Redistributed Manufacturing Healthcare Network (RiHN)

Launch Event and Sandpit Workshops – Forum Outputs

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The Redistributed Manufacturing Healthcare Research Network (RiHN) aims to deliver a single vision of the research needed to position the UK at the forefront of healthcare manufacturing. Network partners include cross disciplinary researchers from the Universities of Cambridge, Brunel Nottingham, Newcastle, Loughborough and the West of England. The network is sponsored by the Engineering and Physical Sciences Research Council (EPSRC) and is supported by Innovate UK.

The RiHN launch event and 1st Sandpit Workshop was held on the 26th March 2015 at the Engine Shed in Bristol. The 2nd Sandpit Workshop was held 28th April 2015 at Nottingham University. The workshops provided an expert forum from which stakeholders of healthcare R&D debated the potential impact of Redistributed Manufacturing (RDM). Event speakers included Sir Mark Walport, Dr Mark Claydon-Smith, Dr Wendy Phillips, Professor Andrew Webster and Professor Nick Medcalf. Between them, the speakers outlined the rationale and importance of the network, as well as political drivers, strategic benefits and technical issues related to the implementation of RDM in healthcare.

The Sandpit Workshops involved two distinct activity sessions, (I) the mapping and identification of priority topics, and (II) critical analysis of topics leading towards potential feasibility studies. This write up covers both the Bristol and Nottingham events and summarises the process adopted and key outputs from the mapping and analysis exercises. The entire process is described in more detail in the Sandpit Approach presentation slides, which are available from the RiHN website.

SANDPIT SESSION 1 OUTPUTS

Participants were assigned to the following specialist groups Dentistry, Medical Devices and Diagnostics, Regenerative Medicine, Pharmaceuticals and to generalist RDM in Healthcare groups.

For the first activity, each pre-assigned group was given the task of answering the question: “What are the research issues at the intersection of healthcare and re-distributed manufacturing?”

They were given pens, post-it notes and the template in appendix 1 to structure the discussion. The template was modified to suit a healthcare audience from a more generic version which was developed and successfully tested by the EPSRC funded 3DP-RDM project, run by the University of Cambridge. The template proved useful in most cases, although a few groups chose instead to structure their thinking solely around the ideas generated by early discussions and post-it notes.

The outputs of this mapping exercise covered both 'management' and 'technical' issues such as:

- Pressures on health services and current supply chain configurations
- Manufacturing costs pressures
- Understanding new economic/funding models, new applications and new models of service delivery
- Managing logistical issues
- Addressing clinical compliance
- Managing variation in process, outputs and patients
- Changes to treatment location and associated dependencies

The discussions around the mapping exercise led to the identification of five priority topics, which were presented back to all participants. This was an opportunity to make some group comparisons. The group results for the first activity are outlined below in figures 1 and 2 and the second activity in figure 3. Issue maps are listed in Appendix B.

GROUPS	**PRIORITY TOPICS**				
Specialist themes	*First*	*Second*	*Third*	*Fourth*	*Fifth*
Dental	**DESIGN AUTOMATION** - Lessons from dental CAD/CAM	**BIOMETRIC MATERIALS AND PROCESSES**	**REGENERATIVE APPROACHES**	**LIFE CYCLE COSTING, ECONOMICS AND VALUE**	**OPERATIONAL AND BUSINESS MODELLING FOR RDM**
Medical Devices & Diagnostics	**SYSTEM THINKING**	**RESILIENCE**	**AGILITY**	**RAPID / ADAPTIVE CERTIFICATION**	**DEMOCRATISATION OF HEALTHCARE TECHNOLOGIES**
Regenerative Medicine 1	**HEALTHCARE INFRASTRUCTURE**	**TECHNOLOGY + PROCESS ENABLERS**	**VALUE PROPOSITION** - Improve outcome at a cost that is feasible - Basis for reimbursement and incentive for adoption - Clinical advocates - Pilot with clinical drive to show how benefit can be delivered	**AGILE, JUST-IN-TIME, RESPONSIVE DELIVERY** - Including adaptive manufacturing to the starting material	**SUPPLY CHAIN MANAGEMENT CHAIN OF CUSTODY**
Regenerative Medicine 2	**LOGISTICS** - Chronic vs. acute - Autologous vs. allogeneic (blood transfusion) - Preservation and transportation - Staff training	**VARIATION** - Inherent variation of biological systems - Operator variation - [from post-it = characterising cellular products to a level that is predictable]	**PRODUCT DIVERSITY** - Combination products (i.e. 3D printed scaffolds) - Anchorage – dependent vs. suspension	**BUSINESS MODEL** - NHS vs. Private - Contract manufacturing (cost-benefit analysis) - Practice vs. manufacturers specifications and prior knowledge	**QUALITY AND STANDARDS** - Harmonisation - Staff training
Pharma	**ENVIRONMENT** - Focus on applications where RDM is attractive - Examine regulatory and policy factors	**RDM QUALITY ASSURANCE MODELS** - Analytics - Methodology - Process -> Outcomes (confidence in outcomes)	**IDENTIFY RDM SOLUTIONS TO UNMET MEDICAL / ECONOMIC NEEDS**	**ADAPTIVE MANUFACTURING** - Reconfigurable - Multi-use - Auto-sensing	**CLOSED LOOP TREATMENT** - Manufacturing and patient compliance through diagnostic monitoring informing RDM need

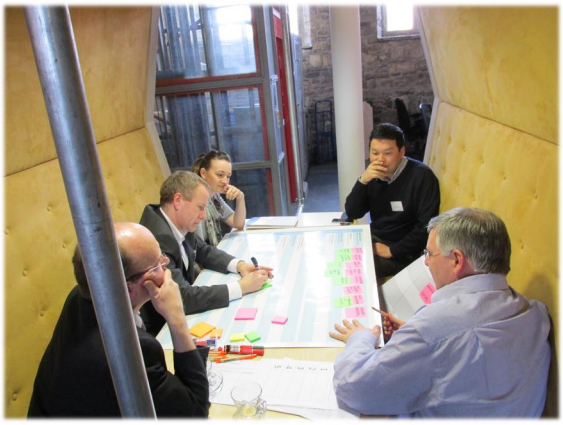
Figure 1 – Sandpit Session 1 priority topics, specialist healthcare groups

Looking across the specialist groups, there was a lot of diversity in terms of priority topics. Some commons threads included understanding the clinical implications, having confidence in new treatments, managing the supply chain impacts and linking patient needs to potential benefits of RDM.

GROUPS	**PRIORITY TOPICS**				
Generalist	*First*	*Second*	*Third*	*Fourth*	*Fifth*
RDM in Healthcare 1	**DESIGN DRIVEN INNOVATION**	**WHO IS YOUR CUSTOMER?**	**WHAT IS THE UNDERLYING POLICY BEHIND HEALTH DELIVERY?**	**HOW DOES REGULATION IMPLEMENT/DRIVE POLICY**	**UPSTREAM SUPPLY STRATEGY**
	- User centric - Where will this have health benefits - [unreadable word] asymmetry	- What will they pay? - Where will this have economic traction - Economic / flexibility	- Who decides what?	- Patient safety - Skills of healthcare professionals	- Points of failure in the supply chain - Resilience of supply chain - Raw materials supply - More localised / smaller suppliers
RDM in Healthcare 2	**PATIENT DRIVEN MANUFACTURE**	**SUPPLY CHAIN 'SECURITY'**	**FLEXIBLE DEPLOYMENTS**	**FISCAL MAPPING**	**ADAPTIVE REGULATION**
	- Highly reactive - Removing forecasting dependency - Where, when, what -> unknowns	- Product integrity - Intellectual property - Quality Assurance / Quality Control - Consistency	- Hub and spoke? - Physical vs. knowledge - Manufacturing-in-a-box - New business models	- Local taxes, tariffs and customs - Business models	- Small batches - Emergency batches
RDM in Healthcare 3	**DIGITAL WORLD: DATA SECURITY**	**USER CENTRIC EXPERIENCE**	**DESIGN / CUSTOMER DRIVEN INNOVATION**	**SHELF-LIFE & SENSITIVITY OF GOODS**	**INFORMATION EXCHANGE BETWEEN ENTERPRISES**
	- Link to brand reputation - Utility - Manufacturing robustness - Internet-of-things	- Journey to drive RDM of future tech, understand the user = needs drive innovation			
RDM in Healthcare 4	**PRODUCT CHARACTERISTICS AT A DISTANCE**	**EVIDENCE BASED REGULATION**	**SYSTEMS ENGINEERING APPROACH TO HEALTHCARE**	**CLINICAL PULL VS. TECH PUSH**	**NEAR PATIENT MANUFACTURING PROCESSES**
	- Use of sensory technologies - Design of feedback loop to inform manufacturing processes	- Research to facilitate transfer to scaled up manufacturing later	- connecting supply chain, R&D, value chain to gain bigger picture	- Interdisciplinary R&D, a common language - Facilitate academic, clinical, industry relationships	- Social science research - Commissioning into hospitals - Adoption of RDM structures, supply chains, methods, etc. - Changes to training at point of care, production and delivery

Figure 2 – Sandpit Session 1 priority topics, generalist healthcare groups

Looking across the generalist groups, there was a clear emphasis on prioritising issues around 'design' and taking a patient and clinician/user led approach. Other common threads included understanding systemic impacts and processes, regulation and certification, and supply resilience.




Pub Stops of Bristol


Engage
Inspire


GROUP D

SANDPIT SESSION 2

For the second session, sandpit participants were asked to reflect on the comparison of their topics with other groups. This was followed by an exercise that involved conducting a gap analysis on the top three or all five priority topics, as identified in the previous session.

Participants were first asked to (I) be creative and debate future scenarios for each priority topic (what might future services, process, performance, etc. look like?); then (II) outline what actually exists today (current level of development, quality and performance, etc.) and lastly (III) specify where the gaps are between the current state and the desired state (identifying challenges, barriers; likely failure points, areas for investment). The results of the gap analysis that were presented back to all groups are outlined in Appendix C. Looking across the findings from each of the groups, the gap analysis presented some interesting directions for future feasibility study proposals[1]. To demonstrate the potential opportunities, some examples are discussed below.

For **Dental**, focusing on 'design automation', there is an opportunity to diagnose patient requirements and offer treatment in a single visit (minutes not days), utilising a joined up process from imaging to production, leading to improved patient outcomes and cost savings. In this case, feasibility studies might focus on speeding up design and manufacturing processes.

For **Medical Devices and Diagnostics**, focusing on 'agility', there is an opportunity to harvest auto transplants 'to order' ensuring the procedure is minimally invasive and done right first-time, addressing wastage, trauma to patients and associated resource costs. In this case, feasibility studies could focus on two directions – the technologies involved or the regulation involved.

For **Pharmaceuticals**, focusing on 'closed loop treatment', there is an opportunity to diagnose patient dosage requirements based on remote diagnosis, which would result in made-to-order treatments (personalised medicine). The current system relies on electronic health records (e.g. insulin usage) and deal with low patient compliance. In this case, feasibility studies might focus on how wearable sensor technology and data/knowledge management can be linked to RDM.

For **Regenerative Medicine**, focusing on 'healthcare infrastructure', there is an opportunity to develop products, produced at or near the point of care ("GMP in a box"), through an integrated, automated manufacturing and delivery process coordinated with the clinical setting and its requirements. Under current arrangements, products are manufactured centrally and transported to healthcare providers. In this case, feasibility studies might carry out a more in-depth analysis of clinical practice to establish the infrastructure information and capability gaps. These gaps include: management of chain of custody; assurance of quality (including the situation where an autologous product is made and there is little or no 'retained stock' in case of the need for re-analysis of batch); resolving the matter of when 'manufacturing' becomes 'practice of medicine' (important for applying the regulations); suitable models of operation with risk-sharing and appropriate indemnification by differing organisations; and management of training standards for operators who are working far from the central manufacturer.

For **RDM in Healthcare**, focusing on 'shelf-life and sensitivity of goods', there is an opportunity to define what best-in-class looks like and to better understand the impact of RDM on current medicine supply chains. In this case, feasibility studies might focus on healthcare application cases that weigh up the benefits of 'localised production' vs 'centralised production and transport' models. For a second **RDM in Healthcare topic**, focusing on 'flexible deployments', there is an opportunity to support medical expeditionary operations ensuring deployment teams have the treatments (equipment, vaccines, etc.) just-in-time as required and are able to tap into centralised expertise. RDM has the potential to transform typical logistical processes, risks and costs. In this case, feasibility studies might focus on rapid diagnosis, production and testing in remote scenarios.

[1] The results of a more detailed and refined list of feasibility studies produced at the Nottingham event are available as a separate PDF or individual image files

NEXT STEPS

Materials and insights generated from both the Bristol and Nottingham Sandpit Workshops will inform the call for feasibility studies which will be released on the RiHN website around the 1st June 2015. All event participants will be kept informed of this.

Ideas for proposals should be developed with consideration of the following funding assessment criteria:

- Highlight research questions that are not currently being addressed
- Potential for the development of a larger funded project
- Evidence of industrial interest and commitment to the feasibility study and especially in support for an follow-on project
- The likelihood of a successful delivery of the project
- Potential for attracting involvement of new industrial members

KEY DATES

- Launch event and first sandpit workshop (Apr 2015)
- Second sandpit workshop (May 2015)

- Call for feasibility studies (Jun 2015)
- Announcement of awards (Aug 2015)

- Feasibility studies commence (from Sep 15 – Apr 16)
- Showcase event (Jul 2016)

If you have any further questions, contact:

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