



Distributed Manufacturing: scope, challenges and opportunities

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Reply to reviewers

Dear Editor (and Reviewers),

We greatly appreciate the opportunity to revise our paper (Manuscript ID: TPRS-2015-IJPR-2003, Distributed Manufacturing: scope, challenges and opportunities) for the special issue. Thank you very much for providing us with the reviewers' comments. We found the comments from the reviewers to be very helpful and constructive, hence, we have incorporated all the major concerns and (most) of the minor suggestions. We trust you will agree, that the paper has benefited from this exercise.

Reviewer(s)' Comments to Author:

Reviewer: 1***Comments to the Author***

Reviewers' comments integrated - OK!

Response: We are very thankful for your kind comments.

Reviewer: 2***Comments to the Author***

A very interesting paper on distributed manufacturing. This paper is multiple case study and focuses on various industries. The paper is well written and consistent. The case study methodology is not very well described and the authors should spend few more lines on this. Also the generalization of the results should be discussed in the final sections with regard to limitations of the study.

Response: We have incorporated your fruitful comments and highlighted in the manuscript.

Reviewer: 3***Comments to the Author***

All my concerns on the previous version of this paper have been well addressed and I agree with its publication in IJPR now.

Response: We are very thankful for your appreciation.

We trust that the above changes to the manuscript and supporting tables, and our summary of responses to Reviewers comments address the issues highlighted.

We look forward to your feedback and thank you once again for your efforts in improving the paper.

Kind regards,

The Authors

Distributed Manufacturing: scope, challenges and opportunities

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Keywords: Distributed Manufacturing, Emerging Production Technologies, ICT, Digitalization, Localization, Personalization, Community-based Production, Urban Environments, Smart City Production Systems

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Abstract

This discussion paper aims to set out the key challenges and opportunities emerging from distributed manufacturing (DM). We begin by describing the concept, available definitions and consider its evolution where recent production technology developments (such as additive and continuous production process technologies), digitization together with infrastructural developments (in terms of IoT and big-data) provide new opportunities.

To further explore the evolving nature of DM, the authors, each of whom are involved in specific applications of DM research, examine through an expert panel workshop environment emerging DM applications involving new production and supporting infrastructural technologies. This paper presents these generalizable findings on DM challenges and opportunities in terms of products, enabling production technologies, and the impact on the wider production and industrial system. Industry structure and location of activities are examined in terms of the democratizing impact on participating network actors.

The paper concludes with a discussion on the changing nature of manufacturing as a result of DM, from the traditional centralized, large scale, long lead-time forecast driven production operations, to a new DM paradigm where manufacturing is a decentralized, autonomous near end-user driven activity. A forward research agenda is proposed that considers the impact of DM on the industrial and urban landscape.

1. Introduction

Previous eras of large-scale manufacturing have been characterized by progressive centralization of operations, dating back to the time of the Industrial Revolution and the emergence of the factory system from the previous artisan-based craft production. Charles Babbage, in *On the Economy of Machinery and Manufactures* (Babbage, 1835), expounded on the economy of labour that was facilitated by machine-based production. The technical developments of his era were accompanied by the emergence of the factory system, and the advantages in terms of productivity that came with standardized tasks with firms seeking production economy-of-scale cost optimization. Over the last three decades, globalization trends have further transformed the industrial landscape with individual international

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3 manufacturing production sites serving regional and global markets. Factories therefore could
4 be efficient, but this centralized paradigm was also characterized by long unresponsive
5 supply chains with manufacturing far from the point of consumption, and often associated
6 with inefficient use of scarce resources.
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11 In this paper we consider recent breakthroughs in production and infrastructure technologies
12 that have enabled smaller (and micro scale) manufacture much closer to the end-user, referred
13 to as Distributed Manufacturing (DM). From a material sourcing perspective, DM operations
14 *can benefit from* more distributed natural capital/material sources. From a production
15 perspective, emerging technologies as they mature may provide improved production process
16 control that enables repeatable, dependable production at multiple locations and at smaller
17 scale. DM is further empowered by modern infrastructural ICT developments, which enable a
18 step change in connectivity to support coordination, governance and control, and crucially
19 enable demand and supply to be managed more real-time.
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28 DM Technology enablers include a range of technologies that are becoming progressively
29 mature, such as sensors and process analytics that may provide enhanced production control,
30 information and communication technologies (ICT) that support supply chain integration
31 utilizing more advanced ERP systems, and data analytics that can provide insights both from
32 raw data and also embedded data on multiple machine/equipment/product objects (Internet of
33 Things (IoT)).
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39 Whereas Industry 4.0 in Europe has introduced cyber-physical systems in a manufacturing
40 context, and Smart Manufacturing concepts in the United States emphasize intelligent and
41 autonomous systems, the concept of DM is arguably broader. In DM, not only are key
42 elements of both of these manufacturing concepts present, such as digitalization and smart
43 machines, but also new societal considerations of a highly participative form of decentralized
44 manufacturing, where participation extends right through to the end-user, and across the
45 manufacturing value chain, i.e., from design to potentially production.
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53 In this paper, we discuss the evolution of DM, examine emerging DM application case
54 studies, culminating in the description of a new DM paradigm emerging from technological
55 and other developments where manufacturing is a decentralized, autonomous near end-user
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3 driven activity. Further, we discuss the generic adoption challenges that might hinder the
4 widespread adoption of DM, challenges that range from the technological to the societal and
5 regulatory. Finally, this paper sets out a future research agenda for the distributed
6 manufacturing paradigm.
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10 11 12 **2. Evolution and Definition of the DM Concept** 13

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15 The evolution of DM can also be viewed within the context of advances in production
16 management. Many of the landmark studies in manufacturing and production systems are
17 focused on the centralized, factory-based paradigm that emerged in the early 1900s (Taylor,
18 1911). It was not until the second half of the 20th century that research began to allude to
19 alternatives to conventional means of production. Wickham Skinner (1969) observed that
20 operating systems for more customized products were responsive by design (Skinner, 1969).
21 Robert Hayes and Steven Wheelwright's manufacturing strategy decision areas include
22 factors such as size, capacity, and location (Hayes and Wheelwright, 1984). And John
23 Dunning described production as being increasingly orchestrated "within a cluster, or
24 network, of cross-border internal and external relationships" involving ownership,
25 internationalization and location (Dunning, 1979, 1988). However, recent advancements in
26 technology require that these academic frameworks to be adapted or reimagined for them to
27 be relevant to the emerging DM paradigm. It is argued that DM is not in fact a new concept,
28 referring to old manual craft production carried out by artisans, who were located closer to
29 end users than the factories that emerged during the Industrial Revolution. However, there are
30 certain key differences between the work of an artisan and production through DM. A good
31 artisan can be consistent in what he/she produces at one location, may even be able to
32 replicate the same product, but there is unlikely to be consistency in the production of the
33 same product across geographies.
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48 An important characteristic of DM is geographical dispersion, and it is the trend towards
49 globalization over recent decades – the breaking up of the value chain into sub-parts and sub-
50 processes with production distributed across different locations – that has also partly
51 precipitated the emergence of this new paradigm (Rauch *et al.*, 2015; Gyires and
52 Muthuswamy, 1993; Magretta, 1998). Over time, geographical distribution came to have a
53 more profound meaning. It went beyond the distance between a company's divisions and its
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3 headquarters, and over time saw production units as comprising production networks
4 (Ferdows, 1997; Shi and Gregory, 1998). Extending further, collaborating companies began
5 to participate in supply networks, with more specialized firms collaborating to deliver
6 products and services (Srai and Gregory, 2008). These networks had many archetypal forms,
7 some involving specialist firms, which created opportunities for small and medium sized
8 enterprises to become part of the extended manufacturing value chain, as observed in the
9 healthcare diagnostic sector (Srai and Alinaghian, 2013).
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16 Demand for more individuality and customer-specific product variants, coupled with
17 localized manufacturing, require new paradigms of production that supplant long-established
18 methods (Matt *et al.* 2015). Small, flexible and scalable geographically distributed
19 manufacturing units are capable of exhibiting the characteristics desired of modern operating
20 systems – just in time delivery, nimble adjustments of production capacity and functionality
21 with respect to customer needs, and sustainable production and supply chains, but even in
22 today's dispersed manufacturing, the production location often appears to be far from the
23 point of consumption. DM entails a deviation from conventional mass production, not only in
24 terms of scale and location, but also the consumer-producer relationship (Kohtala, 2015). The
25 implication here is a shift from long, linear supply chains, economies of scale and
26 centralization tendencies, towards a move towards a more distributed production model.
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36 The user interface is also changing, with the blurring of the boundary between consumers and
37 producers (leading to the term 'prosumer' (Benkler, 2006)), with consumers empowered to
38 provide design input into production, enabled in large part by digitalization and the internet,
39 and leading to greater product personalization and customization. Concomitant with these
40 enablers is an emerging culture of sharing community manufacturing facilities, with DM
41 offering the potential to transform the industrial and urban landscape. [Threadless](#) – an online
42 apparel/prints company – is an example of a company that facilitates this level of customer
43 involvement and feedback, enabling the customer to set their preferences and partake in the
44 design of the product.
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53 The evolving DM paradigm will therefore be characterized by new business models operating
54 in "distributed economies" (Johansson *et al.*, 2005), whose small-scale, flexible networks will
55 have a more local dimension, utilizing local materials and other resources, thereby offering
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3 environmental benefits and leading to more sustainable forms of production, i.e., energy-
4 efficient and resource-saving manufacturing systems (Kohtala, 2015; Rauch *et al.*, 2015; Srαι
5 *et al.*, 2015). The network element inherent in the DM paradigm can lead to reduction of
6 emissions through reduction of transport. These developments are arising against the
7 backdrop of future supply chain design, which are in part geared around managing scarcity of
8 resources (Malik *et al.* 2011; Nguyen *et al.* 2014, Srαι *et al.*, 2015). The emerging circular
9 economy aims to make better use of resources/materials through recovery and recycling, and
10 also to minimize the energy and environmental impact of resource extraction and processing
11 (Manyika *et al.* 2012). Innovation and new technology in the circular economy will also have
12 a community impact (World Economic Forum, 2013). It could be argued that DM in this
13 sense represents a growing democratization and decentralization of manufacturing, and to
14 some extent the transition to a circular economy. Fully enabling cooperative and
15 collaborative manufacture capabilities involving diverse and disparate stakeholders – a key
16 characteristic of the DM paradigm – is contingent on the development of suitable standards
17 and protocols. Manufacturing ontologies, semantic tools recognized as a means of
18 formalizing descriptions of concepts and relationships (Borgo and Leitão, 2004; Lemaignan
19 *et al.*, 2006), will have a role to play in broadening the use and acceptance of DM methods as
20 the concept matures.

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35 Manufacturing can be understood to be an activity that is not just about making things, but
36 where multiple people including end-users can come together and do things in a codified
37 way, making things through quantified processes. Here lies the difference in context between
38 old and new forms of distributed manufacturing – instead of the know-how being associated
39 with the person doing the work, manufacture is achieved by means of modern processes and
40 digitalization, enabling multiple people being able to do things in a codified way across many
41 locations, most notably including the end-user. As mentioned, the era of the artisan gave way
42 to centralized mass production, which is now giving way to a new form of decentralized
43 manufacturing that is not artisan. This paradigm has a locational element, a value element and
44 a technology element. A definition of DM would therefore entail visualizing this new
45 paradigm in the context of a redistribution of value where the OEM and specialist actors are
46 less dominant. Various other definitions and concepts of DM, according to its various
47 contexts (economic, societal, sustainability, etc.), are provided in Table 1.

<<Insert Table 1 here>>

In defining what DM is today, it is particularly characterized by technological developments in engineering and computing that bring new capabilities to manufacturing in terms of automation, complexity, flexibility and efficiency. One of the significant enabling technologies of DM is 3D printing, which is emblematic of a shift to on-demand, smaller scale, localized manufacturing. The re-distribution of manufacturing is being enabled and driven today by this and other advanced manufacturing technologies, such as digital fabrication technologies, continuous manufacturing in previous batch-centric operations, stereolithography, laser-cutting machinery, and tools for electrical component assembly. Not only are such technologies changing how and where goods are produced, established organisational practices and value chains being disrupted by the adoption of these technologies. Literature on DM is fragmented because of its demonstrable applicability in a wide variety of sectors, and in varying contexts. Therefore, in this paper, we examine DM's scope, challenges and opportunities by means of a panel discussion and six case studies, where DM is already being deployed or has the future potential to be applied.

3. Approach

This study focuses on DM in the present industrial context. A mixed methodology was employed, involving expert group input, and followed by a multiple case study method. The case study objectives were to investigate the scope, challenges and opportunities of specific DM innovations and to identify future research agendas. The initial stage consisted of 18 experts who shared specific case studies and then participated in group panel discussion. Panel participants are active in DM specific research projects, and acted as respondents in this study relating pertinent information and context concerning their fields of interest as they apply to emergent DM concepts. The expert input provided by respondents was gathered and discussed, leading to an informed judgment (Flynn et al., 1990). The results of that process presented here are the compiled responses of our assembled experts. Case example evidence was subsequently expanded to strengthen the evidence base and arguments made during the panel discussions and structure subsequent case example supporting evidence. The case example evidence to explore the nature of DM was structured to capture the following:

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- Description of the specific product and production technology system context
- Characterization of DM for a given technology production system
- Enabling production technologies and infrastructure
- Governance and regulatory issues to be addressed
- Resilience and Sustainability considerations
- Transformation challenges

A cross case analysis, consisting of the six case examples was performed in order to identify generalizable patterns and build consensus on the future DM landscape.

4. Case Studies

4.1 3D Printing (*Simon Ford*)

This case study focuses on 3D printing technology. The existing manufacturing system is based on centralized production processes that focus on benefits from economies of scale.

3D printing (also known as additive manufacturing) is one of the key advanced manufacturing technologies. The term 3D printing covers a range of manufacturing processes that create three dimensional artefacts through the layer-by-layer deposition of material. The first of these processes originated in the 1980s and were applied in rapid prototyping. The major advantage of this technology is that it can allow the manufacture of economically viable customized products on-demand. Among other benefits, the technology also allows new design freedoms, democratizes manufacturing through prosumption, and holds the promise of sustainability benefits across the product and material life cycles.

As 3D printing technologies have improved, their application has expanded beyond this domain into rapid tooling and finally to direct digital manufacturing. Alongside these industrial and enterprise applications, consumer 3D printing has been made possible through work originating in the open source RepRap project, with 3D printer commercialization enabled by crowdfunding platforms such as Kickstarter and Indiegogo.

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3 3D printing technology is currently being applied in various sectors including fashion,
4 automotive and aerospace in a limited way. It is becoming increasingly popular at end-user
5 level. However, adoption of this technology at mass scale remains at the conceptual stage. As
6 the performance of consumer 3D printing improves there may be convergence between
7 consumer 3D printing networks such as 3D Hubs and inter-organisational industrial 3D
8 printing networks. There remain significant adoption challenges limiting such convergence
9 and the distribution of manufacturing through 3D printing. Participants of the 3DP-RDM
10 network have identified these challenges to include 3D modeling; material supply chain
11 issues; standards (including file formats), compatibility, regulation and certification; the
12 absence of software and conceptual infrastructure; the ability of organizations to create and
13 capture value; ownership issues; and business model uncertainty.
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24 **4.2 Healthcare (*Wendy Phillips*)**

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26 This case study focuses on the healthcare sector and more especially on autologous cell based
27 therapies (ACBTs), which are poised to revolutionize the healthcare sector, offering a novel
28 approach for the repair and regeneration of diseased or damaged tissues and organs.
29 However, despite the successful entry of a small number of products such as Genzyme's
30 Carticel®, the market for ACBTs is growing slowly due issues such as regulatory barriers,
31 transportation constraints and the use of unconventional manufacturing processes.
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37 A DM approach would exploit the patient-specific characteristics of the products to
38 advantage and develop small, automated or semi-automated units capable of producing the
39 therapies from, for example, kits provided by the OEM. The manufacturing process could be
40 proven in the laboratory at the scale at which they will be made commercially, thus reducing
41 business risk. Through DM, ACBTs could be produced at or near the point of care, through
42 integrated, automated manufacturing and delivery processes coordinated within the clinical
43 setting and its requirements.
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50 Distributed manufacturing of ACBTs associated products is at the conceptualization stage,
51 but the potential clinical, social and economic advantages of manufacturing ACBTs on a
52 local and customized basis include reduced waste and transportation costs and a decrease in
53 repeat visits by the patient. The ability to rapidly provide the best therapy for an individual
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3 patient will be a key part of the growth of ACBTs, but the cost and difficulty of maintaining
4 manufacture to the same quality at several sites, of control of transport and delivery of the
5 therapies act as significant barriers. A more in-depth analysis of clinical practice is required
6 to establish the infrastructure information and capability gaps including: management of
7 chain of custody; assurance of quality; resolving the matter of when 'manufacturing'
8 becomes 'practice of medicine'; suitable models of operation with risk-sharing and
9 appropriate indemnification by differing organizations; and management of training standards
10 for operators who are working far from the central manufacturer.
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21 **4.3 Consumer Goods and Connected Manufacturing (*Ashutosh Tiwari*)**

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23 This case study focuses on distributed and digitally connected models for consumer goods
24 sector.
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28 The production of consumer goods has remained largely unchanged and places emphasis on
29 mass manufacture through multi-national corporations and globally dispersed supply chains
30 (Ellen MacArthur Foundation, 2013).
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35 The distributed and digitally connected alternative model not only demonstrates optimization
36 of manufacturing processes and logistical operations but also presents a radically different
37 model of consumer goods production, purchase and use, new opportunities for businesses to
38 share data, engage in data-driven open innovation and create radically distinctive business
39 models. The integration of distributed knowledge, production, distribution and
40 technologically driven manufacture enables: Connected, more meaningful and durable
41 relationships with the end user; Automated monitoring, control and optimization of stock and
42 material flows; User-driven design of customized goods and services at a local scale through
43 connected supply chains and on-demand production; Mass customization and bespoke
44 fabrication; Open Source Innovation and Distributed Retailing.
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53 Traditionally, consumer goods production, has progressively led to a void between the
54 manufacturer and individual end user, limiting the opportunity for personalization, up scaling
55 of local enterprise and the development of user-driven products that are tuned to the
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3 requirements of local markets. It is proposed that DM enables a more connected, localized
4 and inclusive model of consumer goods production and consumption that is driven by the
5 exponential growth and embedded value of big data. Graze.com (Food Manufacture, 2015),
6 an East London based online retailer and manufacturer of healthy snacks have adopted a
7 digitally connected and distributed approach to the automated production of personalized
8 products, a digitally optimized production process and supply chain and distributed retail of
9 unique boxes delivered directly to the end consumer.
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16 The application of distributed and digitally connected model in consumer goods industry is
17 limited. A significant challenge of distributed manufacturing has been the ability to up-scale
18 whilst retaining the value that the model aims to create through personalization, localization
19 and inclusivity. A number of smaller organizations that are successfully disrupting the sector
20 are tackling this challenge through the steady development of franchises or production hubs.
21 In 2013 Graze opened a US kitchen and distribution hub in New Jersey and within two weeks
22 had 20,000 customers across 48 states enables largely through the use of social media (Burn-
23 Callander, 2013). The case study demonstrates many opportunities of data integration and
24 analytics. However, challenges concerning business-to-business and business to consumer
25 data sharing, governance, ownership and security are key barriers to adoption. Additionally
26 new technical skills are required by organizations wishing to engage with distributed and
27 connected production such as data analytics and visualisation. Distributed and connected
28 manufacture enables monitoring, control and optimization of stocks and material flows.
29 Increased resilience is enabled through use of local producers and a closer relationship with
30 the end user provides opportunities for closed-loop production and consumption such as
31 monitoring and re-capturing valuable materials and incentivizing take-back and reward
32 schemes for more durable consumer goods.
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47 **4.4 Community based production (*James Tooze*)**

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49 This case study focuses on digital platforms that connect a distributed network of makers,
50 including open access workshops with a distributed network designers. This combination of
51 digital networks and digital fabrication enables decentralized and geographically independent
52 distributed production. These new types of workshops and tools cater for a new generation of
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3 designers, makers and tinkerers, enabling new sites of physical production as well as the
4 seeds of a community based production system.
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8 Opendesk are such an example of a new type of manufacturing company who through their
9 web platform have built a network of designers and fabricators to enable the local design and
10 manufacture of furniture and other products, made (predominantly) from birch plywood using
11 a CNC router. Here, licensing and web infrastructure connects consumers, producers and
12 suppliers in ways that give a distinct approach to the end product. It reflects a growing
13 understanding that physical products can increasingly be treated as information products. The
14 platform based approach transports data not materials, taking advantage of the growing ad-
15 hoc infrastructure of open access workshops, and global standards and protocols.
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23 There are a number of adoption challenges associated with this disruptive innovation.
24 Designers must have an understanding of the constraints of the production tools (CNC
25 routers). Designers also face a risk of unpredictable financial returns, as they only earn (a
26 percentage of the total product price) each time a design is sold online. For producers, they
27 will have to be willing to do piece work and be public facing. For companies that previously
28 focused only on CNC milling sheet materials they would have to take on the role and
29 responsibilities of a maker. Open access machine workshops that want to operate as
30 producers will need to have the capacity and expertise to manufacture high quality furniture.
31 To fully engage with the process the customer will need to be near to a maker or open access
32 workshop with CNC routing facilities. For customers that are price sensitive this approach
33 does not result in the cheapest option on the market when compared to some mass-produced
34 designer furniture.
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45 The challenges of adoption are balanced by several opportunities. Designers can get their
46 work into the public domain without the need for too much up-front investment. Producers
47 will be able to open up their business to another audience, utilize any spare capacity and be
48 visible on a digital platform. Customers are able to have an intimate understanding of the
49 provenance of their product; as they are made, finished and installed by local
50 producers. Where possible, locally sourced materials could be substituted for birch plywood.
51 This proximity to and interaction with the maker will give customers the ability to
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3 be involved in the production and customization process as well as being a (relatively) cost
4 effective means to have bespoke items made for them.
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8 **4.5 Smart City Production System and 3D Weaving Technology (Gary Graham)**

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10 The final dismantling in the West Riding of Yorkshire (England) of its Woollen textile
11 industry in the 1980s led to the area's rapid deindustrialization and a (manufacturing)
12 productivity gap that has grown ever since with London and the South East. The only woollen
13 sectors that survived were the high value niche "luxury" segments for apparel, domestic and
14 contract furnishings and accessories. The seasonal and on-trend nature of luxury fabrics
15 results in much smaller production batch sizes, especially where mass customization is
16 concerned.
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24 The potential of 3D weaving to revitalize the West Riding is examined as a case example and
25 could be achieved through: firstly, re-shoring and repatriating textile manufacturing,
26 secondly; the establishment of a new "production" materiality (Leonardi, 2012), thirdly;
27 through the development of new organisational forms and fourthly; providing creative routes
28 out of austerity for the working poor. This is a key policy item for the Alliance project that
29 feeds directly into the all-party UK parliamentary manufacturing group¹. The 'Future city
30 production system' for luxury fabrics combines distributed manufacturing (3D weaving),
31 logistics and spatial dispersed units. These cooperate and communicate over processes and
32 networks in order to achieve the optimum localized manufacturing output (per day) to meet
33 city demand. It is designed to ensure firstly that there is a close proximity of manufacturing to
34 urban customers and this would certainly remove one of the main obstacles to meeting the
35 fast delivery requirements of consumers and retailers. For instance, a current operational
36 problem for many luxury fabric manufacturers is the time taken to transport products from
37 the manufacturer to the customer. Secondly there are strong co-creation and sharing
38 components with public space manufacturing capacity (e.g. schools, libraries, shopping
39 centres, youth centres, community and village halls).
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56 ¹ Please refer to: [http://www.policyconnect.org.uk/apmg/events/launch-alliance-report-repatriating-uk-](http://www.policyconnect.org.uk/apmg/events/launch-alliance-report-repatriating-uk-textiles-manufacture)
57 [textiles-manufacture](http://www.policyconnect.org.uk/apmg/events/launch-alliance-report-repatriating-uk-textiles-manufacture).

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3 Sitting somewhere between the traditional art of weaving and the recent public availability of
4 3DP printers, innovative manufacturers are creating ways to weave materials such as wool
5 and cotton in three dimensions before they are sealed to maintain a rigid structure. For
6 instance, a highly successful localized textile manufacturer (since 1838) in the local (Leeds)
7 area, is now exploring the potential of 3DP to improve the woven structures of their luxury
8 wool fabrics. Furthermore, there are currently textile laboratory experiments with 3D
9 weaving innovations on the fabrics inside the soles of shoes for more padding.²
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16 Can 3D weaving advance so that it becomes a reality and in doing so that much of the current
17 design prototyping will progress to production tooling? If 3D weaving is to revolutionize the
18 textile industry in stimulating more decentralized and democratic modes of production, then
19 how much and when this will happen will of course depend on several factors across
20 economics, technological feasibility, policies and institutional factors. While the per-unit
21 manufacturing costs are not as low as a mass manufactured item, there is an incredible
22 flexibility and capability to customize. Also, for items with very scarce demand, the cost of
23 production can be lower than the sum of the costs associated with manufacturing, holding,
24 transporting, and product shrinkage. Furthermore, there are also significant sunk costs in
25 building this new production materiality as it requires public investment in distributed
26 manufacturing in inner city public spaces. There will also be a need for IP policing for the
27 prevention of copyright infringement for design and development work.
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39 **4.6 Pharmaceutical Case study- Continuous Manufacturing and the Digital Supply** 40 **Chain (*Jag Srui*)** 41

42 This case study focuses on continuous manufacturing and digital supply chain in the
43 Pharmaceutical sector. The industry is facing a number of manufacturing challenges
44 regarding the efficient supply of medicines to markets where increased product variety
45 (SKUs), and drugs that target more niche patient populations are exacerbating the already
46 profligate inventory models in the industry (inventory levels end-to-end typically 18 months).
47 This high inventory cost model, driven by large and centralized batch manufacturing plants is
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54 ² Please refer to: [http://www.theguardian.com/business/2015/may/03/the-innovators-the-3d-](http://www.theguardian.com/business/2015/may/03/the-innovators-the-3d-weaving-machine-putting-new-heart-into-soles)
55 [weaving-machine-putting-new-heart-into-soles](http://www.theguardian.com/business/2015/may/03/the-innovators-the-3d-weaving-machine-putting-new-heart-into-soles)
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3 not sustainable within a multi-tier supply chain that has the added complexities of primary
4 Active Pharmaceutical Ingredients (API) manufacture, secondary Formulation, and in some
5 cases remote Packaging manufacturing sites in cost/tax efficient locations. Similarly, the
6 post-manufacturing downstream supply chain model involves specialist warehousing and
7 logistics providers, serving in most countries a dispersed pharmacy model.
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13 Continuous processing within Pharma provides new opportunities to change production scale,
14 reduce the number of discrete unit operations within the manufacturing process, manufacture
15 products and product varieties that would otherwise be uneconomic, and drive a more make-
16 to-order model. Although continuous processing in Pharmaceuticals at large scale is not new,
17 they remain few in number. Recent advances in continuous processing (e.g. high quality API
18 continuous crystallizations in high drug loading products, continuous formulation to provide
19 SKU variety to support critical drug switching capabilities) have also introduced the
20 possibility of small-scale distributed operations, specifically in the production of HIV
21 products where target volumes are typically small and product variety critical to treatment.
22 Here the large-batch to small-continuous manufacturing transformation would be akin to
23 similar transformations in other industries (e.g. decorative industrial printing) and represent
24 an exemplar form of DM.
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35 Looking ahead, reconfigurable continuous process equipment can also drive new
36 redistributed manufacturing supply chain models, through digital supply chains. In this
37 future scenario, reconfigured production process-pack-distribution models, including
38 enablement of manufacturing closer to the point of need. These supply models target complex
39 product portfolios focused on more niche patient segments or indeed personalized products
40 by the seamless reconfiguration of operations at multiple volume scales. Through digitization
41 of the supply chain, supply network reconfiguration strategies are being developed to
42 consider how advanced production process analytics may support integration with emerging
43 technologies in smart packaging, cloud based distribution systems and patient diagnostics.
44 Cross-sector learnings that will contribute to the design of more adaptive, resource and
45 energy efficient supply chains, and critically the development of information systems that
46 will enable the complexity of more segmented portfolios to be managed across more
47 dispersed operations, increasingly self-managed to changing consumer demand. These
48 disruptive production and supply chain technologies together provide integration
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opportunities e.g. digitally enabled inventory light manufacturing, information technologies that support improvements in near real-time consumption and patient adherence, with new institutional governance arrangements that support outcome-centric medicines contracting and servitization models.

Both the current developments in small scale pharmaceutical production, and the future digitalization of pharmaceutical supply chains, present challenges on the maturity of process technology, requiring greater understanding of processing limits, sensor technologies that underpin process analytics, quality and regulatory controls that potentially utilize continuous processing data to demonstrate conformance, rather than batch QC testing and 'batch lot' approvals, and intelligent packs (e.g. printed electronics) that 'carry' data to ensure production and distribution environmental compliance (temperature, humidity). The controlled sharing of information on patient/consumer consumption, or through medical diagnostics product efficacy post product use completes the potential for end-to-end integration. Several type of case studies are described in nut shell to be emphasized the point leading to adoption of distribution manufacturing, idea and concept to enhance the productivity. There are certain limitations with respect to each case study, but due to brevity it is not described in details. In our brain storming session, details of these cases is presented here and we described in limited manner.

<<Insert Table 2 here>>

<<Insert Table 3 here>>

5. Discussion

5.1 DM characteristics and scope

Cross case analysis, as set out in tables 3 and 4, identifies five key characteristics of DM. These include *digitalization, personalization, localization, new enabling technologies, and enhanced user and producer participation*. Digitalization, increasingly ubiquitous in the modern world, is necessary in the DM context. It is a relatively new, pervasive and disruptive phenomenon in manufacturing, and essentially permits a product to exist perpetually in a

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3 virtual form, ready to be physically rendered at any time. This feature means that it can be
4 potentially produced anywhere given the local availability of resources and access to the new
5 production technologies. New production technologies, because they can operate at small
6 scale and possess the agility that implies, permit a proliferation in the number of production
7 sites, as well as less restrictions on where they might be located. Small-scale distributed
8 operations permit the location of production facilities in central urban districts, clinics and
9 hospitals, and even disaster areas. All of these characteristics feed into new possibilities for
10 the user, who not only has an enhanced interactive role but also agency in the manufacture of
11 the product. Customization of goods and services, opportunities for personalization,
12 collaborative production, and integrated products is increasingly user-driven.
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21 Some of DM's key characteristics are enablers for further features. Customization and
22 personalization are direct consequences of digitalization, which facilitates the modification,
23 both subtle and extensive, of physical products. There are also developments arising out of
24 localization that are leading to new business models. DM represents an up-scaling of local
25 enterprise that is in tune with DIY culture, heralding the development of user-driven products
26 that are attuned to the requirements of local markets. Fast delivery, desired both by
27 consumers and retailers, is enabled by production being in closer proximity to the point of
28 consumption. Just-in-time delivery, particularly important for perishable products, is another
29 feature of DM. Further to that, local sourcing of materials and other resources reveals DM
30 might be a manufacturing system with potential for greater efficiency and resilience. Other
31 significant characteristics include cloud manufacturing services, rapid prototyping and
32 tooling, automated monitoring, control and optimization of stock and material flows, and
33 dynamic production environments. Furthermore, enhanced connectivity via IoT enables
34 adaptive supply chains. In some sectors, such as textiles, DM could bring about the re-
35 shoring and repatriation of manufacturing.
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48 These developments have wide ranging consequences. For example, it does not simply imply
49 a greater number of dispersed locations of manufacture, but changes the nature of the value
50 chain, with further implications for markets, organisational structures and distribution
51 networks. It brings with it changes, in terms of location and scale, to manufacturing's
52 economics and organization. Avoidance of investment risk arising from high up-front capital
53 cost is possible, and there are further reductions in operational overheads. With these
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3 manifestations of Commons Based Peer Production (CBPP), along with co-creation and the
4 growth of public space manufacturing capacity, we are seeing the democratization of
5 manufacturing in action.
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8 9 10 **5.2 Enabling production technologies and Infrastructure**

11 *Technologies:* The challenges surrounding the enabling of production technologies for DM
12 concern both technology readiness and production readiness. DM is only possible if we can
13 digitize information and control it. The prerequisites for DM include maturity of technology,
14 material control, understanding of material properties, monitoring (e.g., remote monitoring),
15 sensors, and connection to the customer base, supplier base, consumer base, etc. This is
16 intended to lead to user-driven design of customized goods and services at a local scale
17 through connected supply chains and on-demand production, with producers sharing support
18 services between local manufacturing hubs.
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27 These requirements are increasingly being met by advancements in areas such as additive
28 manufacturing. Two-sided platforms have been created, linking customers wanting to access
29 3D printing capability with owners of 3D printers. The range/library of materials conducive
30 to 3D printing/additive manufacturing is constantly expanding, and the software that enable
31 3D printing files to be created, modified and distributed is inexorably improving. Critically,
32 the cost of 3D printing equipment and materials is reducing. There remain skills challenges
33 around the CAD skills required to create designs, and the new technical skills that are
34 required for data analytics, integration and visualisation.
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42 Taking other examples, the production of furniture and other products is feasible using a
43 CNC router, though there are challenges around proximity to and awareness of CNC routing
44 facilities. In pharma, continuous crystallization enhances API quality, whilst continuous
45 formulation can provide both product variety and SKU complexity management.
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50 *Infrastructure:* Infrastructural capability is crucial to the long-term expansion and adoption of
51 DM, from web platforms to community manufacturing spaces. Connectivity is an integral
52 part of this, combined with advancements in digital infrastructure, data and data analytics,
53 and 'Big data'. Concerning the digital infrastructure, that can enable process analytical
54 technologies (PAT), smart packaging using printed electronics, RFID, Near Field
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3 Communication (NFC) and patient management systems. The possibilities of connectivity
4 include the ability of networks of designers and fabricators enabling the local making of
5 designs. There are, however, concerns about the management of training standards for
6 operators who are working far from the central manufacturer.
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11 Open manufacturing, as envisaged as part of the DM paradigm, entails the creation of
12 community spaces. There is a growing ad hoc infrastructure of open access workshops and
13 globally standard protocols. Collaborative production utilizes creative commons licensing
14 and the infrastructure of the web to connect designers, producers and end users in ways that
15 enable a distinctive approach to the product. Suitable models of operation with risk-sharing
16 and appropriate indemnification by differing organizations will need to be factored in,
17 however. There are also infrastructural implications for global logistics.
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24 **5.3 Governance and regulatory issues**

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26 DM faces a number of regulatory and governance challenges that will need resolution in
27 order to facilitate its socio-economic-policy acceptance and spread. These will entail
28 challenges related to liabilities, coordination and governance, intellectual property,
29 transformation, regulatory approval both for production technologies and urban landscapes,
30 etc. A framework is necessary for regulation to keep pace with advancements in technology,
31 otherwise a number of institutional factors has the potential to frustrate the adoption of DM,
32 such as regulators not approving individual products, or permitting production in residential
33 areas or central city locations. There is further demand for regulatory and commercial
34 pathways that challenge current funding, reimbursement and commissioning models.
35 Standards, compatibility and certification are other outstanding topics, while DM will also
36 need to navigate different layers of governance.
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47 By its nature, DM enables multiple inputs in design. This may have implications for the
48 robustness of a product, perhaps even compromising product integrity. There are also glaring
49 IP implications in terms of ownership, necessitating a framework for IP sharing. IP protection
50 will be necessary for the prevention of copyright infringement for design and development
51 work. Business-to-business and business-to-consumer data sharing, governance, ownership
52 and security are key potential barriers to DM's adoption.
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3 In the pharmaceutical industry, several key issues arise. Quality approval regime is batch-lot
4 based, a system that is not strictly compatible with DM, and raises the question as to how
5 regulatory requirements for continuous processes are handled. The governance of dispersed
6 and remote operations is also an unresolved issue. GPs and Pharmacies digitally administer
7 prescription issuance and delivery, but they are static SC actors. And patient confidentiality
8 requires 'Chinese walls' within an integrated supply chain.
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13 14 15 **5.4 Resilience and sustainability considerations**

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17 Manufacturing processes can be proven in the laboratory at the scale at which they will be
18 made commercially, thus reducing business risk. It presents a useful means of optimizing
19 manufacturing processes and logistical operations. There are further prospects for closed-loop
20 production and consumption and the re-capturing of valuable materials. The cost of
21 production can be lower than the sum of the costs associated with manufacturing, holding,
22 transporting, and product shrinkage. We see that manufacturing is no longer informed solely
23 by a particular organization or group context, but instead is being shaped by cooperation and
24 communication over processes and networks, as end users engage with local makers and
25 designers across the world.
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34 In the clinical space, there are advantages regarding reduction of waste, transportation costs.
35 Access for advanced therapeutics that are otherwise difficult to transport and too costly to
36 make could be much improved. For pharmaceuticals, DM enables operations to be Inventory
37 light, thereby avoiding unnecessary production and wastage while being responsive to real
38 demand. There is improved access to drugs in a given geography, along with lower costs.
39 Reduced solvents in manufacturing will reduce Green House Gas emissions.
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46 DM poses new opportunities for businesses to share data, engage in data-driven open
47 innovation and create radically distinctive business models. There is greater flexibility and
48 capability to customize, and also meet the fast delivery requirements of consumers and
49 retailers. The platform-based approach of DM transports data, not materials, i.e., the 'maker'
50 can produce, finish and install the product. There are further benefits with regard to
51 personalization, up-scaling of local enterprise, and the utilization of spare capacity.
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3 There are, however, current performance limitations that include the quality and limited range
4 of materials, as well as their functionality. Business model uncertainty also surfaces. There is
5 both cost and difficulty associated with maintaining manufacture to the same quality at
6 several sites, along with control of transport and of delivery. There is also a shortage of the
7 required software and conceptual infrastructure. There are resilience challenges related to
8 disruptive impact, sustainable materials, environmental imperative, and liability of DM.
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13 14 15 **5.5 Transformation Challenges**

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17 One of the key transformational aspects of DM is the social context of the small-scale
18 economic model, along with the development of new organisational forms. The combination
19 of a digital network combined with digital fabrication enables decentralized and
20 geographically independent distributed production, and is fostering connected, more
21 meaningful and durable relationships between the producer and the end user. However, data-
22 sharing protocols do not currently exist within a digital connected supply chain. There are
23 also high up-front costs in new technology development, continuous processing systems and
24 IT infrastructure.
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32 DM represents a radically different model of consumer goods production, purchase and use.
33 DM offers a means for organizations to create and capture value, and it further holds the
34 promise of sustainability benefits across the product and material life cycles. DM might also
35 tackle unsolved problems, such as those related to the 'Factory in container' concept:
36 Operations issues, responsiveness, shelf life, perishability, wastages, demand driven supply
37 chains, scarcity driven supply chains, natural capital, reducing point of stress in the supply
38 chain, etc. Though there remains ambiguity about economic and environmental impacts, with
39 the risk of unpredictable financial returns, while material supply chain issues may also arise.
40 Per-unit manufacturing costs are generally not as low compared with mass manufacture.
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49 3D printing offers small-scale mass customization on a localized basis. Moreover, there is
50 potential for convergence between consumer 3D printing networks and inter-organizational
51 industrial 3D printing networks. In terms of the clinical, social and economic advantages DM
52 might provide, they include reduction of waste and transportation costs. It might also mean
53 the potential for provision of tailored, right-first-time treatments to all patients, and removal
54 of the need for repeat visits by the patient. DM will lead to improved access for advanced
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3 therapeutics that are otherwise difficult to transport and too costly to make. There are
4 infrastructure information and capability gaps, however, which include: assurance of quality,
5 resolving the matter of when ‘manufacturing’ becomes ‘practice of medicine’, etc.
6 Furthermore, chemists, engineers and operators are more familiar with existing batch plants,
7 with new skills being required for running continuous operations.
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13 There is a growing understanding that physical products can increasingly be treated as
14 information products, altering the basis for the distribution of manufacturing. New DM
15 technologies allow new design freedoms, democratizing manufacturing through prosumption.
16 DM enables a connected, localized and inclusive model of consumer goods production and
17 consumption that is driven by the exponential growth and embedded value of big data. There
18 may also be an ethical context, in that these trends might reduce social exclusion, and also
19 feeding into the ‘self-reliant city’ concept. However, there are challenges to up-scale whilst
20 retaining the value that the model aims to create through personalization, localization and
21 inclusivity. Moreover, building infrastructural capability entails significant sunk costs, as for
22 example it requires public investment in distributed manufacturing in inner city public
23 spaces.
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33 There continues to be uncertainty and ambiguity regarding how governance structures will
34 emerge and evolve. Indeed, there is a comparative lack of regulatory harmony across
35 different geographical markets. Regulatory approval will be required for sites that may
36 function as a mobile ‘factory in a box’. Unregulated production may lead on to production
37 and consumer demand ‘anarchy’ (e.g., plastic guns), so there will be an onus placed on DM
38 to be socially responsible, and to promote a responsible behavior of consumption.
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45 **6. Opportunities and Challenges**

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47 As DM continues to be rolled out in real world scenarios, a more coherent picture of the
48 opportunities and challenges for DM are emerging. This overall status could be prone to
49 fluctuation as certain problems are resolved and others arise during the course of DM’s
50 development.
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55 **7. Conclusion and Future Research Agenda**

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3 In conclusion, drawing from the case examples, DM can be defined as *'the ability to*
4 *personalize product manufacturing at multiple scales and locations, be it at the point of*
5 *consumption, sale, or within production sites that exploit local resources, exemplified by*
6 *enhanced user participation across product design, fabrication and supply, and typically*
7 *enabled by digitalization and new production technologies'*.
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13 DM potentially presents significant opportunities, most notably an enhanced capability to
14 manufacture closer to the point of demand, with greater specificity to individual needs. DM
15 could thus become a vehicle for mass customization, inventory-light manufacturing models,
16 improved accessibility to new customers and markets (e.g., in healthcare), with small-scale
17 factories deployed (and perhaps re-deployed) to the point of need. DM encapsulates social,
18 economic, and technological aspects. From our case analysis, it is enabled both by new
19 production and infrastructural technologies. Whereas there are varied definitions of DM, a
20 number of key characteristics are discernible that distinguish DM from the centralized
21 production paradigm and yet bear resemblance to the earlier artisan era of craftsmanship. The
22 emerging characteristics of DM include:
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- 31 • Digitalization of product design, production control, demand and supply integration,
32 that enable effective quality control at multiple and remote locations
- 33 • Localization of products, point of manufacture, material use enabling quick response,
34 just-in-time production
- 35 • Personalization of products tailored for individual users to support mass product
36 customization and user-friendly enhanced product functionality
- 37 • New production technologies that enable product variety at multiple scales of
38 production, and as they mature, promise resource efficiency and improved
39 environmental sustainability
- 40 • Enhanced designer/producer/end-user participation, unlike the world of the artisan,
41 enabling democratization across the manufacturing value chain
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52 The below table illustrates how DM contrasts with other recent manufacturing paradigms.
53 The list here includes cloud manufacturing, a significant topic of recent research (Ren *et al.*,
54 2014; He and Xu, 2014; Xu, 2014; Wu *et al.*, 2013; Wu *et al.*, 2014). However, as can be
55 readily seen, none of the other major paradigms covers the gamut of characteristics –
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3 personalization, digitization, localization, new production technologies, multi-user
4 participation – that DM exhibits.
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12 There are a number of unknowns that invite caution about making predictions about the
13 widespread adoption of DM, and key specific questions need to be resolved in order for DM
14 to realize its potential. For example, it is yet to be determined for which products and
15 production systems DM looks most promising. Moreover, where does value-add shift within
16 a DM landscape? Is it going to be in process technology equipment, raw materials, design,
17 sensor technology, ICT and data analytics? There are also some key challenges for DM to
18 overcome if it is to supplant the prevailing paradigm based on low cost geographically
19 dispersed mass production. Is DM going to be characterized by lower system costs? Will it be
20 more resilient, more resource efficient, or more sustainable? Will DM flourish within a new
21 community model featuring shared manufacturing systems and community manufacturing
22 facilities? Does DM offer a new industrial and urban landscape? And will it also operate
23 within an ethical context that seeks to minimize social exclusion?
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34 Whether DM will be mainstream or remain a niche activity will vary from sector to sector,
35 and will likely also be informed by regulatory contexts. DM might significantly reduce
36 supply chain costs, improving sustainability and tailoring products to the needs of consumers.
37 An effect of these advances is the advent of new business models, supply chains and
38 emerging industrial systems, which themselves will have ramifications influencing industrial
39 and social policy. DM itself is likely to evolve, and require redefinition as it matures.
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46 From a policy perspective within post-industrial societies, DM may present opportunities for
47 revitalizing manufacturing through the establishment of a new manufacturing materiality.
48 This may take the form of re-shoring and repatriating of high quality, design-led products, the
49 development of new manufacturing organizational forms and business models as the eco-
50 system evolves from communities of practice into industrial capacities, and the provision of
51 innovative routes out of austerity. This may require a mixture of social and industrial policy.
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3 For instance, the availability of “free” 3DP technology in social spaces, publicly or privately
4 funded, together with subsidized printer supplies and raw materials (grapheme, plastics).
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8 In both developed and developing world, DM, with careful state management could lead to
9 ordinary citizens having access to their own means of production. Such a diffusion of small
10 sized affordable 3D printing capacity would promote a model of environmentally sustainable
11 technological and economic development. Consumers will operate as pro-designers in the
12 future 3DP production system rather than their traditionally passive role of low involvement
13 and participation in the manufacturing process.
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19 There is a need for further research work, including prototyping, case studies and impact-led
20 investigations, that explore the feasibility of firms, individuals and communities
21 implementing this disruptive technology and developing new organizational forms and
22 business models.
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29
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Author	Perspective	Key Definitions and Concepts	Summary
Kohtala (2015) Johansson et al. (2005)	Economy	<p>“The notion of distributed production conceptualizes a shift in consumption and production patterns away from conventional mass production, with its long, linear supply chains, economies of scale and centralizing tendencies.”</p> <p>“The notion of “distributed economies” promotes small-scale, flexible networks of local socio-economic actors using local resources according to local needs, in the spirit of sustainable development.”</p> <p>“Distributed economies (DE) is currently best described as a vision by which different innovative development strategies can be pursued in different regions. Similar or complementary schemes can be brought together into networks to provide the advantage of scale without the drawbacks of inflexibility. Rapid implementation offers a means of exploiting the large wealth of knowledge and potential innovation developed in universities and research institutes.”</p>	<p>DM embodies a new form of production inimical to conventional centralized mass production.</p> <p>DM fits into a concept of “distributed economies” that features different regions pursuing different innovation development strategies according to local needs, and further characterized by flexible networks of diverse actors.</p>
Leitao (2009), Kohtala (2015), Tuma (1998), Windt (2014)	Firm	<p>“... the companies tend to divide into small sub-companies, each one having a specific core business, focusing on the production of a few specialized ranges of products.”</p> <p>“... the companies tend to share skills and knowledge, networking together to achieve global production. This situation provides the opportunity for small and medium enterprises (SME) to improve their competitiveness within the global economy, participating in supply chains or forming virtual enterprises and e-alliances to fulfil specific customer demands.”</p> <p>“DM takes the perspective of production planning for networked or “virtual” enterprises aiming for flexibility, agility and greater customer orientation in manufacturing and mass customization.”</p> <p>“The idea of virtual enterprises is to implement modern management-trends like key operations”, “distributed production” and “maximal customer orientation” with the support of advanced computer and telecommunication systems.”</p> <p>“Two different interpretations of the term Distributed Manufacturing (DM) exist. The first one refers to the concept of creating value at geographically dispersed manufacturing locations of one enterprise. The second interpretation of DM is in the context of Distributed Manufacturing Systems (DMS), which are defined as a class of manufacturing systems, focused on the internal manufacturing control and characterized by common properties (e.g., autonomy, flexibility, adaptability, agility, decentralization).”</p>	<p>Within the DM paradigm firms operate via networks sharing skills and knowledge, in order to achieve global production. SMEs are empowered to participate in supply chains and form ‘virtual’ enterprises. There is implicit flexibility, agility and greater customer orientation in manufacturing and mass customization.</p> <p>DM comprises a category of manufacturing systems characterized by autonomy, flexibility, adaptability, agility, and decentralization.</p>
Kohtala (2015)	Supply chain	<p>“The notion of distributed production conceptualizes a shift in consumption and production patterns away</p>	<p>DM marks a shift from long supply chains, with agility being a key characteristic, and is best</p>

		<p>from conventional mass production, with its long, linear supply chains, economies of scale and centralizing tendencies.”</p> <p>“Agility is a key characteristic, as the term distributed has its roots in computing and communications, when a more robust network that distributed nodes rather than centralizing or decentralizing hubs or switches was developed.”</p>	depicted by networks of distributed nodes.
Kohtala (2015) Benkler (2006)	Societal	<p>“The blurring between production and consumption, another key characteristic of distributed production, may instead be referred to as “prosumption” and the consumer a “prosumer”.”</p> <p>“The target was a spectrum of distributed prosumption activities as the focus of research, where the consumer (customer, user, prosumer or ‘maker’) is able to intervene in design and production to a greater extent than in mass production, resulting in a tangible artefact. This increased agency, integration or input ranges from personalized options in a mass customizing or distributed manufacturing service to fabbing: machine-aided self-fabrication of one's own design, e.g. in a Fab Lab (a space equipped with small-scale digital manufacturing equipment the individual operates herself).”</p> <p>“The networked environment makes possible a new modality of organizing production: radically decentralized, collaborative, and nonproprietary; based on sharing resources and outputs among widely distributed, loosely connected individuals who cooperate with each other without relying on either market signals or managerial commands.”</p> <p>Key disruptive characteristics include: “personal manufacturing, personal fabrication or fabbing, commons-based peer production of physical goods, or simply making.”</p>	<p>DM provides a vehicle for the ‘prosumer’ to become a prominent actor in the realm of contemporary manufacturing.</p> <p>The prosumer has agency to contribute to all phases of design and production, becoming integrated into the process to whatever degree they choose, up to the level of ‘fabbing’ - machine-aided self-fabrication of one's own design. Their input provides the impetus for customization and personalization of products and services.</p> <p>This decentralized, collaborative and nonproprietary modality of production has acquired the label “commons-based peer production”.</p> <p>The personal dimension to DM is one of its most disruptive characteristics.</p>
Kohtala (2015)	Sustainability	“Material, physical goods as the output of distributed production call particular attention to appropriate, responsible and equitable use of materials and energy.”	The use of materials and energy in DM is, by intended design, more responsible and equitable.

Table 1. Key DM definitions and concepts from literature.

Cases	Context	Characteristics of DM	Opportunities and Challenges			
			Enabling production technologies and Infrastructure	Governance and regulatory	Resilience and sustainability	Transformation
1	3D printing	<ul style="list-style-type: none"> ▪ Production when needed and closer to point of consumption ▪ Integrated product ▪ Direct digital Manufacturing – rapid prototyping and tooling ▪ Economically viable, customized product on demand 	<ul style="list-style-type: none"> ▪ Two-sided platform linking customers wanting to access 3D printing capability with owners of 3D printers ▪ Software that enable 3D printing files to be created, modified and distributed ▪ Low cost of 3D printing equipment and materials ▪ CAD skills required to create designs. 	<ul style="list-style-type: none"> ▪ Standards, compatibility, regulation and certification ▪ Ownership issues 	<ul style="list-style-type: none"> ▪ Sustainability benefits across the product and material life cycles ▪ Business model uncertainty ▪ Material supply chain issues ▪ Current performance limitations including the quality, limited range of materials and functionality 	<ul style="list-style-type: none"> ▪ Convergence between consumer 3D printing networks and inter-organisational industrial 3D printing networks ▪ Ability of organizations to create and capture value ▪ Ambiguity about economic and environmental impacts ▪ Uncertainty and ambiguity regarding how governance structures will emerge and evolve
2	Healthcare	<ul style="list-style-type: none"> ▪ Supports a highly customized, low volume, localized, “Make to Order” (MTO) approach ▪ Just-in-time delivery, particularly important for perishable products ▪ Reduction of operational overheads ▪ Avoidance of investment risk arising from high up-front capital cost ▪ Cost reduction through terminal customization close to consumption 	<ul style="list-style-type: none"> ▪ Sharing support services between local manufacturing hubs ▪ Management of training standards for operators who are working far from the central manufacturer ▪ Suitable models of operation with risk-sharing and appropriate indemnification by differing organizations 	<ul style="list-style-type: none"> ▪ Demanding regulatory and commercial pathways that challenge current funding, reimbursement and commissioning models ▪ Assurance of quality ▪ Comparative lack of regulatory harmony across different geographical markets 	<ul style="list-style-type: none"> ▪ Manufacturing process could be proven in the laboratory at the scale at which they will be made commercially, thus reducing business risk. ▪ Clinical, social and economic advantages – reduction of waste, transportation costs, decrease in repeat visits by the patient ▪ Tailored, right-first-time treatments to all patients, improving access to ACBT that are otherwise difficult to transport and too costly to make. 	<ul style="list-style-type: none"> ▪ Infrastructure information and capability gap ▪ Multiple regulatory regimes across different geographies ▪ Cost and difficulty of maintaining manufacture to the same quality at several sites, of control of transport and of delivery of the therapies

3	Consumer Goods and Connected Manufacturing	<ul style="list-style-type: none"> ▪ Opportunity for personalization ▪ Up scaling of local enterprise ▪ Development of user-driven products that are tuned to the requirements of local markets ▪ Automated monitoring, control and optimization of stock and material flows ▪ Mass customization and bespoke fabrication 	<ul style="list-style-type: none"> ▪ Data integration and analytics ▪ New technical skills are required for such as data analytics and visualization ▪ Incentivizing take-back and reward schemes for more durable consumer goods ▪ User-driven design of customized goods and services at a local scale through connected supply chains and on-demand production ▪ Open Source Innovation Distributed Retailing 	<ul style="list-style-type: none"> ▪ Business-to-business and business to consumer data sharing, governance, ownership and security 	<ul style="list-style-type: none"> ▪ Opportunities for closed-loop production and consumption ▪ Re-capturing valuable materials ▪ Optimization of manufacturing processes and logistical operations ▪ Opportunities for businesses to share data, engage in data-driven open innovation and create radically distinctive business models 	<ul style="list-style-type: none"> ▪ Challenge to up-scale whilst retaining the value ▪ Connected, localized and inclusive model of consumer goods production and consumption that is driven by the exponential growth and embedded value of big data. ▪ Connected, more meaningful and durable relationships with the end user ▪ Monitoring, control and optimization of stocks and material flows
4	Community based production	<ul style="list-style-type: none"> ▪ Collaborative production ▪ Physical products can be treated as information products ▪ Open access workshops and low cost digital fabrication tools ▪ DIY culture 	<ul style="list-style-type: none"> ▪ Infrastructure of the web to connect designers, producers and end users web ▪ Infrastructure of open access workshops and globally standard protocols ▪ Proximity to and awareness of CNC routing facilities 	<ul style="list-style-type: none"> ▪ Commons licensing product ▪ Access workshops and globally standard protocols. 	<ul style="list-style-type: none"> ▪ Producers will be able to open up their business to another audience ▪ Utilize any spare capacity ▪ Engage with local makers and designers across the world. 	<ul style="list-style-type: none"> ▪ Linking digital network combined with digital fabrication ▪ Independent distributed production. ▪ Understanding and designing to the constraints of CNC routers. ▪ Risk of unpredictable financial returns ▪ Willing to do piece work, being willing to be public facing, and taking on the role of a maker rather than solely being a bureau service
5	Urban case study – smart city production system	<ul style="list-style-type: none"> ▪ Re-shoring and repatriating textile manufacturing ▪ Establishment of a new “production” materiality ▪ Creative routes out of austerity for the working poor 	<ul style="list-style-type: none"> ▪ Eco-system of manufacturing 3D weaving innovations ▪ Cooperate and communicate over processes and networks 	<ul style="list-style-type: none"> ▪ Need for IP policing protection for the prevention of copyright infringement for design and development work 	<ul style="list-style-type: none"> ▪ Incredible flexibility and capability to customize ▪ Cost of production can be lower than the sum of the costs associated with manufacturing, holding, transporting, and product shrinkage 	<ul style="list-style-type: none"> ▪ Significant sunk costs in building this new production materiality as it requires public investment in distributed manufacturing in inner city public spaces ▪ Per-unit

		<ul style="list-style-type: none"> ▪ Close proximity of manufacturing to urban customers ▪ Co-creation and sharing components with public space manufacturing capacity 			<ul style="list-style-type: none"> ▪ Manufacturing will no longer be informed by a particular organization or group context ▪ Fast delivery requirements of consumers and retailers 	<p>manufacturing costs are not as low as a mass manufactured</p> <ul style="list-style-type: none"> ▪ Development of new organisational forms
6	Continuous Manufacturing	<ul style="list-style-type: none"> ▪ Niche volumes for rare diseases ▪ Small scale distributed operations, located in clinics, hospitals, disaster areas ▪ Digital supply chain supported by sensors, intelligent packs ▪ Cloud based ERP distribution systems ▪ Real-time patient data on compliance ▪ Connected SC using IoT enables adaptive supply chains 	<ul style="list-style-type: none"> ▪ Continuous crystallization enabling API quality ▪ Continuous formulation providing product variety & SKU complexity management ▪ Digital infrastructure including: <ul style="list-style-type: none"> - Process analytical technologies (PAT) - Smart Packaging using printed electronics, RFID, Near Field Communication (NFC) - Patient Management Systems 	<ul style="list-style-type: none"> ▪ Quality approval regime is batch-lot based – how to handle regulatory requirement for continuous processes? ▪ Governance of dispersed and remote operations ▪ Managing remote plant operations to GMP standards ▪ GPs and Pharmacies digitally administer prescription issuance and delivery – but static SC actors ▪ Patient confidentiality requires ‘Chinese walls’ within an integrated Supply Chain 	<ul style="list-style-type: none"> ▪ Improved quality but more informed QA practices based on advanced understanding of kinetics, processing ▪ Inventory light avoiding unnecessary production / wastage and responsive to real demand ▪ Improved access to drugs in a given geography ▪ Lower costs and improved affordability of medicines ▪ Reduced solvents in manufacturing will reduce Green House Gas emissions 	<ul style="list-style-type: none"> ▪ Existing assets in batch manufacturing are sunk costs ▪ Chemists/ Engineers/ Operators more familiar with existing batch plants – new skills required for Continuous Data-sharing protocols do not exist within a digital connected supply chain ▪ Regulatory approval for multiple productions sites – sites that may be mobile ‘factory in a box’ ▪ High up-front costs in new technology development in Continuous Processing, IT infrastructure

Table 2. Cross case analysis – DM characteristics and key opportunities and challenges.

DM characteristics	Case 1 3D Printing	Case 2 Healthcare	Case 3 Consumer Goods and Connected Manufacturing	Case 4 Community based production	Case 5 Smart City Production System – 3D Weaving	Case 6 Pharmaceutical Case study
Personalization	Allows new design freedoms, rapid prototyping. Lot size down to one (job shop production at economic cost), where required.	Exploit the patient-specific characteristics of ACBT products.	Mass customization and bespoke fabrication.	Proximity to and interaction with the maker will give customers the ability to be involved in the production and customization process as well as being a (relatively) cost effective means to have bespoke items made for them.	Made to order due to production being near to market or individual customer, allows co-creation in product development.	Emergence of personalized and stratified medicines.
Digitalization	Rapid prototyping, tooling. Direct digital manufacture.	Develop small, automated or semi-automated units capable of producing the therapies from, for example, kits provided by the OEM.	Automated monitoring, control and optimization of stock and material flows. Open Source Innovation Distributed Retailing.	Digital networks. Platform based approach transports data not materials, taking advantage of the growing ad hoc infrastructure of open access workshops and globally standard protocols.	Cooperation and communication over processes and networks in order to achieve the optimum localized manufacturing output (per day) to meet city demand.	Digital factories, smart packaging, and sensors. Medical devices.
Localization	Manufacture of economically viable customized products on-demand.	Through DM, ACBTs could be produced at or near the point of care.	Radically different model of consumer goods production, purchase and use. Increased resilience. Closed-loop production and consumption.	Decentralized and geographically independent distributed production. Open access workshops.	Re-shoring and repatriation of textile manufacturing. Close proximity of manufacturing to urban customers.	Intervention in local spaces – pharmacy, clinics, hospitals, home.
New production technologies	3D printing (additive manufacturing).	Automated manufacturing and delivery processes coordinated within the clinical setting.	Optimization of manufacturing processes.	Digital fabrication. Physical products can increasingly be treated as information products.	3D weaving, e.g., to improve the woven structures of their luxury wool fabrics.	Micro-reactors and continuous manufacture providing high variety, low volume.
Multi-user participation	Democratizes manufacturing through presumption.	Multiple healthcare professionals involved in therapy selection and delivery.	User-driven design of customized goods and services at a local scale through connected supply chains and on-demand production.	Community based production system - new generation of designers, makers and tinkerers.	Strong co-creation and sharing components with public space manufacturing capacity.	GPs, clinics, manufacturers, patient (compliance), regulators (technology process approval).

Table 3. Key characteristics of DM implied in exemplar cases.

	Personalization	Digitization	Localization	New production technologies	Multi-user participation
Virtual Enterprise	No	Yes	Partly	Implied	No
Industry 4.0	Possible, but not at the individual level	Yes	No	Yes	Partly, but not end user
Grid Manufacturing	No	Yes	Partly	Implied	No
Concurrent Engineering	No	Possible	No	New	Partly, but not end user
Cloud based manufacturing	No	Yes	Partly	Implied	No
Smart manufacturing	Possible, but not at the individual level	Yes	No	Yes	Autonomous manufacturing, but does not involve end user
Distributed Manufacturing	Yes	Yes	Yes	Yes	Yes

Table 4. Comparison of other new manufacturing paradigms with Distributed Manufacturing.