

A Review of In-House Medical Device Manufacturing at Swansea Rehabilitation Engineering

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Aims and Background: The in-house manufacturing workshop within Swansea's Rehabilitation Engineering Unit (REU) manufactures bespoke medical devices for the Specialist Seating Service and the Pressure Ulcer Prevention & Intervention Service (PUPIS). It is estimated that the workshop manufactures 600 medical devices per year (including modifications/repairs). The team comprises of engineers and technicians who cover all aspects of manufacturing ranging from machining to upholstery. With the new MDR being introduced, the department implemented a Quality Management System (QMS) and sought ISO 13485 accreditation, which it was successful in obtaining in 2021. This has led to:

- Increased structure and formality to processes relating to the in-house manufacture of custom devices
- Traceability of devices
- Up-to-date records of custom devices
- Assurances to our service users of quality and safety

Furthermore, to ensure safe workshop practice, the team developed a set of training competencies for each piece of machinery to enable non-workshop staff to use the workshop, where appropriate.

Within the workshop structure, there are two sub divisions, manufacturing and upholstery. Activity from both sub divisions are audited, with a target of two weeks from the clinician requesting a custom device to the manufacture of that device being complete. This audit data has led to the development of key performance indicators, which the department are monitoring regularly. These are subsequently reported to senior management.

Workshop Activity:

The overall number of custom medical devices manufactured in-house has increased from 491 in 2019 to 588 in 2022. This data has enabled the department to justify additional staff resource to keep up with demand and allow custom equipment to be delivered to service users in a timely manner.

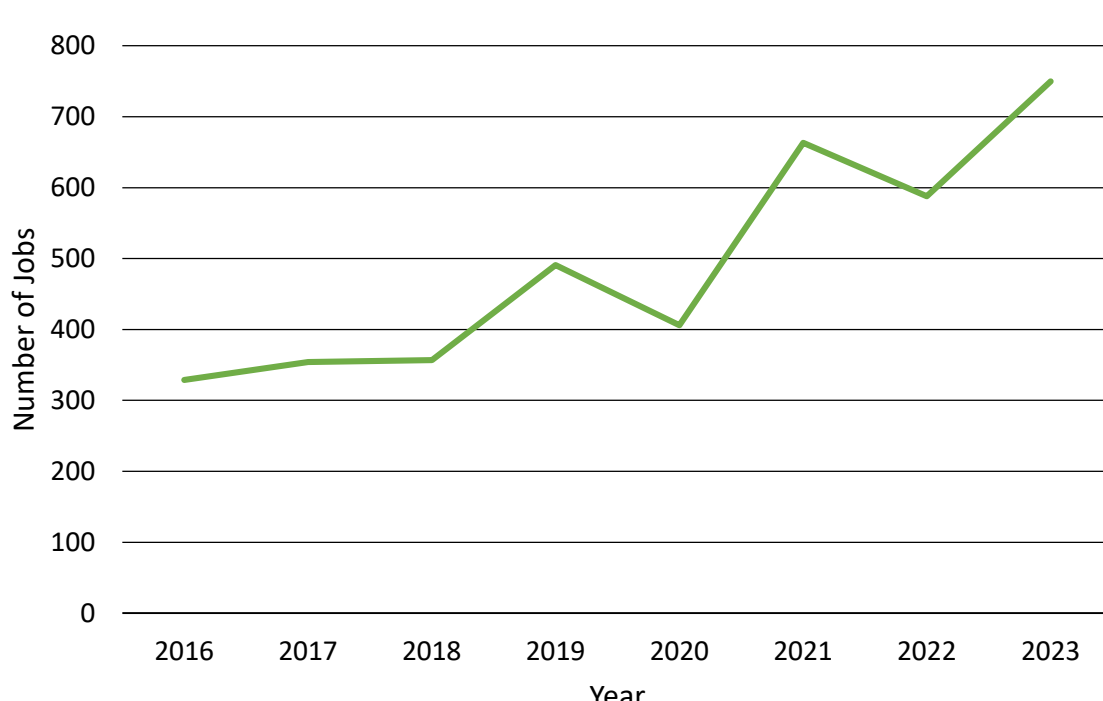
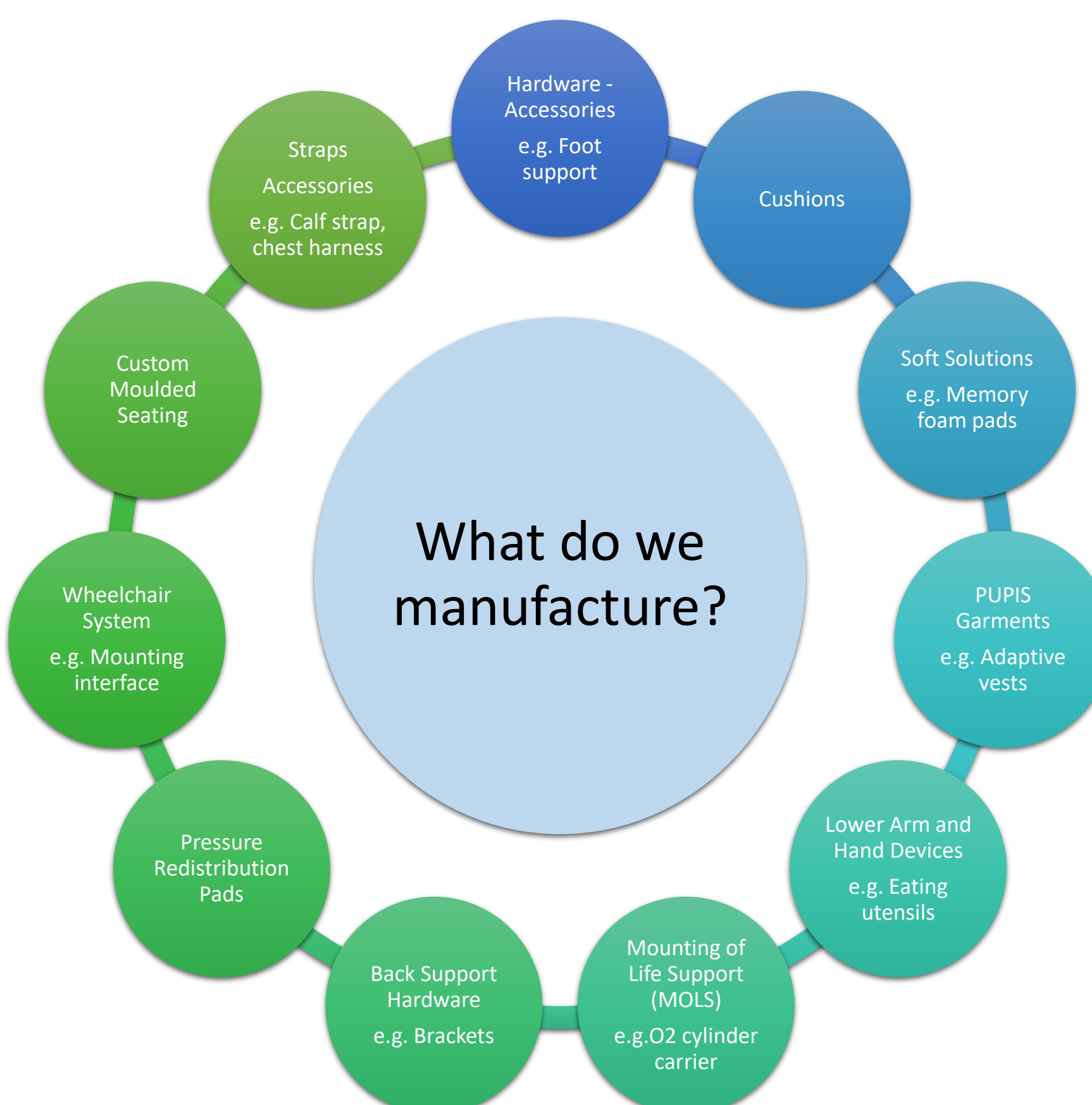


Figure 1: Number of jobs completed per year from 2016-2023. 2023 data includes projected data based on current trending

As shown in figure 1 above, the projected number of jobs that will be completed in 2023 is approximately 750. This is an increase of 49% and 28% when compared to total jobs completed in 2019 and 2022, respectively.



Audit Results:

An audit of custom moulded seat provision has revealed a 63% increase in demand of custom moulded seating when comparing pre (2019) and post (2022) COVID-19 pandemic periods, as shown below in figure 2.

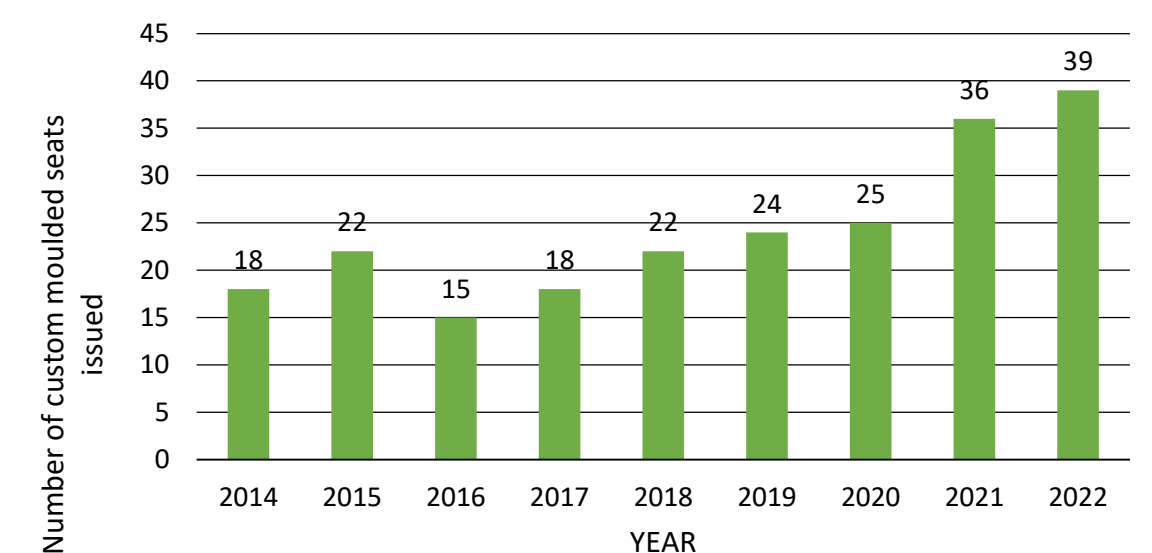


Figure 2: Number of custom moulded seats provided each year from 2014 to 2023

Our target is to reduce the number of custom manufactured devices waiting over two weeks from request to manufacture to 1 in every 5 jobs (20%).

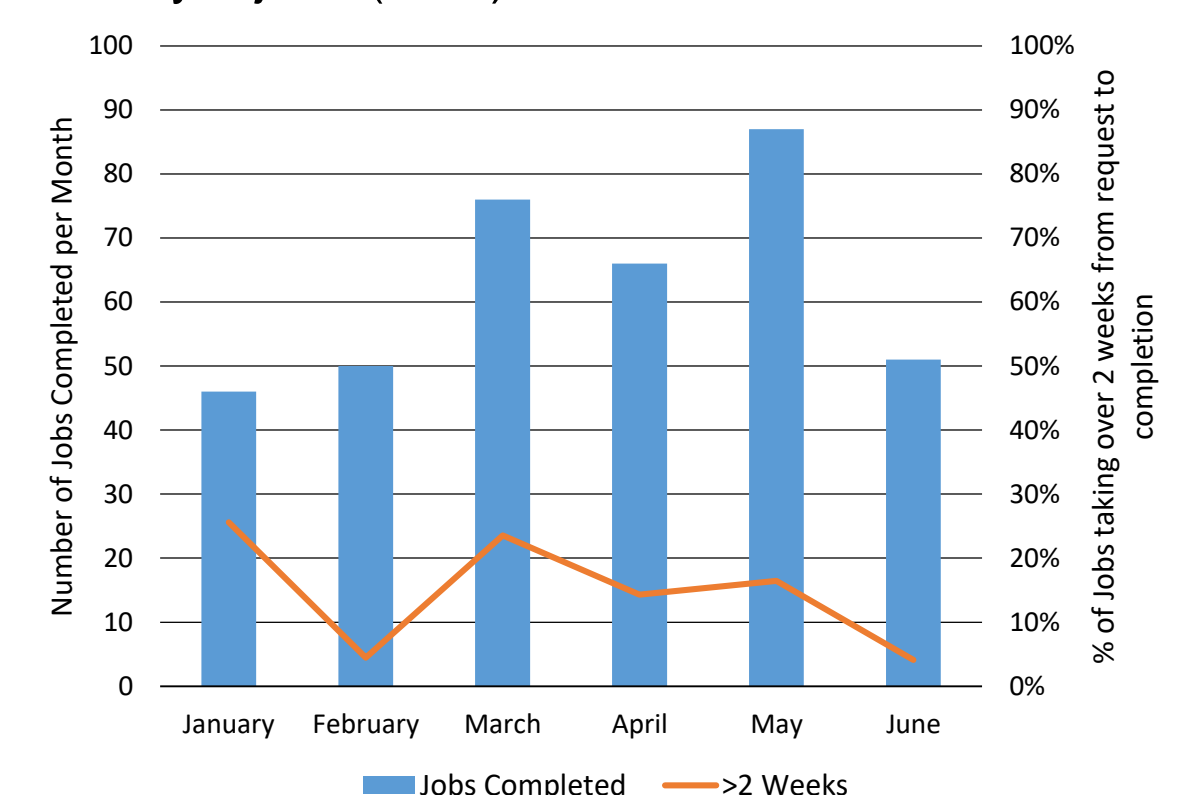


Figure 3: Number of jobs completed per month and the percentage of jobs taking over two weeks from request to completion in 2023

Workshop Resource Allocation:

The two production streams of upholstery and manufacturing total 2.3 whole time equivalent (WTE). Production of custom equipment is primarily for the Specialist Seating Service, as shown in figure 4 (right). A review of workshop skill mix has allowed for more efficient allocation of work that has assisted with decreased lead times in the workshop. Having both production streams in-house benefits the department in a number of ways, including cost savings and turn around times. Figure 4 below shows the split between upholstery and manufacturing job requests and their respective WTE.

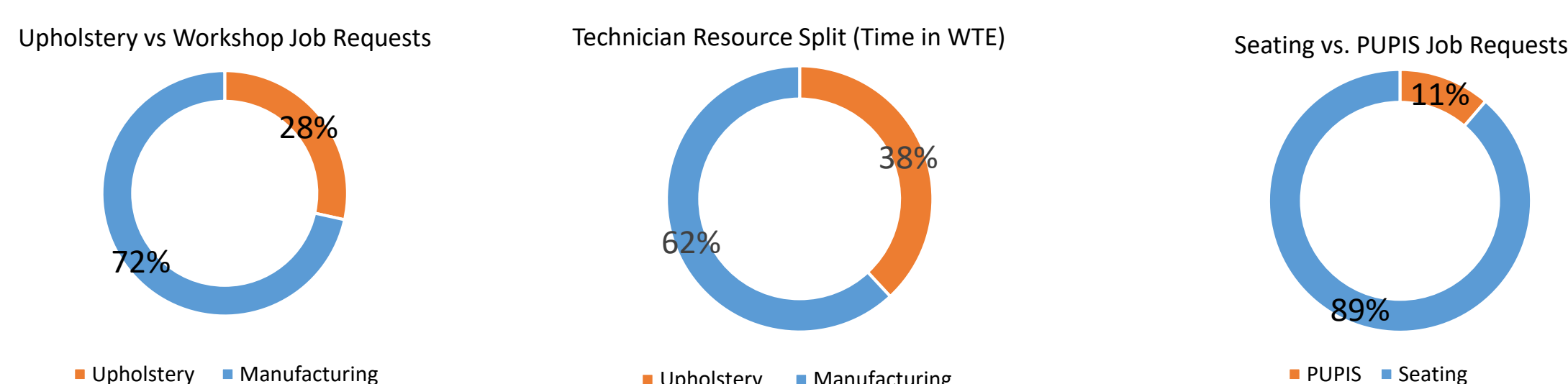


Figure 4: A comparison of time resource in WTE between upholstery and manufacturing (left), percentage of jobs requesting upholstery or manufacturing input (centre) and percentage of jobs requested by Specialist Seating or PUPIS (right). Jan-June 2023 data

Discussion: Audit data has provided an insight into the impact that the COVID-19 pandemic had on services. Custom moulded system data is suggesting that there is an increase in the complexity of our service users post pandemic. Reduced access to services may have contributed to this.

Regulation changes have had an overall positive impact on in-house manufacturing within REU. This has in-directly improved the service user's experience because the department now has robust processes, which provide assurances to service users that devices are made to a set of standards, whilst retaining the innovation required to meet the individual needs of our service users. Projects on sustainability and green practice as well as the refinement of manufacturing techniques to improve the aesthetics of custom equipment are a few examples of on-going workshop innovation. Expansion and manufacturing opportunities are being considered.



Acknowledgements: Dr. Rebecca Nix - Regulatory and Compliance Manager
All staff within the Swansea Rehabilitation Engineering Unit

