

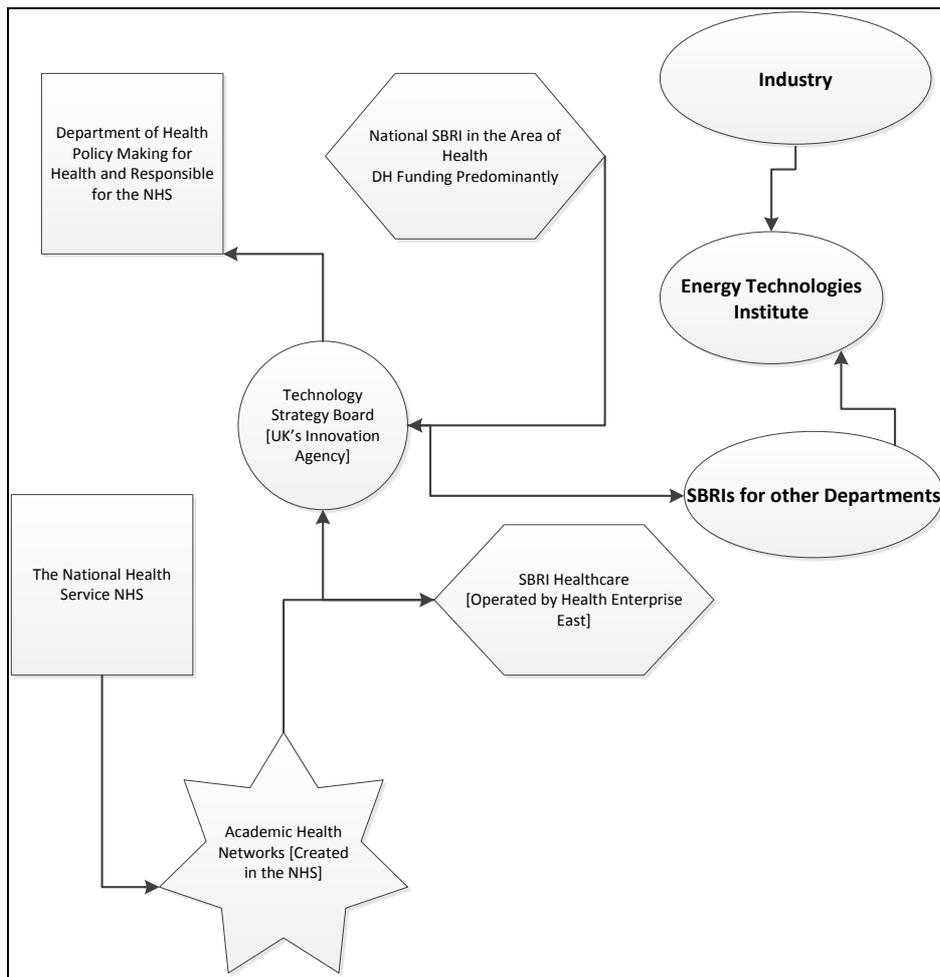
Feasibility study for the Design and Implementation of Demand-side Innovation Policy Instruments in Estonia

Case Study: the UK Small Business Research Initiative for health

Introduction

This case is of the use of the demand side measure, pre-commercial procurement in the context of health technology development and innovation in the United Kingdom, Wales and Scotland. In the UK, a number of organizations that have public sector status operate pre-commercial procurement. The UK's innovation agency, the Technology Strategy Board, based in Swindon, operates and supports pre-commercial procurement for government departments and for bodies that lie below the level of government departments. In all, nearly 50 public sector organisations (departments or sub-departments / agencies are users of the programme or procedure). Other public sector organizations can operate pre-commercial procurement if they wish although, so far as we are aware, all public sector use of pre-commercial procurement is currently conducted with the help of the Technology Strategy Board (the TSB). There is one further and important an example of a public private partnership pre-commercial procurement scheme; this is the Energy Technologies Institute. The following figure identifies the levels at which pre-commercial procurement operates in the UK with particular respect to the health sector.

Figure 1 DH and NHS Implementations of the SBRI



Source: Interviews with TSB done by JR, April 2014

The Case – The UK SBRI within the Health Sector

In the UK, the government’s health department (the Department of Health or DH) operates a pre-commercial programme to develop new technologies which will be of use within the context of healthcare. This programme uses the assistance of the UK’s innovation agency, the Technology Strategy Board (TSB). There is another organization that uses the Small Business Research Initiative (SBRI) programme in the UK in the context of public health, this is the National Health Service (the NHS), and like the DH, it has used the Technology Strategy Board to help it operate the SBRI process.

Thus there are therefore **two main clients** for the use of the SBRI for the development of new technologies in the context of healthcare in the UK: the Department of Health (DH) on the one hand and the National Health Service (NHS) on the other. The division of SBRI healthcare activities within the UK reflects the traditional divide between the government department responsible for health care *policy* and the *delivery side*. The delivery side in the UK is the NHS. The distinction between these two implementations of the SBRI is not always easy to make however. Both the DH use of the SBRI programme and the NHS use of the SBRI programme relies upon the assistance of the Technology Strategy Board to varying degrees, and some procurements of R&D that take place involve both the NHS and the Department of Health at the same time. Thus, while there are two implementations of the SBRI, they sometimes work together.

The NHS operation or management of the UK SBRI is conducted by a publicly owned company called Health Enterprise East (HEE). Health Enterprise East acts on behalf of a set of organizations located within the UK called academic health science networks (AHSNs). These academic health science networks are innovation hubs or innovation centres. These are located within regions of England and there are 15 of them currently operating. These organisations are located in the NHS and are publicly owned. Their creation was announced in May 2013 (NHS England, 2013b). A list of the networks is given in an annex. The networks do not cover Scotland, Northern Ireland or Wales. The academic health science networks (ASHNs) were established following the publication in 2012 of “Innovation Health and Wealth” (Department of Health Improvement and Efficiency Directorate; Innovation and Service Improvement, 2012), a document that outlined how innovation within the area of public health sector was to be supported. The Health Enterprise East (HEE) has aimed to develop capacity to undertake SBRI activities and to coordinate the demands of the whole of the NHS. The AHSNs are intended to be closer to the operational needs of the NHS.

The government has recently set targets for departmental use of the programme. In the last spending review (SR2013), the government indicated that the following six government departments would be expected to spend the following amounts of money from their procurement budgets through the SBRI scheme. In the next year 2014-15, these amounts are thought likely to double again. Health use may then reach £100 million (€122 million per annum).

Figure 2 UK Government Departments’ Targets for SBRI Use

Department	SBRI target 2013-14, £ million
Defence	50
NHS (Health)	30
Transport	7
Home Office	7
Energy and Climate Change	3
Environment, Food and Rural Affairs	3

Source: HM Treasury Spending Round 2013

Other policy mix

The UK Health sector is largely publicly funded. The share of the public sector spend accounted for by health is around £140b or €200b a year. The provision of health care in the UK is generally public, i.e. publicly funded bodies provide much of the care, doctors and nurses are paid by publicly funded organisations, although general practitioners are self-employed in the UK system but are still publicly funded. **UK government has therefore strong interest in innovation** within the healthcare system to achieve public health goals and to improve the efficiency of the services which it pays for.

As the UK health care system is very largely publicly funded, and although there is a quasi-market within public health, on the whole, the public sector acts both as a provider of health care (*supply*) and as a shaper (and *demand*) for services. This arrangement is similar to what has been tried in the past, but is now formalized with a market system in which public organisations represent both demand *and supply of health services* although there is considerable private involvement in the provision of services through the NHS. The major changes follow the Health and Social Care Act of 2012 (“Health and Social Care Act,” 2012; NHS England, 2013a, 2013b). In essence, the system is one where demand and supply are interacting and originate from the same source, the government.

The health sector is therefore affected by a large number of initiatives to improve performance and increase innovation, including support to new technologies. Initiatives are occurring across a range of health conditions (stratified medicine) and areas of work.

These initiatives are diverse and not all are government policy. For example, at the level of individual workers within the health service, there are a number of incentives that encourage the use of the state of the art and development of new technologies ideas and approaches to patient care.

- The training of doctors and nurses by their respective professional bodies encourages innovation
- Payment of NHS staff, particularly at consultant level encourages innovation (British Medical Association, 2014) within the NHS (and it may spillover into the private health sector).

Such initiatives constitute both demand and supply pressure: for example, training affects the supply of innovation, while incentives increase the demand for innovation from outside the NHS from technology providers, including medical technology firms.

At institutional level, payments are also made. One important feature of the way payments are made in NHS is the process of service commissioning through the “Commissioning for quality and Innovation CQUIN) payment framework. This framework allows those organisations that commission health care services (within the quasi-market of the NHS) to “reward excellence”. This is done by connecting payment for services by hospitals and other providers to health improvements which may occur as a result of the adoption of new working practices but may also results from the adoption of new technologies. The so-called CQUIN framework was introduced in (2009/10). A wide range of so-called CQUIN schemes have been implemented.

Also, the NHS has its own agency to improve quality of care which replaces a previous innovation agency strategy and innovation promotion agency. This new organisation (located within the NHS) is NHS Improving Quality (<http://www.nhsiq.nhs.uk/>). It has the following four areas of work which are high level goals for health policy but which nevertheless constitute a shaping of demand for health services but also represent a shaping of the supply of health care:

- Living longer lives
- Enhancing quality of life for people with long term conditions
- Helping people to recover from episodes of ill health or following injury
- Ensuring that people have a positive experience of care
- Treating and caring for people in a safe environment and protecting them from avoidable harm.

At the larger level, the government has proposed the Medical Innovation Bill (“Medical Innovation Bill,” 2013) which would encourage doctors to try new treatments and innovate more regularly in their practice.

Medicine is also heavily regulated. In the UK, the principle regulator of what is health care is delivered is the National Institute of Health and Care Excellence. Medicines and health products are also regulated. This is done by the MHRA Medicines and Healthcare Products Regulatory Agency.

Regulation is also undertaken at other points within the system of healthcare provision. For example, at the level of individual practitioners (nurses, doctors and allied professions), there are professional regulatory bodies. Medical doctors are now required to undertake a five yearly quinquennial re-validation in order to retain their right to practice.

The government also attempts to coordinate research in the area of health through The Office for Strategic Co-ordination of Health Research (OSCHR). This is based in the NHS.

Beyond government, the UK has other important actors that influence innovation and whose status within the demand – supply dichotomy is ambiguous. Such organisations constitute important elements of the policy mix. For example, the medical charities in the UK system, invest significant amounts of money on research, some of which is intended to support innovation (Focus Area 2). The Wellcome Trust spends around €1 billion per annum on research (Wellcome Trust, 2013).

SBRI and the TSB Policy Mix

The SBRI programme is one of a number of measures that the TSB operates and fits into an overall remit that seeks to achieve the following: a) delivering programmes to improve the UK's innovation performance; b) support for specific technologies to realize UK government aims; c) input to policy of the government and development of strategic partnerships. As well as the specific health related actors noted above, TSB provides programmes and policies that potentially also impact upon the health sector although they are not health sector programmes. These policies and programmes include supply side (R&D Programmes, supporting large and small firms alike, and services style support comprising networking and integrating programmes that bring supply and demand side actors together (industry and research performers) but which are sometimes considered supply side.

Rationale of the Measure

The SBRI programme is programme that encourages and facilitates the purchase by the public sector (usually one organisation such as a government department) of a research and development service from private sector. The process must be competitive, and nearly always operates with two rounds. While R&D procurements with competition can be undertaken directly by government departments, in most instances of R&D procurements with competition, a government department (the public sector body) is assisted by an organisation that has specialized in technology development and acquisition. IN the UK, the SBRI Programme is managed by the Technology Strategy Board. IN the US, where this kind of approach has originated, it is managed by the Small Business Administration (SBA). In the UK, as elsewhere, SBRI/SBIR are regarded as a demand side measure. **The UK scheme has the following main rationales:**

- 1) R&D procurements through the SBRI programme it develops innovation solutions – mainly technologies – that will be of use to the public sector, such as the health service (or the Department for Transport DfT) – so to improve the way in which so called *operational needs* are met;
- 2) is develops innovation solutions that may help government with policy decisions (policy needs) and in generating solutions to problems more widely where there is a private sector customer ultimately willing to buy the solution developed by the competition (so called catalytic procurement);
- 3) by supporting the development of innovations for either operational or policy / catalytic purposes, new companies are formed, firms increase turnover and employment is created.

In supporting new firms, the SBRI may act to bridge what some commentators have called the equity or financing gap whereby small firms with viable ideas are unable to source the capital they need to bring their product to the market. The existence of the SBRI provides a customer who can support the necessary research and development required to bring the creation of that technology about. Furthermore, when firms win

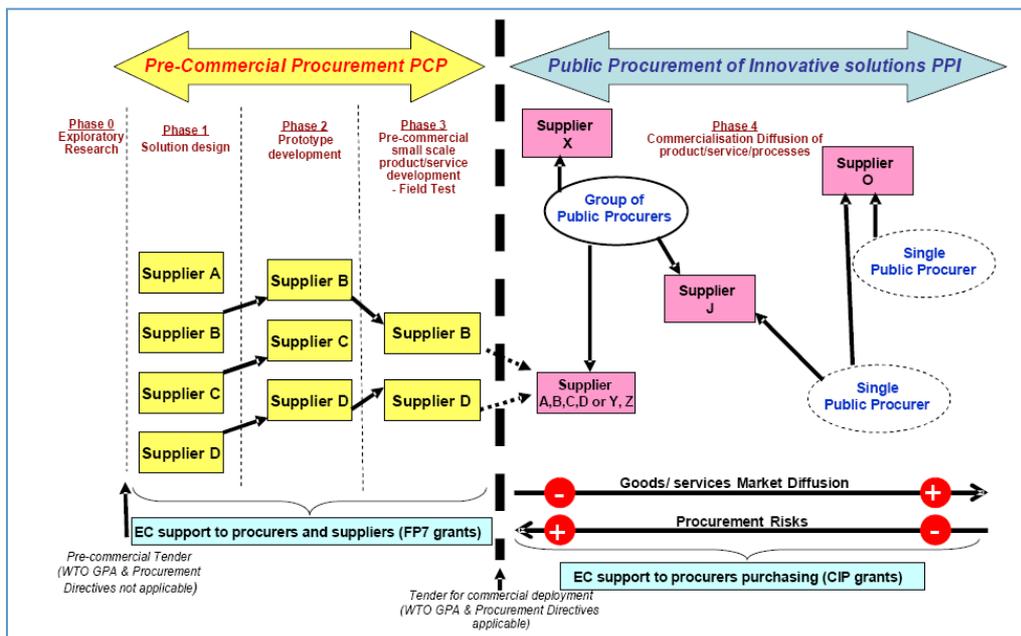
competitions in the SBRI programme, they signal their greater capacity and this allows them to attract capital. The NESTA report on pre-commercial procurement refers to this discussion (Rigby, 2013), the citation here is to Lerner (Lerner, 1999). The SBRI provides 100% of the cost of conducting the research, unlike a grant which may fall short of the full amount. While the cost of the R&D is paid for, and, within the UK system the contractor is allowed to keep the R&D (with the SBRI programme keeping some usage rights), the process is competitive and there is guarantee that the winners of the competition will ultimately be able to sell their technology in commercial quantities.

Design of the instrument

1.1 Main Features

The UK SBRI was inspired by the US SBIR (Small Business Innovation Research Programme) but follows the EU model but with certain exceptions, notably on Intellectual Property Rights (IPR) where the public sector retains a usage right. Under the EU Treaty, and EU procurement rules, it is not permissible for the UK to exclude firms from access to the programme on the basis of their size or location (within the EU). In the US, the SBIR programme is not open to firms which have more than 500 employees. EU law makes it impossible to implement such exclusions in the UK (as in other Member States).

Figure 3 Bos, L. PCP and PPI – Including the SBRI Process (Phases 1 and 2)



Source: (Bos, 2014)

The UK scheme is as noted above a competitive R&D programme. Normally there are two phases. The programme is designed on the US model and most other pre-commercial procurement schemes operate in this way.

1.2 Previous Version of the Programme and the Policy Learning Experience

The current SBRI programme is the second version of this initiative in the UK. The first establishment of the SBRI programme in 2001 was unsuccessful for a number of reasons (Tredgett & Coad, 2014):

- Government departments disliked the obligation to use such a large proportion of their budgets for the programme (they were asked to use 2.5% of their R&D budgets on the scheme although it was not compulsory until 2005);

- Departments did not have capacity to operate the scheme;
- Few departments actually used the scheme to procure innovation, most used it to conduct research and development, not to develop innovation (although the line is sometimes difficult to draw, particularly at when what is being procured is advice for policy);
- Small firms (generally the target of the programme, but not exclusively) were attempting to find funds for expansion from other areas, so the scheme was not capable of supporting them.

A number of changes were then made to the scheme and the following box, from Tredgett and Coad (2014) shows the features of the scheme. These are then discussed in more details in the next section on implementation and operation.

Box 1 The Sainsbury Review Recommendations on the UK SBRI and TSB

Recommendation 8.8¹ The SBRI should be reformed, adopting the following principles of the successful US SBIR scheme:

- Departments should focus on active engagement with innovative businesses and act as intelligent customers to fulfil their departmental objectives;
- Departments should specify up front, in a simple and standard format, and update on a fixed and regular basis, the technological areas in which they would like to see projects, in a simple, standard format;
- SBRI contracts should adopt a two-phase structure, tendering a second, larger award after successful completion of a smaller, early-stage development, so as to minimise risks associated with innovation;
- SBRI awards must take the form of contracts, not equity loans or grants; this will ensure that departmental objectives are clearly identified and met, and will enable the award of an SBIR contract to act as a “seal of approval”, reassuring future investors and customers of the firm’s value;
- SMEs should retain the intellectual property associated with any new technology, boosting incentives for high-quality small businesses to bid for SBIR awards; and
- to maximise the SBIR’s effect, award availability should be restricted to products and services meeting the HM Treasury’s R&D tax credit criteria; this would exclude humanities and social science research and consultancy, for which the scheme was never intended.

Recommendation 8.9

In order to ensure this time that the new SBRI scheme achieves its objectives, this Review recommends that a central administrative role be given to the TSB. Government departments should be required twice a year to notify to the TSB in a standard form those technological areas where they would like to support projects. The TSB would then be responsible for publishing twice a year, at fixed dates, a list of the projects notified to it by government departments so that SMEs are readily able to find them. The awarding of contracts should also be administered by the TSB, with assessment of proposals being made jointly with the relevant government departments

10 SBRI targets for extramural departmental R&D should build up over three years, from 1.5 per cent in the first year to 2 per cent in the second year and 2.5 per cent in the third year.

Source: (Lord Sainsbury of Turville, 2007)

¹ Numbering refers to the Sainsbury Review

Implementation and Operation

1.3 Implementation

As we have noted above, the SBRI process for the health sector is implemented by two different organisations. The DH operation of the programme involves the TSB while the NHS version of the programme also involves the TSB but uses the Health Enterprise East to conduct the consultations within the AHSNs to develop statements of need that form the basis for competitions.

1.4 Operation

The SBRI process operates in the following way. The figure shown below provides a visual presentation of the steps involved.

The first step is that a government department (here either the Department of Health or one of the organisations within the NHS connected to the Healthcare SBRI) identifies a challenge area which the development of technology is like to provide a solution. This is done in conjunction with the TSB in the case of the DH defined needs and with the SBRI Healthcare programme operated by Health Enterprise East, in the case of the NHS.

The next step is for a consultation to be designed in which the attempt is made to determine whether there is in fact technology in existence already that might meet the needs that have been defined. In the event that existing technologies are available but not yet applied, the SBRI programme moves directly to a Phase 2 competition. The rest of the time, a Phase 1 competition is conducted first.

This next stage is an application process. An advertisement is placed by the TSB or the SBRI Healthcare Programme and it is open to firms within the EU to compete. Applications are received and assessed. Those that are rated higher go through to the next stage which is a funded R&D competition.

This competition is in two parts, a Phase 1 and Phase 2 part. In the EC process, there is a contract to cover both parts (although some firms will drop out normally at the end of Phase 1). In the UK case, there are two separate contracts covering each phase.

The first phase is known as a Phase 1 competition and its purpose is to select firms that will receive a contract for R&D services. Successful firms at this stage receive a contract that in the UK case pays for the whole costs of the R&D contract. This is also known as the first feasibility phase. This may last 2-6 months. The development contracts at this first phase are usually between €75K and € 150K. There can be variation however in the amounts awarded. The number of firms who are given contracts at this stage might be around 10 and this is the number generally for the health sector.

Once the phase 1 comes to an end, the TSB / SBRI Healthcare assess the outputs from the contracts. This is the second assessment phase. The assessment is done in the case of the health sector by a panel consisting of around two specialist reviewers who know the technology area well and are independent. Those firms that have generated successful feasibility studies are then paid to conduct a further piece of R&D development of a prototype. This is the Phase 2 part of the competition. Contracts to conduct Phase 2 may not all signed at the same time and have the same final / end date. The amounts of money in this next stage can be larger, up to around €1.2m. Amounts in other areas of technology can be larger, and the amount can be smaller. The general band is said to be between €900k and €1.2m.

Companies that receive Phase 2 Awards carry out their research but there are no commitments to acquire the technology. Departments retain usage rights (at Phase 1 also). In a small number of cases, firms may withdraw from Phase 1 or Phase 2. The reasons for this are yet to be investigated. It is not known if this has happened in the context of health.

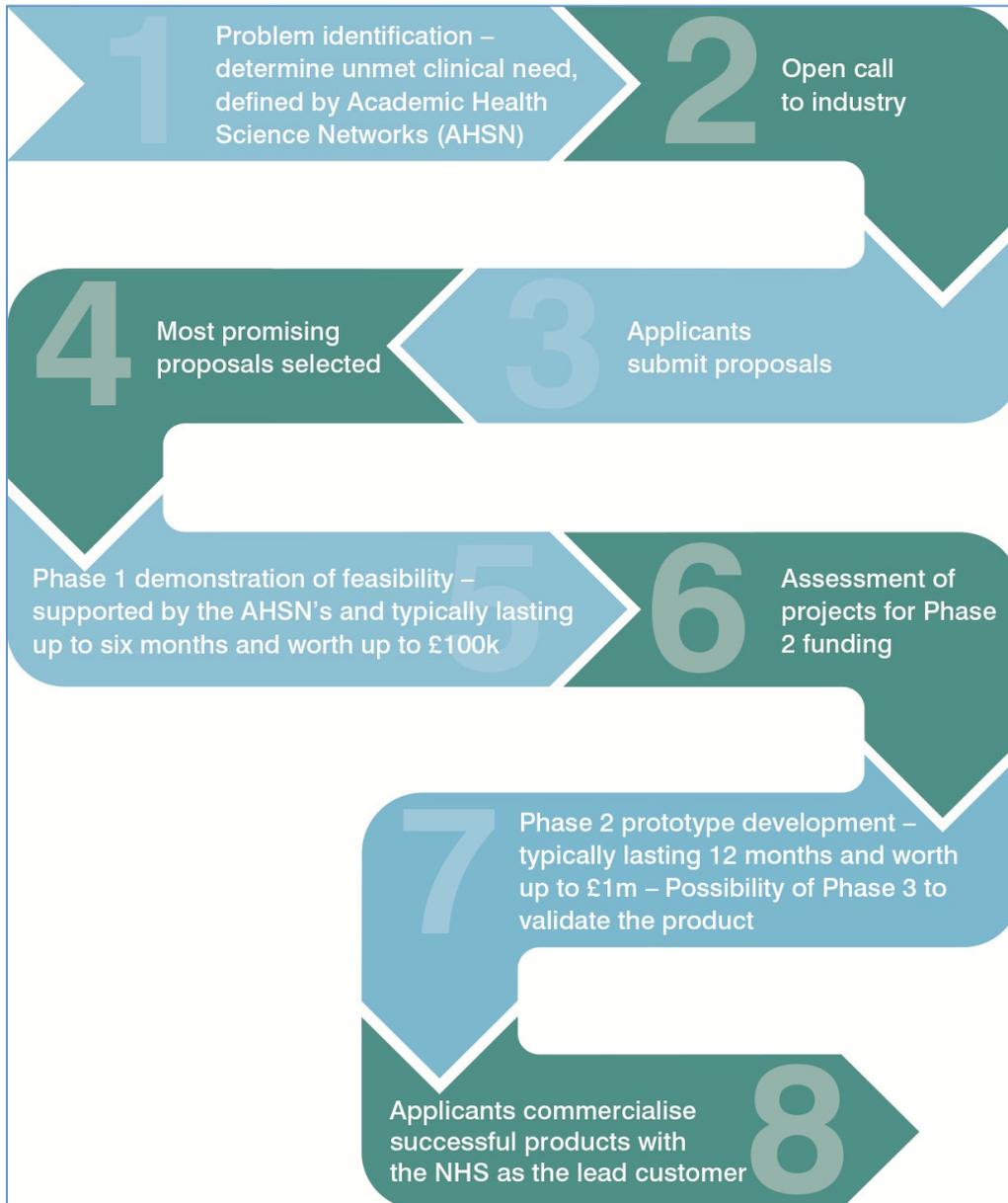


Figure 4 UK SBRI Healthcare (NHS) Process Diagram

Monitoring Evaluation and Impact

To date, no in-depth evaluation of the UK SBRI has been undertaken. However, a review of the scheme by NESTA (Bound & Puttick, 2010) noted that, in its initial form, the scheme was “hampered by limited public sector take up, and where SME contracts were awarded, researchers found that less than 1 per cent of them were for research and development”. As a consequence, a revised version of the SBRI scheme was piloted in 2008 and rolled out fully in April 2009. The review undertaken in 2010 was, in the authors’ own words, “a ‘health-check’ rather than an impact assessment”. Thus, it was restricted to an examination of a selected sample of new SBRI competitions in order to analyse the effects of SBRI on both the companies and public sector bodies engaged in the scheme. This was accompanied by a more summative examination of the descriptive statistics relating to the uptake of the scheme. At the time of the NESTA review both the Department of Health and the National Health Service were using the scheme and, of the ten case studies carried out, the review included five in the health-related field.

The NESTA study found, overall, good evidence that the scheme had been well taken up: at that point, thirteen public sector bodies were engaged in the scheme and 28 competitions (projects) were in place with 425 confirmed contracts amounting to a combined value of £27m (c. €33m). The interviewed companies stated that the scheme was filling a funding gap for innovation, with “specific and appropriately sized R&D contracts combined with a need to solve live public challenges... accelerating technology development”. The review also provided evidence that public sector departments and agencies were learning how to communicate their needs more effectively to the private sector, with “genuinely interesting solutions going to market that would not have been reached by other means” (Bound and Puttick, 2010).

The NESTA review concluded that the “SBRI is an appealing concept because of the three-way benefits it promises:

- Driving improvements in the quality and cost-effectiveness of public services and helping solve policy challenges.
- Accelerating the commercialisation of technology and filling a damaging gap in innovation financing.
- Supporting the growth of small companies and consequently economic growth and recovery.” (Bound & Puttick, 2010).

Three main recommendations were put forward: to scale up the scheme to optimise its impact on public bodies, and to reach many more promising small companies; to focus on quality with any increase in the number of competitions, to ensure that it remain an effective source of genuine innovation and; to recognise SBRI as a powerful tool in a wider system of demand-side policy levers for driving innovation.

Finally, the authors cautioned that the recommendations “should not be overlooked or watered down to focus solely on short-term efficiency rather than long-term innovative capacity”.

Whilst the NESTA review remains the only critical appraisal of the UK SBRI scheme, Health Enterprise East and the Eastern Academic Health Science Network (EAHSN), which runs the Small Business Research Initiative for Healthcare (SBRI Healthcare) on behalf of NHS England and the other regional AHSNs, have recently announced its intention to commission a review of this particular programme. More specifically, the review is intended to examine the success and return on investment to date of the health related SBRI competitions run over a four year period.

The invitation to tender (ITT) notes that the EAHSN has “run 11 competitions in total with over 700 applications received across a variety of topics including patient safety, managing long terms conditions, dementia, medicines management and improving patient experience at end of life. A total of 65 phase one contracts and 27 phase 2 contracts have been awarded to date with total funding of over £15m [c. 17.8m] allocated. A few of the companies have reached the market however many are still in the development stage and range from technical feasibility (phase ones) through to clinical trial or pre-market stage”².

The aim of the evaluation is to provide evidence to stakeholders about the outcomes achieved to date, the potential future benefits of technologies emerging through the programme and the scheme’s value for money in order to support continuing investment.

Specifically, the ITT states that the evaluation of the programme will be used to:

- assess the value delivered by the programme to companies who have received awards under SBRI

² <http://www.sbrihealthcare.co.uk/wp-content/uploads/2013/11/Invitation-to-Tender-for-Evaluation-of-SBRI-Healthcare-Programme.pdf>

- establish the appropriate metrics for measuring the success of the programme, now and in future years
- assess the impact of the programme to date in terms of wealth creation (the precise metrics to be defined)
- identify any barriers that have limited/restricted the impact of the programme
- promote the success of the programme to stakeholders including government, the media, AHSNS and clinicians within the NHS more widely
- encourage other companies to apply for future SBRI competitions, and
- make recommendations to the SBRI Management Board about how the programme should be developed to ensure successful outcomes

Regarding the preferred methodology, the ITT seeks a mixed qualitative and quantitative approach, involving a survey/questionnaire (the mode of delivery is not specified) to all participant companies, together with more in-depth qualitative responses obtained through interviews with at a sample (at least 10%) of the participants and qualitative interviews with key members of the SBRI project team and Management Board to investigate process and operational issues.

Finally, the TSB have also recently commissioned an evaluation of the entire SBRI scheme (which includes coverage of the SBRI Healthcare). The remit of the evaluation is to focus on three areas: the impact of the Spending Review target which set specific targets for the involvement of named UK government departments, the SBRI process itself, and the impacts of the Programme. At present the methodology for this is being finalised but it will include:

- Development of a formal logic chart design in order to develop a better understanding of the Programme's scope and possibilities.
- Interviews with industry stakeholder bodies.
- A CATI based company (econometric) survey of 40% of recipients over the 2009-12 period (c. 350 firms) and a matched control group of similar size.
- Interviews with SBRI operational programme staff within the TSB.
- A series of 12 case studies based around single competitions and designed to include interviews with representatives of firms successful to Phase 1, firms successful to Phase 2 and firms successful in commercialising their project outcomes, plus representatives of sponsoring Government Departments.

The approach represents a balanced effort designed to capture the potential additionality effects of the programme on participating firms (compared with carefully matched non-participants), the learning effects of operating procurement schemes on participating Departments and other public sector bodies and the broader effects on UK business together with the impacts on the delivery of UK public services. The evaluation is due to report in early 2015.

Future Plans

In the UK, the expectation is that both the DH and NHS versions of the SBRI will increase in use. Government targets for the use of the SBRI have risen such that in the forthcoming financial period, 2014-15, departments that have targets (which includes the DH) will spend 1/2 of one percent of their procurement budgets through this mechanism. While the immediate impact on the use of the SBRI is the raising of targets for the programme across government and within the Department of Health and NHS, there are other important contextual factors that will affect the use and success of the healthcare SBRI activities of the Department of Health and the NHS.

The most important factor affecting the sector is Health and Social Care Act 2012 which aims to encourage more competition and market processes within the whole sector (Department of Health, 2010). This is likely to act as a stimulus to innovation as a whole. Another major factor that will affect the innovation within the sector is that of the spending plans of the government and how much money will go to the sector as a whole.

Lessons learned relevant for Estonia

- TSB as a specialised agency with appropriate competences and experience in PCP supports the ministry.
- The scheme is mandatory for the ministry, i.e. a specific budget allocation must be used for PCP.
- Mandatory budget allocation forces the ministry to plan more long term, at least for the PCP part - hence introducing also the idea of using innovation to improve healthcare quality and efficiency.
- Longer term political commitment, which encourages the ministry to develop its own competences. Capacity in running competitions is essential within user departments / agencies.
- SBRI is supported by other policy measures via TSB.
- A 2-stage approach for the PCP which allows to both jump the 1st step (if technologies exist) and exit after 1st step if no prototype can be developed (technology or application too demanding/difficult)
- Slow roll-out of the measure would be sensible, targeting departments that are likely to be heavy users or users with highest potential benefits from innovation.
- Only when systems operating successfully should measure be targeted more widely.

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Annex

1.5 The UK's Academic health science networks

1. East Midlands
2. Eastern
3. Greater Manchester
4. North East and North Cumbria
5. North West Coast
6. Imperial College Health Partners
7. Oxford
8. South London
9. South West Peninsula
10. Kent, Surrey and Sussex
11. UCL Partners
12. Wessex
13. West Midlands
14. West of England
15. Yorkshire and Humber