Digital transformation of supply chain: A study on additive manufacturing practice in medical device in Australia

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Abstract

Purpose: Drawing on a dynamic capability view, this study develops a decision support model that determines the most suitable configuration of strategies and challenges to adopt additive manufacturing (AM) to expedite digital transformation and performance improvement of the surgical and medical device (SMD) supply chain.

Methodology: To investigate the research objective, a multi-method and multi-study research design was deployed using quality function deployment and fuzzy set qualitative comparative analysis.

Findings: Our study finds that only resilience strategies or negation (i.e., minimisation) of challenges are not enough; instead, a configuration of resilience strategies and negation of challenges is highly significant in enhancing performance.

Practical Implications: SMD supply chain decision-makers will find the decision support model presented in this study as beneficial to be resilient against various challenges in the digital transformation of service delivery process.

Originality: This study builds new knowledge of the adoption of AM technology in the SMD supply chain. The decision support model developed in this study is unique and highly effective for fostering digital transformation and enhancing SMD supply chain performance.

Keywords: Additive manufacturing, digital transformation, configuration, challenges, resilience strategies, dynamic capability.

1. Introduction

The application of new knowledge and technologies create new opportunities but at the same time pose numerous challenges. Organizations need to sense the rapid changes in the external business environment and develop dynamic capabilities to transform business processes to adapt to the changes (Kokshagina 2021; Hullova *et al*., 2019; Qiu *et al*., 2020; Teece, 2009). Additive manufacturing (AM) or three-dimensional (3D) printing, a digitally enabled technology, has transformed the global manufacturing landscape. It encompasses a range of disruptive technologies that use digital fabrication techniques to build 3D objects in a layer-by-layer process (ASTM International, 2013; Lipson and Kurman, 2013). Digitalization of health service process may offer numerous opportunities and offset many healthcare challenges (Niemela et al., 2019). Similarly, by enabling digital design and manufacturing, AM offers many benefits in health service process because of its ability of low volume production, high flexibility, customised output and complex geometric designs at a lower cost (Pucci *et al*., 2017; Ryan *et al*., 2016; Thawani *et al*., 2016). In essence, AM technology has the potential to significantly improve supply chain dynamics (Li et al., 2017); dramatically change business and innovation models, and alter the global economy (Niaki and Nonino 2017). Because of numerous benefits, the AM industry is growing over time in many parts of the world, and the global market for AM products is projected to reach USD 23.33 billion by 2026. However, this required practitioners to be digitally literate to successfully adopt the technology.

While AM has been adopted in various industries, the medical sector is an early adopter of the technology because AM has the flexibility to produce patient-specific medical, dental and surgical devices derived from scanned images (Guibert *et al*., 2018; Philippe, 2013; Stübinger *et al*., 2013). Moreover, AM can be utilised by health professionals across many specialities, such as orthopaedics and implant dentistry (Philippe, 2013; Stübinger *et al*., 2013). Further, because of the ability to produce patient-specific, personalised products, AM has seen substantial growth in the medical industry over the last couple of years. Indeed, AM has immense potential in the digital transformation and future growth of the SMD supply chain.

Despite many promises and potentials of AM in the digital transformation of SMD supply chain, like any other technological change, adoption of AM in facilitating SMD supply chain necessitates addressing the potential challenges effectively (Javaid and Haleem, 2018; Mitchell *et al*., 2018; Tofail *et al*., 2018). Developing dynamic capability has been proven as effective capability to manage context specific challenges in a complex and changing environment (e.g.

Chowdhury et al., 2019; Ali et al., 2022). Yet, the construction of capabilities and strategies useful for mitigating the challenges of digital transformation of health care has received limited attention by academics, despite dynamic capabilities framework being one of the most effective tool in the strategic management domain (Warner and Wäger, 2019). Therefore, developing dynamic capabilities is salient in addressing the potential challenges of AM enabled SMD supply chain. However, existing studies fall short of offering any theoretically grounded and empirically tested decision support model to determine the most suitable configuration of capabilities to mitigate the challenges of digital transformation of health care supply chain in general and SMD supply chain in particular to the enhance performance. A few studies offer a decision model for AM in health care, but those are mostly fragmented and deal with either challenges (Choudhury *et al.*, 2021), importance (Parry and Banks 2020; Patel and Gohill 2021), impact (Muir and Haddud 2017; Özceylan *et al.* 2018) or feasibility of implementing the technology (Emelogu *et al.,* 2016). None of the studies offers any strategic direction for the health care decision-makers to mitigate the challenges of adopting AM in the health supply chain and enhance performance. Against this backdrop, relying on a dynamic capability view (DCV), this study aims to develop a decision support model that enables decision-makers to identify and evaluate the SMD supply chain challenges and determine the most suitable configuration of capabilities which in our study are strategies to manage challenges to enhance performance by considering the Australian SMD supply chain as the empirical context.

To address the research objective, this study adopts a multi-method and multi-study research design using both qualitative and quantitative approaches. In Study Phase 1, we conducted interviews with SMD supply chain members (manufacturers, material suppliers and doctors/surgeons) using semi-structured interviews to explore challenges and strategies. In Study Phase 2, we administered a questionnaire survey to complete the quality function deployment (QFD) matrix to prioritize challenges and strategies. In Study Phase 3, to determine suitable configuration of most important challenges and strategies, we conducted another questionnaire survey for fuzzy set qualitative comparative analysis (fsQCA), a widely used configurational analysis, using a set theoretic approach (Ragin, 2008). The rationale for using multiple methods is described in the methodology section.

This study has several contributions to theory and practice. Drawing on DCV and adopting multi-method and multiple studies (three studies), this research delivers a robust decision support model to aid determining appropriate configuration of strategies to mitigate the challenges presented by the external environment and manage the performance of the SMD supply chain through effective adoption of AM. This study contributes to strategic management discipline, specifically extends DCV with an empirically validated and novel decision support model for the digital transformation and performance improvement of SMD supply chain. SMD supply chain managers will gain serious benefit from this research through achieving superior performance outcomes within challenging business context. Finally, the findings of this research will aid policy makers to formulate appropriate policy intervention to expedite gaining the benefit of AM by the supply chain partners and the end customers.

2. Literature Review

This section critically reviews the extant literature to explicate the critical challenges in SMD supply chain and AM based supply chain processes, and suggested strategies by the scholars for adopting AM based medical and surgical devices supply chain and managing SMD supply chain performance. The findings of this section will aid to develop a conceptual foundation for our decision support model.

2.1 Challenges in SMD supply chain

The key ecosystem partners in AM based medical and surgical device supply chain include the raw material suppliers, 3D printer manufacturers, software providers, 3D printing facilities, AM based medical and surgical device manufacturers, hospitals, medical professionals and patients (Gibson and Srinath, 2015). Potentially, AM has significant implications on the upstream supply chain as well as downstream customers of the SMD supply chain, as AM processes can receive orders directly from customers and fulfil them within proximity of the location of demand. This potentially eliminates activities involves in logistics, transportation or shipping and warehousing enabling mass customisation (Javaid and Haleem, 2018; Mitchell *et al.*, 2018; Tofail *et al.*, 2018). However, managers may face serious difficulties due to complexity of AM adoption across different layers of the SMD supply chain; therefore, a superior understanding of the potential challenges and AM adoption strategies in the SMD supply chain is critical to pursue developing a decision model.

2.2 Challenges of AM in SMD supply chain

The context of AM based SMD supply chain presents several challenges. First challenge is the significant amount of time required for planning and creating the 3D model. Generally, To create the computer-aided design model using the software requires 10–12 hours, making the adoption of 3D printing technology difficult in emergency scenarios, busy hospital care environments, as well as within the context of hospitals with high performance, productivity and patient turnover. However, 3D printing results in a significant increase in pre-operative time consumption and a substantial decrease in intra-operative time (Garg and Mehta, 2018). Further, despite of rapidly increasing number of 3D printable materials, there is a shortage of materials that are biocompatible, flexible and FDA approved for the purpose of medical applications (Cheng *et al.*, 2016). Further, a lack of standardisation of material testing and cleansing protocols (Cheng *et al.*, 2016), authorisation of supplier payment and verification of quality and quantity may potentially impact the accuracy of the resource capacities, which may affect capacity utilisation by supply chain partners (Golz *et al.*, 2018). The absence of approved printable materials from regulatory bodies, appropriate bio-inks and long production time ultimately limit the development of bioprinting for clinical purposes (Mok *et al.*, 2016). Finally, the establishment of a 3D printing centre for a medical program involves considerable costs, including a medical-grade 3D printer, material costs, the cost of segmentation software and individuals having necessary 3D printing expertise (Anwar *et al.*, 2018). Therefore, although AM technologies offer promising features because of high production and AM machine costs, ‘make-or-buy’ decisions are not straightforward and necessitate rigorous planning and appreciation of potential challenges across supply chain processes (Go and Hart, 2016).

Sourcing process across the supply chain of the medical devices and bio-printed implant industries presents distinctive challenges in applying 3D printing following AM principles. Medical device manufacturers face increased costs to mitigate risks of compliance and offset margin pressures, timelines and cost of new product introduction; the lack of supply chain stability; significantly long waiting times required to prepare implants; and the high cost of surgical procedures and associated post-operative care (Gibson and Srinath, 2015). Next, making/production processes may need to address the challenges of the related constraints of wider adoption of AM. This may include reliability and stability of the print process, imprecision of scanning equipment, lack of machine parameter manipulation, low processing speed and low throughput, post-processing requirements, the risk of piracy (Verboeket and Krikke, 2019) and lack of automation (Ozbolat *et al.*, 2017). Further, pre-processing activities are time consuming and labour intensive, especially where product attributes require exploration prior to determining processing parameters (Ryan *et al.*, 2021). Lack of awareness and demand for AM based products in SMD is a challenge for distributed manufacturing in different parts of the world, which impedes the distribution and delivery of the product in a short time during an emergency (Loges and Tiberius, 2022; Scerri *et al.*, 2020). Finally, Peng *et al.* (2018) highlight that return process within the supply chain of the medical devices and bio-printed implant industries create unique challenges to adopt AM based 3D printing technologies. The environmental impact of AM waste requires sincere consideration, and appropriate measures to minimise or eliminate the adversarial impact (Peng *et al.*, 2018). Based on the above discussion, a summary of the challenges of AM based SMD supply chain is outlined in Table 1 as below:

Table 1: Challenges of AM based medical and surgical supply chain

Sources	**Key challenge**	**Key findings related to challenges of AM based medical and surgical devices supply chain**
Thomas-Seale *et al.*, 2018	Cost	Cost of new material development and quality control complexities
Tofail *et al.*, 2018	Complexity of raw material characterisation	Complexity of material characterisation of AM parts due to high degree of customisation requiring in situ measurements
Blok *et al.*, 2018	Characteristics of raw materials	Thermoplastic materials used in 3D printing carry low mechanical properties compared to engineering materials
Singh and Ramakrishna, 2017	Characteristics of raw materials	Absence of various geometrical parameters

Liu *et al.*, 2019; Bishop *et al.*, 2017	Standard	Absence of standard for bio-based materials with explicit user-defined mechanical and biochemical and properties
Seale *et al*, 2018; Ozbolat *et al.*, 2017	Lack of available technologies	Constrained by the commercially available technologies
Pucci *et al.*, 2017	Time	Required time to identify the appropriate 3D printer, maintenance, and costs to sustain the printer
Ngo *et al.*, 2018,	Quality of 3D printed biomedical parts	The inferior anisotropic behaviour and mechanical properties of 3D printed parts
Louvrier *et al.*, 2017	Capacity utilisation	Rare usage of specific components' printing machinery may demotivate continuity of using the machine
Wang *et al.*, 2017	Complex production processes	Construction of 3D architectures with high levels of complexity due to shear stress produced during printing

2.3 Strategies for AM based SMD supply chain

To effectively address the challenges of the SMD supply chain at the advent of AM, formulating appropriate strategies are critical for this sector (Javaid and Haleem, 2018). Chowdhury and Quaddus (2017) ascribe the strategies to manage changes and challenges in the supply chain as an essential dynamic capability for firms and their supply chain. In the same vein, we posit that the SMD supply chain needs dynamic capability, which in this study is developing various resilience strategies to mitigate the challenges in SMD supply chain with the adoption of AM. Previous studies articulate useful strategies to mitigate the existing challenges. To address the increased complexity within the supply chain due to reduced actors and the risk of high capital and capacity utilisation problem inherent with AM technology, Strong *et al*. (2019) suggest establishing an AM hub to optimise the cost of infrastructure across a geographic territory with plans for the future scope of expansion. Moreover, establishing 'digital innovation hub' will foster collaboration across industry and research institutes to build world-class competencies through accessing critical knowledge, technology development processes and quality and testing facilities (Tofail *et al*., 2018). The excessive cost involved in AM based processes is a critical challenge as AM incurs two kinds of cost: process-level costs related to machines, materials and labour, and system-level costs (Go and Hart, 2016). Some of the costs of a 3D printing centre to a medical program can be reduced by having printing off-site by commercial vendors; however, this approach should be evaluated by a trade-off between long-term cost and turn-around time (Anwar *et al*., 2018). To attain the benefit of AM to deliver superior product customisation and utilisation at a reasonable cost, health service professionals need to engage in close collaboration with commercial AM researchers and commercial product developers (Javaid and Haleem, 2018). Table 2 outlines recommended strategies suggested by the scholars based on extant literature.

Table 2: Strategies for the SMD supply chain based on extant literature

Sources	**Main strategies identified from the extant literature**
Strong *et al.*, 2018	To address the key challenge of cost, sourcing and utilisation of the capacity with maintaining highly skilled workforce, the authors suggest establishment of strategically located AM hubs integrating hybrid-AM processing capabilities of isolated AM facilities, considering the geographical data, cost of hybrid-AM processing and demand.
Bouten *et al.*, 2017	Lack of specific regulatory guidelines negatively affecting the adoption of AM across medical and health industry, therefore the authors suggest developing and updating the materials testing standards to provide precise guidance in assessing 3D printed materials.
Ozbolat *et al.*, 2017	The authors suggest effective integration of inspection capabilities and online monitoring within bioprinter technologies will play critical roles to achieve the expected quality required by the market standard. Presently, the AM industry lacks consistent and stringent quality management procedures that adversely affect the adoption of the technology.
Pucci *et al.*, 2017	To foster high quality medical research and patient care, the authors recommend developing necessary standard for the 3D printing process that will enable standardization and consistency across the AM industry.
Pucci *et al.*, 2017	The authors strongly recommend strong collaboration among health service and products developer companies such as Johnson and Johnson Inc. and the ICT (information and communication technology) companies such as HP, with an aim to devise personalised health care solutions leveraging AM technologies.
Singh and Ramakrishna, 2017	For medical device, instruments and implants high quality functionality is critical for the effectiveness, to attain this objective, this study recommends optimisation of process parameters following design experimentation.
Ngo *et al.*, 2018	The authors suggest planning the entire process considering the availability of necessary raw materials and components in advance. To limit deviation from design to execution resulting in inaccuracies and defects, the authors suggest adopting fine tessellation, although this method is time consuming and complex.
Seale *et al.*, 2018	The authors suggest developing a set of necessary skills by the engineers as required to support the processes involved in AM based production.
Maini *et al.*, 2018	AM based production of surgical and medical devices require significant input from the doctors, therefore the authors recommend paying attention to uplift the skill set of the surgeons.
Chaunier *et al.*, 2018	To enable achieving desired properties within the final outcomes of AM printed products, the authors suggest adoption of a reverse engineering approach combining algorithms for building structures and modelling following deterministic finite element considering alternative sources of raw materials.

Peng *et al*., 2018	The authors highlight research on improving systematic data management and integration, developing intelligent machinery, associated energy and quality, material preparation and paying attention to recycling and discovering creative and innovative applications of AM technologies. Therefore, the authors recommend adopting eco-design principle through energy and environmental optimisation following the process- and system-specific modelling.

2.4 AM based SMD supply chain performance

Robust application of appropriate strategies for adopting AM within the SMD supply chain can result in significant performance outcomes to the supply chain and supply chain partners. Careful consideration of AM technologies can benefit raw material suppliers, AM printer manufacturers, AM printing software developers, AM producers, health care service providers and surgical raw material suppliers (Bishop *et al*., 2017; Feldmann and Pumpe, 2017; Peng *et al*., 2018; Pucci *et al.,* 2017; Thadani, Riaz and Singh, 2018). Researchers have identified that adoption of AM based technologies may deliver improved performance of the SMD supply chain and partnering companies in areas of efficiency improvement (Bishop *et al*., 2017), capacity utilisation (Feldmann and Pumpe, 2017), optimisation of cost related to 3D printed biomedical objects (Louvrier *et al*., 2017; Pucci *et al*., 2017; Valverde, 2017), improved quality and standard (Valverde, 2017) and superior design (Peng *et al*., 2018). Table 3 illustrates the performance benefits of adopting AM based technologies in the SMD supply chain context.

Table 3: Performance outcomes of AM adoption in SMD supply chain

Sources	**Performance outcomes**
Bishop *et al*., 2017	The authors identified improvement of efficiency as the key outcome of adoption of AM technologies in SMD supply chain due to ability to offer to customise solutions that may reduce waste related to stock and inventory.
Feldmann and Pumpe, 2017	As the AM enabled SMD supply chain can attain personalised requirement of the client, higher capacity utilisation of the infrastructure can be achieved when the demand and supply are managed in an agile manner.
Louvrier *et al.,* 2017	The authors highlight that the advantages of AM adoption can be reduction of cost of 3D printed biomedical object and reduced cycle time in compared to traditional approach.
Pucci *et al*., 2017	The authors point the associated cost of AM technology adoption within SMD supply chain such as training and skill development, acquisition of new skill set such as managing AM printer require serious consideration.
Valverde, 2017	The study suggests precision of accuracy, preparation time, and cost and quality standard are major area that AM enabled SMD supply chain need to consider adoption.
Peng *et al*., 2018	The study recommends superior design of AM machines for high quality outcomes.

Strong *et al.*, 2018,	The researchers suggest that organisations using traditional manufacturers can overcome many challenges through adopting 3D printing technologies.
Thadani *et al.*, 2018	The study recommends adoption of AM enabled solutions to address present challenges of delivering application in health service context following traditional manufacturing processes.

A robust theoretical underpinning is important to address the challenges and implement relevant strategies derived from the decision support model in an objective, critical and non-biased manner to attain the improvement of supply chain performance.

3. Theoretical Foundation

This study aims to develop a decision support model to determine the most suitable configuration of strategies for managing the changes and challenges of digital transformation in adopting AM technologies within the SMD supply chain. The decision support model is grounded in DCV due to suitability of the theoretical framework to tackle challenges arising from the business environment. Although, the notion of capability, or know-how is used interchangeably in extant literature (Pisano 2015), scholars have agreement that capabilities are collections of organisational routines that enable a firm to perform a set of tasks in a repeatable and consistent basis (Pisano 2015; Winter 2003). Winter (2003) distinguished dynamic capabilities from ordinary (or operational) capabilities, as dynamic capabilities are concerned with change, and govern the rate of change of ordinary capabilities. So, dynamic capabilities are the firm's abilities to identify changes, challenges and opportunities, and effectively integrate, develop and transform organisational resources and capabilities to capitalise on opportunities or mitigate challenges of the business environment (Helfat and Winter, 2011; Teece, 2007; Teece *et al.*, 1997; Collis 1994). Pisano (2015) claims firms possess a repertoire of capabilities from general purpose to application specific and that firms can choose to deepen their existing capabilities or broaden their repertoire to include new sets of capabilities. Firms can of course do both, however due to resource constraints are faced with making choices at the margins (Pisano 2015).

Due to the rapidly changing nature of technological development, the context of AM can highly benefit by adopting the theoretical lens of DCV (Teece, 2009). Within the context of a rapidly changing business environment, DCV posits that to sustain competitive advantage, organisations attempt to pursue innovative initiatives individually or be part of a supply chain network to create idiosyncratic resources through sensing, seizing and reconfiguring initiatives (Hullova *et al.*, 2019; Lynch, 2019; Qiu *et al.,* 2020; Teece, 2009; Wang and Ahmed 2007;

Zhou *et al.,* 2019). According to Li et al., (2021) digital transformation of organizations needs to address at strategic level and the transformation process requires various resources and capabilities. Through a DCV lens, Ali *et al.* (2022) and Chowdhury and Quaddus (2017) identified that sensing, seizing and reconfiguration capabilities are essential for resilience against supply chain disruptions. Further, sensing, seizing and reconfiguration capabilities are essential for managing the challenges and environment, which ultimately enhance firm performance and competitive advantage (Altay *et al*., 2018; Sabahi and Parast, 2020; Teece, 2007). The mitigation strategies through resilience capabilities require the development of firms' readiness against disruptions, effective crisis responses and defined processes of recovery initiatives considering the focal firm's identified capabilities and strategic exploitation of external resources (Altay *et al.,* 2018; Chowdhury and Quaddus, 2017, 2021; Jiang *et al*., 2021; Sabahi and Parast, 2020). Determining the appropriate portfolio of strategies is an important task for managers of relevant supply chain partners because of the highly contextual and complex nature of AM based technologies as well as the SMD supply chain. Besides, the rapidly changing technological landscape driven by digital transformation and AM technologies requires the internal resources and capabilities of firms within the SMD supply chain to appreciate, evaluate and tackle this dynamic environment (Jiang *et al*., 2021) and thus manage their operations appropriately.

Dynamic capability view has been applied widely in the research of digital transformation of supply chain in present business ecosystem. Warner & Wäger (2019) identify digital transformation as a continuous process recognizing agility as the core mechanism for the strategic renewal and highlight the critical important of business model, collaborative approach and appropriate culture. Further, Dubey et al. (2022) stress the importance of collaboration and adoption of decision support system by the practitioners within same business domain to foster sustainable supply chain in the wake of supply chain disruption. Further, Dubey (2022) suggest that digital technologies with the moderating effect of the crisis leadership can significantly improve the visibility of information visibility and the collaboration within the emergency supply chain workers. Therefore, SMD supply chain can take the benefit of digital transformation to improve the resilience in the context of supply chain discontinuity (Harland 2021). However, this requires a level of digital literacy within SMD supply chain. According to Ng (2019), digital literacy is thought to include cognitive, technical and socio-emotional elements. Digital literacy is defined as an individual's ability to use, digital tools and systems within a specific context.

Within a supply chain context, the open innovation model of decentralized approach for innovation and improvement has gained serious attention (Bogers et al. 2019). Considering the critical importance of dynamic capabilities for effective digital transformation through strategic renewal (Warner & Wäger 2019), scholars have demonstrated how incumbent-born digital healthcare platforms can succeed in health care technologies and exploit the underlying value of emerging technologies. Further, Matarazzo et al. (2021) demonstrate that SMEs in Italy successfully attain customer value creation through dynamic capabilities enabled digital transformation. In a complex and disruptive environment, a cooperative, collaborative, and open approach towards innovation and resilience will aid health care supply chain (Harland et al. 2021), as well as enhance organisational performance through effectively building dynamic capabilities. Finally, Schilke, Hu, & Helfat, (2018), suggest scholars to apply dynamic capability view across multidisciplinary context with methodological pluralism and experimentation. This study aims to contribute within this debate of the theoretical development.

Based on DCV, we argue that organisations develop resilience against various challenges of SMD supply chain to enhance performance by (i) adopting proactive capabilities to sense and explore the changes and challenges in the SMD supply chain in the digital transformation - adopting AM, which creates a readiness to manage challenges; (ii) developing strategies to seize opportunities or respond to challenges; and (iii) configuring and reconfiguring resources, strategies and organisational routines for managing challenges and recovering performance. Therefore, relying on DCV, our decision support model is formulated in three systematic steps: (i) sensing or exploring the SMD supply chain challenges and associated strategies; (ii) responding to the key challenges by prioritising the strategies to mitigate challenges; and (iii) configuring and reconfiguring most suitable combination of strategies to mitigate SMD supply chain challenges and enhance performance.

4. Methodology

In line with the research objectives, drawing on sensing, seizing and reconfiguring concept of DCV, this study develops a decision support model which was operationalised using an innovative multi-method and multi-study-based research approach. We adopted three stages because the study extends the outputs and findings from one stage as data inputs for the next stage. This progressive approach ensures the reliability and validity of study findings. The multiple study research design is explained below.

Study Phase 1, in line with research objective 1, aims to identify/sense the challenges of adopting AM in the SMD supply chain and corresponding strategies to mitigate the challenges. objective 1 is exploratory in nature, in study 1 we adopted a qualitative study consisting of a literature review and semi-structured interviews with SMD supply chain members in Australia given that qualitative interview is a common technique for exploring social reality. In the interview process, using purposive sampling, we collected data from 11 key informants of 3D printed SMD supply chain consisting of raw material suppliers, manufacturers, industry specialists and clinician/surgeons. Purposive sampling enables the qualitative researchers to recruit participants based on their ability to provide in-depth knowledge of the topic under investigation. As such, key informants were selected based on their existing involvement in 3D printing within the medical device supply chain and were recruited following an invitation by email from the research team. The demographic profile of the interviewees is presented in appendix A. Interview questions were asked following a protocol that includes questions i) SMD supply chain processes using AM, ii) Challenges of SMD supply chains in adopting AM iii) Strategies to mitigate the challenges iv) AM based SMD supply chain performance. We compared the findings from the literature review and interviews to develop a comprehensive list of challenges and mitigation strategies. The inputs from Study Phase 1 are instrumental for Study Phase 2.

Study Phase 2, in line with research objective 2, aims to respond to key challenges and determine the most important strategies to overcome the challenges. This phase deployed a quantitative approach using QFD because QFD is a popular tool for designing and prioritising strategies (Chowdhury *et al*., 2015, 2018, 2020). The study participants from Phase 1 and an additional five supply chain members were invited to participate in a workshop to collect data from 16 SMD supply chain members. As the key informants were based in Melbourne, Australia, the workshop was conducted locally and face-to-face in Melbourne in October 2019. Demographic profile of respondents for study 2 is shown in appendix B. Participants of the workshop completed structured questionnaire to populate the QFD matrix. Data collection for completing the QFD matrix is an exhaustive and time-consuming process; therefore, a small sample size is suitable for such studies (e.g., Chowdhury and Quaddus, 2015, 2016; Chowdhury *et al.,* 2019). Figure 2 shows a typical QFD model where WHATs are the SMD supply chain management challenges due to AM, and HOWs are the strategies to mitigate those challenges. The relationship between WHATs and HOWs (shown in the middle of the figure) is important to understand to what extent the strategies (HOWs) are effective for mitigating the challenges (WHATs). To develop the relationship matrix, our respondents were asked to what extent strategy “j” is effective in mitigating challenge “i”, using the scale 0,1,3,5,7, and 9, where 0 = no relation, 1 = very weak relation, 3 = weak relation, 5 = moderate relation, 7 = strong relation and 9 = very strong relation.

Study Phase 3, in line with research objective 3, aims to determine the most suitable configuration of strategies that mitigate challenges and influence SMD supply chain performance. In this regard, we adopted configurational analysis using fsQCA. Configurational analysis is highly suitable for determining the best combination of causal conditions, which in our study are a combination of strategies leading to performance outcomes (Fiss, 2011). For fsQCA analysis, we collected data from 37 SMD supply chain members (raw material suppliers, manufacturers and clinicians/surgeons) using a structured questionnaire. Appendix B shows demographic profile of survey respondents for study 3. As there are limited number of suppliers, producers and users of 3D printed SMD products finding a large sample size is extremely difficult. However, for configurational analysis small sample size is suitable (Marx 2006). Based on the multiple methods and multiple studies, our decision support model is presented in Figure 1.

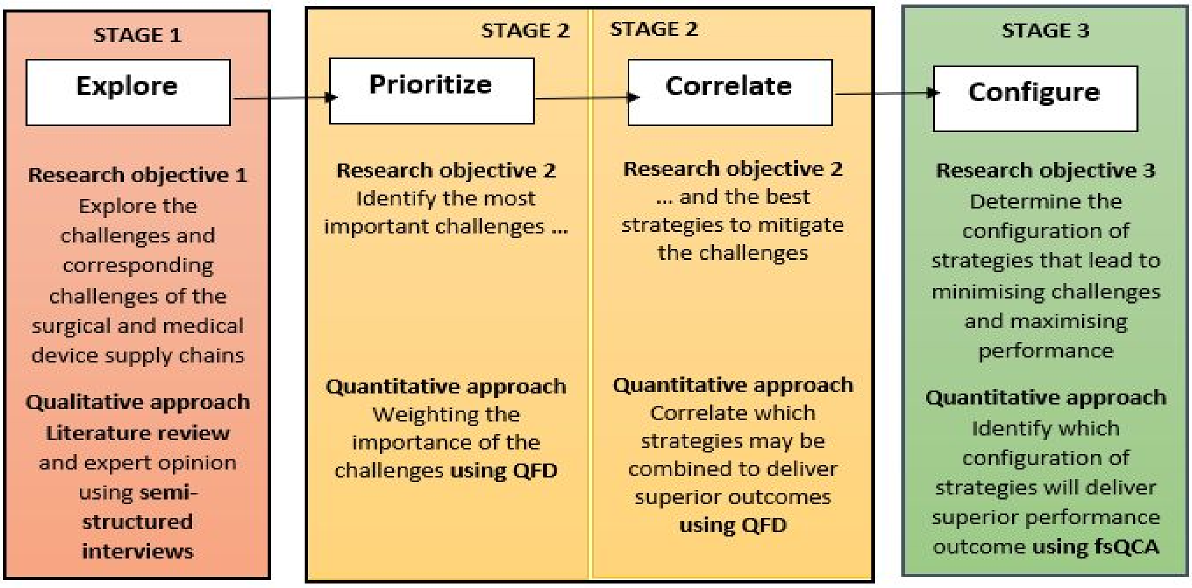


Figure 1: Decision support model developed in this study

5. Findings and Analysis

This section presents the results of the study's three stages, including the results of interviews, QFD analysis and configurational analysis.

5.1 Findings from Study Phase 1

During interviews, the participants repeatedly stated various challenges, such as the need for evidence and case-based practice, access to funding to support the broader implementation efforts, promotion and acceptance of quality processes, and access to detailed costings to support AM business case development. Among the challenges, participants mostly focused on the lack of evidence. For example, Participant X stated: "*we don't truly understand if you do additive manufactured implants ... will they wear quicker than if you are doing the machined implants or implants which have been through 250 degree Celsius ... so that remains unclear*." Another challenge supported by most of the respondents was cost. For example, Participant Y indicated: "*depending on the end product ... the business case is not always easy to develop due to unknown process costs, type of technology and regulatory queries*." Based on the interview findings, we selected the 10 most agreed challenges (see Table 4). When making a direct comparison to the literature in Table 1, we found that Ch 2 – Limited (capability) technology aligned with Seale et al. 2018 and Ozbalat et al. 2017, in describing the current limitations and constraints in commercially available and relevant technology, which ultimately creates blockages for investment in 3D printing processes. Similarly, Ch 1, 3 and 7 (from interviews) corresponds with Thomas-Seale et al. (2018), Blok et al. (2018), Pucci et al. (2017) and Ngo et al. (2018), in outlining that the need for high quality, production value and speed is paramount and a current challenge for 3D medical device printing. However, there was limited reference to social challenges within the literature related to culture, capability and collaboration as found in the qualitative research, which is where this paper provides unique findings.

Corresponding to the identified challenges, we also explored strategies to mitigate the challenges. Participants frequently echoed numerous strategies, such as the development of case studies that shared knowledge of how other firms had approached AM or addressed challenges or how regulatory authorities had worked in partnership to address AM opportunities. Among the strategies most frequently echoed was sharing knowledge on evidence-based practice. Surgeon X mentioned: "*If I get a 3D printed cage, does that improve my patient outcome? So, as a clinician, that is how we will look at implants.*" Other highly focused strategies that emerged from our interviews were standardisation of the AM process and improving skillsets relating to digital design and production. For example, a participant manufacturer stated: "*there is a need to ensure a level of quality is achieved as well as optimising the AM process for implant production*". The manufacturer also stressed that "*AM introduces new post-processing steps to the product manufacturing value chain, such as heat treatment and there is limited capability, skill and infrastructure in these areas in Australia*". From the identified strategies, we selected the 10 most agreed strategies (see Table 5). Notably, the selected challenges and strategies presented in Table 5 are also supported by extant literature, which ensures the content validity of our findings. For example, Bouten et al. (2017), Ozbolat et al. (2017), Pucci et al. (2017), Singh and Ramakrishna (2017) and Ngo et al. (2018) all focus on strategies related to the development of 3D printing technology (CSt1), materials (CSt5/6) and inspection (CSt2) which are consistent strategies to help guide the sector. The remaining strategies from the literature are focused on capability building and skills development, whereas, education, focused research and environmental benefits were not found across our literary search.

Table 4: Challenges for implementation of AM in SMD supply chain

No	**Theme of Challenge**	**Challenge description**
Ch1	Quality process	Need for ensuring quality during production and optimising the AM process across the whole ecosystem
Ch2	Limited capability (technology)	Current limitations in technology and infrastructure capability to improve quality, speed, finish and overall process
Ch3	Business case and cost	Cost of production to cost of sale, business case development for justification to proceed
Ch4	Evidence	Need for evidence and challenges in addressing AM in medical field to determine benefits and regulatory approval
Ch5	Limited capability (social)	Limited skill sets and supply chain capability, need for training, education and awareness building in Australian industry and health sector generally
Ch6	Collaboration	Ecosystem and collaboration, lack of stakeholder collaboration and connection across the industry
Ch7	Time	Lack of speed in production
Ch8	Standards & Flow	Lack of processes and standards in hospitals for AM adoption
Ch9	Culture	Conservative approach from industry, hospitals, surgeons, and associated challenges
Ch10	Funding	Lack of funding

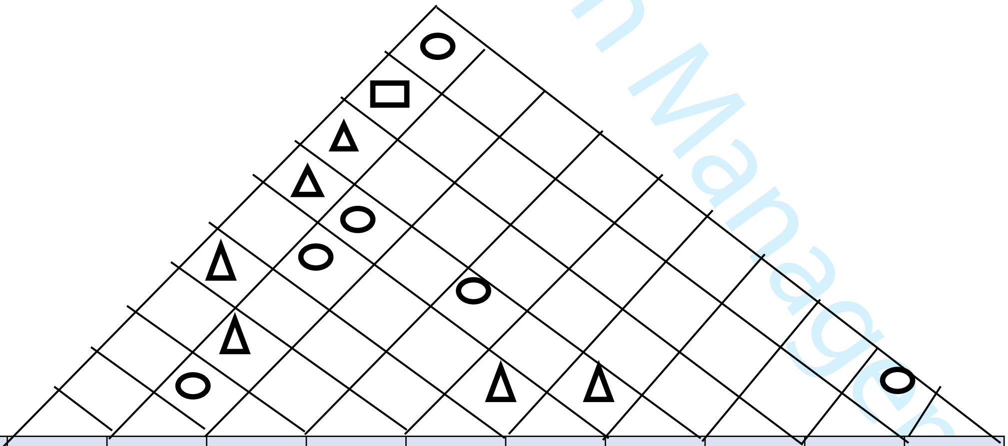
Table 5: Strategies to overcome challenges for AM in SMD supply chain

No	**Strategies**	**Strategy description**

CSt1	Technology development	Enhancing technology development to meet the need for rapid production, speed, process improvement and reducing costs of processes and parts
CSt2	Standards	Standardisation of AM processes for clinicians to enable a streamlined and consistent approach
CSt3	Skills development	Improve skills and awareness of clinicians across AM technologies and industries
CSt4	Collaboration	Sharing of knowledge across the ecosystem (i.e. SMD supply chain)
CSt5	Inspection	Improve real-time monitoring and inspection capabilities
CSt6	Material improvements	Improve availability of new materials for printing
CSt7	Focused research	Increase industry-applicable research in material and printer capabilities in Australia
CSt8	Education	Provide education and advice for printer and associated technology purchases
CSt9	Design	Designing out post-processing steps to reduce complexity and costs
CSt10	Environmental benefits	Understanding and application of eco-and environmental benefits of AM

5.2 Findings from Study Phase 2

In Study Phase 2, we determined the importance weights of the identified challenges and strategies derived from Study Phase 1. We used the QFD technique (see Figure 2) to determine the importance weights of challenges and strategies. From Figure 2, we find that the top-rated challenges are need for evidence (Ch4), cost of production to delivery (Ch3), limited capability (Ch5), and lack of processes and standards in hospitals for AM (Ch8). To determine the importance weights of strategies, we calculated correlations between challenges and corresponding strategies, which are shown in Figure 2.



Challenge (Ch)	Importance Weight	St1	St2	St3	St4	St5	St6	St7	St8	St9	St10
Ch1	6.67	7.17	6.42	3.50	5.08	7.42	5.42	5.83	3.75	6.17	2.58

Ch2	6.67	8.08	4.33	3.50	5.08	6.33	5.75	6.08	5.67	6.58	3.00
Ch3	7.17	7.00	2.83	3.50	5.17	5.42	5.75	4.92	5.25	6.83	4.75
Ch4	8.58	3.33	6.00	6.42	7.25	5.08	4.17	4.75	3.58	3.50	3.50
Ch5	7.08	3.33	4.08	6.67	7.58	2.00	2.08	4.75	6.67	3.42	4.50
Ch6	5.75	2.42	5.42	6.25	8.17	1.58	2.42	4.92	5.92	2.75	4.75
Ch7	5.25	7.25	6.17	5.75	5.25	5.92	5.58	5.42	4.17	7.00	3.33
Ch8	7.08	2.67	8.50	6.67	5.75	4.50	4.25	3.75	5.00	3.67	4.08
Ch9	6.75	3.00	7.17	7.08	7.17	3.25	2.08	4.58	3.83	2.92	4.50
Ch10	5.83	3.58	4.92	4.25	4.25	3.25	3.42	4.58	3.17	3.08	4.25
	A.I	316.06	373.18	360.00	409.17	301.22	273.48	330.04	314.04	304.42	262.08
	R.I	0.097	0.115	0.111	0.126	0.093	0.084	0.102	0.097	0.094	0.081

Figure 2: Correlations between challenges and strategies

Based on the correlations between challenges and corresponding strategies, we determined the absolute importance (A.I) scores of each strategy (Chowdhury and Quaddus, 2015). From the A.I scores, we also determined the relative importance (R.I) of each strategy (Chowdhury and Quaddus, 2015). Relying on the A.I and R.I values, we find that among 10 strategies, the most important strategies are sharing knowledge across the ecosystem (St4, R.I = 0.126), standardisation of AM process for clinicians (St2, R.I = 0.115), improving the skill set of clinicians regarding AM products (St3, R.I = 0.111), Increase industry-applicable research in material and printer capabilities in Australia (St7, R.I = 0.102), and Enhancing technology development (St1, R.I = 0.097).

From the QFD analysis, we find that some of the strategies are correlated to each other. Correlation among the strategies is shown in the roof of QFD model (see Figure 2) by using different symbols such as an oval, triangle and rectangle. The ovals represent weak correlation while triangles and rectangles show medium and high correlations, respectively. Correlations among the strategies assist managers in understanding and developing an implementation plan. For example, correlated strategies may save time and cost when implemented simultaneously. Thus, managers need to develop implementation plans and operations strategies by carefully considering interdependence among the strategies. The roof matrix of Figure 2 shows that St1 and St5 have a medium correlation. Similarly, St1 and St6 have a strong correlation, St1 and St7 have a medium correlation, and St2 and St3 have a weak correlation. Thus, these interdependent strategies may save managers cost and time if implemented simultaneously, and managers can carefully quantify these savings. Therefore, apart from the importance score (A.I and R.I) the roof matrix in QFD may provide complimentary information to the managers while selecting optimal strategies. In this research, for a parsimonious model, we considered only the importance scores in selecting the optimal strategies for the next step of the decision support model. However, future research may include both criteria (importance score of strategies and correlation of strategies in roof matrix) in selecting optimal strategies.

5.3 Findings from Study Phase 3

Following Study Phase 2, Study Phase 3 adopted fsQCA to determine the most suitable configuration of strategies to mitigate health service operational challenges and improve performance. fsQCA is a configurational approach that explores the necessary and sufficient configurations of causal conditions leading to the outcomes (Fiss, 2011). As the main objective of this research is to determine the most suitable portfolio of strategies to mitigate health service operational challenges, fsQCA is a highly relevant approach to operationalise the research objective. To conduct fsQCA analysis, the important challenges and mitigation strategies were identified from the findings of Study Phase 2 via QFD analysis. In our fsQCA analysis, we identify which configuration of strategies (Sts) would negate the challenges (Chs) to improve health service performance. To test different configurations of causal conditions leading to an outcome, we tested two models:

Model 1: $\sim Ch = f\,(St)$

Model 2: $P = f\,((\sim Ch)^{*}\,(St))$

Model 1 hypothesises that resilience strategies help minimise the challenges of AM based surgical and medical supply chain.

Model 2 hypothesises that a combination of negating challenges and implementing resilience strategies help improve surgical and medical supply chain, which enhances supply chain performance.

fsQCA Results: For conducting fsQCA analysis, at the first step, we completed fuzzy set calibration. To calibrate crisp values of scale items, each scale item was measured using a seven-point Likert scale. To calculate fuzzy values, three qualitative anchors were used where scale score 6 was considered as the full membership, 2 as full non-membership, and 4 as the cross-over point (Pappas, 2018).

In the next step, we checked whether any causal conditions were necessary to the outcome, which in our study is performance. A causal condition is considered necessary if it is a compelling condition for an outcome (Ragin, 2008) and if the consistency score of the causal condition exceeds the threshold of 0.90 (Pappas, 2018). Recently, Rasoolimanesh et al. (2021) suggested that a condition is necessary for an outcome if both consistence and coverage is ≥ 0.90. Considering the guideline of Rasoolimanesh et al. (2021), we find that none of the conditions (see Table 6) seems necessary for enhancing performance.

In the following step, to analyse sufficient conditions, we produced a truth table to derive combinations of challenges and strategies to generate performance as an outcome. Each row in the truth table is a configuration (Ragin, 2008). To simplify the truth table, we considered the consistency cut-off 75% and frequency 1 (Ragin, 2006). Corresponding to each model, we ran cross-tabulation to see contrarian cases. Some contrarian cases were found in each model, which bring complexity to the problem. As mentioned above, fsQCA considers contrarian cases of the relationship between the causal and outcome variables, hence it is an appropriate method in this study. Based on the truth table, multiple configurations were derived based on the four different models developed for this study. The results from the fsQCA using the 4 models as mentioned earlier are outlined in Table 7.

Table 6: Necessary condition for performance

Conditions	**Coverage**	**Consistency**
St1	0.842	0.931
St2	0.770	0.916
St3	0.796	0.947
St4	0.803	0.951
St7	0.807	0.950
Ch3	0.861	0.787
Ch4	0.896	0.695
Ch5	0.890	0.920
Ch8	0.872	0.827
Ch9	0.967	0.498

Table 7: Sufficient condition analysis for mitigating challenges and improving performance

	Raw coverage	**Unique coverage**	**Consistency**
Model 1: ~Ch = f (St) Configurations:			
~St1*St2*St3*St4*St7	0.526	0.526	0.757
solution coverage: 0.526 solution consistency: 0.757			
Model 2: SCP = f ((~Ch)*(St)) Configurations:			

Ch3*Ch4*Ch5*~Ch8*~Ch9*St1*St2*St3*St4*St7	0.213	0.110	0.965
solution coverage: 0.558 solution consistency: 0.978			

Note: Ch= Challenge, St= Strategy, SCP= Supply Chain Performance.

The model ~Ch = f (St) refers resilience strategies help minimising the challenges of AM based surgical and medical supply chain. In this model the outcome variable "Ch" were calculated by averaging the survey response values of 5 most important challenges derived from stage 2 of the research. The model produces only one configuration of strategies that meet the recommended consistency threshold (consistency ≥0.75) (Ragin 2006). Therefore, the configuration (St1c*St2c*St3c*St4c*~St7c) is sufficient to minimise the overall challenges of AM in SMD supply chain. In other words, implementation of St1 (focus on technology improvement), St2 (focus on standardisation), St3 (focus on improving skill) and St4 (focus on sharing knowledge) while ignoring St7 (select and source right printer) is sufficient to minimise the overall challenges of SMD supply chain.

From model SCP = f ((Ch)*(St)) we found one suitable configuration of resilience strategies and challenges which meet the recommended consistency threshold (consistency ≥0.75). This Configuration (Ch3*Ch4*Ch5*~Ch8*~Ch9*St1*St2*St3*St4*St7) implies that implementing St1 (focus on technology improvement), St2 (focus on standardisation), St3 (focus on improving skill), St4 (focus on sharing knowledge) and St7 (select and source right printer) and minimizing Ch8 and Ch9 (lack of supportive culture) will improve SMD supply chain performance significantly even at the presence of Ch3 (lack of business case), Ch4 (lack of evidence) and Ch5 (lack of skill and awareness). Thus, our result reveals that a combination of resilience strategies and negating challenges better predict SMD supply chain performance instead of implementing resilience strategies and negation challenges as standalone approaches.

6. Discussion and Implications

The objective of this study is to develop a decision support model to determine the most suitable configuration of challenges and strategies for mitigating challenges of implementing AM in the SMD supply chain and improving performance. We align building blocks of DCV (Teece, 2009) with the dimensions of digital literacy and develop the decision support model through utilising the rich insights obtained through qualitative analysis of the conducted semi structured interviews followed by operationalisation of QFD and fsQCA based analysis. Our decision model is consistent with the key research objectives, which broadly followed a systematic process to **explore** the challenges and strategies, **prioritise** the challenges and strategies, **correlate** the strategies most likely to increase the impact of overcoming the strategies, and **configure** the most relevant combination of negating challenges and implementing strategies with the overall goal of improving supply chain performance. In the following sections we discuss the theoretical contributions, managerial and policy implications, disclose the limitations of the research and finally suggest future research direction.

6.1 Theoretical contributions

Our study offers three theoretical contributions. **First**, our model extends the highly influential dynamic capability framework with sensing, seizing and reconfiguring capability as higher order capabilities through validating the critical importance to simultaneously negate challenges and adopt strategies in a certain configuration to improve performance across SMD supply chains. In this way, we address the call of Schilke, Hu, & Helfat, (2018) to integrate dynamic capability theory with emerging disciplines such as SMD within the context of supply chain management through developing an empirically validated framework. Further, following Bogers et al. (2019) we demonstrated how SMD supply chain can foster through an open innovation model of dynamic capabilities through fostering innovation and resilience across the supply chain partners. In our model, we demonstrated the scope of interconnected supply chain partners (Harland (2021) to manage discontinuities through adopting the potential of emerging digital technologies (Dubey, 2022) during crisis.

Second, we extend DCV through integrating QFD and fsQCA, that enhance the DCV framework with resilience capacity along with capacity to combine and incorporate new technologies and opportunities. Further, aligning sensing to explore, seizing to prioritise challenges and strategies, and correlating resilience strategies we maintain consistency while extending the theoretical capacity of the DCV framework and align them with the three dimensions of digital literacy, cognitive, technical and socio-emotional capabilities (see Figure 3). The integration of DCV with the well-known strategy tools of QFD and fsQCA was applied for adopting new and emerging technologies in the digital transformation of supply chain processes. Scholars investigated the relationship with dynamic capabilities and firm performance (Fainshmidt et al. 2016), our findings and adopted method can further guide the scholars and practitioners to achieve a superior control over the process of dynamic capabilities building over time and how and where dynamic capabilities may be engaged throughout the process- exploring, prioritizing, correlating and configuring/reconfiguring.

Finally, we responded to calls from industry wanting to explore the challenges of digital transformation in adopting AM and its impact on SMD supply chains (Harland et al. 2021). Our findings contribute to the research stream focusing on medical and health care research in general (Pundziene et al. 2022), with robust empirical findings on devising, selecting and executing appropriate strategies for adopting emerging technologies within a complex operating context such as SMD supply chain. Therefore, following research objectives, DCV theory and the application of QFD and fsQCA, this study identifies that cognitive, technical and collaborative capabilities are required to negate challenges and implement strategies to improve performance in supply chains in general and SMD supply chain in particular.

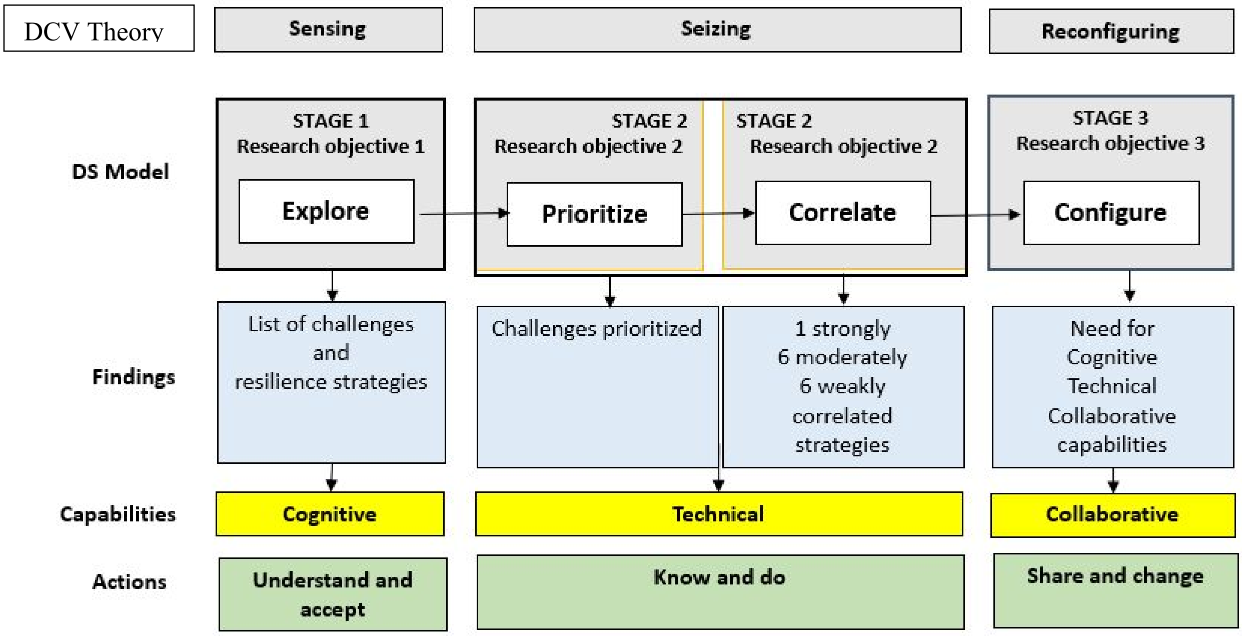


Figure 3: Decision support model aligned to DCV

6.2 Managerial and Policy implications

The findings of this study offer important practical implications. First, practitioners and managers of the SMD supply chain partners with significant value through the development of a theory-led decision support model in digital transformation journey. The decision support model in our study showed supply chain performance can be maximised by negating challenges and adopting resilience strategies simultaneously. The findings of this study deliver a key message to the managers that to predict SMD supply chain performance appropriately, a combination of resilience strategies and negating challenges are more effective rather implementing resilience strategies and negation challenges in isolation. Following the findings derived from the model, managers can be benefited with the configuration of strategies and challenges to improve the SMD supply chain performance. More specifically, a combination of technology improvement, standardisation, improving skill, knowledge sharing and selecting and souring the right printers while, minimising impact of unsupportive culture, absence of business case and evidence and lack of skill and awareness needs managerial attention to improve performance in SMD supply chain.

Second, the findings led to understanding which core capabilities were required to enable dynamic capabilities within the context of AM in SMD supply chains. This will assist practitioners to use resources to develop and deliver appropriate programs and communication that can increase the relevant capabilities (cognitive, technical and socio-emotional) to maximise SMD supply chain performance. Finally, following the research findings, it has been revealed that there are strategies that are common across different configurational models such as technology improvement, standardisation and improving skill. As a result, supply chain managers or operations managers of a partnering organisation of the SMD supply chain can be benefitted through making effective decisions at various stages of AM adoption across the SMD supply chain. .

This study has important implications for the policy makers. First, policy makers need to prioritize and leverage resources to assist improvement of the technologies associated with the AM adoption through superior accessibility, resource availability and support. Secondly, the relevant regulatory authorities for SMD supply chain, need to act in an orchestrated manner to initiate the process of standardization of AM related raw materials, processes, products or services. Finally, government need to pay sincere effort to enhance the skills of local practitioners to effectively gain the benefit of AM within SMD supply chain.

6.3 Limitations and future directions

As with all studies, this study has some limitations. For example, the study is conceptualised based on digital transformation of SMD in Australia using AM technology, which implies it may not be generalised to other new or emerging technologies, other supply chains contexts or other markets. Ideally, future research will be applied so that comparative studies show the progression of capability development at different points in time and focus on other new and emerging technology in SMD supply chains. This future research focus should show the technology trajectory of different technologies and different capabilities in the digital transformation of SMD supply chains. A new study that actually measures supply chain performance should be considered to ensure the approach leads to the best possible performance outcomes. Another limitation is the limited sample size for the survey. As AM based SMD supply chain members are limited in Australia, a large number of sample respondents is difficult to manage. Further, this study is based on cross-sectional data; however, the challenges of adopting AM in the SMD supply chain and corresponding strategies may change over time. Therefore, a longitudinal study with panel data can address the dynamic changes in challenges and strategies. Future research may be conducted using longitudinal data.

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Appendix A: Demographic profile of the interviewees

Participants	Position	Business type	Firm size (No. of employees)
P1	Operations Manager	Manufacturer	50+
P2	Owner	Manufacturer	25–50

P3	Owner	Manufacturer	25–50
P4	Business Manager	Material Supplier	50+
P5	Owner	Material Supplier	25–50
P6	Manager	Material Supplier	25–50
P7	Additive Consultant	University Research Centre	1–25
P8	Additive Consultant	University Research Centre	1–25
P9	Surgeon	Clinician	1–25
P10	Surgeon	Clinician	1–25
P11	Surgeon	Clinician	1–25

Appendix B: Demographic profile of survey respondents for study 2 and 3

Study 2		Study 3	
Respondents category	Percentage (%)	Respondents category	Percentage (%)
Manufacturer	41.45	Manufacturer	36.95
Suppliers of material	26.35	Suppliers	28.25
Clinicians	32.2	Clinicians	34.8
Number of employees		Number of employees	
< 20	28.4	< 20	23.80
20-50	43.45	20-50	49.45
50+	28.15	50+	26.25
Number of years in business		Number of years in business	
<=5	56.5	<=5	62.65
6-10	29.3	6-10	19.40
10+	14.2	10+	17.95