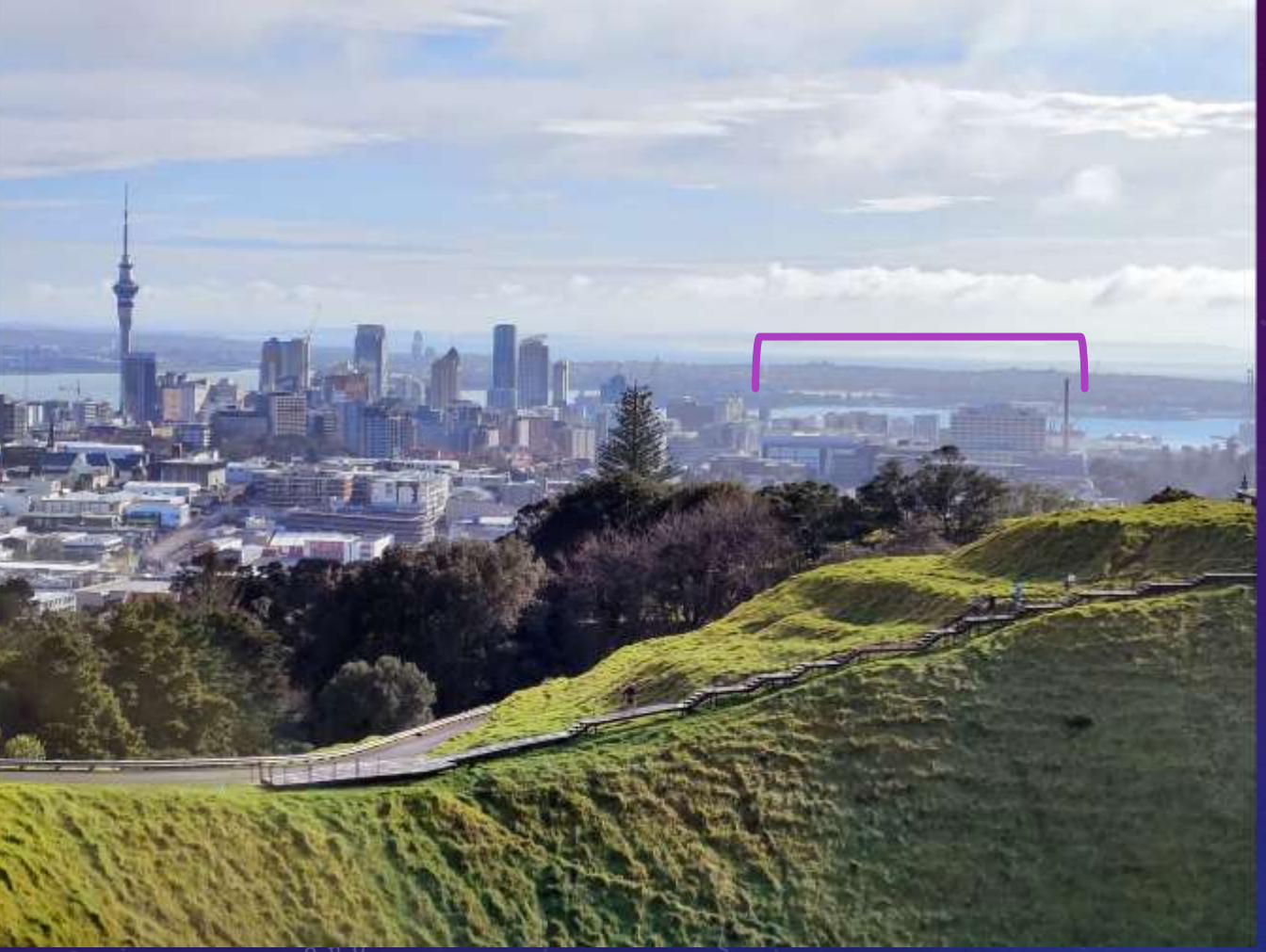


OASIS
Obstetric Anaesthesia Special Interest Symposium

ROLLING OUT NEURAL CONNECTORS IN YOUR HOSPITAL

MATT DRAKE

SERVICE CLINICAL DIRECTOR

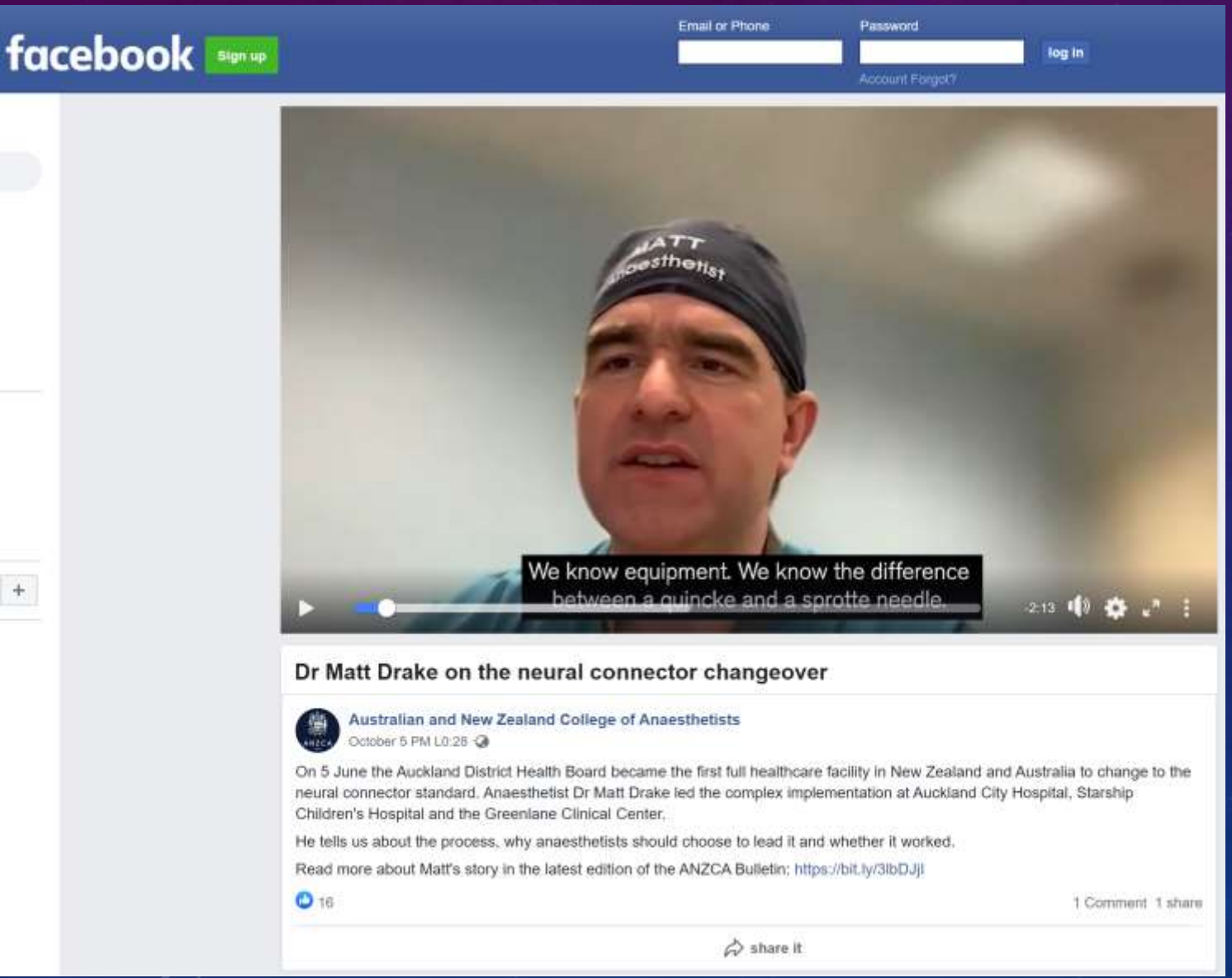
NATIONAL WOMEN'S HEALTH ANAESTHESIA, TE TOKA TUMAI AUCKLAND

OASIS 2022

DISCLOSURES

- Occasional coffee with suppliers (+ lunch on implementation day)
- I use these products
- No financial interest in any of the companies in this presentation or in GEDSA (“neural connectors”)

SPRING 2021 ANZCA BULLETIN



TE TOKA TUMAI AUCKLAND: AN AUSTRALASIAN FIRST (NEARLY)

- 1100 beds, all services including neurosurgery, transplant, cardiac
- 3 hospitals
- 70 new products
- 2 years planning
- 3 different project managers
- One weekend implementation

MULTIPLE ITERATIONS UP TO THIS POINT..

- B-link Ltd (UK)
  Neurax®

- InterVene Ltd (UK)
  Spinalok®

- Only is ISO approved (ISO 80369-**6**)
- Introduced 2017 (UK + USA)

ISO 80369 (2016)

Breathing systems and driving gases	Enteral	Urinary collection
Limb cuff inflation	Neuraxial	Intravenous

TO ERR IS HUMAN…

International Journal of Obstetric Anesthesia (2006) **15**, 63–67

doi:10.1016/j.ijoa.2005.06.009

CASE REPORT

IJOA International Journal of Obstetric Anesthesia

Inadvertent administration of magnesium sulfate through the epidural catheter: report and analysis of a drug error

E. J. Goodman, A. J. Haas, G. S. Kantor

Department of Anesthesiology, Case Western Reserve University School of Medicine and University Hospitals of Cleveland, Ohio, USA

SUMMARY. We present two reports of pregnant women in labor who inadvertently received a magnesium sulfate solution in their epidural space. Both women received approximately 9 mg of magnesium sulfate, and neither of them demonstrated any signs or symptoms of focal neurological toxicity. Once the mistakes were discovered and appropriate medication was delivered, the patients attained an acceptable level of analgesia.

Keywords: Drug error; Inadvertent; Epidural; Magnesium sulfate

REFERENCES - EPIDURAL

- Methohexitone
- Thiopentone
- Ranitidine
- Intralipid
- TPN
- Ephedrine
- Ether
- Potassium chloride
- Diazepam
- Magnesium
- …also Tranexamic Acid, Labetalol

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CAN BE FATAL – INTRATHECAL VINCRISTINE

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

AUSTRALIA, 2004. A 28-year-old male with Burkitt's lymphoma was receiving methotrexate via a spinal route. The doctor documented that "vincristine and methotrexate [were] given intrathecally as requested". The warning label on the vincristine was incomplete, and in small print, being read in a darkened room. The error was not recognized until five days later, after paralysis of the lower limbs had occurred. The patient died after 28 days.

https://www.who.int/medicines/publications/drugalerts/Alert_115_vincristine.pdf

MAYRA CABRERA

- Postpartum haemorrhage
  - Bupivacaine mistaken for IV fluid & administered
  - Cardiac arrest & died (2004)
  - Initially said to be AFE

http://news.bbc.co.uk/2/hi/uk_news/england/wiltshire/7226836.stm

E-mail this to a friend Printable version

Mother's epidural death unlawful

A theatre nurse who died after wrongly having a drug used in epidurals pumped into her arm was unlawfully killed, an inquest jury has ruled.

Epidural drip 'killed' mother
In quotes: reaction

Mayra Cabrera, 30, died shortly after giving birth to son Zac at the Great Western Hospital, Swindon, on 11 May 2004. The baby survived.

Midwife Marie To is alleged to have administered the drug Bupivacaine but denied this in evidence.

Swindon & Marlborough NHS Trust had previously admitted liability.

The jury said gross negligence by the trust, specifically sub-standard storage of drugs in the maternity unit, had led to the death.

A spokeswoman for the trust apologised after the inquest, adding: "This case should not have happened and I hope other hospitals will be able to learn from the bitter lessons we have learnt."

BUT SHOULD YOU CHANGE?

- An international standard exists
- Products are available locally
- Te Toka Tumai are doing it

- Can you justify a neuraxial wrong route error in your hospital?

IT STARTED WITH A PRODUCT TRIAL

- Trialled with epidural & spinal insertion
- Connectors as good or better
- LA for skin in Luer – not able to inject into epidural needle
- Overall happy to change
  - Keen to do so due to ongoing risk of IV local anaesthetic via PCEA

STEP 1: IDENTIFY LOCAL CHAMPIONS & DETERMINE SUPPLIERS

(June/July 2019)

NEARLY EVERY HOSPITAL AREA IS AFFECTED

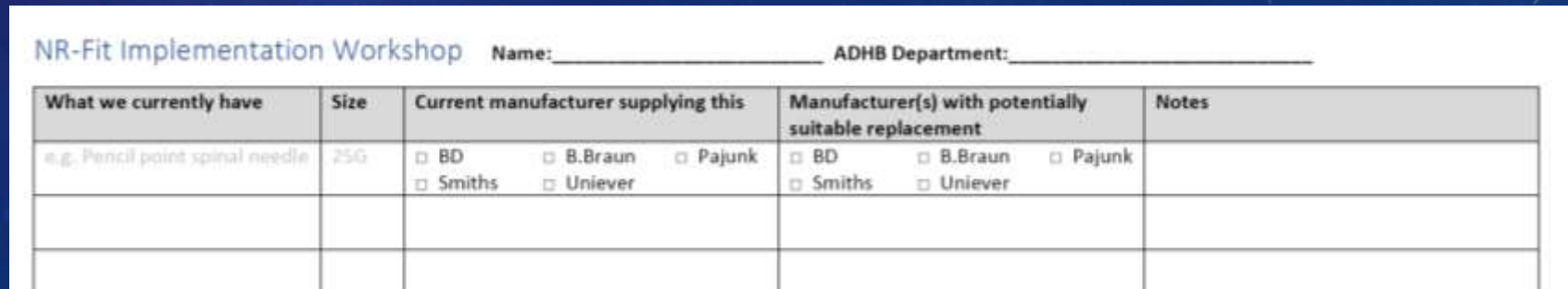
- Anaesthesia
- Critical care
- Gen Med (neurology)
- All surgical specialities
- ED
- Oncology
- Paediatrics
- Neonates
- Neurosurgery
- Paeds cardiac (transducers)
- Radiology
- Ortho, urogynae, resp medicine
- Pain-spinal cord stimulators, palliative care intrathecals

SAME WORKSHOP, 3 DATES TO MAXIMISE ATTENDANCE

- Ask for nominated neural connector lead from each clinical area
- (Well-connected team support)
- Invite to workshop
  - Introduce ISO 80369-6 standard & reasons to change
  - Invite needle & syringe reps to bring their neural connector offerings

LOCAL CHAMPIONS

- Asked to identify potentially affected items in their clinical areas
- Met reps at workshop to determine alternatives
- Invaluable throughout process:
  - Local knowledge
  - Conduit of information to/from clinical areas
  - Assistance with education prior
  - Planning & executing implementation



NR-Fit Implementation Workshop Name:_____ ADHB Department:_____

What we currently have	Size	Current manufacturer supplying this	Manufacturer(s) with potentially suitable replacement	Notes
e.g. Pencil point spinal needle	25G	☐ BD ☐ B.Braun ☐ Pajunk ☐ Smiths ☐ Uniever	☐ BD ☐ B.Braun ☐ Pajunk ☐ Smiths ☐ Uniever	

INITIAL SUPPLIERS

- Invited all current needle & syringe suppliers
- Only ones with product at the time were:
  - Pajunk (imported to NZ by Jackson Allison, Surimex in Australia)
  - B Braun
  - Smiths Medical (did not attend workshops)
  - Rocket Medical
  - (OnQ painbusters)
- Vygon, Uniever, BD – not able to supply
- None had any items currently in Australasia
- Not all who promised actually delivered….

INVENTORY – AFFECTED ITEMS

- Not all items easily identified:
  - Not specifically coded
  - Some not inventory managed
  - Some used in luer applications e.g. Interventional Radiology
- Local champions helped

STEP 2: PROJECT PLAN (+ EXEC SPONSOR)

"JUST A FEW NEEDLES AND SYRINGES"

(July 2019)

“JUST A FEW NEEDLES & SYRINGES”

- About 80 affected items – c.20 ‘additionals’, some consolidation
- Prefilled syringes – Biomed, Baxter, iMix
- Electronic manometers
- Neurosurgery
- Radiology
- Materno-fetal medicine

- Not hypodermic needles
  - LA for skin still luer – 2 standards per procedure

VISIT TO ISO80369-6 HOSPITAL IN AUSTRIA (NOV 2019)

- See first-hand implementation & use of products
  - Group of hospitals worked with needle manufacturers to determine first neural connector portfolio
- Link with Austrian anaesthetist to assist with problems

STEP 3: MAP CURRENT AGAINST POTENTIAL ALTERNATIVES

…THE NEURAL CONNECTOR SPREADSHEET

(July-December 2019)

PRODUCT MAPPING

- Difficult as:
  - Samples take weeks to arrive (none in continent)
  - Available products limited (portfolio expanding all the time)
  - Suppliers not able to supply up-to-date listings
  - Minimum order quantities, limited manufacturing capacity
- Initially predominantly B Braun and Pajunk
  - B Braun like-for-like; Pajunk/B Braun/alternatives for others
  - GBUK identified via Google – useful for bespoke products, syringes etc.
- Procedure packs assembled & verified (several iterations)

STEP 4: ADDITIONAL ITEMS REQUIRED FOR NEW STANDARD

(July-December 2019)

ADDITIONAL ITEMS FOR NEURAL CONNECTORS

- Drawing up needles
- Caps & Stoppers
- Syringes
- Microbore tubing
- Sets for infusion pumps
- (infusion pump fleet replacement)
- Epidural blood patches
- Omaya access devices

EPIDURAL BLOOD PATCH SET (PAJUNK)

- Luer tubing for IV
- Luer M to ISO80369-6 F adapter
- ISO80369-6 syringe

- Epidural needle/LORS etc

- No Luer Female to ISO80369-6 Male available
- Luer Male to ISO80369-6 Female adapter not available separately

STEP 5: FORECASTS, ORDERS, CONTRACTS

(October 2019- Feb 2020)

FORECASTS

- Imperative you don’t run out!
- Volumes may determine pricing
- Robust ongoing supply chain with sufficient locally held stock

- Previous annual consumption to predict usage
  - Difficult where items will continue to be used in luer form
- Best guess where items didn’t exist previously
  - Caps/Stoppers/Syringes
  - New plexus catheter sets – local champion advice

CONTRACTS

- Ongoing negotiation
  - “available” vs “can supply”
- Ultimately changed from a 2 main supplier model to mainly one
  - Some risk however 2 supplier model still has only one supplier per product
  - Allowed negotiation of volume discounts
  - 1 less supplier to coordinate

STEP 6: POST-COVID ADDED COMPLEXITY

(June 2020)

POST-COVID

- Limited airfreight to NZ
  - Initial stock purchase increased to 9 months, with 6 month stock requirement either in warehouse on en route
- Raw materials shortages/manufacturing shutdowns/higher prices contributed to change in supplier
  - Revised spreadsheet & product list

ORDER PLACEMENT

- Each manufacturer served with notice:
  - Gained business
  - Lost business
- Order codes set up with inventory & “Onelink” warehouse
- SLT endorsement – c.15-25% uplift in pre-covid cost of items

- Prefilled syringes – stability testing and order process commenced
- In-house chemotherapy compounding (unable to test until stock arrived)

(Oct 2020)

ONE-OFF ISSUES

PHARMAC approved medical device list

Product registration

STEP 7: EDUCATION

NEARLY EVERY HOSPITAL AREA IS AFFECTED

- Anaesthesia
- Critical care
- Gen Med (neurology)
- All surgical specialities
- ED
- Oncology
- Paediatrics
- Neonates
- Neurosurgery
- Paeds cardiac (transducers)
- Radiology
- Ortho, urogynae, resp medicine
- Pain-spinal cord stimulators, palliative care intrathecals

(Feb 2020-May 2021)

OTHER EDUCATION

- Specific factsheets for various groups
- Samples of luer & neural connector products
- Department educators
- Presentations at department meetings (a lot!)
- Screensavers
- Video
- Intranet page

OTHER THINGS TO THINK ABOUT

- Where to keep it all?
  - Syringes
  - Drawing up needles
  - Mostly yellow but not all
- Putting “a bit more LA” down a needle
- Infusion lines/epidural pumps

NO CHANGE TO THE NEEDLE
DIFFERENT COMPANIES ARE INTERCHANGEABLE

- Limited choice of NRFit items
- Further constrained by contracts & COVID
- Majority of items Pajunk
  - Rocket, Obex, Dash, GBUK
  - (Portex paediatric epidural kits)
  - CADD pumps have NRFit sets
  - Limited NRFit infusion lines (1, small bore)
- Epidural, spinal, CSE and epidural blood patch kits all stocked
- Caps vs stoppers

STEP 8: IMPLEMENTATION LEAD-IN

SYSTEM LEVEL AVOIDANCE OF WRONG ROUTE ERROR

Unlike ENFit – no adapters available

Piecemeal implementation isn't an option

Nearly 100 items affected at ADHB – replaced with about 70 NRFit ones

LEAD UP TO CHANGEOVER

- Education +++
- Key stakeholders – Charge techs, theatre managers, ED, CED, ICU, Pain, Oncology, Pharmacy
- Granular plan for swapping each area
- Ordering in replacement stock & running down stocks
- Identify liaison people for swap day
  - Some came in to help….others sent a list….some didn’t engage at all
- “I didn’t know about this….”

DETERMINE IMPLEMENTATION DATE

- Coordination of:
  - 2 pharmaceutical suppliers
  - 5 equipment suppliers
  - Completion of education
  - Availability of implementation team
- Plan for 29 May 2021…but…

REVISED DATE

- ‘Drop dead’ date 13 May (2 weeks to unload etc)
- Postponed to 5 June
- Ship docked 14 May

LAST MINUTE PROBLEMS

Shipping delay for majority of stock (late leaving Melbourne then 7 days in Auckland waiting to unload)

- Implementation delayed by 1 week
- Oncology delayed by 1 month (stability testing on syringes)

Portex – “Items not available – recommend finding substitute”

Premixed syringes from Biomed – caps don’t fit – used ADHB buffer stock

CHANGEOVER DAY(S) – SAT 7AM-SUN 9PM

- Area by area, by patient flow
- Items identified, substitutes located, labels printed, stock picked, swapped over
- Workaround – swap luer epidural catheter connectors (sited pre-swap in DU/OR) with NRFit
- “You’ve been changed to NRFit” shelf labels
- Charge nurse/midwife of area informed & “just in time” education provided
- Old stock boxed up in case needed later

IMMEDIATE ISSUES

- 8am Saturday “Matt all the old stuff is here still”
- 19G vs 20G epidural catheter connectors – staff “having a go”
- Incorrect use of clamp – several disconnections (no longer a significant problem)
- “I can’t inject skin LA with a 10ml syringe”

EARLY ISSUES

- Starship Neurology & digital manometers – not happy with 2 needle types
- Neurosurgeons & Lumbar drains
- Manometers for neurosurgery
- Cardiac surgery LA & PA lines
- Portex Paediatric epidural sets – sciatic nerve catheter
- Breast implants – no 50mL NRFit syringe
- ENT – requested tonsil injection (150&180mm needles)
- ENT – T&A prepacks
- Delayed implementation in Oncology
  - Omaya reservoir access devices/3 way taps
- Filters unsuitable
- “Too many syringes in these packs”

OUTSTANDING PROBLEMS

- Later implementation Portex paediatric epidural sets (Aug), Pudendal block needles (promised Aug 21), Electronic manometers (promised Dec 21)
- Radiology
- CSE locking device came in next consignment
- Incorrect forecasts:
  - 35mm 22G Quincke needle too popular (sub for 50mm)
  - Filter drawing up needle looks identical to non-filter version (switching to all filter)
  - Spreadsheet error – 1 item-787pa, ordered 7873

STAFF FEEDBACK

- Some complaints initially – now much less
- “Love these new needles!” (ED-better USS visibility)
- CSE locking device
- Revision of syringes in future packs

SHOULD YOU DO IT?

- Supply chain/registration/pricing now set up – so you can just buy what we have & implement
  - Alternative products – lots more work
- Do it now whilst there is a limited portfolio to choose from!
- We have done it so if you have a wrong route error in your hospital….
- More hospitals using ISO80369-6, better supply security

- Min 6 months….lots of stakeholders….needs hospital SLT buy-in
- Could do theatre-only + ward epidural implementation instead of whole hospital