

MDVSN Sandpit Event 8th October 2015
ENGAGEMENT WORKSHOPS
Delegate Notes from October 2015 Sandpit

CLINICAL EXAMPLES - DEVICE RELATED DEVICES

- Pressures from respiratory masks, CPAP and other masks, tubes eroding nasal septum – children and neonates hard plastic used for masks
- Pressure wounds from inappropriate dressings
- Pressure damage after amputation
- Beds, hoists, mattresses, slings, chairs and commodes - inappropriate sizing, configuration at weight limit
- Misuse of waist belts, strapping issues in wheelchairs
- Patient turned out of bed using turning device
- Catheters and incontinence devices, Incontinence pads – moisture and impede pressure relieving devices
- Inappropriate use of devices e.g. sitting on commodes for long term use
- Efficacy of devices
- Pressure garments, compression bandages, TED/AES stockings – poor fitting, rolling down
- Tubing round nasal bulb, ears – tightened to stay on
- Plaster casts
- Orthotic footwear
- IV sites (extravasation)

CLINICAL EXAMPLES - TISSUE

- Neonatal skin problems

BARRIERS

- Lack of clinical leadership.
- Consistency in procurement
- Improving clinical practice
- People not allowed to go on training due to staffing and general professional development
- Reluctance to pay for expensive/high quality devices
- Clinicians are not aware of where they can record MDRPUs
- Patients do not accommodate variability in patient shape and size
- Is the health care sector and community in general accessible to new ideas
- Role of orthotist and prosthetists in registering MDRPUs
- Inability to consistently define terms for both wounds and trauma in general
- Skin damage is not necessarily an 'immediate' effect and is not considered to be responsibility of the clinician - no benefit to reporting – need change in social behaviour and responsibility
- Performance review of long term devices should be made mandatory
- Implementing the use of the device – Education is key – including how the system works particularly when you are introducing disruptive technologies

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- Implementation of device systems – ICT service documentation
- Company looks at market worth and is there a business case
- Skin friction issues – micro motion must be controlled
- 45 or so devices were implicated in Joyce Black's audit (priority list of these devices?)
- Buyers want cheap match – NHS push for value for money
- Regulatory issue – standards (NICE) take years to agree and are not always useful or adopted clinically.
- Cyclical interaction between academia, clinical colleagues and patients
- Shear forces are not always taken into account
- Gaining information on micro environments under medical device/dressing
- Clinical champion is needed
- Do NHS want to identify low risk conditions? Seems to be more focus on higher risk devices
- Prevention devices do not get as much recognition/adoption as devices used to treat patients (relevant outcomes for patient)
- Improving clinical practice
- Issues re reporting NHS England not requiring medical device related injuries
- Lack of awareness on who is responsible
- Fear of repercussion
- Lack of time/long process
- Not straightforward diagnosis
- Funding and commissioning
- Start-up funding – capital items, funding in NHS (where is budget)
- Who is buying it?
- Clinician fear of new technology
- Patient resistance
- Access to grants – more grants available and collaboration with NHS

FACILITATORS

- Adoption of new technology in the NHS/NICE (especially as an SME)
- Fail safe concept introduced in device design as in medication issues
- Simple process – who is responsible, how is it done
- EPUAP guidelines
- Education within Trust and company based
- Increasing awareness of MDRPUs

BARRIERS TO CREATING NEW/NOVEL MEDICAL DEVICES

- Lack of clinical trials to validate/test efficacy of devices – new devices (no money to test them)

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- Inappropriate standards – accountability? Need appropriate personnel involved in developing standards for products (standard take ~ 20 years to develop and may not have clinical utility)
- Clinical judgement not always appropriate
- Device technologies need to be more patient centred – e.g. patient involvement in conceptualisation/design of devices
- Facilitate discussion between patient, nurse, carer to ensure devices used effectively – concordance will be higher if patient/staff understand value/utility of devices
- Necessary but difficult to create appropriate standard of evidence (functional performance vs skin damage)
- Barriers to communication and training between industry, clinicians and nursing care
- Challenge of understanding the tissue damage that devices cause
- Device related PUs not inevitable if appropriately used
- Time and money to develop
- Ethics for trialling new products/devices is a challenge

APPLYING RESEARCH

- Impregnating devices with new cell therapies – current approaches lab based
- Use more appropriate interface materials to be more conducive to soft tissues (with existing devices)
- Difficult to get funding for incremental improvement/product development - more interest in novel concepts
- NIHR funding streams? Intended to bridge gap between bioengineers and clinicians is essential. This link needs to be consolidated.
- Traffic light signal for tissue tolerance based on sensing technologies
- As a result of 45 different devices, we need to develop generic solutions that could be appropriate to a range of devices in the form of modular components i.e modulus matched interface materials to control mechanical factors and the microclimate at the interface.
- Loaded material multidisciplinary tissue network (?)
- Shape memory devices
- Innovative materials to reduce mechanical damage

MULTIDISCIPLINARY TEAMS

- UK MDTeam related to medical device related PUs (similar to TV Network)
- Multidisciplinary Networking
- Communicating projects/achievements and expertise to Network
- Reducing blame culture through interdisciplinary working including allied health professionals
- Reverse perceived view that device-related damage is inevitable

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CLINICAL TRIALS REGULATORY BODIES

- NICE, MHRA, DoH
- Multiple agencies with separate IT systems not talking to each other - ideally single recording system
- Pressure Ulcers are viewed to occur as a result of lack of care, need education
- Networks
- Clinical trials with routine follow up of results
- Centralised reporting

TRAINING AND EDUCATION

- Training of caregivers/reporting
- Ongoing training on devices
- Instructions in simple language
- Getting the right product – knowledge and education
- Guidance

DEVICE INFO, STANDARDS AND PATIENT INVOLVEMENT

- Very simple instructions
- Evidence based (Gold standards)
- Research into clinical practice
- Evaluation of devices
- Regulation
- Patient Involvement

INDUSTRY

- New device to market
- Barriers
- Time/regulation for successful product introduction
- Regulations - systems commissioning
- Product innovation
- Funding
- Commissioning
- Resources