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Tith healthcare budgets being squeezed ever tighter and management teams constantly striving to maintain or improve reductions in pressure ulcer incidence, while demonstrating costsavings and efficiency gains, there are clear, and often conflicting pressures on both primary healthcare providers and their staff when it comes to selecting and using specialist, powered air mattress replacement systems for the prevention and management of pressure ulcers.

ISSUES FOR FRONTLINE COMMUNITY STAFF

Preventing pressure ulcers to save money

Clinical budgets and spending are often tightly controlled by finance, which can result in nurses and therapists being reluctant to propose or prescribe a certain product or treatment, as they are often working with one eye on the patient's needs and the other on the budgetary impact of their recommendation.

This approach can result in clinical teams having to justify why they need specialist pressure area care (PAC) mattresses for their patients, particularly for pressure ulcer prevention when a patient currently does not have any pressure-related skin damage.

Where budget holders do not have a clinical background or clinical

Feeling the pressure of support surface selection

experience, it may be a struggle for them to understand that proactively providing patients with an 'expensive' PAC mattress to prevent the development of a pressure ulcer is actually a shrewd financial move when considering the significant costs associated with the reactive treatment of patients that develop pressure-related skin damage.

In reality, developing and implementing a care plan and care package for a patient that develops a pressure ulcer, especially a fullthickness wound, is far more costly than the comparatively minor spend associated with the provision of a suitable PAC mattress, which could have prevented the wound developing in the first instance. Deciding to pursue a reactive approach to pressure ulcer treatment, as opposed to a proactive approach to their prevention, is a false economy that will undoubtedly cost providers more in the long run.

By the time you factor in dressing costs, increased visits by nursing staff and therapists etc, it costs many more multiples to treat a pressure ulcer than it does to prevent it, and this takes no account of patients' quality of life, their right to harm-free care', and the driver for all healthcare providers to reduce the risk of preventable harm to patients.

Working with distributors

When working with an equipment loan store, it is essential that there is adequate communication between all team members involved in equipment provision, i.e. the community nursing staff and distributors (equipment loan store staff).

Community nurses need to leave clear instruction about which

mattress is required, where it needs to go, and how it needs to be set up upon delivery, to ensure it delivers the correct PAC to patients. Miscommunication can result in the right product being delivered but not being set up and remaining unused for days or weeks until the nursing staff return to the patient's home. Clearly, this has a knock-on effect of putting the patient at increased risk as a result of not receiving the correct PAC that they require.

A good working partnership between the distributor and the community nursing team is essential for the seamless delivery of harm-free patient care. This requires:

- Community nurses to give correct and full information to the equipment loan store about the product required and what must be done with it once it is delivered to the patient's home
- Effective communication between all those involved in product delivery and use
- Arranging visit times between the clinical staff and the loan store delivery staff to ensure that the right product is delivered, set up and used correctly
- Arranging training for carers working with the patient in their own homes to ensure that they are aware of the correct setting and troubleshooting should the mattress alarm go off or it stops working, for example.

ISSUES IN CARE HOMES

Problems faced in care homes differ from those in the community and include the following.

Availability and getting hold of the right PAC mattress from stock can cause issues in the care home setting. This can result in staff being overly protective of their mattresses and once they have secured it in their area they can be reluctant to let it go again. This can result in inappropriate use of these specialist support surfaces, with a resultant increase in overall spend.

Lack of education for care home staff may result in inappropriate use, therefore there is a clear need for providers to ensure that their staff have pressure ulcer prevention, management and PAC product education. This will ultimately result in a more informed workforce who will have greater ability and confidence when providing patient care, which in turn can potentially reduce the spend associated with over prescription of mattress systems.

ISSUES FOR HEALTH-CARE PROVIDERS

Before nurses and therapists can choose which mattress they provide to meet patients' PAC needs, the healthcare provider's management team will have gone through a rigorous tendering process, during which multiple stakeholders will have decided which mattresses to select.

So, what are the issues faced by tissue viability as a key stakeholder in the tendering process for the selection and provision of PAC mattresses for their patients?

A complex and confusing market place

NHS budget cuts have created a more competitive healthcare market in recent years. This has seen an influx of cheap, no-frills, low-end, powered PAC support surfaces appearing in this increasingly price sensitive and crowded sector of the medical device market. The result is a market place where powered PAC air mattress replacement systems can cost anywhere from £300 to £1,500 or more.

With such a vast difference in product pricing, it is logical that not all of these products will be equivalent to each other in terms of product performance, clinical efficacy, device safety, quality, reliability, longevity, etc. How do we,

as clinicians, assess these different parameters between products and make the right choice for our trust and patients?

There is no magic formula available to allow assessment and ranking of all of the various parameters across all of the products being tabled in the tendering process. Quite simply, it is an almost impossible task to present the tender team with the 'best' product which meets the needs of all stakeholders involved in the process. Finance will typically want the cheapest product; tissue viability want the most clinically effective product; while equipment stores/service technicians want a quality, reliable, and robust product.

So, realistically, how can we compare or test for differences between products — what is the 'benchmark' that we can use?

Comparing PAC mattress systems

Unfortunately, there is currently no agreed set of UK national or international standards which permit a comparison of the physical/mechanical performance characteristics of these specialist PAC mattress replacement systems.

However, earlier this year in the USA, the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) published the American National Standard for Support Surfaces Volume 1 (SS-1). 'Requirements and Test Methods for Full Body Support Surfaces'. This is essentially a set of seven US specific test methods, which can be used to qualify some of the physical performance characteristics for support surfaces sold in the USA.

The test protocols for the RENSA SS-1 standard were developed by the Support Surface Standards Initiative (S3I) group in the USA, a sub Committee of the National Pressure Ulcer Advisory Panel (NPUAP) Research Committee.

A little closer to home and perhaps of greater UK relevance was the publication in July 2019 of BS EN ISO 20342-1:2019 'Assistive products for tissue integrity when lying down. General requirements'.

Part 1 of the BS EN ISO 20342 standard applies to the safety and performance of PAC products (i.e. mattresses). Therefore it is entirely reasonable for healthcare providers to expect all PAC mattress manufacturers who make product claims about pressure redistribution and the prevention and management of pressure ulcers to comply with this new ISO standard.

Part 2 of the BS EN ISO 20342 standard will focus on the test methods used to qualify some of the physical performance characteristics of PAC mattresses. However, the ISO working group is still developing these test protocols, so realistically we are several years away from having an agreed set of ISO approved test methods which can be used to make a direct comparison of at least some of the physical characteristics of these medical devices.

Once Part 2 of the ISO standard is published, it will in theory allow PAC mattress tender teams to compare a range of performance characteristics across multiple products. While this should not be used as a 'buyer's guide', it may help to inform the decision-making process and allow us to narrow the field when selecting a shortlist of PAC products.

It remains to be seen how the ISO standard progresses and whether the S3I test methods are adopted beyond the USA and any impact they may have on the PAC mattress landscape.

Although the development and release of these standards is potentially helpful when benchmarking products, it is important to recognise that these will not represent a panacea for the selection of support surfaces. It will still be incumbent on tissue viability to look beyond the laboratory data that these tests will generate, and interpret this in terms of relevance to patient's clinical needs and ultimately to clinical outcomes and effective pressure ulcer prevention and management.

Finance versus clinical outcomes

With a constant focus on healthcare budgets, the considerable difference in the price of PAC mattresses can significantly influence healthcare providers when they are tendering for these devices, either directly or via community equipment loan stores. This focus on price can be especially true if the budget is held by the local council rather than the NHS. Broadly speaking, when the budget is held by councils and not 'health', they are not always aware of the intricacies and nuances associated with clinical efficacy and product performance that can be critical to successful patient outcomes.

The picture can become increasingly complex for providers when some of these entry level, budget devices are accompanied by the manufacturer's expansive and impressive marketing claims around product performance.

Furthermore, some equipment loan stores will propose that these budget devices are 'close technical equivalents' to existing, more established mattresses with a proven track record in the prevention and management of pressure ulcers. The equipment loan store claims of 'close technical equivalence' are often made with little, if any, supporting clinical data and it can then be left to already stretched tissue viability teams to prove or disprove these 'equivalence' claims as part of the tendering process. This is a heavy and potentially unfair burden for tissue viability teams to bear.

For the teams involved in the tendering process, the significant differences in product costs, similar 'face value' product performance claims, where the budget sits, and the commercial drivers and fine margins that some equipment loan stores operate on, can result in tissue viability teams having a major fight on their hands to justify why they are opting for one particular mattress over another.

For those members of the tender process focused solely on finances,

a low cost product with far reaching claims of clinical effectiveness can be appealing when looking to reduce spend and eek out resources even further.

As a result, tissue viability teams and those members of the tender group focused on patients' clinical outcomes and preventing pressure ulcers (a widely recognised preventable patient harm), can come under major internal pressure (from finance) and external pressure (from budget holders and the equipment loan stores) to take on the more budget end, low-cost air mattress replacement systems.

Despite the board level priorities associated with harm-free care and the clear focus on reducing pressure ulcer incidence, at times it can feel as though the patients' clinical needs and quality of life take a back seat behind the financial case being made.

PUTTING PATIENTS FIRST

Tissue viability teams typically have many years of experience they can call upon when it comes to assessing which products meet their patients' clinical needs. In the tendering process, this 'gut feeling' or 'personal preference' simply is not enough when facing hard facts and figures from the budget holders and the tender stakeholders who are purely focused on finance.

To support a case for selecting the most effective product from a clinical perspective, a business case needs to be constructed based around the following headings, which can then be presented to the tender group in order to justify our decision.

- Product performance: this could be interface pressure testing or similar
- Clinical effectiveness: evidence of PU incidence reductions (either from your own patient population, or from data published or presented on the product in question, or from the manufacturer's clinical evidence base). Ineffective products will result in needing to treat more patients with pressure ulcers,

- thereby incurring significant treatment costs
- Mattress quality/safety: what classification of device is the product in question? Remember, that performance and safety claims for class IIa medical devices are highly regulated by independent Notified Bodies, class I mattresses are unregulated medical devices
- Reliability: how often do products break down? What is the spares spend to maintain a fleet of mattresses? Broken products are a clear risk to patients and incur costs of repair and replacement of broken parts
- Longevity: how long will these mattresses last? One year, three years, five years... etc. Mattresses with a short lifespan will incur costs when being replaced.

The above information should be requested from either the mattress manufacturers or the equipment loan store, and it should then be a case of tissue viability dropping this into the matrix. Failure from either to provide supporting documentation may start to raise a concern around whether the product is the right one for patients.

Although the above is not an exhaustive or prescriptive list, building a matrix for each product being tendered and basing it on these points is likely to be a good starting point against which to counter the 'cheap is best' option, which is often tabled by some internal or external tender stakeholders.

SUMMARY

Effective prevention and management of pressure ulcers and the ongoing focus at board level to reduce the incidence of this recognised patient harm are overarching priorities for all healthcare providers. However, there are clear challenges both at management level to ensure the right products are selected, and then at the individual patient level to ensure that the most appropriate products are set up and used correctly and at the right time.