

# Reporting user experiences of a powered pressure area care support surface in a university hospital as part of proactive Post-Market Surveillance

Sue Hopewell, Clinical Affairs Associate & Honorary Tissue Viability Nurse, Talley Group Limited, Romsey, UK.

## Introduction: what is post-market surveillance and why is it important?

Post-market surveillance (PMS) is a critical element of the Quality Management System (QMS) for every medical device manufacturer.

Each company's post-market surveillance system should actively and systematically gather, record and analyse device specific data in order to identify any preventive or corrective actions that must be taken to ensure device quality, performance and safety throughout its entire lifetime.

The data generated from all PMS activities is collated together and the device specific reports are reviewed by senior members of the company's management team. This data informs regular, structured reviews of the device risk/benefit balance whilst informing future product development.

## Pro-active post-market surveillance

PMS is a relatively broad 'catch all' term for a range of both 'reactive' and 'proactive' activities that all medical device manufacturers are required to undertake as part of their routine workflow. See Figure 1 for an illustration highlighting the constituent parts of PMS and how it feeds into a company's Quality Management System.

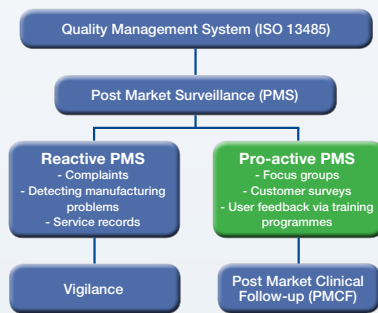


FIGURE 1. Simplistic overview of reactive and proactive PMS activities and how they feed into the QMS

The pro-active element of PMS is of significant importance as it requires medical device manufacturers to actively seek out the views and experiences of end users (i.e. clinicians) for the devices they make.

This proactive approach to data gathering and data analysis ensures that any issues around product quality, safety and performance are reported back into the manufacturer sooner than if the company relied solely on reactive data, such as customer complaints.

The benefit of this is the early identification of any device related problems or issues, thereby allowing manufacturers to minimise risk, enhance patient safety and optimise patients' clinical outcomes when using their devices.

Although PMS was a requirement of the Medical Device Directive (MDD), with the new EU Medical Device Regulation (MDR)

fully applicable from 26th May 2020, Notified Bodies are now paying particular attention to this aspect of every company's Quality Management System and the Technical File documentation for each product.

In line with the MDR it is necessary for each product Technical File to have a dedicated post-market surveillance plan and in terms of PMS reporting, the MDR states;

*'Manufacturers of Class I devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority [MHRA] upon request.'*

*'Manufacturers of Class IIa, Class IIb and Class III devices shall prepare a periodic safety update report ('PSUR') for each device summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken.'*

*'Manufacturers of Class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall be part of the technical documentation.'*

## Implications for pressure area care (PAC) support surface manufacturers and healthcare professional

Every PAC support surface manufacturer must now have a dedicated PMS plan for each of their products and perform ongoing post-market surveillance throughout the lifespan of each PAC product line.

Therefore, irrespective of whether a pressure area care (PAC) support surface is a Class I medical device (i.e. a high specification foam mattress) or a powered air mattress (registered as either a Class I or a Class IIa device), PAC support surface manufacturers must now proactively collect and review user experiences on all their devices from a representative range of clinical settings and geographical locations, on an ongoing basis.

Manufacturers' PMS systems must actively and systematically gather, record and analyse data on device quality, performance and safety from a diverse range of sources. Therefore, healthcare providers, tissue viability nurses, link nurses, care assistants and students using PAC products within both hospital and community settings should from time to time expect to see the PAC manufacturers' PMS questionnaires requesting feedback on these products.

Whilst manufacturers acknowledge that this requires a small amount of time and additional input from clinical staff, this is ultimately being done to ensure the safety, performance and quality of these devices for the patients that use them. Wherever possible manufacturers should look to streamline the process of data gathering to ensure it is quick and simple for clinical staff to complete.

## Aims

The aim of this work was to undertake a pro-active, prospective customer survey of clinical staff with experience of using a powered PAC support surface from Talley Group Limited within a University Hospital in Europe. The data will be used by Talley to support its PMS activities for this product.

## Methods

The work reported in this poster reflects the user feedback from clinical staff using the QUATTRO® Plus support surface from Talley within a University Hospital in Europe.

The QUATTRO Plus (Figure 2) is a Class IIa, electrically powered PAC support surface which delivers active therapy through a 1-in-4 cell cycle.

Between January and March 2019 structured questionnaires were used to determine device performance, safety and user experience with a powered PAC support surface which had been used by the hospital for the prevention and management of pressure ulcers for several years.



FIGURE 2. QUATTRO Plus mattress replacement system

## Results

Over fifty clinical staff returned completed questionnaires and the results are summarised below in Figure 3 and Table 1.

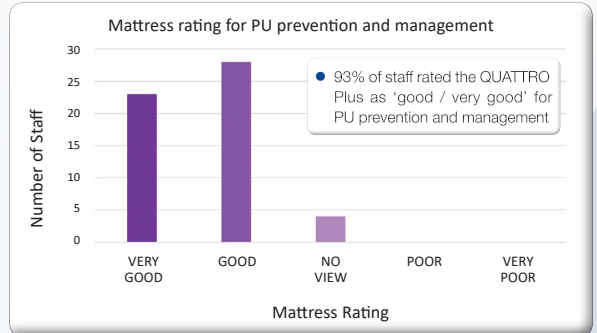


FIGURE 3. Staff feedback when asked how effective the QUATTRO Plus mattress system is for pressure ulcer prevention and management

	USER VIEWS / RESPONSES				
	Very Good	Good	No View	Poor	Very Poor
How easy is the mattress to set up and use for patients?	26	27	0	0	0
How would you rate mattress noise when in use? (good = quiet)	4	43	11	5	0
How would you rate patient safety / stability when using the mattress?	13	36	2	4	0
How would you rate patient comfort when using the mattress?	4	39	7	3	0
How would you rate the quality / reliability of the mattress?	19	32	2	0	0

TABLE 1. User views from clinical staff asked about the performance characteristics of the QUATTRO Plus support surface

In addition to Figure 3 and Table 1 above, forty four staff reported that they used the QUATTRO Plus mattress system for the treatment and management of patients with all categories of pressure ulcer, including those patients with full thickness, category 3 and category 4 pressure ulcers.

The data generated from this survey has been fed back into the Talley Group PMS process for this device and will be included in the next periodic safety update report (PSUR) for this product.

## Discussion

In addition to being the UK's largest privately owned manufacturer of specialist PAC support surfaces and having a significant presence in the UK healthcare market, Talley also export class leading medical devices to over fifty countries around the World.

As a result of this global footprint, it is essential that our proactive PMS activities reflect the geographical areas where the products are used and therefore our PMS must also include data from end users in overseas markets to ensure we have a representative data set to review.

The data reported on the Talley QUATTRO Plus support surface from this customer survey demonstrates that the majority of clinical staff from a leading European University Hospital rate this support surface very highly across all of the variables around device performance, safety and quality. The product clearly meets the PAC needs of both patients and staff and is widely accepted as an effective part of the pressure ulcer prevention and management care bundle within the hospital.

This customer survey is one example of the type of pro-active information that can be gathered by PAC companies to support their post market surveillance activities and to help meet their PMS requirements under the new MDR.

From a manufacturers perspective it is encouraging to see that the findings from this work support the results of previous evaluations on the QUATTRO Plus mattress system.<sup>1,2,3</sup> There is a clear and obvious consistency in the positive user experiences being reported both with this European customer survey and with previous work performed in the UK and Ireland.

The consistency of these results across different clinical settings in different countries suggests that the QUATTRO Plus will deliver the required pressure area care performance, irrespective of either the country or the care setting it is used in, thereby assisting healthcare providers with the delivery of safe, effective, harm-free care for service users at an elevated risk of pressure ulceration.

## Conclusions

The requirement for manufacturers to undertake regular, structured, proactive post market surveillance for all medical devices is here to stay and it will affect every PAC support surface manufacturer irrespective of whether they sell foam, hybrid or air mattresses.

Manufacturers must actively seek-out post market surveillance data from customers in both domestic and overseas markets where their device is used. When healthcare providers and clinicians are asked to provide PMS data to manufacturers, they can be re-assured that this data is being used to help ensure the performance, safety and quality of the PAC device they are using for their patients.

Whilst manufacturers acknowledge that due to workloads and time pressures, clinical staff are unlikely to welcome the request to participate in proactive PMS data gathering, it should ultimately be seen as a positive as it means that the manufacturers are fulfilling their requirements under the new MDR. Indeed, it is those manufacturers who never request assistance with gathering PMS data that should probably set the alarm bells ringing as one would have to question how they comply with the new medical device regulations around product safety, performance and quality.

## References

- Harrison K. Adopting a new mattress replacement system as part of a comprehensive care bundle aimed at reducing pressure ulcer incidence across the Trust. European Wound Management Association conference poster presentation. 2015, London, UK.
- Heywood N, Poppleston A, Povey A. Reducing the incidence of hospital acquired pressure ulcers.
- Strapp H. A formal evaluation using an active therapy mattress system for pressure ulcer prevention in an acute care setting. Wounds UK conference poster presentation. 2016, Harrogate, UK.