Redistributed manufacturing of home-use medical devices

Team: Michael Drinnan (PI)[1], Costanzo Di Maria[1], Alison Bray[1], Mike Whitaker[1], Javier Munguia[2], Yi Zhang[2], Thomas Honey[2].
1. Medical Physics, Newcastle upon Tyne Hospitals NHS Foundation Trust
2. School of Mechanical Systems and Engineering, Newcastle University

Scope

Conventional medical device manufacture involves various costly elements, such as:

- Initial outlay for equipment purchase, e.g. mould tools, jigs
- Subcontracting of manufacture, assembly and distribution to different agents
- International, national and local shipping and storage

Expense is accumulated at each stage; the cost to make a device is just a small proportion of the final sale price.

Redistributed manufacturing aims to disrupt the traditional model by:

- Moving manufacture and assembly closer to the end user
- Reducing storage and shipping burden
- Allowing customisation

Our project explored the technical feasibility of, and opportunities offered by, redistributing the manufacturing of home-use medical devices. We used the PeePod, a device previously developed by members of the project team, as a case study. The device, now licensed to MMS-Laborie as the Flowtaker (flowtaker.com), is a single-patient-use urine flowmeter for home use.

Technical development and evaluation

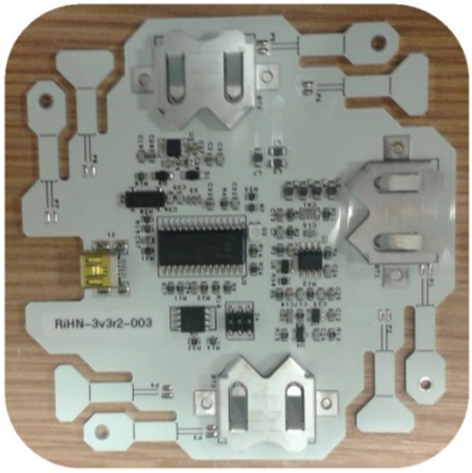
We aimed to redesign the PeePod into a form suitable for redistributed manufacturing (the 'RiPod').

Identification of suitable technology

Various additive manufacturing technologies were considered, including selective laser sintering, stereolithography and fused deposition modelling (FDM). FDM (one technique used for 3D printing) was found to be superior in terms of safety, accessibility of equipment, cost and usability.

Design changes

- Four complex plastic components were replaced with one simple part, suitable for FDM
- Several screw fixings were replaced with clipping mechanisms
- The load beam was removed and the sensing element integrated into the circuit board (below right)



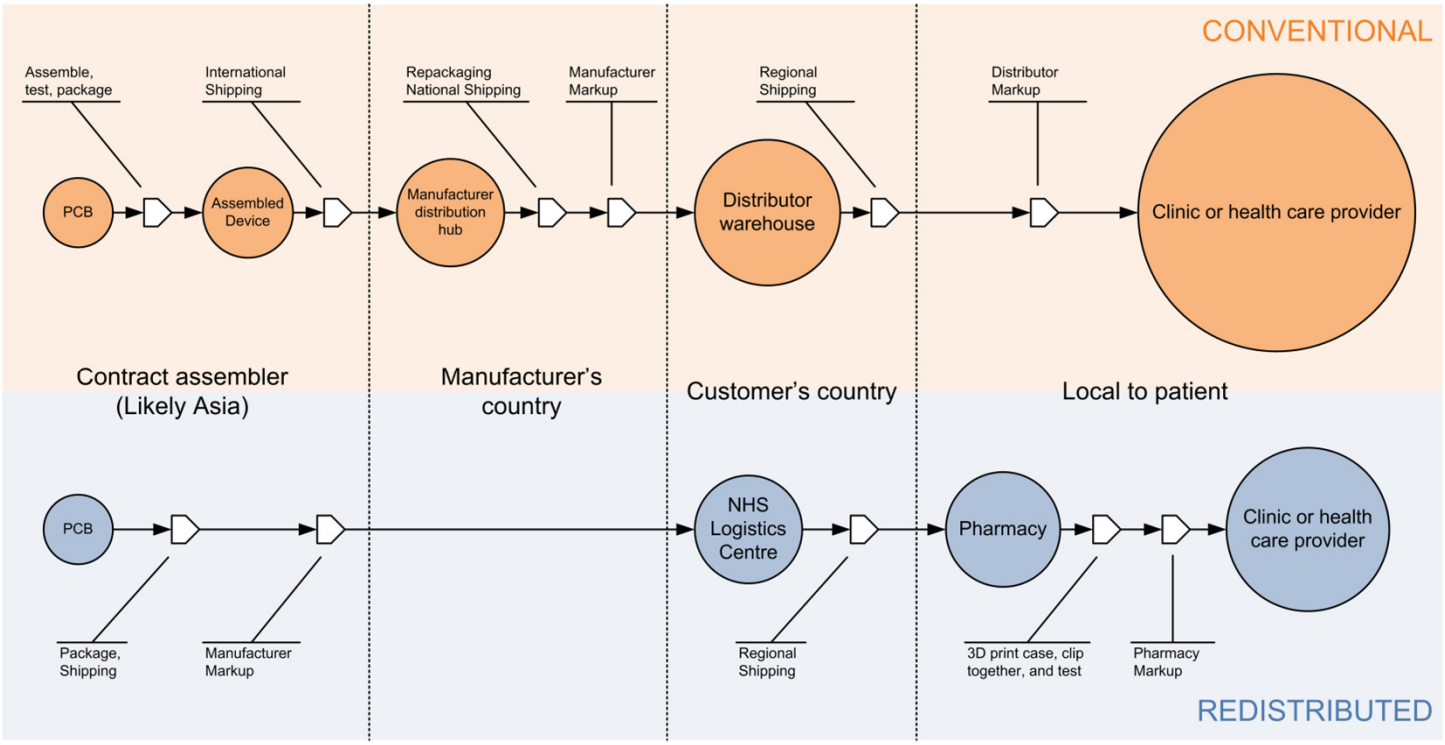
Testing

The RiPod was tested using a constant flow rate generator, and results compared to those from the PeePod:

- Average flow rate was measured extremely accurately by the RiPod (correct to within 0.5 ml/s, sufficient for the clinical application)
- The variability of flow rate measured by the RiPod was 2 to 3 times higher than the PeePod
- We believe this is due to technical issues that can be addressed in further iterations of the device

Cost modelling

We developed a cost model comparing the estimated final costs of the RiPod and PeePod (below, bubble areas are directly proportional to the cost at each stage). Based, for example, upon a reduction in part count from over 30 down to 6, we estimate a 65% saving in the cost to the consumer.



Evaluation of likely patient uptake

Focus groups were held with members of UK North East public involvement group VOICENorth (ncl.ac.uk/ageing/partners/voicenorth). We discovered that:

- There is enthusiasm for replacing inconvenient or undignified hospital tests with home-based alternatives, and a related next step may be to produce the required equipment at home
- 3D printing only makes sense for customised devices
- The present older generation may not have had sufficient technological exposure to favour self-printing but this is likely to change over coming years
- 'Digital fabrication spaces' with associated support may be a good solution in the meantime
- Simple designs, along with methods to ensure and test product quality, are crucial
- Flexibility is key; self-produced devices should supplement, not replace, conventional methods

"Probably the idea is more suitable for the 'next' older generation..."

Next steps

We plan to further this project by continuing to improve the technical performance of the RiPod, assessing its robustness in patient use, and exploring the regulatory implications and framework.

Thank you to the RiHN for the opportunity to work on this project