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# A Shortcut to Medical Device Reimbursement in the UK – July, 2012

This is the third article in this series. The previous two articles - A Shortcut to Medical Device Reimbursement in:

| Country | Can be downloaded at: |
|---|---|
| ▪ Germany: | http://www.mediclever.com/resources/5.pdf |
| ▪ France: | http://www.mediclever.com/resources/8.pdf |

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## *1. The Problem*

You developed a new and innovative medical device that provides substantial clinical benefits in a cost effective manner.

You know the UK has one of the largest medical device markets in the world, positioned alongside France as the second largest in Europe behind Germany[1].

You plan on getting your product approved in Europe and complete the CE mark process relatively quickly and you already signed agreements with local UK distributors.

The only problem – will your device be reimbursed, or in other words, will the UK National Health Service (NHS) pay for it?

Since your device is new, there are probably no existing reimbursement mechanisms (codes, coverage and payment rates) into which it could fit. On the other hand, in order to apply for the development of new reimbursement mechanisms, your device should first be in wide use by UK physicians for the local patient population. But since your device doesn't currently fit into any reimbursement mechanisms, physicians are reluctant to use it, and therefore it will never reach a wide user base to justify the creation of new reimbursement mechanisms...

Sounds like a Catch-22, right?

Luckily, the NHS operates an Innovation Procurement Plan designed to encourage the quick uptake of innovative new technologies. Similar to the USA Centers for Medicare & Medicaid services (CMS) "Health Care Innovation Awards" program, the UK's NHS understands that "innovation must be central to the NHS", indicating that innovation will be driven regionally by strategic health authorities (SHAs) with a legal duty to promote innovation; and that front-line innovation will be supported through the creation of substantial new innovation funds held by SHAs.

In this article, we will try to describe the requirements, the relevant decision makers and the overall process that may help you leverage this plan to expedite the commercialization of your product in the UK market.

But first, we provide a short description of the NHS below.

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[1] *Espicom, 2011*

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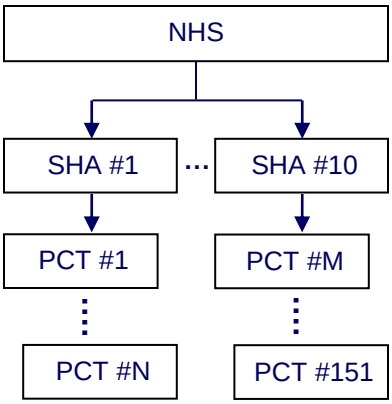
## *2. The UK Healthcare System*

- The United Kingdom of Great Britain and Northern Ireland (commonly known as the UK) consists of England and the devolved administrations of Northern Ireland, Scotland and Wales, each with varying powers.
- Population: 62 million[2].
- Type of Healthcare System: Single Payer / national health service (NHS).
- Public health system: England[3] provides public healthcare to all of its permanent residents. Public healthcare is free at the point of need. The responsibility for providing NHS healthcare services in England is divided between 10 Strategic Health Authorities (SHAs – see map on the right).


SHAs issue guidelines for healthcare in their region, verify appropriate distribution of funds and carry out regional plans and projects to improve public healthcare. In addition, each SHA is responsible for the Primary Care Trusts (PCTs) in its region.




PCTs examine local needs and negotiate with healthcare providers to provide health care services to the local population. PCTs have their own budgets and set their own priorities, within the overriding priorities and budgets set by the relevant SHA and ultimately the national Department of Health (DH).

PCTs provide a range of community health services, including: funding for general practitioners, medical prescriptions, and commissioning of hospital and mental health services, as such they are considered key stakeholders in healthcare decision making.

Altogether, there are 151 PCTs in England.

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[2] *England:* 51.5, *Scotland: 5.1, Wales: 3.0, Northern Ireland: 1.8.*

[3] *The devolved administrations of Scotland, Wales and Northern Ireland run their local NHS services separately.*

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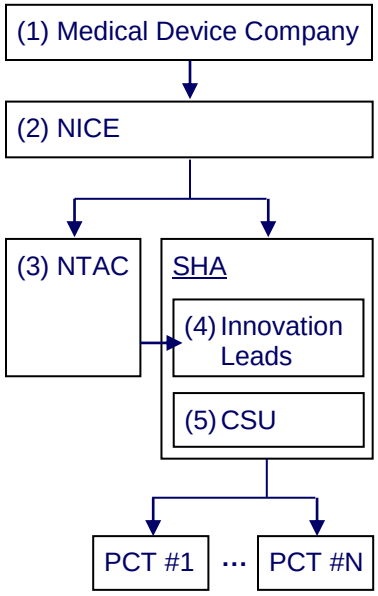
## *3. National Innovation Procurement Plan*

As mentioned above, the NHS is interested in encouraging the diffusion of innovation into the healthcare system and has launched a package of proposals to promote this. One of them is the National Innovation Procurement Plan[4] which seeks to bring clarity and coherence by organizing the adoption of technology-led innovation at the regional level. Supporting this legal duty, an Innovation Fund has been created worth £220m over five years. This fund will support faster innovation and more universal diffusion of best practice - innovation will be encouraged, recognized and rewarded.

### *a. Process*

(1) Medical device companies, usually partnered with local healthcare providers, may submit details of specific medical technologies that can contribute to the NHS by downloading a submission form from the DH website and submitting details of innovative technologies using the email address of: innovation.procurement@dh.gsi.gov.uk.

(2) NICE (National Institute for Health and Clinical Excellence)[5] - analyzes and prioritizes submitted technologies according to their potential to increase the quality of care provided to patients, whilst reducing the overall cost of care for the NHS. The NICE Implementation Collaborative (NIC) supports implementation of NICE guidance within each SHA[6].




The prioritized list is then shared to inform the technology selection process with:

(3) NTAC (NHS Technology Adoption Centre) - formed in 2007 following recommendations by the Health Care Industries Taskforce who recognized that the NHS, despite the potential of innovative healthcare technologies to improve health outcomes and productivity, is slow to adopt healthcare technology when compared to health care systems in other developed

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4 *National Innovation Procurement Plan, December 2009.*

5 *Initially, this task was assigned with the Department's Procurement Investment and Commercial Division (PICD) which later on was renamed as the Innovation Technology Adoption Procurement Programme (iTAPP). In 2012, according to the "Innovation Health and Wealth" document, NICE replaced iTAPP and took responsibility for these applications.*

6 *The Department for Business Innovation & Skills (BIS), Strategy for UK Life Sciences.*

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countries. NTAC was commissioned by the DH to support NHS regional Innovation Leads to facilitate the selection of high impact technologies for wide adoption across their regions. Working with key regional influencers, NTAC helps individual NHS organizations to deploy the selected technologies

(4) Regional Innovation Leads - each SHA holds a legal duty to promote innovation, raising the profile of innovation and encouraging a more rapid adoption of innovation throughout the health service. 'Innovation leads' are employed in each SHA to deliver this requirement.

(5) Commercial Support Units (CSUs) are being created in each region, and as part of their role, will support their innovation lead by providing a key interface between industry and the NHS.

### *b. Application*

All companies that make in-scope submissions will be offered an initial meeting with the iTAPP team (now, NICE). This meeting will be used to clarify any queries relating to the submission and to:

- Gain a deeper understanding of the potential benefits for patients and taxpayers;
- Explain how the program operates;
- Agree any next steps.

Technology submissions will be made up of three sections:

- Management Case: To demonstrate the overall benefits and challenges of adopting the proposed technology;
- Clinical Case: To demonstrate the clinical benefits offered by adoption of the proposed technology;
- Financial Case: To demonstrate the costs and savings applicable to adoption of the proposed technology.

### *c. Prioritization*

The process does not provide a pass/fail approach to inclusion of technologies on the list. Instead, all technologies remain on the list so that they can be re-categorized and reprioritized in response to changing circumstances. Technologies are categorized on the list as follows:

- Level 3: On the market, with sufficient evidence for wide adoption
- Level 2: On the market, without sufficient evidence for wide adoption
- Level 1: Not yet on the market

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- Level 0: Out of scope (ie not a medical technology)
- Level -1: Pending categorization
- Level -2: Withdrawn by manufacturer

Levels 1, 2 and 3 represent a pipeline of innovative medical technologies. The overarching aim of iTAPP (now, NICE) to realize benefits from technology adoption earlier than would otherwise be the case, supports high impact technologies to move through the pipeline more quickly.

Within each category, technologies are prioritized based on an impact scoring calculation, as follows:

| | Low | Medium | High |
|---|---|---|---|
| ▪ Benefitting population | < 250k | 250k - 2.5m | > 2.5m |
| ▪ Net financial savings | < £250k | £250k - £2.5m | > 2.5m |
| ▪ Deployment timescale | < 3 yrs | 2 yrs | > 1 yr |

In each case, high scores 3, medium scores 2, and low scores 1. To calculate the total score, the scores are multiplied together. This gives a maximum score of 27 and a minimum score of 1. Advice is sought from National Clinical Directors at the Department of Health to enable a clinical perspective to be added to each technology.

The list of all technologies, indicating their level and primary benefit, can be downloaded from the DH website[7].

As can be noted, the device's score is **not** affected by the number of UK physicians that currently use the device for the local population.

## *4. The Strategy*

Each of the SHAs publishes calls for applications for its regional innovation fund. Prior to submitting an application, we recommend taking the following Steps.

### *a. Step 1 - Reimbursement Landscape Report*

The purpose of this Step is to understand the current reimbursement landscape for the company's device. It includes:

[7] *http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_121249.pdf*

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- Identification of relevant coding systems, available coverage policies, limitations and guidelines, relevant payment mechanisms and payment rates, outside of the National Innovation Procurement Plan.
- Identification of existing reimbursement mechanisms that could be utilized or compared to the company's device, regardless of the National Innovation Procurement Plan. Recommendation on whether new mechanisms will have to be developed and if so, which mechanisms.
- Identification of the main decision makers and their specific incentives and a description of the typical path towards obtaining third-party reimbursement, including milestones and typical timelines.

### *b. Step 2 - Plan Evidence*

Following the completion of Step 1, the company should clarify what 'evidence' needs to be developed in order to receive high prioritization according to the above mentioned criteria of: (1) Benefitting population; (2) Net financial savings; and (3) Deployment timescale. This step includes:

1) Development of a Value Story, indicating specific claims that explain how the use of the new device promotes the above criteria in comparison with the current alternatives.
2) Development of an Economic Model, quantifying the economic benefits and allowing for sensitivity analysis.
3) Verification of available clinical data supporting the clinical and economic claims in the above Value Story and Economic Model. If needed, the addition of reimbursement related aspects to any planned clinical study protocols.
4) Presentation of the above Value Story, Economic Model and existing/planned clinical data to relevant stakeholders within the NHS. It is important to verify, in advance, that these stakeholders understand the benefits and would agree to provide funding for the new device, should the generated data support the claims in the Value Story and Economic Model.

In case of negative feedback consider changing the Value Story, Economic Model, clinical data or product. Repeat this step until receiving positive feedback from the relevant stakeholders.

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### *c. Step 3 - Generate Evidence*

Perform clinical study/ies to substantiate the claims in the value Story or verify that existing clinical data supports them. Compile the Value Story, Economic Model and clinical data to a Dossier.

### *d. Step 4 - Establish Support / Demand*

Use the developed dossier to:

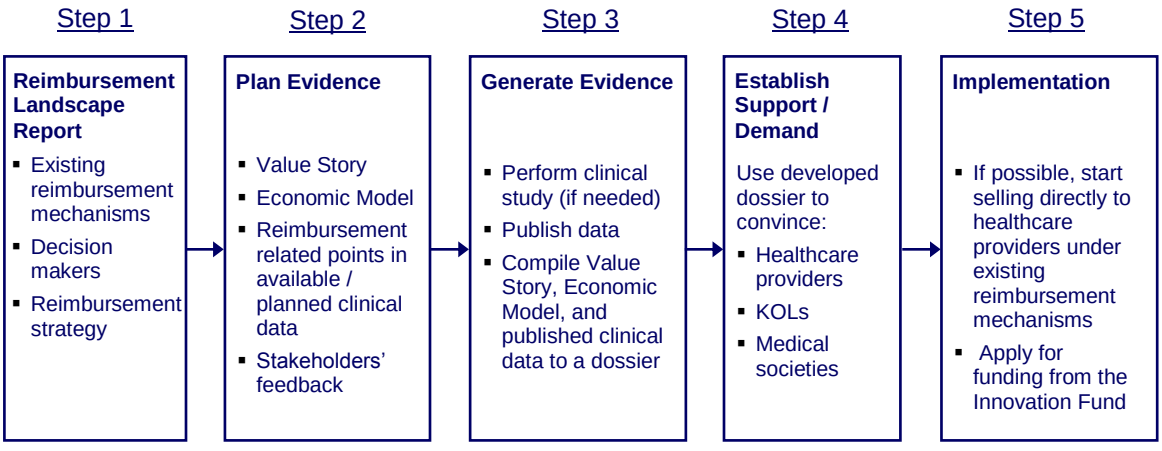
1) Convince the relevant healthcare providers in the clinical and economic benefits of using the new device.
2) Convince the local key opinion leaders to provide lectures, write articles and issue supportive letters highlighting the benefits of using the new device.
3) Similarly, convince the relevant medical societies and organizations to provide position statements.

Add these documents to the dossier.

### *e. Step 5 - Implementation*

Use the developed dossier as a sales tool and apply for funding from the Innovation Fund.

The flowchart below illustrates the suggested process:



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## *5. Conclusion*

According to an assessment conducted by PwC, the UK, with its largely single-payer, government-controlled system, ranks third in ease of reimbursement and significantly above European countries such as Germany and France[8]. The NHS's focus on innovation may make it even easier for smaller companies, introducing their first product into the market.

It should be noted that in order to prepare a winning application, a great deal of preparatory reimbursement related work should take place, in advance. This preparatory work should result in the development of evidence, supporting the required criteria for high prioritization on the list of new devices, which are candidates for funding from the Innovation Fund.

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Amir Inbar is the founder and CEO of Mediclever Reimbursement Consultants (www.mediclever.com), which provides end-to-end reimbursement consulting services to life-science companies, selling pharmaceuticals and medical devices in the USA and Europe.

With a chain of over 30 experts throughout the USA and Europe, and with more than 100 clients worldwide, Mediclever assumes full responsibility for the reimbursement of pharmaceuticals and medical devices, from early strategy development to the establishment of specific codes, payment rates and favorable coverage.

Mediclever consultants have experience in preparing value dossiers and other value communication tools, performing pricing and reimbursement assessments, creating tools for health economic modeling and developing market access strategies.

More recently, Amir also founded GLiSCO, the Global Lifescience Consulting Organization (www.glisco.org), which is a network of experts in the field of IP, Regulatory, Quality and Clinical Research, Reimbursement and Pricing, Product Commercialization and Fund Raising. The GLiSCO experts coordinate their developed strategies and implementation activities with each other, providing the client with one coherent consulting package.

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[8] *"Medical Technology Innovation Scorecard – The race for global leadership", January 2011, PwC. Other countries included in this study and their ranks are: Israel (1), US (2), Brazil (4), India (5), France (6), Germany (7), China (8), Japan (9).*