

User research in medical device development: an overview

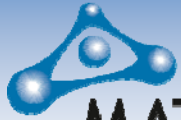
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Overview

- Introduction to MATCH
- User needs around medical devices
- Industry perspectives
- Innovation in methods



MATCH

Introducing MATCH

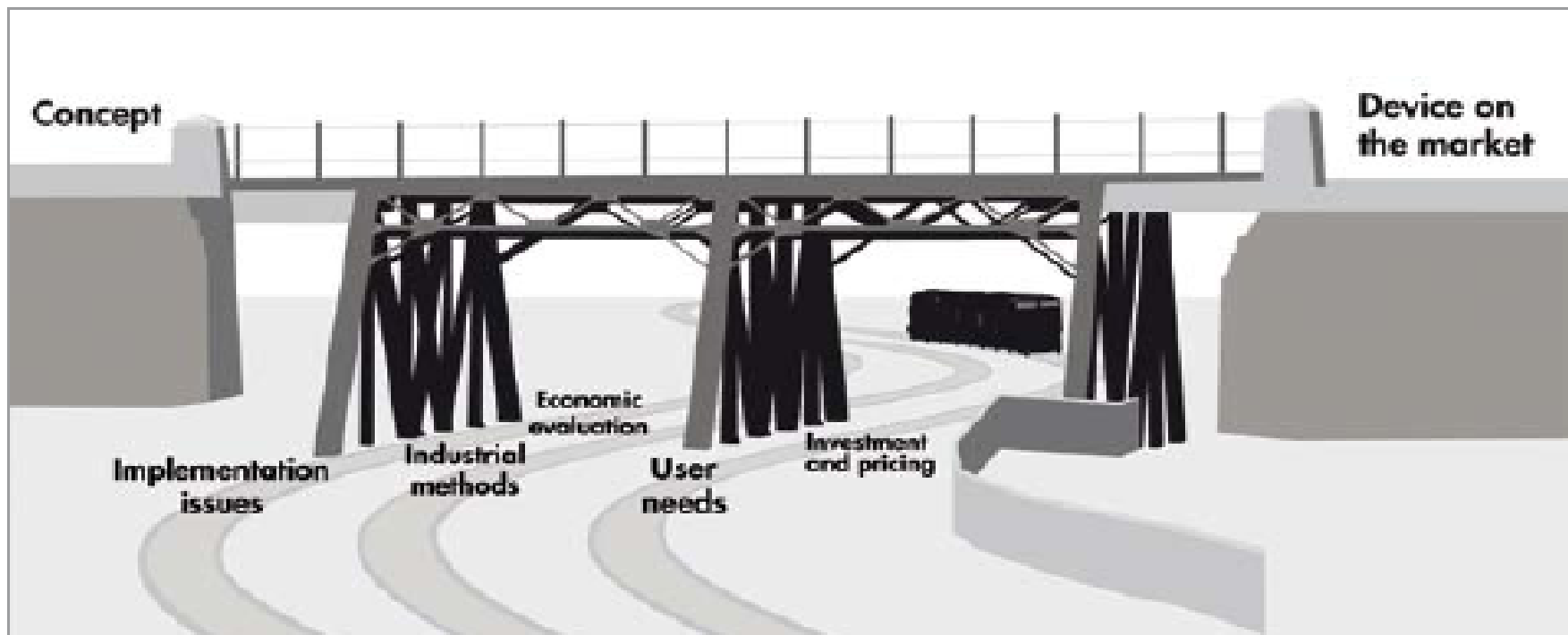
Ten year EPSRC funding as an Innovative Manufacturing Research Centre (2003-2013)

Universities of Brunel, Nottingham, Ulster and Birmingham

Engineers, medics, health economists, ergonomists, sociologists, information scientists, social psychologists



Research that spans the space between device as a concept and the device on the market
Key focus on VALUE – to industry, the NHS, and users





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.

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- Instrument, apparatus, appliance, software, material
- Diagnosis, prevention, monitoring, treatment or alleviation
- Investigation, replacement or modification of the anatomy or of a physiological process
- Disease, injury, handicap

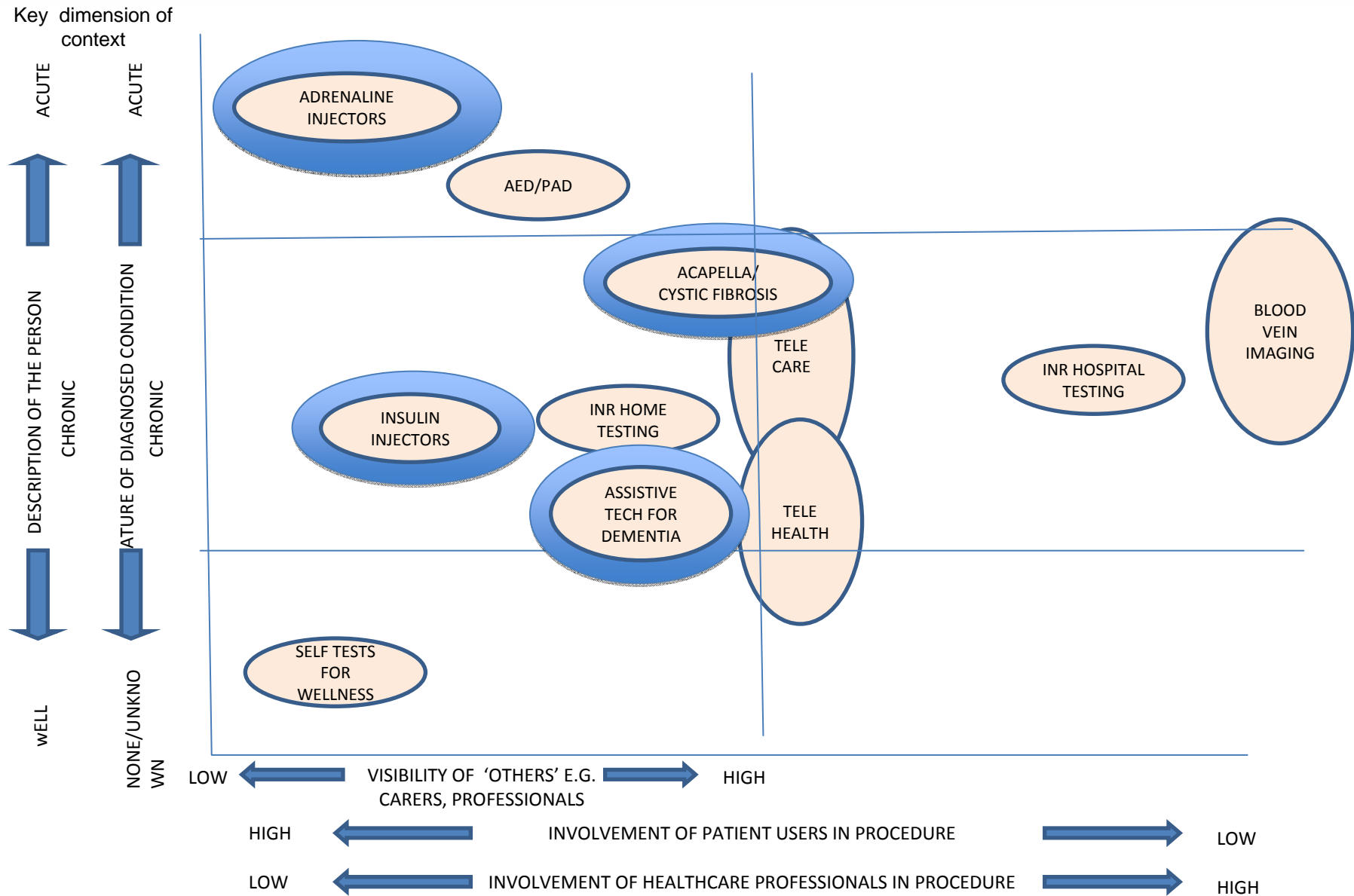
- SMEs dominate the medical device industry landscape
- Less likely to have specialised user needs expertise in house
- Research needs to be mindful of product development life-cycle and associated time constraints

- Relevant to distinguish between professional and non-professional users
- Arguably greater 'within' category variation than 'between'
- MATCH user needs work has particularly focused on non-professional users
- Rise in home based care and self care important policy context

- MATCH focus on guide and tool for methods choice considerations
- Considering the potential of social media for informing SMEs of user perspectives on particular medical devices
- Necessary – but not sufficient – to produce a medical device that is clinically effective and safe



DEVICE LANDSCAPE USER NEEDS RESEARCH





Imperatives and barriers to user involvement

Regulatory imperative requirements to demonstrate that human factors engineering approaches have been used and usability issues have been addressed

Requirements of funders of healthcare technology research to commit to consult/involve users and stakeholders

Guidance available for conducting user centred research



Lack of resources (money and time) for resource intensive user involvement

Difficult route between collecting data and using it

Results not readily appropriated into device development process

Developer has different criteria of successful user involvement than researchers

Future gains are uncertain

Users may have changing needs, preferences and goals

Money, A.G., Barnett, J., Kuljis, J., Craven, M.P., Martin, J.L. and Young, T. (2011) The Role of the User within the Medical Device Design and Development Process: Medical Device Manufacturers' Perspectives, *BMC Medical Informatics and Decision Making*, 11:15



MATCH

Responses to user facing research

Results and recommendations were not integrated into the development process. Why?

Mismatch between research results and expectations of developer – revealed clinical need was unexpected

Unrealistic/simplistic view of ‘user input’

Lack of integration between user and technology arms of the project – no interdependencies between user and technological arms of work

No formal requirements for interdependency even though funding is contingent on user research being conducted

Sub-optimal communication of results to developers?

Work of external researcher may be easier to dismiss?



“users will tell us how the device should look”



Methods for eliciting user perspectives

Analysis of product reviews from Amazon about AED found similar themes to focus group research

- analysis of 81 reviews compared to results of an interview study with 31 users and found strong similarities
- device ownership increased personal efficacy whilst desired role for device operation was passive
- strong emotional content to arguments for ownership
- cost effective way of capturing early user experiences of product?

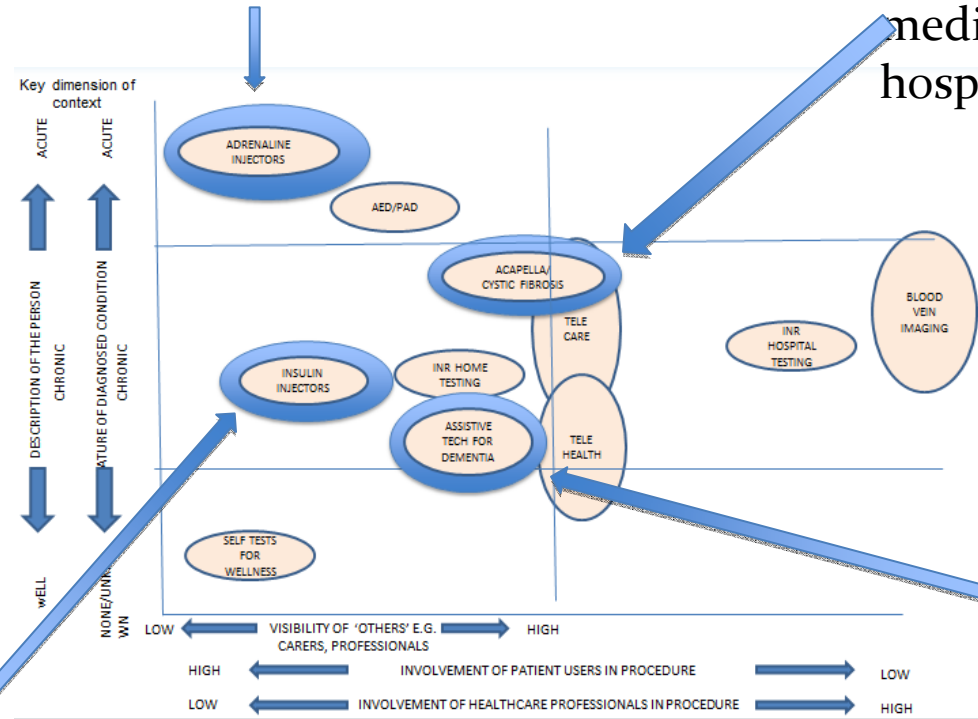
Analysis of patient blogs of home users of INR (blood coagulation) testing

- similar issues raised as in (limited related) literature
- few evident implications for design
- lack of differentiation between device and health care systems within which embedded



Arthur Money: Motivation and attitudes of users of adrenalin auto-injectors

Alex Lang: Patients (patience) in research. The challenges of interviewing adolescent medical device users in hospital clinics



Sonja O'Neill: Incorporation of carer and patient needs in the development of assistive technology for people with dementia

Jennifer Martin: Self management of Type II diabetes: the role of blood glucose monitoring

Ed Morris: Development of a tool to support method selection in medical device user needs elicitation and evaluation



Thank you for listening!

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