Devices for Dignity
Healthcare Technology
Co-operative

NHS
National Institute for
Health Research

Annual Report 2013/14

Delivering innovative technology solutions to support people with long-term conditions, preserving their dignity and independence.

“The D4D pilot HTC has allowed the rapid creation of technologies that can enable patients to remain in their homes, providing independence and dignity, and reducing the need for hospital admission. The NIHR D4D HTC can continue to support and develop innovations for unmet needs as one of the newly funded NIHR HTCs over the next three years.”

- Professor Dame Sally C Davies FRS FMedSci
Chief Medical Officer and Chief Scientific Advisor, Department of Health

Contents

Clinical Director's Comments

The National Institute for Health Research Devices for Dignity Healthcare Technology Co-operative (NIHR D4D HTC) has been working towards - and delivering - a wide range of technology solutions to patients' needs since 2008. We have achieved much in this time, and we continued to expand our activities during 2013-14.

One of our key activities during 2013-14 has been to work with the Department of Health to propose and manage a £3.6 million Small Business Research Initiative (SBRI) within our Renal Theme. This has enabled us to form new partnerships and support exciting new projects that will contribute to our overall aim of helping people suffering from long-term conditions or disabilities to maintain or regain their dignity and independence.

Collaborative working within expert networks is an important aspect of our approach. In February 2014, the Engineering and Physical Sciences Research Council (EPSRC) confirmed the participation of Devices for Dignity in three of the eight national academic networks that were awarded. This funding will enable us to form closer bonds with the other HTCs, and work on projects that span the boundaries between our usual areas of clinical expertise.

Patient involvement is inherent in our approach to finding solutions to unmet clinical needs. The unmet need might be identified by a patient in the first instance, or brought to our attention by a clinician on their patient's behalf. Most of our projects include patients or carers throughout, which helps us to ensure that we're delivering solutions that are acceptable to their users.

Whilst 2013/14 has focused on this detailed level of patient contribution to individual projects, in 2014/15 we will be broadening the range of meaningful ways in which we will involve patients in our activities.

Unfortunately 2013-14 brought sad news. It is with sorrow that I report that we lost one of our theme leads, Professor Bipin Bhakta, to illness. We are very grateful for the expertise and dedication he brought to his role whilst he was with us, and we extend our condolences to his family.

We have welcomed Dr Rory O'Connor as a new Theme Co-Lead alongside Professor Mark Hawley, and we look forward to new opportunities in the Assistive and Rehabilitative Technologies theme arising from his input and expertise.

I would like to thank all our funders, partners and collaborators for their ongoing support and involvement, and for enabling us to continue to work for the benefit of patients. I have no doubt the coming years will continue to present increasingly complex unmet needs and unexpected challenges, but I believe D4D will continue to approach these challenges with our unique combination of collaboration, imagination and expertise.

Professor Wendy Tindale OBE
Clinical Director, NIHR Devices for Dignity HTC, Consultant Clinical Scientist and Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Tindale was named one of the top 50 most inspirational female leaders in healthcare by the Health Services Journal in 2013

Our activities during 2013-14

23 active projects

26 recruits to pilot clinical studies

Visibility, engagement and dissemination:

6 publications
2 reports
3 posters presented at international conferences
1 EXPO stand
9 presentations
6 seminars
2 focus groups
1 new website launched

£2,172,000 external funding

£3.6 million SBRI funding, 41 applications, 14 projects funded

D4D is a partner in **3 of 8** new EPSRC-funded networks

59 Unmet needs submitted via D4D website with **5** being funded

22 unmet dysphagia needs identified

1 new theme under development

4 projects in receipt of industry funding, **8** additional projects funded through normal routes

10 projects with significant industry input interactions with **100** companies during year, of which **84** were Small and Medium-sized Enterprises

55 Non Disclosure Agreements (NDAs), **47** of which were SMEs

2 clinical trial agreements

About us

The NIHR D4D HTC was established in January 2008 as a pilot HTC, supported by the NIHR, the Technology Strategy Board (TSB), the Engineering and Physical Research Council (EPSRC) and the Medical Research Council (MRC).

Since the outset our purpose has been to deliver innovative healthcare technologies that preserve dignity and promote independence for people living with long-term conditions. We aim to make a difference to the wellbeing of patients, the effectiveness of the NHS, and the wealth of the nation.

Working in partnership is core to all of our HTC's activities and project. We operate by bringing together the right teams of expert clinicians, academics, members of the public, patients, carers and industry to develop real solutions to areas of unmet clinical and patient need. Our current specialist Themes are:

- **Renal Technologies**
- **Assistive and Rehabilitative Technologies**
- **Urinary Continence Management**

Individual projects from each of these themes, and the impact they may have, are described on pages 10-21.

D4D is hosted by Sheffield Teaching Hospitals NHS Foundation Trust and is made up of a series of partner organisations, shown on page 23 of this Annual Report.

Following the success of the pilots, the HTCs are now a recognised part of the NIHR's innovation landscape. In November 2012 we were successful in becoming one of the eight new NIHR HTCs, with funding from 1 January 2013 until 31 December 2016.

Our Networks

The NIHR D4D HTC plays a key role nationally in engaging NHS staff in healthcare technology developments whilst championing partnerships with industry. Our network of expertise stretches across the country, and we work with over 200 experts across a number of universities, charities, patient associations, Small and Medium-sized Enterprises (SMEs) and large companies.

Our well-established networks are able to respond rapidly to new opportunities and challenges in the creation and adoption of new technologies. We undertake a multidisciplinary approach that is constantly evolving and adapting to the challenges at hand. This enables us to support the development of new technologies and treatments, enabling translation into practice more quickly, improving healthcare quality and wellbeing for patients.

For further information please contact our Programme Manager, Dr Nicola Heron:

Dr Nicola Heron

nicola.heron@sth.nhs.uk
0114 271 3737

What does NIHR D4D HTC do?

We have developed a methodology that enables us to work on a pipeline of innovation projects at different stages of development.

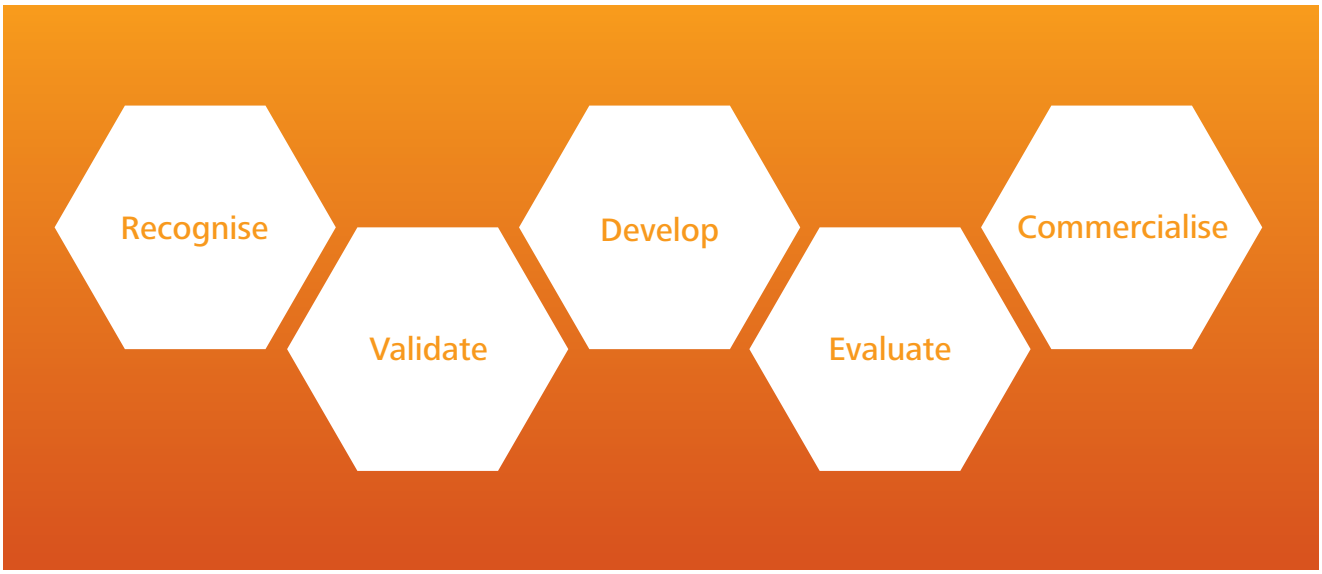
We follow an innovative model of buying out the time of clinicians, academics and other healthcare professionals to work on projects, so the HTC can respond rapidly to industry needs and provide a single entry point for accessing and working with the NHS.

Recognising potential unmet needs

There are several ways that we might become aware of a potential unmet clinical need, such as directly from patients, or from clinicians describing unmet patient needs that they have recognised, or through the 'submit an unmet need' form on our website. Industry partners also approach us with new products ideas. Once a potential unmet need has been recognised it will require validation.

Validating potential unmet needs

By integrating broad-ranging information from a variety of professionals, patients and other sources we can provide a rigorously validated definition of each unmet clinical need; in other words, we determine precisely what the issue is and the impact of solving this problem. We determine whether the identified problem already has an existing solution, or whether it is a problem that we might be able to address.



Developing a solution

Patients and healthcare providers are an integral part of the process of working towards a well-designed technology solution. By listening to patients' needs and articulating them to people who can respond with new products and services, we can ensure that the right product is developed in the right way and for the right reason.

One of the HTC's strengths is drawing together the right expertise from a range of different fields and sectors from across the UK.

Our network of experts can help to:

- **design proof of concept projects**
- **identify regulatory and practical challenges and solutions**
- **advise on commercialisation strategies**
- **highlight necessary steps in considering long-term adoption of the developed product**

Developing effective solutions involves input from a range of disciplines. We work within our professional and academic communities to continually expand our networks with relevant experts. We stay abreast of developments within our themes, and keep our professional and academic communities informed of our projects, whilst also respecting commercial confidentiality.

People only benefit from new technology when they know about it, so as well as helping to develop the evidence needed to support the use of new technologies and keeping professional communities informed, we also work to ensure relevant patient, carer and healthcare provider communities know about our new devices to help ensure they are adopted by the NHS.

Evaluating the solution

NIHR D4D HTC will ensure that new products are tested within clinical practice and with user groups to provide evidence that they are fit for purpose before entering the market where appropriate. The HTC works with the other parts of the NIHR infrastructure such as the Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) and Clinical Research Networks (CRNs) to facilitate this stage.

Commercialising the device

The HTC works with industrial partners at all stages of the research, development and commercialisation process for new medical devices and technologies. We can identify innovative market opportunities that have been qualified from both clinician and user standpoints, and put together collaborative multidisciplinary development teams with expertise in the required areas.

NIHR D4D HTC has developed a commercial arm, Devices for Dignity Limited (D4D Ltd), to be our interface with the medical device industry. You can read more about D4D Ltd on page 9.

"When developing a medical device it's important to understand all the user needs at the outset to increase the likelihood of getting the design right first time. The considerations are simple to write down: Why is it needed and who will pay for it? Who will use it? What is it intended to do and what difference will it make? Where will it be used? When and how often will it be used? The questions are not always easy to answer but the most important, having satisfied the 'why', is - who will use it? The device design needs to be as 'inclusive' as possible to maximise its benefits for people with different conditions and capabilities."

- Dr Avril McCarthy, MedTech Lead

D4D Ltd

Devices for Dignity Ltd (D4D Ltd) was incorporated in May 2013, and began operation in October 2013.

D4D Ltd's purpose is to realise the value of the intellectual capital of the HTC. The aim is to maximise our ability to assist the MedTech industry through working closely with industry partners. This increases the impact of D4D's activities by making D4D's expertise available to companies, and simultaneously supports the sustainability of D4D into the future.

D4D Ltd brings a number of valuable skills and services to NIHR D4D HTC. D4D Ltd has been the focus of the HTC's engagement with the medical technology industry, and the primary contact point for companies. Building on Oliver Wells' 30 years' experience in the health technology industry, it brings a first-hand understanding of many of the problems faced by companies in developing and marketing innovative technologies into the global marketplace. Focusing primarily on companies that are active in the HTC's themes, D4D Ltd is working on building strategic links with some of the world's largest health technology companies, as well as working with many SMEs across the UK.

D4D Ltd plays an important role in delivering the commercial aspects of the D4D project portfolio through working with our partner organisations' commercialisation teams. D4D Ltd's business experience is also highly valuable from the early stages of putting together project proposals such that proposals balance the need for clinical innovation and the HTC's focus on patient dignity with the need for products to be commercially viable if they are to have an impact on people and the healthcare system.

D4D Ltd is also directly involved in the delivery of the HTC's projects, and the exploitation of the resulting products and technologies. This includes finding and negotiating licensing agreements with companies who are able to manufacture and take the products to world markets. Almost all new projects within the HTC's portfolio now include industrial collaborators.

Altogether during 2013/14, D4D Ltd was in active contact with well over 100 companies. In every case, the goal was to find ways to bring better technologies to healthcare providers and patients, and, in doing so, benefit the economy.

For more information please contact D4D Ltd's Commercial Director, Oliver Wells:

Oliver Wells

oliver.wells@d4dltd.co.uk
0114 271 2970
07771 598644

Renal Technologies Theme

With over 50,000 people in the UK suffering kidney failure, D4D's Renal Technologies theme aims to develop systems, devices and services to assist people with renal conditions to maintain their independence.

Nocturnal haemodialysis - overcoming the technical challenges

For renal patients who need it, haemodialysis can take up a significant proportion of their lives. In-centre dialysis usually takes place three times a week, and may take seven hours from start to finish. Home haemodialysis has many advantages for some patients, though uptake is currently much lower than the 15 percent the National Institute for Health and Care Excellence (NICE) suggests services should aim for.

Nocturnal haemodialysis (NHD) allows patients to dialyse for longer, but without feeling like dialysis has taken over their life, as it takes place overnight. For the patient it means fewer medications, fewer restrictions on their diet and fluid intake, greater energy levels, and more time to pursue everyday activities. NHD can mean patients have survival rates as high as patients who receive a kidney transplant. Nocturnal HD also increases the chance of conception for female HD patients. Although dialysing at home, patients remain under the overall care of a dialysis unit.

However, there are some concerns around NHD. The Renal Technologies Theme has produced some guidance on how the technical challenges of offering NHD can be overcome, which may promote improved uptake of home haemodialysis.

The full article can be found in the British Journal of Renal Medicine[1] and further information is available through our website: **www.devicesfordignity.org.uk/nhtaforum**

Phosphate levels in drinks

Phosphate is normally excreted in the urine so it tends to accumulate in the body when kidney function is impaired. Dialysis can help, but if patients are eating well it is impossible to remove enough phosphate with treatment regimes other than very long (nocturnal) sessions. To avoid the harmful effects that high levels of phosphate in the blood can lead to, patients with chronic kidney disease often need to control their phosphate intake and take tablets with meals to limit the amount of phosphate absorbed from food. Drinks can be problematic as they may contain high levels of phosphates in a form that is very easily absorbed in the gut, especially when consumed between meals as is often the case when socialising. Knowledge of the phosphate content of different beverages would enable patients who have to limit their phosphate intake to make informed choices.

In the UK, manufacturers have to publish the additives in soft drinks like colas, so you can look for phosphoric acid or E338 on the label. Additionally, tables listing the phosphate levels in different brands of soft drinks are available on the internet. However, this information is not available for all brands and is difficult or impossible to obtain for alcoholic drinks. It is known that phosphate levels vary considerably between different beverages.

We wondered if the tests that hospital pathology labs routinely carry out could also be used to measure the phosphate content of aqueous beverages.

[1] Lindley, E.J. and Mitra, S. (2013). Overcoming the technical challenges of implementing anocturnal haemodialysis programme. British Journal of Renal Medicine 18;4;12-14

Devices for Dignity tested a range of beers, wines and soft drinks using the standard 'phosphomolybdate' assay that is used by most labs to measure phosphate in urine. We were able to show that this could also provide accurate measurements of phosphate levels in drinks regardless of the colour or the concentration of sugar or alcohol. We found that traditional Yorkshire ales had less than half the phosphate content of the 'pilsner' type beer. Although white wines tended to have lower phosphate levels than reds, the level was unpredictable and we are now collaborating with a renal unit and a micro-winery in Australia to investigate the variation in phosphate with the production method. We hope this work will give patients a better understanding of where phosphate comes from and which drinks need to be taken with food and phosphate binders to reduce the amount of phosphate absorbed.

Collaborators:
Leeds Blood Sciences Department
Leeds Teaching Hospital NHS Trust

Body Composition Monitoring

Most patients receiving dialysis to replace some of the functions of the kidney do not pass sufficient volumes of urine to maintain fluid balance. It is important to assess the fluid status of individuals regularly. Leaving patients chronically overloaded with fluid leaves them at a greater risk of cardiovascular complications, while removing too much fluid can lead to hypotension, cramps, nausea and loss of residual renal function. Furthermore, without an accurate assessment of fluid status it is impossible to monitor changes in the patient's body composition, for example muscle loss due to poor appetite.

Clinical assessments have traditionally been used to estimate fluid status. These are based on signs and symptoms such as blood pressure, problems during dialysis, puffy tissue and breathlessness. However, these indicators could also be caused by conditions unrelated to fluid status and so clinical assessments end up being rather subjective.

Bioimpedance involves sending tiny electric currents through the body. The ease with which the current passes through the body can be related to the amount of fluid is in the tissues. The technique is simple, non-invasive, harmless and inexpensive.

The Body Composition Monitor (BCM, Fresenius Medical Care) uses an innovative model to analyse bioimpedance data. It provides measurements of lean tissue and body fat which are used to find the patient's 'normally hydrated' weight. Knowing how far they are from normal hydration enables patients and their carers to optimise the removal of fluid during dialysis and avoid the problems described earlier. The BCM can also be used to monitor the impact of interventions to improve nutritional status or fitness.

The BCM was well validated for standard tests in adults but not in children. One of the first D4D projects was to validate the device for use in paediatrics. We have also shown how it can be used in amputees and other patients where the standard wrist-to-ankle test can't be used.

There was also very little guidance on how to use the BCM in busy dialysis units and how to interpret the results as part of fluid management strategies. To help ensure the rapid adoption of the use of BCM we worked with the NHS Technology Adoption Centre* to produce an implementation pack to help Trusts to use BCM in a planned and sustainable way.

The implementation pack is available online:
http://devicesfordignity.org.uk/projects/renal-technology-projects/78-body-composition-monitoring/265-body-composition-monitoring-bcm

Collaborators:
Fresenius Medical Care
MRC Human Nutrition Research Labs
Leeds Metropolitan University
The NHS Technology Adoption Centre

* The NHS Technology Adoption Centre is now the Health Technology Adoption Programme (HTAP), and is part of NICE

Small Business Research Initiative (SBRI) Kidney Care Competition

14 percent of the UK population suffers from Chronic Kidney Disease (CKD) and the number of sufferers increases markedly with age. More than 25 percent of the adult population over the age of 65 are in one of the more advanced stages of CKD. CKD is associated with high morbidity and mortality, with 5 year survival rates comparable to those of some forms of cancer such as bowel cancer. The treatment of advanced kidney disease currently commands 2 percent of the annual NHS budget.

Early diagnosis of CKD could allow interventions to be made that could help to slow disease progression. New approaches to aid earlier diagnosis of kidney disease could also reduce the number of affected individuals progressing to more advanced stages. These advanced stages of CKD require frequent hospital attendance and life-long dependence on healthcare for survival. Therapeutic innovations could give patients greater independence and enable treatment closer to home.

Although kidney disease in CKD develops over a number of years, kidney failure can occur acutely due to a number of causes. Often, this can be reversed, and importantly, it is preventable. Acute Kidney Injury (AKI), is estimated to occur in 4.9 percent of hospital admissions, and can carry a mortality of 10-20 percent per year. Early identification of at risk individuals can prevent AKI, and early diagnosis can give affected individuals the best chance of recovery.

NIHR D4D HTC partnered with the Department of Health to deliver a Small Business Research Initiative (SBRI) competition to fund the development of innovative technologies to address unmet needs in kidney care.

D4D was able to maximise chances of success for the teams by providing hands-on and structured project support by David Coyle (D4D project manager and a kidney patient himself) and Nicos Mitsides (D4D Clinical Innovation Fellow from Central Manchester Foundation Trust) and access to D4D's extensive networks of expertise.

Technology-based Innovative Solutions to Promote Patient Empowerment and Sustainability in Kidney Care

There were 41 applications to the competition, with the winners covering issues addressing all areas of nephrology. These projects were initially funded for six months in order to develop the initial concept.

- **Three of the funded projects were aimed at AKI:**
  - the University of Cambridge and SensorHut Ltd collaborated on a project to develop an innovative bedside sensor that can detect AKI by sensing volatile molecules in urine.
  - Patientrack Ltd and Western Sussex Hospitals NHS Trust were funded to develop an automated information technology system to calculate risk of AKI and alert clinical teams appropriately.
  - DocCom Careflow was awarded funding to develop technology to assist with ensuring faster treatment of AKI. The new technology would use secure messaging to deliver alerts to clinicians in real time and then enable instant, cross-team referrals and conversations using smartphone technology.
- **The commonest condition causing CKD is diabetes. Early diagnosis of kidney disease in diabetes can lead to interventions that can delay disease progression.**
  - Helier Scientific Ltd was funded to develop a sensitive test for urinary K-Cadherin, a marker of kidney disease progression in patients with diabetes.
- **For many patients, the best treatment for renal failure is transplantation, but the availability of organs and organ compatibility is a limiting factor. Two of the projects relate to this area:**
  - Randox Laboratories Ltd were funded to develop a test for Aminoacylase-1, a biosensor for early assessment of transplant function.
  - the University of Leeds was awarded funding to design plasmapheresis technology that can be combined with haemodialysis technology to make transplantation between blood-group incompatible recipients and organ donors easier, which reduces both the treatment time and the time spent in hospital.

- **Patient support for self-management was addressed by one project:**
  - Atlantis Healthcare was funded to develop an online self-help support programme to improve self-management. This could delay disease progression and aid shared decision-making around dialysis in order to reduce distress and conflict around decisions.
- **Patients waiting for, or unsuitable for, a transplant, and who require renal replacement therapy, are treated with dialysis. In the majority of cases this is haemodialysis in a hospital or satellite unit carried out 3 times a week for about 4 hours. Patient transport and the way that patients use dialysis services are the subjects of two projects:**
  - 365 Response Ltd - This project aimed to enable better transport arrangements by developing a booking app for transport, a key factor for delays in haemodialysis treatment.
  - Frazer-Nash Consultancy Ltd was funded to model the 'dialysis day' with the aim of minimising delays in haemodialysis patient treatment.

Proportion of projects to which SBRI funding was allocated that affect various categories of patient care

- **Peritoneal dialysis is one of the forms of renal replacement treatment that can be delivered by the patients in their own home. The commonest reason for hospital attendance in this group of patients is peritoneal infections.**
  - Microsensor Limited is developing a micro-sensor that can be incorporated into peritoneal dialysis equipment to provide early diagnosis of peritoneal infections.
- **The last 3 of the funded projects aimed to improve patient independence and encourage patient empowerment.**
  - East and North Hertfordshire NHS Trust was awarded funding for a telemedicine platform that is aiming to reduce patient hospital attendance by using telemedicine technology to support remote clinics.
  - UK Renal Data Collaboration was funded to develop a system to deliver patient results in real time, and modules to allow patients to flag up mistakes and changes in their medical records.
  - IF Sensing Ltd is working towards a device for monitoring renal function at home using interstitial fluid, which would allow out-of-hospital monitoring of kidney function.

For further information about our Renal Technologies Theme please contact our Theme Leads:

Dr Sandip Mitra
sandip.mitra@cmft.nhs.uk
Tel: 0161 276 4488

Dr Elizabeth Lindley
elizabeth.lindley@nhs.net
Tel: 0113 206 4119

Urinary Continence Management Theme

Continence problems can result in loss of employment and social isolation, and comprise quality of life. Continence problems can result in loss of employment and social isolation, and comprise the second most common reason for older people moving into care. NIHR D4D HTC is focusing on improving diagnosis, treatment and management of bladder dysfunction for those experiencing urine storage or voiding difficulties. We play a major role in prevention, alleviation of symptoms and, importantly, in management of continence where drugs or surgery are inappropriate or have failed.

ELAROS

Over the past year NIHR D4D has collaborated with ELAROS 24/7, a spin-out company that the HTC established in collaboration with two NHS Innovation Hubs (Medipex and Innovations North) two years ago. We have developed an electronic bladder diary and service components to help with the initial assessment, diagnosis and triaging of patients with lower urinary tract symptoms (LUTS), as well as long-term management and monitoring. The service components include a handheld device, information and software. These components have been designed for integration into existing services provided by GPs, specialist continence providers, community health organisations and acute trusts. The HTC has provided clinical and regulatory expertise in developing this device and components, as well as testing how usable the system is, and a range of other activities and know-how.

The information gathered from the ELAROS system provides an immediate indicative diagnosis and recommended clinical action. This will reduce the need for patients to go back and forth to their GP and cuts out inappropriate and unnecessary referrals to hospitals. The time taken to diagnose and treat a patient's symptoms is reduced, which reduces anxiety for the patient as well as potentially offering quicker relief from symptoms that may have a significant impact on their quality of life.

ELAROS helps to provide a more effective patient-centred service and facilitates improved compliance with NICE guidelines. The HTC's involvement has helped ensure the device has developed towards clinical practice quickly, with patients directly involved in the process. Once adopted into routine clinical use we anticipate the device will lead to more rapid diagnoses, and potentially savings of NHS resources.

www.elaros247.org.uk

Partners in ELAROS:
MDTi
Medipex Ltd
NHS Innovations North
Sheffield Teaching Hospitals NHS Foundation Trust

Collaboration with the Bladder and Bowel Foundation

Technology related to urinary continence management has changed very little over the last decades, meaning that opportunities are emerging for innovative solutions to long-standing problems. As with all other healthcare areas, input from patients and healthcare professionals is essential in the development of innovative technology solutions.

The Bladder and Bowel Foundation (B&BF) is a patient-focused charity seeking to aid the management of urinary continence problems. The B&BF is an important partner for the Urinary Continence Management (UCM) theme within the HTC. This partnership provides patients and healthcare professionals with an opportunity to be heard and present their thoughts and opinions about the unmet clinical needs that the HTC works to address. The partnership between the B&BF and the HTC also supports active patient participation and recruitment to projects.

In 2013/2014, in response to discussions with B&BF nurse continence specialists, NIHR D4D HTC and the B&BF have created a Patient Involvement Framework, which is an important step in deepening our partnership. This will help us to create an environment where patients and healthcare professionals work effectively together.

Lunch clubs

With the support of Big Lottery Funds, the HTC is collaborating with Voluntary Action Sheffield and the Bladder and Bowel Foundation to offer a series of informative sessions in Lunch Clubs for older people across Sheffield to promote effective and appropriate management of urinary continence issues.

Sharing information about common bladder problems and how to manage them could improve the quality of life of affected local older people in Sheffield. In addition, easy and discrete access to information about potential solutions could reduce distress and isolation problems in the target audience.

A few hours spent at a Lunch Club can make a real difference to older people's lives. As well as providing a healthy, homemade meal they also provide informal help and support with health, social care and day-to-day needs. There are social and wellbeing benefits too, as it may be the only social interation that some of the members may have. Some of these clubs cater for specific groups, such as people with mobility difficulties, minority groups, and people with dementia.

Collaborating Organisations:
Voluntary Action Sheffield
The Bladder and Bowel Foundation

"The HTC considers patients in all of our projects. We're always looking for new and effective ways of reaching and engaging with people who might use or be involved in the development of our devices."

- Dr Angel Jimenez-Aranda, Project Manager

Baby Bear

A cute and simple teddy bear leg bag could revolutionise care for small babies and children, their parents and carers when urinary catheters need to be fitted due to surgery or health problems. Urine collection leg bags are usually worn attached to one leg, enabling the patient to move around freely. Adult bags may not fit correctly around a child's leg, and can be uncomfortable, as well as dragging on the catheter.

NIHR D4D HTC has worked with Great Bear Healthcare Ltd to develop Baby Bear (150ml) and Mummy Bear (250ml) leg bags, which are more comfortable and lighter for children to use, so offer a less unpleasant experience for young children. The bags are deliberately designed to look more appealing to young patients, as is the strap that comes with the bags to secure the bag to the child's leg. The strap can be cut to the right size to fit each patient.

Both sizes of the leg bags:

- are available with either a direct inlet or an adjustable tube,
- have soft and breathable fabric backing,
- can be used with a night bag for overnight drainage, and
- comply with the relevant standards.

Great Bear will make these bags commercially available in 2014. Pippa Bowkett, Marketing Director for Great Bear Healthcare Limited said:

"There is always a stigma to wearing any bodily worn appliance and, for the very young, it is sometimes hard to accept that these types of appliances will be with them for the short and/or long term. Great Bear is passionate about improving the quality of life for those who use urinary drainage bags and we saw an opportunity for a niche product that could really make such an experience easier for both the child and their respective parents/guardians. We are delighted to bring this product to market with the help of the NIHR Devices for Dignity HTC."

For further information visit: **www.greatbearhealthcare.co.uk/our-products/mummy-baby-bear-leg-bag**

Don't Wee

The pelvic floor muscles are a group of muscles that form a dome which supports organs such as the bladder, uterus and bowel. If the pelvic floor muscles become weak, these organs are not properly supported, and this can result in incontinence or organ prolapse.

A few people are born with weaker muscles, but more commonly, damage can occur during childbirth, especially with difficult births. Also, as people get older, changes in hormone levels can result in muscle weakness and in having reduced control.

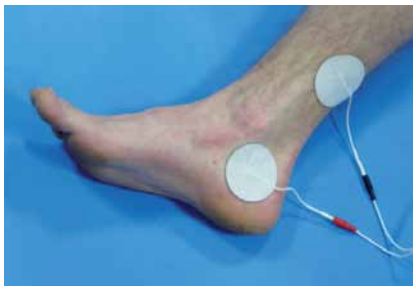
Just like any other muscle in the body, exercise can strengthen the pelvic floor. Doing pelvic floor exercises regularly can help to prevent problems later in life, or reduce the severity of problems. Pelvic floor exercises can be done almost anywhere, standing, sitting or lying down. These exercises should be repeated several times a day, every day, if possible. It is important to try to make pelvic floor exercises a regular part of the daily life. For this reason, the HTC has created a video, publicly available in YouTube, to raise awareness of the importance of pelvic floor exercises in young women: www.youtube.com/watch?v=jDAhKgsZ_1w

Who was involved in this project?
North Bristol NHS Trust
Brunel University London
The University of the West of England
All the film's participants
South West Film

Non-invasive electrical stimulation for the treatment of overactive bladder

Many people give very little thought to the sensation that leads them to pass urine. However for a certain group of our population this sensation is different to an extent that affects their lives. They have urgency - a sudden desire to pass urine, the main symptom of overactive bladder syndrome. They also need to pass urine more often, and sometimes more than once during the night. One third of the patients are also affected by urinary incontinence. There are over 5.15 million people (19 percent) in the UK over the age of 40 for whom quality of life is affected by the symptoms of overactive bladder.

The first treatment option is usually bladder training or lifestyle changes. Medication may be advised instead, but may not be effective for all patients, or might not be tolerated due to side effects. Therefore it is important to investigate alternative therapies that may offer an additional treatment pathway and may have a substantial impact on the patient's quality of life.



We are investigating a promising non-invasive option for the treatment of overactive bladder symptoms using electrical stimulation. A conventional TENS (Transcutaneous Electrical Nerve Stimulation) stimulator with surface electrodes, placed on the ankle and connected to a conventional TENS machine, activates nerves connected to the bladder control system.

With repeated use this may help to manage the symptoms. This option might offer a cost effective choice in the patient's treatment pathway. A clinical trial using this therapy is currently underway to help us to determine whether this approach should be considered for adoption into routine clinical use.

Tissue engineering to treat prolapse and incontinence

Regenerative medicine requires a multi-disciplinary team and offers the potential to solve many of the problems relating to disorders of the lower urinary tract. In the field of incontinence there has been recent controversy relating to the use of synthetic materials next to or within the urinary tract as treatment for genitourinary prolapse. We believe tissue engineering provides an alternative solution by introducing the potential for absorbable synthetic materials, combined with tissues grown from the patient's own cells. This may provide a solution in the future treatment of pelvic organ prolapse and stress urinary incontinence. There is ongoing work within the theme looking into this, and hopefully work relating to this will come to fruition within the next couple of years.

Collaborating organisations:

Sheffield Teaching Hospitals NHS Foundation Trust

Bladder and Bowel Foundation

The non-invasive electrical stimulation project is being undertaken with funding from the European European Commission's Research and Innovation Framework Programme (Marie Curie Actions Initial Training Network) for the TRUST project (Training Urology Scientists to Develop Treatments), Grant Number 238541.

For more information please contact our Urinary Continence Management Theme Lead:

Professor Chris Chapple

c.r.chapple@shef.ac.uk

Tel: +44 (0)114 271 3048

Assistive and Rehabilitative Technologies Theme

There are over 11 million people with a limiting long-term illness, impairment or disability in the UK. NIHR D4D HTC's work in Assistive and Rehabilitative Technologies aims to provide innovations that help people to perform tasks more independently, regain control over aspects of their lives and assist them with daily living.

AMPCARE

Difficulty swallowing (dysphagia) is common after stroke, affecting up to 70 percent of patients. It is associated with aspiration (when food or fluid gets into the airway) which can lead to increased mortality, longer hospital stays, pneumonia, reduced quality of life, tube feeding, and can be expensive for the NHS.

Dysphagia care currently focuses on managing the symptoms through adapting food and drink textures, and adapting the patient's posture, rather than direct treatment to restore functional swallowing. The HTC supported a trial to evaluate a new treatment programme that aims to directly restore safe swallowing in people with persistent swallowing disorders post-stroke, called AMPCARE Effective Swallowing Programme.

The pilot Randomised Controlled Trial (RCT), based on a successful feasibility study, involved 30 patients, separated at random into two groups. Patients that were in the new treatment group received treatment for five days per week for four weeks. The new treatment incorporates a new healthcare technology which combines transcutaneous electrical nerve stimulation (TENS) with specialised throat exercises, performed against the resistance of a specially designed postural device. Patients in the other group received the equivalent care to that which is usually given, which includes diet adaptations and postural changes.

The outcome of this D4D study will potentially identify an effective new therapy to help a large number of patients to return to safe and comfortable eating and drinking, leading to improved quality of life for patients.

D4D has contributed regulatory expertise in achieving CE marking of the new electrode design used for the treatment. D4D is now in the process of negotiating with AMPCARE, the US-based company which has developed the treatment package, to commercialise the Effective Swallowing Programme if the trial demonstrates that it is effective. This would help make a completely new treatment technology available to patients and clinicians within the UK and Europe.

Project partners:
Sheffield Teaching Hospitals NHS Foundation Trust
NIHR CLAHRC for South Yorkshire
Ampcare

Identifying and validating unmet needs in dysphagia

During 2013/14 the Assistive and Rehabilitative Technologies (ART) theme received 22 suggestions for potential areas of research around swallowing difficulties (dysphagia) from our expert network. We were keen to test out the validity of these potential ideas with groups of patients and clinicians, and to find out from these groups which projects they felt needed to be tackled as priorities.

We contacted a range of clinicians to ask which patient groups they felt might be affected by each of the potential areas of research, and whether there was already solutions available. The clinicians then rated each topic as high, medium or low priority. Results from clinicians suggested two priorities:

- **Improved bedside assessment technology**
- **Technology for improved oral hygiene**

We then met with two patient groups - Heads Together, a support group for people who have had head/neck cancer, and Dysphasia Support, for people who have had a stroke.

We went through the suggested areas of research with the groups' members. We gave them the opportunity to ask questions before they rated the ideas by priority. The patient groups selected the same two priorities as the clinicians. Work has therefore been taken forward on the two validated and prioritised projects.

carla
A Devices for Dignity Product

CARLA

Carla is a computer-based, accessible, receptive language assessment which is being developed to help assess the level of understanding of spoken communication (receptive language) in children with physical disabilities. This group of children are unable to access conventional assessments as they require a child to be able to point.

We collected the views of speech and language therapists, who confirmed that there was a clinical need for a better way of assessing children who could not participate in existing forms of assessment. We confirmed that there was a clinical need for a more adaptable and objective means of assessing children who could not access existing assessments. CARLA was thus developed to be computer based - allowing a child to use whatever method of access they are able to (e.g. eye-gaze, or pressing switches) and also for CARLA to be automatically scored (reducing the potential for bias or error). CARLA was developed to consider areas of receptive language relevant to the use of Augmentative and Alternative Communication (AAC), which is a set of techniques, strategies and equipment that children can be use to support communication if they have difficulty in speaking.

Prototypes of CARLA were developed and used to decide whether it would be feasible to use CARLA in a pilot study, and to consult with professionals. A commercial partner was then sought, and an agreement is being finalised with Jabbla, a company based in Belgium with a background in communication technologies.

Project partners:
Barnsley NHS Foundation Trust
Jabbla

Head Up - the Sheffield Support Snood

People with motor neuron disease (MND) are currently offered a neck orthosis (collar) to help with neck weakness and control. However, patients often find the collars to be inadequate, so we worked with patients, healthcare professionals and designers to produce a new prototype, the Sheffield Support Snood (SSS), which would be more acceptable to patients.

Once we had obtained the necessary CE mark for the the snood we asked people living with MND to use the snood for a month, and then report back to us with their views. Participants described the impact of neck weakness on their quality of life, and the limitations of existing supports. Patients using the snood reported an improved permissible range of movement, better support, more flexible use, and improved appearance and comfort, though some problems were also described. Using the feedback we have modified the design to achieve a better fit and have overcome the initial problems that were identified.

We have also worked in collaboration with INSIGNEO researchers at the University of Sheffield to use sensors to demonstrate that the snood can offer as much support or restriction of movement, when this is required, as the current standard collar. This shows that by re-designing the collar we were able to retain vital support features, whilst also introducing the additional benefits of the snood.

The results of the evaluation suggest that the snood could become a valuable option for people with MND, and potentially other patient groups who would benefit from a neck orthosis. We are now planning a larger trial of the snood, and will be looking for commercial partners.

"It's a lot more comfortable. With the collar on I get no pain at all."

"I think it's more supportive in the right places."

"It looks like an item of clothing and you could wear a scarf over it or something."

"I love the idea that you can adjust it in lots of different ways because obviously you know different weaknesses."

Project collaborators:
The Sheffield Institute for Translational Neuroscience (SITraN) at the University of Sheffield
Sheffield Hallam University
MND Association and Expert Patient Group
INSIGNEO

This project received funding from NIHR i4i II-ES-0511-21003

Upper limb rehabilitation

The HTC works extensively with patient and carer members of the Rehabilitation Technologies User Group (RTUG) at Leeds Teaching Hospitals NHS Trust, to identify unmet needs in therapy provision, and in the development of devices.

During 2013-14 the HTC supported two upper limb rehabilitation projects:

1. We worked on a device that combines upper limb robotics and functional electrical stimulation.
   We were able to demonstrate upper limb function improvements with up to 10 combined treatment sessions.
2. 10 paediatric NHS teams contributed to a multi-centre randomised control trial of home-based rehabilitation robotics for children with cerebral palsy. We were able to recruit our target number of patients by February 2014, and expect to report on the outcomes of this project at the Society for Research in Rehabilitation Summer Meeting in Newcastle in June 2015.

We are now planning further trials of both systems and are awaiting outcomes of grant applications that will enable us to continue to develop and test these very exciting rehabilitation technologies. We plan to use home-based robotics systems in children with cerebral palsy and in adults with stroke who have completed their standard NHS rehabilitation treatment. We will also widen the scope of the treatments by including people who have had other conditions affecting their arms, including those who have survived trauma.

Collaborating organisations:
Odstock Medical Ltd
Leeds Teaching Hospitals NHS Trust
Leeds Community Healthcare NHS Trust
University of Leeds
Coventry University
Greater Manchester NHS Trust
Key Engineering Solutions

For further information about D4D's Assistive and Rehabilitative Technologies Theme please contact our Theme Leads:

Dr Rory O'Connor
r.j.o'connor@leeds.ac.uk
Tel: 0113 392 2560

Professor Mark Hawley
mark.hawley@sheffield.ac.uk
Tel: 0114 222 0682

Our Partners

NHS Partners

Sheffield Teaching Hospitals NHS Foundation Trust

Barnsley Hospital NHS Foundation Trust

North Bristol NHS Trust

The Leeds Teaching Hospitas NHS Trust

Sheffield Children's NHS Foundation Trust

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Central Manchester University Hospitals NHS Foundation Trust

University Partners

The University of Sheffield

Sheffield Hallam University

University of Cambridge

Coventry University

Charity Partners

Assist UK

Bladder and Bowel Foundation

Research reported in this publication was partially funded by the NIHR D4D HTC at Sheffield Teaching Hospitals NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

www.devicesfordignity.org.uk
enquiries@devicesfordignity.org.uk
0114 271 2159
@Devices4Dignity #MyDignityMeans