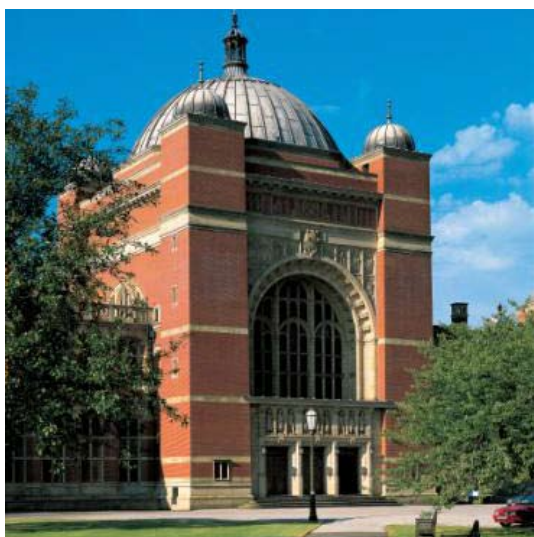




Multidisciplinary Assessment of Technology
Centre for Healthcare
Year 7 Annual Report



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Director's Introduction

When MATCH started in November 2003, there was a widespread feeling that things were awry with the medical devices sector in its ability to improve care and lower costs. The Health Industries Task Force was stirring and the National Institute for Health and Clinical Excellence (NICE) was increasing its interest in devices alongside drugs.

The call which MATCH won was targeted at the difficult and largely untrodden terrain linking technological innovation with business process and the clinical context. This diffuse requirement evolved as the rather lengthy Vision statement you can see below.

MATCH Vision

To transform the medical devices sector by researching, testing and making methods available to cut the time and cost from concept to continuous improvement in the market, in support of device users, the medical device industry, regulators and reimbursement agencies and healthcare providers, such as the NHS.

This has always been something of a mouthful – essentially, it boils down to:

To provide what healthcare users really need: more effective and efficient service, based on better technology that has been selected and developed through value-based choices.

At the renewal of the MATCH contract in 2008, Kings College London stepped down, the Universities of Birmingham, Brunel, Nottingham and Ulster continuing to the second phase.

Key achievements of MATCH include:

- Cutting time-to-market has largely focused on early-stage decisions: developing methods, guides, tools and training.
- Scaling up our outreach by employing half a person with BITECIC¹ (an SME), and developing business models for working with other collaborators.
- Supporting the industry with theory to link clinical evidence to business decisions in pricing and investment.
- Securing the Chief Executive of the Association of British Healthcare Industries as chair of the MATCH Steering Committee.

¹ Biomaterials and Tissue Engineering Centre of Industrial Collaboration, Leeds www.bitecic.com



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- Writing a guide on methods for user testing issued by the National Patient Safety Agency.
 - Supporting manufacturers with theory on the value of safety. This has been extended to value user preferences in design under MATCH Plus¹.
 - Supporting regulators and re-imbusement agencies by engaging with, for instance, PASA, NIC, NICE and NPSA².
 - Supporting the Department of Health and the National Health Service through contracts and consulting.

This report tells the story of who we are, how we have set about this endeavour and the progress we have made.

We commend it to you.



1 A further £1.7 million of funding from EPSRC and the Department of Health

2 The NHS Purchasing and Supply Agency, the NHS National Innovation Centre, the National Institute for Health and Clinical Excellence and the National Patient Safety Agency

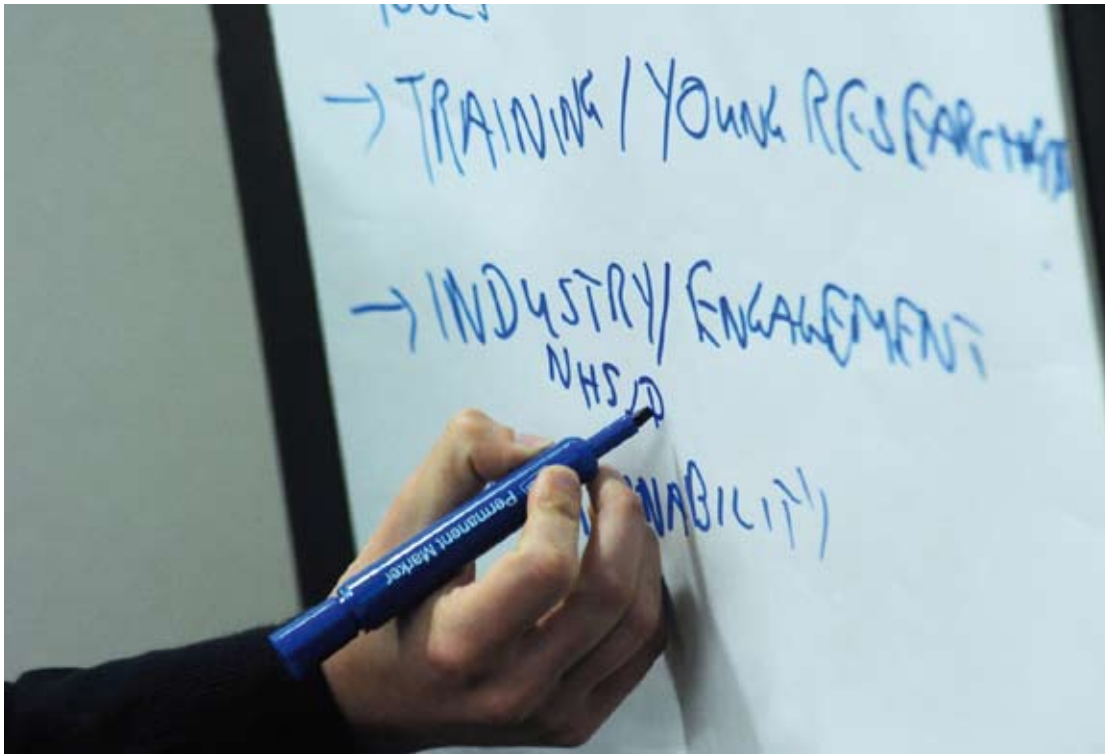
Executive Summary

What has MATCH achieved in the past seven years?

First, it has built a team of cross-disciplinary experts and forged new research agendas that cut across both traditional disciplinary lines and university boundaries. MATCH was the first to link evidence from clinical trials to business planning, investment and pricing. It leads the charge to put a premium on safety and user preferences in order to drive design towards higher-value products. MATCH's social scientists understand economic evaluation and its engineers undertake social science research. MATCH people go on to better things, they are invited to speak at meetings that matter around the world, and in the last year, Professor Martin Buxton, one of the founding MATCH academics, has picked up a prestigious lifetime achievement award.

MATCH continues to leave a legacy of methodological development: split-choice theory, true choice theory, pricing theory, investment decisions, value-of-safety, the transferability of health economic results, Real Options in healthcare, the experience curve, user-centred requirements elicitation and design, workshop techniques and tools for use with adolescent users – all these represent studies where MATCH pioneered something novel, often by looking over the disciplinary horizon. The methods developed for evaluation of devices at the design stage have turned out to be generic and our recent work published in the British Medical Journal [26] has shown how they can be applied to interventions designed to strengthen the organisation of the services in which devices are used.

MATCH is involved in decisions of significance.



One company withdrew a proposed development worth many millions of Euros when our Headroom Method showed there was no future in tissue-engineered bladders and resources were allocated to repair of large hernias instead (See Sofradim Case Study, Annex 8). When the Department of Health NHS Procurement, Innovation and Commercial Directorate (PICD) evaluated technologies to save £5 billion a year for the NHS, it contracted with two MATCH universities, Brunel and Birmingham, while another, Nottingham, was an approved contractor for the Centre for Evidence-Based Purchasing (CEP).

MATCH has taken academic theories to industry and healthcare providers. Starting with a spreadsheet tool to assess new inventions, researchers have worked hard to reduce to practice, methods that have hitherto remained in the academic or consultancy domain. We have trained people from over 100 companies and organisations to use the MATCH Health Economic Evaluation Tool and our guide to methods for user testing has been published by the National Patient Safety Agency.

In the last 5 years, we have worked with 32 organisations¹ that paid to belong to the MATCH programme. However, the economic crisis around the world saw a dramatic cut in external spending from companies of all sizes and our membership dropped dramatically. We are therefore sculpting strategy to find better routes to market for our guides, training and expertise. As part of this, we have teamed up with an SME and hired someone to take training and consultancy out.

The challenge is to sustain the research beyond the grant and continue to deliver tools, methods and critical information to medical device communities around the world – a market that spends around €200 billion a year. We are working on some exciting business models to do just that: offering services to industry, support to healthcare providers and providing underpinning research findings to universities around the world, freeing them up to provide applied services to the industries that surround them.

¹ 28 industrial companies, NPSA, PASA, NIC and Invest Northern Ireland

The MATCH Vision:

To provide what healthcare users really need: more effective and efficient service, based on better technology that has been selected and developed through value-based choices.

The Vision

MATCH's vision is expansive: to bridge between the development of health technology and its impact through markets on a critical outcome: our health. It also connects academe with industry, embracing the realms of ideas and practice, to deliver valuation tools that work reliably. Horizons as wide as this encompass many stakeholders and the task is complex.

Nonetheless, we have reached a tipping point where we can connect critical islands of information in new and important ways. A bridge analogy is both helpful and frustrating, helpful because it indicates that there are separated regions of research, policy and practice that need to be connected, frustrating because it implies that we are addressing a linear problem in which each new stanchion is simply linked to those on either side.

Traditionally, the gulf between concept and the marketplace has been bridged in narrow slices. Thus governance, regulation and CE-marking (e.g. MHRA¹) is separate from value for money (e.g. NICE), while the academic world has many specialist centres such as the National Coordinating Centre for Health Technology Assessment (Southampton) and the groups it funds, or mainstream Health Economics (e.g. Oxford, Sheffield and York).

1 Medicines and Healthcare products Regulatory Agency



MATCH has contributed in all these areas and focuses on connecting them up through a shared view of value. Links from concept to commercial adoption include:

- Linking internal business decisions to NICE-type analysis of evidence.
- Exploring the link between economics and the supply chain for medical devices.
- Linking ergonomic and social science views of user preferences to economic evaluation (started under MATCH and progressing under MATCH Plus).

From the start, MATCH has maintained a strong research focus on both *Economic Evaluation* and *User Needs*. These are two of the key themes of MATCH. Work carried out within the other themes (*Implementation* and *Tools & Training*) also resonates strongly with these. MATCH has researched practice within industry, issues of adoption, and pathway re-engineering to implement new technology.

In terms of sustainable impact, the question has always been what to provide and how to set up channels that will fund it once the grant is over. In terms of what to provide, while some of the bigger companies have wanted analysis and support of value propositions (see DePuy Case Study, Annex 10), most want accessible software or guides. Thus, the main offering has been:

- Tools to provide industrial and NHS users with accessible economic evaluation
- Guides to provide industrial and NHS staff with methods to access user needs and evidence.
- Training sessions to support both economic evaluation and user needs.

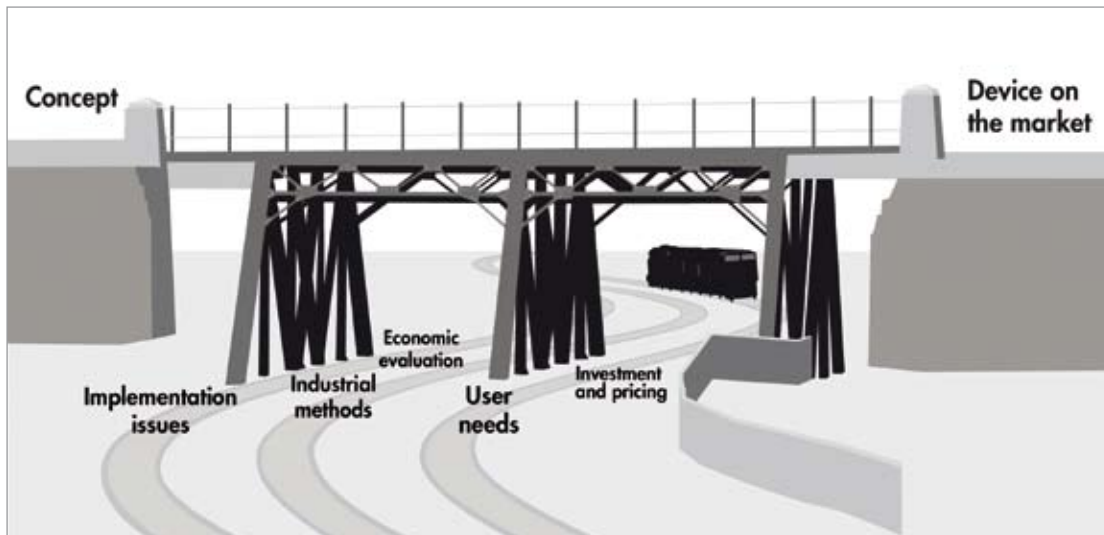


Figure 1: Schematic of the regions of research policy and practice that are connected by MATCH

In terms of payment (an important measure of whether something is valued), MATCH started with a membership model at different levels, which raised nearly £620k for the programme from industry and an unexpected £250k or so from government Departments in addition to a £250k contribution from the National Patient Safety Agency. MATCH has also enjoyed support from Invest Northern Ireland, worth over £420k, which, for much of the programme, has paid for part of an administrator and a researcher.

However, there was pressure to change the model – companies said they wanted a lower premium and then to pay directly for add-ons. The change in model was followed quickly by the global economic downturn and budgets for all extraneous spend were slashed across the industry. This threw all our predictions and we have had to regroup quickly and develop a new approach for the promotion of MATCH tools, training and consultancy.

Over the course of MATCH, two things have become clear. First, sustainable engagement with companies can only take place through commercial channels or organisations; companies talk to companies. And so, MATCH has planned a series of ventures in which commercial partners will take MATCH methods, tools, techniques and expertise into medical device companies, and to NHS Trusts.

Secondly, the global market in healthcare technology, worth €200billion a year, needs a centre with a guaranteed future and a full set of commercial functions. Regional players exist but there is a gap in provision. To this end, we have plans that will meld the initial ventures into a more coherent whole under a MATCH Company.

The key challenge is for MATCH to become a self-sustaining entity, paid for by the margins and profits of its ventures, which will return as grants to the collaborating MATCH universities thus maintaining the research. Our business modelling indicates that sufficient money could flow into the MATCH universities within 6-7 years, although we have a shortfall to cover of around £700k/annum between 2013 and 2016 – which we plan to fill through grants.

In terms of broad societal benefit and benefit to patients, MATCH's contribution is mediated through three communities (see 'Are we making a difference?' on p.11 and the diagram on p 12). The first of these is industry. As an IMRC, MATCH has a responsibility to those who manufacture, and MATCH methods are designed to help companies make better decisions about which products to pursue, and to make them earlier in the development cycle. It also aims to help industry better articulate the value of products that confer greater clinical benefit. We believe that a stronger industrial sector is good for UK plc. The second community is those selecting technology, where it is important that choices are made on the basis of real value and that the products bought are what users really need. Finally, through policy, we hope to influence those who set up the system so that rational decision-making, based upon economic evaluation and robust needs analysis, supports a better dialogue between vendors and purchasers in each succeeding year. Through our user needs work, we are also striving to give the user a greater say in what products are brought to market and what features they support.

This part of the vision takes MATCH into new territory and has involved a huge effort in planning and negotiating and, if successful, will probably involve a new type of agreement between universities. But the prize is to become the international centre that researches methods and offers tools to academics, industries and healthcare providers around the world. We believe that is a vision worth pursuing.

“HTA is not always considered to be particularly accessible for Med Tech SMEs and is often applied retrospectively to support sales. However, the workshop and tools provided a very useful insight as to how HTA could be rapidly and practically applied at a stage early enough to help influence the development of a new product. Functions such as headroom analysis stimulate debate and aid communication that ensures products can focus on the right attributes that potential users and purchasers are seeking.”

Giles Proffitt, Product Innovation & Operations Manager, Medilink



Relevance

The drivers that gave birth to MATCH are much stronger now than ever before:

- The Healthcare Industries Task Force (HITF) closed at the start of 2007, but the agenda has been amplified through the Post-HITF Strategic Implementation Group, and key elements of the Darzi Review (2008-2009). Moreover, the idea that technology can improve care while curbing costs is at the heart of QIPP (Quality, Innovation, Productivity and Prevention). However, the methods that will drive value-based adoption have still to be regularised and in many cases, developed.
- World Class Commissioning is to be re-invented under the new NHS Commissioning Board and GP consortia and it is likely that new tools and methods will be needed.
- NICE's position in supporting rational decision-making for drugs and devices has strengthened steadily in the last 10 years with critical favourable judgements endorsing their methods – if occasionally calling for more transparency. Moreover, NICE's portfolio has grown over the period of MATCH and will cover the provenance of all healthcare evidence.
- The level of interest in the area is evident from the HTAi (Health Technology Assessment International) annual conference. In Dublin in 2010 - it attracted 1300 delegates from industry, health services and academics. At a time of pared travel budgets, this is indicative of the interest and importance of the field.

“After decades of research, there is an acute lack of knowledge about ways to promote the design of more valuable innovations. Part of the solution, we suggest, is to develop a new collaborative policy-oriented research agenda that can bridge design processes, and health care needs and priorities. This idea is beginning to be recognized by academics and high-level policymakers around the world. However, only a few concrete initiatives have been implemented in North America and Europe (see www.match.ac.uk)...”

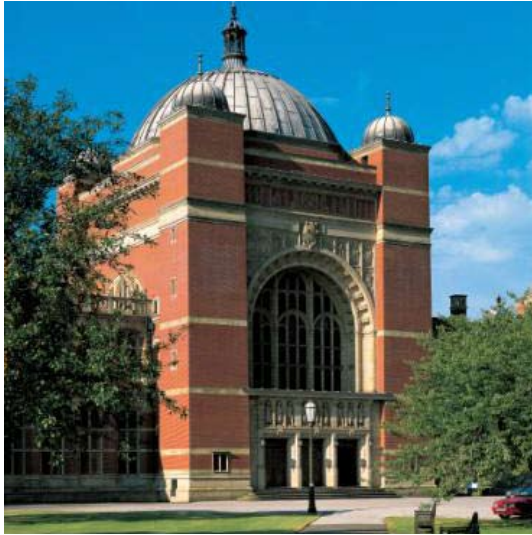
Lehoux, P., Williams-Jones, B., Miller, F., Urbach, D., & Tailliez, S. (2008). What leads to better health care innovation? Arguments for an integrated policy-oriented research agenda, *Journal of Health Services Research & Policy*, 13(4), 251-254

NHS restructuring away from regional and local area commissioning, a move to widespread GP fund holding and the end of PCTs and SHAs over the next 3 years, means that the decision-makers for new technologies are changing and MATCH will be looking for engagement opportunities here. A National Commissioning Group will remain for some specialised services and this provides an opportunity for further collaboration at the higher level. The National Innovation Centre will also likely see its role change with the closing of the NHS Institute for Innovation and Improvement. Finally, the disbanding of the Procurement and Supply Agency by the last government and the move of the device evaluation centres from CEP has provided an opportunity for closer involvement with NICE.

All this creates an opportunity to form, or be at the heart of, a globally-linked network of centres generating methods, tools and intelligence for this market, and delivering them in timely and accessible ways. Within MATCH, we see more people coming to us – from industry and from Government. MATCH is timely, working in the right fields and pulling disparate strands of thinking together in a critically important way.

“MATCH is an important project because it will help the healthcare industry develop an understanding of what is important when demonstrating the value of new products and will provide the practical tools to do this. Key contributors such as Professor Young, Professor Buxton, and Professor Lilford, have also helped to shape the way NICE evaluates new healthcare technologies. We are very grateful for their interest and input and look forward to a continuation of the successful interaction we have with MATCH.”

Dr Carole Longson, Director, Centre for Health Technology Evaluation at NICE



The Centre

MATCH has enjoyed stability as well as growth, and 6 of the original 10 Investigators are still with the programme – one having withdrawn, one having become Deputy of the HTA, and two having retired. Of the original crop of Research Fellows, six are still in post. Of those who have left, one now has a Chair in China, while two others are consulting commercially. Clearly, MATCH has benefited and been of benefit to some very bright and active people.

We have been fortunate to see this core augmented by many highly talented and motivated researchers, and with the PhD students that have increased capacity, MATCH now represents a significant and cohesive group of people.

The Principal Investigator, Professor Young, along with the Management and Administration team, is based in the School of Information Systems, Computing and Mathematics at Brunel, where, since the start of MATCH, a new healthcare research grouping has come together that includes Drs Barnett, Clarke and Taylor as co-investigators. The rest of the Brunel team is located in the Health Economics Research Group, founded by Professor Buxton (MATCH CI) and now directed by Professor Trueman. Over the period of the grant this team has maintained a research capacity of 3-4 Research Fellows including Drs Eatock and Shah who have been with MATCH since its inception. Currently there are 3 full-time PhD students at Brunel.

The Birmingham team is situated in the School of Public Health and the main investigators are Professor Lilford and Dr Cummins. The research strength has grown under the renewal from a single Senior Research Fellow (Girling) to two senior and one ordinary research fellow, with two PhD students.

The Nottingham team initially spanned three schools: Medicine, Social Science and Engineering. However, it is now concentrated in the Faculty of Engineering, and the three Co-Investigators are Professors Crowe and Morgan and Dr Sharples. The research team has averaged 3-4 people (Drs Craven and Martin being there from the start) and there are currently two PhD students.

The Ulster team spans the Schools of Engineering, Computing and Information Engineering and the Ulster Business School, and has four CIs: Professors McClean and Meenan and Drs Brennan and Dixon (who started as a founding researcher along with Dr Davey). The research team again averages 3-4 including the position originally supported by Invest Northern Ireland (FitzGibbon). There are no DTA students because Northern Ireland is funded differently, although the PVC (Research) has allocated a PhD studentship to MATCH and MATCH funded Dr Garg's PhD as part of the RIGHT commitment.

How good is our research?

There are three perspectives on evidence of academic quality in this Annual Report: the quality of the research in fields that we share with others, the quality of new and cross-disciplinary research where we can point to 'firsts,' and the quality of the people undertaking the research¹.

Firstly, then, we research in fields where others have dedicated research activity. Thus MATCH has competitors with greater critical mass in user needs and economic evaluation. Nonetheless we compete

¹ All references produced through MATCH are cited via the bibliography number. The full bibliography can be found in Annex 12. In contrast, MATCH-related papers appear as footnotes



in these fields. The Dong and Buxton paper [18] (nominated for best paper in the International Journal of Technology Assessment in Health Care for that year) is an example of the quality of research, and there are other examples in user needs analysis [74]; and in economic evaluation [20].

Secondly, research ‘firsts’ and examples of connecting previously unconnected concepts. We note that such work is harder to place for publication and the publications outlets that exist are still building their citation indices. Brown et al. [120] was, to our knowledge, the first demonstration of the experience curve applying to healthcare markets, while Dixon et al. [186] was, as far as we are aware, the largest survey of success factors in bringing new medical products to market. Both were published in new journals and both have established important links from which to extend current knowledge into the world of manufacture and the market.

Cross-connecting research includes the work linking economic evaluation to safety [57], or economic evaluation to business decision-making [20, 204]. The entire MATCH Plus agenda is an exciting initiative to fuse social science methods in user needs evaluation to economic analysis. The enormous payoff for such research lies in enabling user preferences to be expressed as economic premiums, which will encourage designers to migrate towards higher value products.

One of the benefits in the strategic investment that MATCH represents is that some work may be initiated early and then makes a connection much later. A case in point was Johal and Williams [1], which explored Real Options among other decision-making processes. We are returning to Real Options from an investment perspective with [20].

Finally, people: Professor Martin Buxton was awarded the ISPOR (International Society for Pharmacoeconomics and Outcomes Research) Avedis Donabedian Outcomes Research Lifetime Achievement Award in 2010 (see p.12). MATCH academics continue to attract invitations to prestigious international events, including 15

invited talks in 2010 alone. We note how some members have gone on to play a wider national role – Professor Hywel Williams, for instance, was an original investigator and is now Deputy Director of the NIHR¹ Health Technology Assessment Programme.

Are we making a difference?

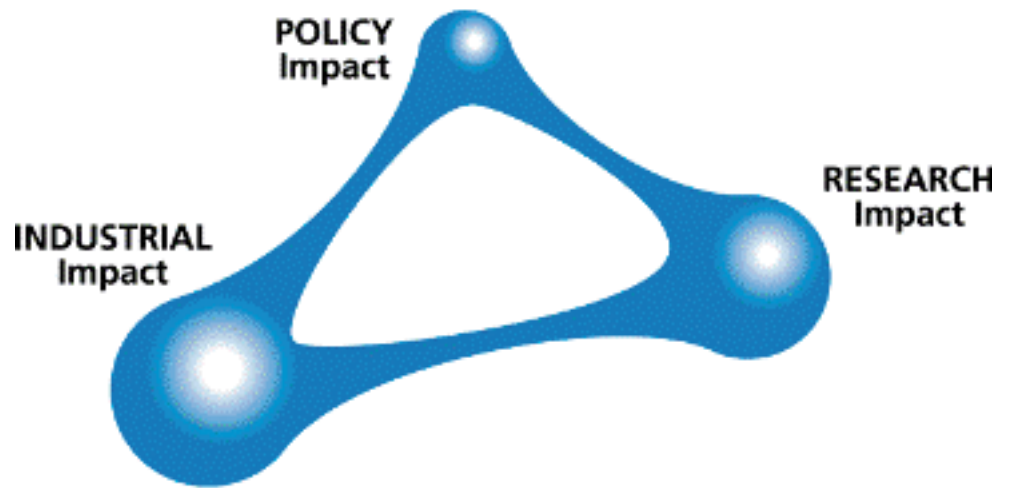
In the MATCH strategy developed in 2005, we emphasised three areas in which we wanted to make an impact. The first was in the world of academic research. The second was the field of policy, and the third is the domain of industry to which we will turn presently. (see Commercial Exploitation p.14)

Research impact

The academic quality and impact of MATCH research is discussed above. In summary here though, a focus on one of the established academic metrics – that of citations – reveals that, even in ISI journals (which do not include many of the cross-disciplinary journals in which we publish) we have a total of 87 citations thus far. In more established fields this would represent a modest position, but we are encouraged by it and note that it is well ahead of our agreed target of 40. In keeping with the range of disciplines and communities of practice which we span, thus far MATCH has articles published or in press across a range of 48 peer reviewed journals. Twenty four of these (50%) have an ISI impact factor. The mean impact factor of the journals we have published in is 2.428 (median 1.7985). The number of journal papers we have published has risen from 15 and 14 in 2008 and 2009 respectively to 19 that are published or in press in 2010. Thus far in 2010 a further 18 have been submitted suggesting MATCH is on track to double the annual publication count in line with the commitment made in this area².

¹ National Institute of Health Research

² Full details of all MATCH publications can be found in Annex 12



Policy impact

MATCH has several different stakeholders at the governmental level and has maintained fruitful channels of communication and endeavour with each.

- Department of Health. The DH has committed £200k/annum to MATCH through the MATCH Plus grant. The Deputy Director of the DH R&D organisation, Dr Russell Hamilton, served for a while as Chair of the MATCH Steering Committee, before withdrawing due to pressure of work. More recently, Jill Dhell commissioned the MATCH guide, *Evaluating Health Devices*.
- NIC has invested £165k in MATCH and the MATCH team has worked on taking the health economics tool out to the Innovation Hubs, and in helping to design the Innovation dashboard (see NIC Case Study, Annex 6)
- NICE does not commission methodological research, but communications have been in both directions through public meetings, shared staff and other interactions. A summary of MATCH engagement with NICE is provided in Box 1.
- MATCH was involved from the inception of the Centre for Evidence-based Purchasing where health economics methods entered medical device procurement for the first time. The CEP work has now migrated to NICE with the creation of the Medical Technologies Advisory Committee (MTAC). MATCH Nottingham was an approved supplier to CEP and is now supplying MTAC via the Evaluation Pathway Programme for Medical Technologies.
- NIHR. The National Institute for Health Research has emerged during MATCH as a funding body of significance in applied research. Two MATCH Investigators, Professors Lilford and Williams, are Senior Investigators in the NIHR Faculty, while Professor Young was a speaker at the launch of the NIHR's i4i (invention for innovation) programme at the QE2 Conference Centre in Westminster on July 16 2008. MATCH Investigators hold many millions of pounds worth of NIHR grants, including the prestigious £10M CLAHRC¹ at Birmingham.

- NPSA: The National Patient Safety Agency invested £250k in the first phase of MATCH. The relationship has been strengthened by two personnel transfers. Firstly, Dr Beverly Norris, part of the MATCH team at Nottingham, took over as the Human Factors lead at NPSA and, while she was on maternity leave, Dr Jennifer Martin, a MATCH Research Fellow, was seconded to NPSA for 2 days a week. This collaboration led to the recently published NPSA guide, published using the MATCH material (see Annex 7).
- PASA: The NHS Purchasing and Supply Agency was party to setting up MATCH and invested £165k in MATCH. MATCH has worked with the CEP to embed MATCH methods in procurement decision-making (see Annex 5).

Although the healthcare landscape is constantly changing - PASA and NPSA are no more, NTAC and MTAC are just emerging - the scene is of a close and consistent engagement with MATCH at a variety of levels – from the coal face to the very top of these organisations.

The 2010 Avedis Donabedian Outcomes Research Lifetime Achievement Award was awarded to Professor Buxton by ISPOR (International Society for Pharmacoeconomics and Outcomes Research), a highly respected global organisation that promotes health economics and the evaluation of how health care interventions affect patient wellbeing².

The Donabedian Award is bestowed on those whose research has shown demonstrable value to health outcomes, rather than purely academic achievement.

Professor Buxton, who is the eighth person to receive the prestigious award is only the second UK academic to do so.

1 Collaboration for Leadership in Applied Health Research and Care

2 http://www.ispor.org/awards/donabedian_.asp

Box 1: MATCH links with NICE

MATCH has maintained a positive working relationship with NICE, through shared meetings, and key personnel. In addition to bilateral meetings, MATCH presented at an early NICE Conference [65], the NICE Chairman, Sir Michael Rawlins, participated in the MATCH Public Interest Forum in 2005, Dr Sarah Garner, Associate Director, Clinical and Public Health Directorate presented at the MATCH Workshop HTAi 2008 and the Chief Executive of NICE, Sir Andrew Dillon presented at the Public Interest Forum in 2009. In addition, we note the following links:

Professor Martin Buxton has been actively involved with NICE since its inception:

- a) Was a member of the first Technology Appraisal Committee (1999 - 2002), of the CJD Sub-Committee of the Interventional Procedures Programme (2004 - 2005), a member, of the STA Review Reference Group (2007 - 8), and of the Appraisal Committee for Patient Safety Programme (2007 - 8).
- b) Is a member of the Diagnostics Methods Working Group (since 2009) and of the panel of experts for NICE early Scientific Advice Programme (since 2009).
- c) He was also an invited speaker for NICE workshops to consider the appropriateness of the NICE Cost-Effectiveness Threshold¹ in April 2009 [37] and to inform the Kennedy Study on valuing innovation in May² 2009 [36].

Professor Richard Lilford:

- a) Served on the NICE appraisal committee 2003-2006.
- b) Was appointed Vice Chair of the NICE R & D committee 2006 and when it was disbanded in 2010 he was appointed to the panel of scientific advisors.

- c) Commissioned a number of research projects for NICE in his role as director of the NHS Research Methodology programme 2001-2006.
- d) Represented NICE on the Institute of Medicine advisory group on clinical trials in Washington DC in January 2007.
- e) Is a previous speaker at the NICE annual conference in Birmingham.

Professor Paul Trueman and Dr Louise Longworth are both currently serving on the NICE appraisal committee and both have previously contributed to the development of national guidance on a range of topics including obesity, smoking cessation and physical activity. Paul was also involved in the early stages of the development of new quality and outcomes indicators for primary care, overseen by NICE.

Professor Terry Young served on the Evaluation Pathway Stakeholder Reference Group Update as part of NICE's setting up MTAC and presented at the 2004 NICE Conference [65].

Dr Joanne Lord and Dr Louise Longworth have both moved from NICE to Brunel and both now contribute to MATCH.

1 <http://www.nice.org.uk/aboutnice/howwework/researchanddevelopment/NICEThresholdWorkshop.jsp?domedia=1&mid=6A8D2D44-19B9-E0B5-D40EAA4E6B761799>

2 <http://www.nice.org.uk/aboutnice/howwework/researchanddevelopment/KennedyStudyOfValuingInnovationWorkshops.jsp?domedia=1&mid=CF117231-19B9-E0B5-D4C85A0EBDA06992>



Commercial Exploitation

In an IMRC context, industrial impact is generally viewed as a primary element of exploitation. From the start, MATCH set out to engage with industry and the clinical sector to undertake research that was oriented towards industrial needs and which took account of the environment in which they are required to operate. There were several barriers to overcome including the fact that much industrial-facing research has little RAE/REF impact, that universities are not well placed to meet industrial deadlines, and that as soon as anything becomes commercially interesting, it can disappear from view.

As an example of this, even though DePuy International Ltd (a J&J company) was funding MATCH and watching the stage-gate research mature and the early-stage decision-making theory come together, it kept the findings from its own in-house enhanced business review pathway under wraps, as it regarded it as commercially sensitive. Nonetheless, Mick Borroff, Clinical and Reimbursement Lead for DePuy International, noted that MATCH had provided the company with an important means to obtain a critical perspective on stage gates for the company.

Nevertheless under this collaboration we achieved the following with companies with whom we worked:

- The added value of using novel methods of hip and knee alignment in orthopaedic surgery and the value of technology to improve clinical outcomes and to track implant alignment post implantation as a means of enhancing patient follow-up. (see DePuy Case Study, Annex 10)
- The value of employing user needs-based research and quantifying the role that it has designing more effective hand-held technology – in this case a device for imaging blood vessels (see Moor Instruments Case Study, Annex 11)
- Boston Scientific and the Regional Supplies Agency (the centre for NHS procurement in Northern Ireland) supplied medical device pricing and cumulative volume data to MATCH which assisted in establishing the relationship between price and total volume of product manufactured [120, 121, 147]. This is the first time that this relationship, previously found in other sectors, has been documented in relation to medical devices. The experience curve methodology was used to inform decisions regarding new product introductions (see Boston Scientific Case Study, Annex 9).

MATCH has undertaken qualitative work to help support preliminary clinical value propositions for new devices. The outcomes from the work have proved to be beneficial for the companies involved.

Such influences are clearly profound, but can be hard to identify using the traditional measures of impact as jobs created, revenue increased, etc. However, it is important that they are recognised and MATCH has tried hard to build evidence in this area. The difficulty of attributing impact directly to research interventions is also evident in the clinical context, as the quote from Clare Picton (Consultant in Emergency Care Nursing at Hillingdon Hospital where MATCH has done modelling research) indicates.

“The work performed by MATCH was very beneficial in providing external and independent validation for the project which is at an early stage of development... I would recommend the use of MATCH as an objective, independent, and importantly, connected resource for companies developing products and services for the Healthcare Sector.”

Gerry Burke, Synergy Flow Ltd.

“Working with MATCH academics has challenged some of our assumptions and internal processes particularly on the early identification and validation of a product’s value to payer and provider stakeholders.”

Mick Borroff, DePuy International (see Annex 10)

“...My company was greatly assisted by the innovative work of the Birmingham team led by Professor Richard Lilford. The supply side economic model they constructed, along with clinical expertise that allowed them to frame the problem appropriately, helped the company to decide very early in the development process in the absence of clinical data and strong market data, to invest in use of regenerative medicine for hernia repair, rather than construction of a tissue engineered bladder.”

Yves Bayon, R&D Expert Covidien – Sofradim Production (see Annex 8)

“Although difficult to say if directly attributable to the model, the Trust has now commenced the process of implementing a bed management module for the current IT system, to aid ‘pulling’ patients through from A&E, rather than A&E having to ‘push’ the rest of the hospital to get them moved on”.

Clare Picton, Hillingdon Hospital (see Annex 2)

The easiest way to determine whether industry values something is to see if it is willing to pay. However, this critical marker is commonly obscured in the health sector by the many initiatives that offer free support, particularly to SMEs, and as a result there is an ethos in the sector that such knowledge is cheap. In these circumstances, MATCH has striven to ensure that the value of the knowledge that it provides is acknowledged even in situations where there is no direct payment. Whereas our funding model currently provides scope for this approach we recognise that sustainability will require a change in how the innovation we provide is supported. The current cull of quangos that provide free services is likely to reveal the nature of the true market and what people are really prepared to pay should emerge.

MATCH methods have been transferred to other major research programmes such as the EU Framework Programme, STEPS, and the EPSRC Grand Challenge, Remedi and thereby to other companies. For example, Sofradim, a company involved in the STEPS project, made an important investment decision worth many millions of Euros to move away from one tissue engineered product to another following the recommendations it received from direct application of the MATCH Headroom method (see Sofradim Case Study, Annex 8).

MATCH teams have been provided to respond to consultancy or short-term requirements. For example, teams of researchers have undertaken contracts for CEP as well as being contracted for PICD and NTAC¹. The latter activity involved evaluation of technologies that the DH believes might save up to £5billion/year if adopted appropriately.

From 2003-2008, the MATCH membership scheme raised nearly £620k from around 30 partners. Although a single contributor (J&J) accounted for over a third of that sum, it did provide for structured interaction with other companies, large and small. Along with the additional grant income attained by the investigators, these funds supported the Research Fellows as the front-loaded MATCH programme funds ran low. The industrial income was targeted in a manner that allowed MATCH to be responsive to emerging opportunities. As it became clear that SMEs, in particular, could not afford the fees required to engage directly with fundamental research, MATCH started to explore the development and use of generic methods and tools based on the work being undertaken in the core themes.

MATCH has been delivering tools and training courses since September 2007. There have been 11 such courses thus far. These have been delivered to 188 people from 119 companies and organisations (see p.36). The reach of these events is broad as eighty seven of the companies attending these workshops were not MATCH members. Process based evaluations of these events have been very positive [3], but it is still early days in terms of evaluations of outcome. On the basis of the positive feedback received to date, it is intended to turn a number of the tools into high-quality (commercial grade) software-engineered packages.

In addition to the training events and workshops over the last two years there has been a range of other events arranged specifically in order to engage with industrialists. Since April 2009, MATCH has held Lunches, a Public Interest Forum, an Ulster Open Innovation Event and a Business Breakfast. These have attracted over 50 companies.

1 NHS Technology Adoption Centre



“Definitely a useful tool which I will be recommending is routinely included in our current stage gate review process. Formalising inclusion will avoid costly revision down the line”

Clinical Director, Orthopaedics Developer

“I will use the MATCH tool to help prioritise product innovation projects”

Innovation Lead, NHS Primary Care Trust

MATCH has started to develop a strategy that will allow it to expand this approach with a series of related commercial ventures. The first of these is a joint venture with BITECIC Ltd, a company offering specialist training and consultancy services to the health industries. As evidenced by the formation of the MATCH/BITECIC strategic partnership, BITECIC have identified the business viability of the MATCH tools and workshops and will be delivering them in the future. The partnership involves the 50:50 co-funding of a staff member to take the tools and training that MATCH has developed out to industries across the UK and globally. The appointment was made in July 2010 for an initial period of 18 months and is funded by money that MATCH has raised independently of its Research Council funding. Working with BITECIC has forced MATCH to re-evaluate its offering and its unique selling points. Much of this new thinking is described in the section on future strategy.

On the basis of the feedback received by SMEs and others, the MATCH membership scheme was changed in 2009 to spread costs more evenly and to promote a model where people joined for a relatively modest fee and then bought specific services. Unfortunately, this coincided with a year that was a commercial disaster for many companies. Willingness-to-pay dropped, and income – a critical marker for MATCH – fell to around 25% of pre-2008 averages. Fortunately, MATCH has reserves from previous years’ fees and additional grant income to allow it to continue to engage with industry during the downturn and to develop a strategy to rebuild the paying-membership base as the economic climate improves. There are already some signs of a recovery with three companies having joined or re-joined MATCH in the last three months.

“Where the SWOT does not show a clear pathway, the MATCH tool may allow some easier internal decision making when making recommendations whether to proceed an ideal/concept to prototype stage.”

Director of Consultancy engaged in market assessment of novel medical devices

“This is an exciting opportunity for us to lend our experience in reaching out to a wider set of users who really need to understand and benefit from MATCH’s tools and guides as they enter a world that demands cost efficiency from new health technologies.”

BITECIC Director Dr John Egan (see Annex 3)

Management

MATCH was the first distributed IMRC and, from the beginning, has operated along slightly different lines from the rest – not least in running an integrated programme with all research costs fully committed from the start. Such an academically-driven, multi-disciplinary, research programme, simultaneously focused on impacting industrial practice and policy, represents an extreme management challenge. Over the course of the MATCH programme, we have addressed this challenge in a number of ways.

There are now many multi-university, multi-disciplinary research centres and MATCH stays abreast of management developments as PI Prof Young peer assists the EPSRC programmes HaCIRIC and CHI-MED, and the NIHR programme PATH, as well as sitting on the Assistive Living Innovation Platform Steering Group for the TSB. The emerging theme is that management requires a mix of structure, vision and lots of interpersonal interaction.

MATCH has experimented with a lot of formal and informal measures over the past seven years and has settled for a system of formal structures of responsibility, and regular, light-touch review, interspersed with plenty of dialogue and consensus building. At times, the process may look a little chaotic but it is delivering.

MATCH management structures

MATCH's *Executive Committee* takes all management and financial decisions related to the MATCH grants (including MATCH Plus) and the industrial and other moneys received by Brunel on behalf of the consortium. It contains a representative from each of the MATCH universities

and is chaired by the PI. As appropriate, the MATCH Programme Manager, Communications Manager or Accountant may be in attendance.

The *Steering Committee* takes a more strategic view and is chaired by the Chief Executive of the Association of British Healthcare Industries and meets twice a year. The Executive Committee seeks to implement its recommendations – for instance to appoint a Communications Manager (which was done, under MATCH Plus funding). Most recently the recommendation was to broaden industry representation on the Steering Committee. This will be implemented by April 2011.

MATCH has a team of *support staff* available – some of whom are partly-funded on other programmes. There is a Programme Manager (Mr Taylor), a Communications Manager (Mrs Deadman), an Accountant (Mrs Jayaratne) and an Administrator (Miss Anagnostou) at Brunel, with Administrators at Ulster (Miss McCormac) and Birmingham (Mrs Hill) and a currently vacant position at Nottingham.

Each of the four themes has (at least) one Manager: Professor Lilford (Birmingham) and Dr Cummings (Birmingham) for Economic Evaluation; Dr Barnett (Brunel) for User Needs (including supervision and integration of the MATCH Plus themes); Professor Morgan (Nottingham) and Dr Taylor (Brunel) for Tools & Training; and Dr Dixon (Ulster) for Implementation. Their task is to coordinate the research, prepare and manage the six-monthly reviews and hold theme meetings every six weeks.



MATCH processes

MATCH has gravitated towards a 6 monthly review cycle of *Internal Review* in which an external chair (Professor Peter Wells, FRS from Cardiff University) and usually one external reviewer (often from the MATCH partner, Adams Business Associates) together with non-executive members of the team review progress. In October 2009, the team was strengthened by an international member, Dr Peter Luijten, Chief Scientific Officer of CTMM in the Netherlands. Each theme leader submits an analysis of the past 6 months and plans for the next 6 months. The Internal Review Committee deliberates, the Executive Committee responds, and the Programme Manager amends the project plan accordingly. These are all on course, with the most recent taking place on the 25th October 2010 in London. As an example of how the process works, the review held on 16th April 2010 was followed by a Principal Investigator response to Theme Leaders on 30th April. The Executive Committee reviewed findings on the 10th June 2010 and a new version of the Project Plan was released on 9th July 2010.

A range of further processes to enable on-going strategy review are in place including:

Monthly telephone conferences between representatives of each university: The teleconference is held on the third Wednesday morning of every month.

Regular Executive Committee Meetings: The Executive Committee meets three times a year – more depending on business requirements.

Steering Committee Meetings: The Steering Committee meets twice a year in April and October. The Chairman, Peter Ellingworth, has been extremely supportive of MATCH research gives his time generously to this end.

Public Interest Forum: Since April 2005 there have been four Public Interest Forums, with a number of eminent speakers including Sir Andrew Dillon, Chief Executive of NICE and Professor Kent Woods, Chief Executive of the MHRA. We are currently organising future PIFs annually and dates have been set for 2011 – 2013.

Internal conferences: These take place twice a year, the last four were held in Windsor (Jan 2009), Melton Mowbray (June 2009), Birmingham (Jan 2010) and Ulster (June 2010). The dates for the internal conferences for the remaining three years of MATCH have already been circulated.

Annual away-day for MATCH investigators: As many MATCH Investigators as can, attend an annual away day in the autumn. The last one took place in September 2010. This event provides a candid forum in which the strengths and weaknesses of the programme can be discussed.

Training

Traditionally, the main development of people occurs through PhD studentships, which are funded either directly on the grant or through the Doctoral Training Account (DTA) system. The exception is Northern Ireland where DTA bursaries are not available although alternative funding has supported Dr Lalit Garg (main MATCH grant) and Jennifer Gillespie (Ulster) in their doctoral studies.

Up till November 2010, four doctoral students linked to MATCH have been awarded a PhD.

- Kirandeep Chahal's research focused on combining hybrid modelling techniques (2006-2010). She graduated from Brunel with a thesis, "A generic framework for hybrid simulation in healthcare." Kirandeep is working as a part-time lecturer and applying for industrial posts.
- Jason Gordon (2004-2008) graduated from University of Birmingham. His research addressed aspects of elicitation and his thesis was entitled, "The elicitation of Bayesian prior probabilities and their use in applications of medical decision making". Jason is currently employed as a Postdoctoral Research Fellow (Health Economics), at the University of Adelaide, Australia.
- Elizabeth Morrow (née Smith) (2005-2008) graduated from King's College London. Her thesis was entitled "Organisational and professional readiness to involve service users in research".

She is currently a Research Fellow in the National Nursing Research Unit at King's College, London.

- Lalit Garg worked primarily as part of the IMRC's contribution to the RIGHT project, from October 2006 and graduated in June 2010 with a thesis on "Unified modelling for care of the elderly." He is currently working at the University of Ulster as a Research Fellow and has published several papers.

MATCH currently has nine full-time on-going doctoral students and 1 part-time student at the following universities:

Birmingham

- Elpiniki Laiou has explored the effectiveness in the training of devices and her thesis was entitled "The effects of practical training methods of different forms and intensities on the acquisition of clinical skills." Elpiniki is currently working as an ICU nurse in her native Greece while her thesis is being assessed.
- Louise Hartley is researching comparative studies of clinical trials and economic evaluation in different countries.
- Amanda Chapman is testing the validity of the headroom method of early economic evaluation for medical devices.

Brunel

- Christian Boehler is researching geographic issues associated with economic evaluation.
- Anila Shah is researching adoption models for telemedicine.
- Urvashi Sharma is conducting research into user perspectives on telemedicine services.
- Dimitra Pappa (part-time fees-only) is researching pharmacovigilance.

Nottingham

- Alexandra Lang has been researching the use of medical technology by adolescents.
- David Keane is researching users' behaviour with respect to imaging diagnostic medical devices.

Ulster

- Jennifer Gillespie is working on Networks of Queues for Patient Pathway Modelling. She is funded through a University of Ulster DEL (Department for Employment and Learning) award provided by Professor Norman Black PVC (Research & Innovation) to support RIGHT/MATCH collaboration.

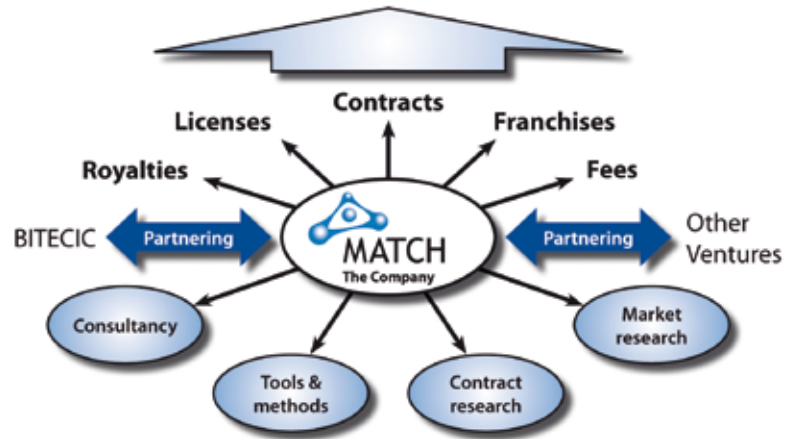
Although not formally recognised as training, the impact of the multi-disciplinary and cross-cultural experiences on research staff is also relevant here and is well reflected in the positions that research staff have moved into when leaving MATCH:

- Dr Nick Botterill moved to a subsidiary of the University of Nottingham, a company called eminate Ltd.
- David Braunholtz moved to the University of Aberdeen as a Senior Statistician.

- Dr Mala Bridgelal-Ram moved to the Royal College of Physicians as a Project Manager at the Health Informatics Unit.
- Alan Brown gained a Lectureship in Bioreactor Technology in 2009 at the University of Ulster.
- Dr Dorian Dixon gained a Lectureship at the University of Ulster in 2006 and is now a Co-Investigator and Theme Leader in MATCH.
- Dr Hengjin Dong became a Group Leader of International Health Economics and Technology Assessment at Heidelberg University in 2006. Subsequently he became Professor and an Executive Director of the Center for Health Policy and Management Studies at Zhejiang University, China.
- Dr Sukhvinder Johal moved to RTI Health Solutions, Manchester.
- Dr Michael Scott left to join the National Coordinating Centre for HTA at Southampton University in 2006.
- Dr Lotte Steuten is now Assistant Professor at the University of Twente (the Netherlands).
- Dr Celia Taylor gained a Senior Lectureship at Birmingham University in 2010.

"From a personal point of view, working on a long-term project such as MATCH has provided an all too rare opportunity: a research post with relatively secure funding! This has allowed me to develop substantial expertise in one particular field of research, and as a result develop a national reputation in this area. In addition, in 2009 I received considerable encouragement from MATCH to complete a 9 month secondment to the NHS National Patient Safety Agency, a role that allowed me to develop new skills as well as to apply those gained through MATCH to specific patient safety projects within the NHS. My time on the MATCH project has allowed me to develop from a junior post-doc researcher to an established expert in medical device human factors, capable of securing my own research funding and managing research staff and students. "

Jennifer Martin, MATCH research fellow from 2003 (see Annex 7)



Where are we going?

Moving the focus from past impacts to the future, our strategy has proven to be robust and sustainable. The main thrust following the mid-term reviews was to develop a roadmap. This has been vigorously pursued, by commissioning two studies on MATCH's options (by YTKO in 2006 and Red Ochre in 2008) and then by putting in a Knowledge Transfer Centre bid, MIKADO. Although this proved unsuccessful in terms of funding, it challenged the four universities to convert the underpinning thinking into some radical, collaborative business planning.

One resulting and exciting prospect is to create a legal entity in which all four partner universities have a stake. The knowledge generated by MATCH will be managed through this vehicle, so that profits from the ventures can be returned to the MATCH universities as research grants.

This is a radical and ambitious vision and as noted earlier, as part of our initial validation, we have teamed up with BITECIC Ltd and Matrix Evidence Ltd to start generating revenue streams around the MATCH tools, training and consultancy. A significant piece of business planning has created an outline portfolio which indicates that MATCH needs 8-12 such ventures to become self-sufficient and to fund the research at its current levels. MATCH is currently in commercial negotiations with several parties interested in potential collaborative ventures, not all of which will be in the public domain by the time this report is submitted.

Figure2: Schematic of a sustainable structure for commercialising MATCH research. Income from a range of revenue streams is eventually returned to the MATCH research Groups as grants for basic research, contracts for applied research, or consultancy.

"We welcome the opportunity to combine MATCH's high quality methods and Matrix's consultancy services within the healthcare sector, to enable decision makers to make the most effective and valuable use of their resources"

Kevin Marsh, Chief Economist, Matrix Evidence (see Annex 1)

Internationalisation

MATCH enjoys a strong international profile, especially in the US, where the Investigators are now making perhaps a dozen invited appearances a year. The MATCH name googles well, rising up the first page, so that it is now preceded only by a commercial dating agency. An analysis a few years ago placed it lower down the list, for instance, behind a betting website, so its profile continues to strengthen. Over the past six months, the average number of monthly visits to the MATCH website has been 330 from the UK, 63 from Europe, 44 from North America, and 27 from the rest of the world.

At the start, the MATCH team agreed that it would not seek an international story until it had something to relate. Thus, the first phase of MATCH was very much focused on generating high quality output and exploiting the customary academic channels of papers, conferences and visits. Latterly MATCH has been seeking a more coherent approach to ensure sustainability of MATCH's developing international reputation.

Attempts to set up a joint position between a MATCH university and a university elsewhere in the world have not yet succeeded, although negotiations went a long way with the University of Twente before it became clear that a 50:50 senior academic or professorial appointment was not a viable option.

MATCH's international reputation has risen, as evidenced by the many prestigious invitations to speak in the US. Elsewhere, MATCH's profile has been boosted by:

- CTMM (the Centre for Translational Molecular Medicine) in The Netherlands, asking Prof Young to sit on its International Scientific Advisory Committee in managing its €300M+ of programmes.
- The Royal Society sponsoring a MATCH/RIGHT event at the University of Cape Town in May 2009. There is strong interest in finding a way of working together and Dr Taylor is taking some of his sabbatical at UCT.
- Follow-up to a Trade Delegation to California in 2010 funded by the TSB, Professor Lilford has requests for closer MATCH ties and he has been invited by the British Consulate-General to make a follow-up visit in February 2011.
- A meeting in February 2009 between the PI and the Haute Autorité de Santé (HAS) in France to talk about linking business-facing and government-facing decisions through a common framework.
- After an introduction brokered by the Association of British Healthcare Industries, the PI's meeting in May 2010 with Assistant Professor Chiaki-san SATO from the Policy Alternatives Research Institute (PARI) at the University of Tokyo to discuss MATCH's work and scope for collaboration.
- Following correspondence during August 2010 with the Department for Medical Technology at the Norwegian Foundation for Scientific and Industrial Research (SINTEF), MATCH's recently proposed meeting to discuss the incorporation of user needs into the process of medical device development.

“With advanced R&D capabilities and engagement of user communities across all major sectors, the experience of MATCH is immediately relevant and timely in the US, where we have a historic opportunity to define national goals and measures for meaningful use of health information technology, authorized under the American Recovery and Reinvestment Act.”

Professor Marietta Baba, Dean, College of Social Science, Michigan State University, August 2010

- The PI's discussions with the Clinical Program Development arm of US Health Insurance company Blue Cross Blue Shield (BCBSM) about meeting with MATCH in Michigan during November 2010.
- Miscellaneous contact in May and June 2010 between the PI and the Danish National Board of Health; the Director of Health Technology Assessment & Innovation at Alberta Health Services in the US; the Senior Medical Adviser to the Ontarian Ministry of Health & Long-term Care; the Canadian Agency for Drugs and Technologies in Healthcare; and the Director of Health Care at the Center for Information Technology in the Interest of Society (CITRIS) at UC Berkeley.
- Following the invited paper by the PI at the Almaden Institute, the PI and Dr Barnett visited the US in November 2011 to meet the Dean of the College of Social Science at Michigan State University.

Under MATCH Plus, some funding is available to support the internationalisation of MATCH. Several things are becoming clear.

Firstly, the MATCH agenda, with its emphasis on connecting diverse elements of new product development, is resonating strongly with key groups around the world. Secondly, a group like MATCH will struggle to strike up a lasting relationship with universities around the world on a university-to-university basis.

MATCH therefore has two elements to its strategy. In the short term, the Executive Committee recognises that MATCH's international profile now warrants a fuller outreach and funding has been allocated to enable a little more travel with a view to setting up strategic ventures.

Meanwhile, and in the longer term, MATCH is working on what a 'product' might look like in terms of meeting the needs of institutions around the world. The idea of MATCH*inside* – a service that offers the basic research results and workshops for academics – is being considered. On this model, academic institutions might sign up as MATCH*inside* partners and receive annual or six-monthly workshop support, and then be able to offer franchised services (training, consultancy, etc) to the local healthcare industry and providers. The planning for this is still at an early stage. However, it offers an innovative way of spreading the brand around the academic world without having to set up bilateral academic exchanges or arrangements.

In summary then, the MATCH message is increasingly popular internationally and there is an appetite, particularly in North America to work with MATCH. The mechanisms being planned now should start bearing fruit by 2012.

The MATCH Projects

Overview

MATCH has evolved through several stages. At the heart of the conceptual and methodological development throughout, lie the *Economic Evaluation* and *User Needs* themes – both broad in their remit. *Economic Evaluation* builds on an excellent pedigree of two well-established groups at Birmingham and Brunel, and has therefore been the most rapid to deliver significant output at the highest level. The *User Needs* theme, as configured under MATCH, links human factors and social science expertise to explore the implications of assessing user needs both for the design process and for the organisations that need to elicit and act upon user needs information.

Implementation has been an important theme in making MATCH accessible to the many stakeholders that will not engage on a purely academic basis. This includes many of the Department of Health and NHS players (CEP, PASA, NIC, Hospital Trusts, etc) as well as the outreach to SMEs through visits and training. These organisations are looking for the MATCH concepts to be fleshed out or are looking for a more pragmatic rationale for technology adoption or re-engineering of their system. There are therefore several examples of simulation, as well as work around point of care devices and telemedicine.

Finally, we have a theme, in *Tools & Training*, with the remit and (shortly the extra resource), to deliver a regular stream of high quality tools and guides with the training packages to promote and back them. The question of ‘tools’ has been difficult from the start. Everyone said they wanted one, few could agree on what a tool was. The development and deployment of the Health Economic Tool and the emergence of guides under the MATCH brand or jointly produced with key agencies, has been a major development of the past 2-3 years and has clarified the way ahead.

Over recent years this portfolio of research has become more integrated - we outline many areas of joint working in the Theme reports below - and the rationale for such a wide-ranging palette of research becomes clearer to our colleagues, collaborators and customers.

People in the *Economic Evaluation* project:

- Brunel: Martin Buxton and Paul Trueman with collaborative support from Joanne Lord
Researchers: Jeshika Singh and Ji Hee Youn
PhD student: Christian Boehler
- Birmingham: Richard Lilford (Project Leader), Carole Cummins and Jianhua Wu
Researchers: Alan Girling and Lily Yao
PhD students: Amanda Chapman and Louise Hartley
- Ulster: Michael Brennan
Researcher: Shirley Davey

Economic Evaluation

Theme Description

This project aims to enhance the process of economic evaluation of devices and hence decision-making across the product development cycle, primarily through improving estimates of effectiveness and using these in more appropriate economic evaluation models. Taking a unique supply side perspective on health economics, where value is defined in health gain per unit cost, empirical work conducted within this theme aims to support product development in the medical device industry through the development of theory and methods. We stress both fast and frugal methods that companies may use as well as more formal methods which exploit decision nodes in the development pathway.

Our work programme can be conceptualised along a spectrum from fundamental development of theory through to collaborative applications in industrial settings. The *economic evaluation* project adds value by considering decision-making as a sequential activity across the whole product development cycle. The development of methodologies from supply side health economics can be seen as occupying the middle ground in this spectrum of activities.

In doing this work we also make some generic contributions which are relevant to both the supply and demand side with special emphasis on both the elicitation and modelling of utilities. Similarly we have carried over some of the models that we have developed into the evaluation of service delivery interventions.

Previous innovative work on optimal pricing mechanisms will be continued in relation to the new government's policy of value based pricing. This is particularly germane to the device industry where heavy production costs may often limit the room for manoeuvre or price elasticity.

Strategy and Objectives

The overall strategy of the *Economic Evaluation* project has been to develop methods to assist industry to determine the likely market for their products while they are still at the concept or development phase. We bring a health economics perspective into these deliberations and extend the reach of health economics on the supply side. A recent systematic review confirms that there has been minimal development of techniques for supply side health economics¹ in respect of medical devices. Our principal task is therefore no less than to develop a set of techniques for health economics to inform investment and development decisions in this area.

We aim to:

- develop the field of health economic analysis as evidenced by a high standard of papers
- take significant steps to strengthen the industry by propagating innovative methods
- increase the rate of adoption by commercial and governmental organisations

¹ Hartz S, John J (2009) Public health policy decisions on medical innovations: what role can early economic evaluation play? *Health policy*, 89, 2 :184-92

Significant research results

The significant contribution of the MATCH *Economic Evaluation* team is located in four main areas:

Supply side health economics

Our unique work in this area is reflected in our publications, both on fast and frugal methods that companies may use in their product development, (including open business models [15-17, 27]) and in formal methods that exploit decision nodes in the development pathway [20]. There are also generic contributions relevant to the supply and demand side with special emphasis on both elicitation and modelling of utilities [26]. Expertise in this area has increased our credibility on commercial exploitation (see Sofradim and DePuy Case Studies, Annexes 8 and 10)

Safety premium

This strand of research explores the phenomenon that decision-makers appear to be willing to spend more to avoid a health loss by averting a lapse in safety standards than to avoid the same loss through 'regular' treatment. We identified in the literature that factors such as preventability, dread, controllability and trust affect the value of safety and decision-makers' willingness to pay and have confirmed that this is indeed the case in a series of structured interviews around safety scenarios with healthcare decision-makers experienced in safety management [29]. To see if their preferences accord with those of the public, a large survey of members of the general public to empirically ascertain their relative preferences for NHS spending to achieve health gains from safety related expenditures and from other health care situations, has just been completed and is currently being analysed. This research will fill an important gap in both the patient safety and health economic literature, and could materially influence resource allocation decisions.

Transferability

We are conducting work to establish the relevance of an economic evaluation produced for one geographic area to another location of interest. Multivariate multilevel modelling is being used to integrate secondary cost-effectiveness data, facilitating the assessment of 'contextual effects' on country level whilst controlling for 'baseline characteristics' of the studies included in the dataset.

These factors include the estimates of effectiveness, a topic which we have explored in depth showing for the first time that there really are inter-country differences in the results of randomised trials. This was part of Louise Hartley's thesis to be submitted for publication in December 2010.

We have developed a form of meta regression, "panoramic meta-analysis", in which we seek to learn about generic scientific principles by studying

"Working with the Birmingham team also improved substantially our organisational awareness and health economics, especially as decision tools for the development of new products at the concept stage"

Yves Bayon, R&D Expert, Covidien-Sofradim Production (see Annex 8)

"The collaborative development through Match of a Markov model to calculate the potential health economic value of Computer Assisted Surgery in knee joint replacement has been of great value to the business. The publication is now a widely quoted key reference in the literature and the results from the model are being integrated into a provider proposition tool which sales people will use to help hospitals understand the economic proposition of adoption of this technology."

Alan Ashby, Vice President Global Concept Development, DePuy International (see Annex 10)

the effect of the same treatment across many different diseases [9, 205] As part of this work we have taken a new approach, going beyond simply looking for a statistical relationship between disease free and overall survival, rather calibrating the size of the relationship between these variables [11].

Finally, we are undertaking studies to demonstrate how Bayesian methods can be applied at a later stage of product development to estimate the performance of a new generation of a device where good evidence exists only for a previous generation. Elicitation techniques are used with expert users to formalise their opinions into priors that, with a Bayesian meta-analysis of the information accumulated in the earlier generation device, can together provide quantitative estimates of the likely performance of the second generation device.

Value of Information and Value of Investment

We have used value of information techniques in their standard form [21] and we have also developed some novel approaches to deal with circumstances for which standard methods are less appropriate [18]. A particular example we have used involved a range of outcomes that affected both the mother and her unborn foetus which would have been very difficult to handle in the standard manner. Moreover, the method we have developed is based on the idea that new information will increase the proportion of decisions made according to individual utilities, as these are much more realistic than the standard assumptions in many scenarios [7]. This links the work of MATCH Plus to our work on split choice theory [22, 23]. One of our 'value of information' analyses was carried out by the request of Professor Sir John Patterson when he was Director of Research and Development at the Department of Health.

Benefits of research for collaborators

Health economic and methodological developments from *Economic Evaluation* inform the *Tools & Training* focus on providing tools for the medical devices sector. The methodologies that we have developed are the basis for the Health Economic Tool workshops that have been run for industry (see Annex 3). The *Economic Evaluation* project also collaborates directly with the NIHR collaboration for applied research and practice for Birmingham and the Black Country. This £10m NIHR research grant with matching funds from the NHS is directed by Richard Lilford. The link between these grants is discussed in more detail in the section on future plans below. Richard Lilford authored the MATCH Guide to Evaluating Health Devices [70] and was part of the Balliol collaboration that published a series of articles in the Lancet on evaluation of surgical treatments¹. One issue to be developed by the Birmingham team here is how the added cost of reducing the size of haemodialysis devices for community use is offset against the potential benefits of the size reduction.

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- 1 Barkun, J.S., J.K. Aronson, L.S. Feldman, G.J. Maddern, and S.M. Strasberg, Evaluation and Stages of Surgical Innovations. *The Lancet*, 2009. 374(9695): p. 1089-1096;
Ergina, P.L., J.A. Cook, J.M. Blazeby, I. Boutron, P.-A. Clavien, B.C. Reeves, and C.M. Seiler, Challenges in Evaluating Surgical Innovation. *The Lancet*, 2009. 374(9695): p. 1097-1104
McCulloch, P., D.G. Altman, W.B. Campbell, D.R. Flum, P. Glasziou, J.C. Marshall, and J. Nicholl, No Surgical Innovation without Evaluation: The Ideal Recommendations. *The Lancet*, 2009. 374(9695): p. 1105-1112.

The methodologies developed have shown direct benefit in clinical studies, for example, the mobile phone work with Belfast City Hospital and the on-going Connected Health Umbrella. Most of the economic development work has been a joint enterprise between Brunel & Birmingham however we increasingly collaborate with Nottingham and Ulster, with reference to user needs and service delivery. University of Ulster has welcomed the heightened national profile that their liaison with economic evaluation expertise on the mainland has afforded. In turn University of Birmingham has enhanced their theoretical work with the offering to industry that their liaison with other MATCH universities has helped to develop. This has, in turn, underpinned other research bids.

Impact on the wider community

Our work on supply side economics – that is applying health economic analysis at the early developmental stage of a new technology - is highly original. The work by Hartz, noted earlier, has confirmed that there are no examples in the public domain of a decision framework for early supply side decision making in medical products. This is a gap in the literature which we are populating with a range of tools to meet user needs. Our set of tools ranges from simple economic modelling through to the adoption of more complex methods and we have already influenced decision making in companies most notably Sofradim and DuPuy (see the corresponding Case Studies, Annexes 8 and 10). The supply side economic work is increasingly attracting attention: Richard Lilford was recently included in a Strategy Board Trade Delegation in California on the strength of his work on supply side economics and has given a Johnson & Johnson keynote address in this area. University of Ulster's paper on management of the early value proposition of healthcare technology won the best paper award at the Irish Academy of Management 2010.

"I have appreciated my involvement with MATCH over recent years. The obvious quality of those involved in the projects, the innovative approach to economic studies, and the rigour of application have highlighted the benefits of good economic analysis at early stage of product development.

Ian McLellan Marketing Manager (UK) GE Healthcare



Plans for the next three years

Our work programme can be conceptualised along a spectrum from fundamental development of theory through to collaborative applications in industrial settings. The development of methodologies from applied side health economics can be seen as occupying the middle ground in this spectrum of activities.

The plans for our work over the next three years, build on the main components of our programme activities to date. The middle ground is occupied by supply side health economics tools in particular. While the methodological work progresses, we are also developing empirical applications, for example, through working with clinicians and SMEs who are developing remote diagnosis of Chronic Obstructive Pulmonary Disease exacerbation. Over the course of MATCH, we have increasingly realised that the organisational framework of the services in which devices are used is crucially important, and accordingly we will be carrying over our economic tool kit into the service delivery domain.

An exciting and unanticipated development of our work involves the discovery that the methods we have developed for individual technologies are transferable to interventions to improve the services where those technologies may be used. Supply side interventions have two strong features in common with service delivery/management interventions:

- Objective statistical controlled comparisons that, by definition, are not available for interventions in the development stage and frequently not available, even at the implementation stage, for service delivery interventions.
- The development of the intervention generally follows an iterative cycle, implying decision gates and option value calculations.

To this may be added a further feature of service delivery interventions, the effects of the interventions, in many cases, span out across the whole organisation with potentially multiple small effects on a very large number of end-points. This has two corollaries explained more fully in the BMJ paper [26].

- The effects of the intervention are likely to be more difficult to detect than in the case of technical solutions targeted on a particular clinical problem.
- Said effects may be highly cost effective nevertheless (this is probably as the costs are shared by many patients).

We are therefore writing a series of papers whose intellectual provenance lies with MATCH and whose practical application will be rolled out through CLAHRC – (see p.12).

Summary

While the quality of the *Economic Evaluation* work is evidenced in high quality publications, methodological developments have also found practical implementation in health economic workshops for industry and a MATCH guide and have already influenced decision-making in industry. The work addresses the demonstrable lack of supply side decision frameworks for medical device development at the early stage, but many of the methodological developments including the safety premium, international transferability of economic evaluations and effectiveness studies and the value of information, have generic relevance and hence will have a wider impact.

People in the *User Needs* Project

- Brunel: Julie Barnett
Researcher: Sarwar Shah
PhD students: Urvashi Sharma and Anila Shah
- Nottingham: John Crowe and Sarah Sharples
Researcher: Jennifer Martin
PhD students: Alexandra Lang and David Keane

User Needs

Theme Description

The User Needs Project is exploring the means, ease and value of assessing user needs requirements across various stages of medical device development. It aims to develop methods that are capable of accurately assessing user needs and presenting the data in ways that can be used by industry to produce products that will be improved from the users' perspective, that will lead to the intended health gains, and that will be cost effective. Work within this theme has been based on a cross disciplinary synthesis of literature concerned with user input in medical device development and a series of empirical case studies focusing on the development trajectories of particular medical devices. Both strands of work have informed methodological work where there has been a particular focus on developing tools and guides to inform industry choices as to how and when to engage device users.

Strategy and Objectives

In March 2010 it became a legal requirement for medical device developers to formally address the usability of a device before placing it on the market anywhere in Europe as the result of the 2007/47/EC amendments to the European Medical Device Directive (MDD) becoming mandatory. This involves considering the "technical knowledge, experience, education and training and where

applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users)". The simplest way for developers to demonstrate that they meet this essential requirement is through compliance with the newly harmonised usability standard: EN 62366: Medical devices - Application of usability engineering to medical devices'. The *User Needs* theme thus resonates even more strongly with the needs of industry than it did at the inception of MATCH. In line with this, work within this theme explores how best to incorporate *early* assessments of user needs within the product development process; how to link these to economic evaluations, and how to meaningfully broaden assessments of user needs beyond those that impact error and safety to those that affect user satisfaction and adherence.

We aim to:

- identify the contexts where assessment of user needs is likely to add more or less benefit to product development
- develop methods for eliciting information that relate to the breadth of the user needs spectrum – not just safety
- develop means for the conversion of rich qualitative user needs data into quantitative metrics and subsequently into QALYs or other economic measures
- explore the relationship between device design and patient focused outcomes such as adherence and satisfaction
- identify implications of the growth of home use devices and thus of both patients and publics as medical device users.

"A wider view of design and Health Economics are tangible benefits from our participation with MATCH."

Dr Rodney Gush, Moor Instruments (see Annex 11)

Significant research results

The significant contribution of the *User Needs* team in MATCH falls into four main areas:

Conceptualising Medical Device Users and their Involvement in Device Development

A series of working papers in the early part of MATCH have led to a body of published work that characterises medical device users [74, 78, 80] and the feasibility of using surrogate users [77]. Having identified barriers to the inclusion of the user in the medical device development [71, 72, 79] later interview and case study work has explored how attending to user needs may clash with other requirements of the product development process [210, 213]. Notably, this work has also demonstrated that work with users at the early stage of device development can lead to revision in developer views as to the range of users the device is targeting and even highlight new areas of clinical need to which the device may be applicable [211].

Matching Methods to Purpose

Characterising the methods that might be used by developers of medical devices has been a key theme of the *User Needs* theme in MATCH [75]. A novel dimension of this has been to articulate potential methods against types of user and stages of the product development process [81]. The need for guidance for developers in this area was recognised by the National Patient Safety Agency and following Jen Martin's secondment there, her work around methods led to a MATCH partnership in publishing the NPSA guide, "Design for Patient Safety"[117].

Focusing on particular methods, a case study relating to early stage involvement of users in the development of an imaging device demonstrated the value of adapting Contextual Inquiry for use in a healthcare environment [209]. The potential value of blogs in providing companies with early intelligence as to the concerns of users has also been explored [214].

The Challenges of Developing Medical Devices for Adolescents

The *User Needs* theme has identified and focused on a population that has largely been neglected in any consideration of medical devices: adolescents. Located within the PhD studentship work of Alexandra Lang, research has identified a range of unique issues faced by companies developing medical devices to be used by adolescents.

In line with the project focus on methods, a variant of the Heuristic Evaluation method has been developed. The Adolescent Medical Device Assessment Tool (AMDAT) [91] provides a list of adolescent 'rules of thumb' against which medical devices designed for use by adolescents can be assessed. Alongside this, in line with the stringent ethical considerations in this area [208], a workshop method for eliciting adolescent opinions has been developed and trialled [116].

"Dr Jennifer Martin was seconded to NPSA to support the work of the Design and Human Factors team on medical device safety. Her knowledge of the medical device development, procurement and standardisation landscape was vital to the on-going work of NPSA to improve the safety of medical devices and equipment. In particular, she brought a joint MATCH/NPSA guide on user testing methods to publication, which will help device developers improve usability and safety. Her understanding of the needs of users, developers, and both the NHS and international device market helped ensure this publication will reach a wide audience"

Dr Beverley Norris, Human Factors Lead, National Patient Safety Agency (see Annex 7)

Improving the Value of Devices

The work conducted within the *User Needs* theme has developed a conceptualisation of value that is focused, not only on safety but other fundamental considerations such as user satisfaction and adherence. Early work in this area developed a model of user engagement to address the lack of early access to user perspectives on chronic wound care [72, 73]. Part of this focused on aligning economic evaluation with device development that was patient-led. It was this interest in linking economic evaluation and the elicitation of user needs that culminated in obtaining funding for the MATCH Plus project.

Benefits of research for collaborators

Developing an online tool to assist SMEs with choosing methods to involve users, as well as contributing to industry workshops has involved close collaboration with the *Tools & Training* project. Strong links with *Economic Evaluation* helped secure MATCH Plus funding and links with health economists are now a core to *User Needs* research. Links to the *Implementation* theme have primarily been in relation to Urvashi Sharma and Anila Shah's doctoral studies focusing on the NHS Nottingham City telehealth trial and have subsequently broadened to consider users of assistive technology managed by Nottingham City Council.

The Nottingham team has worked closely with a number of industrial and NHS collaborators and conducted research with a MATCH member (Moor Instruments), Nottingham University Hospitals NHS trust and the Royal Devon and Exeter NHS Foundation Trust. Jennifer Martin developed a programme of user engagement for another MATCH member as part of their successful application to the Department of Health's Health Technology Devices (HTD) grant programme. Supervision and guidance around user needs for other funded work has also been provided by Jennifer Martin and John Crowe, including work on a clinical monitoring instrument for sickle cell patients (funded by the Big Lottery) and a new heart rate monitoring device for new-borns requiring resuscitation (funded by Action Research/ MRC).



“Certainly the contribution of MATCH, through Dr. Martin, was essential in being able to assess the product and its likely commercial success. What we have learned, and the decisions we have taken subsequently, depended very directly on MATCH’s involvement. Also in future, we will be applying this thinking to our future needs – especially user needs and cost-benefits thinking.”

Dave Boggett, Managing Director of Moor Instruments (see Annex 12)

New collaborations on applications for further funding have developed as a result of links between the *User Needs* theme and other academics. Dr Julie Barnett collaborated with Professor Maarten Ijzerman (University of Twente, Health Technology and Services Research) and a team from Aston University and submitted a joint proposal to the ESRC/NWO research councils focusing on self-testing medical devices.

Impact on the wider user community

MATCH aims to improve the quality of medical devices available to healthcare providers, healthcare staff and patients. It has been essential therefore to translate the *User Needs* research findings in ways that are usable and understandable for the wider user community, including medical device developers, academic researchers and healthcare providers.

A rigorous analysis of the potential of user research to reduce the risks associated with product development resulted in a publication linking the *User Needs* research to established stage-gate processes [212]. A range of publications in trade magazines disseminated some of the key messages about user involvement to industry [108-115].

Our industry-focused approach to dissemination and training has been validated by the measurable success of the MATCH workshops on user-centred design. The extensive need for training in this area, and MATCH’s expertise and reputation, has been

recognised by the award of an EPSRC Knowledge Transfer Secondment grant to support the development and commercialisation of a MATCH human factors training package.

The MATCH and NPSA guide on user testing was primarily targeted at increasing and improving user-centred design practices within medical device companies. Since its publication in March 2010, more than 1000 hard copies have been circulated to developers across the UK and the guide is also freely available to download from the NPSA website. The guide has also been shown to be a useful resource for the NHS – we have received requests for the guide from more than 50 NHS staff concerned with: procurement, clinical testing and evaluation and medical device training. To date, dissemination of the guide has mainly been through: conference presentations, MATCH workshops and meetings with MATCH stakeholders.



Plans for the next 3 years

In the light of research results so far there will be a dual focus to the research activities within the *User Needs* theme for the next 3 years of MATCH. In line with the rise in home use medical devices, NHS initiatives to increase individual responsibility for healthcare and increasing regulatory requirements to attend to user needs in the development of medical devices, one stream of work will focus on patients as medical device users. This will not simply focus on the safety of devices but will explore how devices are actually used and the way in which this relates to adherence to the intended purposes of the device. Secondly, continued liaisons with SMEs will further identify the challenges of early user involvement in device development, delineate the contexts in which user involvement is most important and characterise the organisational structures that lend themselves to incorporation of the findings from early identification of user needs.

Summary

The *User Needs* work is developing a body of research that, in the light of recent regulatory requirements, is more relevant now than ever before. The translation of research into tools and guides and working with *Tools & Training* to embed these in industry training remains core to achieving impact. The quality of the *User Needs* work is most evident in relation to the early assessment of user needs within the product development process.

People in the *Implementation Project*

- Ulster: Dorian Dixon, Brian Meenan, Sally McClean
Researchers: Francis FitzGibbon and Duncan Jackson
PhD student: Jennifer Gillespie
- Brunel: Malcolm Clark
Researcher: Julie Eatock
- Nottingham: Steve Morgan:
Researcher: Michael Craven

Implementation

Theme Description

Devices which have a revolutionary influence on care delivery or devices with a low unit cost typically fall outside the current scope of HTA bodies such as NICE. A major concern of the *Implementation* project is developing and validating techniques to describe, model and assess devices which dramatically change care delivery (including telemedicine devices) and to develop tools for simplified HTA. Assessing the impact of new technologies in complex treatment and diagnosis pathways is central to the project. Given current pressure on healthcare expenditure, combined with the increasing costs associated with providing effective healthcare to an ageing population it is critical that common methods are developed for assessing the impact of devices which alter and potentially streamline patient care.

Strategy and Objectives

The *Implementation* project addresses implementation and procurement issues, with the aim of developing and validating new methods for the assessment of medical healthcare technologies – particularly focusing on revolutionary technologies. The project has three interconnected strands.

We aim to:

- develop effective methods to assess the impact of new technologies which can alter the way in which patients "flow" through treatment systems
- apply health economics to the early stages of product development and across the full range of stakeholders

- focus on the evaluation of telemedicine and assisted living devices

Significant research results

Patient Pathways

The patient pathway strand of the *Implementation* project covers a range of application areas. One key area is the point-of-care testing for cardiac markers conducted in collaboration with clinicians from the Belfast Royal Victoria Hospital. This research looked at how introducing this type of device had an impact on patient flow [140, 160], healthcare professionals [191] as well as the barriers to its adoption [132, 133].

Another key research initiative here was instigated by discussions between MATCH and senior management in Accident and Emergency (A&E) at Hillingdon Hospital. Clinicians were exploring ways to improve their performance on the 4-hour standard for getting patients through A&E. A simulation model was built that captured the activity in the department and the peak in the discharge times at the 4-hour target [126, 129]. This work has formed the basis of an application for further funding on building generic A&E models and of further analysis of the factors that affect patient throughput times in an A&E department and how resources could be better utilised. A follow-on project focusing on the development of a dementia pathway will be conducted in association with the Avon and Wiltshire partnership, looking at a change in the diagnostic process and the impact on overall costs and care issues.

Further work on patient pathways, again strongly embedded in clinical settings, focused on modelling integrated services for care of the elderly [136, 137, 171], cutting across both hospital and community services and characterising associated patient

“MATCH has played a key role in the development of methods for assessing healthcare innovations at the National Innovation Centre”

Brian Winn, Acting Manager, National Innovation Centre (see Annex 6)

pathways and associated costs [169]. A particular area of interest has been the use of analytical and simulation models to assess various strategies for the treatment of stroke patients [139, 218, 219] where treatment costs in hospital, such as thrombolysis (clot busting drugs) can be balanced against the cost of care and rehabilitation in the community. Other research is investigating the flow of patients through a streamlined referral system for orthopaedics.

Integrated Clinical Assessment and Treatment Services (ICATS) for orthopedics have been introduced to a number of trusts over recent years, facilitating the provision of services by integrated multi-disciplinary teams of health service professionals. The introduction of such services substantially modifies the patient pathway with the aim of significantly reducing outpatient waiting times through integrating paper and face-to-face triage with treatment. Based on analyses of demand, activity and cost of such pathways we have developed a simulation model, which enables us to compare capability, assess performance, and carry out capacity planning. Relative costs of the previous 51 week pathway approach and ICATS options are also being assessed.

Early Stage Health Economic Model

The early stage health economics tool developed in the *Tools & Training* project enables the potential economic and clinical effects of a new device to be considered relative to current treatments and for this information to be modelled within the early stages of product development. The tool acts as both a training aid to increase awareness of key HTA concepts and as an assessment tool to be used by both the demand and supply sides of the medical device market. The *Tools & Training* project has greatly benefitted from the engagement of the *Implementation* team with industry, CEP and NIC, and has also been favourably received by university academics [2, 127]. The project also partnered with the Nottingham University Hospital Trust to become a supplier to CEP and is now supplying to the NICE Evaluation Pathway Programme for Medical Technologies [199, 200] including current work for them under subcontract to the External Assessment Centre in Derby (called HITEC).

This strand of the *Implementation* project has also considered a range of other factors which affect adoption of revolutionary medical technologies during early stage development. This research has investigated pricing strategies [121], the impact of volume on pricing [120] and a range of other factors which can impede the implementation of a new medical technology [132, 133, 190, 191]. Additional outputs have also resulted directly from a range of work with industry, including a broad

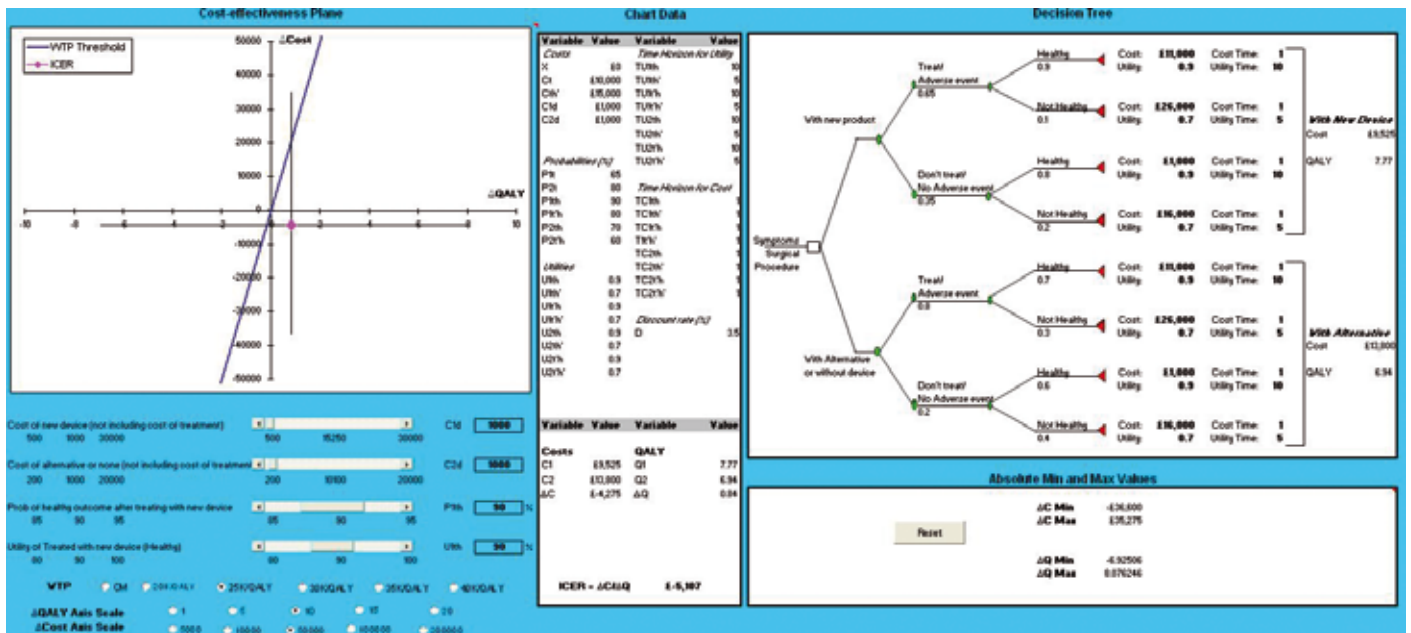


survey of new product development in the medical device sector and industrial engagement during the development of the early stage health economics tool [119, 130, 146].

Telemedicine

Telemedicine, with its ability to dramatically change care delivery, provides a particularly challenging and powerful focus for the *Implementation* project. Although telemedicine promises improved quality in healthcare provision, greater access to care, as well as prompt service and costs savings, fundamental requirements such as clinical effectiveness and safety, cost effectiveness and patient satisfaction are still often neglected or assessed in an ad-hoc or unscientific manner [176]. A key strand of MATCH work here has concentrated on surveying the use of evaluation in the telemedicine literature [222], with a particular focus on satisfaction [220, 221]. A new approach to telemedicine stakeholder satisfaction measurement is being developed and evaluated within the MATCH Plus user needs evaluation of the mobile, video-based CPVS reminder system for mild-stage Alzheimer's disease. Economic evaluation is another key area for the uptake of telemedicine systems and we have also carried out a literature survey of previous economic models for healthcare. Again, the MATCH Plus project is providing a good testbed for initial developments in this area. Currently, we are engaging with a number of developers and companies (e.g. Intelesens, CPVS, Cornwall and Scillies Whole System Demonstrator project) in the telemedicine area with an ultimate objective of developing a MATCH standard tool for evaluation and costing within telemedicine, alongside a group of tool evaluators and users.

A second strand of telemedicine work has focused on modelling patient flow. MATCH aims to develop an assessment framework for this critical set of medical technologies. This is critical in assessing the economic and health implications of adopting such technologies. A piece of collaborative work in this strand investigated the use of remote dermatology consultations in an out-patient clinic in Massachusetts General Hospital in Boston, US. The research developed after we were contacted by clinicians at the hospital who had seen other work by members of the MATCH team on patient pathway aspects of implementation [125]. The aim of this particular piece of research was to assess the impact that incorporating remote consultations would have on patient waiting times for appointments [131].



MATCH was also invited to undertake the evaluation of the large telemedicine project to be implemented by Nottingham City Primary Care Trust. The project was envisaged to install at least 300 home based monitors to patients suffering from chronic diseases including COPD and CHF and to undertake evaluation of clinical outcomes, service impact, cost-benefits and user perspectives. Ethical approval was received in April 2009 and patient recruitment commenced in June 2009. However, organisational changes also meant that there was no longer a full time manager of the project and there was some resistance from the nurses to the random allocation of patients to receive the technology. This culminated in Nottingham City PCT cancelling the study. This was regrettable; however the experience clearly indicated the magnitude of the often underestimated resource necessary to implement such systems. MATCH involvement through two PhD studentships has re-focused on exploring the causes of the project's failure. Talks are currently underway with Lagan Valley Hospital regarding a trial studying the effect of home monitoring 102 COPD patients which may prove to be a suitable replacement for the Nottingham study.

collaboration with its External Assessment Centres. These relationships were initiated via MATCH's involvement in the Healthcare Technologies Task Force (HITF) process and subsequent work on pilot projects with CEP. As implied above, there has been extensive collaboration on a range of research studies with clinicians, and industry – both within the UK and the US.

Impact on the wider user community

The *Implementation* project is particularly relevant to industry and therefore the research has been presented at trade shows (e.g. MedTec Ireland, network events (e.g. Medilink), and widely disseminated through trade articles [184-196]. In addition to the *Implementation* projects' involvement in tools and training workshops, relevance to the industrial community is further evidenced through the fact that MATCH has secured funding through regional development boards for projects with two medical device companies: Heartsine in Ulster to assess human factor methods appropriate for critical care devices (through the INI Innovation Voucher scheme); and Neurocare in Nottingham (though the BioKneX voucher scheme). The MATCH team at University of Nottingham has also received an award for Industrial Collaboration at the Healthcare business awards 2008, hosted by Medilink East Midlands. Malcolm Clarke is the UK Principle Expert serving on ISO TC 215 WG7, CEN/TC251/WGIV, and IEEE 11073 standards committees for medical devices. He is the chair of the lower layers committee IEEE 11073 SWG7.2.

The funding vouchers, the Industrial Collaboration award and leadership of an international standards committee demonstrate the fact that the work undertaken, not just by the *Implementation* project, but MATCH as a whole, is indeed of relevance and useful to industry, policy makers and practitioners alike.

Benefits of research for collaborators

The relationships formed through dissemination of the tools and guides have given a platform to the other projects. In particular the *Tools & Training* and *User Needs* projects have benefitted from the close relationship formed with NHS organisations NIC and CEP [158]. On the basis of the patient pathway modelling work Julie Eatock was actively sought as a lead modeller for an MRC/NIHR-funded grant that combines simulation modelling techniques with health economic modelling techniques to provide information for forthcoming NICE guideline updates. Building on his work in MATCH, Mike Craven has conducted evaluations of medical device cost effectiveness for NICE through

In April 2009 we published the paper "Perspectives on the impact of point-of-care testing for cardiac markers on healthcare professional working relationships" written by you and your colleagues at Radiometer Medical's knowledge website www.acutecaretesting.org. The issues discussed in this paper are very relevant to our business and it is my pleasure to inform you that the paper has till now been opened 2683 times. This shows that it is considered relevant by our readers.

Suzanne Ekelund, Radiometer Ltd.

"The Report issued by Francis FitzGibbon and Professor Brian Meenan has exceeded my expectations in its clarity and coverage, and HeartSine will be able to use its findings extensively in, both the generation of future HFE strategies and in academic support for them. HeartSine is pleased to confirm that it will be continuing, and indeed expanding, its involvement with MATCH and will be exploring the possibility of further projects, all of which will have a most positive effect on the business."

Jim C. McAnlis - Manager, Special Projects, HeartSine Technologies Ltd,

Work on the Health Economic Evaluation Tool has also secured additional funding through collaboration with CEP and the National Innovation Centre within the NHS Institute for Innovation and Improvement. This additional work has strengthened links with the NHS¹ and embedded MATCH methods within PASA and the NHS Institute through assessment of a series of innovative healthcare technologies. MATCH work with CEP has now been transferred to NICE since PASA has recently been disbanded. The Nottingham Partnership (MATCH and Nottingham University Hospitals Trust) is currently engaged with the NICE Evaluation Programme for Medical Technologies. This is expected to increase through an External Assessment Centre partnership. The NHS National Innovation Centre, as a MATCH partner, continues to support the application of the MATCH Health Economic tool amongst SMEs and NHS commissioning organisations. The dissemination of the tool is due to continue as part of a coordinated deployment of tools in collaboration with ABA, another MATCH partner, and through the strategic partnership with BITECIC.

¹ <http://gow.epsrc.ac.uk/ViewGrant.aspx?GrantRef=EP/F037775/1>

Plans for the next 3 years

The three strands addressed in *Implementation* project have the common aim of developing new methods to assess medical devices in the early stages of their development. The project is particularly concerned with those devices which dramatically alter care delivery. Developing a standard MATCH framework for assessing telemedicine/connected health type medical devices is the third central aim of the project. The work for the next three years will focus on three critical areas. Firstly, the early stage health economics tool will continue to be developed and widely applied across both the medical device industry and among health care providers. Due to NHS restructuring there will be new opportunities to engage with the needs of commissioners in addition to bodies concerned with innovation and procurement that we have worked with to date. The second major goal is to further validate the pathway approach to device assessment and convert the approach into a standard tool. Development of this approach will be further refined using data from a number of ongoing case studies. These include the diagnosis of chest pain in A&E using a pathway which does include point of care diagnostics and the Ulster based MATCH Plus project on cognitive prosthetics. The pathways work will draw heavily on the process simulation and modelling expertise available within the *Implementation* project team. The final aim of the *Implementation* theme over the next 3 years is to develop a standard MATCH framework for assessing telemedicine initiatives.

Summary

The *Implementation* theme, which builds upon previous MATCH research, has been at the forefront of developing new medical device HTA assessment methods. Much of the value of these techniques will come from applying them earlier in the development of a medical device and ensuring that a common concept of value exists across producers, users and suppliers of healthcare products.

The quality, impact and relevance of the work are further evidenced by the extensive range of clinical and industrial collaborators and by the additional grant funding secured by the team. As the cost effectiveness and clinical impact assessment of medical devices becomes ever more critical so will the influence of the methods developed and validated by the team.

People in the *Tools & Training* Project

- Brunel University: Simon Taylor
- University of Nottingham: Steve Morgan
Researchers: Mike Craven and David Morris

Tools & Training

Theme Description

The *Tools & Training* theme operates at the interface between MATCH and its end-users in the medical devices industry and NHS. Tools and Guides are developed which aim to condense methods developed within MATCH and the wider academic community into a form that can be readily applied by the industry and healthcare decision makers. These are delivered in conjunction with training at regional workshops.

In developing and delivering tools and training, MATCH has also worked closely with the Health Technology and Medicines Knowledge Transfer Network¹, Medilink UK² and the Association of British Healthcare Industries³. We are now working closely with BITECIC who are delivering our now well established health economic evaluation workshop on our behalf.

Strategy and Objectives

The main focus of the *Tools & Training* theme is to package knowledge from within MATCH into a form that can be easily understood and applied by the medical devices industry and healthcare providers. The flow of information is not solely in one direction.

We aim to

- understand the needs of the medical devices sector

1 ktn.innovateuk.org/web/healthktn

2 www.medilinkuk.com

3 www.abhi.org.uk

- feedback this information into the wider MATCH team to ensure relevance of the core research
- deliver methods developed within MATCH to industry and healthcare decision makers

Significant research results

The most significant achievements of the *Tools & Training* theme are the following tools, training and guides for the medical devices industry and healthcare providers.

Tools

The most significant tool has been a Health Economic Evaluator. The tool is based on a decision tree framework and aims to aid industry and healthcare providers in making early decisions about the development or adoption of devices. The tool forms the basis of the training package where attendees are introduced to basic health economic evaluation concepts such as how to calculate the cost and quality of life improvements associated with a new device and how to obtain the relevant data to populate a model.

“Easy to understand workshop on a complex area. Simple tool interface which should aid decision making.”

Director of Consultancy engaged in market assessment of novel medical devices

“We’ll use the tool. Different uses at different development stages from initial development decisions through to sales force training & customer use. To help customers understand their own costs (in our market segment these are often not well understood”

Marketing and New Product Development Director, Large Medical Device Company

The health economics tool and workshop example provides a useful framework for developing other tools and training. Collaboration with the MATCH *User Needs* theme is currently developing a software tool and training package for selecting the most appropriate user elicitation method to apply in order to ascertain the needs of users in the device development process. The MATCH/NPSA Design for Patient Safety guide on 'user testing in the development of medical devices' [117] is used as the basis for the tool and training. Collaboration with the MATCH Plus project is developing a software tool for eliciting the needs of users.

Other significant contributions have been the development of an Experience Curve Calculator based on a study within MATCH [121] that found that the Experience Curve can be used to describe medical device price behaviour, and that a significant number of medical devices exhibit slower price decline rates than the typical 70 – 80 % rates seen in other industries.

Training

11 workshops, which presented the Health Economic Evaluation Tool and a MATCH method or tool (on either user requirements or pricing strategies), were run between 2007-2010

Date	Workshop conducted for
14/09/2007	MATCH partners
19/03/2008	3M, Loughborough
10/09/2008	Medilink Yorkshire and Humber
02/12/2008	Medilink West Midlands
19/06/2009	University Academics and Technology Transfer Officers
22/06/2009	South East Health Technologies Alliance
22/09/2009	Association of British Healthcare Industries
27/10/2009	Medilink East Midlands
27/04/2010	Brunel University
27/05/2010	Medilink East Midlands
01/10/2010	Medilink West Midlands

A total of 188 people from 119 companies and organisations from a diverse audience participated in these 11 workshops. Participants came from the medical device industry, NHS and private healthcare service providers, government agencies, academics, technology transfer professionals and consultants.

At most of these workshops, attendees filled in a questionnaire which provided us with a snapshot of the knowledge and attitude of the healthcare industry and the NHS to economic evaluation of medical devices at an early stage in the development process. The workshops also provided a useful forum for discussion of the meaning of value and helped contribute to

a common understanding between the industry and healthcare providers. Of the respondents to the questionnaire given at the workshops, more than 90% rated the workshops as either excellent or good. In collaboration with the MATCH *Implementation* theme, the tool has been trialled by the NHS National Innovation Centre with the aim of identifying new technologies that will have a significant impact on healthcare in terms of patient benefit and cost savings [127]. As the health economics workshop has been adopted by our strategic partner BITECIC since January 2010, this has allowed the *Tools & Training* team to concentrate on developing further tools.

With recent requirements by the EPSRC to demonstrate potential impact of a new technology, we proposed a method by which health economics could be incorporated into the device development process in academia and used to demonstrate impact [2]. To examine the value of this, one workshop was delivered to academic researchers and technology transfer officers with an interest in innovations in healthcare and a modified questionnaire was developed, tailored to the specific audience.

Guides

MATCH and the NPSA jointly produced the Design for Patient Safety guide on 'User Testing in the Development of Medical Devices' [117]

A guide to evaluating devices has also been recently published [70] which aims to set out both the broad context of invention and development and the more specific elements around strategies for trials.

Benefits of research for collaborators

The *Tools & Training* project has provided benefit and benefitted from working closely with other MATCH projects to help them disseminate their methods through tools and training.

For example the Health Economic Evaluation Tool has been developed in a close collaboration with researchers in economic evaluation at Brunel University (*Economic Evaluation* theme). The MATCH/NPSA guide to user involvement (*User Needs* theme) and the MATCH Experience Curve Calculator were disseminated to the medical devices sector through MATCH workshops. Help with questionnaire design for the workshops was sought from the *User Needs* project team. The Health Economic Evaluation Tool has been trialled with the NHS National Innovation Centre by the MATCH *Implementation* theme.

From the beginning of MATCH, the *Tools & Training* project has been informed by the needs of the MATCH industry and NHS partners and they have actively engaged with the design process of the Health Economics Evaluation Tool in particular. In addition to the partnership with BITECIC, the NHS National Innovation Centre has adopted it on a trial

basis for evaluating products from SMEs that have come through its innovation gateway.

For the researchers in the *Tools & Training* project along with those in the *Implementation* theme, this has provided a route through which the utility of MATCH tools can be validated on real world medical devices at an early stage of development.

Impact on the wider user community

Tools and Guides are developed which aim to condense methods developed within MATCH and the wider academic community into a form that can be readily applied by the industry and healthcare decision makers. Working at the interface between the medical devices industry, the NHS and MATCH's core research has allowed MATCH's research to reach a wider audience and to ensure its relevance.

Training in health economics has been an important aspect of the workshops. Evaluation questionnaires completed at six of the workshops reported that the 45 out of 69 attendees (65%) previously had little or no knowledge of health economic evaluation and the vast majority (90%) had never used a decision-support tool.

In addition, we have attracted a diverse audience, including manufacturers (the majority), NHS and private services providers, government agencies, academics and consultants. This is encouraging because a common language for evaluation is an important element in the wider adoption of HTA methods.

The Medilink partners have been very enthusiastic about the workshops. In the East Midlands the event was so popular that a second event was put on at the same venue just 7 months later. MATCH was also awarded the Medilink East Midlands (BioKnex) award for University collaboration with industry in 2008.

Our guides have been published in collaboration with the National Patient Safety Agency and the Department of Health i4i programme. In particular, the MATCH user needs guide has been published by the NHS National Patient Safety Agency as part of their prestigious 'Design for Patient Safety' (DPS) series. The DPS series recently won 'best management of design in a public or non-profit organisation' category at the Design Management Europe Awards. This publication, which has been reviewed and endorsed by the Department of Health and NICE, is a clear acknowledgement of the quality and value of the MATCH user needs work. An initial print run of 1000 copies has been circulated to medical device companies and NHS procurement departments and is also available to download from the NPSA website¹. The guide is being disseminated at our workshops alongside the User Requirements presentation. The MATCH Implementation theme has also taken out the



"The Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) can assist in the methodologies required to undertake supply side health technology assessments through the provision of software and tools that help predict sales volumes and the value of treatments. See www.match.ac.uk for details."

Quotec guide: "Commercialising Medical Devices - A Guide for UK Based Small Companies"²

health economic tool and applied it in collaboration with the NHS National Innovation Centre.

Plans for the next 3 years

We now have a framework in place for identifying, developing & delivering tools and evaluation & training inspired by MATCH themes. Currently a User Research Methods Selection identification tool is under development that will assist developers in selecting the most appropriate methods to apply to user research.

At this current stage, further tools/guides have been identified:

- *User elicitation tool* is a software based tool which will aid the industry in obtaining the views of users at an early stage in the device development cycle.
- *A guide to NICE's Medical Technologies Advisory Committee* will provide advice to companies on how to prepare their application for the new assessment process and where to obtain data.
- *Analysing Social Media for Health Technology Innovation* is a checklist tool and supporting guide that will help innovators to elicit user information from social media across the internet.

1 <http://osc2.triplearc.com/npsa/images/productreviews/1184.pdf>

2 <http://www.quotec.co.uk/attachments/article/37/Commercialising%20Medical%20Devices.pdf> (page 19)



- *Open business models tools* will assist innovators in presenting and assessing their business case and financial offerings, as well as reflecting on what kind of enterprise they should develop.
- *Headroom tool* will take the principles of the headroom method developed within the *economic evaluation* theme and turn them into an accessible tool for the medical devices industry.
- *Treeage HE Tutorial Guide* will provide practical health economic examples for medical devices in using a sophisticated health economic software package and further support risk/economic analysis.
- *Assessing the impact of health technologies on care pathways guide* will help innovators to understand the operational impact of their technologies on actual health processes using process-based simulation.

Beyond this lies the challenge of reducing to routine practice the business of identifying a potential guide or tool, anticipating and then verifying the needs of its potential users, and then producing code or documents quickly that meet those needs. Furthermore, we need to understand the adoption and uptake of our tools, guides and training so as to better support decision making by all stakeholders. An additional member of staff has been approved at Brunel University for application development for MATCH tools which will accelerate tool creation and web-based deployment.

Summary

The *Tools & Training* theme is important as it takes out the methods of assessing value and the needs of users to the wider community through training workshops and accessible tools. Industry benefits from learning about methods of assessing value at an early stage in the development cycle, and also how to demonstrate value to purchasers. A common understanding of value is facilitated between healthcare providers and industry.

Matrix Evidence Ltd Case Study

Summary of Case Study

The IMRC has entered a commercial joint venture with a company specialising in analysis for policy and management through operational research, economic appraisals, public policy evaluations and evidence reviews, to design and supply consultancy services to help healthcare technology developers make better value-based product-development decisions. The target markets for these services include pharmaceutical and medical device companies in both UK and overseas markets. The IMRC also intends engaging in longer-term related collaborative activities with the company, which are at present subject to commercial confidentiality.

Research outcomes achieved with the EPSRC IMRC funding

The joint venture began in mid 2010. The project's duration remains unspecified until a full legal contract is drawn up, but is meanwhile subject to three-monthly stage-gate reviews. Research outcomes so far have been in terms of laying an evidence base for the enterprise to build on in developing, refining and assessing the commercial viability of its offering.

How were these research outcomes taken forward?

The venture involves the exploitation of outputs from MATCH academic research into methods for establishing the clinical value of medical technology, which is why a Non Disclosure Agreement has been drawn up to safeguard Intellectual Property.

The first stage has been to design a set of commercial offers, based on MATCH methods. The next stages will be to: refine the offers that have been developed; organise and run a promotional event at which the joint offers can be presented to potential clients; and further refine the offers and identify additional markets.

Future plans include supplementing the initial offer with new methods for assessing the value of innovation, and quality assurance of the use of these methods.

Evidence of impact on the economy and/or society

The collaboration is exploring how economic valuation techniques and real options approaches can be employed to improve upon the standard health economic techniques already widely applied in industry and the collaborating company believe the development of these methods will enable industry to improve product development decisions by allowing a better treatment of the uncertainty associated with decisions early in the product development process and by basing decisions on a more accurate assessment of commissioners' and clinicians' willingness to pay for health technologies.

"We welcome the opportunity to combine MATCH's high quality methods and Matrix's consultancy services within the healthcare sector, to enable decision makers to make the most effective and valuable use of their resources"

Kevin Marsh, Chief Economist at Matrix Evidence

Evidence of potential impact on wider industry will begin to be amassed during Winter 2010/11 at a joint workshop and subsequent promotional event, and quantitative impact will thereafter be incorporated into documented assumptions underpinning a joint business plan.

Additional spin-off benefits to researchers, students, or collaborators

The venture involved seconding MATCH Researcher Jeshika Singh from the *Economic Evaluation* theme into the company for two weeks during September 2010, providing her with exposure to industry and a learning experience from interacting and working in a different environment to academia. The experience also helped her explore use of economic evaluation at different stages of decision making regarding product development as well as different kinds of decision making by decision makers. It also reinforced her belief that MATCH was one of the forerunners to have understood that economic evaluation of health technologies is different from standard economic evaluation of drugs and encourage multidisciplinary assessment and that...

"...it is really trying to 'match' the needs of users with product development by exploring different methods of assessment and through the perspective of different stakeholders, and create a win-win situation for suppliers, regulators and consumers".

Jeshika Singh, *Economic Evaluation* Theme, MATCH programme

Any other information and relevant website(s)

Matrix Evidence Ltd website¹

Background

The joint venture partners are MATCH members Matrix Evidence Ltd; one of the employee-owned Matrix Knowledge Group of companies, specialising in analysis for policy and management through operational research, economic appraisals, public policy evaluations, and evidence reviews.

The engagement crystallised during Summer 2010, with the signing of a Non Disclosure Agreement in June and a Memorandum of Understanding in August, because both parties recognised collaboration as a way of combining complementary strengths: MATCH's as a successful developer of approaches and tools for assessing value and economic impact for industry and Matrix Evidence's considerable experience of enabling sound decision-making within the public and third sectors, through use of evidence and analysis.

The parties agreed to formalise their business relationship by creating a partnership to discuss and assess the viability of the design, promotion and delivery of consultancy and other services liked to

outputs from MATCH to existing clients of either party or new customers from health technology industry. In partnership with the IMRC, the aim is for Matrix Evidence to supply consultancy services to industry clients that are based on embedding within the clients' organisations a value-based risk assessment capability, using methods designed by the MATCH programme.

Collaboration

Matrix Evidence and MATCH have collaborated loosely since 2008. The first stage of a more formalised engagement was the above-mentioned secondment of an academic resource to work during September 2010 at the Matrix group's London offices. She conducted an exploratory study with Matrix's Economics Team into how the company might, in partnership with the IMRC, provide consultancy services to the health technology industry within UK, based on the incorporation of MATCH methods into value based decision making.

During the secondment, the researcher was asked to collate as much information as possible to bring the Matrix team up to date on how the health technology industry was organised, how technologies were developed and the methods used for economic evaluation, so that they could form a general overview of how the industry worked and how economic evaluation methods could be used in decision making, as a prelude to developing commercial services for presenting to the sector.

Based on this initial work, the collaboration will continue, with Matrix taking the lead in shaping and providing consultancy services to clients from the industry based on methods developed by MATCH.

"...as a researcher working on (an) individual project and having MATCH spread across four universities one often gets to a point where you can't see the wood for the trees. This experience has helped me understand and appreciate work done by other members of MATCH".

Jeshika Singh, *Economic Evaluation* Theme, MATCH programme

Evidence of impact

The work is in preliminary stages. However the collaboration aims to equip the technology industry with academically robust and customised methods that will help companies deal with uncertainty and aid in decision making process.

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The Hillingdon Hospital Case Study

Summary of Case Study

Clinicians from Hillingdon Hospital Accident & Emergency (A&E) Department approached MATCH to determine whether the use of an electronic whiteboard would improve their adherence to the government target to have patients either admitted or discharged within 4-hours. This device had proved effective in another hospital and they wanted us to tell them which whiteboard would be the most effective for them

In order to analyse the impact of any changes we had to first map the patient flows through the department and develop a simulation model that reflected their current practice.

We noticed that there was a sharp rise in the number of patients discharged from the A&E or admitted from there to the hospital just before the 4-hour deadline. This phenomenon is replicated in many hospitals across the UK. This is partly due to the re-prioritising of patients as they approach this deadline. Previous research studies have not captured this re-prioritisation strategy, and therefore not been able to replicate the discharge pattern. Our work has enabled Hillingdon to reflect on the causes of this behaviour and to investigate possible solutions.

Research outcomes achieved with the EPSRC IMRC funding

A discrete event simulation (DES) model was built that effectively captured the re-prioritisation strategy, and accurately reflected the discharge distribution, which we believe to be a first in A&E modelling. Using the model we were able to show that the use of a fast-tracking service, successfully

adopted in some other hospitals, would not improve service times within Hillingdon Hospital. We also facilitated discussion on alternative coping strategies. The work so far has successfully produced two journal papers and a conference publication [126, 129, 161].

How were these research outcomes taken forward?

The coalition government has now abandoned the former four-hour target and we await the announcement of the new guidelines. New guidelines are inevitable to retain control of A&E waits prevent them from slipping back to the pre-4 hour target scandals of 24-hour trolley waits.

We are also seeking follow-on funding in association with Warwick Medical School and University Hospital Coventry and Warwickshire to develop and generalise our approach to other A&E Departments in the UK. The work at Hillingdon A&E was brought to the notice of Professor Matthew Cooke, National Clinical Director for Urgent and Emergency Care, who is a co-investigator on the new proposal.

Evidence of impact on the economy and/or society

The model we built for Hillingdon Hospital showed that the use of an Emergency Nurse Practitioner (ENP) system to fast-track minor cases would not improve their patient throughput. Unfortunately, the model took longer than expected to build and by the time it was complete, Hillingdon had decided to try introducing the ENP system. They found that the system did not work, and that the model had produced very similar results to what had transpired.

This provided us with a perfect example of an improvement strategy that had been successful in a number of other hospitals, not working in this particular case. The model however would have been able predict this, and so would have prevented the disruption and expense caused by implementing an ineffective strategy.

This also showed that the model was a good predictor of the impact that changes would have on patient discharge times, and gave us confidence in the results from other modelling scenarios. This could have an impact on NHS spending as successful strategies to meet targets can be identified using the model, reducing the cost and disruption caused by implementing new strategies that do not give expected results.

“The A&E model allowed the A&E staff to highlight concerns around patient flow through the department. Although difficult to say if directly attributable to the model, the Trust has now commenced the process of implementing a bed management module for the current IT system, to aid ‘pulling’ patients through from A&E, rather than A&E having to ‘push’ the rest of the hospital to get them moved on.”

Claire Picton, Consultant in Emergency Care Nursing

Additional spin-off benefits to researchers, students, or collaborators

Whether by diffusion of ideas, but probably not by direct effect, the modelling experience has provided a backdrop for some serious remodelling of the rest of the hospital.

Also, as a result of this research, a grant proposal was submitted for NIHR funding to explore the feasibility of a generic A&E simulation model that local hospital could quickly adapt to reflect their particular hospital. This proposal was written in conjunction with Warwick Medical School and University Hospital Coventry and Warwickshire

Any other information and relevant website(s)

Background

Hillingdon Hospital has a longstanding strategic relationship with Brunel University and has a University research facility on hospital premises. This latest research opportunity arose from earlier simulation work carried out as part of the EPSRC sponsored ‘Research Into Global Healthcare Tools’ project, during the course of which relationships were established with Hillingdon’s A&E personnel. Through this channel, Hillingdon learnt of the IMRC’s work and approached MATCH.

Collaboration

This work involved the researchers having close collaboration with senior members of the A&E department. Initially a team of researchers observed the general processes within the department, which allowed for a basic pathway model to be devised. This was further developed following a series of in-depth interviews with a senior nurse in charge of the department.

Evidence of impact

We were able to show the possibilities of applying simulation modelling to a naturally complex system, and demonstrate that realistic results could be obtained through this method. The model could then be used to test other possible scenarios that would help the hospital improve their performance.

“Working with Brunel has been time-consuming but also beneficial in providing an idea of the A&E workload to a wider audience. It has helped me personally and hopefully other staff in the Trust.”

Claire Picton, Consultant in Emergency Care Nursing

Who should we contact for more information?

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MATCH Workshops Case Study

Summary of Case Study

MATCH has, to date, delivered 11 training workshops in the UK to an industry and NHS audience. Each of the workshops provided training in Health Economics and one of either user requirements or pricing strategies. MATCH tools provided a platform within the workshops to illustrate basic concepts.

The workshops benefitted attendees as Health Economics is increasingly recognised by healthcare reimbursement agencies as an effective methodology to evaluate innovative healthcare technologies. It is also widely recognised that there are many regulatory and reimbursement hurdles to be overcome when bringing a medical device to market. It is therefore advantageous for companies to identify which products are likely to have the greatest impact early in the development process.

The majority of the workshop events were organised and marketed collaboratively with the Health Technologies KTN (Knowledge Transfer Network) and the regional Medilinks, plus one with the Association of British Healthcare Industries (ABHI).

Demand for such workshops is high and this has been identified as a good business opportunity. A company, BITECIC, is now delivering the workshops on behalf of MATCH

Research outcomes achieved with the EPSRC IMRC funding

A questionnaire filled in by attendees provided us with a snapshot of the knowledge and attitude of the healthcare industry, the NHS and academia to economic evaluation of medical devices at an early

stage in the development process. One accepted journal paper and one poster at an international conference have resulted from this research [2-4].

How were these research outcomes taken forward?

MATCH and BITECIC, a MATCH partner, formed a strategic partnership to market and deliver MATCH tools and workshops from January 2010.

MATCH are also currently investigating the possibility of running workshops in Brussels (via Eucomed), South Africa and China.

Evidence of impact on the economy and/or society

From 14th September 2007 to 1st October 2010 the following workshops were delivered;

- Brunel University - to MATCH partners (14/9/2007)
- 3M, Loughborough (19/3/2008)
- Medilink Yorkshire and Humber (10/09/2008)
- Medilink West Midlands (02/12/2008)
- University of Nottingham – Bridging the Gaps workshop for University Academics and Technology Transfer Officers (19/06/2009)
- South East Health Technologies Alliance (22/06/2009)
- Association of British Healthcare Industries (22/09/2009)
- Medilink East Midlands (27/10/2009)
- Brunel University (27/4/2010)*

- Medilink East Midlands (27/5/2010)*
- Medilink West Midlands (1/10/2010)*

* In association with BITECIC

In these, 188 people from 119 companies and organisations (including the NHS and academia), 87 of which were not MATCH members. The people have been trained in health economic evaluation and how this can be used to make early decisions about healthcare technology innovations. From a questionnaire completed at the workshops around 93% of respondents rated the workshop as excellent or good. Many attendees stated that the workshop had given them a good start in a complex area and expressed great interest in working with MATCH to evaluate their own products. Comments included:

“Definitely a useful tool which I will be recommending is routinely included in our current stage gate review process. Formalising inclusion will avoid costly revision down the line”

Clinical Director, Orthopaedics Developer.

“I will use the MATCH tool to help prioritise product innovation projects”

Innovation Lead, NHS Primary Care Trust.

“Occasionally I assess an innovation that ‘sits on the fence’ in strength and opportunities of threat (SWOT) not show clear pathway. MATCH tool may allow some easier internal decision making when making recommendations whether to proceed for an ideal/concept to prototype stage.”

Director of Consultancy engaged in market assessment of novel medical devices.

“Easy to understand workshop on a complex area. Simple tool interface which should aid decision making.”

Director of Consultancy engaged in market assessment of novel medical devices

“We’ll use the tool. Different uses at different development stages from initial development decisions through to sales force training & customer use. To help customers understand their own costs (in our market segment these are often not well understood”

Marketing and New Product Development Director, Large Medical Device Company.

Additional spin-off benefits to researchers, students, or collaborators

MATCH researchers and students have benefited through being exposed to the real problems faced by companies in bringing a medical device to market.

By creating the tool and workshops, and in particular the collaboration of engineers at Nottingham with health economists at Brunel, this has enabled engineering researchers who were previously not expert in health economics, to gain understanding and subsequent skill that is now deep enough for them to be able to conduct health economics evaluations independently.

Any other information and relevant website(s)

- Health Technologies KTN²
- Medilink East Midlands³
- Medilink West Midlands⁴
- Medilink Yorkshire and Humber⁵
- SEHTA for The South East Health Technologies Alliance⁶
- ABHI for Association of British Healthcare Industries⁷

Background

MATCH researchers initially engaged with Dr Tom Pinto of the Health Technologies KTN and arranged a series of meetings with the regional Medilinks and the ABHI.

The various Medilinks are engaged with supporting business development in their regions amongst manufacturers of medical technologies and aim to provide value for their membership, which is made up mainly of SMEs, through events and workshops. Their involvement in the early planning and delivery stages of the workshops provided crucial access to those in industry that were most likely to benefit from the content and tools provided during such events.

Although the focus of initial discussions with Dr Tom Pinto was to develop links with those in industry, the involvement of delegates from the NHS and academia was also considered due to the benefits that they can gain from involvement. The NHS audience has an interest in learning more about cost-effectiveness methods and tools because Health Technology Assessment is expanding its remit outside of the usual NHS bodies e.g. NICE, HTA Programme.

In order to access academia, the ‘Bridging the Gaps workshop for University Academics and Technology Transfer Officers’ held in 2009 was primarily aimed at involving academics in the workshops, so that they could gain an understanding of HTA processes and consider how they might apply it to their research.

Having completed a range of workshops and identified demands within industry, healthcare and academia, in 2010 MATCH formed a strategic partnership with BITECIC to further develop and extend the MATCH workshops.

BITECIC Ltd manage collaboration, and provide professional services to industry, universities and

healthcare professionals, The company draws on expertise from a world-class group of business, clinical and research personnel, and actively support organisations aiming to take new concepts through to market in all areas of healthcare and medical device technology. The strategic partnership with MATCH was identified as a unique business proposition for BITECIC, and MATCH identified benefits in accessing the experience and the strong links to SME's held by BITECIC.

“There's a clear synergy in this partnership. MATCH is a successful developer of approaches and tools for assessing value and economic impact, while BITECIC provides ongoing operational support, especially to SMEs in the healthcare sector”

Professor Terry Young, MATCH

“This is an exciting opportunity for us to lend our experience in reaching out to a wider set of users who really need to understand and benefit from MATCH's tools and guides as they enter a world that demands cost efficiency from new health technologies.”

BITECIC Director, Dr John Egan

As part of the partnership, Dr Matthew Allsop was recently appointed to a newly created, jointly funded MATCH-BITECIC role, with responsibility for facilitating easier access to MATCH tools, methods and advice for achieving and demonstrating the value of new treatments for both industry and the NHS. In order to do this, Dr Allsop has been developing the MATCH workshops and has taken over the role of their delivery. In addition to the workshops, Dr Allsop and BITECIC are supporting organisations that choose to implement the health economics tools and methods developed by MATCH.

Collaboration

MATCH (and since 2010 the MATCH/BITECIC strategic partnership) has co-organised six of its 11 Health Economics/User Requirements/Price Optimisation workshops in partnership with the Health Technologies KTN and regional Medilinks at events around UK in 2008-2010 and another with the ABHI in 2009

Amongst the non-Medilink workshops was an event at University of Nottingham aimed at academics that was run in collaboration with Bridging the Gaps, an endeavour to support interdisciplinary networking in universities (19/06/2009).

Evidence of impact

Working at the interface between the medical devices industry, the NHS and MATCH's core research has allowed MATCH to extend to a wide audience and ensure its relevance.

Training in health economics has been an important aspect of the workshops. Our questionnaires reported that the majority of attendees (65%) previously had little or no knowledge of health

economic evaluation and the vast majority (90%) had never used a decision-support tool.

In addition, participation records show that the workshops are attractive to a diverse audience, including manufacturers (the majority), NHS and private services providers, government agencies, academics, technology transfer professionals and consultants. This is encouraging because the fostering of a common language for evaluation is an important element in the wider adoption of HTA methods.

The Medilink partners have been very enthusiastic about the workshops. In East Midlands, the event was so popular that a second event was put on at the same venue just 7 months later. In addition to this, the formation of the MATCH – BITECIC partnership was in part due to an identified business viability in developing and delivering the MATCH tools and workshops.

In addition to business viability, the workshops were also recognised at an early stage of their delivery, where MATCH received the BioKneX prize for Industrial Collaboration at the Medilink East Midlands 'Healthcare Business Awards 2008'.

“HTA is not always considered to be particularly accessible for Med Tech SMEs and is often applied retrospectively to support sales. However, the workshop and tools provided a very useful insight as how HTA could be rapidly and practically applied at stage early enough to help influence the development of a new product. Functions such as headroom analysis stimulate debate and aid communication that ensures products can focus on the right attributes that potential users and purchasers are seeking.”

Giles Proffitt, Product Innovation & Operations Manager, Medilink

“We hosted two very successful MATCH events in the last year. The benefit to delegates is that MATCH provides a systematic economic evaluation model for those looking to sell their products into the NHS. Its strength is the ability to evaluate the economic effects of numerous variables such as competition, price, volumes and product efficacy. Recognised by the NHS, this is a valuable resource for anyone looking to break into this market.”

Costa Philippou, Business Development Manager, Medilink East Midlands

Who should we contact for more information?

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Healthcare Industries Task Force Case Study

Summary of Case Study

MATCH participated in the Healthcare Industries Task Force (HITF), a government-industry-academia initiative that was launched in October 2003 and reported in November 2004. The main outcomes of the report were ways to stimulate innovation in the NHS and industry and to increase the adoption of useful medical technologies. Professor Steve Morgan (MATCH investigator) and Dr Michael Craven (MATCH senior research fellow) participated in the HITF Working Group 2: Research & development and industrial base, working mainly within the Working Group: Assessment Methodologies.

From the initiative as a whole, a policy action plan was subsequently published in the HITF report *Better health through partnership: a programme for action*⁸ on 17/11/2004. This report provided a programme of action aimed at benefiting patients and the NHS and stimulating science and industry in the UK to improve growth in manufacturing, investment, employment and exports. The plan was subsequently enacted through the Strategic Implementation Group (SIG), co-chaired by Lord Hunt and Sir Christopher O'Donnell. As explained in the SIG report *Innovation for health: Making a difference*⁹, March 2007 (p18), the Task Force viewed device evaluation as a catalytic mechanism crucial to accelerating uptake of new medical technology. A discussion paper on innovation and procurement entitled *Assessing the Value of Medical Devices*¹⁰, was produced by MATCH in June 2007 and circulated amongst healthcare and industry stakeholders (including the Association of British Healthcare Industries) who were involved with taking forward the plan of action from the HITF process.

Two of the main outcomes of HITF were

- the former Device Evaluation Service (DES) undergoing a major redesign, transferred to NHS Purchasing and Supply Agency (PASA) in September 2005, renamed the Centre for Evidence-based Purchasing (CEP)
- the creation of the NHS National Innovation Centre (NIC). MATCH continued to work closely with both of these organisations who joined MATCH as Research Partners.

Research outcomes achieved with the EPSRC IMRC funding

Health Industries Task Force (HITF), *Better health through partnership: a programme for action*^{viii}, 17/11/2004. *Morgan S. and Craven, M.* were participants in HITF^{xiii} Working Group 2: Research & development and industrial base; Little Working Group: Assessment methodologies.

HITF Strategic Implementation Group (SIG) report, *Innovation for health: Making a difference*^{ix}, March 2007.

How were these research outcomes taken forward?

Of most relevance to MATCH research were

- the former Device Evaluation Service (DES) undergoing a major redesign, transferred to NHS Purchasing and Supply Agency (PASA) in September 2005, renamed the Centre for Evidence-based Purchasing (CEP),
- the creation of the NHS National Innovation Centre (NIC). MATCH continued to work closely with both of these organisations in developing methods for assessing the value of devices.

Evidence of impact on the economy and/or society

A Ministerial Medical Technology Strategy Group (MMTSG)¹¹ was established in accordance with the recommendation of the Healthcare Industries Task Force (HITF) Strategic Implementation Group (SIG). The group will take forward the SIG recommendations and provide a strategic forum for joint discussion of other issues of importance.

Any other information and relevant website(s)

- MATCH Nottingham hub with web links to all reports¹²
- Healthcare Industries Task Force¹³
- Ministerial Medical Technology Strategy Group (MMTSG)^{xi}
- National Innovation Centre¹⁴
- Centre for Evidence-based Purchasing¹⁵
- Statements of Clinical Need¹⁶

Background

MATCH was originally invited on to the government-industry-academia Healthcare Industries Task Force in 2003 as a stakeholder from academia. As the time MATCH's partnership was mostly with the medical devices industry. Professor Steve Morgan (MATCH investigator) and Dr Michael Craven (MATCH senior research fellow) participated in the HITF Working Group 2: Research & development and industrial base, working mainly within Little Working Group: Assessment methodologies.

Collaboration

Through Professor Steve Morgan and Dr Michael Craven at the University of Nottingham, MATCH participated in the HITF Working Group 2: Research & development and industrial base, working mainly within Little Working Group: Assessment methodologies (2003-5)

Evidence of impact

The HITF Strategic Implementation Group report Innovation for health: Making a difference^x, March 2007 (p18) explains how MATCH proceeded to collaborate with CEP (and the Centre for Research in Strategic Purchasing and Supply at Bath University) on a set of four medical device pilot projects bringing together the aspirations of the HITF outputs on both market access and product evaluation, with the aim of creating a common understanding of value across a diverse range of technologies.

Who should we contact for more information?

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Purchasing and Supply Agency and Centre for Evidence-based Purchasing Case Study

Summary of Case Study

One of the major outcomes of the Healthcare Industries Taskforce was that the former Device Evaluation Service (DES) underwent a major redesign, being transferred to NHS Purchasing and Supply Agency (PASA) in September 2005, renamed the Centre for Evidence-based Purchasing (CEP). The new Centre required new methods for evaluating medical devices.

MATCH worked closely with CEP (and the Centre for Research in Strategic Purchasing and Supply at Bath University) on a set of four medical device pilot projects bringing together the aspirations of the HITF outputs on both market access and product evaluation, with the aim of creating a common understanding of value across a diverse range of technologies. MATCH's major contribution to the pilots was to work alongside PASA Health Economist Lizzy Bower to assist CEP with the introduction of economic evaluations and reviews of their products^{xvii}

Subsequently MATCH, in collaboration with the Nottingham University Hospitals trust successfully bid to become a CEP service supplier, providing evidence and economic reviews. CEP transferred to NICE in 2010 as part of the move to create a Single Evaluation Pathway and we continue to provide evaluation services to NICE's Medical Technologies Advisory Committee.

Research outcomes achieved with the EPSRC IMRC funding

Reports [199, 200] plus contributions to other reports¹⁷

How were these research outcomes taken forward?

The development of new tools is part of the MATCH agenda.

Evidence of impact on the economy and/or society

MATCH is supporting the NHS in making better choices of technology through studies. In collaboration with the Nottingham University Hospitals NHS Trust successfully bid to become a CEP service supplier, and has taken on its first study, worth around £30k. Following the transfer of CEP to NICE in 2010, MATCH is applying for approved supplier status to NICE's Medical Technologies Advisory Committee to continue providing evidence and economic reviews.

Additional spin-off benefits to researchers, students, or collaborators

MATCH researchers are now engaged with contract work for the CEP and subsequently NICE.

They have gained experience with writing Evidence Reviews and Economic Reports for the NHS.

Background

MATCH contributed to the government-industry-academia Healthcare Industries Task Force in 2003 as a stakeholder from academia. One of the main recommendations of HITF was the formation of the CEP and they required assistance in developing new methods of assessing medical devices. MATCH was a natural partner.

Collaboration

MATCH in collaboration with CRiSPS (Bath University) worked with PASA on the initial CEP pilots including providing the health economics component of the VAC Therapy pilot (one of the four pilots) and participated in the Steering group for all four pilots.

Nottingham University Hospitals NHS Trust and MATCH provide reviews for CEP and subsequently NICE.

Evidence of impact

MATCH has produced to 2 reports for CEP [199, 200] and contributed to a 3rd^{xvii}

NIC and PASA both subscribed to MATCH as Research Partners.

MATCH is a supplier to CEP (now within NICE)

Who should we contact for more information?

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National Innovation Centre Case Study

Summary of Case Study

Working closely with the NHS National Innovation Centre (NIC) to take health economic tools into the NHS to support the innovation agenda. MATCH has taken its Health Economic Evaluation Tool (HEET), based on decision trees, to three companies that were seeking to introduce their technologies into the NHS. MATCH Senior Research Fellow Dr Michael Craven worked closely with the NIC and the companies involved in analysing three products

- saturation-driven oxygen therapy,
- optical blood glucose monitoring,
- varicose vein closures.

One of the main lessons learnt from this work was that a lack of firm data at an early stage of development or deployment of a medical technology innovation is not a barrier to mutual understanding of value between NHS staff and industry. The companies involved were able to ascertain under what conditions (price and performance) their device would be cost-effective. The process of using the MATCH tool helped to facilitate this understanding. Based on feedback from the NIC and industrialists involved in this study MATCH launched its series of workshops in collaboration with Medilink UK.

More recently, MATCH researchers have been collaborating with NIC and another MATCH partner Adams Business Associates (ABA) to facilitate the knowledge transfer of tools to the NHS regional Strategic Health Authorities. The aim is that the tools should support the SHAs in their decision-making in order to assess which innovations to fund from the Innovation Fund announced by Lord Darzi in 2009. Although there is a changing

landscape within the NHS it is likely that the new NHS Commissioning Board and GP consortia will require similar tools to aid decisions.

Research outcomes achieved with the EPSRC IMRC funding

The development of the Health Economic Evaluation Tool was achieved under MATCH and the studies to explore its impact have also been part of the research programme. A paper has been published [127] and abridged version disseminated to a wider audience as an innovation pamphlet, "What's it worth" [185];

How were these research outcomes taken forward?

As a result of the initial exemplar work, MATCH successfully bid for funding 'Exemplar studies in assessing the value of innovative medical devices for adoption within the NHS' - EP/F037775/1. This £110k grant, which started in August 2008, involved Lizzy Bower of PaSA (NHS Purchasing and Supplies Agency) and Brian Winn (NIC) on the steering committee and has successfully been completed.

This work provided a foundation to forward the HEET outreach with BITECIC in reaching more SMEs

Evidence of impact on the economy and/or society

The work directly impacts on the organisational capability of the SHAs to assess innovations. The Innovation Fund will be invested directly into a combination of projects on the ground and at regional level, speeding up the time it takes for innovative solutions to get from design bench to NHS bedside. This will benefit patients directly and increase the quality of the care they receive.

Additional spin-off benefits to researchers, students, or collaborators

Researchers have gained direct experience working with NHS staff and other MATCH partners and have published [127]. An abridged version of the paper was more recently disseminated to a wider audience through the UKRI Innovation UK publications 'Innovation What's It Worth' [185]¹⁸

Any other information and relevant website(s)

- Innovation UKxviii
- NIC¹⁹
- ABA²⁰
- Over £220 Million To Boost Innovation In The NHS, Medical News Today²¹ 29 Apr 2009²²
- Making sense of the new innovation landscape, Briefing paper (April 2009)²³

Background

MATCH contributed to the government-industry-academia Healthcare Industries Task Force in 2003 as a stakeholder from academia. One of the main recommendations of HITF was the formation of the NIC and they required assistance in developing methods of assessing innovation. MATCH was a natural partner.

England's ten Strategic Health Authorities (SHAs) received £2 million in 2009, and expect £5 million in each of the following four years to support frontline NHS staff in developing innovative ideas. The funds will be invested directly into a combination of projects on the ground and at regional level, speeding up the time it takes for innovative solutions to get from design bench to NHS bedside. This will benefit patients directly and increase the quality of the care they receive. NIC is responsible for implementing tools to support spending of the Innovation Fund and it was intended that the MATCH Economic Evaluator tool would be used by SHA Innovation Leads/Fund Managers to support their decision-making as to which innovations to commission. Due to recent plans from the new government to restructure NHS and abolish the SHAs by 2012, there is a new opportunity to work with the NIC to tailor the HE tool to the needs of alternative commissioners such as GP consortia.

Collaboration

Meetings were held to plan tool integration and deployment between MATCH, NIC, ABA, Matrix and the Young Foundation.

MATCH and NIC met at DH Whitehall with Miles Ayling (DH Director of Service Design) to approve the collaboration on supporting the SHA Innovation Fund (2009).

MATCH researchers and ABA have worked together on a number of medical exemplars to ensure that the 'interim tool' and the 'MATCH tool' are well integrated. This has involved selection of the following health care areas, for example:

- Self-monitoring of blood glucose level for diabetes using optical metering
- Management of stroke on admission to A&E using CT scanners

Evidence of impact

Work is ongoing to deploy MATCH tools to support the spending of the £220m Innovation Fund that will bring new innovations into the NHS. SHAs will benefit from the use of tools to support their decision-making.

"MATCH has played a key role in the development of methods for assessing healthcare innovations at the National Innovation Centre"

Brian Winn, Head, NHS National Innovation Centre

Who should we contact for more information?

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National Patient Safety Agency Case Study

Summary of Case Study

In 2006 Dr Beverley Norris left the MATCH team at the University of Nottingham to join the NHS National Patient Safety Agency as Human Factors Lead. She identified her experience on the MATCH project as a significant factor in securing this role.

In 2008 the NPSA advertised the role of Human Factors lead as maternity leave cover for Dr Norris. They contacted Dr Jennifer Martin, a MATCH research fellow, and asked her to consider applying as they wished to appoint a human factors specialist with particular expertise in healthcare and medical device design. Dr Martin's application was successful and between January and October she performed this role as a part-time secondment.

The skills and expertise that Dr Norris and Dr Martin gained through their involvement with MATCH were instrumental in their appointments and this is tangible evidence of the impact that MATCH has made on policy makers within the NHS.

During the secondment Dr Martin led a number of initiatives including:

- Advising the Department of Health (DoH) and Welsh Assembly Government (WAG)
- Implementing a new standardised patient ID wristband across the NHS
- Encouraging safe use of nasogastric tubes
- Purchasing for safety - collaboration with NHS procurement agencies.
- Safe use of insulin

Dr Martin also led the development and review of the joint NPSA/MATCH publication: 'Design for patient safety User testing in the development of medical devices. This was published in March 2010

This secondment provided benefits to the NPSA in terms of the human factors expertise provided by Dr Martin. The strategic advice provided to the DoH, WAG, combined with individual patient safety initiatives across the NHS, will result in long-term improvements in safety practice with consequent benefits to patients. It also led to a number of MATCH publications that are in press already [117] or have been submitted and are currently under review [209, 211, 212]

Research outcomes achieved with the EPSRC IMRC funding

During the secondment Dr Martin began the development of a human factors checklist to be used during the procurement of new medical devices. This initiative was the result of the unique insight into the needs and capabilities of both the NHS and the medical device industry that working on the MATCH project has provided as a result of the importance that has been placed on working closely with both of these key stakeholders. The MATCH framework for user-centred design (105) was successfully applied during this project.

Dr Martin used the knowledge and experience gained through this secondment to develop a training workshop for industry: 'The Benefits of Involving Users and Professionals in Medical Device Development'. This aims to provide industry with the knowledge needed to collect information

on the safety of their products and then to communicate this information effectively to the NHS.

How were these research outcomes taken forward?

This project has also resulted in the NHS supply chain re-designing their online catalogue - NHS Cat- to allow developers the opportunity to present evidence of how their devices meet NPSA safer practice notices or address current safety concerns. When this is in place, it will provide NHS purchasers with easily accessible and up-to-date information on safety.

Seven MATCH training workshop has been successfully delivered, alongside the MATCH Health Economics workshops, which are described in a separate case study. Over 300 individuals have attended from a wide variety of organisations including: venture capitalists, medical device developers, NHS managers and procurers (including NHS Clinical Procurement Specialist Network) academic spin-outs and R&D funders (NHS invention for innovation i4i):

As a result, the workshop is now going to be extended to provide a commercial training package on usability standards. Funding to support this work (£45K) has been secured through an EPSRC Knowledge Transfer Secondment grant that will fund Alexandra Lang (current MATCH PhD) student to work with BITECIC to produce the training package. This is due to start in January 2011 and be completed by September 2012.

Evidence of impact on the economy and/or society

The new standardised patient ID wristband has now been successfully rolled out across the NHS. It is anticipated that this will lead to a significant reduction in medication errors.

Dr Martin was invited to address a conference of NHS managers on designing and purchasing for safety: 1st Annual Safety Management in Health Services Conference. 27th September 2010

More than 130 members of the medical devices industry, NHS and academia have received the MATCH human factors training package.

- The NHS supply chain are re-designing their online catalogue - NHS Cat- to allow developers the opportunity to present evidence of how their devices meet NPSA safer practice notices or address current safety concerns. When this is in place, it will provide NHS purchasers with easily accessible and up-to-date information on safety.
- Dr Martin led a workshop on user-centred design and its potential for procurement of devices for the National Network of Clinical Procurement Specialists (August 2009)

Additional spin-off benefits to researchers, students, or collaborators

Dr Martin benefitted considerably from completing this secondment. It provided a valuable opportunity to test the approaches and theories developed during her research on the MATCH project within the NHS as well as the opportunity to develop management and leadership skills.

Any other information and relevant website(s)

NPSA Publication²⁴

NPSA Standardising wristbands improves patient safety²⁵

Background

Dr Martin applied for the temporary position of NPSA Human Factors Lead after seeing it advertised in the Ergonomist magazine. After being offered the position, she discussed the possibility of completing this as a secondment with the University of Nottingham, the NPSA and MATCH colleagues.

Collaboration

Between January and October 2009 Dr Martin led the Human Factors team within the National Reporting and Learning Service (NRLS).

A major part of Dr Martin's working time was spent analysing the safety incidents reported to the (NRLS). This used human factors tools such as Root Cause Analysis to establish the causes of these and develop strategies to prevent similar incidents from happening in the future.

The secondment involved close collaboration with a wide range of NHS and governmental stakeholders as part of the following projects:

- Purchasing for safety: this involved continuous collaboration with various NHS purchasing agencies including: NHS Supply Chain, collaborative procurement hubs, individual NHS trust procurement departments and the National Network of Clinical Procurement Specialists.
- Development of the joint MATCH and NPSA publication 'Design for Patient Safety: User testing in the development of medical devices'. Specifically facilitating the review of this document with bodies including The Department of Health, MHRA (Medicines and Healthcare products Regulatory Agency, The National Institute for Health and Clinical Excellence (NICE) and The Association of British Healthcare Industries (ABHI).
- Safe Use of Insulin: Collaboration with the Department of Health's National Clinical Director for Diabetes during the Safe Use of Insulin initiative.
- Dr Martin was invited to advise the Welsh Assembly Government on specific human factors initiatives to improve patient safety.

Evidence of impact

1000 copies of the MATCH/NPSA guide have been printed and circulated to NHS trusts and Medical Device Companies. It is also freely available to download from the NPSA website.

Following the publication of the guide, Dr Martin was invited to address a conference of NHS managers on designing and purchasing for safety (September 2010) and also to advise the Welsh Assembly Government on patient safety initiatives.

More than 130 members of the medical devices industry, NHS and academia have received the MATCH human factors training package.

“Dr Jennifer Martin was seconded to the NPSA to support the work of the Design and Human Factors team on medical device safety. Her knowledge of the medical device development, procurement and standardisation landscape was vital to the ongoing work of the NPSA to improve the safety of medical devices and equipment. In particular, she brought a joint MATCH/NPSA guide on user testing methods to publication, which will help device developers improve usability and safety. Her understanding of the needs of users, developers, and both the NHS and international device market helped ensure this publication will reach a wide audience”

Dr Beverley Norris, Human Factors Lead at the NPSA

Who should we contact for more information?

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Sofradim Case Study

Summary of Case Study

Some of the MATCH methods have been exploited through further research, in this case, through an EU Framework 7 Programme called STEPS. The Birmingham team became involved in STEPS, entirely through their partnership with MATCH.

Sofradim was one of the STEPS partners, a French company based in Lyon, which was involved in tissue engineering products. It was setting out to develop Urothelium, with a view to creating tissue to replace either the urethra or the bladder. One critical question was whether the products would succeed in the market place, even if the venture proved feasible from a technical point of view. MATCH was asked to conduct a study of this topic.

Our first task was to more precisely define the clinical problem to be solved. This issue resolved into four distinct clinical issues:

- Urothelium to breach large defects in the Urethra.
- Bladder reconstruction following surgical removal of the bladder in the treatment of Bilharzia (schistosomiasis).
- Following removal of the bladder (cystectomy) for unstable/dysfunctional bladder syndromes.
- Following cystectomy for cancer.

A simple economic “head-room” method was used to show that:

- The tissue engineered urethra was unlikely to prove viable, since there was already a very good alternative method using Buccal Mucosa. The short term gains that could be achieved by avoiding a small mouth operation to harvest the Buccal Mucosa were not commensurate with the costs of a tissue engineered solution.
- The prevalent areas for Bilharzia coincide almost exactly with the poorest countries as defined by per capita GDP at purchasing power parity. Clearly this was not a viable market.
- Clinical experience confirms that bladder removal is sparingly used for dysfunctional bladder syndromes and, moreover, a highly effective non-invasive therapy had recently come into use in the form of Botulinum toxin.
- Most cases of bladder cancer are treated by a total rather than a partial cystectomy. Nevertheless, a tissue engineered solution was potentially cost effective in these circumstances, largely because it could avoid the need to use bowel to create a neo-bladder. A less morbid operation, reduced hospital days, and the long term benefits of avoiding a bladder composed of bowel, were all factored into this decision.

However, even in the case of bladder removal for cancer, the likely volumes were low, unless operations to spare the urethral sphincter became commonplace. Moreover, it remains very uncertain as to whether a tissue engineered bladder would become innervated. If this was not the case, then the advantages of a tissue engineered bladder over a bladder fashioned from bowel would be more marginal.

Research outcomes achieved with the EPSRC IMRC funding

The case study led to the following peer reviewed journal publications [15, 27].

The Birmingham team have used this example in a large number of presentations – for example to the HTA commissioning group, the York Health Economics group and the California Institute for Regenerative Medicine

How were these research outcomes taken forward?

Sofradim, largely on the basis of our model, decided not to proceed with the development of a tissue engineered bladder or urethra.

They asked us instead, to carry out a study of the role of tissue engineering in hernia repair. This report (unpublished) showed clearly that there will be no such role for small (inguinal) hernias because, again, existing methods were so successful, leaving little head-room for an expensive alternative. However, there were large potential gains with respect to big incisional and stomal hernias. The company therefore has re-directed its efforts towards these applications.

Evidence of impact on the economy and/or society

The gradual acceptance of “supply side economics” will strengthen the economy, by increasing the chances that society as a whole will benefit by optimising market clearing.

“Working with the Birmingham team also improved substantially our organisational awareness and knowledge of health economics, especially as decision tools for the development of new products at the concept stage.”

Yves Bayon, R&D Expert

Additional spin-off benefits to researchers, students, or collaborators

Helen McAteer who carried out much of this work has completed her PhD.

Background

Sofradim asked MATCH to work on this project. We were introduced to Sofradim through the STEPS project in 2005, as described above.

Collaboration

This work was carried out by Helen McAteer, working closely with Professor Richard Lilford and Mr Alan Girling. We also worked closely with Yves Bayon from Sofradim.

Evidence of impact

This has been described above – development of this product would have consumed many millions of Euros.

Who should we contact for more information?

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“This is to confirm that my company, Covidien – Sofradim Production, was greatly assisted by the innovative work of the Birmingham team led by Professor Richard Lilford. The supply side economic model they constructed, along with clinical expertise that allowed them to frame the problem appropriately, helped the company to decide very early in the development process in the absence of clinical data and strong market data, to invest in use of regenerative medicine for hernia repair, rather than construction of a tissue engineered bladder.”

Yves Bayon, R&D Expert

Boston Scientific Case Study

Summary of Case Study

Boston Scientific, a MATCH partner, manufactures a wide range of medical devices centred on technologies which enable minimally invasive procedures. The Galway, Ireland, site has a focus on vascular products and coronary stents in particular. An opportunity arose to apply the work on medical device pricing developed within MATCH to coronary stents in conjunction with Boston Scientific. This piece of work built upon previous collaboration with Boston Scientific, investigating their in-house stage gate processes for new product development. This early work on stage gate processes informed the later new product development research within MATCH which resulted in several publications [130, 146, 159, 186].

Boston Scientific and the Regional Supplies Agency (the centre for NHS procurement in Northern Ireland) supplied medical device pricing and cumulative volume data to MATCH. The analysis of this data was used to establish relationships between price and total volume of product manufactured. This novel work represents the first publication of data supporting a relationship between price and volume for medical devices. Similar relationships in which the cost drops by a fixed percentage with every doubling of cumulative volume, have been previously observed in a range of other sectors, including polymer production and steam turbine equipment manufacture.

Boston Scientific whilst a MATCH partner, used the results of this research which predicted the likely development of the drug-eluting stent (DES) market to assist in internal decision making.

Research outcomes achieved with the EPSRC IMRC funding

The case study has led to a series of peer reviewed journal [120, 121] and conference publications [147].

How were these research outcomes taken forward?

In addition to the specific impact with Boston Scientific described herein, this work on pricing has formed the basis of a MATCH software tool which is available on the publically accessible section of the MATCH website. The dissemination of the MATCH tools in described in under the tools section of the report

Evidence of impact on the economy and/or society

Coronary stents have been used to improve the success of angioplasty procedures since the early 1990's. A stent is a small metal tube which assists in holding open an artery. Early stents were bare metal; however drug eluting stents, the first of which was launched in 2003 by Johnston and Johnston resulted in a step change in the market. DES aim to reduce re-stenosis (narrowing of the artery) after the angioplasty procedure by gradually releasing a drug in order to control thrombosis. The original Cypher stent by Johnston and Johnston had an initial selling price of approximately \$3000. However, by 2005 the average selling price had declined to ~\$2000, largely as a result of the launch of the first Boston Scientific DES in 2004. Medtronic and Guidant have also since joined the DES market which was valued at \$4.2 billion in 2008²⁶.

The research collaboration between MATCH and Boston Scientific investigated the decline in price with increasing volume for the US market, from the launch of the first commercial product in 2003 until 2005. A two stage relationship was observed with a constant rate of price decline with volume both before and after a step change in price which resulted from the launch of the Boston Scientific product. It was observed that the price declined by ~6% every time the volume of stents manufactured up to that point doubled. The technique was also applied to bare metal stent price and volume data, and found to accurately predict price decline.

It was found that the approach accurately modelled the price decline over the time period studied, and predicted the future market dynamics. The research was used by Boston Scientific to help inform decision making relating to market strategy.

“The work made predictions about where things were going in terms of the commoditisation of the DES market. In particular, the predicted fall in selling price resulting from increased volume and competition, has since born true. The work was presented within Boston Scientific in the US, at Vice Presidential level and raised awareness of the likely future development of the DES market within the company. Boston Scientific is still worldwide number one in the stent market, but as predicted by the MATCH work, any increases in profit margin resulting from continual product innovation have been limited”

Chris Dufresne, Development Manager, Vascular Division, Boston Scientific Ireland Ltd.

Additional spin-off benefits to researchers, students, or collaborators

Participating in this project provide MATCH researchers with complex real world problems. The data resulting from the project was used to validate the research model.

Background

Boston Scientific joined MATCH as a network partner at the funding rate applicable for larger companies. The engagement was with the Boston Scientific Europe, Vascular Division located in Galway, Ireland. Chris Dufresne, who was Development Manager in the company at the time of the project, led the industrial side of the project.

Collaboration

The industrial collaboration with Boston Scientific was led by Chris Dufresne, with Alan Brown leading the MATCH research team which also contain, Professor Brian Meenan, Professor Terry Young and Dr Dorian Dixon.

Evidence of impact

In addition to the impact within Boston Scientific described above, the work was also presented to the Regional Supplies Agency. This highlighted the potential application of the approach during procurement negotiations. The work has also led to a number of journal and conference outputs. The research led to the creation of a MATCH software tool which has been widely disseminated to MATCH partners and the wider device industry, by means of a tool brochure, trade articles and workshops. The tool and a printable user guide are currently available on the MATCH website. It is hoped to further develop the methodology through addition industrial and NHS engagement.

Who should we contact for more information?

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DePuy Case Study

Summary of Case Study

DePuy, one of the MATCH Research Partners, sells hip and knee implants. One value-add opportunity was to develop knee replacement instrumentation that could work with an alignment system, marketed by a commercial partner, BrainLAB to further improve patient outcomes.

The initial question was whether the extra cost of equipment could be justified in terms of better outcomes, and so MATCH undertook a study carried out by Dr Hengjin Dong and Professor Martin Buxton from Brunel University.

A Markov model was built which mapped out the different states patients might find themselves in following a knee-replacement operation. Making the right connections required expert clinical opinion – an orthopaedic surgeon. The first critical data needed to run the model was of the utilities of the various states. These would quantify, for instance, how much worse a total knee replacement with serious complications was over one with minor complications. The second set of data was the transition probabilities – namely how likely a patient was to move into or out of the various states shown in the Markov model. These data are quite difficult to estimate, and require considerable research, reading and then judgement to populate an entire model.

By comparing the runs achieved with data that related to standard surgery with runs using data that related to computer-assisted surgery, it was possible to estimate how much better one was than the other. In order to address the fact that the variables contained a degree of estimation or judgement, a sensitivity analysis was performed, in which the models were run many times, during which critical variable would be run across a range

of values. This provided a statistical foundation for the findings and also showed which data were most critical to the model.

The main calculation concerned the incremental cost effectiveness ratio (ICER) and it was possible to calculate that the computer-aided system represented value-for-money, within the NICE framework to a very high probability.

Research outcomes achieved with the EPSRC IMRC funding

The case study has led to a series of peer reviewed journal [18, 19], conference publications [46-48] and trade articles [68].

How were these research outcomes taken forward?

DePuy International developed an interactive spreadsheet tool to support a dialogue with customers across the UK, France, Germany, Switzerland and South Africa, as described below.

Evidence of impact on the economy and/or society

The market for knee implants in Europe, Middle east and Africa (EMEA) is worth €1-2 billion per annum. The navigated sector is something like 10% in Germany, 20% in Switzerland, but less than 5% in the UK. In EMEA, the navigated market is perhaps worth €100M per annum.

However, the sales route for computer assisted surgery (CAS, also 'navigated surgery') is indirect, since DePuy sells knee implants, but not the

computer-based system, which has been developed and is marketed by its commercial partner, BrainLAB. A further difficulty is that supportive pieces of equipment are often termed 'instruments' and hospitals expect them to be thrown in for free. However, because the computer assistive system is not DePuy's and because of the high capital cost, they have to enter into a dialogue to persuade customers that this is an investment worth making.

Over the past 4 years or so, DePuy has embedded the model in its thinking, using bought-in activity and some in-house effort – perhaps €50k in total – to produce an interactive spreadsheet tool that links evidence in the form of papers to the economic case, which in turn can be informed with local data. The EMEA sales structure involves 8 clusters and 4 of them use the tool to facilitate a dialogue. This has involved training 5-6 people to use the tool, who can take the dialogue to surgeons and hospital managers.

It is hard to connect the evidence in a causal manner, but the model was finally rolled out in Spring 2010 (4-5 years after the initial research). Dr Thorsten Burger, Commercial and Technical Manager CAS, EMEA, said, *“the model enables us to move the discussion around CAS from purely being seen as a cost factor for the providers/payors to a value based discussion”*. The situation continues to evolve and is expected to do so more when the 5-year survival figures become available.

For the purposes of MATCH, the commitment over several years to embed a MATCH method into their system is significant evidence of impact. It will take several years to understand the fuller story.

“The collaborative development through Match of a Markov model to calculate the potential health economic value of Computer Assisted Surgery in knee joint replacement has been of great value to the business. The publication is now a widely quoted key reference in the literature and the results from the model are being integrated into a provider proposition tool which sales people will use to help hospitals understand the economic proposition of adoption of this technology.”

Alan Ashby, Vice President Global Concept Development, DePuy International

Additional spin-off benefits to researchers, students, or collaborators

Participating in this project provide MATCH researchers and students with a real-world problem of high complexity.

Any other information and relevant website(s)

DePuy²⁷

Background

DePuy International Ltd signed a “Statement of Conditional Commitment to Joining as a MATCH Research Partner in August 2002 a year before the MATCH programme began. When MATCH commenced in November 2003, DePuy became a MATCH Research Partner throughout the first phase of MATCH. J&J, acting through DePuy invested significantly in MATCH during that period.

Collaboration

Dr Dong and Professor Buxton carried out their initial research at Brunel University but travelled to Germany to support the handover.

Evidence of impact

See above for a detailed analysis.

The first level of impact was the customer's desire to take up the model and build it into its own systems. Secondly, in making it a key plank of its platform to approach customers, it has stated the importance of this work in a multi-million Euro field of operations. Finally, the increasing level of uptake for CAS indicates that these measures have been part of a successful campaign, and shows at some level that customers find the MATCH case convincing, too.

“Working with MATCH academics has challenged some of our assumptions and internal processes particularly on the early identification and validation of a product's value to payer and provider stakeholders.”

Mick Borroff, Clinical and Reimbursement Lead for DePuy International

Who should we contact for more information?

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Moor Instruments Case Study

Summary of Case Study

From 2005 – 2009 MATCH collaborated on a Technology Strategy Board funded project to develop a new medical imaging device. The project was entitled BVIPS (Blood Vessel Imaging for Phlebotomy and Surgery). The BVIPS project was a collaboration between industry (Moor Instruments, academia (Nottingham University) and the NHS (Nottingham and Royal Devon and Exeter). The project team consisted of experts in: biomedical and clinical engineering, medical physics and nursing.

The BVIPS grant included funding to conduct user research as part of development, however the team had no expertise in this area and this was the reason for MATCH involvement. Dr Jennifer Martin, A MATCH research fellow in Human Factors, joined the BVIPS project team in January 2006. She designed and led the user research conducted at each stage of development and oversaw the data collection at the 2 NHS sites. As part of this work a number of novel and rigorous research methods were applied which allowed the project team to build a deep and comprehensive understanding of potential users and their needs, characteristics and capabilities.

This project also provided MATCH with a valuable opportunity to investigate a number of our research questions, specifically: the tangible benefits of adopting MATCH user research methods early in product development and the barriers to conducting user research in the clinical environment.

The feedback from the project team revealed that MATCH made a significant contribution in refining the concept for the device and identifying the

target users (both clinical and patient). In addition a number of previously unknown clinical needs were identified. The outcome of this being that the device will be targeted at the clinical areas where there is the greatest need, i.e. where there is the greatest potential for improved health outcomes for patients.

As well as informing the development of the BVIPS device, the results from this study resulted in a number of academic publications [209, 210, 211]. The results have also been disseminated in a variety of ways to the NHS and the medical device industry [95, 117].

Research outcomes achieved with the EPSRC IMRC funding

The main outcome of MATCH's involvement in this study was that the BVIPS project team was able to make a critical business decision on what the concept of the medical device should be. The research found that there was not a widespread need for the new imaging device within a general hospital population which was the target patient population. However a number of significant clinical needs in renal and oncology departments were identified that had not previously been considered. This meant that the primary users of the device would be completely different groups of healthcare staff. As a result of these findings the concept of the device was changed to ensure that the needs of the healthcare staff treating these patients were prioritised.

A second study, which evaluated an early prototype of the new device within the clinical environment, identified a number of design requirements. Most notably, the portability and weight of the device were not seen as critical factors, which contradicted

the prior beliefs of the development team. Of far greater importance was that the device should have a short start-up time and that once alongside the patient it should be easily manoeuvred to easily allow any part of the body to be imaged.

The user data collected in this study was successfully implemented into the design of the new medical device, which is now on the market as the 'moorLDLS2 rapid line scanning system'. Applying the MATCH user research methods resulted in the company identifying a number of clear clinical needs for the device, factors which will be important during marketing of the device. The MATCH methods also allowed the company to identify and measure the needs and capabilities of the wide range of potential users of the device as well as the physical and organisational barriers to adoption. This will increase the likelihood of safe and effective uptake of the device in the clinical environment.

How were these research outcomes taken forward?

Moor Instruments are currently deciding on the most appropriate route for commercialisation and new funding and investment is being sought to support the next stages of development.

Evidence of impact on the economy and/or society

The main result of this case study is a quality new medical device, which meets the needs of those people who will use it. By using this device, clinicians will be able to treat patients more effectively and with less pain and distress. A wide range of patients will benefit from the device including patients with burns and wounds as well as those in need of blood vessel access to treat acute and long-term conditions. In addition, healthcare providers and clinical users will benefit from the improved efficiency that will result from using the device.

Additional spin-off benefits to researchers, students, or collaborators

Participating in this project provided Jennifer Martin with the opportunity to conduct research within the NHS and also within industry. It is very likely that this experience played a part in her appointment as Human Factors Lead at the NHS National Patient Safety.

Any other information and relevant website(s)

Moor Instruments²⁸

Background

The BVIPS project was organised by Moor Instruments, who are a MATCH industrial partner. The other organisations that were part of the development team were: Nottingham University Hospitals NHS Trust, Nottingham University Department of Electrical & Electronic Engineering, Gooch & Housego and Peninsula College of Medicine & Dentistry (Universities of Exeter and Plymouth)

Moor Instruments was a MATCH partner and therefore we were aware of this study and proposed that we join the project team to provide expertise on user research.

Collaboration

Dr Martin worked with the team to plan, conduct and analyse the user research throughout the 3 year project. The data collection was performed in a number of clinical departments at 2 NHS trusts: Nottingham University Hospital NHS trust and Royal Devon and Exeter NHS trust.

Phase I User requirements Specification:

Individual semi-structured interviews with a sample of potential users of the proposed new device. The aim of this study: was to refine the concept for the device, identify the target clinical and patient users; identify any potential barriers to the safe and effective adoption of the device; and to collect user opinions on possible designs.

Phase II Early Prototype Evaluation: A novel technique called Contextual Inquiry was used to study how potential users operated the device within the clinical environment. The aims of this study were to: evaluate the quality of the images from the device; collect user opinions; identify organisational and environmental constraints to safe and effective operation of the device.

Dr Martin worked closely with a medical physicist and registered nurse to collect and then analyse the data.

Evidence of impact

The interviews with the BVIPS project team discovered that they believed that conducting early and rigorous user consultations had benefited the development of the new device. It resulted in a better understanding of the clinical need for the device as well as how the device would be used in clinical practice. Moor Instruments reported that this knowledge led to better decision making throughout development which may ultimately result in shortening the time to market for the device.

The results of this case study were used to write a MATCH guide aimed at industry on how to conduct user testing in medical device development. This guide is being published by the NHS National Patient Safety Agency as part of their well-established 'Design for Patient Safety' series, and will be disseminated widely to developers of medical devices within the UK. This is an acknowledgment of the importance of our research, as well as its relevance to industry, which is a key priority of MATCH.

We have been invited to present our research knowledge to a number of organisations by the use of workshops on user-centred design:

- Regional Medilinks
- Association of British Healthcare Industries
- Institute of Physics and Engineering in Medicine
- NHS National Institute for Health Research: Invention for Innovation (i4i) Programme

This is evidence of the impact that MATCH is having on the medical device community by disseminating our research findings on how to successfully apply user-centred design in healthcare design.

“Certainly the contribution of MATCH, through Dr Martin, was essential in being able to assess the product and its likely commercial success. What we have learned, and the decisions we have taken subsequently, depended very directly on MATCH’s involvement. Also in future, we will be applying this thinking to our future needs – especially user needs and cost-benefits thinking.”

Dave Boggett, Managing Director of Moor Instruments

Who should we contact for more information?

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Annex 12 MATCH Publications

Tools & Training

Journal articles

1. Johal, S.S., P. Oliver, and H. Williams, (2008), *Better Decision Making for Evaluating New Medical Device Projects: A Real Options Approach*. Journal of Medical Marketing, 8(2): p.101-112.
2. Lu, B., J.L. Martin, M.P. Craven, and S. Morgan, (Accepted), *Can Health Economics Aid Decision Making in Healthcare Innovation in Academia?* International Journal of Technology Transfer and Commercialisation.

Conference articles

3. Crowe, J.A., M.P. Craven, and B. Lu, (2010) *Experiences of Using a Spreadsheet Decision-Tree Tool with Non-Professional Health Economists. [Poster]* in proceedings of 7th Annual Conference of the International Society for Health Technology Assessment. Dublin, Ireland, 6th-9th June.

Trade articles

4. Craven, M., A. Brown, E. Deadman, J. Martin, P. Taylor, and S. Taylor, (Accepted), *MATCH Tools Workshops – Distilling Expertise for Health Technology Innovation*. Innovation UK special issue 'Innovation in Healthcare'.
5. Johal, S. and H. Williams, (2007), *Decision-Making Tools for Medical Device Development*. Focus Magazine, Association of British Healthcare Industries, March: p.20-22.
6. Merritt, J.P., (2009), *Tools for Assessing the Value of Medical Devices*. European Medical Device Technology (EMDT), (March/April), March.

Economic Evaluation

Journal articles

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8. Bowater, R. and R. Lilford, (2010 (online)), *Clinical Effectiveness in Cardiovascular Trials in Relation to the Importance of the Clinical End Points Measured*. Journal of Evaluation in Clinical Practice.
9. Bowater, R., S.A. Stirling, and R. Lilford, (2009), *Is Antibiotic Prophylaxis in Surgery a Generally Effective Intervention?: Testing a Generic Hypothesis over a Set of Meta-Analyses*. Annals of Surgery, 249(4): p.551-701.
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12. Brown, C.A. and R.J. Lilford, (2009), *Should the UK Government's Deep Cleaning of Hospitals Programme Have Been Evaluated?* Journal of Infection Prevention, 10(4): p.143-147.
13. Buxton, M., (2005), *How Much Are Health-Care Systems Prepared to Pay to Produce a QALY?* European Journal of Health Economics, 6(4): p.285-287.
14. Campbell, H., S. Tait, L. Sharples, N. Caine, T. Gray, P. Schofield, and M. Buxton, (2005), *Trial-Based Cost-Utility Comparison of Percutaneous Myocardial Laser Revascularisation and Continued Medical Therapy for Treatment of Refractory Angina Pectoris*. European Journal of Health Economics, 6(4): p.288-297.
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16. Davey, S.M., M. Brennan, B.J. Meenan, and R. McAdam, (Accepted), *Innovation in the Medical Device Sector: An Open Business Model Approach for High-Tech Small Firms*. Technology Analysis and Strategic Management Journal.
17. Davey, S.M., B. M., M.B. J., and M. R., (Accepted), *The Health of Innovation: Why Open Business Models Can Benefit the Healthcare Sector*. Irish Journal of Management.
18. Dong, H. and M. Buxton, (2006), *Early Assessment of the Likely Cost-Effectiveness of a New Technology: A Markov Model with Probabilistic Sensitivity Analysis of Computer-Assisted Total Knee Replacement*. International Journal of Technology Assessment in Health Care, 22(2): p.191-202.
19. Dong, H., D. Coyle, and M. Buxton, (2007), *Value of Information Analysis for a New Technology: Computer-Assisted Total Knee Replacement*. International Journal of Technology Assessment in Health Care, 23(3): p.337-342.
20. Girling, A., T. Young, C. Brown, and R. Lilford, (2010), *Early-Stage Valuation of Medical Devices: The Role of Developmental Uncertainty*. Value in Health, 13(5): p.585-591.
21. Girling, A.J., G. Freeman, J.P. Gordon, P. Poole-Wilson, D.A. Scott, and R.J. Lilford, (2007), *Modeling Payback from Research into the Efficacy of Left-Ventricular Assist Devices as Destination Therapy*. International Journal of Technology Assessment in Health Care, 23(2): p.269-277.
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27. McAteer, H., E. Cosh, G. Freeman, A. Pandit, P. Wood, and R. Lilford, (2007), *Cost-Effectiveness Analysis at the Development Phase of a Potential Health Technology: Examples Based on Tissue Engineering of Bladder and Urethra*. Journal of Tissue Engineering and Regenerative Medicine, 1(5): p.343-349.
28. Scott, M.A., C.P. Price, M.R. Cowie, and M.J. Buxton, (2008), *Cost-Consequences Analysis of Natriuretic Peptide Assays to Refute Symptomatic Heart Failure in Primary Care*. The British Journal of Cardiology, 15(4): p.199-204.
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30. Steuten, L., L. Vallejo-Torres, P. Bastide, and M. Buxton, (2009), *Analysing Uncertainty around Costs of Innovative Medical Technologies: The Case of Fibrin Sealant (Quixil®) for Total Knee Replacement*. Health Policy, 89(1): p.46-57.
31. Steuten, L., L. Vallejo-Torres, T. Young, and M.J. Buxton, (2008), *Transferability of Economic Evaluations of Medical Technologies - Exemplar of a New Technology Used in Orthopaedic Surgery*. Expert Review of Medical Devices, 5(3): p.329-336.
32. Vallejo-Torres, L., L. Steuten, B. Parkinson, A. Girling, and M. Buxton, (Accepted), *Integrating Health Economics into the Product Development Cycle: The Case Study of Absorbable Pins*. Medical Decision Making.
33. Vallejo-Torres, L., L.M.G. Steuten, M.J. Buxton, A.J. Girling, R.J. Lilford, and T. Young, (2008), *Integrating Health Economics Modelling in the Product Development Cycle of Medical Devices: A Bayesian Approach*. International Journal of Technology Assessment in Health Care, 24(4): p.459-464.
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35. Brown, C., (2008) *Should the UK Government's Deep Cleaning of Hospitals Programme Be Evaluated?* in proceedings of Improving Patient Safety 2008: From Safe Design to Safe Practice. Cambridge, UK, 16th-18th July.
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37. Buxton, M., (2009) *The Cost-Effectiveness Threshold: A Brief History of Time and Some Theoretical Concepts* in proceedings of Threshold Technical Workshop. London, 20th April. NICE (National Institute of Health and Clinical Excellence).
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39. Buxton, M., (2006) *How Much Should a Healthcare System Be Prepared to Pay for a QALY?* in proceedings of Centre for Health Policy/Centre for Primary Care and Outcomes Research Special Seminar. Stanford University, Stanford, California, 30th January.
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47. Dong, H. and M. Buxton, (2005) *A Deterministic Markov Model to Assess the Cost-Effectiveness of Conventional Total Knee Replacement Vs. Computer-Assisted Total Knee Replacement* in proceedings of 5th iHEA World Congress: Investing in Health, The International Health Economics Association (iHEA). Barcelona, Spain, 11th-13th July.

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35. Brown, C., (2008) *Should the UK Government's Deep Cleaning of Hospitals Programme Be Evaluated?* in proceedings of Improving Patient Safety 2008: From Safe Design to Safe Practice. Cambridge, UK, 16th-18th July.
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48. Dong, H. and M. Buxton, (2005) *A Deterministic Markov Model to Assess the Cost-Effectiveness of Conventional Total Knee Replacement Vs. Computer-Assisted Total Knee Replacement* in proceedings of Bringing HTA into practice, 2nd Annual Meeting. Rome, Italy, 20th-22nd June. Special Issue: Italian Journal of Public Health.
49. Girling, A., (2007) *Defining and Assessing Value for Patients and Organisations* in proceedings of Delivering Innovation, organised by the National Innovation Centre. Wellcome Trust, London, 5th November.
50. Girling, A., (2006) *Optional Treatments: Economic Analysis and Trial Design* in proceedings of Birmingham and District local group of the Royal Statistical Society. Birmingham, England, 6th April.
51. Girling, A. and R. Lilford, (2008) *HTA in the Commercial Development Cycle for New Devices: The Role of Early- and Late-Stage Models* in proceedings of V Annual Conference of the International Society for Health Technology Assessment (HTAi). Montreal, Canada, 6th-9th July.
52. Girling, A., R. Lilford, D. Braunholtz, and W. Gillett, (2006) *Assessing the Impact of Clinical Trials on Patient-Level Treatment Decisions - a 'True-Choice' Model* in proceedings of European meeting of the Society for Medical Decision Making. Birmingham, England, 12th-13th June.
53. Laiou, E., C.-B. TH, C. Brown, and R. Lilford, (2008) *The Management of Life Threatening Illness (MOLTI) Course: An Efficacy Assessment on the Simman* in proceedings of AMEE 2008. Prague, Czech Republic, 30th August -3rd September.
54. Scott, M., (2005) *Health Economics of BNP [Invited Talk]* in proceedings of (Invited by Bayer Diagnostics). Copenhagen, Denmark, 11th December.
55. Steuten, L., (2009) *Early to Late Stage HTA in the Medical Device Sector [Invited Presentation]* in proceedings of 6th Annual Meeting of the International Society for Health Technology Assessment (HTAi). Singapore, 21st-24th June.
56. Steuten, L., (2008) *Economic Evaluation of Healthcare Innovations: How to Move from Believe to Proof?* in proceedings of Annual Conference ZONMW & Trimbos Institutes. Amsterdam, The Netherlands, January.
57. Steuten, L. and M. Buxton, (2008) *Economic Evaluation of Safety Improvements in Healthcare - Which Health and Non-Health Attributes of Safety Are Considered Most Important by Healthcare Decision-Makers? [Poster]* in proceedings of V Annual Conference of the International Society for Health Technology Assessment (HTAi). Montréal, Canada, 6th-9th July.
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59. Steuten, L. and M. Buxton, (2007) *Valuing Safety in Health Care - Need for a New Approach?* in proceedings of Health Economics Study Group Conference. London, UK, September.
60. Steuten, L., J. Janssen-Boyne, T. Gorgels, and H. Vrijhoef, (2008) *Feasibility and Impact of a Homebased Telemonitoring System (Health Buddy®) to Support Case- and Self-Management for Adults with Chronic Heart Failure - Results from a Multi-Site Study in the Netherlands* in proceedings of V Annual Conference of the International Society for Health Technology Assessment (HTAi). Montréal, Canada, 6th-9th July.
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62. Steuten, L., L. Vallejo-Torres, and M. Buxton, (2007) *Transferability of Economic Evaluations of Medical Devices: An Example of the Use of Fibrin Tissue Sealant in Orthopaedic Surgery* in proceedings of ESF Conference: The International Regulation of New Medical Technology: health technology adoption in the European Union, North America, East Asia, and in the Developing World. Salgau, Germany, 7th-11th May.
63. Vallejo-Torres, L., L. Steuten, B. Parkinson, A. Girling, and M. Buxton, (2008) *Integrating Health Economics Modelling in the Product Development Cycle of Medical Devices: A Bayesian Approach* in proceedings of V Annual Conference of the International Society for Health Technology Assessment (HTAi). Montreal, Canada, 6th-9th July.
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65. Young, T.P., (2004) *MATCH: A Role for Academia and Major Research Funders in Generating Research Evidence* in proceedings of Delivering Quality in the NHS. M. Rawlins and P. Littlejohns, (Eds.). Oxford, Radcliffe Medical Press.

Trade articles

66. Buxton, M. and R. Akehurst, (2006), *How NICE Is the UK's Fast-Track System?* Scrip Magazine, 152 p.24-25.
67. Davey, S., M. Brennan, B. Meenan, and R. McAdam, (2010), *Innovation in the Medical Device Companies*. Innovation in Healthcare and Medical Technologies, 6(1) p. Supplement 29-31.
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Other publications

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User Needs

Journal articles

71. Bridgelal Ram, M., N. Campling (née Browne), P. Grocott, and H. Weir, (2008), *A Methodology for a Structured Survey of the Healthcare Literature Related to Medical Device Users*. *Evaluation*, 14(1): p.49-73.
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73. Grocott, P., H. Weir, and M. Bridgelal Ram, (2008), *A Model of User Engagement in Medical Device Development*. *International Journal of Health Care Quality Assurance*, 20(6): p.484-493.
74. Martin, J.L., E. Murphy, J.A. Crowe, and B.J. Norris, (2006), *Capturing User Requirements in Medical Device Development: The Role of Ergonomics*. *Physiological Measurements*, 27(8): p.R49-R62.
75. Martin, J.L., B.J. Norris, E. Murphy, and J.A. Crowe, (2008), *Medical Device Development: The Challenge for Ergonomics*. *Applied Ergonomics*, 39(3): p.271-283.
76. Morrow, E., F. Ross, P. Grocott, and J. Bennett, (2010), *A Model and Measure for Quality Service User Involvement in Health Research*. *International Journal of Consumer Studies*, 34(5): p.532-539.
77. Shah, S.G.S., A. Farrow, and I. Robinson, (2009), *The Representation of Healthcare End Users' Perspectives by Surrogates in Healthcare Decisions: A Literature Review*. *Scandinavian Journal of Caring Sciences*, 23(4): p.809-819.
78. Shah, S.G.S. and I. Robinson, (2008), *Medical Device Technologies: Who Is the User?* *International Journal of Healthcare Technology and Management*, 9(2): p.181-197.
79. Shah, S.G.S. and I. Robinson, (2007), *Benefits of and Barriers to Involving Users in Medical Device Technology Development and Evaluation*. *International Journal of Technology Assessment in Health Care*, 23(1): p.131-137.
80. Shah, S.G.S. and I. Robinson, (2006), *User Involvement in Healthcare Technology Development and Assessment: Structured Literature Review*. *International Journal of Health Care Quality Assurance*, 19(6): p.500-515.
81. Shah, S.G.S., I. Robinson, and S. AlShawi, (2009), *Developing Medical Device Technologies from Users' Perspectives: A Theoretical Framework for Involving Users in the Development Process*. *International Journal of Technology Assessment in Health Care*, 25(4): p.514-521.
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84. Grocott, P., (2007) *A Translational Research Model for New Product Development in Wound Care* in proceedings of How to enter the technical textiles markets conference 4th Symposium, Porto, Portugal, 23rd-24thMarch.
85. Grocott, P., (2004) *Wound Dressings for Fungating Wounds* in proceedings of World Congress of Wound Healing. Paris, France, 8th-13thJuly.
86. Grocott, P. and H. Weir, (2007) *Valuing the User in Medical Device Development: A Case Study in User Engagement* in proceedings of European Healthcare Management Conference. Lyon, France, June.
87. Grocott, P., H. Weir, and M. Bridge Ram, (2006) *A Model of User Engagement in Medical Device Development* in proceedings of 7th Annual Conference of the International Network of Integrated Care Models and Innovations in Chronic Disease Management and Long Term Care. Excel Conference Centre, London, 29th-30thNovember.
88. Lang, A., J. Martin, S. Sharples, and J. Crowe, (2009) *Enabling Adolescents to Participate in the Design and Improvement of Medical Devices* in proceedings of International Ergonomics Association, 17th World Congress on Ergonomics. Beijing, China, 9th-14thAugust.
89. Lang, A.R., (2010) *Adolescent Participation in HTA: The Identification of Appropriate Proxies for Adolescent User Needs of Medical Devices [Poster]* in proceedings of 7th Annual Conference of the International Society for Health Technology Assessment Dublin, Ireland, 6th-9thJune.
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95. Martin, J.L., (2010) *Understanding the Clinical Environment in a Usability Engineering Process* in proceedings of Institute of Physics and Engineering in Medicine (IPEM) Medical Physics and Engineering Conference and Bioengineering. 14th-17thSeptember.
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Conference articles

83. Crowe, J., J. Martin, and E. Murphy, (2008) *The Role of Users During the Development and Value Assessment of New Medical Technology* in proceedings of V Annual Conference of the International Society for Health Technology Assessment (HTAi). Montreal, Canada, 6th-9thJuly.

97. Martin, J.L., E. Murphy, and J.A. Crowe, (2008) *An Industry-Focused Approach to Medical Device Development: A New Blood Vessel Imaging Device* in proceedings of 2nd International Applied Human Factors & Ergonomics Conference. Las Vegas, USA, 14th-17th July.
98. Osvalder, A.L. and S.G.S. Shah, (2008) *Who Is Driving the Wheelchair? Interactive HTA to Improve Usability of Medical Equipment* in proceedings of Enlightened Development and Informed Decision Making for Medical Devices to Improve User Access - Preconference workshop at V Annual Conference of the International Society for Health Technology Assessment (HTAi). Montreal, Canada, 6th-9th July.
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