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Safety net or hole in the cheese?



Non-Luer neuraxial connectors are a hot topic at the moment. The ISO 80369-6 has been ratified and NRFit spinal needles are now widely available. The Association of Anaesthetists have produced a Frequently Asked Questions (FAQ) information sheet.¹ However, the fact still remains that one can draw up whatever drug one wishes into an NRFit syringe and administer it through an NRFit spinal needle. The new non-Luer connectors have given us an engineered solution to the problem of connecting a Luer syringe containing a drug intended for intravenous administration to a neuraxial administration device (spinal needles only at present; epidural catheters to follow in the future). Yet latent errors still exist in the system: firstly, we need to draw up the drug intended for neuraxial administration from a drug ampoule or fluid bag and errors can occur at this point. A second issue relates to the old but ongoing problem of drug labelling and off-label use of drugs intended for the neuraxial route. Drug ampoules or bags containing fluid intended for epidural administration clearly state on them that the drug is ‘for epidural use only’. The glass ampoules that we use for the preparation of our spinal anaesthetic mixture often do not. In our institution we use 0.5% bupivacaine 5 mg/mL (Marcain Heavy, Astra-Zeneca) plus fentanyl 50 µg/mL, 2 mL (Martindale Pharma) and morphine 1 mg/mL, 10 mL (Torbay Pharmaceuticals). The local anaesthetic ampoule states that the drug is ‘for intrathecal injection only’. The opioids are not licensed for neuraxial administration and therefore contain no reference to administration via that

route: rather the fentanyl ampoule states ‘for IV or IM injection’ and the morphine ampoule states ‘for IV use’.

There are surprisingly few preparations of morphine that are licensed in the UK and one needs to consider the complexities of the pharmaceutical industry to understand this predicament. A drug can be *suitable* for many things but may only be *licensed* for a single application. Obtaining a licence for a drug is an expensive business: The UK Medicine and Healthcare products Regulatory Agency states it will cost £92,753². If a licensed drug exists, hospital pharmacies are obliged to purchase that drug, even though they may be able to produce the drug more cheaply themselves. Changing the licence of a drug is also expensive, perhaps prohibitively so. The fee is £25,643.

Have we reached a point where we should be lobbying health regulators to supply us with drugs licensed for the neuraxial route? The fee of ‘only’ £25,000 is small when one considers the cost of a neuraxial drug error. Having identified the issue of still being able to draw up any drug one wishes to administer via our NRFit syringe, surely we need more precise ampoule labels to reduce the chance of an error?

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