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DOCUMENTED
BRIEFING

Health Innovation Transfer from South to North

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RAND EUROPE

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Preface

This report presents findings from an exploratory study of health innovations being transferred from South to North. This was an independent project conducted over the summer of 2010 as independent research in RAND Europe.

Normally, technology transfer refers to a process where developed countries forge ahead in technology development, while laggard countries adopt technologies in their wake. This briefing examines technologies explicitly developed for developing country settings, which then may have an application in the UK National Health Service (NHS). This allows for a revealing and unusual insight into technology transfer by examining the barriers and enablers to adoption in the UK NHS.

Multiple methods were used including a literature review and case studies involving document reviews, key informant interviews and a survey. The study found several sets of factors that are key to adoption, many of them highly contextual. It concludes that further research is needed to understand how generalised these findings can be, and to ascertain whether a 'reverse innovation' trend is emerging.

The briefing will be of interest to policymakers who are finding that their concerns are beginning to overlap with those of developing countries (such as sensitivity to cost). The briefing also will be of interest to researchers wishing to understand the development and adoption of new technologies.

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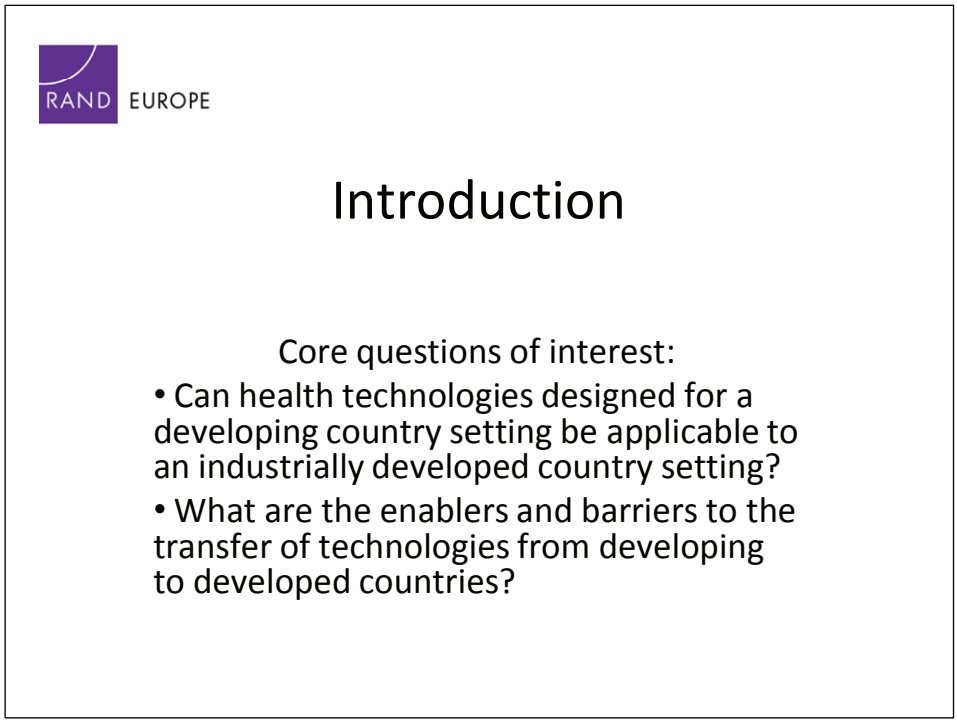
The authors would like to thank key informant interviewees for their help with this project. Thanks go to Johana Amar (Médecins Sans Frontières), Dr Philipp du Cros (Médecins Sans Frontières), Dr Fiona Duxbury (General Practitioner, Oxford), Jennifer Hislop (National Institute for Health Research, Health Technology Assessment), Dr Helen Lee (Diagnostics Development Unit, Cambridge University), Dr Victoria Lilford (General Practitioner, Birmingham), Dr Marc Mitchell (D-Tree International), Alan Barclay (Program for Appropriate Technology in Health, PATH) and Dr Bernhard Weigl (PATH).

CHAPTER 1 Introduction



Can health technologies designed for a developing country setting have an application in an industrially developed country? This study examines the transference of technologies that are being used in the South to the North, with the aim of identifying the barriers as well as the enablers in this process. The barriers and enablers will be examined in order to determine the scope of such a transfer, and to discuss prospects for its viability.

This documented briefing will look at a process of innovation whereby innovations are emerging as a result of different institutional set-ups. It will address the issue of how similar aims across different institutions are met differently, and how one context can inform another. The policy focus of the briefing will be to examine the potential of innovations developed for use in the South to address similar health problems in the North.

These key questions will be approached somewhat narrowly through two case studies (the Chlamydia Rapid Test and the careHPV test), with the aim of highlighting issues for

consideration rather than providing definitive answers to the core questions. The broad topic of technology transfer will be addressed via the differences in dissemination of innovation between a developing country context and the UK context. This narrow focus on one country means, by definition, that any assumptions about the industrially developed world should be treated with caution; however, the existence of this exploratory piece can be useful in that the methodology can be used in future studies to highlight enablers and barriers to technology transfer in industrially developed countries other than the UK. The case studies were analysed descriptively according to a framework covering the following dimensions:

- financial
- ethical
- regulatory
- infrastructural
- competitive advantages
- the role of the media and consumer
- social/cultural/religious and spillover or unintended consequences.

This is very much an exploratory piece. This is the first time that any data has been produced on this topic, and with very little literature on the topic we hope that this piece will be a pioneer in the thought in this area.

Global health is the health of populations in a global context and transcends the perspectives and concerns of individual nations. With increasing globalisation, infectious diseases that once affected mainly developing countries now affect the whole world, just as more chronic diseases of the industrially developed countries are on the rise globally (PricewaterhouseCoopers, 2007). The health of populations around the world is intertwined and interdependent, therefore it is increasingly important to talk about the interchange of innovations between North and South. People tend to focus on one direction of innovation and knowledge transfer – from North to South – and this study contributes a different perspective: the transfer of innovations developed for the South to use in the North.

It may be necessary to consider innovation interchange within an austere economic climate, whereby experience in developing countries of the challenges of resource constraint in technology innovation may have greater relevance to industrially developed countries.

Not only might there be useful lessons between the regions, but there is also an argument for maximising the benefits of each innovation for all people equally, given the limited funds and resources available for innovation globally (Grueber and Studt, 2010).

Cooperation, coordination and careful planning between researchers and implementers can result in innovation altering the face of healthcare worldwide, such as in the example below of the first home pregnancy test. Novel methods of healthcare must be introduced sensitively, so as not to upset the possibly fragile balance of socio-economic, political, cultural and regulatory systems in the region concerned.

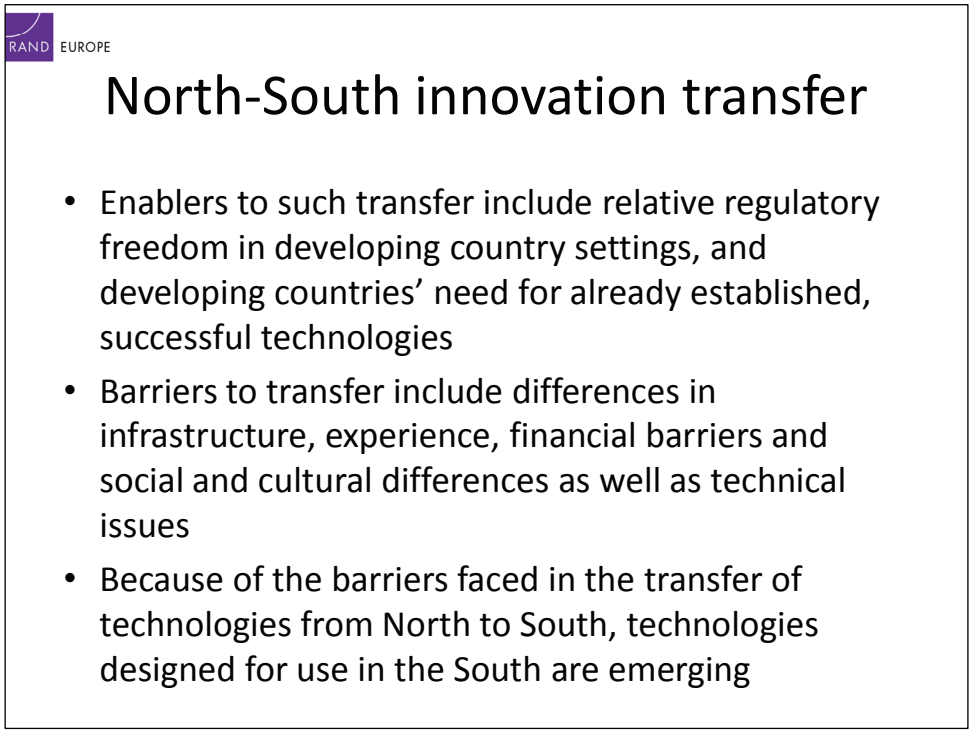
As social, political, technological, economic and health issues are intertwined, differences between the contexts in which a technological innovation is implemented will naturally

result in differences in how the innovation is perceived and implemented: its role in the healthcare system and its impact will vary from place to place.

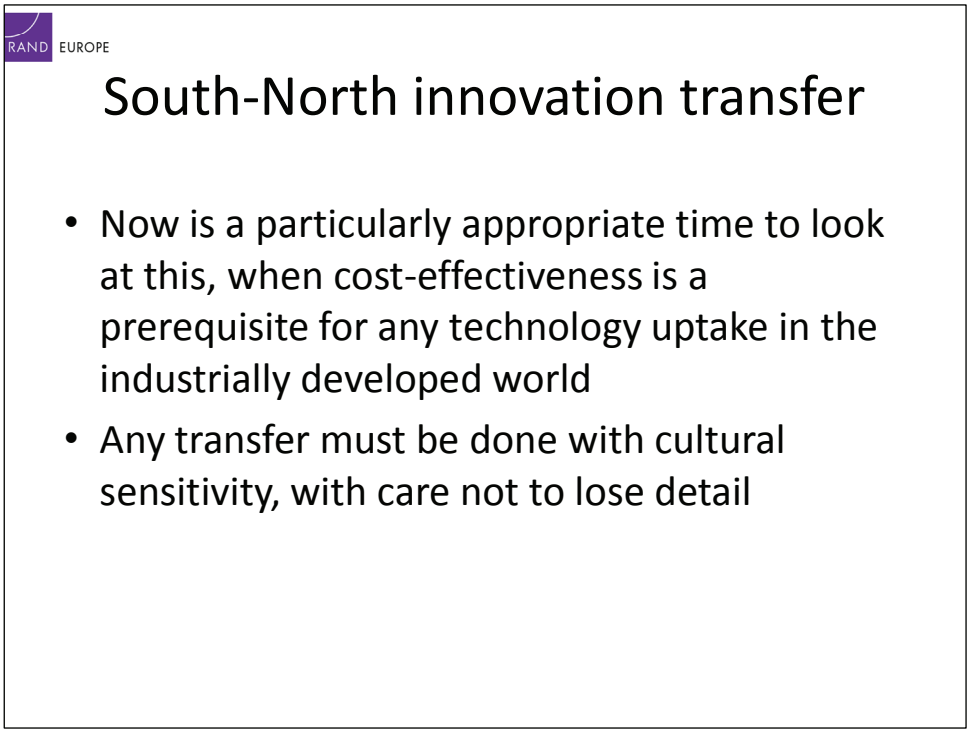
How much value healthcare workers, patients, governments, industries and other stakeholders place on the innovation will be dependent on the context. The level of health and economic benefit, the chances of success of the innovation and the education and culture of the actors are just some examples of relevant dimensions. Therefore, the selection criteria for deciding whether or not to adopt a specific innovation may vary quite widely according to the context. Technological paradigms of regions have a powerful exclusion effect, usually focused in precise directions (Dosi, 1982). Geographical variation in patients' and doctors' views of the innovation, and their power to make decisions on technology uptake, are also factors influencing innovation uptake and assimilation.

Diffusion and assimilation of an innovation in any situation involves moulding the original innovation to fit particular conditions of use and further improving the innovation. This process will vary depending on the actors involved, their tacit and cumulative knowledge, the infrastructure as well as other external environmental features available to support changes (Bell and Pavitt, 1993). For one country an innovation may be viewed as an incremental change along an existing trajectory, and for another it may be a discontinuous jump. An innovation may be an isolated technology in one context, and in another it may initiate a cascade of change.

Of course, all of these considerations are not necessarily homogeneous over one country or one region, and intranational variations must be recognised.

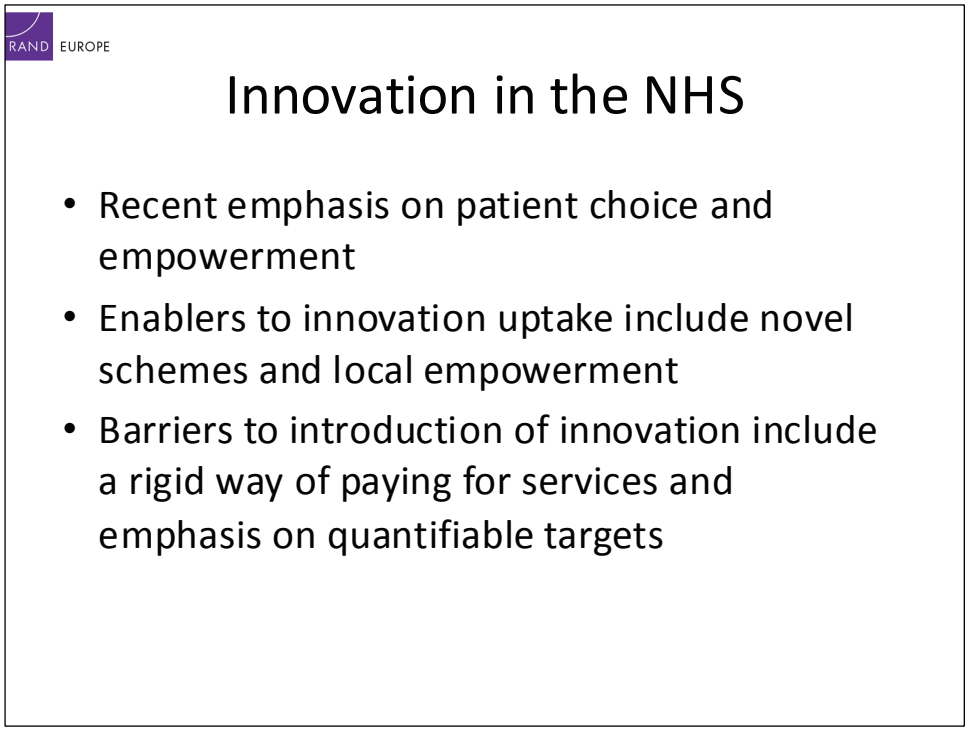


There have been attempts, with varying degrees of success, to transfer, translate and adapt technologies designed for industrially developed country settings to developing country settings. An image of the industrially developed world as the leaders in innovation, technology and healthcare systems is due partially to firms directing their research at the industrially developed world for purely commercial reasons. In an increasingly globalised world, many companies have looked to expand their business by marketing technologies in the South which have been developed for the North. Enablers to such transfer include relative regulatory freedom in developing country settings and the possibility to exploit well-established, successful technologies. With varying, if not limited, research and development capacity in the South, many developing world countries rely on technology from the industrially developed countries. However, barriers to transfer include differences in infrastructure, as well as technical problems (eg cold storage), financial barriers and social and cultural differences. In many cases innovations designed for the North have been adapted to the new context, but other stumbling blocks to the introduction of an innovation may still arise: for example, the technology may be affordable only to the affluent members of such societies, or may rely on a certain infrastructure. Because of these difficulties, there is a new wave of innovations designed for developing country settings in the health context (Immelt et al., 2009). This concept is being picked up by non-governmental organisations (NGOs), and is the idea behind the Gates Foundation Grand Challenges in Global Health Prize (Gates Foundation, 2011), an initiative to encourage South-specific innovation.



Many innovations designed for developing country settings are not appropriate or necessary for industrially developed country settings, as often adequate provisions for healthcare are already in place. However, a few innovations stand out, such as the rapid diagnostic tests used as case studies in this documented briefing. Diagnostic tests have the potential to be used in the industrially developed world, thanks to characteristics that are increasingly sought after in the North: for example, cost-effectiveness and patient empowerment. The present is a particularly appropriate time to consider this South–North transfer, with cost-effectiveness increasingly becoming a prerequisite for any technology uptake in the industrially developed world (Warner, 2011). This briefing discusses the opportunities as well as the complexity of the transfer of innovations from developing to industrially developed countries.

Any transfer, from North to South or vice versa, must be understood as a language translation, in a manner that is sensitive to contextual difference while not losing detail. It is important to view relationships between individual initiatives and larger institutional background. However, because of the different cultural and social contexts, as well as the political, economic and infrastructural situation where the innovation is to be used, it will be difficult to make any predictions about the effect of any healthcare innovations in varying settings.



The focus of transfer in this briefing is on the UK National Health Service (NHS). Recent emphasis within the NHS has been on patient choice and empowerment (Department of Health, 2002). Occasionally this empowerment has been a barrier to adoption and assimilation of new technologies, despite the intention of giving more freedom and flexibility to stakeholders, such as patients, doctors and nurses, in decisions regarding innovation uptake. An example of an empowerment initiative being a barrier is the centralised information and communication technology health system of summary care records, the most recent development in the Connecting for Health programme to maintain and develop the NHS national information technology infrastructure, which has been in existence since 2005.[1] The development is under serious scrutiny because of patients' and doctors' confidentiality concerns (Brittain, 2010).

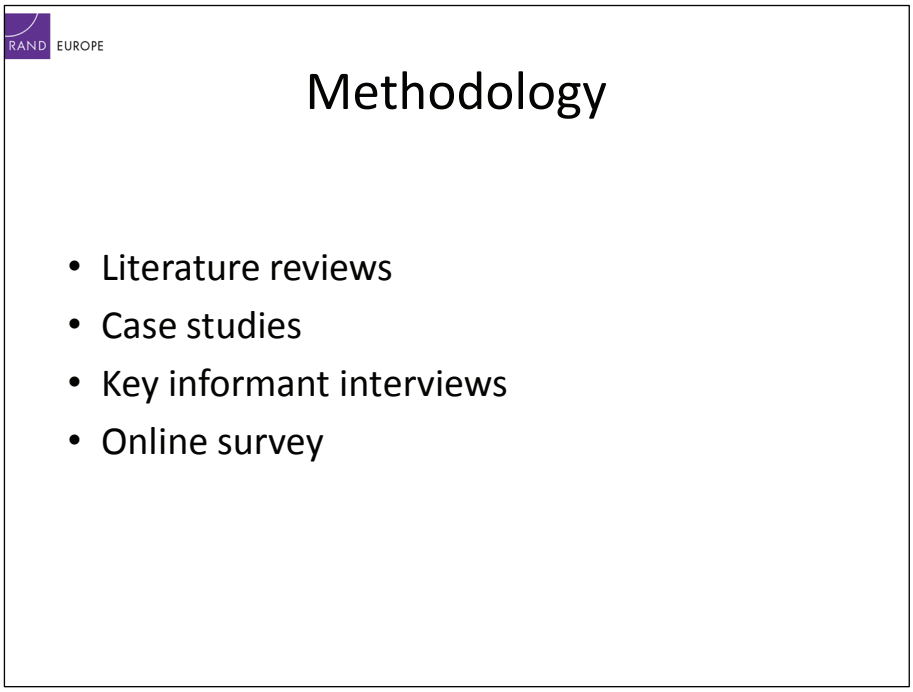
Despite such barriers, several innovations designed for use within the NHS setting have been implemented in the NHS and fully 'normalised': that is, they have become fully integrated into the healthcare system – for example, the Map of Medicine[2] and the home pregnancy test (Leavitt, 2007).

This briefing discusses some anticipated enablers and barriers to implementing innovations designed for developing country contexts within the NHS. More specifically, it will focus on point-of-care diagnostic tests for two different sexually-transmitted diseases (chlamydia and the Human Papilloma Virus, HPV).

[1] Http://www.connectingforhealth.nhs.uk/, accessed 19 July 2010.

[2] Http://mapofmedicine.com/, accessed 21 July 2010.

CHAPTER 2 Methodology



The methodology used in this study consisted of a combination of literature reviews and two case studies. The case studies were examined using a combination of semi-structured key informant interviews, literature reviews of the technologies as well as the environments for technology implementation, and a survey in order to inform on aspects not covered in the available literature.

The literature review, which included unpublished as well as published sources, was the starting point for analysing the existing evidence base on health technology adoption and transfer from North to South and vice versa. A list of designated keywords and phrases was used for each issue under investigation:

- innovation transfer;
- innovation translation;

- learning from the developing world; and
- knowledge exchange.

Google Scholar was the database searched and the list of designated keywords and phrases were selected in consultation with experts.

The two case studies examined in this study were both rapid-result, point-of-care diagnostic tests, the first being the Chlamydia Rapid Test, and the other the careHPV test for the diagnosis of HPV, which is used to inform diagnoses of cervical cancer. Information for each case was gathered using a variety of techniques such as semi-structured key informant interviews and document reviews, and in the first case study, a survey. The case studies were selected after reviewing a number of health technologies used in developing country settings. The studies chosen were the technologies with the most apparent relevance and utility in a developed country setting, as well as in the intended setting for its development. The case studies were analysed descriptively according to a framework covering the following dimensions:

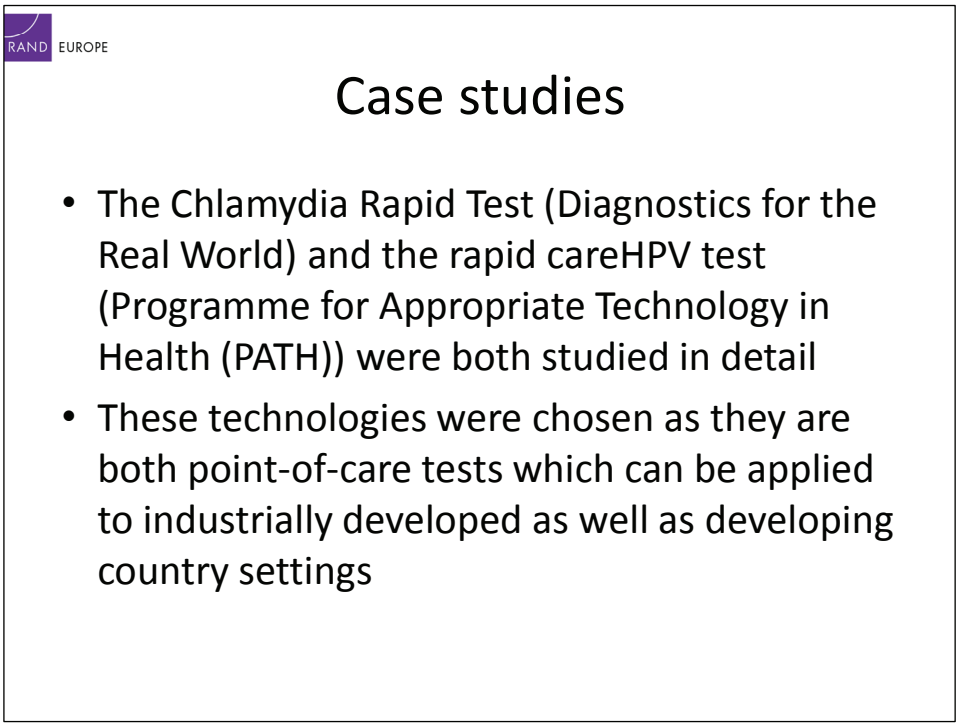
- financial
- ethical
- regulatory
- infrastructural
- competitive advantages
- the role of the media and consumer
- social/cultural/religious and spillover or unintended consequences.

This framework was created *ex post* as informed by the literature review, case studies and interviews (Walker and Whetton, 2002; Scott et al., 2008).

As mentioned previously, the key informant interviews were semi-structured interviews with the primary goal of obtaining qualitative descriptions of perceptions or experiences in relation to both technologies under study. Interviews were carried out face-to-face as well as over the telephone. The interviewees in this study included four technology developers, two developing world non-governmental-organisations (NGOs), six medical doctors in the UK, ten staff in the national screening programmes and 20 patients. Interviewees were chosen based on diversity of organisations. The interviews were not recorded, and the participant's consent to use the information provided was obtained.

A survey on the utility of one of the technologies in question was posted on Facebook and given to passers-by at a chlamydia screening outreach day (Notting Hill Market, 18 June 2010). The response rate for the survey was 12% ($N = 72$, comprising 54 responses out of 564 requests on Facebook, and 18 responses out of 38 requests during a chlamydia screening day). The aim of the survey was to evaluate the individual's perceived added value of the rapid-result nature of the Chlamydia Rapid Test, in particular with regards to 'experience factors' (ie factors affecting patients' experience of the diagnosis protocol), of the point-of-care Chlamydia Rapid Test.

CHAPTER 3 Case studies



The case studies were selected after reviewing a large number of innovations designed for the developing world. The majority did not have relevance to industrially developed country settings for a variety of reasons, including a lack of necessity (from disease burden – that is, the impact of a health issue in an area, as measured by financial cost, mortality, morbidity or other indicators – to infrastructural differences), and so lower cost-effectiveness compared with their use in their intended countries. In addition, legal issues may arise in developed countries, for example with lowered clinical sensitivity of technologies. Often this is not an issue in developing countries because of the decreased availability and suitability of alternatives, as well as a less extensive culture of regulations, guidance and protocols (field key informants, 2 September 2010). An example of a technology designed for the developing world that is not appropriate in the industrially developed world is the e-IMCI, an easy-to-use, mobile electronic diagnosis pathway developed by D-Tree International (Mitchell et al., 2010). However, in the USA, liability

issues would arise with such a preset diagnostic pathway used by healthcare workers. Such liability issues may arise due to the over-rigidity of protocols and an inability for scope for flexibility with regards to exceptions for unique cases. However, it may have a utility in some cases: for example, in the armed forces (industry key informant, 1 June 2010).

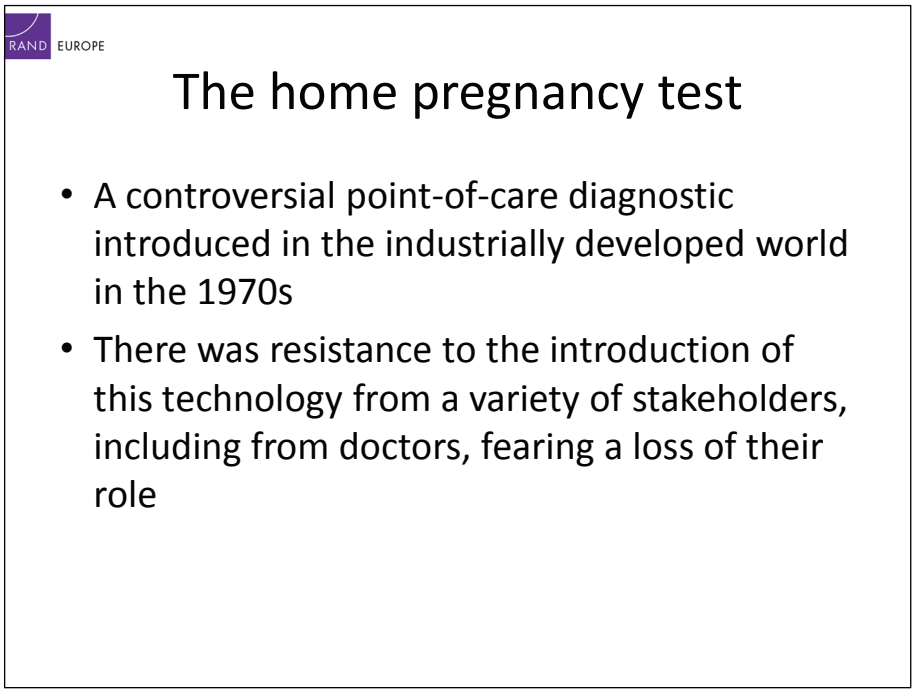
The two technologies studied in detail here are point-of-care diagnostics. Point-of-care diagnostics are diagnostic technologies available for use at point-of-care with no infrastructural requirements, and are often vital in developing countries where little or no central laboratories are available. There is often a trade-off between quality and rapid implementation, lower infrastructural requirements, less follow-up, and fewer transportation issues.

However, in the UK NHS, often point-of-care tests are not a priority. Health systems have been developed with central laboratories in place. With factories scaled up, it is commonly felt that there is little need for point-of-care tests, and so there is little incentive to change. However, a case for point-of-care tests in the UK NHS would be in outreach screening programmes, in the growing field of home care, and within the shift from acute care medicine to preventive medicine. This can be illustrated by the introduction of the home pregnancy test (see p. 14).

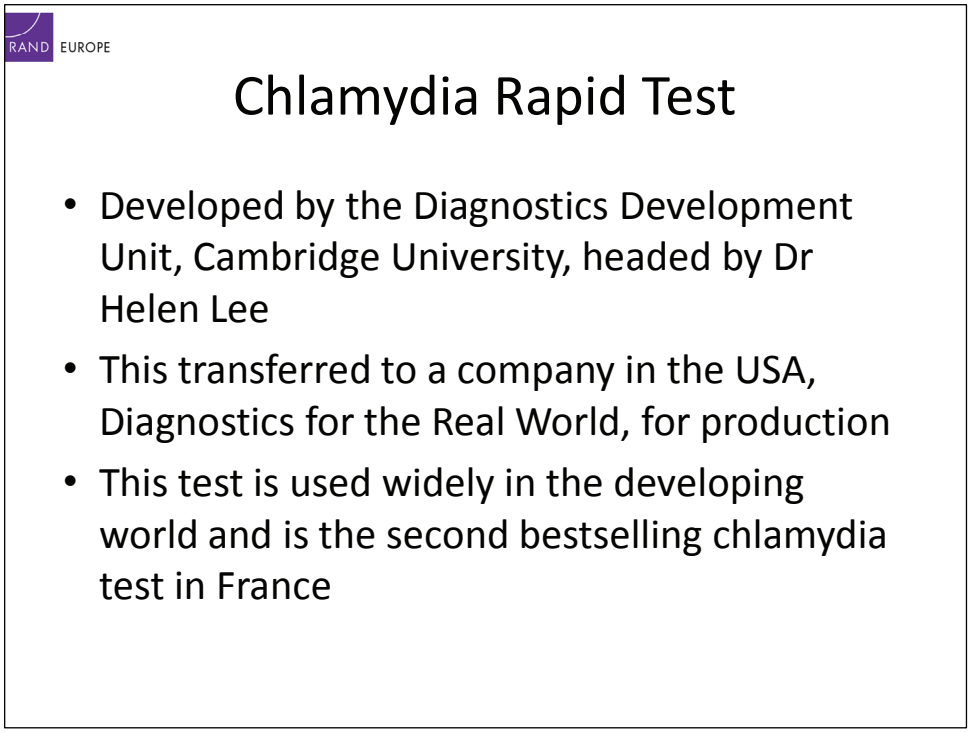
The two technologies in this study have relevance in the UK NHS. These are:

1. the rapid Chlamydia test – a rapid-result, point-of-care test for the sexually-transmitted infection chlamydia; and
2. the careHPV test – a rapid-result, point-of-care test for HPV, a virus causing 95% of cervical cancer.

Increasing empowerment and privacy concerns, in particular with regards to sexual health screening, may result in a rapid-result, point-of-care test increasing the extent of population coverage due to the discrete nature of the test (Calnan, 1995; medical key informant, 9 August 2010).



The introduction of point-of-care tests in the industrially developed world began in the 1970s with the introduction of the home pregnancy test. In 1976, the first home test (the early pregnancy test by Warner Chillcot) was introduced in the USA. The test arrived at the time of the Women's Liberation Movement, which included women's right to bodily integrity and therefore their right to choose medical treatment, including abortion, which became legalised in many states. As Leavitt explained, these contextual factors enabled widespread implementation of the technology. In addition, doctors were concerned at the time about their diminishing role and the possible adverse consequences of home testing. However, the test was warmly welcomed by women and the widespread publicity of the product was phenomenal, with advertisements in magazines, television, books and films (Leavitt, 2007).



The Chlamydia Rapid Test was developed in response to a need for easier, cheaper and more accurate diagnosis of sexually-transmitted infections in developing countries. With the asymptomatic nature of the chlamydia infection, many cases go undiagnosed, particularly in the developing world where screening programmes are not well established. In women, an undiagnosed chlamydia infection can lead to pelvic inflammatory disease which, if left untreated, can result in infertility. The previously available rapid tests for chlamydia were of low sensitivity and poor performance. Dr Helen Lee and her team at the Diagnostics Development Unit, Cambridge University, developed a high-sensitivity rapid test. The availability of this simple and rapid test allows for the screening and treatment of more individuals in developing countries, especially members of high-risk populations such as female sex workers. Dr Lourdes Mahilum-Tapay, who led the clinical trials, commented:

> Because the test is easy to use and is robust, it can be used in a clinic in London or the Philippines. The test can be implemented easily without the need for laboratory equipment or highly trained staff. (Wellcome Trust, 2007).

This was exemplified within a year of its production, with the test available in developing countries and, according to an industry key informant, rapidly becoming the second bestselling chlamydia test in France, after an unnamed bestselling test (industry key informant, 17 May 2010).

The development of the test was funded by the Wellcome Trust's Technology Transfer Division, and is now provided at cost price to public sectors in developing countries. This was possible through subsidisation from market price sales in the developed world (Wellcome Trust, 2007).

The authors believe that this test would have an advantage in the UK's National Screening Programmes over the tests that are currently used, due to its rapid result nature. Current tests (the gold standard test is based on a Nucleic Acid Amplification Test, NAAT) require a sample to be taken (which is possible at home), then to be sent away to a laboratory, with results usually available within 14 days. Coverage in England in 2009/2010 for screening was 22.1% (National Chlamydia Screening Programme, 2010). The authors believe that with a rapid result, screening and treatment coverage could be greatly increased, thus having a public health benefit. The authors propose that primarily this test would greatly enhance the capabilities of current outreach screening programmes, and eventually would be a useful home diagnostic tool.

Chlamydia trachomatis costs the NHS up to £100m a year in treatment costs associated with lower genital tract infections in men and women, and in long-term complications including ectopic pregnancy, tubal infertility and pelvic inflammatory disease (House of Commons, 2010). As a significant cost to the NHS, weight should be placed on the diagnosis coverage and treatment of chlamydia through increased screening.

Below, we summarise the enablers and barriers to introducing the Chlamydia Rapid Test in both developing country settings, broadly speaking, and the UK NHS. Based on the innovation literature, seven parameters were chosen to assess key enablers and barriers to uptake of a given technology, so as to highlight the key issues to be addressed in the process of adopting a technology. These parameters include:

- financial
- ethical
- infrastructural
- regulatory
- competitive advantages of the technology
- the role of the media and consumer;
- the social/religious/cultural environment and potential spillover and future complications.

As documented evidence of enablers and barriers varies in quantity and quality, this study has made a distinction between 'evidence-based' and 'speculative' enablers and barriers in reporting its findings. Evidence-based information has been extracted from official written sources, while speculative information has been the authors' presumptions derived from the personal experience of interviewees, and by drawing inferences from previous events: for example, events with similarity of characteristics such as the rapid HIV test. As many columns were empty, they have been removed where appropriate.

RAND EUROPE

Financial enablers and barriers to uptake of the Chlamydia Rapid Test in developing countries

	Enablers	Barriers
	Evidence-based	Speculative
Price	Tiered pricing of product, sold at manufacturing price in developing countries (Wellcome Trust, 2007) Used either in a healthcare setting or at home, savings in professional and laboratory time, as well as follow-up costs, are predictable (Wellcome Trust, 2007) The majority of chlamydia diagnoses are done based on syndromic management. This is seen as the most cost-effective way of managing the disease. It is cheaper than a screening programme and the use of a diagnostic technology (Saison et al., 2007)	Home testing can result in duplication and inefficiency Used in a healthcare setting, there will be training and switching costs
Funding		NGOs' and governments' priority for funds does not lie with Chlamydia diagnosis (field key informant interviewee, 2010) Corruption is an issue with regards to uptake of certain technologies, with funding and tenders going to favoured manufacturers (field key informant interviewee, 2010) From 2003, President's Emergency Plan For AIDS Relief (PEPFAR) would not fund non-governmental organisations (NGOs) which did not preach abstinence and fidelity, therefore preventing a lot of sexual health aid from reaching the populations in need Although there has been a new strategy since 2009, there is still some confusion on the policy of funding and funding preference for abstinence programmes

http://www.pepfarwatch.org

RAND EUROPE

Financial enablers and barriers to uptake of the Chlamydia Rapid Test in the NHS

	Enablers	Barriers
	Evidence-based	Speculative
Price	Current test = £56 average to process, including follow-up of positive patients (House of Commons, 2010) Test in France being reimbursed at €8.10 (=£7.12 6 April 2011) (industry key informant interviewee, 2010) Used either in healthcare settings or at home, savings in professional and laboratory time, as well as follow-up costs predictable (Wellcome Trust, 2007)	Home testing can result in duplication and inefficiency If used in a healthcare setting, there will be training and switching costs
Funding	There is good funding for chlamydia screening programmes. The National Chlamydia Screening Programme has spent £100 million since 2003 (Department of Health, 2009)	Reimbursement for General Practitioners (GPs) only if the test is on the national guidelines. Therefore it is not financially advantageous for GPs to adopt any other technology until on the national guidelines (medical key informant interviewee, 2010) GPs get more money for smoking cessation and obesity consultations (medical key informant interviewee, 2010) Aiming for increased coverage, this may increase overall cost to programme, but with a cheaper test, may be cost-neutral Targets in testing have not been reached by the national screening programme, therefore funding may be cut (House of Commons, 2010)

There is limited funding for chlamydia testing in both developing countries and the UK due to the fact that chlamydia is not necessarily at the top of the healthcare priority list. However, the low price and possible savings in professional and laboratory time has facilitated uptake of this technology in developing country settings. In the economic climate in the UK at the moment, the cost-saving potential of this technology is also a potential facilitator to uptake within the NHS.

RAND EUROPE

Ethical enablers and barriers to uptake of the Chlamydia Rapid Test in the UK NHS and developing countries*

	Enablers	Barriers
	Speculative	Speculative
Autonomy and non-maleficence	Non-invasive tests appeal to age group of women targeted, potentially increasing coverage obtained The possibility of home testing and a rapid result empowers men and women, giving them privacy, and potentially increasing coverage obtained	
Beneficence and distributive justice		Counselling opportunities are harder to project with use as a home test If used at home, it is more difficult to monitor the national situation, and to educate sexually active young people

*Both developing and the UK NHS experience similar ethical enablers and barriers to the uptake of the Chlamydia Rapid Test

Another key factor facilitating the uptake of this technology in developing and developed countries alike is the privacy and patient empowerment that it offers, with the non-invasive sample types and possibility of home testing. These features support the ethical principle of autonomy and non-maleficence, respectively (Bulger, 2007). With the test used in healthcare settings, a rapid result gives an increased opportunity for counselling patients whose test results are both negative and positive. For harder-to-reach populations, the likelihood of following through treatment and contact tracing (ie the process of contacting all of the patient's sexual partners in order to prevent the risk of further spread of the sexually-transmitted disease) to reduce new cases is increased with a rapid result. These are consequences that are relevant in developing as well as industrially developed country settings, supporting the ethical principles of beneficence as well as distributive justice.

However, using the technology in home testing would result in a loss of counselling opportunities for NHS providers, and consequent loss of data collection and monitoring, limiting the utility of this test from a public health perspective. This results in difficulty in following the ethical principle of beneficence, and creates a trade-off with regards to the ethical principles supported by the features of the technology. Different principles will weigh more heavily in different societies, and trade-offs of ethical principles will vary, thus altering the value of the technology in question.

RAND EUROPE

Regulatory enablers and barriers to uptake of the Chlamydia Rapid Test in developing countries

	Enablers	Barriers
	Speculative	Speculative
Legislative		Corruption may be an issue with regards to uptake of certain technologies (field key informant interviewee, 2010) There may be barriers to importation of a technology by an NGO if the technology has not been approved by the Ministry of Health (field key informant interviewee, 2010) As the technology was developed by a UK-based team, uptake and regulatory approval may have been hindered by not involving the country in question early on in clinical studies and workshops, etc.
Recommendations and guidance	The Sexually Transmitted Diagnostics Initiative promotes the evaluation, development and application of diagnostics for use in developing countries, disseminating information on the technology (World Health Organization, 2009)	Corruption may be an issue with regards to uptake of certain technologies As the technology was developed by a UK-based team, uptake and regulatory approval may have been hindered by not involving the country in question early on in clinical studies and workshops, etc.

RAND EUROPE

Regulatory enablers and barriers to uptake of the Chlamydia Rapid Test in the NHS

	Enablers		Barriers	
	Evidence-based	Speculative	Evidence-based	Speculative
Legislative	CE-approved*			
Recommendation		Patient choice in Health Technology Assessment (HTA) report only features willingness to wait and preference for collection. As women valued experience factors in the provision of chlamydia screening, cost-effectiveness studies should take other such values into account (Watson et al., 2009) The assessment has been made using the cost of test estimated at £21.74, which is considerably higher than actual cost	Findings in report on Rapid Chlamydia Test are that test is not cost-effective, has reduced sensitivity in comparison with NAATs and that the technology will not increase the number of chlamydia cases treated (Hislop et al., 2010)	In a time of recession and budget cuts, HTA and cost-effectiveness evaluations are likely to have more influence (Garrido et al., 2009)
Guidance	No National Institute for Clinical Excellence (NICE) guidelines for chlamydia diagnosis		No NICE guidelines for chlamydia diagnosis	

http://www.ce-approved.org/
http://www.chlamydiascreening.nhs.uk/ps/index.html

*CE-stamp to declare that the product meets European Union health and safety requirements

Although regulatory systems are often more complex in developed countries, there are still regulatory issues that act as enablers and barriers to technology uptake in developing countries. In order to gain an accurate picture of regulatory enablers and barriers, countries must be examined individually.

The rigid and formal technology evaluation and regulatory systems in the UK can behave as enablers or barriers to technology uptake, depending on the technology in question and the alternatives available. For example, the absence of National Institute for Clinical Excellence (NICE) guidelines on chlamydia could be an enabler (with no currently recommended test, there may be a free space for entry of a new technology) and a barrier (with no NICE recommendations, promotional and reimbursement opportunities are lost) to uptake of a new technology. As medical professionals' compliance with evidence-based guidelines is variable across the NHS, it is difficult to assess the importance of guidelines in technology uptake and 'normalisation': that is, incorporation into everyday practice. However societal changes, such as those the current economic climate may be bringing about, can act as facilitating factors to increase the demand and use of assessments and evaluations in healthcare policymaking as well as guideline compliance, due to the need to save costs in healthcare practice. For this reason, it may be all the more important at the moment to gain good evaluations and have wide stakeholder involvement in these evaluations in order to ensure successful uptake of the technology.

RAND EUROPE

Infrastructural enablers and barriers to uptake of the Chlamydia Rapid Test in developing countries

	Enablers	Barriers	
	Evidence-based	Evidence-based	Speculative
Technical	No other equipment required No electricity or water needed Performs well under variable conditions (Saison et al., 2007)		
Training	Low training requirements (Saison et al., 2007)		There will be training required for use in a healthcare setting
Capacity		There is very little screening of women for sexually-transmitted infections (STIs) in developing countries, therefore no capacity since infrastructural referral pathway and treatment scale up are absent (Saison et al., 2007)	Are there sufficient treatments available for positive patients? Advances derived from the use of better tests would only result in noticeable reductions in complications arising from chlamydia if the screening programme in its entirety is functional and efficient over extended periods of time

RAND EUROPE

Infrastructural enablers and barriers to introduction of the Chlamydia Rapid Test in the NHS

	Enablers	Barriers
	Evidence-based	Speculative
Technical	No other equipment required (Saison et al., 2007)	
Training	Low training requirements (Saison et al., 2007)	There will be training required for use in a healthcare setting
Capacity	National Chlamydia Screening Programme is well established, therefore referral pathways, etc are well established (Saison et al., 2007)	

The technology of the Chlamydia Rapid Test was designed for low resource settings: that is, it requires little to no infrastructure, is robust, easy to use and has no transport or storage problem. These features, which facilitate introduction of the technology into developing countries, also could enhance uptake in developed country settings (although to a lesser extent). It is advantageous in any situation to have a robust, easy to use, stand-alone technology.

Although the technology has low training requirements, its use in a healthcare setting will require a certain amount of training. However, where a national screening programme is already in place, generally there will be training update requirements every so often, so this may mean that there will be no further training requirements as a result of the new technology.

However, the capacity for testing varies between countries. With very little screening and treatment available in developing countries, the advantages of this technology are less pronounced in comparison with the UK NHS, where screening programmes and referral as well as treatment pathways are well established parts of national screening programmes. Although this capacity issue may be a barrier to uptake in developing countries, this should not necessarily be the case, as diagnosis and treatment are often in a 'chicken and egg'

situation, whereby increased diagnosis may facilitate an increase in treatment availability (Rosenberg, 2002).

RAND EUROPE

Competitive enablers and barriers to introduction of the Chlamydia Rapid Test in developing countries

	Enablers	Barriers
	Evidence-based	Evidence-based
Scientific	Sensitivity (83.5%) and specificity (98.9%), positive predictive value (86.7%) and negative predictive value (98.5%) of the Chlamydia Rapid Test are higher than for any other point of care test (Mahilum-Tapay et al., 2007) Studies show that a lower sensitivity is acceptable if there is transmission of the disease during the delay in treatment for the gold standard test and/or few women return for treatment (Vickerman et al., 2003) Currently, diagnosis and treatment of chlamydial infection is often done based on syndromic management principles, which has poor specificity (Saison et al., 2007)	Sensitivity and specificity does not match the best NAATs (range sensitivities 80-100%, specificities 93-100%) (White and Perry, 2004)
Logistical	NAATs require specimen transport, storage and laboratory throughput (White and Perry, 2004)	

RAND EUROPE

Competitive enablers and barriers to introduction of the Chlamydia Rapid Test in the NHS

	Enablers	Barriers
	Evidence-based	Evidence-based
Scientific	Sensitivity (83.5%) and specificity (98.9%), positive predictive value (86.7%) and negative predictive value (98.5%) are higher than any other point-of-care test (Mahilum-Tapay et al., 2007) Studies show that a lower sensitivity is acceptable if there is transmission of the disease during the delay in treatment for the gold standard test and/or few women return for treatment (Vickerman et al., 2003)	Sensitivity and specificity does not match the best NAATs (range sensitivities 80-100%, specificities 93-100%) (White and Perry, 2004) With the high sensitivity of NAATs, they are the gold standard on national guidelines (White and Perry, 2004)
Logistical	NAATs require specimen transport, storage and laboratory throughput (White and Perry, 2004)	

With different competitors (ie other chlamydia diagnostics) available, and different commonly used tests in developing and developed countries, the competitive advantage of the Chlamydia Rapid Test varies with the context.

The value of the sensitivity and specificity of a diagnostic test will vary from country to country. For example, with enhanced sensitivity over any other point-of-care test, the Chlamydia Rapid Test is scientifically valuable in developing country settings, where a point-of-care test is often the only viable way to obtain widespread screening. However, the sensitivity of the test is lower than that of the Nucleic Acid Amplification Tests (NAATs) currently used as a gold standard in the UK, which could be a barrier to introduction of the technology in the UK NHS.

RAND EUROPE

The role of the media and consumer as enablers and barriers to uptake of the Chlamydia Rapid Test in developing countries

	Enablers	Barriers
	Speculative	Speculative
Role of the media		Not a huge amount of media coverage for chlamydia infections in developing countries
Role of the consumer	Support of the technology is likely to rise with non-invasive tests, and empowerment from home testing and a rapid resuilt	Often in developing countries the voice of the consumer, in particular of the female, is weak Would women who are hard to reach at the moment be any more likely to take up the test?

RAND EUROPE

The role of the media and consumer as enablers and barriers to uptake of the Chlamydia Rapid Test in the NHS

	Enablers	Barriers
	Speculative	Speculative
Role of the media	The national campaign 'Chlamydia: Worth Talking About', presents a window of opportunity to enter with a novel technology (NHS Choices, nd) There has been a lot of bad press about rising cases of chlamydia as well as inefficiency of current screening methods, giving a window of opportunity to enter with a novel technology and screening method, as stakeholders are looking for a new solution to the problem (The Online Clinic, 2010)	There may be an issue with increasing coverage as this inevitable increases disease burden statistics for the UK, which projects badly in an international arena
Role of the consumer	The consumer has a strong role in the UK and with emphasis placed on consumer satisfaction, the support of this test is likely to rise with non-invasive tests, empowerment of home testing, thus assisting changes in policy and uptake of the technology	Would women who are hard to reach at the moment be any more likely to take up the test?

Often, consumers and media do not have much influence over policy and changes within healthcare systems in the developing world. However, in the UK, their role could potentially enable uptake of a technology into the NHS. The media contributes to consumer demand both actively and passively: one way is by presenting and exaggerating windows of opportunity for introducing novel technologies or service innovations.

RAND EUROPE

Social/cultural/religious enablers and barriers to uptake of the Chlamydia Rapid Test in developing countries

	Enablers		Barriers
	Evidence-based	Speculative	Speculative
Social	Rapid result is invaluable where disease transmission between test and result is likely (eg female sex workers) (Mahilum-Tapay et al., 2007)	Rapid result is invaluable where follow-up of patients is difficult , particularly for hard-to-reach populations, where there is a need to capitalise on a single contact point	
Cultural/religious			The introduction of any technology, but in particular a technology relating to sexual health, comes up against certain barriers such as: •-issues in the healthcare service, lack of funding and services •structural issues, taboos and cultural or religious barriers •lack of awareness and education of individuals

RAND EUROPE

Social/cultural/religious enablers and barriers to uptake of the Chlamydia Rapid Test in the NHS

	Enablers	Barriers
	Evidence-based	Speculative
Social	Percentage of positive index patients reported to be treated ranges from 100% to 59% (by area) (National Chlamydia Screening Programme, 2010) 12% of those reported positive did not collect treatment in 2008/09 (National Chlamydia Screening Programme, 2010) Estimated that 1/3 of people in England remain sexually active while they wait for their Genitourinary medicine (GUM) appointment (Terrence Higgins Trust, 2004) 3% of women develop pelvic inflammatory disease in the interval between testing and receiving their results (Hook et al., 1994) Studies show that home screening is an effective way of reaching young people who have little or no contact with health services, and that men are as likely to respond as women (Stephenson et al., 2000)	Doctors may oppose the use of a home test, fearing a loss of their role (Leavitt, 2007) Any advantages to arise from a new technology must be accompanied by the appropriate outreach schemes, and developments in equality of access to healthcare
Cultural/religious		The introduction of any technology, but in particular a technology relating to sexual health, comes up against certain barriers such as: •taboos and cultural or religious barriers •lack of awareness and education of individuals

A rapid result is invaluable in situations where the follow-up of patients is difficult, and where disease transmission between testing and result is likely. In the developing world as well as in the industrially developed world, a rapid result for sexually-transmitted disease diagnosis would have public health benefits, in particular for high-risk populations such as female sex workers, to ensure that the infection is not spread any further (where treatment is available and provided). Often in the developing world, patients travel a long way to a clinic, and so it is unlikely that they will return soon afterwards for the results or treatment. In situations such as these, the rapid result is invaluable to have a 'test and treat' strategy in a single visit. However, the barriers to introduction of such a technology in the South, as well as in the North, include cultural taboos regarding novel technology as well as sexual health issues, and a lack of awareness of disease and treatment possibilities (Rosen, 2000).

The impact of such a technology in the UK, as elsewhere in the world, also depends on the awareness and education of patients as well as care providers. The technology potentially increases screening coverage because of the simple and rapid nature of the test. However, while more people *could* be screened and diagnosed quickly, it does not necessarily make them come in and use the technology. Therefore, the success of the technology is dependent on an accompanying change in culture around patient behaviour, perceived risk and other social determinants of health, without which a substantial advantage over the previously used diagnostic is unlikely to be evident.

RAND EUROPE

Spillover/unintended consequences as enablers and barriers to uptake of the Chlamydia Rapid Test in developing countries

	Enablers		Barriers
	Evidence-based	Speculative	Speculative
Spill over	A modified version of the technology has been developed for trachoma, the most common infectious cause of blindness (Michel et al., 2006) Home testing will release a burden from professional health workers (Wellcome Trust, 2007)	If this test was to assist development of national screening programmes, this would create jobs	
Unintended consequences		The Rapid Test Paradox supports the hypothesis that more people can be tested and treated using a less sensitive rapid test, thus reducing the disease burden more than if a more sensitive laboratory-based test was to be used (Kassler et al., 1999)	There is no fallback around the world when a technology is used widely and fails (Blume, 2005) For home testing it is necessary to establish a support system with regards to treatment and contact tracing

RAND EUROPE

Spillover/unintended consequences as enablers and barriers to uptake of the Chlamydia Rapid Test in the NHS

	Enablers		Barriers
	Evidence-based	Speculative	Speculative
Spillover	Home testing would release a burden from professional health workers (Wellcome Trust, 2007)		As it has been developed and produced for a developing country setting, it may be difficult to see the adverse consequences There is no fallback around the world when a technology is used widely and fails (Blume, 2005)
Unintended consequences		The Rapid Test Paradox supports the hypothesis that more people can be tested and treated using a less sensitive rapid test, thus reducing disease burden more than if a more sensitive laboratory-based test was to be used (Kassler et al., 1999)	May threaten jobs if the national programme is conducted mainly at home For home testing it is necessary to establish a support system with regards to treatment and contact tracing

The spillover and unintended consequences of introducing this technology varies according to the context. While introducing this technology may assist the development of sexual health screening programmes in the South, and therefore have a large spillover, it may replace or diminish screening programmes in the North, and thus face resistance from healthcare workers.

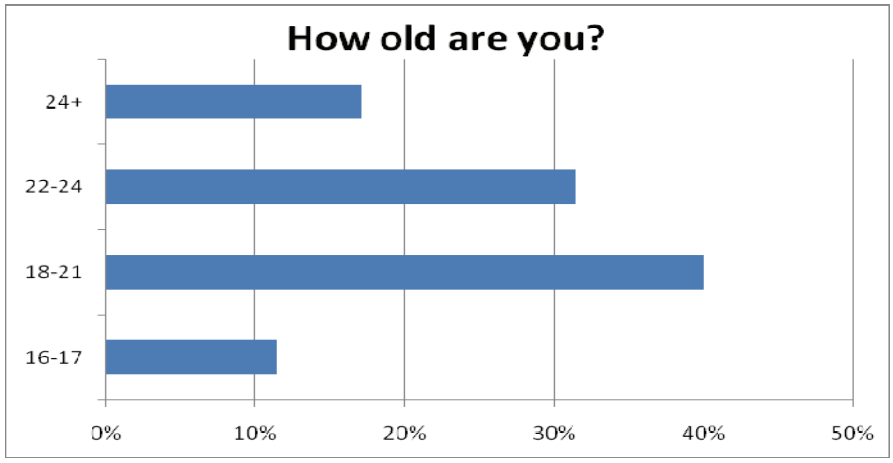
The online survey was carried out in order to gain further information on added value for users, in particular with regards to the 'experience factors' of the point-of-care Chlamydia Rapid Test. In the cost-effectiveness assessment, the National Institute for Health Research Health Technology Assessment (HTA) report on the technology omitted the value of factors such as potential increased coverage, treatment and contact tracing as a result of its discrete and rapid nature (Hislop et al., 2010). The age and background of respondents was asked in order to ensure representation of a wide sample of the population. The questions aimed to discover patient preferences with regards to chlamydia testing, and whether preferences could influence behaviour with regards to frequency of testing, acceptance of treatment and likelihood of contact tracing as reported by the survey respondents.

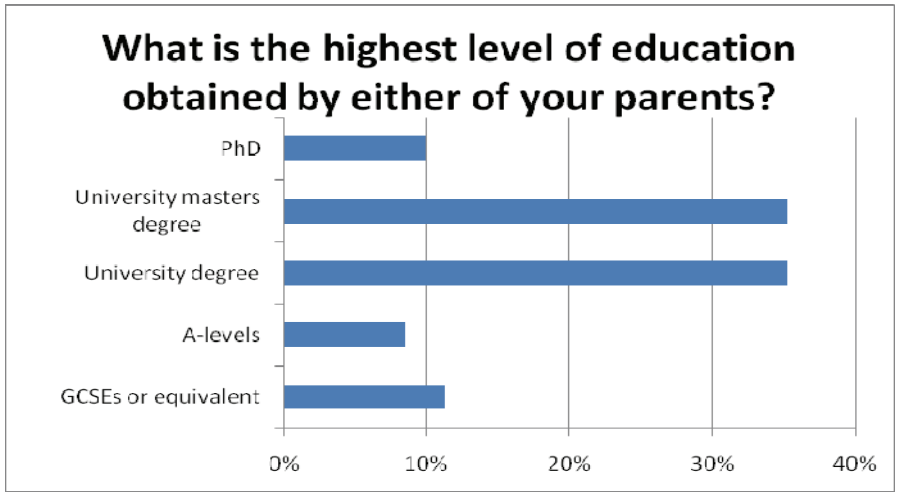
The survey was limited by at least two sources of bias. The small sample size (72) is likely to introduce bias in the findings, and since participation was voluntary, bias also may result

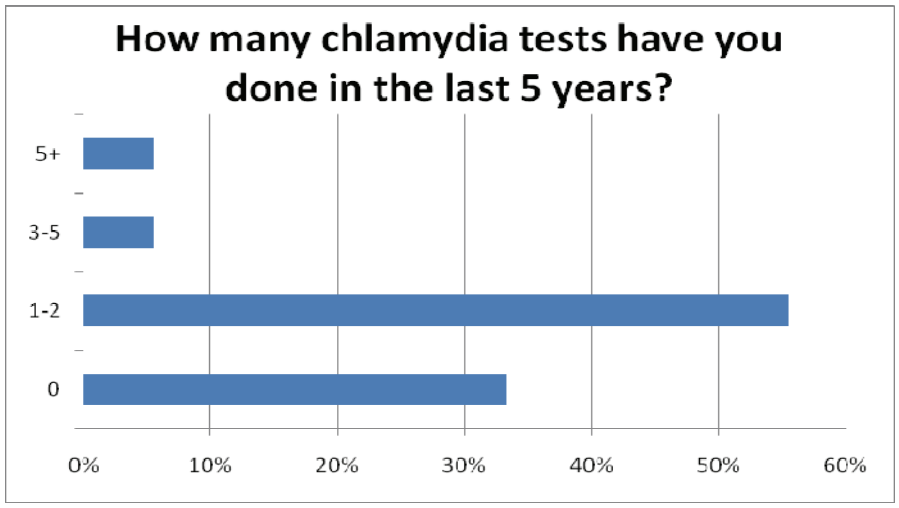
from the fact that the respondents were likely to have an interest in the topic and may not represent the more 'hard-to-reach' populations which might respond differently to the questions. Another source of respondent bias derives from the sensitive nature of the topic under investigation, insofar as respondents may be more likely to provide socially desirable answers, even despite survey anonymity.

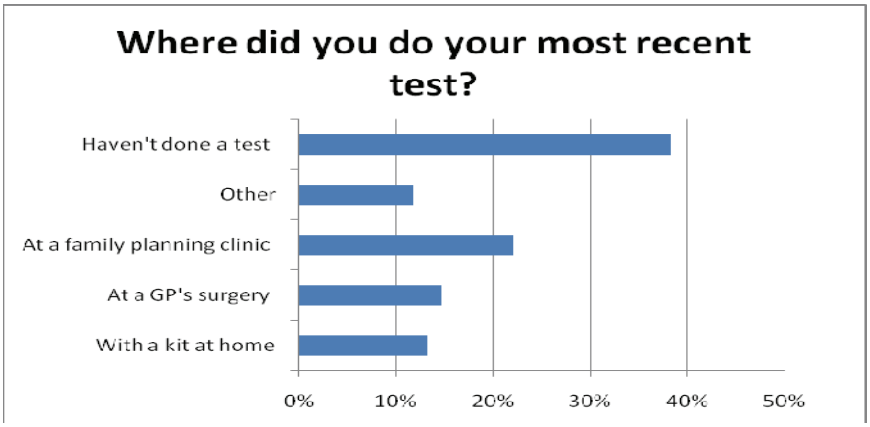
However, the results were qualitatively positive with regards to the utility of the test in increasing population coverage and improving treatment-seeking behaviour, as well as contact tracing.

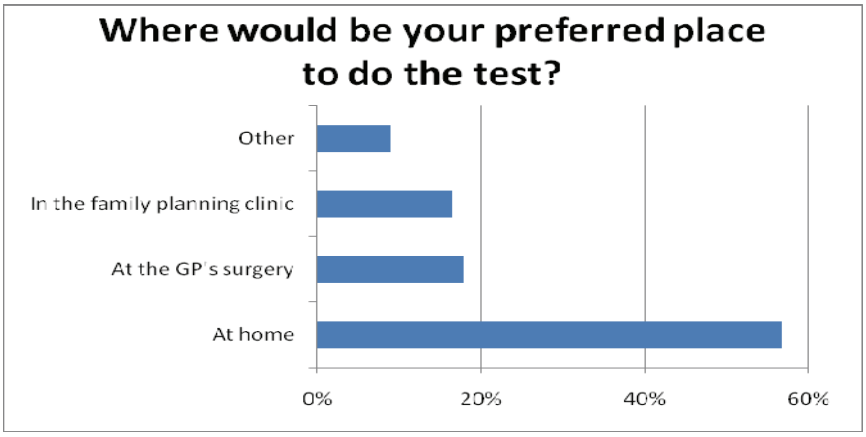
Survey results (N = 72)

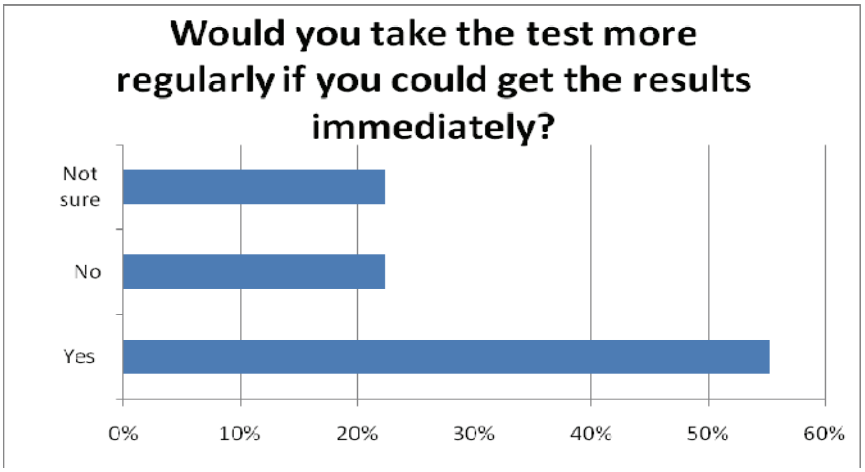


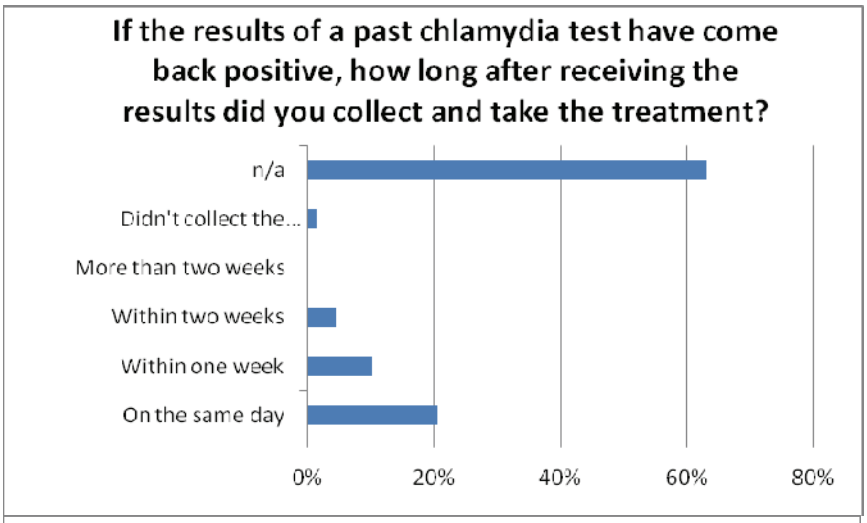


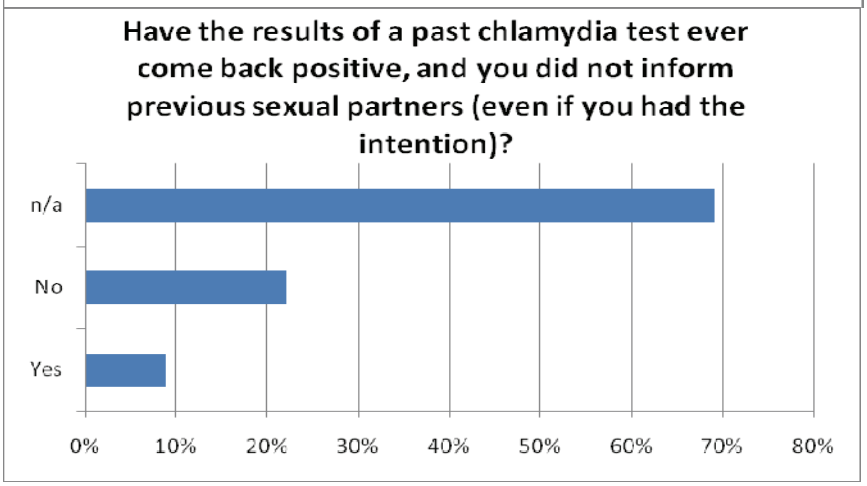


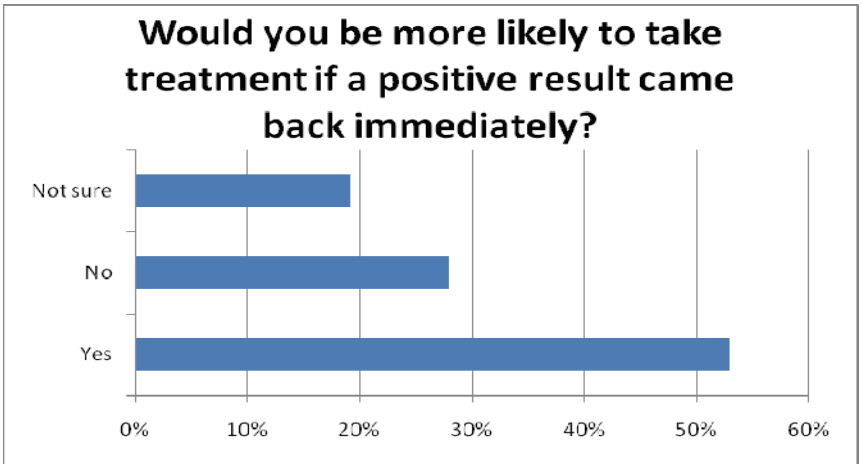

Where did you do your most recent test?
Haven't done a test
Other
At a family planning clinic
At a GP's surgery
With a kit at home
0%
10%
20%
30%
40%
50%

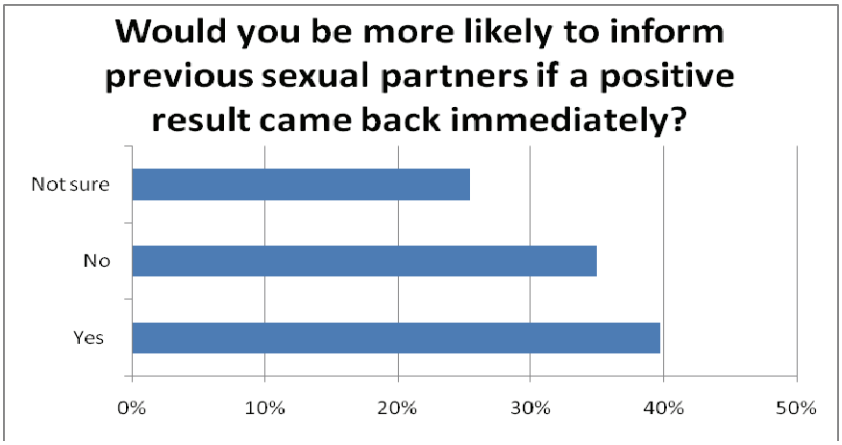

Where would be your preferred place to do the test?
Other
In the family planning clinic
At the GP's surgery
At home
0%
20%
40%
60%


Would you take the test more regularly if you could get the results immediately?
Not sure
No
Yes
0%
10%
20%
30%
40%
50%
60%

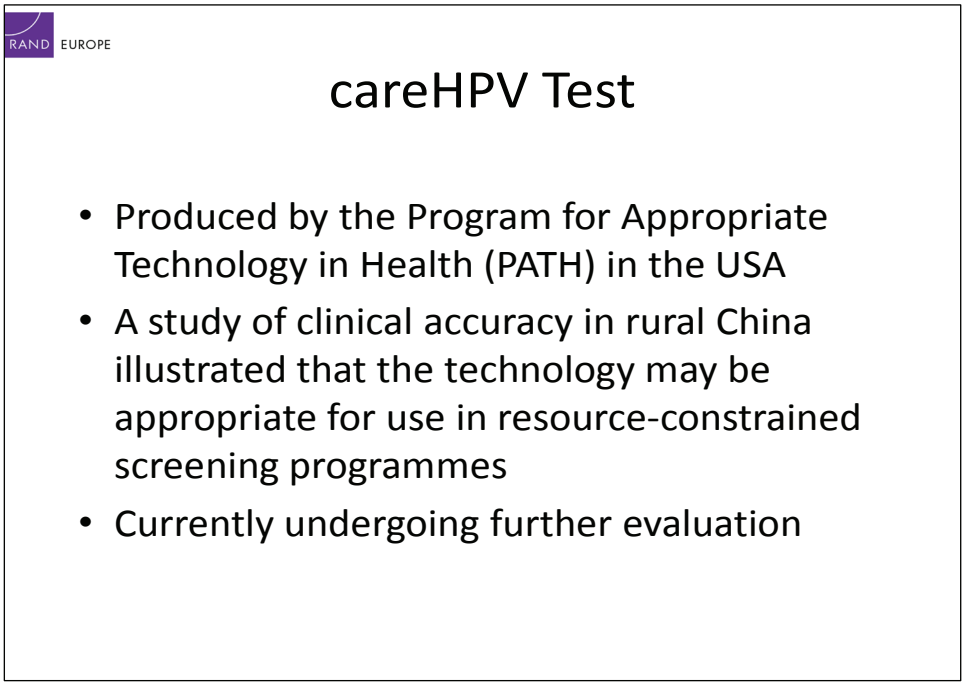

If the results of a past chlamydia test have come back positive, how long after receiving the results did you collect and take the treatment?
n/a
Didn't collect the...
More than two weeks
Within two weeks
Within one week
On the same day
0%
20%
40%
60%
80%


Have the results of a past chlamydia test ever come back positive, and you did not inform previous sexual partners (even if you had the intention)?
n/a
No
Yes
0%
10%
20%
30%
40%
50%
60%
70%
80%


Would you be more likely to take treatment if a positive result came back immediately?
Not sure
No
Yes
0%
10%
20%
30%
40%
50%
60%



The survey results support the idea that a rapid-result, point-of-care chlamydia test will increase screening coverage, the frequency with which people take the test, as well as the probability of those patients who test positive for chlamydia collecting treatment and informing previous sexual partners. However, further research is required to ascertain the likelihood that the survey responses will play out in practice, as it is known that action does not always follow intention (Wicker, 1969).



Cervical cancer is the second most common type of cancer affecting women worldwide. Women in the developing world carry 80% of the global burden of this cancer. HPV is the virus present in more than 95% of invasive cervical cancer. The HPV test is very sensitive but as there is no way of determining which cases of HPV infection will go on to cause cervical cancer, and with no available treatment for HPV, this is a controversial diagnostic test.

Many industrially developed countries have successfully reduced the incidence of the cancer through comprehensive screening programmes. These involved laboratory examination of cells (cytology) taken from a female patient's cervix: the 'pap smear'. One of the disadvantages of cytology is the requirement for trained personnel who can identify abnormal cells, which adds some (human error) bias to the test.

With many women having limited access to routine healthcare and the lack of good quality smear tests, the prevalence of the cancer in low-resource settings, such as in the South, remains high. Often, a test to detect the DNA of the virus is used due to its objective nature, but there is still a need for a diagnostic with rapid results, no special storage conditions or instrumentation necessary and low cost. PATH partnered with Qiagen to develop such a rapid test for high-risk groups which is based on detecting the DNA of the virus. The careHPV point-of-care diagnostic has been produced in the USA and tested in China in a study involving 2,530 women (Qiao et al., 2008).

PATH is a non-profit organisation collaborating with organisation community groups, other non-governmental organisations (NGOs), governments, industry and United Nations agencies.

The World Health Organization (WHO) supports HPV testing in developing countries as a triage tool to determine a patient's condition and prioritise treatment based on the severity of symptoms where cytology programmes already exist, and as primary screening where no system is in place. As cytology varies in sensitivity and specificity across the developing world, the use of the objective HPV test is welcomed. However, with good-quality liquid-based cytology as the gold standard in the National Cervical Cancer Screening Programme in the UK, there is no such a pressing need for HPV testing. Using HPV testing as a primary screening tool would require a change to the entire screening protocol in the UK. However, currently it is being piloted as a test of cure of cervical cancer, as well as a test for borderline cytology cases (as women with a negative HPV result are unlikely to have significant disease). It may be an appropriate time to introduce this point-of-care tool into discussions of the UK National Screening Programme.

The UK National Screening Programme, which aims to screen all women between the ages of 25 and 64, provides free cervical screening tests every three to five years. The programme screens almost 4m women in England each year. Of the women in the target age group, most were tested following an invitation and the rest were screened opportunistically at the suggestion of a provider or of the woman herself. For clinical reasons some women have more than one test during the course of a year, and nearly 4.5m samples are examined by pathology laboratories every year.[3] UK coverage for screening eligible women from March 2009 to March 2010 was on average 78.9%. Cervical screening, including the cost of treating cervical abnormalities, has been estimated to cost around £157m a year in England.

Again, looking at enablers and barriers to introduction of the technology, according to the seven parameters described earlier, it was possible to assess the differences and similarities of the key enablers and barriers to technology uptake in different country development settings.

[3] Http://www.cancerscreening.nhs.uk/cervical/about-cervical-screening.html#how-many, accessed 12 July 2010.

RAND EUROPE

Financial enablers and barriers to introduction of the careHPV test in developing countries

	Enablers		Barriers	
	Evidence-based	Speculative	Evidence-based	Speculative
Price	Using HPV tests in one or two clinical visits is a cost-effective alternative to conventional three visit cytology-based screening programmes in resource-poor settings (Goldie et al., 2005)	Savings in professional and laboratory time predictable	Cytology and visual inspection techniques are attractive options, being very low cost (Peck et al., 2008)	For use in healthcare settings, there would be switching and training costs
Funding				Corruption may be an issue with regards to uptake of certain technologies, with funding going to favoured manufacturers

RAND EUROPE

Financial enablers and barriers to introduction of the careHPV test in the NHS

	Enablers	Barriers
	Evidence-based	Speculative
Price	Cost per smear using liquid-based cytology ranges from £2.37 to £4.26 (Moss et al., 2004) or £29.30 (Whynes, 2009) including professional and laboratory time, transport and storage costs, etc In relation to existing cytology screening programme there would be a cost saving ranging from £38 to £48 per test depending on the test used (cytology or HPV) to triage borderline cases in the National Screening Programme (Ballegooijen et al., 1997)	There would be switching and training costs
Funding	There is good funding for cervical cancer screening. The national screening programme, including the cost of abnormalities is estimated to cost £157m a year	Reimbursement for GPs only if the test is on the national guidelines. Therefore it is not financially advantageous for GPs to adopt any other technology (medical key informant interviewee, 2010)

http://www.cancerscreening.nhs.uk/cervical/about-cervical-screening.html

In both the North and the South, the low price of this technology, as well as saving potential in laboratory and professional time, are facilitators to its uptake and assimilation. With good funding available for cervical cancer screening, and with studies illustrating its cost-effective nature, there are few financial barriers to uptake of this technology and use of HPV testing as a triage protocol for borderline cases, as well as a test of cure in the NHS. However, as mentioned previously, its uptake requires a change in the whole screening protocol, which can be costly and timely.

RAND EUROPE

Ethical enablers and barriers to uptake of the careHPV test in developing countries and the UK NHS

	Enablers	Barriers
	Speculative	Speculative
Autonomy and non-maleficence	Non-invasive test appeals to women, potentially increasing coverage obtained	
Beneficence and distributive justice		There is currently no cure for HPV There is no current method to determine whether a HPV infection will advance to cervical cancer Stigma attached to HPV as a sexually-transmitted infection (Cuzick et al., 2003)

Both developing and the UK NHS experience similar ethical enablers and barriers to the uptake of the careHPV test

Empowering women with non-invasive tests may enhance uptake in any country. As with the previous case study, these support the ethical principle of autonomy. Society values liberating women from the need to undergo invasive scanning before getting a result, as well as the rights of women to be informed quickly of their own health status. However, the issues associated with diagnosis in the absence of a HPV cure, and raising issues of home testing (counselling opportunities lost, etc) are likely to be barriers to uptake in any country, and make it very difficult to follow the ethical principles of both beneficence and distributive justice. Again, the trade-offs between ethical principles will vary from country to country and in the end, the technology that is chosen reflects in part the values of the society and the system in which the technology operates and of which it is a part (Winner, 1980).

RAND EUROPE

Regulatory enablers and barriers to uptake of the careHPV test in developing countries

	Enablers	Barriers
	Evidence-based	Speculative
Legislative		There may be barriers to importation of a technology by an NGO if the technology has not been approved by the Ministry of Health (field key informant interviewee, 2010)
Recommendation/ guidance	WHO supports HPV testing as triage where cytology programmes are already in place and as primary screening where no screening is established (WHO, 2002) Alliance for cervical cancer prevention suggested HPV-DNA tests to be used as a primary test in screening for cervical cancer	It is necessary to gain the support of the Ministry of Health in each country in order to establish a widespread screening programme (field key informant interviewee, 2010) Corruption is an issue with regards to uptake of certain technologies (field key informant interviewee, 2010)

http://www.alliance-cxca.org/

RAND EUROPE

Regulatory enablers and barriers to uptake of the careHPV test in the NHS

	Enablers	Barriers
	Evidence-based	Evidence-based
Legislative		Not CE-approved
Recommendations	A 2009 pilot to assess the use of the HPV test as a triage for borderline changes and cell abnormalities showed a cost-effectiveness of 3,700 per life year saved (Kitchener et al., 2009) It is acknowledged that the use of HPV tests as the primary test could reduce frequency of testing in comparison to the current pap smear (Cuzick et al., 2000) Now undergoing a pilot to use the HPV test as a 'test of cure' for women who have undergone treatment for cervical cancer (Cuzick et al., 2000)	A 2000 evaluation showed no cost-effectiveness or advantage to using HPV tests alongside liquid-based cytology for primary care screening (National Institute for Health and Clinical Excellence (NICE), 2003) Unethical to evaluate use of HPV alone as primary test as international standard is cytology (Cuzick et al., 2000)
Guidance		Liquid-based cytology is the NICE recommendation for cervical cancer screening (NHS Cervical Screening Programme, nd)

Regulatory approval for the technology and the screening process proposed required varies from country to country.

As mentioned previously, liquid-based cytology is the gold standard in the UK's National Cervical Cancer Screening Programme. There are regulatory barriers acting against the introduction of careHPV technology and the use of HPV testing as a primary screening method as a new alternative. The UK National Institute for Health Research Health Technology Assessment (HTA) reports that it is cost-effective to use HPV testing as a test of cure of cervical cancer (ie to monitor the clearance of the HPV virus from the body) and as a triage tool for borderline cytology cases, and so this may be the most viable position for uptake of the technology in the NHS (Kitchener et al., 2009). However, the technology cannot be used in the UK without CE approval, and so this is a regulatory hurdle which may or may not be overcome.

RAND EUROPE

Infrastructural enablers and barriers to uptake of the careHPV test in developing countries

	Enablers	Barriers	
	Evidence-based	Evidence-based	Speculative
Technical	Requires no special storage conditions No transport to laboratories required Can be powered by a rechargeable battery No other equipment needed (Qiao et al., 2008)		
Training	Minimal training required (Qiao et al., 2008)	There is training required	
Capacity		Screening programmes in developing countries have an effective coverage of 19% of eligible women, in comparison to 63% of women in developed countries (Gakidou et al., 2008)	With no screening programme established, there is no capacity for additional tests and treatment expected following positive HPV results Advances derived from the use of better tests would only result in noticeable reductions in mortality from cervical cancer if the screening programme in its entirety is functional and efficient over extended periods of time

RAND EUROPE

Infrastructural enablers and barriers to uptake of the careHPV test in the NHS

	Enablers		Barriers	
	Evidence-based	Speculative	Evidence-based	Speculative
Technical	No other equipment required Requires no special storage conditions No transport to laboratories required (Qiao et al., 2008)			
Training	Low training requirements (Qiao et al., 2008) As health workers in the UK must retrain in liquid-based cytology every 3 years, HPV training could be encorporated into this retraining (medical key informant interviewee)		Additional training required	
Capacity	4 million women a year are screened for cervical cancer, therefore economies of scale will apply (Cervical Screening Programme England, 2009)	National Cervical Cancer Screening Programme has been in place for a substantial amount of time, therefore referral pathway, etc are well established		Screening programme has recently changed to liquid-based cytology technique for screening, therefore there may be reluctance to add further steps in the current practice so soon

The careHPV test is a robust technology designed for low-resource settings, therefore it is easy to use and requires very little infrastructure for use. These factors are also enablers to uptake of the technology in the UK, and although they are of a lower priority in the developed country setting, these features allow for flexibility of testing. One barrier to introduction of this technology in a developing country setting is a lack of capacity to increase screening and treatment. However, with the National Cervical Cancer Screening Programme well established in the UK, there is good infrastructure available to absorb a novel technology for borderline cases, and potential to increase coverage by reaching hard-to-reach populations. It is important to add that the utility of the test still depends on wider efforts to reduce inequality in access.

RAND EUROPE

Competitive enablers and barriers to introduction of the careHPV test in developing countries

	Enablers	Barriers
	Evidence-based	Evidence-based
Scientific	Clinical sensitivity (90%) and specificity (84.2%) for cervical specimens and for vaginal specimens (81.4%) and (82.4%) respectively (Qiao et al., 2008) Cytology requires skilled professionals to interpret, and gives a subjective result, thus it is not always appropriate for the resources available in developing country settings, often resulting in low sensitivity (Peck et al., 2008)	
Logistical	Other HPV-DNA tests require well-equipped laboratories, skilled technicians and specialised equipment (Peck et al., 2008)	Visual cervix examination has a low equipment use but is a subjective test, therefore there is a need for frequent retraining (Peck et al., 2008)

RAND EUROPE

Competitive enablers and barriers to introduction of the careHPV test in the NHS

	Enablers	Barriers	
	Evidence-based	Evidence-based	Speculative
Scientific	Clinical sensitivity (90%) and specificity (84.2%) for cervical specimens and for vaginal specimens (81.4%) and (82.4%) respectively (Qiao et al., 2008) Cytology is subjective and repetitive, which can lead to interpretive errors	HPV tests are substantially more sensitive but less specific than cytology (National Institute for Health and Clinical Excellence (NICE), 2003)	In the UK liquid-based cytology has good sensitivity due to thorough training, therefore there is little need to replace this method
Logistical	Logistical implications of implementing liquid-based cytology include specimen transport, storage and laboratory throughput		

The competitive advantage of the careHPV test will vary, depending on a country's existing technologies and their suitability to a given context. With a relatively new satisfactory screening technique based on liquid-based cytology in the UK, the careHPV test has little competitive advantage as a primary screening tool in the NHS. However, with unsatisfactory methods, including subjective cytology and visual cervix testing, HPV-DNA tests which require high infrastructure in place, together with low coverage in the developing world, there is a window for entry of the novel technology in such settings.

RAND EUROPE

Role of the media and consumer in uptake of the careHPV test in developing countries

	Enablers	Barriers
	Speculative	Speculative
Role of the media		
Role of the consumer	The support for this technology is likely to rise with non-invasive tests	Often in developing countries the voice of the consumer, in particular of the female, is weak Would women who are hard to reach at the moment be any more likely to take up the test?

RAND EUROPE

Role of the media and consumer in uptake of the careHPV test in the NHS

	Enablers		Barriers
	Evidence-based	Speculative	Speculative
Role of the media	The 'Jade Goody Effect' increased awareness and coverage. Women are now taking a more active role in their health relating to cervical cancer (Elliott, 2009)		
Role of the consumer attitude		The consumer has a strong role in the UK and with emphasis placed on consumer satisfaction, support is likely to rise with non-invasive tests	Would women who are hard to reach at the moment be any more likely to take up this test?

In developing country settings, where the political system is often more autocratic, the voice of consumers may have a different importance than that in a liberal democracy. As the advantage of this technology lies in its easy-to-use characteristic and its potential for increased patient comfort, it may be important to have the support of the consumer and the media for its successful uptake and assimilation in the UK.

In the UK, screening coverage has increased hugely, following the death of a young celebrity, Jade Goody, from cervical cancer in 2009. This illustrates that the media has a role in shaping cultural practices and treatment-seeking behaviour. However, as with the previous case study, there is a necessity for community-based initiatives and awareness campaigns to increase access in order for hard-to-reach populations to be affected by the advantages of this novel technology.

RAND EUROPE

Social/cultural/religious enablers and barriers to uptake of the careHPV test in developing countries

	Enablers	Barriers
	Speculative	Speculative
Social	Rapid result is invaluable where follow-up of patients is difficult, particularly for hard-to-reach populations, where there is a need to capitalise on a single contact point	
Cultural/religious		Novel technology will not alter the existing inequalities and social determinants for hard-to-reach populations The introduction of any technology, but in particular a technology relating to sexual health, comes up against certain barriers alongside the often poor healthcare service, lack of funding and services: •structural issues, taboos and cultural or religious barriers •lack of awareness and education of individuals for need of testing and perceived risk of sexual behaviour

RAND EUROPE

Social/cultural/religious enablers and barriers to uptake of the careHPV test in the NHS

	Enablers	Barriers
	Speculative	Speculative
Social	Rapid result is invaluable where follow-up of patients is difficult	
Cultural/religious		Novel technology will not alter the existing inequalities and social determinants for hard-to-reach populations The introduction of any technology, but in particular a technology relating to sexual health, comes up against certain barriers: •taboos and cultural or religious barriers •lack of awareness and education of individuals for need of testing and perceived risk of sexual behaviour

Barriers to the uptake of any technology in both the South and the North include cultural taboos and a lack of awareness and education of the affected stakeholders, patients and healthcare providers. These barriers are exaggerated with the introduction of a sexual health-related technology, with resistance to discuss, educate and accept sexual health issues from a cultural and religious standpoint (Rosen, 2000).

As with the previous case study, within the UK and developing countries, the impact of such a technology in increasing screening coverage depends on the awareness and education of patients as well as care providers in terms of access and perceived risk. Therefore, the success of the technology is dependent on an accompanying change in the many barriers to access and health-seeking, particularly among hard-to-reach populations.

RAND EUROPE

Spillover/potential future complications/unintended consequences as enablers and barriers to uptake of the careHPV test in developing countries

	Enablers	Barriers
	Speculative	Speculative
Spillover	If this test was to assist development of national screening programmes, this would create jobs while releasing the burden from professional health workers	Not made by a local company, therefore not necessarily adding to local knowledge and possibly not able to develop innovation over time (Stephenson et al., 2000)
Future complications	HPV vaccine availability	HPV vaccine availability
Unintended consequences		Concerns about whether the technology will be produced domestically or imported may arise

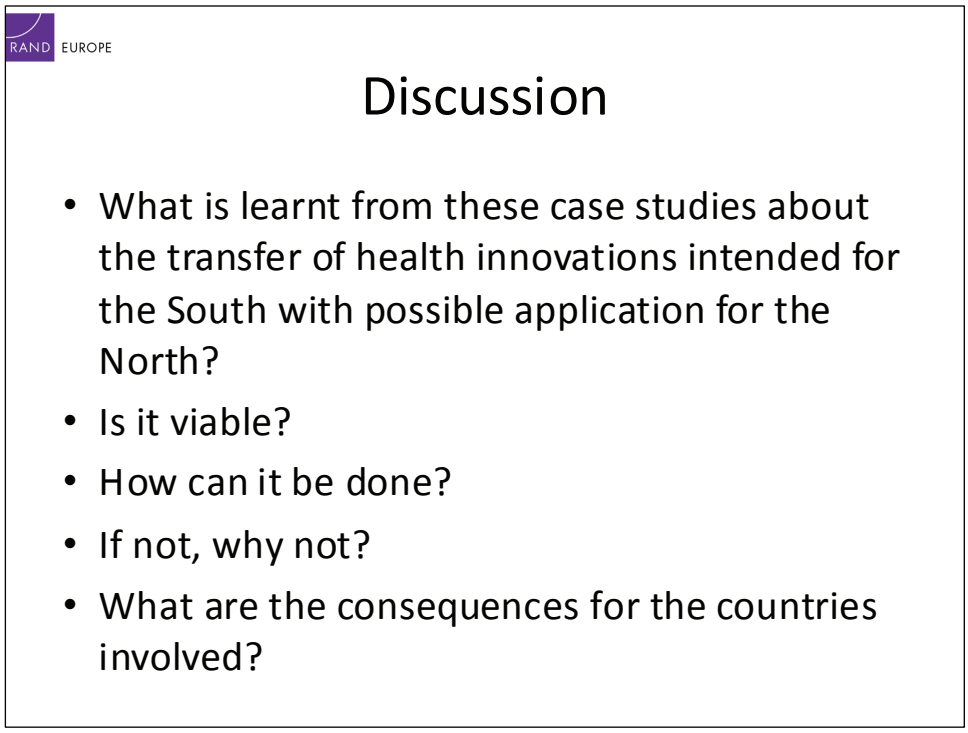
RAND EUROPE

Spillover/potential future complications/unintended consequences as enablers and barriers to uptake of the careHPV test in the NHS

	Enablers	Barriers
	Speculative	Speculative
Spillover		
Future complications	HPV vaccine may disrupt screening	HPV vaccine may disrupt screening
Unintended consequences	The Rapid Test Paradox supports the statement that more people can be tested and treated using a less sensitive rapid test, thus reducing the disease burden more than if a more sensitive laboratory-based test was to be used (Kassler et al., 1999)	As it has been developed and produced for a developing country setting, it may be difficult to see the adverse consequences There is no fallback around the world when a technology is used widely and fails (Blume, 2005)

The availability of the HPV vaccine is likely to disrupt screening programmes (established or yet to be established) in both the North and the South, and it will be important to determine how to screen vaccinated females (Kitchener et al., 2009). The introduction of the HPV vaccine could create a window of opportunity for entry of a novel technology as screening programmes are disrupted and rearranged, but equally, if screening programmes are to be terminated or scaled down, this could be a barrier to introducing a novel technology as a result of limited funding and the coverage obtainable. However, there will still be a screening programme, as the vaccination does not cover all HPV cervical cancer-causing types.

CHAPTER 4 Discussion



The varying methodologies contributed to the analysis of the case studies and therefore the conclusions of the study. The extensive literature review highlighted enablers and barriers in North–South technology transfer. With little to no literature on South–North health technology transfer, this exploratory study offers a novel perspective on the topic of innovation. The literature review also covered general innovation implementation and technology transfer theory, which provided a background for the study.

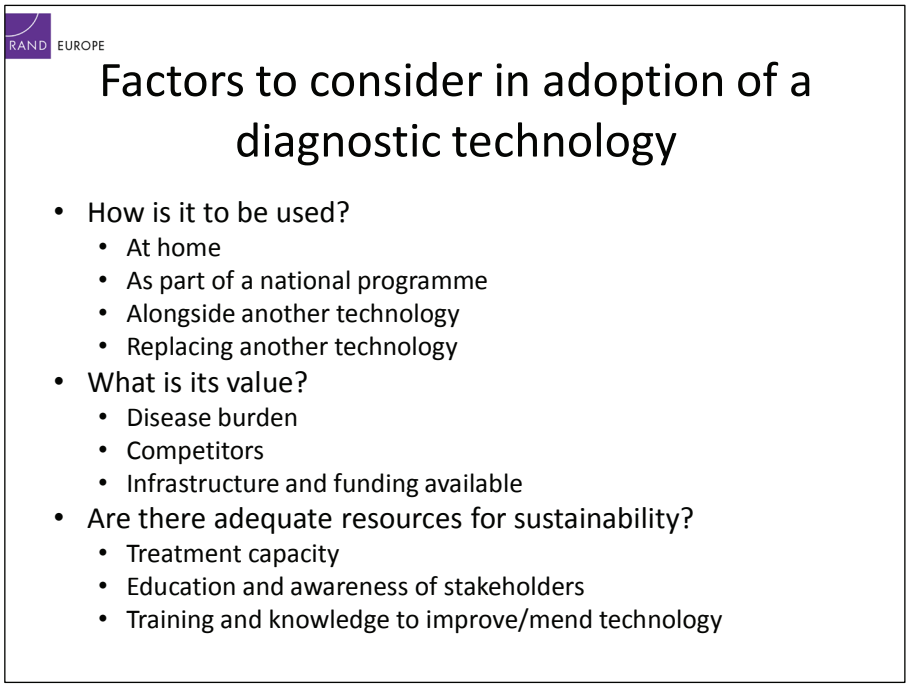
This study has considered the potential situations and specific technologies where innovation transfer from South to North would be advantageous. For example, in a situation of budget restraint in the North, the transfer of a low-cost alternative which has been produced for developing country settings would be attractive (financial enabler). A technology designed for the developing world with a low infrastructural dependence also would be transferable for use in home care in industrially developed country settings (infrastructural enabler). Also discussed in this study are situations in which a technology

designed for developing countries cannot be applied to an industrially developed country setting for a variety of reasons.

An important conclusion from the case studies is that generalisations cannot be made about the viability or approach to transfer of health technologies – even diagnostic technologies. Each technology and country must be treated individually in order to determine the enablers and barriers to technology uptake in a given country. It is always necessary to clarify who the stakeholders are, and to identify what is static and dynamic in an area.

Health technologies transferred from one country to another may have a different role in different countries: for example, a diagnostic technology used by community health workers in the developing world may be useful as a home technology in the industrially developed world, and with this alteration in use comes different enablers and barriers to implementation.

This new trend of 'reverse innovation' has potential in terms of development and capacity-building for developing countries, as well as satisfying a preference in industrially developed countries.



The likelihood and rate of adoption and assimilation of a diagnostic technology in any country depends on several key factors. First, the situation in which the diagnostic is to be used will affect its uptake: for example, if the diagnostic is to be used at home, there are several ethical and structural issues that must be addressed. There are logistical and financial concerns if the technology is to assist an established screening programme or aid the introduction of a screening programme. Second, the question of whether it is to replace an existing technology, work alongside currently used technologies or be a novel form of diagnosis, also will affect adoption.

Finally, if the resources for ensuring disease diagnosis and treatment in the long run are inadequate, then the technology may be an unwise way to spend limited funds. The capacity for treatment and diagnosis often exist as a 'chicken and egg' dilemma: with improved diagnosis, capacity for treatment also may increase. However, with limited treatment availability there are ethical arguments against the use of a diagnostic. For successful adoption and 'normalisation' of a technology, the stakeholders (patients, care providers, parents/carers) must have adequate education and awareness of the disease and treatment, as well as the training and capacity to use the technology. Once in use, then there would be demand-driven improvements by manufacturers, which in turn embed adoption of the technology.

RAND EUROPE

Key factors for adoption in the NHS

Enablers	Barriers
Cost-effectiveness assessments are likely to have an increased role in the economic and political climate	Strict regulation and evaluation
Point-of-care technology requires little infrastructure and training. Home care is popular at the moment Good capacity for treatment with national programmes well established	
Funding available	Complicated funding process with GPs priorities determined by funding
	Good competitors available and well established
Strong media and consumer role	Cultural/religious factors affecting attitudes towards the technology and its utility Barriers to access to healthcare

RAND EUROPE

Key factors for adoption in developing countries

Enablers	Barriers
Relative regulatory freedom	Corruption in regulatory process
Point-of-care technology requires little infrastructure	Limited infrastructure for treatment and increasing capacity
Point-of-care technologies are low-cost alternatives	Poor funding and inability to make out-of-pocket payments
Competitive, scientifically and logistically, with commonly used technologies	There may be cheaper alternatives with lower scientific accuracy or higher logistical requirement
Potential spillover	
	Cultural/religious barriers affecting attitudes towards the technology and its utility Barriers to access to healthcare

RAND EUROPE

Similarities and differences in the contexts for adoption of technologies in developing countries and the NHS

Similarities	Differences
Value of cost-effective technologies	Funding available
Patient requirements and ethics of testing	Differences in available information and access schemes
Difficulties in ensuring equality in access to healthcare	Competitors available
	Infrastructure
	Regulations and evaluations
	Cultural and religious views
	Role of the media and consumer

The two case studies above show that the key factors acting as enablers and barriers in the introduction of novel technologies into developing country settings as well as the NHS reveal several differences with respect to technology uptake. However, differences in enablers and barriers to uptake of a technology in different countries does not suggest that a technology adopted in one country will be rejected in another; rather, it suggests that for different regions, different features of the technology and contextual factors may act as enablers for, or barriers to, uptake.

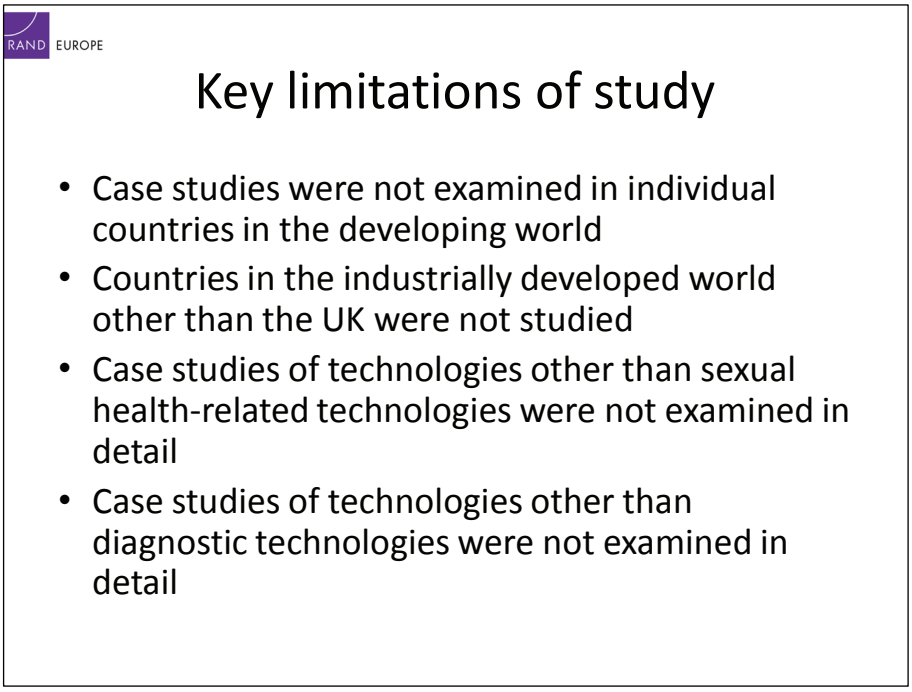
More than ever in the current UK political and economic environment of austerity, cost-effectiveness in healthcare is as necessary in the industrially developed world as it is in the developing world. Technologies designed for developing country settings, with acceptable pricing, have a place in the industrially developed world.

It can be observed that the ethical principles supported by the features of such technologies will weigh differently in different countries. Thus, features of a technology which may support certain ethical principles in one country may be traded off differently by another principle that is not supported in another country. This could result in the technology having more or less value in different countries, due to ethical enablers and barriers to its adoption and assimilation.

The health system infrastructure and capacity in countries vary, and therefore the value of a technology that is designed for low-resource settings may vary across settings. However, often such technologies are valued with different purposes in mind. For example, a technology designed to increase screening coverage in a low-resource setting through its

mobile, robust, easy-to-use and reliable nature, may find value as a home technology in the industrially developed world as a tool to increase patient empowerment and flexibility. Although regulatory and evaluation processes differ from country to country, generally a regulation will be published after consideration of other available technologies. The technologies used in a country depend on multiple factors such as funding, infrastructure and technological advances. These factors affect the strength of regulatory barriers across countries and regions, hence the relative importance of this barrier or enabler must be assessed at country level.

Finally, political, cultural and religious contexts affect all aspects of healthcare, including technology uptake. These are complex parameters: it is very difficult to draw conclusions about technology uptake without taking into full consideration the wider social and political values underlying the entire health system, and its use of technology in its own country.



There are several limitations to this study which should be noted and could be addressed in future work.

Primarily, the narrow scope of the study and the use of only two case studies present a major limitation to any ability to generalise its findings. The narrow set of case studies is a helpful approach to offer a window of investigation into the study's area of innovation interchange or reverse innovation. However, other innovations that are not related to sexual health or to point-of-care diagnostics are needed to give a wider view on scope for technology transfer, as the barriers and enablers may differ across regions and countries.

The analysis of the introduction of technologies in developing country settings was limited by a lack of readily available documented evidence. Therefore, the information used in this study was based on expert knowledge of manufacturers and people working in the field, as well as some literature on technology adoption in developing country settings.

Due to the narrow nature of this study, further research into the enablers for and barriers to introducing non-sexual health-related diagnostic technologies, and looking into Northern countries other than the UK, would be necessary in order to make any conclusions on the topic.

As mentioned previously, cultural and religious context affects all aspects of healthcare, including technology uptake. This study would be complemented by further study into the wider social and political values underlying the entire health system and its use of technology.

As this study was an exploratory study to be used as a platform for further discussion in this area, some broader issues have been highlighted in the slide above around the subject of 'reverse innovation'. Further explanation of the issues raised above may be interesting for policymakers, industry, academic researchers and international charities, among others.

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