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## **Innovation in healthcare manufacturing: transforming deployed medical care**

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**Abstract:** This paper analyses the case for transforming deployed medical care through innovations in advanced manufacturing. Early-stage findings present expert views based on a cross-disciplinary roadmapping workshop, designed to steer requirements and identify desirable applications across a range of medical manufacturing engineering disciplines. This paper proposes how the adoption of Redistributed Manufacturing (RDM) has the potential to transform operational patient care pathways and supply chains in the context of military and emergency medicine. This encompasses the use of technologies such as additive manufacturing, bioprinting and other distributed approaches. This work is part of a national UK research programme and sets out the foundations for a position paper to guide future research and investment in both academia and practice.

**Keywords:** Redistributed Manufacturing; Deployed Operations; Medical Innovation; Military and Emergency Medicine

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## 1. Delivery of healthcare in deployed operations

Medical professionals and first-responders face the challenge of rapidly responding to urgent and unforeseen consequences in a range of logistically constrained environments, increasing in occurrence due to climate change, geopolitical instability, conflict, terrorism, pandemics and other factors. In this context, timing and access to specialist expertise, medical equipment and medicines are critical, as is the ability to innovate and adapt to new threats and situations (Ford, Hodgetts and Williams, 2017). Whilst valuable advances in medical practice have been made in recent decades, interventions in the deployed space are typically conducted with limited availability of basic and complex medical supplies. Typical medical patient pathways place a directional emphasis on medical evacuation back to safer and better resourced locations. Investments in technologies such as drones are being made to help overcome supply issues.

Breakthroughs in ‘advanced manufacturing’ R&D hold the potential to be a real game changer, delivering greater freedom of action to treat patients closer to the site of medical and humanitarian emergencies or in deployed field hospitals (Ramadurai and Bhatia, 2018). In the case of serious injuries, the promise of innovative distributed portable, small-scale advanced manufacturing units/devices (e.g. including but not limited to Additive Manufacturing) can offer: (I) medical interventions earlier in the casualty treatment process, reducing the loss of life and risks of sustaining longer-term health conditions and rehabilitation costs, and also (II) help increase medical capability for enhanced Prolonged Field Care (PFC) and deployed hospital care. Emerging exemplars include the US Military pilot testing of a bioprinter capable of biofabricating a scalpel handle and hemostat, bioactive bandages, meniscus cartilage and surgical models of T9 vertebrae to assist the best course of medical intervention; and a compact refrigerator size on-demand and highly modular pharmaceutical production device, capable of delivering at least hundreds (per day) of oral and topical dose medicines (Adamo, et al. 2016; Geneva Foundation, 2019).

The adoption of advanced manufacturing innovations presents compelling propositions for organisations involved in emergency, defence and humanitarian services. Yet, further research is needed to understand the impact of emerging R&D, and assess implications such as the trade-offs between current operating models (centralised manufacture, supply and stockpile to established locations)

and new ways of working that are decentralised, on-demand, more sustainable and involve end-users in the process. This transformation of strategy, systems and technology is broadly encompassed by the term Redistributed Manufacturing (RDM), which whilst nascent in theory and practice may represent a wider paradigm shift in manufacturing and product-service systems for healthcare and other sectors (Harrison, Rafiq and Medcalf, 2018; Srai et al, 2020).

Prior research into humanitarian innovation (Bessant et al, 2019) has identified the role of user-led innovation e.g. front-line workers. Although not a humanitarian agency, the military are often deployed into humanitarian situations to provide medical aid and support. Prior research (Phillips et al, 2018) has identified defence medical services as a potential lead user of mobile RDM innovations, who in line with von Hippel's concept of lead users, operate in extreme conditions, adopting medical innovations which, over time, diffuse into civilian healthcare systems. In deployed operations there is an acute and urgent demand for medical products or supplies, e.g. humanitarian crises, natural disasters or emergencies. Timing is critical for saving lives or reducing the chances of long-term debilitating conditions. RDM systems could seek to deliver rapid diagnosis, production and testing in remote conditions.

Extant research and current interpretations and distributed forms of manufacturing typically assumes a degree of stable environmental conditions and relatively fixed locations with few operational limitations (i.e. workshops/hospitals/clinics/home). There is limited scholarly research that focuses on mobile/deployable production systems and much less on applications in healthcare. We contend that further research is needed to bridge advanced manufacturing R&D with end-user requirements in deployed operations, to better inform early design considerations and translation to practice.

## **2. Research design and methodology**

### *2.1 Roadmapping future applications*

This paper presents the findings of a one-day strategic roadmapping workshop, which served to define research directions for a larger research programme (research in-progress) in the United Kingdom. The workshop involved 25 expert participants, with five experienced practicing military and emergency clinicians, five defence laboratory and procurement professionals and fifteen academic researchers covering engineering, manufacturing, operations and innovation management. Participants focused on defining current requirements and operational conditions in deployed medical care, leading to a prioritisation of clinical needs and exploration of future RDM scenarios.

Roadmapping exercises followed an established approach from the innovation literature (Phaal and Muller, 2009) and provided a rare opportunity for knowledge exchange between research and practice. Following expert presentations providing the operating context and the potential of RDM, the first stage involved dividing up into three break-out groups to conduct a scoping exercise. Each group was provided with large generic roadmap templates in the gap analysis format (past, gap, future) to help post and cluster ideas. The second stage involved shortlisting priority requirements and research areas (results articulated in 2.1 and 2.2). The third and final stage involved establishing potential research project areas, drawing

together and focusing expertise on a set of highly desirable manufacturing capabilities for deployed operations.

In undertaking the roadmapping exercise we aimed to address the following research questions:

1. What are the military and emergency medicine requirements for manufacturing innovations in deployed operations?
2. For deployed medical care, where is RDM most likely to deliver impact?
3. What are the priority areas for future R&D feasibility studies?

### **3. Findings**

#### *3.1. Requirements*

Feedback from medical practitioners and those with experience of operating in deployed environments articulated the need for manufacturing innovations to address the following requirements:

- Increased agility and immediacy for clinical effect (improved diagnostics, improved recovery)
- Enables PFC or immediate recovery stages before or after, according to operational demand/circumstances
- Enables genuine transformation of medical activities in deployed operational locations, rather than facilitating improvisation/compromise
- Reduces complexity – allowing for reconfigurability, adaptability, modularity, reduction in raw materials dependence, and if beneficial, new designs that make use of delayed final assembly at the point of need
- Resilient, survivable, integrated, adaptive manufacturing units/devices or networks
- If applicable, units/devices allow for secure integrated data transmission or portability of useful data (i.e. anthropometric)

Furthermore, running through various technological solutions, training and analysis resources should be provided (distributed and supported) and doctrine must be considered.

#### *3.2. Priority areas for research and development*

In small groups, workshop discussion centred around real-world scenarios, challenges of operating in the field, identification of capability deficiencies, benefits and limitations of scientific and engineering interventions, technology acquisition issues (financial, logistical, technical, safety) and impact on patients and end-users. Outputs were reviewed with manufacturing engineering experts and provided the basis for a successful national research programme grant.

The following provides a summary outline of immediate focal areas for priority research and development:

In-field deployed manufacture of:

- Medicines and therapeutics to support patients with traumatic injuries (i.e. analgesics, antibiotics, plasma and clotting factor replacement, etc.)

- Medical devices to support PFC and damage control surgery (external-fixators, nails, plates, splints, etc.), where the design is bespoke and output is ‘need’ led and not ‘technology’ led
- Clean sterile water/saline (scale up and out) and other clinical grade fluids (cleaning, IV, drinkable, etc.)
- Blood and blood products, or temporary synthetic substitutes that allow stabilisation of the patient for transport
- Bespoke individualised tissues for burned skin coverage, fracture healing, temporary functional organ replacement, and dressings (synthetic),

Advances in manufacturing technology that address:

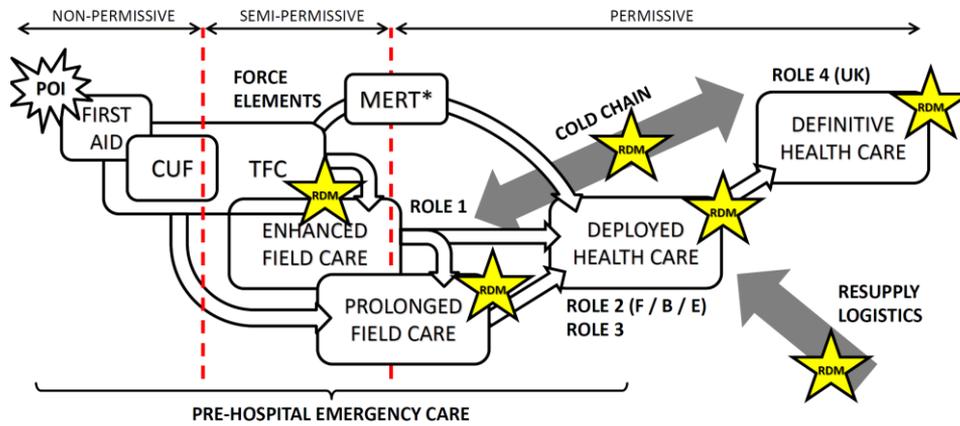
- Additive Manufacturing technologies for application in-theatre (Forward Operating Bases and mobile platforms), with the aim of overcoming operating constraints and increasing medical freedom of action
- Multi-use of raw and novel materials to reduce logistical and storage burden (i.e. inputs for Additive Manufacturing)
- Customisation of Personal Protection Equipment (PPE), to reduce potential injury (e.g. boots, concealed body armour, hearing protection, etc. to lower potential burden)

Running through all areas of research is the need for innovators to inform and involve medical regulators to ensure they keep pace with leading edge developments in advanced manufacturing and management of ethical challenges.

#### **4. Redistributed Manufacturing and the Operational Patient Care Pathway**

To best demonstrate where the roadmapping exercise identified where RDM is likely to deliver impact, it is helpful to draw on recent military medicine literature, which provides a useful landscape of the dynamic process involved in treating casualties under deployed conditions (Bricknell, 2014). We also note that the language and concepts are transferrable to emergency and humanitarian operations, where casualties include those affected by disease and non-battle injuries and require treatment prior to their admission into a dedicated medical facility (Garber *et al*, 2020).

Focusing on the Operational Patient Care Pathway (OPCP), provides a useful visual frame of reference, illustrating the end-to-end process (see figure 1) from the Point of Injury (POI), where medical interventions may be limited to first-aid and delivering care under fire, towards definitive health care in a stable setting. In this context, timing of medical interventions is often critical. The chain of care describes the importance of so-called golden hour, where initial focus involves life-saving first aid, attempts to stop bleeding and maintain the airway, and then the need for advanced resuscitation/pre-hospital emergency care (NATO, 2019). This has implications for innovations in advanced manufacturing, which must be time responsive to the severity of the injury. Also, with reference to figure 1, the portability and purpose/functionality of the manufacturing unit/device is clearly a major factor where operational constraints are less at Role 3 than at Role 1.



CUF: CARE UNDER FIRE  
TFC: TACTICAL FIELD CARE

\* MEDICAL EMERGENCY RESPONSE TEAM (MULTI-PLATFORM)

**Figure 1** – Potential opportunities for the application of RDM in the OPCP

Based on our analysis, as illustrated in figure 1 using yellow star markers, we argue that RDM can play a meaningful part in supporting deployed medical care in:

- **ROLE 1:** Primary Health Care (PHC); enhanced first aid; triage; initial resuscitation and stabilisation.
- **ROLE 2:** Reception and triage of casualties; Damage Control Resuscitation (DCR), which may focus on minimising blood loss, maximising tissue oxygenation, and mitigating environmental effects; and an Damage Control Surgery (DCS), which may focus on interventions that sacrifice completeness of immediate surgical repair/functional restoration to achieve haemorrhage control, minimise contamination and prevent physiological deterioration. This includes:
  - **(F) FORWARD:**DCR + DCS; light and highly mobile; limited capacity and resource.
  - **(B) BASIC:**DCR + DCS, emergency medicine, acute medicine, radiology, labs.
  - **(E) ENHANCED:** As for BASIC with enhanced capabilities and greater resources; able to prepare casualties for aeromedical evacuation.
- **ROLE 3:** Secondary health care with specialised surgery, care and additional services.

## 5. Discussion

A key motivation for this research was to present clear guidance that will help shape future public and private research investment and accelerator funding competitions, leading to enhanced medical capability for application in deployed operations. Advanced manufacturing innovations in areas such as medical devices, cell and tissue therapies, clinical fluids and pharmaceuticals have significant potential to deliver benefits to casualties/patients and medical practitioners working in conflict and disaster zones, emergency services and humanitarian operations.

Building on the findings of this work, and with the support of additional funding, we intend to deliver in-depth requirements and guidance for RDM in deployed operations, Working with the military as extreme lead users to better understand challenges and enablers, we also aim to translate implications for wider health system diffusion and technology management (i.e. R&D, procurement, support).

Where adopted, RDM could shake up the industrial supply of medical products and services and depending on their complexity raises important early stage questions around design, functionality, ownership, user operation, upgrades and maintenance. This is particularly salient in the current climate where the COVID-19 pandemic has laid bare issues relating to large scale, standardised manufacture of products across multiple continents and the lack of resilience in this approach. There is a call for more distributed, localised modes of production which has already been realised by the military who, in their quest for a more resilient and secure supply of equipment and medicines, have recognised the potential of RDM and its role in contributing to their ultimate end goal of a 'zero-logistics tail'.

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