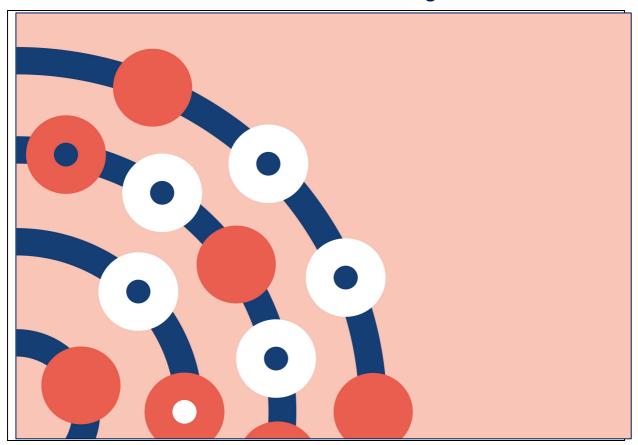


Main conclusions of the National Meeting 2019



TRANSFORMATIVE TECHNOLOGIES

NIHR Surgical MedTech Co-operative | St James's University Hospital | Leeds | LS9 7TF | e: surgicalmic@leeds.ac.uk | website: http://surgicalmic.nihr.ac.uk



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 2019 NIHR Surgical MedTech Co-operative

Thank you to our Sponsors & Exhibitors

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Exhibitors:





















Key Highlights



Creating, Developing and Testing New Surgical Innovations	Page 7
VSI - Virtual Surgery Intelligence	Page 8
New Frontiers of 3D Bioprinting for Surgical Biocompatibility	Page 9
Introducing the Surgical MIC spokes/hubs	Page 11
Developing a peripheral vascular assessment device through	Page 12
the NIHR i4i programme	
Progress since National Meeting 2018	Page 13
2019 Proof of Concept Funding Recipients	Page 21
IDEAL Framework for Evaluation of Innovation in Surgery &	Page 27
Devices & its Practical Application.	
Showcase - Dr Yeshwanth Pulijala, CEO Scalpel Ltd	Page 28
MedTech Foundation Programme	Page 29
PhotoVoice Challenge	Page 30
Social Media Highlights	Page 43
Next Steps	Page 45
Associate Membership	Page 46
National Meeting 2020	Page 47

TRANSFORMATIVE TECHNOLOGIES



Transformative technologies are those with the potential for transformative impact in life sciences research (both biological and biomedical). Chances are that these technologies will be novel and based on new advances in fundamental engineering, physical and life sciences.

Transformative technology is hardware- and software-based tools designed to enhance human psychological well-being, cognitive function and physical capabilities.

We are familiar with the following transformative technologies for surgeons and other healthcare professionals:

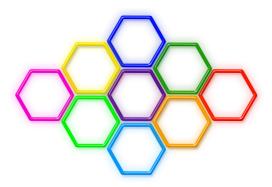
- Robot-assisted surgery can reduce variation in performance between hospitals, allow better access to traditionally hard to reach parts of the body and improves accuracy and precision in procedures.
- Genomic testing to improve cancer detection and personalised medicine

An independent Commission has predicted that surgery is about to be transformed for millions of patients by a new wave of technologies – driven by changes in digital technology and our understanding of human biology – which in some cases are only months away (Royal College of Surgeons of England).

- 3D bio-printing could reduce complications associated with transplants and involves layering living cells on top of each other to eventually create an artificial living tissue. Since it creates tissues and organs derived from the cells of the patient requiring a transplant, it eliminates the likelihood of rejection and the need for life-long immunosuppressive drugs.
- Artificial intelligence will make diagnosis and treatment more precise by analysing huge amounts of data quickly and spotting anomalies and providing useful insights.
- Augmented reality (AR) and Virtual Reality (VR) are currently used by the NHS
 to help train the next generation of surgeons, as well as allowing them to
 rehearse procedures on patient-specific simulations.

For this National Meeting, we decided to explore how some the transformative technologies can support the well-being of patients and how the Surgical MIC can facilitate the development of technologies that directly benefit patients.

Creating, Developing and Testing New Surgical Innovations: People and Prototyping



Gareth Loudon, Professor of Creativity at the <u>Cardiff School of Art and Design</u> (<u>CSAD</u>) and co-founder and Director of the <u>Centre for Creativity Ltd</u> started the day's proceedings with his experiences and lessons learnt from his time at Apple (speech and writing recognition) and Ericsson (design of 3G mobile phones and applications). Professor Loudon defined creativity as "*the ability to come up with ideas or artefacts that are novel, valuable and substantive*", and introduced the four key aspects of creativity - person, place, product and process.

He introduced the following principles of Human Centred Design Process and their application to transforming the design of surgical technologies:

- The design is based upon an explicit understanding of users, tasks and environments
- Users are involved throughout design and development
- The design is driven and refined by user-centred evaluation
- The process is iterative
- The design addresses the whole user experience
- The design team includes multidisciplinary skills and perspectives

To summarise, surgeons and patients provide real-life accounts of the activities, desires, beliefs and values involved in the use of surgical technologies. Their input is invaluable to innovators as it highlights the differences between what people do and what they say they will do, in addition to discovering needs that have not been directly expressed.

The Surgical MIC can assist innovators to identify clinical and patient benefit early on in the design process, to increase chances of clinical adoption. Talk to us about setting up patient and clinical focus groups to inform the design and use of your technology.

VSI - Virtual Surgery Intelligence



Sirko Pelzl, CEO and CTO of <u>apoQlar GmbH</u> followed the proceedings with his talk on virtual surgery intelligence (VSI).

He presented apoQlar's vision to implement a scalable, fully integrated, comparably low cost, cloud-based data interaction standard in healthcare; where every surgeon wears a VSI Hololens and hospitals have no monitors or navigation systems. Sirko set the scene with examples of the quality and quantity of information surgeons have to make their decisions and contrasted these with what their technology could do for surgeons and their patients. Delegates were treated to demos of:

- Using 3D to visualise the sentinel lymph node for removal surgery.
- Seeing the arteries in real time, reducing the imagination and experience needed for surgery to remove the cancerous half of the liver.
- Superimposing the ventricle on the patient to assist surgeons in finding the correct entry for Ventriculoperitoneal Shunt Surgery (Hydrocephalus).

This technology has potential applications for patient education, surgery planning, telesurgery, holoportation, documentation and natural rendering.

The Surgical MIC can facilitate these and similar collaborations by identifying suitable collaborators, arranging events and workshops. We can also secure funding for workshops, academic visits and placements with our partner organisations.

New Frontiers of 3D Bioprinting for Surgical Biocompatibility



Dr Luigi Pugliese, General Surgeon from <u>Unit Fondazione IRCCS Policlinico</u> San MatteoPavia, Italy started with a a brief introduction to 3D printing in general for those not familiar with the technology which is a quite recent acquisition among the innovations in medical imaging across the history of modern medicine.

3D printing is a process of making three dimensional objects from a digital file and this is achieved through an additive process. In this way, the object is created by laying down successive layers of material until the final shape is completed. Each of these layers can be seen as a thinly sliced horizontal cross-section of the final object. This process is actually the opposite of subtractive manufacturing which is cutting out a piece of material and therefore enables to produce complex shapes using less material than traditional methods.

The relationship between this technology and its use in surgery stems from the idea of simplifying one of the basic need of surgeons - that is the ability of spatial reconstruction of the anatomy of interest by integrating standard two-dimensional medical imaging with the real three-dimensional anatomy of the patient. A complex mental process, though incredibly important for surgical planning which is based on deep anatomical knowledge and reinforcement by intraoperative feedbacks. However, it might result extremely challenging even for expert surgeons due to the great anatomical variations between patients and the distortion induced by disease which might not be easily understood from conventional imaging.

To summarise, the 3D printed model assists surgeons with surgical planning, surgical training and simulation, intra-operative navigation and communicating with patients.

provision of clinical expertise, as well as patient expertise during the technology development process.				

Introduction to Surgical MIC spokes



The role of the "spokes" is to promote NIHR Surgical MIC activity, reaching out to individuals and institutions with similar clinical and research ambitions. The "spokes" provide the extended network for the NIHR Surgical MIC making it a national collaborative initiative.

Professor Chris Halloran, Professor of Pancreatic Surgery at the University of Liverpool leads our newly formed spoke in Liverpool and their clinical focus will be all things pancreatic. This is ideal for both Liverpool and the Surgical MIC as Prof Halloran's network is a high-volume centre and has the full depth and breadth of clinical pancreatology. They also bring with them, a history of developing practice changing trials such as <u>ESPAC</u>, <u>Pet-Panc</u>, <u>Dispact</u>, and <u>ChroPac</u>. In addition to this, they have the largest number of research active pancreatologists.

Ultimately, the Liverpool spoke would like to get involved in multiple grant applications that will lead to trials for patient benefit. A project collaboration has already been identified and it involves using artificial intelligence for radiology, in particular real time alerts to reporting variance for pancreatic imaging.

Developing a peripheral vascular assessment device through the NIHR i4i programme



Dr Andrew Sims from The Newcastle upon Tyne Hospitals NHS Foundation Trust presented on this topic on behalf of the NOTEPAD project team.

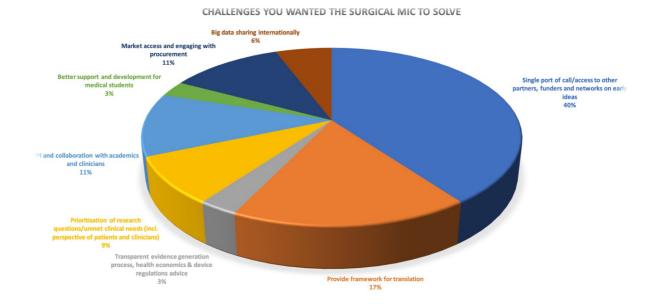
Dr Sims' talked us through his journey from idea to applying for the NIHR Invention for Innovation (i4i) funding and their area of interest was in demonstrating the utility of non-invasive diagnosis of peripheral arterial disease in primary care. This involved understanding the prevalence of vascular disease (coronary artery disease, peripheral arterial disease and cerebrovascular disease) in people over the age of 62 and associated outcomes of patients with peripheral arterial disease.

Tips for potential NIHR i4i applicants included:

 identifying the weaknesses on your team - ours included the absence of evidence, experience and engagement in primary care; no technical file, health economic case, case for adoption and route to commissioning.

On addressing these weaknesses for the application, the team was successful and is now using the funding to finesse the final design.

The Surgical MIC supports and collaborates on grant funding applications. Our involvement can be arranging lay summary review from our Patient & Public Involvement Group to full-on clinical or academic involvement.



At the 2018 National Meeting you asked us "Wouldn't it be great if the Surgical MIC could...." So here is an update

You wanted a "single port of call and access to other partners, funders and networks on early ideas" - the Surgical MIC is currently developing a translational toolkit that will also demonstrate when and where to contact the NIHR MICs. This toolkit should also "provide a framework for translation" and set out a "transparent evidence generation process, health economics and device regulations advice". In addition to the toolkit, we have recently developed a smartphone/tablet app for use on Android and Apple operating systems.

You wanted us to "prioritise research questions and unmet clinical needs that are inclusive of the patient and clinician perspective" - a list of current unmet needs has been published on our website with details of organisations involved. The only area that we are yet to publish on is HPB as the planned workshop was postponed due to the COVID-19 lockdown. However, the current unmet needs will give you a good indication of the areas that funders and the Surgical MIC will prioritise.

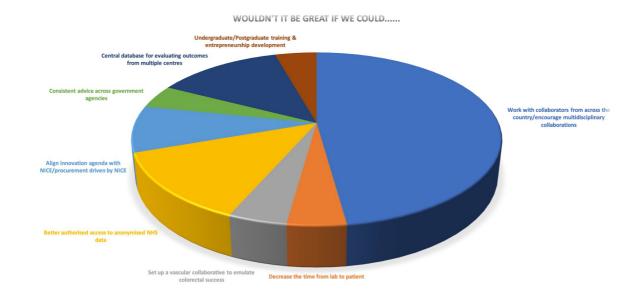
You wanted "patient and public involvement and collaboration with academics and clinicians" - the Surgical MIC has now embedded PPI within its project management systems, which means that PPI members are notified of projects at a much earlier stage, allowing them to be part of the discussion when it matters the most.

You wanted "better support and development for medical students" - the MedTech Foundation has grown from strength to strength, as we launched the

Network and successfully engaged a couple of companies to support the groups across the country. We recognise that the journey is far from over, and we shall continue to push the agenda. More information on progress and what we have been up to can be found on their <u>website</u>.

You wanted more support with "market access and engaging with procurement" - in July 2019 the Surgical MIC together with the University of Southampton and Device Access, launched a Market Access course in Southampton. This course did deal specifically with Market Access, however there are plans to run procurement workshops for industry later on in 2020.

You wanted "big data sharing internationally" - this is still ongoing and we have made a start by working in collaboration with the <u>IDEAL collaboration</u> and other national/international networks to raise the importance of this.



At the 2018 National Meeting we asked "Wouldn't it be great if we could...."

You said "work with collaborators from across the country and encourage multidisciplinary collaborations" - the Surgical MIC has always been a national collaboration and we frequently hold and host workshops in the North. We are considering hosting events in other regions and are working collaboratively with other organisations to widen our reach. In the meantime, access to collaborations can be gained by signing up to our mailing list as this is the only way we can contact individuals with opportunities https://form.jotformeu.com/81303313436345 or download the Surgical MIC app to place a request or see what ideas are floating around. You can also discuss co-hosting an event in your region with us.

You said "decrease the time from lab to patient" - look out for our toolkit which aims to clarify our role and how we can help you and your technology get to the patient quicker.

You said "set up a vascular collaborative to emulate colorectal success" - the Surgical MIC works closely with the VERN Collaborative and we sponsor an annual award to stimulate MedTech research in this area.

You said "better authorised access to anonymised NHS data" - access to anonymised NHS data has always been possible however one needs to be aware of the pre-requisites for this, one of them being a research question. We can certainly direct people to the appropriate contacts, as long as we are mindful that the NHS will just not release data without some possible patient benefit in the future.

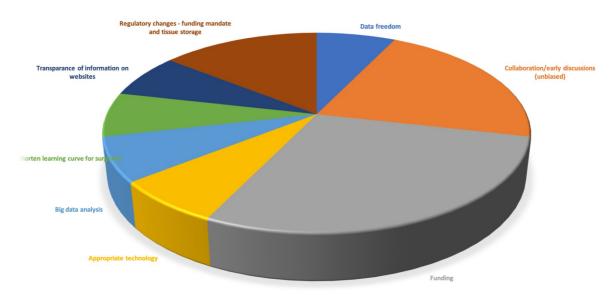
You said "align innovation agenda with NICE/procurement driven by NICE" - the Surgical MIC agenda has to be aligned with unmet clinical needs and patient benefit in the first instance. NICE and other bodies are in the process of reviewing their procedures for medical technology which should help in aligning the NIHR agenda for patient benefit, with that of NICE and procurement.

You said "provide consistent advice across government agencies" - the Surgical MIC works to guidelines set by our funders. We can only provide advice that is consistent with our remit, however, where inconsistencies have been identified, please let us know and we can escalate these and seek clarification.

You said "have a central database for evaluating outcomes from multiple centres" - this is still work in progress as it will require additional funding to coordinate this work across multiple centre and infrastructure units. The other way of achieving this is for publications to be made available.

You said "provide undergraduate/postgraduate training and entrepreneurship development" - this is done via our MedTech Foundation programme, and those in Yorkshire can access additional resources via Grow MedTech and Adventure.





At our 2018 National Meeting we asked you what was missing from the giant MedTech jigsaw?

You said "Funding" - funding is an essential component of any development and whilst the Surgical MIC has a small pot of pump prime funding available, it is still not sufficient to cover the entire pathway. To maximise funding opportunities for our projects, we are working collaboratively with a wide range of funders to understand their criteria and angel investors/venture capitalists. Where we think certain projects will benefit from additional funding, this will be discussed with the innovator. We can provide advice on the appropriate funding stream for your technology stage.

You said "Unbiased collaborations/early discussions" - collaborations with the Surgical MIC have to fit an identified unmet clinical need and these are available on our website - https://surgicalmic.nihr.ac.uk/about-us/. These unmet clinical needs have been validated by the clinical and professionals associations, and are also areas the NHS is keen to explore new technologies for. We can certainly discuss how well your technology meets these needs and whether there is scope for repurposing. Either way, we welcome early discussions.

You said "Data freedom" - there are standard contract clauses on this topic and our advice is that you discuss this at the contract negotiation stage. Data freedom will be dependent on the organisation that owns the data and what you plan to do with that, including commercialisation as a result of receiving this data.

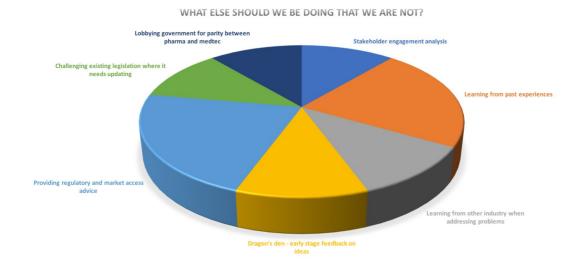
You said "Regulatory changes - funding mandate and tissue storage" - unfortunately we are not in charge of this aspect, but will happily signpost you to appropriate contacts and organisations.

You said "Transparence of information on website" - we believe we are transparent enough with our website and regularly update the information, however if you identify anything that is not clear then please contact us and we will rectify the issue.

You said "Shorten the learning curve for surgeons" - we are working closely with various organisations that also want to address this issue. Part of our initial technology assessment also considers this aspect as it will impact on market access and adoption in the NHS.

You said "*Big data analysis*" - the Surgical MIC partner organisations have expertise in this area, and we would signpost you to these organisations. It is also worth checking out the Leeds Institute for Data Analytics.

You said "*Appropriate technology*" - this is linked to our unmet clinical needs. For technology to be appropriate for the NHS, it has to solve an unmet clinical need.



At our 2018 National Meeting we asked you what else we should be doing that we are currently not?

You said "Learning from past experiences" - this is something we strive to do and will continue to improve our offer to you based on this learning.

You said "Learning from other industries when addressing problems" - this is very important as it stops us from reinventing the wheel for certain ideas. For

example, we have facilitated the transfer of volatile organic compound research derived from the horse racing/veterinary sector for appendicitis and colorectal cancer. If you are aware of potential technologies in other sectors, please talk to us.

You said "*Dragon's Den - early stage feedback on ideas*" - we generally give feedback on early stage ideas and we also launched a Super Connect Event series with <u>Empact Ventures</u> to facilitate this for start-ups in surgery.

You said "Providing regulatory and market access advice" - we held a Market Access Course with the University of Southampton and intend to make this an annual event. We have had to skip this for 2020 due to current restrictions.

You said "Challenging existing legislation where it needs updating" - we frequently respond to consultation and continue to work closely with those that are closer to the legislators.

You said "Lobbying government for parity between pharma and MedTech" - we work closely with organisations like the Northern Health Science Alliance, Health Tech Alliance and Medilink UK by providing evidence to support their lobbying efforts.

You said "Stakeholder engagement analysis" - we have conducted a stakeholder engagement analysis and we are having discussions on the optimum engagement techniques we can use.

Surgical MIC – Our role in technology development



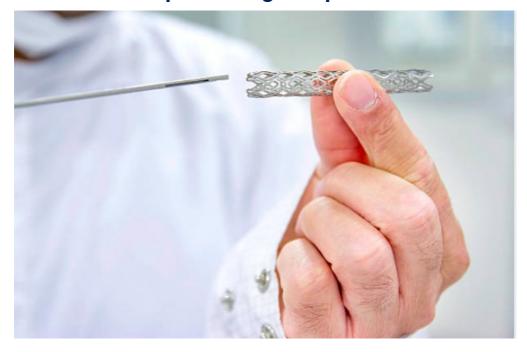
The main remit of the Surgical MIC is to:

Develop research collaborations - These can be academic collaborations (nanotechnology, robotics, engineering, pathology), clinical collaborations and 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. Funding opportunities will be posted on their 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 - 2019



The NIHR Surgical MedTech Cooperative in collaboration with Research England funded <u>Grow MedTech programme</u> is 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 is 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 2019/20 - 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 2019/20 - 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 aspect in evaluating submitted projects is the potential to develop into a more substantial project that can apply for external funding.

For more information, visit our website here.



1 - An innovation in bowel cleaning and blockage

Proof-of-Concept Recipient: Dr Joe Norton, Storm Lab UK, University of Leeds

An innovation in bowel cleaning and blockage removal

Colonoscopy outcomes are hugely dependent on the quality of bowel preparation. Current standard is an oral laxative which requires upfront administration and diet modification, and also sometimes ineffective. This procedure is poorly tolerated by patients, and attracts high costs and risks via prolonged procedure and the

high probability of repeat procedures. In some patients with comorbidities this solution can also be lethal.

The team has received funding from the Surgical MIC to develop a non-invasive bowel preparation device that will be better tolerated by patients and that will completely clean the large bowel. The project objectives are to:

- complete and comprehensive literature review on bowel preparation & current methods;
- develop a first stage benchtop prototype of the full concept;
- conduct In-vitro tests showing technical feasibility of core concept;
- produce a fully developed prototype for testing on an ex-vivo model;
- conduct clinical feasibility tests, performed first on benchtop simulator and then on ex-vivo porcine samples.

The funding will enable the team to employ a research assistant; purchase ultrasound equipment and consumables; and enable networking with project partners. In addition, the funding will support patient involvement for valuable feedback and insights; support networking with clinicians & industry for project collaborations.



2 - Extracorporeal Shockwave Therapy for the treatment of Diabetic Foot Wounds: a pilot mechanistic evaluation.

Proof-of-Concept Recipient: Ms Louise Hitchman, Vascular Surgeon Trainee, Hull Teaching Hospitals NHS Trust

Extracorporeal Shockwave Therapy for the treatment of Diabetic Foot Wounds: a pilot mechanistic evaluation.

Diabetes affects more than 3.7million people in the United Kingdom. One in four of these patients with diabetes will develop a diabetic foot ulcer, Diabetic ulcers take months or years to heal, severely reducing quality of life. The current treatments for diabetic wounds, such as simple dressings, off-loading footwear and antibiotics, are of limited effectiveness.

There is an urgent need to identify new treatments for diabetic foot ulcers and demonstrate their effectiveness. Extracorporeal shockwave therapy (ESWT) is a new treatment that has been shown, in clinical studies, to reduce the time taken for diabetic foot ulcers to heal. ESWT uses sound waves to stimulate local healing, and is thought to promote blood vessel growth and reduce the risk of wound infection. However, we do not fully understand how ESWT therapy promotes wound healing in humans or what the optimum dose of ESWT should be.

The team has received funding from the Surgical MIC to use laboratory models of diabetic foot wounds to investigate how ESWT beneficially stimulates cell function, while also evaluating the optimal way to deliver ESWT. Pilot data generated in this study will underpin further, more substantial evaluation of ESWT in the clinic.

The project objectives are to:

- Determine the optimal dosing strategy for ESWT to promote wound healing.
- Explore the mechanism of action of ESWT on wound healing
- Test the antimicrobial effect of ESWT in wounds

The funding will enable the team to procure laboratory reagents to be used for: ex vivo human skin culture – tissue culture media, supplements, plasticware, membranes, biopsy punches, histological analysis – slides, wax, blades, cassettes, reagents, immunohistochemistry – antibodies, novared, confocal imaging, microbiology – plates, media, disposables, reagents, vitek 2 cards.



3 - Health Economics for drone usage within the NHS

Proof-of-Concept Recipient: Thomas Franchi, Director and Co-Founder, MEDeus Ltd

Health Economics for drone usage within the NHS

MEDeus Ltd was founded with the mission to procure, vet and integrate

the use of drones into the NHS. In order to validate their business model, they need to prove that this is worth pursuing and that there is evidence to support clinical benefit. One branch of this evidence will be to conduct health economic analysis to highlight some of the potential savings that drones could bring to the NHS.

The team has received funding from the Surgical MIC to collate NHS Blood and Transplant (NHSBT) data for hospital logistics and clinical outcomes. The project will give an overview of the impact that drones may have.

The project objectives are to:

- Use modelling to compare the use of drones in the same clinical settings and quantifiably state how much it could improve clinical outcomes for patients, as well as reduce financial and environmental burden on the NHS.
- Conduct an in-depth logistical review of the status-quo for organ transplantation (may include an audit),
- Quantification of each part of the logistical pathway in organ transplantation from the moment an organ is ready for collection, through to delivery for testing and matching and any further deliveries to the matched recipient,
- Quantification of the loss in time and finances and other measurables.
- Creation of data model to predict the resultant change if drones were to be used in the logistical pathway,
- Detailed analysis of the various benefits arising from the time-savings which arise due to our proposed drone-delivery service and the predicted resultant change.

The funding will enable the team to complete the relevant health economics analysis.



4 - Computer vision to automatically monitor urine output

Proof-of-Concept Recipient: Dr Stefan Williams, Leeds Teaching Hospitals NHS Trust

Computer vision to automatically monitor urine output

At present, busy nursing staff can only write down the level in the urometer collection bag occasionally on a paper chart, and can miss entries on this chart. This means that the first sign of kidney damage - reduced urine - is often missed, or picked up late, causing patient harm (and preventing optimum recovery from surgery).

The project will collect a large number of anonymous photographs and use this set of photographs for a computer program that can learn to recognise and measure the urine level.

The project objectives are to:

- Collect between 1000 and 3000 photographs of urometers from patients (who have given informed consent) on the renal medicine wards of Leeds Teaching Hospitals NHS Trust (this includes patients who remain in hospital for 5 days monitoring after renal surgery)
- Process these photographs using a range of machine learning techniques, such that we develop a computer program that is capable of 'reading' the level of urine in a urometer photograph with a defined (percentage) accuracy (compared with the 'gold standard' of manual human reading of the level shown in the photograph).
- Produce a simple 'prototype device' that demonstrates in principle that urometer images can be automatically captured and processed, to determine urine level.

The funding will enable the team to hire a healthcare assistant to manage the large number of photographs involved in the project, the development and refinement of computing algorithms to 'learn' to 'read' the urometer level and the development of a simple prototype device with associated basic equipment costs.



5 - Developing 3-D printed hydrogel models for a national programme of home-based vascular simulation training

Proof-of-Concept Recipient: Ms Rachel Falconer (Vascular trainee and MD student, University of Aberdeen/NHS Highland)

Developing 3-D printed hydrogel models for a national programme of home-based vascular simulation training

There are challenges to delivering comprehensive training within the current healthcare system. Endovascular simulation can significantly

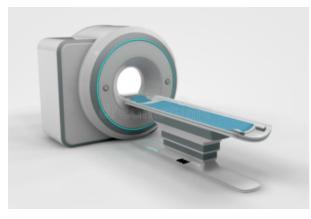
reduce critical errors and procedure time in theatres.

This shows simulation can have a positive impact on the safety and quality of patient care, without compromising the training of future generations of vascular surgeons. New technologies are revolutionising the ability to create realistic models for open surgical simulation.

Pioneering 3-D printing techniques, combined with a new hydrogel material, allows for the manufacture of high-fidelity models which contain no human or animal tissue, are biodegradable and low cost.

The project objectives are to validate novel 3-D printed models for vascular anastomosis and evaluate the impact of a home-based programme of practice on skill acquisition of junior vascular trainees.

The Surgical MIC funding will enable the team to develop and validate pathological models, including purchase of raw materials and instruments/sutures, printing and transport/distribution costs.



6 - Towards Precision Medicine: a MagnEtic Resonance Imaging-based measure of fibrosis in enTeric Crohn's disease. The MERIT pilot study.

Proof-of-Concept Recipient: Dr Gordon Moran, Clinical Associate Professor of Gastroenterology, Nottingham University Hospitals NHS Trust & the University of Nottingham

Towards Precision Medicine: A MagnEtic Resonance Imaging-based measure of fibrosis in enTeric Crohn's disease. The MERIT pilot study.

Crohn's disease (CD) causes bowel inflammation in ~200,000 UK people. Recurrent inflammation causes scarring, leading to blockages with 50% of patients needing surgery within ten years of diagnoses. The cost to treat CD is ~£6000/patient/year.

Measuring scarring is important and studying the bowel removed after surgery is the only way to do so. Medications only work if the bowel is inflamed. Patients may be incorrectly receiving unnecessary medication that does not work, postponing required surgery, whilst suffering side-effects of inappropriate medication and costing NHS money. Knowing the amount of scarring without doing surgery will help doctors make better treatment decisions to improve patient outcomes and the use the NHS budget.

Magnetic Resonance Imaging (MRI) scanners can create images of the bowel. MRIs help to measure the extent of inflammation in CD but are not reliable at measuring scarring.

The team has received funding from Bowel & Cancer Research and the Surgical MIC to use a set of MRI scans together to measure scarring. This will involve the recruitment of CD patients who need surgery and the team will use the bowel sample from surgery to measure scarring and use this to learn what we see on the scanner.

The project objectives are to:

• validate the candidate MRI measures as fibrosis imaging biomarkers.

The funding will pay for MRI scanning and associated costs, and histopathological analyses.

IDEAL Framework for Evaluation of Innovation in Surgery & Devices & its Practical Application



The IDEAL Collaboration

Idea, Development, Exploration, Assessment, Long-term Follow-up, Improving the Quality of Research in Surgery

The IDEAL Collaboration was born out of a series of conferences between surgeons and methodologists at Balliol College, Oxford which was convened to study why high-quality trials in surgery were genuinely difficult to conduct, and what could be done to improve the evidence base for surgery.

The conclusion was that innovation in surgery inevitably follows a pathway with important differences from that followed by pharmacological developments, and that a different approach to evaluation is therefore needed. It was noted that many non-surgical disciplines had similar problems with evaluation of such treatments (termed as "interventional therapies"), which rely on operator skill and tailoring of the intervention to the patient (for example, cardiac catheterisation, endoscopic techniques, or physiotherapy).

The IDEAL Collaboration developed a framework for the stages in surgical innovation (idea, development, exploration, assessment, and long-term study) and a set of recommendations on how evaluation should be conducted at each stage. The collaboration also proposed how the environment for surgical research could be improved by editors, regulators, funders, and professional societies.

More information can be found here - http://www.ideal-collaboration.net/ Additional reading - https://www.bmj.com/content/346/bmj.f3012

This breakout session was led by Prof Peter McCulloch, Chair of IDEAL and Prof of Surgical Science & Practice at University of Oxford & Allison Hirst, Ideal Collaboration Project Manager & Researcher

Feedback from Dr Yeshwanth Pulijala, CEO Scalpel Ltd - recipient of 2018 Surgical MIC Proof-of-Concept funding



In 2018 Scalpel Ltd were awarded funding for their project looking at a "Technical iteration and evaluation of Smart Check – a novel surgical safety solution".

Dr Pulijala talked about how their software reduces preventable surgical errors and increases surgical productivity, and how collaborating with the Surgical MIC led to follow on funding from Innovate UK.

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 to unmet clinical needs. The foundation also manages a series of summer research internships and international exchanges with our global partners.

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

They would to expand the benefits of the MedTech Foundation to other institutes outside Leeds and MICs nationally 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.

Photovoice Challenge:

transforming surgical technologies for patient benefit

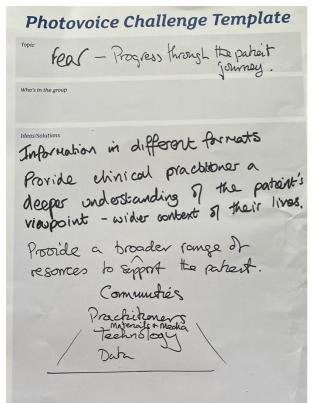


Ideas for medical devices and technologies can be initiated and driven by private companies, academics, healthcare professionals and patients/carers. However, there are plenty of devices and technologies that solve the technical or logistical problems but they may not always directly benefit the patient.

We launched the Photovoice Challenge to explore the lived experiences of patients (and their carers) that are about to or have undergone surgery. These could be experiences from before the operation, to patient care and experiences after the operation.

We used a technique called "Photovoice" which allows individuals to express concerns and issues most important and relevant to them via images. Because "a picture is worth a thousand words", it can be a powerful way to help others understand and connect with the issues.

We used our National Meeting as a platform to raise awareness to innovators of the lived experiences of patients, and to initiate a discussion on how new medical devices and technologies can include the patient/carer perspective. A summary of those discussions is summarised below:



Fear

Fear in this context is related to the unknown - individuals did not feel that they knew how they would progress through the patient journey. Not knowing what procedures were coming next, what would happen or what equipment would be used was a source of fear for many.

Summary of Discussion

There is a need to provide information in different formats for patients - some prefer video information, others prefer paper, whilst others prefer smartphone-based information. Patient information tends to be one dimensional and focuses on what the healthcare

professionals want you to know, however patients want to know how their healthcare experience will impact on their personal life, their employment and relationships with others. This information is hardly ever present in any of the patient information documents.

- The Surgical MIC is currently working with Professor Maria Lonsdale (Professor of Information and Communication Design) on this subject for patients with bowel cancer. If you would like to get involved or find out more then please contact surgicalmic@leeds.ac.uk.
- We are also exploring a collaboration with a company that specialises in language analytics. Their artificial intelligence technology can analyse sample text and determine which mode of communication, and type of information that would appeal to each patient. This would enable the development of a variety of different formats. If this is of interest, then please contact us on surgicalmic@leeds.ac.uk.

Photovoice Challenge Template Topic POST ORGATIVE RELOVERY Who's in the group ENCINEER MEDIC, MEDICAL TOWN RESPONDED ENCINEER MEDIC, SCIENTIST, MEDICAL TOWNS. RATTENT COMMINTY. Ideas solutions RATTENT EXPORTE OF TO OHER OPP. TO ILLARE INFORMED DECISION RATTENT EXPRESSIONE UIDEOS - CON MIS LEBELLE?) RATTENT EXPRESSIONE UIDEOS - CON MIS LEBELLE?) RATTER CARE CONTRAL POINT TO CONTRAL UN PHONE AFTERWARDS - (OUTSOURCE) BATHENT SUPPORT ACCOUNTS - WITH PROPUR WHO HAVE HAD EXPRESSIONE UIDEO SIMPLE TION STORTS OF PROPIE WITHO THAD OP & THOSE TIMP DIDN'T. TECHNOLOGY, AIDS: - SUPPORTING BOTH BATTOON WITH REMINDERS, & WHS CESS APPOINTMENTS IF DOING WELL.

Post-Operative Recovery

Post-operative recovery is important for patients and their carers as it impacts on all aspects of their life. A change in lifestyle is something that is expected following surgery, especially when the post-operative prognosis was grim.

Some patients experience regret when post-operative recovery goes wrong - for example, some patients end up acquiring hospital infections following surgery and this will slow down/delay recovery.

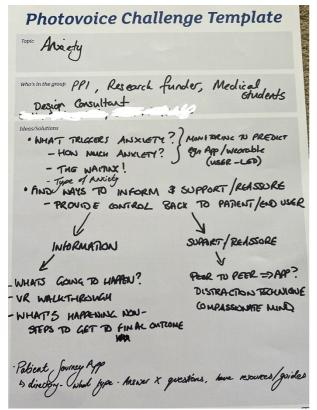
Patients want more research in this area and one example given was that of the

effects of gallbladder removal given the frequency of pain and discomfort that is experienced by patients.

Summary of Discussion

Managing patient expectations was the main theme of this discussion and it was felt that patients could benefit from some sort of education before they have surgery so that they fully understand what their recovery could look like. This could be supplemented by a patient support group so that they can share potential remedies to alleviate post-operative effects, and the ability to contact a healthcare professional for advice. Some patients feel that the absence of these support mechanisms can make them feel isolated and that they are alone in experiencing slow recovery.

- The Surgical MIC is currently working with Professor Maria Lonsdale (*Professor of Information and Communication Design*) on this subject for patients with bowel cancer. If you would like to get involved or find out more then please contact surgicalmic@leeds.ac.uk.
- We are also exploring a collaboration with a company that has developed a
 Smart Consent tool that would incorporate videos and simulations of surgery
 to enhance the patient understanding of the procedure. There is the
 opportunity to modify this tool to make it more relevant to the NHS. If this is
 of interest, then please contact us on surgicalmic@leeds.ac.uk.



Anxiety

Anxiety is a feeling of worry, nervousness, or unease about something with an uncertain outcome. Patients undergoing diagnostic procedures for cancer experience anxiety as a result of delayed diagnosis, especially if they have to wait a couple of days or weeks to get a definitive diagnosis. Even when patients get the definitive diagnosis there is uncertainty regarding life expectancy with or without surgery and this results in anxiety. Once they have had their surgery patients often have to deal with lifestyle changes and come to terms with the new "normal" which is another anxiety-inducing event.

Summary of Discussion

The focus of this discussion was on finding ways to inform, support and reassure patients about the procedure and what to expect by providing tools such as virtual reality walkthroughs, distraction techniques and peer-to-peer networks. These would tackle the source of anxiety for patients and would provide the patient with the ability to control and manage their anxiety. Mobile apps were suggested to support patients.

- A Patient Journey app was suggested by the group this has been developed and is available for hospitals here https://patientjourneyapp.com/.
 Unfortunately, it is only possible to use Patient Journey App if it has been provided by your hospital.
- The Surgical MIC will discuss the virtual reality (VR) walkthrough suggestion with companies in our database. If this is of interest, then please contact us on surgicalmic@leeds.ac.uk.
- The Surgical MIC will explore the peer-to-peer network idea with relevant patient groups. There is a possibility that this already exists but is not widely publicised.



Quality of Life

Quality of life is important for patients especially when deciding whether to proceed with surgical and/or other invasive procedures. Quality of life is about the standard of health, comfort, and happiness experienced by the patient following surgery.

Some patients with Inflammatory Bowel Syndrome (IBS) felt that they were not being supported in managing their condition, some felt that not enough resources were being put into finding a cure, and others needed education on how they can cope and deal with this debilitating condition.

Their quality of life had dropped as a

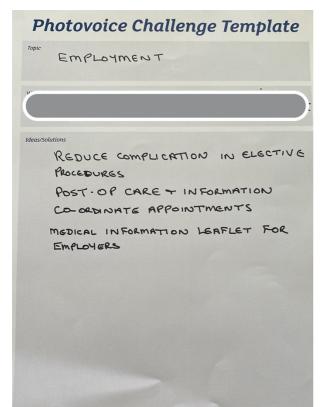
result of multiple A&E visits, daily pain, multiple endoscopies/colonoscopies, numerous tests, bloating, trapped wind, no holidays and multiple medications.

Summary of Discussion

There was a need for psychological support for patients whose quality of life had dropped. Patients wanted education and support with coping strategies, healthy living, dietary advice as well as coaching and mentoring. They wanted a holistic approach to supporting patients and one where all patients could benefit regardless of their location. They would like healthcare professionals to include them when deciding treatment options.

Next steps

 The Surgical MIC is consult with patient support organisations as this support exists for some patient charities/health conditions.



Employment

For patients that are in employment, time away from work is an important consideration. If you are self-employed you may not have the freedom to take long periods off from work. If you are employed, you will consider your organisational policy on leave.

If you develop post-operative complications, then you may not be able to return to work for a long time, if at all and all of this introduces uncertainty and anxiety for patients.

Summary of Discussion

The focus of this discussion was on minimising complications for elective

surgery/procedures as this is the time that the patients' expectations would be shattered. Complications result in an increase in hospital appointments and unplanned hospital stays which may not be compatible with their employment situation. If individuals lose their job and apply for new ones, they often face anxieties when their work history is questioned at interviews as they believe that their health condition will jeopardise their employment prospects.

Next steps

 The Surgical MIC to explore the suggestion that it could be useful to have medical information leaflets for employers to help them better support their employees when they return to work following major and/or life transforming surgery.

Photovoice Challenge Template Topic Procedures Who's in the group Clinician Engineers Med Student Ideas/solutions Pre-Procedure Intervention Pain assessment derice Ver lect to educate potents / Web based counselling Intra-Procedure Non investme imaging techniques Biomorters Medication/delinery incorporated into derice Poin relief Makei at and Size Post-Procedure Automated Follow-up Virtual Follow-up

Procedures

Some hospital procedures have developed a reputation for being painful and/or uncomfortable, such as a sigmoidoscopy which is an examination of your back passage and some of your large bowel using a device called a sigmoidoscope.

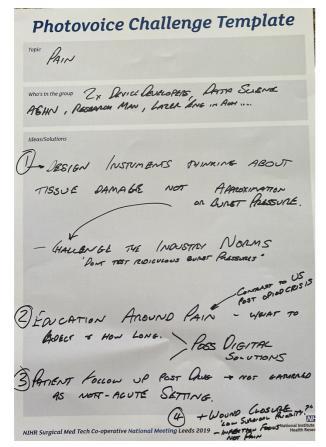
A sigmoidoscope is a long, thin, flexible tube attached to a very small camera and light. It's inserted into your bottom and up into your bowel. The camera relays images to a monitor and can also be used to take biopsies, where a small tissue sample is removed for further analysis. The pain associated with this

procedure puts individuals off from having this diagnostic procedure especially if sedation is not offered. Patients also expressed their frustration when sedation was declined on the grounds that this was classed as a minor procedure.

Summary of Discussion

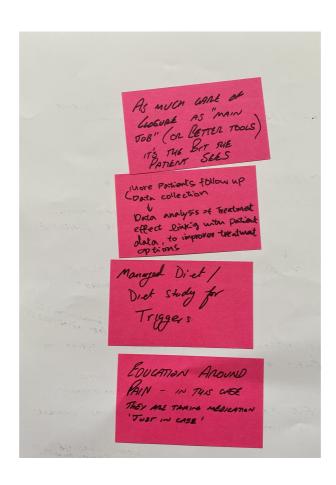
Investigative procedures should not be invasive to the point that they cause pain and discomfort. Was it worth having a pain assessment before and during the procedure so that the patient experience was improved, as well as future compliance for those that are newly diagnosed? This group wanted to see more research into non-invasive imaging techniques, biomarkers and novel drug delivery devices to replace the current invasive procedures. They also suggested that patients would benefit from automated or virtual follow up, instead of being asked to come back to a hospital site where they possibly had the invasive procedure.

- The Surgical MIC has the development of non-invasive procedures as one of its priorities and we will continue to prioritise this research. We have also initiated discussions with a NIHR Biomedical Research Centre on a biomarker collaboration. If you would like to get involved or find out more then please contact surgicalmic@leeds.ac.uk.
- One of the Surgical MIC's academic work streams' is nanotechnology and this includes the development of drug delivery devices. This work is still at an early stage and publications are available on our website under publications.



Pain

Pain is very common after surgery and for some patients this gets better and gradually disappears over time. For other patients, pain becomes part of the new "normal" as they learn to live and cope with it. Some patients have experienced chemotherapy induced peripheral neuropathy as a result of bowel cancer treatment and their new life now includes 24/7 pain in both feet, they cannot walk far, they have to wear thick bed socks to stop contact with bedding, and they cannot engage in sporting activities. Neuropathic pain is a deep nerve pain due to damaged nerve in surgery. Chronic pancreatitis patients also report being on strong pain medication daily.



Summary of Discussion

This table focussed on the design of surgical instruments and how this could contribute to tissue and nerve damage. They wanted to challenge the industry norms that prioritised the testing of "burst pressures" for devices. There was a need to explore possible digital solutions for education on pain medication (and learn from opioid crisis in the United States) and patient follow-up. They also explored how wound closure seems like it has low surgical priority as the focus is on reducing infection and not pain.

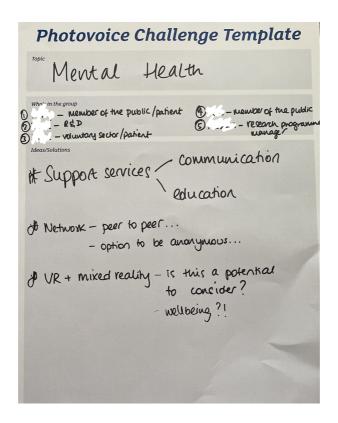
Next steps

 Surgical MIC to explore how data analysis of treatment effect can link with patient data to improve treatment options, and education around pain management following surgery. If you would like to get involved or find out more then please contact surgicalmic@leeds.ac.uk.

Mental Health

Mental health was the underlying theme that ran through all the discussions and examples included:

- anxiety that goes with concealing fistula leakage and odour, leaving noticeable smell on chairs, developing wet stains - only wearing dark clothing to conceal stains.
- depression being a man and wearing incontinence pads, they feel they cannot mention it to anyone
- depression following ascending aortic aneurysm sudden diagnosis and unsure about prognosis/life expectancy



Summary of Discussion

Mental health was very important for this group as patients can be affected throughout the entire process - from pre-operative to post-operative care. There's a lot of support for patient physical care but very little in terms of acknowledging the mental health challenges that will develop. It is clear from the examples provided in the challenge that patients require more support to cope with the new challenges that have arisen as a result of the need for surgery.

Next steps

 The Surgical MIC to explore a collaboration with MindTech MIC (focus on mental health) for the suggestion of using virtual and/or mixed reality for improving well-being.

Sponsorship & Exhibition Opportunities

Our National Meeting attracted over 120 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 - £5000 + 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 - £2500 + 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.

Events Calendar

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

Funding Opportunities

NIHR Artificial Intelligence Health and Care Award

MedTech Navigator Innovation Grants

COVID-19 Rapid Response Rolling Call - open call

Defence and Security Accelerator: Open Competition COVID-19 - Rapid Sanitising

<u>Technology</u>. Deadline: rolling deadline

Open Call for Proposals "Space helping UK on COVID-19 and other pandemics"

NIHR-BHF Cardiovascular Partnership framework for Covid-19 research

Sony Research Award Program - 15 September 2020

<u>Disruptive Technologies Innovation Fund</u> – 18 September 2020

<u>Transformative Healthcare Technologies 2.0</u> – October 2020

<u>Biomedical Catalyst 2020 Round 1 Early & Late Stage Competition</u> – 07 October 2020

Clinical Academic Research Partnerships Round 3 – 29 October 2020

Fast Funding for COVID-19 Science - 31 December 2020

Innovator Awards - no time limits

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

British Heart Foundation New Horizons Grants - no deadline

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

Ad-Venture Grant Funding for SMEs

Macmillan research grants scheme

Social media highlights





Marcus Orton @MarcusOrton · Nov 19, 2019
Exploring advances in medical device innovation at the Surgical MIC, national meeting - Surgery 2030: Transformative Technologies #surgery2030 @MIC_Foundation @MedTechGroup @The_NHSA



lizogilvie @lizogilvie - Nov 19, 2019

Here is Co-production in action at @surgicalMIC #Surgery2030 working on real life problems and coming up with ideas to make a difference to people's lives



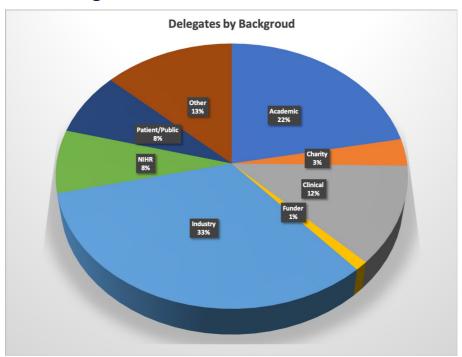


Cecilia Pompili MD, PhD @pompili_cecilia · Nov 20, 2019

Fantastic example of integration of creativity, technology and research to improve patient experience during surgical journey yesterday at the NIHR surgical MIC annual conference @surgicalMIC #surgery2030 #MEDTECH #PatientExperience @LeedsMedHealth #innovation #surgery



National Meeting 2019 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.
- Outputs from the roundtable afternoon workshops will be used to shape our proof-of-concept/market funding call in March/April 2020. 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 <u>website</u> and sent to those subscribed to our "<u>Events</u>" 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</u> <u>site</u> if you are a clinician or academic?
- join our Patient and Public Involvement group 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 Co-operative 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 with colorectal disease 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 2020



SAVE THE DATE - Thursday, 28th January 2021

Our November 2020 National Meeting will take place in January 2021 as a virtual meeting. More details will be made available in due course.

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



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/