Surgical MedTech Co-operative



Main conclusions of the National Meeting 2018



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NIHR MedTech and In vitro diagnostics Co-operatives (MICs) build expertise and capacity in the NHS to develop new medical technologies and provide evidence on commercially-supplied in vitro diagnostic (IVD) tests. Leading NHS organisations act as centres of expertise, bringing together patients, clinicians, researchers, commissioners and industry.

We are one of eleven MedTech and In vitro diagnostics Co-operatives (MICs) funded by the National Institute for Health Research (NIHR) to act as a centre of expertise that focuses on clinical areas of high morbidity and unmet need for NHS patients.

The <u>NIHR Surgical MedTech Co-operative</u> supports the development of medical technologies in the fields of colorectal, vascular and hepatopancreaticobiliary (liver, gall bladder and pancreas/HPB) surgery to improve healthcare and quality of life for patients. We are hosted by the <u>Leeds Teaching Hospitals NHS Trust</u>, the second biggest healthcare provider in the UK, working in partnership with the <u>University of Leeds</u>, a leading UK University with strengths in biomedical research.

The aims of the NIHR Surgical MedTech Co-operative are to:

- To develop new concepts, demonstrate proof of principle and devise research protocols for new medical technologies that are applicable across the NHS.
- Improve the quality of life and effectiveness of healthcare services for patients undergoing colorectal, hepatobiliary (HPB) and vascular surgery.
- Work collaboratively with patients and patient groups, charities, industry, clinicians and academics.

Our National Meeting is an opportunity for delegates to network and create new multidisciplinary collaborations and secondly to stimulate development of innovative ideas to address challenges in surgery.

November 2018

NIHR Surgical MedTech Co-operative

Thank you to our sponsors and exhibitors

Sponsors / Exhibitors





























MEETING EXPERIENCE

The NIHR Surgical MedTech Cooperative and NIHR Global Health Research Group in Surgical Technologies are currently researching ways of improving surgical training in the NHS and overseas with the use of immersive technologies.

We have partnered with a virtual reality (VR) company called Medical Realities www.medicalrealities.com



You can view information videos about the NIHR Surgical MedTech Cooperative and the National Meeting, as well as 360 degree video demonstrations of some of our latest technology projects. **All you need to do to access** these videos is download the free app:

Search 'Medical Realities' in the app store and click 'sign up' to create a free account

Use your own device and the viewing lenses on the tables provided (please do not remove them from the meeting) or at the VR stand.

Surgical MedTech
Co-operative

National Institute for Health Research

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SMART SURGERY FOR TOMORROW'S NHS



Smart surgery is about improved decision making by surgeons and other healthcare professionals that is enabled by the novel provision of information. The healthcare professionals generate a lot of information from medical devices and we need to make use of this data for the benefit of patients. Smart surgery is about consolidating this information in real-time and making it available.

Smart surgery is distinct from surgical navigation, robotic surgery and computer assisted surgery...

Smart surgery was the topic for our first National Meeting, as big data, artificial intelligence, informatics, etc are gaining prominence in the research field. Other sectors have used virtual reality, augmented reality and decision-making tools to benefit their customers, and our question was "how do we harness these technologies to benefit patients?"

It is time to put patients at the front of care and not the centre!!!

Still not sure what smart surgery looks like? It includes:

- surgical instruments that can provide feedback to the surgeon on the force or pressure they are applying to tissue or instruments with sensors to detect certain compositions.
- the provision of live data during surgery so that the surgeon always has up-to-date information on vital signs and the early detection of adverse reactions.
- novel imaging systems so that surgeons have better visuals on tissues, organs, vasculature (blood vessels) and tumours.

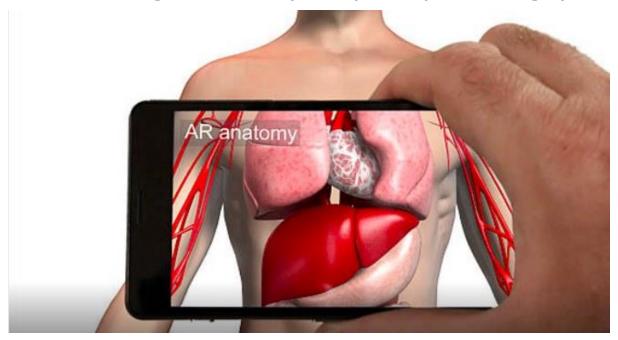
Endocuff Vision: From Concept to Combating Cancer



Chander Kainth, Head of Projects at Arc Medical Design started the day's proceedings with his presentation on how one can conceive an idea in the "garden shed" and progress that to a commercial product and company. Arc Medical Design is a Leeds-based company that designs devices to improve clinician and patient outcomes within the gastroenterology (GI) sector. Chander talked us through the design journey of the Endocuff device and how it went from a product which was initially conceived to help improve intubation to a product which has been proven to increase Adenoma Detection Rates by up to 15%.

The Surgical MIC can assist innovators to identify clinical and patient benefit early on in the design process, to increase chances of clinical adoption.

Smart Liver – Augmented Reality for Laparoscopic Liver Surgery



Dr Matt Clarkson, Associate Professor in the Department of Medical Physics & Biomedical Engineering at University College Hospital started off with a vision that:

"All patients that require liver surgery will be able to benefit from laparoscopic or "key hole" surgery".

Approximately 90% of liver surgery is still performed as major open surgery, and this is associated with physical and psychological burdens in the way of more pain, complications, and longer recovery times when compared to patients undergoing laparoscopic surgery. This also has an impact on the length of hospital stay and patients' ability to return to work. The low laparoscopic uptake is down to the complex liver anatomy, the inability to palpate cancers/ structures at laparoscopic surgery and concerns regarding bleeding/damage to vital structures.

Dr Clarkson also laid out the solutions his team was working on to aid laparoscopic liver surgery, as well as the challenges they encountered along the way. He finished off his talk with a call to action for collaborators.

The Surgical MIC can facilitate these and similar collaborations by identifying suitable collaborators, arranging events and workshops.

Principles of Successful NHS Market Access



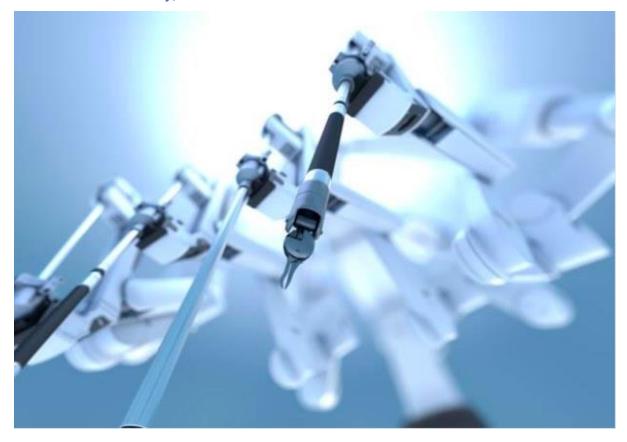
Mr Mike Branagan-Harris, CEO of <u>Device Access UK Ltd</u> presented on the principles of successful NHS market access. Mike articulated the need for better market access methods by medical technology companies and added that NHS access was greatly improved when companies:

- Had products which drove efficiencies,
- Understood the right outcomes to facilitate adoption, and
- Communicated clinical features and benefits, as well as addressed the financial requirements in the NHS.

Mike outlined the traditional market access methods which result in the limited adoption of innovative procedures / products because they do not take hospital pressures/payment flows into account, innovators often don't sell the real value of their technology and there is a lack of awareness of the evidence required for NICE medical device approval.

The Surgical MIC facilitates the generation of clinical and economic evidence, provision of clinical expertise, as well as patient expertise during the technology development process.

Priorities of today, collaboration of tomorrow



The final speaker of the morning was Dr Stephen Knight, Surgical Registrar and he presented on the initial results of the <u>Association of Upper Gastrointestinal Surgeons (AUGIS) of Great Britain and Ireland</u> and <u>Great Britain and Ireland Hepato Pancreato Biliary Association</u> (<u>GBIHPBA</u>) priority setting exercise using the Delphi process. The aim of this exercise was to:

- Develop consensus opinion on hepatopancreaticobiliary (liver, pancreas and gallbladder/HPB) research priorities
- Set research agenda on a *national level* over the coming years
- Drive well-designed, high quality research
- Identify areas for innovation

Whilst the results have not been published yet, Stephen was able to give us a glimpse of the HPB priorities, which *the Surgical MIC will assess and take forwards*. These priorities include:

- Screening and early detection for early stage pancreatic cancer
- Imaging
- Predictive markers
- Optimising the patient pathway

What's missing from the jigsaw?



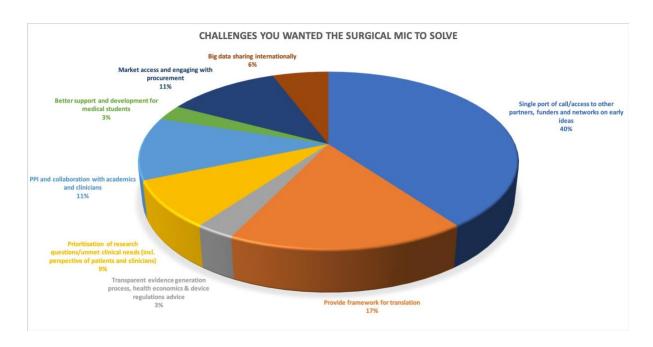
What challenges would you like the Surgical MIC to solve?

Most of our delegates would like us to be the *single port of call for surgical medical technology.* We frequently get asked about spinal, orthopaedics and other surgical areas that we do not cover, and we will introduce you to the relevant individuals/organisations that can support early ideas.

As part of our remit we also *facilitate collaborations* with academics, clinicians, patients and members of the public; and we have been tasked with *identifying the unmet clinical needs* (clinical and patient) for surgical technology in our areas of expertise. We will be hosting an "unmet clinical needs" workshop in 2019 to identify our research priorities.

Market access and engaging with procurement was another popular one, and plans are underway with our host, the Leeds Teaching Hospitals NHS Trust, to run a workshop on this. If you would like to be informed when this happens then please sign up to our mailing list here - https://form.jotformeu.com/81303313436345.

The other challenges identified will be addressed in other areas in this report.

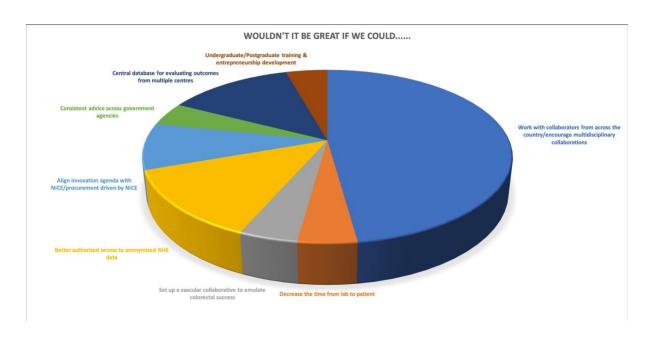


Wouldn't it be great if the Surgical MIC could...?

Our delegates want us to encourage *multidisciplinary and national collaborations*. Even though the Surgical MIC is based in Leeds, we are a national organisation and are keen to facilitate and work with collaborators from all over the country. If you would like to be informed collaboration opportunities, please sign up to our mailing list here - https://form.jotformeu.com/81303313436345.

We will also play our part in highlighting the following suggestions to *national working groups*: the provision of consistent advice across government agencies, aligning the innovation agenda with NICE, better authorised access to anonymised NHS data and training/entrepreneurship development for undergraduates and postgraduates.

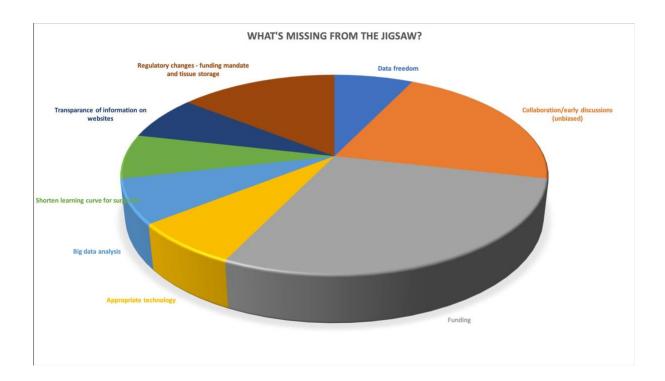
In addition to playing our part in *decreasing the time from lab to patient*, we are currently identifying sites/collaborators to set up a vascular <u>surgical test bed</u> (and we already work with the <u>Vascular and Endovascular Research Network</u>), and there are opportunities for setting up a central database for evaluating outcomes that we are currently exploring.



What's missing from the jigsaw?

The Surgical MIC does provide <u>pilot/proof-of-concept funding</u> via an annual open call, for ideas and concepts that are likely to leverage additional research funding. We use our unmet clinical needs to prioritise projects we fund, and where they do not meet these then we will identify other suitable sources of funding.

Early discussions are welcomed to allow enough time to identify and engage suitable collaborations. This is very important for grant funding collaborations - our clinicians and supporting departments require at least 4 weeks' notice to submit a high quality application.

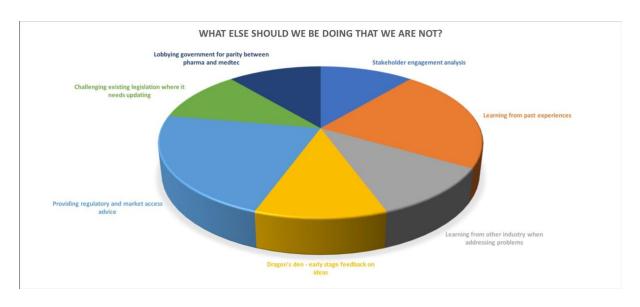


What else should we be doing that we are not?

Learning from past experiences and other industries - augmented and virtual reality technologies are perfect examples of this. We also have an example of technology used in a veterinary setting being tested to <u>detect volatile compounds in humans</u>.

Dragon's den for early feedback on ideas - another good suggestion, and we are planning to have these as quarterly events. Keep an eye out for further communications on this.

Challenging legislation and lobbying government - our mechanism is via our reporting processes to the Department of Health and Social Care. We also work closely with the Medical Technology Group and Health Tech Alliance and they actively lobby government.



Surgical MIC - Our role in technology development

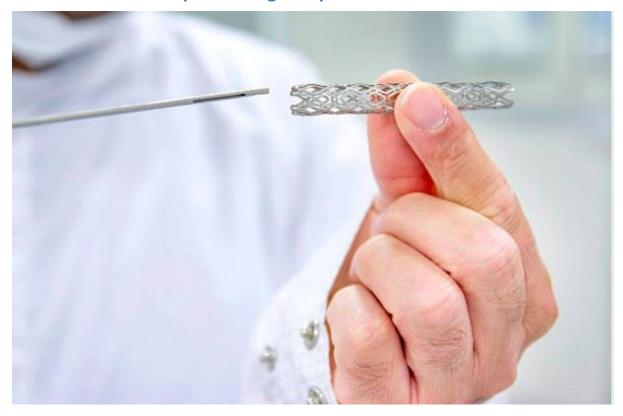


Vee Mapunde, Programme Manager for the Surgical MIC gave an overview of how the Surgical MIC engages with industry and distributes pump priming grants.

The main remit of the Surgical MIC is to:

- **Develop research collaborations** These can be academic collaborations (nanotechnology, robotics, engineering, pathology), clinical collaborations or patient collaborations. The Surgical MIC has access to mobility and placement funding for those wanting to set up collaborations with partners from the University of Leeds.
- •Fund relevant pilot/proof-of-concept studies to support larger scale research projects (including full medical device development, health economics and care pathway assessments) The Surgical MIC runs its own proof-of-concept funding and incubator packages every year, with the next call due to open in March/April 2019. Funding opportunities will be posted on our website. The Surgical MIC is also open to setting up funding collaborations to increase the impact and outputs of applicants. Recent examples of this include our joint medical technology proof-of-concept call with Bowel and Cancer Research and the EPSRC Impress Network.
- •Leverage additional research funding to undertake full scale studies Once we have demonstrated proof-of-concept, the Surgical MIC can collaborate with innovators to secure additional funding from bodies such as the NIHR, Innovate UK and SBRI (and many more) to fund evaluation and effectiveness studies.

MIC Proof of Concept Funding Recipients - 2018



Background to Proof-of-Concept Calls

The NIHR Surgical MedTech Cooperative in collaboration with Research England funded <u>Grow MedTech programme</u> invited industry, researchers and clinicians working in colorectal, HPB and vascular surgery to apply for pump-prime or clinical session funding.

Funding is available to support the development of new concepts, demonstration of proof of principle, expedite translation of research to the clinic, and devise new research protocols for new medical devices, healthcare technologies or technology-dependent interventions for surgical technologies.

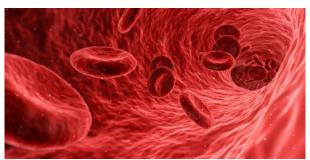
Our funding competition was split into two parts: a strategic call that is focused on future unmet needs and a reactive call that is focused on the immediate needs in surgery.

Future Unmet Needs Call for 2018/19 - This call comprised two themes – a *technology driven theme* to attract industry and/or academic-led applications; and a *clinically driven theme* for clinically-led applications.

Reactive Funding Calls - Incubator Packages for 2018/19 - This was a seed funding call (up to £5K) for the early development of novel technology-based solutions applicable to colorectal, HPB and/or vascular surgery (including wound care).

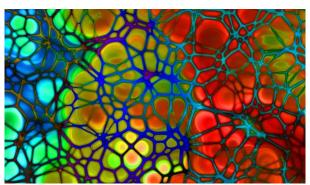
An important consideration in evaluating submitted applications is the potential for the proposals to be developed into more substantial grant funding applications.

For more information, visit our website here - http://surgicalmic.nihr.ac.uk/support-available/funding-competitions/



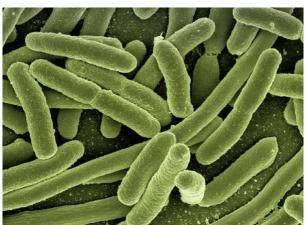
1 - Proof-of-Concept Recipient: Mr Patrick Coughlin, Vascular Surgeon, Cambridge

The effect of neurostimulation on patient relevant outcomes in patients with intermittent claudication: a feasibility study.



2 - **Proof-of-Concept Recipient:** Dr Peter Worsley, Lecturer within Health Sciences, Southampton

A Novel Evaluation of Radiotherapy Positioning Boards: Optimizing Safety in Design



3 - **Proof-of-Concept Recipient:** Dr James Fullerton, NIHR Clinical Lecturer, London

Ex-Vivo Perioperative Immune Monitoring: a Proof-of-Concept Study (ePIMMS)



4 - **Proof-of-Concept Recipient:** Dr Yeshwanth Pulijala, Founder & CEO of Scalpel, London

Making Surgery Safer and More Efficient

NICE - Claims of Benefit for Medical Devices



Dr Chris Pomfrett, Technical Adviser - Research Commissioning, <u>NICE</u> provided an overview of NICE and presented findings from one of his publications on assessing the value of innovative medical devices, and the importance of clear and relevant claims of benefits. It was made very clear that claims of benefit do not equal evidence.

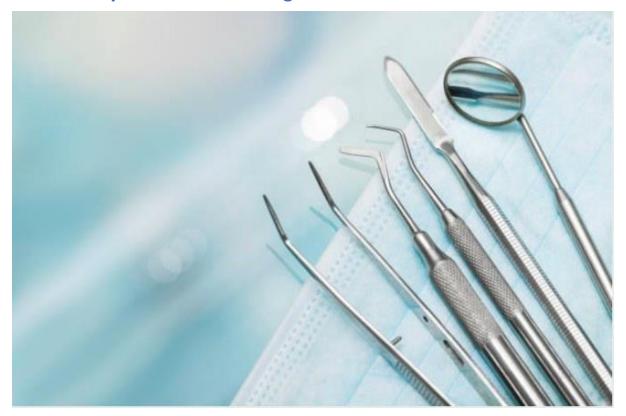
- Technologies that were selected had significantly greater total numbers of studies to support the claims than those that were not selected. This is one of the roles of the MICs - we facilitate and support the evaluation of technologies for the purpose of generating evidence.
- Technologies that were selected did not always have large-scale randomised studies, but most generated their evidence from cohort studies, surveys and cost analyses.
 The Surgical MIC is supported by the Clinical Trials Research Unit and Academic Unit for Health Economics at the University of Leeds.

Types of study that were associated with technologies not being selected:

- pilot studies;
- unpublished studies submitted in confidence;
- •marketing claims with no substantiating evidence.

The take home message was that the evidence should match the claims.

Scan4Safety: Innovation Through Standardisation



Mr Stuart MacMillan from <u>Leeds Teaching Hospitals</u> (LTHT) took us on a journey from problem identification to implementation in the NHS.

This was a case study of the Scan4Safety implementation for stock management and Stuart started off with what the problem looked like to the NHS in the form of hours wasted by various members of staff and poor patient outcomes (e.g. product recalls). Once the unmet needs had been articulated, LTHT turned their attention to identifying the standards required which led to the Scan4Safety system.

More information is available here - https://www.scan4safety.nhs.uk/leeds-implements-patient-tracking/

This case study demonstrates that adoption is not a myth and can happen if the right conversations take place. The role of the Surgical MIC is to identify those unmet needs across the NHS and not just one hospital, so that the potential impact of adoption is greater.

MedTech Foundation - An Interdisciplinary Student and Trainee-led Innovation Collaborative



Dr William Bolton, NIHR Clinical Research Fellow closed the day with an overview of the MedTech Foundation which is a student-led medical technology and innovation network, that enables members from different scientific disciplines to get involved in cutting edge biotechnology research.

Their main activity is the annual innovation programme, involving a series of workshops covering the skills involved in interdisciplinary collaboration to develop novel technology solutions for unmet clinical needs. The foundation also manages a series of summer research internships and international exchanges with our global partners.

<u>MEDx</u> is a new initiative that offers fascinating, intriguing, and thought-provoking talks on everything from ground-breaking medical innovation to essential entrepreneurship knowhow for innovating within medical industries.

Upcoming MEDx Talks

 January 2019, University of Leeds Campus, 18:00-20:00, venue TBA – Technology in Global Health

Previous MEDx Talks

 23rd October, University of Leeds Campus, 18:00-20:00 – Wearable Technologies: YouTube clip

• 27th November, University of Leeds Campus, 18:00-20:00 – Robotics in Healthcare: The robot will see you now...

They would like to expand the benefits of the MedTech Foundation to other institutes outside Leeds via a "Hub" and "Spoke" expansion model, to promote the activity of MedTech Foundation at their localities and provide the extended network for the MedTech Foundation making it a national collaborative initiative.

 Current network (Cambridge, Birmingham, Kings College London, Warwick and Edinburgh)

Find out more about our MedTech Foundation on our website.

Soapboxes

A **soapbox** is a raised platform on which one stands to make an <u>impromptu</u> speech. The term originates from the days when speakers would elevate themselves by standing on a wooden <u>crate</u> originally used for shipment of <u>soap</u> or other dry goods from a manufacturer to a retail store (Wikipedia).

Vascular surgeon is looking for technology that can help determine the optimal amputation location.

Tookie has driven the development of an innovative product portfolio and robust clinical 'adoption' processes for patient, carer and clinician driven innovations to make '#ALifeMoreNormal' a reality. Vascular access is essential and lifesaving therapy. We would like to explore collaboration opportunities with clinicians.

Are there alternatives to bone sawing (for amputations), which avoid producing a lot of airborne debris?

SwabTech Ltd is developing a simple device to automatically extract blood from surgical swabs for subsequent processing via the ICS system. The company would like to collaborate with clinicians.

Newtec Vascular Products Ltd is developing a device which addresses Neo Intimal Hyperplasia - the blockage of vessels by scar tissue as a result of vascular graft surgery. The device has shown good efficacy in pre-clinical studies and Newtec are currently preparing for their first-in-man trials. The company would like to develop new collaborations.

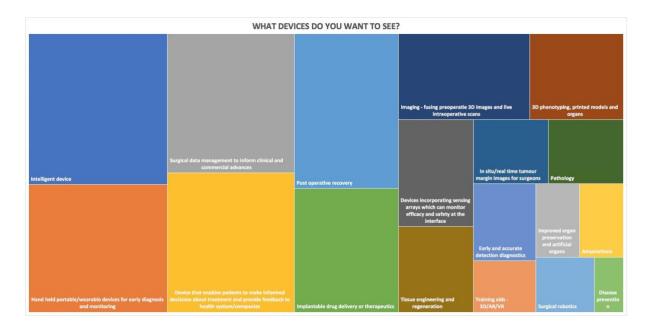
Chemistry student seeking placement, internship or work experience opportunities.

Clinician looking to collaborate with interested parties to develop and test a gasless laparoscopic system.

Business development and grant support is available to SMEs from the local authorities.

An academic with an interest in applying artificial intelligence to healthcare communications

"What device would you develop if money were no object?"



As part of the morning table exercise, we asked delegates to name a technology they would develop if they had all the money in the world. We have grouped the responses into device/technology types for ease of presentation and they have been ranked in order of popularity in the image above and the text below:

- Intelligent devices Intelligent devices to rapidly and effectively transect liver tissue laparoscopically, Intelligent prosthetic leg, instrument for gasless laparoscopy, endovascular device to abolish restenosis risk, ultrafast laser to remove blood clots, surgical dead space filler, stoma innovation to tackle herniation and new adhesive technologies, incontinence pad that would powderise faeces, smart laser scalpel that includes metrology and diagnostics, cost effective single use endoscopy with artificial intelligence capability, surgical swab blood recovery.
- Hand held portable/wearable devices for early diagnosis and monitoring Appendicitis diagnosis, see-through human body, wearables, 3D
 scanner/materialiser, smart watch, non-invasive scanner for providing a regular
 check-up for early warning of diseases, a comprehensive physiological monitoring
 system incorporated into an item of clothing.
- Surgical data management to inform clinical and commercial advances Automated sending of data queries, resolution and data collection for clinical trials, app to report complications consistently to clinical trials unit, algorithm to calculate with some precision the number of participants required for a trial to prevent under-recruitment, single method to capture in real time what happens in a single episode of care like images, voice capture, scans to reduce IT burden on clinicians and

improve patient outcomes, TaTME - new surgical technique, efficient theatre management systems.

- Device that enables patients to make informed decisions about treatment and provide feedback to health system/companies Health information chatbot that works for everyone, secure online referrals for wounds, meta device bar code scanner to log other devices and stick data to health records, optimisation of mobile technology to improve patient care (collection of real time data), medical devices connected to AI which allows instant information to patients to improve health, patient information that is accessible anytime to doctors, microchip with medical data that can be used for medical emergencies/circumstances, patients should get more options before deciding on surgery, digital solutions/apps and communication between NHS IT systems, more alternative therapies on NHS.
- Post-operative recovery Method of accurately determining outcome following
 aortic aneurysm surgery, wearable to monitor post-operative recovery at home,
 device to eliminate/reduce the risk of pancreatic leak after pancreatic surgery,
 temporary/removable intra-abdominal monitor for anastomotic leaks or high-risk
 anastomoses, immuno-detector to quantify your immune competence, physiological
 monitoring poor outcome prediction, influence patient outcome.
- *Implantable drug delivery or therapeutics* for preventing cancer recurrence, tumour diagnosis and treatment, nanotechnology.
- Imaging fusing preoperative 3D images and live intra-operative scans Augmented reality, holograms, guidance, locational imaging, software for real time
 clinical guidance based on patient specific, preoperative data and evolving
 conditions during procedures, integrated near-infrared sensor of capable of
 selectively identifying colon carcinoma cells in tumour margins labelled with high
 yield fluorescent nanoparticles.
- 3D phenotyping, printed models and organs Pancreatic anastomosis, training, bioprinting with stem cell grafting.
- Devices incorporating sensing arrays which can monitor efficacy and safety at the
 interface Dressing with wound environment monitoring, SMART adaptable surfaces
 for stratified/optimised interfaces, laboratory on a plaster (rapid assessment of
 biomarkers to diagnose and monitor disease, and update patient data using artificial
 intelligence), biosensing preoperatively.

- *Tissue engineering and regeneration* In vitro long-term liver scaffold perfusion device, tissue engineering for the GI tract.
- In situ/real time tumour margin images for surgeons For difficult locations and small sizes, liver, identifying microscopic tumour tissue.
- *Pathology* Anything that reduces pathology workload, devices that identify specimen that are unlikely to show significant pathology, intra-operative histopathological diagnosis (preliminary).
- Early and accurate detection diagnostics Cancer, upper GI, with rapid DNA
 analysis, low cost spectrometer, at home diagnostics, pancreatic cancer, noninvasive, alternatives to colonoscopy, generic reader and suite of specific biosensors,
 simple test (blood/breath) that identified very early on which patient suffering an
 attack of acute pancreatitis will go on to develop complications so that care can be
 optimised, biomarkers for detection, follow up treatment.
- Training aids 3D/AR/VR An all-encompassing model of human physiology/biomechanics
- Improved organ preservation and artificial organs
- Amputations Precision cutting, Smart upper limb prosthetics
- Surgical robotics Automated robotic surgical grasper, semi-autonomous robotics
 using artificial intelligence and surgical experience (pattern recognition from
 previous procedures).
- Disease prevention Aid for digestive system

AFTERNOON ROUNDTABLE WORKSHOPS



Improving surgical precision & patient safety

Improving surgical precision & patient safety - hosted by Stuart MacMillan and Dr Anita Blakeston

Digital Health/Surgery allows for the consolidation of information from multiple medical devices in real-time, to reduce the burden on healthcare professionals, shorten surgical time and share information. This session explored the potential for collaborations to leverage artificial intelligence, deep learning image analysis, bioprinting, big data, etc to assist healthcare professionals with real-time patient monitoring and aid decision making.

Initial ideas centred on leveraging Artificial Intelligence (AI) to improve patient safety by reducing "never events" which include retained foreign objects following surgery and wrong site surgery. Opportunities were identified to use existing patient data and equipment logs in the form of readable QR codes. Delegates also explored how financial penalties could be used to drive adoption in this area and identified the following barriers to adoption:

- the ability of the technology to link to electronic health records (EHR)
- cost structures within the NHS
- evidence to demonstrate that innovation has actually improved patient safety
- lack of clarity over who pays for the innovation

Solutions and next steps - The involvement of human factors experts was important for digital health/software innovations, as it would improve the quality of training by making the applications more intuitive and simpler. It was also important for innovators to understand the hospital/theatre environment before spending a lot of time developing their technology.

Human factors expertise can be found at the Yorkshire and Humber Patient Safety Translational Research Centre - http://yhpstrc.org/

Another idea for improving patient safety involved the use of genome sequencing data to provide patients with a personalised treatment pathway.

Improving detection via better imaging technologies

Improving detection via better imaging technologies – Hosted by Prof Giles Toogood and Dr Matt Clarkson

The ability to visualise tissue, critical structures and tumours is essential for smart surgery. This information already exists for preoperative diagnosis and surgical planning, but the real innovation is in making this information available during surgery to inform decision making. This session explored the potential for collaborations to leverage existing or new imaging/visualisation technologies for colorectal, HPB and vascular surgery.

This group prioritised the following clinical areas for better imaging technologies:

- Colorectal (pelvic recurrence post radiotherapy). There is a need for solutions to detect and identify tissues.
- 2. **Brain cancer** (high grade cancers, recurrence, change of grade and biomarkers). There is a need for solutions to help clinicians predict the cancers that are likely to move from low to high grade; biomarkers to support monitoring, brain shift and detect how much tumour remains. Intra-operative imaging is difficult in this area because imaging is not integrated and it is also important for insertion.
- 3. **Liver** (tumour removal deep and superficial). Clinicians currently use intraoperative ultrasound however this is not ideal for seeing into the liver which is solid and opaque. The real need is for solutions to map preoperative imaging onto liver, and do an overlay. This technology should be multi-modality, identify landmarks and cope with the movement/distortion of liver.
- 4. **Pancreas** (early detection, iron particles, antibodies, chemotherapy). There are currently 62 pathways for treatment of pancreatic cancer. We need to make chemotherapy better by using nanoparticles so that treatment gets to the cells.

Solutions and next steps

- What? Development of new nanoparticles for theranostics (diagnosis and treatment). For brain this would be good post resection
- Why? prevent reoccurrence of cancer
- **Support required?** Incubator package for a multi-disciplinary focus group to include patient and public involvement, business analysis and health economics.

Developing the next generation of smart surgical instruments

Developing the next generation of smart surgical instruments – Hosted by Dr Manish Chauhan

Haptic feedback is essential for the development of next generation surgical instruments, as it will enable real-time feedback during surgical procedures. This not only applies to graspers, but for sutures as well. There are opportunities for embedding sensors onto surgical instruments and implants, opening up the possibilities of round-the-clock patient monitoring. This session explored the needs, potential funding streams and opportunities to collaborate with our academic leads in biosensing, nanotechnology, mechanical engineering and robotics.

Initial Ideas:

- Optimise patient selection, re-occurence mitigation
- Tool for measuring OMEGA-3 in blood (implementation)
- Imaging, adapting use of CT scan, virtual reality technology, precision
- Implants electronic sensors, retraction sensor, ophthalmology (pressure sensors), intraoperative sensors like Doppler probes (costly)
- Laparoscopic/Robotic can we use both techniques for mitigating costs e.g. removing gall bladder, ergonomics for surgeons, articulation instruments. Indirect benefit to patients, how do we justify cost to the NHS. Investment is there to attract surgeons not for patient benefit.
- Diabetic foot operation, foot pressure
- Haptic robotics automation, pressure/force measurement
- Finger retraction
- Trainee application medical reality
- Powered devices electronic power, mini hand-held robot

Next steps and solutions

- Technology an instrument that has the following: haptic feedback, electronic sensor, image processing, virtual reality, articulation of instrument, ergonomics, automation suturing/force measurement.
- Challenges implementation, cost, who is really benefiting (patient or surgeon),
 patient pathway, complexity, risk of damage, easy access, single use/disposables
 (environmental issues), procedure length. e.g. retraction of bowel in lap surgery,
 spleens are damaged in surgery
- *Inspiration* inflatable balloon like a human hand, with bio-implantable remote sensors that can detect tissue stiffness, can be sterilised and pressure sensors for minimising tissue trauma.

Improving long term management of surgical patients

Improving long term management of surgical patients – Hosted by Ms Candice Downey and Dr Hafdis Svavarsdottir

Monitoring post-operative recovery in surgical patients is essential for the detection and management of post-operative complications. There are a number of devices on the market which monitor patients' physiology through vital signs such as temperature and heart rate. Other devices incorporate biosensors to detect the presence of chemical biomarkers in bodily fluids. This session explored the unmet needs in this area and the potential for research collaborations to take these concepts forward.

Initial Ideas on surgical outcomes

- Which outcomes are important? morbidity vs. mortality (soft social implications)
- Postoperative monitoring at home monitoring, exploring existing technology
- Intra-operative biomarkers of risk
- Pre-operative physiology, mental health, rehabilitation, mental and physical preparation
- Risk information sharing

Pre-operative risk discussion

Identification of risk - physiology, CT, smartphone technology, other biomarkers, questionnaires - needs

Treatment - family advice (identifying issues), preparation (exercise, nutritional, mental health)

Information sharing and signposting of external agencies

Outcomes - risk communication, complications long term outcomes, what matters to patients (mental health, dependence, prediction)

Solutions and next steps

Develop a comprehensive peri-operative information sharing app/system

Importance - personalised care, shared decision making, optimising preoperative risk, extended patient engagement post-operative, patient centred outcomes
 Support - exploit existing smartphone sensors, incorporate external sensors (physiological and biomarkers). Bring existing technology together (patient reported outcome measures, wearables, patient information, interventions, questionnaires)

Understanding the role of Clinical Trials and Health Economics in smart surgery

Understanding the role of Clinical Trials and Health Economics in smart surgery – Hosted by Prof Deborah Stocken and Dr Armando Vargas-Palacios

The availability of a new technology is not enough for NHS adoption. The NHS is interested in technologies that are driven by clinical needs, that demonstrate a clear patient benefit, reduce risk to the patient and technologies that provide health economic benefits. This session provided delegates with an opportunity to find out more about what's involved in evaluations, and how to make the most of early health economic modelling.

Initial ideas

- design for regulatory process usability, costs, health economics, and procurement not accounted for by NICE
- how to tie in health economics analysis into trials and early health economics modelling to identify winners
- pragmatic adaptive trials robust evidence required. (how to get evidence efficiently using existing knowledge, registry to health economics model, evidence potential. efficient designs impact on delivery).
- clinical understanding of research (biostatistics, Bayesian) requirement to encourage understanding to research teams
- simulations can we simulate, use existing data not start from scratch, can we learn from other studies
- funding registries to collect and manage data
- can we cost the patient journey and how do we record the impact of decision making?

Solutions and next steps

Problem - the lack of longer-term data/evidence.

Idea - model register of devices for transparency of research and access to results.

Researchers can upload data, post marketing data, and in the longer term this would facilitate relevant trials looking at long term benefits and risk. It would also be good to evidence sustainable impacts of intervention to support practice, simulate health economics modelling, increase precision and overall sustainability of intervention.

Support - NIHR could be involved in setting up EU database of devices (and NIHR registries to record longer term patient journey) and ensure correct access information and access to data. Possibly get industry support via sponsorship.

PPI Working Group, Recovery after Surgery

PPI Working Group, Recovery after Surgery—Breakout room Seamstress Suite hosted by Dr Stephen Chapman LTHT, Dr Julia Ambler, BCUK and Simon Pannett, Coloplast

Recovery after surgery is a source of anxiety for patients. Doctors often provide written information on what patients can expect after their operation, but sometimes this is difficult to understand or overburdening. We want to hear about your experiences of recovery and understand what information you want to know before surgery. Specifically, we wanted to know which parts of recovery, and in how much detail, you wish to be informed about.

Eleven people from across the United Kingdom took part in a focus group at the NIHR Surgical MedTech Co-operative National Meeting. The focus group had two aims. The first was to find out what aspects of recovery after surgery are most important to patients. This will help researchers to design the content of future information resources. The second aim was to explore how and when the information should be provided. This will help to avoid situations where patients feel overburdened.

The focus group ignited lively discussion from participants who had very diverse experiences. It was fantastic to hear real-life perspectives from people who were enthusiastic about improving care for others in the future. Both positive and negative insights were shared and key areas for improvement were identified. It became clear that collaboration between patients, healthcare professionals, and information design specialists would be essential for designing new and effective resources in the future.

Outcomes

Following the focus group, the researchers will produce a summary of results. This will be used to decide how current information resources about recovery can be improved. The results will be published in a scientific journal and sent directly to people who took part in the focus group. The researchers are particularly interested in how patients and the public can stay involved in future stages of this work. Their insights and experiences will be essential to make sure future information resources are relevant to patients from all backgrounds.

For a summary of this session, please visit our Patient and Public section of our website.

IMPRESS Network

IMPRESS Network -Hosted by Dr Pete Culmer and Ms Sarah King

The IMPRESS network is a research hub for engineers working to address the management and treatment of incontinence. The Surgical MIC will be incorporating this work stream into the Colorectal theme, and this session will explore how we can raise awareness, support research, collaborate with researchers and patients, and influence policy makers and funders. Have a look at their website - http://impress-network.com/.

Initial idea

- Mesh alternatives must be sought for patients. Magnetic sphincter trials were shelved (missed opportunity for patients)
- Scoping out potentially affected populations at risk of incontinence and what already exists or what we know
- Worth revisiting the Continence Report/Workshop for outputs and ideas; as well as NICE guidelines on incontinence
- How do address the variation of care regarding NHS pathways? Standardising using guidelines, champion a best practice example to illustrate cost/benefit.
- How to engage industry in this area and scientists

Solutions and next steps

- Develop regular forum for different groups
- Revisit existing guidance and further develop recommendations
- Inform study into best practice (NICE)
- Highlight key patient groups and target innovation e.g. mesh replacement and sphincter augmentation

The importance of innovating for adoption

The importance of innovating for adoption –Hosted by Mike Branagan-Harris, Device Access, Dr Chris Pomfrett, NICE and Mr Richard Hall, Pd-m.

NHS adoption is considered the final hurdle for most medical technology innovators, and there is a general lack of awareness on the best pathway to clinical adoption. The barriers to adoption are many and vary from increased procedural cost to a lack of clinical evidence for patient benefit. Innovators also need to consider whether their technology will impact negatively on the current treatment pathways. Innovating for smart surgery means innovators need to demonstrate that their technology will improve surgical workflow, improve decision making and patient outcomes. This session provided delegates with an opportunity to find out more about the steps required to get a technology adopted into the NHS, and what factors are important to NICE.

Summary

NHS access/adoption is dependent on the four principles of market access, that need to be met for success. Usability was also very important for the NHS, and the Trauma MIC provide this as a paid service via http://www.md-tec.com/. Innovators were urged to use the NIHR MICs to define the following points, that are important for innovating for adoption:

- Population who needs it? NHS clinicians and patients can define this population based on need and important outcomes
- Intervention what does it do? How does your technology meet the needs & contribute to improved outcomes of the defined population
- Comparator How are patients currently treated? What is the standard of care for the defined population? What are the current pathways of treatment? Where does your technology fit in within established pathways? Would your technology negatively disrupt the pathway?
- Outcome what's the difference between intervention and comparator Do you have evidence to prove your technology is better than standard of care/comparator in terms of quality of care, patient outcomes, cost-benefit and cost-effectiveness?

Endoluminal Interventions

Endoluminal Interventions -Hosted by Professor Julian Scott and Dr Venkat Subramanian

Endoluminal endoscopic interventions for diagnosis and therapy are evolving, and there is a need to assess how clinical needs might be addressed. As minimally invasive surgery is being adopted in a wide range of surgical specialties, there is a growing trend in precision surgery, focussing on early malignancies with minimally invasive intervention and greater consideration on patient recovery and quality of life. This session explored unmet needs for the Surgical MIC to prioritise and support with a view to developing solutions.

Initial ideas

- In silico trials to simulate device performance and outcomes, with virtual subjects/statistical populations.
- Images and quality models e.g. pill cams 18-hour video, vision system is artificial intelligence, tracking system, model colour
- Collaborations to look at the interaction between wall and fluid. e.g. angioplasty shear stress viability cells,
- Improving outcome prediction
- Using nanotechnology

Solutions and next steps

- Patient and public input for pill cam vs colonoscopy idea
- Develop artificial intelligence colonoscopy video library
- Develop nanoparticle small molecule for model spray technology
- Develop In silico trials in this area

MedTech Foundation

MedTech Foundation – Hosted by Vincent Ng, James Kinch, Molly Northcote and Will Bolton

The MedTech Foundation is our engagement initiative for university students, early career researchers and clinicians. This initiative is driven by an interdisciplinary group of students and trainees from healthcare, engineering, physics, chemistry, product design and business. Each year, the Foundation delivers an educational Innovation Programme and organises several research and industry internships, giving its members enhanced training and opportunities to engage with real-world MedTech innovation.

Summary

The main topic for this session was securing long term funding to sustain the Foundation's activities. The MedTech Foundation's activities are currently funded by sponsorship and exhibition fees from the National Meeting. They recently secured funding from the NIHR Academy to support national expansion.

Additional funding would allow the Foundation to:

- Engage in more collaborative activities and support projects
- Offer more international internships and work experiences, as well as term-time opportunities
- Support a buddy scheme
- Support better management of Intellectual Property

Sponsorship & Exhibition Opportunities

Our National Meeting attracted over 140 people with a good mix of clinicians, academics from engineering, nanotechnology and biosensing backgrounds, industry and a number of patient representatives.

Why Should You Sponsor?

Show case your organisation to the current key players and collaborators in the national network, interact with key opinion leaders from academia, the NHS and industry on key research issues and network with other sponsors and develop relationships beneficial to your company.

Sponsorship money is used to support innovation workshops, internships, education and engagement activities for the MedTech Foundation.

Platinum Sponsor - £3000 + VAT

- Opportunity to host 10-minute lunchtime innovation showcase
- 3 delegate invitations to pre-event dinner with key opinion leaders and speakers
- Acknowledgement in digital communications, conference material, announcements, electronic program and website
- Company logo featured prominently (largest company logo) on all event promotional material including event programme and badges.
- Company logo to appear on interval slides between presentations in plenary sessions
- An exhibition stand in a prominent place at the National Meeting
- Banners at the welcome coffee and lunch stands

Gold Sponsor - £2000 + VAT

- 1 delegate invitation to pre-event dinner
- Acknowledgement in digital communications, conference material, announcements, electronic program and website
- Company logo featured on all event promotional material including event programme and badges.
- Company logo to appear on interval slides between presentations in plenary sessions
- An exhibition stand in a prominent place at the National Meeting
- Banners at the welcome coffee and lunch stands

Silver Sponsor - £1000 + VAT

- Company logo featured on all event promotional material including event programme.
- Company logo to appear on interval slides between presentations in plenary sessions
- An exhibition stand at the National Meeting

Technology Demonstration Surgery - £1,500

We welcome proposals from industry/charities/other organisations for the provision of technology demonstrations and other educational sessions. This can range from scientific papers to hands-on sessions and simulator sessions.

Companies will be allocated time within this surgery. We ask that each company submits their proposal to the Surgical MIC with a brief description on how this time will be utilised. The only requirement is that the sessions do not coincide with the main programme.

A timetable of available slots will be issued and an allocation of times will be given. Examples of how this time can be utilised:

- Presentation on a new product or new data
- Technology demonstrations or service presentations
- A meet-the-expert session (a session in which several users of your technology discuss how and why they use it)

This package includes space with power/furniture, booking facility to register interested delegates, company name and logo on website and position for roll up banner.

Exhibition Stand is £500 + VAT

Stands with table/chairs provided and space for roller banners.

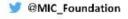


MedTech Foundation National Expansion Meeting

Thursday 24th January 2019 12:30-18:30 Horizon Leeds, 3rd Floor, Brewary Wharf, Leeds LS10 1JR

Time	Session	Speaker	Location
12:30-13:00	Arrival and Coffee	2	
13:00-13:15	Welcome and Introduction to MedTech Foundation	William Bolton	Create
13:15-13:45	NIHR Surgical MedTech Cooperative	Prof David Jayne	Create
13:45-14:15	MedTech Foundation Student Experiences	1 2 3	
14:15-14:45	Student Internships in Academia	Pete Culmer	Create
14:45-15:15	Student Internships in Industry	Martin Stanley/Richard Hall	Create
15:15-15:45	Tea, Coffee and Refreshments	-	
15:45-16:15	MedTech Foundation Spokes	1 2 3	
16:15-17:15	Breakout Tables Discussion "How can we enhance engagement of students and early carer researchers and clinicians in interdisciplinary medtech innovation?" Barriers Motivators Opportunities		Create
17:15-17:30	Conclusions, Summary and Next Steps	William Bolton	Create
17:30-18:30	Networking Buffet		





EDUCATE-COLLABORATE-INNOVATE



| /MedTechFoundation | www.surgicalmic.nihr.ac.uk

surgicalmic@leeds.ac.uk



Events Calendar

MedTech Foundation National Expansion Meeting – 24 January 2019

<u>Academia-Industry networking event on 'Early Detection of Cancer using Big Data and AI – 25 January 2019</u>

Save the date: Leeds Pathology 2019 2 – 4 July, 2019

Keep up to date here - http://surgicalmic.nihr.ac.uk/category/news/events/

Funding Opportunities

Safety Innovation Challenge Fund – 21 December 2018

<u>Clinical Outcomes Associated with the use XCM BIOLOGIC® Tissue</u>

Matrix – contact us for more information. *Deadline* – 31 *December* 2018

Testing new medical technologies in the NHS: apply for funding – 30 January 2019

Bowel Cancer UK Project Grant – 31 January 2019

Vasculitis Research Call for Research Grant Proposals – 31 January 2019

One-Year Surgical Research Fellowship – 28 February 2019

Clinical Academic Research Partnerships – 12 March 2019

Digital technologies to improve health and care – 19 March 2019

<u>The Jean Shanks/Pathological Society (JSPS) Clinical Lecturer Support Grant</u> – 1 *April 2019*

Bowel Cancer UK Pilot Grant - 2 May 2019

Innovator Awards – no time limits

Healthcare Technologies: Call for Investigator-led Research Projects - no deadline

Pancreatic Cancer Scotland – Pump-priming research grants – no time limits

Ad-Venture Grant Funding for SMEs

Social media highlights



Following

Loving exploiting VR surgical environments, training from anywhere, anytime @MedRealities @MIC_Foundation @OfficialNIHR @surgicalMIC #innovation



11:42 AM - 7 Nov 2018





Attending the "Smart Surgery for Tomorrow's NHS, national meeting"

@AUHE_Leeds @surgicalMIC



11:30 AM - 7 Nov 2018



Follow

Thoroughly enjoyed today's @surgicalMIC #patientinvolvement session on recovery after #colorectalsurgery Thank you @ambler_julia @Lisa_Wilde and all of our



6:44 PM - 7 Nov 2018 from Quebecs Hotels



Follow

An excellent and motivational annual conference and stands at the NIHR Surgical Medtech Co-operative (@surgicalMIC) in Leeds today. Brilliant organisation & facilities.



6:00 PM - 7 Nov 2018



Follow

Great to assist @ambler_julia & @Lisa_Wilde in #bowelcancer surgical outcomes research without any scalpels required!
@bowelcanceruk and a great group of bowel



4:02 PM - 7 Nov 2018 from Leeds, England



Follow

On Wednesday our Head of Projects
Chander opened talks at the annual
@surgicalMIC conference on Smart Surgery
for Tomorrow's NHS. Talking about the
Endocuff Vision and the journey from
'Concept to Combating Cancer'.

#nhs #medtech #surgery #bowelcancer #endocuffvision



10:32 AM - 9 Nov 2018



Jacqueline Andrews @Andrewsjackie1 · Nov 7
Great interactive start to national @surgicalMIC event. What #MedTech device would you create?? @LeedsHospitals @LeedsMedHealth #SmartSurgery





Encouraged to cooperate to advance surgical innovation #wouldntitbegood for #smartsurgery

Surgical MedTech Co-operative @surgicalMIC
Prof Jayne introducing the Surgical MIC and setting the scene for the day
#smartsurgery

10:20 AM - 7 Nov 2018



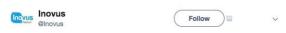




Nice way to start todays national conference for @NIHRLeedsMIC on #smartsurgery . We'll be hosting an @IMPRESSleeds interactive session in the afternoon on improving continence healthcare.

Surgical MedTech Co-operative @surgicalMIC Leeds receives £10m investment for Al and digital pathology ow.ly/HARa30mw7bp

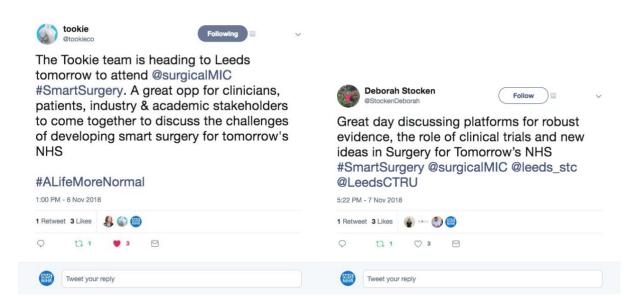
9:33 AM - 7 Nov 2018



We are @surgicalMIC #smartsurgery conference today discussing #MR and #VR in surgical simulation and how we are bringing high fidelity simulation to the masses at low fidelity prices. Stop by our stand for an update on progress on some very exciting product developments #meded

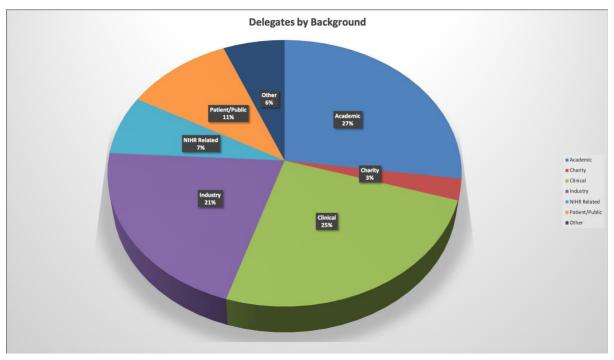








National Meeting 2018 in numbers



Next steps.....

The Surgical MIC actions:

- Work behind the scenes to address your suggestions from the group exercises
- Send delegates a link to the National Meeting "Dating Wall" so that they can follow up on collaboration opportunities
- Make the technology wish list available on our website for potential collaborators to request introductions to the relevant people - http://surgicalmic.nihr.ac.uk/get-involved/surgery-innovation-forum/
- Outputs from the roundtable afternoon workshops will be used to shape our proof-of-concept/market funding call in March/April 2019. Delegates are also welcome to apply for incubator packages to facilitate initial discussions and set up collaborations at any time. Details are available here http://surgicalmic.nihr.ac.uk/support-available/funding-competitions/
- Outputs from the roundtable afternoon workshops will also be used to shape themes for our events and workshops. Dates and details of workshops will be available on our website and sent to those subscribed to our "Events" mailing list.

In the meantime, you can:

- sign up to our mailing lists here https://form.jotformeu.com/81303313436345
- think about how you can support our MedTech Foundation
- contact us for more information on becoming a <u>Surgical MIC satellite/spoke site</u> if you are a clinician or academic?
- <u>join our Patient and Public Involvement group</u> we are keen to work with a wide range of individuals and organisations.
- enquire about using our <u>Surgical Technology Testbed</u> for your early and late phase clinical evaluations.

Associate Membership

The Surgical MedTech Co-operative is working with universities and organisations around the UK to develop novel solutions to a series of clinical and patient led challenges. Anyone with an interest in technology development for patient benefit, whether you are already involved in the medical field or not, can become an Associate Member and work with the Surgical MedTech Co-operative on innovation for patient benefit.

Membership commitment

Membership is free, all we ask is that you promote the work of the Surgical MedTech Cooperative within your own networks, support our events and encourage like-minded colleagues to join!

Membership benefits

- updates on your area(s) of interest
- access to seminars and events related to your area of interest
- industry, NHS, patient and academic networking opportunities
- access to a panel of scientific, academic, clinical and patient experts for idea development
- access to the Associate Forum to engage in group discussions
- opportunities to visit NHS theatres and view surgical procedures
- an entry point into the NHS Innovation landscape
- access to expertise in design of pilot studies and clinical trials
- access to clinical advisory panels (*paid service)
- access to patients for clinical validation studies
- access to other technology and clinical networks through MIC partnerships
- bookable workspace in Leeds city centre, and many more.

http://surgicalmic.nihr.ac.uk/about-us/associate-membership/

National Meeting 2019



SAVE THE DATE - Tuesday, 19 November 2019

Please contact us on surgicalmic@leeds.ac.uk to discuss any of the following:

- sponsorship options and packages (we can arrange bespoke packages)
- exhibiting at the meeting
- hosting an afternoon breakout session/workshop
- presenting at the National Meeting
- you can also suggest a session

PILOT & FEASIBILITY STUDIES IN CANCER & PALLIATIVE CARE:

Why, when & how to conduct for complex intervention studies



Location: University of Leeds

Date: 17 January 2019, 9:30-16:00

Fee: £20



Overview

The Clinical Trials Research (CTRU) at the University of Leeds is supported by Yorkshire Cancer Research to deliver a series of workshops aimed at providing cancer & palliative care clinicians with the knowledge to allow them to design & conduct clinical trials of Complex Interventions.

Why should you attend this workshop?

Efficient, well-designed & well-conducted early studies are vital to ensuring the robust design & implementation of large scale randomised controlled trials – especially those for complex health or social care interventions.

Who will benefit from this workshop?

Clinicians & researchers interested in designing or running pilot & feasibility studies for complex interventions in cancer or palliative care – especially those seeking research funding.

No previous experience is necessary; basic knowledge of clinical trials would be an advantage.

Goals

By the end of this workshop, attendees will have gained an understanding of:

- Design & rationale for pilot & feasibility studies;
- Sample size determinants;
- Robust progression criteria;
- Reporting standards;
- Considerations for effective study monitoring.

Attendees will be provided with a comprehensive list of key publications and will be in a strong position to develop a funding proposal.

Feedback from previous workshop

"Use of examples to put theory into context. Mixture of theoretical & practical info relating to design & conduct of trials. Useful group work exercises to apply learning."

"Fantastic speakers, very knowledgeable + passionate! Fab introduction to CIs"

"Good introduction to a wide range of challenges & considerations required in the design of trials related to complex interventions."

How to apply

Email the CTRU to register interest:

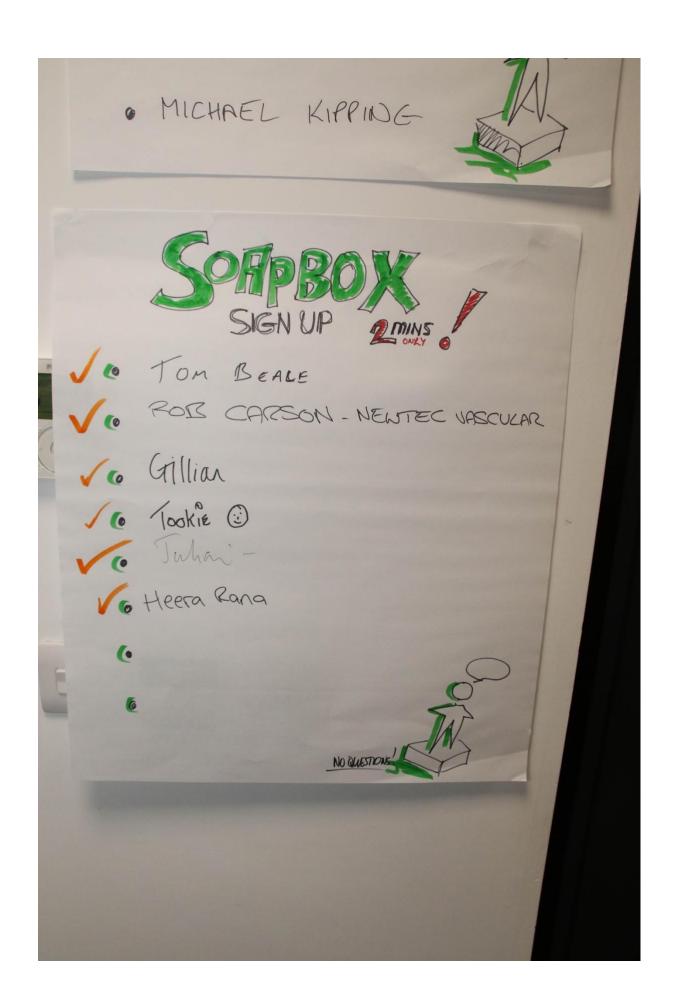
CTRU_CID@leeds.ac.uk

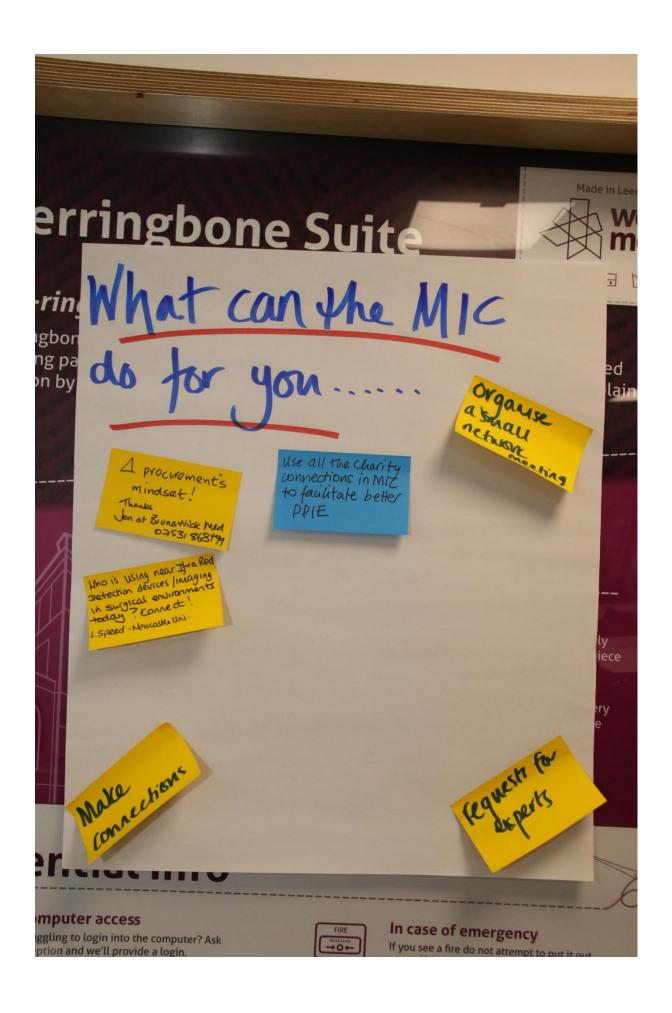


UNIVERSITY OF LEEDS

This workshop is supported by Yorkshire Cancer Research and is CPD accredited







Surgical MedTech Co-operative



We are interested to hear from you if you have a new technology or technology-led interventions, please use the '<u>submit an idea form</u>'. Alternatively, if you wish to collaborate with the Surgical MedTech Co-operative or if you are a patient or member of the public who wishes to get involved in surgical research activities.

Surgical MedTech Co-operative

St James's University Hospital, Beckett Street Leeds, West Yorkshire, LS9 7TF United Kingdom surgicalmic@leeds.ac.uk

Visit us on the web at http://surgicalmic.nihr.ac.uk/

