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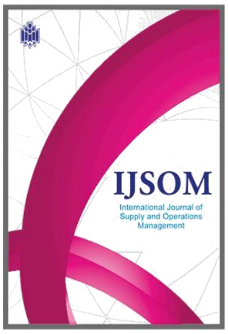

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Modelling and Analysis of Challenges for Industry 4.0 Implementation in Medical Device Industry to Post COVID -19 Scenario

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Abstract

Today, the health care and medical sector is adopting digital technologies aggressively. However, this adoption also has significant challenges, especially during COVID-19. This research aims to identify and categorize the significant challenges related with application of Industry 4.0 (I4.0) technologies in the medical device industry. An expert-based survey is carried to capture the perception of medical device industry leaders about the challenges associated with the implementation of digital technologies. Further, interpretive structural modeling (ISM) method was used for an empirical investigation of the hierarchy and interdependencies of identified challenges. The authors have proposed a mind map and conceptual model of hierarchy and interdependencies of challenges associated with the digital transformation of the medical device industry towards I4.0. Industry leaders and policymakers worldwide are defying challenges while the digital transformation of the organizations post COVID-19. The I4.0 implementation challenges identified and ategorized in this research may aid as a guide for medical device manufacturing organizations while designing a strategy for I4.0 transformation and to make sure that they start on the right -footing. Most of the existing work is focused on the advantages of I4.0 for managing the organization's post-COVID-19, lacks thoroughness and testing. Owing to the identified gap, this study intends to empirically identify the critical challenges associated with applying I4.0 technologies in the medical device manufacturing sector. This study is a pioneer in identifying and categorizing the vital challenges needed to deal with this critical situation. A potential area of future research can be the validation of the identified challenges with a larger sample size.

Keywords: Industry 4.0; Medical device manufacturing; Digital technologies COVID-19; Interpretive structural modeling (ISM); Smart factory.

1. Introduction

Due to the coronavirus outburst, industrialized operations across the globe are witnessing unforeseen disruption (Mitra et al., 2020; Nicola et al., 2020). The prime focus in the current scenario acclimatizing to the absurdly transformed state of affairs (Ranney et al., 2020). The medical sector shows incredible agility to meet the increasing demand for medical devices, health care equipment, personal protective equipment (PPEs), and medicines (Spina et al., 2020). The

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coronavirus pandemic has hit worldwide trade and investment at an unmatched speed and scale (Ivano, 2020; Nicola et al., 2020). With the surge in COVID-19 cases, nations are under lockdown; businesses are shut down (Nicola et al., 2020). This is also validated in a report by Fortune (2020), indicating that 94 % of Fortune 1000 companies are facing disruptions in the operational and supply chain. Additionally, the study of Dun and Bradstreet (2020) highlights that nearly fifty-one thousand industries have suppliers/ manufacturing zones in Wuhan, China, which subsequently disturbed business operations. The state of affairs is serious in developing nations struggling with scarce resources (Khan and Ghauri, 2020). There is increasing mindfulness that administrations need to be prepared to deal with this pandemic in their backyards (Koonin, 2020; Kruger et al., 2020; Fadel et al., 2020).

Unfortunately, as the treatment method of the virus has not been identified, there is no precise drug for these patients, except for symptomatic and supportive treatment. Respiratory support devices such as life-support machines, oxygen generators, atomizers, and monitors are the primary clinical treatment medical devices to combat the pandemic (Ranney et al., 2020; Livingston et al., 2020). Thus, from diagnosis to cure, the necessity for medical devices and life-support systems is on the increasing trend (Ranney et al., 2020). However, the scarcity of key materials and the lockdown restrictions have restricted the production of medical devices. Industries worldwide are struggling in managing supply chains due to the disruptions posed by the pandemic (Ivanov, 2020). It has exposed the susceptibilities of numerous establishments, particularly those who have a significant dependency on manual process and long supply chains (Nicola et al., 2020; Wuest et al., 2020). The pandemic can be considered as a black swan event forcing the organizations to transform the strategic and operational plans (Ivanov, 2020). Conventional understanding holds that medical devices manufacturing organizations are mostly insulated from disruption due to the massive demand for medical products and devices. However, there will be a series of positive and negative demand shocks, as business organizations and their supply chains respond to changing needs of customers (Martin, 2020). Also, the COVID-19 pandemic illustrates that numerous businesses were not completely aware of the vulnerability of their supply chains due to global shocks (Ranney et al., 2020).

Sulkowski et al. (2020) highlight that the coronavirus pandemic is a fast-tracking I4.0 implementation and digital workflows across industries. The vital need to plan smarter, robust, flexible, and agile supply chains has been one of the critical lessons of this pandemic (Ivanov, 2020). Fortunately, new-fangled digital technologies of I4.0 are emerging that consequently may increase visibility across the complete value chain and aid organizations' ability to battle such disruptions (Ivanov and Dolgui, 2020). The customary linear value chain model is transmuting into digitally integrated where silos are broken down, and organizations become coupled to their widespread supply chain system. This exercise aid to empower real-time visibility, agility, collaboration, and optimization. Medicinal devices and apparatus manufacturers noticed that with the rise of I4.0 technologies, applying computerization in their processes advances output and quality and provides other benefits (Prisecaru, 2017; Javaid and Haleem, 2019; Haleem et al., 2020). I4.0 technologies are connected to lights-out manufacturing, which signifies an entirely automated work environment.

This awareness has gained an instantaneous value as the COVID-19 is expanding its hold. The notion of a completely functional industrial unit with the least personnel may support to endure production without any restrictions, especially during the coronavirus phase. On the other hand, large organizations are hesitant to adapt to this level of automation. The smart factories will enormously decrease the amount of personnel required as the repeated jobs are mechanized. The study of Ghobakhloo (2018) emphasized the need for thinking out of the box and fast-tracking the implementation of digital technologies for sustainability. The investigation of AlMaadeed (2020) emphasized the role of I4.0 technologies to design and develop innovative materials. Building upon the same, Ito et al. (2020) also explained the role of coronavirus in revealing the vulnerabilities of worldwide value chains and stressed the role of digital technologies of I4.0 in restoring the operations post-COVID 19. The study of Verawardina et al. (2020) stressed the impact of digital technologies of I4.0 in creating the online learning systems in managing the risks posed by COVID-19. The study of Vaishya et al., 2020 highlighted the influence of digitalization on decreasing the impact of COVID 19 on industry and society.

The necessity for carrying an investigation on the influence of I4.0 technologies on the industrial surroundings is also emphasized by Haleem et al. (2020). Before the coronavirus outbreak, I4.0 was an area of enormous interest for many businesses. It was perceived as an inspiring theme with vast futuristic benefits. I4.0 is not only as vital as it was before the outbreak, but it also appears to be more appropriate in the current transformation (AlMaadeed et al., 2020; Javaid et al., 2020). Though the studies of AlMaadeed et al. (2020); Haleem et al. (2020); Ivanov, (2020); Ito et al. (2020); Sulkowski et al. (2020) acknowledged the role of I4.0 technologies in managing the operations during the coronavirus pandemic.

As the medical device industry navigates unchartered and choppy waters, the industry leaders might want to review their strategies to manage the interruptions. So, with all of these disruptions, can it be presumed that coronavirus has prompted a premature renovation in industrial operations? The motivation of the research complies with the above-stated research gaps that most of the current works done are focused on the role of I4.0 to manage the businesses and to minimize the risk associated with coronavirus transmission (Ito et al., 2020; Vaishya et al., 2020; Sulkowski et al., 2020). Besides, the scope of the current studies is limited to the advantages of I4.0 technologies in reducing the risks and enabling business continuity. Furthermore, the studies focusing on the challenges of I4.0 implementation are generic and at the conceptual level. It is also significant to note that no prior research has evaluated the challenges of implementing I4.0 technologies in the medical device sector, especially in the disruptive environment of a pandemic like COVID-19. Most of the past research works are at an abstract level without any clear and empirically tested indication of potential challenges related with the application of I4.0 in the medical sector. Even though organizations are keen on implementing new-fangled technologies to scale up their industries in the disruptions posed by COVID-19, there are great challenges to overcome. This also poses a question that what are the critical challenges associated with the application of I4.0, particularly in the medical sector. Considering the above-stated gaps, this work focuses on the investigation of the challenges associated with the application of I4.0 in the medical device sector with the following objectives:

- To propose a conceptual mind map from experts' feedback for the synthesis of implementation challenges of I4.0 in the medical device industry.
- An empirical investigation of the hierarchy of I4.0 implementation challenges using the ISM technique.

This research contributes to the theory of knowledge by empirically investigating the significant challenges of implementing digital technologies of I4.0 in the medical device manufacturing sector post-COVID-19. This study is structured as follows. The following section, literature review, offers a deep insight into the challenges related to the implementation of I4.0, identifying the research gap trailed by research methodology, detail of expert survey, development of mind map of I4.0 implementation challenges, data analysis using integrated structured modeling and discussion. In the last section, we conclude the outcomes of our analysis and directions for future research.

2. Literature Review

Industry 4.0 offers innovative technologies to create innovative concepts in the medicinal field by amalgamating digital technologies with traditional machines (Javaid and Haleem, 2020; Frederico et al., 2020; Thuemmler and Bai, 2020). I4.0 helps manufacture high quality, regulated medicinal instruments and customize as per patient requirements (Prisecaru, 2017; Sunil et al., 2020; Yadav et al., 2020). Digital technologies can support all the value chain facets, comprising design and development, supply chain, manufacturing, sales, and service (Ghobakhloo, 2018; Luthra et al., 2019). The influence of I4.0 technologies in moderating the issues posed by social distancing, supply chain interruptions, shortages of skill sets, restrictions of trade, and the demand shock is addressed by Wuest et al. (2020). I4.0 displays the wide-ranging capability of manufacturing newfangled mass customized implants, state-of-the-art tools, and apparatuses for the health and medical field (Kumari et al., 2020). In line with the same, healthcare 4.0 is a terminology that has emerged late and is consequent from I4.0. It is about applying digital technologies in the health sector (Thuemmler and Bai, 2020). Today, the health care and medical sector is more digital than in the past, with the broad spectrum of digital technologies supporting healthcare 4.0 (Sannino et al., 2018). The application of digital technologies like networked cloud-based health record systems, industrial internet of things, and enhanced analytics, is being carried out in the healthcare and medical industry across the globe (Sannino et al., 2018; Thuemmler and Bai, 2020).

Building upon the same, Kumari et al. (2020) and Lee et al. (2020) also discussed recent advances such as digital technologies coupled with collecting real-time data, its analytics, and amplified usage of artificial intelligence for better management of operations. Also, real-time collaboration, coherence, and convergence help the medical and healthcare establish a comprehensive monitoring system that satisfies the customized requirements (Thuemmler and Bai, 2020). Javed et al. (2020) identified numerous digital technologies and their capabilities in the medical field. I4.0 by the development of customized medical equipment. The study of AlMaadeed et al. (2020), Javaid et al. (2020) also highlights the role of the smart supply chain of medical devices and apparatus to the patients.

The digital product twin, digital process twin, and digital performance twins produce a new cybernetic world (Ghobakhloo, 2018). Digital technologies enable real-time communication and interchange of data and information with the assistance of IoT, software, devices, autonomous robotics, cloud computing for faster analysis, and corrective actions in the value chain. (Brettel et al., 2014; Javaid and Haleem, 2020; Luthra and Mangla, 2018). I4.0 technologies have the potential to mass customized requirements during this emergency (Javaid et al., 2020). The conception of I4.0 is anticipated to carry a host of benefits for manufacturing value creation (Luthra et al., 2018; Prisecaru, 2017; Sannino et al., 2018; Haleem et al., 2020; Javaid et al., 2020; Thuemmler and Bai, 2020).

Nevertheless, the associated challenges may hamper its application. In view of the high significance of digitalization it is critical to appreciate the fundamental challenges related to their implementation. Regarding the economic challenges, the key issues are associated with the high investments coupled with the unclear economic paybacks and the transformation in the business models (Oesterreich and Teuteberg, 2016; Luthra and Mangla, 2018). The administrations are not clear on how and when they will be able to recover their investment (Birkel et al., 2019). Although the technologies of I4.0 are exceedingly useful, they take a specific time to reveal tangible benefits. Furthermore, the utmost benefits, such as real-time analytics, shorter cycle time, reduced safety issues, do not give clear and direct financial benefits (Birkel et al., 2019). Unless the paybacks are distinguishing and time-bound, organizations hesitate to capitalize and delay the investments (Neirotti and Raguseo, 2017).

The study of Hariharasudan and Kot (2018) stressed the issue of inadequate skills and low awareness levels of individuals to manage technology as one of the significant challenges in employment of I4.0. Especially in the health care and medical sector wherein the proficiency of persons in digital technologies is relatively low (Porter et al., 2016). They may be specialists in a specific technology, but that is founded more on skill and number of the year worked rather than on learning (Ghobakhloo, 2018). Besides, the technologies of the I4.0 are complex, and the people have somewhat lower awareness, skills, and competencies in their learning and adoption. Also, the benefits of I4.0 technologies can be leveraged if the transformation agendas also thrive in reducing the internal resistance embedded in the corporate culture. This human side of transformation is most challenging for the reason that it speaks to people's deep needs for steadiness and an instinctive resistance to change. Confronted with a constantly growing range of digital technologies, leaders and policymakers face trouble in deep understanding all the digital technologies and lack the vision and strategies for their implementation (Brettel et al., 2014; Shamim et al., 2017).

Besides, the infrastructure shortcomings associated with the traditional and outdated infrastructure may also create information technology interface problems and the need to re-design existing infrastructure (Salimova et al., 2019; Xu et al., 2018). I4.0 technologies are poised to increase the skills gap as the nature of occupations that need to be done and the skill sets required are continually shifting (Shamim et al., 2017). Businesses will face the challenges of investing in up skilling and reskilling their employees and bring technology in empowering life-long learning for their employees. The state of affairs is likely to get challenging with evolving I4.0 technologies, which are much more skill-based and capital intensive resulting in job loss (Wuest et al., 2020). The shutdowns caused by the coronavirus pandemic could speed up and increase the course of mechanization and job losses as businesses and consumers were forced into speedily acclimatizing new-fangled technologies due to social distancing measures (Sulkowski, 2020).

The digital technologies of I4.0, cyber-physical systems, and cloud networks lead to a snowballing complexity of operations (Tupa et al., 2017; Akdil et al., 2018). The interconnected nature of I4.0 technologies driven operations and the stride of digital transformation means that cyber-attacks might have far more far-reaching effects than ever before, posing a great challenge (Tupa et al., 2017; Ivanov, 2020). Cyber-security could turn out to be an essential part of the strategy, design and development, and operations in the I4.0 era (Akdil et al., 2018). Also, I4.0 systems demand reliable high-speed internet with a large bandwidth, which poses internet connectivity issues (Akdil et al., 2018; Birkel et al., 2019).

The complete integration of the value chains both horizontally and vertically and the continuous flow of data poses the challenge of intellectual property rights (Birkel et al., 2019). A foremost obstacle facing digitized manufacturing is standardization. Standards and optimization models are critical to ensure data interchange amongst machines, production lines, plants, supply chains, and end customers in the complete value chain. (Kıran et al.,2012; Cho et al., 2016; Akdil et al., 2018; Khalilpourazari et al., 2019; De Vries and Van Wassenhove, 2020). They would also be significant for warranting that digital technologies and robots can be assimilated into the manufacturing process through simple plug-and-play. The citation of challenges related to the application of I4.0 technologies is summarised in Table 1. A wide range of multi-criteria technique has been used in past research works to analyze the hierarchy (Ahmed et.al., 2020; Amini, A., & Alinezhad, 2017; Basak and KG, 2015; Hoseini, et.al., 2019; Panahifar et al., 2014; Seknickova and Jablonsky, 2020;). Table 1 shows the citation table the I4.0 implementation challenges.

Table 1. Citation table of the I4.0 implementation challenges

Code	Challenge	Reference
F-1	High investments cost	Oesterreich and Teuteberg, 2016; Ivanov,2020; Büchi et al., 2020; Ivanov et al., 2019; Mhlanga, 2020
F-2	Unclear economic benefits	Neirotti and Raguseo, 2017; Akdil et al., 2018; Ghadge et al., 2020
F-3	Re-design of existing facilities	Porter et al.,2016; Salimova et al., 2019; Xu et al., 2018; Ivanov et al., 2019
F-4	Internal resistance and corporate culture	Akdil et al., 2018; Birkel et al., 2019; Ghadge et al., 2020; Ghadge et al., 2020
F-5	Operational complexity	Tupa et al., 2017; Akdil et al., 2018; Snieška et al., 2020; Kaviani et al., 2020; Kumar et al., 2020
F-6	Transformation of business models	Kiel et al., 2017; Akdil et al., 2018; Birkel et al., 2019; Frederico et al., 2020
F-7	Fear of job loss	Kiel et al., 2017

F-8	Infrastructure shortcomings	Drake et al., 2016; Akdil et al., 2018; Birkel et al., 2019
F-9	Dependence on technology providers	Akdil et al., 2018; Birkel et al., 2019
F-10	Technology interface problems	Kiel et al., 2017; Tupa et al., 2017; Birkel et al., 2019; Fazli-Khalaf et al., 2019; Yadav et al., 2020
F-11	Lacking standards	Tupa et al., 2017; Akdil et al., 2018; Birkel et al., 2019
F-12	Internet connectivity issues	Akdil et al., 2018; Birkel et al., 2019
F-13	IPR issues	Birkel et al., 2019
F-14	Low awareness and inadequate skills	Shamim et al., 2017; Tupa et al., 2017; Akdil et al., 2018; Hariharasudan and Kot, 2018; Ivanov, 2020; Birkel et al., 2019; Büchi et al., 2020; Mhlanga, 2020
F-15	Leadership and strategy	Brettel et al., 2014; Shamim et al., 2017; Akdil et al., 2018; Luthra and Mangla, 2018; Ghadge et al., 2020
F-16	Cyber security risk	Kiel et al., 2017; Tupa et al., 2017; Akdil et al., 2018; Ivanov,2020; Birkel et al., 2019
F-17	Technical integration	Dube et al., 2016; Kiel et al., 2017; Birkel et al., 2019
F-18	The high cost of technology	Birkel et al., 2019; Ghadge et al., 2020
F-19	Data security	Tupa et al., 2017; Akdil et al., 2018; Ivanov,2020; Ivanov et al., 2019
F-20	Information security	Akdil et al., 2018; Ivanov,2020; Ghadge et al., 2020

3. Research Methodology

This section discusses the approach of constituting data collection, expert surveys, and data analysis. The challenges associated with applying digital technologies in the medical sector in the situation of coronavirus are identified using expert's feedback. The sample for this investigative study involved n=31 industry leaders from 24 medical device manufacturing industries and 07 health care organizations. All the selected experts are working on implementing I4.0 technologies in respective organizations. One-to-one interviews were carried out with the experts over the Phone/Zoom/Google meet/Skype platform for 30 minutes to 45 minutes. The respondents were requested to share their viewpoints on the I4.0 implementation challenges. An expert survey was used, given the possible problems in the study of the I4.0 implementation challenges. This is vital considering that very few establishments have employed the evolving technologies of I4.0.

Expert surveys help in offering a quantitative measure to the models being inspected. Considering the uniqueness of the work the sample size is satisfactory and is in line with the necessities of research pragmatism (Buchholz et al., 2009). The interviews were carried out during the period of 25th Apr-10th May 2020. Before starting the meetings, emails are sent to the shortlisted experts to clarify the purpose of this study and to schedule a virtual meeting as per their availability. The one to one interactions consequently facilitated to capture the perception of industry experts. These responses consequently helped in identification of the challenges related with I4.0 implementation in the medical device sector. The expert's response keywords were compiled to create a mind map of critical challenges and sub-challenges associated with the implementation of I4.0 in the medical sector. The developed mind map is shown in Figure 2. Also, as per the experts' feedback, four challenges, as mentioned in Table 1, found to be repetitive. These include "technical integration" with "technology interface problems," "high cost of technology," with "high investments', "data security" and "information security" with the "cyber-security." Hence the n=20 identified challenges are reduced to n=16 as per the expert's feedback by removing the above mentioned four duplicate challenges. The experts were asked to rate if the literature review's recognized challenges are valid regarding the application of I4.0 in medical device manufacturing.

This was carried out by the Likert scale of 1 to 5 (1-not valid, 5-absolutely valid). Owing to the past research works (Faisal et al., 2006), ISM is used to determine the interdependencies amongst I4.0 implementation challenges. This study focuses on analyzing the challenges linked with the application of I4.0 in the medical sector using the ISM approach. The results analysis is used to establish a hierarchy for I4.0 implementation challenges and determine the interdependency among them. The steps and methodologies of research methodology are given in Figure 1.

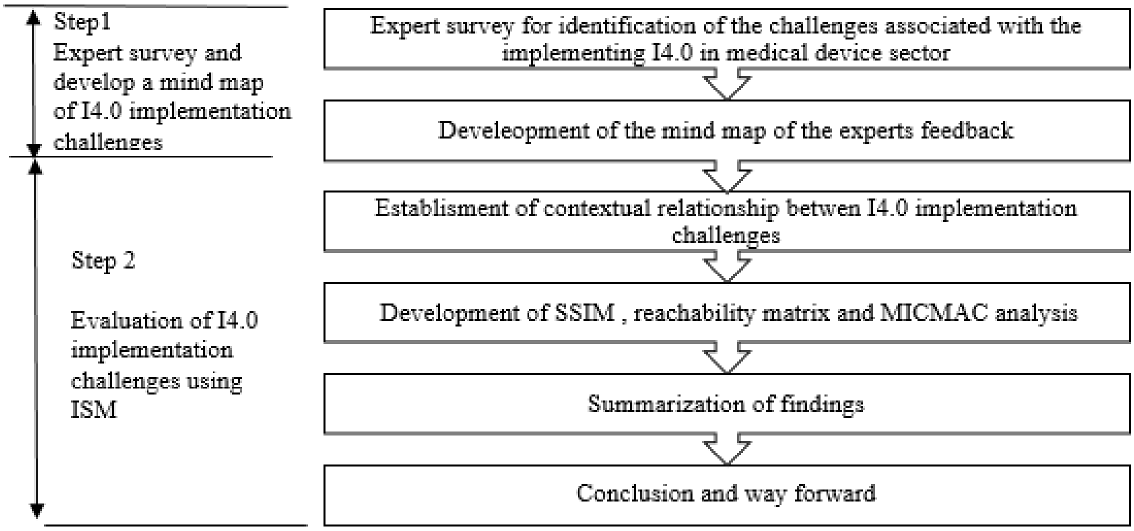

Figure 1. Steps and methodologies of research methodology

As shown in Figure 1, the role of step 1 is to identify the challenges related to the application of I4.0 and develop a mind map of expert feedback. In step 2, challenges are analyzed in the I4.0 implementation of the medical sector using ISM. Subsequently, the hierarchy for identified challenges is obtained by ISM. A structural model of challenges for implementing I4.0 in the medical device manufacturing industry has also been put forward by the ISM technique. Prominent scholars have applied ISM in different fields such as manufacturing (Panahifar et al., 2014), the energy sector (Alizadeh et al., 2016); the automobile industry (Gopal and Thakkar, 2016), green supply management (Sivaprakasam et al., 2015) and lean production (Vasanthakumar et al., 2016). The hierarchy for I4.0 implementation challenges in the medical device manufacturing industry is determined based upon dependence and driving power by using MICMAC analysis.

4. Data Analysis, Results, and Discussion

The descriptive statistics of the expert's feedback provides a high mean score ranging from 4.57 to 4.90, with a low standard deviation ranging from 0.30 to 0.50. In turn, these attributes indicate that the challenges identified in Figure 2 are highly significant concerning the employment of I4.0 in the medical sector. The Cronbach's alpha was also found to be 0.8135, which indicates that internal data is consistent. Figure 2 summarizes the expert's feedback on the implementing I4.0 in medical device manufacturing.

Investment in digital technologies of I4.0 is vital for businesses in today's disruptive business environment. At the same time, it will turn out to be one of the leading challenges due to the concerns related to high investments with unclear economic benefits. Any new-fangled technology demands an investment, which may not have a clear-cut timeline of returns of investment. Digital technologies are enormously useful, but they take a specified period for the demonstration of perceptible paybacks. Furthermore, the utmost benefits such as effective analytics, reduced risks, mass customization may not offer indistinct and direct paybacks. Unless the advantage is clear and time-bound, the leadership of medical device organizations may pause to spend on new technologies and wait. These findings are also in line with the findings of Neirotti and Raguseo, (2017), and Birkel et al. (2019).

Over the last few years, rapid advances are made in digital technology, increasing automation, data collection, analytics, and monitoring becoming the norms. The environment of the medical device industry means that the employees are required to be extremely skilled in digital technologies. However, the contemporary generation of industry leaders is not digital natives. Those who are currently coming through the schooling system inevitably lack industrial experience. Given the complex nature of I4.0 settings, the ability of medical device industries to source the skilled workforces needed for managing their operations will be highly significant. Preparing for a progressive, intelligent future also poses the challenges of interactions between humans with machines and robotics and manages complex systems with many data.

The I4.0 implementing medical organizations is also challenged by the inadequate broadband and internet infrastructure issues, inadequate design, insufficient wireless access points, and cloud capacity issues resulting in connectivity and operational issues. Besides, operational challenges include an amalgamation of existing infrastructure to the cloud and

IoT, higher complexity, and cost. Medical device manufacturing organizations are always under incredible pressure from snowballing expenses. When a novel technology is implemented, it starts giving outcomes after an incubation phase; until such time, the cost of the novel technology will be an enormous burden, since it is not sure whether anticipated dividends will be realized (Kumar et al., 2019). Also, achieving I4.0 will require a transformation in industrial communications to fashion uninterruptedly data sharing capabilities among the machinery and systems. On the other hand, there are, at present, very few open standards for industrial remote communication across the value chain, especially in the medical device manufacturing sector.

Numerous internet companies are flooding the marketplace with different types of devices that use numerous protocols or software. The real-time exchange and actionable usage of the information require common standards across the value chain of the medical industry. A deficiency of standards and protocols concerning digital technologies will be makings it challenging to join value creation networks with different standards and norms. At a period where susceptibilities are frequently being exposed in devices, digital devices are becoming more of a target for cyber attackers. In this regard, the medical industry must deploy robust cyber-security systems. Cyber-security challenges include the transmission of data from and to unauthorized devices and repudiation attacks. Any new-fangled technology brings certain new challenges with itself. Using the internet of medical things (IoMT), much data is produced in medical organizations, which is exceptionally significant for the organization's performance. The real-time connectivity enabled by IoMT also poses the challenge of theft of business trade secrets and intellectual property rights (IPR) issues, lack of adaptability, dependency on technology providers. I4.0 systems demand constant high-speed internet with an enormous bandwidth and absence of the same pose connectivity issues. Whenever a new-fangled technology is applied, it leads to high maintenance in the commencement.

Furthermore, the upkeep of state-of-the-art technology also demands a new apparatus for maintenance. This as well leads to a need for higher competency in workforces. Whether medical device organizations will be willing to afford higher maintenance costs when profit margins are plummeting in pandemic times will be another challenge. Thus the synthesis of experts' feedback in the mind map (refer Figure 2) highlights numerous challenges that medical professionals and organizations must aptly address before the business can exploit the host of benefits from the technologies at hand.

Figure 2: Mind map of expert's feedback on challenges related with I4.0 implementation in the medical sector

4.1. Evaluation of I4.0 implementation challenges using ISM

The sixteen challenges considered for implementation of ISM are taken from expert feedback in Figure 2. The structural self-interaction matrix (SSIM) is used for the analysis. This (SSIM) matrix specifies the pairwise relationship between the sixteen I4.0 implementation challenges (Figure 2). Group discussion between n=31 experts is used for the development of the relationship between the identified challenges. Table 1 shows the SSIM for challenges for implementing I4.0 implementation. The signs indicating the direction of the relation amongst the challenges are explained in Figure 3. Here i represent the type of challenge in the row and j the type of challenge in the column.

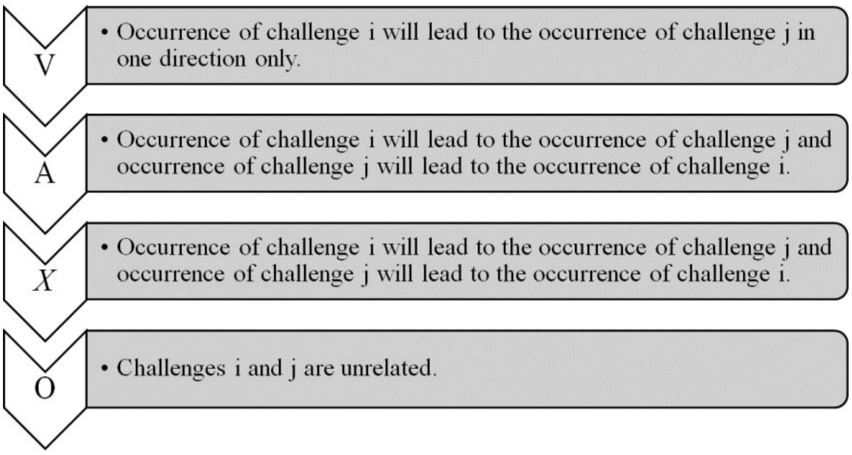

Figure 3. Interpretation of "V", "J", "X" and "O"

Reachability matrix

The reachability matrix is an outcome of the SSIM matrix (Table 2) and is in binary form.

This is done by replacement of "V", "A", "X", and "O" by "0" and "1". The rules are explained in Figure 4.

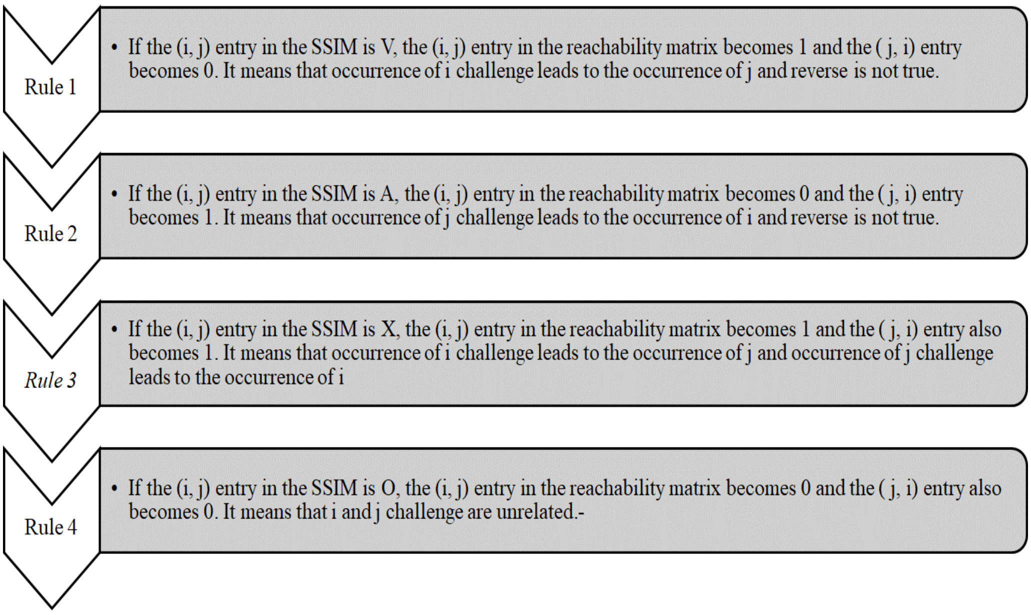

Figure 4. Rule of the reachability matrix.

Table 2. SSIM for challenges for I4.0 risk in the medical sector

Challenge	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15	F16
F1	X	A	V	A	V	V	V	O	V	V	O	V	V	V	O	V
F2		X	V	V	V	V	V	O	V	V	O	V	V	V	O	V
F3			X	X	O	O	V	O	V	V	V	V	O	V	O	V
F4				X	V	V	V	V	V	V	V	V	O	V	V	V
F5					X	A	X	A	V	V	A	V	V	X	O	V
F6						X	V	O	V	O	A	V	O	V	O	V
F7							X	V	V	V	V	V	V	V	O	O
F8								X	V	O	A	V	O	O	A	A
F9									X	V	V	A	X	A	A	V
F10										X	O	O	O	A	A	O
F11											X	A	A	A	O	V
F12												X	X	V	O	V
F13													X	X	X	O
F14														X	A	X
F15															X	V
F16																X

The refinement of the reachability matrix is carried out by the transitivity rule. It articulates that if "A" is linked with "B" and "B" is linked to "C", then consequently "A" is related to "C". The reachability matrix for challenges associated with I4.0 in the medical sector is shown in Table 3.

Table 3. Reachability matrix for challenges associated with I4.0 in the medical sector

Challenge	F 16	F 15	F 14	F 13	F 12	F 11	F 10	F 9	F 8	F 7	F 6	F 5	F 4	F 3	F 2	F 1	Dependence Power
F1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	15
F2	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	16
F3	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	15
F4	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	15
F5	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	12
F6	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	12
F7	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	12
F8	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	12
F9	0	0	0	0	1	1	0	1	1	1	1	1	1	1	1	1	11
F10	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1
F11	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	12
F12	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	12
F13	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	12
F14	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	12
F15	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	12
F16			0	0	1	1	1	1	1	1	1	1	1	1	1	1	12
Dependence Power	3	3	4	4	15	15	14	15	15	16	15	15	15	15	15	15	

Level Partitions

The reachability matrix for challenges associated with I4.0 in the medical sector is segregated into a reachability set and an antecedent set corresponding to each type of challenge (Warfield, 1974). It relates to each type of challenge consisting of itself and those challenges it may aid to happen. In contrast, the antecedent set corresponds to each challenge consisting of itself and those challenges, which might help it occur. The intersection set is created by the intersection of the reachability and antecedent sets. Once the reachability and intersection sets are equal, then challenges are denoted as the level 1 challenge. Level 1 challenges will not affect the higher-level challenges but are affected by them. This process is repeated to attain more iteration, summarized in the conceptual model of the hierarchy of I4.0 implementation challenges in the medical device industries.

Creation of Hierarchal Structure

It is apparent from Figure 5 that challenges associated with the dependence on technology providers are at level 1. It infers that level 1 challenges are much reliant on the incidence of the balance challenges. Opposing these other challenges like the re-design of existing facilities at level 5 strongly influences the high investments, unclear economic benefits, internal resistance, and corporate culture placed in level 4. In other words, these three challenges in level 3 have a high possibility of happenings when a re-design of the existing facilities is carried out. These observations concerning the level of challenges. The very real reflection is that the lower level of the challenges must be resolved first. Therefore, level 1 challenges, i.e., dependence on the technology providers, have to be targeted first for removing the challenges of I4.0 implementation in the medical sector. The level 2 challenges, i.e., infrastructure shortcomings, operational complexity, cyber security, internet connectivity issues, lacking standards, IPR issues, operational complexity, low awareness and inadequate skills, leadership and strategy, and technology interface problems, need to be target second. The conceptual framework of the hierarchy of I4.0 implementation challenges in the medical device sector is summarized in Figure 6.

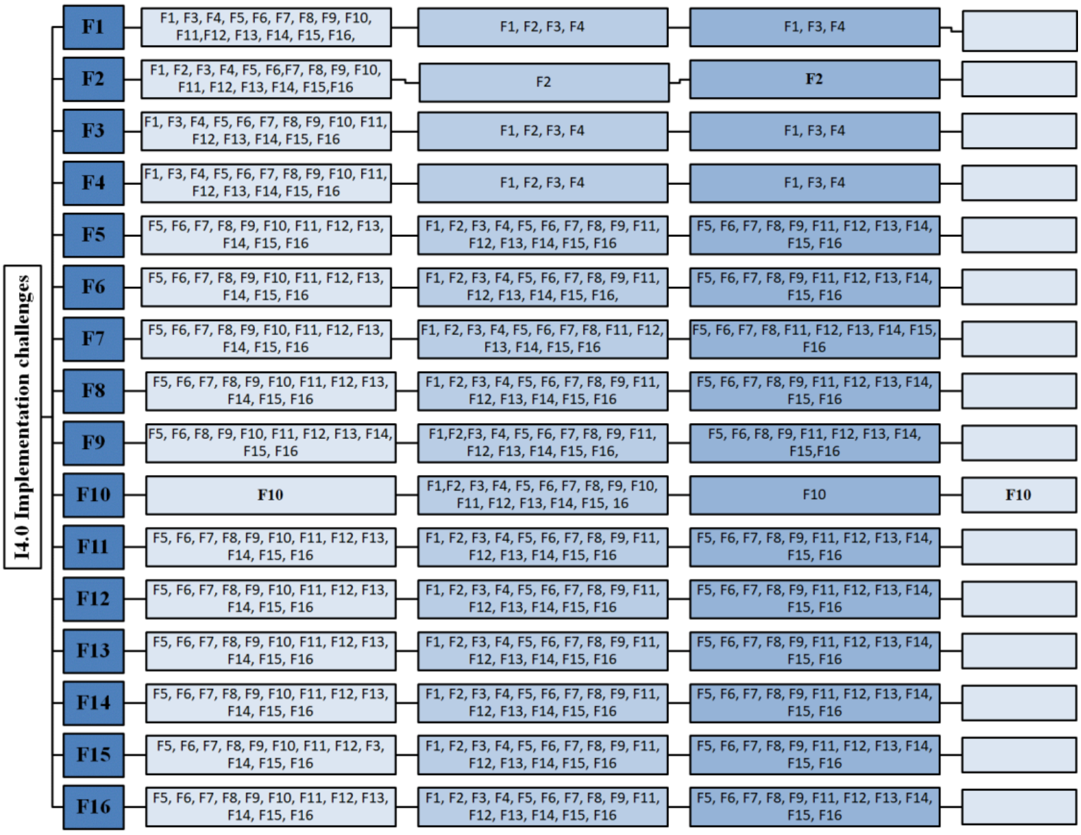

Figure 5. Summary of the first iteration and level of challenges

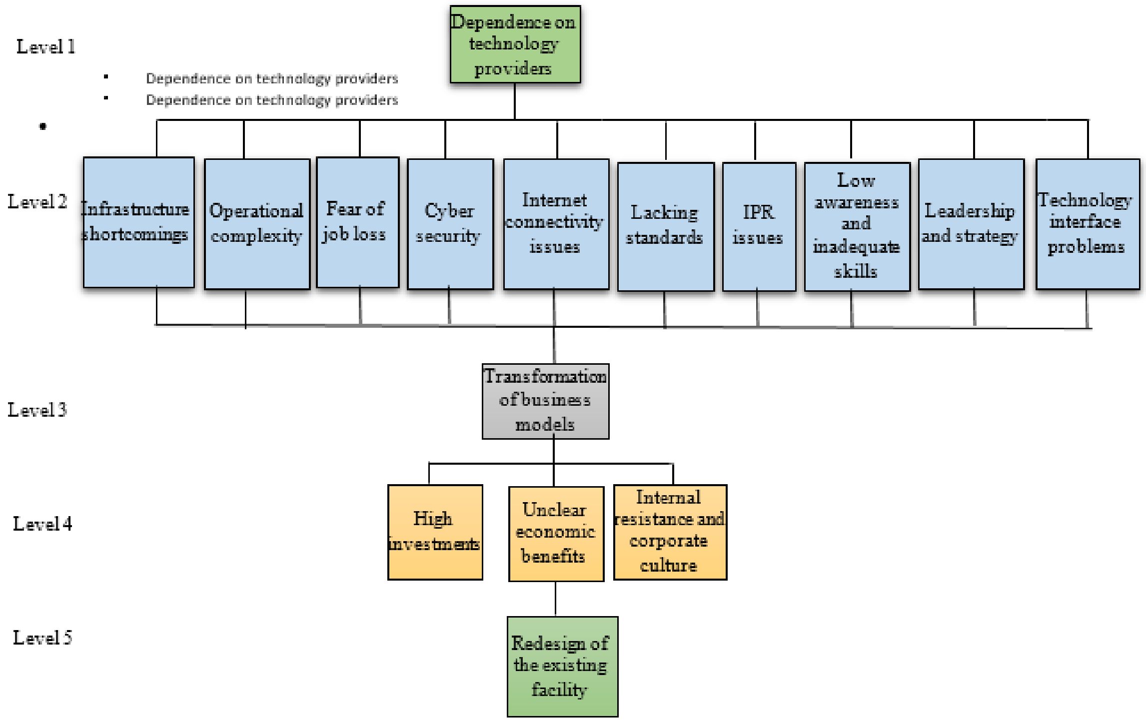

Figure 6. Conceptual framework of the hierarchy of I4.0 implementation challenges in the medical device sector

Matrices d'Impacts Croisés-Multiplication Appliquée à un Classement (MICMAC) analysis:

The MICMAC analysis involves cross-impact matrix multiplication, which helps in categorization. The dependence and driving power of the challenges associated with the implementation of I4.0 are evaluated. The basis of categorization I4.0 implementation challenges in the medical device sector is summarized in Figure 7. This analysis helped classify the sixteen challenges classified into the four categories and presented, as shown in Figure 6, Figure 8, and Table 4.

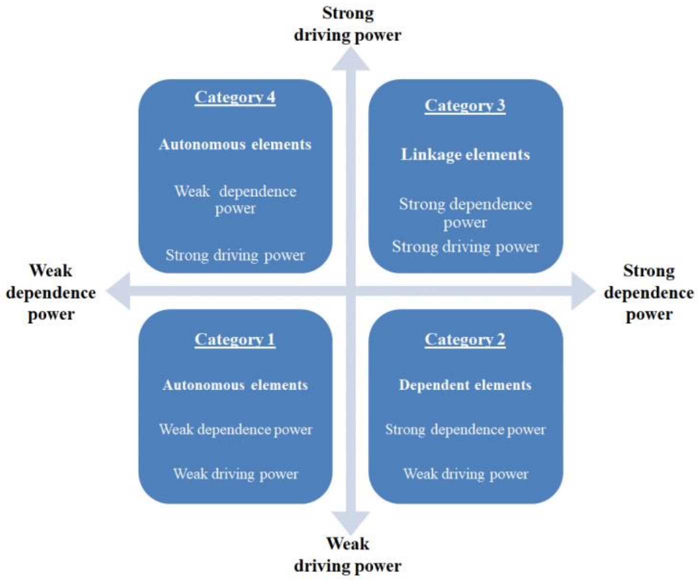

Figure 7. Basis of classification of the I4.0 implementation challenges

Table 4. Driving power and dependence power of challenges associated with the implementation of I4.0 technologies

I4.0 implementation challenges	Dependence	Driver Power
F1	4	15
F2	1	16
F3	4	15
F4	4	15
F5	15	12
F6	15	12
F7	14	12
F8	15	12
F9	15	11
F10	16	1
F11	15	12
F12	15	12
F13	15	12
F14	15	12
F15	15	12
F16	14	12

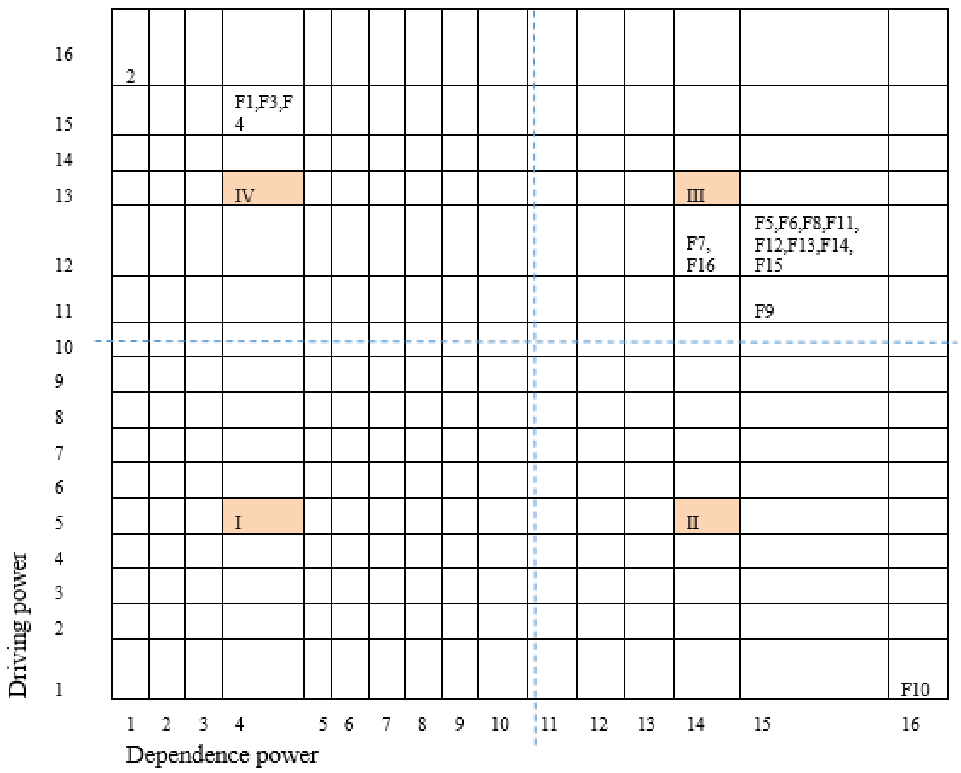

Figure 8. Summary of the driving power and dependence power of I4.0 implementation challenges

This MICMAC analysis summarized the driving and dependence power of all challenges related to the application of I4.0 in the medical sector. No challenge is observed in category 1, i.e., autonomous elements with weak dependence and driving power. The dependence on the technology providers is observed in category 2, which signifies strong dependence, however, and weak driving power hence termed as the dependent element. A big challenge confronted by establishments is to get their employees to adapt to change. This is also in line with the findings of Akdil et al. (2018); Birkel et al. (2019); Ghadge et al. (2020); Ghadge et al. (2020); Birkel et al. (2019).

This can also be validated by the fact that technology providers chart a significant role in reducing the operational complexity, resolving the shortcoming of the operational complexities, information technology interface problems, information connectivity issues. Digital transformation can be a disruptive process. That is why the organizations may need the technology service providers to support them in simplifying the process (Akdil et al., 2018; Birkel et al., 2019). The technology service provider's support analyzing a company's infrastructure finding gaps and closures. Besides, the technology providers are also driven by the need to create the I4.0 implementation standards, resolve the IPR issues, and impart adequate skills and awareness to the people for implementing the I4.0 technologies. These findings are also validated by the research of Ghobakhloo (2018); Ivanov (2020); Birkel et al. (2019); Büchi et al. (2020); Mhlanga (2020).

All the identified challenges in category 3, as shown in Figure 8, have high driving as well as dependence power. Therefore, they are called the linkage elements between level 2 and level 4 challenges. The category 3 challenges include the operational complexity, transforming business models, shortcomings in the infrastructure, lack of standards, connectivity issues, IPR issues, low awareness, and inadequate skills and leadership and strategy related challenges. The leadership challenges include being too absorbed in short-term results, managing operational issues posed by pandemic, and lack of vision for the deployment of the I4.0 technologies in the medical device industries (Luthra and Mangla, 2018; Ghadge et al., 2020; Ghadge et al., 2020).

The landscape for innovative approaches offered by I4.0 technologies might be stimulating the policymakers, but its realization pivots on how speedily industries can recognize prospects and implement them. Today's leaders and decision-makers, however, are stuck in multiple crises created by the COVID -19, demanding their attention, in managing disruptions and innovation shaping their establishment's future. Enterprise-wide transformation needs a workforce that is well-prepared, receptive to big ideas, and ready to accomplish new-fangled technologies of I4.0. Existing workforces may feel their skillsets are not aligned with changing expectations due to the lack of awareness and inadequate skills (Hariharasudan and Kot, 2018; Ghobakhloo, 2018; Birkel et al., 2019; Ivanov, 2020). This poses a big challenge for implementing I4.0 technologies.

The manufacturing skills have been moving away from mostly manual labor to further skill-intensive programming, analytical, and control of multifaceted smart machines. As I4.0 rapidly advances innovative manufacturing processes, certain companies may find the need for skilled workforces to manage the new-fangled technologies and work hand-in-hand with them for the progress of the organization. Therefore, workers with lower qualifications are at high risk of becoming replaceable unless they can be and are reskilled. Many manufacturers are entering I4.0 with technology systems and business procedures better suited for a previous era. Companies are eyeing a digital future ripe with promises for optimization and innovative business models. On the other hand, a widening skills gap looms to cripple the prospects, putting pressure on educational institutes and industry to step up efforts to increase the competency level of employees in both emergent I4.0 and legacy automation technologies. To be even more precise, companies may find that the way they support their business is out-of-date due to the infrastructural shortcomings, information technology interface problems, and internet connectivity issues (Tupa et al., 2017; Akdil et al., 2018; Birkel et al., 2019). These issues will also lead to the challenges related to the high investments, unclear economic benefits, and internal resistance are found to be in category 4, which is also termed as autonomous elements. Furthermore, I4.0 is altering the occupation landscape with the necessity for workforces to attain new-fangled skills. Repetitive task workforces will face tests in keeping up with the industry as their occupations are phased out or handled by smart machines.

A foremost challenge in digitized manufacturing is standardization (Tupa et al., 2017; Akdil et al., 2018; Birkel et al., 2019). Standards are vital to warrant the exchange of data and information amongst machinery, processes, and systems within the value chain as a product moves through an interconnected, intelligent factory towards its completion. The proprietary and locally recognized communication protocols are lead to communication issues. On the other hand, autonomous, universally established, worldwide accepted standards can guarantee interoperability across diverse sectors and different countries. The unclear economic benefits, high investments, internal resistance are very important challenges for the application of I4.0 technologies and are categorized in level 4. The implementation of digital technologies requires the re-design of the existing facilities, which may also result in the internal resistance of its implementation. Moreover, the digitization of systems is a vital feature of i4.0 meaning there are more devices connected to IoT. This signifies an enormous challenge in terms of the security of data. This determines the need to implement a robust cyber security system (Akdil et al., 2018; Ivanov, 2020; Birkel et al., 2019; Ivanov et al., 2019).

Companies cannot afford to wait on the sidelines and risk missing out on first-mover advantages of I4.0. At the same time, there is a challenge in making significant investments that might swiftly become obsolete and never pay off due to unclear economic benefits of its implementation. Moreover, the evolution of I4.0 is not merely a matter of specifying and installing equipment or even building a new factory: it fundamentally affects how manufacturing companies operate.

6. Conclusion

This research started with an aim to classify the significant challenges associated with the implementation of I4.0 technologies in the medical device sector in the post-COVID-19 lockdown scenario by an expert survey with industry leaders of the medical sector and analysis of the findings using the ISM approach. This study offers a conceptual model and mind map of expert's feedback showing sixteen challenges for implementing I4.0. These challenges are categorized in the five hierarchy levels and three categories, i.e., dependent, linkage, and autonomous elements based on the driving power and dependence power chart. Our findings indicate that challenges related to dependence on technology providers are at level 1 and need to be targeted first. On the other hand, other challenges like the re-design of existing facilities at level 4 have its strong effect on the high investments, unclear economic benefits, internal resistance, and corporate culture ranked at level 3. The identified challenges will act as a baseline for developing I4.0 implementation strategies.

These challenges will significantly influence how medical device industries are organized and managed while transitioning to the I4.0 transformation in the post-COVID-19 arena. To actively shape the change, organizations need to take substantial actions to embrace the enabling technologies of I4.0, considering the sixteen identified challenges. They must also address the requirement to acclimatize the apt infrastructure, connectivity, reskilling, and new skills development to smart factories in the medical sector. Besides, the absence of an examination of interdependencies of I4.0 implementation challenges is a limitation of our work. Nevertheless, we believe that this study is surely in the right direction, which would aid in crafting further structured models for risk management of I4.0 implementation.

For that reason, this study was severely dependent on the experts' opinions and some rigorous examination of perceived cause and effect relationships using ISM. These limitations are considered while our decision to use the ISM approach with expert’s survey. As the medical device organizations will implement digitalization, they might offer real-time and tangible data and reflectiveness on the various difficulties they may perhaps face. This might further open up a requirement for examination of associations. The categories might need regrouping, and diverse cause and effect associations may emerge. More studies may be desirable to appraise the relative effectiveness of the actions implemented by the numerous medical device organizations in the diverse state of affairs and challenges.

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