

Industrial strategy: government and industry in partnership



Renal: A Capability Assessment

INTRODUCTION

Context

The Government has identified Life Sciences as one of the ten sectors under the Government's industrial strategy. This high tech sector will generate significant welfare gains from increased health and longevity, with ageing populations and life style changes leading to significant increases in global demand for personal and healthcare products.¹

The medical technology market is a key contributor to the UK economy – encompassing 3,000 companies (1500 manufacturing), employing 64,000 individuals and generating £15bn per year (including consultancy and services), making the UK market the second largest in Europe. It has, therefore, been identified as a sector that must build a strategic partnership with Government.

Building and sustaining a strategic relationship is a lynchpin of the Government's ambition to strengthen the UK supply base, especially in Life Sciences where Government plays a pivotal role as a procurer of goods and services via the National Health Services (NHS).

This capability analysis of Renal demonstrates how a strategic relationship between Government and industry can ensure both parties are better prepared to respond to the UK's health needs and build the UK supply base.

This document also supports the steps outlined in the 'NHS Procurement: Raising our Game'² document which highlights the necessary actions to ensure that procurement is central to driving and delivering value in the NHS.

It is vital that the NHS procurement function becomes world class, focusing on outcomes, not just cost, whilst being responsive to creative ideas and innovations. Sir Ian Carruthers OBE, Chief Executive of the NHS South of England is leading on this work, which began with an 'Open Call' for evidence, the output of which is expected early 2013.

In December 2012, the 'Life Sciences: One Year On' document will provide an update about implementation of the measures outlined in the Strategy for UK Life Sciences.

Government and the NHS acknowledge the importance of signalling to the market the longer term future requirements for service delivery/demand and the desired measureable health outcome. One of the many keys to successful procurement is a clearly articulated commissioning strategy that supports not only the needs of the

¹ BIS economics paper No.18 industrial strategy: UK sector analysis, September 2012

² Department of Health publication: NHS Procurement: Raising our game, 28 May 2012

current population, but also that of future demand and challenges. This could be in identified disease areas, or areas that are projected to be of significance to the economy in terms of healthcare expenditure or the wider economic opportunity cost associated with the increase in chronic diseases for example. This is closely aligned to the 2012/13 NHS Operating Framework and the key focus on enhancing quality of life for people with long term conditions.

Clearly any capability analysis should allow for sight of what is needed today and going forward to accurately inform the procurement strategy alongside that which encourages growth for the UK supply base, and the Research and Development (R&D) sector to develop technology and pathway innovations to meet the future areas need.

As the commissioning function matures, we anticipate commissioners will work more closely with providers and their suppliers to ensure innovation flows from the supply base across the entire care pathway.

The Renal Market

The Renal market has been identified by the Department of Health (DH) as a key area on which to undertake a capability analysis. It is recognised that the publication of this document will form the basis of future discussions with industry and the NHS to build on the action plans contained to address the issues highlighted.

Attached at Annex 1 is additional background, which provides a definition of kidney disease including Chronic Kidney Disease (CKD), Acute Kidney Injury and End Stage Renal Disease (ESRD) and a description of the various Renal Replacement Therapies (RRT) including Haemodialysis, Peritoneal Dialysis and Haemofiltration.

This document:

- Provides context including the scale of the issue, the scope of kidney disease, and the challenges the NHS subsequently faces.
- Reviews Renal and the associated market as a sub-section of the Clinical and Medical Life Sciences sector, in order to understand the wider supply chain issues.
- Examines the capabilities of the supply chain to meet future demand, identifies capability gaps, proposes actions to address them and explores potential benefits for UK based firms.

THE SCALE OF THE CHALLENGE

"I welcome this initiative for managing kidney disease as it is a team effort. With patients, families and carers at the centre with Health Care Professionals focused on quality improvement and patient experience. Working in partnership with people suffering from kidney disease and industry colleagues to discover new treatments, using innovative thinking to improve the quality and outcomes of interventions for kidney disease this year, next year and into the future."

Professor Donal O'Donoghue, National Clinical Director for Kidney Care, Depart for Health

Prevalence

In England 1.8 million people have been registered with Chronic Kidney Disease (CKD). This figure, however only represents the people who have been detected and registered: there are thought to be an additional 1.0 million people who have yet to be diagnosed.

Failure to diagnose means people are not getting the lifestyle advice and treatment they need. In addition, they are not receiving essential medication at the appropriate stages to slow the disease progression, leading to poorer health outcomes and a massive drain on NHS resources.

Earlier diagnosis and treatment significantly improves people's quality of life, cuts their risk of heart attacks and stroke and minimises their likelihood of needing dialysis or transplant, again saving NHS resources.

A significant amount of work has already been completed with many General Practitioners (GPs) tackling the problem and educational tools have been made available. As a result there has been a reduction in the number of CKD patients presenting in Accident and Emergency (A&E) with End Stage Renal Disease (ESRD) from 30% to 19%.

There are pockets of good practice, for example, where with the use of information technology, individual localities have reduced this figure even further.

System for Early Intervention in Chronic Kidney disease (SEIK) - East Kent University Hospitals NHS Foundation Trust

SEIK is a clinical decision support system that was developed to screen patients in primary care who have serum creatinine estimations recorded on the primary care database. Data pertinent to identification and management of chronic kidney disease (CKD) is regularly extracted from primary care sources and patient specific advice is given regarding referral, medicines management and further investigation. The system is currently active in a primary care population of 354,322 people of whom 151,158 (43%) have had a valid serum creatinine recording affording screening for CKD.

Practices using the system have higher ascertainment rates of CKD, refer patients with advanced CKD earlier and more appropriately but also have lower overall referral rates. They have also demonstrated sustained improvement in blood pressure control in patients with CKD, although it is not possible to say how much of this effect is also due to other influences. Data will soon be available to assess whether or not there has been an impact on progression of CKD and other adverse outcomes of CKD in practices using the system.

With Acute Kidney Injury (AKI), the population incidence from UK data ranges from 172 per million populations (pmp) per year up to 486 – 630 pmp per year.

In terms of ESRD, 40,000 patients in the UK are currently receiving dialysis or have functioning kidney transplants: 28,000 receiving haemodialysis (HD), 4,000 at home and 5,000 on peritoneal dialysis (PD).





The overall market for treatment is growing at a fast pace, approximately 7% year on year. One of the key factors is changes in lifestyle, but also as treatments in other disciplines improve, for example blood pressure and diabetes controls patients who previously did not survive are now doing so; however their co-modalities ultimately lead to CKD.

Cost to the NHS

The current cost of treating ESRD is 1-2% of the NHS budget, but comprises 0.05% of the population.

A recent report published by NHS Kidney Care has found that CKD costs the NHS in England more than £1.4 billion each year incorporating dialysis and kidney transplantation. This is more than the combined £1.37 billion the NHS spends on breast, lung, colon and skin cancer.

Delivery of Kidney Services

The majority of mild kidney disease is managed in primary care, with an emphasis on early detection and management of CKD.

More severe CKD and ESRD cases are managed in secondary care (commissioned via specialist commissioning groups), and traditionally centred on hospital haemodialysis. In the 1970s and 1980s, programmes of home haemodialysis and peritoneal dialysis were established, followed in the 1990s by the 'hub & spoke' model with satellite units linked to main hospital sites.

Additionally, kidney transplantation is managed by specialised commissioning groups and is at the forefront of high quality care, focusing on retrieval and live donor programmes.

Procurement

From a procurement perspective, the Renal market is not managed nationally across England.

The NHS Supplychain has a Renal dialysis procurement framework, incorporating haemodialysis equipment, consumables and solutions and haemofiltration equipment, consumables and solutions. This was launched in November 2011 for a twelve month period with an option to extend for a further twelve months. However, this agreement only captures a small percentage of the market spend.

There is also a national agreement for peritoneal dialysis which is currently facilitated by a Trust, but again this does not capture the complete NHS spend.

Haemodialysis is managed either individually by centres or by geographic consortia. Participating centres will enter into contracts or framework agreements but there are no co-terminus renewal dates, or transparency/data sharing between the contract/framework negotiators.

In addition, there are 53 Renal centres and 144 satellite units in England. Of the 144 satellite units, 57 are contracted out in the main by Fresenius & B. Braun and, as such, would provide their own product ranges.

In order to support this capability analysis it is important to link in with the pipeline initiative and to have full visibility of planned procurement activity across the NHS.

The Clinical and Medical Life Sciences pipeline is one of the Government's eighteen pipelines where Government projects and contracts worth up to £84 billion are shared transparently with industry to stimulate growth and help businesses forward plan.

The Clinical and Medical Life Science initially focussed on NHS Supplychain and DH Commercial Medicines Unit but now includes the first entries from NHS trusts. The need to populate the pipeline database with the full range of proposed Renal procurement activity is an integral part of this capability analysis.

A strategic procurement decision would then need to be made as to whether these plans should continue in isolation, collaborative opportunities be explored, or national approaches taken.

As mentioned already the capability analysis needs to be developed in conjunction with the commissioning strategies and the procurement pipelines with a mind to how this will drive procurement of services and goods in the future. Government will consider how this will be achieved as commissioning landscape matures.

This is not unique to the Renal market and is a challenge across many categories. This is well recognised and a key focus for improvement highlighted in 'NHS Procurement: Raising our Game'³ and the actions now underway will facilitate the development of future pipelines and capability assessments.

Action: We will work with the NHS to increase transparency of procurement plans within the Renal market and develop the appropriate strategic approach

UK BASED SUPPLY CHAIN

THE UK FOOTPRINT: KEY SUPPLIERS AND MANUFACTURING SITES

As illustrated by the maps below, the majority of Renal consumables and equipment are currently manufactured outside the UK. This, coupled with the limited number of suppliers and bespoke nature of their products, has caused serious supply chain issues of late as a result of earthquakes in Italy and the lack of contingencies in place to ensure continuity of supply.

³ Department of Health publication: NHS Procurement: Raising our game, 28 May 2012



Diagram 1: The maps illustrate the supply chain by country for key products - bloodlines, dialysers, needles and machines.

Attached at Annex 2 is a table outlining an initial assessment of key Haemodialysis and Haemofiltration suppliers and identifies the scope of their supply in equipment, consumables, solutions and manufacturing sites that each have.

Action: In partnership with industry, we will undertake further work to map the supply networks in order to monitor gaps in the supply base.

THE OPPORTUNITY

Supply Chain and Increase in UK Based Activity

Although, limited supply chain analysis has been undertaken above further analysis is needed to understand the full supply chain process, including the current activities contracted out and whether this needs review to mitigate against potential risks.

Using this analysis we will work with industry, to assess what could be changed to bring activity in to UK business as well as seeking the assurance for continuity of supply. Fundamental to this would be working with incumbent suppliers but also attracting new suppliers to the Renal market.

There is potentially an opportunity to increase the UK footprint to manage security of supply of key consumables and equipment.

Action: We will work with industry to identify opportunities to attract investment into the UK to manage security of supply of key equipment and consumables

SKILLS AND TECHNOLOGICAL OPPORTUNITIES

Increased Drive for Home Haemodialysis

This is not a new concept, indeed the first Technology Appraisal (TA) from NICE was back in 2002, TA48⁴. Currently the prevalence of home dialysis is much lower than the 12% set by NICE. However, it is likely to grow as demand increases from patients in order that it fit in with their lifestyles, and the emerging evidence of better outcomes which is starting to be published.

This low uptake of NICE guidance is not isolated; Innovation Health and Wealth (IHaW)⁵ recommended the need for greater compliance with NICE recommendations and compliance with the TA is under consideration for possible scorecard monitoring.

Under the home haemodialysis service the patient and key carer undertake an intense training programme and there is a 24 hour on-call helpline in addition to support networks. The move from hospital based to home dialysis will have an impact on both the capacity of organisations providing this service and the skills needed.

However, there are good examples of where activity has been undertaken to meet the recommendations of the NICE guidance.

⁴<u>http://www.nice.org.uk/usingguidance/measuringtheuseofguidance/searchernie/resultsummary.jsp?o=11472</u>

⁵ Department of Health publication: Innovation health and wealth: Accelerating adoption and diffusion in the NHS

Central Manchester Foundation Trust

Manchester Home Dialysis training centre is a conventional dialysis unit redesigned and adapted for patient learning and empowerment to enable self care, minimal care and home hemodialysis (HHD). Patient pathway redesign, individualised learning strategy, enabling technology and an open policy of patient acceptance and choice has allowed a range of patients (age 25-82, all backgrounds, comorbidities) to undergo training for hemodialysis at home, resulting in a host of qualitative (liberal diet and fluid, less medications, less travel to units) and quantitative (better survival and superior clinical outcomes) benefits. The program is supported by 24/7 in centre helpline, home nurse visits and respite care in-centre with step-down and step-up facility as needed. The patients set up at home are then able to have more flexible dialysis with frequent and longer schedules in the home environment. This option thus allows nocturnal home HD treatment (at night whilst asleep) which is considered the gold standard in achieving the best dialysis outcomes.

The Manchester program has to date, trained 210 patients with kidney failure since 2006, with high technique and training success, and has sustained 12-15% prevalence rate. The option of greater dialysis dose at home and its benefits is achieved at a lower cost than in-centre hemodialysis, making HHD the most cost-effective dialysis modality in UK.

In addition, the development of Shared Haemodialysis Care (SHC) which encourages patients participation in their dialysis care.

York NHS Foundation Trust

Shared Haemodialysis Care (SHC) – Encouraging patient participation in their dialysis care

Over 90% of haemodialysis patients have their treatments within hospital or satellite facilities. Most patients will spend 12 hours a week receiving treatment in these centres. Our nurses utilise this time to encourage patients to actively participate in their care by educating, supporting and developing dialysis skills. Patients choose the skills they want to learn and nurses facilitate this learning. Patients are empowered and in control of their treatment.

The majority of our haemodialysis patients participate in SHC and they express enhanced satisfaction as a result of participation in their care. More patients express interest in Home Haemodialysis as a result of increasing confidence. Patients require less time for home haemodialysis training as a result of skills gained whilst dialysing in the renal centres. We have noted an increased uptake of home dialysis as result of SHC.

Capacity for Renal Replacement Therapy (RRT)

When patients with CKD reach 30% functioning kidney level they are referred to secondary care/consultant and typically RRT would commence when their

functioning kidney level reduced to about 10% function. Renal units, including associated satellite units, tend to work at maximum capacity, although the number of shift patterns per unit varies across the country.

The trigger point of about 10% is a guide and other clinical considerations e.g. general wellbeing/sickness would be considered.

Currently, Renal units cannot accommodate patients from elsewhere in the country leading to a perception that it is easier to secure holiday cover haemodialysis for patients abroad than in another location across England. Patients currently on home haemodialysis would also encounter this challenge, as the current home machines are not transportable.

Skills Profile

Haemodialysis is managed by Registered Nurses who undertake additional training and reflecting other services, the role of healthcare assistants (band 3 or 4) has been developed into dialysis support assistants.

In recent years hospital Renal departments would have looked at overseas recruitment to fill these key roles (e.g. India).

The move towards home dialysis, whilst reducing the demands on the Renal units, requires a different skill set: - to both facilitate training in the first instance and then a requirement for a support mechanism going forward.

With this increasing shift and developing expertise, it is likely there is an opportunity for the UK to consider exporting this nursing capability in the future. This will be explored as part of Healthcare UK and NHS Global whose respective roles are:

"To deliver UK healthcare excellence to international markets through the promotion of the best of the NHS and commercial healthcare industry and for the benefit of UK plc" and "To support the NHS to engage with international markets, both commercial and philanthropic, by providing leadership and expertise that enables the NHS to increase the volume and impact of its overseas engagement."

Reaching, or even forecasting, a critical mass in the home dialysis market will have significant implications for the supplier base and the mix of equipment/consumable/maintenance and resultant whole service delivery as well as the skills base referred to above.

A greater shift to the use of home haemodialysis will:

- Reduce the required provision of on-site equipment and facilities.
- Significantly increase the provision of 'home' equipment and processes. These will need to be designed:

- in such a way that devices can be easily repaired, decontaminated, reconditioned or remanufactured for reissue to other patients
- with energy and water efficiency as a key consideration

Increase the scope for a UK-based servicing, maintenance and repair sector as well as a reconditioning and remanufacturing sector for home haemodialysis equipment.

There are potentially additional social and economic benefits to patients including time and costs savings from not having to travel, and treatment can be scheduled more flexibly to fit in with work and other commitments. In some instances this may make entering employment a viable proposition for patients previously restricted by frequent visits to renal centres. Conversely, the social interaction that some elderly and isolated patients experience through visits to Renal centres is greatly valued by them, and consideration should be given to patterns of care that compensate for this.

Technology Development/Innovation

Notwithstanding the profile of Renal and the drive towards home haemodialysis, the actual process of haemodialysis and peritoneal dialysis has seen very little technology development and in many ways individuals today receive the same service/therapy that patients would have done twenty years earlier.

This is very unusual particularly when compared to how other services have developed.

On the horizon, there are several developments including alternative therapies to fistula needles as well as developments in home dialysis machines and a key enhancement to the transportability of the equipment.

Activity is also under way under the Devices for Dignity (D4D) Healthcare Technology Co-operative, which focuses on developing technology that can provide direct patient benefit and transform kidney care within the NHS.

Devices for Dignity D4D

The Devices for Dignity (D4D) Healthcare Technology Co-operative based innovation initiative has a specialist interest in enabling patients to perform haemodialysis in their own homes, avoiding the need for regular visits to hospital for treatment. D4D is a national consortium of NHS trusts and within the renal theme, brings together expertise from 4 leading UK centres:

- Central Manchester Foundation Trust
- Sheffield Teaching Hospitals
- Leeds Teaching Hospital
- North Bristol NHS Trust

In addition, D4D focus on developing technology that can provide direct patient benefit and transform kidney care within the NHS. A goal is to improve patient care in home dialysis by removing technological and adoption barriers to home dialysis and shared care (investigating unmet clinical needs requiring technology development to enable patients to take greater control of their treatment). Patient focussed technology will be developed for greater uptake of self care dialysis, with potential to improve patient outcomes through extended dialysis and cost effectiveness to service providers.

Action: We will explore with industry and the NHS how we can accelerate the development of these sectors in the UK through mechanisms such as the Small Business Research Initiative (SBRI) and 'Innovation Challenge Fund' for local economy closed loop projects, initiated under the Government's Resource Security Action Plan, led by BIS and Defra. In addition, assess the feasibility of an all encompassing Renal focus SBRI run by the DH

Summary

This is the beginning of a key and exciting initiative to harness a strategic approach to procurement and build a strategic dialogue between the NHS and industry. This approach is vital both to ensure that the UK capability and economy grow and are sustained, whilst at the same time improving NHS outcomes for Renal patients.

ANNEX1: definitions

Kidney Diseases Definition

Kidney disease can be classified under 3 sub-sections:

- Chronic Kidney Disease (CKD) describes abnormal kidney function and/or structure. It is common, frequently unrecognised and often exists with other conditions e.g. cardiovascular disease and diabetes
- Acute Kidney Injury (AKI) this is a rapid onset condition where the patient either recovers or it becomes CKD
- End stage Renal disease (ESRD) this is a long-term irreversible decline in kidney function, for which Renal replacement therapy (RRT) is required if the individual is to survive. RRT can take a number of forms, kidney transplantation, haemodialysis (hospital or home) and peritoneal dialysis.



Haemodialysis – this is the process of removing waste and excess water from the blood. A patient typically receives 3 treatments per week for up to 4 hours per session. Home haemodialysis allows patients to be more flexible and schedule for clinical benefits and ease lifestyle challenges.

Peritoneal Dialysis – This process uses the patient's peritoneum (the membrane surrounding the abdominal organs) to act as a dialyser. The treatment is undertaken at home/work by the patient and involves the administration of the dialysate fluid into the peritoneal cavity through a catheter. The fluid/blood then exchanges over a



period of time. Patients can do this overnight or during the day known as Continuous Ambulatory Peritoneal Dialysis (CAPD).

The "used" dialysate is then drained out of the abdomen into a sterile container. The peritoneal cavity is then filled again with fresh dialysate.

Renal Replacement Therapies

Haemofiltration – Used in acute Renal failure in Intensive Care Unit. It is a slow continuous treatment that usually lasts between 12 to 24 hours. A patient's blood is passed through a set of tubing via a machine to a semi permeable membrane (the filter) where waste products and water are removed. Replacement fluid is added and the blood is returned to the patient.

ANNEX 2: key haemodialysis and haemofiltration suppliers

The following table is an initial assessment of key Haemodialysis and Haemofiltration suppliers and identifies the scope of their supply in equipment, consumables, solutions and manufacturing sites that each have.

Company	Manufacturing Sites	Products
Asahi Kasei Medical (UK)	Asahi Kasei Medical Co Ltd Tokyo, Japan	Dialysers
Haemodialysis Consumables	Bain Medical Equipment* China *Outsourced Manufacturer	AVF Needles Blood Tubing Sets
B Braun Avitum Ltd Haemodialysis Equipment,	B Braun Avitum Ltd Germany	Dialysers Filters Bicarbonates Cartridges Machines
Consumables and Solutions	B Braun Avitum Ltd Thailand	Needles
Haemofiltration Equipment and Solutions	B Braun Avitum Ltd Italy and Hungary	Blood Lines
	B Braun Avitum Ltd Switzerland	Disinfectants
Baxter Healthcare Ltd	Nipro Europe NV UK* Japan *Outsourced Manufacturer	Dialysers
Haemodialysis Consumables and	Nipro Europe NV UK* Thailand *Outsourced Manufacturer	Needles
Solutions	Baxter Italy	Bicarbonate Cartridges
Fresenius Medical Care	Fresenius Medical Care Germany	Dialysers Diasafe Plus filters Dialysis chairs
Haemodialysis Equipment, Consumables and Solutions		Aqua Uno Acute Fluids Acute Filters Acute kits Machines: 5009, 5008S
Haemofiltration Equipment,		and MultiFiltrate
Consumables and Solutions	Fresenius Medical Care Italy	Bloodlines Tubing for acute kits

	Fresenius Medical Care UK	Renalyte Acid concentrate
	Fresenius Medical Care France	Dialysers Bi Bags
	Bionic* Japan	Standard needles Premium needles Buttonhole needles
	Nipro Europe* Thailand	Standard needles Premium needles
	*outsourced Manufacturer	
	Fresenius Medical Care Japan	Dialysers
	Fresenius Medical Care Belarus	Bloodlines
	Fresenius Medical Care Turkey	Bloodlines
	Fresenius Medical Care Macedonia	Bloodlines
	Fresenius Medical Care Greece	Bloodlines
	Fresenius Medical Care Serbia	Bloodlines
Gambro Lundia AB Haemodialysis Equipment, Consumables and Solutions	Gambro Lundia AB Germany	Gamcath Catheters Polyflux Dialysers Dialox Disinfectants Filters Fistula Needles
Haemofiltration Equipment, Consumables and Solutions	Gambro Lundia AB Italy	Blood Lines Artis 230v Select Bag Solution
	Gambro Lundia AB France	Evodial Dialysers Nephral Dialysers
	Gambro Lundia AB Sweden	CleanCart Disinfectants BiCart Solution Machines; AK96, AK200, WRO300
	Gambro Lundia AB Japan	Plume Needles

	Gambro Lundia AB Thailand	Blunt Needles
Kimal Renal Care	Kimal Renal Care	AVF Needles
	UK	Blood Lines
Haemodialysis		Fistula Needles
Equipment,		
Consumables and	JMS*	AVF Needles
Solutions		Fistula Needles
L filtration		D
Haemonitration	Allmed	Dialysers
Equipment,	Germany	Bicarbonate Cartridges
Consumables and	*Outsourced Manufacturer	
Solutions		
Kimai PLC		NIKKISO machines
	Japan	
Haemodialysis	*Outsourced Manufacturer	
Equipment,	GMBH	NIKKISO Machines
Consumables and	Germany	
Solutions	^Outsourced Manufacturer	
	NxStage Medical Inc	NxStage Machines
Haemonitration	United States	
Equipment,	^Outsourced Manufacturer	
Consumables and		
Solutions	Nipro Europo Ny LIK	Dialyzara
	Japan	Dialysers
Nipro Europe Ny UK	Nipro Europe Ny UK	Blood Lines
	Thailand	Fistula Needles
Haemodialysis		
Consumables	Nipro Europe Nv UK	Bicarbonate
	Spain	Cartridges

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