Redistributed manufacturing ecosystems for healthcare: an in-depth case study of on-body manufacturing using a micro-factory.

Abstract

The shift from centralised to redistributed manufacturing (RDM) enables lower volume production closer to the site of use. The potential benefits of RDM are highlighted in the literature, but in this emerging field, understanding of how its adoption changes relationships within an ecosystem is limited. We provide a novel case study of an emerging portable, digitised micro-factory technology from healthcare that localises manufacture of therapeutics on the body of the patient. Taking a manufacturing ecosystems perspective, the paper contributes empirical evidence showing how the introduction of the micro-factory causes a change in the context of manufacture at the micro level and a change in inter-organisational and institutional relationships at the meso level. Our research shows how inanimate agents, such as digital micro-factories, can be actors within an ecosystem. We position the digitised micro-factory engaged in the service encounter as a resource integrating actor at the micro level of our ecosystem. The micro-factory's structure, components and architecture, are positioned at a new 'sub-micro level'. This paper contributes to RDM theory, showing that technical

advances can push redistribution of manufacturing to the individual level, where components of the micro-factory enable simultaneous production and use.

Managerial Relevance Statement

The study is of relevance to managers implementing RDM in healthcare. The shift to RDM is regarded as a key strategy in meeting the rising costs of caring for an aging population and in meeting demand for specialist personalised therapies. The findings demonstrate that whilst the move to RDM may act as an enabler for scalable solutions, the digitised device does not replace the service delivery by people. Instead, established relationships are changed, and new roles and relationships are formed. The inclusion of the patient and the patient's family as actors in the ecosystem highlights how the costs and responsibility for personal care (physical, social and emotional) are not removed from the system, but shifted to other actors. This finding is important as for a new digital device to be successfully adopted into a healthcare ecosystem, time and space is required for new trusting relationships to be developed.

Keywords: Redistributed manufacturing; healthcare; ecosystem; sub-micro level

1. Introduction

Manufacturers face the challenge of delivering operational efficiency whilst providing customised solutions at scale [1]. Redistributed manufacturing (RDM), provides a potential solution by creating radical change in the location of manufacture, away from a centralised manufacturing unit producing high volumes, to geographically dispersed sites, located closer to the point of use, and where production volumes are low [2]. This shift, typically enabled by digitization and new production and infrastructure

technologies, allows for the customization of a product at multiple scales and locations [3]. The shift also creates change in the end user role, allowing participation in design, production and supply processes, enabling customisation [2]. The transformative potential of RDM is of particular interest to the field of medical care [4-5], providing the potential to meet the needs of an aging population, personalised treatments, increased patient freedom of movement, and improved resilience due to a reduced reliance on supply chain logistics [6-7]. Phillips et al. [4] highlight that as RDM entails the shift of location of production closer to the patient, there is a need to map the new configuration of industrial roles and responsibilities, new clinical processes, associated risks and dependencies.

This study provides a novel case study of a prototype healthcare technology. The Optimising Me Manufacturing System [OMMS] prototype proposes a break from the current system of centralised, laboratory-based therapeutic production with drug delivery in a hospital setting, to a distributed system of therapeutic manufacture and delivery via a digitised, autonomous micro-factory, located at the point of use on the patient's body. The technology places the customer central to the co-creation of the health service. The role of the end user as a co-creator of value is therefore key to the RDM model, however the RDM literature has so far focused on supply chain actor relationships, with limited attention to the role of the customer or end user (demand side). This is recently recognised in a study [8] where it is noted that healthcare supply chain and ecosystem studies have primarily focussed on hospitals and their upstream suppliers. Given this shortcoming, Phillips et al. [4] argue that an integrative value perspective of RDM is needed, which includes the manufacturer, the healthcare system, the customer and the patient population. To provide this holistic view of RDM,

encompassing all who contribute to and benefit from the system [9] this paper applies an ecosystems perspective [10-11].

An ecosystem view emphasises interactions at multiple levels. At the micro level are dyadic actor to actor relationships. At the meso level are midrange interactions between industries or communities, and at the macro level are wider social structures and activities [12]. By employing the ecosystem model as a lens, we are able to locate and understand changes in relationships at different levels during RDM. However, there is currently a lack of clarity and evidence on the role and position of tangible products and their digitised components (e.g., OMMS technology) within the ecosystem. Combined with calls from Phillips et al., [4], it is evident from the literature that the following research questions need addressing:

Research questions:

1. What is the role and position of the digitized object in the RDM ecosystem?
2. How does the shift to redistributed manufacturing, and the introduction of a portable micro-factory, impact on the roles and relationships between actors in the ecosystem?

This paper contributes to the RDM and ecosystem literatures by revealing how the introduction of a portable, automated micro-factory [OMMS] causes a change in the context of service delivery at the micro level, and a change in institutional and socio-technical relational context at the meso level. We give empirical evidence for the positioning of the digitally enabled object at the micro level. In doing so we identify a new layer of value creation, ‘the sub-micro level’, representing the micro-factory’s components and architecture. We demonstrate that the capability to deliver a bespoke therapeutic treatment at scale is enabled by the micro-factory’s digital sensors and modular architecture at this sub-micro level. RDM is theorised as shifting manufacture

closer or at the point of use. This paper extends theory by showing that RDM can enable a shift to simultaneous production and use.

This paper is structured as follows. Section 2 presents background literature on redistributed manufacturing and ecosystems. Section 3 presents the methodology, introducing our exploratory case study. Section 4 presents our findings, before section 5 concludes the paper with theoretical and managerial implications, limitations and future research directions.

2. Literature Review

2.1 Centralised and Re-distributed Manufacturing Within Healthcare

Redistributed manufacturing (RDM) is a paradigm shift in manufacturing, towards a system of dispersed manufacturing facilities, located close to the point of use, with low volume production [2; 13]. The move to RDM involves changes to three key elements of the traditional system: a change in the location of production; the development of new technology; and the involvement of the end user [14]. Radical change in the geographical dispersion of manufacturing is driven by the development of new infrastructure and production technology, such as 3D printing and continuous manufacture, which provide new capabilities of automation, flexibility, complexity and efficiency [15]. Technological developments and proximity to the customer enables a change in role of the consumer, who can participate in the design, production and supply process, leading to greater customisation [2]. In healthcare, RDM means shifting manufacturing systems closer to the point of clinical need, with health service providers forecast to operate and maintain manufacturing platforms in hospitals, clinics and mobile vehicles. The shift to RDM is regarded as having potential to deliver cost effective treatments and reduce wastage and travel time, resulting in a lower carbon

footprint. As such, RDM is considered a key strategy in meeting the rising costs of caring for an aging population and in meeting demand for specialist personalised therapies [6].

Personalised medicines, made from patients' blood cells, have been highly effective in clinical trials and have the potential to revolutionise cancer care [16-17]. Treatments are costly, involve frequent hospital visits and often long stays in specialist care units. Personalised medicines involve therapeutic manufacture in a laboratory and delivered in hospital, which represent a system heavily reliant on skilled human labour at all stages and involves complex and high-risk transport and logistics. A RDM system in which therapeutics are manufactured in a bench top machine within laboratories located closer to the patient is being explored [18-19]. In the benchtop system the location of the manufacture of the therapeutic changes, but the context of therapeutic delivery to the patient (the hospital), and the patient and their families' experience remains largely unchanged. Hospital care places a heavy burden on families and impacts on quality of life [20]. In addition to the side effects of treatment, and high risk of hospital-acquired infection, patients commonly experience exhaustion, disruption of family life, long distance travel, isolation and confinement to hospital [21-22]. To address these issues, programmes have been developed to provide some parts of cancer treatment at home.

In the UK, delivering care closer to home has become an NHS priority as it reduces the burden on hospital beds and supports the ethos of person-centred care [23]. Treatment at home remains dependent on a centralised system for therapeutic manufacture, but changes the location of therapeutic delivery, requiring a new configuration of healthcare delivery, heavily reliant on human labour [24]. For example, in home chemotherapy for paediatric leukaemia, therapeutics are manufactured by

skilled operatives in a laboratory and the first therapeutic dose is administered in hospital under the care of an oncology consultant. Follow-on doses are then administered to the patient at home, overseen by a specialised nurse who makes regular home visits, supported by community nurses who provide continued care [24]. While care at home can reduce costs to the health services provider, it carries a large [often hidden] cost to informal caregivers (e.g. family). Informal caregivers provide assistance with daily living activities and nursing care and often do so without training and with limited resources [25]. Informal carers often have little support and forfeit employment and career progression, impacting their short- and long-term finances [26].

A shift in context for therapeutic delivery, from the controlled hospital environment to an unknown and dynamic home setting, causes concern for some healthcare providers. Gavin *et al*., [27] reported that while healthcare providers supported home therapeutic delivery in principle, there are concerns over loss of control and oversight of the process. Doctors reported a decrease in patient interaction and felt treatment was better delivered in hospitals that contain the resources and knowledge, established protocols and communication systems [28]. Nurses delivering therapeutics in the home expressed concerns over the availability of resources, the lack of policies and structures to ensure safe and effective treatment, and increased workloads [27]. Patients are reported to prefer treatment at home, but also have concerns over the reduced medical expertise in the home setting, and felt more secure in a hospital. These fears were mitigated with clear communication protocols between the medical staff and the home [21] and clear protocols for therapeutic administration and management of hazardous material [27]. Also important to successful home treatment are strong communication links between medical staff and patients, this is enhanced by digital

communication which provides improved access to information and increased flow of information across the healthcare system [29].

The current three systems of cancer care discussed (centralised, RDM, and at home delivery) are delivered through a complex set of relationships between the laboratory, the hospital, the patient, the patient's family, and community healthcare workers. Within the centralised system, the therapeutic is manufactured in a laboratory and delivered in hospital; in the RDM system, the therapeutic is made closer to the patient and delivered in hospital; in the home delivery system the therapeutic is manufactured in a central lab, but the patient remains at home. All three systems rely on clinically trained staff who can oversee the manufacture of the therapeutic product and its delivery to the patient, and involve transportation of the therapeutic from the lab to the patient. This paper develops understanding of potential changes to a healthcare ecosystem when a more radical OMMS RDM at home system is created, and treatment is manufactured and delivered on the patients' body while at home.

2.2 An Ecosystems Approach

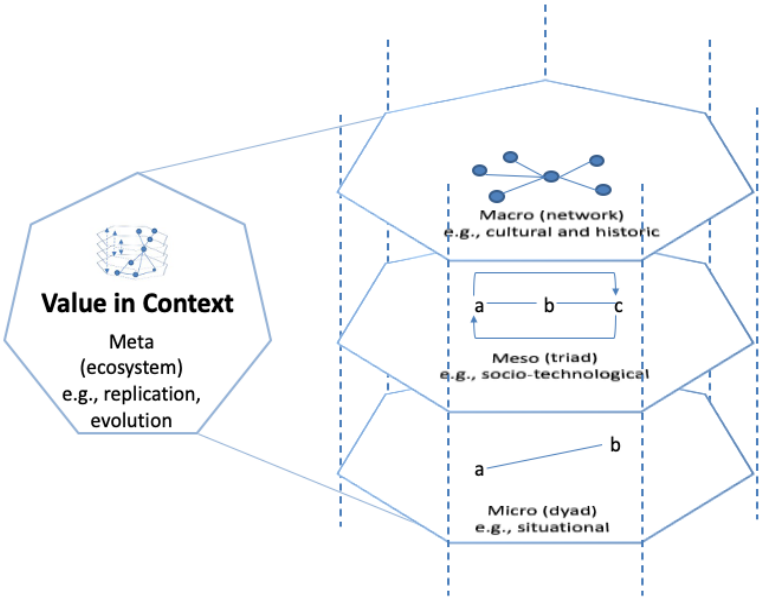
Despite the importance of the end user within the RDM model, RDM literature has tended to focus on supply-side dynamics [see 2; 6; 30; 31], excluding the end user and their partners as co-creators of value. To address this gap, we draw on the ecosystems literature to enable the inclusion of the patient and their wider support networks as actors in the system of therapeutic manufacture and delivery. An ecosystem perspective provides a holistic view of service provision from the perspective of a focal actor, extending beyond the boundary of the firm to include all actors in the firm/client network who interact to co-create value [32]. In contrast to a linear value chain perspective, which is solely focused on financial value as an end point for the firm, an

ecosystem encompasses a wider set of interconnected and interdependent stakeholders, all of whom must both contribute and derive benefit for the system to thrive [9].

Embeddedness within an ecosystem, and a capability to utilise ecosystem knowledge, improves competences [33]. Depending on the unit of analysis, an ecosystem may be focused around a central actor (e.g. the entrepreneur or firm) and their affiliated communities and contexts [34]; a digital platform and its peripheral firms who connect via a shared interface [35]; or around a value proposition and the activities involved in creating and realising value [11]. In this paper we take the latter view. Key elements of the ecosystem from the value proposition perspective are the activities that need to happen to realise that value proposition, the actors who undertake these activities, the positions of the actors within the activity streams, and the links between them through which knowledge, data, materials and funds are transferred [11].

An ecosystems approach emphasises a multi-level perspective on value creation, encompassing micro, meso and macro levels of interaction [12], see figure 1. The multi-level perspective reveals details surrounding value co-creation that may be missed when studying only dyadic relationships, i.e., a single level [36]. At the micro level are interactions between individual actors, e.g., actor level dyadic service encounters that may be B2C or B2B. At the meso are wider interactions, creating value at the wider industry or community level. The macro view highlights cultural contexts in which actors' operate. Levels of the ecosystem are not mutually exclusive, but interconnected and continually evolving.

Figure 1. Layers of the Ecosystem: micro, meso and macro [12].



Digitised objects are influential in value creation, but their role within the ecosystem has not been sufficiently theorised [36]. Machines, technologies, and inanimate agents have been included as actors at the micro level [32 ;36]. Lusch and Nambisan [32] define information technology as an active agent, triggering or initiating innovation, impacting other actors and their choices, and enabling efficient and effective value creation. Akaka and Vargo [37] argue that technology is shaped by the macro level social structures of the people who designed it and therefore technology itself acts to reinforce social structures. They view technology as an operant resource, capable of acting on other resources to create value, suggesting that digitised products may be classed as actors. However, these authors propose that the issue needs further exploration and deeper understanding [36], as does the question of whether products with autonomous capabilities are classed as inanimate agents [38]. Research on these topics therefore remains incomplete and this leads to our first research question:

RQ1: what is the role and position of a digitized micro-factory in the ecosystem?

2.3 Actor relationships in digital ecosystems

Digitisation requires extensive interactions between actors at the micro and meso levels of the ecosystem. Digitization enhances existing connections between people, organisations and things, and creates new connections [10], leading to increased levels of engagement between actors across the ecosystem [39]. At the micro-meso level, Lusch and Nambisan [32] suggest that the introduction of digital technology may improve information sharing, and so contribute to the fostering and maintenance of a shared world view among actors. Whilst the introduction of digital technology may improve information sharing, the successful introduction of new technology is dependent on heterogeneous actors having a shared world view on technology itself, and a willingness to adopt innovative technological services. A key reason innovations fail in the market place is social resistance; new propositions will only be accepted if institutions in the ecosystem can adapt [40].

Walrave *et al*. [40] argue that actors in an existing ecosystem are invested in an established regime and are locked into solutions that support or improve that regime, putting innovators at a structural disadvantage in the market. Lock-in goes deeper than just the micro level actor-to-actor interactions, extending to the meso and macro levels. When innovations are adopted, the process is not straightforward and takes time, as innovative solutions need to be integrated at all levels of the ecosystem [41; 42]. To overcome resistance, Walrave et al. [40] suggests pioneers adopt strategies at the meso level to increase likelihood of actors accepting the new proposition. Innovating firms can interact with actors to establish trust, share knowledge and build support for the new proposition [40].

The increased level of interconnectivity enabled by digitised objects changes how actors and resources are monitored and controlled, leading to a lack of clarity over

who owns the resulting data and issues of data privacy and governance [35].

Digitisation enables increased levels of information sharing in healthcare at the micro level e.g. between doctors and pharmacists, at the meso level, e.g. between hospitals and local government when dealing with infection outbreaks; and at the macro level, e.g. in providing statistical data on the functioning of the healthcare system to central government [43]. While the empirical evidence of RDM in healthcare is limited, some understanding of the changes in activities, the positions of actors and the links between them is emerging. Harrison *et al*. [18] identify that changes in activities of human operators, and the replacement of some roles by an automated service provider will lead to a shift of the burden of responsibility, and potential social and commercial barriers to adoption of RDM. In their white paper on RDM in healthcare, Phillips *et al*., [4] highlight that hospitals will need to adapt to become manufacturing sites, and there will be an integration between healthcare providers and commercial entities. Skilled laboratory operators will need to be available for localised manufacture, the multiple stakeholders involved in service provision will be required to share potentially commercially sensitive information, and new data management and communications systems will need to be established and maintained.

As yet unaddressed in the literature are the changes in relationships in the wider ecosystem in the shift to RDM. Wilden *et al*. [44] identify the need for research into actions and processes at the micro-meso levels that can be linked back to macro level research. These gaps lead us to our second research question:

RQ2. How does the shift to redistributed manufacturing, and the introduction of a portable micro-factory, impact on the roles and relationships between actors in the ecosystem?

3. Methodology

This study presents an exploratory case study of the prototype Optimising Me Manufacturing System [OMMS], a healthcare innovation is designed to manufacture and deliver therapeutics in a small device on the body. OMMS is in development and is currently at technology readiness level 3-4, developing proof of concept and laboratory bench level research prototypes. The prototype resulted from sandbox discussions between clinical experts. A digitised, modular system for manufacture and delivery has been developed, though each module is in the early stage of development. As OMMS is a new technology and a first of its kind, this paper pursues a single case study research design. The selection of a single case does not provide the explanatory power of multiple case studies or provide the confidence for generalizability, but two criteria meant that a single case study was suitable for this study. First, ecosystems are under-research in OM, which means the opportunity to investigate a complex phenomenon such as ecosystems and re-distributed manufacturing within its natural setting is welcome in order to provide novel insight, understanding and theory development for the research community [44; 45]. Such a process of generating a detailed understanding was supported by the rich dataset presented in this research [46]. Second, the specific case of healthcare ecosystems and the introduction of new medical devices was selected because it offered a persuasive and novel example of the challenges associated with ecosystem change more generally. This is because healthcare ecosystems have significant implications for society as a whole, but face unique and interesting challenges when it comes to change given the regulations surrounding it, the volume of actors involved in healthcare, and cultural norms around the location and oversight of healthcare provision. The unit of analysis is the ecosystem within which the case study is embedded, and the interaction between the ecosystem levels depicted within figure 1.

The main source of data are semi-structured interviews, which are triangulated with documents, observations, process maps and field notes.

The case selected is the OMMS, a prototype innovation in the manufacture and delivery of CAR T cell immunotherapy; a personalised therapy that has been successful in the treatment and cure of some forms of cancer. The OMMS prototype takes a laboratory manufacture and hospital delivery system and transforms it into a micro-factory where manufacture and delivery of therapeutics takes place in a small device on the body. The new system transforms service provision and changes the context of manufacture and use, as the patient can undergo treatment at home. We term this RDM home delivery.

3.1 Data Collection

Research investigated the role and position of a digitised micro-factory within an ecosystem and the impact a micro-factory will have upon relationships within that ecosystem. Data collection took place between February 2018 and June 2020. 38 semi-structured interviews were conducted, each lasting between 90-120 minutes. The purpose of the interviews was to build an in-depth understanding of the as-is and to-be ecosystems, understand the role and position of the microfactory within the ecosystem and finally, understand changes in the ecosystem following the microfactory introduction impact on the roles and relationships of actors in the ecosystem. To avoid subjectivity and bias from the interviews, respondents were sought from a broad spectrum of roles. In addition to the semi-structured interviews with relevant experts, an extensive set of archival and secondary data were collected and analysed to triangulate the findings from the interviews [45,46]. All secondary and archival data were collected from existing activities related to OMMS and the healthcare context studied (i.e., they

were not created for the purpose of this research). The secondary data supported the analysis and findings from primary data, adding validity to the results.

Interviewees included hospital directors and managers (7), paediatric and cancer consultants (7), oncologists (5), general practitioners (3), oncologist nurses (2), microbiologist (1), healthcare professionals (5), parents/legal guardians of children which survived treatments (2), and from the OMMS development team biochemical engineers (2), biochemist (1), specialist in computing, electrical, manufacturing and aeronautical (for fluid flow) engineering (1), and business researchers based in academic institutions across the UK (2). An interview protocol was developed from the literature reviewed in section 2 and used as an interview guide [46]. The interview protocol focussed on asking questions about the existing service, actor roles and relationships within the existing ecosystem, the proposed new treatment process (i.e., OMMS) and the role and impact of the digitised micro-factory on the new service ecosystem and actor relationships within it. See appendix A for interview protocol. A member of the OMMS team acted as project champion [45]. The project champion supported the recruitment of key informants for interviews and supported identification and provision of relevant documents.

Prior to the interviews, process maps of the current therapeutic delivery in hospital and proposed OMMS future state systems were created using the IDEF0 methodology. The current hospital process map was initially created from secondary data [47; 48], then adapted and validated by two CAR T bioprocessing academics and two domain expert clinicians. The OMMS delivery system IDEF0 map was created in a workshop with 5 project co-investigators, and further iterated during OMMS researcher interviews [total = 15]. The process maps were used as epistemic objects within

interviews [49], facilitating knowledge capture by engaging interviewees with a visual process image and reflective discussion via the structured representation of their design decisions, focussing attention on functions and overall process. To facilitate knowledge sharing the complex IDFE0 maps were simplified to produce process flow diagrams (Figure 3).

3.2 Data Analysis

To satisfy our objectives and address our research questions, the lead researcher coded and analysed the data using thematic analysis [50]. The analysis was checked by a second researcher and once agreement was reached, findings were presented to the wider research team to check, discuss and confirm. Group consultation resolved any disagreements about coded data and emergent themes. The six step process defined by Braun and Clark [50] was followed. An additional step called "preparation for fieldwork" that precedes the six steps defined by Braun and Clark [50] was added in line with Raja et al., [51] and Davies et al., [52]. The data structure that emerged from the data analysis is presented in figure 2, showing from left to right first order categories, sub themes and themes. The approach merged theoretical and empirical knowledge, allowing the theoretical framework to emerge (see figure 4).

3.3 Assessment of Research Quality

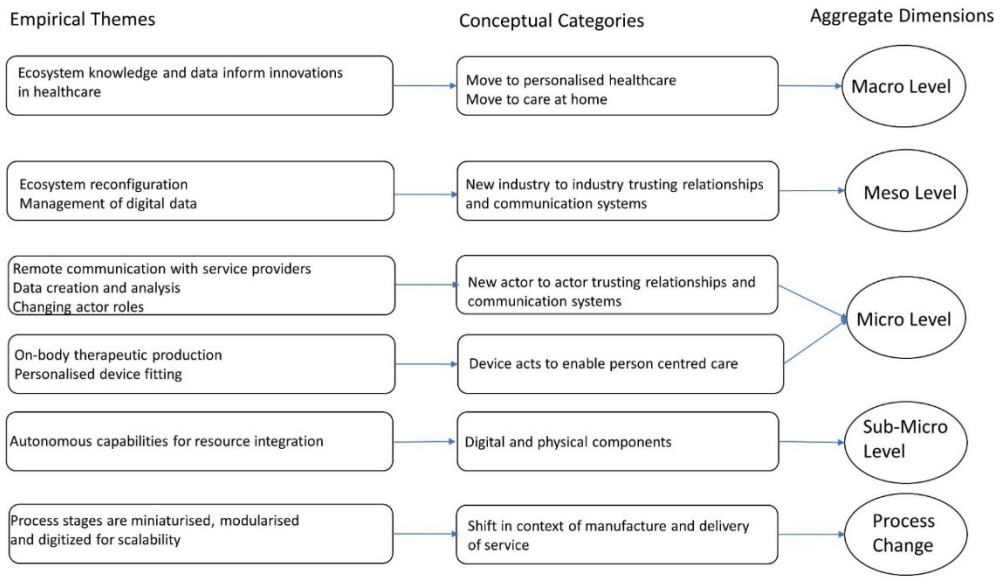
This paper draws on the four criteria of confirmability, credibility, transferability and dependability [53]. Data triangulation was employed [44] using information from multiple sources of evidence, indicating convergent validity and protecting against bias and subjectivity [54]. Efforts were made to establish a clear chain of evidence through transparency of the research design and clear presentation of data to show how conclusions were drawn [55] to ensure confirmability was satisfied. For credibility,

findings were presented to the project champion after the conclusion of the interview phase to ensure findings reflected practice. The project champion was provided with a final report at the end of the project for review, validation and feedback. These activities ensured congruency between information obtained and researchers' interpretation of the phenomenon [45]. To support transferability, the research context and the assumptions underlying the research have been described in great depth allowing other researchers the opportunity to transfer the methodology and results to other contexts.

4. Findings

In this section, detailed evidence of processual changes in the transition to RDM and the creation of a digital micro-factory is presented (see figure 2). From these findings, and building on the three-tiered ecosystem framework in figure 1, we place the dynamic capabilities of the sub-components of the OMMS device at the sub-micro level. We then present findings on changes to the ecosystem at the micro and meso levels (see figure 4).

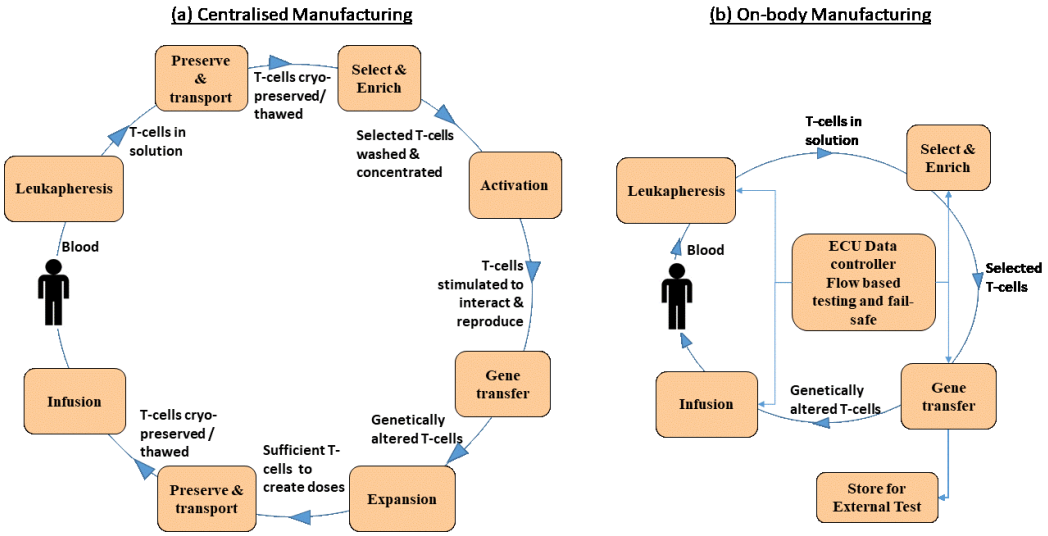
Figure 2. Data Structure



4.1 Process overview: the transition to digitised service system and the creation of a digitised device

CAR T cell therapy removes, modifies and multiplies patient's own immune cells, then re-administers them to the patient where the cells attack cancer in their body. In the current system of manufacture and delivery there are many potential process pathways, but all follow a similar overall sequence (figure 3a).

Figure 3. Process flows for (3a) centralised and (3b) on-body manufacturing



First, blood is collected from the patient in hospital. White blood cells are then separated from whole blood in a process called apheresis. Next, the white blood cells are prepared for transportation to a laboratory where they are used as starting material to be manufactured into the therapeutic treatment. Few manufacturing facilities exist, and the primary manufacturer is based in the US. For transportation, temperature control or cryopreservation is needed. In the laboratory, blood cells are thawed and taken through a set of complex processes in which T cells are selected, modified and multiplied (expanded) to create the required therapeutic dose. Manufacture is tailored to the individual as patients' T cell starting material varies. The manufacturing process

involves open handling by skilled operators who can recognise and react to variation in the blood cells and optimise viability and yield. After manufacture, the therapeutic is transported back to the hospital, cryopreserved if required. Finally, the therapeutic is administered to the patient in hospital. Many quality and purity tests, and monitoring procedures are undertaken throughout manufacture.

CART –T cell treatment is promising with demand for the therapy growing, but the current system is complex and faces three major challenges. First, the system contains the risk of contamination and operator error during transportation and manufacture, leading to manufacturing failure and sample rejection at testing. Second, the therapy takes up to 30 days to manufacture, a long time for patients with rapidly developing cancers. The third challenge is cost: a single intravenous infusion is priced at £280,000 [56], plus the cost of additional care and support that can be significant. This bespoke treatment will only be truly effective if it can be reliably and affordably manufactured and delivered at scale.

OMMS offers a solution to these challenges. OMMS is designed as a continuous manufacturing process, continuously modifying cells and reinfusing them to the patient, rather than the batch process in the laboratory. It takes the form of a tangible device designed to be worn on the patient's body, which operates a continuous system of therapeutic manufacture and delivery (see figure 3b). Blood is taken from the patient into the device, where it is processed and manufactured into the therapeutic treatment, tested, and re-infused directly to the patient. Inside the device, process stages formerly undertaken in the laboratory have been modularised into distinct miniaturised processing units, creating a 'micro-factory'. Each module in the system is individually developed and validated [57]. Modular design utilises standardised interfaces, which bind the modules into process stages. Non-value adding stages, (preservation,

transportation, activation and expansion stages), are removed, reducing complexity, costs and carbon footprint.

The modularity of the processing units means that functionality is not fixed: units can be interchanged over time responding to patient needs and tech innovations. Each module is designed for digitalised control. Novel biosensors are embedded into the unit and connect to a data controller that collects, stores and monitors information. The biosensors analyse patient's starting material and the device will adjust physical elements within the unit to alter outcomes. Sensor data will be employed to make process adjustments according to individual needs, enabling the device to respond dynamically to create a bespoke treatment. Miniaturisation enables the creation of a lightweight portable device, offering patient mobility and the potential for treatment to be delivered at home. The outer casing of the final device will be 3D printed to fit the contours of the body, further adding to patient comfort and mobility.

Through the development of miniaturised and digitised modular processing units, the automated micro-factory will enable the hyper local manufacture and delivery of a bespoke treatment at scale. Digitalisation of the units enables dynamic changes to the device to meet customer's heterogeneous needs and data collected can provide insight to optimise process outcome. Sensors must signal device faults or deviation in treatment to healthcare providers to provide rapid response. The system removes risks associated with transportation and open handling, and reduces the costs of skilled laboratory operators. The device's portability enables treatment at home, lowering the costs of hospital stays and improving quality of life for patients, their family and carers.

4.2 Changes to the ecosystem

The proposed move away from a hospital and lab-based system, to an on-the-body automated device causes significant changes to the ecosystem at the micro and meso

levels. Investigating the socio-impact of these changes is an essential step to understanding if the micro-factory can meet the objectives of improving quality of life and reducing reliance on hospital resources, as well as acceptance of the new technology among the heterogeneous actors in the ecosystem. The laboratory and firms involved in the transportation of blood products are removed from the ecosystem, as are the skilled laboratory operators. In their place is a new material resource, the OMMS device, and a new focal actor, the OMMS service provider. The proposed relocation of therapeutic manufacture and delivery onto the patient in the home changes the context from a controlled to a dynamic environment. The shift causes changes at different levels of the ecosystem.

4.2.1 Macro level changes

Our findings are focused at the meso and micro levels of the ecosystem, however indications of impacts at the macro level are evident. The microfactory, and the personalisation of treatments, contributes to changes in wider healthcare treatment delivery, supporting the move to care at home, and providing personalised treatment at a lower cost, increasing availability:

> The feedback loop, the personalisation of treatment, has potential to change the entire way in which the healthcare system can be delivered and make it much more accessible (Biochemical Engineer)

Data collected by the microfactory in the process of therapy production and delivery feedback to the research and development community, informing future innovations and shaping policy.

4.2.2 Meso level changes

The proposed redistribution of manufacture and delivery creates fundamental change at the meso-level through the relocation of treatment and requirement to provide support

in the home. Such a move requires the creation of new governance structures and institutional norms.

> '…this is a new platform to deliver the therapy in a new way because it is personalised but it is also delivered in a new way because it is responsive… That is a completely different vision for healthcare…We are throwing the healthcare model out the window somewhat and in all our conversations we are trying to work out how it fits within the current healthcare model' (Biochemical Engineer)

At the meso level, relationships of trust are changed between institutions: the families, hospitals and service providers. Doctors are familiar with institutional norms and current risks of the laboratory and hospital system. Trust has been developed in the skills and knowledge of the laboratory operators, testing protocols, quality controls and management of critical situations that develop when caring for patients. In the conservative area of healthcare, developing trust in the micro-factory and the service operators may prove to be a difficult ask of doctors:

> '… something we will always have to worry about is the percentage of failure (…) we will have to come up with a way to fix problems very quickly, or just supply another device'. (Oncology Nurse)
>
> 'with the introduction of this OMMS device, we need to think about spare parts or spare devices and how these be provided in cases of emergencies.' (Hospital General Director)

OMMS requires the development of new relationships with the OMMS service providers and trust in their capabilities to reliably and safely deliver OMMS in a dynamic home context. A new role in healthcare services will be created, the healthcare engineer, able to understand to the data collected by the microfactory, and the changing

needs of the patient, and trained to assemble and change components of the microfactory in response:

> We would have a library of potential modules that fit with the device that can be 3D printed and fitted by the healthcare engineer at the bedside or the patients home (Biochemical Engineer)

The data generated by the OMMS device will be essential to healthcare professionals and the OMMS service providers, and requires the establishment of new practices, protocols, and effective systems of communication between actors. A rich dataset will generate insight into patient treatment in context, widening knowledge and providing important data for future research. Governance and privacy of sensitive healthcare data from the micro-factory will need careful consideration, as the use of the data could have implications for patients' lives beyond their medical care, for example their ability to access to insurance. This issue is especially pertinent in the OMMS context as the therapeutic will treat paediatric leukaemia, meaning any issues that arise from data collected in childhood could have life-long implications to the patient.

> The data is going to go to the patient, to the healthcare provider, back into academia for further research, and to supplier who will want to know about efficiencies, but also could be used by people like insurers. So management and governance of that data needs to be properly thought through (Biochemical Engineer)

4.2.3 Micro level changes

At the micro level, the move to a digitised service requires the development of new actor-to-actor trusting relationships to facilitate the service encounter. Within the established hospital-laboratory system, the patient interacts with doctors to receive treatment, and the hospital interacts with the laboratory to send blood and receive

bespoke therapeutics. In the OMMS system, relationships are fundamentally changed as the patient remains at home, engaging with doctors remotely and engaging directly with the OMMS micro factory. Family members and/or community healthcare providers take the place of the hospital in providing meals, personal care and laundry services. While there is a potential cost saving, caregivers providing home care will need to be supported with appropriate skills training and access to financial support to replace lost income. Healthcare professionals and patients' parents and carers recognised the benefits of patient mobility and treatment at home, but with reservations. A doctor highlighted a need for oversight and control of the device, stating that:

> 'the features of the OMMS device (…) will be decided with the clinicians, depending how long they (patients) will be away from the hospital.'

Trust in the OMMS device was highlighted as a critical factor by most interviewees. The parents and guardians of patients who we interviewed trusted traditional procedures, however they were willing to explore the use of the OMMS device. They commented on the need for clear communications, with the device indicating if it is working or not, and if not, they wanted to know the process for recovery of the treatment.

> 'During night, I need to have an indication that the device is operating and if it does not work, who shall call?' (Parent)

Parents and guardians considered home treatment preferable to a hospital stay, though some had concerns about safety.

> 'they would be with family and would feel a greater privacy.' (Parent).
>
> 'I would accept [OMMS treatment at home], as long as the same care, rigour and attention of a hospital was present at home.' (Parent)

One parent commented that their trust in the system would be dependent on their confidence in the healthcare staff and agreed that efficient communications between healthcare professionals would increase their trust in the safety of the OMMS. Concern over service failure and the need for clear communication systems between the device, patient and hospital was also voiced by hospital managers and healthcare professionals:

> 'For a remote device to work well, alerts are vital.' (Oncologist)
>
> 'We want to make an interface that is very easy for the physician and the rest of the team to understand, nothing too complicated or too scientific.' (Oncology nurse)

Parents and guardians were mostly trusting of the micro-factory, and welcomed the idea of treatment at home. In contrast, doctors felt treatment to be better delivered in hospital, where immediate interventions could be delivered in an emergency situation, and where the patient had social interactions outside of the home. However, some doctors recognised the benefit of home treatment.

> 'Although I agree the treatment at home gives higher privacy, I believe that the treatment at the hospital is better suited since immediate intervention might be needed which at home might not happen so fast and thus, result in terrible outcomes' (Doctor).

For parents and guardians, both hospital and home contexts are novel, and we find parents place their trust the healthcare provider and doctor's judgment over which system is appropriate. Medical staff had a sense of unease as they faced a change in context of RDM manufacture through the micro-factory.

The ecosystem will require new communication systems between the device, the doctors, the patient, and those involved in patient care (families and healthcare providers). The OMMS process of therapy manufacture and delivery generates a

constant data stream that will be monitored, transmitted, stored and analysed. Data on the effectiveness of the treatment and signals can be designed to give people specific information.

> ‘The message is personalised for key ecosystem members, such as directors, nurses, oncologist and parents/carers.’ (Oncologist)
>
> ‘Signal and data processing, in the future we will need to integrate people who manage these with the healthcare providers, as they will manage all the data that goes through the system (Biochemical Engineer)

Data will be used to manage patient treatment, and generate insights for future research, but requires new protocols for data use and security. Although there are concerns over treatment at home among both doctors and patients, delivering care close to home has become socially desirable. The micro-factory acts at the micro level to embody, enable and re-enforcing a macro level social shift towards personalised care and home treatments.

4.2.4 The sub-micro level

The capabilities of the micro-factory to dynamically respond to changing requirements in use is enabled by its digitised components.

> ‘…we are taking raw ingredients, some are from our own body, some are provided by suppliers, we are bringing them together to manufacture something new, which is the Cart-T cells, which we then deliver to the patient using our manufacturing platform on the body. (Biochemical Engineer)

Components act to integrate resources for the manufacture and delivery of a bespoke product. The micro-factory acts as a dynamically responsive resource integrating actor, with subcomponents adapting to need.

> The data we are monitoring… are from the manufacturing processes, the modification of the cells, making sure through a quality control check that [the process is working]. There is an internal feedback loop that says this is doing this, modify this, because patient cells are going to vary. That's the internal feedback loop between manufacturing pathways and quality control (Biochemical Engineer)

Device components create a new level of the service ecosystem, placing the capability to dynamically and autonomously integrate resources at a sub-micro level.

5. Discussion and Conclusions

The shift to RDM enables low volume production located closer to the point of use production [2] and is driven by developments in digital infrastructure and the digitisation of production technology [14]. RDM opens up exciting possibilities for greater personalisation, higher quality and lower costs in healthcare, changing positions, roles and relationships between manufacturers, service providers, healthcare professionals and patients and their families [4]. However, as this is an emergent field understanding of these changes are limited. Positioning our research within the ecosystems literature allowed us to identify the role and position of a proposed digitized micro-factory within the ecosystem. Further, the ecosystem approach enabled an holistic view of all actors contributing and benefitting from a healthcare ecosystem [9], and understand the impact of the move to RDM on relationships at different levels within the context of a healthcare ecosystem. This paper provides theoretical implications for the RDM and ecosystems literatures and has implications for senior managers within healthcare responsible for operations strategy and delivery system design.

5.1 Theoretical Implications

Taking an ecosystems perspective enables an understanding of value co-creation through interactions between actors at multiple levels of analysis [12; 32]. In the case example presented, the change in context caused by the shift to RDM enables a macro level social shift toward patient centred care delivered close to home [21; 24]. The device is designed to be molded to the patients' body, enabling patient mobility, and employs sensor data and analytics to deliver a personalised theraputic. The shift to RDM creates new challenges at the micro and meso levels.

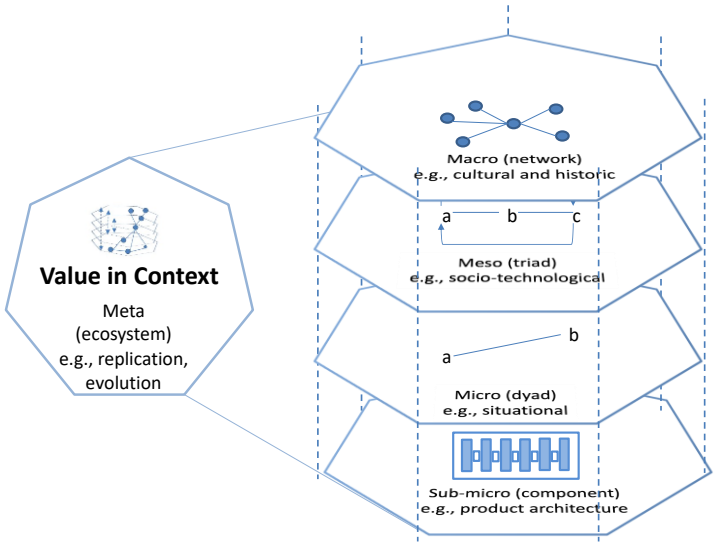
At the meso level the institutional relationships between family, therapeutic manufacturer and the hospital where their 'product' was delivered is altered, as the context of manufacture shifts from firm to customer context. We find the shift in trust in service delivery value creation is not dominated by Business to Consumer (hospital to patient) challenges, but includes significant Business to Business challenges in the move from an established laboratory and hospital system, to an integrative hospital and home system, enabled by capabilities of the OMMS service provider. Currently the culture of care holds that a hospital is a secure and controlled environment [21; 27; 28]. Our findings identify that a shift in perceptions of what constitutes a control/safe context will be needed at the meso and macro level.

At the micro level, the service delivery context shifts from actors engaging within specialist organisational units (oncology in hospital), to actors engaging with the customer (patient) within their home environment, with extensive use of digital signalling. The home was perceived by doctors as variable, dynamic and outside of the well understood institutional norms for hospital doctors and oncology specialists. However, this is a question of familiarity and perspective. From the patient perspectives the institution of the hospital is the unknown and dynamic setting compared to the

institutional norms and familiarity of home life. The study contributes to ecoystems literature by offering evidence of the digitised micro-factory as an actor at the micro level. The micro-factory is automated and responsive, classified as an inanimate agent by Lusch & Nambisan [32] the micro-factory integrates resources (blood, therapeutics and personal data), and is a digitised resource-integrating actor. Following Akaka and Vargo [12], we show that the device is shaped by the macro level social structures of the system designers, and so acts at the micro level to reinforce social structures.

Digital elements enable the dynamic functionality of physical elements contained within modules. This coordination enables the manufacture of a bespoke product alongside collection, storage and analysis of data, and creating alerts that initiate actionable directives. Digital components, material properties and modular architectures are core to a system's operation and influence value creation [58]. These are not micro-level actors, but sit at a level below the micro, shaping actions. We contribute to mid-range ecosystem theory by demonstrating that the capability to manufacture a bespoke theraputic product is enabled at this lower level, we define as the 'sub-micro level': the architectural/structural, physical and digital elements that constitute the physical device (see figure 4). The micro-factory spans sub-micro and micro levels, as the meta-value creation level lens draws different focus on the value created by modularity and the value created by the device as a whole.

Figure 4. Layers of the ecosystem: sub-micro, meso and macro



Finally, RDM is defined as a system that enables manufacture at or closer to the point of use [2; 4; 14]. Our case study explored a proposed micro-factory capable of manufacturing a therapeutic product not just close to, but on the body of the patient, working in a cyclical fashion by continuously taking blood directly from the patient into the micro-factory, responding to the patient's individual and dynamic requirements to manufacture the therapeutic product, whilst simultaneously delivering the product into the body of the patient. This contributes to the RDM theory by revealing RDM's potential to offer simultaneous production and use.

5.2 Managerial implications

The study provides an important managerial implication for RDM in healthcare. Whilst the move to RDM may act as an enabler for scalable solutions, managers need to recognise that the digitised device does not replace service delivery by people. Instead, established relationships are changed, and new roles and relationships are formed. By including the patient and the patient's family as actors in the ecosystem highlights how the costs and responsibility for personal care (physical, social and emotional) are not

removed from the system, but shifted to other actors. This finding is important as changes in relationship require time and space to be allocated for trust to be developed, funds made available, and systems of communication to be implemented, if a new digital device is to be successfully adopted into a healthcare ecosystem.

5.3 Limitations and further research

The study has several limitations that could form the basis for future research. First, the findings are based on a single case study in healthcare. Further research on the impacts of digital micro-factory's and RDM in other industries would be useful to test the boundary conditions of research conducted in the manufacturing industry, where the majority of work has taken place to date. Second, our data indicated that at the macro level the OMMS system appears to facilitate the UK government's priority of delivering care closer to home. Two directions for future research are identified. First, once the socio-technological objectives of the micro-factory are demonstrated (to provide safer treatment, improve quality of life and reduce reliance on hospital resource are demonstrated), research will be needed to further develop the business case for the micro-factory. This approach of demonstrating the use case is in line with recent advances in technology adoption, whereby the use case is demonstrated before the business case [59]. Second, research is needed to understand macro level changes and how micro-factories acting at the micro and meso level impact on society at the macro level.

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Appendix A – Interview Protocol

1) Introduction

What is your role?

What do you do exactly regarding cancer treatment?

2) Customer

What percentage of this hospital does blood cancer affect (approximately)?

How many patients does it refer to?

3) Treatment

Characteristics

Is this blood cancer only treated by chemotherapy? If no, what are the other options?

How long do patients have to stay in the hospital for chemotherapy?

Monitoring

How do you know if the patient's treatment is effective?

Do you have a private way/platform to communicate with the patients/their parents?

Who needs to see how treatment is going in the healthcare sector?

Cost

Who is paying for the treatment? What is the role of the NHS?

4) Micro factory wearable solution

Pains

What are your main challenges today?

Do you have problems of space? Of waiting time for some patients?

Benefits

What would be the benefits for you to have this device to cure patients?

What would be the benefits for other care providers or patients?