

### MICs MedTech and in Vitro Diagnostic Co-operatives

NIHR Roadshow for MedTech SMEs: East of England

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Brain Injury MedTech Cooperative NHS National Institute for Health Research



## What 'grassroots' structures will galvanise MedTech innovation?



## The TBI Care Pathway Matching MedTech resources to our patients



## How to open doors?



## Communication Institutions – People including Patients – Ideas - Industry

Why Medtech and in vitro diagnostics Cooperatives?

Successors to Healthcare Technology Cooperatives HTCs



•Centres of expertise that focus in clinical areas or themes of high morbidity and unmet need which have high potential for improving quality of life of NHS patients and improving the effectiveness of healthcare services that support them

•Cost-effective technology-based solutions: develop new medical devices, healthcare technologies or technology-dependent interventions, which improve treatment and quality of life for patients

•Act as a catalyst for NHS "pull" for the development of new medical devices, healthcare technologies and technology-dependent interventions

•Work collaboratively with patients and patient groups, charities, industry and academics.

•Innovative care pathways, novel networks, novel funding opportunities and new intellectual property.

#### **NIHR Healthcare Technology Co-operatives** National Institute for (HTCs) in the news Health Research



London air ambulance trials hand-held brain scanner

30 December 2015 Last updated at 08:51 GMT

Innovative new collar to end MND patients' neck distress



Opening the skull of patients after head injury reduces risk of death from brain swelling

## The Telegraph

#### HOME » NEWS » HEALTH » HEALTH NEWS

End of the thermometer as first NHS hospital trials wireless monitoring

The initial trial will take place on 100 patients recovering from bowel surgery who are at significant risk of problems.

**Robotic system for Transoesophageal Echo in heart operations** One of the HTC funded project on the Robotic assistance system in the trans-oesophageal echo operating environment has demonstrated improvement on the safety and efficacy of the procedure. This project was selected for an oral presentation at the World Extreme Medicine Expo 2015.

**HTC helps** develop 'handsfree' bowel cancer screening

NHS

## **NIHR Brain Injury MIC**

































#### The NIHR Brain Injury Healthcare Technology Co-operative (HTC) in numbers



Since 2014, the NIHR Brain Injury HTC ran 8 strategic roadmapping workshops and 10 patient and carer workshops

**70 unmet needs** have been prioritised through the various structured initiatives facilitated by the HTC to create an **'Unmet Needs Directory'** 

#### **PATIENT CENTRED**

7031 participants recruited to NIHR HTC studies



The Register for Healthcare Involvement and Technology Evaluation (RHITE) has transitioned to an online platform, and has noted a



## SUPPORTED PROJECTS & BRAIN INJURY DEN





**101** peer reviews have been conducted

**30** projects have received **feedback** from experts and leaders in healthcare innovation as part of the Brain Injury Den



with partners

£59,562,367

FOSTER

Supported-projects generated **272** publications



The NIHR Brain Injury HTC 'Innovations Small Funding Competition 2014-15' and the 'SeedcornFunding Competition 2016-17' have seed funded 38 national projects that address the unmet needs that have been identified.



#### BRAIN INJURY TECHNOLOGIES THINK (BITT) TANK

Over 4 years, the HTC ran **5 BITT tanks**, which have been attended by **103 companies** 

**54** SMEs, start-ups and project teams showcased technological innovations to a panel of patients, carers, clinical and academic experts

**49** new collaborations formed following the BITT tanks

Since 2013, the HTC has worked with 182 SMEs



Professor Christi Deaton

Patient & Carer Register <u>https://brainhtc.org/getinvolved</u> Roadmapping – themed workshops

## Pre-Hospital Microwave Imaging for Neurotrauma





### NCCU The Wolfson Brain Imaging Centre



'Sick patients cannot go to the scanner; the scanner must come to the patient'











#### home search a-z help



School of Clinical Medicine > Department of Cli

ICM+



a state of

Marek Czosnyka











> Neurosurgery Unit > ICM+





• Now used in >130 centres

Adoption requires an international solution



Life Sciences Industrial Strategy - A report to the Government from the life sciences se



#### **National Registries**

For certain therapy areas, there is a strong case for establishing of further national data registries, following NDG recommendations and ideally building upon existing datasets or automated collections.<sup>75</sup> For example, there are systems in mental health that are well placed to enable registries.<sup>76</sup> For rare or orphan diseases, a registry approach could work with regional hubs to enable the required population sizes for research.<sup>77</sup> Patient trust would be enhanced if these are co-ordinated by the relevant patient charities, who should also have an active role in their governance and direction. These registries could also be well-positioned to identify patients appropriate for recruitment into clinical trials.

National registries of therapy-area-specific data across the whole of the NHS in England should be created and aligned with the relevant charity.

This data work programme should be carried forward in light of the National Data Guardian's recommendations on patient data and the associated government response.

## **Clinical Informatics**

#### National prospective databases

- UK CSF shunt registry
- Vestibular schwannoma registry
- Children's Epilepsy Surgery Service

#### Service tools

- Major trauma rehabilitation prescription
- Neuroscience emergency referrals
- Ward tasklist
- NF-2 quality of life collection

#### **Studies and audits**

- Melatools-Q
- EPIPEG
- Neuro-oncology quality of life
- Chronic subdural haematoma audit
- -Impaired consciousness research database

#### Requirements

- -User support
- -Technical development
- -Data management
- -Statistical analysis



Dr. Alexis Joannides





Codma









Preoperative screening Prophylactic antibiotics Consultant delivered operation Minimal handling protocols Theatre protocols Wound edge drapes Antibiotic impregnated sutures Topical antimicrobials Financial incentives & penalties

Paediatric

**Shunt infections** 



**CQUIN** 

Capacity building and ORPHAN Diseases Cervical Spondylotic Myelopathy



Dr Mark Kotter

- Neurosurgeon & NIHR Clinician Scientist 2016-2021
- Myelopathy.org to define unmet need, natural history and aid recruitment to clinical trials: n=530 < 6 months</li>
- International Clinical Standards Committee
- Spin-out Elpis Biomed for OPTi-OX platform
- NIHR TCC funded RECEDE Myelopathy RCT





### Proactive & Agile Systematic approaches: what works and what does not

### www.brainMIC.org

### National Institute for Health Research: integrated health-research system

**NHS** National Institute for Health Research



**Clinical Research Network** 

### NIHR Medtech and In vitro diagnostic Co-operatives (MICs)







NIHR Medtech and *In vitro* diagnostic Co-operatives (MICs)



- Funding for
  - the development of medical technologies in areas of high patient morbidity and
  - evidence for diagnostic tests leading to benefits in healthcare services and the quality of life of NHS patients.
- Total funding of £14.25m over 5 years from 1 January 2018 for 11 NIHR MICs.

### NIHR MICs



- Work collaboratively with clinical and other healthcare professionals, patients / patient groups, charities, industry and academia;
- Reach across primary, secondary and other health and care sectors, professional bodies and relevant national networks of clinical champions;
- Build appropriate links with NHS landscape, NIHR infrastructure and other relevant infrastructure;
- Clinical areas and/or themes which have the potential to produce tangible benefits for patients, the health service and for broader economic gain;

### **NIHR MICs**

**NHS** National Institute for Health Research

- The focus of the activity within an NIHR MIC will be the development of collaborations, but the NIHR MIC scheme will also fund relevant pilot/proof of concept studies.
- These pilot/proof of concept studies should aim to support further larger scale research projects, including aspects such as full medical device development, health economics and care pathway assessment.
- NIHR MICs are expected to leverage additional research funding, including from other public, charity and industry research funding sources to undertake full scale studies. Follow-on research projects may be funded through a range of existing mechanisms.

## Summary

**NHS** National Institute for Health Research

- Medtech is front and centre in the government's initiatives for the life sciences and the acceleration of adoption of new innovations into the NHS.
- NIHR MICs have a significant role to play by supporting the development of new medical technologies and/or developing the evidence to will enable IVDs to be more readily taken up.
- MICs to be the 'go to place' for industry and academics.
- MICs are the experts in methodology development; health economics; device proof of concept studies; and evidencing for IVDs.
- Maximise the opportunities to support key stakeholders in the innovation landscape, including industry, charities, patients and regulators.

# Advances in TBI care – the Professionals' view

- Prevention and public health measures WWII
- Neuropathology
- Avoidable factors
- CT scanner
- Glasgow Coma Scale and Glasgow Outcome Scale
- Guidelines
- ICP monitoring & Neurointensive care
- RCT platforms but failure of translation of neuroprotective drugs & hypothermia (unlike SAH): heterogeneous patient populations, windows of therapeutic opportunity, unknown drug penetration, unrealistic 'magic bullet' outcome measures, 'Ten ton truck' syndrome, statistical modelling - sliding dichotomy
- Decompressive craniectomy
- Detection of covert cognition in Prolonged Disorders of Consciousness
- Some ways forwards: new process/deficit-specific targets (memory, criminality, late axonal, amyloid and tau degeneration), multimodality bedside monitoring, functional brain imaging, physical and cognitive neurorehabilitation, regenerative medicine, more realistic outcome measures.

## What do Patients really want? 'The Patient will see you now' (Eric Topol) Professionals know best - but who is the professional?

the late Sam Galbraith, Neurosurgeon, MP and longest surviving lung transplant





- Nocturnal fits in childhood
- Melanie Reid, SCI & Sunday Times columnist







## **Building Health and Wealth**



Clinical research does not have to be expensive Clinical research networks with proven track record in UK

## SPICH, Brant, EBIC, UK CSF, RescueICP

British Neurosurgical Trainee Research Collaborative

The SILVER (Silver Impregnated Line Versus EVD Randomized Trial) Keong et al, Neurosurgery 2012.



**Santarius T**, Kirkpatrick PJ, Ganesan D, Chia HL, Jalloh I, Smielewski P, Richards HK, Marcus H, Parker RA, Price SJ, Kirollos RW, Pickard JD, Hutchinson PJ. <u>Use of drains versus no drains after burr-hole evacuation of chronic subdural haematoma: a randomised</u> <u>controlled trial.</u> Lancet. 2009 Sep 26;374(9695):1067-73

Brennan PM, Kolias AG, Joannides AJ, Shapey J, Marcus HJ, Gregson BA, Grover PJ, Hutchinson PJ, Coulter IC; British Neurosurgical Trainee Research Collaborative.

The management and outcome for patients with chronic subdural hematoma: a prospective, multicenter, observational cohort study in the United Kingdom.

J Neurosurg. 2017



## National Institute of Health Research £1 billion / year

The central role of NIHR research in the innovation pathway





# Mind Your Head

Headway Cambridgeshire Grand Challenge in collaboration with NIHR Brain Injury Healthcare Technology Co-operative

Piecing lives together since 1989

- ✓Crowd-sourcing
- ✓Open innovation
- ✓ Social entrepreneurship
  - positive return to society
- ✓UNITE the county of Cambridgeshire in a way that has not been achieved before

4 groups of participants: seekers, solvers, sages, supporters

Educating the next generation: "Pitch Your Project" Event Selected teams present their projects to everyone involved in Mind Your Head







### Cinderella patients Vegetative state: 40% misdiagnosis rate

fMRI Volition task: A measure of awareness

















Science, NEJM.

## Good ideas – what are the blockers to adoption?

Perverse short term commissioning and tariffs

A cost effective delivery system for FloSeal during endoscopic and microscopic brain surgery. Brand, Narayanan, Prepageran, Waran.World Neurosurg. 2016 Mar 14.



## **Problem of NHS adoption**

Remember

L-DOPA for Parkinsons – unaffordable

**Deep brain stimulation - unaffordable** 

The drug model of innovation is unaffordable for technology-driven solutions



NHS England & NHS Improvement National Tariff Proposals for 2017/18 & 2018/19.

## 5.12. Introducing an innovation and technology tariff

To date, the NHS has been relatively slow at introducing and spreading innovations in medical technology in a timely manner.

The NHS currently encourages the development of innovation through the NHS Innovation Accelerator, the NHS test beds, and the Commissioning through Evaluation programme.

We propose to encourage the uptake and spread of technology by identifying potential innovations that we could encourage via the tariff.