

Impacts of Additive Manufacturing for the Surgical and Medical Device Supply Chain

ASSOCIATION FOR SUPPLY CHAIN MANAGEMENT

FINAL RESEARCH REPORT

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EXECUTIVE SUMMARY

Revenue generated through the suite of digital manufacturing technologies, collectively known as additive manufacturing (AM), or 3D printing (3DP), reached $7.34 billion US in 2018. The health sector was an early adopter of this type of technology, with the number of medical applications manufactured using AM continuing to expand rapidly. There are indications AM could revolutionise the medical device industry over the next decade. This would have significant implications for supply chain management and operations, as discussed in this report.

The aim of this research project was to review the challenges and opportunities for surgical and medical device development industries through the lens of supply chain organisation and management and explores strategies that correspond to the identified challenges and opportunities. It highlights new knowledge, discusses the implications for operational practice and provides recommendations on responding to key issues, in the short term and for further research follow up.

Key challenges highlighted include:

- the need for evidence gathering not only for refining the regulatory and safety settings for improved patient outcomes but also to build the case for using AM technology within a clinical setting and as an alternative production technique for manufacturers,
- the need for building an accurate business case for AM that reflects accurate costings to encourage uptake of the technology in hospital settings and across industry,
- limited technological, organisational and business capability in generating AM uptake across the ecosystem, and
- a lack of standards and flow processes within clinical environments that provide a level of confidence for surgeons and medical users to investigate the use of the technology for improved patient outcomes and health system benefits.

Key opportunities highlighted include:

- AM enables a level of personalised treatment for patients through the use of patient-specific design processes, small volumes and maker iterations,
- design flexibility awarding users and manufacturers to collaborate closely on design fit for the patient and matching anatomical function for improved patient outcomes, and
- facilitating a level of learning for a new generation of surgeons and health professionals who are innovating in the continuum of care pathways for health care treatments.

The rapid development of digital technology over the last twenty years has seen companies changing practice in order to remain viable. Businesses that failed to anticipate, or respond adequately to, changing paradigms suffered a loss of revenue or closure. High profile examples include companies such as Kodak photography and Blockbuster video. At the same time, digital technology presents opportunities for new business initiatives, and for agile organisations to transition from traditional processes to new ways of working and customer interactions.

This research project considers the changing paradigm affecting companies involved in the supply of medical devices, with recent investments by leading companies in AM. It provides insight into the experience, attitudes and concerns of stakeholders within the medical device industry, where AM is beginning to influence the development of infrastructure and operational practice. The research also highlights changes in the supply of raw materials and the professional development of skills required to support the handling and processing of those materials, the development of appropriate designs for AM, the use of technical equipment, and other factors impacting the service value network.

The results of the research illustrate the uneven response within the medical device industry in preparing for the potential impact of AM technology. This has the potential to reduce the industry to key players only, with implications for established supply chain operations worldwide.

GLOSSARY OF ACRONYMS

3D	Three Dimensional
3DP	Three Dimensional Printing
AM	Additive Manufacturing
ASTM	American Society for Testing & Materials
CAD	Computer Assisted Design
COVID-19	Coronavirus Disease - 19
CT	Computed Tomography
FDA	Food & Drug Administration
ISO	International Organisation of Standards
MRI	Magnetic Resonance Imaging
OEM	Original Equipment Manufacturer
SC	Supply Chain
SCOR	Supply Chain Operations Reference
SLS	Selective Laser Sintering
SMDSC	Surgical and Medical Device Supply Chain
STL	Standard Tessellation Language
TM	Traditional Manufacturing
USD	United States Dollar

1. INTRODUCTION

Digital disruption is a phenomenon where new and emerging technologies challenge the status quo of traditional businesses, industries and supply chains. The introduction and diffusion of new technologies and their associated processes, products and service offerings provides challenges and opportunities that require managers to deploy appropriate strategies in order to minimise potential negative effects and maximise opportunities that arise.

Additive Manufacturing (AM) or 3D printing (3DP), as it is commonly referred, encompasses a range of disruptive technologies that use digital fabrication techniques to build three dimensional (3D) objects in a layer by layer process. Some applications use heated, extruded filament, others are gel or resin based and others use powdered material. Arguably, the most important shared feature of the different technologies is that they build parts without tooling. This means that each part can be specified individually without an investment in up-front tooling, such as a mould. As such AM enables low volume, highly customised output and products with complex geometric designs to be manufactured at relatively low cost.

AM is a rapidly growing technology. It is estimated that revenue generated in the United States (US) from AM was USD$7.34 billion in 2018 which subsequently attracted the 'America Makes' program to invest USD$90 million in the sector. The global AM market is expected to reach USD$23.33 billion by 2026 and given the full scope of the use of the technology is in its infancy, it is expected that AM will have a significant disruption on many conventional manufacturing markets in the long term. According to Jeremy Hsu, a Tech News Daily Senior Writer, "The technology could end up affecting every major industry – aerospace, defence, medicine, transportation, food, fashion – and have an even bigger impact on (US) manufacturing than the robot revolution."

Benefits arising from AM technology such as, lower resource requirements, faster production cycles, decentralised business models, flexible design and substantial savings on tooling contribute to justifying the reasons why the technology is gaining traction and attention across a number of industry sectors, along with attracting substantial government support.

Whilst AM has been adopted across various industries of the economy, the medical sector was an early adopter. This initial take up was due to the technology facilitating access to a wide range of biocompatible 3D printing materials for customising patient-specific medical and dental products derived from CT-scans and specialised instrumentation.

In very recent times, the level of interest in AM technology and its associated production process has increased, fuelled by shortages of medical and hygiene supplies as a result of the COVID-19 pandemic. Shortages of ventilators and other hygiene products such as surgical masks and gowns are limiting the ability of health institutions to provide urgent and appropriate treatment to patients and putting doctors, nurses and other hospital staff at risk. A combination of these risk factors has resulted in an increase in the number of deaths attributed to the disease.

The ability to quickly mobilise existing 3D printing resources to facilitate local production and distribution of these products is seen by many as a necessity to limit the impact of COVID-19 and to save lives. This unprecedented event is subsequently increasing the interest, diffusion and value of AM as a viable ongoing and future production method in the medical and surgical device sector. However, the unsuitability of the technology for mass production, and the need for medical equipment to be approved by the Food and Drug Administration (FDA) means this interest needs to be supported by credible research for translation into significant practice. Even so, a number of research facilities and AM providers are working with surgeons and other health professionals to test and pilot the use of 3D printed components which can be fitted to existing medical and non-medical products and can be easily and quickly 3D printed to increase limited capacity, with worthwhile results. However, at the same time there is much still to learn and investigate about how and where 3D printing can be used for such a global pandemic. Appendix A provides several case studies and exemplars of how 3D printing has been mobilised during the COVID-19 emergency. Please note, the case studies extracted from industry reports have not been validated by UTS research.

The emergence of AM brings challenges and opportunities for medical and surgical supply chains. Therefore, this report proposes a decision model that identifies the most important challenges and opportunities for decision makers and poses suitable strategies to overcome the most important challenges and avail the most attractive opportunities.

Three key objectives shape the deliverables of this report, these are to:

- identify and understand the key challenges and opportunities for supply chain management practices that AM brings to the medical and surgical device supply chains,
- highlight and evaluate changes in practice relevant to supply chain operations and service value networks that are occurring as viable AM technologies emerge, and
- provide direction for supply chain management and service value network practitioners, administrators and policy makers in responding to the challenges and opportunities that the introduction of AM presents to the medical and surgical device supply chains.

Following this introduction, the report is structured into five further sections.

- Section two provides an overview of AM technology – materials and production processes, and its application in the medical device sector, with comparisons to applications fabricated using conventional manufacturing techniques.
- Section three introduces the Supply Chain Operations Reference (SCOR) model as the conceptual framework guiding the research.
- Section four presents the research findings identifying the challenges, opportunities and strategies across the AM supply chain within the medical and surgical device sector.
- Section five provides the supply chain and managerial implications of the research.
- Section six concludes the report.

2. ADDITIVE MANUFACTURING – AN OVERVIEW

The shaping of material into objects within a manufacturing process can be achieved using one or more of three basic principles. These principles include subtractive shaping, formative shaping and additive shaping.

- Shapes using subtractive shaping are achieved by the selective removal of materials using manufacturing processes such as milling, turning and drilling.
- Formative shaping methods are produced by directing pressure onto raw materials (for example injection moulding).
- Additive shaping uses a technology where the desired shape is produced through building successive layers of material.

According to the International Standards Organisation (ISO) and the American Society for Testing and Materials (ASTM) the definition of AM is the "process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies."

Conventional manufacturing methods rely on economies of scale to mitigate production set up costs. As a result, they lack agility. AM, on the other hand allows for the 'manufacture' or printing of physical goods directly from a digital data file without costly tooling. The production costs are independent of production volumes, allowing businesses to focus on economies of scope, rather than economies of scale.

The AM process can be divided into four steps as illustrated in Figure 2.1. 3D digital models are created using one of the many 3D design software tools that are available, or based on 3D scanning data such as from a Magnetic Resonance Imaging (MRI). A MRI is a medical imaging technique used in radiology to generate pictures of internal anatomy. Once the 3D model is created, the surface is divided into triangles, a technique called tessellating. This information is contained in a file format most commonly known as Standard Tessellation Language (STL), which was the native file format for the resin-based 3D printing systems called Stereolithography developed by 3D Systems. The design is then split into layers ready for 3D printing. The standard 3D printing file formats are readable by a number of common and freely available software programs. The 3D printer prints the file layer by layer using input material provided with the printer. Depending on the technology, post-production may be required to finish the model to the desired standard either in terms of finish or performance characteristics. The most common post processing technique used in metal processing is heat treatment.

Figure 2.1 – 3D printing process



AM technologies are organised into seven families of processes. These are binder jetting, direct energy deposition, material extrusion, material jetting, powder bed fusion, sheet lamination and vat photopolymerization. The SCOR model v12 (introduced in Section 3) describes each of the seven 3D printing categories:

- Binder Jetting is where powdered material is bound together with an adhesive deposited from multiple print heads,
- Direct energy deposition uses thermal energy to fuse powder whilst it is being deposited onto a surface, and
- Material extrusion is where filament is extruded through heated nozzles,
- Material jetting is where droplets of the actual build material are deposited on a platform to build into 3D form,
- Powder bed fusion used thermal energy, such as from a laser, to fuse the 3D form in layers of powdered material,
- Sheet laminating is where thin sheets of a material are bonded in layers to build a 3D form,
- Vat photopolymerization is where a liquid vat of resin is selectively cured using a laser or an ultraviolet light.

Within these groups, there are multiple processes, developed by different companies for different applications. Table 2.1 lists examples of specific technology processes that are available for the standard categories of AM technology.

Table 2.1 – AM standard category and technology

Standard category	Technology
Binder jetting	Three-dimensional printing
Direct energy deposition	Laser cladding
Material extrusion	Fused deposition modelling
Material jetting	Polyjet
Powder bed fusion	Selective laser sintering
Powder bed fusion	Selective laser melting
Powder bed fusion	Electronic beam melting
Powder bed fusion	Selective heat sintering
Sheet lamination	Laminated object material
Vat photopolymerization	Stereolithography
Vat photopolymerization	Digital light processing

Of these, the most commonly used 3D printer technology used to produce medical applications are polymer, selective laser sintering (SLS), and metal selective laser melting (also called direct metal laser melting), both forms of powder bed fusion, material jetting (most commonly used for multi-material, multicoloured visualisation models for surgical planning), fused filament fabrication (FFF) and resin-based stereolithography..

Each AM process has different constraints, just as with conventional production technologies, such as injection moulding. Designing for an extruded filament technology is very different to designing for a laser-based powder technology. For example, in a filament process the part is built on a platform and a support structure will need to be printed alongside the part, that will then need to be removed. In a laser-based powder process, unfused powder provides support for the part as it is being printed, which changes the constraints and opportunities for the design. In addition, there is frequently user confusion between the capabilities of different levels of printer. For example, a basic, desktop printer costing less than USD$500, with a single filament, may share some design constraints with a dual filament, industry level extrusion-based system that costs over USD$70,000, but the constraints, capabilities and outcomes are very different. Metal implants, for example, are printed on high-end machines that cost upwards of USD$600,000. As a result, a designer with expertise in design for AM with industry level machines appropriate to the particular product and material is needed to ensure the quality of the outcomes. Materials available for 3D printing include polymers, metals, ceramics and resins. The selection of material depends on the product/item being printed.

For all AM processes there are considerable additional design flexibilities as the technology allows for the specification of geometrical complexities that are not possible to manufacture with conventional production techniques. Parts can be optimised for function without the usual manufacturing constraints and assemblies can be 3D printed as single parts, and this impacts the organisation of production. The production workforce will need to be reskilled to work with the technology.

From a supply chain management perspective, AM is disruptive because of its potential to impact business practices, as well as production practice. For example, all AM technologies enable short runs or bespoke parts to be fabricated without the upfront tooling costs generally present in conventional manufacturing. This means that designs can be personalised, or adapted after each iteration. This has significant implications for the way products are developed and marketed. Customer interactions are more likely to be part of an AM business model, for example, and this may be a new approach for a company. Overall, supply chains will be disrupted, either because they are condensed as elements of production or are completed in-house, rather than in stages through production partnerships, or because the business model is changed to include upstream/downstream interactions, or because material and equipment suppliers are from different industry sectors to those built up over the life of the company.

AM inventory can be stored as digital files and sent to distributed manufacturing facilities if required, changing the model for spare parts supply. AM is not merely an additional manufacturing technology, rather it has the potential to create a paradigm shift in patterns of production and consumption that need to be understood by individual industry sectors for their effective integration into the supply chain.

2.1 Manufacturing medical devices

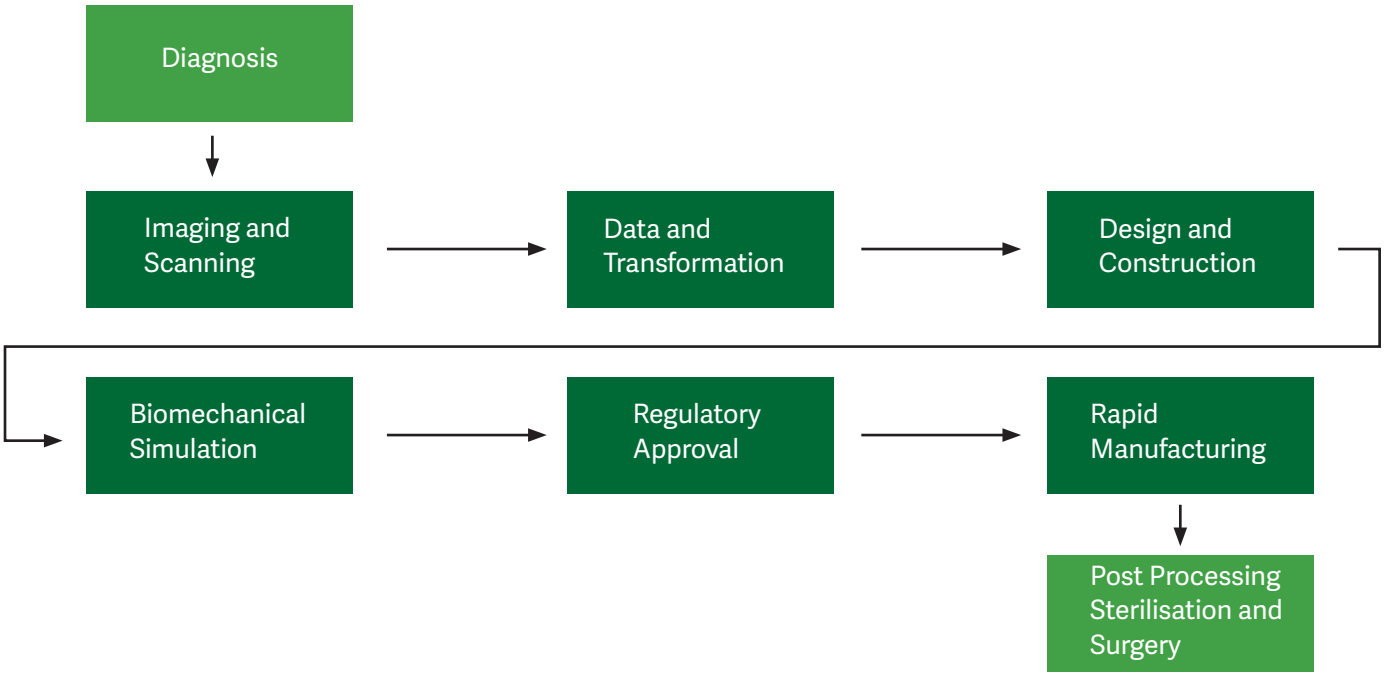
The manufacture of medical devices refers to products designed and manufactured for use inside or outside the body, and in support of the operation to implant or fit a product into, or externally onto, the patient.AM medical and surgical production can be grouped into five main arenas:

- Medical models
- Surgical implants
- Surgical guides
- External aids
- Bio-manufacturing

Starting points for this project were determined by an evaluation of the disruption to current practice determined by the change in the design, use and impact of a product through the introduction of AM technology. In addition, products were sorted into temporary and semi-permanent according to their use.

Patient specific implants are arguably the most significant development in the product range because of their potential to impact the long-term quality of life of the patient. They are also the most complex in terms of approvals, testing and monitoring. The personalisation of products (unique product or an inventory of one), is developed using the process illustrated in Figure 2.2:

Figure 2.2 – Process of AM in the production of medical devices



As a result, at this time AM is a limited field for research in terms of supply chain, as each process is individually developed by a limited number of actors in the field.

Alongside the development of implants, patient-specific surgical guides produced using AM technology are increasingly in demand. A surgeon may use a 3D printed, patient specific guide for a variety of medical interventions, not necessarily involving a 3D printed implant. Surgical guides are 3-dimensional products designed to fit the patients' anatomy, to provide the surgeon with information on where a pre-planned incision or insertion (for example of a screw) needs to be made. Surgical guides can incorporate data collected from an external scan of the body, depending on the surgery, but predominantly the information the guide is built on is provided by internal scan data in the form of CT and MRI scans. The geometry of the guide needs to be informed by the surgeons plans for the surgery.

In addition to the knowledge of the surgeon, the guide has to be designed based on expertise in design for AM. In order for the part to be stable and accurate, it needs to be designed with an understanding of the specific AM technology chosen (refer to the seven groups of AM technology listed earlier in Section 2). Each has different design requirements. Most commonly, surgical guides are manufactured using a process called SLS. A manufacturer of surgical guides has to have expertise and experience of working with selective laser sintering, and in particular of quality control systems implementation to ensure that the part is free of contaminants, able to be sterilised and has been properly cleaned and prepared.

Custom cutting guides themselves are not new, but creating one accurately and quickly without this process is difficult. 3D printed surgical guides are less of a risk than implants, and are useful in a wide range of surgical situations and therefore, in more widespread use than implants. As a result, this provides an interesting use-case for 3D printing technology, with respect to the impact on current practice and the development of a supply chain for the technology.

2.2 Potential Supply Chain Impacts

Five noticeable differences emerge when comparing conventional manufacturing technologies with AM methods for the medical and surgical sector. These include:

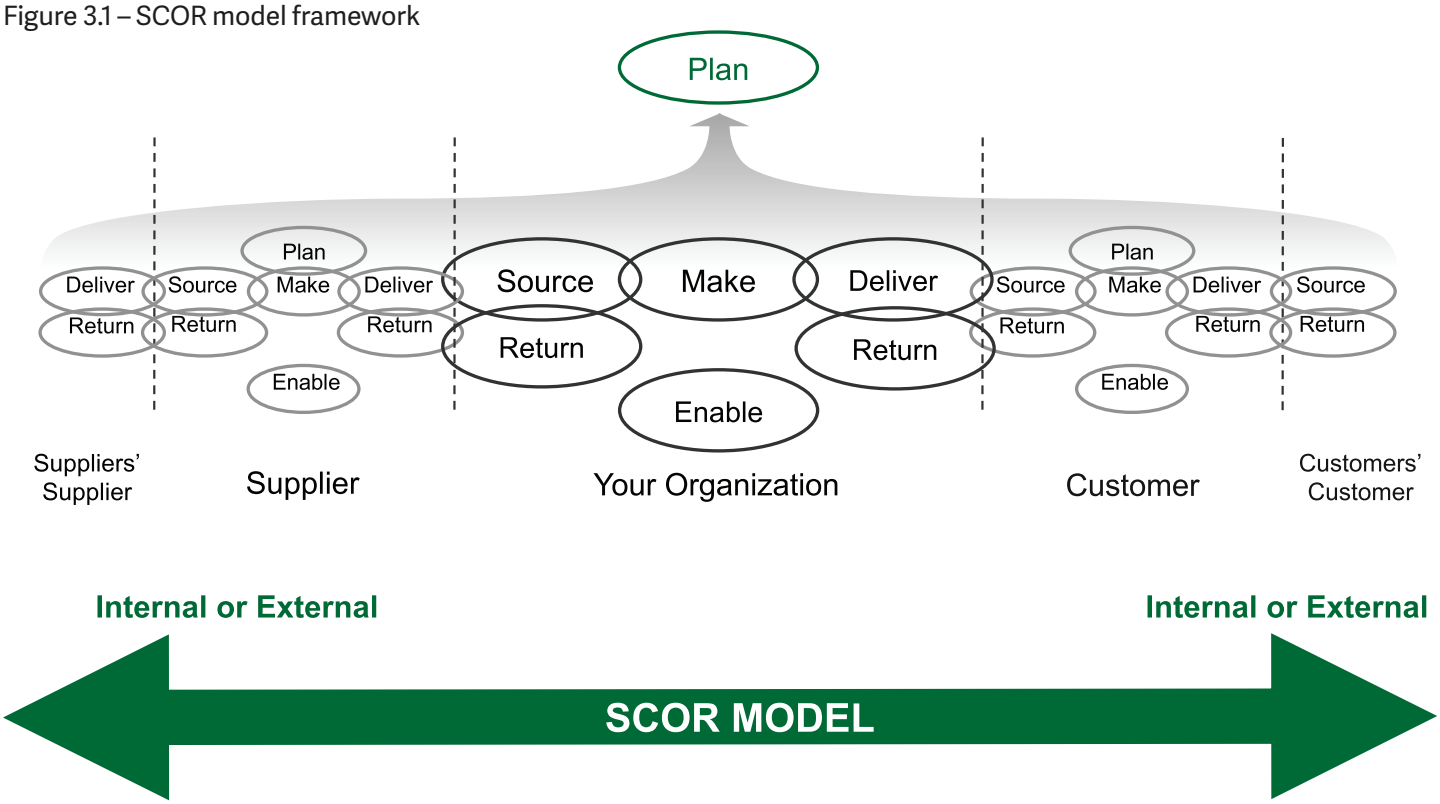
- the planning process, which is much more complex due to the high-level of customisation and the introduction of design as a critical element of the manufacturing process,
- new sources of raw materials that are required, and knowledge on which material is suitable for patient specific devices,
- production location decisions given the possibilities of AM for in-clinic, in-hospital or local decentralised production,
- the complexity of manufacturing decisions which are usually outside the scope and capabilities of medical practitioners, unless they have a specific interest in the technology, and
- user acceptance of AM products as end use products, beyond prototyping and pre-surgery planning.

3. SUPPLY CHAIN OPERATIONS REFERENCE (SCOR) MODEL – A CONCEPTUAL FRAMEWORK

The SCOR model is a management tool widely used in practice to improve and communicate supply chain management decisions and issues within a company and with suppliers and customers. The SCOR model, highlighted in Figure 3.1, describes the business activities associated with all phases required to satisfy customer demand. The model is organised around six key management processes of Plan, Source, Make, Deliver, Return and Enable. The model also provides a set of performance metrics that can be used to understand the outcomes of the supply chain. The model is designed and maintained to support the analysis of supply chains of varying complexities and across multiple industries.

The focus of the model is on three process levels and leaves each organisation to determine how business systems and information flows are tailored. For the purposes of this report, SCOR model level 1 is used as a framework for considering where the key differences exist to produce medical and surgical devices between conventional manufacturing and AM.

Figure 3.1 – SCOR model framework



The following six key SCOR management processes are outlined in further detail and used as the conceptual framework to guide the findings of this report.

PLAN process within the SCOR model includes demand and supply planning and management. It involves balancing resources with the requirements and determining the communication that occurs across the whole supply chain or service value network. This process also includes setting business rules to enhance supply chain efficiency across areas such as inventory management, transportation, assets and regulator compliance. The alignment of supply chain requirements with the financial plans of the company are also considerations during this phase.

SOURCE process includes the sourcing of infrastructure and materials. Typically, the process includes the management of inventory, supplier networks, supplier agreements, supplier performance, supplier payments and when to review, verify and transfer products.

MAKE defines the manufacturing and production processes such as make to order, make to stock, or engineer to order. Activities include production, packaging, staging product and releasing. Management of the production network, equipment and facilities and transportation are also included as part of this process. It is important to acknowledge the level 2 processes of MAKE as three possibilities, make to stock, make to order and engineer to order.

According to the SCOR reference guide v12.0 AM is considered an emerging technology. Make to stock, is inventory driven (PLAN), with standard material orders suitable to products with high fill rates and short turnarounds. Make to order is customer order driven, using configurable materials and requiring longer turnaround times. Engineer to order is customer requirements driven, with new materials sourced, and suitable for products with low fill rates and long lead-times.

DELIVER process includes order management, warehousing and transportation. It also includes more specific activities such as receiving customer orders, invoicing after receipt of goods. Consequently, the management of finished inventories, assets, transportation, product life cycles and importing and exporting requirements are included in this process.

RETURN process includes the methods required to handle the return of containers, packaging or defective product. Management of business rules, return inventory, assets, transportation and regulatory requirements are included in this phase of the process.

ENABLE is the process associated with management of the supply chain and includes business rule definition, performance management, data, resources, facilities, contracts, supply chain/service value network management, management of regulatory compliance and risk management.

SCOR performance metrics is a categorisation of metrics used to express a specific strategy. The metrics included as part of SCOR measure the ability to achieve strategic directions. SCOR recognises five performance attributes, reliability, responsiveness, agility, cost and asset management efficiency (Assets).

Given the intended audience of this report and their assumed familiarisation with the SCOR model, the level 1 processes were used to compare the supply chain configuration between conventional manufacturing and AM.

4. CHALLENGES, OPPORTUNITIES AND STRATEGIES – KEY RESEARCH FINDINGS

The challenges, opportunities and corresponding strategies related to AM in the surgical and medical device supply chain were obtained from the following data collection methods:

- The first stage of the research identified the key challenges, opportunities and strategies for supply chain management and practice that AM brings to surgical planning and logistics. To achieve this, a systematic review of current literature relevant to supply chain management for AM was conducted.
- This list was then contextualised by conducting in-depth, semi-structured interviews with ten relevant industry representatives. Appendix B provides a list of the industry stakeholder types interviewed. The identified challenges and opportunities were then prioritised using multi-criteria decision modelling and a structured questionnaire was administered to the same respondents.
- The list of strategies was contextualised by the results of the semi-structured interviews and the research team applied quality function deployment (QFD), a widely used strategy design tool to determine the most important strategies, by developing a relationship matrix between the identified challenges and opportunities with the corresponding strategies.

Semi-structured interviews were used to ensure contemporary issues and similarities were captured and compared with those found in the literature. This process improves the reliability and validity of the research findings. Through the interview process, three of the challenges identified in the literature were validated and an additional seven were introduced. The interviews also validated seven of the opportunities and added an additional three others.

In order to align the key challenges, opportunities and corresponding strategies to practice, each was categorised by three researchers according to the SCOR Level 1 process model.

The next section summarises the key challenges identified in the literature and presented across the SCOR model Level 1 process. Section 4.2 illustrates the top ten ranked challenges by level of importance. The top ten strategies to mitigate the challenges are subsequently illustrated with corresponding strategies. Section 4.3 mirrors section 4.2 for opportunities identified. Section 4.4 outlines the importance weights of opportunities and corresponding strategies to avail the opportunities.

4.1 SCOR Challenges

The following challenges are presented for Plan, Source, Make, Deliver, Return, Enable and Performance.

Plan

Despite the rapidly increasing number of 3D printable materials, there is a limited amount of materials that are flexible, biocompatible, and FDA approved for medical applications. Additionally, there are a lack of printable and regulatory body approved materials and suitable bio-inks, as well as lengthy production time limits prohibiting the development of bio-printing for clinical use.

There is a lack of standardisation of material testing and cleansing protocols, authorisation of supplier payment, verification of quality and quantity that has a potential impact on the accuracy of resource capacities which may impact capacity utilisation by supply chain partners.

The cost of a 3D printing centre to a medical program is also significant, and at a minimum includes the cost of segmentation software, a medical-grade 3D printer, material costs, and personnel with 3D printing expertise. Therefore, despite the promising features of AM technologies, the make-or-buy decisions are not straightforward and require careful investigation for planning AM production due to the relatively high AM machine and production costs.

The very nature of surgical and medical device demand forecasting creates difficulties and challenges for relevant decision makers to determine a sound plan for sourcing and making the required amount of products.

Source

The sourcing process within the supply of medical devices and bio-printed implants presents distinctive challenges to applying AM principles. Although the AM process is time tested and aims to ensure increased safety and stability both for the patient and the clinicians, it carries a number of challenges that may delay the adoption of AM into routine care. Medical device manufacturers face ongoing increased cost pressures to mitigate risks of compliance and to offset margin pressures. These pressures lead to supply chain instability, changing costs and timelines of new product introduction. Surgeons and hospitals need to perform operations without suitable practice standards, unfamiliarity with the device, low customization, increased bargaining powers with the Original Equipment Manufacturer (OEM) who control the technology. Finally, patients may experience accepting devices and implants which are not completely customized, long waiting times for preparation of implants, high cost of surgeries and post-operative care. The lack of awareness about AM based product sourcing decisions specifically identifying good suppliers, selecting suppliers, determining quality and standard for procurement specifications are difficult.

Make

3D printing, carries unique challenges in the making process within the supply chain of the medical devices and bio-printed implant industries. The key challenges for wider adoption of AM requires the elimination of bottlenecks related to production processing. These include the imprecision of scanning equipment, (size) limitations, stability and reliability of the print process, absence of machine parameter manipulation, low process automation, low processing speed and low throughput, high equipment and manufacturing costs, post-processing requirements, and the risk of piracy.

Pre and post-processing activities can be both time consuming and labour intensive, particularly where attributes of the product needed exploration before processing parameters can be determined.

Furthermore, a lack of automation in the AM process can be compared to conventional manufacturing and is a potential challenge to further adoption. Due to the biological and fragile nature of raw material used in medical sector AM, it is challenging to contain the shape of the produced 3D biomedical products in cases that involve jelly natured raw material. The time required to plan and create the 3D model has been considered a constraint as it requires the creation of a Computer Aided Design (CAD) model that takes between 10 to 12 hours to develop, which makes the 3D printing technology impractical to use in emergency cases and in hospitals with high output and patient turn over. 3D printing also leads to a substantial increase in pre-operative time, but actually results in a decrease in the intra-operative phase.

Deliver

The delivering process within the supply chain of the medical devices and bio-printed implant sector requires appreciating new challenges posed by AM production methods. Due to the multiple steps involved such as, computer-assisted segmentation of the patient's scan, virtual correction of the stenosis, design of the 3D stent and mould, fabrication of the stent, and sterilisation of the stent, creates complexity of the 3D process making it not suitable in an emergency setting of health services and posing serious challenges for the adoption of this promising technology in tertiary health sector.

Return

The return process within the supply chain of medical devices and bio-printed implant sector presents novel environmental management challenges to the adoption of 3D printing technologies. The environmental impact of AM waste requires serious consideration and appropriate measures should be taken to minimise or eliminate the impact. Practical methods to recycle unused material powder have been proposed as material recycling rates significantly contribute to reducing the impact reduction.

Enablers

3D printing technologies require explicating the challenges concerning the enablers facilitating the supply chain of the medical devices and bio-printed implant industries. Physicians often lack the technical skill set to use 3D design and modelling software. This limitation leads to slower adoption of 3D printing in the health-care field. Also, 3D computer images are limited by the two-dimensional nature of the computer screen, therefore, depth perception and relative size cannot be comprehended on the computer screen, which may cause errors. Therefore, real-size 3D printed bio-models are invaluable to study complex anatomy and to provide extra dimension.

As 3D printing requires extensive input from clinicians, the lack of technical skill can inhibit the AM procedure and can be a key impediment for greater adoption. Other human-centred-related bottlenecks include cultural changes required in the ‘way of thinking’ of traditional designers, a lack of skilled machine operators, workers’ resistance to change, a lack of management and government support, a lack of cost calculation knowledge, a lack of customer awareness, and issues related to the customer acceptance of AM.

Performance

The challenges relating to performance include capacity utilisation, cost of 3D printed biomedical objects, cycle time reductions, current costs of AM, precision, preparation time, cost and quality, lack of familiarity of AM machines, change management in the transition from conventional manufacturing to AM of existing manufacturers, and nuances of the application of AM in the medical and surgical device context.

4.2 Determining level of challenge importance and corresponding strategies

Determining priority challenges and corresponding strategies was accomplished using a three-step process.

4.2.1 Step 1- Top ten challenges

The most relevant challenges were synthesised from the literature and validated by the semi-structured interviews. Using the survey tool, the list was prioritised and themed to produce the top ten challenges. Table.4.1 summarises the most relevant/contextualised challenges and corresponding importance weights. The importance weights for each challenge were assigned in a scale 1 to 9 where 1= very low importance and 9 = very high importance. The importance weights assigned by the respondents were averaged and presented in Table 4.1. The light blue highlighted sections illustrate the most important challenges, which will be discussed in section 5.

Table 4.1 – Challenges with the implementation of AM in medical and surgical supply chains

No.	Challenge	Challenge description	Importance
Ch1	Quality process	Need for ensuring quality during production as well as optimising the AM process across the whole eco-system	6.67
Ch2	Limited capability (technology)	Current limitations in technological and infrastructure capability to improve quality, speed, finish and overall process	6.67
Ch3	Business case and cost	Cost of production to cost of sale, business case development for justification to proceed	7.17
Ch4	Evidence	Need for evidence and challenges in addressing AM in medical field for determining benefits and regulatory approval	8.58
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	7.08
Ch6	Collaboration	Ecosystem and collaboration, lack of stakeholder collaboration and connectiveness across the industry	5.75
Ch7	Time	Need for speed and lack of in medical AM	5.25
Ch8	Standards & Flow	Lack of processes and standards in hospitals for AM adoption	7.08
Ch9	Culture	Conservative approach from industry, hospitals, surgeons and challenges associated	6.75
Ch10	Funding	Lack of funding …	5.83

Through survey tool validation, Table 4.1 illustrates the top ranked challenges include; Evidence (Ch14, 8.58), Business Case & Cost (Ch13, 7.17), Limited Capability (social) (Ch15, 7.08) and Standards & Flow (Ch18, 7.08). The implications of these most important challenges will be discussed in Section 5.

4.2.2 Step 2 – Corresponding Strategies

In this step, corresponding strategies to overcome the challenges were identified through the literature and validated using the semi-structured industry interviews. Table 4.2 illustrates the identified strategies to avail the challenges with a brief outline of each provided. The light blue highlighted sections illustrate the most important strategies, which will be discussed in section 5.

Table 4.2 – Corresponding strategies to overcome challenges of implementing AM in medical and surgical device supply chains

No.	Challenge Strategy	Challenge Strategy Description
CSt1	Technology development	Enhancing technology development to meet the need for rapid production, speed, processes 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 industry
CSt4	Collaboration	Sharing of knowledge across the eco-system
CSt5	Inspection	Improve real-time monitoring and inspection capabilities of technology
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

4.2.3 Step 3 – Correlations between strategies

Once strategies were determined, the correlations between challenges and corresponding strategies were calculated, shown in Table 4.3. Correlations between challenges and corresponding strategies exhibit to what extent strategies are effective to mitigating challenges using a scale 0 to 9 where 0 indicates no correlation (a particular strategy is not effective in mitigating a corresponding challenge) and 9 indicates a very high correlation (a particular strategy is very highly effective in mitigating a corresponding challenge). The relationship scores assigned by the respondents were averaged and presented in Table- 4.3. For example- the correlation score corresponding to Challenge 1 and Strategy 1 (Ch1St1) - 7.17 - illustrates high correlation between Challenge 1 and Strategy 1 and is derived from the average correlation score of our respondents.

Table 4.3. Correlations between challenges and corresponding strategies

Challenge (Ch)	Importance Weight	CSt1	CSt2	CSt3	CSt4	CSt5	CSt6	CSt7	CSt8	CSt9	CSt10
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		0.10	0.12	0.11	0.13	0.09	0.08	0.10	0.10	0.09	0.08

Note: Light geen highlight indicates most important strategies

Based on the correlations between challenges and corresponding strategies, the absolute importance (A.I) scores of each strategy were determined. These scores were derived from the summation of (weights of challenges X challenge-strategy correlation values) scores of each strategy.

From the absolute importance scores, the relative importance (R.I) of each strategy was also determined. Relying on the A.I and R.I as shown in the last two rows at the bottom of Table 4.3, the most important strategies are Collaboration for sharing knowledge across the ecosystem (CSt4, R.I = 0.13), standardization of AM process for clinicians (CSt2, R.I = 0.12) and improving the skill sets of clinicians regarding AM products (CSt3, R.I = 0.11).

4.3 Opportunities

The following opportunities are presented for Plan, Source, Make, deliver, return, Enable and Performance.

Plan

AM can facilitate planning supply chain networks such as closed loop supply chain designs that extend product life cycles, reduces fixed time, improves equipment up-time, and reduces costs, thus making the supply chain more responsive, cheaper, and closed. AM can also enable information communication to facilitate planning smart supply chains to perform real time communication, to share data, and to make optimal decisions to support consumers through the cloud. AM can facilitate surgical planning initiatives that also assists in persuading practicing clinicians to opt into AM technology.

Moreover, the flow of ideas and iterations, enables more complex design of medical devices, development of complex geometry and precise correlation to patient-specific data. The potential of AM is evident in planning surgical procedures as it provides superior scope to surgeons to assess feasibility of the procedure in a more accurate manner. One of the key factors in selecting surgical strategy is lesion size that determines the choice between partial or total resection and heart transplant, as 3D printing with different materials and colours can reveal structural complexity of the organ in a vivid and realistic manner that critical representation such as lesion position in heart surgery becomes accurately understood. 3D models have been utilised to plan the Glenn procedure of a five-year old boy having left heart hypoplasia and aortic obstruction at several locations. Additionally, AM can play a vital role in the design and testing of personalised implants such as external aortic root support implants, an innovative alternative for minimising dissection risk and stabilizing the distended aortic root for Marfan syndrome patients.

Source

The adoption of AM for fabricating biomedical implants at hospitals offers many potential benefits as biomedical implants fabricated via conventional manufacturing are generally availed by suppliers out of the immediate region, whereas biomedical implants fabricated through AM offers scope to receive more customised, patient-specific parts with faster response time at a lower inventory level and reduced delivery cost. On the other hand, open sourcing of implants provides huge benefits to the users sourced from overseas which makes storing them in one location (single location sourcing) or few regional central locations from where they could be delivered to the AM facilities a viable option.

Development of new bio-printing approaches and broader adoption through custom-built and lower-cost commercial bio-printers fostered by open-source hardware and software technologies have played a key role in reducing the cost of systems capable of precise layer-by-layer material deposition in three dimensions. AM machines supported by open source software and hardware are affordable and recently incumbent firms such as Autodesk are facilitating development of bio-printers. Additionally, Microsoft has announced support for developers of Windows 8.1 for 3D printing machines.

Make

To reduce high inventory levels and associated costs, conventional manufacturing of several medical implants need batch production. A minimum of two month's supply of stock is required at all times for machining partners in conventional approaches of orthopaedic implants applying CNC machines that necessitates the need for a warehouse facility. On the other hand, since AM operates generally by staying closer to the end-product point of use, it is able to achieve a cost-effective and leaner supply chain that results in less inventory holding costs and relies less on safety stock because of reduced steps in production operations and less requirements for additional tooling. These features of AM offer reduced cost and lead times especially for low volume and complex parts as in orthopaedics.

Finally, AM can be used in conjunction with the conventional manufacturing process. Following Pareto's 80–20 principle and "focused" production, where a relatively small number of SKUs are produced in large quantities could continue being manufactured using a mass production system, whereas large numbers of SKUs produced in small quantities could be additively manufactured, exploiting AM's merit in mass customisation.

Manufacturers that follow conventional forms of production of medical implants need to commit more capital on the overhead for inventory and warehousing of sufficient levels of fixed-sizes implants. Therefore, AM production processes may eliminate the cost of excess inventory to achieve a superior demand-based manufacturing advantage over conventional techniques in the production of metallic medical implants. As pointed out in the literature, a minimum order of 500 units is needed from a financial feasibility standpoint whereas for a particular implant the demand may stand between 50- 100 units resulting in significant inefficiency from the conventional process. AM can deliver efficiency through producing the exact match of the demand.

AM is needed for designing and manufacturing of bio-models, implants, various scaffolds for tissue engineering, surgical aid tools and development of multiple medical devices and surgical training approaches. The AM ecosystem provides more experimentation and the immediacy of the results to foster effective flows of ideas and iterations compared to conventional techniques with reduced turnaround times. It enables customisation through developing patient specific solutions and also ignoring patient specific issues that can be addressed at a later time. AM is specifically beneficial in processes that involve complex geometry, as. medical models are complex because of the 'free-form' nature of the objects, utilising patient-specific data, 3D models can create implants that precisely map to a patient's musculoskeletal framework that enable surgeons to perform intensive and critical surgeries.

The ability to use patient-specific 3D medical imaging data obtained from MRI and CT, offers the potential to repair regions of diseased or damaged tissues, or even entire organs. The ability to generate 3D models from patient data allows physicians to create custom prosthetics and implants, visualize complicated pathologies better, and teach trainees in a more realistic manner. In interventional pulmonology CAD patient-specific devices have assisted surgeons to overcome several therapeutic impasses and possess room for application in wider situations. Rapid adoption sources report the use of 3D models by U.S. foot and ankle group for preoperative planning in Charcot foot reconstruction. In areas of neurosurgery, a realistic 3D model can be utilised to identify the safest surgical corridor, used by surgeons-in-training in the area of neuro-oncology. When applied to model personalisation with brain tumours, and their surrounding structures this may assist surgeons to explain the procedure to the patient and prepare for highly tailored procedures on a case-by-case basis.

Deliver

The deliver process involves activities related to building, maintenance and fulfilment of customer orders, validation and scheduling delivery of orders and invoicing the customer. The delivering process within the supply chain of medical devices and surgical device industries can exploit new opportunities applying AM productions. AM favours near-shoring; thus, it can fundamentally affect Total Landed Cost through reduced emissions, safety stock and pipeline inventory. AM adoption will result in reduced distance from production to customer, reduced warehousing, and shipping. Overall transportation of goods is expected to be shifted from long distance transport of finished products delivered to retailers to raw materials ordered from short distances, considering that production sites could be strategically scattered near customers in order to significantly decrease lead time. Logistics of the surgical and medical device supply chain (SMDSC) can be benefitted by AM; as orders could come directly from consumers to the near factory that can potentially reduce cost and lead-time. Finally, during the medical service delivery procedure, the use of 3D models by the surgeons reduces operation time and intraoperative blood loss, resulting in superior outcomes for the patients. Furthermore, the application of 3D models provides patients rich insights of their situation, surgical plan, and potential risks that result a positive attitude towards this technology.

Return

AM has the potential to reduce waste related costs. Extensive commercialisation of AM of pharmaceuticals can disrupt the traditional supply chain used by the global health care sector through minimising waste related to unused, expired medications. Furthermore, AM holds the scope to reduce the required amount of raw material in the supply chain that will reduce the energy usage, waste, and pollutants throughout the manufacturing processes, therefore, enabling flexible and efficient product design. Finally, more than 95% of waste material can be reused in AM based 3D printing in general which is a significant opportunity for surgical and medical devices supply chain.

Enablers

AM based 3D printing technologies present considerable opportunities for enablers facilitating the supply chain of the surgical and medical devices supply chain. AM processes allow rich flows of information across the eco-system members. For example, despite ideal conditions, some surgeons may have difficulty carrying out planned resections. 3D printed models have been useful for transferring information to the surgeon to allow numerous revisions of their planning and to enable a more tailored patient approach. Moreover, 3D model based simulation has been recommended as a potential method of developing new surgical skills with no exposure of patients to the operative learning curve of the surgeon. Therefore, AM based 3D printing facilitates transferring specialised skill to overcome training constraints within most surgical fields due to increased sub specialization. On the other hand, in traditional surgical methods, surgeons need to mentally integrate critical information to formulate a pre-operative plan. This can be avoided by applying 3D printing resulting in reduced complexity for the surgeons. A final enabling feature that provides an opportunity to grow the 3D printing sector includes, regional collaboration. Regional partnerships can leverage the AM industry and allow necessary access to knowledge, technology development methods and testing facilities that would previously have not been available to firms. .

Performance

AM is suited to closed loop supply chain designs as the additive nature of AM requires no product specific equipment, thus allowing for on-site repair, that extends the product life cycle, reduces fix time, improves equipment up-time, and reduces costs, thus making the supply chain more responsive, cheaper, and closed loop. Additionally, AM reduces the stock-keeping costs, obsolescence risk, warehousing and material handling costs (personnel, transportation), as well as unavailability costs, leading to improved product and volume flexibility. Designs can be easily created, personalised, and modified according to any requirement of the consumer. They also provide the possibility of sharing the design, so that the manufacturing process can be easily carried out in many different places simultaneously. The'Time Driven Activity Based Costing' approach is used to estimate costs of different process steps, including preparation, production, supports removal, and post-processing activities. To determine the economic feasibility of AM, the key cost parameters are the ratio between the unit production costs of AM and traditional manufacturing (TM) as well as product lead time and demands.
Within the context of surgical and medical device application in health sector AM offers fast, convenient, and accurate process. The use of 3D models reduces operation time, therefore resulting in less operative time and potentially less blood loss by the patient and reduced risk. Additionally, AM offers better clarification of the potential treatment to the patient creating better acceptance by the patient and the carers and decreasing the risk of misinterpretation of the medical problem.

4.4 Determining level of opportunity importance and corresponding strategies

Determining priority opportunities and corresponding strategies was accomplished using the three step process outlined in section 4.2.

4.4.1 Step 1 – Top ten opportunities

The most relevant opportunities were synthesised from the literature and validated by the semi-structured interviews. Using the survey tool, the list was prioritised and themed to produce the top ten opportunities. Table 4.4 shows most relevant/contextualised opportunities and corresponding importance weights. The importance weights for each opportunity were assigned in a scale 1 to 9 where 1= very low importance and 9 = very high importance. The importance weights assigned by the respondents were averaged and presented in Table 4.4. The light blue highlighted sections illustrate the most important opportunities, to be discussed in section 5.

Table 4.4. Opportunities and level of importance

No.	Opportunity	Opportunity description	Importance weight
Op1	Iterative process	Iterative process and design assists with change management across the organisation by understanding each AM stage and applying the learnings	1.50
Op2	Just in time delivery	Lowering inventory costs and faster response times	4.42
Op3	Distributed production	Close to market and decentralise production	3.42
Op4	Surgical planning	Less surgical time in operating theatre	4.67
Op5	Optimal decision making	Cloud based connected facilities using optimal decision making tools (smart supply chains)	3.92
Op6	Open source technologies	Technology and processes are more accessible	4.33
Op7	Design flexibility	Accommodate complex geometries	5.17
Op8	Personalised treatment	Rapid proto-typing patient specific shapes to fit tailored patient anatomy for functional fit and alignment	5.50
Op9	Rapid learning	Used as a learning tool for training purposes	5.00
Op10	Increased productivity	Lowering costs, improved capacity and patient outcomes	4.42

Through the survey tool validation, Table 4.4 illustrates that the top ranked opportunities include; Personal treatment (Op8), Design Flexibility (Op7) and Rapid Learning (Op9)

4.4.2 Step 2 – Corresponding Strategies

In this step, corresponding strategies to avail the opportunities were identified through the literature and validated using the semi-structured industry interviews. Table 4.5 illustrates the identified strategies which were contextualised and relevant to the study. The light blue highlighted sections illustrate the most important strategies, which will be discussed in section 5.

Table 4.5 Corresponding strategies to avail opportunities

Strategy number	Opportunity Strategy	Opportunity strategy description
OSt1	Closer collaboration	Increased collaboration between medical and AM supply chain and stakeholders
OSt2	AM Business case	Develop AM business case for supply chain partners
OSt3	Policy sector education	Broadening of AM education across the policy sector
OSt4	Industry capability	Develop AM industry capability and eco-system
OSt5	Funding	Increase funding levels and research output
OSt6	Regulatory strategy	Develop regulatory strategy that ensures quality and supports innovation
OSt7	Improve AM capacity	Improve AM capability in hospitals for surgical model and tool building – incorporate into quality management systems
OSt8	Technology Improvement	Technology improvements
OSt9	Material process improvements	Bio-mechanical and material process improvements

4.4.3 Step 3 – Correlations between strategies

Once strategies were determined, the correlations between opportunities and corresponding strategies were calculated to determine the level of importance for each strategy, shown in Table 4.6.

Table 4.6 Correlation and ranking of opportunity strategies

Opportunity (Opp)	Importance Weight	OSt1	OSt2	OSt3	OSt4	OSt5	OSt6	OSt7	OSt8	OSt9	OSt10
Op1	1.50	3.17	4.67	4.50	5.42	4.50	5.67	3.83	3.83	3.33	5.08
Op2	4.42	5.42	4.92	3.17	4.92	2.83	4.67	4.67	5.25	4.42	3.25
Op3	3.42	5.83	5.75	2.33	4.42	3.92	4.33	4.75	3.83	3.50	4.58
Op4	4.67	4.92	3.42	3.25	3.83	2.42	4.83	5.00	4.67	4.67	4.33
Op5	3.92	4.58	4.17	3.67	4.25	3.33	3.92	3.50	4.25	2.92	3.50
Op6	4.33	4.00	3.08	4.33	4.00	3.58	4.08	3.25	5.25	3.08	3.67
Op7	5.17	3.92	3.00	4.33	4.08	3.33	3.25	4.83	5.75	4.08	3.67
Op8	5.50	5.25	3.67	4.33	4.92	3.67	4.08	5.00	5.50	4.67	4.92
Op9	5.00	3.67	2.67	4.67	3.83	4.17	2.42	3.25	3.33	3.50	4.17
Op10	4.42	5.17	4.92	3.83	5.58	4.17	4.33	3.83	6.00	5.08	4.08
A.I		197.09	164.71	163.50	188.78	149.13	169.98	179.36	206.35	169.75	172.30
R.I		0.111923	0.093535	0.092848	0.107203	0.084687	0.096527	0.101854	0.117181	0.096397	0.097845

Note: Light geen highlight indicates most important strategies

Relying on the A.I and R.I as shown in the last two rows at the bottom of Table 4.6, the most important strategies are Technology improvement (OSt8, R.I = 0.117181), Closer collaboration (OSt1, R.I = 0.111923) and Industry capability (OSt4, R.I = 0.107203).

Appendices C and D present a snapshot of the Quality Functional Deployment methodology used to analyse which strategies are correlated to each other. Correlations among the strategies are shown in the roof of the QFD model by using different symbols to indicate the relational strength.

5. SUPPLY CHAIN AND MANAGERIAL IMPLICATIONS AND STRATEGIES - DISCUSSION

The analysis and findings in Section 4 illustrate there are four main challenges and three main opportunities impacting practitioners in the implementation of AM in the surgical and medical device supply chain within Australia. This chapter will explore these challenges, opportunities and the associated strategies.

5.1 Challenges impacting practitioners

Four main challenges were identified to the implementation of AM in the surgical and medical device supply chain within Australia. These challenges were:

- the need for evidence and case based practice,
- access to funding to support the broader implementation effort,
- the promotion and acceptance of quality processes, and
- access to detailed costings to support AM business case development.

The following subsections explore these challenges, the key implications and associated strategies

5.1.1 Need for evidence

The need for evidence gathering is critical across the AM industry. This evidence pertains to technological and product viability as well as quality, process improvement and cost, etc. Accompanying this challenge, is the need to gather evidence to satisfy the changing regulatory and reimbursement landscape as it prepares to harmonise global standards.

Evidence is particularly important to developing and facilitating credibility across the AM sector, and more particularly in the medical and surgical supply arena. Because of strict health and safety requirements medical devices and equipment sourcing requires a high credibility of suppliers. Therefore, evidence and instances of effective and efficient use of AM based products are crucial for improving decision making and credibility..

As industry develops this evidence, in partnership with universities or other mechanisms, the question of intellectual property (IP) rights also arises as a challenge, particularly around who owns the IP. The key question for AM is – 'How does the industry actually track evidence across the product journey map and how is this framed and supplied to the relevant industry bodies and regulatory authorities to adhere to the strict quality standards?'

Evidence is also critical for justifying a user's business case to its organisation to select an AM product over a conventional or off-the-shelf product. For example, a surgeon would need to justify to the hospital administration and funding agency why a custom AM implant that currently costs more would be preferable over selecting an off-the-shelf product, or why a surgeon would want to purchase a printer to produce anatomical models for surgical planning. For example, one surgeon outlined this challenge as:

"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."

"If I get a 3D printed cage, does that improve my patient outcome. So, as a clinician, that is how we look at implants."

5.1.1.1 Key implications and corresponding strategies:

- Without reliable and ongoing gathering and tracking of evidence, all stakeholders will be reluctant to invest 100% in AM technology and production. If users cannot access the evidence, this will flow on to the supply chain with less demand for AM products.
- The Australian AM community, whilst small, is largely disconnected. It is challenging to identify who would collect and track such evidence for the industry as a whole ecosystem.
- Poor technical integration, data custodianship, and mercenary monetisation of data and models create barriers for health systems to partake in AM. Healthcare payers are reluctant to fund AM if they believe cost-effectiveness cannot be demonstrated.

Strategies such as sharing knowledge on evidence based practice across the ecosystem is critical. Standardising the AM process for clinicians and manufacturers will speed up the process of gathering evidence and enable the development and upskilling of health care professionals.

5.1.2 Costing and Business Case development

Changes will be essential to adapt health systems to suit longer lifespans and maximise health and well-being at all ages. An opportunity and a threat, these changes place pressure on the medical technology sector. Patients will demand new and best-in-class technologies, but access will be determined by governments' and healthcare providers' judgements about the economic sustainability of those technologies, driven primarily by the twin imperatives to keep costs down while providing more and better quality care for patients.

The business case for AM requires a clear and accurate picture of the type of investment that is needed from the user and supply chain perspective. Depending on the end product, this business case is not always easy to develop due to unknown process costs, type of technology selection, regulatory and reimbursement queries.

By its very nature, AM is suited to low volume manufacturing which creates an added challenge for down-stream suppliers to justify the investment versus cost of goods sold.

Further, in AM based surgical and medical device supply chain, tracing the end to end supply chain cost is difficult due to lack of awareness and availability of data which makes the investment decision difficult for the decision makers. Thus, it is a challenge for businesses exploring the potential of investment in AM to get a clear understanding on the return on investment and justification for AM versus conventional or subtractive manufacturing.

There are a lack of processes and standards across the Australian health and hospital system to enable the adoption of AM technology. Surgeons and physicians are unaware of how/if AM technology can benefit the patient and the system and thus, there is a lack of preparedness to explore such a pathway. In addition, patient specific designs and solutions complement AM and therefore, assessments need to be conducted to understand whether the Australian health system is ready to adopt such an approach.

Risk is a significant disabler to AM adoption. Users, manufacturers and suppliers are unsure of 'where the buck stops' with taking responsibility for the process and the end product – who is actually accountable? There are a limited number of cases that can be used as a precedent for such a challenge.

5.1.2.1 Key implications and corresponding strategies

- Product manufacturers and suppliers are reluctant to invest in AM or down-stream processing of AM products until technology or markets are ready or volume increases
- Users of AM products are limited in the scale of choice of manufacturer/supplier and these vendors may end up being located overseas if a domestic partner cannot be located due to the small size of the Australian market.

Strategies such as the development of case studies of successful and non-successful applications of medical AM products and the business case relevance would be useful to share across the ecosystem. Improving the awareness levels of the Australian AM community throughout the supply chain will expand the capacity for choice of local content and hence, greater opportunity to scale parts of the supply chain. Categorisation of products based on levels of customisation required for making the product will be helpful in setting strategies such as local vs international suppliers, insourcing vs outsourcing decisions, etc.

As well as technology development, business model development and innovation is required across firms to assist in the understanding of where AM could be an organisational fit.

5.1.3 Limited capability

A requirement in many medical and surgical instances is the need for speed to production as well as delivering on a quality process and finished product. As user demands change quickly, the speed at which technology can supply also needs to meet demand. However, current printing and material technological capability is limited to truly achieve all three of these requirements for the end user.

In addition, in contrast to subtractive manufacturing approaches, depending on the type of AM machine chosen, AM introduces new post processing steps to the product manufacturing value chain, such as heat treatment, sterilisation, and clean and packaging. In Australia and globally, these supply chain options are limited and as such, there is either a monopoly over the service delivered or the service simply does not exist and needs to contracted to an overseas vendor. Combined with limited technological capability challenges, there are also challenges associated with limited (social) capability. Existing AM skill sets and expertise are limited and need to be carefully sourced. In addition supply chain capability in the areas of post-processing are limited and sterilization and clean and pack vendors are limited to less than a handful in Australia.

Aside from the direct benefits to the clinicians and patients, there is likely to be overall cost improvement provided competition can flourish and as the technology and technique scales. A critical factor in achieving the predicted adoption rate will be the ability for healthcare regulations to keep up with the opportunity across geographic regions. Therefore, the organisations that actually guide industry adoption in technology need to keep abreast of a rapidly changing manufacturing landscape and build credible capability in this space.

At the demand side of the supply chain, there is a limited awareness in the health sector of which companies can provide advice or products for use or even where to locate this information. There is a need to understand how Australian educational institutions are preparing the next generation of manufacturers and medical practitioners for working within the AM industry and the benefits or challenges it poses.

5.1.3.1 Key implications and corresponding strategies

- Product manufacturers are limited in choice for post processing supply chain vendors
- Users are unlikely to adopt technology that does not produce what is required and are not likely to invest until the technology is ready
- Opportunity for new supply chain vendors, but where is the ROI?
- User are unaware of where to obtain advice on AM and are then less likely to adopt the technology or product
- Without credible and reliable AM capability, there is a limit to the trust that can be built across the supply chain

5.1.4 Standards and Flow and Quality processes

One of AM's unique value offerings is its potential to produce tailored geometrical shapes that fit a patient's specific anatomy. For patient specific medical implants, this process often requires 'one-off' designs to be created and manufactured. Therefore, there is a need to ensure quality is achieved as well as optimising the AM process for implant production. Such a challenge needs to incorporate the monitoring and inspection effort for each build, which is currently time consuming and costly, but at the same time critical for patient safety.

More generally, for models and non-sterile surgical guides, whilst quality and process is also a challenge to achieve, an added element to reduce cost and time to production is the potential to control the production process in-house and reduce the supply chain components and need for vendors.

5.1.4. Key implications and corresponding strategies

- Printer manufacturers need to continuously adapt technology to eliminate production steps and/or incorporate new steps such as automated monitoring and inspection per build
- Product manufacturers need to adapt business models to service and/or design AM products for hospitals and customers to print in-house and support with training and advice
- Surgical and technical limitations arise in more-complex use cases and where procedures raise ethical and regulatory concerns.

Strategies that include the role for the regulatory authorities and industry groups to share case study knowledge and quality processes across the ecosystem should be developed. By standardising the AM process for clinicians to be able to use and apply consistently, supply chain stakeholders will have the opportunity to provide consistent customer value as opposed to 'second guessing' what skill and education level the user has. Through the development of new technology, quality processes will be built and machine learning will play a role here. However, it will still be necessary to facilitate a level of training and professional development for clinicians across the AM product range to enable quality and informed choices to be made.

5.2 Opportunities impacting practitioners

Three main opportunities were identified to the implementation of AM in the surgical and medical device supply chain within Australia. These opportunities were:

- Personalised treatment
- Design flexibility
- Rapid learning

The following subsections explore these opportunities.

5.2.1 Personalised treatment

AM is able to accommodate the production of complex geometries compared to subtractive manufacturing methods. A printer receives a CAD file of a product and is able to print that file according to its specific measurements and requirements, enabling patient-specific design and product solutions to become a reality.

As described above, AM enables patient-specific solutions to become a reality through rapid proto-typing patient specific shapes and enabling point of care manufacturing and personalised treatment. Point-of-care manufacturing not only brings the patient value from a custom designed and AM implant, it recognises the need to improve the 'care' experience, at the same time as working with the health insurance and regulatory sector to optimise patient outcomes, as a surgeon explains:

"Personalised treatment ensures that the patient gets exactly what the patient requires, rather than an off the shelf solution that may not, that may need to be adapted for them."

"I guess with Additive Manufacturing, it brings together so many different philosophies that work and the sum effect of that is probably better in terms of complex geometry, you know better finish in terms of you didn't have to have two bits to a mould, which at the moment leads quite a pronounced, almost joining stripe on the implant that was being manufactured by traditional methods."

5.2.2 Design flexibility

One of AM's unique value offerings is its potential to produce tailored geometrical shapes that fit a patient's specific anatomy. For patient specific medical implants, this process often requires 'one-off' designs to be created and manufactured.

As described above, AM technology enables patient specific implants to be manufactured more readily and easily. One of the main reasons AM enables this benefit is due to its ability to provide flexibility of design and production. As one surgeon comments:

"Additive Manufacturing allows you to build things that you couldn't before. What you have to do is find out what was it that you couldn't build before that you can use AM for."

5.2.3 Rapid learning

A key opportunity for AM is for surgeons and clinicians to use AM as a learning tool for future surgeries and procedures. In addition, a younger generation of practitioners and scientists moving through the university systems and fellowship programsin hospitals also have the opportunity to use AM technologies for learning and development. There is also a perception of risk associated with experienced physicians that affect a 'reputational risk' of a new technology as opposed to a younger trainee learning on a particular technology for research, as a surgeon attests:

"Youngsters that are coming out of, you know ... training, are probably much more gung ho and much more "let's use the latest technology". They haven't got their reputation to damage."

Surgical planning and surgical tool development are a great way to learn with the AM technology and apply in 'real time', as a product manufacturer suggests:

"Simpler than implants are surgical tools and pre-surgical planning models. And I think it would be a great way to start because it would provide an access and provide education and communication."

5.3 Strategies to exploit opportunities

Three main strategies were prioritised to avail the opportunities identified by practitioners. Ranked on level of importance these are:

- Technology improvements
- Close Collaboration
- Industry Capability Building

The following subsections further explore these strategies.

5.3.1 Technology improvements

Digitisation facilitates the adoption of state-of-the-art clinical decision support algorithms, and enables health systems to design scalable, repeatable processes and workflows that optimise care delivery. The end result is first-time-right diagnoses that improves patient outcomes and reduces health care costs. The post-operative, rehabilitation phase is just as important as the pre-operative and intraoperative stages for the patient's return to maximal health. After leaving the hospital, treatment effectiveness can be measured using continuous monitoring. Built-in feedback loops allow the fine-tuning of treatments to coach patients back to healthy lifestyles.

AM is developing at a rapid rate. Australia has access to many centres of excellence and training in AM that specialise in defence, aerospace and medical technology manufacturing. It is within these education and university centres that opportunity is created for learning innovative AM practices, processes and technology changes.

The challenge for the medical technology industry is that there are numerous health care stakeholders — patients, providers, payers, innovators, etc. — demanding value, but there is no consensus on the definition of what value is. Current incentive systems reward the old ways of working. However, payers and providers are embracing value-based care that prioritise outcomes over throughput.

The partnerships medical technology supply chain players must now forge with payers and providers are fundamentally different from the transaction-based contracts that were constructed in the past. These new partnerships require firms to make up-front investments and share risk as members of a health care ecosystem.

Companies are willing to provide evidence to meet the needs of new payment models, but the type of evidence needs to be appropriate for the technology and the risks involved. The important thing is that the frameworks are not designed as a 'one-size-fits-all' formula.

Bringing together the new entrants and the more traditional players, both groups benefit from hearing different perspectives and can help craft policy positions that foster innovation, not inhibit it. As technology improves, AM will lower the cost of goods sold, improve the capacity to produce mass customised product and improve patient outcomes. However, the AM ecosystem needs to work together to enable this vision within Australia and globally.

Current health systems will need to implement new business models to deliver scalable, efficient and high quality patient care outcomes, and to reduce waste, redundancies and inefficiencies that threaten the system's sustainability. Supply chains can play a key role in collaboratively working with its clinical partners, to not only offer high quality manufactured medical device solutions, but in-house performance solutions to improve business efficiencies, through the use of safe, standardised and evidence based processes and effective innovative technologies. A requirement in many medical and surgical instances is the need for speed to production, as well as delivering on a quality controlled process and finished product. As user demands change quickly, the speed at which technology can supply also needs to meet this demand. However, current printing and material technological capabilities are limited in their use to truly achieve all three of these requirements for the end user.

5.3.2 Close collaboration

While the AM community in Australia is relatively small in comparison to European and North American markets, the ecosystem of stakeholders is relatively fragmented. Surgeons and medical practitioners are unsure where to locate information or advice about AM technology or products and the evidence of such AM solutions. Product and printer manufacturers are unsure how to collaborate with the health care sector and the regulatory industry and post-processing suppliers are unsure how to build networks across the ecosystem to increase volume and the business case for AM processing. This presents a cultural divide within the sector.

Overarching the series of challenges is Australia's current culture and mindset towards AM. The language used to represent the AM industry can be technical and non user-friendly and therefore, does not encourage collaboration. Media articles often depict AM as the next industrial revolution or the worst investment of the century without any research substance provided. On the other hand, research and journal publications are not developed for the average industry partner to digest and so the cycle of 'non-development' continues.

Industry, hospitals and surgeons are conservative in transitioning to AM technology. This approach is justified as it is the patient outcome that is the source of the AM solution at the end of the day. However, without informed education and awareness the industry cannot move forward and misinformation will only perpetuate a risk averse culture with innovation in AM slowly developing in the background.

5.3.3 Industry capability building

The building of industry capability is viewed on two fronts, the building of technical capability as well as social capability (organisational and business model adaptation).

In addition, in contrast to subtractive manufacturing approaches, and depending on the type of AM machine chosen, AM involves post processing. These steps add to the product manufacturing value chain, such as heat treatment, sterilization, and clean and packaging. The supply chain options for post processing are currently limited and, as such, there is either a monopoly over the service delivered or the service might simply not exist in a location, and needs to be outsourced to an overseas vendor.

The building of social capability on the other hand will enable those with limited technological capability challenges, with the language and understanding of multi-disciplinary teams to come together and collaborate in a more meaningful and productive manner. Existing AM skill sets and expertise are limited and need to be carefully sourced. In addition, supply chain capability in the areas of post-processing are limited and sterilization and clean and pack vendors are limited to less than a handful in Australia.

Aside from the direct benefits to the clinicians and patients, there is likely to be overall cost improvement provided competition can flourish and as the technology and technique scales. A critical factor in achieving the predicted adoption rate will be the ability for healthcare regulations to keep up with the opportunity across geographic regions. Therefore, the organisations that actually guide industry adoption in technology need to keep abreast of a rapidly changing manufacturing landscape and build credible capability in this space.

At the demand side of the supply chain, there is a limited awareness in the health sector of which companies can provide advice or products for use or even where to locate this information. There is a need to understand how Australian educational institutions are preparing the next generation of manufacturers and medical practitioners for working within the AM industry and the benefits or challenges it poses, as one product manufacturer explained:

"One thing that is really problematic is having things like ..., heat treatment capability and CT scanning; that's just really quite absent in Australia."

6. CONCLUSION

As a global association serving supply chain professionals and organisations, understanding the impact of emerging trends on global supply chains is core to APICS' mission. It underlies the association's ability to ensure that supply chain organisations and professionals are well prepared to take advantage of future opportunities to differentiate themselves and maintain their relevancy in a rapidly changing world. As such, APICS is best placed to consider the findings outlined in this report to examine for further research or implementation.

This project has identified the challenges and opportunities present in the surgical and medical device supply chain resulting from the implementation of AM as a viable means of production and has explored the corresponding strategies to address the challenges and exploit the opportunities. The introduction of digital technologies in other industry sectors has had devastating effects on some incumbent industry players. At the same time, this report has outlined AM technology presents significant opportunities for new entrants and agile organisations able to transition from traditional processes to new and evolving digital supply chains and service value networks.

Key challenges highlighted include:

- the need for evidence gathering not only for refining the regulatory and safety settings for improved patient outcomes but also to build the case for using AM technology within a clinical setting and as an alternative production technique for manufacturers,
- the need for building an accurate business case for AM that reflects accurate costings to encourage uptake of the technology in hospital settings and across industry,
- limited technological, organisational and business capability in generating AM uptake across the ecosystem, and
- a lack of standards and flow processes within clinical environments that provide a level of confidence for surgeons and medical users to investigate the use of the technology for improved patient outcomes and health system benefits.

Corresponding strategies include focusing on standardising AM processes for clinicians to enable a streamlined and consistent health care approach, improving skills and awareness of clinicians across AM technologies and facilitating collaboration and knowledge sharing across the AM ecosystem.
Key opportunities highlighted include:

- AM enables a level of personalised treatment for patients through the use of patient-specific design processes, small volumes and maker iterations,
- design flexibility awarding users and manufacturers to collaborate closely on design fit for the patient and matching anatomical function for improved patient outcomes, and
- facilitating a level of learning for a new generation of surgeons and health professionals who are innovating in the continuum of care pathways for health care treatments.

Corresponding strategies include developing closer collaboration between medical and AM supply chain stakeholders, building AM industry capability and strengthening the ecosystem and investing in technological improvements.

As the technology of AM matures, new opportunities are emerging to circumvent conventional manufacturing, supply chain operations and change the configuration of service value networks and business models. AM technology enables objects to be produced directly from digital models in a layer-by-layer process from an increasing variety of materials.

With hardware (printer and supporting machinery) costs rapidly declining, it is becoming increasingly feasible for the production of mass customised products to be located at the place of demand. Consequently, technicians located close to the customer or end user with access to a printer and refined materials, such as powdered polymer or metal can produce a functional product on demand.

This change of process eliminates the need for centralised manufacturing processes where large volumes of products are created, stored, inventoried and transported to global markets. Products will be mass customised and produced through distributed manufacturing which is localised manufacturing, thereby requiring the supply chain to transition from a traditional mass produced goods model and physically focused supply chain to a more distributed digital service value network. Such changes in the supply chain may create myriads of challenges and opportunities. In order to gain competitive advantage, organisations need to develop dynamic capabilities and continuously engage with emerging technologies to ensure they remain relevant in a rapidly changing environment.

6.1 Report Limitations

The scope of the research limited the project to focus on high level challenges, opportunities and strategies for the surgical and medical device industry. However, the research methodology could be specifically enabled and applied to one product area of medical devices (surgical guides or medical implants) as well as being generally applied to other specific sectors that are further along the AM development path, such as dental.

6.2 Future research

Whilst it was not the intended scope for the research team to focus on COVID-19 related AM topics, the case studies in Appendix A specifically highlight the attention the AM sector has brought to assisting in the pandemic. Future research to validate industry and supply chain approaches and collaboration would build on the findings of this report and distil confusion about the adequacy of such a disruptive technology in the face of a global crisis. The opportunity for 3D printing to fill supply chain gaps during a pandemic is a big one or during any sort of emergency for that matter (bush fire, flood, etc). As suggested in section 6.1, the research methodology and findings for the COVID-19 case studies could also be compared across a more mature AM sector such as medical, aerospace and defence.

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APPENDIX A – COVID-19 CASE STUDIES

Please note: Due to the fact the following COVID-19 case studies are based on recent events, none of the information can be verified, but it is relevant and interesting because it does indicate the potential of AM technology to disrupt supply chains, and circumvent established supply chains where necessary. For the purpose of this report, a key point to note is that where hundreds of thousands of an object may be needed, or even millions in the case of, for example, hospital gowns, these strategies need to be kept in perspective. That said the below case studies are indicative that with a change in thinking, the businesses could form the basis for a more permanent reworking of manufacturing and supply chains.

Formlabs

One of the biggest issues during COVID-19 is the lack of available tests for coronavirus. Formlabs, a company based in Somerville in Massachusetts, is a developer and manufacturer of 3D printers and related software. There is a nationwide shortage of the nasopharyngeal (NP) swabs needed to collect samples for COVID-19 testing. NP swabs are flexible sticks with a bristled end that are inserted into the nose to the back of the nasal cavity and swept around to collect material that sticks to or wicks up the bristles. The swab is then placed into a vial that contains a culture medium.

Formlabs is using 250 printers in its Ohio factory to manufacture 100,000 nasal swabs for COVID-19 testing each day. These swabs are necessary components in test kits and are used to accurately diagnose and treat patients. After identifying that nasal swabs for testing COVID-19 were in high demand and extremely limited in supply, a team from the USF Health's 3D Clinical Applications Division created an initial design, working with Northwell Health and collaborating with Formlabs to develop prototypes and secure materials for a 3D printed alternative. Over the span of one week, the teams worked together to develop a nasal swab prototype and test it in the USF Health and Northwell Health labs. In two days, USF Health and Northwell Health developed prototypes using Formlabs' 3D printers and biocompatible, autoclavable resins. Now that clinical validation is complete, 3D printers at USF Health and Northwell Health will produce the swabs and provide them to their patients.

NASCAR

NASCAR has a research and technology centre that uses 3D printing to build composite parts for the next generation of stock cars. However, now that the NASCAR season has been put on hold, the company is using its 3D printers to churn out PPE for healthcare workers. NASCAR's printers are running 18 hours a day to manufacture face shields to donate to hospitals. NASCAR is following the lead of its three main manufacturers: Ford, Chevrolet, and Toyota, Ford is working with GE Healthcare to build air-pressured ventilators, with a goal of manufacturing 50,000 units in the next 100 days. Chevrolet (General Motors) is partnering with Ventec Life Systems to build ventilators and has vowed to produce more than 50,000 face masks per day. Toyota is building face shields and collaborating with medical device companies to speed up the manufacturing of ventilators.

CORE Autosport, a team in IMSA's WeatherTech SportsCar Championship, is similarly committed to helping out. Its team shop is manufacturing thousands of face masks for distribution across the country. Technique Inc., a Michigan-based company that normally supplies chassis components to NASCAR teams, has turned its efforts during this pause in racing to making face shields for medical distribution and ramped up production to 20,000 shields per day.

Roush Fenway Racing has developed a special prototype "transport box" that helps provide a safe, workable barrier between COVID-19 patients and the many medical personnel treating them in hospital rooms and transporting them on hospital floors.

ISINNOVA

Dr. Renato Favero approached Isinnova to help deal with the possible shortage of hospital C-PAP masks for sub-intensive therapy, which is emerging as a concrete problem linked to the spread of COVID-19: Dr Favero's idea was to construct an emergency respiratory mask by readjusting a snorkelling mask already on the market.



Isinnova contacted Decathlon, as the creator, manufacturer and distributor of the Easybreath snorkeling mask. The company immediately became available to collaborate by providing the CAD drawing of the mask identified. The product was dismantled, studied and the changes made were evaluated. The new component for the connection to the respirator was then designed, which was quickly printed using 3D printing. The hospital itself was thrilled with the idea and decided to test the device on a patient in need. The testing was successful. Neither the mask nor the valve fitting are certified and their use is subject to a situation of mandatory need. Use by the patient is subject to acceptance of the use of a non-certified biomedical device, through a signed declaration.

Given the success of the project, Isinnova decided to urgently patent the connection valve (patent n, 102020000006334), to prevent any speculation on the price of the component. The patent will remain free for use so that all hospitals in need can use it.

Materialise

In order to help global containment efforts, Belgian software and 3D printing service provider Materialise opted to make its 3D printed hands-free door opener free for users to print around the world. The door opener makes it possible to open and close doors with the arm, eliminating the need for direct contact with door handles. Such a measure can potentially help reduce the spread of the virus.



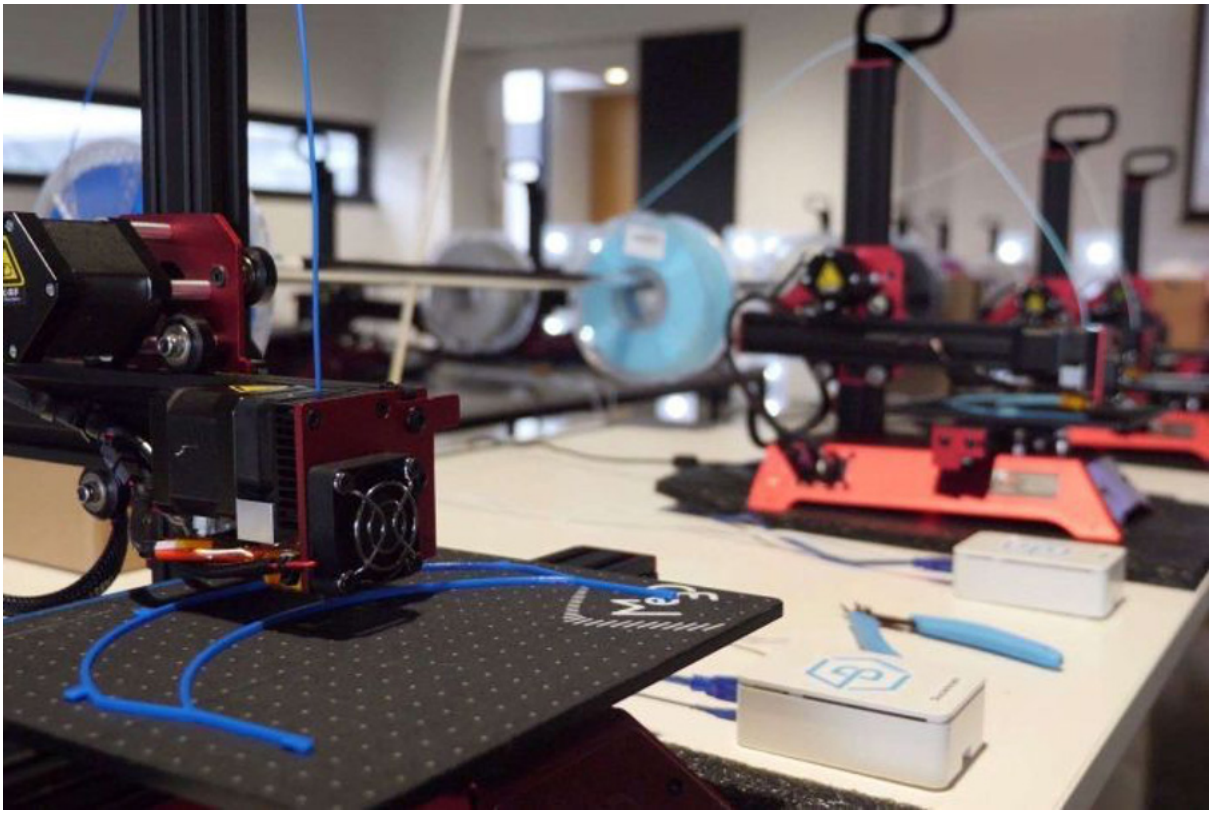
According to experts, the coronavirus is capable of surviving on surfaces for extended periods of time, and door handles represent a high risk of contamination, requiring individuals to come into contact with them frequently. During an internal meeting at Materialise, the company set about establishing measures to help protect employees and visitors, which is where the idea for the door opener originated.

The 3D printed door opener has been designed by Materialise to attach to existing door handles without drilling holes or replacing the handle. It features a paddle-shaped extension, allowing people to open and close doors while using their arm instead of their hands, as most doors can't remain open due to safety reasons. The first model of the door opener can be attached to cylindrical handles; Materialise has plans to introduce additional designs leveraging different 3D printing technologies in response to the spread of COVID-19.

Me3D

In an empty lecture theatre at the University of Wollongong campus in Australia, a local start-up company has set up a 3D print farm. Forty machines, soon to be 140, are making face shields for frontline workers as part of the battle to slow the spread of coronavirus.

Me3D co-founder and engineer Matthew Connelly said the operation would ramp up quickly. His company usually created and designed 3D printers for schools, but has swung into gear during the downturn after being asked to help and is using leftover stock.



3DMEDiTech

3DMEDiTech is working with Melbourne University and the Austin Hospital, Australia to Design a better Pressure Modulation Diffuser used in the ventilation system of the HAZMAT suits worn by clinicians treating infected patients. The idea was born on a Sunday morning and initial parts went into action the following Tuesday afternoon.

Also, through their global network of medtech solution providers, 3DMEDiTech accessed the latest open-source designs coming out of Harvard and Silicon Valley, real-time, and began 3D printing and testing swab designs. A unified 3D printed shaft and tip design, coupled with 3DMEDiTech's ISO certified clean room medical device production facility enabled 3DMEDiTech to begin production of this vital part in a matter of days.

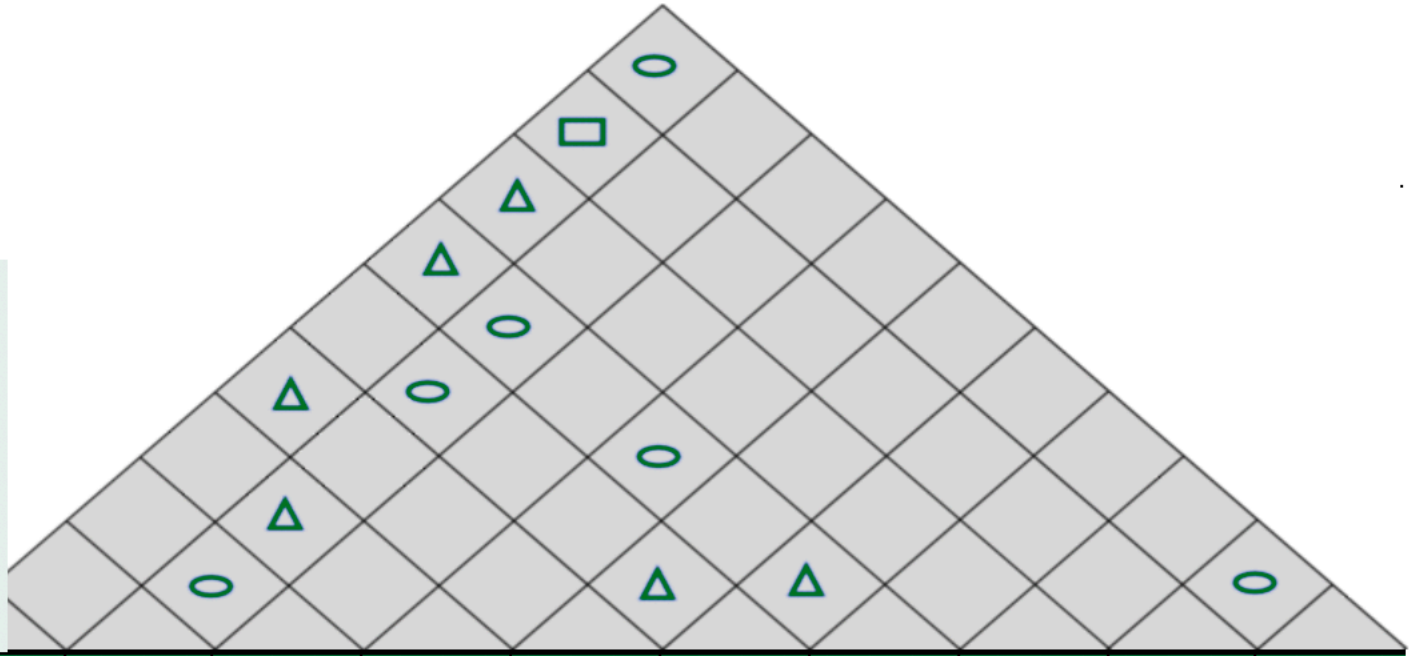
APPENDIX B – SEMI-STRUCTURED INTERVIEW AND WORKSHOP STAKEHOLDER INVENTORY TABLE

Data Type & Quantity	Date Data Was Gathered	Original Data Source and No. of Interviews
10 semi-structured interviews for *Impacts of Additive Manufacturing for the Surgical and Medical Device Supply Chain*	January – February 2020	Informants from: **Industry** 2 x additive manufacturing specialists 3 x product manufacturers 1 x printer manufacturer 1 x post processing supplier **Health/Clinical** 3 x surgeons from Sydney and Melbourne hospital
12 workshop participants for *Impacts of Additive Manufacturing for the Surgical and Medical Device Supply Chain*	February 2020	Informants from: **Industry** 4 x additive manufacturing specialists 5 x product manufacturers 1 x printer supplier 1 x additive manufacturing industry **Health/Clinical:** 1 x surgeon

APPENDIX C - QFD MODEL FOR CHALLENGES AND CORRESPONDING STRATEGIES

Icon Key:

- ○ = Weak Relation
- △ = Medium Relation
- □ = Strong Relation

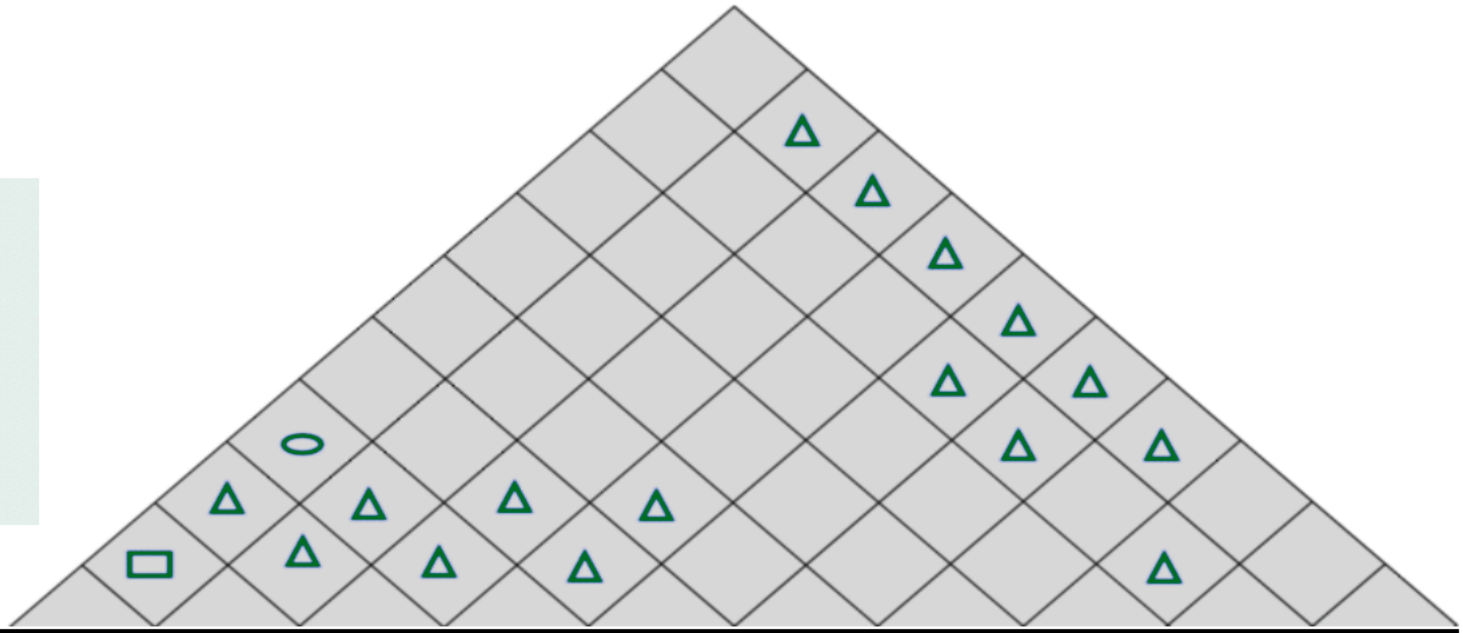


Challenge (Ch)	Importance Weight	CSt1	CSt2	CSt3	CSt4	CSt5	CSt6	CSt7	CSt8	CSt9	CSt10
Ch1	6.67	47.78	42.78	23.33	33.89	49.44	36.11	38.89	25.00	41.11	17.22
Ch2	6.67	53.89	28.89	23.33	33.89	42.22	38.33	40.56	37.78	43.89	20.00
Ch3	7.17	50.17	20.31	25.08	37.03	38.82	41.21	35.24	37.63	48.97	34.04
Ch4	8.58	28.61	51.50	55.08	62.23	43.63	35.76	40.77	30.76	30.04	30.04
Ch5	7.08	23.61	28.92	47.22	53.72	14.17	14.76	33.65	47.22	24.20	31.88
Ch6	5.75	13.90	31.15	35.94	46.96	9.10	13.90	28.27	34.02	15.81	27.31
Ch7	5.25	38.06	32.38	30.19	27.56	31.06	29.31	28.44	21.88	36.75	17.50
Ch8	7.08	18.89	60.21	47.22	40.73	31.88	30.10	26.56	35.42	25.97	28.92
Ch9	6.75	20.25	48.38	47.81	48.38	21.94	14.06	30.94	25.88	19.69	30.38
Ch10	5.83	20.90	28.68	24.79	24.79	18.96	19.93	26.74	18.47	17.99	24.79
A.I		316.06	373.18	360.00	409.17	301.22	273.48	330.04	314.04	304.42	262.08
R.I		0.10	0.12	0.11	0.13	0.09	0.08	0.10	0.10	0.09	0.08

APPENDIX D - QFD MODEL FOR OPPORTUNITIES AND CORRESPONDING STRATEGIES

Icon Key:

- ⬭ = Weak Relation
- △ = Medium Relation
- ▭ = Strong Relation



Opportunity (Op)	Importance Weight	OSt1	OSt2	OSt3	OSt4	OSt5	OSt6	OSt7	OSt8	OSt9	OSt10
Op1	1.50	4.75	7.00	6.75	8.13	6.75	8.50	5.75	5.75	5.00	7.63
Op2	4.42	23.92	21.72	13.99	21.72	12.51	20.61	20.61	23.19	19.51	14.35
Op3	3.42	19.93	19.65	7.97	15.09	13.38	14.81	16.23	13.10	11.96	15.66
Op4	4.67	22.94	15.94	15.17	17.89	11.28	22.56	23.33	21.78	21.78	20.22
Op5	3.92	17.95	16.32	14.36	16.65	13.06	15.34	13.71	16.65	11.42	13.71
Op6	4.33	17.33	13.36	18.78	17.33	15.53	17.69	14.08	22.75	13.36	15.89
Op7	5.17	20.24	15.50	22.39	21.10	17.22	16.79	24.97	29.71	21.10	18.94
Op8	5.50	28.88	20.17	23.83	27.04	20.17	22.46	27.50	30.25	25.67	27.04
Op9	5.00	18.33	13.33	23.33	19.17	20.83	12.08	16.25	16.67	17.50	20.83
Op10	4.42	22.82	21.72	16.93	24.66	18.40	19.14	16.93	26.50	22.45	18.03
A.I		197.09	164.71	163.50	188.78	149.13	169.98	179.36	206.35	169.75	172.30
R.I		0.111923	0.093535	0.092848	0.107203	0.084687	0.096527	0.101854	0.117181	0.096397	0.097845

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