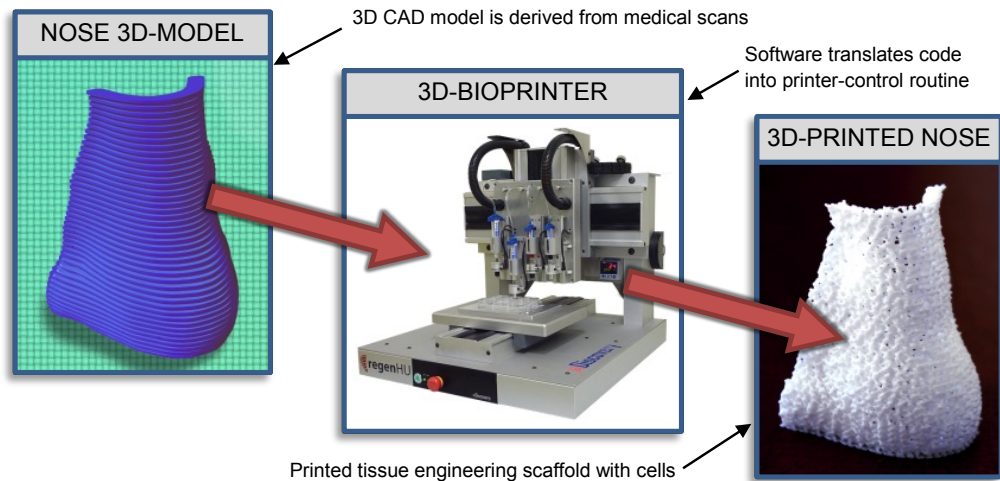


3D Bioprinting: Commercialising Personalised ATMP/Device Combination Products



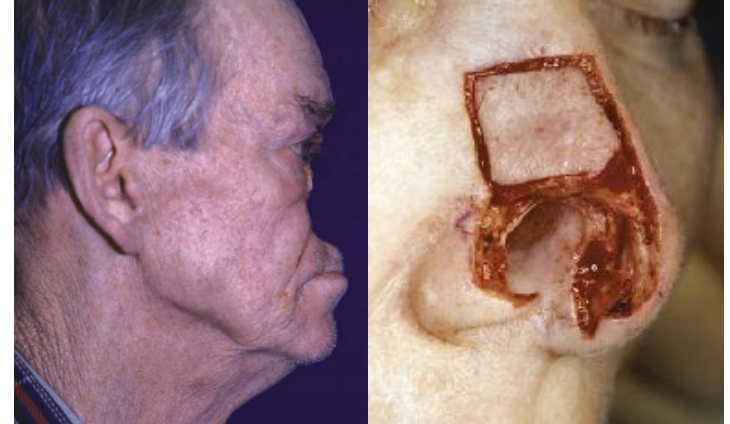
RiHN Feasibility study launch event, Loughborough University,
19/11/2015

Andy Gleadall

Joel Segal, Paul Hourd, Nick Medcalf

BACKGROUND

- Why replacement noses?
 - Carcinomas
 - Trauma
 - Substance abuse, infections, etc.
- Why bioprinting?
 - Customisable
 - Potentially better patient outcome
- Bioprinting technology:
 - Ideal candidate for RDM
 - Not within the current regulatory framework
- Previous project: Challenge-Led Regenerative Medicine Manufacturing Research



EPSRC Centre for Innovative Manufacturing
in Regenerative Medicine

AIM AND OBJECTIVES

- Aim:
 - To identify the possible modes of operating a commercial-scale distributed business for bioprinting implants containing living cells
- Objectives – identify the following:
 - Technical, economic and regulatory constraints
 - More appropriate regulatory framework options
 - Alternative methods for RDM
 - Required research areas

BENEFITS AND IMPACTS IDENTIFIED

- Benefits of bioprinting:
 - Save surgery time
 - Implications on cost, patient outcome, number of operations, etc.
 - Better patient outcome
 - Nose reconstruction fidelity, potentially improved functionality, surgical success rate, etc.
- Benefit of RDM
 - Determine this during the project
 - Why not use a centralised approach?
 - E.g. less transport of cells / tissue

NOVELTY

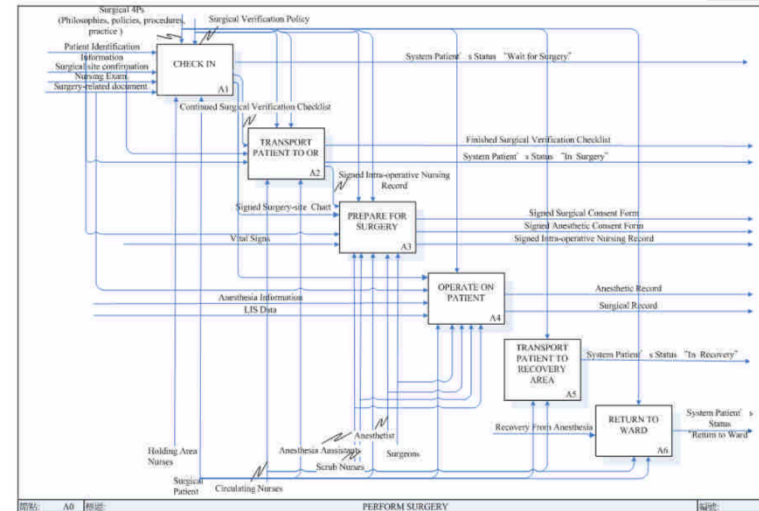
- Little existing work on:
 - Challenges of applying regulatory framework -
Impact on:
 - Product /patient
 - Bioprinting feasibility
 - RDM feasibility
 - Are there potential adaptations to the regulatory framework?

APPROACH

- Risk analysis for RDM bioprinting
- Interview, visits to clinics, workshops
- Model RDM bioprinting (GRAI Grid, IDEFO).

FCTS H/P	EXTERNAL INFORMATION	TO MANAGE PRODUCTS TO PURCHASE TO SUPPLY	TO PLAN MANUFACTURING	TO MANAGE RESOURCES	TO DELIVER	INTERNAL INFORMATION
1 year 1 year	Sales forecast per family	-to look for suppliers -to negotiate markets	to fix the supplying parameters	budget	equipment & employees program	
4 months 2 months	Sales forecast /product Backlog of orders	To adjust markets	To adjust supplying parameters	Master production schedule	To do load leveling /month / shop	
1.5 month 1 week			Load planning	To share the employees per team and per section		Stock - E.P. - Manufactured components
1 week 1 week		To supply raw material and components	Quantity to manufacture	Assembly		Stock - R.M. - Bought components
1 week 1 day	Urgent deliveries	Tracking	Assembly planning / day / team	Manufact scheduling per machine	Ordering planning	

Doumeings, G., Vallespir, B. and Chen, D. 1998. "Decisional modelling GRAI grid."



Su, C.-J. and Chou, T.-C. 2009 "Improving patient safety and control in operating room by leveraging RFID technology."

OUTPUTS

- Gap analysis and future status of combination products
- Framework for future operational business models
- Publication and dissemination of results

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 - Joel Segal – University of Nottingham
 - Nick Medcalf – Loughborough University
 - Paul Hourd – Loughborough University
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