MHRA updates

11/11/2021

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Off-label use of a medical device

Advice on MHRA Website

Modify medical devices – in line with instructions

No option but to use a device off-label – You must balance the risks and benefits to the patient taking into account recommendations which include:

- carrying out a risk assessment and documenting it
- considering the ethical and legal implications
- implementing suitable precautions to minimise the risk
- reviewing the risk assessment at suitable periods
- getting approval from MHRA for exceptional use of non-complying devices (if necessary)
- You must inform the patient during the consent procedure and make a note on their records that you will be using a medical device off-label.

Examples – see also one-liner in MDSO resource

A tongue depressor used a split in IV infusion for neonates	Fungal infection – amputation and/or death
IV cannula / catheter used as arterial catheter	On removal, a section of the catheter was left in the patient.
A contact lens solution used during surgery rather than after surgery as stated in the instructions	Central toxic keratopathy.
Bed-rails used not compatible with type of bed	Entrapment.

Virtual Ward – Pulse Oximeters

Is the device CE marked as a medical device? You can get fitness ones

Is the device intended to be read by the patient or the healthcare professional – numbers mis-read upside down

Have users been told to remove the plastic overlay?

Skin pigmentation affecting the readings

Hoist & Sling Training Survey

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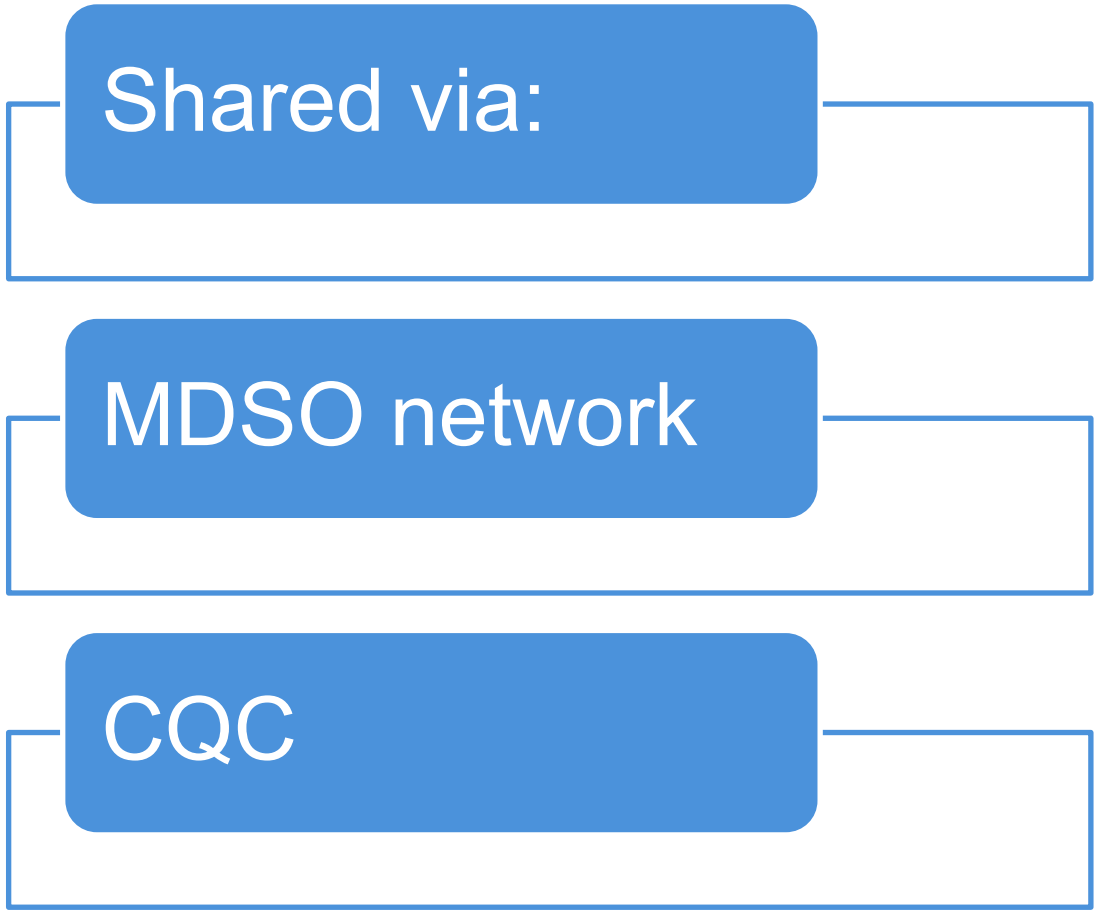
Introduction:

The Assistive Technology Group at the MHRA undertook a survey to collect information on how hoists and slings training is carried out in hospitals and the community.

Survey undertaken on surveymonkey.com during July-August 2021



Results:

516 responses:

- 175 responses via the MDSO network (NHS Trusts)
- 341 responses via the CQC network (Care Homes)

4% stated no training given

3% stated training not mandatory

8% either didn't know or stated that training was not qualified

6% did not feel they were trained to show consequences of poor use

101 responders stated that they supplied equipment to 3rd parties

31% did not supply training in use to 3rd parties

25% stated non-professional users were not trained

Comments given:

“Yes I'm trained but because I don't come into contact with them regularly, I do not feel confident in using them.”

“According to the standards they are, but that isn't really enough”

“Covid 19 has had an impact on training”

“All training since going to … online and I feel that quality has been lost”

“We don't know whether all staff in member boroughs have been trained”

Manufacturer input:

Generic training

IFU rarely read

Lack of consistency

Whose responsibility to train people using the devices at home?

One sling used for all and passed around. User guide downloads do not match number of times device has been passed around the community.

Next steps

- MHRA will share with CQC, NHS E&I and HSE suggestions regarding improving training requirements, for example:
  - Mandatory training for all users (including non-professionals and third parties)
  - A sling prescribers' course is necessary
  - Equipment providers need educating as well as users
  - Basic online training, followed by in-house physical training
  - Training should include the consequences of incorrect device usage
  - Face-to-face in-house training should be given by a qualified trainer who can pass the training down
  - Annual development training
  - Potential for an accreditation scheme so users can take their training over to another employer
- MHRA will also share the findings with BHTA and NAEP to maintain awareness on this issue

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