What is Quality 4.0? An exploratory sequential mixed methods study of Italian manufacturing companies

Abstract

The purpose of this paper is to contribute to the scientific debate on Quality 4.0 by exploring the main theoretical themes underpinning the Quality 4.0 model and how the model may be developed. An exploratory sequential mixed methods design was employed to study two different samples of Italian manufacturing companies over two phases. For each sample, a different questionnaire was distributed to the companies' quality managers. As a result, eleven themes were elicited and tested. These themes are related to model development, top management, process mapping, data collection and integration with the enterprise resource planning system, use of artificial intelligence software, machine-to-machine data communication, product identification and traceability, document control and digital skills for quality control staff. A theoretical model for Q4.0 is proposed that encapsulates eleven themes of Q4.0 across three categories-people, process, and technology. Results could be particularly helpful for practitioners who may use them as a guideline for implementing and developing Quality 4.0 in a typical Industry 4.0 environment.

Keywords Quality 4.0, Industry 4.0, Quality management, Manufacturing companies, Exploratory sequential mixed method design

1. Introduction and motivation for the research

The term 'Industry 4.0' (I4.0), first coined in 2011, is based on the German *Industrie 4.0*, a federal German government strategic agenda (Kagermann *et al.* 2011; Tortorella *et al.*, 2020) to increase German competitiveness, particularly in the manufacturing sector. I4.0 was initially studied from a technological standpoint (Liao *et al.* 2017; Kolberg *et al.* 2017; Schroeder *et al.* 2019; Ivanov *et al.*, 2021; Bittencourt et al., 2021); thus, there are multiple papers on the implementation and integration of cyber-physical systems (CPS) (Kagermann *et al.* 2011) such as collaborative robots, artificial intelligence, automated guided vehicles, augmented reality, additive manufacturing and smart sensors and products. However, I4.0 is not simply the integration of CPS or the intensification of process automation (Xu *et al*. 2018). Indeed, many authors consider I4.0 a business model in which vertical, horizontal and end-to-end engineering integration must be managed (Brettel *et al.* 2014; Zhou *et al.* 2015; Stock and Seliger 2016; Jeschke *et al.* 2017; Mrugalska and Wyrwicka 2017; Chiarini *et al.* 2020). Employees still play a central role in embracing Industry 4.0 practices for greater integration and improving organisational and supply chain resilience (Ivanov *et al*., 2021; Bittencourt et al., 2021).

Vertical integration refers to the integration of the production level with higher business levels; horizontal integration refers to the integration between operations, customer service processes and the supply chain; and end-to-end engineering integration refers to the integration of the entire value chain, from product design and development to customer experience and satisfaction (Chiarini and Kumar, 2020). These three dimensions of the I4.0 model are likely to influence a company's quality management system (QMS) (Foidl and Felderer 2015). International Organization for Standardization (ISO) standard ISO 9001 (ISO 2015) stipulates that a QMS must comply with the Plan-Do-Check-Act (PDCA) approach, which follows both vertical and horizontal integration, including the integration of customer needs into the whole chain from design to after-sales processes and the integration of operations and supply chains. This may be why practitioners, through social media, associations, blogs and journals, have coined the term 'Quality 4.0' (Q4.0), considered 'a trend within a trend' (Johnson 2019), even prior to academics starting to analyse the relationship between I4.0 and quality management.

In the era of the fourth Industry revolution (I4.0), the quality profession faces the challenge to adapt itself and keep the field relevant in the face of changes in the business environment (Carvalho *et al*. 2019; Sampaio and Saraiva 2016). This era, called as Quality 4.0, is redefining its approach to managing quality by showing adaptability in dealing with disruptive information technologies (Carvalho *et al*. 2017; Nenadál 2020), increased vertical, horizontal and end-to-end connectivity in the supply network (Foidl and Felderer 2015; Chiarini and Kumar 2020), and using the increased volume of data inputs to provide feedback in decision making based on evidence (Gunasekaran *et al*. 2019; Stefanovic *et al*. 2019).

Dan Jacob, research director and principal analyst for quality within the LNS research (leading manufacturing research and advisory firm), first coined the term Quality 4.0 (Jacob, 2017). Thereafter, a series of papers in this area has appeared, though the conceptualisation of the term is still evolving in 2020 (Sony et al., 2020). The purpose of Quality 4.0 was to prepare the quality function and the profession to take a leading role in using I4.0 technologies to consistently deliver a high-quality product (Jacob, 2017; Sony et al., 2020). The president of LNS Research, Matthew Littlefield, presented the current state of understanding of Quality 4.0 in 2020 and defined Quality 4.0 as it *"provides quality leaders an industry-aligned framework and language to derive step-change performance benefits that stretch across the entire value chain, including consumers, customers, field service, logistics, manufacturing, engineering, R&D, and suppliers"* (Littlefield and Murugesan, pg.1, 2020).

In layman language, the concept of Quality 4.0 (Q4.0) is aligning the quality management practices and techniques with the emerging capabilities of I4.0. For example, in-built and automated statistical process control charts in a machine can provide a signal to operators when the machine is likely to produce a defect. This will help the operator to apply built-in-quality concept (Guh 2003) and prevent the occurrence or passage of a defect to the next stage. However, this evolution forces quality professionals to rethink their job roles (Zairi 2017; Srinivasan et al. 2020; Bittencourt et al., 2021) and adapt to technological innovation and big data analytics techniques that form the basis of the fourth Industrial revolution (Zonnenshain and Kenett 2020). Srinivasan et al. (2020) highlighted that in the era of Industry 4.0, employers need to focus on acquiring and managing the workforce that leverages I4.0 technologies. They further stated that the role of a typical worker or function would change drastically when they upskill or reskill themselves in cognitive, problem solving, and communication skills to embrace I4.0. Similarly, Bittencourt *et al*. (2021) suggested that there will be no human capability loss in Industry 4.0 era as the smart systems and processes will lead to more capability enhancement and new skill development. In addtion, Romero et al. (2019) discussed how traditional quality management is rather different from the new digital manufacturing systems when using human capabilities and/or digital capabilities.

Nevertheless, the academic literature discussed in the following section does not appear to offer an accurate or complete theoretical framework concerning the relationship between I4.0 and quality management and the development of a possible Q4.0 model (Sony *et al*. 2020). Consequently, this research aims to contribute to the scientific debate about the nature of Q4.0. Specifically, it attempts to answer the following main research question:

RQ. What are the main theoretical themes underpinning the Q4.0 model?

To answer this question, we limited our inquiry to the Italian manufacturing sector. We used an exploratory sequential mixed methods design involving two phases. Participants included the quality managers of large and medium-sized enterprises that had been affected in recent years by the implementation of I4.0 projects.

The remainder of this paper is structured as follows. Section 2 discusses the background of the relationship between I4.0 and quality management. Section 3 presents the qualitative and quantitative methodologies adopted as well as the findings. Section 4 discusses and interprets the findings. Section 5 concludes the paper by discussing the originality and limitations of the research, practical implications and avenues for further research.

2. Background of Industry 4.0 and quality management

Since 2011, there has been a rapid expansion of the literature dedicated to I4.0 and its technologies and principles. To answer our research question, we limited our literature review to studies on the relationship between I4.0 or Q4.0 and quality management. We first briefly present the different quality eras and how the Q4.0 era forces the quality profession to rethink their role in the I4.0 era.

Quality has been pursued and deployed through different methods, as witnessed in the evolution of quality eras to meet market demands and user-perceptions (Carvalho et al. 2019; Watson 2019; Zonnenshain and Kenett 2020). Following Table I, we can say that companies over time have changed their approaches from quality through basic inspection or no inspection at all (Quality 0.0), quality through measurement, inspection, and control (Quality1.0), quality through standards and quality assurance (Quality 2.0) and quality improvement by means of initiatives such as TQC-TQM (Total Quality Control/ Total Quality Management), Lean, and Six Sigma (Quality 3.0). Motivations of these changes are mainly connected with the changes in the market and customer attitude, especially from the so-called mass production where quality was often secondary to the current mass customisation and servitisation where quality is at its maximum.

Table I. Industrial revolutions and quality approaches

Industrial revolution	Quality approach	Changes and characteristics
First	Quality 0.0 (Inspection) & Quality 1.0 (Control)	- Transformation from handicrafts into mechanised industrial system is the goal - Production volume is much more important than product quality - Quality, when present, is a typical measurement or basic inspection (Watson 2019) and further using control charts to control quality
Second	Quality 2.0 (Assurance)	- Productivity at its maximum is the main goal - Quantity is still more important than quality for markets - Quality is based on inspection, control (using SPC) and audits carried out by specialised people who are using standards (Watson 2019) - Quality assurance starts to be applied in some particular industries, emphasizing on more involvement of employees across the organisation
Third	Quality 3.0 (Improvement)	- As per capita income increases, customers start demanding more quality. Quality has become an imperative; no more a choice but essential for increasing market share - ISO 9000, TQC, TQM and Six Sigma are the most important quality movements - Customer satisfaction and continual improvement are amongst the more important principles as highlighted by Continuous improvement initiatives such as TQM, Lean, and Six Sigma - All the employees are involved in creating quality and solving problems
Fourth	Quality 4.0	- Servitisation and mass customisation are dominating markets - CPS and the IoT have further automated and integrated processes within and outside the company - Machines and processes managed by AI - New digital quality skills are needed

Transitioning from the inspection-based to quality control and assurance era shifted the focus from identifying defects through inspection to collecting and analysing data to understand the sources of variation in product and processes. The field saw another shift in focus from detecting and rejecting defects through quality control to preventing defects following a rigorous QMS based on ISO 9000, which required wider participation from employees and management. The quality improvement era (Quality 3.0) shifted focus towards total quality management where each employee takes ownership of quality and emphasis is also on developing a good relationship with their customers and suppliers (Dale *et al*. 2016).

Similar to Lean and Six Sigma being included within strategic objectives of the business (Chiarini and Kumar 2020; Tortorella *et al*. 2020), the next quality era termed Q4.0 should be considered a strategic approach to integrating quality with the I4.0 initiative (Littlefield and Murugesan 2020). The 250 participants responding to the Q4.0 survey conducted by LNS research in 2019 reported that companies who have embarked on the Q4.0 journey are transitioning from being compliance-centric and process enabled to being customer-centric and digitally-enabled (Littlefield and Murugesan, 2020). This new era brings together speed, creativity, data analytics, and AI to provide a holistic approach for meeting the dynamic customer requirements (Park et al., 2017).

In the era of I4.0, the unpredictable and fast-changing market environment due to the application of I4.0 technologies is forcing quality profession and quality managers in organisations to redefine new boundaries for their discipline to keep quality field relevant in the digital age and compete with professionals that are entering from other disciplines and communities (Carvalho *et al.* 2019; Stefanovic *et al*. 2019; Saraiva *et al*. 2018). It challenges the profession to take an entrepreneurial and active role in the digital era by absorbing changes in the new product development, cycle time compression, and matching employees' effort with customer expectations (Gunasekaran *et al*., 2019; Zonnenshain and Kenett, 2020).

Early research from Foidl and Felderer (2015) shows that I4.0 may be integrated with quality management through the three standard dimensions of the I4.0 business model: vertical integration, horizontal integration and end-to-end engineering integration. Despite the paper being based on a single Austrian case study, it suggests some interesting avenues for research. Indeed, the authors highlight that with respect to vertical integration, machinery and processes should automatically collect data not only for the higher business levels but also for staff dedicated to quality control and management. With respect to the horizontal dimension, data should be communicated from machine to machine (M2M) for improved planning and scheduling of production routing. According to Foidl and Felderer (2015), a CPS should also be used to help track products in terms of scheduling and test results, and this information should be shared with customers to improve customer satisfaction. With respect to end-to-end integration, the product itself should communicate data during its life cycle to enable optimal engineering along the entire value chain.

The ample I4.0 literature, which primarily focuses on production, logistics and supply chain processes, includes some studies on the influence of I4.0 on quality management. One line of inquiry addresses the possibility of better integrating customer's needs and their relationships with company's marketing, design and production processes (Majeed and Rupasinghe 2017; Rojko 2017; Ibarra *et al.* 2018; Saucedo-Martínez *et al.* 2018; Ardito *et al.* 2019; Santos and Martinho 2019). According to these studies, customer satisfaction and experience may be improved by using a series of CPSs to foster 'servitisation'. For instance, customer relations could be strengthened through the use of customer relationship management (CRM) software and business analytics, while artificial intelligence (AI) could be used to monitor and collect data on customer experience (Morrar *et al.* 2017). Although several authors have explored the topic of AI in relation to I4.0 and quality management in the past, it has mainly been studied as a natural companion to quality management. Burgess (2000) was one of the first to understand the potential of AI as an aid to problem-solving. Guh (2003) explored how to apply AI to statistical process control, while Lau *et al.* (2009) and Yussupova *et al.* (2016) analysed the wide contribution of AI to quality management and continuous improvement processes. Sahu *et al*. (2020) further elaborated on how augmented reality usage in the assembly and maintenance operations, with the support of AI, can result in cost-effective and enhanced quality output.

Other authors have focused on product identification and traceability, both within companies and across entire supply chains (Gilchrist 2016; Roblek *et al.* 2016; Bortolini *et al*. 2017; Buer *et al.* 2018; Koh *et al.* 2019; van Hoek 2019). In this context, radio-frequency identification (RFID) and smart sensors have become essential technologies for understanding the status of products or services such as whether they are functional or conform to standards (Velandia *et al.* 2016; Zhong *et al.* 2017). Moreover, several authors (Gilchrist 2016; Funk *et al.* 2016; Romero *et al.* 2016; Bortolini *et al.* 2017; Satoglu *et al.* 2018; Tortorella et al., 2021) have shown that CPSs may be used to reduce human error, especially in more labour-intensive stages.

Illés *et al.* (2017) show that it is possible to collect quality control data through the use of I4.0 technologies and enterprise resource planning (ERP), which has not been possible until now. According to these authors, the challenge is to identify where, how and what to collect and how to analyse the produced big data. Their research also considers several possibilities already discussed, such as material and product traceability in process and supply chains as well as the monitoring of equipment, tools and gauges through sensors.

In an editorial, Gunasekaran *et al.* (2019) summarised some potential future research questions related to quality management and I4.0/Q4.0. According to Gunasekaran *et al.* (2019, p. 127):

> […] Until now, the research on [the] involvement of human[s] in quality challenges is not progressing as per the pace of technology development. A potential research gap exist[s] that needs to be addressed.

Johnson (2019) and Veile *et al.* (2019) have also discussed the issue of human involvement and expertise in Q4.0. Presenting an example from Ralco Industries, Johnson (2019) stated how the company had developed an intelligent mistake-proofing mechanism due to vertical integration between SOPs followed at each stage with their cloud-based ERP system. If an employee is not adhering to SOP during the initial job set-up stage, the ERP system will not allow the production to begin until the required procedure is followed (Johnson 2019). This shows the role of quality function is shifting from policing focus where they were expected to catch bad parts before they get shipped to the customer to a more strategic role where quality is integrated with organisation's digital transformation initiative to manage quality at source (Johnson 2019; Littlefield and Murugesan 2020).

Sony *et al.* (2020) studied for the first time how to effectively implement Q4.0 based on conducting a review of existing literature on I4.0 and Q4.0 related topics. This study revealed eight key components of Q4.0 development: the handling of big data; the improvement of prescriptive analytics and AI; the effective use of Q4.0 in vertical, horizontal and end-to-end integration; the use of Q4.0 for strategic advantage; leadership of Q4.0; training in Q4.0; organisational culture of Q4.0; and top management support for Q4.0. As well as providing a theoretical framework for Q4.0, Sony *et al.* (2020) also offer suggestions for conducting qualitative research to verify proposed ingredients and explore any additional key ingredients of Q4.0 in future research.

In summary, few theoretical frameworks have been developed to integrate quality management and I4.0, creating a specific model. The majority of papers have focused on the implementation of I4.0 in the more general processes of production, logistics and the supply chain, with quality management as a component of these. Specifically, the literature claims that:

- Q4.0 may be considered a component of the broader I4.0 model, and a similar three-dimensional Q4.0 model may be developed.
- Data related to quality should be collected and integrated using ERP software, analysed using AI and predictive software, managed at all levels and shared with staff.
- Data related to quality should be collected from various components, including machinery, production processes and customers, and horizontally integrated throughout the supply chain. Product traceability and identification is an important quality management process that may be improved through the use of CPSs.
- End-to-end integration of CPS and specific software may improve customer satisfaction and experience with products and services and enhance servitisation.
- Human involvement in quality management and new technologies is important.

These five issues were translated into five open questions that were asked during semi-structured interviews in the qualitative stage of the sequential mixed methods study.

3. Methodology

Given the research on integration between I4.0 and Q4.0 is still developing, this research was primarily based on an exploratory sequential mixed methods design combining both qualitative and quantitative methods in triangulation (Raturi and Jack 2006). An exploratory sequential mixed methods design begins with a qualitative phase involving the collection and analysis of qualitative data. During the qualitative phase, various qualitative methods may be used, including interviews, grounded theory, case studies or thematic content analysis. The results of this phase are used to develop or inform the subsequent quantitative phase, which can involve a survey or other type of quantitative data collection (Creswell and Clark 2017). The intersection between the two phases is known as the ‘point of interface’, and an exploratory sequential design can prioritise either the qualitative or the quantitative phase.

Creswell and Clark (2017) label an exploratory sequential design in which the study is more qualitative and focused on theme development as *QUAL → quant*, as opposed to *qual → QUANT.* In this light, we used a more inductive *QUAL → quant* approach, which involves an initial exploration of the research topic to generate the variables to be measured (Creswell and Clark 2017). This approach may be adopted when the variables are unknown and there is no pre-existing theory or model to use as a guide. The main purpose is to evaluate the possibilities for generalising qualitative findings to a larger sample. Figure 1 schematically shows the sequential mixed methods design and the adopted qualitative and quantitative methodologies.

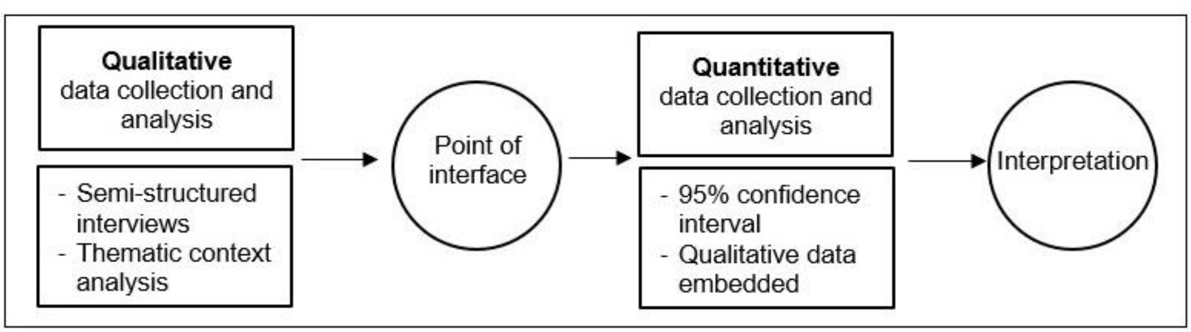

Figure 1. Exploratory sequential design

3.1. The qualitative phase

The initial qualitative phase involved conducting semi-structured interviews with a sample of quality managers from Italian manufacturing companies. The literature is not specific in terms of determining adequate sample size for qualitative inquiry; therefore, we followed the concept of data saturation (Guest *et al.* 2006). Data saturation refers to the point at which no new information or themes emerge from the data. We interviewed 21 quality managers from 21 companies. Companies were selected based on the following characteristics:

- location in the business-to-business sector, which provides products to other companies rather than to individuals;
- implementation of I4.0 technologies in the previous three years;
- implementation of an ISO 9001 QMS with third-party certification of compliance;
- implementation of total quality management and kaizen initiatives;
- an organisational structure that included a marketing and sales department, technical department, production and logistics department and quality control department;
- a production process that included both assembly workstations and machinery;
- implementation of an advanced information and communication technology system and ERP covering all main functions and processes;
- involvement in I4.0 implementation and quality initiatives for customers and the supply chain;
- more than 50 employees.

Table II shows the main characteristics of the 21 companies in terms of products and dimensions.

Table II. Characteristics of the 21 companies involved in the first phase

Company	Product	Turnover	No. Employees
1	Aeronautical components	€45 M	150
2	Automotive interior components	€110 M	350
3	Tractor components	€23 M	120
4	Custom electronic circuits	€32 M	100
5	Custom electronic circuits	€12 M	60
6	Brake components	€38 M	150
7	Furniture	€140 M	400
8	Gearboxes	€14 M	60
9	Heaters and boilers	€85 M	220
10	Hydraulic integrated circuits	€28 M	105
11	Hydraulic pumps	€260 M	800
12	Plastic components	€25 M	90
13	Kitchen furniture	€42 M	180
14	Lift components	€102 M	300
15	Lightning products	€110 M	250
16	Food and beverage machinery	€25 M	140
17	Lorry-mounted cranes	€70 M	210
18	Lorry-mounted cranes	€72 M	190
19	Mechanical rollers	€18 M	55
20	Oil and gas components	€20 M	80
21	Power transmissions	€55 M	200

Names of the 21 quality managers were derived from an Italian consultancy company specialising in operations management, including total quality management and I4.0 services. All quality managers selected had expertise in both quality management and I4.0 and had managed a QMS for at least 10 years. All had participated as team members in I4.0 implementation projects and had attended several courses on the topic in recent years.

Quality managers were interviewed using a semi-structured questionnaire with five open-ended questions that were derived from the results of the literature review:

In what way are you developing your Q4.0 model (if any)? For instance, using a vertical, horizontal or end-to-end approach or in other ways?

In what way are you collecting, analysing and sharing quality data from the shop floor to the business level?

In what way are you integrating quality data through your machines, production and logistics processes, including the supply chain?

In what way are you developing end-to-end engineering integration from customers through the entire life cycle of the product?

In what way are you involving people, improving their competencies for Q4.0?

Each interview lasted 30–45 minutes and was digitally recorded. The 21 media files were transcribed using TranscribeMe before being entered into NVivo. Thematic content analysis was employed for analysis and coding. According to Sandelowski and Barroso (2003), research findings can be placed on a continuum indicating the degree of transformation of the data from pure description to interpretation. Thematic content analysis is similar to coding in grounded theory methodology, leading to the identification of a set of theoretical themes. NVivo software was used to find, code and group theoretical themes. A code is a basic unit of analysis, a label that describes a specific phenomenon. Usually, the code is close to the interviewee's language, and the thematic content analysis produces numerous codes that have to be gathered together into categories and then into themes (Wong 2008). For instance, from the interview files, several codes emerged, such as:

- “products are identified in their status through chips”
- “components could be tracked down using tags and RFIDs”
- “CPS are useful for identifying nonconforming products from the others”

These codes were grouped into a specific category, “product identification and traceability” that become part of the theme “Smart technologies for identification and traceability”. In this way, eleven themes were extracted. Table III shows the hierarchy of the themes.

Table III. Emergent themes from thematic content analysis

No.	Theme
1	Quality 4.0 based on Industry 4.0
2	Quality 4.0 based on ISO 9001 (Plan-Do-Check-Act model)
3	Top management • Top management involved • Top management committed
4	Process mapping
5	Automatic data collection • Internal data • Product life cycle data • Customer data
6	Integration of data with the enterprise resource planning system • Customer relationship management • Product life cycle management • Manufacturing execution system
7	Artificial intelligence and predictive software
8	Machine-to-machine communication
9	Smart technologies for identification and traceability • Product identification and traceability • Measurement instrument control
10	Automated document control
11	Digital skills for quality staff

To increase the reliability of results, especially when coding and grouping the interview data into themes, the lead researcher developed a codebook with a description of each theme (see Table IV) (Creswell 2013). This codebook was then used by a second researcher to code and extract themes. To assess interrater reliability, we used the formula:

$$Reliability = \frac{number\ of\ agreements}{number\ of\ agreements + disagreements}$$

We obtained a value of 91%, which is considered sufficient for mitigating interpretative bias (Walther *et al.* 2013).

Table IV. Codebook and description of each theme

No.	Theme	Description
1	Q4.0 based on I4.0	Q4.0 model based on I4.0 dimensions: horizontal (streaming of data from machinery and processes in the supply chain up to the business level); vertical (data exchange at the organisational level); end-to-end (customer requirements integrated into product life cycle)
2	Q4.0 based on ISO 9001	Q4.0 model based on ISO 9001:2015 (Plan-Do-Check-Act)
3	Top management	Commitment and involvement of top management to I4.0/Q4.0 development and provision of resources and strategic goals
4	Process mapping	Mapping to identify data needed from which processes and for whom, with consideration of automated data collection, interface with ERP and data exchange between equipment and processes
5	Automatic data collection	Automatic collection of data throughout the product lifecycle using CPS and sensors connected to the IoT
6	Integration of data with ERP	Use of ERP to integrate data throughout the product life cycle (e.g. manufacturing execution system for shop floor data; customer relationship management for customer satisfaction; product life cycle management to meet customer requirements)
7	Artificial intelligence and predictive software	Use of artificial intelligence and predictive software for problem-solving and prevention of product failure/nonconformity
8	Machine-to-machine communication	Horizontal or vertical exchange of data between machines and production/logistics processes to automatically control scheduling and sequencing
9	Smart technologies for identification and traceability	Use of radio-frequency identification, smart sensors and CPS connected to the IoT to automatically identify and trace products, equipment, calibration instruments, people and processes throughout the supply chain
10	Automated document control	Integration of quality management documentation into ERP modules and automatic revision when products/processes change

11	Digital skills for quality staff	Knowledge of CPS (especially data analysis and prediction software) by quality staff

Note. CPS: cyber-physical systems; ERP: enterprise resource planning; I4.0: Industry 4.0; IoT: Internet of Things; Q4.0: Quality 4.0.

The first phase results show that there was some disagreement between the 21 interviewed managers on the 11 themes. Specifically, with respect to the first two themes, we found that 13 of the 21 interviewees believed that a Q4.0 model should be similar to I4.0, while the remaining eight believed that a Q4.0 model should follow the ISO 9001 structure. Nevertheless, the 21 interviewed quality managers provided interesting comments and suggestions that were analysed alongside the quantitative data collected during the quantitative phase.

3.2. The quantitative phase

In the quantitative phase of the research, we attempted to confirm the theoretical themes generated by transforming them into 11 variables and, consequently, 11 hypotheses to be tested. We used a 95% confidence interval (CI) to calculate sample proportions (Smithson 2003). According to Pfenning (2010), the population size should be at least 10 times the sample size. Each theoretical theme was translated into a question, with answers based on a 5-point Likert scale (5 = *strongly agree*; 4 = *agree*; 3 = *undecided*; 2 = *disagree*; 1 = strongly *disagree*). For example, the first theme (*Q4.0 based on I4.0*) became:

> *Q1: Do you think that a Quality 4.0 model should be based on the three-dimensional model (vertical, horizontal and end-to-end) similar to the Industry 4.0 model?*

The operationalised variable for this question was expressed as *THREEDIM*. Ten other questions were established for which their operationalised variables were expressed as *ISO9001*, *TMGMT*, *MAPP*, *AUTOM*, *ERP*, *PREDIC*, *M2M*, *IDTRAC*, *DOC* and *SKILLS*, respectively.

To avoid sampling bias, we began by identifying the number of Italian manufacturing companies that had already invested in I4.0. According to an Italian Ministry of Economic Development survey (MISE 2018), the total number is unknown; however, the survey included a sample of 23,000 Italian companies that had implemented I4.0 technologies. The survey results showed that 47.1% of manufacturing companies had more than 250 employees, 35.5% had between 50 and 249 employees and 17.4% of companies had fewer than 50 employees. The survey also found that small companies were less inclined to invest in I4.0. In light of these results and given that we did not include small companies in the first phase, we used stratified random sampling (Antonius 2003) to create a sample comprising 57% large companies and 43% medium-sized companies, with small companies excluded.

We began with a sample of 3,865 large and medium-sized manufacturing companies provided by the same consulting company specialising in operations management. All companies were ISO 9001 certified, had launched total quality management and kaizen initiatives, had a production and design department and were located in the business-to-business sector. We created an online questionnaire for the quality managers of these companies, explicitly stating on the first page that the questionnaire was intended for quality managers with knowledge of I4.0 technologies and systems. To this end, we asked quality managers to rank their level of knowledge of I4.0 technologies on a 4-point scale (1 = *very poor*; 2 = *poor*; 3 = *fair*; 4 = *good*). Moreover, we asked them about the number of employees in the company. We gathered 282 questionnaires, of these, 47 were excluded because the respondents declared that their knowledge of I4.0 was either poor or very poor, leaving 235 completed questionnaires (141 from large companies and 94 from medium-sized companies). To retain the proportion of 57% large companies and 43% medium-sized companies, we randomly excluded 19 questionnaires from large companies. The final sample comprised 122 large companies (56.5%) and 94 medium-sized companies (43.5%) for a total of 216 manufacturing companies. Table V shows the distribution of the companies in the sample according to industry.

Table V. Number and industry of companies in the sample

Industry	No.
Manufacture of wood and wood products	2
Chemicals, chemical products and fibres	8
Rubber and plastic products	8
Non-metallic mineral products	4
Concrete, cement, lime and plaster products	8
Basic metal and fabricated metal products	42
Machinery and equipment	24
Electrical and optical equipment	18
Electronic equipment	36
Pneumatic components	12
Automotive and motorcycle components	54
Total	216

Each question in the online questionnaire provided a space for comments and suggestions regarding the item being addressed. Along with the data from the 21 semi-structured interviews, this embedded qualitative component provided useful information for interpretation, giving more context to the quantitative results.

A CI serves as an estimate of the population mean by producing an interval that is likely to contain the mean. Consequently, the null hypothesis H_0 can be stated as:

H_0: There is no significant difference between the population mean and the means of the 216 answers to each question.

Thus, statistical analysis of the 11 questions in the questionnaire was used to infer the characteristics of Italian manufacturing companies.

Statistical calculations were performed using SPSS software. The quantitative results for means and standard deviations (SD) of the sample are shown in Table VI. The final column shows the standard error of the mean (SEM), which is the estimated difference between the mean of the population and the mean of the sample. The lower the SEM, the better the accuracy of results.

Table VI. Means and standard deviations of the sample

Variable	*n*	Mean	*SD*	*SEM*
THREEDIM	216	4.5370	0.66172	0.06367
ISO9001	216	2.1944	1.22633	0.11800
TMGMT	216	4.5833	0.62838	0.06047
MAPP	216	4.3611	0.88030	0.08471
AUTOM	216	4.3333	0.77339	0.07442
ERP	216	4.6944	0.63332	0.06094
PREDIC	216	4.3148	0.83887	0.08072
M2M	216	4.4444	0.92052	0.08858
IDTRAC	216	4.5370	0.77852	0.07491
DOC	216	4.5926	0.69762	0.06713
SKILLS	216	3.4259	1.31990	0.12701

Table VI shows that the mean of the answers to the second question (*ISO9001*) was less than 2.2, meaning that the majority of respondents disagreed that Q4.0 should be based on ISO 9001 (PDCA model). The *SKILLS* variable had a mean of 3.4259, indicating that respondents were undecided about whether quality staff needed new digital skills for quality management. The SDs of these two variables were also the highest, 1.31990 for *SKILLS* and 1.22633 for *ISO9001*, showing a spread of values in the sample distribution that deviates from the mean and, consequently, a level of disagreement among respondents. All other means were greater than 4 (*agree*), showing that nine of the 11 themes were considered relevant to the implementation of a Q4.0 model.

To validate the quantitative results shown in Table VI, a *t*-test was conducted, with the test value being the closest approximate value greater or lesser than the corresponding mean. The first column of Table VII shows the *t*-values (Student's *t*-statistic), which represent the ratio of the difference between the sample mean and the SEM. The smaller the SEM, the higher the *t*-value, thus the smaller the *p*-value (Sig. 2-tailed). The third column of Table VII shows that there was no significant difference from the test value. The two columns dedicated to the 95% CI of the difference show the range of values within which we are 95% certain lies the mean of the population. Therefore, the mean of the variable *ISO9001* is between 1.9549 and 2.4228 and that of *SKILLS* is between 3.2 and 3.7036. The first is less than 3 (*undecided*), and the second is less than

4 (*agree*) as expressed by the 5-point Likert scale. For all other variables, the mean of the population was higher than 4 (*agree*).

Table VII. One-sample test results

Variable	*t*	*df*	Sig. (2-Tailed)	Mean Difference	95% CI of the Difference		Test Value
					Lower	Upper	
THREEDIM	0.582	215	0.562	0.03704	−0.0892	0.1633	4.5
ISO9001	−0.047	215	0.963	−0.00556	−0.2395	0.2284	2.2
TMGMT	1.378	215	0.171	0.08333	−0.0365	0.2032	4.5
MAPP	−0.459	215	0.647	−0.03889	−0.2068	0.1290	4.4
AUTOM	0.448	215	0.655	0.03333	−0.1142	0.1809	4.3
ERP	−0.091	215	0.928	−0.00556	−0.1264	0.1153	4.7
PREDIC	0.184	215	0.855	0.01481	−0.1452	0.1748	4.3
M2M	0.502	215	0.617	0.04444	−0.1311	0.2200	4.4
IDTRAC	0.494	215	0.622	0.03704	−0.1115	0.1855	4.5
DOC	−0.110	215	0.912	−0.00741	−0.1405	0.1257	4.6
SKILLS	0.204	215	0.839	0.02593	−0.2259	0.2777	3.4

Finally, we performed a common method bias test. Among the potential sources of common method bias was the propensity for respondents to maintain consistency in their responses to questions, the propensity to agree (or disagree) with questionnaire items independent of their content and the use of a common scale format (Podsakoff *et al.* 2003; p. 882). The test was performed by means of factor analysis. Table VIII shows the results of this test. The eigenvalues shown in the second column measure how much a factor explains the variance of variables. The percentage of variance shown in the third column highlights that the first factor accounted for less than 50%, meaning that common method bias did not affect the results.

Table VIII. Total variance explained

Component	Initial Eigenvalues		
	Total	**% of Variance**	**Cumulative %**
1	3.777	34.340	34.340
2	2.127	19.334	53.675
3	1.710	15.547	69.221
4	0.973	8.845	78.067
5	0.742	6.742	84.809
6	0.488	4.436	89.245
7	0.423	3.845	93.090
8	0.340	3.090	96.179
9	0.183	1.662	97.842
10	0.176	1.598	99.440
11	0.062	0.560	100.000

4. Analysis

Hereafter, we refer to the 21 quality managers interviewed in the first phase as ‘interviewees’ and the 216 quality managers who completed the online questionnaires in the second phase as ‘respondents’. Participants in both samples made interesting comments, which were analysed and interpreted along with the quantitative results.

4.1. Quality 4.0 based on Industry 4.0

As shown in Table VI, the mean and SD for *THREEDIM* were 4.5370 and 0.66172, respectively. This indicates that respondents agreed (or strongly agreed) that Q4.0 could be implemented using a similar model to the three-dimensional I4.0 model. The relatively low SD also implies agreement among respondents. The similar comments and suggestions concerning this theme also confirm these results. Thirteen interviewees directly referred to the three-dimensional model, stating that the vertical dimension is mainly bottom-up and that data related to quality control should flow from each machine, assembly workstation, warehouse, logistics equipment, tool and gauge through the ERP modules, providing a real-time dashboard at each organisational level. In contrast, 12 respondents commented that in the vertical dimension it is important for top management to define strategic goals for Q4.0 and periodically review whether these goals had been attained. Thirteen interviewees and 12 respondents also stated that data should be exchanged at the shop-floor level, starting from customers and throughout the entire supply chain. With respect to end-to-end integration, 13 interviewees and five respondents believed that the most important process was the automatic collection of data during the entire life cycle of the product.

A company from the automotive sector, focusing on three dimensional I4.0 model, analysed all the machines and assembly lines to evaluate what kinds of quality data they needed (e.g. number of nonconforming products, number of hours for reworking products, number of scraps, etc.), how to take them out from these processes (e.g. smart sensors, RFID, bar codes, cameras, etc.), how to collect them through the ERP modules and how to display them (e.g. reports, statistics, diagrams, etc.) at the different organisational levels from workers to the CEO. The company also vertically connected several machines for quality data to be exchanged between machines, operators, and other internal stakeholders such as the quality team. An example of a smart machine provided was that if a machine slows down because of poor quality, the other machine on the production line can reduce its pace as well. Similarly, quality data from suppliers' production processes are collected in order to evaluate whether or not the supplier is aligned with the production schedule. Finally, critical to quality characteristics are discussed and reviewed with the customers in the early stage of product design, throughout the entire product life cycle. These data are typically managed using Product Life Management (PLM) modules within the ERP and streamed down to the shop floor to each machine, assembly line and suppliers.

4.2. Quality 4.0 based on ISO 9001 (PDCA model)

The variable *ISO9001* had the lowest mean (2.1944) and the second highest SD (1.22633). Therefore, it appears that respondents disagreed with the implementation of a Q4.0 model based on ISO 9001 (PDCA model). However, the high SD also indicates that there was some disagreement among respondents, with some rating their answers as 4 (*agree*) or even 5 (*strongly agree*). Indeed, suggestions made by both respondents and interviewees occasionally contrasted with each other.

Nineteen respondents believed that the ISO 9001 PDCA model and requirements was not suitable for a Q4.0 model. They considered ISO 9001 incapable of integrating a QMS with numerous I4.0 CPSs. However, eight interviewees and seven respondents believed that ISO 9001 could offer a foundation and guideline for implementing a Q4.0 model. For instance, one respondent stated that:

> […] The International Organization for Standardization should issue a standard based on the ISO 9001 high-level structure where each CPS and smart system should be integrated in specific requirements, forming a proper management system.

Indeed, one of the most important principles introduced by the ISO is a high-level structure (ISO 2015) applied to systems, including quality, environmental, health and safety, energy and information technology management systems. According to ISO (2015, p.1):

> […[] The concept of [a high-level structure] is that management standards are structured in the same way, regardless of the domain of application. Users who are familiar with one [management system standard] will immediately feel at ease with another, even when using it for the first time.

A company in the oil and gas and another one in the plastic components approached Q4.0 following the classic PDCA scheme fostered by ISO 9001. In both these companies, we can find that they planned the Q4.0 model implementation at a strategic level, defining strategic objectives and plans (e.g. how to integrate processes, dedicated investments, resources, times and responsibilities). Then they rolled out the plans to achieve such strategic objectives, checking the results and learning from their mistakes to improve the Q4.0 implementation in other processes. In this way, following the PDCA approach, they implemented a Q4.0 model in a more gradual manner, even if, looking at the final Q4.0 model we can say that they followed a three dimensional model of vertical, horizontal and end-to-end integration. Therefore, interviewees and respondents who considered ISO 9001 a suitable vehicle for introducing a Q4.0 model believed that this high-level structure could work in the same way for the three-dimensional model.

4.3. Top management

The variable *TMGMT* had a high mean and a relatively low SD, indicating a level of mutual agreement among respondents who, like the interviewees, considered the involvement and commitment of top management essential. Similarly, our interviewees and respondents believed that for the successful implementation of a Q4.0 model, top management needed to be involved and committed. Similar to the first theme, 12 respondents suggested that top management should establish strategic goals, objectives and indicators for Q4.0 and communicate them to staff, supporting its implementation through resources, training and reviewing achieved results. Six respondents believed that to implement I4.0 or Q4.0, the company needed a knowledgeable leader, labelled by one respondent as a 'digital leader':

> […] What we really need for implementing Q4.0 is a new kind of leader able to deploy digital objectives motivating people towards a new challenge that will change our skills and the way we make decisions and solve problems.

The majority of the interviewees agreed that senior quality leader in the organisation such as Quality Director should redefine their department focus and objectives to ensure their actions are aligned with the digital transformation journey that their company has embarked on. The quality team should collaborate with manufacturing, production, R&D, marketing & sales teams to support the company's ambition to realise the three-dimensional model for I4.0 implementation.

4.4. Process mapping

Similar to the previous variable, *MAPP* had a high mean and a relatively low SD. Respondents and interviewees both believed that at the beginning of the Q4.0 journey, company processes should be mapped to evaluate needs in terms of collecting data and connecting, integrating and automating processes and activities. Six respondents believed that this highly complex task should be assigned to an external consultancy company with significant expertise in information and communication technologies. Three respondents also highlighted the need for new mapping tools for evaluating processes, types of data, potential CPS, automation, integration with ERP and other pieces of software. According to one respondent,

[…] We are all accustomed to mapping tools such as value stream, swim lane, turtle diagram, et cetera. We should invent a new peculiar mapping tool for improving quality management through digitalisation'.

The majority of the interviewees (15) believed that streamlining processes and taking out wastes from the process are very important before they can be integrated with digital tools. Here, initiatives such as Lean can effectively streamline business processes to aid effective integration with I4.0 technologies. Eight interviewees also suggested that the Quality team should work closely with the Lean team to ensure SOPs are updated after Lean projects are completed.

4.5. Automatic data collection

Automatic quality data collection is closely connected with both the previous theme and the subsequent theme concerning the integration of data with the ERP system. Twelve respondents and 18 interviewees commented on data collected directly from CPS and smart sensors installed or embedded in machinery, workstations, products, tools, warehouses and logistics vehicles. Some respondents highlighted the challenges of collecting data from outdated machines, while others commented on the importance of managing data using ERP modules such as the manufacturing execution system (MES) or product life cycle management (PLM). With respect to the type of data to be automatically collected, we found many examples in the comments, including the quantity of nonconforming or scrap products, the number of labour and machine hours spent on reworks and the number of complaints and returned products. The data should be automatically collected and aggregated to calculate the real-time cost of quality. Interestingly, one respondent wrote:

[…] In the Quality 4.0 smart factory of the future, I will not spend any time in preparing weekly or monthly cost of poor quality reports for my boss. At each level of the organisation charts and quality indicators will be always 'on tap', updated and visible.

Another six respondents added that it is important to automatically collect data on supplier performance, particularly on-time delivery performance and quality of products.

Moreover, 18 interviewees and 20 respondents believed that customer-related data such as product requirements, complaints and satisfaction levels should be collected automatically. A range of possible solutions was provided, particularly by respondents. For example, six respondents commented that they simply shared an ERP module with customers in which product requirements and production scheduling were inserted and reviewed. Another respondent referred to a specific quality function deployment software based on an AI algorithm that was connected to a range of social media, including Facebook, LinkedIn and discussion forums, in which potential customers and users could provide opinions about the company's products and its competitors.

In contrast, there was a consensus between respondents and interviewees that there should be smart solutions in place for collecting data about the customer experience of products. Twelve respondents had already or were planning to embed their products with smart sensors that could transmit data about reliability and other product characteristics. Moreover, eight respondents emphasised that smart sensors and other technologies could activate or deactivate product features on demand to enhance servitisation.

4.6. Data integration with enterprise resource planning

As discussed in the previous sections, respondents and interviewees agreed that it is important to have vertical integration from the shop floor to the top business level using various ERP modules. The *ERP* variable had the highest mean of all variables at 4.6944. Eighteen interviewees and eight respondents highlighted the relevance of MES, PLM and CRM but also of other modules such as those dedicated to production scheduling, warehouse management and quality control. This is summarised in the following comment by one interviewee:

> […] In our company we have launched a digitalisation project regarding quality management and Industry 4.0. Essentially, quality data are collected automatically from different processes and managed within the MES and the PLM, which are integrated with all the other ERP modules. For instance, if we receive a big claim through the CRM module, the information goes immediately to all the machines which are still working, the faulty part number and to the warehouse management software, which immediately tracks down the storage locations of the product.

Although this comment does not describe exactly what happens to the machine or in the warehouse, we can assume that the process would be automatically halted to find the cause of the problem. In this way, the MES and in particular the PLM become essential for the management of quality-related data. Nine respondents explained that PLM software is important for collecting data over the entire product life cycle, creating a valuable end-to-end integration with the customer.

It is interesting to notice how all the 21 companies integrated their quality data within the ERP using similar modules for doing this. Consequently, we can see, for instance, that customer's data and requirements such as product/process requirements, complains, quality reports, etc. have been gathered and managed through a PDM/PLM module. The PDM/PLM module is usually integrated with the shop-floor modules, in particular with the MES. This represents the fundamental link between the horizontal and vertical integrations of the model. So, customer data can flow from the PDM/PLM to the MES and to all the production and logistics processes. The PDM/PLM can send to the production and supplier/distributor processes critical to quality characteristics, as well as tolerances, control plans, quality procedures and instructions, drawings and technical specifications, etc. Conversely, the MES can collect and manage quality data from production and logistics processes such as nonconforming, test results, process capabilities (Cp and Cpk), state of the product and product traceability, overall equipment effectiveness (OEE), etc. These data are then available inside the PDM/PLM and/or inside ERP business modules such as analytics and AI software. The majority of the companies also integrated the MES and the PDM/PLM module with pre-existing modules such as statistical process control (SPC), gauge control and calibration, problem solving, FMEA, etc. It is interesting to notice how just a couple of companies, one in the automotive sector and another one in the oil and gas sector have implemented an AI module for managing these data. In any case, all the companies have planned to implement in their ERPs such a module in the future.

The comments referred to a vast collection of data, including customer and product requirements, technical documentation, procedures and work instructions, production flow, storage time, bill of materials, test results, product performance, complaints, nonconformities, product maintenance reports and end-of-life reports. However, the respondents highlighted that in a Q4.0 model, the PLM is rarely integrated with the QMS documentation, as discussed in the penultimate theme.

4.7. Artificial intelligence and predictive software

Table VI shows that the respondents also agreed with the possibility of using AI software, especially for predictive and preventive interventions. Similarly, interviewees and respondents believed that AI could be used in applications devoted to quality management and to predict nonconforming products. Twenty interviewees and 14 respondents commented on the relevance of AI software for the prediction and prevention of faults. Interestingly, six respondents discussed the possibility of improving statistical process control software, as illustrated by the following comment:

> […] Smart sensors embedded in machinery and equipment lead to collect data automatically. A new kind of SPC [statistical process control] based on machine learning predicts all kinds of defect during machining and gives feedback to the machine itself, automatically correcting its parameters. No need for human intervention.

4.8. Machine-to-machine communication

As discussed, both respondents and interviewees believed that data from machinery, assembly stations, warehouses and logistics vehicles should be acquired and exchanged using MES software. The following comment from an interviewee summarises the potential for this connection:

> […] When we test our products, in case of nonconforming products, the MES automatically alerts all the involved workstations and machines as well as the warehouse. Depending on the kind of nonconformity, the workstation could be halted, and a team has to find the root cause. Similarly, we could retest products still in the warehouse.

It is noteworthy that three respondents also commented that quality-related data acquired from machinery and assembly stations could give feedback to the software dedicated to production scheduling, which can reschedule production in the case of machines stopping because of quality-related issues.

4.9. Smart technologies for identification and traceability

The quantitative and qualitative results of this research confirm the findings in the I4.0 literature. Smart technologies can significantly assist companies in the identification and tracking of products and tools. This is a precise requirement of the ISO 9001 standard. Clause 8.5.2 *Identification and Traceability* of ISO 9001 (ISO 2015) states that companies must identify outputs when necessary to ensure the conformity of products and retain documented information to enable product traceability. Respondents strongly agreed with this requirement, probably because they had an in-depth understanding of ISO 9001. Indeed, 18 comments were made on this issue.

The majority of respondents and interviewees were particularly drawn to RFID technologies and smart sensors on products and packaging to identify and trace products, and even people control. RFID is preferred because it can be written and read in an aggregate fashion; thus, it is easier to automatically identify using RFID whether a product is nonconforming and its status in the production flow. One of the most interesting applications can be found in the automotive sector, where all the products, tools and gages have been tagged along with the operator's badge. This allows the company to have perfect traceability in terms of who made the product, which gauge measured the product and the result of each inspection. In the case of a claim or product to be returned, the company can track down whatever data/information related to the product for specific corrective and preventive actions. This particular RFID application also allows workers and quality inspectors to figure out at once if they are using a gauge whose calibration is due.

Fourteen interviewees also suggested the possibility of controlling all the tools on the shop floor, particularly measurement instruments. Interviewees commented that it might be possible to identify all of them along with their calibration status.

4.10. Automated document control

The possibility of using electronic documentation for QMS has been discussed since the 1990s (Karapetrovic 1999; Schlickman 2003). Nine interviewees stated that it is now taken for granted that QMS should be paperless. However, it appears that the integration of quality-related documentation within the ERP has not been fully implemented. Eight respondents commented that they were still hoping for automatic and real-time document control, specifically for drawings and work instructions. One comment was:

> […] When the design department changes product characteristics, we should automatically receive in our workstations and machines updated electronic documents as well as correction of machine parameters. Similarly, in the warehouse, picking of components should be mistake-proofing, avoiding the circumstance of obsolete components.

Two other respondents noted that they had achieved a high level of automated document control through the integration of the MES and PLM modules and ultimately the control of the QMS documentation.

4.11. Digital skills for quality staff

The mean of this variable was 3.4259 and it had the highest SD, with the mean of the population being between 3.2 and 3.7036. Therefore, it appears that respondents were somewhat undecided about this theme, even though the 21 interviewees seemed more inclined towards the need for digital skills. Interviewees believed that quality control staff should acquire more knowledge of CPS and its application for quality management. Seventeen of 21 interviewees expressed a particular interest in software for data analysis, specifically for predictive and preventive interventions as discussed previously. However, in the analysis of comments made by 18 respondents, words such as *human* and *intelligence* dominated. The respondents were both worried and suspicious about digital skills, especially for problem-solving activities. Several comments were similar to the following:

> […] I am trying to familiarise myself with these new technologies and software, and I have to say they are very useful. However, when it comes to problem-solving, I think that nothing could compare with the human intelligence. I hope in the future no machine could replace my brain and my job.

This is the most delicate theme we found through the interviews with the managers who seem a bit worried about their future work. Apart from the usual concern of being replaced one day by a robot or an AI software, people are worried to not keep up with the knowledge connected with some CPS. One quality manager, for instance, said:

> […] My company asked me to learn AI, specifically machine learning and statistics, because they want to introduce a piece of software for predicting nonconforming situations in the grinding machines. But it sounds very difficult to me.

Another manager stated:

> […] All these CPS are confusing me, every day they propose me a different one based on new technologies that I have never heard of them. How can I make the right choice in such a dynamic and unstable field?

On the contrary, we also noticed that in the more mature companies, the quality managers are Six Sigma Black Belt or Master Black Belt. This has been facilitating their upgrade in terms of skills, especially towards AI and analytics where statistics is very important. One quality manager, for instance, stated:

> […] Studying and implementing machine learning for predictive patterns I found out that it is based on statistical knowledge such as regressions and design of experiment which I can easily master being a Six Sigma Black Belt.

Therefore, it is very clear how quality staff are going to enlarge their skills from just quality management to quality plus information technology. One interesting aspect of this, highlighted by several quality managers, is that quality staff will spend less time in operative tasks such as inspections and more time in problem solving and preventive activities.

5. Discussion and Conclusion

The findings from the exploratory sequential mixed-method study have revealed eleven themes that help to understand the Q4.0 phenomena and how it links to I4.0. Researchers have a varied opinion about Quality as a function, with some suggesting they may not have a role in functional management (Wadell and Mallen, 2001; Sandholm, 2005) and others arguing on the central role they will play in enhancing the competitiveness of organisations (Elg *et al.*, 2011; Stefanović, 2019). Elg *et al.* (2011) study reported that quality managers perceived themselves as an expert, leading and supporting improvement works, providing guidance on tool usage, and acting as an internal consultant, which is also aligned with the findings of our study where managers are seen being more entrepreneurial in redefining their roles in the era of I4.0. Even with the increased level of automation in the automotive sectors, there are several episodes of a product recall in the last decade (Gunasekaran *et al*., 2019). This shows the relevance and importance of quality practitioners in acting as gatekeepers to manufacture quality products internally within the organisation and interacting with external stakeholders with the aid of digital technology to monitor product performance and take evidence-based decisions before a weak signal leads to defect catastrophic failure.

Revisiting the definition and overarching themes of Q4.0 provided by Jacob (2017) and Littlefield and Murugesan (2020) from LNS research, we define Q4.0 as *'a customer-centric and digitally-enabled approach to the integration of people with process and technology across the value chain (including vertical, horizontal, and end to end integration) for taking evidence-based decisions in collaboration with internal and external stakeholders in the value chain'*. In our definition of Q4.0, influenced by Littlefield and Murugesan (2020), people, process and technology are considered as an overarching theme of Q4.0. The recent publications in production research (Ivanov *et al*., 2021; Bittencourt *et al*., 2021; Tortorella et al., 2021) also highlighted the importance of the human factor and process in embracing technological advancements witnessed in the Industry 4.0 era. Ivanov et al. (2021) also suggested the importance of the interdisciplinary team, as suggested in our definition of Q4.0, to investigate operations management problems in the Industry 4.0 era as this will enable vertical integration across the organisation. Bittencourt et al. (2021) and Tortorella et al. (2021) highlighted the importance of management along with a focus on process and people in facilitating Industry 4.0 adoption. The eleven themes identified through this research can map across the aggregate order concepts of people, process, and technology.

There is no doubt that people will still be central to I4.0 and Q4.0 implementation and integration. The dichotomy between people who consider automation and new technologies as helpful and those who worry about the possibility of being replaced by technology is well known in the literature (Cagliano et al. 2019; Ivanov et al., 2021; Bittencourt et al., 2021; Tortorella et al., 2020, 2021). Indeed, the role of the blue- and white-collar workers may evolve in the era of I4.0 and Q4.0 (Srinivasan *et al*. 2020) with some jobs disappearing, though several other jobs or new roles will emerge as a result of Q4.0 implementation (Sony *et al*. 2020), as witnessed in this research. A classic example from a mature I4.0 company in this study shows how the role of Lean Six Sigma Black Belt is changing with an expectation that they develop expertise in AI and machine learning. Similarly, other examples discussed before showed that quality teams had upskilled themselves in machine learning and analytics topics to transition from policing role to taking a more proactive role in predicting machine failure inside the company or product failure at the customer end, which is also aligned with some recent publications on Q4.0 (Carvalho *et al*. 2019; Stefanovic *et al.* 2019). Here, quality leaders will be expected to take an entrepreneurial role and redefine their skills and approach to managing quality (Carvalho *et al*. 2017; Gunasekaran *et al*. 2019; Nenadál 2020).

Our findings from theme 11 (Digital skills for quality staff) primarily focused on developing the digital skills of managers and limited evidence to support the development of softer skills, including communication and social skills, were reported. Recent research from Srinivasan *et al*. (2020) clearly highlighted different roles that employees may take, requiring a range of foundational skillsets, including technical, social, communication, problem-solving, and cognitive skills. However, to enable such transformation to happen, the top management role is critical in creating a culture based on trust, empathy, and emotional intelligence to encourage employees to embrace I4.0 technologies. The importance of top management in I4.0 implementation is well known and has been studied by several authors (Shamim et al. 2016; Lin et al. 2018; Picarozzi et al. 2018; Sony and Naik 2019; Sony *et al.* 2020; Bittencourt *et al*., 2021). The discussion above is aligned with two key themes (theme 3- Top management; and, theme 11 - Digital skills for quality staff) from our study that can be grouped under the second-order category of 'people'.

The second-order category in our definition of Q4.0 is 'process'. Under this category, we can group the following six themes: Theme 1- Q4.0 based on I4.0; Theme 2- Q4.0 based on ISO 9001; Theme 4- Process mapping; Theme 5- Automatic data collection; Theme 6- Integration of data with ERP; and Theme 10 – Automated Document Control.

All the six themes under the ‘process’ category are basically focused on the process of mapping quality function activities with other departments, machines, QMS, and other platforms such as ERP/MES/SCADA to extract and gather data that is directly relevant to the quality function such as defect, scrap, specifications, complaints, etc, for evidence-based decision making. At the beginning of the Q4.0 journey, a company should map its processes to evaluate the type of quality-related data needed, from where they should be collected and how to automate the collection and integration processes. In this stage, new process mapping tools are likely needed. The role of digital process mapping tools (theme 4) for streamlining wastes in the processes and updating the SOPs were considered an important role within Q4.0 domain. The literature evidences the benefit of applying Lean first before digital transformation to ensure processes are streamlined before replaced by technology (Bittencourt et al., 2021; Chiarini and Kumar 2020; Tortorella et al. 2019, 2020; Buer et al. 2018). Using tools such as smart Value Stream Mapping (Chiarini and Kumar 2020; Tortorella et al., 2020) can facilitate achieving horizontal and vertical integration (Buer et al. 2018).

As our findings revealed, the quality managers in mature companies played an active role in facilitating vertical integration within the organisation and horizontal/end-to-end integration externally in the supply chain (theme 1) by making use of big data in real-time and cloud technologies for evidence-based decision making aligned with customer’s requirements (Stefanovic *et al.* 2019). Our findings also implied that the connectivity and interaction facilitated between different entity involved in the digital transformation (i.e. themes 5, 6, and 10) through deployment of Industry 4.0 technologies (machines, employees, organisational units, and external stakeholders in the supply network including suppliers and customers) are not the aim but means to achieve efficient and effective quality improvement (Jacob 2017; Nenadál 2020; Ivanov *et al.*, 2021)

The development, implementation, and maintenance of the online documentation (i.e. theme 10) for quality management can be facilitated through cloud technologies and integrated with organisation’s MES/ ERP system will allow for real-time up-gradation of the SOPs if any changes are made internally or externally in the supply chain (Stefanovic *et al.* 2019). The natural storage for the collected quality-related data is the ERP, in particular the CRM, MES and PLM modules. Through complete vertical integration, quality-related data was automatically collected and aggregated to create real-time indicators, cost of poor quality, supplier performance and other reports. Particular attention was given to quality-related data from customers, which should be collected throughout the entire product life cycle. These actions allowed quality managers to shift their focus from being compliance-centric and process enabled to being customer-centric and digitally-enabled (Stefanovic *et al*. 2019; Littlefield and Murugesan 2020).

Integration with ISO 9000 received mixed response though the interviewees and respondents who replied positively to this question viewed ISO 9000 as in-built features that are aligned with Q4.0 focus on improving traceability of products and processes (Johnson 2019). The data generated from intelligent machine allows line supervisors to remotely monitor employee's adherence to specification (a key principle of ISO 9000 QMS) and have the ability to remotely initiate the shutdown of upstream processes to prevent the passage of non-compliance parts to downstream operations (Johnson 2019). The traceability feature of Industry 4.0 technologies allow the quality function to work in collaboration with engineers and the R &D team to monitor the product or machine performance at the client end and identify any abnormal patterns in real-time, which will help them to proactively identify the failure modes. In addition, Stefanovic *et al*. (2019) research also stated that the evidenced-based decision-making role of the quality manager is also aligned with the basic principles of quality management according to ISO 9001: 2015.

The last category in our definition of Q4.0 is 'technology' which encapsulates the following three themes identified from our study: Theme 7 - Artificial intelligence and predictive software; Theme 8 - Machine-to-machine communication; and Theme 9 - Smart technologies for identification and traceability. The interviewees illustrated how the use of I4.0 technologies such as the Industrial Internet of Things (IIoT), machine learning, and AI (Jacob 2018; Sony et al. 2020) allowed them to visualise patterns in data for evidence-based decision makings. From the I4.0 literature, it is well known that AI has been used to improve predictive maintenance and related issues (Ghobakhloo 2018; Sahu et al., 2020; Ivanov et al., 2021). The advanced sensing technologies coupled with advanced predictive analytics capabilities allow to measure and predict product and process quality far in advance, i.e. having prognostic capabilities, and changes the role of the quality function from preventive to predictive quality management (Zonnenshain and Kenett 2020). Given quality is now a prerequisite requirement in a product or service offerings all across the supply chain tiers, the I4.0 technologies provide an opportunity to improve traceability and real-time monitoring of product quality across the supply chain (Jacob 2017; Johnson 2019). Aligned with theme 9, our findings also reported that the smart sensors and other technologies could activate or deactivate product features on demand to enhance servitisation (Grubic 2014).

To summarise, our study is amongst very few empirical studies that have identified key themes of Q4.0 and have grouped those themes under a theoretical model for Q4.0, see figure 2. This will pave the path for future researchers to test the validity of the proposed theoretical model through empirical research.

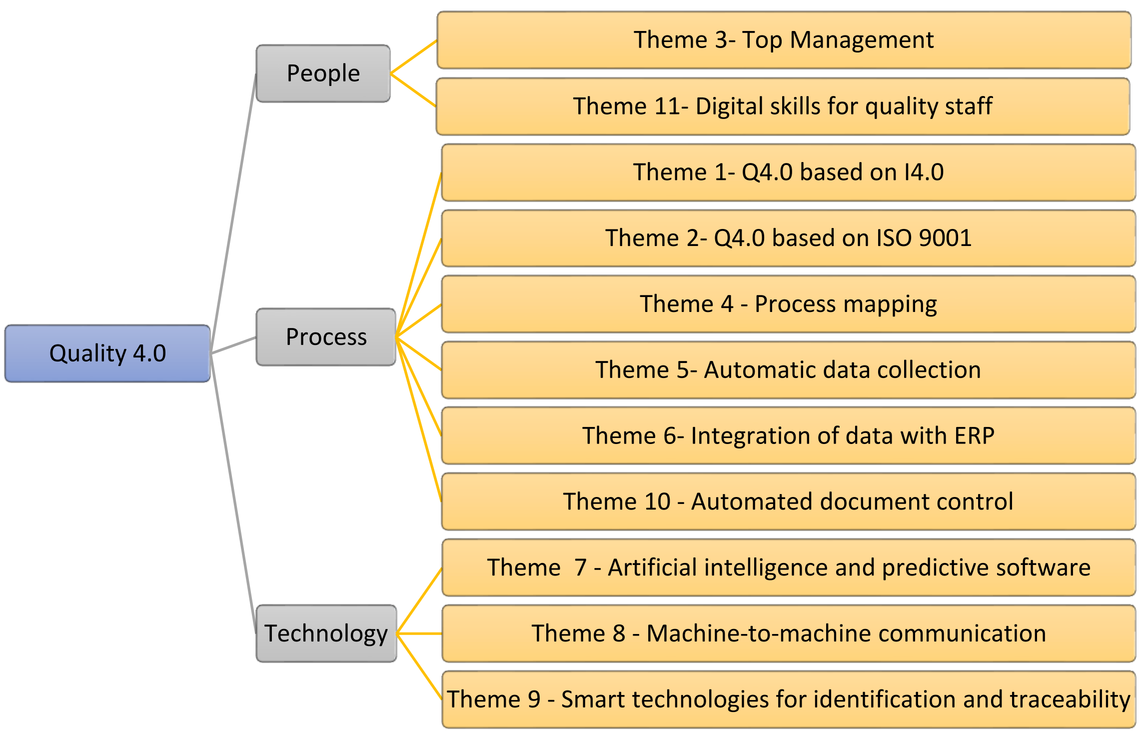

Figure 2. A theoretical model for Quality 4.0

5.1. Concluding remarks

This research, which was conducted in the Italian manufacturing context, has provided novel findings to our research question and contributed to advancing the production research body of knowledge. Ivanov et al. (2021) stated the need to go beyond operations management focus to accelerate the adoption of Industry 4.0 technologies, which is the focus of this research study. We elicited specific eleven first-order themes that were grouped under three second-order factors to represent the Q4.0 model that provides a better understanding of what Q4.0 could be and secondly suggest how this model may be developed. The Q4.0 model requires a digital leader or top management involved, as identified by Bittencourt *et al*. (2021), and committed to Q4.0 and provides top-down resources, training and strategic goals. Similar to findings reported by Srinivasan *et al*. (2020) and Bittencourt *et al*. (2021) on the importance of human factors in I4.0 implementation, our research also reports that people will drive innovation in processes through vertical, horizontal and end to end integration of I4.0 technologies across the value chain. The findings from the study have revealed the changing role of quality managers in the era of I4.0, which requires managers to acquire new digital skills and knowledge regarding CPS and its effects on quality management. However, as stated by some quality managers, this should be implemented without instilling the 'digital fear' of becoming redundant because of technology.

From the 21 involved companies in the first phase of this study, we noticed that the two belonging to the automotive components sectors have gone to great lengths to develop a Q4.0 and an I4.0 model. We also noticed that the size of the companies could affect this development. However, we do not have any figures to confirm this due to the limited sample size of the sample and the kind of information we gathered from the interviews.

5.2. Implications for practitioners

Results from this research have manifold relevance to practitioners. A Q4.0 model has been depicted through a range of theoretical themes, which could be used as a guideline for implementing and developing Q4.0 in a typical Industry 4.0 environment. The results of the study have highlighted the urgent need for quality managers to rethink their departmental role and responsibilities if they would like their job to be relevant in the era of Industry 4.0.

The examples from mature I4.0 implementing companies revealed the changing role of quality professionals as they embraced digital tools to enable vertical, horizontal, and end to end integration of their functions with the entire value chain. To embrace that change, quality managers have to upskill and reskill themselves in the usage of I4.0 technologies for prognostic management and traceability of product quality, process quality, and end-consumer data on product usage. However, the authors have highlighted that digital skills will not be enough for quality managers to achieve the true potential of Q4.0. They need to upskill themselves not only in digital skills but also in social and communication skills (Srinivasan *et al*. 2020; Bittencourt *et al*., 2021) as they will be expected to interact with intra-department workers (Ivanov et al., 2021; Sahu et al., 2020) and external stakeholders, including end-consumer.

The findings also highlight that quality managers need to understand what type of data they need, how to automate data collection from the ERP/MES/SCADA/CRM/PLM software, how to use AI and machine learning knowledge to do data analytics and identify weak signals that may lead to catastrophic failure in the future. Another important finding for the manager was the important role played by ISO 9000 QMS and Lean in streamlining the processes before the process is digitised (Tortorella *et al*., 2020, 2021; Bittencourt *et al*., 2021; Ivanov *et al*., 2021). Rushing for automation and digitisation without streamlining operations may augment inefficiency in the digital processes. The Black Belts leading Lean Six Sigma initiatives in organisation are also expected to upskill themselves by learning how to use AI and machine learning for data analytics. There are ample opportunities for quality professionals to embrace the eleven themes of Q4.0 models, though it also brings significant challenge and digital fear for many practitioners who are not yet sure about the relevance of I4.0 technologies to their profession. Here, senior management needs to play a proactive role in supporting quality managers to transition from Q3.0 practices to Q4.0 practices.

5.3. Limitations and agenda for further research

This research has several limitations that open avenues for further research. First, it was limited to Italian manufacturing companies; thus, confirmation from other geographical areas is needed. Second, we excluded small manufacturing companies, which could have other theoretical themes underpinning Q4.0. For example, small companies often do not have an ERP system (Bahri et al. 2017) and are less inclined towards I4.0 technologies (MISE 2018).

Several comments by participants also suggest agendas for further research. Among the most frequent was the relationship between ISO 9001 certification and I4.0, digital leadership characteristics and management involvement, AI and quality management, M2M data exchange and the effect of CPSs on job organisation, competency and motivating factors. We will test the theoretical model by conducting quantitative research in the next phase of the study.

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