Hiding in plain sight: ISO20342-1 is the new international mattress safety standard published in June 2019. Do you know about it and how does it benefit you and your patients?

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Background

The pressure ulcer care-bundle acronym aSSKINg from the NHS core curriculum [1] highlights 'Surface' (i.e. the patient's mattress) as a critical element for patients at risk of pressure related tissue damage (see Figure 1).

With UK healthcare providers focussed on reducing preventable pressure ulcers and clinical staff tasked with delivering safe, effective, harm-free care to patients, it is logical to assume that medical devices pivotal to patient safety and successful clinical outcomes must attain the highest standards of performance and safety before they are marketed and sold to healthcare providers.

Assess risk	Do you know how important risk assessment is and what increases risk?
Skin	Early inspection means early detection – show patients and carers what to look for. Do you know how important skin assessment is and what to look for?
Surface	Make sure your patients have the right support. Do you know how important the right surface is and how to check it is being used correctly?
Keep moving	Keep your patients moving. Do you know how important keeping moving is? Mobility and the ability to reposition are absolutely crucial!
Incontinence	Incontinence/increased moisture. Do you know how much incontinence increases risk? It's so important to keep skin clean and dry.
Nutrition	Nutrition/hydration – help patients have the right diet and plenty of fluids. Do you know how important nutrition and hydration are and how to improve these?
Give information	Do you know how important it is to give patients and carers information to help them participate in their own PU prevention?

FIGURE 1.
Overview of the aSSKINg care bundle

PAC mattress regulation under the Medical Device Directive (MDD)/ Medical Device Regulation (MDR) is complicated by these devices currently falling across two medical device classifications. The majority are registered as 'unregulated' Class I medical devices with a minority registered as highly regulated, Class IIa devices.

In practical terms, Class I PAC mattresses are never subjected to independent Notified Body auditing at any point during their product lifecycle, whereas Class IIa PAC mattresses receive stringent independent Notified Body auditing throughout their entire product lifecycle.

For PAC mattress products registered as Class I medical devices, manufacturers claims around performance and safety are never independently scrutinised. This contrasts sharply where PAC mattresses are registered as Class IIa devices and all claims of device performance and safety are heavily scrutinised by an independent Notified Body.

Setting aside complexities and differences in device classification, PAC mattresses deliver either 'reactive therapy' or 'active therapy' to patients. Examples of different types of support surface that fit into these broad therapeutic categories are listed in Figure 2.

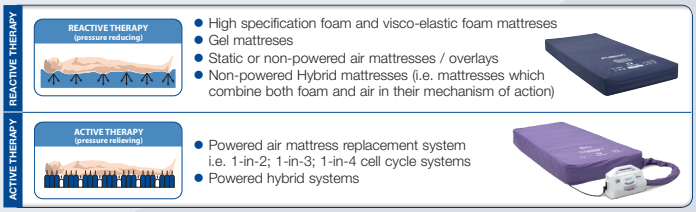

FIGURE 2.
Examples of different types of mattress covered by the new ISO 20342-1 standard

In June 2019 the first ever internationally agreed safety standard was published which focussed specifically on pressure area care mattresses. This new ISO standard applies to ALL types of PAC mattresses listed in Figure 2 and the title of this new ISO standard is;

> *ISO 20342-1:2019 Assistive products for tissue integrity (APTI) when lying down — Part 1: General requirements* [2]

Aims

This poster aims to raise awareness about this new ISO standard developed specifically for APTIs (this includes all PAC mattresses, irrespective of medical device classification) and considers how and why it is important to healthcare providers, clinicians and patients.

What does the new ISO 20342-1 standard cover?

The standard covers (but is not limited to) all mattresses and overlays intended for the prevention and, or treatment of pressure ulcers and it is designed to complement and build upon the broader remit of ISO 13485 which encompasses all medical devices. Therefore this standard applies to all types of foam, hybrid and air mattresses and overlays.

ISO 20342-1 describes the minimum requirements and necessary device development activities that must be met by all PAC mattress manufacturers or distributors to ensure their devices are safe and conform with all applicable standards.

Key points of interest

Section 4 - General requirements and safety

Section 4.2 Intended use

The manufacturer's intended use statement for their PAC mattress should include the application environment, patient population (i.e. PU risk level), and general medical claims (such as claims to reduce the risk of pressure injuries).

BENEFIT TO PROVIDERS AND PATIENTS: A clear 'intended use' statement from manufacturers will potentially help providers when selecting and using the PAC mattress as it will lay out which clinical settings and patients the product is suited to.

Section 4.2.3.1 Claims

This section ties in with 'intended use' and essentially states the manufacturer will set out clear device claims i.e. what the APTI will do from a clinical standpoint. The standard stipulates that all claims related to the products 'intended use' statement must be supported by evidence either with a specific test or clinical evidence demonstrating that the mattress delivers the clinical outcome the manufacturer claims.

BENEFIT TO PROVIDERS AND PATIENTS: Supporting product claims with test data or clinical evidence ensures manufacturers do not overstate product performance. This helps ensure product marketing claims can; 1) be trusted – when prescribing products to patients, and 2) be challenged as part of a tendering process.

Section 4.6 Clinical evaluation

Manufacturers are required to compile a full clinical evaluation report to MEDDEV 2.7/1 for all PAC support surfaces. [3]

BENEFIT TO PROVIDERS AND PATIENTS: Accurate claims of product performance and safety allow providers and clinicians to match product performance to patients' clinical needs.

Clinical Evaluation Reports (CERs) focus on PAC mattress performance and safety and ensure all product performance and safety claims are supported by relevant clinical data. CERs prevent manufacturers making spurious, far reaching claims they cannot evidence.

NOTE: Notified Bodies already audit CERs for Class IIa PAC mattresses. However, CERs for Class I devices are never audited by a Notified Body. Healthcare providers setting up a PAC mattress tender should specifically request sight of, or evidence of, the CER for any Class I PAC support surface they are considering using as it ensures manufacturers product claims are accurate, supported by suitable data and that they are adhering to the MDD/MDR and ISO20342-1 PAC mattress standard.

Section 5 - Safety requirements

Section 5.1.3 Education and training

Manufacturers who offer education and training on the safe use of their PAC support surface must clearly describe the intentions and outcomes from this activity and outline the duration, and any cost implications associated with the training. Manufacturers must also provide all relevant test, examinations and certifications.

BENEFIT TO PROVIDERS AND PATIENTS: Patients will be far more likely to gain maximum benefit from the mattress if clinical staff set it up correctly for patients' individual needs. Where there is a clear training need PAC mattress manufacturers should offer product education and training to ensure clinical staff can operate the product safely whilst ensuring patients get optimal clinical outcomes. Training may take the form of either;

- 'Awareness' training – where staff are given a product overview including basic set up and use. *OR*
- 'Competency based' training – offering clinical staff a greater product understanding, potentially as a 'train-the-trainer' approach where staff cascade training down to others in the organisation.

Section 8 - Safety of electrical equipment

Section 8.1 General electrical requirements and 8.2 Electromagnetic compatibility

Manufacturers of an APTI containing electrical or electronic devices/components shall conform to IEC 60601-1-2.

BENEFIT TO PROVIDERS AND PATIENTS: Manufacturers of electrical equipment must ensure that it meets the highest IEC safety standards. Conforming to these standard ensures that any electrical safety risks posed by the equipment is minimised.

Discussion

With all healthcare providers and clinicians focussed on reducing preventable pressure ulcers and delivering safe, effective harm-free care it is essential that every PAC mattress (APTI) attains the highest standards of device safety and claims of product performance are accurate and supported by appropriate clinical data.

Having an agreed baseline for the safety of all foam, hybrid and air mattresses and transparency around device performance claims allows providers to choose their preferred PAC products by aligning product claims with their patients' demographics and clinical needs.

ISO 20342-1 applies to all UK PAC support surface manufacturers and distributors and is primarily focussed on setting a minimum safety requirement for these medical devices. All healthcare providers and stakeholders involved in PAC support surface procurement and provision should be aware of, and familiar with, ISO 20342-1 as it may impact on their choice of PAC mattress.

Conclusions

Understanding the content of the new ISO standard allows stakeholders involved in mattress procurement to call-out specific elements of mattress safety pertinent to them and include these in their mattress tender specification.

For example, the need to have an intended use statement and a Clinical Evaluation Report written to MEDDEV 2.7/1 could be included as part of the tender specification for all mattresses. This would ensure the products in the tender meet the healthcare provider requirements and that device performance and safety claims are not overstated as they must be supported by relevant evidence and clinical data.

When tendering for powered PAC mattresses perhaps an obvious requirement in the tender specification would be for the product to meet the current electrical safety standards?

With an increasing focus on patient safety and preventing patient harm from pressure ulcers, setting a 'minimum bar' for PAC support surface safety is clearly a step in the right direction and should be welcomed by policy makers, providers, clinicians, patients, manufacturers and distributors of these medical devices.

By making part, or all, of ISO 20342-1 a mandatory requirement in PAC support surface tender specifications, healthcare providers can drive manufacturers and distributors to adopt and comply with this new device safety standard, which will ultimately be reflected in enhancing patient safety and reducing the risk of preventable pressure ulcers.

References

1. NHS Improvement. Pressure ulcer core curriculum. 2018 (June). Available from: https://improvement.nhs.uk/documents/2921/Pressure_ulcer_core_curriculum_2.pdf. Accessed on-line on 17/02/20.
2. BS EN ISO 20342-1:2019. Assistive products for tissue integrity when lying down. Part 1: General Requirements.
3. MEDDEV 2.7/1 revision 4. Medical devices directives. Clinical investigation clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC. June 2016.

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