clinical research facility
EDINBURGH

September 2015

Delivering excellence in clinical research

Edinburgh Clinical Research Facility - Key Milestones

- **1997** Edinburgh awarded Millennial Funding to develop Wellcome Trust Clinical Research Facility (WTCRF)
- **1998** Pilot Facility opened at Western General Hospital (WGH) and Satellite Facility opened in Royal Infirmary Edinburgh (RIE)
- **2001** Official Opening of WTCRF by HM Queen Elizabeth II
- **2003** Launch of WTCRF Education Programme
- **2003** Sister Facility (RIECRF) opened in New Royal Infirmary of Edinburgh
- **2005** Scottish Clinical Research Facilities Network Inaugural Meeting
- **2006** Launch of Academic and Clinical Central Office for Research and Development (ACCORD) supporting joint working between NHS Lothian and University of Edinburgh (UoE)
- **2006** SHEFC Brain Imaging Research Centre (now Brain Research Imaging Centre – BRIC) integrates with WTCRF to form Imaging Core
- **2006** Paediatric CRF Service launched with appointment of Scottish Medicines for Children Network (ScotMCN) Research Nurse
- **2006** NHS Education Scotland (NES) funds nationalisation of WTCRF Education Programme
- **2006** Clinical Research Infrastructure Award for Clinical Research Imaging Centre (CRIC) under Directorship of Professor Newby
- **2007** Community Research Nurse Service initiated
- **2007** Launch of Scottish Imaging Network a Platform for Scientific Excellence (SINAPSE)
- **2008** UK Clinical Research Facilities (UKCRF) Network officially launched
- **2008** Edinburgh CRF Director Professor Newby appointed Director of R&D for NHS Lothian
- **2009** First WTCRF Public Open Day
- **2009** Paediatric CRF opened in Royal Hospital for Sick Children (RHSC) by Sir Chris Hoy
- **2010** CRF Mass Spectrometry Core receives £750,000 Wellcome Trust equipment award for major new investment
- **2010** Official opening of the Clinical Research Imaging Centre (CRIC) by HRH Prince Phillip, Chancellor of the University of Edinburgh
- **2011** Edinburgh CRF is the first hospital based non-commercial unit in the UK to receive accreditation under the MHRA Phase I scheme
- **2011** Edinburgh CRF celebrates its 10th Anniversary
- **2012** CRFManager® becomes a registered trademark
- **2013** Genetics Core Director Professor David Porteous receives an OBE for Services to Science
- **2013** Patient and Public Involvement (PPI) advisor is appointed in response to funders' requirements for evidence of public engagement in clinical research
- **2013** Edinburgh CRF receives re-accreditation under the MHRA Phase I scheme
- **2013** The Clinical service converts to a 24 hour working pattern to support high-intensity studies
- **2013** UoE Distance Education Initiative funded online MSc Clinical Trials launches with an initial intake of 21 students
- **2014** Genetics Core replaced their 10 year old liquid handling robot with a new and improved model.
- **2015** Wellcome Trust CRF building achieved Bronze level in the University of Edinburgh Sustainability Awards
- **2015** Children's CRF accredited under the MHRA Phase I scheme
- **2015** UK Clinical Research Facility Network initiates a new IT/CRFManager® Workstream headed by Edinburgh IT team
- **2015** Genetics Core awarded Wellcome Trust Institutional Strategic Support Fund funding for a Covaris E220 focussed ultrasonicator platform to be used for DNA, RNA and chromatin shearing

Introduction

Clinical Research Facilities across the UK are now widely accepted as valuable infrastructure for the delivery of quality, safety and efficiency in clinical research. Close collaboration between NHS Lothian and the University of Edinburgh is fundamental to Edinburgh CRF's delivery of clinical research across three hospital sites in Lothian.

We were delighted this year when our Children's Clinical Research Facility (CCRF) achieved accreditation under the MHRA Phase I Scheme alongside our two adult facilities (WTCRF and RIECRF) - first accredited in 2011.

To support the delivery of early phase and complex trials we created a Lead Nurse for Phase I / Education post, and we welcome Fiona Mitchell to this new and exciting role. Further information on our Phase I Accreditation can be found on page 9.

Strong collaborations and high quality standards are central to our operation. Edinburgh CRF's Education Programme, as part of a Scotland wide initiative supported by NHS Research Scotland (NRS) and several pharmaceutical industry partners, this year launched a GCP training course approved under the TransCelerate mutual recognition programme. The course is accepted in both academic and industry settings and will provide financial and time savings for local researchers.

GCP Training

"This morning's session of the GCP course was an incredible insight into why we have legislation today - thank you! #GCP"

Academic Foundation Year 1 Doctor

Edinburgh CRF offers a diversity of support delivered through our Core areas to meet the needs of an ever changing research environment. In January 2015 the CRF Mass Spectrometry Core, in collaboration with University of Edinburgh colleagues, commenced a pilot service for the analysis of biochemistry samples for clinical research. This initiative will provide a readily accessible biochemistry service for local academic researchers.

For further information on support for clinical research provided by Edinburgh CRF please see our specialist research services section on pages 10 to 14.

Although our focus is on complex and experimental medicine, our portfolio of work continues to grow and in 2014/2015 we supported over 400 studies across our clinical and Core areas (see pages 4 and 5).

Our track record for supporting word leading experimental medicine research is illustrated in the projects and initiatives and publications sections on pages 6 to 8 and 16 and 17 respectively.

At the heart of any successful organisation is a dedicated and committed team, and that is true of Edinburgh CRF. We pride ourselves on the care and safety of our patients and volunteers, the quality and governance of our work and, crucially, the can-do attitude of everyone in Edinburgh CRF.

Finally, we are very grateful for the support of NHS Research Scotland which allows us to deliver such a diverse portfolio of work.

NHS SCOTLAND
NHS RESEARCH SCOTLAND

A special acknowledgement goes to Heidi Dawson, CRF Critical Care Nurse, who volunteered for 6 weeks in Monrovia, Liberia as part of a team researching a treatment for Ebola virus.

See page 10 for Heidi's story.

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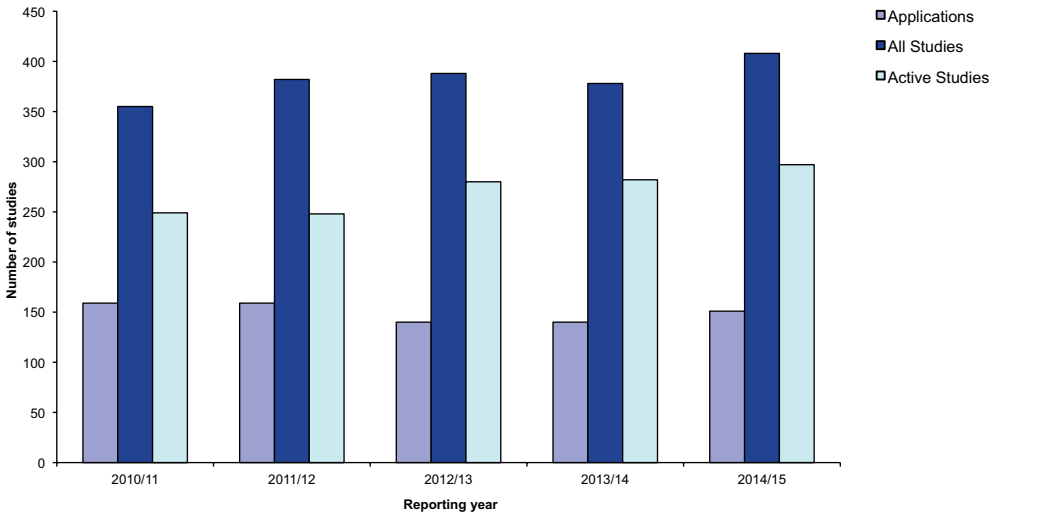
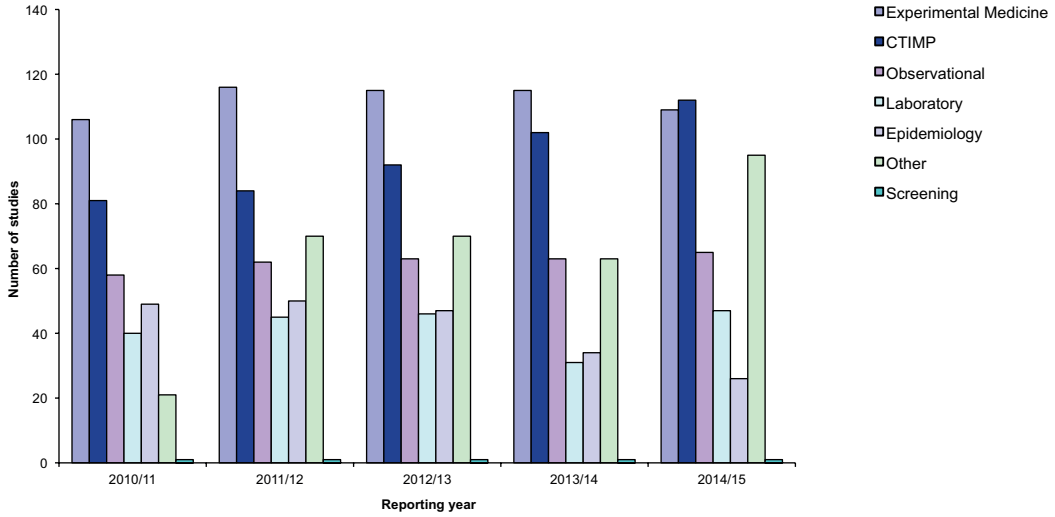
Edinburgh Clinical Research Facility - Selected Metrics

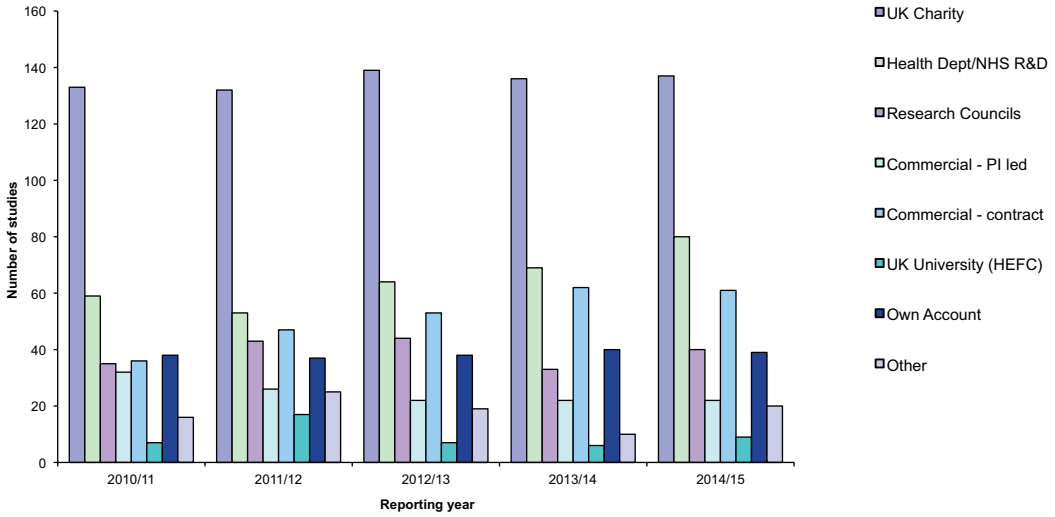
Edinburgh CRF studies



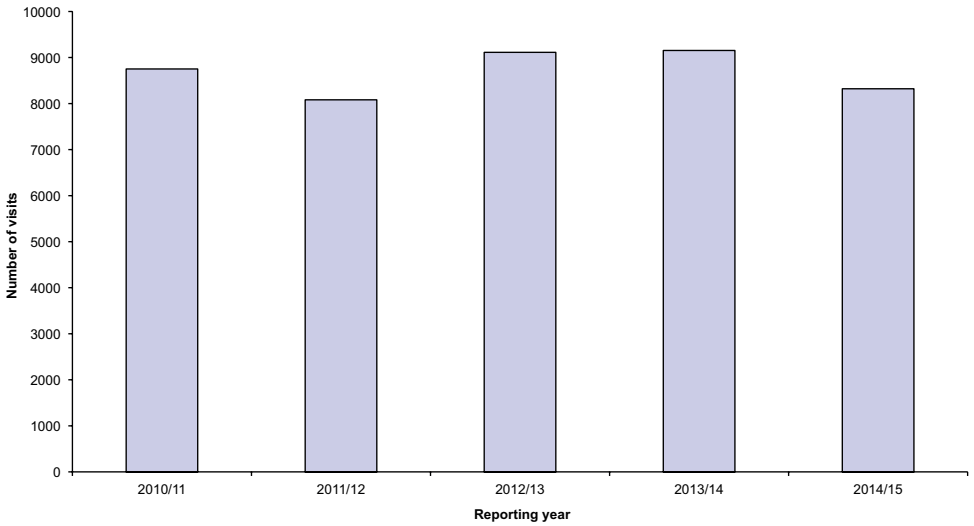
Range of CRF study types



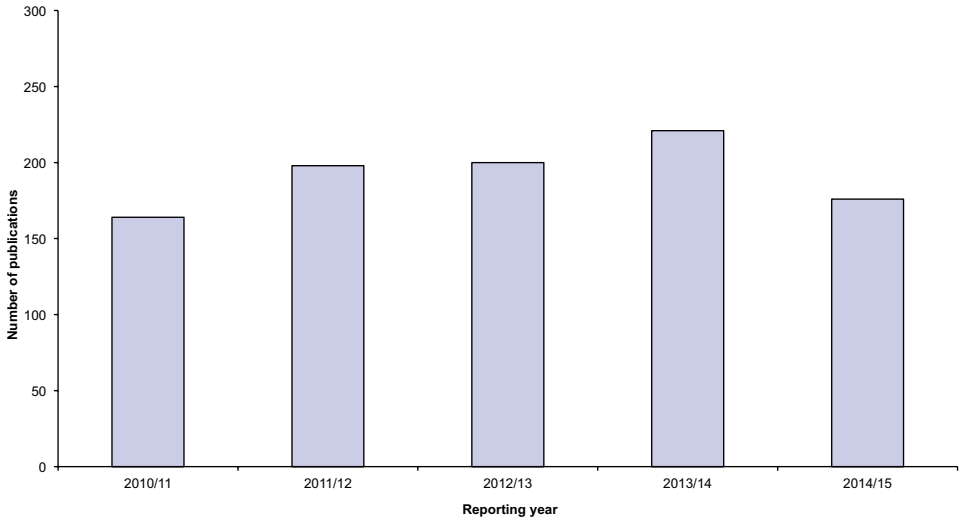
Funding sources for CRF studies



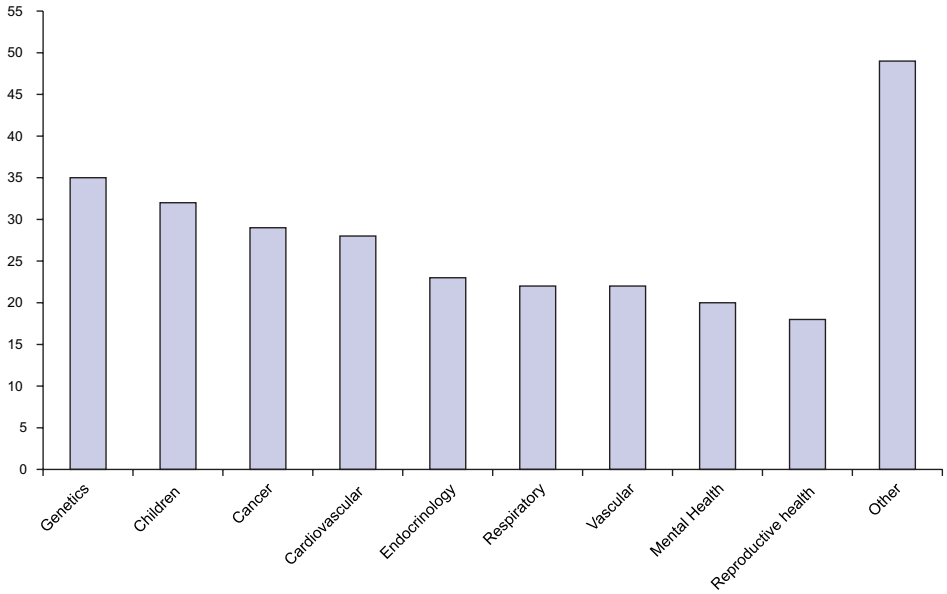
Number of participant visits to the CRF



Number of publications linked to CRF studies



Range of clinical specialties using the CRF in 2014/15



Edinburgh Clinical Research Facility - Projects and Initiatives

The NAP Study- Exploratory optical molecular imaging of neutrophils in the lung using a neutrophil smart probe

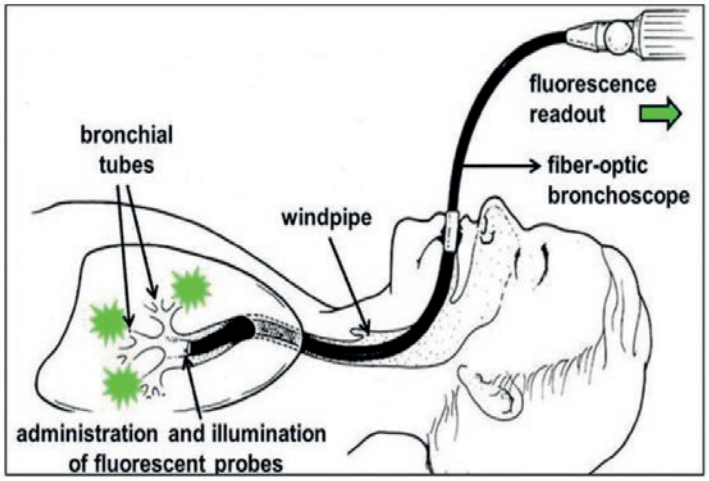
Acute lung disease is a common reason for patients to be admitted to the intensive care unit. These patients often need to be sedated and mechanically ventilated to keep them alive. There is a wide range of conditions that can cause a person's lungs to become acutely diseased but working out the cause is often difficult. This means patients often get treatments they don't need or don't get the treatment they do need.

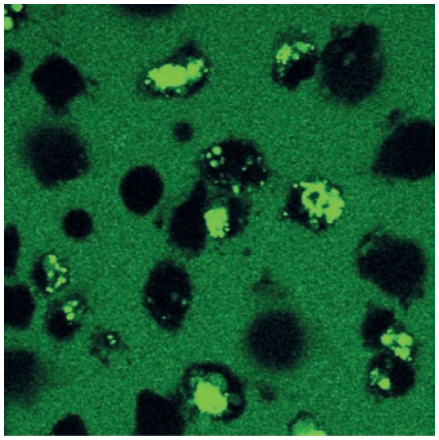
Many acute diseases involve neutrophils, which normally work to destroy pathogens and restore health, but the excessive activity of neutrophils has been implicated in the pathogenesis of several conditions such as acute respiratory distress syndrome. If it were possible to assess the activity of neutrophils in the lungs of critically ill patients it would be possible to stratify them for different and specific treatments, representing a step change in management and a move towards personalized medicine.

Supported by the Medical Research Council and the Department of Chemistry at the University of Edinburgh we designed a chemical probe, known as NAP (Neutrophil Activation Probe) that can be sprayed in tiny quantities into the lungs of patients. In the presence of neutrophils that are actively working the probe becomes fluorescent. In the absence of the active neutrophils there is no fluorescence. This probe has been extensively tested in the laboratory and before moving to the intensive care unit we wanted to see how the probe would work in healthy volunteers.

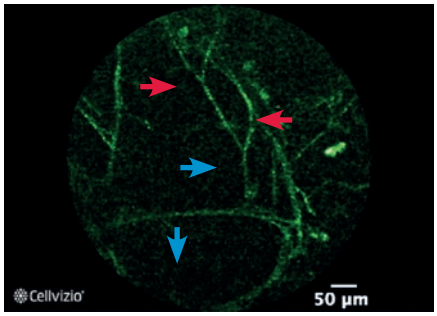
We designed and conducted an ambitious phase I clinical trial of an investigational medicinal product with support and guidance from the local Phase I Study Review Committee and within the MHRA framework. Six healthy volunteers underwent screening assessment in the Royal Infirmary of Edinburgh Clinical Research Facility (RIECRF) before undergoing the study procedure itself. The probe is delivered via bronchoscopy and the fluorescence is detected using a technically advanced piece of equipment known as a fibered confocal fluorescence microscope. Each volunteer stayed overnight to undergo rigorous safety assessments. The RIECRF were able to provide state of the art purpose built facilities for exactly this type of study as well as providing expertise and support to facilitate the smooth running of the study within the regulatory requirements, including preparation for an inspection by the MHRA.

With the work done here and on the intensive care unit a larger study is planned to assess the utility of NAP in critically ill patients. In addition a whole range of chemical probes (which detect different disease processes in the lung) are at different stages of development and several further first-in-human studies are planned.





NAP highlights activated neutrophils magnified using a bench top laboratory microscope.



Normal appearance of healthy alveoli in human lungs visualized using the fibered confocal fluorescence microscope. There are one or two resident white cells (red arrows) adherent to the alveolar walls (blue arrows).

Dr Kev Dhaliwal, Senior Clinical Lecturer in Pulmonary Molecular Imaging, University of Edinburgh

Telemonitoring in hypertension, stroke, diabetes and pulmonary disease

Telemonitoring is a system where people with different medical conditions take measurements at home. The measurements give patients information about their condition and are automatically shared with their doctor or nurse who can give advice or change treatment. Between 2008 and 2014, we ran a Chief Scientist Office funded Programme of research looking at whether telemonitoring systems help improve the control of a number of long-term conditions - uncontrolled high blood pressure, stroke or a transient ischaemic attack (TIA) with uncontrolled BP, chronic obstructive pulmonary disease (COPD) and type 2 diabetes.

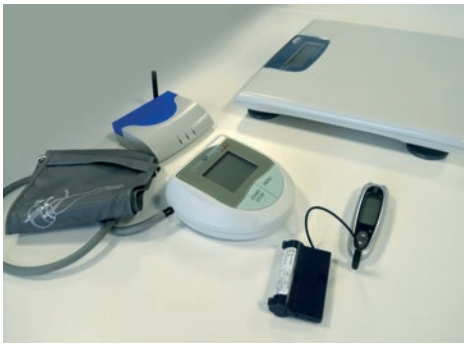
1000 patient participants were enrolled into three randomised controlled trials (RCTs), and one feasibility RCT (in the Stroke/ TIA group). Participants were randomly allocated to receive either standard care or the telemonitoring system.

We recorded hospital admissions, patient and clinician time. Qualitative studies looked at patient and staff experience and perceptions of telemonitoring and we ran health economic analyses to compare costs and cost effectiveness of the different systems.

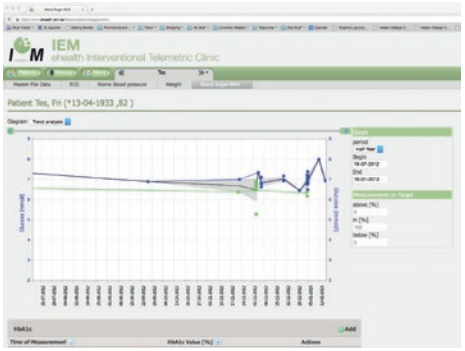
We found that telemonitoring is effective in helping control blood pressure in people with hypertension, and helping people with diabetes control both glycated haemoglobin (HbA1c: a measure of blood sugar control) and BP. However, no evidence was found that telemonitoring postponed admissions to hospital in participants with COPD.
A feasibility trial of people with stroke/ TIA showed that it is feasible to run a trial of telemonitoring in this group of patients and initial results suggest that telemonitoring had a positive effect on BP control. In most cases, telemonitoring systems were very positively viewed by participants, whether they had an impact on the primary outcome (e.g. blood pressure, HbA1c, hospital admissions) or not. Views of telemonitoring from staff groups were more mixed: while the potential benefits were acknowledged, the impact on workload and staff roles, and the lack of integration with current electronic health records were raised as barriers.

This is the most comprehensive programme of telemonitoring RCTs ever undertaken. While telemonitoring systems are popular amongst patients with long-term conditions and can improve the control of some conditions, they do not, in the short term, reduce clinician workload or save resources. In COPD, we found no evidence that telemonitoring improved outcomes. The results from the COPD RCT have been influential in the UK and internationally and have in many areas stopped the use of intensive telemonitoring for COPD. The results from the hypertension trial have led to a large scale roll out of blood pressure telemonitoring in general practices in Lothian.

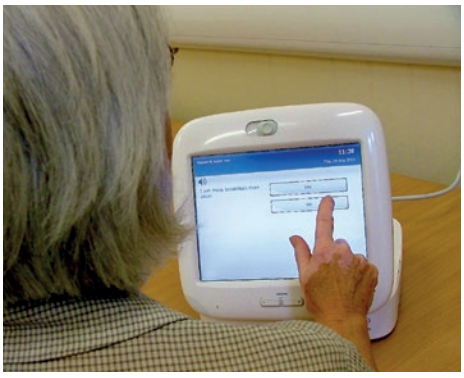
For each of our trials the CRF community research nurse team worked in general practices and in patients' homes to carry out a number of trial activities. This included recruiting, gaining consent from and randomising nearly 900 patients from 39 general practices, baseline and follow up data collection and training on the use of the intervention devices. The nurses also attended our monthly meetings and assisted in the development of the trial protocols and procedures. The work of the Edinburgh CRF community research nurses was crucial in helping us to recruit our participants and gather high quality data for these important trials.



Equipment used in the diabetes trial.



What the clinicians see for the diabetes trial



Equipment used in the COPD Trial.

Professor Brian McKinstry, Professor of Primary Care E-Health, University of Edinburgh

www.telescot.org

Edinburgh Clinical Research Facility - Projects and Initiatives

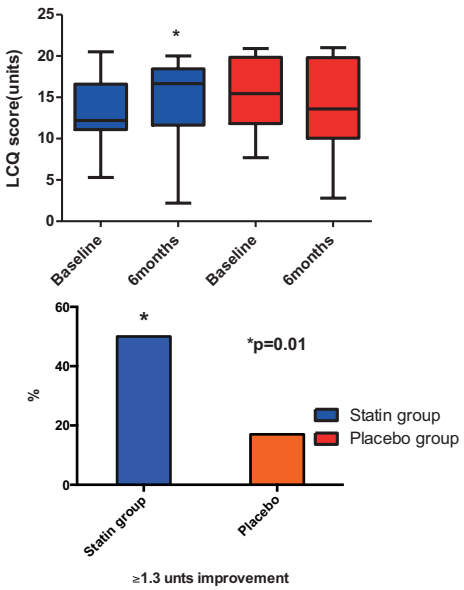
Statins in the treatment of bronchiectasis

Bronchiectasis is a a chronic lung condition with permanently dilated and damaged airways and patients present with chronic cough, sputum production and recurrent chest infections. The condition is characterised by excess neutrophilic inflammation in the airways and depite this there is perpetual bacterial infection. My research group is exploring ways to break the vicious cycle of infection and inflammation in bronchiectasis.

Statins have been shown to have anti-inflammatory properties including attenuating neutrophil influx into the lungs and our hypothesis was that statins could be a potential long term anti-inflammatory treatment in bronchiectasis. Edinburgh CRF Statistics Core assisted in the design and analysis of the study.

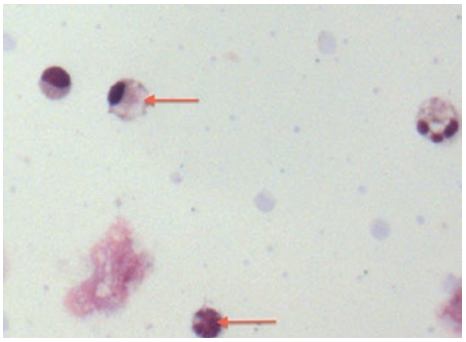
The main aim of our study funded by the Chief Scientist Office was to establish if long term statin treatment (given orally for 6 months) can improve cough in patients with moderately severe bronchiectasis.

Patients aged between 18 and 79 were recruited from SE Scotland Bronchiectasis Clinic in the Royal Infirmary of Edinburgh. All patients had an established radiological diagnosis of bronchiectasis (CT of the chest). Patients had clinically significant bronchiectasis and were coughing up sputum when clinically stable with at least 2 chest infections per year.
30 patients received 80mg atorvastatin and 30 patients received placebo orally for 6 months. Both the researchers and study participants were blinded to the treatment received. Pharmacy randomized the study and held the unblinding code. Patients were reviewed at baseline, 3 months and 6 months. Cat Graham from Edinburgh CRF carried out the statistical analysis.



Cough severity as measured by LCQ

6/30 patients discontinued treatment due to side effects in the statin group compared with 1/30 in the placebo group. Atorvastatin given for 6 months significantly improved cough and airways neutrophil apoptosis. There was a trend towards reduction in sputum neutrophils and serum C-Reactive Protein and an increase in exercise tolerance but this failed to reach conventional statistical significance. There was a trend for fewer numbers of patients having 3 or more exacerbations while on statin therapy but this too failed to reach conventional statistical significance. There was no improvement in spirometry, bacterial colonization, bacterial load or quality of life. The study was however not powered for these secondary end points.



Cytospin of induced sputum from patient on 6 months Atorvastatin

This is the first international study of statins in bronchiectasis. Statins given over 6 months improved cough and the mechanism for improvement is thought to be enhanced airway neutrophil apoptosis. As one of the cardinal symptoms of bronchiectasis, cough is an important clinical end point.
Multi-centred studies are now needed to assess whether long term statin therapy can reduce exacerbations. In addition, further studies are needed to assess statin treatment in severe bronchiectasis chronically colonised with Pseudomonas aeruginosa.

Dr Adam Hill, Consultant Physician and Honorary Reader, Respiratory Medicine

Phase I and First in Human clinical trials

In July 2011, Edinburgh CRF became the first hospital based, non-commercial clinical research unit in the UK to achieve accreditation under the Medicines and Healthcare products Regulatory Agency (MHRA) Phase I Scheme. The Children's CRF was accredited in July 2015.

"The scheme aims to make sure trials are as safe as possible and to create public confidence in the regulation of phase I clinical trials. Organisations in the scheme have to exceed the basic regulatory good clinical practice (GCP) standards by having additional procedures that include the highest standards for avoiding harm to trial subjects and for handling any medical emergencies."

Medicines and Healthcare products Regulatory Agency

Located within the heart of the acute hospital setting, our clinical facilities are ideally positioned to provide the infrastructure and expertise necessary to conduct Phase I/ First in Human (FIH) studies to the highest safety and quality standards.

Our facilities have the same access to emergency teams and Intensive Care services as any other acute NHS hospital department.

Edinburgh CRF is a joint venture between NHS Lothian and the University of Edinburgh. Our directors and many of our investigators are clinical academics and we benefit from their clinical research experience and their access to a network of experts in all aspects of the design and conduct of early phase and FIH trials.

A unique approach to risk management

Edinburgh CRF collaborated as part of the MHRA stakeholder group to develop new procedures to enable academic hospital based units to work to Phase I Accreditation Scheme standards.

Our Phase I Study review process was incorporated into the Scheme revision in 2013 as a means of assessing the conduct of early phase trials.

Our Phase I Study Review Committee (PISRC) advises and gives guidance on all aspects of safety in the design and conduct of Phase I and FIH studies with particular reference to:

- Expertise of the Principal Investigator and Research Team in the conduct of early phase trials
- Trial design
- Pre-clinical and clinical work already undertaken
- Dose escalation strategies
- Risk mitigation

The PISRC is managed by the CRF Clinical and QA Managers. A Risk Assessment (RA), based on the EMA Guidelines on Strategies to Identify and Mitigate Risks for FIH Clinical Trials with IMPs, is reviewed by the committee. Following approval it forms the basis for the conduct of the trial within Edinburgh CRF and includes a contingency plan which is adhered to by all those involved in the trial.

Investment in personnel and systems

Edinburgh CRF has invested in expert personnel and bespoke systems to support the conduct of early phase trials to accreditation standard.

- A Lead Nurse responsible for Phase I activity and staff education
- Research nurses trained in Immediate Life Support (ILS) and Good Clinical Practice (CGP)
- A project support team to ensure data quality
- A QA team and a robust Quality Management System to ensure compliance with Research Governance, Regulatory requirements and Accreditation Scheme Standards

Phase I Study Review Committee membership:

- Experts in:
  - Clinical Pharmacology and Toxicology
  - Statistics
- Clinicians (adult and paediatric)
- CRF Directors and Deputy Director
- CRF Clinical and QA Managers
- NHS Lothian Research and Development Management
- Clinical Trials Pharmacist

Contact us: If you are planning an early phase or first in human trial, please get in touch with **Finny Paterson** or **Sharon Cameron** Applications to the PISRC should be submitted to the CRF QA Lead **James.Gibson@nhslothian.scot.nhs.uk**

Edinburgh Clinical Research Facility - Specialist Research Services

Nursing and Clinical Team

Edinburgh CRF offers purpose built facilities on three hospital sites:

- Wellcome Trust CRF at the Western General Hospital
- Royal Infirmary of Edinburgh CRF
- Children's CRF at the Royal Hospital for Sick Children

Nursing and Clinical team

Our research nurses are trained in Immediate Life Support (ILS) or Paediatric Immediate Life Support (PILS) and Good Clinical Practice (GCP) as standard. They work to basic as well as advanced clinical competencies including venepuncture, cannulation, and the administration of chemotherapeutic and biological agents.

Study specific competencies include skin punch biopsies, joint assessment, and flow mediated dilatation (FMD) measurement.

Edinburgh CRF offers:

- CRF based research nurses
- community research nurses who recruit and attend to patients in their GP practice or their own home
- critical care research nurses
- a 'bank' of ILS and GCP trained nurses allowing us to offer a 24 hour service

The Scottish Diabetes Research Network (SDRN) and the Scottish Mental Health Research Network (SMHRN) nurses are appointed via the CRF.

In 2015 we appointed a specialist Lead Research Nurse for Phase I and Education. This role was created in recognition of the enhanced clinical, education and administrative requirements underpinning our accreditation under the MHRA Phase I scheme.

"Kindly, supportive and very understanding. Staff made you feel like an individual and not just a number"
(from our 2014/5 patient experience survey)

Edinburgh CRF Facilities include

- Study bedrooms
- Day study areas
- Intensive studies rooms
- Consultation rooms
- Managed and calibrated research specific equipment
- Personnel and space for clinical sample processing and storage

Research Nurse Manager: Finny Paterson – 0131 242 7185 – Finny.Paterson@nhslothian.scot.nhs.uk

Ebola research in Liberia

In December 2014 following a UK wide appeal for nurses to support the outbreak of the Ebola Virus in West Africa, Heidi Dawson a CRF Critical Care Nurse volunteered to work in Liberia. Heidi was recruited to support the RAPIDE (Rapid Assessment of Potential Drugs and Interventions for EBOLA) clinical trial managed by the University of Oxford.


BBC NEWS
Health
Ebola drug trial starts in Liberia
By Smitha Mundasad
Health reporter, BBC News
7 January 2015 Health
Drugs, vaccines and blood products are being tried against the disease
A trial of a potential drug to treat Ebola has started at a Medecins Sans Frontieres centre in Liberia.
Ebola crisis

Heidi travelled in a party to the Eternal Loving Winning Africa (ELWA) 3 hospital run by Médécins sans Frontières in Monrovia. Their first week involved training in keeping themselves and others safe from the highly infectious virus. Heidi's role during her 6 week stay included recruitment, dosing, data collection and observation of trial participants.

At a time when the public health measures were finally reducing the numbers of new cases, the clinical trial was not able to provide evidence of the vaccine efficacy, however for Heidi this was a unique and humbling experience. In particular, it gave her an insight into the challenges and availability of healthcare in the region.

"There is so much more work to be undertaken in these countries. The health care system was not strong to start with and now it has been left struggling to cope with providing health care that we take for granted. Vaccination programmes and maternity care are two of the most worrying issues."

We were delighted that Heidi returned safe and well and are proud of her willingness to undertake this important work in such dangerous circumstances.

Education

The importance of education and training in the rapidly changing environment of clinical research has been recognised from the inception of the Edinburgh CRF. Our Programme provides:

MSc in Clinical Trials Online

For information on clinical research training in Scotland visit **www.crts.org.uk**

For information on our courses, events management and other services visit

WTCRFEducationProgramme

@WTCRF_Education

MSc/Dip/Cert in Clinical Trials (launched 2013)

This University of Edinburgh Online Distance Learning course aims to address the demand for appropriately qualified health professionals to lead all phases of clinical trials. The programme provides a flexible, tailored learning experience, responsive to the diverse needs of candidates. It is relevant both to those wishing to gain an overall understanding of clinical trials before moving into the field and to those who already have experience in this area and are looking to broaden their role in the design, management, analysis and reporting of clinical trials. Students take a 'drug', 'devices' or 'management' route to their learning. Key aims for the medium term are to develop our participatory approach to curriculum planning and to build an international reputation as leaders in the provision of excellent online learning.

We currently have 40 students undertaking either our certificate or diploma-level courses.
www.ed.ac.uk/medicine-vet-medicine/msc-clinical-trials

Patient and Public Involvement Advisory Service

The Patient and Public Involvement (PPI) Advisor, Allison Worth, helps researchers and patients/members of the public work together to design, conduct, analyse and disseminate research. Edinburgh CRF has its own Patient and Public Advisory Group, comprising 20 people, to advise us on our research and educational activity. This aims to improve the quality and relevance of research by ensuring the patient experience and public perspective is incorporated in all our research. Members of the group sit on research steering groups, speak to health professionals and researchers at national and local educational events, review grant applications, give advice on patient information leaflets, help to write information for our website and co-present with us at conferences.

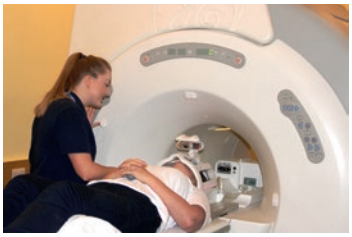
The popular training event, 'A Practical Guide to Patient and Public Involvement in Research', gives researchers the essential skills to conduct meaningful PPI. A module on PPI will be delivered soon as part of our MSc in Clinical Trials.

The PPI Advisor and the CRF nurses have developed a patient experience questionnaire for routine use with people taking part in studies in our facilities. Our public engagement work includes advice to a community arts project in an area of multiple deprivation, aimed at engaging young people with science.

Allison Worth – 0131 537 3348 - allison.worth@ed.ac.uk

Edinburgh Clinical Research Facility - Specialist Research Services

Imaging Core



The University of Edinburgh continues to be a front-runner in the field of medical imaging and Edinburgh CRF Imaging Core is central to this. Clinicians and academics from diverse fields of research are supported by medical physicists, image analysts, research radiographers, data management experts, IT support staff, and facility administrators.

Our facilities:

CRIC (Clinical Research Imaging Centre) - the UK's first fully integrated imaging facility currently housing:

- high strength wide bore magnetic resonance imaging (MRI) scanner
- advanced computerised tomography (CT) scanner
- CT-positron tomography scanner (PET-CT)
- cyclotron
- extensive MHRA accredited radiochemistry suite (GMP and research)

BRIC (Brain Research Imaging Centre) - housing a 1.5T neuro-optimised MRI scanner. BRIC will move to a new site in 2016 with the addition of a 3T scanner

Major developments in 2014/15

- Lothian Stroke Team led by Professor Joanna Wardlaw was shortlisted for the BMJ Imaging Team Award 2015 and is classed among the top 5 imaging teams in the UK
- Our online Masters Imaging program containing modules on specific imaging themes, such as clinical imaging, image analysis, microscopy and pre-clinical imaging continues to be popular with student numbers growing annually
- Our online platform supports the delivery of CPD/CME training courses in collaboration with the NHS
- Two students on our online Masters in Neuroimaging for Research have been awarded Pass with Distinction

Future developments in 2015/16

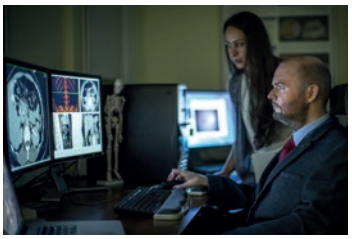
- Relocation of the Brain Research Imaging Centre (BRIC) facility to the Little France Campus in 2016. A 3T MRI scanner will be housed adjacent to A&E at the Royal Infirmary of Edinburgh.
- Installation in the Clinical Research Imaging Centre (CRIC) of a new system combining Magnetic Resonance Imaging (MRI) with Positron Emission Tomography (PET) imaging to produce high-resolution pictures of brain tissue. This MRI-PET scanner will complement existing facilities at the University of Edinburgh, which are helping research across the spectrum of human health from pregnancy to ageing.
- Launch of our fortnightly Imaging Seminar Series

Business Manager: Duncan Martin – 0131 242 7767 – duncan.martin@ed.ac.uk

Image Analysis Core

Medical imaging has become a crucial component of early phase and exploratory studies in clinical research. Our understanding of normal physiological function and of disease processes continually improves as a result of new discoveries arising from imaging data. New imaging analysis techniques allow the identification of biomarkers to aid in diagnosis, quantify disease progress, assess treatment response and inform decision making in drug discovery. In addition it is increasingly possible to relate imaging to genetic traits in individual and population studies.

Our expertise helps to ensure that the appropriate imaging data are acquired, interpreted and analysed correctly, in order to access their full potential.



We have experience with a variety of modalities including MRI, CT, PET, ultrasound, retinal imaging and microscopy. Our aim is to equip researchers with the skills necessary to perform image analysis on their own data in an appropriate and informed manner. We provide training and access to computer workstations with specialist software packages. We are also available to undertake analysis of data or the development of new methods. Our specialist input will enhance any project involving imaging data.

Highlights

- The IA Core collaborated with Dundee University School of Computing, to use our joint VAMPIRE (Vessel Assessment and Measurement Platform for Images of the Retina) software to analyse images from more than 2,500 people whose retinal scans were stored in the UK Biobank. This was the first time the retinal images in this databank have been utilised. Following the success of this analysis the intention is to analyse the UK Biobank's 80,000-strong retinal dataset in order to gain valuable information about the health and condition of small blood vessels.
- With the official launch of our TIMS (Trial Image Management Service) we are able to offer secure and professional management of imaging data to internal and external research teams.
- We contributed towards high impact research outputs included in the UoE submission to the Research Excellence Framework assessment. University of Edinburgh College of Medicine and Veterinary Medicine was ranked in the top 5 UK institutions in REF2014.
- We conducted successful Image Analysis & Signal Processing workshops earlier this year, and plan an Image Analysis workshop for October 2015.

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Epidemiology and Statistics Core

The aim of the Epidemiology and Statistics Core is to improve the methodological quality of clinical research through the provision of expert statistical input. The Core is involved in studies at all stages from initial design through to analysis and dissemination. By encouraging investigators to approach the Core at an early stage we support the development of the highest quality study designs for submission to regulators, ethics committees and grant awarding bodies. We also have an educational remit and run a popular 'Introduction to Statistics for Clinical Research' course.

Through our collaborations with local research groups we have contributed to a substantial list of publications enhancing the profile of Edinburgh CRF beyond the local setting.

- Scottish Human Papilloma Virus Reference Laboratory whose work continues to advance screening methodology as well as disease understanding.
  - Stanczuk GA, Currie H, Baxter G, Foster A, Gibson L, Graham C, Cuschieri K. Cobas 4800 HPV detection in the cervical, vaginal and urine samples of women with high-grade CIN before and after treatment. *J Clin Pathol. 2015 Jul;68(7):567-70*
  - Cuschieri K, Brewster D, Graham C, Nicoll S, Williams A, Murray G, Millan D, Johannessen I, Hardie A, Cubie H. Influence of HPV type on prognosis in patients diagnosed with invasive cervical cancer. *Int J Cancer. 2014 Dec; 135(11): 2721–2726*
  - Cubie HA, Canham M, Moore M, Pedraza J, Graham C, Cuschieri K. Evaluation of commercial HPV assays in the context of post-treatment follow-up: Scottish Test of Cure Study (STOCS-H), *J Clin Path. 2014 Jun;67(6):458-63*
  - Cuschieri K, Cubie H, Graham C, Rowan J, Hardie A, Horne A, Earle CB, Bailey A, Crosbie EJ, Kitchener H. Clinical performance of RNA and DNA based HPV testing in a colposcopy setting: Influence of assay target, cut off and age. *J Clin Virol. 2014 Feb, 59(2): 104-8*
- Edinburgh Centre for Neuro-Oncology [ECNO] - we have contributed to the design and analysis of a number of projects including the work of Dr Simon Kerrigan and colleagues into mental incapacity in patients undergoing neuro-oncologic treatment.
  - Kerrigan S, Erridge S, Liaquat I, Graham C, Grant R., Mental incapacity in patients undergoing neuro-oncologic treatment: A cross-sectional study. *Neurology. 2014 Aug; 83(6); 537-41*

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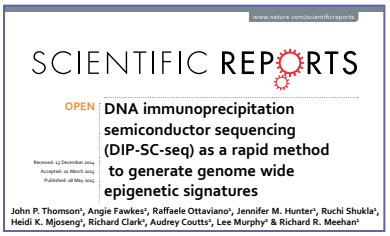
Genetics Core


www.nature.com/scientificreports

SCIENTIFIC REPORTS

OPEN

DNA immunoprecipitation semiconductor sequencing (DIP-SC-seq) as a rapid method to generate genome wide epigenetic signatures

Received: 13 December 2014
Accepted: 20 March 2015
Published: 28 May 2015

John P. Thomson[1], Angie Fawkes[1], Raffaele Ottaviano[1], Jennifer M. Hunter[1], Ruchi Shukla[1], Heidi K. Mjoseng[1], Richard Clark[1], Audrey Coutts[1], Lee Murphy[1] & Richard R. Meehan[1]

A major strength of the Genetics Core is the team of technicians whose hard work and dedication make the Genetics Core so easy to manage. This year we were sorry to see Jude Gibson leave but were pleased that this was so she could start her PhD with Professor Andrew McIntosh on the STRADL project. Jude will be analysing the genotyping data that she helped produce while working in the CRF. Dr Tammy Gilchrist, Alan MacLean and Nicola Wrobel joined the team this year taking our staff number to eleven. We were also delighted that Professor Tim Aitman agreed to join Professor David Porteous as co-director.

Another strength of the Genetics Core is the diversity of workflows that we offer, the ability to take a sample from receipt through processing, storage and on to analysis, all controlled by our Laboratory Information Management System. We have expanded our sample processing portfolio to include RNA extraction and storage from blood, cells and tissue and these samples can then feed in to our microarray and RNA-seq workflows. In addition, we have recently qualified for Certified Service Provider status for the Ion Torrent Transcriptome kit allowing gene expression analysis of FFPE and low input samples.

Ensuring equipment is updated and fit for purpose is always a challenge. This year saw the replacement of our 15 year old genotyping platform with the QuantStudio 12K Flex for low to medium throughput genotyping and qPCR projects. We also added the Qiagen PyroMark Q24 to our sequencing provision, mainly for use in validating methylation results from Illumina Methylation450K arrays. Our biobank has been refreshed by replacing all of our DNA freezers with energy efficient -20oC models. We were very pleased to be awarded Wellcome Trust ISSF funding for a Covaris E220E focused ultrasonicator platform that will be used for DNA, RNA and chromatin shearing.

We are always looking at ways of improving and expanding the facilities we can offer. Over the next year we plan to improve our sequencing provision and look forward to working with our colleagues in the new HiSeq X facility.

If there are any areas that you would like to see developed please do get in touch.

Working with our colleagues in the Institute of Genetics and Molecular Medicine (IGMM) we have developed a fast and cost-effective method to sequence genome-wide epigenetic DNA modification patterns on the Ion Proton. This is particularly useful in understanding the different influence of 5-methylcytosine and 5-hydroxymethylcytosine that cannot be differentiated by array-based approaches.

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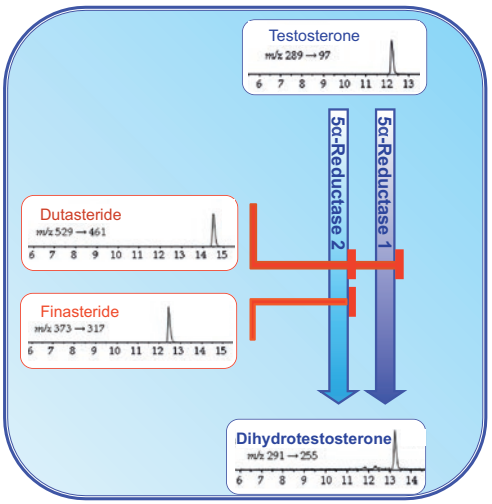
Edinburgh Clinical Research Facility - Specialist Research Services

Mass Spectrometry Core

A wide range of research projects have been supported by the Mass Spectrometry Core during the last year, covering basic and clinical studies in the fields of drug discovery, reproductive biology, hepatology, oncology, toxicology and steroid hormone action. These projects represent investigators from across the University of Edinburgh College of Medicine and Veterinary Medicine and NHS Lothian. Within the laboratory we continue to encourage both open access to the instrumentation and also to provide a service for investigators who prefer a more 'hands-off' approach. Quantitative analysis continues to be our major area of work and metabolite identification is also offered as routine analysis on our QTrap mass spectrometer.

The work of the Core has been well received locally, nationally and internationally. We also continue to support post-graduate students in their development of skills in the field of Analytical Chemistry.

Core Manager: Natalie Homer – 0131 242 9333 – n.z.m.homer@ed.ac.uk



Liquid Chromatography Tandem Mass Spectrometry was used to assess changes in levels of active androgens brought about by 5-alpha-reductase inhibitor drugs

Information technology (IT)

Our IT area specialises in developing small and large scale web and Windows based solutions for the CRF and clients within the UK and abroad.

Key projects include:

- **CRFManager®** – a comprehensive facility management tool used by around 40 sites across the UK and Ireland. We now offer external sites a hosting service for CRFManager® which can include hosting patient demographics. Hosting makes support and updates easier, and is likely to significantly reduce hardware costs for the site **www.crfmanager.com**
- **CourseManager** – a course administration system that has contributed to the success of our Education Programme. Associated with this is the Clinical Research Training Scotland (CRTS) website, used across Scotland to publicise clinical research related courses and events
- **NRS Finance System** – this CSO funded national database supports the collection of pre-award study data for R & D departments
- **Accord Trial Recruitment System** – developed in collaboration with NHS Lothian R & D department, this website captures study and recruitment data directly from investigators for approval by R & D data managers and subsequent export to NIHR and CSO

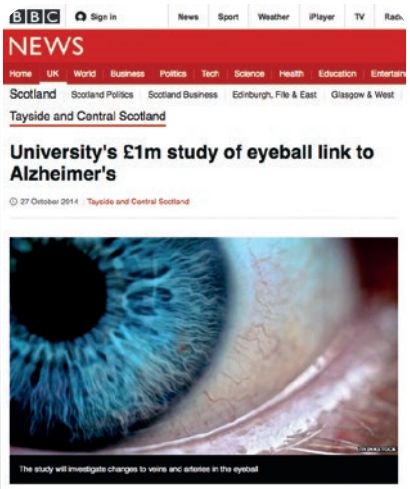
We constantly strive to improve our practice and are working towards assessment for the following compliance certifications:

- NHS Information Governance Toolkit (IGT)
- ISO27001 Information Security Management Systems

Please get in touch if you would like us to discuss and quote for your web development project.

IT Manager: Elizabeth McDowell – 0131 537 3353 – elizabeth.mcdowell@ed.ac.uk

Edinburgh Clinical Research Facility - Hitting the headlines



Retinal imaging – Image Analysis Core

www.bbc.co.uk/news/uk-scotland-tayside-central-29758311

Lothian Birth Cohort

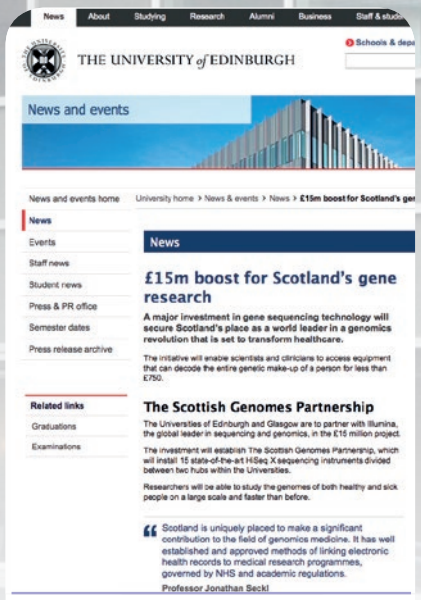
www.lbclifetimes.org/

Quick Thinkers

www.dailymail.co.uk/health/article-3041892/Quick-thinkers-born-not-speed-process-new-information-written-genes.html

Gene Therapy

www.newscientist.com/article/dn27832-gene-therapy-works-in-cystic-fibrosis-for-the-first-time/



Genetics Core collaboration with IGMM

www.ed.ac.uk/news/2015/scottishgenomes-120115

SMART oncology trials

http://news.stv.tv/scotland/289889-large-numbers-of-cancer-patients-suffer-from-depression-says-study/

Trust Me I'm a Doctor

www.bbc.co.uk/programmes/articles/3B4pFccSwjT9nslWMcM10VF/should-i-avoid-the-sun

Edinburgh Clinical Research Facility - Selected Publications

Gene Therapy in Cystic Fibrosis

Alton EW *et al.*

Repeated nebulisation of non-viral CFTR gene therapy in patients with cystic fibrosis: a randomised, double-blind, placebo-controlled, phase 2b trial.

Lancet Respir Med. 2015 Jul 3. doi: 10.1016/S2213-2600(15)00245-3. [Epub ahead of print]

Lung disease is the main cause of morbidity and mortality in individuals with cystic fibrosis, with a median age at death of 29 years (95% CI 27–31).

This randomised, double-blind, placebo-controlled, phase 2b trial aimed to assess the efficacy of non-viral CFTR gene therapy in patients with cystic fibrosis.

Patients with a forced expiratory volume in 1 s (FEV1) of 50-90% predicted and any combination of CFTR mutations, were randomly assigned to receive 5 mL of either nebulised pGM169/GL67A gene-liposome complex or 0·9% saline (placebo) every 28 days for 1 year. The primary endpoint was the relative change in % predicted FEV1.

We recorded no significant difference in treatment-attributable adverse events between groups. Monthly application of the pGM169/GL67A gene therapy formulation was associated with a significant, albeit modest, benefit in FEV1 compared with placebo at 1 year, (3·7%, 95% CI 0·1-7·3; p=0·046) indicating a stabilisation of lung function in the treatment group.

Edinburgh CRF was one of the two clinical sites involved and recruited 46 adult and paediatric participants. Two bespoke negative pressure dosing cubicles were installed to support this important trial.

Metformin in pregnancy – EMPOWaR

Chiswick C *et al.*

Effect of metformin on maternal and fetal outcomes in obese pregnant women (EMPOWaR): a randomised, double-blind, placebo-controlled trial

Lancet Diabetes Endocrinol. 2015 Jul 9. pii: S2213-8587(15)00219-3. doi: 10.1016/S2213-8587(15)00219-3. [Epub ahead of print]

The mechanism by which maternal obesity leads to increased birthweight, and obesity and premature mortality in adult offspring is not well understood, but maternal hyperglycaemia and insulin resistance are both implicated.

This randomised, double-blind, placebo-controlled trial ran in 15 National Health Service hospitals in the UK and aimed to establish whether the insulin sensitising drug metformin improves maternal and fetal outcomes in obese pregnant women without diabetes.

449 pregnant women between 12 and 16 weeks gestation with a BMI of ≥30 kg/m2 and normal glucose tolerance were randomly assigned to receive oral metformin 500 mg (increasing to a maximum of 2500 mg) or matched placebo daily until delivery of the baby. Primary outcome was Z score corresponding to the gestational age, parity, and sex-standardised birthweight percentile of liveborn babies delivered at 24 weeks or more of gestation. Analysis was by modified intention to treat.

Mean birthweight at delivery was 3463 g (SD 660) in the placebo group and 3462 g (548) in the metformin group. The estimated effect size of metformin on the primary outcome was non-significant. The difference in the number of women reporting the combined adverse outcome of miscarriage, termination of pregnancy, stillbirth, or neonatal death in the metformin group (n=7) versus the placebo group (n=2) was also not significant.

Metformin has no significant effect on birthweight percentile in obese pregnant women. Further follow-up of babies born to mothers in the EMPOWaR study will identify longer-term outcomes of metformin in this population.

Rehabilitation after intensive care – RECOVER study

Walsh TS *et al.*

Increased Hospital-Based Physical Rehabilitation and Information Provision After Intensive Care Unit Discharge: The RECOVER Randomized Clinical Trial.

JAMA Intern Med. 2015 Jun;175(6):901-10. doi: 10.1001/jamainternmed.2015.0822.

Patients surviving critical illness frequently experience disabilities, poor health-related quality of life (HRQOL), and reduced ability to undertake activities of daily living. Long-term costs of critical illness at individual, family, and societal levels are high.

This parallel group, randomized clinical trial aimed to evaluate the effect of enhancing rehabilitation and provision of information during the post-ICU acute hospital stay by dedicated rehabilitation assistants on subsequent mobility, HRQOL, and prevalent disabilities.

Both groups received physiotherapy and dietetic, occupational, and speech/language therapy. Patients in the intervention group received rehabilitation that typically increased the frequency of mobility and exercise therapies 2- to 3-fold, increased dietetic assessment and treatment, used individualized goal setting, and provided greater illness-specific information.

Primary outcome was the Rivermead Mobility Index (RMI) at 3 months - higher scores indicate greater mobility. Secondary outcomes included HRQOL, psychological outcomes, self-reported symptoms, patient experience, and cost-effectiveness during a 12-month follow-up.

This study did not demonstrate significant difference in physical recovery, self-reported symptoms or HRQOL between the two groups, but patients in the intervention group reported greater satisfaction with physiotherapy, nutritional support, coordination of care, and information provision.

Edinburgh CRF critical care research nurses supported this trial.

Our community research nurses supported and delivered an outstanding 96% non-mortality patient follow-up rate.

Mum and baby in EMPOWaR study

CT coronary angiography in heart disease – SCOT-HEART

Newby DE *et al* SCOT-HEART investigators.

CT coronary angiography in patients with suspected angina due to coronary heart disease (SCOT-HEART): an open-label, parallel-group, multicentre trial

Lancet. 2015 Jun 13;385(9985):2383-91. doi: 10.1016/S0140-6736(15)60291-4. Epub 2015 Mar 15.

This prospective open-label, parallel-group, multicentre trial aimed to assess the effect of CT Coronary Angiography (CTCA) on the diagnosis, management, and outcome of patients with suspected angina due to coronary heart disease.

4146 patients aged 18-75 were randomly assigned to receive standard care plus CTCA or standard care alone. The primary endpoint was certainty of the diagnosis of angina secondary to coronary heart disease at 6 weeks.

47% of participants had a baseline clinic diagnosis of coronary heart disease and 36% had angina due to coronary heart disease. At 6 weeks, CTCA reclassified the diagnosis of coronary heart disease in 558 (27%) patients and the diagnosis of angina due to coronary heart disease in 481 (23%) patients (standard care 22 [1%] and 23 [1%]; p<0·0001). Although both the certainty and frequency of coronary heart disease increased, the certainty increased and frequency seemed to decrease for the diagnosis of angina due to coronary heart disease. This changed planned investigations (15% vs 1%; p<0·0001) and treatments (23% vs 5%; p<0·0001) but did not affect 6-week symptom severity or subsequent admittances to hospital for chest pain. After 1·7 years, CTCA was associated with a 38% reduction in fatal and non-fatal myocardial infarction, but this was not significant.

In patients with suspected angina due to coronary heart disease, CTCA clarifies the diagnosis, enables targeting of interventions, and might reduce the future risk of myocardial infarction.

This study was supported by the CRF Imaging and Image Analysis Cores, and the CRF Community, WTCRF and RIECRF Research Nurses.

Statins in pulmonary disease

Mandal P *et al.*

Atorvastatin as a stable treatment in bronchiectasis: a randomised controlled trial.

Lancet Respir Med. 2014 Jun;2(6):455-63. doi: 10.1016/S2213-2600(14)70050-5. Epub 2014 Mar 24

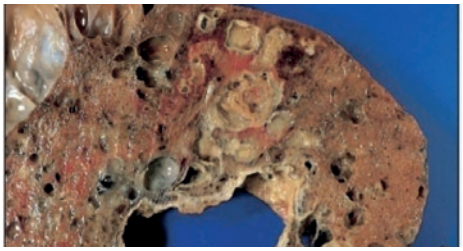
Bronchiectasis is characterised by chronic cough, sputum production, and recurrent chest infections. Pathogenesis is poorly understood, but excess neutrophilic airway inflammation is seen. Evidence of the pleiotropic effects of statins suggest they could be a potential anti-inflammatory treatment for bronchiectasis. Our proof-of-concept randomised controlled trial aimed to establish if atorvastatin could reduce cough in patients with bronchiectasis.

60 participants with clinically significant bronchiectasis were randomly allocated to receive daily oral high-dose atorvastatin (80 mg) or placebo for 6 months. Primary endpoint was reduction in cough from baseline to 6 months, measured by the Leicester Cough Questionnaire (LCQ) score - minimum clinically important difference1 ·3 units. Analysis was by intention-to-treat.

Results demonstrated a mean change of 1 ·5 units in patients allocated atorvastatin versus –0 ·7 units in those assigned placebo (mean difference 2 ·2, 95% CI 0 ·5–3 ·9; p=0 ·01). 12 (40%) of 30 patients in the atorvastatin group improved by 1 ·3 units or more on the LCQ compared with five (17%) of 30 in the placebo group (difference 23%, 95% CI 1–45; p=0 ·04). There was no significant difference in adverse events reported between the groups. No serious adverse events were recorded.

6 months of atorvastatin improved cough on a quality-of-life scale in patients with bronchiectasis. Multicentre studies are needed to assess whether long-term statin treatment can reduce exacerbations.

Edinburgh CRF Statistician assisted in the design and analysis of this Chief Scientist Office funded trial.



Permanently damaged and inflamed airways

Alcoholic hepatitis – the STOPAH trial

Thursz MR *et al.*

Prednisolone or pentoxifylline for alcoholic hepatitis.

N Engl J Med. 2015 Apr 23;372(17):1619-28. doi: 10.1056/NEJMoa1412278.

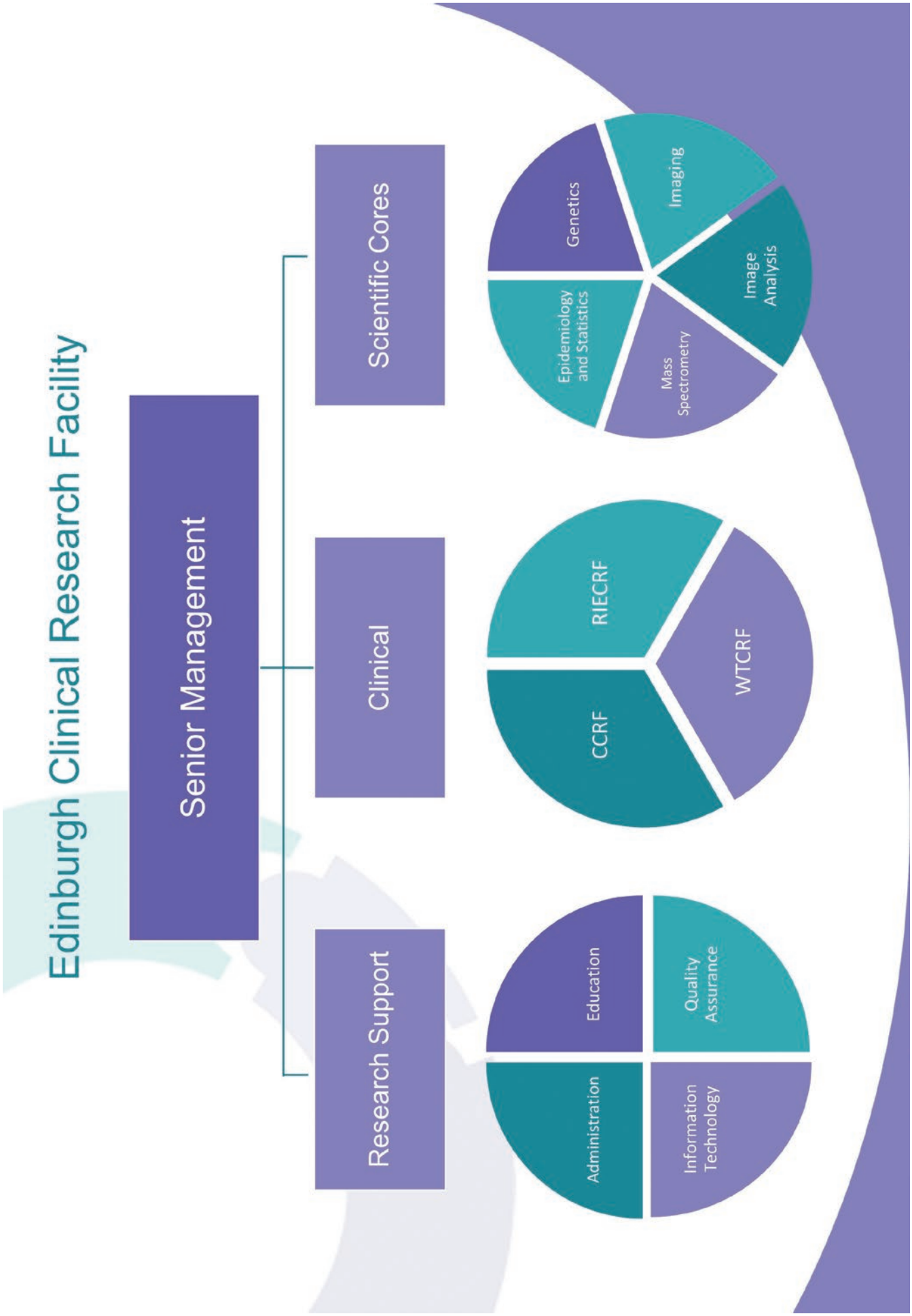
In alcoholic hepatitis jaundice and liver impairment occur in patients with a history of heavy and prolonged alcohol use. The short-term mortality among patients with severe disease exceeds 30%. Prednisolone and pentoxifylline are both recommended for the treatment of severe alcoholic hepatitis, but uncertainty about their benefit persists.

This multicenter, 2-by-2 factorial, double-blind, randomised trial aimed to evaluate the effect of treatment with prednisolone or pentoxifylline. The primary end point was mortality at 28 days. Secondary end points included death or liver transplantation at 90 days and at 1 year. Patients were randomly assigned to one of four groups to receive: pentoxifylline-matched placebo plus prednisolone-matched placebo (group 1); prednisolone plus pentoxifylline-matched placebo (group 2); pentoxifylline plus prednisolone-matched placebo (group 3); both prednisolone and pentoxifylline (group 4).

Data from 1053 out of 1103 randomised patients were available for the primary end-point analysis. Mortality at 28 days was 17% in group 1, 14% in group 2, 19% in group 3, and 13%) in group 4. The odds ratio for 28-day mortality with pentoxifylline was 1.07 (95% confidence interval [CI], 0.77 to 1.49; P=0.69), and that with prednisolone was 0.72 (95% CI, 0.52 to 1.01; P=0.06). At 90 days and at 1 year, there were no significant between-group differences. Serious infections occurred in 13% of the patients treated with prednisolone versus 7% of those who did not receive prednisolone (P=0.002).

Pentoxifylline did not improve survival in patients with alcoholic hepatitis. Prednisolone was associated with a reduction in 28-day mortality that did not reach significance, and with no longer term improvement in outcomes.

Edinburgh Clinical Research Facility - Organisation



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Queen's Medical Research Institute
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Professor David Newby
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NHS RESEARCH SCOTLAND

NHS Lothian

THE UNIVERSITY of EDINBURGH

CHIEF SCIENTIST OFFICE

wellcome trust

UKCRF NETWORK
UK Clinical Research Facility Network

THE SICK KIDS

NEUROIMAGING SCIENCES
The Brain Research Imaging Centre

clinical research imaging centre EDINBURGH

clinical research training for scotland

accord
Academic and Clinical Central Office for Research and Development

NHS Lothian

2014-15 Office Awards
BRONZE WINNER

Design: Graphic Design Service, LTW, ISG, The University of Edinburgh www.ed.ac.uk/is/graphic-design