vector) on the plane with coordinates PI and SI. Possibility = F(PI, SI), where PI – point estimate of "probability of potential improvement"; SI – point estimate of "significance of positive consequences of the expected improvement"; F – designation of the function, which puts a point on **Figure 3** in accordance with the coordinates of PI and SI.

In the figure, the boundary of the desired values of the indicator "possibility" is plotted with the coordinates of PI and SI. Going to or beyond this boundary means that the situation is promising for the project to use the available opportunity of improvement. There are cases if a point lies in the area of low values of the indicator "possibility" or if a point lies in the area of high (desirable) values of this indicator. If a point lies on the border, it is also corresponding to high (desirable) values of the "possibility" indicator. The two-dimensional evaluation of the "possibility" indicator seems to be the most convenient and universal. Interpretation of this indicator ("possibility") as a set of two indicators of PI and SI allows to enter the following definition: indicator of "possibility" of improvement is "probability of realization of potential improvement" (PI) taking into account "significance of positive consequences of supposed improvement (SI)."

4. Conclusion

The use of big data seems obvious and inevitable: "the industry 4.0 revolution was entirely based on the new technologies, mainly in computer and information technologies. With the introduction and the use of Internet of things, cloud services, big data, artificial intelligence, various algorithms result in integrated systems providing excellent customer service for the organization activities" [14]. However, the analysis and application of processing results require resources and should be built into the quality management system of the university.

In all educational systems, foreign and national, the object of education quality assessment is the quality of educational services, which is traditionally evaluated by the results, which are understood as learning outcomes (experience accumulated in the learning process). The content of the concept "quality" is largely determined by the system of quality assurance and control adopted in the sphere of education in this or that state and, primarily, by the government's powers in solving these problems.

The HEI quality management system can be built in accordance with the requirements and recommendations of international ISO 9000 Series of Quality Standards, the principles of Total Quality Management (TQM), or based on the model of the European Foundation for Quality Management (EFQM).

Universities need to find their own methods, techniques, procedures of self-assessment, and self-analysis of activities, to create associations of single-profile educational organizations and enterprises—consumers of specialists for an adequate and effective quality audit. In modern conditions practically every HEI is interested in creating a system that would constantly monitor, evaluate, forecast, plan, and manage all the processes in the HEI. The need for this system is justified, and its reasonable application will allow the institution to successfully compete in the labor market and educational services.

One of the main difficulties that exist today for the implementation of big data in university management practices is the difficulty of translating data sets into simple indicators. The expensiveness of the use of big data is obvious, while the efficiency is recognized insofar as we are living in the era of another technological revolution. In addition, the processing of big data requires software and specialists. In practice, universities engage professional marketers and market specialists to solve their problems. It is necessary to provide a mechanism for translating big data into a few simple indicators that reflect management efficiency.

The use of big data in higher education is necessary. First of all, it is the analysis of attendance at the university website and university profiles in social networks. This analysis involves serious analytics and statistical processing that will never be of deep interest to middle and upper management because of its complexity. This is another reason for converting the data into simple metrics. Big data analysis should be implemented, first of all, in monitoring the results of educational services.

To sum up, the mission, vision, goals, development strategy, and quality policy of the HEI together form an important strategic management tool, which expresses the spirit of the organization, states what the organization stands for, what its purpose is, what its goals are, where it is going, how it is going to achieve all this, and what important points everyone has to focus on. They shape the collective ambition of the organization, have an important influence on the connection of employees and employees to the organization and to the quality of their work. A successfully articulated collective ambition reveals to people how their activities contribute to the common cause, how they work together to achieve goals that contribute to a higher quality of performance in the organization.

After developing strategic plans, determining critical success factors and performance metrics, defining policies, and setting quality goals for the organization, there appear: the strategic plan of the organization as a whole; operational plans for the departments (services) of the organization; specific quality improvement projects. After approval of these strategic and operational plans, they proceed to implement them. The specific actions are usually defined in operational plans for the various business functions, usually developed over a period of time for various business functions, usually developed for a period of up to one year. The central issues of such operational plans are:

- what market research needs to be done?
- what new specialties need to be opened?

- what academic disciplines will be introduced in the new academic year?
- what new educational laboratories should be created?
- what needs to be financed?
- what human resources will be needed?
- what will have to be purchased?
- what research and development
- what repairs and (or) maintenance will have to be performed?
- what services (third-party organizations, partners) will be required?

Only after the answering the above questions it will be possible to begin to achieve the goals set by implementing the strategic and operational plans of the organization. These questions are useful in that they capture those areas of activity where the use of big data is appropriate.

Conflict of interest

All authors declare that they have no conflicts of interest.

Appendices and nomenclature

EFQM	European Foundation for Quality Management
HEIs	higher educational institutions
IIoT	Industrial Internet of Things
PI	probability of realization of potential improvement
QMS	quality management systems
SI	significance of positive consequences of the supposed improvement
TQM	Total Quality Management

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Chapter 7

Accelerated Change for the Good (ACG™)Facilitator – A Transformational Approach to Perform Continuous Improvement (CI)

Andrew Wowczuk, Yurij Wowczuk, Zenovy Wowczuk and Borys Wowczuk

"Long-term commitment to new learning and new philosophy is required of any management that seeks transformation. The timid and the fainthearted, and the people that expect quick results, are doomed to disappointment."

—W. Edwards Deming, Author of Out of the Crisis (1986).

Abstract

This chapter introduces an updated Kaizen-based concept of facilitation through a uniquely guided organizational approach and certification program. The Accelerated Change for the Good (ACG) Facilitator program was developed exclusively by the Civil-Military Innovation Institute (CMI2). The contents of the program follow best practices in Lean and Six Sigma methods using DMAIC (Define, Measure, Analyze, Improve, and Control) problem-solving techniques and stress modern facilitation skills. From an implementation perspective, ACG accelerates an organization's initiation of continuous improvement (CI) by overcoming the constraints of traditional Lean/Six Sigma deployments. The ACG framework has been structured into an interactive 30 h of contact time using various blended knowledge transfer techniques. To obtain certification, a student must complete all workshop activities, pass a 50-question web-based quiz, and submit written evidence of leading or participating in a live event by applying the tools and techniques provided. The submittal of an event requires documentation by an exclusive workbook provided in the workshop. The program has been approved as a micro-credential activity at SUNY Maritime College and will be rolled out to several other academic institutions in the next 24 months. CMI2 has customized the program to meet client needs and has delivered the contents using both classroom and virtual platforms (e.g., Zoom, MS Teams) with a diversified cross-functional mix of participants. The research initially conducted during the formative stages of this framework consisted of a review of the lean

management, continuous improvement, and operational excellence literature with a particular view toward defined and tested models (e.g., Toyota Production System, Danaher Business System). Particular emphasis was placed on methods that were applicable for a variety of industries and organizational/business structures, and that emphasized sustainability, human capital development, and focus on innovation.

Keywords: kaizen, Lean/Six Sigma, continuous improvement, ACG, process improvement, quality engineering, team dynamics, business process improvement, team dynamics

1. Introduction

ACG is an acronym for "Accelerated Change for the Good, which replaces the Japanese term Kaizen. Kaizen translates to "good change," "change for the better," or "improvement." This methodology is a replacement for traditional Lean/Six Sigma methods. **Figure 1** shows terms typically used in ACG [1].

ACG promotes an attitude where incremental changes, accomplished a set timeframe, creating a major impact to the organization over time. It requires organizational buy-in and typically includes stakeholders and sometimes even customers [2]. As a methodology, ACG improves specific processes and systems in a company or organization by involving both management and frontline employees to initiate simple changes, knowing that many minor improvements can yield significant results. Emphasis on non-capital (CAPEX) expenditures exploiting all the resources available in existing organization is priority [3].

The notion of incremental change as a management improvement tool can be traced back to post-World War II, when economic reform consequently took over US, Japan, and trading partners. In Japan, the Toyota Motor Corporation implemented the Creative Idea Suggestion System in 1951, which resulted in changes and innovations that spawned higher product quality and worker productivity, contributing to the company's development.

In 1955, Japanese executives started visiting the United States as one of the initiatives of the Japan Productivity Center to benefit from American Innovation and know-how. Integrating the American way of doing business with a humanized approach pushed Japanese companies into worldwide competitiveness. During the 1980's, management consultant Masaaki Imai worked with Taiichi Ohno to spread the message of the Toyota Production System (TPS), a result of several years of continuous improvements.

Figure 1.
Typical words describing ACG.

Problem-Solving Method				
The DMAIC Roadmap				
				
Define	Measure	Analyze	Improve	Control
• Initiate the Project • Define the Process • Determine Customer Requirements • Define Key Process Output Variables	• Understand the Process • Evaluate Risks on Process Inputs • Develop and Evaluate Measurement Systems • Measure Current Process Performance	• Analyze Data to Prioritize Key Input Variable • Identify Waste	• Verify Critical Inputs Using Planned Experiments • Design Improvements • Pilot new Process	• Finalize the Control System • Verify Long Term Capability

Table 1.
The DMAIC process: Problem-solving in five phases found in Lean/Six Sigma.

Considered the Father of Incremental Change, Masaaki Imai globally introduced a new systematic management methodology in *Kaizen: The Key to Japan's Competitive Success (1986)*. Today, organizations across different industries adopt incremental change as a part of their core values and practice continuous improvement on a daily basis with best practices and tools from Lean/Six Sigma. Problem-solving is guided by DMAIC (Define Measure, Improve and Control) as shown in **Table 1**.

> "Kaizen is an everyday improvement—every day is a challenge to find a better way of doing things. It needs tremendous self-discipline and commitment."—*Masaaki Imai, Founder of Kaizen Institute*.

2. Core principles and key elements required for successful ACG implementation

One of the goals of ACG certification is to accelerate the knowledge transfer processes in CI by making ACG facilitators the in-house champions for methodology acceptance. Traditional Lean/Six Sigma certification bypasses the applied learning of new techniques and does not tie methodology transfer with project execution. The Implementation of CI in the workplace can be difficult or nearly impossible because management usually expects immediate dramatic results. Therefore, many Lean/Six Sigma initiatives have not shown benefits tangible, sustained. Companies often miss out on improved safety performance, optimized business processes, and enhanced employee engagement due to an exclusive focus on breakthrough performance.

- Maximize Employee Involvement and Empowerment in CI with Emphasis on "Value Add"

Ensure there is an understanding of how "value" is determined in the organization. Encouraging workers to keep adding value to the products and services will boost morale. It also gives everyone ownership of continuous improvement.

Process and Value stream mapping (VSM) are utilized as a process improvement tool. The ACG framework shows explicitly how the DMAIC problem-solving methodology should align with process improvement for impact in any type of business environment or function [4].

ACG implements from the perspective of the employee executing individual job responsibilities—it is the employee that knows their job more definitively than anyone. Managers and leaders should create an environment where people feel empowered to contribute so that suggestions for improvement can come from all levels and ranks. Create a continuous learning environment where best practices are applied during ACG events [5].

- Management responsibility

One of the most common reasons CI implementations fail is the lack of support and, more importantly, action from the organization's management and leaders. Imai states, "The top management of the company has the most important role in implementing this kaizen approach, and then every manager, then it goes down to rank-and-file employees." When top management demonstrates its long-term commitment to continuous improvement, managers inevitably follow through on ACG initiatives and workers personally develop an ACG mindset.

- Practice employee empowerment

Leaders should create an environment where people feel empowered to contribute so that suggestions for improvement can come from all levels. Encouraging workers to keep adding value to the organization boosts morale and gives everyone ownership of continuous improvement efforts, which contributes to the successful implementation of ACG.

- ACG events are performed at the workplace with frequently scheduled Gemba walks

Achieving operational efficiency begins where the actual task happens, not from a conference room. A Gemba Walk—derived from the term gemba or gembutsu, which means "the actual place where the work is performed"—is usually done by managers to learn or review exactly how a specific process works and gain insights from workers about its improvement. A Gemba Walk Checklist is provided with the workshop material and guides the observers in asking relevant questions to determine the root cause of problems and the next steps. Every employee should be required to participate in a least two ACG events as part of their annual performance review. An ACG event is typically 2–5 days long, and all action items are completed within a month following the completion of an event [6–9].

- 5S + 2S

One of the most significant barriers to continuous improvement is clinging to old practices or assuming new methods will fail. The 5S principles (sort, set, order, shine, standardize, and sustain) aim to enhance workplace efficiency by constantly looking for ways to eliminate waste and improve local housekeeping. The initiation of 5S is usually the start of organizational involvement in Lean practices [10].

Organizations should refrain from thinking that just because something worked before means, it will continue to work. Status and progress in 5S + 2S should be

measured in a standardized metric visible at the Gemba. The original 5S in lean is now supplemented by two additional S—safety and security, emphasizing the setup of preventive controls and protection for safe work operations. A 5S + 2S program are initiated as part of continuous improvement.

> "Progress cannot be generated when we are satisfied with existing situations."—*Taiichi Ohno, Father of the TPS—the basis of lean manufacturing*

3. Workshop delivery and the certification process

The workshop knowledge transfer consists of an interactive presentation and a specialized workbook guiding facilitator activities [11]. The pages are annotated and work standalone learning material in a live ACG event. Workshop execution and documentation is accomplished by completion of the facilitator workbook.

Workshop facilitators also act as mentors and coaches to the participants as they execute their first project.

The workshop can be delivered in a live classroom environment or by distance learning using a virtual platform. The live classroom version is designed for 30 h over three days with approximately 5 h of homework/self-study. For the proctored virtual version, the workshop is delivered in 10 one-and-a-half-hour sessions using the content outline shown on the last page. Both versions will be preceded by a 1-h kick-off session using a virtual platform providing examples of past projects and a unique method of project evaluation.

The delivery of a workshop and certification can be customized to the requirements of the participants and typically takes the following format:

1. A virtual kick-off session for 1.5 h held 1 week before the start of the actual workshop—introduces the concept of continuous improvement and starts the process of potential project selection.

2. Two days, 20 h of face-to-face classroom time.

3. 10 h of Zoom work sessions to complete workshop assignments and imitate certification event—Zoom sessions are held in the evening and typically are 1.5 h long over a 4-week duration.

4. Completion and review of a 50 question, open book exam (taken online).

5. The completion and submittal of an ACG event must be accomplished within 6 months after finishing a workshop.

6. Final certification is issued within one month of submitting a project.

4. ACG facilitator workshop contents/syllabus

This workshop/event includes following 22 sections with over 320 PowerPoint slides and a facilitator workbook. Supplemental material is provided through access in a Dropbox file maintained by workshop facilitators. New material is added as it becomes available. Five versions have been delivered to date.

4.1 Define current state (define phase of DMAIC)

- Potential focus areas for ACG start with a detailed review of the current state process(es). The concept of creating a SIPOC is introduced.

Learning Outcome: The Student will be able to define a ACG project. Document current state. Complete a process map and project charter demonstrating business benefits to the organization and define how the project relates to strategic planning.

4.2 Using 5 W ad 1 M

- A problem statement to be used in a project charter is constructed with 5 Ws (What, Why, When, Where, and Who) and 1 M (a related measurement).

Learning Outcome: This technique is introduced in the kick-off session and serves as a way to draft and validate ideas for potential projects.

4.3 Data collection

- The importance to capturing the current performance with the right data is explained. An introduction is provided to Measurement System Analysis (MSA).

Learning Outcome: ACG practitioners learn how to characterize different types data and use the results to guide for decision making.

4.4 Descriptive statistics

- ACG practitioners see the value of characterizing data beyond just calculating an average.

Learning Outcome: Excel methods are introduced to calculate the range of descriptive parameters for both sample and population data.

4.5 ACG explanations

ACG Event purpose and execution – elimination of waste by removing Non-Value Adding activities resulting in standardized systems, improved efficiency of processes, higher quality, faster delivery, and cost savings.

4.6 ACG history

- Learn the history of ACG.

Learning Outcome: Understand the history of ACG as it developed from Toyota Kaizen events and how American companies and civil institutions have adapted it.

4.7 Future state

- To get to the future state, you undertake a focused effort that looks at each element of the current state and how to make it better.

- ACG uses the DMAIC (Define, Measure, Analyze, Improve, and Control) as a Lean operating model.

Learning Outcome: Basic understanding of future-state and the ACG experience. Understand DMAIC phased problem-solving.

4.8 Value stream and process mapping

- Following an explanation of value, the concept of viewing all aspects of an organization as a value stream is introduced.

Learning Outcome: Workshop participants understand how to create and interpret an organization's value stream.

4.9 ACG versus other improvement methodologies

- Lean, Six Sigma, and ACG are all continuous improvement methodologies. They vary in application but all help with providing the framework for improvement of processes.

Learning Outcome: Understand the difference between a ACG project and other improvement methodologies.

4.10 ACG characteristics

- ACG is an intensive burst of business process improvement.

Learning Outcome: Understand the characteristics of a ACG project and how it is structured.

4.11 Lean principles

- Lean is generally referred to as a manufacturing or production improvement methodology but has expanded to health care and office environments.
- It is exemplified by the Toyota Production Method (TPM) and related frameworks.
- As a term in business, it has a broad-based customer focus that concentrates on providing more to the customer with the same resources.

Learning Outcome: Understand that ACG events build on lean principles. Learn those principles.

4.12 Lean process management

- When you start to undertake Lean reviews within an organization, you could integrate it into the corporate strategy and long-term vision for the business. Likewise corporate strategies and strategic plans should include CI initiatives as a primary lever to achieve desired results.

Learning Outcome: Understand the process of lean management using balanced scorecard reports.

4.13 Lean industries (control phase)

- Although Lean principles were developed for manufacturing, it is now recognized within a whole range of business sectors.

Learning Outcome: Learn how different industries use Lean principles.

4.14 Lean analysis tools and measurements

- Within every workflow or production path, there are core elements that are essential to its success.
- Simple metrics exemplify improvement in the processes before and after improvement.

Learning Outcome: General overview of the tools used during an ACG project, including Critical Path Analysis, TIMWOOD, Kanban, JIT, Push & Pull, 5S, Cause & Effect, Poka Yoke.

4.15 ACG events (ACG project)

- ACG Events are relatively simple in format and can be used to make significant improvements when continually applied within your organization.

Learning Outcome: Understand the major components and subcomponents of a ACG Event.

4.16 Forming an ACG event team

- An ACG event should always have an executive team member participate to display organizational support and alignment with the strategic goals.

Learning Outcome: Understand the key members who should be on an ACG project and how they are selected. Understand current practices on defining CI functions and roles.

4.17 Event kickoff

The event kickoff is the opportunity to build the energy for the event.
Learning outcome:

- Understand the need for the event kickoff.
- Review typical program materials presented in a kick-off event.

Learning Outcome: Recording Current-state.

8

4.18 Effective facilitation

- The role and responsibility of an event or meeting facilitator is explained with examples. How to recognize and alleviate misbehavior is explained. Team dynamics are defined.

4.19 The language of lean

- Value Stream—This describes the activities that provide the customer with value in delivering their product.

Learning Outcome: Understand a Value Stream & Value Stream Mapping.

4.20 Three forms of waste

- In Lean you have three types of waste: Mura, Muri, Muda

Learning Outcome: Understand Musa, Muri, Muda.

4.21 The eight elements of waste

- The eight classic wastes introduce) include overproduction, inventory, defects, over-processing, waiting, motion, transportation. In the US an eight waste is added—untapped creativity.

Learning Outcome: Understand the 7 + 1 elements of waste.

4.22 Performing root cause analysis

- Once wastes are determined you can begin looking into the root causes of problems of the process.

Learning Outcome: Understand Root Cause Analysis.

4.23 Prioritizing improvements (improve phase)

- The team may develop a multitude of possible solutions to resolve problems or a multitude of solutions for just a single problem so it may be advantageous for the team to utilize some sort of prioritization or scoring matrix.

Learning Outcome: Understand how to prioritize the improvements and using a matrix diagram.

Figure 2 shows the contents of the main agenda for a workshop-based workshop.

5. In summary

The ACG framework can dramatically improve the efficiency and standardization of your company's workflows, processes, and procedures. Following the format and methods provided in the ACG workshop can make a significant impact on employee

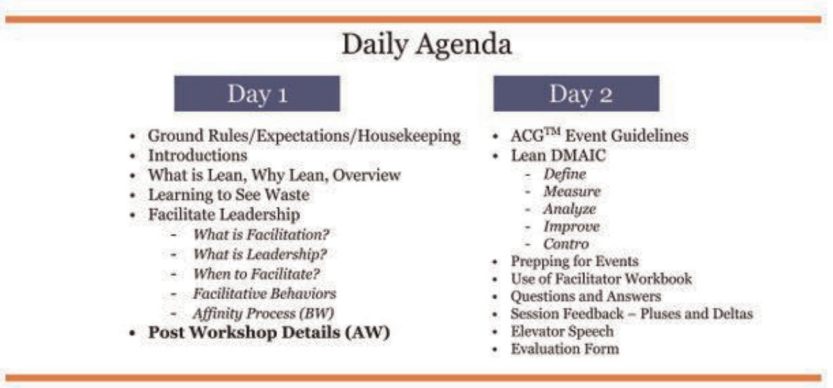

Figure 2.
Typical classroom-based agenda.

engagement and culture, and workflow improvements. ACG is a way to transform the way your business works if everyone is committed to making positive changes at all company levels. Certification follows a successful project submission. An advanced version of the ACG workshop is planned for 2023.

It is not necessity to change. Survival is not mandatory. —W.E. Deming.

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Chapter 8

Impact of Corporate Investment on Business Performance: The Case of Slovenian Firms for the Period 2000–2017

Vladimir Bukvič and Metka Tekavčič

Abstract

This paper, which is derived from comprehensive research based on the microeconomic theory of investment and the theoretical approach to measuring the financial performance of firms, presents a conceptual model to define, assess, and measure the impact of corporate investment on business performance. In terms of investment, the focus falls only on tangible fixed assets, whereas business performance is defined solely as performance measured by the relevant financial indicators. Several research hypotheses are tested on an extensive sample of Slovenian firms. A statistically significant correlation between investment and financial performance indicators is found for the period 2000–2017. This correlation is particularly strong with net sales revenues, added value, and operating cash flow (EBITDA). Since the global financial crisis occurring at the break of the last decade is also included in the designated period, the creditless growth of investment together with the simultaneous deleveraging that took place after the financial crisis is explored and compared with the growth of selected financial performance indicators.

Keywords: corporate strategic investment, tangible fixed assets, dynamics of investment, rating and indebtedness, financial performance

1. Introduction

The purpose of this research is to determine how corporate investment influences the business performance of firms. This also can be considered as our research question. We explore this issue in the case of Slovenian firms, specifically, how successful they were with their investments in the period from 2010 to 2017. The reason why this topic has been chosen as a research subject lies in the fact that in spite of the relatively high capex being spent in firms in the last decade, quite a few of these firms have not performed well for many years. How many of them did not perform well is also the subject of our research, with investments achieving neither a satisfactory return on equity, ROE, nor the planned adequate cash flow.

We might venture to claim that the investment projects should have been justified by investment programs, or that a better business performance should have been

foreseen, expressed either by higher net sales revenues, higher earnings before interests and taxes plus depreciation and amortization, EBITDA, a higher net profit, a higher ROE, a higher return on assets, ROA, or a higher positive cash flow, CF, etc. If we suppose that at the time when the investment decision was made, the investment projects as such had been assessed as profitable and economically justified, that is, economically sound, well set up, and promising for the investors, then the question might be raised, did these investment projects turn out to be as efficient as anticipated or as they should have been, or to put it another way, did these investments improve the business performance of the firms. Similarly, the investment project implementation with respect to what had been planned is also questioned, for example regarding the suitability of its technology and equipment, the planned investment budget, its sufficient and reasonable financial resources, reliable market projections, agile management, qualified labor force, etc. There is also doubt about achieving the required rate of return on investment projects and other relevant financial ratios by which business performance is measured and which are expected to be met by various stakeholders, mainly owners and creditors. Surely, not everything listed above is valid for all the firms. Among them, there are some who have improved their business performance due to their investments.

The research problem in our study can be addressed operationally in the following way. We base our research on resources as key drivers by which successful investment project implementation and the sustainable and profitable growth of a firm should be assured. As strong evidence for such a statement, we rely on the theoretical standpoints and comprehensions of various authors, and from the perspective of the operationality we set up a simple conceptual and measurement model, which links investments in tangible fixed assets and the business performance of the firms, expressed by a number of relevant financial indicators and ratios. From this model, a *basic research thesis* is erected: *corporate investments in tangible fixed assets have a positive impact on business performance*.

The existing research has mainly considered the effects of individual investments and their performance, and very rare the researchers have studied how investments do influence the business performance of the firms. Our research is grounded on a holistic view of the impact of investments on the business performance of firms, which can be accounted for as a novelty in this field. The potential contribution of our paper is to highlight the impact of Slovenian firms' investments on their business performance in a rather long time span, including the big financial crisis as well, which can be also considered as a novelty in the area of corporate investment activity.

Based on the literature review, the authors develop a simple conceptual and measurement model to study the performance of the firms deriving from their investment. They establish a set of financial indicators and ratios, relating mainly to increase in sales, productivity, profitability, and cash flow, and find their correlation with the investment in tangible fixed assets. They try to find out if these correlations are statistically significant and how strong they are. Some of this research is quite similar to what some researchers have already done using the data for their national industries. Their scientific contribution in this field is an integral approach, a set of two groups of financial measures of the business performance and establishing or confirming their relevance to assess the effect of investments on business performance. Such a concept—corporate investments generally influence firms' performance—has not been used before, and it is empirically tested on a rather big sample of Slovenian firms.

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On top of that, the authors also study the behavior of the firms as investors, and they show how the firms as investors were able to exploit investment opportunities, what their prevailing motives to invest were, how often and when they invested (investment dynamics), what their investment growth in the longer study period was, what efficiency of their investment implementation was, and last but not least what economic effects they achieved by their investments. Such a complex and all-embracing analysis of the investment activity of the firms in the real economic sector in a longer period of time (after the last big financial crisis) at the national level has not been carried out recently either.

The relevance of this research can be pinpointed by the fact that investment activity is crucial for the firms' sustainable growth and their long-lasting performance, and that the interest of the managers should be increased by the appropriate recovery of their consciousness and education in the sense that they consider all the resources that define and influence their investment ability differently than they do currently. Investment ability manifests in investment implementation and business performance. For this reason, it is very important that firms do not pay attention only to the pre-investment period when they make investment decisions, but also to the implementation of their investment and to the post-investment period, when they have to accompany and measure the financial results of their investments to find out how successful and efficient their investment was. It is especially relevant to know what financial indicators and ratios the investment influence. All this is the authors' important contribution to the existing body of literature.

In the theoretical part of our research, the concepts and basic issues related to corporate strategic investments and their impact on business performance are presented. The scientific method of description and scientific methods of classification, comparison, analysis, and synthesis are used. A central issue in implementing this investigation is to find out whether there exists a correlation between investments in tangible fixed assets and the financial performance of firms. We do not deal with the total factor productivity (TFP). It is not an investigation to obtain any relevant measures of TFP.[1]

The empirical part of our research is based on the use of several research methods. As a basic method of our empirical research work, the statistical method of primary data analysis is used. Preliminary data were obtained by a questionnaire sent to Slovenian large and medium-sized enterprises (SMEs), classified from A to J according to the SKD 2008, V2 classification. Only the firms in the non-financial sector were observed. The financial data for the firms that responded to the questionnaire were collected from the GVIN (BISNODE—D&B) database. For testing the hypotheses, the chi-square test, t-statistics, and linear regression were used.

As already mentioned above, before testing our research hypotheses, the investment activities of the firms from our sample in the study period are presented from various aspects and illustrated graphically. Some results of this kind of research based on a sample of Slovenian firms are quite surprising.

At the end of this paper, we summarize the main findings of our research, in the first place the results of testing our research hypotheses. Limitations are also exposed, as are guidelines for further research work in the field of studying business performance due to investments.

[1] There is a bulk of literature focusing on the estimation of productivity [1–3].

2. Theoretical and conceptual background, and research hypotheses

In the theoretical framework of our research, first, a literature review is highlighted supporting the relevance of the research question. Thus, business performance related to corporate investments is presented and addresses our research hypothesis. Second, strategic corporate investments are defined with the emphasis on the dynamics of investment and its funding. Third, a conceptual and measurement model of investment impact on business performance is set up.

2.1 A literature review from the perspective of the relevance of the research question

The author of this paper tends to show in a systematic and critical manner how the existing literature deals with the relationship between investments and a firm's performance, how it measures the effects of the investments on business performance, and to what conclusions the researchers have come so far studying this issue. Only on this basis one can better understand what the contribution of this paper stated above is like, how this paper is attached to the findings of the existing research work, what in essence this paper adds to the existing body of literature, and last but not least, why this research question is relevant.

For many years, a number of authors, such as Schultes [4], have studied the numerous factors that influence the performance of investments, and quite a few academicians and experts, for example, Grazzi et al. [5], have followed similar topics in the field of business, especially as they relate to investments in fixed assets (tangible and intangible), and studied the measurement of their efficiency from the point of view of business performance. A relatively strong interest in this field has emerged especially with regard to strategic investments and their role in strategic planning. They are considered as a key driver of a firm's growth and progress [6].

Assessment of the impact of corporate investments was not a relevant research topic in the past, mainly due to a lack of data on investments. One of the first steps in this field was made by Doms and Dunne [7] who investigated corporate investments of American firms. The other researchers followed their case and they have found similar results: the years of investment inactivity or only of repairs and maintenance of tangible fixed assets followed the years of intensive investment activity in the firms and in the whole industry. Carlson and Laseen [8] showed that models of non-convex cost of adjustment offer a more suitable frame for better understanding of investment decisions and they reject those models that assume regular capital accumulation samples.

Although a lot of research has been done assessing the impact of various factors on investment project performance [9, 10], there are only a few empirical studies aimed at investigating the correlation between individual investment project performance and the firms' financial performance. We should mention the research work done by Pollack and Adler [11]. They assert that there is a positive relationship between these two kinds of performance, which sounds logical and can be supported by project management theory. In some cases, the size of investment projects, innovation, and technological uncertainty, investment projects are not supposed to generate only profits, but they should also bring about strategic organizational benefits, such as product diversification to increase market share, the creation of new technical competences, the installation of new production lines, and the acquisition of new markets [12]. Ekrot et al. [13]

advocate the thesis that a firm's performance and efficiency, strongly based on project management organization, depend to a great extent on the performance of each individual project. Serrador and Turner [14] have found that the efficiency of investment projects measured by time, budget frame, and scope correlates significantly with a broader range of qualitative performance indicators, for instance, customer satisfaction, and general firm performance, the latter being expressed by financial ratios, which is also the subject of our research.

Some literature exists that studies the relationship between the increase of the firms' wealth based on investment and their business performance as revealed by productivity and growth rate [15–19], by employment growth [20], by sales growth [21], or by other production factors [18, 22].

Models advocating the "learning by doing" principle argue that there is a certain time needed for workers to learn how to use new technology. For this reason, their productivity following the investment will very likely be U-shaped. This means that it decreases at the very beginning and then starts to increase, eventually reaching a higher level. The majority of empirical researchers [15, 17, 19, 22] provide evidence that the effect of investment on productivity growth is negative in the short run. Researchers who study long-term effects do not support a positive relationship between investment and productivity growth either. This causes quite an enigma from both the theoretical and the empirical aspects. Why invest in fixed assets if these investments do not generate benefits? The above-mentioned authors have studied this relationship in greater detail using a more sophisticated approach and providing evidence in the case of Italian and French firms that investments *de facto* improve the firms' performance. Meanwhile, Power [15] has not found any evidence of a positive correlation between productivity and high recent investment spikes. Still, on the other hand, Huggett and Ospina [17] have found that productivity in fact decreased right after the implementation of a big investment. Bessen [16] has come to the conclusion that the productivity in newly built production plants increases over time, which he ascribes to the process of learning by doing. Power [15] has revealed a positive correlation between labor productivity and the age of production plants. Shima [19] has even observed a negative relationship between technical efficiency and the age of equipment. Kapelko et al. [23] have studied a sample of Spanish firms and they have come up with an interesting finding, namely that investment spikes cause productivity to decrease in the first year after an investment (cf. Ospina), that the relationship between technical changes and investment spikes is U-shaped, and that the effects of investment spikes on the dynamics of productivity changes differ depending on the size of the firm.

Based on a different econometric approach, Nilsen et al. [15] have found a positive and significant effect of investment implemented in the same year on labor productivity. It is interesting, though, that these effects disappeared throughout the following years. Their study also revealed that the group of firms with a bigger investment spike in at least 1 year of the sample period demonstrated a significantly higher productivity level than the group of firms with no bigger investments. Similarly, Grazzi et al. [5] have found a positive relationship between investment spikes and the firm's sales growth. Having studied this particular relationship in the case of Italian and French firms, they realized that if the firms had at least one bigger investment in the study period, they increased their sales volume and profitability as well. The effect of the investment was strongest right after its implementation, in the period of the first year of its operation, afterwards, it decreased.

2.2 Corporate strategic investments, the dynamics of investment, and its funding

Investments are expenses designed for increasing or maintaining the stack of capital. We deal only with net investments designating a real capital increase. Meanwhile, following the statistical definition, an investment is everything that cannot be consumed, and following the general definition, an investment is every expense designed for increasing income in the future [24]. While investment expenses or capex can be aligned into several categories, the subject of this research is long-term corporate investments comprising corporate expenses for durable goods (equipment, premises).

Whenever we analyze corporate investments, the following questions are raised: How much capital do the firms want to use, at what given costs, and what return of capital and product level should be considered? What defines the desired stack of capital, that is, that stack of capital the firms want to possess in the long run? Clearly, firms cannot adjust their stack of capital to the level needed in their production right away. They need a certain period of time. We speak of an adjustment rate at which the firms adjust themselves from the existing stack of capital to its desired level. The adjustment rate defines the investment rate. Thus, investments express an adjustment rate of the economy to its desired level [24]. Technological modernization of production processes, such as robotization in firms, is an example of such an adjustment on the micro level. Today, we are witnessing the 4th industrial revolution, where cyber-physical systems, the internet of things, IoT, artificial intelligence, AI, and fast-growing production efficacy methods are broadly applied in the corporate industrial sector and elsewhere.

When Weissenrieder [6] asked himself what investments create value, he sorted investments into two groups, namely strategic and non-strategic investments. Strategic investments are those that pursue the goal "to create new value for the owners and to ensure the firm's growth." Non-strategic investments are those that maintain and save the value made by strategic investments. Strategic investments, such as investments in new product development or investment in acquiring new markets, are followed by more non-strategic investments. A strategic investment can be an investment in tangible fixed assets, which is the subject of our research, or in intangible fixed assets. It is irrelevant whether we talk about capex or not. Everything that counts as a cash expense in a firm is closely tied to new value creation and can be, according to Weissenrieder [6], defined as a strategic investment.

In relation to capital adjustment in firms, there are several studies [7, 25–27] that have found that firms adjust their production factors, such as capital, in a lumpy fashion.

A team of researchers [5] supports the thesis that decision-making dealing with rather big investment projects and their temporal dimension is linked with the managers' expectations about future business opportunities, and with investment cycles. From the perspective of investment dynamics, Gourrio and Kashyap [28] provide evidence that the majority of the aggregate investment changes are explained by the changes in the number of firms being in the phase of comprehensive investments and having so-called investment spikes. Similarly, just as in macroeconomics, where we are interested in how to explain changes in aggregate investments and how these changes affect economic growth, we would also like to understand heterogeneous behavior at the micro level.

Sometimes firms renounce their investment, sometimes they are captured by a real wave of investment. Caballero [29] asserts that accounting for such lumpy

investments is critical because it has an impact on the formation of the dynamic behavior of aggregate investments. Gourrio and Kashyap [28] have supported this thesis with their research of American and Chilean firms. They called the waves of investments investment spikes. The investment growth rates are mainly due to the firms' investment spikes.

As the size of corporate investments depends on the available financial resources, besides own funds also borrowings, there arises the following issue: In the first decade of this century, the dynamic growth of corporate investments has been supported mainly by debt.

At the onset of the financial crisis, the delayed opening of the economy and the late arrival of international financial markets led to interaction among the financial accelerator channel, the liquidity channel, the banking credit extension channel, and the capital surge. A drastic reversal of foreign capital flows, triggered by banks from the most developed EU countries, caused a contagion of illiquidity, which drastically affected all the countries in the region. It led to bankruptcies and liquidations of firms [30].

After the great financial crisis at the break of the first decade, investment growth slowed down, firms were obliged primarily to deleverage, and at the very beginning, commercial banks stopped crediting the firms (credit crunch). Later after the financial crisis, the criteria and conditions for acquiring credits and loans became very strict. Thus, after the year 2010, we can observe an economic creditless recovery. This phenomenon is known as the Phoenix Miracle [31]. For this reason, we have established another hypothesis and tested it on the case of Slovenian firms, that is: *The rating, defining, and monitoring of firms by commercial banks is closely tied to the firms' indebtedness, which can point us to an important source of corporate investment funding, and which strongly influences corporate investment activities.*

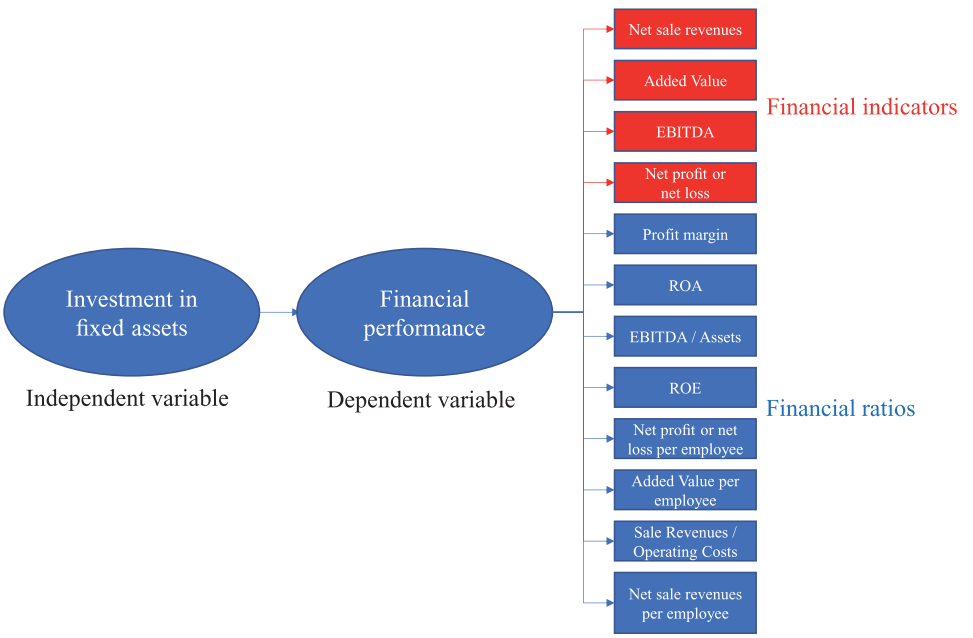

Figure 1.
Conceptual and measurement model of investment impact on business performance. Source: Author.

The rating of firms shows to a certain extent the credit capability of firms, but ultimately not whether they are able to exploit investment opportunities on the market and ensure themselves sustainable growth and development.

2.3 Conceptual and measurement model

Figure 1 presents the conceptual and measurement model relating to the hypothesis that investment in tangible fixed assets as an independent variable directly influences financial performance as a dependent variable, expressed by some most commonly used financial indicators and financial ratios.

The business performance of a firm, defined in our conceptual and measurement model as a dependent variable, can be measured and assessed by a wide range of financial indicators. In our research, the following financial indicators are used: Net sales revenues, Added value, EBITDA, and Net profit or net loss. Furthermore, the following financial ratios are used: Profit margin, ROA, EBITDA/Assets, ROE, Net profit or net loss per employee, Added value per employee, Sales revenues/Operating costs (thriftiness), and Net sale revenues per employee. Both groups, financial indicators and financial ratios, derive from the accounting databases of the firms in our sample.

3. Research methodology

3.1 Questionnaire design

The questionnaire was designed according to the relevant guidelines [32, 33]. Respondents chose among pre-defined possible answers. The closed questions design was preferred since it makes the alignment of answers easier and more reliable, hence facilitating statistical analysis.

The questionnaire consisted of two sections. The first section consisted of key questions inquiring about the opinions of respondents (mainly financial managers and CEOs), about the investment activity in their firms. The questions in this section were split into two subsections. The first one deals with the investment activity in their firms and is relevant for this paper. The second subsection deals with the investment ability. As this research is rather comprehensive and complex, the investment ability is a subject of another paper.[2] Anyhow, the questionnaire as a whole is enclosed in this paper.

The second section of the questionnaire gathered general data on the respondents, such as their position in the firm and age, as well as general data on their firms, for example, the firm's year of incorporation, size, average number of employees, and technical staff.

The first draft of the questionnaire was pilot tested on a convenience sample of 20 financial managers and CEOs. The final version was designed with minor amendments.

The questionnaire analysis relating to the investment activity of the firms in the study period is presented in Section 4.1 of this paper.

[2] See a paper "Impact of companies' investment ability on their performance" [34].

3.2 Data collection and sample

The primary data were collected in the period from January to April 2017 by means of the questionnaire being distributed to 1142 Slovenian large and medium-sized enterprises, sorted from A to J according to the Slovenian Standard Classification of Activities (SKD) 2008, V2. The segmentation into large and medium-sized firms was based on the Slovenian Companies Act (Paragraph 55, ZGD-1-NPB14). In total, 293 questionnaires were completed (of which 91.14% were useable). Thus, we have received 267 valid questionnaires (with a respondent rate of 23.40%). The sample consists of large firms (29.21%) and medium-sized firms (70.79%). Firms from all Slovenian statistical regions [12] were included in the sample. In terms of their legal and organizational status, the majority of the firms in the sample were limited liability companies (74.54%) and stock companies (21.35%). Almost 72% of the firms in the sample fall in the age span between 11 and 30 years, which means that the majority of the firms in our sample are mature from the perspective of their life cycle.

The financial data of the firms that sent back the questionnaires were acquired for the period 2010–2017 from the GVIN database, generated from the annual reports of the firms.

3.3 Data analysis

The causal links in our proposed conceptual model have been tested by bivariate analysis. This is a statistical method used to analyze the relationship between two variables. It enables us to draw conclusions from the sample and generalize them to the entire population. It means that we are able to infer the behavior of the population as a whole based on the results of the sample analysis. This has been carried out by setting up hypotheses, which can be either confirmed or rejected by statistical inference.

By means of the SPSS 25 software platform, we have calculated Pearson's and Spearman's correlation coefficients.

Contingent tables (Crosstabs) have also been used to study links between variables or constructs in our conceptual model and thereby test our research hypotheses. Additionally, we wanted to test the link between two nominal variables. Crosstabs are multidimensional frequency distributions, which generally enable one to infer about the link between two variables.

Values of dependent variables Y, which are in our case financial performance indicators, that is, Net sale revenues, Added value, EBITDA, and Net profit or Net loss, need to be expressed by the independent variable X, in our case by investments in tangible fixed assets, in the form of linear connection:

$$Y = a + \beta X + \varepsilon \tag{1}$$

Our research sample can be written as:

$$y = \hat{a} + \hat{\beta} x \tag{2}$$

The regression line is a line with the equation $y = \overline{a} + \overline{\beta} x$, which best fits the data in the plane (x_1, y_1), (x_2, y_2), ..., (x_n, y_n) (it is determined by the least-squares method) and serves as a mathematical model used to estimate the expected value of the variable Y by a given value of the variable X.

The validity of the linear model can be tested by a variance analysis based on size by the model explained variance for an alternative hypothesis:

$$H_1 : R^2 \neq 0 \text{ (linear model is appropriate)} \tag{3}$$

The reliability of the calculated parameters of the regression line can be tested by the t-test:

$$H_1 : \beta \neq 0 \ (a \neq 0). \tag{4}$$

Let us also state, that explanatory variables in the context of regression are sometimes referred to as endogenous. Thus, ordinary least squares (OLS) can produce biased and inconsistent estimates. In our statistical analysis, we have not included any instrumental variables to avoid biased estimates, which can be considered as one of the limitations of our research.

By testing the hypotheses, we have to arrange the time series of the chosen variables first, for we have conducted a time series analysis. The investment in tangible fixed assets was calculated as the difference between two sets of data for the consecutive years, that is, as a difference between two book values of the tangible fixed assets in year t + 1 and year t. If the book value of the tangible fixed assets in year t + 1 was higher than the book value of the tangible fixed assets in year t, the following conclusion can be made: a firm has increased the book value of its tangible fixed assets, a firm has invested. If the book value in year t + 1 was lower than that in previous year t, a firm has depreciated its tangible fixed assets more than it has invested.

An increase in the book value of fixed assets could be also influenced by a revaluation of the fixed assets. We have not accounted for this issue because the requisite data, that is, revaluation reserves data were not available. For this reason, our calculations might not be quite accurate, but there was no inflation worth mentioning; in fact, in the last years of our study period, there was even deflation. However, we can assume that the firms did not revaluate their tangible fixed assets, or if they did so (of course only a few of them), this might not have caused a serious problem, it can imply only a negligible error in our analysis. However, this issue can be considered as a certain limitation of our research.

Further, we have to calculate for each year of the study period relevant financial indicators or financial ratios for each firm in our sample. To get relevant indicators and ratios for the whole sample, we have scaled them with the net sales revenues of the firms. Similarly, we have done such a scaling with the investment in tangible fixed assets. To get the investment in tangible fixed assets for the whole sample, we have scaled them with the total assets of the firms. Thus, we have avoided possible heteroscedasticity problems in our regression analysis.

4. Empirical results

4.1 An outline of Slovenian firms' investment activity in the period 2010–2017 viewed from various aspects

4.1.1 Exploitation of investment opportunities

Our research embraces in its 8-year period also the last 2 years of the great financial crisis and economic recession, that is, the years 2010 and 2011. Therefore, it is logical

that almost 15% of the firms in our sample responded that they were primarily constrained to deleverage due to the credits and loans acquired in the past. This means that the firms have not or have only partially taken advantage of those business opportunities on the market that required some investments to be made.

Almost 23% of the firms in our sample responded that they did not have sufficient funds to invest, and more than 8% of the firms did not manage to acquire borrowing funds. This also implies that a certain number of firms did not borrow money for new investments in that period because they already had high financial leverage, that is, an inadequate capital structure, or simply that they could not get new credits and loans due to the credit crunch.

More than 45% of the firms in our sample responded that, in the 8-year period, they totally exploited those business opportunities in the market that required some investments. This means that these firms increased their business if we exclude those who only modernized their production process (automation and robotization). As already mentioned, the period after the financial crisis was characterized by a credit crunch. Therefore, we can identify creditless economic growth, which was typical for Slovenia in the period from 2013 up until the end of 2015 [35]. Creditless growth is a special (marginal) form of financial leverage decrease. We even witnessed this decrease later, after the recovery of the Slovenian banking sector, with episodes of the economy recovering without a simultaneous or precursive credit growth recovery. This phenomenon has been perceived in the case of exits from crises by Calvo et al. [31]. The genesis of these crises was closely tied to the unexpected blockade of capital inflow into developing countries. The same authors, as well as others [36], found similar patterns at the time of exits from crises with different geneses, including in developed countries. This phenomenon of creditless growth is called the Phoenix Miracle.

We have checked if such a recovery without credits also took place in the case of our sample firms. **Figure 2** shows that investments in tangible fixed assets increased in parallel with bank credits and loans from the beginning of the previous decade up to the great crisis in 2009. This implies that bank credits and loans were a generator and

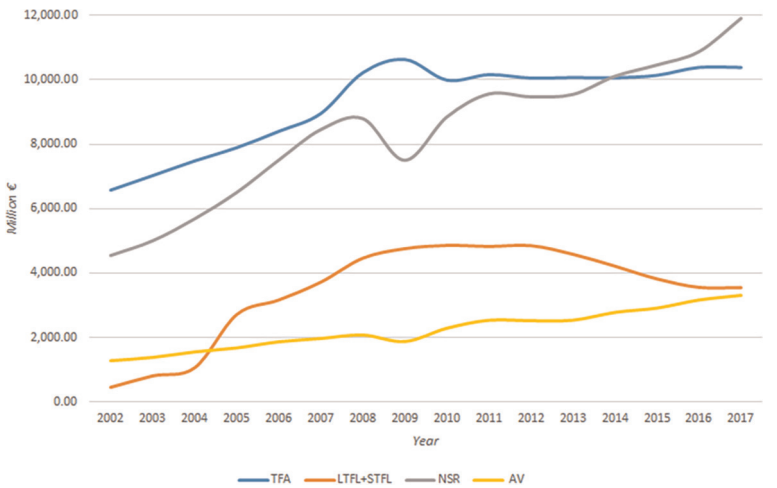

Figure 2.
Increase of tangible fixed assets, net sales revenues, and added value versus decrease of financial liabilities (credits and loans) after the last recession. Source: Author (AJPES database for the period 2002–2017).

accelerator of investment growth.[3] After the great financial crisis and the global recession, investments in the greater part of the firms from our sample stagnated (investments took place in the amount of depreciation, or better said, the firms implemented only replacement investments). Investments started to grow again after 2014, while the post-crisis bank credits and loans apparently decreased up to 2016. The economic recovery of the firms in our sample was accompanied by either a decrease or negative growth in bank credits and loans.

4.1.2 Main themes to invest

The firms in our sample were mostly motivated to invest by technological progress (a need to modernize their technological processes), new opportunities on the market, and an increase in their customers' demand. These three motives or main themes represent more than two-fifths of all the given incentives and impulses to increase investments in the past 8-year period.

4.1.3 Dynamics of investment

More than one-half of the firms in our sample invested in the past 8-year period evenly, that is, without bigger investment spikes. This finding relates to more or less big and medium-sized firms. However, approximately one-fourth of all the firms in our sample invested in a concentrated manner, with an investment spike in 1 or 2 years at the end of the 8-year period. Investment activity was a little bit more pronounced in medium-sized firms in our sample. This can be explained by the fact that those firms that incurred excessive debt after the last financial crisis directed their accumulation into deleveraging and less so into purchasing new fixed assets. We can refer to the financial accelerator and support the above-given statements with findings from the study conducted by Bole et al. [37]. They advocate the thesis that the financial accelerator changes not only in individual phases of the business cycle (boom, bust, recovery) but also with various kinds of investments, including investment in the real economic sector, furthermore in various industries and regions, and last but not least even with respect to the solvency of commodity producers.

Besides data acquired by means of the questionnaire, we also acquired financial data from the AJPES database. Among other things, we looked for the book value of fixed assets of the firms in our sample for each year in the study period 2010–2017. Thus, we found out whether, firstly, their book value increased or decreased in the last 8 years, secondly, what was their average rate of growth or drop, and thirdly, by what kind of dynamics their value changed, that is, evenly or in a concentrated manner at the beginning, end, or in the middle of the studied period.

Table 1 shows the number and structure of the firms that increased or decreased the book value of their fixed assets (2017/2010). The average growth rates of their increase and decrease, respectively, are shown as well. The latter has been calculated as a geometric mean of chain indices through individual years for each firm in our sample, and for all of the firms together as well.

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[3] In the SPSS 25 software platform, we carried out a linear regression between investments as a dependent variable and bank credits and loans as an independent variable. The value of R^2 is 0.842, which means that bank credits and loans can explain the 84.2% variation in investments. For these data, the F statistic is F = 74,49, which is statistically significant at $p < 0.001$ level.

Movement	Number of firms	%
Increase of book value of tangible fixed assets	157	58.81
Decrease of book value of tangible fixed assets	107	40.07
Unchanged book value of tangible fixed assets	3	1.12
Total	*267*	*100*
Positive growth	150	56.18
Negative growth	105	39.33
Zero growth	12	4.49
Total	*267*	*100*
Average rate of increase of book value of tangible fixed assets	16%	
Average rate of decrease of book value of tangible fixed assets	8%	
Average growth rate of investment for all the sample firms	6%	

Source: AJPES database for the period 2010–2017.

Table 1.
Number and structure of the firms according to book value of their tangible fixed assets in the study period 2010–2017.

It can also be seen that 150 firms (a little less than three-fifths of the total) in our research sample had a positive investment growth (16%) in the past 8-year period, furthermore that 105 firms (two fifths) evidenced a negative investment growth (−8%) in the same period, and, last but not least, that approximately 5% of the firms in the sample had zero investment growth. In the period 2010–2017, the average investment growth for all the firms in the research sample was 6% per year. This means that almost three-fifths of the firms invested more in that period than they depreciated their tangible fixed assets.

4.1.4 Efficiency of investment implementation

Almost four-fifths of the firms responded that they realized their investments in tangible fixed assets successfully at the time (only investments bigger than EUR 100,000 were taken into account). A little bit less than one-half of the firms reported that they implemented their investment projects within the scheduled financial budget, and almost two-fifths of the firms asserted that they stuck with the physical scale of their investments.

Considering the first three answers, indicating that the firms finished their biggest investments in tangible fixed assets on schedule (or even sooner), in the planned physical volume, and within their financial budget, we get into the cross-section of a very small number of firms (less than 1% of all the firms in our sample). If we consider the combinations of only two kinds of answers, we get very low percentages as well (a maximum of 7%). This supports the thesis that quite a few of the firms did not implement their investment projects successfully, which can imply their insufficient investment ability.

Whether the size of a firm has any impact on investment project implementation has been tested by the chi-square test χ^2. The test has shown that there is no statistically significant correlation between these two variables (Pearson's chi-square = 0.686,

p = 0.421). The size of the firms in our sample does not influence investment project implementation neither in terms of financial budget nor time schedule.

4.1.5 Achievement of the planned economic effects of the realized investment projects

Figure 3 shows what real economic effects compared to goals the firms realized with their investments in the 8-year period.

It can also be seen that more than two-thirds of the firms in our sample responded that they realized the economic effects of their investments in the range of 91–100% in comparison to what they had planned (a little bit less than one-half of the firms in the sample), or even exceeded it (one-fifth of the firms in the sample). This means that the investments of big and medium-sized Slovenian firms in tangible fixed assets should contribute considerably to business performance improvement. One-fifth of the firms in the sample estimated the economic efficiency of the implemented investment projects in a range of 71 to 90% in comparison to what they had planned, and less than one-tenth of the firms in the sample are critical of the results achieved (in the range of up to 70%; 2% below 51%). From this review, the conclusion can be drawn that the output of investments in tangible fixed assets was at a level of a little over two-thirds (68.17%).

In this case, we have also carried out the chi-square test χ^2 to test the hypothesis whether the size of firms influences the achievement of the economic effects of their realized investments. The test has revealed that there is no correlation between these two observed variables.

4.2 Hypotheses testing

4.2.1 Testing of the hypothesis: the rating of firms influences their borrowing as a relevant factor of the firms' investment activity

The investment activities of firms are mainly restrained by financial restrictions, which to some extent exclude the possibility to exploit opportunities for growth. According to Fazzari et al. [38], Kaplan and Zingales [39], Dasgupta et al. [40], Gatchev et al. [41], Ostergaard et al. [42] and Drobetz et al. [43], the restrictions

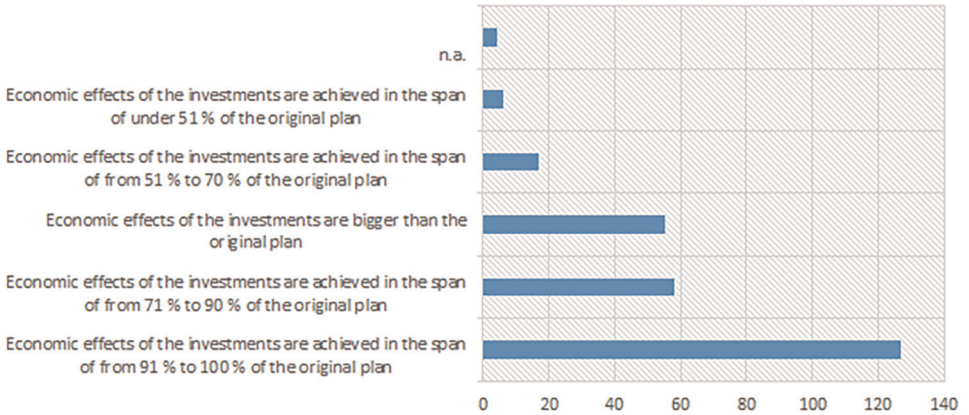


Figure 3.
Achievement of the economic effects of the investments implemented. Source: Investment ability of the companies, questionnaire 2018.

derive from market imperfections, especially from information asymmetry and wrong choice, all being dependent on the firms' ratings. The latter is crucial for acquiring borrowing funds, that is, bank credits and loans. Due to these restrictions, firms cannot access the borrowing funds for their investments as economically justified by positive net present value (one of the dynamic investment criteria). For this reason, their investments can be funded only by their own funds. Therefore, the volatility of proper funds can be demonstrated through the volatility of their investments, although the elasticity of investments increases relative to operating cash flow. On the other hand, well-performing firms are not financially restricted, their investments are independent of short-term oscillations in business performance, and elasticity is zero or very low [35]. Fazzari et al. [38] claim that when operating cash flow increases, the firms with restricted access to funds and with good investment opportunities use this cash flow to fund their investments.

Table 2 shows the ratings of firms from our sample. Besides the qualitative data (the classification of firms into rating categories based on answers from the questionnaire), we also used the NFD/EBITDA ratio as an approximate estimate for the rating of the firms, calculated from the data acquired for each year from the AJPES database. The NFD/EBITDA ratio explains relatively well the current capability of a firm to generate cash flow for repaying its debt, which has been supported by other authors who used this ratio as well [35]. In the financial crisis, the firms decreased their debt due to their own motives and reasons. The consequences of the customers' and suppliers' push, which increased the insolvency of business partners, cannot be overlooked either. In such a situation, the greater part of cash flow is assigned to lowering indebtedness. Consequently, the sensitivity of investments to operating cash flow is lower than usual.

For the last year of the study period (2017), we tried to check whether there is any correlation between these two sets of data. To find out, in the case of our sample of big and medium-sized firms, how the NFD/EBITDA ratio reflects the capability of a firm to generate cash flow for debt repayment and thus also the investment ability of the firm [34], all the firms were sorted into three segments according to their indebtedness. In the first segment, there are firms with an NFD/EBITDA ratio less or equal (≤2). At the beginning of our study period (in 2010), there were 109 such firms (40.8%), and at the end of the study period (2017), there were 164 such firms (61.4%). These firms were able to repay their financial debt within the time span of 2 years, which means that the banks were ready to lend them new credits and loans. As a matter of fact, we put into the first segment all those firms that were net creditors

Ratio	**Rating**					
NFD/EBITDA	**A**	**B**	**C**	**E**	**Unknown**	**Total**
≤2	151	10	1		2	164
>2 in ≤5	47	13	2	2	1	65
>5	16	17	3		1	37
n.a.	1					1
Total	215	40	6	2	4	267

Source: Questionnaire and AJPES database for 2017.

Table 2.
Number of firms in terms of rating and indebtedness measured by the NFD/EBITDA ratio.

with negative net debt. These were the firms whose cash balance exceeded financial liabilities. In 2010, there were 42 such firms (15.7%), and in 2017 there were 77 such firms (28.8%). In the second segment, we put firms that were more indebted, having higher financial leverage. Their indebtedness ranged from 2- to 5-times EBITDA. In 2010, there were 72 such firms (27%), and in 2017 there were 65 such firms (24.3%). In the third segment, we put firms with very high financial leverage, having a NFD/EBITDA ratio higher than 5. In 2010, there were 71 such firms (26.6%), and in 2017 there were 37 such firms (13.9%). The firms with a negative EBIDTA, that is, a negative operating cash flow, were excluded from our analysis. There were only a few.

For the last year of the study period (2017), we carried out the chi-square test. For each variable we set two categories, "good rating" and "bad rating", and "appropriate" and "inappropriate" indebtedness. Pearson's chi-square test, χ^2, examines if there is any correlation between two nominal variables, in our case between the rating of the firms and their financial leverage (indebtedness). The Crosstabs procedure generates a contingent table, the results of the chi-square test, its characteristics, and the significance value. The results are presented in **Tables 3** and **4**.

Pearson's chi-square test examines if the two perceived variables are independent. If the significance value is small enough (Sig. < 0.05), then we reject the hypothesis

			Indebtedness		
			Inadequate	**Adequate**	**Total**
Rating	Good	Count	68[a]	149[b]	217
		Expected count	87.3	129.7	217.0
		% within rating	31.3%	68.7%	100.0%
		% within indebtedness	64.8%	95.5%	83.1%
		% of total	26.1%	57.1%	83.1%
		Std. residual	−2.1	1.7	
	Bad	Count	37[a]	7[b]	44
		Expected count	17.7	26.3	44.0
		% within rating	84.1%	15.9%	100.0%
		% within indebtedness	35.2%	4.5%	16.9%
		% of total	14.2%	2.7%	16.9%
		Std. residual	4.6	−3.8	
	Total	Count	105	156	261
		Expected count	105.0	156.0	261.0
		% within rating	40.2%	59.8%	100.0%
		% within indebtedness	100.0%	100.0%	100.0%
		% of total	40.2%	59.8%	100.0%

Each subscript letter (a, b) denotes a subset of indebtedness categories whose column proportions do not differ significantly from each other at the 0.05 level.
Source: Questionnaire and AJPES database for 2017.

Table 3.
*Relationship between the rating of the firms and their indebtedness measured by the NFD/EBITDA ratio. (rating*indebtedness crosstabulation).*

	Value	df	Asympt. Sig. (two-sided)	Exact Sig. (two-sided)	Exact Sig. (1-sided)
pearson chi-square	42.341[a]	1	.000	.000	.000
Continuity correction[b]	40.175	1	.000		
Likelihood ratio	43.388	1	.000	.000	.000
Fisher's exact test				.000	.000
N of valid cases	261				

Source: Questionnaire and AJPES database for 2017.
[a]0 cells (0.0%) have an expected count of less than 5. The minimum expected count is 17.70.[b]Computed only for a 2 × 2 table.

Table 4.
Chi-Square test for the rating of the firms and their indebtedness.

that variables are independent, and we can trust that the variables are somehow correlated [44]. The value of chi-square statistics, shown together with the degrees of freedom and the significance value, is 42.341, which is within the round-off error. This value is strongly significant ($p < 0.001$), which shows that the rating of firms has a strong impact on whether the indebtedness of firms is appropriate or inappropriate, or the other way around, that the indebtedness of firms has a strong impact on whether the rating of the firms is good or bad.The very distinctive result shows that there is a correlation between rating and indebtedness irrespective of whether the latter is appropriate or inappropriate. In other words, in our sample of answers, there is a distinctive difference (i.e., between the portion of firms having a good rating and the portion of firms having a bad rating) in the case of two kinds of indebtedness. By means of the z-test, we have found that well-rated firms are significantly less indebted, and inversely, that poorly-rated firms are significantly more indebted and have higher financial leverage. This important finding can be considered from another perspective as well, that is, in percentage: more than 60% of the firms with a good rating (A and B) are appropriately indebted, and more than 85% of the firms with a bad rating (C, D, and E) are inappropriately indebted. The following conclusion can be drawn: the indebtedness of a firm significantly influences the rating, that is, the rating of a firm is good if a firm is appropriately (less) indebted and hence has low financial leverage.

Similarly, we have calculated the correlation between these two kinds of data, shown in **Table 2**. It can be seen that there were 151 firms in 2017 whose financial managers reported the rating A (at least their commercial banks rated them like this) according to the financial data from the AJPES database, and these firms had an NFD/EBITDA ratio of less than or equal 2. Such a result is logical. It is also logical that a firm with the rating E was in the category with the highest NFD/EBITDA ratio, with high financial leverage. However, it is not logical that at the same time 16 firms were rated A while being very much indebted, or that a firm with the rating C is in the first category, with low financial leverage.

We have calculated Spearman's correlation coefficient, r. Both sets of data have got an appropriate rank, rating A being assigned the highest rank, that is, 5, and rating E the lowest rank, that is, 1. The least indebted firms, that is, the firms having an NFD/EBITDA ratio of less than 2, are given rank 3, medium indebted firms rank 2, and the most indebted firms rank 1. The results are shown in **Table 5**.

					Rating
Spearman's rho	**Rating**	**Bootstrap[b]**	**Correlation coefficient**		**1000**
			Sig.(2-tailed)		
			N		261
			Bias		.000
			Std. Error		.000
			Bca 95% Confidence Interval	Lower	1000
				Upper	1000
	NFD/EBITDA	Bootstrap[b]	Correlation coefficient		.437**
			Sig. (2-tailed)		.000
			N		261
			Bias		.000
			Std. error		.055
			BCA 95% Confidence Interval	Lower	.332
				Upper	.539

***Correlation is significant at the 0.01 level (2-tailed).*
[b]Unless otherwise noted, bootstrap results are based on 1000 bootstrap samples.
Source: Questionnaire and AJPES database for 2017.

Table 5.
Spearman's correlation coefficient for two variables, the rating of the firm and the NFD/EBITDA ratio.

4.2.2 Testing of the hypothesis: Increase of investment in tangible fixed assets influences some financial indicators and ratios

Let us further test the hypothesis stating that an increase of investment in tangible fixed assets significantly influences some financial performance indicators, such as Added value per employee, Profit margin, ROE, ROA, Net sales revenues per employee, Net profit per employee, EBITDA to Assets, and Net sales revenues to Costs of goods sold. For this analysis, we used a longer time series of financial data for the firms in our sample, encompassing the 18-year period from 2000 to 2017.

As already mentioned, the analysis is based on financial data from the AJPES database, and its chart of accounts derived from the general ledger of firms. Account No. 0010102 presents the net book value of tangible fixed assets. This value constantly changes over time, within an individual year, and over the years. This value changes due to depreciation and the sale-off of assets (disinvestment). Both of these reduce this value on said account. On the other hand, this value also changes due to the purchase of new assets (including those acquired by financial lease). As already explained, for the purpose of our analysis, revaluation, which could have influenced the net book value of assets, was ignored. As inflation during our study period was low (in some years there was even deflation), we assumed that it had no important impact on the aforementioned value. If the difference between the purchasing value of new tangible fixed assets and the depreciated value of the existing fixed assets or the value reduced by disinvestments is positive, we get net investments in tangible fixed assets. If we consider these net book values of tangible fixed assets throughout a longer period of time, we can find out from the differences (or from calculated chain indexes) whether the firms in our sample invested or disinvested. The difference

between the two annual balances (at the end of each calendar year, as of December 31, Year X) of the net book values of tangible fixed assets $TFA_t - TFA_{t-1}$ (Account No. 0010102) represents the net investment in tangible fixed assets in year t.

As we quite considerably prolonged our study period, and to assure comparability of the data through time, all values were properly corrected by deflators or inflators of the individual year (SURS—recalculation of the financial data in time series due to inflation for the period 2000–2017).

We computed the average values for each of the above-presented variables for each individual year for the entire sample of 267 firms.

Chain indexes have been computed for each firm included in the sample and on their basis the average growth rate for each variable. The geometric mean has been computed as follows:

$$\left(\prod_{i=1}^{n} a_i\right)^{\frac{1}{n}} = \sqrt[n]{a_1 a_2 a_3 \ldots a_n} \tag{5}$$

For carrying out linear regression, investment in tangible fixed assets was taken as an independent variable, while several financial indicators, such as Net sales revenues, Added value, EBITDA, Net profit, ROA, and others, were accounted for as dependent variables for each year of the computed average values.

Impact of the increase of investment in tangible fixed assets on Net sales revenues.

Linear regression for the first pair of dependent variables, that is, for tangible fixed assets and Net sales revenues is calculated and presented in **Tables 6–9**.

R^2 is 0.673, which means that investment in tangible fixed assets represents more than two-thirds of the variation in Net sales revenues. In other words, if we try to explain why firms increase the sale of their products/services and commodities/materials, we can look at the variation in Net sales revenues. There is a great number of factors that can explain this variation. In 67%, though, this variation can be explained by our model as comprising only investments in tangible fixed assets. Certainly, there are also other factors, other variables that influence the increase in sales.

Model	R	R square	Adjusted R square	Std. error of the estimate
1	0.821[a]	0.673	0.652	4054964.139

[a] *Predictors: (Constant), Tangible fixed assets.*

Table 6.
Model summary.

Model		Sum of squares	df	Mean square	F	Sig.
1	Regression	5.085E+14	1	5.085E+14	30.926	0.000[b]
	Residual	2.466E+14	15	1.644E+13		
	Total	7.552E+14	16			

[a] *Dependent variable: net sales revenues.*
[b] *Predictors: (constant), tangible fixed assets.*

Table 7.
ANOVA[a]

Model		Unstandardized B	Coefficients std. error	Standardized coefficients beta	t	Sig.
1	(Constant)	−2365465.1	9981459.460		−2.370	0.032
	Tangible fixed assets	1.505	0.271	0.821	5.561	0.000

[a] *Dependent variable: Net sales revenues.*

Table 8.
Coefficients[a].

Model		B	Bias	Std. error	Bootstrap[a] Sig. (2-tailed)	BCa 95% Confidence Interval Lower	Upper
1	(Constant)	−23654658.1	−818984.712	11901364.94	.116	−47733387.8	−666241.520
	Tangible fixed assets	1.505	0.027	0.338	0.012	0.894	2.193

[a] *Unless otherwise noted, bootstrap results are based on 1000 bootstrap samples.*
Source: *Questionnaire and AJPES database for 2017.*

Table 9.
Bootstrap for coefficients.

The ANOVA tells us whether the model, overall, results in a significantly good degree of prediction of the outcome variable. The sums of squares and the degrees of freedom are calculated. From these two values, the average sums of squares (the mean squares) can be calculated by dividing the sums of squares by the associated degrees of freedom. The most important part of this calculation is the F-ratio and the associated significance value of that F-ratio. For these data, F is 30.93, which is significant at $p < 0.001$ (because the value in the column labeled Sig. is less than 0.001). This result tells us that there is a less than 0.1% chance that an F-ratio this large would happen if the null hypothesis were true. Therefore, we can conclude that our regression model overall predicts Net sales revenues significantly well. Such a result is quite logical and expected.

Calculation of linear regression for the investments in tangible fixed assets and Net sales revenues.

Other factors that can influence the bigger volume of sales (although they are not considered in our research) can be the increase in sales prices, the increase in productivity, export incentives or customs relieves, business process rationalization and improvement, organizational changes, etc.

As previously mentioned, the ANOVA shows whether our model predicts the outcome variable well enough. However, it does not show the contributions of individual variables, except in our model where only one independent variable exists, and we can infer that this variable is a good predictor.

The regression calculation provides estimates of the model parameters (the beta values) and the significance of these values. From this calculation, we can conclude that b_0 is EUR 23.6 million, which can be interpreted as follows: when no money is spent on investment in tangible fixed assets (when X = 0), the model predicts that all firms in our sample will decrease their Net sales revenues in the amount of EUR 23.6 million. We can also read off the value of b_1 from the regression calculation. It is 1.505.

Although this value constitutes the slope of the regression line, it is more useful to think of it as representing the change in the outcome associated with a unit change in the predictor. Therefore, if our predictor variable is increased by one unit (if the investment in tangible fixed assets is increased by EUR 100), then our model predicts that EUR 150.5 of extra Net sales revenues will be generated, which can be considered a good result with respect to the fact that an increase in investment contributes more than two thirds to the increase in Net sales revenues.

Let us look in this calculation at the values for t. The t-test tells us whether the value of b is different from zero (0). The statistical tool SPSS 25 provides the exact probability of the perceived value of t occurring if the value of b in the population were zero. If this observed significance is less than 0.05, then the result reflects a genuine effect. In our case, this holds entirely. For one t value, the probability equals 0.032, for the other t value, the probability equals 0.000. Thus, we can claim that the probability of these t values occurring if the values of b in the population were zero is less than 0.001. Therefore, the values of b are significantly different from zero. In the case of the b for investment in tangible fixed assets, this result supports the thesis that investment in tangible fixed assets makes a significant contribution ($p < 0.001$) to predicting the increase in Net sales revenues.

In the same calculation, the bootstrap confidence interval suggests that the population of b values for tangible fixed assets is likely to fall between 0.894 and 2.193, and because this interval does not include zero (0), we would conclude that there is a genuine positive relationship between investment in tangible fixed assets and Net sales revenues. Also, the significance associated with this confidence interval is $p = 0.012$, which is significant. **Figure 4** shows the distribution of correlation coefficients between these two variables for all the firms in our sample.

Linear regression has also been calculated for the other pairs of dependent variables. We were always interested in the impact of the independent variable, that is, investment in tangible fixed assets on financial indicators. Regarding Added value, this impact is medium strong ($R^2 = 0.531$; $b_1 = 0.461$; Sig.: 0.001). In the case of b for investment in tangible fixed assets, this result means that investment in tangible fixed assets significantly contributes ($p = 0.001$) to predicting the increase of Added value. An increase of tangible fixed assets by EUR 1000 generates EUR 461 of Added value.

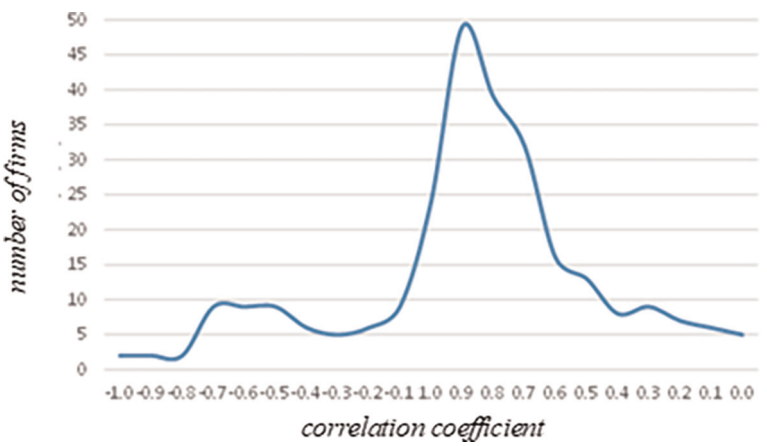


Figure 4.
Distribution of correlation coefficients for two variables, Investment in tangible fixed assets and net sales revenues, for all the sample firms in the period 2000–2017.

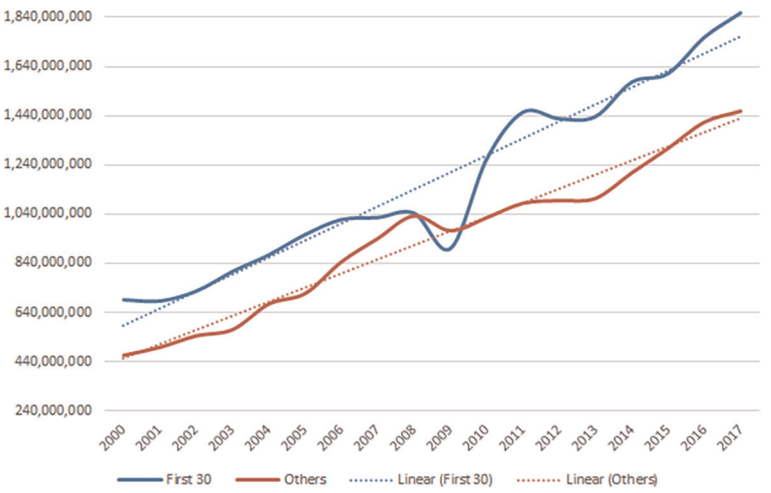


Figure 5.
Movement of added value for the 30 biggest sample firms in the period 2000–2017.

4.2.2.1 Impact of the increase of investment in tangible fixed assets on Added value

As this financial performance indicator is very important for the firms' benchmarking, the dynamics of Added value for the firms in our sample in the period 2000–2017 are shown in **Figure 5**. From this chart, a change in the relationship between the Added value of the 30 biggest firms in the sample and the Added value of the remaining firms in the sample over the 18-year period can be seen as well. Each year, except in the year of the last biggest financial crisis and global economic recession (2009), the 30 biggest firms in the sample taken together generated more Added value than the rest of the firms in the sample. Afterward, the scissors started to open gradually.

Figure 6 shows, for all the firms in our research sample, a course of two performance indicators, that is, productivity expressed by Net sales revenues per employee and Added value per employee. The data are presented for the period 2000–2017. It can be seen how the financial crisis and economic recession hurt our sample firms. After the crisis, Added value per employee increased faster than Net sales revenues per employee, although the firms did not yet reach their prior levels.

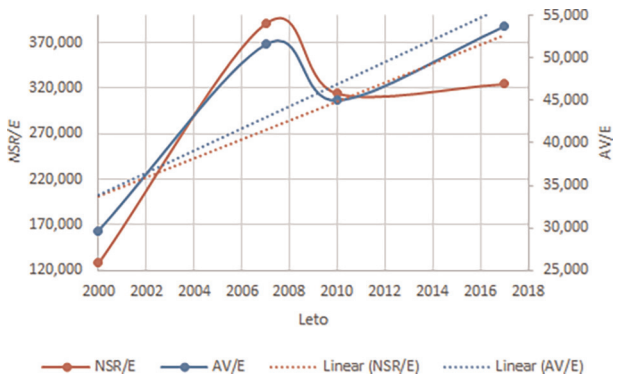


Figure 6.
Movement of productivity for the sample firms in the period 2000–2017.

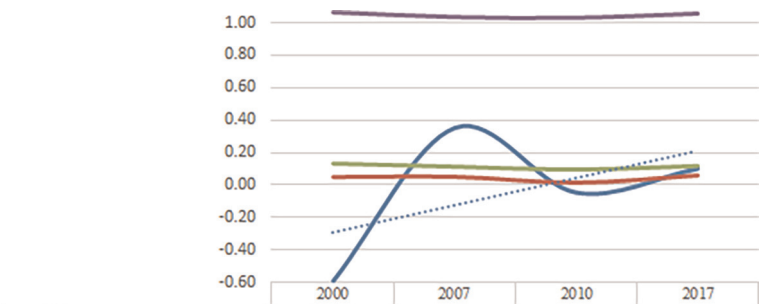
4.2.2.2 Impact of the increase of investment in tangible fixed assets on financial performance ratios

Impact of the independent variable, that is, investment in tangible fixed assets, on the financial indicator EBITDA is weak (R^2 = 0.305; b_1 = 0.145; Sig.: 0.02). In the case of b for investment in tangible fixed assets, the result suggests that investment contributes significantly (p = 0.02) to the prediction of EBITDA increase. The increase of investment in fixed assets by EUR 1000 generates an operating cash flow in the amount of EUR 145. This relates to one year. However, the investment generates operating cash flow for its entire life span, which lasts several years, depending on the type of tangible fixed asset. By all means, this is not high profitability, though, if we compare it to the profitability of common riskier financial investments.

Let us consider the question of how investment in tangible fixed assets influences Net profit. In the case of this particular financial indicator, the predicting value of the regression coefficient b becomes totally vague (R^2 = 0.025). As a matter of fact, in the period 2000–2017, there was no profitability of investments implemented in tangible fixed assets by the firms in our sample and measured by Net profit. Taking into account interests, we get an answer as to why Net profit is relatively weak or even negative (loss). As already explained, the firms substantially increased their indebtedness due to investments before the financial crisis in 2008. This implied high rates of interest paid to creditors, which lowered their Net profit a great deal.

As there is a strong positive correlation between investment in tangible fixed assets and Net sales revenues (their impact amounts to more than two thirds), we could draw the conclusion that even an increase of Net sales revenues due to investments positively influences select financial performance ratios, such as ROA, ROE, EBITDA/Assets, and Sales revenues/Operating costs.

Consequently, we could expect an increase in ROA (return on assets). Good exploitation of the production assets should imply a higher ROA. The question can be raised whether the tangible fixed assets were well used (does the production run in fewer than three or four shifts?), and last but not least, whether the firms in our sample met all the customers' needs. Linear regression shows a statistically significant but relatively weak correlation between ROA and Net sales revenues (R^2 = 0.236; Sig.: 0.048).



	2000	2007	2010	2017
ROE	-0.59	0.35	-0.05	0.10
ROA	0.05	0.05	0.01	0.05
EBITDA/Assets	0.13	0.11	0.10	0.12
Sales revenue / Cost of goods sold	1.07	1.04	1.04	1.06

Figure 7.
Movement of profitability ratios and sales revenues/operating costs ratio for the sample firms in the period 2000–2017. Source: AJPES database of the sample firms for the period 2000–2017.

Similar findings about a weak correlation between the compared variables have been revealed with other financial performance ratios, specifically ROE, EBITDA/Assets, and Net sales revenues/Operating costs. For all of them, linear regression with Net sales revenues has been calculated. The course of the relevant ratios for the firms in our sample for the period 2000–2017 is presented in **Figure 7**. The blue curve presenting ROE is strongly accentuated. This ratio was high in 2007 (0.35), before the financial crisis, then it kept decreasing up to 2010. The owners' capital of the firms in our sample reached average annual profitability of 10% no sooner than in 2017.

4.2.2.3 Trend of the increase of investment in Slovenian firms compared to the course of select financial indicators in the period 2000–2017

Figure 8 presents the trend of nominal average values of some of the most relevant financial indicators, including financial costs (interests), for the population of our sample firms in the period 2000–2017. It is understood that this 18-year time span also includes a period denoted by a financial crisis and global economic recession, which endured from 2008 to 2012. The dynamic growth of financial indicators, for instance, Net sales revenues, Added value, and Net profit, stopped in 2009 (of Net profit already in 2008). The inertia of the growing trend of the increase of investments in tangible fixed assets, however, lasted up until the end of 2009 (finishing the implementation of investments made before the crisis). In 2010, there is a considerable decrease in the book value of tangible fixed assets (touching bottom) as the book value of these assets decreased by 6% and remained at this level until 2015. A year later, the average book value of such assets increased by 3%, although it did not yet reach its pre-crisis level. On the other hand, after a considerable drop in 2009, Net sales revenues started to increase slightly, even during the crisis. Similar findings have been revealed for Added value. The crisis had the biggest impact on Net profit, which started to decrease considerably in 2008. It grew a little bit in the next 2 years but

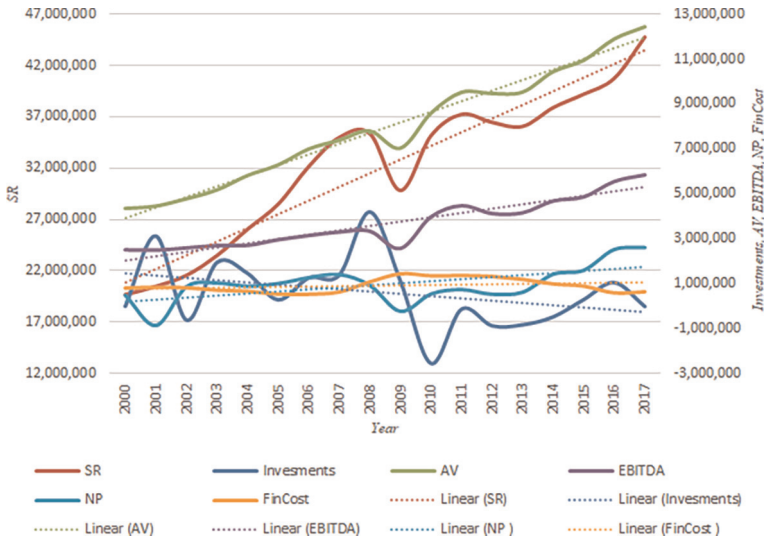


Figure 8.
Impact of investment in tangible fixed assets on select financial ratios for the sample firms in the period 2000–2017.

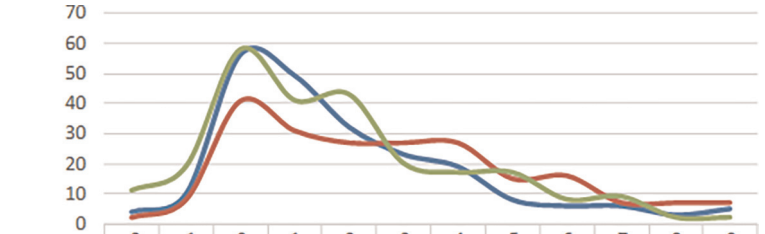
remained at half its 2007 value until 2013. From 2008 to 2013, the total financial costs (interest) for our sample firms were in fact higher than their total Net profit.

4.2.2.4 The changing of financial costs (interest) due to the indebtedness of firms and its impact on profit margin

While estimating investment profitability, all the stakeholders who provided funds for the investments must be taken into account. As this includes financial institutions, the interests on credits and loans constitute returns generated by investment projects. These returns do not pertain to the firms or their owners, though, they are returns produced only by the investments.

For this reason, we are also interested in how Financial costs (interests) changed in the study period – the relevant data are available for the sample firms for the period 2005–2017 – due to the financial leverage, and what is the linear regression between the NFD/EBITDA ratio and Financial costs. **Figure 9** shows three curves of NFD/EBITDA ratio distribution for three temporal cross-sections (cuts), that is, for 2007 (before the financial crisis), 2010 (during the financial crisis), and 2017 (after the financial crisis). It can be observed that the red curve representing a normal NFD/EBITDA ratio distribution for the sample firms for 2010 is asymmetric to the right (the same goes for the other two curves), more flattened (the other two curves are more squeezed, with higher peaks), more elongated (stretched) to the right, and generally lies above the other two curves. This means that in the year of the last biggest financial crisis, absolutely more firms had a higher NFD/EBITDA ratio (more EBITDA was needed to cover net financial debt). On the curve, this is visible to the right from value 0. The left side of the curve from value 0, which lies underneath the other two curves, implies a similar conclusion. Those firms in our sample that were not indebted—meaning that their NFD/EBITDA ratio was negative—had more cash and cash equivalents or a lower EBITDA or both at the time of crisis. Thus, more firms had an NFD/EBITDA ratio equal to 2 in 2007 and 2017 than in the years of the crisis.

As Net profit is the main source for repaying debt, we were also interested in the relationship between the indebtedness of our sample firms and their profit margin throughout the study period. This is shown in **Figure 10**. The profit margin started to improve right after the financial crisis and economic recession, and it reached 5% in 2017. The firms with higher financial leverage generated financial resources for repaying their debt. This thesis can be supported by the finding that the firms in our sample started to decrease their indebtedness in the same period. The NFD/EBITDA



	-2	-1	0	1	2	3	4	5	6	7	8	9
2007	4	10	56	49	32	23	19	8	6	6	3	5
2010	2	8	41	31	27	27	27	15	16	7	7	7
2017	11	19	58	41	43	20	17	17	8	9	2	2

Figure 9.
Distribution of NFD/EBITDA ratios for the sample firms for the years 2007, 2010, and 2017.

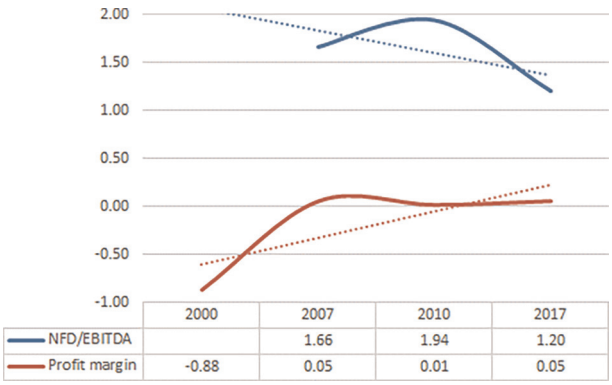


Figure 10.
Movement of indebtedness (NFD/EBITDA ratio) and profit margin of the sample firms in the period 2000–2017. Source: AJPES database of the sample firms for the years 2000, 2007, 2010 and 2017.

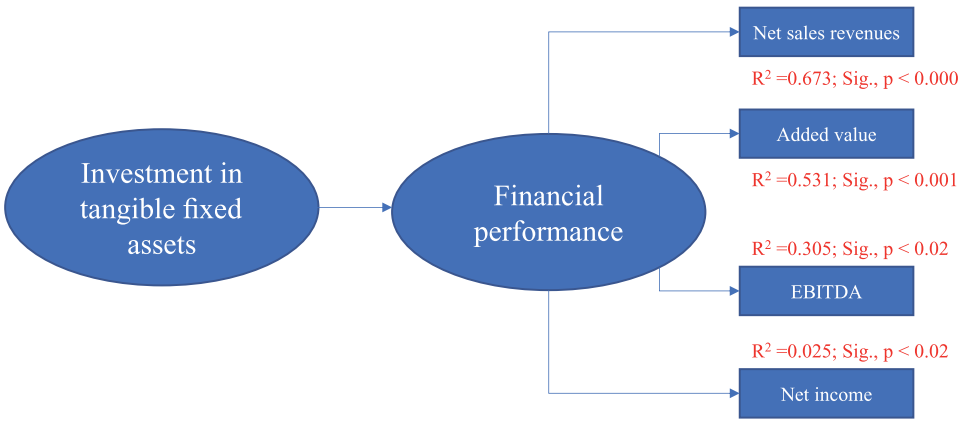


Figure 11.
Estimate of the conceptual model of the impact of investment in tangible fixed assets on business performance for Slovenian firms. Source: Author.

ratio—which was almost 2 in the year 2010—reached 1.20 in 2017. As already mentioned, this is a weighted average ratio of all 267 firms, calculated by means of the weights of the Net sales revenues of each firm.

Following our findings and statistical analyses, our conceptual model can be adjusted so that only those financial indicators are included where there exists a statistically strong and medium-strong correlation with investment in tangible fixed assets. From **Figure 11**, looking at the correlation coefficients, it can be understood that the correlation is strong with Net sales revenues, Added value, and EBITDA, and less so with Net profit. However, only very weak correlations exist between investment in tangible fixed assets and financial performance ratios. Therefore, we skipped them in **Figure 11**.

5. Conclusion, limitation, and future directions

This study is based on the micro theory of investment and theoretical approaches to measuring firms' financial performance. It relies on a simple conceptual model consisting

of only two constructs, investment in tangible fixed assets on one side and financial performance on the other. By means of this model, we try to find out and assess how much investment in tangible fixed assets improves the business performance of firms, expressed and measured by the relevant financial indicators and financial ratios.

Let us first summarize the general findings from the empirical part of the research, based on the answers of the financial managers responding to the questionnaire. A little bit less than half of the sample firms exploited the investment opportunities in the study period 2010–2017 in their entirety. The other firms exploited their investment opportunities partly, while some firms exploited none of them since they were primarily obliged to deleverage or did not have enough funds at their disposal, neither their own nor borrowed. They could not access borrowing funds due to either the credit crunch or their excessively high financial leverage.

The prevailing motives of the firms to invest were a need to modernize technology processes, to exploit new opportunities on the market, and to meet the growing demands of customers (new increasing orders).

In the investigated 8-year period, more than one-half of the firms under study invested evenly, without bigger investment spikes, whereas approximately one-fourth of the firms invested in a concentrated manner, with an investment spike in 1 or 2 years toward the end of this period.

A little bit less than three-fifths of the firms evidenced a positive investment growth (16%), while two-fifths of them reported a negative growth (−8%). All the firms in our research sample evidenced an average annual investment growth rate in intangible fixed assets of 6%.

In terms of investment implementation efficiency, almost four-fifths of the firms realized their investment in tangible fixed assets successfully, meaning on time, with a little bit less than one-half of the firms performing their investment within the scheduled financial budget, and almost two-fifths in the planned physical scale, that is, without additional works and assets. If all the aspects of efficiency are taken into account simultaneously, quite a few of the studied firms were not efficient enough throughout the realization of their investment projects. In this, the size of the firm did not play a special role.

From the point of view of achieving economic effects, investments in tangible fixed assets are supposed to contribute a great deal to the firms' business performance improvement, which partly agrees with the findings of our conceptual model.

To verify our conceptual model and test our research hypotheses, we analyzed a temporal series of financial data extending back to the year 2000. In this way, we captured a period of intensive investment in the first decade of this century until the occurrence of the great financial crisis in 2008.

The results of our research carried out on big and medium-sized Slovenian firms for the period 2000–2017 partly support our hypotheses set up in the introduction. Investment in tangible fixed assets positively influences the financial performance of firms, as expressed by financial indicators and financial ratios. Statistically significant (Sig., $p < 0.000$), there exists a strong correlation between investment in tangible fixed assets and Net sales revenues ($R^2 = 0.673$), which has already been confirmed by studies undertaken by Licandro et al. (2001) and Grazzi et al. [5]. However, there is also a quite strong statistically significant (Sig., $p < 0.001$) correlation between investment in tangible fixed assets and Added value ($R^2 = 0.531$), which has not yet been substantiated in the literature. Statistically significant is also the correlation between investment in tangible fixed assets and the operating cash flow (EBITDA); it can be designated as a medium-strong correlation ($R^2 = 0.305$). This particular

relationship has not been studied yet or is at least not observed in the literature. Last but not least, there is a statistically significant correlation between investment in tangible fixed assets and Net profit (Sig., $p < 0.02$), which has been previously supported by Grazzi et al. [5]. However, in our case, this correlation is negligible ($R^2 = 0.025$).

Our research has not revealed any significant correlation between investment in tangible fixed assets and the selected financial ratios we originally included in our conceptual model. There is no correlation found between investment in tangible fixed assets and financial ratios, specifically Added value/Employee, Profit margin, ROE, ROA, Net sales revenues/Employee, Net income/Employee, EBITDA/Assets, and Business revenues/Operating costs.

We are aware of the limitations of the present study, in terms of the relatively small sample size and company size, and the endogeneity of the variables included in our linear model. Our sample includes a relatively high number of large and medium-sized firms. If the survey had been conducted internationally, it would have included a greater number of large firms, where the impact of strategic investments is more pronounced. Endogeneity refers to situations in which an explanatory variable is correlated with the error term. By using an instrumental variable in a linear model more consistent estimates may be obtained.

Another limitation of our research is a lack of data referring to the revaluation reserves in the balance sheet of the firms in our sample, which might be considered as a certain deficiency in the calculations of the financial ratios.

The third limitation refers to the methodological part. Instead of conducting time series analysis, we use geometrical means, which caused a certain reduction of the observations in our model. Consequently, the results could be more accurate.

In the future, we also plan to introduce certain methodological improvements in the questionnaire, which will include a number of other determinants from sources found in the field of investment activity, and performance indicators, including non-financial ones. The relevant literature furthermore led us to consider the directions of causality in the model. Since our research is based on a cross-sectional database, we cannot prove causation but can only confirm the assumed paths. The direction of causality could be determined only by a longitudinal study, which represents an important opportunity for further research.

A. Questionnaire

#V	Questions
1	Data on interviewee
1.1	Questionnaire completed by
1.2	E-mail address of the interviewee
1.3	Position in the company
1.4	Number of years in this position in the company
2	Information on the company
2.1	Identification number of the company /Matična št. je sicer Company Registration Number
2.2	Name of the company

#V	Questions
2.3	The company is situated at/in ...
2.4	Address of the company
2.5	Size of the company
2.6	The year of the company's foundation
2.7	Legal and organizational status of the company
2.8	Core business/activity of the company according to SKD 2008
2.9	Predominant activity of the company according to SKD 2008
2.10	Average number of employees in 2017
2.11	Average number of employees in technical (investment) department in 2017
2.12	If your company is a stock company, is it listed on a stock exchange?
2.13	Current rating at the parent bank the company mainly works with
2.13.1	Class A: the companies for which the banks do not foresee any problems with settling their liabilities
2.13.2	Class B: the companies which for the time being have a weak financial strength, but it does not seem to be getting worse and they frequently settle their liabilities with delay
2.13.3	Class C: the companies which do not have sufficient long-term financial resources and the bank does not receive from them satisfactory current information or appropriate documentation regarding their debt
2.13.4	Class D: the illiquid and insolvent companies, whereat there is a high probability for not settling the liabilities
2.13.5	Class E: the companies which are supposed not to be able to settle their liabilities; thus they define their "expected" solvency and according to this estimation they run their proper credit policy
2.14	Management of the company
2.14.1	The company has one-member board (general manager/president of the management board)
2.14.2	The company has a managing board consisting of several members
2.15	Ownership structure of your company
2.15.1	One private shareholder/associate has at least 50% share in the company
2.15.2	Two biggest private shareholders/associates together have at least 50% share in the company
2.15.3	One shareholder/associate owned by the state has at least 50% share in the company
2.15.4	Two biggest shareholders/associates together have at least 50% share in the company, whereat one of them is state owned
2.15.5	One shareholder/associate is a financial holding and has more than 50% share in the company
2.15.6	Two biggest shareholders/associates together have at least 50% share in the company, whereat one of them is a financial holding
2.15.7	Neither one shareholder/associate by himself/herself nor the two biggest shareholders/associates together have at least 50% share in the company
3	Implementation of the investment opportunities in the last 8 years
3.1	Have you in the last 8 years (from 2010 to 2017) succeeded in taking advantage of those business opportunities in the market which required investments?
3.1.1	Entirely
3.1.2	Partly

#V	Questions
3.1.3	No
3.2	We have not taken advantage of (all) the business opportunities being offered to our company in the market in the last 8 years, because:
3.2.1	our company has not had enough of its own financial resources for the necessary investments
3.2.2	our company has not succeeded in acquiring (borrowing) debt financial resources for the necessary investments
3.2.3	first our company had to free from debts (deleveraging) acquired in the past
3.2.4	the strategic guidelines (directives) for the necessary investments (the investments were not planned in our strategic business plan) have not been confirmed
3.2.5	the owners /through their supervisory board/ have not accepted/confirmed the business plans
3.2.6	we have not been ready for the implementation of the new investments /in the sense of getting ready with the project documentation and acquiring all the required licenses and permits
3.2.7	the investments have been too demanding with respect to the necessary funds
3.2.8	the investments have been too demanding with respect to technology
3.2.9	our company has not had sufficient human resources /lacked qualified physical labor force/
3.2.10	our company has not had sufficient human resources /lacked technical skill/
3.2.11	our company has been overtaken by competition
3.2.12	our company has not received new orders (in pipeline) from the existing clients
3.2.13	our company has not received new customers/clients for its products/services relating to the new planned investments
3.2.14	in the meantime, some organizational changes in our company occurred
3.2.15	other /please explain what ... /
4	Investment activity of our company in the last 8 years (from 2010 to 2017)
4.1	What has encouraged your company to invest in the last 8 years?
4.1.1	Competition which invests
4.1.2	Increase in the customers' orders
4.1.3	Increase in the sale in the previous year
4.1.4	Increase in export
4.1.5	Increase in productivity
4.1.6	New business opportunities in the market
4.1.7	Relatively high degree of the write-off of your equipment
4.1.8	Technological progress (a need for modernization)
4.1.9	Innovativeness and own R&D activities
4.1.10	Substitution of manual work with the process automation
4.1.11	Increase of profit
4.1.12	Offer of favorable financial resources
4.2	Has your company implemented bigger and financially demanding investments in the last 8 years:
4.2.1	equally, each year in approximately the same value
4.2.2	concentrated with an investment spike in one or two years at the beginning of the 8 year period
4.2.3	concentrated with an investment spike in one or two years at the end of the 8 year period

#V	Questions
4.2.4	concentrated with an investment spike in one or two years in the middle of the 8 year period
4.3	How has your company implemented the biggest investments in fixed assets in Slovenia in the last 8 years? This question relates to one or more investments the joint value of which exceeded 100 thousand €:
4.3.1	The biggest investments were successfully finished before the deadline
4.3.2	The biggest investments were successfully finished on time
4.3.3	The biggest investments were successfully finished in the expected volume (size)
4.3.4	The biggest investments were successfully finished in the scheduled financial frame
4.3.5	The biggest investments were not realized according to the time schedule
4.3.6	The investment implementation was delayed due to acquiring the licenses and permits
4.3.7	During the investment implementation, some important technical changes occurred
4.3.8	The delay of the investment implementation was due to force majeure (weather, strikes, epidemic diseases, etc.)
4.3.9	During the investment implementation, the suppliers of the equipment were late
4.3.10	During the investment implementation, the constructors did not adhere to the time schedule
4.3.11	The investments were not realized in the expected volume (size)
4.3.12	The cost of the investment was exceeded due to the price increase
4.3.13	The cost of the investment was exceeded due to the excessive and additional unexpected works
4.3.14	The funds for the planned investments were not provided on time
4.3.15	The financial resources for the investments were different from those originally planned
4.3.16	The borrowed funds were bigger than the originally planned
4.3.17	In the end, the investments required additional employment, more workers than planned
4.3.18	Orders of the customers decreased either during the investment implementation or at the very end
4.4	Please estimate the economic effects of the investments (their performance) by choosing an appropriate answer below
4.4.1	Economic effects of the investments are bigger than the originally planned
4.4.2	Economic effects of the investments are achieved in the span from 91–100% of the originally planned
4.4.3	Economic effects of the investments are achieved in the span from 71–90% of the originally planned
4.4.4	Economic effects of the investments are achieved in the span from 51–70% of the originally planned
4.4.5	Economic effects of the investments are achieved in the span under 51% of the originally planned
5	Financial flexibility of the company
5.1	Capability to acquire financial resources
5.1.1	Capability to acquire financial resources (also in financial distress and during the financial crisis)
5.1.2	Capability to borrow in the long run when necessary
5.1.3	Cumulation of cash reserves to be able to borrow in the future
5.1.4	Capability to use financial leverage for new investments
5.2	Capability to manage the risk of being able to pay

#V	Questions
5.2.1	Capability to manage the financial risk (exchange rate, interest rate, investment)
5.2.2	Capability to protect itself against a sudden drop of cash-flow (smaller vulnerability)
5.2.3	Disposal of cash reserves
5.2.4	Capability to maintain a good rating with banks (B and higher than B)
5.3	Capability to maintain capital adequacy in the long-run
5.3.1	Capability to maintain an appropriate capital structure (Debt to Equity Ratio) while respecting a balance golden rule
5.3.2	Capability to restructure short-term financial resources considering their time span and price
5.3.3	Disposal of cash reserves
6	Knowledge - competencies and dynamic capabilities
6.1	Technical competences
6.1.1	The employees have plenty of technical knowledge and skill
6.1.2	There are clearly defined needs for professional knowledge in our company
6.1.3	The employees learn fast and they are able to manage new technologies and implement them in the processes
6.1.4	Development of new products /services is supported by own knowledge in the company
6.1.5	The employees are able to receive and transmit good practices (technical solutions) from outside of the company and within it
6.1.6	The employees' capability of innovation is comparable to the competition's or is even bigger
6.1.7	Managers with technical competencies influence the innovativeness of the employees
6.1.8	Managers with technical competencies influence the permanent learning of the employees
6.2	Organizational and managerial competences
6.2.1	Middle management (leaders of sectors and services) is familiar with the strategy of the company
6.2.2	Middle management in our company takes part in investment planning
6.2.3	Business processes in our company are backed up with modern IT
6.2.4	From an organizational perspective, the management successfully delegates the tasks and empowers the employees
6.2.5	Management effectively supervises and controls the implementation of the tasks and projects and takes timely measures if deviations from goals and objectives occur
6.2.6	Implementation of the demanding tasks and projects is based on teamwork
6.2.7	There is a two way and effective communication among the employees in the company (each employee receives all the necessary information for the execution of his/her tasks)
6.2.8	For all the stakeholders involved in investment projects, there is an effective awarding system set up in our company
6.3	Project competences
6.3.1	Implementation of demanding projects is based on project management
6.3.2	For the majority of the suppliers for the investment implementation, the company acquires at least three bids
6.3.3	Strategic suppliers are involved in the design and development of the investment projects
6.3.4	As early as in the phase of the investment project design the crucial risk in the phase of implementation is assessed by the project managers who also prepare several scenarios

#V	Questions
6.3.5	Project managers master all the phases of the investment projects
6.4	Dynamic capabilities
6.4.1	Investment project managers (within the company) are familiar with the development strategy of the company
6.4.2	Investment project managers (within the company) are involved in the design of the company's development strategy
6.4.3	Top and middle management are involved in investment designing
6.4.4	Managers responsible for individual processes are able to perceive the strengths /weaknesses and opportunities/threats in the company and environment ahead of the competition
6.4.5	Managers responsible for individual processes continually observe and research the markets, technologies, and business environment
6.4.6	Top and middle management are able to identify business opportunities
6.4.7	Top and middle management are able to achieve the goals of the company
6.4.8	Top and middle management are able to decide, take decision, and then undertake the necessary measures to reach the goals
6.4.9	Top and middle management are able to combine and transform the resources
6.4.10	Top and middle management are able to transform the organizational structure in line with changes in the environment
7	Performance of the company in the last 8 years
7.1	Non-financial aspect
7.1.1	New products/services related to the new investments were marketed faster than those by the competition
7.1.2	The performance of the new products/services related to new investments was high
7.1.3	New investments increased the market share of our products/services
7.1.4	Turnover of workforce in the company is low
7.1.5	Turnover of technical staff in the company is low
7.1.6	Satisfaction of our customers increased after the investments were finished
7.1.7	Satisfaction of our employees increased after the investments were finished
8	Choose if you want to receive the feedback and results of this questionnaire and research
8.1.1	Yes
8.1.2	No
9	Comments/remarks

JEL:

C12; D25

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Chapter 9

Mediation Impact of Supplier Quality on Association between Top Management Commitment and Resource Utilization in Indian Automotive Sector

Gaurav Goyal

Abstract

The study intends to investigate mediating role of supplier quality improvement on relationship between top management commitment and resource utilization in Indian automotive sector. It is a given that the management of an organization plays a vital role in the success of an organization, which includes managing strategic resources and forming strategic alliances with key stakeholders. For manufacturing organizations where suppliers become an indispensable stakeholder in the organization's value chain, maintaining supplier quality leads to sustainable profits for the organization. Hence, a conceptual framework based on extant literature review is proposed for extracted constructs, namely top management commitment, supplier quality improvement, and resource utilization to analyze a possible relationship between the three constructs. To validate the proposed hypothesized relationships, data were collected by sending research instrument to senior management executives of Indian automotive organizations. Results of data analysis suggest that supplier quality improvement mediates the impact of top management commitment on resource utilization. Study strongly recommends that for optimum utilization of resources, automotive organization(s) must develop long-term relationship with selected set of trusted supplier's. Further, results suggest that as much as possible real-time voice of customer ought to be communicated to the selected set of suppliers.

Keywords: top management commitment, supplier quality, resource utilization, mediation analysis, automotive industry

1. Introduction

For manufacturing organizations where suppliers become an indispensable stakeholder in the organization's value chain, maintaining supplier quality is directly associated with sustainable profits for the organization [1]. Global competitive environment has forced these manufacturing organizations to focus on their

inherent resources to be competitive and sustainable. With resources being limited, it becomes pertinent for top management to have a renewed emphasis on utilization of the strategic resources at their disposal. Resource-based view of the firm also advocates the fact that creation and sustenance of competitive advantage are heavily dependent on optimum utilization of the core resources and capabilities by the concerned firm [2–4]. Moreover, resource-based view implies that interfirm activities involved in a supply chain system possess a high impact on resource utilization [5, 6]. One of the prominent ways through which interfirm activities can be improved includes focusing on continual improvement of suppliers' quality based on customer demands. Researchers and industry practitioners (alike) have argued that managing quality from the very beginning of the supply chain results in significant improvement in the firm performance. Researchers have suggested that firm performance is improved by reducing both waste and number of quality inspections required at the same time [1, 7–10].

India in recent time has emerged as one of the favored destinations for manufacturing a quality product at lower cost. Recent report by "Deloitte & Touche" and the Council on Global Competitiveness for global manufacturing competitiveness index has indicated India as one of the potential nations that will emerge as a big manufacturing hub in the time to come [11]. This optimistic view on India arises due to the abundance of cheap labor, favorable demographic profiles, and sustained economic growth. GDP of Indian manufacturing sector has reached an all-time high of INR 5331.94 billion in the first quadrant of 2017, with automotive sector representing a major share [12]. In fact, in post-COVID era as well, automotive sector is one of the major sectors about which Indian government is quite bullish for bailing out its economy from the postpandemic depression. India's strength in this sector emancipates from its large domestic consumption base for automobiles as well as due to its cost-competitive value chain (low labor and material cost) and strategic geographical location [13]. Moreover, few other industry reports suggest that market size of automotive sector is going to quadruple by the year 2026, that is, an increase from INR 4701 billion in year 2015 to INR 20,100 billion by year 2026 [13, 14]. This competitiveness of the Indian automotive sector can also be attributed to the ever-demanding Indian customers who want to have best of both worlds, i.e., price and performance. Researchers have also argued that customers change their buying decision(s) due to late delivery of automobiles caused by quality-related problems of suppliers [14, 15]. Thus to retain and boost their market share, top management of automotive organizations must emphasize on improving suppliers' quality. The improved suppliers' quality will help firm to reduce waste and rejections during quality inspection, thus leading to enhanced utilization of organizational resources.

This paper aims to investigate the same empirically by validating the proposed conceptual framework following the regression process procedure laid out by Preacher and Kelley [16] using Hayes PROCESS [17] for Indian automotive organizations. The presented study's structure includes sections covering literature review, methodology, theoretical and managerial contribution, and conclusion. Literature review section explores the extant literature available on top management commitment and resource utilization in light of supplier quality. Methodology section concentrates on data collection, reliability analysis, correlation analysis, and mediation analysis. Managerial and theoretical contribution section elaborates on importance of results from the presented work to managers and academicians. Last section of the study leads to recommendations and scope for future research in the underlying area.

2

2. Literature review

Researchers have articulated on the fact that pertinent way through which organizations compete on competitive performance has shifted from manufacturing to supply chain management [18–21]. Supply chain management has sought to enhance the competitive performance by closely integrating internal functions within a company and effectively linking them to external operations of suppliers, customers, and other channel members for optimum utilization of resources [22, 23]. Resource-based view had also emphasized on the fact that firm can attain competitive advantage (exploiting transaction specific investments) by creating a competitive cost barrier [24, 25]. This signifies that manufacturing firms can attain sustainable competitive advantage by judiciously managing its heterogeneous set of strategic resources (that cannot be easily bought, transferred, or copied) [2, 26–28]. Resource utilization concentrates on deployment of excess buffer capacity so that manufacturing organizations can attain cost minimization [29]. Resource-based view of the firm suggests that creation and sustenance of competitive advantage are dependent on the way core resources and capabilities get utilized in a supply chain system that also involve interfirm activities [2–4, 30]. Researchers have suggested that interfirm activities are dependent on top management commitment and supplier's quality improvement, thus bearing a direct impact on resource utilization [1, 27, 31]. Management of interfirm activities for understanding and improving quality deficiencies of their suppliers involves selection of supplier based on quality, training of suppliers on upgrades in quality improvement and frequent visits of organizational representative to suppliers' facilities. Improvement in supplier's quality helps organizational management not only in reducing waste but also in paving their way toward optimal utilization of resources for delivering finished product at a minimal price to end customers. However, one research question that remains unanswered is whether supplier's quality improvement mediates the relationship between top management commitment and resource utilization or not?

2.1 Top management commitment and supplier's quality improvement

Customers are demanding superior-quality product at lowest prices in the global competitive environment. This emphasizes on the fact that Indian automotive sector has to deliver quality product at lowest cost possible. The post-COVID forecast for the Indian automotive industry is quite bullish. This bullish forecast for Indian automotive industry is lunged forward by demand of high-quality product at nominal prices [32, 33]. Top management of organization by optimally utilizing the firm's resources in the supply chain system would be in a position to cut short on their internal cost of production, thereby able to offer their respective products at nominal prices [5, 33, 34]. Supply chain presents an ideal area where optimizing activities implemented by strong leadership could yield considerable synergy and competitive advantage [35–40]. One of the prominent ways through which top management of a manufacturing organization can improve interfirm activities include focusing on continual improvement of supplier's quality based on frequent upgrades in customer quality requirements [27, 41–44]. Fulfillment of the customer's expectations ensures that quality standards of the higher order in the supply chain are continuously met [1, 20, 45–47]. Commitment from organization's top management is required to assure that these high customer expectations are repeatedly satisfied by incorporating these expectations into supply chain processes from the very beginning enabling the firm to manufacture the desired quality product

[5, 48–50]. This calls for embedding of quality management in supply chain processes involving interfirm activities as well [20, 51]. The above discussion indicates that top management commitment impact's supplier quality improvement, thereby helping us in postulating our first hypothesis as

$$H_{1a} = \textit{Top management commitment positively impacts supplier's quality improvement}$$

2.2 Top management commitment and resource utilization

Improvement in supplier's quality helps organizational management not only in reducing waste and number of quality inspections but also in paving their way toward optimal utilization of resources for delivering finished product at a minimal price to end customers. More the top management is focused on utilization of resources, better will be the competitive positioning of the concerned firm. This phenomenon has been well documented by a number of previous researchers in their studies [32, 33, 39, 45, 48, 52–54]. Moreover, resource-based view implies that interfirm activities involved in a supply chain system have a high impact on resource utilization [5, 6]. Indian organizations experience a significant socioeconomic difference with respect to their global counterparts [55]. Thus, the following hypothesis has been conceptualized:

$$H_{1b} = \textit{Top management commitment positively impacts resource utilization}$$

2.3 Top management commitment, supplier's quality improvement, and resource utilization

Organization must possess a system for collecting complaints and suggestions from their customers and communicating the same to all the related stakeholders as soon as possible [45, 56]. Thus, top management of the organization should periodically share information regarding risk and rewards of quality parameters with its various supply chain partners [43, 48, 57, 58]. This periodic performance feedback serves dual benefit of supplier development as well as maintaining healthy competition among firm's suppliers [23, 56, 59, 60]. Suppliers by getting periodic feedback on quality improvement parameters enable them to develop, which in turn helps the concerned manufacturing organization in meeting the stringent customer quality requirements [5, 6]. This ability of supplier to fulfill the quality demands of customer not only affects the competitive advantage of the said supplier but it also significantly influences the competitive positioning of the manufacturing organization in question [1, 48, 61, 62]. It becomes extremely important for top management to keep motivating their organization's suppliers for continuous improvement on quality front for retaining the dual benefit of suppliers' own development and sharpening their competitive edge as well [23, 62, 63].

Top management ought to concentrate on interfirm alliances [20] by placing their executives at the business facilities of their upstream supply chain partners for continually enhancing their supplier's quality [57, 64]. This would motivate firm's suppliers for manufacturing according to the customers' quality parameters [49, 57]. Highly motivated suppliers might result in optimal utilization of inventory and minimization of waste, thereby translating into enhanced resource utilization [20, 45, 65]. This clearly highlights that top management commitment impacts supplier's quality

improvement and resource utilization. However, it will be interesting to investigate whether supplier's quality improvement has a mediating impact on the relationship between top management commitment and resource utilization in the context of Indian organizations. Thus, the next hypothesis is formulated as given below:

$$H_{1c} = \textit{Top management commitment positively impacts resource utilization with respect to supplier's quality improvement.}$$

Top management of organization from long had been focusing on dealing with a select supplier base that is chosen on the basis of customer feedback related to quality aspects, [27, 56], ISO standards [1], efficient inventory echelon models [66], and improvised supply chain networks [56]. Current extant literature fails to address whether supplier quality improvement mediates the relationship between top management commitment and resource utilization. Both researchers and industry practitioners have considered that top management commitment and supplier's quality improvement play a distinct role in contributing to resource utilization [6, 27, 35, 45, 49, 59, 65]. However, in this study it is proposed that top management commitment is an antecedent to supplier's quality improvement leading to the conceptual research framework as shown below in **Figure 1**. **Table 1** provides description and supporting references of the constructs used in the presented study.

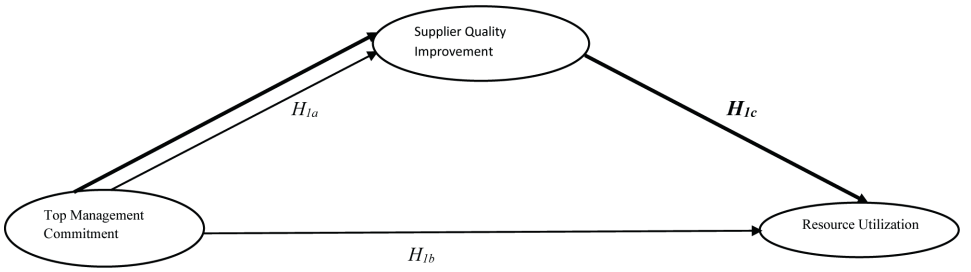

Figure 1.
Conceptual framework.

Sr. No	Constructs	Description	Supporting references
1	Top Management Commitment (TMC)	Engaging/motivating/training supplier and employees for quality improvement; feedback from customer on quality improvement; long term relationship with supplier	[32, 33, 39, 45, 52–54, 56, 67]
	Mediator		
2	Supplier's Quality Improvement (SQI)	Continual improvement in quality of supplies; feedback on quality aspects at regular intervals; Supplier commitment to upgrade the technology	[1, 18, 41, 48, 58, 63, 68]
3	Resource Utilization (RU)	Efficient utilization of resources for an overall reduction in the internal cost	[20, 31, 57, 69]

Table 1.
Construct description and supporting references.

3. Methodology

This section of the study is divided into four subsections. Survey instrument and data collection section emphasizes the development of scale, sampling technique used, and response rate of the study. Reliability section concentrates on determination of Cronbach alpha using SPSS 21.0 software. Correlation matrix section checks whether there exists a significant correlation among constructs of the study. At last, regression analysis section elaborates on mediated regression analysis as proposed by Preacher and Kelley using Hayes [17] PROCESS macro in SPSS 21.0.

3.1 Survey instrument and data collection

In-depth structured interviews with top management officials of Indian automotive organizations were conducted for identifying the pertinent items for the constructs. These interviews have helped in ensuring that constructs and their relationships are consistent with industry practices. After gathering valuable industry feedback, a draft is prepared and sent for feedback to selected academicians with relevant experience in the automotive sector. The process helped to obtain feedback on comprehensiveness, clarity, face validity, and readability of the scale of survey instrument. This valuable feedback helps in revising and finalizing the questionnaire as presented in **Table 2**.

Five-point Likert scale (1 – Strongly Disagree, 5 – Strongly Agree) was used to capture organizational responses of the questionnaire. Further, the research team distributed the research questionnaire based on snowball sampling. Reason for choosing snowball sampling was that respondent's references were considered for sending questionnaire to other respondents. Respondents of the study include the top level managers, chief executive officer's (CEO's), chief operational officer's (COO's), supply chain manager's and quality manager's; of 300 automotive organizations across India, and they were contacted through various modes, namely email, personal visits, and postal mails. This study has considered that the respondent was replying on behalf of the organization. Hence, the organization is considered as the unit of analysis. One-hundred and thirty automotive organizations responded to the questionnaire. After a careful examination of responses, 98 organizational responses are selected as valid for study. The reason for not selecting the other responses was due to either their incomplete or invalid response. Overall, the response rate of the study is 32.67% that is acceptable as per the literature [56, 57, 70, 71].

3.2 Reliability

The research team computed Cronbach's alpha [72] of constructs using SPSS version 21.0. The reliability results are presented along with the questionnaire in **Table 2** above. The construct's Cronbach alpha values presented in **Table 2** were found to be greater than 0.7, which is acceptable as per literature [1, 27, 63, 68, 72]. Thus, Cronbach alpha values validate the reliability of scale for further research usage.

3.3 Correlation matrix

To perform the regression analysis, it is first required to test the interrelationships between the study constructs. **Table 3** presents the interrelationships among the various study constructs. Top management commitment and supplier's quality

Construct	Reliability (Cronbach Alpha)	Item description
Supplier quality improvement	0.720	Shares both quality improvement benefits and risks with their supply chain partners
		Provides quality performance feedback periodically to suppliers
		Communicates product specifications and quality requirements at regular intervals
		Significant investments in tooling and equipment from suppliers to improve quality of the final product
Top management commitment	0.849	Focuses at continuously improving the supply quality of the product by making it as one of its organizational goal
		Has a system to collect complaints on product quality aspects from customers.
		Encourages active participation of employees in the production activities to assure quality
		Committed to develop long-term relationship with suppliers by improving their processes in the long run
		Places executives at the business facilities of its supply chain partners to facilitate collaboration
		Cooperates extensively with customers with respect to selection of quality processes for improvement in product design
		Contacts end users of its product(s) to get feedback on product performance
		Collects and evaluates both formal and informal complaints for the satisfaction of its customers to strengthen long-term relationships
Resource utilization	0.768	Ability to minimize total product cost for final customers
		Possesses good inventory management process which results in reduction of inventory cost
		Ability to minimize all types of waste throughout the supply chain

Table 2.
Research questionnaire.

	Mean	SD	RU	TMC	SQI
RU	3.9111	0.66818	1		
TMC	4.1251	0.59272	0.708**	1	
SQI	4.2477	0.57694	0.669**	0.805**	1

***Correlation is significant (p < 0.01).*

Table 3.
Mean, standard deviation (SD) and correlations.

improvement are significantly correlated with resource utilization ($p < 0.01$). It is also evident from **Table 3** that top management commitment is significantly correlated to supplier's quality improvement ($p < 0.01$).

3.4 Regression analysis

Three-step mediation analysis procedure as proposed by Baron & Kenney [73] has been considered to be the most traditional approach to mediation analysis with a limitation of use of descriptors such as "complete" and "partial" mediation [16]. Researchers had advocated that bootstrapping, a nonparametric resampling method, is a robust alternative to overcome this shortcoming [16, 74, 75]. Therefore, it is being recommended that constructs of bootstrapping confidence intervals (CI) for the indirect effect must exist between the limits.

Indirect, direct and total effects mediation analysis procedure [16] is used to investigate the mediating role of supplier's quality improvement using PROCESS macro [17] in SPSS version 21.0. Proposed framework with various notable research values is presented in **Figure 2**.

It is evident from **Figure 2** that regression coefficient of top management commitment ($\beta = 0.7834$, $p < 0.05$) with respect to supplier's quality improvement is positive. Additionally, top management commitment accounts for 63.92% of the variance in the supplier's quality improvement. Moreover, the results presented in **Table 4** below suggest that the "p" value for hypothesis H_{1a} is significant ($p < 0.05$), thereby validating hypothesis H_{1a}.

Figure 2 also highlights that the coefficient of top management commitment ($\beta = 0.7981$, $p < 0.05$) with respect to resource utilization is significant. Furthermore, the results presented in **Table 4** validate the hypothesis H_{2a}, which states that top management commitment positively influences the resource utilization of the firm.

Preacher and Kelly's regression method suggests that the total effect and the direct effect must be significant ($p < 0.05$) to validate the mediating impact of supplier's quality improvement. To significantly validate the indirect impact, boot standard error (SE) values must be within the boot upper limit confidence interval and lower limit confidence interval, and it is a must that the limits must not possess zero [16]. Thus, standard error must be positive and must be between positive control limits. Total and direct effect results presented in **Table 5** given below significantly validate that top management commitment impacts resource utilization with respect to supplier's quality improvement. Further, **Table 6** proves that there exists an indirect impact of supplier's quality improvement on the relationship between top management commitment and resource utilization, thereby validating hypothesis H_{3a}. Therefore, it can be said that there exists a mediating role of supplier's quality improvement on the relationship between top management commitment and resource utilization.

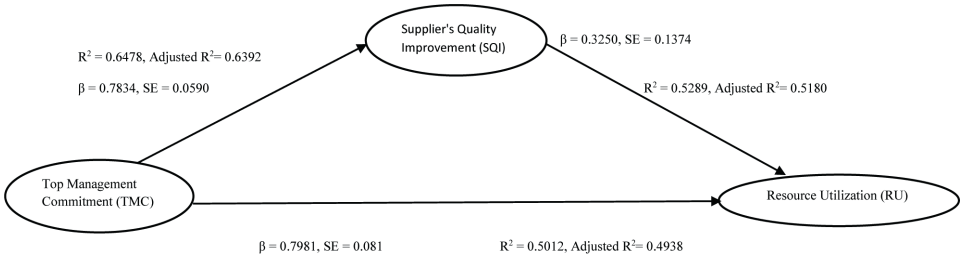

Figure 2.
Framework with notable research values.

Structural path	Hypothesis	Effect	SE	t-value	p-value*	UCL**	LCL**	Significant/Not Significant
TMC → SQI	H_{1a}	0.7834	0.0590	13.2883	0.0000	0.6664	0.9005	Significant
TMC → RU	H_{1b}	0.7981	0.0813	9.8212	0.0000	0.6368	0.9594	Significant
TMC → SQI → RU	H_{1c}	0.3250	0.1374	2.3647	0.0201	0.0521	0.5978	Significant

**The bold values represent significance level at $p < 0.05$.*
***Bootstrap upper and lower confidence intervals for the indirect effect.*

Table 4.
Regression model results.

Type	Effect	SE	t-value	p-value*	LLCI**	ULCI**	Significant/Not Significant
Total	0.7981	0.0813	9.8212	**0.0000**	0.6368	0.9594	Significant
Direct	0.5435	0.1338	4.0630	**0.0001**	0.2779	0.8090	Significant

**The bold values represent significance level at p < 0.05.*
***Bootstrap sample size = 1000 (α = 0.05), LLCI = Lower limit confidence interval, ULCI = Upper limit confidence interval.*

Table 5.
Total and direct effect results.

Type	Indirect	Effect	Boot SE	Boot LLCI*	Boot ULCI*	Significant/Not Significant
Indirect effect	**SQI**	0.2546	**0.1035**	0.0501	0.4650	Significant
Preacher and Kelly	**SQI**	0.1900	**0.0796**	0.0333	0.3464	Significant

**Bootstrap sample size = 1000 (α = 0.05), LLCI = Lower limit confidence interval, ULCI = Upper limit confidence interval.*

Table 6.
Indirect effect and Preacher and Kelly results.

4. Theoretical and managerial contributions

4.1 Theoretical contribution

The study validates the mediating role of supplier's quality improvement on the relationship between top management commitment and resource utilization in the context of Indian automotive organizations. The resource-based view has focused on economies of scale but somehow lacks in its coverage of the role played by top management in improving the supplier's quality for achieving better resource utilization. This research has enriched the literature by investigating the same for Indian automotive sector. India is a major contributor in the Asian automotive sector [13, 14, 76], thus researchers primarily working in the area of Asian automotive sector can use this model in various other Asian countries.

The existing literature has already captured the competitive edge attainment by dwelling on selecting supplier based on quality customer feedback [27, 56], ISO standards [1], efficient inventory echelon models [66], supply chain flexibility issues [15], supply chain networks [56], supply chain risk [77], and flexible supply chain capabilities at various tiers [78]. However, the findings of the presented study add another dimension to the same by suggesting that suppliers' quality improvement can mediate the relationship between top management commitment and resource utilization, thereby providing better competitive positioning to the concerned firm.

4.2 Managerial contributions

The mediating role of supplier's quality improvement in the Indian automotive sector suggests that top management must be committed to improve the supplier's quality for optimum utilization of resources. The automotive management must ensure the same so that they can obtain a sustainable competitive advantage through

various ways covering employee commitment on quality issues, shortening of product development time, and communicating the updated customer requirements to suppliers in real time or as soon as possible. The achieved sustainable advantage will not only improve the manufacturing capability but also help automotive organizations on achieving the customer delight. The delighted customer will enable automotive organizations to enrich their market positioning not only at national level but also at the Asian level.

The top management of the automotive organization must assure that all organizational employees are also committed toward supplier's quality improvement so that they can obtain a sustainable competitive advantage through utilization of resources [79]. The committed employee will enable the automotive organization to cut short on their internal cost of production, thereby able to offer their respective products at nominal prices [5, 33, 34]. This will help the automotive organizations to attain a strong competitive advantage in the Asian market.

Report by India Brand Equity Foundation [14] considered India to be a potential manufacturing choice by most of the leading automotive organizations, and these organizations are expanding their product portfolio in the Indian Market as well. The top management of automotive units must work along with their trusted set of suppliers for solving quality-related issues in the development phase of an automobile itself, thus shortening the product development time. For doing so, top management of the firm is required to communicate the updated customer quality requirements as well as the customer's quality feedback as quickly as possible to all the respective suppliers. This will ensure that suppliers remain updated for delivering the demanded product by modifying their interfirm quality processes for delivering the said product. The automotive units will be able to reduce the internal cost of production as per the resource advantage theory leading to the manufacturing success resulting in higher utilization of resources and building of long-term relationships with the trusted set of suppliers.

The discussed strategies can be used by researchers as well as management professionals for boosting the manufacturing capability of the Asian automotive sector. The researchers can perform the same research in the various Asian markets and compare the results with the current study.

5. Conclusion and future scope

This study validates the mediation impact of supplier's quality improvement on the relationship between top management commitment and resource utilization in the context of Indian automotive organizations. Results of the data analysis suggest that top management of automotive organizations must focus on building long-term relationships with trusted set of suppliers so that they can improve quality of supplies, which translates into optimum utilization of inventory and minimization of waste.

Another recommendation of the study is that organizations must provide up-to-date quality expectations of customers to their supplier in real time, if possible. By doing so, suppliers have a chance to update their system for quality improvements, which will ultimately result in reducing the internal cost of production in-line with the resource advantage theory. Management can utilize these savings for further improving supplier's quality that will help automotive organizations in fulfilling high expectations of customers. These accrued savings can further be utilized by the firms in strengthening their research and development wing helping the firm concerned

with attaining a sustainable competitive advantage in today's dynamic and volatile business environment.

However, there are a few limitations of this study. Firstly, the sample collected for this study was relatively small, but an effort has been made to cover a substantial number of units in terms of market share. Secondly, this research had not captured the secondary data (like internal manufacturing data) to crosscheck the resource utilization issues. The reason for not using secondary data was the unwillingness of the Indian automotive organizations to provide the secondary data due to their organizational policies.

The study being done in the automotive area provides an opportunity for researchers to carry out research studies of similar nature in the other industrial manufacturing sectors such as food and beverages, electronics, furniture, and pharmaceuticals. Another opportunity for researchers can be to work on a comparative analysis by comparing results across geographical locations for automotive organizations and thus coming out with a comprehensive model suiting the global requirements. Lastly, the researchers can work on the limitations of the study.

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Chapter 10

Trends in the Accreditation of Medical Laboratories by ISO 15189

Paulo Pereira

Abstract

In areas such as transfusion, transplantation, and sports medicine, laboratory results are critical to the diagnosis of pathologies. In order to minimize intra- and interlaboratory variability of results, it is equally important to harmonize quality management and technical practices in the medical laboratory. To ensure the competence of medical laboratories, ISO 15189, 3rd edition, establishes international standards. A set of critical principles for effective management and control of technical specifications has been outlined in this document. December 2022 marked the publication of the fourth edition of this standard. An in-depth analysis of the ISO 15189 standard is presented in this chapter.

Keywords: accreditation, assessment, medical laboratory, ISO, technical, QMS

1. Introduction

The pivotal significance of laboratory results in healthcare is underscored by their contribution to 70% of clinical diagnoses [1]. This underscores the need for performance assessment techniques to ensure that these results are reported in alignment with their intended purpose. However, it is equally essential to maintain control over the entire technical environment and support infrastructure.

The quality and competency standards for medical laboratories are delineated in ISO 15189 "Medical laboratories - Requirements for quality and competence", an International Organization for Standardization (ISO) standard [2]. ISO 15189 serves the dual purpose of establishing quality management systems (QMS) for medical laboratories and evaluating their competence. Moreover, third parties, including customers, regulatory bodies, and accreditation entities, employ these standards to affirm or acknowledge a laboratory's competency.

As part of its standard life cycle, ISO standards necessitate a comprehensive review every 5 years. This review process falls under the purview of the Technical Committee ISO/TC 212, focusing on "Clinical laboratory testing and *in vitro* diagnostic test systems." ISO 15189 is categorized in the International Classification for Standards (ICS) under 03.120.10, which pertains to quality management and quality assurance, and 11.100.01, encompassing laboratory medicine in general. The ICS framework functions as a structure for compiling international, regional, and national standards, along with other normative documents. It also serves as a basis for standing-order systems [3]. For detailed information on the revision cycle, please refer to [4].

The ISO 15189:2022 is a 76-page document. The current edition, which is the fourth, was published in December 2022, and it supersedes the third edition, which has since been withdrawn [5]. This chapter delves into the foundational principles of the present ISO 15189 editions, taking into consideration anticipated changes and emerging trends. The target audience for this chapter includes individuals with prior experience in ISO 15189 accreditation, including those who have been audited and auditors familiar with this standard.

2. Verbal forms

Drawing from our experience as auditors, we are often reminded of instances where requirements were mistakenly regarded as recommendations, and vice versa. It is of paramount importance to grasp the distinctions between what is mandated, suggested, or allowed in order to gain a comprehensive understanding of the standard and how it should be applied. This principle holds true not only for those being audited but also for auditors themselves, particularly internal auditors, who can sometimes introduce misconceptions when interpreting the standard. This applies to various fields, including management and technical. ISO 15189 employs specific verbal forms to convey these distinctions, and they are as follows:

- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates permission, and;
- "can" indicates a possibility or capability.

The ISO/IEC Directives, Part 2:2001, titled "Principles and rules for the structure and drafting of ISO and IEC documents," outlines the fundamental principles governing the drafting of ISO and the International Electrotechnical Commission (IEC) documents. It also prescribes specific rules aimed at ensuring these documents are clear, precise, and unambiguous. These rules are not only essential for clarity but also for maintaining the effectiveness of each document in contributing to the cohesive and interconnected body of knowledge generated by ISO and IEC. In fact, this standard aligns with the principles governing the use of verbal expressions for provisions, as outlined in Section 7 of the ISO/IEC Directives ([6], Section 7).

3. Conceptual changes

3.1 Intended use/fitness for purpose

The updated ISO 15189 version includes the assessment of performance specifications based on the intended use of the method, whether it is for validation - harmonized methods; "commercial assays" - or verification - developed or modified methods - purposes. As a result, laboratories will be responsible for establishing the performance specifications, ideally drawing upon third-party peer-reviewed research. This methodology for assessing and ensuring precision in both

(quantitative) measurements and (qualitative) examinations is of paramount importance for making accurate clinical decisions and subsequent actions.

Within the scope of intra-laboratory applications, it becomes imperative to take into account the guidelines provided by national accreditation agencies. These guidelines may even be obligatory for achieving recognition of ISO 15189 accreditation. Consider the example of glucose and its diverse applications, ranging from excluding diabetes, diagnosing diabetes, and ruling out hypoglycemia in emergency settings, to maintaining precise glycemic control in intensive care units. There are no systems with "pure" ISO 15189 accreditation, the system being a combination of other guidelines, in which the legal ones overlap.

To address these varied purposes, the laboratory should proactively consult the most current literature for state-of-the-art methodologies in the assessment of both quantitative, for example, using the Clinical and Laboratory Standards Institute (CLSI) EP15-A3 guideline [7], and qualitative assays, encompassing binary, unordered (nominal), and ordered (ordinal) categorizations, for example using CLSI EP12-A3 [8], Pereira [9], and Eurachem guide [10]. This literature selected is not only peer-reviewed papers but also regulation of *in vitro* diagnostic medical devices (IVD-MD) and inserts from manufacturers of this type of devices. In this step, it will be demonstrated whether the laboratory can achieve/replicate the required performance under its conditions, whether through regulation or that stated in the manufacturers' inserts.

3.2 Risk-based decisions

Laboratory techniques come with inherent risks and opportunities, which are identified within the laboratory setting. The laboratory is required to respond to these identified risks. To address these risks, a proportional response is essential, taking into account their potential impact on laboratory test results and the safety of both patients and personnel. The principles of ISO 15189 and ISO 22367:2020 [11] closely align with the requirements for risk management. A risk-oriented approach is pervasive throughout the entire ISO 15189 document, particularly in Sections 5.6, titled "Risk management" and 8.5 "Actions to address risks and opportunities."

In addition to establishing and implementing a management system for the laboratory, the laboratory director has the responsibility of applying risk management principles to all aspects of laboratory operations. By systematically identifying and addressing any risks that could affect patient care and identifying opportunities for improvement, the laboratory director ensures the seamless operation of laboratory activities. In cases where these processes are found to be ineffective, the laboratory director ensures that they are evaluated and, if necessary, modified and implemented effectively.

It is imperative to identify risks associated with emergencies or situations where laboratory activities are limited or unavailable. A coordinated strategy should be developed to enable the recovery of systems and the continuity of operations after a disruption. This involves the development of plans, procedures, and technical measures.

Throughout the pre-examination, examination, and post-examination processes, the laboratory must identify potential risks to patient care. As part of the risk assessment process, efforts are made to mitigate these risks where possible, and they are communicated to users most appropriately. The ongoing monitoring and evaluation of identified risks and the effectiveness of mitigation measures are critical to ascertain whether there is any potential harm to the patient.

Laboratory management bears the responsibility of developing, implementing, and maintaining processes for identifying risks that could harm patients in relation to

examinations and activities. These processes are also tasked with devising actions to address the identified risks and opportunities.

Furthermore, this risk analysis process, established by the laboratory, leads to the definition and determination of immediate and long-term actions. Laboratories are obligated to rectify any non-conforming work, taking into account the likelihood of its recurrence in the future. In cases where there is a risk of harm to patients, examinations are halted, and reports are withheld to prevent such harm.

3.3 Leadership

Leadership involves the capacity of an individual, a group, or an organization to "lead," exert influence or provide guidance to other individuals, teams, or entire organizations. Professionals, as a rule, do not like being forced to carry out specific and extraordinary tasks. On the other hand, maintaining competency matrices especially in complex techniques or with large teams can consume a considerable amount of time and effort. Leadership is influential but also influenced by the specific demands of the laboratory and the circumstances surrounding the risks of failure it faces. It must be clear that all activities, including support activities, always depend on a leadership policy.

4. Structure

4.1 Relationship with ISO/IEC 17025, ISO 9001, and ISO 15189:2012

The ISO 15189 structure is built upon ISO/IEC 17025:2017 [12], much like the previous versions. ISO 15189 aims to enhance patient well-being by instilling confidence in the quality and competence of medical laboratories. The 4th version can be viewed as less prescriptive in defining "what" is required and instead embraces a risk-based approach for determining "how" requirements are met, placing more emphasis on the interplay between different elements. This structure adheres to the principles outlined in the ISO Casco 1700 series for accreditation standards [13].

Similar to ISO/IEC 17025, ISO 15189 follows an input-output structure, aligning with ISO 9001 [14], which pertains to the QMS. This means that laboratories with QMS certification under ISO 9001 will undergo third-party audits for ISO 15189 accreditation, focusing primarily on technical requirements. The contemporary structure also addresses management responsibilities, with a focus on the flow of processes within the medical laboratory, encompassing recognized pre-analytical, analytical, and post-analytical phases.

A summary of the key changes and updates from ISO 15189:2012 to ISO 15189:2022 can be found below:

- Management requirements:
    - ISO 15189:2012 had a section on "Management Requirements" that covered various aspects of laboratory management.
    - ISO 15189:2022 introduces new sections, "Structural and governance requirements," and "Requirements regarding patients," which detail the structural organization and patient-related aspects of laboratory management.

- The 2022 version places more emphasis on the "Requirements regarding patients" and "Advisory activities" ("Needs of users") and includes information on "Objectives and policies," "Structure and authority," "Quality management," and "Management system requirements."

- Quality management system:
  - ISO 15189:2012 had sections on "Quality management system" and "Documentation requirements."
  - ISO 15189:2022 introduces "Management system documentation" and specifies the documentation and control of management system documents.
  - The requirement for a "Quality manual" is marked as optional and is no longer mandatory in ISO 15189:2022.

- Service agreements:
  - In ISO 15189:2012, there were two sub-sections related to "Service agreements."
  - In ISO 15189:2022, these are now merged in the section "Service agreements."
  - Evaluation and audits:
  - ISO 15189:2012 had sections on "Evaluation and audits."
  - ISO 15189:2022 introduces a more structured approach with "Evaluations", "Quality indicators" and "Internal audits."

- Management review:
  - Both versions have sections on "Management review" but provide more details on the structure of this review in ISO 15189:2022.

- Technical requirements:
  - ISO 15189:2012 included sections on "Technical requirements."
  - In ISO 15189:2022, these are categorized under "Resource requirements."

- Personnel:
  - ISO 15189:2012 had sections regarding personnel qualifications, job descriptions, and staff performance reviews.
  - ISO 15189:2022 adds a section on "Competence requirements and provides more detailed information about "Continuing education and professional development."

- Accommodation and environmental conditions:
  - These requirements remain mostly consistent between the two versions, with some slight reorganization and clarifications.
- Laboratory equipment, reagents, and consumables:
  - The sections about laboratory equipment, reagents, and consumables have been restructured, but the core requirements remain consistent.
- Pre-examination, examination, and post-examination processes:
  - ISO 15189:2022 revises the structure and organization of requirements related to pre-examination, examination, and post-examination processes.
  - While the core elements remain similar, the new version offers more clarity and detail.
- Laboratory information management:
  - ISO 15189:2022 includes new sections on "Downtime plans," "Off-site management," and "Continuity and emergency preparedness planning."
- Annexes:
  - ISO 15189:2022 includes additional annexes, such as "Additional requirements for Point-of-Care Testing" and tables comparing the standard to ISO 9001:2015, ISO/IEC 17025:2017, and ISO 15189:2012.

In summary, ISO 15189:2022 builds upon the foundation of ISO 15189:2012, offering a more comprehensive and structured framework for quality management in medical laboratories. It places a greater emphasis on the needs of users, quality indicators, and external assessments, and provides additional guidance in various aspects of laboratory management and operations.

4.2 POCT integrates ISO 22870

The basis for point-of-care testing (POCT) requirements in the new ISO 15189 edition is a blend of the principles from the previous ISO 15189 version and ISO 22870:2016 [15]. Consequently, this edition incorporates ISO 22870 principles relevant to medical laboratories supporting POCT. Hospitals, clinics, or other ambulatory care healthcare facilities may conduct POCTs, aligning with ISO specifications.

An additional pertinent technical standard is ISO/TS 22583 [16], which offers guidance for supervisors and operators of POCT services conducted independently of medical laboratories' oversight and support. As a result, ISO/TS 22583 can be seen as complementary to an ISO 15189 accreditation project.

Moreover, the technical specifications encompass several crucial elements that must be taken into account to ensure the safety and reliability of POCT results. In the ISO 15189:2022 context, POCT is treated as any other service provided by a medical

laboratory, guided by the requirements and service level agreements, and tailored to the interaction with users based on medical needs.

4.3 Sampling is related to ISO/TS 20658

Starting from 2017, ISO/TS 20658:2017 [17] establishes a set of requirements and best practices for collecting, transporting, receiving, and handling samples intended for medical laboratory examinations. Within ISO 15189, sampling specifications retain their crucial role, incorporating the principles delineated in ISO/TS 20658. This technical specification serves as a valuable reference for sampling procedures.

The latest iteration of ISO 15189 now integrates specific requirements for the preparation and identification of suitable samples. These elements are essential components of the new sampling specifications. Additionally, the updated version introduces a risk-based assessment of criteria for accepting suboptimal samples, as well as acceptance and rejection criteria for sampling. So, it is essential to emphasize that the decision to reject a sample should never be "automatic" - it must be made with the patient's best interests in mind, based on clinical data and prognosis.

4.4 Refers to ISO/TS 22367 on risk management

ISO 22367:2020, titled "Medical laboratories - Application of risk management to medical laboratories" [11], corresponds closely with the ISO 15189 criteria for risk management. The principles established in the med lab standard are harmonized with the risk management requirements. Medical laboratories are encouraged to utilize this document as a tool for recognizing and addressing risks associated with medical laboratory examinations, benefiting both patients and staff. A robust risk management process encompasses the identification, assessment, evaluation, control, and monitoring of risks.

In addition, this document sets forth stipulations encompassing all facets of medical laboratory examinations and services, spanning pre-examination and post-examination protocols, the examination process itself, and the accurate transmission of test results into electronic medical records. Furthermore, it includes various technical and managerial procedures relevant to the field.

4.5 Interrelationship between personnel

Every member of the medical laboratory staff is obligated to adhere to the guidelines that govern the medical laboratory. These guidelines outline their roles, authority, communication channels, and how they interact with others involved in managing, executing, or validating laboratory results.

5. Metrological traceability

ISO 15189 is firmly anchored to ISO 17511 [18], which centers on metrological traceability. This standard establishes the technical prerequisites and essential documentation for achieving metrological traceability for quantities gauged IVD-MD. The highest level of metrological traceability for human samples is attained through Reference Measurement Procedures (RMP) and Certified Reference Materials (CRM). However, these materials are not always available, being rare or integrated

into kits. The traceability remains considered in the scenario where primary reference materials or reference methods are unavailable. So, traceability must always be ensured for the quality control material, even if metrological traceability is not possible. This traceability refers to the reference of the materials, such as the batch and expiration date. Note that "metrological traceability", by definition in VIM, is only applicable to quantitative quantities, not qualitative properties, as true/false, positive/negative.

The new version also deals with commutability issues within the traceability chain. Comparatively, the new ISO 15189 requirements can be interpreted as more pragmatic and forward-thinking when contrasted with the previous version. They comprehensively link all elements concerning metrological traceability. In fact, measurement traceability mainly refers to verification, validation, measurement uncertainty, internal quality control, and external quality assessment of methods.

6. Performance assessment

The performance specifications for each examination method should be directly linked to its intended use and the influence it has on patient care. The laboratory establishes a verification procedure to confirm its competence in conducting examination methods before their implementation. Verification thus applies to all standardized assays or methods - referred to as "commercial" - which have been subject to extensive validation and evaluation by a notified body. This process involves ensuring that the necessary performance criteria, as defined by the manufacturer or the method itself, can be consistently met.

Otherwise, non-normalized assays or methods, such as laboratory-designed or developed methods, methods used outside their originally intended scope, and validated methods subsequently modified, are validated. This process is deeper and more extensive than the one called "verification", as it involves more complex components. For example, establishment cutoff. In the med lab, it is associated with rare or reference tests.

By providing objective evidence based on performance characteristics, the test will confirm that the specific requirements for its intended use have been met. To ensure consistency in the validity of the results relevant to clinical decision-making, the laboratory shall conduct sufficient verification or validation of the examination method. Which characteristics are relevant? The ones that are relevant to the intended use.

7. Refers to ISO/TS 20914 on measurement uncertainty

In the 4th edition, the measurement unit (MU) [19, 20] will undergo a comparison with performance specifications, the results will be documented, and regularly reviewed. In the current edition, ISO/TS 20914 [21] establishes itself as a definitive best practice guide for handling measurement uncertainty. It is crucial to assess and manage measurement uncertainty in a manner that aligns with its intended purpose, and this principle is part of the ISO/TS. When reporting uncertainty internally, it is imperative to take into account several sources of uncertainty, which may include, but are not limited to, factors related to biological variation. It must be clear what the components of uncertainty are. If a "top-down" model [22] is used in computing, important literature references can also be shared with the total analytical error

determination (measurement analogous to uncertainty), such as CLSI EP15. The difference between the approaches can be summarized as being due to the different combinations of sources, where bias is seen as a source of uncertainty through bias uncertainty and the combination follows the laws of variance combination.

In cases where it is not feasible or relevant to estimate the MU for examination procedures, the justification for excluding MU estimation should be documented. MU details will be provided to laboratory users upon request.

The consideration of MU during the verification or validation of a method is advisable. However, it is important to note that this recommendation is only mandatory if the medical laboratory deems it relevant to the assessment.

In examinations producing qualitative results, the assessment of MU in intermediate measurement steps or internal quality control results that generate quantitative data should also be extended to critical (high-risk) stages of the process [23–24]. However, this reported recommendation is rarely put into practice. The reason is that there are other quality control practices regularly applied by laboratories with success. For further details on MU in med lab, see [25].

7.1 Internal quality control

The primary objective of internal quality control is to ensure the intended quality of the results. Internal quality control can be deemed as fulfilled, given that it is contingent on the release of the patient's results. In the fourth edition, there is a novel proposal addressing trends and shifts, as well as the inclusion of a data generator for assessing measurement uncertainty, which represents a focus on long-term compliance.

7.2 External quality assessment

External quality assessment (EQA), also known as proficiency testing (PT), is essentially an interlaboratory comparison. In the fourth edition, there is the introduction of a target value and verification of trueness following current schemes. Whenever feasible, achieving metrological traceability to reference methods is encouraged. The target value may be determined based on consensus within a peer group. The notion of "commutable material" indicates that it responds to measurement methods similarly to patient specimens, emphasizing the necessity of commutability. In cases where a suitable EQA scheme is not available, an alternative approach should be considered. For an introduction to EQA see [26].

8. Discussion and conclusion

The present version of ISO 15189 does not require specific documented procedures. However, this should not be understood as "not documenting" but rather as a model open to different documentation approaches. In fact, a basis for documenting could be to follow a similar approach to the previous version, when we asked, "what to document?". While the previous version is clear on the do ("do this, do that"), the new edition focuses on doing what is needed. While the technical aspects of performance assessment may have traditionally emphasized measurement-related criteria, the fourth edition has shifted its focus toward the medical significance of these criteria. For instance, the European Federation of Clinical Chemistry and Laboratory

Medicine (EFLM) criteria take into account medical requirements, biological variation, and contemporary conditions. It also emphasizes the specific purpose of each measurement and the intended use of the test, be it for screening, clinical diagnosis, or other purposes. As a result, the present edition can be seen as providing fewer rigid guidelines and, in turn, will demand more thoughtful consideration, making it a more challenging endeavor to implement.

A recurring limitation found in prior editions is the standard's potential to foster better alignment of practices, especially in the context of performance assessment. Nonetheless, we recognize that this limitation will persist in present and future versions, as it could potentially conflict with prevailing national regulations, which always take precedence over standard norms. An example of this lack of harmony is evident in the variation of acceptable error limits.

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Chapter 11

Quality 4.0: Data Quality and Integrity – A Computational Approach

Rob Christiaanse

Abstract

The use of modern techniques, such as IOT, AI, and machine learning, revolutionized the idea of quality and quality control. Auditors face a tidal wave of data. One of the key challenges is how to determine the quality of the data, systems and processes produce. We propose a computational model to learn the inherent uncertainty to data integrity subsumed in the claims actually done by stakeholders within and outside the organization. The decision procedure combines two strong forms of obtaining audit evidence. These two forms are external conformation and re-performance. The procedure fits in the current modern computational idea data-driven assurance, which is consistent with quality 4.0 concepts in quality control and quality audit practices.

Keywords: data integrity, measurement, uncertainty, quality control, quality audit, quality standards, assurance, data quality

1. Introduction

It is to be expected that emerging technologies will have a profound impact on how we produce products, grow our food, use resources, organize services, and so on. We call these systems cyber-physical systems (CPS). A key characteristic of CPS is that information is infused in physical infrastructures to improve performance, flexibility, up-time of machines, product quality, minimize rejection rates, and improve the perceived product and service quality by end users, such as customers, regulators, and other stakeholders coined as society at large [1].

The key idea buttressing these developments lies in the realm of measuring things. In our daily lives, the act of measuring things is very important. Think of the simple act of buying groceries, in our case tomatoes, at your local grocery store. You enter the store and ask for 2 kilograms of tomatoes shown on the counter display. The grocer will pick the tomatoes and put them on a scale. He or she reads from the device the weight in grams. After having done this, the grocer will calculate the amount due in the local currency. You pay the amount due to the grocer, and he or she will hand over the tomatoes you have just bought. The problem you might face is whether the measured quantity is correct, which is the physical quantity in metrology subject to measurement. In general, metrology is the science of measurement and its

applications. A measurement is said to be traceable when an unbroken chain of calibrations is established to a specific reference measurement standard, in particular realizations of the measurement units of the international system of units (SI) [2]. So, the grocer must be aware that the scale he or she uses does, in fact, measure grams in the correct way. Needless to say that this is far from simple to establish by him or herself. So, the grocer trusts the claim of the manufacturer of the scale. But there is an extra problem you might be aware of. The tomatoes you have just bought must be compliant with the regulation (EC) No 178/2002 of the European Parliament and of the council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. The general food law regulation is the foundation of food and feed law. It sets out an overarching and coherent framework for the development of food and feed legislation both at union and national levels. To this end, it lays down general principles, requirements, and procedures that underpin decision-making in matters of food and feed safety, covering all stages of food and feed production and distribution. Food manufacturers, that is, tomato growers must make sure that their products are safe and do not endanger a human health. In North America, similar legislation is applicable, see Ref. [3]. Businesses involved with food must meet national safety and hygiene requirements in order to safeguard consumer health. So, the grocer again trusts the claim made by the tomato grower(s).

Clearly, there is a relationship between you buying tomatoes from the grocery store and the trust you must have in the measuring capabilities of the grocer using a scale and the quality of the tomatoes provided by the grocer trusting him or her that the tomatoes will not endanger your health. On a more abstract level, we face a network of interconnected entities like humans and objects like things interacting with each other. An ecosystem characterized as a communication and information exchange network in the world coined as social material systems (SMS) [4].

1.1 Research question and research approach

A quality control system (QCS) typically involves monitoring the performance of measuring instruments, standards of reference, and measurement information systems within the scope of the QCS. One might ask "How are ecosystems characterized as a communication and information exchange network, linked to a QCS so that we can trust the claim of suppliers making up the network?" In fact, this question is really about whether we can trust the data we use in the assertion of whether the claim of suppliers in a network is accurate. In this chapter, we propose a computational approach as a computational model to learn the inherent uncertainty to data integrity subsumed in the claim of stakeholders within and outside the organization. This research is in the realm of design science research and is to be characterized as design theory [5]. In this respect, this research coined as design relevant explanatory/predictive theory (DREPT) augments the "How" part or question with explanatory information on "Why" one should trust the proposed design will actually work. The key point is that the explanatory information is obtained using kernel theories. Kernel theories are established theories from social sciences, economics, mathematics, computer science, logic, and so on. We are interested in theory building on how to design effective and efficient governance and control systems, which may be interpreted as experimental scientific investigation. The ultimate unit of analysis is the individual coined as methodological individualism [6]. This chapter is outlined as follows. In chapter 2, we elaborate upon measurement, uncertainty, and how to model exchange

relationships mathematically. Next, we define what data integrity actually entails. In chapter 4, we elaborate on modeling decisions as evaluation procedures in auditing and quality control. The last two paragraphs put the procedure in the context of the strength of the audit evidence followed by conclusions.

2. Measurement and uncertainty

NIST defines measurement as an experimental or computational process that by comparing with a standard as a norm, produces an estimate of the true value of a property of a material, a (virtual) object, a collective of (virtual) objects, a process, an event, and a series of events, together with an evaluation of the uncertainty associated with that estimate and intended use in the support of decision making [7]. Measurement uncertainty concerns, that is, express the doubt about the true value of the measurand as the estimate of the true value of a property as defined after a measurement. The doubt relates to or is associated with the level of rigor to be determined on the level of uncertainty and what is needed to demonstrate its credibility that determines the adequacy to meet users' needs and wants. Most probably the adequacy is influenced by regulatory rules and regulations set by governmental bodies, such as governments, customers, demand, reputation of the company, ethical standards, and so on. This makes traceability to standards and assurance a complex endeavor to reach and maintain traceable performance standards.

Traceable to (SI) standards is not the same as counting objects. A claim that counts, as a result of a sample, are traceable to (SI) standards is not correct because it neglects the fact that counting inextricably involves the definition of what is being counted which definition is not a part of the (SI) standard, but when some characteristic of the object is measured then it might be possible that this particular measurement result is traceable to the (SI) standard. Making counting traceable to the (SI) standard is very important for economic life, one's health, one's security, and so on. The value lies in the precision of the measurement and therefore the measurement result. Put in other words: "Knowing the measurement uncertainty contributes to one's belief whether a measurement result as a count represents the quantity one has measured traced back to the (SI) standard."

Note that the noun phrase value like the noun clause traceability of measurement results has different meanings considering the situations in which the notions as concepts are used by humans interacting with artifacts, such as machines, software, and so on. This is why we must address the importance of measuring correctly when we evaluate the operational performance of some (organizational) entity that uses the measurement result for some purpose. Measuring correctly is inextricably related to data quality, but first, we have to model a standard that inextricably defines what is counted making it possible to make what is counted to be traceable to the (SI) standard.

2.1 Canonical model of exchange relationships

Exchanges are by definition reciprocal in nature and come in a large variety of what we coin as means like signed contracts, shaking hands, etc. For example, signing a contract by both parties is performative in nature; by the act of signing, we communicate that the exchange is done. Hence, a signed contract affords exchange. An affordance establishes the relationship between an object or an environment and an

organism here a (human) agent through a stimulus to perform an action. In our example, the stimulus is the signed contract and the detectable change in the external environment. We assume that the agent is sensitive and therefore able to respond to external (or internal) stimuli [8, 9].

Bilateral contracts are commonly used in business transactions. You buy 2 kilograms of tomatoes in our introductory example is a type of bilateral contract. The grocer promises to deliver the tomatoes and you promise to pay for the tomatoes by giving the grocer the indebted amount you have agreed upon when receiving the tomatoes. More formally, we can depict the canonical description of a value exchange cycle as in **Figure 1**. We use the following notation.

Notation 1.1: (Bilateral contract—canonical model), we will use the left and right harpoons exclusive for a bilateral contract between two agents $S \rightleftharpoons B$. Furthermore, actions are denoted as round-edged rectangles. Action nodes are connected via arrows that specify the control, that is, the information and communication flow. Together with the initial and the final node depicted as a solid circle and a solid circle surrounded by a hollow circle, we have a correct descriptive model of the value exchange cycle.

Note that money is exchanged for goods and or services. The exchange will actually occur in practice when parties agree upon a contract, that is, the transaction governance, the transaction structure, and the transaction contents, by the act of signing denoted by the initial node depicted as a solid circle. The contents reflect the objects of exchange. In our case tomatoes, now it is possible to extend the bilateral contract from a market point of view as depicted in **Figure 1** into a value exchange cycle from an organizational point of view. The final result is depicted in **Figure 2**.

Remark 1.2: (Bilateral contract—organizational view): Mark that the value exchange model described the sell-side of agent A and the buy-side of agent B. Now, it

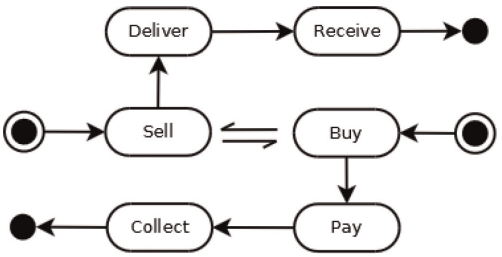

Figure 1.
Value cycle exchange.

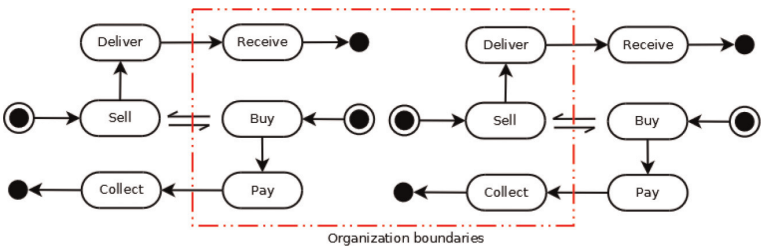

Figure 2.
Value exchange cycle double.

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is easy to see that agent A as an organization must also have a buy-side otherwise he would not be able to deliver the ordered goods or services. The same type of reasoning does apply to buyer B who must have a sell-side otherwise or has enough budget to consume the goods or services. By simply doubling the model of the value exchange cycle (i.e., the bilateral contract—Marker view) we get the precise description of the value cycle of an organization in which organizational boundaries are denoted as the dashed line in red. For a more detailed exposition, we refer to Ref. [10].

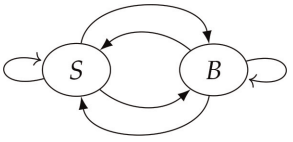
This concludes our informal description of bilateral contracts used in value exchange situations. We will see that under specific conditions the market view model is equivalent to the organizational view model. It is also easy to see that the organizational point of view is easily extended in a net(work) of contracts similar to supply chain models commonly used in logistics [11, 12].

2.1.1 Bilateral contract—Market graph

It is quite straightforward to translate the give-and-get relationship depicted in **Figure 1** in a mathematical graph. More specifically a give-and-get relationship is a directed graph. Formally a graph is defined as follows [13].

Definition 1.3: (Graph): A graph G = (V, E) is a mathematical structure consisting of two finite sets V and E. The elements of V are vertices (or nodes), and the elements of E are the edges. Each edge has a set of one or two vertices associated with it, which are called endpoints. A formal specification of a general digraph D = (V, E, endpoints, head, and tail) is obtained from the formal specification of the underlying graph by adding the functions head: $E_G \rightarrow V_G$ and tail: $E_G \rightarrow V_G$, which designate the head vertex and the tail vertex of each arc.

Translating the value cycle exchange market view of the bilateral contract into a directed graph gives us the following result.



In a bilateral exchange relationship, money is exchanged for goods and or services. This is true from the buyers' perspective as well as from the sellers' point of view. We say that the proportion of goods and or services to money equals the proportion of money to the goods and or services. So, we get the following equality:

$$\frac{Goods}{Money} = \frac{Money}{Goods} \tag{1}$$

Let χ denote the goods and μ denote the money, so, we get:

$$\frac{\chi}{\mu} = \frac{\mu}{\chi} \tag{2}$$

Nodes S and B are in fact rationals, defined as follows [14]:

Definition 1.4 (Rational number): A rational number is an expression of the form a//b, where a and b are integers and b = nonzero; a/0 is not considered to be a rational number. Two rationals are considered to be equal, a//b = c//d, if and only if ad = bc.

Given the definition of a rational remark that money, goods and services are not equal objects, but that the exchange relationship itself is equal. We observe that

$$S = \frac{\chi}{\mu} \Rightarrow \frac{\chi}{\mu} \cdot \frac{\mu^2}{\chi^2} \Rightarrow \frac{\mu}{\chi} = B \tag{3}$$

and

$$B = \frac{\mu}{\chi} \Rightarrow \frac{\mu}{\chi} \cdot \frac{\chi^2}{\mu^2} \Rightarrow \frac{\chi}{\mu} = S \tag{4}$$

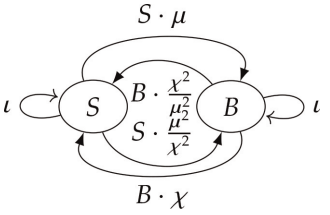
It follows that the following equality holds:

$$B \cdot \ S = \frac{\mu^2}{\chi^2} \cdot \ \frac{\chi^2}{\mu^2} \tag{5}$$

Remark 1.5 (Equality—bilinear): Equality (5) is not that easy to understand. For now, it suffices to state that the multiplication symbol as a connective is to be understood as a multiplicative $B \otimes S$ which is the bilinear version of and, dominated by the linear negation $(\cdot)^{\perp}$, which is a constructive and involutive negation defined in linear logic [15].

To be precise, the bilateral exchange relationship preserves the identity of the objects denoted as rationals. Consequently, S delivers χ, denoted as $S \cdot \mu$ and B pays the money μ, denoted as $B \cdot \chi$. Mark that ι denoted as a loop in the graph serves as an explicit precondition(s). Now, we can label the nodes and edges.

Remark 1.6 (Equality—linear): It is important to note that $S \cdot \mu$ and $B \cdot \chi$ are additives in linear logic, which is the linear version of and denoted as $S\&\mu$ and $B\&\chi$.



Returning to our example, suppose you have to pay 4 € for 2 kilograms of tomatoes. The grocer will hand you the 2 kilogram tomatoes expressed by $S \cdot \mu$. You pay 4 euros expressed by $B \cdot \chi$. Both actions will take place under the strict condition that you and the grocer agreed upon the contract denoted by ι and the unit tomatoes per euro preserving the identity expressed as: $S \cdot \frac{\mu^2}{\chi^2}$ and $B \cdot \frac{\chi^2}{\mu^2}$. Mind that S and B are rationals.

Up till now, our notions of goods, services, and money are in fact dimensionless. Parties will also have agreed upon the unit of measurement of the goods or services the seller will deliver and get paid for, respectively, the buyer will receive and is obliged to pay for the received goods or services from the seller. We will use the following notation.

Notation 1.7 (Units: measures and measurement): The quantity of the object O is measured in some standard unit expressed as a number and a reference denoted as superscript st and superscript m, the dimension quality denoted as (q) of object, and the dimension absolute frequency as a number of objects. Standard units expressed as

a number and a reference $Q_O^{st}Q_O^m$ can be denoted as $U_{(O_q)^S}$ for the sell-side and $U_{(O_q)^B}$ for the buy-side, where U denotes the standard unit expressed as a number and a reference. The quantity of the object O is measured in some standard unit U and the measurement is expressed as a product Q · U, the dimension quality denoted as q of object, and the dimension absolute frequency as a number of objects.

We denoted χ for the goods and services and μ for money. For the sell-side we get:

$$Seller\chi := \quad Q^S_{\chi_q} \cdot U^S_{\chi_q} \cdot U^S_{\chi} \tag{6}$$

$$Seller\mu := \quad Q^S_{\mu_q} \cdot U^S_{\mu_q} \cdot U^S_{\mu} \tag{7}$$

For the buy-side we get:

$$Buyer\chi := \quad Q^B_{\chi_q} \cdot U^B_{\chi_q} \cdot U^B_{\chi} \tag{8}$$

$$Buyer\mu := \quad Q^B_{\mu_q} \cdot U^B_{\mu_q} \cdot U^B_{\mu} \tag{9}$$

We stated earlier that traceability to (SI) standards is not the same as counting objects. A claim that counts are traceable to (SI) standards is not correct in the case one neglects the fact that counting inextricably involves the definition of what is being counted which definition is not a part of the (SI) standard. The canonical model of the bilateral contract ensures that all characteristics of an object can be identified and thus be measured, so that the particular measurement results are by design traceable to the (SI) standards. Remark that money is considered as an abstract object alike goods and services. As we will see later on in this chapter it is this particular characteristic which is very convenient, that is, helpful, but first, we have to extend our model to fit the organizational view.

2.1.2 Bilateral contract: Organizational graph

From a business perspective, we have to translate the value cycle exchange market view of the bilateral contract into a directed graph representing the bilateral contract organizational view. To do so, we have to extend our definition for rational numbers for sum, product, negation, subtraction, and quotient.

Definition 1.8 (Rational number—sum, product, negation, subtraction, and quotient). If a//b and c//d are rational numbers, we define:

$$[sum](a//b) + (c//d) := (ad + bc)//(bd) \tag{10}$$

$$[Product](a//b) \cdot (c//d) := (ac)//(bd) \tag{11}$$

$$[Negation] - (a//b) := (-a)//b \tag{12}$$

$$[Subtraction](a//b) - (c//d) := (ad - bc)//(bd) \tag{13}$$

$$[Quotient]x/y := x \cdot y^{-1} \tag{14}$$

Next, there are basic properties of order on the rationals. Following Tao they are [14]:

Proposition 1.9 (Basic properties of order on the rationals): Let x, y, and z be rationals, then the following properties hold:

Laws 1.10 Order trichotomy. Exactly one of the three statements x = y, x < y or x > y is true.

Laws 1.11 Order is antisymmetric. One has x < y if and only if y > x.

Laws 1.12 Order is transitive. If x < y and y < z, then x < z.

Laws 1.13 Addition preserves order. If x < y, then x + z < y + z.

Laws 1.14 Positive multiplication preserves order. If x < y and z is positive, then xz < yz.

Via law 1.10 order trichotomy, we know that it must be the case that exactly one of the three statements x = y, x < y or x > y is true. It follows that:

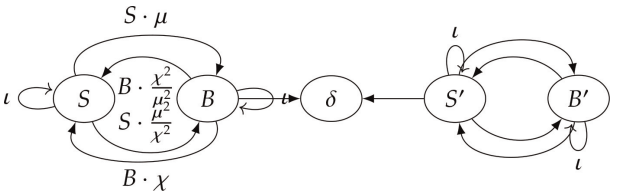
Laws 1.15: In the case S=B, then it must be the case that x equals y. In the case $S \neq B$, then it must be the case that x < y or x > y.

Now, we introduce the notion of distance.

Definition 1.16 (Distance δ): Let x and y be rational numbers. The quantity |x - y| is called the distance between x and y denoted as d(x,y), thus d(x,y): =|x-y|.

It follows that d(x,y) = 0 if and only if x = y and $d(x,y) \neq 0$ if and only if $x \neq y$.

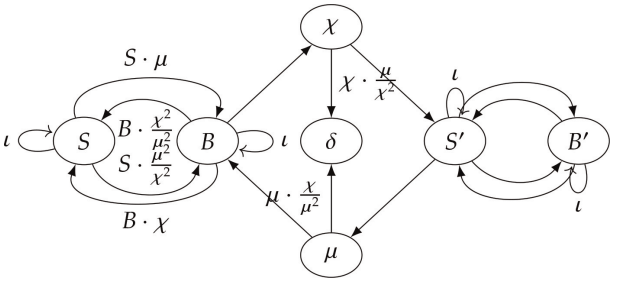
Translation of the value cycle exchange market view of the bilateral contract into a directed graph representing the bilateral contract organizational view we get the following result.



Subtraction of rationals is defined in eq. 13. When we apply subtraction of B and S′ and take the absolute value, then we get the distance:

$$|\frac{\mu}{\chi} - \frac{\chi}{\mu}| = |\frac{\mu \cdot \mu - \chi \cdot \chi}{\chi \cdot \mu}| = \delta \tag{15}$$

Extending the graph gives us the following result.



Remark 1.17 (Equality - δ): To see that the extended graph—organizational view is equivalent to the canonical model of the bilateral contract—market view we take eq. 3, 4, and 15 into account. Eq. 15 gives the definition of δ:

$$|\frac{\mu}{\chi} - \frac{\chi}{\mu}| = |\frac{\mu \cdot \mu - \chi \cdot \chi}{\chi \cdot \mu}| = \delta \tag{16}$$

The formulas $\chi \cdot \frac{\mu}{\chi^2} \otimes \mu \cdot \frac{\chi}{\mu^2}$ can be rewritten by substituting χ by S $\cdot\mu$ and substituting μ by B $\cdot\chi$. We get:

$$S = S \cdot \mu \cdot \frac{\mu}{\chi^2} \;\Rightarrow\; S \cdot \frac{\mu^2}{\chi^2} \;\Rightarrow\; \frac{\chi}{\mu} \cdot \frac{\mu^2}{\chi^2} = \frac{\mu}{\chi} = B \tag{17}$$

and

$$B = B \cdot \chi \cdot \frac{\chi}{\mu^2} \;\Rightarrow\; B \cdot \frac{\chi^2}{\mu^2} \;\Rightarrow\; \frac{\mu}{\chi} \cdot \frac{\chi^2}{\mu^2} = \frac{\chi}{\mu} = S \tag{18}$$

Now, it is easy to see that both models—market vs. organizational view—are equivalent, that is, isomorphic.

When we interpret the graph, then it is easy to see that δ is only meaningful if and only if the units of measurement are identical. The following axioms must hold:

$$\textit{Equality of units of measurement}\chi \qquad U^S_{\chi_q} \cdot U^S_{\chi} = U^B_{\chi_q} \cdot U^B_{\chi} \tag{19}$$

$$\textit{Equality of units of measurement}\mu \qquad U^S_{\mu_q} \cdot U^S_{\mu} = U^B_{\mu_q} \cdot U^B_{\mu} \tag{20}$$

In the case, B and S′ are the same agents as S and B′, then δ = 0. In the case, they are not the same agents then δ can have three values of which exactly one of the three statements x = y, x < y, or x > y is true. It follows that when x = y that the following laws hold:

$$\textit{Equality} \qquad B = S \tag{21}$$

$$\textit{Equality} \qquad S = B \tag{22}$$

If x < y or x > y is true, then the following equalities hold, respectively:

$$\textit{Equality} \qquad B + \delta = S \tag{23}$$

$$\textit{Equality} \qquad B = S + \delta \tag{24}$$

Remark that we are interested in the proportionality and not in the quotient arithmetically.

With this description, we are complete to elaborate on the notion and role of data quality in a rigorous way, but first, we have to elaborate on the notion of data integrity.

3. Data integrity

Making counting traceable to a (SI) standard contributes to the precision of the measurement itself and it determines whether the measurement result is acceptable to the adhered standards, implying that there exists a decision procedure as an evaluation procedure warranting that the standards are met.

A decision procedure as described assumes that the data quality is up to standards. To understand the concept of data quality, one needs to understand data

integrity. Data integrity in itself is defined as "the state that exists when data are unchanged from its source and has not been accidentally or maliciously modified, altered or destroyed" [16]. This view is consistent with the model proposed by Boritz in Ref. [17, 18] in which data integrity is subsumed in the notion of information integrity. Boritz defines information integrity as the representational faithfulness of information to the true state of the object that the information represents. His aim was to define and validate a general purpose framework that can be used for controlling and as well as for auditing purposes. In this way, information integrity impairments can be addressed in an organized and rigorous manner to guide management risk assessments and control deployment on the criteria to be addressed to attain reasonable assurance of whether information integrity objectives are met. Information integrity really concerns the validity and completeness aspects of the representation itself. Indeed, the object actually measured.

Boritz distinguishes (core) attributes from enablers, helping realize representational faithfulness. In his view, representational faithfulness is viewed as a degree of achievement of it rather than absolute quality. Practically it is all about accuracy/correctness, which has two dimensions viz. completeness on one side and validity on the other side. In the case, these dimensions are flawed, then it has negative consequences for the accuracy/correctness assertion. Obviously, there is a trade-off. Consequently, representational faithfulness is subject to some degree of imperfection, with the tolerable degree of imperfection being defined differently in different domains and contexts. In **Figure 3**, this trade-off relationship is depicted by the pointed arrows.

Now, it is quite logical how these core attributes help in realizing the representational faithfulness of information to the true state of the object that the information represents. From an user perspective, granularity enables understandability and relevance buttressing the decision-useful approach in decision-making. From a systems view is it essential that all data are available and accessible as enablers helping to warrant that the data are complete, current, and timely. From a data integrity perspective, security warrants as an enabler that the proper authorization is realized subsumed in validity. The attributes predictability, consistency, and neutrality preserve the informational quality as measurement. Neutrality warrants from this point of view that the information is free from biases, that is, neutrality preserves that objective standards are met. Verifiability as an enabler warrant the ability that independent observers, applying the same processes and tolerances for completeness, currency, timeliness, and validity that are used to produce the information, to replicate substantially the same result. Where auditability refers to the possibility to trace information back to its source and confirms the representational faithfulness of the information. It applies to all enablers that we design and implement controls to assure that the core attributes are fulfilled and therewith the representational faithfulness is attained. In **Figure 4**, we have extended **Figure 3** with the attributes which determine and influences the accuracy of the data.

Figure 3.
Accuracy data.

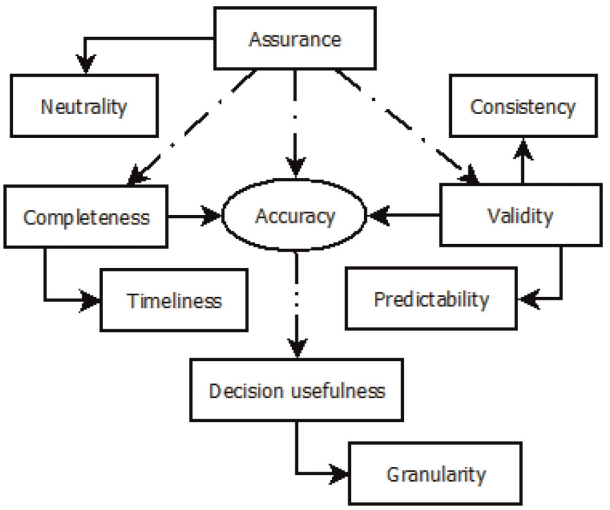


Figure 4.
Accuracy data and their properties.

4. Modeling the decision procedure as in auditing and quality control

In describing the decision procedure we use a pseudo-code format as in Ref. [19]. Our motivation is to reveal the algorithmic idea behind quality auditing and quality control practices within a business context but not limited to so. We happily leave it to the reader to make a final choice on how to implement algorithms using the program technology of his or her choice. It is important to be aware of what is to be considered as the object language. An object language is used to denote the language talked about for example formal expressions of propositional logic, linear logic, and so on. A metalanguage denotes the language in which we are talking about the object language, for example, a natural language augmented by a variety of common mathematical symbols. We think for the purpose of this chapter comprehensibility is preferred to the level of mathematical, that is, computational rigor required for implementing algorithms in some program technology running on some (preferred) hardware configuration part of a technological infrastructure coined as an information and communication network.

As we have stated in paragraph 2, measurement uncertainty expresses doubt about the true value of the measurement, as the estimate of the true value of a property as defined after a measurement. The doubt about the true value concerns the result of an evaluation of the uncertainty associated with the actual measurements compared with the estimated uncertainty and the intended use in the support of decision-making. In paragraph 2.2.1, we defined the notion of distance δ giving us the means to quantify the expected measurement result and to quantify simultaneously the actual impact of noncompliance by comparing the actual business outputs with expectations. This type of analysis is commonly known as variance analysis. Expectations are thought of as norms and predict normative behavior [20]. Norms in itself can be thought of as preconditions or postconditions that serve as conditionals in the determination of whether to accept the input conditions or to accept the output conditions. In the next sub-paragraphs we will elaborate on how to model an evaluation procedure to assess the data integrity. We define a process modeling language to translate the value exchange cycle as depicted in **Figure 2** to model the evaluation procedure to assess the data integrity of given data sets.

4.1 Modeling evaluation procedure data integrity

Accepting conditions presumes a decision procedure where inputs are compared with the norm(s) applicable to the input(s). So, we assume that there exists for any set S of formulas a valuation of S, which is a function v from S into the set t,f, where t denotes true and f denotes false coined as truth values. We say that X is true under v if v(X) = t, and false under v if v(X) = f. So, accepted inputs or outputs make up the truth set [21]. We give the following definition:

Definition 1.18 (Boolean valuation):

- B_1: The formula $\neg X$ receives the value t if X receives the value f and f if X receives the value t.
- B_2: The formula $X \wedge Y$ receives the value t if X, Y both receive the value t, otherwise $X \wedge Y$ receives the value f.
- B_3: The formula $X \vee Y$ receives the value t if at least one of X, Y receives the value t, otherwise $X \vee Y$ receives the value f.
- B_4: The formula $X \supset Y$ receives the value f if X, Y receives the respective values t, f otherwise $X \supset Y$ receives the value t.

By an interpretation of a formula X, we mean an assignment of truth values to all the variables which occur in X.

Proposition 1.19 (Accuracy): The data is accurate and is TRUE if and only if:
(1) the data is VALID is TRUE is TRUE ∧ the data is COMPLETE is TRUE is TRUE.

Algorithm 1: Decision procedure interpretation

```
   Input: Accuracy data model
1  ▹ see figure 3;
   Output: TRUTH set
   Data: data file
2  ▹ collection of attributes representing the object and its properties;
   Result: Assurance accuracy data
3  ▹ result of the decision procedure;
4  initialization: read data file ▹ one or more data files;
5  if the data is ¬ VALID is TRUE ∧ the data is ¬ COMPLETE is TRUE then
6  |  the data is ¬ ACCURATE;
7  else
8  |  if the data is VALID is TRUE ∧ the data is COMPLETE is TRUE then
9  |  |  the data is ACCURATE;
10 |  else
11 |  |  the data is VALID is TRUE ∨ the data is COMPLETE is TRUE;
12 |  end
13 end
```

This completes our description of the decision procedure. Now, we have to address the data. Data integrity are subsumed in the notion of information integrity coined as

the representational faithfulness of information to the true state of the object, measured and registered in an information system, that the data as information represents. Following Clark and Wilson [22], we recognize the notions of internal consistency and external consistency of the data produced by a system. The distinction is similar to the distinction between internal and external validity made in research methods. Suppose we have a well-managed computer system. Its specifications have been verified to be correct and the system itself has been tested and behaves according to its specifications. That means that when we enter data into the system that is valid, valid data will ensue (internal consistency). However, even in such a near-perfect system, there is nothing to ensure correspondence with reality (external consistency). In general, external consistency can only be ensured by a combination of organizational measures (segregation of duties, policies, and so on), procedural measures (e.g., processing controls and supervision), and physical measures (e.g., gates, fences, and use of IDs). These measures are basic and some authors, therefore, call these measures indispensable controls, because they must ensure external validity of the (quality) control and (quality) audit evidence. From a design point of view, the key questions we have to address are whether we can trust the data and can use the data. The question can we use the data really concerns the question of whether the data actually registered in the information system itself actually fits our information needs. This is the first step we have to consider and is directly related to the data file at the start of our decision procedure. In the case, the data file actually represents the data as information for decision purposes then it is useful to check whether the data file contains data that are valid and complete. To answer these questions, we extend our bilateral contract—organizational view, as depicted in **Figure 2** by introducing our process-model language.

4.2 Process-model language: Definition and meaning

For our purposes, we need a language to make sure that our reasoning is precise and most of all easy to use. There are numerous ways to model processes, techniques to choose from and methodologies to apply. For our purposes, it suffices to use UML (unified modeling language) because UML provides a common meta-model that formally defines the abstract syntax of all sorts of diagrams for modeling process behavior. The declarative meta-model is a very good alternative to grammar used to define formal languages. As we will see, this feature characteristic provides the possibility to reason in a correct way. In our exposition, we use activity diagrams to model process behavior. The next section is based on Ref. [23].

Actions describe the tasks that have to be performed in realizing a primary function to be viable [24]. An action stands for some transformation in the modeled system to be performed. The sequence in which the actions must be executed is the most fundamental control structure. As we have seen actions in our language are denoted as round-edged rectangles. The arrows between the action nodes are the activity edges which specify the control flow. Together with the initial and the final node depicted as a solid circle and a solid circle surrounded by a hollow circle we have a correct specification of the control flow (**Figure 5**).

The semantics is defined as a token flow that can also be used to refer to data and physical objects. The tokens are referred to as control tokens and as object tokens. Mind that actions can only start when tokens are available from the proceeding action or actions along the incoming edges. We say that tokens are consumed when action starts. Consequently, tokens are produced, that is, offered to the outgoing edges when

Figure 5.
Control flow.

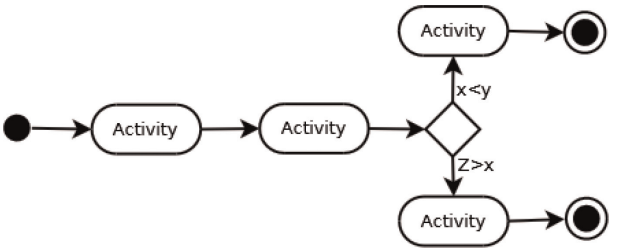


Figure 6.
Decision nodes and guards.

completed. In some circumstances, decisions have to be made for the choice of alternative control flows. Decision nodes are denoted as diamonds annotated by guards. The extended control flow can be depicted in **Figure 6**. Guards are logical expressions ending up to be true or false. Either we can state them in natural language, programming language constructs, or in formal mathematical logic. Guards can be refined as being pre and postconditions. When needed we will introduce them. The control logic remains the same. There are many more types of nodes used in modeling control flows, such as fork nodes, merge nodes, and join nodes. These types of nodes can be useful.

Finally, we have two types of nodes that are essential for our purposes. These are object nodes and data store nodes. Object nodes are needed to model the occurrence of objects at a particular moment or point in the process. Objects can be typed. We will extend this formalism extensively for our theory. To capture the object flow, the token flow semantics of activity diagrams is extended with object tokens. An object token behaves like a control token but it carries additionally a reference to a certain object type. Remark that we have to consider object type compatibility. This requirement is of utmost importance for our theory which we will see later in this chapter. A very convenient modeling notion is to use input pins and output pins which enables us to know which input and output parameters are assigned to various actions in the process. Pins are depicted as small hollow squares with their type written next to the square. In the case, we want to store information about orders, for example, than we can model such an action as a data store using data store nodes denoted as a rectangle. A data store node keep all tokens that enter it, copying them when they are chosen to move downward. See **Figure 7** for an example.

4.3 Modeling evaluation procedure data integrity extended

Now, we can extend our bilateral contract—organizational view to get a clear view about the informational needs and therewith next to it the requirements to meet a company's control and auditing objectives. The result is depicted in **Figure 8**.

Our objective is to assert whether the data stored as depicted in **Figure 8** can be considered to be accurate. More specifically these data stores enable us to extract one or more data files we need as input data in our decision, that is, evaluation procedure

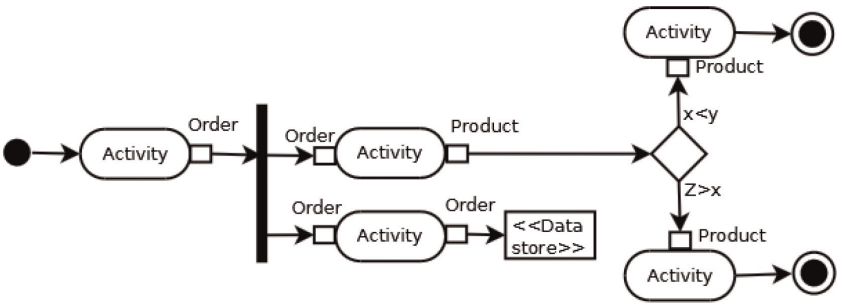


Figure 7.
Pins and data store.

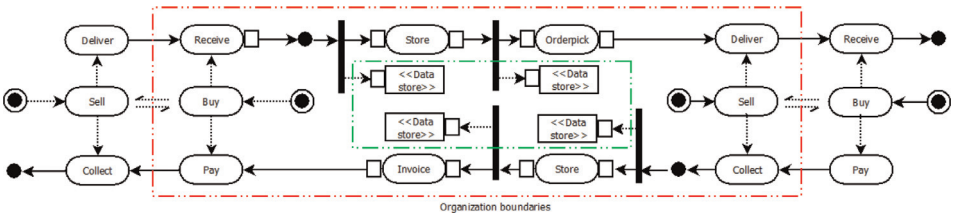


Figure 8.
Control flow extended.

to assert the accuracy of the extracted data set(s) and its acceptability, that is, adequacy for quality control and quality audit purposes. In our example, we have identified data about stored goods, data about order-picked goods (to be) delivered, data about the collected revenues of the goods sold, and data about the actual payments of invoices received from suppliers for the goods we have received and stored in the warehouse. In general, a process stands for the behavioral pattern of an object, as far as it can be described in terms of the given named activities selected as its alphabet [25]. An alphabet denotes a permanent predefined property of an object. Remark that the name of an activity denotes an event class. There may be many events in a single event class named as an activity. Choosing an alphabet involves careful deliberation to decide which properties should be considered. A trace of the behavior of a process is defined as a finite sequence of symbols recording the event in which the process is engaged up to some moment in time. More formally:

Definition 1.20 (a trace is the sequence of symbols separated by commas closed by angular brackets):

- < x,y > denoting two events, x followed by y,
- < x > denoting one sequent, containing only the event x,
- < > denoting an empty sequence.

So, our extracted data set(s) from the data store(s) must contain all traces of the goods received from suppliers, all traces of the order picked goods (to be) delivered, all traces of the collected revenues goods sold to customers, and all traces of the paid invoices for the received goods from suppliers. It follows from the definition of a process that an alphabet defines the dimensions as column attributes giving us the names of all attributes making up the first row of the data set extracted from the data store(s) stored in the data file. The alphabet also gives us precise definitions of the object types and their properties. How do we proceed from here? Let us extend our running example.

4.3.1 An example

Suppose the organization we focus on is a trading organization specialized in tomatoes. On a daily basis, the organization buys the needed tomatoes at a local vegetable auction. The clients of the organization are retail organizations serving end customers. It is important to point out the fact that the organization has to comply with strict food safety regulations like Ref. [3]. For tomatoes quality indicators have been well established by total soluble solids measured by Brix-scale, dry matter, and acid contents. A Brix rating is important because it informs us about the quality of the tomato. The measurement is worked out on a scale based on 1° Brix denoted as °Bx, which is 1 g of sucrose per 100 g of solution. A low Brix rating indicates a nutrient deficiency. The Brix rating is used to measure the sweetness of tomatoes, but the rating is also linked to the acidity or PH level of the tomato. Tomatoes have on average a PH level between 4.3 PH and 4.9 PH on a scale of 0–14 PH. It is the combination of sweetness vs. acidity that gives the tomato its unique flavor. The Brix rating can be measured by using techniques labeled as NIR-spectroscopy, see Ref. [26]. From quality control and quality audit perspective, we need to know the unit(s) of measurement to determine whether the procured and sold tomatoes comply with quality standards to adhere for tomatoes. Relative density or specific gravity is defined as the ratio of the density (mass of a unit volume) of a substance to the density of a given reference material (substance). More formally:

$$RD = \frac{\rho_{substance}}{\rho_{reference}} \tag{25}$$

where RD denotes the relative density and ρ denotes density. So, a reference material is indicated as $RD_{substance/reference}$ which means the relative density of substance with respect to the reference. This description is equivalent to the notation and definitions introduced in paragraph. 2.1.1. Mind that mass and weight are separate quantities, they have different units of measure.

Let us assume that the organization bought 4000 kg of tomatoes and sold the 4000 kg to clients of the company. The company trades in one type of a large variety of tomatoes is the assortment. The buying price was €2,51 kg. The selling price was €2,63 kg. The agreed-upon contracts stipulates all sorts of requirements, including quality standards, applicable to the tomatoes. Parties agreed upon the acidity of the tomatoes must have a PH level between 4.3 PH and 4.5 PH on a scale of 0–14 PH and a sucrose RD of 9,993,325 °Bx.

4.3.2 Data integrity revisited

To assert whether the data stored as depicted in **Figure 8** can be considered to be accurate one needs to understand the objective of the evaluation procedure modeled in Algorithm 1: Desicion procedure interpretation. The proposition is:

Proposition 1.21 (Accuracy): The data is accurate is TRUE denoted as T if and only if:

The data is VALID is T is T $\wedge$ the data is COMPLETE is T is T.

In paragraph 3, we elaborated on the concept of data integrity. In **Figure 4**, we depicted the accuracy data model and its key aspects that determine the accuracy of the data. There are three major aspects that determine the accuracy of the data and therefore its data integrity. These are:

- Consistency
- Predictability
- Timeliness

All other aspects are derived from notions necessary to trust the data and to strengthen one's belief that the information integrity is assured. Consistency has a variety of meanings, such as coherent, consistent, cohesive, connected, connective, sequacious, and so on. So, it is important to be specific about what is to be understood in the context of data accuracy. In this chapter, we choose a mathematical logical definition, which fits its purpose [21]. On the other aspects, we will elaborate in due course.

Definition 1.22 Consistency: A set X is called consistent if and only if for no finite subset Y of X at most one of A and A belongs to X, but not both. Meaning A cannot be both true and false.

As we can see, there is a strong relationship between the contract with the supplier and the purchase order of the goods here tomatoes. The contract specifies the conditions the organization and the supplier agreed upon. So, we have data about the price, quantity ordered, and quality norms applicable to the tomatoes. The same is true for the contract agreed upon with the customer and the sales order. Remark that next there is a strong relationship between ordering goods and money outflow due to paying the invoice. The same is true with respect to the sales of tomatoes and receiving the money. The type of controls to re-perform the relations are called reconciliation controls [27]. These types of controls follow directly from paragraph 2.1.2—extended graph bilateral contract—organizational view and **Figure 8** control flow extended.

4.3.3 The nature of controls: A classification

Before we extend our evaluation data integrity procedure, we have to elaborate on the nature of internal controls to be distinguished from processing controls, such as quality controls and quality audits. Internal controls are subsumed in processing controls as data integrity is subsumed in information integrity (**Table 1**).

As we see, there are two categories of controls making up five types of controls.

A. Access controls are what we coin as identity access controls (IAC) also known as segregation of duties controls. We prefer the term IAC. There are three elements

Type controls	Data integrity	Information integrity
Internal controls	Access controls	Accessibility controls
	Application controls	
	Reconciliation controls	
Processing controls	Availability controls	Usability
	Process logic controls	

Table 1.
Typing controls.

that buttress IAC. First identity control think of your user-ID. Secondly, there is authentication control, think of your password or passport. Thirdly, there is access control, think of authorization entering a theater or some office building where the porter lets you in. IAC enables an organization to safeguard assets or data of an organization. Remember, data integrity in itself is defined as "the state that exists when data are unchanged from its source and has not been accidentally or maliciously modified, altered or destroyed" [16].

B. Application controls come in a large variety. The there main purpose is to enforce that data is entered in the correct way. Well-known examples are field check, sign check, limit check, range check, size check, completeness check, validity check, and closed loop verification. Application controls make sure that the right syntax is used and make it possible to implement business rules and constraints that fit the authorization level of an employee.

C. Reconciliation controls are simply a comparison of the amounts that appear on the company's balance sheet general ledger accounts to the details that make up those balances, while also ensuring that any differences between the two are adequately and reasonably explained.

D. Availability controls are part of what is coined as information technology general controls (ITGC), which are the basic controls that can be applied to IT systems, such as applications, operating systems, databases, and supporting IT infrastructure. The objectives of ITGCs are to ensure the integrity of the data and processes that the systems support.

E. Process logic controls are controls that determine whether the process is executed in the sequence that must be executed. For example, a procurement activity can not start in the case the contract with the supplier is not signed by an authorized employee.

When we map the data integrity controls onto the properties of data accuracy, we get the following result (**Table 2**).

Remark that the listed data integrity controls instantiate of what we have addressed as guards in our process-model language to be considered as preconditions

Type controls	Data integrity	Property	Completeness	Validity
Internal controls	Access controls	Consistency	X	X
	Application controls	Consistency		X
		Completeness	X	
	Reconciliation controls	Completeness	X	
Processing controls	Availability controls	Techn. data integrity	X	X
	Process logic controls	Timeliness	X	
	Process logic controls	Predictability		X

Table 2.
Typing controls.

and postconditions. Now, we are able to extend our evaluation data integrity procedure computationally.

4.4 Evaluation procedure assessment data integrity

We have seen that by typing controls in terms of internal controls and processing controls, we are able to clarify the property of the control subsumed in completeness and validity. We see that access controls and availability controls both underpin completeness and validity. Availability controls can be characterized as technical preconditions defining the types of attributes enabling us (human or machine) to register data in the preferred format, ensuring data integrity and data processing integrity, so no data get lost (in the information system). Considering the control flow depicted in **Figure 8**, and we analyze the data given in our example as given in paragraph 4.3.1, we come up with a specification of the attribute types specified in **Table 3**. We have listed the attributes and definition of its syntax, making up the alphabet as described earlier in this chapter. This completes our description of the alphabet we need.

The combination of unique number of ContractID, ActivityID, EmployeeID, RoleID, ProductID, and MachineID with the units °Bx, kg, €, and PH preserves the

Attribute definition	**Description**	**Attribute definition**	**Description**
ContractID =:: <integer>	Unique number	NetTotalInvoice =:: <00000,00>	Total invoice excl. VAT
AgentType=:: <integer>	Unique number	€	valuta r
AgentTypeDescription =:: <text>	Supplier, Buyer	TotalInvoice =:: < 00000,00>	Total invoice incl. VAT
NameAgentType =:: <text>	Description	MinAcid =:: <00,00>	Minimum PH
ActivityID =:: <integer>	Unique number	MaxAcid =:: <00,00>	Maximum PH
ActivityDescription =:: <text>	Buy, Receive,		
	Sell, Deliver,		
	Collect, Pay	PH	Unit PH
ActivityDate =:: <dd-mm-yyyy>	Date activity	Brix =:: < 000000000,00000 >	Brix ratio
SigDate =:: <dd-mm-yyyy>	Date signature	°Bx	Unit Brix
EmployeeID =:: <integer>	Unique number	QuantityWeighted =:: <00000,00>	Weighted kilos
NameEmployee =:: <text>	Name	Kg	Unit kilogram
RoleID =:: <integer>	Unique numberr	MachineID =:: <integer>	Unique number
RoleDescription =:: <text>	Description Role	MeasuredAcid =:: <00,00>	Real measured PH
ContractPrice =:: <00,00>	Decimal price	MeasuredBrix =:: < 0000,00000 >	Brix ratio real measure

Attribute definition	Description	Attribute definition	Description
€	Valuta	ExpAcitviityDate =:: <dd-mm-yyyy>	Expectation
VAT =:: <00,00>	Perinuage		
ProductID =:: <integer>	Unique number		
ProductDescription =:: <text>	Description		
Quantity=:: < 000000000,00>	Quantity		
Kg	Unit kilogram		

Table 3.
Attribute types description.

identity, which is elementary for data integrity in itself and the processing of data, so no data are lost. Put in other words. It is expected that the system is consistent. This notion as concept is fundamental to understand from a mathematical logical point of view but also to understand the notion of uncertainty.

Earlier we addressed that we make a distinction between the object language and metalanguage. In our pseudo code, the metalanguage is expressed as comments on the algorithm for its purpose. The logic is we have input data; we get output data for some purpose to be interpreted by a machine, human, or both. The algorithm specifies the rules fulfilling some computational task realizing the goal function [28].

4.4.1 Evaluation procedure: Availability

The first step is to create our alphabet in the database. The procedure describes the creation of the attributes in the reference model attribute database which serves as a reference to asses the data integrity of external data sets.

Algorithm 2: Create definition attribute types

```
[1]  Input: input data: definition attribute types table attribute types description
[3]  Output: output data: reference model definition attribute types
[5]  /* This procedure implements the necessary conditions data
        integrity definitions. Function assign variables as
        attributes write to database ▹ Reference model attributes
        database                                                  */
[6]  forall elements of Data file attributes do
[7]      Create attribute variable in data base: write attribute variable;
[8]      Define attribute type in data base: write attributes variable type;
[9]  end
```

The procedure describes the creation of the attributes in the reference model attribute database which serves as a reference to asses the data integrity of external data sets.

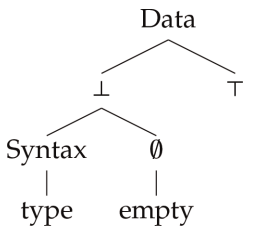
4.4.2 Evaluation procedure: Application controls

Next, we give the upload procedure data files for assessment reference attribute syntax in data file with reference to reference model definition attribute types.

Algorithm 3: Syntax data quality attributes of data files

```
[1]   Input: input data: definition attribute types table attribute types description
[3]   Output: output data: database contents data file input including interpretation
            syntax
[5]   /* This procedure implements the assessment of the data
         syntax quality in external data files write to database ▹
         Reference model attributes syntax – data file T or F     */
[6]   forall elements of external data file attributes do
[7]       Select first row and create header attribute variable in data base: write attribute
            variable;
[8]       Select second and write value of attribute to data base: write value variable
            type;
[10]      repeat
[11]          value of attributes of rows to data base: write value variable type ;
[12]      until last row;
[13]      if the attribute syntax data file = reference attribute syntax of reference is
            TRUE then
[14]          the data syntax of data file TRUE: write T in database;
[15]      else
[16]          the data syntax of data file ¬ TRUE is T write F in database ;
[17]      end
[19]      return done
[20]  end
```

The result can be presented as a tree. On top, coined as the root, we see the data. Our algorithm checked the syntax of the data with the reference attributes as defined. The result is a clear insight per attribute into whether the syntax is correct or not. Hence, that empty attributes are distinguished from wrong types.



Remark 23 (Granularity): Remember that syntax type information is stored, so the syntax type can be specified in the details of the reference attribute types.

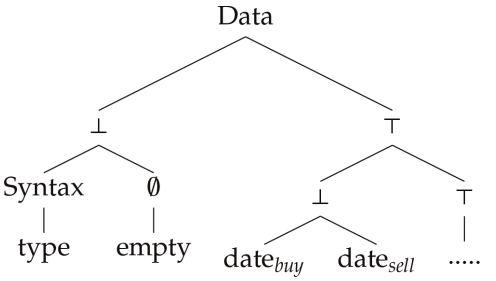
4.4.3 Evaluation procedure process logic controls: Some examples

The next step is to verify whether the process is executed as expected.

Algorithm 4: Process logic quality timeliness and predictability of processes

```
[1]   Input: input data: database contents data file input including interpretation syntax
[3]   Output: output data: database contents data file + interpretation syntax +
            interpretation process logic rules
[5]   /* This procedure assesses whether the process is executed in
         the sequence that should be executed. ▹ Reference model
         attributes values – data file T or F                    */
[6]   forall elements of external data files attributes do
[7]       Bundle data files: write values to data base bundle;
[8]       Select second row of all data form data bundle;
[10]      repeat
[11]          write value interpretation variable type constraints ;
[12]      until last row;
[13]      if Date buy < Date receive is TRUE then
[14]          Date buy of data file is TRUE: write T in database;
[15]      else
[16]          Date buy of data file ¬ TRUE is T write F in database ;
[17]      end
[18]      if Date sell < date deliver then
[19]          Date sell of data file is TRUE: write T in database;
[20]      else
[21]          Date sell of data file ¬ TRUE is T write F in database ;
[22]      end
[24]      return done
[25]  end
```

As we have seen, we can present the result as a tree. On top, coined as the root, we see the data. Our algorithm checked the syntax of the data with the reference attributes as defined. Now, you see that on the right-hand side, some dates of buying and selling transaction are not timely.



Remark 24 (Granularity): Remember that the date buy and the date sell can be specified in the details of the reference attribute types.

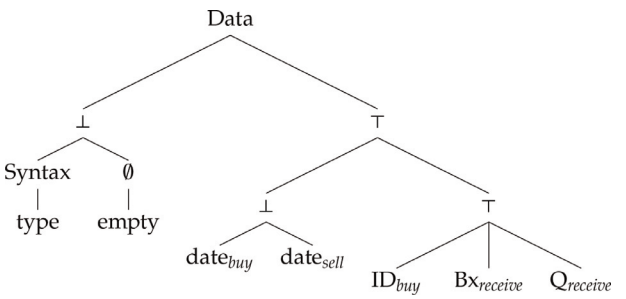
4.4.4 Evaluation procedure application and reconciliation

Now, we start to look at the content matter of the data.

Algorithm 5: Contents of the process is complete and consistent

```
[1]   Input: input data:database contents data file + interpretation syntax +
            interpretation process logic rules
[3]   Output: output data: database contents data file + interpretation syntax +
            interpretation process logic rules + reconciliation
[5]   /* This procedure assesses whether the contents of the
         process is complete and consistent. ▹ Reference model
         attributes values – data file T or F                    */
[6]   forall elements of external data files attributes do
[7]       Bundle data files: write values to data base bundle;
[8]       Select second row of all data form data bundle;
[10]      repeat
[11]          write value interpretation variable type constraints ;
[12]      until last row;
[13]      if ContractID type buy = ContractID type receive is TRUE then
[14]          ContractID of type buy of data file is TRUE: write T in database;
[15]      else
[16]          ContractID of type buy of data file ¬ TRUE is T write F in database ;
[17]      end
[18]      if MeasuredBrix type receive = Brix type buy then
[19]          MeasuredBrix type receive of data file is TRUE: write T in database;
[20]      else
[21]          MeasuredBrix type receive of data file ¬ TRUE is T write F in database ;
[22]      end
[23]      if Quantity Unit type kg Type received = Quantity Unit type kg Type buy then
[24]          Quantity Unit type kg Type received of data file is TRUE: write T in
              database;
[25]      else
[26]          Quantity Unit type kg Type received of data file ¬ TRUE is T write F in
              database ;
[27]      end
[29]      return done
[30]  end
```

When we look at tree result, then we see that the interpretation of the algorithm result gives us, on the right-hand side, the truth conditions about the unique ID, the unique measure of the quality Bx and the quantity received from the supplier.



Remark 25 (Model consistency): Remember that all transactions in the database which do not have the interpretation of being TRUE, under de conditions specified in our algorithm, are ¬ TRUE registered in the database as F. So, we can switch if we are interested in the counterpart of the data set under consideration. This can be understood as a direct result of the compactness Theorem for ordered trees using Konig's Lemma see Ref. [21]. Mind that for unordered trees we need the axiom of choice.

5. Evaluation procedure data integrity

As we stated in paragraph 4.1, the accuracy of a data file under consideration is said to be accurate when the following proposition hold:

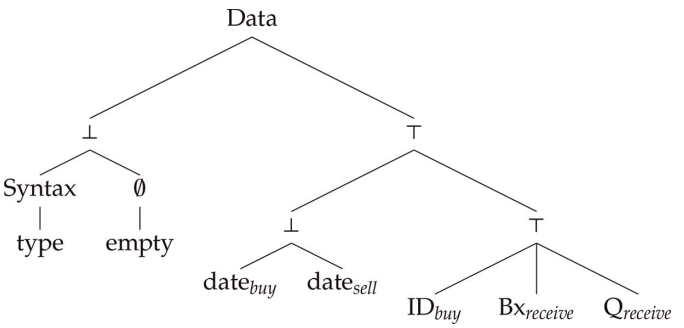
Proposition 26 (Accuracy): The data is accurate is TRUE if and only if:

(1) the data is VALID is TRUE is TRUE ∧ the data is COMPLETE is TRUE is TRUE.

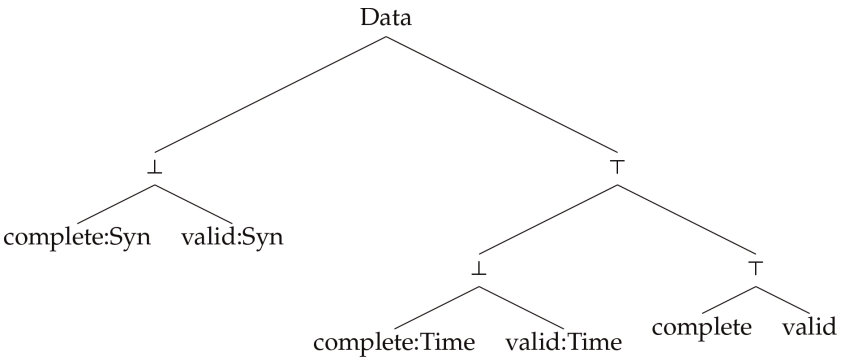
Algorithm 6: Decision procedure interpretation

```
   Input: Accuracy data model
1  ▹ see figure 3;
   Output: TRUTH set
   Data: data file
2  ▹ collection of attributes representing the object and its properties;
   Result: Assurance accuracy data
3  ▹ result of the decision procedure;
4  initialization: read data file ▹ one or more data files;
5  if the data is ¬ VALID is TRUE ∧ the data is ¬ COMPLETE is TRUE then
6  |  the data is ¬ ACCURATE;
7  else
8  |  if the data is VALID is TRUE ∧ the data is COMPLETE is TRUE then
9  |  |  the data is ACCURATE;
10 |  else
11 |  |  the data is VALID is TRUE ∨ the data is COMPLETE is TRUE;
12 |  end
13 end
```

The result of our algorithm can be depicted as:



The types of controls give us the information about the property of some control preserving the data integrity. So, the outcome of our algorithms can be mapped onto our decision procedure. The result can be depicted as a tree:



The proof of our proposition is to be found in the mathematical theory as developed in chapter 2, the application of propositional Linear Logic [15] and analytical tableaux [21]. For now, we have decided to leave this formal proof out of this chapter for clarity reasons en left it for future research.

6. Re-performance as evidence in quality control audits

In general, there are six ways of obtaining audit evidence: (1) inspection, (2) external confirmation, (3) observation, (4) re-performance, (5) analytical procedures and (6) inquiry [29], see also the ISA 500 standard on audit evidence [30]. Re-performance refers to the practice where the auditor makes essential calculations and verification are again based on raw evidence. Automated forms of control, such as controls built into business processes, are more difficult to manipulate and can in principle cover the whole relevant population, not just a sample. These various ways of obtaining audit evidence can be ranked in a kind of hierarchy of evidence reliability. Inspection (1), external confirmation (2), and re-performance (4) are considered stronger because they produce relatively direct forms of evidence without the interference of the auditee, whereas observation (3), analysis (5), and inquiry (6) are considered relatively weaker depending on the sources (human or automated), expectations, procedures, and audit planning. Note, moreover, that evidence collection types (1), (2), and (4) are also the most time-consuming for the auditor and therefore the most expensive for the client. Audit fees are born by the company being audited and make up a large part of the costs of control [31]. Our decision procedure combines two strong forms of obtaining audit evidence. These two forms are external conformation and re-performance. The procedure fits in the current modern computational idea data-driven assurance, which is consistent with quality 4.0 concepts in quality control and quality audit practices. The computational approach as developed in this chapter combines the logic of product and process audits, which ensures that the uncertainty inherent to data integrity can be known as a distribution. It follows from the computational approach that auditors can apply dual-purpose testing which

fits a data-driven, that is, fact-driven approach to decision-making of management and the stakeholders of organizations.

7. Conclusions

In this chapter, we have proposed a computational approach as a computational model to learn the inherent uncertainty to data integrity subsumed in a claim or claims made by stakeholders inside or outside the organization. Knowing the measurement uncertainty contributes to one's belief whether the measurement result as a count represents the quantity one has measured traced back to (SI) standards. Our computational model makes counting objects, persons, buildings, and so on traceable to the (SI) standard. The novelty in our approach is that the notion of equality has two different properties as being bilinear and linear. Our canonical model of the bilateral contract ensures that all characteristics of an object can be uniquely identified and thus be measured so that the particular measurement results are by design tractable to the (SI) standards. The result of our evaluation procedure of the data integrity is in fact an ordered dyadic tree whose presentation is understandable by humans and gives good insights into where to start the audit investigations in QCS.

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