

Scoping the impact of UK membership of the EU on UK health research

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Published by the RAND Corporation, Santa Monica, Calif., and Cambridge, UK

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Preface

The UK government is currently undertaking a series of reviews on the balance of competencies between the UK and Europe in different areas in order to understand the benefits, costs and complementarities of European Union (EU) membership. In light of this, RAND Europe conceived this exploratory study to help frame the debate on future EU membership in the context of UK health research. UK health research is highly diverse and there are a number of ways in which health researchers and research institutes interact with the EU. The study approach is multidimensional – that is, not only focusing on funding, but looking at other aspects such as research environment, research infrastructures, network effects, and the wider regulatory landscape. At this scoping stage we draw on existing evidence in the literature and identify the important knowledge gaps that will need to be filled for a more complete assessment.

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Summary

The objective of this study was to examine existing evidence about the effect of EU membership on health research in the UK and to develop a conceptual approach for assessing the costs and benefits of membership. The first phase of work was to establish the background and context of the issue through a rapid evidence assessment of literature on the costs and benefits of EU membership for health, and of specific studies that looked at UK health research supported by the EU. The second phase was to develop a conceptual framework for understanding the research inputs, processes, outputs and outcomes for UK health research. This framework was then discussed, amended and validated through a small number of scoping interviews with UK health researchers and funders across different health subject areas with varying degrees of experience of EU-funded health research. The final phase of work was to develop future scenarios for UK health research looking at different possible arrangements between the UK and the EU and to analyse each scenario to judge how the current strengths of the UK health research system could be preserved should there be any change in the UK's current membership of the EU.

As part of the ongoing debate regarding the UK's membership of the EU, the UK government has undertaken a Balance of Competences Review to analyse what the UK's membership of the EU means for the UK's national interest across various domains of public policy. The review aims to develop an evidence base and inform government discussion on modernising, reforming and improving the EU in the face of collective change. In July 2013, the health review was published which considered the EU's impact across the whole area of health, including medicines and medical devices, public health, and the NHS and patient services (HM Government, 2013). Although the review provides a full overview of the interaction between the UK and the EU in health, the impact of EU membership on UK health research was not explored in depth. Given the intrinsic relationship between the different elements of the health ecosystem in the UK and the current significance of EU health research funding to UK institutions and researchers, we have endeavoured in this paper to scope out the impact of EU membership on health research. The aim is thereby to better understand how decisions about EU membership might affect health research in the UK and, as a consequence, the wider health system in this country.

The impact of EU funding on UK health research

The UK is a global leader in health research with a mature research ecosystem comprising world-class universities, institutes and public sector agencies. UK health research benefits from EU support in a number of ways, with EU funding of particular importance to the support of UK research activity. While overall the UK is a net contributor to the EU, in terms of health research specifically the UK is a net recipient, accessing more funding from EU research and innovation programmes than would be expected

on the basis of its population. For example, in the health theme of the Seventh Framework Programme (FP7), the UK has attracted over €570m in EU funding, representing 17 per cent of the entire EU contribution (HM Government 2013, 57). In terms of European Research Council (ERC) grants, the UK is in receipt of 20 per cent of all funding awarded (HM Government 2013, 57).

Aside from research funding, EU membership brings other benefits to health research, such as the freedom of movement for people (and hence labour and skills), the easy transfer of medical materials such as blood and tissue, and access to pan-European collaborative networks. These ‘softer’ elements are also important, particularly the mobility of researchers, but are often excluded from the financial calculations on EU membership and so their significance to the UK health research system is often overlooked.

There is also a wider strategic value that comes with EU membership that resonates across the UK health ecosystem from the level of UK government down to individual researchers. Strategic value is difficult to quantify and measure, but refers to the capacity of the UK to lead, influence, lever resources, create synergies and engage at all levels. This can include a diverse range of benefits such as the ability to communicate UK health research priorities to powerful European stakeholders or the potential to level more resources from European institutions and Member States to support health research.

The impact of the UK withdrawing from EU membership is almost impossible to assess as it would depend greatly upon the terms and conditions of any such change. The previous paragraphs mentioned benefits of EU membership; there is also some evidence that European legislative and regulatory mechanisms can be problematic. For example, the Clinical Trials Directive had been reported to have had an impact on the number of trials being carried out in the UK (and Europe more widely) and has made both the UK and Europe more widely a less attractive prospect as a base for clinical trial research. However subsequent revisions have moved to alleviate some of these concerns (NHS European Office 2009, 2014).

It should also be noted that a withdrawal from EU membership would not necessarily preclude the UK from participating in EU funding programmes. In fact, there are several precedents for non-EU nations accessing EU funding and actively taking part in EU-wide research collaborations. Horizon 2020, like its predecessor FP7, is open in principle to non-EU countries who wish to apply for funding, although the application procedures and funding possibilities vary for different groups of countries (European Commission 2012).

Priority areas for consideration

The issue of EU membership and its effect on UK health research goes beyond pure financial impacts, so this study has focused on the identification of key areas in which the EU contributes to the current strength of UK health research, and which should be considered and negotiated should there be any change in the UK’s relationship with the EU. These are:

Access to EU funding:

- Research activities that are currently supported by the EU will need to be protected in order to maintain the UK’s current strengths in these areas. This means that the UK must ensure

that funds are made available to continue to support the kind of multi-centre and multi-disciplinary work that is currently primarily carried out through EU funding.

- This could potentially be achieved by a ‘buy-in’ scheme whereby the UK could continue to contribute to the EU funding pot and, in turn, UK researchers would be able to participate in research funding calls and receive grants.

Mobility of researchers:

The free movement of researchers both into and out of the UK is regarded as a key advantage of EU membership. This enables the UK to easily recruit the best scientific and research talent from Europe into the UK and provides all European researchers, including UK researchers, with an advantage over their overseas counterparts when it comes to the competitive pursuit of jobs and positions at universities, laboratories and research institutes.

Access to information:

The EU facilitates shared access to bio banks and data sharing across Member States. This access is vital for current UK both health research activity and health security and should be prioritised in the case of any change to the UK’s relationship with the EU.

Recommendations for further research into the impact of EU membership on UK health research

Despite the importance of the issues investigated in this report, the lack of evidence available on the subject meant that it was not possible to explore all aspects of this debate in detail and assess the full impact of EU membership on UK health research. We have therefore identified key elements to be investigated in this area which would further establish the evidence for this debate and help answer the questions raised by it:

- Research must be undertaken into the **financial implications of EU membership**. It is very difficult to access reliable and unbiased figures on the costs and benefits of EU membership from an economic point of view.
- Further research is needed to test the views expressed by our interviewees on the **particular value of EU funding** and the expected difficulties of replacing the EU’s funding of specific project types and specific research areas that might arise if the UK were to withdraw from the EU.
- Further qualitative research encompassing **interviews with senior key informants** from the UK government, universities and health institutions would add to the evidence base on the strategic benefits of UK membership of the EU and possible counterfactual scenarios.
- **A survey of health researchers** would be a useful tool to understand the benefits of European funding, networks, and strategic value for those currently engaged in health research activities. This would also enable us to gather the views and experiences of a large sample of those involved in health research in the UK across a wide spectrum of research areas and levels of engagement with the EU.

- **Case studies** would provide an opportunity to produce meaningful data from which we could draw conclusions on the impact of EU-funded health research in the UK. Case studies would enable us to focus on either individual projects or specific research areas, e.g. mental health or an area of cancer, and explore in far greater depth the impact of EU funding and aspects of EU membership more generally on the quality of research and health outcomes on a given topic in the UK.

Acknowledgements

The authors would like to thank those individuals who provided the time to be interviewed for the scoping exercise. We would also like to thank Jonathan Cave, Alex Pollitt and Saba Hinrichs for their participation in an internal workshop for the study and their contribution to the development of scenarios.

We are grateful to our Quality Assurance reviewers, Stijn Hoorens and Steven Wooding, for providing peer review and constructive feedback throughout the study and on the final report. Special thanks also to Jonathan Grant who provided advice on the conceptual framework and approach for the study.

This is an independent report commissioned and funded through the Policy Research Programme in the Department of Health. The views expressed are not necessarily those of the Department.

Abbreviations

ABPI	Association of the British Pharmaceutical Industry
BBSRC	Biotechnology and Biological Sciences Research Council
BIS	Department of Business, Innovation and Skills
CA	Competent Authority
CAP	Common Agricultural Policy
CERN	European Organisation for Nuclear Research
CORDIS	Community Research and Development Information Service
DG RTD	Directorate-General for Research and Innovation
DG SANCO	Health and Consumer Protection Directorate General
EEA	European Economic Area
EFTA	European Free Trade Area
ERC	European Research Council
EU	European Union
FP	Framework Programme
GDP	Gross Domestic Product
HEDIS	Health Emergency & Diseases Information System
JRC	European Commission Joint Research Centre
ICT	Information and Communications Technology
MRC	Medical Research Council
MSCA	Marie Skłodowska-Curie actions
NHS	National Health Service
NIHR	National Institute for Health Research
NHSBT	NHS Blood and Transplant
NIHR	National Institute for Health Research
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs

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1. Introduction

1.1. Introduction to the issue

There has been ongoing debate in the UK concerning the UK's membership of the European Union (EU). Since joining in 1973, membership of the EU has been a controversial issue in the UK with a group of 'Euro-sceptics' persistently arguing that the UK would be better off outside the political and economic bloc. Recent polls by YouGov suggest that if there was an immediate referendum a majority of UK citizens would vote for the UK to leave the EU (Kelner 2013). The debate is characterised by a polarisation of public opinion between those who are committed to the European project and the benefits it brings to the UK versus those who oppose European political integration (Hannan and Alexander 2012).

Despite the intensity of the public debate there is a lack of evidence across different areas of public policy to evaluate the costs and benefits which EU membership brings to the UK. It is in this context that the Foreign Secretary launched the Balance of Competences Review in Parliament on 12 July 2012. The review takes forward the Coalition commitment to examine the balance of competences between the UK and the EU (Foreign and Commonwealth Office 2013). The review aims to provide an analysis of what the UK's membership of the EU means for the UK's national interest. Aside from developing an evidence base, the exercise seeks to contribute to a wider debate concerning modernising, reforming and improving the EU and the UK's relationship with it.

As part of the review, the Department of Health undertook a consultation to gather evidence on the balance of competencies between the UK and EU in health between November 2012 and February 2013. Evidence was provided by a number of different institutions, including health associations, royal colleges, health charities, regional bodies and the NHS. The review considered the EU's impact across the whole area of health including medicines and medical devices, public health, and the NHS and patient services. However, while the review provided a full overview of the interaction between the UK and the EU in health, the impact of EU membership on UK health research specifically was not focused on in any depth. What the review did tell us, however, is that the UK is the largest EU Member State beneficiary of EU funding for health research, and the UK benefits from partnerships between universities and non-governmental organisations for sharing knowledge amongst Member States (Foreign and Commonwealth Office 2013). More research and analysis is thus required to understand the added value of EU membership for UK health research and to assess the relative trade-off between what the UK invests into the EU versus what it takes out or how resources could otherwise be used if not spent in Europe.

1.2. Research objectives

This study is exploratory in nature, seeking to map and examine existing evidence on a highly complex policy issue and to develop a conceptual approach for assessing the costs and benefits of EU membership for UK health research. Our approach has been to use existing evidence where possible, but also to be creative in thinking through a conceptual framework and how UK health research may look in the future under different scenarios for future UK membership of the EU.

The scoping exercise proceeded in three key stages:

- The first phase was to establish the background and context to inform further the study objectives through a rapid evidence assessment of literature on the costs and benefits of EU membership for health and specific studies attentive to UK health research supported by the EU.
- The second phase was to develop a conceptual framework for understanding the research inputs, processes, outputs and outcomes for UK health research. The framework was then discussed, amended and validated through a small number of scoping interviews with UK health researchers and funders across different health subject areas with varying degrees of experience of EU-funded health research.
- The final phase of the scoping exercise was to develop scenarios for UK health research depending on possible future arrangements between the UK and the EU. These scenarios were used to identify key areas of the UK health research system that were most valuable to the UK's current research strength and which should be the focus of any negotiation should a change in the UK's relationship with or membership of the EU take place.

Our approach has been limited by time and resources and in the conclusion for the report we suggest a number of directions for further research which could help bolster the evidence base and fill any gaps. The indicators and data sources for understanding EU benefits are identified also in Chapter 3 which presents a conceptual framework for understanding how the EU interacts with UK health research.

1.3. Structure of report

The report is structured to deliver key insights from the research and each chapter presents findings from different phases of the scoping exercise. Chapter 2 sets out the policy context for the debate on future membership of the EU and the implications for health research. Chapter 3 reflects on the literature and describes the conceptual framework for testing the impact on health research of the UK being a member of the EU or not. This chapter incorporates views from health researchers and funders and provides information on the different indicators that could be used to measure research inputs, processes, outputs and outcomes. This chapter also describes the conceptual framework that was developed during this study for understanding the relations between these and different scales in the UK health research ecosystem (the macro-scale of the UK, the meso-scale of institutions and the micro-scale of individual researchers). Chapter 4 presents the results of our scenarios-based analysis of a set of potential futures for UK health research under different institutional arrangements between the UK and the EU. We paint several pictures

of different scenarios within which UK health research might develop in the future and the implications of this for UK government strategy. Finally, in Chapter 5 we return to the central questions of the scoping exercise and identify future research directions.

2. Contextualising the debate on UK health research on the EU

2.1. The health research 'ecosystem' in the UK

In the UK, spending on health research and development is estimated to represent almost a third of all research and development expenditure. The UK Health Research Analysis report, published in 2012, estimates that £8.3bn was spent in 2009/2010 on research and development across all public, private and not-for-profit sectors by UK organisations involved in health research (Medical Research Council 2012). Of this, over half of the monies spent (approximately £4.5bn) is on research carried out by industries and companies from the private sector, leaving in the region of £3.5bn of activity in the public and not-for-profit sectors, provided by the research councils, medical charities such as The Wellcome Trust, UK government departments, and the European Commission (Medical Research Council 2012).

The largest funders of research in the UK are:

- **National Institutes of Health Research (NIHR)**
The goal of the NIHR is to establish a health research system in which the NHS supports outstanding researchers who are conducting cutting-edge research. The NIHR funding portfolio includes all funding for NHS research in England, as well as funding to support clinical research and academics.
- **Medical Research Council**
The UK Medical Research Council supports research across the biomedical spectrum, from fundamental research to clinical trials.
- **Biotechnology and Biological Sciences Research Council (BBSRC)**
The BBSRC supports research related to the understanding and exploitation of biological systems across a range of sectors, including agriculture, bioprocessing, chemical, food, healthcare, pharmaceutical and other biotechnological related industries.
- **Medical Research Charities, including The Wellcome Trust**
There are a large number of medical research charities in the UK and these spent more than £1.2bn on medical and health research in 2012 (Association of Medical Research Charities 2013). Of these, The Wellcome Trust, in 2012/2013 provided more than £700m in funding for health research and direct charitable activities, mostly through grants to UK-based scientists working in medical research (Wellcome Trust 2013a and 2013b).

Against this national funding profile, the EU provides an additional and significant stream of funding which supports various areas of research activity. In particular, EU funding plays an important role in providing funding for research across Member States that teams of European researchers can access and

which enables researchers to take part in large-scale multi-centre studies.¹ The EU's many funding programmes support research activities across a wide range of areas related to health, health systems and healthcare delivery, including:

- Specific disease areas, such as cancer, cardiovascular disease, and rare diseases.
- Healthcare delivery, including quality and patient safety, cost benefit and financing models.
- Public health such as reducing health inequalities, health promotion and lifestyle related issues such as obesity, smoking and alcohol.
- Technological developments, such as e-health and ICT.

The Seventh Framework Programme (FP7), coordinated by the Research and Innovation Directorate General (DG RTD) of the European Commission, has been the central research funding source operated by the EU (CORDIS 2014). The overall objective of FP7 is to respond to Europe's needs in terms of jobs and competitiveness, and to maintain leadership in the global knowledge economy. FP7, which ran from 2007 until the end of 2013, had a total budget of €50,521m partitioned along specific programmes as follows:

- Cooperation: €32,413m
- Ideas: €7,510m
- People: €4,750m
- Capacities: €4,097m.

The Health theme, which sits within Cooperation, is a major priority area for the EU and has a budget of €6.1bn (European Commission 2014a). Projects are supported in various thematic domains (medical research, infectious diseases, etc.) with some general and specific issues cutting across these themes (personalised medicine, SMEs, etc.). The overall aim of EU support for health research is to improve the health and wellbeing of European citizens, to address global health issues and to boost the competitiveness of European health-related industries.

Since 2007, UK scientists in businesses, universities and elsewhere have received around £3.7bn from the EU, making the UK second only to Germany in terms of the total amount received. In fact, the UK had, as of 2011, won 16 per cent of all FP7 funding to EU Member States and 27 per cent of ERC funding. These fractions are higher than the overall UK contribution to the EU budget (about 11.5 per cent) and the UK's share of overall EU spending (about 5.6 per cent) (The Russell Group of Universities 2013a).

FP7 is now being replaced by Horizon 2020, the European Union's Research Framework Programme for 2014 to 2020 (Horizon 2020 2014). The first calls for funding for Horizon 2020 came out in December 2013 and the programme will be rolled out fully to replace FP7 in 2014. Health will remain one of the priority areas for Europe under Horizon 2020. Lifelong health and wellbeing for all, high-quality and economically sustainable health and care systems, and opportunities for new jobs and growth are the aims of support to research and innovation in response to this challenge and will make a major contribution to Europe 2020.

The ERC complements other funding activities in Europe, such as those of the national research funding agencies, and is one of the four main specific objectives under the Excellent Science pillar of Horizon

¹ A number of health researchers interviewed identified this as an important benefit.

2020. The ERC's mission is to encourage the highest quality research in Europe through competitive funding and to support investigator-initiated frontier research across all fields of research on the basis of scientific excellences. The ERC complements other funding activities in Europe, such as those of the national research funding agencies, and is a flagship component of the 'Ideas Programme' of the European Union's FP7. Significantly, by being 'investigator-driven', or 'bottom-up', in nature, the ERC approach allows researchers to identify new opportunities and directions in any field of research, rather than being led by priorities set by government (ERC 2014). The ERC has been a productive source of funding for UK researchers and the UK is the largest recipient of the ERC by some distance.² In fact, the UK has won significantly more ERC awards than other Member States; that is 841 awards³ compared with Germany's 540 (Joint National Academies 2013). A significant number of ERC grant holders from other Member States also choose to host their research project at a UK institution. According to the Royal Society of Chemistry, between 2007 and 2012, the UK had the largest number of ERC grant holders (starting and advanced) who are non-UK nationals. This highlights the UK's status as an attractive prospect for the world's best international researchers and the strength of the UK's science and health research infrastructure (Royal Society of Chemistry n.d.).

2.2. The economics of EU membership

Those who champion the case for the UK's withdrawal from the EU often highlight the high costs of membership. The UK is one of the four largest net contributors in absolute terms to the EU budget alongside Germany, France, and Italy (see *EU Budget* 2013). As a result, the UK does not make any *cash* financial gain from EU membership (Allen, Thompson and Dar 2013); though previous and current governments have judged there are many other benefits and advantages for trade and employment that make membership worthwhile. For research, these benefits include funding but also access to networks, research infrastructure, institutional partnerships and wider strategic value for UK health research. Details are discussed further in the next section.

The challenge when examining studies that estimate both the current cost of membership to the EU and the financial impact that a potential change in the UK's EU membership status could bring about is that they use various sources of evidence and are subject to the prejudices of the author. For instance, the National Institute of Economic and Social Research calculated that ceasing to be a member of the EU would reduce Britain's GDP by 2 per cent; other researchers see EU membership as a strain on growth that costs about 3 per cent of GDP every year (Volkery 2013). The Office for Budget Responsibility has forecast the UK's net contribution⁴ to the EU budget for 2013–2014 at £9.3bn, climbing to £10.3bn for 2014–2015 (Office for Budget Responsibility 2010).

In fact, it is extremely difficult to produce a clear calculation of the financial costs and benefits of being an EU Member State because so many of the costs and benefits of EU membership are intangible and

² These findings were supported by feedback with the European policy and funding manager at the University of Cambridge.

³ The total value of ERC funding to the UK, up to March 2013, was just under €1.2bn (Joint National Academies 2013).

⁴ It should be noted that there are different ways of calculating net contribution depending on whether one attributes direct and indirect contributions and returns.

diffuse.⁵ Whilst some attempt may be made to calculate the basic costs of membership; it is a far more challenging exercise to place a monetary value on the myriad EU funds and areas of financial support that the UK is in receipt of and, to an even greater degree, the more intangible benefits and advantages of membership. In addition, when attempting to calculate the economic impact of a potential withdrawal from membership of the EU, a host of assumptions must be made about the terms and conditions of any such change, all of which might drastically alter the overall financial picture and greatly colour the impression of any associated benefits or disadvantages. For example, were the UK to change its current EU membership status, the terms of any negotiated access to the EU as part of the European Economic Area (EEA) or European Free Trade Area (EFTA) are unclear and difficult to predict. Although Norway and Switzerland have access to the single market and have bilateral agreements, it is uncertain whether the UK would be able to follow a similar path. There have been no recent studies that have thoroughly tested how sensitive their findings are to alternative assumptions, policy scenarios, trade relationships and counterfactuals (Thomson and Harari 2013).

A research paper prepared by the UK House of Commons Library argued that most of those studies which find a significant **net cost** to EU membership tended to ‘take a static approach, calculating the various impacts – fiscal, regulatory, trade-related, etc. – in a given year and summing them to produce an overall cost’ (Miller 2013, 8).⁶ Those that then take a forward-looking perspective, it said, often ‘judge that the process of harmonisation and integration taking place in the EU will exacerbate those costs identified in the static analysis’ (Miller 2013, 8). The parliamentary paper asserted that most studies that produce a more pessimistic vision of the UK’s membership of the EU also tend to focus on areas of contention such as agriculture, monetary policy, tax and regulation, public finances and social policy such as the controversial Working Hours Directive. On the contrary, studies that find a **net benefit** to membership, it said, tend to look at the longer-run effects of the UK’s membership of the EU versus a more restrictive trading arrangement (Thomson and Harari 2013).

When we reduce the financial question down to the level of the value of research funding, the evidence suggests that the UK receives more in the research portion of the EU budget than it puts in. However, the difficulties arise when we attempt to estimate the potential savings that could be made in membership costs and other subsidies which might potentially outweigh any immediate financial loss to the UK research community.

When reflecting on the economics of EU membership, there are two key points that must be borne in mind. Firstly, by reducing this debate to a financial argument – monies paid in versus monies received – the considerable benefits of EU membership that cannot be as easily quantified are excluded from the calculations and their considerable value to the health research system is overlooked. In the case of health research, these include elements such as the free movement of people and skills, the easy transfer of medical materials such as blood and tissue, and access to pan-European collaborative networks. These benefits are explored in further detail in the next chapter in our conceptual framework. Secondly, the

⁵ See for example the strategic value of EU membership in terms of influence; it may provide Member States with leverage that is important but difficult to quantify.

⁶ It should be noted there are various approaches for measuring net cost and net benefit and a lack of consensus as to which method works best.

relative success and failure of a potential change in the UK's membership of the EU further depend upon the ways in which the UK government might fill any shortfalls, both in terms of research funding and the policies and other regulatory conditions which pertain to research and development in the UK.

A perception from the researchers we interviewed for this study is that one of the major advantages of EU membership in terms of health research is that it provides UK researchers with access to funding that supports the kind of large-scale multidisciplinary research that is not readily funded at present through the research councils and medical charities in the UK. It is possible that the loss of this important funding stream could be replaced by a realignment of national funding in the wake of a potential change in EU membership status, but would this happen? It cannot be assumed, were the UK to cease membership in the EU, that the funding 'gap' would be filled by the UK government and that savings in EU membership fees would be apportioned to support a particular research stream that was previously funded by the EU. The research councils and, in particular, the medical charities tend to support specific research areas and therefore projects that bridge different subject or specialist areas may find it difficult to secure funding. There is no evidence that this situation would change, were the UK to potentially withdraw from the EU, without a major change to the research funding infrastructure in the UK. Thus, in conceiving ways in which the UK could protect its current position in health research if there were to be a change in the UK's membership of the EU, the first step would be to maintain continued access to funding and mechanisms to enable researcher mobility.

2.3. The value of EU funding to UK health research

In the debate about the UK's membership of the EU, the value of EU research funding is frequently omitted from discussions about the financial implications of a withdrawal from the EU as the focus tends to be on other more controversial policy and legislative areas, such as employment and trade.⁷ The benefits of EU funding to UK health research are considerable and all the more apparent given the UK's success across the EU's funding programmes. In addition to the Health theme of FP7, through which the UK was a major recipient of health research funding, and the increased funding opportunities that are represented by Horizon 2020, EU membership provides access to a range of programmes, and regional and social funds, which often include components that could be used to support research.⁸ Research within these programmes, however, is usually complementary to other activities and is more focused on technological development (Andersen 2013).

The UK's success in accessing EU research funding is even more pronounced in the case of the ERC grants, where the UK is one of four countries (along with Belgium, Cyprus and the Netherlands) that

⁷ While some commentators, such as the Department of Business Innovation and Skills (BIS), indicate that some 3.5 million jobs in the UK are linked to EU membership, the Economist has suggested that the UK's withdrawal would bring with it many benefits, such as cheaper food, greater control over its own fishing rights, and the dissolution of some unpopular regulations such as the EU's Agency Worker Directive (see *The Economist* 2012).

⁸ Examples highlighted by Andersen (2013) were LIFE+ and ERASMUS,

hosts a higher share of ERC grants than expected from their population size, GDP and research investment.⁹

As previously mentioned, some critics of the UK's membership of the EU may argue that the savings from EU membership could be directed towards funding health research in the UK, but this is an oversimplification of the matter. Whilst any savings could certainly be potentially directed towards organisations such as the MRC and other UK funders to provide a greater funding stream in the UK, a fundamental problem voiced by our interviewees was that multi-centre studies of diseases such as cancer or dementia – that is diseases that affect all countries to a similar extent – or studies of rare diseases which require a larger population size than can be found in a single nation, can only be funded by an EU-level centralised funder.¹⁰ Other areas of work such as microbial resistance and influenza are real health threats which are likely to affect the UK adversely in the future and which call for a coordinated response from EU Member States. According to a research funder we spoke to, an increasingly isolationist UK would not be equipped to counter these threats on its own without the cooperation and collaboration of its current European research partners.

It is the general view of the researchers and funders we interviewed that national funders are not likely to support research that requires funding to be directed to other nations and national research systems. There is no precedent for this level of funding from within the UK. Although there are some cases of national funders, such as the MRC, supporting international collaborative projects, overall the funding models operated by the UK research councils, charities and trusts are inconsistent with the provision of a significant level of international collaborative funding.

The response from the Russell Group, a group of 24 research-intensive universities in the UK, to the Government Review of the Balance of Competences between the UK and the EU further underlined the importance of the EU funding stream to health research in the UK and the particular value that it provides beyond the financial dimension. EU funding streams were described as 'key to the continued growth of research excellence in the UK and to innovation and the creation of economic value.' (Russell Group 2013b, 1). The Russell Group further characterised EU funding as an 'irreplaceable source of funding for UK universities', particularly as the UK is the largest recipient of ERC funding which contributes £1bn to UK universities, and argued that the EU provided UK researchers with a unique and highly collaborative platform for international collaboration (Russell Group 2013b, 1). Significantly, the Russell Group response stresses that while the national funders in the UK provide robust funding for research, development and innovation, the EU funding stream is complementary to this and cannot be seen either as a substitute for the UK's own investment in research or as a revenue stream that could easily be replaced. The scale and multinational scope of EU research would very difficult to fund from within the UK alone.

While there are valid concerns about whether EU funding could be replaced by national funding agencies in the UK to support health research there is insufficient evidence to make firm conclusions either way.

⁹ The University of Cambridge alone hosts 95 ERC grants, which is more than the whole of Ireland, Portugal, Poland and the Czech Republic combined.

¹⁰ This was the view of all health researchers and funders interviewed as part of this scoping study.

Both the Russell Group and the small number of health researchers interviewed agree that EU funding is strategically important because of the amount of research monies provided and the type of projects it supports. Beyond these sources we found no other evidence to support this claim and would argue that more research needs to be undertaken to understand the true value of research funding and whether funding is likely to be replaced, and by who, if the UK were to potentially withdraw from the EU without negotiated access to EU research and innovation funding. Further interviews with key stakeholders and discussions with health researchers would help to develop the evidence base and assess these claims more robustly.

2.4. The value of EU membership to UK health research

2.4.1. Freedom of movement

One of the central benefits that the UK enjoys as a member of the EU is the free movement of skilled people. The freedom to easily recruit researchers and scientists from across the EU is a feature of EU membership that benefits the research quality of the UK and facilitates the establishment of stronger research bases. In the same way, free movement also provides UK researchers with an advantage over their counterparts from the US, China and elsewhere when it comes to the competitive pursuit of research positions in institutions across the EU. A UK researcher can be recruited to a European project or laboratory with relative ease whereas an overseas competitor will be a much more difficult prospect for any recruiting institution given the paperwork and legal barriers that must be overcome. In the Government Review of the Balance of Competences, NHS Blood and Transplant (NHSBT) and the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) both endorsed the impact of the EU on increased cooperation and the sharing of information between UK and EU colleagues (HM Government 2013). In particular, NHSBT acknowledged the ease with which young scientists from across the EU can contribute to UK health research. In the event of a potential withdrawal from the EU, it would appear that protecting this free movement of people across the EU must be considered a priority.

The benefits of this mobility apply to students as well as well as researchers. One popular EU programme is the university mobility scheme Erasmus, which enables students and staff to study or work at another higher education institution in the EU and has been running since 1987.¹¹ Over 7,000 British students went to universities elsewhere in the EU in 2008/09 and 16,000 students from other EU countries came to the UK in the same year (*EuroMove* 2011). Overall, about 1% of Erasmus participants are doctoral students (European Commission 2013b). A related EU programme, Erasmus Mundus, ran from 2004-2013 and supported academic cooperation and exchange between the EU and other countries (*Erasmus+* 2014).

¹¹ In 2014, Erasmus became part of Erasmus+, which includes multiple programmes: The Lifelong Learning Programme (Erasmus, Leonardo da Vinci, Comenius, Grundtvig and Jean Monnet), The Youth in Action Programme, five international cooperation programmes (including Erasmus Mundus) and a sport programme (European Commission 2014).

2.4.2. Enabling collaboration

Science is inherently and increasingly collaborative. Over 35 per cent of articles published in peer-reviewed journals have co-authors based in more than one country (Royal Society 2011). There is also evidence that international collaboration increases the citation impact of a paper (Royal Society 2011).¹² Similarly, another study, providing a bibliometric analysis of publications from FP7 projects, concluded that improvements in impact tended to be associated with increases in collaboration across all EU Member States (*Thomson Reuters* 2010). The UK's membership of the EU therefore provides the UK not just with a network of research partners but, crucially, a network which has access to the same source of funding. UK research benefits from the existing collaborations that are taking place with institutions across Member States and these collaborations would be much more difficult if all partners were not being funded by the same source. Interviews with health researchers suggested that it was highly beneficial to have all researchers funded under the same programme (e.g. FP7) and abiding by the same rules and administrative processes. This makes collaboration easier than requiring researchers from different member states to apply under different national funding programmes to work on topics of shared interest. Helping to facilitate this collaboration, the EU-funded Marie Skłodowska-Curie actions (MSCA) programme is especially valuable. The programme, which comes under Horizon 2020's Excellent Science pillar, is to award €6.16bn over 2014-2020 for research training and career development fellowships and programmes. The MSCA provide support in four main areas: research training networks, individual fellowships (for experienced researchers moving between countries), research and innovation staff exchanges to promote cooperation between sectors and countries, and co-funding of research training and fellowship programmes (for doctoral candidates and more experienced researchers) that involve inter-country mobility (European Commission 2014d). EU funding programmes in general are valuable because they not only make it possible for researchers across Europe to collaborate, but actively encourage collaboration through the regular condition that funded projects must include partners from three or more EU Member States.

2.4.3. Movement of students

Returning to a financial argument, it may be suggested that a potential withdrawal of the UK from the EU would enable universities to charge EU students higher fees to attend UK universities. It may then be argued that if these higher fees were introduced, EU students would no longer choose to come to the UK in the same numbers. However, despite a near trebling of fees in 2012-13, EU entrant numbers declined by only 12.4 per cent (UCAS 2013). This change was described by Nigel Healey, pro vice chancellor at Nottingham Trent University, as 'a significant fall, but not one that suggests that the market is particularly price sensitive' (Gibney 2013).

What has not been tested yet is the restriction of access to UK funding grants and loans for EU students. The removal of this funding source would perhaps act as a greater disincentive for EU students to attend UK universities. However, a *Times Higher Education* report revealed in August 2012 that almost one third

¹² The Royal Society has shown that for each international author on an article, there is a corresponding increase in the impact of that paper, up to a tipping point of around 10 authors (after which the impact of extra country authors is less clear).

of former EU (non-UK) students at UK universities were not repaying their student loans, and administrative hurdles made it more difficult for UK authorities to collect repayments from this group (Gibney 2013). By removing this group from the pool of graduate debtors, it is likely that the UK government would save money by incurring fewer bad debts and achieving a reduction in the number of resources spent on claiming repayments from EU-based graduates. However, such a move may also limit the contribution European students make to UK universities.

2.4.4. Other benefits

A further benefit of EU membership is the free movement of tissues, cells, blood and organs between Member States facilitated by EU-wide minimum standards. These benefits, however, usually pertain more to medical treatments and health outcomes rather than health research itself. Cell-based treatments which are not available in the UK can be imported for named patients and UK citizens can receive suitable organs from across Europe. In terms of health research, this means that if tissues or cells are imported into the UK from another Member State, ‘an import licence is not required as the tissues/cells will already have been assessed as meeting the regulatory requirements by the Competent Authority (CA) or another member state.’ (Human Tissue Authority, quoted in HM Government 2013, 33). According to the Review of the Balance of Competences, although the UK previously had excellent practices in place before the directives, several respondents – such as the health authority NHS Blood and Transplant (NHSBT), the UK’s Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), the National Blood Transfusion Committee, and the British Medical Association – believe that the EU has been responsible for an overall improvement across Member States in blood and tissue transfer, reducing variation in practice and improving the traceability of blood and blood components (HM Government 2013).

According to SaBTO, ‘Up to date information is...shared between European countries on the incidence of new and emerging infections’ (SaBTO, quoted in HM Government 2013, 34). While this access to information provides an advantage to organisations such as Public Health England, who monitor infection risks, the research community also benefits from the free sharing of information on infectious disease. In line with this, the European Commission’s Joint Research Centre (JRC), in collaboration with the Health and Consumer Protection Directorate General (DG SANCO), developed the Health Emergency & Diseases Information System (HEDIS) to provide support to DG SANCO and Member States in cases of disease outbreaks and other health emergencies.

2.5. Disadvantages of EU membership to UK health research

The disadvantages of EU membership for UK health research are not easily identified, but two sources of concern have been the EU Clinical Trials Directive (which has now been revised) and proposed amendments to a draft EU Data Protection regulation. Another challenge that has been cited is the level of bureaucracy in EU research funding programmes.

2.5.1. Clinical Trials Directive

The EU Clinical Trials Directive, which was implemented in 2004, has been revised and a new regulation came into force in 2014. However, the directive is thought to have had a significant impact on clinical

research in the UK and Europe. Intended to ensure consistency in the standards for clinical trials research across member states and facilitate cross-border collaboration, the directive is considered to have increased administrative burdens, delays and costs for clinical trials, and caused an adverse effect on the number of trials being carried out in the EU (NHS European Office 2014). The directive was also subject to a certain degree of interpretation at the member state level because it needed to be transposed into national law. In contrast, the new regulation, which is expected to be applied from 2016, is a law that will be applied directly in each member state, ensuring consistency across the EU. The regulation is expected to reduce regulatory and administrative burdens, and reduce delays in starting clinical trials (NHS European Office 2014).

Prior to the revision, concerns about the directive were raised by a range of stakeholders, including research funders, the pharmaceutical industry and the UK government. According to the Association of British Pharmaceutical Industry (ABPI):

The implementation of the EU Clinical Trials Directive in 2004 was intended to harmonise the standard of clinical research performed in the EU. Unfortunately, different interpretations of the legislation across the Member States, different national laws, and a general increase in the number of requirements greatly increased the administrative burden associated with performing clinical research. This increased the time taken to obtain key documents such as Clinical Trial Approvals (CTAs). This steep increase in complexity is considered to have contributed, along with other factors, to the steady decline in the number of clinical trials performed in the EU since 2004. (ABPI, quoted in HM Government 2013, 31). The Government Review of the Balance of Competences stated that the current legislation around Clinical Trials made it difficult to conduct cross-border trials and expensive to get approval for a clinical trial in the EU (HM Government 2013). As a result, it said, many researchers started conducting research outside of the EU.

2.5.2. Data protection legislation

Another aspect of potential EU legislation has been criticised by researchers and research groups from the UK and across Europe. It is the reform of European data protection legislation, which is taking place in an effort to improve the safety and security of EU citizens' personal data. In particular, groups have opposed amendments adopted in by the European Parliament in 2014 to a regulation proposed by the European Commission. Discussion of the regulation is still ongoing within the EU government. They are concerned that the amendments, which are intended to support personal data protection and privacy, would make health research involving personal data 'at worst illegal, and at best unworkable' (Wellcome Trust et al 2014, 2).

The regulation covers how personal data would be used in a range of different areas. It would require explicit consent for the use and storage of personal data, but the European Commission's original draft included an exception for research (provided that ethical approval and confidentiality standards are met). The Parliament's amendments would reduce this exception, meaning that researchers would need to obtain consent from patients for every specific use of their data in research. Researchers would be unable to reuse data, needing instead to re-contact participants every time their data was to be used in a study – and this requirement would create a significant cost and time burden.

The requirement put forward ‘fails to take account of the fact that this research is subject to ethical approval and strict confidentiality safeguards, and the identify of individuals is often masked,’ said a statement published in 2014 and signed by around 100 non-commercial research organisations and academic groups (Wellcome Trust et al 2014, 1). It continues, saying the requirement ‘would put at risk significant European investments in genetics, cohort studies, biobanks, disease registries and the use of routinely collected data, and associated progress towards understanding society, health, and disease that delivers real patient benefit.’ If the amendments were to be adopted, it appears the regulation would have a significant, negative impact on health research in the UK and EU.

2.5.3. EU funding bureaucracy

Burdensome bureaucratic processes have long been a cliché of EU administration and the health researchers we spoke to endorsed this as a real and continuing disadvantage of EU funding. For example, while the FP7 requirement that consortia include partners from at least three Member States provided a real incentive for cross-country collaboration, it also added another level of complexity to the process of coordinating and developing proposals, submitting bids and managing projects. This criticism was voiced not in relation to the actual process of collaborating with research partners in other Member States – the value of which was recognised and highly prized – but rather in relation to more practical issues such as language and time spent on travel. For example, all FP7 funding bids must be submitted in English and therefore UK partners tended to spend a disproportionate amount of time involved in the writing and reviewing of written work prior to submission. Similarly, the administration of grants often entails meetings in Europe to update funders on progress and milestones which take a lot of time and were seen by researchers as a drain on project time and resource. However, it is worth noting that while the processes of EU funding policy and administration were often regarded as burdensome and unnecessary by those researchers we spoke to, none of them felt that this was sufficiently disadvantageous to the research process to merit withdrawing from such EU programmes altogether. On the contrary, interviewees hoped this aspect of EU funding would improve but they still saw EU funding as worth the effort overall given its considerable value and importance to their research portfolio and professional development.

3. Conceptual framework

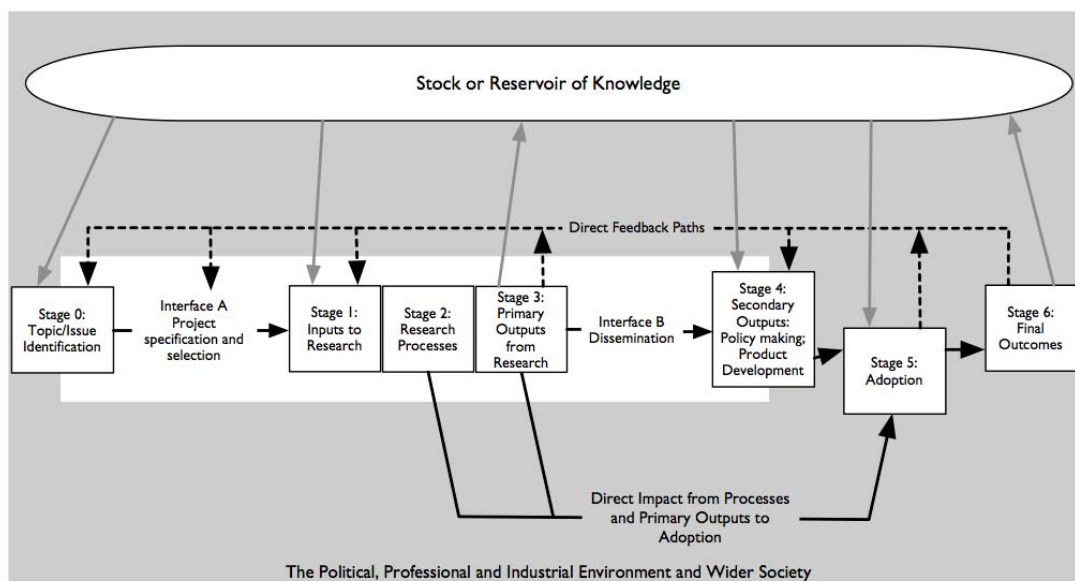
The previous chapter outlined the context to the debate and identified some of the benefits of EU membership for UK health research. This chapter builds on this evidence to present a conceptual approach for understanding the impact of UK membership of the EU on UK Health Research. The approach described in this chapter is both a conceptual framework and an empirical tool for understanding the question at hand. Firstly, the model takes an abstract view of how the EU benefits to UK health research may be conceptualised and categorised. Secondly, the model has an empirical function in the way it can be used to understand inputs and outputs in specific areas of health research or case study projects or programmes.

3.1. Our approach

The conceptual approach (an adapted input-process-output-outcome logic model) is useful in this context because it can depict UK health research processes in real life based on assumptions about specific inputs, activities and results.

Logic models are widely used in evaluation methodology to understand input-process-output relationships and break down research programmes into their component parts. RAND Europe has used logic modelling in the Payback Framework, a logic model developed in collaboration with colleagues at the Health Economics and Research Group at Brunel University to understand research processes. The payback model has been applied in several contexts, including early clinical research and basic research, health services, social science, and arts and humanities research (see, for example, Levitt 2010; Wooding et al. 2004, 2011 and 2013). The Payback Framework is currently the most widely used and comprehensive method available to measure payback from research in a systematic way. In it, any assessment of the scientific quality of research (e.g. journal articles, the training of future researchers and the development of careers) is part of the broader assessment of impact: the societal impact of research is the key issue in the multidimensional categorisation of the benefits from research. A schematic of the payback logic model is shown in Figure 1. This model can be used to frame a range of different evaluation approaches, from case studies to surveys.

Figure 1. Logic model used in the payback framework



Adapted from Hanney S, Gonzalez-Block M, Buxton M and Kogan M, The Utilisation of health research in policy-making: concepts, examples and methods of assessment. *Health Research Policy Systems* 2003, 1:2

Developing a model to understand the impact of EU membership on UK health research is a particularly difficult task considering the complexity of the relationship and the challenges in quantifying the inputs and outputs. While the model is a useful way to frame our understanding of the research questions, there are clear limitations where data do not exist or where it is not possible to quantify particular inputs or outputs. Rather than populate the model fully, our approach has been to modify it according to UK health research and to identify relevant variables and indicators that can be analysed through future research on the topic.

The section below describes the model while Annex B provides details on different indicators for the different inputs, processes, outputs and outcomes that can be used to populate the model. These indicators are based on our independent assessment of the inputs that make UK health research possible, the processes through which research occurs and the outputs of this research and the longer-term outcomes that might transpire. It is possible to identify, and in some cases quantify, the inputs, processes and outputs; although quantification is a challenge due to the lack of aggregate data.

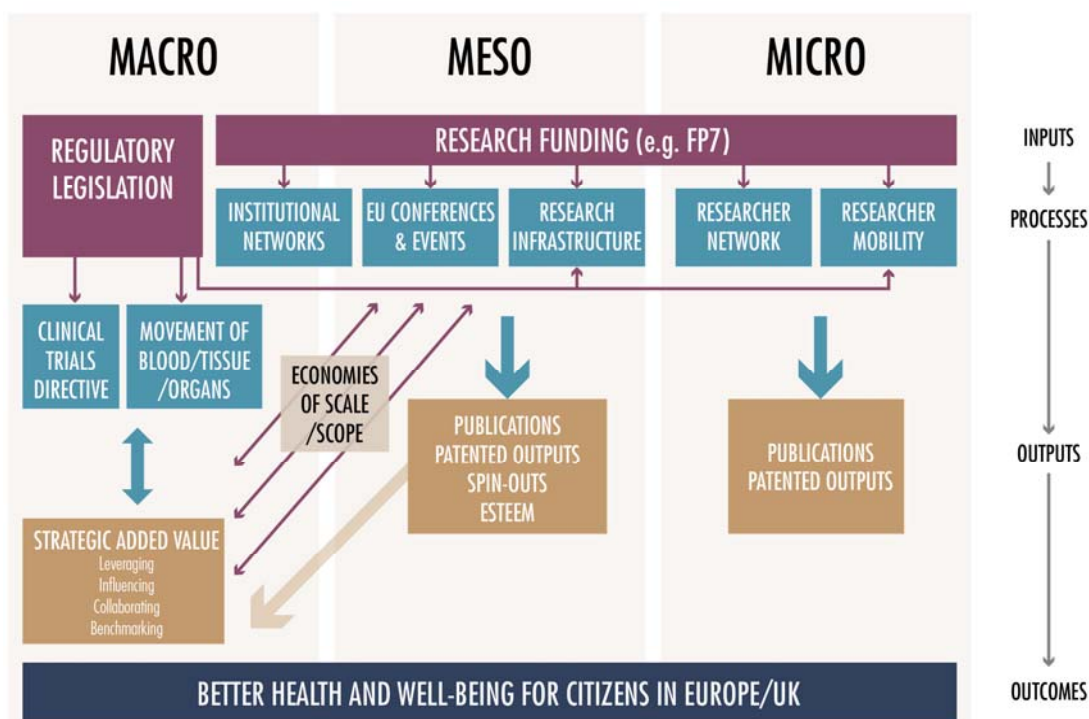
The outcomes of health research are more abstract and are included in the model for the purposes of illustration but it is not possible within this exercise to attribute the outputs of UK health research supported by the EU to any of the outcomes identified. The outcomes represent the ultimate objectives of health research for any researcher, funder, research institution, Member State or European institution. They include economic, social, health and system-level outcomes for the Member State whose health research is supported by European institutions.

Table 1. Categories for inputs, processes, outputs, outcomes

Inputs	Processes	Outputs	Outcomes
<ul style="list-style-type: none"> • Research funding • Researchers and students (PhDs, Postdocs) • Equipment • Laboratory space 	<ul style="list-style-type: none"> • Knowledge exchange and transfer • Division of labour and expertise through collaboration • Institutional partnerships • Regulatory and legislative • Clinical trials 	<ul style="list-style-type: none"> • Publications • Patents • Medical devices • Treatments and treatment approaches • Adoption of findings by clinical guidelines 	<ul style="list-style-type: none"> • Improved health and wellbeing for citizens • Economic growth through knowledge spillovers, jobs creation, entrepreneurship, gross-value added • System level outcomes for UK health/healthcare systems

The conceptual framework combines the design of a logic model with sensitivity to the different scales of engagement between the UK and Europe. The scales provide a perspective for understanding the costs and benefits of EU membership for UK health research for different actors within the UK health research ecosystem. The approach is also reflective of the conceptual approach to the balance of competencies review undertaken by the UK government to assess the costs and benefits of EU membership whereby interactions with Europe can be considered at different scales. The framework is broken down into three scales: micro-scale of individual researchers; the meso-scale of research institutions and the macro-scale of the UK as a whole (Figure 2).

Figure 2. Conceptual framework for understanding costs and benefits



In terms of the evidence we have gathered thus far and perspectives garnered in scoping interviews, the major benefit of EU membership for UK health research is funding. Funding is the main input to the UK health research ecosystem and is sourced through grants from framework programmes, ERC grants and other European mechanisms. Funding is the enabler for research to happen across all scales of the UK health ecosystem and supports researcher salaries, researcher mobility, research infrastructures and activities for networking and dissemination (e.g. conferences, seminars). Importantly funding helps to support the mobility of researchers which is important both at the micro and meso scales. Researcher mobility is a vital process because it facilitates not just the exchange of ideas but also encourages long-term partnerships to develop between researchers and institutions. There are differences between the benefits of EU membership across the different scales that require further exploration.

At the macro-scale the benefits of EU membership are harder to identify due to the complex mechanisms through which the UK government influences and is influenced by the EU and the difficulty in capturing the strategic added value. It is evident that the EU influences UK legislation and regulation across a range of different spheres. These influences have a tangible effect on how research activities happen, but tracing through what this means for health research activities and outputs is difficult. Moreover, we know that being a Member State brings strategic added value for the UK government in being able to influence European policies and priorities and achieving economies of scale and scope across a range of areas. Understanding what strategic added value means for the UK health ecosystem requires more evidence and consultation with key informants and institutions.

At the meso-scale institutions also benefit from funding but there are also wider benefits of being engaged in networks with institutions across Europe. This can facilitate researcher mobility and the coordination of activities that provide universities with economies of scale and scope for undertaking and disseminating their research. The outputs of research would again be the publications and patents that are produced from research projects hosted by the institution, but could also encompass the creation of firms spun-out from the university and the wider esteem that would result from being a node for European funding, activities and institutional networks. For more prominent institutions (e.g. elite universities, research institutes) there is also scope to leverage strategic added value identified at the macro-scale and could include leveraging other sources of funding, influencing research priorities and benchmarking activities with different institutions.

At the micro-scale individual researchers have many avenues through which funding can be secured, including the Marie-Skłodowska-Curie actions, ERC grants and framework programme calls. Funding enables researchers to undertake research projects which will aid career development and networks across Europe. For individual researchers publications and patents may result from the inputs of research funding and activities supported, although this will depend on the area of health research in question.

In sum, the framework provides an analytical lens for understanding the European interactions with the UK health system and the various inputs, processes, outputs and potential outcomes resulting from this. The framework is deliberately broad in scope so it is applicable to UK health research at large. Further research and thinking is required to understand how the framework might be tailored to more specific areas of health research or to individual activities supported by Europe.

One of the difficulties with looking at such a large subject as health research as a single uniform area of work is that it is very difficult to capture the complexity and, more importantly, the diversity of activity within the field. For example, it may prove that while EU funding has been a critical and essential source of added value in the area of heart disease in the UK, it has less impact on research activity and outcomes in the area of mental health. Similarly, while EU funding might be having a major impact on the strength and value of interdisciplinary research across the spectrum of health research, more targeted projects funded through the EU might not be achieving a comparable level of impact in their intended fields. Moreover, in order to apply the conceptual framework to the subject of health research, we need to somehow identify and select only EU-funded research projects that were carried out in the UK for the purposes of our analysis. This is unsurprisingly a difficult and time-consuming task.

The conceptual framework is dynamic and fluid and the balance of inputs, processes and outputs will change according to different political, economic, technological, scientific priorities and trends. For example, it is likely that the framework will alter under changes to European research and funding priorities and mechanisms under Horizon 2020. We do not know exactly how the balance of funding or the funding availability for different areas of health research will play out in the future. The next chapter presents possible scenarios for the future of UK health research under different institutional arrangements between the UK and the EU.

4. The future of UK health research under different EU membership scenarios

4.1. Introduction to scenarios

A scenario is intended to provide a picture of the future which is credible and challenging to stakeholders. Scenarios are not predictions of the future, but can provide insight into future trajectories and logics governing development. The analysis of scenarios enables us to identify the potential implications of decisions made today and think through and prepare for the consequences and implications of those decisions and choices. This analysis highlights linkages among different aspects of the future which might not otherwise be apparent and so can be a useful tool in considering different options and trade-offs for the future.

In the absence of certainty regarding the terms and conditions upon which any potential change in the UK's EU membership status would be predicated, we can only explore the likely scenarios that might arise and develop a policy response to each eventuality, aiming to limit any potential damage to health research. In developing scenarios for the future of the UK health research ecosystem in the context of EU membership, we used an intuitive scenario development process rather than a more formalised approach (Hoorens 2009).

To create the space for the development of scenarios we coordinated an internal workshop comprising RAND experts with experience in health, research evaluation and European policy issues. The conceptual framework discussed in Chapter 3 was the starting point for discussion and helped frame the debate on the various inputs, processes, outputs and outcomes that EU membership brings to UK health research. From this discussion we then considered what might be the certainties and uncertainties of influencing the future of UK health research, the UK and Europe. From these assumptions we developed a range of scenarios based on our understanding on the different possibilities for the future relationship between the UK and the EU. This meant that we thought about UK health research in light of future decisions the UK government may need to take about its relationship with the EU and the wider political-economic context.

We present four major scenarios for the future of UK health research. These scenarios are underpinned by specific assumptions concerning future political-economic arrangements between the UK and the EU (Table 2). The assumptions are the building blocks of our scenarios and serve to differentiate one scenario from the other. For instance, the future of UK health research in a scenario where the UK would be

entirely outside the EU will look quite different from a scenario whereby the UK is an associate member with access to research and innovation funding. In developing these scenarios we have attempted to be thorough in trying to understand the effects of changes in institutional arrangements to research and innovation funding, researcher mobility, access to networks, infrastructures and wider strategic value. However, there is a great deal of uncertainty regarding the likely institutional arrangements that might be formed if the UK was to leave the EU. These different arrangements will have important and far-reaching consequences across a range of different public policy spheres. The focus of our analysis is solely on the implications for UK health research.

Table 2. Summary of scenarios and key assumptions

Scenario	Institutional arrangement	Access to single market?	Access to research and innovation funding?	EU member
(1) Status quo	Full EU Member State	Yes	Yes	Yes
(2) Negotiated access	Associated EU member through EEA or EFTA	Yes	No (depending on terms of negotiation)	No
(3) Out	Out of EU	No	No	No
(4) Closer integration	Full EU and Eurozone member	Yes	Yes	Yes

In developing these four scenarios, we identified a number of contextual certainties and uncertainties which would influence future decisions (Table 3). These certainties and uncertainties came out of our internal scenarios workshop and were informed by our informant interviews and literature review.

Table 3. Contextual elements of the scenarios: ‘Knowns’ and ‘unknowns’ for the future of health research, the UK and Europe

What we know (certainties)	What we do not know (uncertainties)
Europe will continue to promote research and innovation collaboration	Level of negotiated access for the UK to EU research funds as an EEA,EFTA member
Europe will increase funding through Horizon 2020	Productivity of building links elsewhere (US, India, China, et al.)
Health is a major funding area under Horizon 2020 (20%)	If UK funders would be able to bridge any funding gap left by the EU (were the UK to cease membership)
Increased scope for cross-border funding under Horizon 2020	Strategic added value of EU membership and the potential implications of losing this
UK is a major recipient of EU health research funds	

When it came to developing the scenarios, we considered both the contextual elements and how these may alter the inputs, processes and outputs discussed in the conceptual framework. Those factors which have greater degrees of uncertainty or which might be reasonably expected to play out differently because of their dependence on other variables were used to differentiate between the scenarios. We then developed narratives around each of these futures and the result is the following four scenarios presented below. It is important to note that we have deliberately pulled each scenario apart and in many cases exaggerated what the future might look like for the purposes of illustration.

The future of UK health research in the context of the UK's relationship with Europe is likely to encompass a mix of the different elements presented in our analysis. In order to do this, we must understand what each scenario looks like independently. These scenarios are illustrative but also challenging to think through due to the complexity of any likely future arrangement between the UK and Europe and also due to a lack of clarity on what the counterfactual might look like.

To help examine each scenario in more detail we conducted a brief analysis considering some of the main strengths, weaknesses, opportunities and threats for the UK health research system within each possible future scenario.

4.2. Scenario 1: Status quo

In this scenario the UK will continue to be a member of the EU under all the terms, conditions and provisions that it currently enjoys. The free movement of researchers, students, and biomedical materials will continue as it does now and established collaborative networks and research partnerships which the UK is a part of will be able to be sustained and consolidated going forward.

For health research, the main advantage of this scenario is that the UK will benefit from the many expected advantages of the Horizon 2020 funding scheme. For example, given the UK's record of securing research funding from the EU, it might be fairly assumed that given no change in the UK's relationship with or membership of the EU, the UK is poised to benefit a great deal from the introduction of Horizon 2020 which, with a budget of €80bn, will have far greater funding provision than FP7 (an increase of about 30% in constant prices). Horizon 2020 also brings with it a greater focus on business and enterprise and the provision of increased funding and collaborative opportunities for both small- and medium-sized enterprises (SMEs) and the pharmaceutical industry. For health researchers in the UK, it is expected that Horizon 2020 will involve less bureaucracy than FP7 and that the administrative burden of coordinating, applying for, and managing grants will be significantly reduced. Horizon 2020 is designed to support the full spectrum of activities throughout the research and innovation cycle, from knowledge and technology transfer to large-scale demonstration actions.

Therefore, under this scenario, by remaining in the EU, the UK will be placed to take advantage of opportunities for new models of innovation that ensure that EU-funded medical research results in affordable and accessible medicines and services. The UK's research into rare diseases will be boosted by increased incentives to study this area of health, while revision of the Clinical Trials Directive may benefit the wider health research community and industry collaborators.

Horizon 2020 is also funding five major Joint Technology Initiatives, including one on innovative medicines which is being set up to develop vaccines and new drugs including treatments for antibiotic resistant infections. In this scenario, the UK is also best placed to form part of a coordinated response across Europe to real, emerging health threats such as microbial resistance and influenza pandemics.

Scenario 1: Analysis

Positive aspects and opportunities for the UK health research system

- Health researchers will continue to access to a large and valuable research and innovation funding stream.
- Avoiding a change in the status quo ensures that existing strengths of the UK health research system are not compromised or threatened. This is particularly important for areas of health research with a greater reliance upon EU funding and collaborative systems.
- Greater opportunities for open innovation in health research and enterprise through Horizon 2020.
- Revision of the Clinical Trials Directive may benefit UK researchers.
- Small to medium-sized enterprises, including those involved in health research, are expected to be the group that will benefit most significantly from the introduction of Horizon 2020. Horizon 2020 will provide support for all types of innovation following a bottom-up approach, including scientific, social and service innovations. This presents a significant opportunity for investment and growth for UK-based SMEs engaged in health research.
- Possibilities for UK charitable health funders and civil society groups to further engage with Horizon 2020's focus on responsible innovation.

Negative aspects and threats for the UK health research system

- The EU health funding agenda is set according to Europe-wide priorities and will not necessarily reflect the national priorities of the UK.
- Previous attempts by the EU to increase SME involvement via quotas failed because SMEs were required to join large projects, meaning their input was marginalised. This situation may persist in Horizon 2020.
- Changes to the bureaucratic and administrative funding process may be difficult to implement. The current systems of funding application are too labour-intensive for most SMEs to negotiate and so significant changes would be required to counter this problem going forward.
- EU legislation has sometimes had an adverse effect on the health research community (e.g. the Clinical Trials Directive, described in 2.5.1)

4.3. Scenario 2: Negotiated access

Under this scenario, we assume that there are going to be major changes to the relationship that the UK currently has with the EU whilst the UK still retains some links to common areas of activity and some access to the same privileges held by EU Member States. The central difficulty with this scenario is predicting the conditions under which the UK might negotiate its potential withdrawal from the EU. If permitted, the UK may elect to join the European Economic Area, like Norway; join the European Free

Trade Association, like Switzerland; or form a customs union with Europe, like Turkey (Buchanan 2012). Under any form of negotiated access, there are three key areas of activity that will need to be carefully considered and negotiated in the event of a UK withdrawal from the EU: (1) retaining access to EU research funding through a 'buy-in' type scheme; (2) retaining the free movement of researchers both into and out of the UK; and (3) retaining access to bio banks and data sharing.

The question of whether the UK will be able to 'buy-in' to continue to participate in EU funding programmes raises the difficulty of how much this will cost and what the willingness to pay will be. It might reasonably be expected that it is in the EU's interests to retain the UK as a fully-viable research partner given the manifest importance of the UK to Europe's broader health research landscape. By removing the UK from the funding framework altogether, the EU's own health research strength is likely to be significantly compromised and maintaining a competitive advantage in the global health research market will be more difficult. From this perspective, it may be possible to argue for the importance of ensuring that the UK remains a fully-functioning research partner, despite any change to its status as an EU Member State. Similarly, there are some precedents for the free movement of researchers that are not from EU Member States so this feature of research activity, which is so valuable to the current system of health research in the UK, might be more readily negotiated and retained. Finally, the terms of access to data and bio banks will perhaps be the most difficult to forecast and will possibly depend upon the negotiated access of UK researchers to EU funding and their subsequent entitlement to use and contribute to bio banks.

Scenario 2: Analysis

Positive aspects and opportunities for the UK health research system

- The UK would have more resources to develop health research links globally whilst retaining a stake in the EU.
- The UK would regain significant autonomy over its own laws and economic policy.
- If the UK can negotiate sufficient access to EU funding to continue to collaborate with European partners on major research areas, there is a possibility of a win-win situation whereby those research areas that depend upon top-down EU funding continue to be supported by the EU whilst at the same time savings from EU membership fees can be used to provide greater funding support for those research areas that are better aligned with the UK's national health priorities and which would previously have been neglected through lack of funding.
- The UK would potentially have greater funding available to support health research areas targeted at UK-specific health concerns.

Negative aspects and threats for the UK health research system

- If the UK is unable to retain access to EU funding, a major and irreplaceable funding stream will be lost and this will have undoubted negative consequences for UK health research.
- As an associate member or a non-member of the EU, the UK loses its current voice in setting the research agenda and its influence over the direction of EU health funding strategy. Large-scale, multi-centre trials will no longer be funded to the same degree and certain critical areas of expertise such as rare diseases are likely to be severely affected.

- The major threat for this scenario is the potential failure to negotiate favourable terms and conditions. It is likely the loss of research funding, increased restrictions on the movement of researchers and the loss of access rights to bio banks and data sets would do significant damage to the current state of health research in the UK.
- There is no comparable precedent for a country like the UK pulling out of the EU and so it is difficult to predict how a potential withdrawal would be managed and whether favourable links could be retained for health research.
- Both Norway and Switzerland have had difficulties developing a form of associate membership that suits both the EU and the individual country (Buchanan 2012). The UK, were it to withdraw from the EU, may experience similar problems in establishing a relationship that provides both the freedoms from EU policy and the access to certain privileges like research and innovation funding that the UK would seek.
- Neither the Norwegian nor the Swiss model of EU relations is likely to be a viable option for the UK in this scenario. The UK would be unlikely to be willing to accept a version of Norway's relationship with the EU, whereby legislation is implemented without consultation. The Swiss model, which is based on bilateral negotiations and agreements, might be more palatable to the UK but has created frustration within Brussels and would be unlikely to be offered as an option for the UK (Buchanan 2012).

4.4. Scenario 3: Full exit from EU

This scenario assumes that the UK withdraws from the EU and loses all rights and privileges associated with EU membership. Whilst this scenario presents a number of benefits for areas of activity outside of research, such as employment, trade, and fisheries, the immediate impact on health research is not so positive. Under this scenario, the UK would be able to redirect savings in membership fees to areas of research and activity that previously depended upon EU support, however, as we have seen elsewhere in this report, any additional funding available for health research may be unable to replace a loss of large-scale collaborative projects. On the other hand, in this scenario, the UK would be able to direct larger amounts of funding to support health research projects that are more in line with national priorities, and there would be increased incentives to create and consolidate bi-lateral research agreements with other nations. However, it would be difficult to balance the savings from membership fees and subsidies with the loss of influence in EU policy and the creation of new legislation.

Scenario 3: Analysis

Positive aspects and opportunities for the UK health research system

- The UK would regain autonomy over its own laws and economic policy.
- The EU costs the UK in the region of £6.4bn in membership fees and this would represent a major saving if the UK were to pull out completely. This saving would provide a greater national funding resource to be channelled toward national priorities, which could include healthcare and health research.

- Incentives to foster greater collaboration with emerging global health research and innovation powers (e.g. China).
- Fair trade agreements, such as those of which Switzerland, Iceland and Norway are part, mean that the UK would almost certainly be allowed to continue to access the single market, which would be important for the competitiveness of UK health innovation.
- Opportunities to establish bi-lateral agreements with European collaborators which would enable the continuation of previously successful health research partnerships.
- Potential would exist to establish a non-EU partnership with Norway and Switzerland and other European nations in order to create opportunities for easier trade, travel and collaboration.

Negative aspects and threats for the UK health research systems

- Outside of the EU there would be a loss in benchmarking of health research activities and approaches across member states.
- Loss of the EU research funding stream would affect areas of research that depend on top-down EU funding support.
- Complete loss of influence over European research and innovation policy. Non-EU countries in Europe, such as Switzerland and Norway, must adhere to certain EU rules but without having any influence over their formation and direction.
- Potential loss of European health research talent currently working in the UK.
- Research and development facilities would potentially pull out of the UK if the UK's centrality as a major European research centre were lost.
- UK would be more vulnerable in terms of developing an effective response to major public health threats such as microbial resistance and influenza given its isolation from the rest of Europe and the research community.
- There would be restrictions on the right of UK citizens to live and work in EU Member States, which would hinder the research activity of a large group of health researchers.

4.5. Scenario 4: Closer integration

The final scenario imagines that the UK becomes more closely integrated into Europe and the EU than is currently the case. This would entail potentially becoming part of the Eurozone and becoming more engaged with EU governance and administration. As part of this development, a major shift in attitudes towards Europe and EU membership would take place, within both government and the general public, who would be supportive of the EU and the UK's place within it to a much greater degree. This would help promote smoother and potentially more effective relationships with research partner countries and facilitate the ease with which collaborative networks and interactions between the UK and others take place across Europe. By establishing itself more firmly at the heart of EU administration, the UK will have a stronger voice in setting the Europe-wide health agenda and can use this influence to ensure that research priorities for EU funding are better aligned with the national priorities of the UK. This would be beneficial for the health outcomes of UK citizens as well as the research portfolio and professional development of UK health researchers.

Scenario 4: Analysis

Strengths

- Closer integration would mean greater influence for the UK at the heart of EU administration.
- Being part of the single currency would facilitate the transfer of funds related to research projects/grants where multinational partners and locations are involved.
- Greater potential to influence the direction of EU research funding priorities, ensuring that they are aligned to the national health priorities in the UK.
- Joining the Eurozone would stimulate trade activities and contribute to more freedom of movement of that could benefit health research.
- There is the possibility for further research collaboration with Eastern European countries as they become more integrated into the EU.
- The UK could become a member of the Schengen Area which would further facilitate the free movement of researchers both into and out of the UK.

Weaknesses

- Closer integration and joining the Eurozone is more difficult to reverse in the future.
- Closer integration is politically sensitive and would be against public opinion.
- The UK would be vulnerable to the fluctuating fortunes of the Euro and would suffer in the event of any collapse in the currency.
- There have been concerns that the participation of large corporations skewed research agendas for FP7 towards narrow interest, e.g. the European Commission's own reviews of FP7 show that SMEs tended to lose out in comparison to larger counterparts (Annerberg et al. 2010). Although Horizon 2020 is aiming to avoid this, there is the danger that this situation would be repeated.

4.6. Conclusion

Each of these scenarios has its own merits, challenges and opportunities. They are presented here as distinct, but in reality there are many overlaps between them to be further examined. The scenarios are useful for stimulating debate and considering what the future for the UK and Europe might be and the implications for UK health research capabilities. What is crucial is the balance between elements in each scenario, and the extent to which different drivers serve as the motivating element for how the UK might wish to interact with Europe. For example, the UK may consider EU funding to be indispensable to health research and would seek to ensure continued access to that funding. Alternatively, if the UK wants access to the single market, this could be achieved through an at-a-distance relationship with the EU through associate member arrangements (Booth and Howarth 2012). Some existing arrangements that are alternatives to the UK's current status are as follows:

- **The 'Norway' option** (EEA membership): The UK would free itself from the Common Agricultural Policy (CAP), EU regional policy and would pay less money in. The UK would retain access to the single market but subject to complex rules of origin and Britain would still be subject to EU regulations on employment and financial services but with no formal ability to shape them.

- **The ‘Switzerland’ option** (EFTA membership): The Swiss-EU bilateral agreement enables to Swiss to retain more sovereignty and opt out of a large amount of EU regulation with a reduced financial contribution. There is no guarantee that the UK would be able to negotiate a similar agreement to the Swiss one, which provides continued access to research and innovation funding and support.
- **The ‘Turkey+’ option** (membership of a Customs Union): Agreeing to participate in a customs union like Turkey will retain access to the single market but reduce the influence of the UK over European institutions. It is likely a separate deal would be needed on research funding, researcher mobility and research materials (eg. tissue, blood, etc.).
- **The clean break ‘WTO’ option:** If the UK were to leave the EU without securing a version of the options above, the UK would potentially be able to fall back on its World Trade Organization membership. This would see some exports facing relatively high tariffs and services facing limited market access. In terms of research, access to funding would be more difficult and the UK would have to seek to align itself as an associate country so UK health researchers could collaborate with EU-based researchers.

Each of these arrangements would create different contexts for the research inputs, processes and outputs described in the conceptual framework of the previous chapter. An interesting avenue for future research would be to understand how these different institutional arrangements would affect the relative benefits to UK health research at the different scales described in Chapter 3. The conceptual framework provides a tool for understanding inputs, processes, outputs and outcomes and the challenge for future research is to populate the framework with evidence and understand the shifts in costs and benefits under these different future scenarios and institutional arrangements.

5. Conclusions

5.1. Main findings

UK a global leader in health research and an important player in EU research programmes

The UK is a global leader in health research with a mature research ecosystem comprising world-class universities, institutes and government agencies (Medical Research Council 2012). The UK leads both in its research capabilities but also in the levels of investment that support cutting-edge health research (Medical Research Council 2012). Considering the UK's strengths it is unsurprising that UK health research benefits from EU support. The UK's universities and research institutes are well placed to apply for and secure funding to support research activity. While overall the UK is a net contributor to the EU, for health research the UK is a net recipient and accesses a large volume of funding from EU research and innovation programmes. In the health theme of FP7, the UK has attracted over €570m in EU funding (HM Government 2013). This represents 17 per cent of the whole EU contribution and €30m more than Germany, the second highest beneficiary, receives. Overall, the UK has won over 16 per cent of all FP7 funding to EU Member States and 20 per cent of ERC funding.

EU funding supports a range of research activities

The EU contributes to UK health research primarily through various research grants including Framework Programme Grants and ERC grants. These sources are an additional and significant stream of funding which supports a range of health research activities. Moreover, the view from the Russell Group and our own interview programme is that EU funding is important as it frequently supports areas of research activity not covered by the existing national funders. EU funding is also perceived to be important as it enables UK researchers to carry out research into those areas not easily studied from within the UK, such as rare diseases, or to take part in large-scale multi-centre studies for major disease areas such as cancer.

Other benefits include mobility of people, researcher material and networks

Aside from research funding, EU membership brings a range of other benefits to health research such as the free movement of people and skills, the easy transfer of medical materials such as blood and tissue, and access to pan-European collaborative networks. These 'softer' elements are also important, particularly people mobility, but are often excluded from the calculations and their considerable value to the health research system is overlooked. These benefits were examined in Chapter 3 and part of the challenge faced by this and future research is in understanding how these elements contribute to UK health research capabilities and their value in positioning the UK as a leading global centre of health research.

Wider strategic value to the UK health research system

There is also wider strategic value from EU membership that resonates across all scales of the UK health ecosystem from the level of UK government down to individual researchers. Strategic value is hard to quantify and measure but covers the capacity of the UK to lead, influence, lever resources, create synergies and engage at all levels. This can include a diverse range of benefits such as the ability to communicate UK health research priorities to powerful European stakeholders or the potential to lever more resources from Europe institutions and Member States to support health research.

Continued EU membership is vital for maximising strategic value because, as the examples of both Norway and Switzerland show, it is much harder to influence European policies and priorities from a distance as an associate member of the EU. However, identifying the outputs and outcomes of strategic added value as it ripples through different scales is challenging. To explore this value, it is important to identify the European stakeholders and partners which the UK government seeks to engage with and influence. Upon identifying these key actors, we may understand how they might behave differently through the strategic value created through UK membership of the EU via the processes identified above.

The disadvantages of EU membership for UK health research are not so easily identified, but aspects of existing and proposed EU legislation are considered problematic for research. One example is the EU Clinical Trials Directive (being replaced by a new regulation that will be applied from 2016). The directive has reportedly had a negative impact on the number of trials being carried out in the UK (and Europe more widely) by making the UK and Europe less attractive places to carry out clinical trials. Proposed amendments to the EU's Data Protection Regulation have also caused consternation among researchers across the EU. Though the legislation is still under discussion, representatives of the research community are concerned that it would create a major threat to carrying out valuable studies using patient data.

Non-EU countries can still participate in EU funding programmes

In principle, non-EU countries can apply for funding from Horizon 2020, and FP7 was open to participation from any country in the world. However, the procedures for participation and the funding possibilities vary for different groups of countries. The research entities from the EU Member States enjoy the broadest rights and access to funding (European Commission 2012). Cooperation with 'third countries' has been an important element of the Framework Programmes so far. Currently third countries account for some 6 per cent of partners in FP7 and the top international partner countries are the USA and the BRICS countries (Brazil, Russia, India, China, South Africa. EIBIR 2011).

5.2. Policy implications

Understanding the policy implications is challenging bearing in mind the difficulty of predicting what the future relationship between the UK and the EU might look like. There are many uncertainties and general unknowns that will influence policy thought and formulation. For example, when attempting to calculate the economic impact of a potential withdrawal of a Member State from the EU, a host of assumptions must be made about the terms and conditions of any such change, all of which might

drastically alter the overall financial picture and greatly colour the impression of any associated benefits or disadvantages.

The counterfactual is difficult, if not impossible, to establish

Indeed, one of the great difficulties with understanding the effects of a change in the UK's current relationship with the EU is in predicting what the extent of the fallout might be and how the myriad diffuse advantages of membership would be affected as well as how their loss might impact on the abilities of UK researchers to maintain those collaborations, networks, systems and processes which are currently wholly dependent on being a EU Member State and which are fundamental to an individual's research portfolio and professional experience. Furthermore, the relative success and failure of the UK's exit from the EU further depends upon the ways in which the UK government fills the vacuum, both in terms of research funding and the policies and other regulatory conditions which pertain to research and development in the UK. Again, it is difficult to assess both the shape of UK policy to come and the policy implications of different UK relationships with EU. The counterfactual is hard, if not impossible, to establish. One concern from health researchers is whether the UK funders, such as UK research councils, charities and trusts will be able to provide the level and scale of funding to support large-scale research delivered through international collaboration.

There are options for negotiated access, but their outcomes are unclear

In terms of future relationships with the EU it is possible that leaving the EU may not necessarily entail leaving the EU's research programmes. It may be possible that the UK could 'buy-in' to these programmes, as other non-EU countries do. There are certainly some countries outside the EU that contribute finance to the EU science programme and in turn can coordinate projects and partake of some of the benefits of being a full EU member. It has been argued that the UK's exit from the EU is unlikely to be well-received by the EU leadership, and so it may be the case that the terms under which the UK could remain involved in the EU research funding programme will be less than favourable. On the other hand, the UK's involvement in these research programmes – particularly with health and biomedical research – is a significant part of why these programmes have been so successful in the first place. The removal of the UK from the European research community will inevitably impact upon the current state of European health research but the degree to which this impact will be a negative one or how the European community would reorganise and rebalance itself is difficult to say.

From the UK's perspective, the greater loss may not be in relation to the access to the revenue stream but rather in losing a voice in setting the priorities for the EU research agenda. Máire Geoghean-Quinn, the European commissioner for research, innovation and science, has said that the UK's withdrawal from the EU would be a 'catastrophe' for the Europe-wide programme for research and innovation, considering the contribution the UK has made to the science excellence carried out across Europe. However, while the UK may still be able to collaborate with EU Member States as an Associate Member, the loss of involvement in setting the EU Funding Programme's priorities would be unequivocal.

Regardless of the future scenario, some benefits of EU membership should be protected

Our scenarios explored the different relationships between the UK and Europe in the future. These scenarios all present different possibilities for the future of UK health research and policy implications are presented for each. Common to all scenarios is a need for the UK Government to protect the benefits that EU membership brings for UK health research. In particular there are three priority areas that are of utmost importance to guide the direction of future policy.

- **Funding:** Funding is crucial in supporting research activities, networks and flows of people and their ideas. Any future political arrangements between the EU and the UK should prioritise the need to access funding streams available at the European level. Maintaining access to funds would require 'buy-in' and negotiated access either from outside the EU or as an associate member would likely be complex and fraught with political and bureaucratic difficulties.
- **Researcher mobility:** EU funding supports researcher mobility directly through the provision of funds but indirectly through directives of the single market which enable the free movement of people. A policy priority is for the UK to maintain access to the single market so that UK health research can recruit the best researchers from across research to maintain the UK's comparative advantage in different areas of health research.
- **Access to data:** Maintaining access to European health data resources and infrastructures is in the UK national interest and important for UK health research capabilities. For example, the European BBMRI aims to build a coordinated, large scale European infrastructure of biomedically relevant, quality-assessed mostly already collected samples (with the possibility to link to related clinical and epidemiological information), to enhance therapy and prevention of common and rare diseases, including cancer. Access to this and other pan-European research infrastructures will be a vital resource for UK health researchers undertaking comparative research or research at the European scale.

5.3. Future research directions

The conceptual framework produced in Chapter 2 provides details on how the EU interacts with the UK health research ecosystem and the benefits it brings. The conceptual framework is a starting point in the research process and more work is needed to understand the benefits and costs of EU membership for UK health research. Our approach has been to draw upon existing evidence in the literature and identify the important knowledge gaps that will need to be filled for a rational assessment. These gaps will need to be addressed over time through future research from different communities. The scoping exercise and conceptual framework developed in this study provides a starting point for these additional research activities. It is our ultimate intention that the findings presented here will stimulate the debate and encourage future research.

From the scoping exercise undertaken thus far we have identified a number of gaps in the evidence base and important questions that remain unanswered. As such there are a range of future research directions and much more research and analysis to be done on such an important topic that is vital to both the UK national interest and the interest of the EU.

Firstly, bearing in mind the diversity of UK health research a more nuanced approach is needed to understand exactly the costs and benefits of EU membership for different kinds of health research and research activities. As an alternative to this high-level view of health research, we suggest that a case study approach would be an alternative means to produce more meaningful data from which we can draw conclusions as to the value and impact of EU-funded health research activity in the UK. This will also enable us to test the validity and applicability of the conceptual framework to the subject of health research and provide a more focused analysis to complement the high level discussion of the core study questions. For example, by focusing on a single area of health research, such as breast cancer, it would be possible to more easily isolate relevant EU-funded studies during a given period of time and then analyse the impact of these on, for example, the NICE guidelines, best practice for breast cancer treatment, and improvements (or otherwise) in breast cancer patient outcomes in the UK following from these EU studies. In addition, by focusing on a single, isolated area of research activity, we would also be better able to unravel the particular EU regulatory procedures and other processes that have facilitated or otherwise impacted upon the development of the given research in the UK. A case study approach would offer a deeper level of analysis but retain sensitivity to the commonalities for UK health research across the macro-, meso- and micro-scales.

Secondly, with more resources to undertake future research a survey of health researchers would be a productive methodology to understand the benefits of European funding, networks and strategic value for those engaged in the day-to-day activities of health research. A survey could be conducted by phone or electronically to reach a large sample of health researchers from different disciplines across UK universities and research institutions. We would propose to sample a wide range of health researchers across different subject areas and include those who have benefitted from European support but may be ideologically opposed to UK membership of Europe. A survey would enable us to probe at different health researcher views and understand the benefits and costs of health researchers engaging in Europe.

Thirdly, a stakeholder assessment of active research scientists would be particularly helpful for probing further the strategic value from UK membership of the EU. In addition, further qualitative research encompassing interviews with senior key informants from UK government, universities and health institutions (e.g. NHS, NICE, NIHR) would add to the evidence base on the strategic benefits of UK membership and the possible counterfactual scenarios of what may happen under different arrangements.

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Appendix: Evidence sources for conceptual framework

The annex builds on the conceptual framework outlined in Chapter 3 by providing a list of indicators for evidence on inputs, processes, outputs and outcomes for understanding the benefits and costs of EU membership of the UK.

Inputs

In the context of UK health research, inputs include support from the European Union that enables the research to happen. This can include the following:

- **Fiscal resources** including the monies invested by Europe in terms of funds to support UK health research.
- **Data and sample resources** including medical data or tissue samples needed to conduct the research.
- **Human resources** such as the number of researchers and students supported by EU and the time invested by them.
- **Infrastructural resources** including both equipment that is purchased using European funding and equipment located in Europe and accessible to European researchers (e.g. JRC-IET Experimental Facilities at Petten, Netherlands. See *Joint Research Centre* 2014).

Table 4. Input indicators

Variables	(Proxy) indicators	What is the existing evidence?	How can the information be used?
Total EU funding for UK health research	<ul style="list-style-type: none"> • Individual FP project data in CORDIS (see CORDIS 2013). • EU FP budget spend by theme (see European Commission 2013a). • Health projects data from EAHC (see CHAFAA 2012). • EU funding received by HEIs (see HESA 2014). 	<ul style="list-style-type: none"> • Individual project data available; amount funded (EU and match). • Funding available on amount of health research supported at EU level. • HEI research funding sourced from European Union. 	<ul style="list-style-type: none"> • Evidence exists, but not aggregated at the country level. • No breakdown of funding by subject area in health. • Data for UK-funded projects will need to be collated and analysed.
Number of researchers supported by EU	<ul style="list-style-type: none"> • Erasmus students in the UK undertaking health research (see Statistics for all 2014) • Institutional participants 	<ul style="list-style-type: none"> • Numbers of Erasmus students in the UK. • List of participating institutions in FP7 	<ul style="list-style-type: none"> • No breakdown of Erasmus student mobility by subject. • Further information

Variables	(Proxy) indicators	What is the existing evidence?	How can the information be used?
	included in project data in CORDIS (see CORDIS 2013).	projects.	needed to ascertain number of researchers supported in UK HEIs funded through FP projects.
Number of infrastructures supported	<ul style="list-style-type: none"> Research infrastructure (RI) supported through EU-funded health research projects (see European Commission 2014c). 	<ul style="list-style-type: none"> Evidence for life-sciences research infrastructures supported. 	<ul style="list-style-type: none"> Detailed evidence on health research not available.
Frequency at which infrastructure is accessed	<ul style="list-style-type: none"> EU research infrastructure (RI) and facilities accessed by UK health researchers (see European Commission 2014 b). 	<ul style="list-style-type: none"> Detailed evidence not available. 	<ul style="list-style-type: none"> No evidence available for different subject areas within health.

Processes

Process indicators describe the various activities and mechanisms that enable UK health research to happen. These are activities and mechanisms that are explicitly cross-border involving research activities, partnerships and networks between UK and European researchers. Process indicators include the tasks, steps, methods, techniques and operations performed in different research contexts. Examples include European networks that UK researchers might engage in, formal mechanisms to support collaboration between researchers, institutions and Member States. Processes also incorporate the wider regulatory and legislative mechanisms that operate at the macro-level between Member States and Europe to enable the movement of people, materials and capital to support health research.

Cross-border research processes and activities between UK and European researchers are difficult to measure. Many of the networks that exist between individual researchers that enable knowledge to be exchanged and research to be conducted collaboratively will be informal. These informal networks are not part of any official UK or European research partnership programmes and may have evolved organically through personal contacts. Furthermore, informal networks and activities would continue if the UK were not part of the European Union to a degree where networks are not reliant upon funded research but rather the exchange of ideas and close ties between individual researchers.

Table 5. Process indicators

Variables	(Proxy) indicators	What is the existing evidence?	How can the information be used?
Participation in European research networks	<ul style="list-style-type: none"> Participation of UK researchers and institutions in European health research networks (see European Health Stakeholders Network 2014). 	<ul style="list-style-type: none"> No existing evidence on UK-EU research networks and projects supported. 	<ul style="list-style-type: none"> Evidence could be used by systematically scanning partnerships UK health researchers/groups

			have with European counterparts. Data could be supported with qualitative research or case studies.
Number of collaborations between UK researchers and researchers from EU Member States	<ul style="list-style-type: none"> Co-authored papers between UK and European researchers. 	<ul style="list-style-type: none"> Bibliometric studies showing levels of collaboration between UK and other EU Member States. 	<ul style="list-style-type: none"> Some work on researcher mobility patterns has already been carried out by Elsevier and Science Europe. Studies don't focus on UK health research
Extent of legislative actions and directives relevant to UK health research	<ul style="list-style-type: none"> Closer examination on mechanisms to support movement of people, capital, materials in context of health research (see European Union 2014). 	<ul style="list-style-type: none"> Evidence exists in various treaties, regulations, directives. 	<ul style="list-style-type: none"> Regulations cover research and innovation at the macro-level.
Participation in pan-European clinical trials and testing mechanisms	<ul style="list-style-type: none"> Numbers of EU-funded clinical trials carried out in the UK. 	<ul style="list-style-type: none"> EU Clinical Trials Register collects information on clinical trials in EU Member States and the EEA. 	<ul style="list-style-type: none"> Not possible to search the database by funding source.

Outputs

Outputs describe the tangible 'end-products' generated by UK health research that is supported through European funding and support. Outputs may include publications resulting from projects, patents, and product development supported by the European funding. Publications are the immediate output from academic research supported by the EU and can be analysed bibliometrically. Patents and product development outputs will have a likely time-lag.

When considering publications and patents a key challenge is the attribution of both to European funding or networks. It is possible to attribute publications to research projects and activities that may have been supported by European research funding or been reliant on cross-border activities and networks. Where papers are co-authored by UK and authors from other Member States and original studies were supported by EU funding it is reasonable to assume that publications would not have been written without the direct support of Europe. Attributing patent and product outputs to European funding becomes more difficult as there are other political, economic, regulatory factors that may influence whether a patent is registered or a product comes to market.

The attribution of outputs is beyond the scope of this scoping exercise but the function of the conceptual framework is to identify outputs. Future research activities may seek to track back outputs to European support activities.

Table 6. Output indicators

Variables	(Proxy) indicators	What is the existing evidence?	How can the information be used?
Knowledge production	<ul style="list-style-type: none"> Numbers of publications from EU-funded health research carried out in the UK. 	<ul style="list-style-type: none"> A number of evidence sources exist. EC impact assessment on all health projects funded between 2002-2010. CORDIS database on FP6 and FP7 funding. OpenAIRE database. 	<ul style="list-style-type: none"> A previous bibliometrics study has been carried out on the numbers of publications arising from EU-funded health research generally. Should be possible to pull out UK research from this but it might be difficult.
Innovation capacity	<ul style="list-style-type: none"> Number of patents attached to EU-funded health research projects carried out in the UK. 	<ul style="list-style-type: none"> EC impact assessment of health research funded under FP6 and FP5 has statistics for numbers of patents produced generally from EU-funded health research. 	<ul style="list-style-type: none"> The data exists but it may be difficult to pull out UK patents from the data. Also time-lag makes attribution difficult. EU impact assessment data not aggregated to the Member State level.
Product development	<ul style="list-style-type: none"> Number of new products attached to EU-funded health research projects carried out in the UK. 	<ul style="list-style-type: none"> Some evidence in the EU impact assessment of numbers of new products arising from FP5 and FP6 health research projects (across EU). 	<ul style="list-style-type: none"> This appears to be more difficult to assess. Attribution is more difficult due to time-lags and wider political, economic, regulatory influences on products coming to market.

Outcomes

Outcomes are the benefits or changes for participants in programs or recipients of services during or after the program or strategy is implemented. Outcomes may relate to improvement in health and well-being, research outcomes and system-level outcomes in improving the standard of the UK healthcare system.

An assessment of the outcome benefits of EU membership on UK health research is beyond the remit of the scoping exercise but may be considered in future work. One of the challenges is for understanding how knowledge and innovation produced through research translates into health outcomes. RAND Europe have recognised and described these challenges at length (see for example Grant & Wooding 2002; Wooding et al. 2013). That said, it is useful to include outcome indicators to understand what the ‘end point’ of European funding for health research may be and how expenditure on research and development relates to wider strategic goals (e.g. Horizon 2020 and ‘grand challenges’).

Table 7. Outcome indicators

Indicator	Sources of evidence	What is the existing evidence?	How can the information be used?
Health outcomes	<ul style="list-style-type: none"> Analyse trends in population health over a period of time – what are the patterns of health gain/loss. Compare UK health performance to comparable countries in the EU and elsewhere. 	<ul style="list-style-type: none"> Evidence for health performance/burden of disease for UK population – but difficult to extrapolate EU impact upon this. Global Burden of Disease Study 2010. 	<ul style="list-style-type: none"> Yes, but will be time-consuming and difficult.
Research outcomes	<ul style="list-style-type: none"> Numbers of researchers (Senior and junior; postdocs, PhD students) in receipt of EU funding or whose careers have benefitted from EU funding. Impact on research infrastructure from EU funding (facilities, equipment etc.). The use of collaborative networks that have been facilitated by EU funding and cooperation. The use of favourable EU regulations to facilitate the transfer of products/scientific samples etc. for analysis and research between Member States. 	<ul style="list-style-type: none"> None. 	<ul style="list-style-type: none"> No current evidence base.
System level outcomes	<ul style="list-style-type: none"> Role of EU funding and collaborations in improving the overall quality of effectiveness of the UK health and 	<ul style="list-style-type: none"> None. 	<ul style="list-style-type: none"> No current evidence base.

Indicator	Sources of evidence	What is the existing evidence?	How can the information be used?
	healthcare system.		