B3.A and B
B3.A

Quality in Design Development at WestMARC

Sara White, The West of Scotland Mobility Centre

Summary

The West of Scotland Mobility Centre (WestMARC) has been ISO-13485 (Medical Device Quality Management System) registered since 2012. WestMARC manufactures medical devices to fit wheelchair bases, these are a mix of standard designs and/or bespoke designs.

Plan to discuss WestMARCs approach to maintaining ISO-13485 standards with reference to design and development.

Aims and objectives

Plan to outline WestMARCs approach to the design and development requirements for maintaining ISO-13485. WestMARC manufactures medical devices to fit to wheelchair bases; these are a mix of standard WestMARC designs and/or bespoke customised designs.

The quality requirements will be outlined for design planning, inputs, outputs, verification, validation, transfer, and review. This will also include detailing design risk assessments and user information.

WestMARC has now had many internal audits and external audits by BSI. Many lessons were learnt for implementing a new design development process as a result of the audit process.

Background, Technique, Standards, Clinical Detail, Results and Testing

In 2019, Medical Device Directive (MDD) was planned to be changed to Medical Device Regulation (MDR); WestMARC implemented many steps to ensure compliance (even though laterally this was not required in UK due to Brexit).

Now medical device designs are regulated under UK MDR 2002. WestMARC designs are normally classified as a Class I Medical Device as per Classification Rules for non-invasive devices. Devices are not placed on the market, so CE marking is not required.

Design work is only undertaken by HCPC registered Clinical Scientists. Initially staff should attempt to fulfil prescriptions using commercially procured devices, where not suitable, a Standard WestMARC designed component is sought.

Designs may include

(1) In-house manufacture - where a device is designed and manufactured in-house.

(2) Modification - where a commercially procured device is modified in some way to alter its function.

(3) Off-label use - where a commercially procured device is used in a manner outside that intended by the manufacturer.

All designs require a unique design file, as required by ISO-13485. The extent of the design file should reflect the complexity and risk associated with the device. WestMARC uses Q-pulse Quality management software to control documentation, this includes design files, technical files,

procedures, prescription forms, drawings, risk assessments, assembly instructions, material data sheets, calculation and tests.

Standard WestMARC Designs are those suited for use across a wide patient cohort, which allows manufacture and stocking of a design, available to all prescribing staff (for example modular seating or arm pads). Other WestMARC designs are one-off bespoke items, designed specifically for an individual patient (Custom Build Design).

Auditing is a requirement of ISO-13485. WestMARC has now had many internal and BSI external audits for design and development. Most audits identify areas for improvement resulting in additional workload. It is important that WestMARC management continue to allocate adequate resources to allow for these improvements to benefit to patient care.

Significant effort has been put into ensuring appropriate user information is supplied for WestMARC standard designs. Work has also been put into creating design files in addition to technical files to show how a standard design adapts for improvements or coping with unforeseen changes. The importance of staff training on prescription completion and manufacturing instructions have also been identified. Since the MDD changes WestMARC has tried to improve design verification with more testing (for example seating crash tests and material flammability testing).

For WestMARC bespoke designs, the main change was to introduce more formalised risk assessments at point of recording a design, not only at delivery. Reviews highlighted gaps in paperwork and a design checklist was introduced. Small group meetings were introduced to share/ review each other's designs; this helped staff to appreciate the required detail. It was beneficial to highlight alternative risk factors.

Monthly design reviews have continued at team meetings. Sharing design findings helps staff to be aware of other ongoing designs and may help to improve other patient's equipment provision.

Discussion

Novel designs offer significant benefits to patients, as off-the-shelf components often cannot be adequately configured to suit. It is important that new designs continue to be used without introducing undue risk to patients.

It is challenging to introduce additional design tasks for clinicians already under a significant workload. Design reviews offer important learning and reflection within the team. Independently reviews help to highlight alternatives and or improvements available, and or potential safety concerns.

Quality lead designs allows for continual improvements to benefit patients.

References

The Medical Devices Regulations 2002 The Medical Devices Regulations 2002 (legislation.gov.uk)

Medical Devices Directive 93/42/EEC.1993 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31993L0042

Medical Devices Regulation (EU) 2017/745. https://eur-lex.europa.eu/eli/reg/2017/745/oj

BS EN ISO 13485: 2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

B3.B

Bridging the Gap: From Standards to Reality in Headrest-Backrest Design

William Dauncey, PDR Design, Cardiff Met and **Ben Aveyard**, Swansea Bay UHB

Summary

This research investigates real-world wheelchair use scenarios and compares them to testing standards, highlighting design improvement opportunities for headrests and seating. We used a custom developed mechanical test rig to replicate forces defined in ISO standards and as measured from a user case study in controlled conditions.

Aims and Objectives

- Analyse a case study of a custom wheelchair backrest failure and the potential cause.
- Quantify forces generated by a wheelchair user who previously experienced backrest failure in real-world scenarios.
- Compare real-world user force data with the ISO 16840-3 standard for postural support devices.
- Develop a custom test rig to replicate real-world and standard testing conditions.
- Test custom wheelchair seating under controlled parameters for failure point identification.
- Share insights on using ISO 16840-3 and real-world data to inform safer and more user-friendly wheelchair design.

Background/Methods/Techniques/Results

Background

Wheelchair headrests and seating exhibit significant variation in design and configuration. Current understanding of their performance under standard mechanical testing (e.g., ISO 16840-3) and real-world use is limited. Existing data also lacks analysis of how established testing standards address actual wheelchair user experiences and component failure. This gap suggests potential for design improvements to enhance user safety and experience.

Methods

1. Case Study Analysis: We analysed a case where a custom fabricated wheelchair backrest failed, investigating the likely scenario that led to the failure.
2. Real-World User Data: We measured the forces generated by an adult wheelchair user with a neurological condition. This data captured the nature and location of force application in real-world settings.
3. Standard Comparison: We compared the real-world user data with the ISO 16840-3 standard, which focuses on static, impact, and repetitive load strengths for postural support devices.
4. Custom Test Rig Design and Fabrication: We constructed a mechanical test rig specifically tailored to replicate both real-world and standard testing conditions.

5. Custom Seating Testing: Custom wheelchair seating was subjected to controlled testing on the developed rig. Parameters included force levels, speed, duration, number of cycles, and failure point identification.

Results

- The case study analysis revealed potential design weaknesses in the custom backrest that could have contributed to the failure.

- Real-world user data showed significantly different and more dynamic force application compared to the static and repetitive loads outlined in the ISO 16840-3 standard.

- Testing on the custom rig demonstrated potential weaknesses in the current custom wheelchair seating designs where failures could occur during extreme cases where users excerpt forces beyond the norms defined in the ISO standard. This suggests that the standard may not sufficiently capture the demands of actual wheelchair use.

Discussion

The research highlights a disconnect between the demands of real-world wheelchair use and current testing standards like ISO 16840-3. By combining case study analysis, real-world user data, and custom testing, we gain valuable insights into design vulnerabilities and identify opportunities for improvement. The development of a custom mechanical test rig allowed for targeted evaluation of wheelchair components under conditions more representative of actual use.

Implications for Wheelchair and Seating Manufacturers

- Incorporating real-world user data and dynamic testing protocols into the design process can lead to more robust and durable wheelchairs that better withstand actual use conditions.

- Manufacturers can utilise the insights gained from this research to optimise headrest and seating designs for improved safety and user experience. There is an opportunity to optimise designs based on user weight and the forces they are likely to apply.

- Collaboration between wheelchair users, researchers, and manufacturers is crucial for developing effective testing standards and implementing evidence-based design improvements.

By bridging the gap between standard testing and real-world use, this research contributes to the development of safer and more user-friendly wheelchairs, ultimately improving the quality of life for wheelchair users.