

In each issue we investigate a hot topic currently affecting you and your community practice. Here, we ask...

Are pressure area care support mattresses being under-regulated?

While regulation is common in many walks of life — health care, the food industry, the building trade, to name but a few — it has become a national hobby to rail against the imposition of standards imposed from above. The phrase ‘health and safety gone mad’ has become common parlance, and is cheerfully bandied about whenever builders are asked to put on a hard-hat, chefs are ordered to wash their hands, or you require a triplicated insurance certificate to put up a shelf in your lounge (the last one is an exaggeration, obviously, but you get the point).

Some regard government regulation as an over-reaction to the potential dangers inherent in going about their daily life, seeing it as a set of unnecessary rules, usually handed down from the EU, and policed by an army of ‘jobsworths’ armed with clipboards and poor social lives.

In health care, however, regulation is there for a very good reason; to enforce standards and ensure that medical equipment is safe, effective and does not harm patients. Regulation ensures that the drugs we take do not contain toxins; that the wound dressings we apply are uniformly manufactured; that the theatre nurse who is attending to our operation is wearing the right kind of gloves.

HOW DOES PRODUCT REGULATION WORK?

Since it is a legal requirement for all medical devices sold in the EU to carry the CE mark, most



This is such an interesting article and has really highlighted potential issues and responsibilities, while raising awareness of the difficulties nurses encounter every day.

In my experience, most trusts procure contracts with a provider of pressure-relieving equipment, thus it is their overall responsibility to ensure that the equipment nursing teams can order is ‘fit for purpose’. The nurse is required to undertake an individualised patient assessment and order the appropriate equipment from a predetermined source. In addition, I am aware that regular audits of equipment are undertaken and if a patient develops pressure damage an investigation is initiated, which involves assessment of any pressure-relieving equipment utilised. This can then lead to changes in equipment via the procurement process. However, this process may be different in other areas, so the issues raised in this article are invaluable.

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people would probably assume that all medical devices are subject to similarly stringent regulation as medicines (‘Medical devices: conformity assessment and the CE mark’ – www.gov.uk).

In reality, this couldn’t be further from the truth, and it is the classification of the device that dictates the level of regulation and independent scrutiny that products are subjected to prior to being awarded a CE mark.

Manufacturers of ‘medium’ to ‘high risk’ medical devices, such as hip joints, breast implants wound dressings, intravenous (IV) equipment are required to undertake stringent clinical trials and/or provide comprehensive Clinical Evaluation Reports to an

independent Notified Body to prove device safety and efficacy before their products are awarded a CE mark.

Manufacturers of ‘low risk’ devices, such as sticking plasters, bed frames, walking aids, are able to ‘self-certify’ their products as safe and effective and they can therefore assign their own CE mark to the products without involving an independent Notified Body to validate any claims of device performance or safety.

Instead, medical devices are classified and carry a CE mark to ensure that the devices you — or your trust procurement department — are buying, such as gloves, IV equipment, wound care dressings etc, meet European safety standards.

Device classification is governed by a set of rules and it is the manufacturers' interpretation of these rules which dictates the class of device that their product fits into. While it is usually straightforward for manufacturers to determine which class of device their product falls into, powered pressure area care (PAC) support surfaces currently fall into a grey area in terms of medical device classification and manufacturers can opt for a Class I (unregulated) or a Class IIa (highly regulated) classification.

It is a requirement for all Class IIa, IIb and III devices to be checked by a Notified Body, i.e. a commercial company designated by the UK Medicines and Healthcare Products Regulatory Authority (MHRA) to provide quality assurance ('UK notified bodies for medical devices' – www.gov.uk). Medical devices are categorised as per *Table 1*.

Most of you would probably assume that all medical devices are checked in some way, audited by a panel of industry experts, for example, to make sure that they meet some kind of minimum standard and that their claims of safety and performance are accurate. But, as you can see from the classification categories in the table, some products (Class I devices) are not audited at all, but are still permitted to have a CE mark.

In fact, rather than being a guarantee of safety and clinical



This is a very informative article, which highlights the vital considerations when selecting pressure-relieving equipment that many would not consider. Within many organisations, whether NHS, social or private sector, although patient safety is the main consideration, cost effectiveness of medical devices purchased or hired is the second biggest driver and this influences what pressure-relieving equipment is purchased.

It is essential that purchasers and clinicians have an understanding of what terms associated with medical devices mean in order to ensure safety and reliability. With this understanding, a balanced decision can be made to protect patient safety.

My colleagues and I have often discussed our concerns with regard to healthcare providers making uninformed choices in their attempt to protect those in their care. And, have also been challenged and frustrated by the minefield of inadequate legislation/quality measures related to pressure-relieving surfaces.

This also applies to the general public, as we often come across individuals who have taken responsibility of their own care or that of a loved one and purchased equipment in the belief that it would reduce their risk or heal their pressure ulcers, only to find that it is not adequate for their needs.

Hopefully this article will provide direction on what questions to ask and consider when being sold equipment under the guise 'that apples and oranges are the same fruit'!

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efficacy, the CE mark is the same regulation that, as reported in the *Guardian*, a Chinese company, for example, would require to sell toys across the European Union ('Medical devices and Chinese toys share same level of safety checks' — www.theguardian.com).

There have always been doubts about the effectiveness of the CE mark system to regulate medical devices safely. This was exposed by a joint investigation by the *British Medical Journal* and the *Daily Telegraph*, where an application was submitted for a hip prosthesis to a notified body in Slovakia; the specifications of the hip prosthesis mirrored a previous product that had been withdrawn from the market for releasing metal ions into patient's blood ('Joint BMJ/Telegraph investigation exposes flaws in regulation of medical devices' — www.bmj.com). The fake hip prosthesis was passed for certification.

And why does this matter? It matters because the Class I products that carry a CE mark do not have to undergo any audit by a notified regulatory body before being awarded a CE mark, nor at any point during the product lifecycle. Therefore, as clinicians, how do we

Table 1: Medical device classifications

| Device class | Type of product | Audit required by an independent Notified Body |
|--------------|---|--|
| Class I | Non-invasive equipment such as pressure-relieving devices, bed frames, walking frames, stethoscopes | No |
| Class IIa | Active devices designed to administer or exchange energy, including pressure-relieving devices, invasive devices, dressings | Yes |
| Class IIb | Active therapeutic devices designed to administer or exchange energy in a potentially hazardous way, including invasive devices, complex wound dressings, ventilator equipment, intensive care monitoring equipment | Yes |
| Class III | Implantable devices such as heart monitors, balloon catheters, pharmaceuticals | Yes |

know Class I devices are safe and effective? Not only that, but Class I products include powered pressure-relieving support surfaces; products that help prevent potentially life-threatening pressure ulcers from developing or becoming worse.

With safe and effective patient care driving reductions in avoidable harms, healthcare providers, clinicians and patients must be confident that the products they are using are both safe and effective.

THE ROLE OF PRESSURE IN TISSUE DAMAGE

Pressure ulcers are a recognised avoidable harm and develop because the patient's tissue, typically that lying over bony prominences in vulnerable areas, such as the sacrum, coccyx, and heels, is exposed to prolonged pressure or pressure associated with shear causing occlusion/reduction in blood supply to the skin, for example, a patient's heels dragging on a bed sheet.

Pressure damage commonly affects patients with mobility issues, for example, those with a spinal cord injury, older patients with frail skin who spend long hours sitting down or in bed, people who are acutely ill, or the very young. Pressure ulcers can begin as superficial injuries that affect the epidermis and dermis, but can quickly move into the subcutaneous tissues and involve muscle, tendon and bone. Not only are many healthcare-associated pressure ulcers now being classified as avoidable events, there is a drive to reduce the significant costs to the NHS budget of this kind of tissue damage.

Support surfaces, such as mattresses and cushions, generally fit into two categories — powered or non-powered. Non-powered support surfaces include foam mattresses and static air-filled mattresses, whereas powered support surfaces include dynamic alternating surfaces; some of these include air-filled sacs that alternately fill and empty, while others laterally rotate to provide relief from pressure.



I find the concept of pressure-relieving equipment quite daunting and extremely challenging. As someone who visits many settings where health care is delivered, both private and in a patient's home, I find myself continually questioning the effectiveness and appropriateness of equipment provided. In fact, fairly recently I was asked to assess a patient who had developed category 3 pressure damage following a relative purchasing and using an aid that was marketed as a pressure ulcer prevention product. This product looked more akin to a washable incontinence sheet and the evidence on the website was even more shocking and may well mislead less informed individuals.

While in the NHS sector we would expect pressure-relieving products to be rigorously tested, the evidence examined and then numerous clinical evaluations undertaken, I am unsure if this happens consistently across the NHS and am even less confident about what happens within the private sector.

I have also found that obtaining information on a device's CE registration is not an easy task. In fact, I have looked on manufacturers' websites of mattresses I have seen in some private sector homes and research on how effective the products are is sadly lacking. The National Institute for Health and Care Excellence (NICE, 2014) does reflect this and recognises that evidence for pressure-relieving products is poor and mostly industry-led. With this in mind, maybe it is time for our regulating bodies to take more interest in what is available. I think that stronger guidance and recommendations would be welcome, especially in ensuring that all pressure-relieving products are registered as Class IIa, and regulated accordingly.

Last, it is important to remember that a pressure-relieving device is only a tool in our box of pressure ulcer prevention and treatment strategies, and should not be considered in isolation. We should not forget that skin examination, repositioning, risk assessment and management of nutrition and incontinence need to be undertaken in conjunction with the use of appropriate pressure-relieving aids if pressure ulcers are to be prevented or treated effectively.

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Similarly, the use of active (those that provide alternating low and normal pressure) and reactive (those that provide a constant lower pressure) support surfaces help to manage the levels of pressure experienced by the immobile patient. Reactive support surfaces apply constant pressure to the tissue until the patient moves or is repositioned, whereas active support surfaces periodically redistribute pressure underneath the body, particularly for patients who cannot be repositioned regularly.

Specialist support surfaces are specifically manufactured to improve tissue perfusion and thereby increase the viability of the patient's skin and underlying tissue. The international prevention and treatment of pressure ulcer guidelines recommend using an active support surface (overlay or mattress) for individuals at higher risk of pressure ulcer development when frequent manual repositioning is not possible (see point 2 on page 29 of the National Pressure Ulcer Advisory Panel/European Pressure Ulcer Advisory Panel/

Pan Pacific Pressure Injury Alliance [NPUAP/EPUAP/PPPIA], 2017 quick reference guide — www.epuap.org/wp-content/uploads/2016/10/quick-reference-guide-digital-npuap-epuap-pppia-jan2016.pdf).

The National Institute for Health and Care Excellence (NICE, 2014) recommends that anyone admitted to secondary care or at high risk of developing pressure damage in primary or community care should have at least a pressure-reducing foam mattress on their bed.

HOW DOES THIS AFFECT PATIENTS?

Choosing the correct support surface can both help to prevent pressure ulcer development, and, for a patient with a pressure ulcer, be crucial to their recovery. However, as Heidi Guy writes in the *Nursing Times*, 'the selection of the correct support system for each individual involves many factors and can, therefore, be quite complex' ('Preventing pressure ulcers: choosing a mattress' — www.nursingtimes.net).

According to the EPUAP, choice of support surface should 'take into consideration factors such as the individual's level of mobility within the bed, his/her comfort, the need for microclimate control, and the place and circumstances of care provision' ('Prevention of pressure ulcers: quick reference guide' — www.epuap.org).

Nurses' decision-making is complicated by the amount of products to choose from. Pressure-relieving equipment alone includes standard foam mattresses, high-specification pressure-reducing foam mattresses, non-dynamic overlays, hybrid mattresses and true dynamic pressure-relieving mattresses.

The current guidelines surrounding medical device classification do not help. For example, some manufacturers classify their powered support surfaces as Class I devices, which means that they can effectively self-regulate their product and release it without any external overview, while others are classified as Class

IIa devices, with manufacturers voluntarily accepting audit by an independent Notified Body.

So, what does this mean in practice? In short, it results in a grey area where the procurement team, risk management, tissue viability and prescribing nurses may not be aware that, even though the powered support surface they have chosen carries a CE mark, it may not have been externally audited. Which, in turn, means that you, as a professionally accountable nurse, could be treating your patients with a product that does not require any technical information to be compiled for audit, nor undergoes any kind of clinical evaluation to confirm any claims of product safety or performance.

WHAT CAN YOU DO?

First, you need to remember that, as a nurse, you are entrusted with safeguarding your patients. This means that you should understand the provenance of any equipment you use, and be confident of its safety. When it comes to pressure damage, one way to ensure this is to make sure that any powered support surface you recommend or procure is registered as a Class IIa medical device and CE marked appropriately. This will ensure that any manufacturer's claims about safety and performance have been independently checked by a registered Notified Body before the CE mark was awarded.

As NHS budgets become ever-more restricted, individual clinicians can also come under pressure to administer, recommend or procure products that are cheaper, while appearing to offer similar clinical benefits. Powered pressure area care (PAC) support surfaces are a perfect example. After all, it would be easy to assume that there was little difference between a cheaper support surface with a Class I CE mark, or a potentially more expensive version with a Class IIa CE mark. While clinical decisions are down to the individual nurse, it is important not to be influenced to invest in cheaper products that do not have a proven

provenance. You have to decide if you are safeguarding your patients by purchasing a cheaper support surface that comes with a lower regulatory audit threshold.

Safe and effective harm-free care is a clear and consistent theme across the Department of Health and Social Care, the NHS Outcomes Framework, the Care Quality Commission, NICE and Sign up to Safety. Therefore, the aim for all healthcare providers and any nurse should be to eliminate, as far as possible, the risk of harm to patients.

It is vital that clinicians involved in the procurement and prescribing of powered PAC support surfaces are aware of how low the regulation is set for Class I devices, and how a lack of awareness of medical device classification in itself poses a risk to patient safety. Educating colleagues about the differences in support surface classification and the variation between Class I and Class IIa medical devices is part of the nurse's duty to provide safe care.

It is clear, then, that powered support surfaces play an important role in the treatment and prevention of potentially life-threatening pressure ulcers. It is also clear that in the world of powered support surfaces, not all are made equal. It is important that, before nurses make a clinical decision, they are able to educate themselves about different products, the evidence for those products, as well as the individual needs of the patient.

As a nurse, only you can decide if you are prepared to use a powered PAC support surface that is manufactured and sold without having to undergo any clinical and regulatory checks. Simply ignoring the evidence really would be health and safety gone mad. **JCN**

REFERENCE

National Institute for Health and Care Excellence (2014) *Pressure ulcers: prevention and management*. Clinical guideline 179. NICE, London. Available online: [/www.nice.org.uk/guidance/cg179](http://www.nice.org.uk/guidance/cg179)