

WORKING WITH THE UK PUBLIC SECTOR: SME MEDICAL DEVICE INNOVATION AND PRE-PROCUREMENT

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Introduction

The provision of high quality healthcare within constrained budgets depends on constant, effective innovation (Weisbrod, 1991). Within the UK, this depends on effective collaboration between public sector healthcare providers and companies within the medical devices (MD) sector (NHS Healthcare Innovation Exposition 2013). SMEs have an important part to play in this sector (NHS Supply Chain Parliamentary Brief, 2013), but they often face many difficulties in engaging with the National Health Service and related government departments and agencies. The National Health Service (NHS) for England is the umbrella organization for publicly-funded primary and secondary health care, available to all UK citizens resident in England. The NHS is divided into regional sections, with individual budgetary and procurement responsibilities.

Healthcare providers are under ever increasing pressure to deliver more technologically advanced care without increasing costs. To do so, innovation is essential (Darzi, 2008; Department of Health, 2012), and for this healthcare providers rely on innovation within commercial companies. These companies in turn rely on collaboration with healthcare professionals. Effective collaboration can lead to the development of products with a genuine impact on health outcomes and greater profitability. However, all too often firms – especially SMEs - encounter obstacles which can thwart their efforts to bring a new product to market. Actors on the buying side fail to understand their own needs for innovative products, or to facilitate innovation amongst current and prospective suppliers (Innovation, Health and Wealth Review, 2012).

This problem is well recognised in the various intersecting UK and EU policy fields relating to business development, SMEs, innovation, international competitiveness, and public procurement. In the UK there are multiple policy initiatives designed to address aspects of the problem including: public procurement from SMEs, forward commitment procurement (En-

vironmental Innovation Advisory Group, 2003-2008) and pre-commercial procurement (Bos & Corvers, 2007). Public bodies seek to adapt their practices to avoid blocking innovation, and to facilitate innovation among suppliers. SMEs must learn how to access resources, engage experts, and cope with the complex structures, processes and long lead times of the health sector. This interface – between innovating SME suppliers and healthcare providers who will ultimately buy the innovative product or service – forms the focus of this paper.

Our aim is to bring together insights from academic research on innovation, procurement and SMEs, with national policy and practice and relate these to practical examples of interorganizational innovation projects. Three objectives are addressed relating to innovation and procurement between the NHS and SMEs in the medical devices sector: to review relevant literature, synthesising key frameworks and recommendations for policy and practice; to identify key national level policies and practices intended to facilitate innovation and pre-commercial procurement; and to critically review these academic insights and national level initiatives in relation to specific interorganizational innovation projects. We explore the issues faced by innovating organizations in the MD sector by inter-relating academic findings, policy publications and practice observations. We show how innovation is both critically important to the future of the health service in England, and critically constrained by regulatory and organizational features of the system.

The paper is structured as follows. The general introduction is followed by an introduction to the NHS. Then a literature review explores innovation and procurement in the context of SMEs and the health sector. The methodology section is followed by findings, in which empirical evidence comes from two complementary perspectives. We first present a national perspective of policy and practice, based on data from participant-observation and documentary sources. Second, fifteen cases of interorganizational innovation projects related to medical devices and associated processes are presented. The final section presents discussion and conclusions providing a critical review of alignment between theory, national policy and local practice: national policies and practices are related to the realities of specific projects and projects are considered in their policy context, and outlining the implications for SMEs and the NHS.

The National Health Service Context

The Department of Health (DH) is the Government Department with responsibility for the NHS, funding, policy and change. The NHS provides care on the basis of need rather than patients' ability to pay. NHS care is 'free at the point of use' (i.e funded through tax). In England there are 10 Strategic Healthcare Authorities with regional responsibility on behalf of the DH, which includes budgetary control and procurement as well as delivering DH policy and change in the region. These SHAs deliver strategy and ensure quality of care in hospital trusts, which are smaller regional hospital groups that are responsible for patient care provision and delivery (RLHNHS Trust, 2009). In April 2013 the implementation of new policy began, seeing the abolishment of these SHAs and Primary Care Trusts. In their place, regional Clinical Commissioning Groups will take responsibility for regional budgetary control, strategy delivery and care provision. Healthwatch England will take responsibility for the patient experience, and identifying trends and issues on a national level that when reported to CCGs will legally require action.

Moves to a more devolved flat structure have also seen other national bodies being set up and given budgetary control to deliver particular policy initiatives, many of which have also been restructured recently. These include NICE (National Institute for Health and Care Excellence) which delivers guidance and regulation on an array of healthcare provision and AHSN (Academic Health Science Networks) set up to enable academics and the NHS to work in collaboration with industry. These DH and NHS agencies, groups, centres and bodies deliver particular strategic and policy agenda. Recent initiatives include engaging with SMEs to support regional economic development, and to promote innovation.

The NHS is renowned for its complex structure, and this also applies to procurement (Harland, Rudd, Knight, Forrest & Bakker, 2007), which features not just local decision making and regional procurement groups, but also a central NHS Supply Chain. Procurement is often locally managed, in order that specific procurement requirements of each hospital trust can be met. The challenge for SMEs is to gain access to procurement decision makers across NHS England on a hospital trust by hospital trust basis. Therefore, National agencies and regional groups are often a key entry points for SMEs.

Literature Review

Innovation and Healthcare

Innovation is the introduction, incorporation or implementation of a new product, service, process, concept or procedure, novel to the working environment (West & Fahr, 1990). In healthcare, innovations tend to be novel services, procedures or technologies (Lansisalmi et al., 2006) and may be a completely new innovation or an incremental change in an existing product, service or procedure (Shaw, 1986). Within the UK healthcare sector although an innovative product may be developed introduced successfully in one location, it may not be widely adopted (Shaw, 1986). Therefore adoption and implementation are critically important.

Firms may face considerable barriers when introducing new products (Mahmood & Lee, 2004). While Hall & Bagchi-Sen's study (2002) in the Canadian biotechnology sector showed that firm size has no effect on innovation, they found that having a ready market and funding from larger corporations impacts upon innovation outcomes. Herzlinger (2006) noted the influence of stakeholders and the policy context which may sometimes strongly favour a product. Barriers can include purchasers' lack of funding, suppliers' (SMEs) lack of resources, the presence of competing solutions and technologies, lack of customer access to knowledge, and uncertainty about accountability should the device fail (Herzlinger, 2006).

Organizations face an inherent problem with innovation. The capabilities which underpin effective exploration are distinct from those which support effective exploitation (Gupta, Smith & Shalley, 2006). Coping with this may involve establishing semi- or quasi-autonomous structures (Brown and Eisenhardt, 1997; Schoonhoven and Jelinek, 1990), or developing as an ambidextrous organization (Benner and Tushman, 2003; Duncan, 1976; O'Reilly and Tushman, 2004). It may also involve interorganizational collaboration (Ahuja, 2000; Deeds and Rothaermel, 2003; Hagedorn, 2002), bringing more and varied areas of expertise and ways to solve problems than without collaboration. Firms that possess a heterogeneous network of collaborative partners perform better in terms of the proportion of turnover realized from new or improved products (Faems, et al., 2005).

These network relationships are drawn upon through specific innovation projects. There are inevitable challenges associated with interdependency in innovation projects (Newell, Goussevskaja, Swan, Bresnen & Obembe, 2008). Blindenbach-Driessen & Van den Ende (2006) report that there is very little research on innovation within project-based organizations, despite the increased use of interorganizational relationships in innovation project practice (Smith Ring & Van de Ven, 1994). Cross-functional team-working within organizations is often portrayed as the key to firm creativity and suc-

cess (Bolwijn & Kumpe, 1990). The literature on team-working, however, emphasizes some of the problems of developing and sustaining collaborative working – problems which are frequently overlooked in prescriptive accounts of the benefits of networking (Bedwell, Wildman et al., 2012).

Grandori and Soda (1995) identify 10 organizational co-ordination mechanisms that are employed in all interorganizational networks: communication; decision and negotiation mechanisms; social coordination mechanisms; integration and linking-pin role and unit mechanisms; common staff mechanisms; hierarchy and authority relation mechanisms; planning and control system mechanisms; incentive system mechanisms; selection system mechanisms; information system mechanisms. Newell & Swan (2000) found different combinations of these co-ordination mechanisms characterised different types of networks.

While co-ordination within these interorganizational networks occurs through these management practices and resources, team building processes have been found to be extremely important in performance of interorganizational project teams (Albanese, 1994). While discussing the effect interorganizational team work has on the overall job satisfaction of the individual, Chan, Ho & Tam (2001) suggest that the relationship between interorganizational team working and project outcomes requires further research, as does the way in which an interorganizational team is set up.

Innovation and Procurement

The early involvement of suppliers (ESI) has featured heavily in the literature on procurement and innovation (Johnsen, 2009). In a healthcare setting this means ensuring a clinical need is fulfilled as effectively as possible whilst also considering all regulatory guidelines during the developmental processes. Primo & Admundson (2002) found that the involvement of new suppliers in times of greater organizational innovation was beneficial to the innovation process, suggesting that to benefit most when undergoing a period of innovation the NHS may be more open to the potential contribution of new suppliers. Johnsen, Calvi & Phillips' (2012) review of ESI and innovation found ESI is critical for both continuous (i.e. more incremental) and discontinuous innovation, where early involvement of the purchasing function was also vital. This suggests that the earlier purchasers and suppliers are able to communicate with each other, the earlier they are able to articulate their needs and capabilities. This allows a two way discourse during the design and prototyping phases, ensuring that the innovation is fit for purpose from an earlier time in the innovation, whether this is an entirely novel device or an incremental change to an existing device. This may not result in direct involvement during the development phase but ensures that procurement factors, such as costs and availability of

materials, supply risk and intellectual property and contractual issues, are considered earlier during product development.

Wert (2012) suggests five difficulties that public procurement people face when buying from SMEs: the wrong incentives are in place; there is a lack of knowledge and capabilities regarding the technology, innovations and world-wide market developments; there is a deficiency in strategy aligning public procurement with public policy objectives and R&D; demand is fragmented; and it is very difficult for innovative SMEs to be involved in public procurement as a supplier.

The UK's Coalition Government has followed previous governments' efforts to address these problems and recently announced that public bodies must help SMEs access public contracts by removing unnecessary obstacles, committing to making the market more competitive and creating new business opportunities for SMEs (Her Majesty's Government, 2010). Such initiatives are in direct tension with public officials' targets to reduce cost (Public Spending Review, 2010) and deliver better value for money (Loader, 2007). Whilst large firms can benefit from economies of scale, small firms can achieve better value for money through greater flexibility and efficiency. Their ability to do so is however limited by the constantly changing environment of the public procurement markets (Loader, 2007).

Pre-Commercial Procurement, Innovation and Healthcare

Public Procurement for Innovation (PPI) occurs when a procuring organization recognises an unmet need and turns to the supply market, making a request (and sometimes contractual commitment to subsequently acquire) for a product and/or service to meet the need, thus prompting innovation by one or more suppliers (Edquist & Zabala-Iturriagoitia, 2012). Edquist et al. (2012) propose two types of PPI – direct and catalytic, recognisable by whether the end user or a procurement agency are spurring the innovation on. Although the majority of public procurements come from regular orders, certain sectors – including healthcare – also engage in PPI more readily. The procurement of technology has been found to have a direct impact on ward efficiency and has links to the objectives of ward management (Ancarani, Di Mauro & Giammanco, 2009).

Innovative procurement as a strategy can take many forms, including pre-commercial procurement (PCP; Bos, 2008) which bridges the gap between R&D of a supplier and market pull of a buying partner. Essentially this leads to a pre-procurement service contract involving end-user informed R&D (Edler & Georghiou, 2007). Martin et al. (2005) found that centering the design around the user is an established approach to ensuring the interest of the end user, while Riemer-Reiss (1999) reported an association with negative outcomes for the device usage when the user-

centred design approach was not employed.

The European Commission (2007) has endorsed the use of PCP which promotes the creation of knowledge, ideas and innovations prior to design completion with a view to acting upon them commercially once fully designed (Rolfstam, 2012). Rolfstam (2012) outlines PCP as starting before the traditional cycle of product innovation, that is that the intention and requirements of procurers is stated prior to the innovation cycle and acts as a catalyst. Additionally Rolfstam (2012) reported PCP as featuring the following stages: "solution exploration" where different options are considered, "prototype development" to test out the solutions with the most potential, small scale testing where a single ward may utilise the product followed by commercial roll out.

Due to the nature of PCP, i.e. it is the procurement of a product that does not tangibly exist, there has been some debate over whether or not it can be considered within the demand side of policy (Edquist & Zabala-Iturriagagoitia, 2012), however it is generally considered to belong to this group. The interest of the EU and UK Government in PCP has mirrored the interest within the literature and research arena. Rigby (2013) outlines the merits of engaging PCP in the public sector. Within the healthcare sector, there is the opportunity to test the solutions on a small scale and the opportunity for the product to be designed with usage and setting in mind alongside healthcare professionals right from the beginning. In addition, Rigby (2013) suggests that the use of PCP opens up the market for SMEs.

Some attention in the literature has been on the mechanisms of funding procurement and innovation within the NHS (Grimshaw et al., 2002). The NHS is funded through the Department of Health by the UK taxpayer. Previously, there were several possible routes for provision of financial resources in the NHS (Phillips, Knight, Caldwell & Warrington, 2007) with PCTs responsible for regional care provision being allocated budgets from the DH (Talbot-Smith & Pollock, 2006). The recent abolition PCTs and SHAs means that the NHS is now divided into local and national structures. Clinical Commissioning Groups hold budgetary control and capacity for implementing strategy and policy on a local and regional level as well as ensuring the delivery of quality health and social care in that region. Services are most often commissioned from NHS hospital trusts, but increasingly private companies are also being contracted in to respond to particular care needs (Grimshaw, Vincent & Willmott, 2002).

There are challenging targets for improving efficient NHS budget (NHS, 2012), putting the spotlight on procurement effectiveness. As well as the general drive for cost reduction, there are some recognised factors which hinder innovation. Typically trust funding was based on historical budget use which created difficulties for procuring slightly more expensive but incrementally improved devices (Phillips et al., 2007).

More recently, payment by results has been implemented (Department of Health, 2013) in the NHS. This fixed price approach for clinical interventions is intended to be a rule based, fair and transparent system based on activity for paying providers. Instead of solely allocating budget based on historical use and the cases presented by executives in negotiations, patient choice is enabled and the activity and actual healthcare provided is used to judge how much budget is required. However, when resources are allocated for a particular procedure the emphasis will be on the more economical device or procedure rather than more novel and/or expensive options which may be more effective in terms of long term health outcomes but more costly. All MD firms could encounter difficulties from this approach but smaller firms are likely to have greater difficulty in meeting the costs needed to acquire a good body of evidence in which to build the business case for their products. Furthermore, with smaller production scales and higher cost for top of the line innovation, product costs are likely to be relatively higher for smaller firms, especially early in the product life cycle. There is a disconnection in how to achieve all strategies at once (Sorenson, Drummond & Wilkingson, 2013).

In the English NHS hospitals can apply for innovation payments for medical devices, new drugs or other technologies (Sorenson et al., 2013). While this is a scheme aimed at helping hospital trusts to deliver the strategic policies of increased innovation and innovative procurement, the applications are judged based on clinical evidence of therapeutic benefit of the device and so are aimed not at enhancing innovation as a process but the introduction of specific novel devices. When applying the concepts of this scheme to common SME medical device projects, the nature of the size of the SME, the resources and therefore the ability to generate systematic clinical evidence of the device this scheme fundamentally puts SMEs at a disadvantage. The cost of small scale production for a product that may subsequently require further adjustment and/or may not be purchased following trials and evidence collection can be particularly difficult for an SME to bear.

This review has focused on academic literature sources. Further insights on the policy context based on other sources are presented below.

Methodology

The paper draws on two datasets gathered as part of a wider project researching innovation in the UK healthcare sector. The first dataset on national policies and practices is from documentary sources and participant-observation. The second dataset is a survey of fifteen cases of inter-organizational innovation projects. Since 2011, the first author has engaged

intensively with Department of Health (DH), National Health Service and company personnel, through a secondment at the NHS Technology Adoption Centre, attending trade events and conferences, and data collection activities for the case projects. Data for innovation projects was gathered through a questionnaire completed by most or all project members. Intense negotiations to organize access and interviews to obtain background information on the projects yielded significant insights both on the projects and their local and national contexts. These ‘informational residues’ (Lincoln & Guba, 1985) are important data that help to weave together the national policy and local project perspectives.

Projects had to meet several criteria, being: related to medical devices; current at the start of the fieldwork; to involve people from two or more organizations across the public health and commercial sectors, and including one or more SMEs. With assistance from contacts in the DH and NHS, access was negotiated to fifteen case projects. Seventy-one personnel, mostly from the NHS and SMEs, completed a survey about their project. Most project teams were briefed about the survey by the first author at one of their project meetings. It was usually possible to observe these meetings. Extensive notes were made during all meetings and communication involving the secondment, each project and during networking opportunities. These, together with informal interviews with project leaders, provided detailed contextual knowledge to complement the survey data.

Tab 1 - Overview of Variables and Measurement Approach

Variables	Measurement
Interview and observational data	
Number of responses/ number of members	Number of survey respondents / total number of ‘core members’ in the project team
Diversity/Complexity of collaboration	Based on comparing the 15 case projects. Designated very high when many different organizations and actors involved, and very low when just two parties involved
Push/Pull	Designated “push” if the original idea stemmed from the SME, with later involvement of the NHS in order to achieve the procurement strategy objectives. Designated a “pull” project when NHS called for a solution to a current clinical problem and public funding had attracted the interest from the SME
Collaboration Resource	Resources for the collaboration indicates where funding and/or non-financial resources are coming from. Where Department of Health (DH) or National Health Service (NHS) funding and collaboration has been formally agreed. Some projects do not have formal ties with the NHS or do not receive regular input from the NHS itself (here we mean procurement and innovation specialists), rather the involvement of a single practitioner outside of their NHS duties

Survey data	
Boundedness Stability Interdependence	Together, these measures indicate the extent that the project group functions as a team. Based on 8 items in the survey, derived from Team diagnostic survey (Wageman, Hackman & Lehman, 2005) and required an answer along a 5-point Likert scale. Boundedness 3 items (total score maximum 15) Stability 2 items (total score maximum 10) Interdependence 3 items (total score maximum 15)
Alliance Performance	10 items relating to effectiveness of the alliance, its efficiency and its responsiveness (Robson, Katsikeas & Bello, 2008). Responses given along a 7-Point Likert scale for all 10 questions, with a total score maximum of 70.
Progress	Derived from statements about the progress made so far, whether the group is on track to achieve its aims, whether there is uncertainty regarding meeting timescales, whether the expectations have been exceeded and whether there are barriers preventing desirable progress. 10 items, 7 -Point Likert scale with a total score maximum of 70.
Current State of Project	Based on respondent selecting most appropriate statement from "Completed with full understanding of the outcomes from the project", "Completed and as yet a partial view of the project outcomes", "Imminent completion and confident in expectations of project outcomes" and "Not yet completed and significant uncertainty over project outcomes".

The aim of this paper is to explore the (lack of) alignment between findings from academic research, policy and practice within projects. The approach is an exploratory, multi-level and broad review to identify issues rather than providing in-depth analysis of a limited number of cases. In the first stage of data analysis the overall team means were calculated from individual team members' responses.

Based on these means, project variables were categorised as high, medium and low. Using SPSS, initial non-parametric tests were conducted. To explore relationships between features of the projects and project outcomes, case profiles were ranked by the two performance measurements of Progress and Alliance Performance. The ranked profiles are shown in Table 2. Finally, two post-hoc between subjects ANOVA were performed on the data. The ANOVAs were performed with all independent variables, using progress and alliance performance as separate dependent variables (See Table 1). A significant difference between the project means for alliance performance (dv) was only found with the variable of team interdependence ($F = 17.073$, $df = 2$, $p = 0.006$). This may be due to the limited number of cases.

Findings

Policy and Business Context: Innovation and Procurement in UK Healthcare

Lord Darzi's "High Quality Care for All: NHS Next Stage Final Review" Report (2008) was highly influential, encouraging widespread recognition that innovation is essential if healthcare is to continue to be publicly funded. Darzi argued that the NHS had to lose its reputation as always being a late adopter, and recommended that those involved in NHS procurement "seek to foster a pioneering NHS" [pp. 13]. His report drew attention to innovation's part in an economically sustainable health service, and also to the role of procurement in facilitating innovation. The National Innovation and Procurement Plan (2009) was a response to the warning that the NHS will hit an extreme budget shortfall by 2014 if procurement practices are perpetuated. The Chief Executive of the NHS recommended that more innovative procurement will help to improve the service quality and productivity of the NHS, also contributing to averting this budgetary crisis.

During adoption and procurement processes, MD organizations must demonstrate their innovation cost-effectively meets a direct clinical need. The National Institute for Health and Care Excellence (NICE) is an independent body set up to provide guidance in four areas: technology assessment, clinical, interventional procedure and public health. It is heavily involved in establishing clinical suitability for new devices and technologies. To ensure MDs are cost-effective, regulated and economical, there is a systematic review process for MDs in the UK often involving rigorous testing. MDs must negotiate this process in order to be considered for adoption on a trial basis within a healthcare authority, prior to larger-scale NHS adoption. This process can be lengthy and difficult for all organizations particularly given that conforming to the regulations does not automatically lead to adoption and procurement.

The NHS Innovation Centre (NIC), and the NHS Technology Adoption Centre (NTAC) were established in 2008 and 2007 respectively to support industry with financial and/or clinical resources and guidance through the stages required by the NHS prior to product adoption and procurement. NTAC (disbanded in 2013) provided MD organization, NHS professionals with responsibility for innovation and NHS procurement personnel with guidance and resources, complementing their involvement with NICE with the appropriate advice. NTAC dealt with 'push' projects, where a device was developed and NHS involvement was being sought in order encourage faster adoptions. NTAC did not have sufficient resources to recruit smaller companies at product development stages, focussing on larger companies or those with devices that had already been engaged in testing.

Conversely to NTAC, the NIC (also disbanded in early 2013) provided

funding opportunities, access, advice, support and resources to organizations with 'pull' projects, for which funding was made available to support calls for solving identified clinical problems/needs. A diverse range of calls was issued, encouraging all sizes of organization to vie for these funding opportunities by submitting a proposal or prototype solution. Several bid winners were SMEs, the winner receiving knowledge and expertise, and possible access to adoption on a trial basis. This process necessarily encourages firms to pay closer attention to clinical needs and facilitates conformity to NICE guidelines and regulation. The intention is to reduce the changes required in the prototypes at each stage, so increasing speed of the design process.

Healthcare buyers' purchasing strategies can unintentionally stifle innovation (Phillips et al., 2007). For example, guidance issued to improve healthcare can mean a standard specification for a product is widely adopted, competition becomes based solely on price, and innovation is stifled as potential new entrants are deterred from the market. Buying decisions might mean the market becomes consolidated and a monopoly emerges. Monopoly suppliers have little incentive to innovate. Similarly certain 'good' purchasing practices can lead to SME exclusion from the market, notably the consolidation of demand into fewer, larger contracts which can be too big for SMEs to cope with. These risks are particularly acute in the UK medical sector, with its publicly funded national health service with distributed decision making, and high costs of market entry for device manufacturers.

The Coalition Government SME agenda set out a cross-government plan to engage SMEs in at least 25% of public procurement by 2015, by making public procurement contracts and tenders visible to all, removing any unnecessary obstacles to SMEs and commitment to making more opportunities for SMEs thus opening the market (Her Majesty's Government, 2010; Booth, 2013). The DH has set out an SME Agenda Action Plan (2012) for the Department and the NHS which aims to engage SMEs in procurement at a level of 18%.

The NHS Supply Chain is a partially outsourced enterprise which solely provides a supply chain service to NHS hospital trusts. Many of the medical items required in healthcare can be purchased through the NHS Supply chain, and DHL provide the logistics for delivery. The NHS Supply Chain (2013) announced itself as a champion of SME suppliers of MDs, harnessing the knowledge and unique ideas that can come from entrepreneurial, smaller organizations (Audretsch, 2004). Links with SME industry are being sought out and an understanding of how to nurture these links is being explored by the DH.

Economic pressures on the NHS have continued to rise. The comprehensive Public Spending Review (Her Majesty's Government, 2010) set

a target for the DH to cut spending on procurement by £1.2 billion by 2015 through procurement savings. This, along with the recognition of the perceived impenetrability of the NHS, and the lack of clarity over the remits of the many DH/NHS organizations involved the innovation and procurement of medical devices and technologies, led to the identification that the procurement and adoption processes for all MDs required extensive review and revision. The findings of the Innovation, Health and Wealth Review (Department of Health, 2012) review have led to a major overhaul of the organization of procurement and of innovation facilitation in the DH and NHS. "NHS England will lead further work on efficiency savings from 2015-16 to meet rising demand from an ageing population. As a first step, the Department of Health will publish plans in the summer for an overhaul of NHS procurement that could save up to £1 billion" (HM Treasury, 2013; pp. 28).

In early 2013, NIC and NTAC (amongst others) were closed as part of restructuring the innovation and medical device/technology side of the NHS. At the Healthcare Innovation Exposition (2013), new Academic Health Science Networks (AHSN) were announced. These networks sit regionally and are designed as an easily accessible resource for all types of projects with funding available also. It seems that instead of either championing early involvement (thus directing the innovation to directly apply 'correctly' to the context) or later involvement (thus redirecting once the true innovation has taken place) AHSNs have been designed to encourage both approaches.

Medical Device Innovation Projects

The previous section describes the policy context and national level initiatives to improve innovation and procurement, especially in relation to SMES. In this section a project level perspective on fifteen recent cases of medical device innovation is described. The cases are profiled and contrasted. Though not a random sample, there is considerable diversity among the cases, which enables a critical review of the policy context and projects, as presented in the Discussion and Conclusions section.

Tab. 2 - Profiles of the interorganizational innovation projects, based on qualitative and survey data, ranked by Performance Measures (Alliance Performance and then Progress)

Project Code	Survey Respondents / Core Members	Push / Pull	Collab Resources	Diversity / Complexity	Boundedness		Stability		Interdependence		Alliance Performance		Progress		Current State of Project
					Mean	Category	Mean	Category	Mean	Category	Mean	Category	Mean	Category	
L	5/5	Push	NHS	VHigh	13.40	High	7.00	Med/High	13.20	High	69	High	65.9	High	Completed, full understanding of project outcomes
M	4/4	Push	NHS	Low	13.50	High	9.00	High	13.25	High	68	High	65.5	High	Completed, full understanding of project outcomes
K	3/3	Push	NHS	Low	10.50	High/Medium	8.50	High	11.50	High	66	High	62.5	High	Completed, full understanding of project outcomes
H	2/3	Push	N/A	VHigh	3.57	Low	4.00	Med/Low	5.14	Medium	59	Medium	24.8	VLow	Not yet complete & significant uncertainty over project outcomes
I	4/6	Pull	NHS	High	6.75	Medium	4.50	Medium	7.50	Med/High	57	Medium	41.4	Medium	Imminent completion, confident in expectations of project outcomes
F	4/6	Pull	NHS	High	3.25	Low	5.25	Medium	5.25	Medium	57	Medium	32.6	Low	Not yet complete & significant uncertainty over project outcomes
J	5/8	Pull	NHS & Other	VHigh	12.75	High	5.75	Medium	10.00	Med/High	55	Medium	53.5	Medium	Completed, as yet partial view of project outcomes
D	7/7	Push	N/A	Low	7.67	Medium	5.00	Medium	7.17	Medium	54	Medium	34.5	Low	Imminent completion, confident in expectations of project outcomes
B	6/8	Pull	DH	Low	8.00	Medium	4.80	Med/High	8.40	Medium	46	Medium	62.5	High	Completed, as yet partial view of project outcomes
N	4/4	Push	NHS	Low	14.00	High	5.57	Medium	5.14	Low/Med	45	Medium	37.2	Low	Imminent completion, confident in expectations of project outcomes
G	5/6	Pull	NHS	High	6.20	Low/Medium	7.40	Med/High	7.00	Medium	41	Medium	58.1	Medium	Imminent completion, confident in expectations of project outcomes
O	4/7	Push	NHS	Low	10.00	Medium	3.17	Low	7.00	Medium	32	Low	36	Low	Not yet complete & significant uncertainty over project outcomes
A	5/9	Pull	DH	Low	4.67	Low	3.00	Low/Med	4.00	Low	31	Low	35.8	Low	Not yet complete & significant uncertainty over project outcomes
E	6/8	Push	N/A	Low	4.60	Low	6.00	Medium	4.20	Low	28	v.Low	24.5	VLow	Not yet complete & significant uncertainty over project outcomes
C	7/7	Pull	DH	Low	8.50	Medium	2.75	Low	4.75	Low	24	VLow	38.9	Low	Imminent completion, confident in expectations of project outcomes

A wide range of MD technologies and processes were investigated, including a tracking system for medical equipment records, a suturing device, a wheelchair, an online patient assessment forum, and a scanning device. To help assure high quality data about the functioning of the project group and project success, the identity of the projects studied is confidential. Table 2 profiles the projects according to the variables described in

Table 1. Clearly the small size and selection method of the sample limits what analyses can be conducted. However, by sorting/ranking the cases it is possible to discern some interesting patterns of variation which, at the least, can point to areas for future investigation. These patterns are discussed below.

The variable 'collaboration resource' indicates whether the DH or NHS were involved from an earlier developmental stage. The notion of 'push' vs. 'pull' innovation is useful here, helping to distinguish projects initiated by firms which had invented new products versus new, healthcare applications for existing technologies from projects initiated by healthcare providers. Some products were created as a result of a call through the DH for a design based solution for an identified need (for example Projects A and B). The company applied with its solution and was allocated funding in order to produce a proposal and prototype and subsequently won the bid to move the innovation and development of the project forward. Public resources were also made available in some 'push' projects; many SMEs had applied to NHS bodies which allocated seed funding and other resources in return for a stake in the innovative device, projects I and L are amongst these types of SME project. In some cases firms also involved non-NHS partners, notably university-based academics for their inventions and technical expertise, and small consultancy businesses to help with the business aspects of the projects.

The notion of push vs. pull should not be conflated with consideration of the resources deployed to support the collaboration. Whilst pull projects receive high attention from healthcare providers, push projects may also receive significant resources from the public sector. It is notable that the highest performing projects, both in terms of progress and alliance performance, are 'push' projects with DH/NHS resources, whilst none of the 'push' projects without DH/NHS resources made good progress. SME respondents in the 'push' projects with little/no direct involvement from the NHS and DH for development purposes complained it was difficult to reach the right person, and this had a significant detrimental impact. One 'push' project lead indicated that the process was taking so long that it was generating extreme financial hardship for the company, creating an uncertainty for the future: "I don't know how I'm going to find money for the next bit".

While the NIC's brief was intended to help avoid this situation, many projects and individuals interviewed were disheartened with the perceived impenetrability of the NHS and the seemingly endless process of adoption. Many had not heard of the NIC though they supported the idea of the NHS' active engagement in supporting firms. However, many respondents mentioned the challenges of getting in touch with the 'right' person. "They're trying to bring SMEs in, but the time it takes (and we need to sup-

port ourselves before we get to sell even one unit) is too long; it's biased to the big fish". Some SMEs had difficulty engaging appropriate individuals in dialogue, and in one 'push' project that engagement came later than it should have done – the product development phase was completed but late engagement revealed some basic problems with the technology not effectively meeting the clinical need.

There is no apparent link between the complexity of the project (the number of individual participants, and the number of organizations involved) and alliance performance or project progress. However in the least successful project teams (see Table 2) diversity is low in all of the projects, while there is no discernible pattern amongst the other variables for these projects. Whilst data for projects ranking medium for alliance performance and project progress are less clear, it is notable that projects with low stability, interdependence, and boundedness, also have low alliance performance and low progress. The converse is also true. It was found that the difference between projects (using alliance performance as the dependent variable) was significant for the team interdependence variable.

The data were reviewed further to consider whether the pattern of alliance performance and project progress might be linked to the type of innovation, perhaps varying by the type of technology and the associated product user. No such links were discernible. Indeed, project B and project C have many similarities in terms of technology (product family, user interface), benefits (type and scale of impact on health outcomes), support from DH/NHS and diversity/complexity, and yet they have made very different progress. The difference in outcomes seems to be explained by the team and alliance performance characteristics.

Discussion and Conclusions

Reviewing the evidence from literature and the policy perspective in the UK health sector shows a close alignment between what is advocated in the academic literature and policy makers' efforts to improve innovation, and SME's contribution to innovation. There is widespread recognition of:

- the critical importance of innovation to the economic sustainability of a publicly funded health service.
- how 'good' purchasing practices can have 'bad' outcomes – unintended consequences which are especially detrimental to SMEs. SMEs face disproportionate challenges in selling to the public sector, and these challenges are especially acute for innovative products.
- how difficult it is for all firms, but especially SMEs, to access the right people and resources within the health sector to support the various stages of the innovation cycle.

Academic research on innovation provides evidence of the positive impact on innovation outcomes of effective user engagement and early supplier involvement. Both practices are in evidence and encouraged within the DH/NHS. The NIC developed an extensive on line 'toolbox', to explain the innovation cycle in the NHS context, in which it specifically highlighted user engagement. The NIC, and others, ran competitions to 'pull' innovation to meet specific needs.

At EU and national level, there is growing attention to 'procuring' innovation. Edquist and Zabala-Iturriagoitia (2012) argue however that there is also much confusion around the terminology. They distinguish between public agencies commissioning R&D (which they term pre-commercial procurement) and contracting for solutions to meet specific needs but for which product-process systems have yet to be developed (termed PPI, public procurement for innovation). Forward Commitment Procurement is a form of PPI which is being widely advocated in the UK public sector but, as yet, is not commonplace. Van Meerveld et al (2012) provide an early review of the impact of FCP in selected health sector projects. Their findings suggest that the outcomes are, in general, positive. However one of their recommendations is to consider formalizing cooperative purchasing, to aggregate demand and reduce transaction costs. This runs counter to the interests of SMEs, which already struggle to cope with excessively big contracts.

Four forms of PPI are identified, against two dimensions. PPI can be direct or catalytic, and adaptive or developmental (Edquist and Zabala-Iturriagoitia, 2012). Among the fifteen case projects, there are some where the NHS contributor is a 'local' actor (that is, based within a hospital) (direct PPI) and others where the support is provided by people in central functions (e.g. NIC) (catalytic PPI). Some of the innovations are more radical (developmental PPI) and others are more incremental, adapting a product to the healthcare setting (adaptive PPI). This categorisation fits well in the NHS context, drawing attention to stakeholders in a project and the degree of risk and uncertainty. However, the evidence from the cases described above does not indicate that the form of PPI is significant in explaining the variation in alliance performance or project progress.

Reviewing policy documentation and the initiatives and organizational arrangements established to meet the policies shows clear recognition of the different stages of the technology life cycle. Support is differentiated according to whether the innovation is in early development, adoption or diffusion stages. Policies and initiatives also explicitly recognise that SMEs face particular and greater challenges in engaging with and selling to the health service. The importance to the UK economy of SMEs and the health sector is acknowledged within the remit of the new Academic Health Science Networks – one of their objectives is wealth creation.

We found however no differentiation of SMEs. In some project cases (Table 2), the SME participant is an established firm. The innovation project is intended to add a new product to an existing range. In other projects however the SME member is a start-up firm, and all is focused on the focal product within the innovation project. Whilst both types of firms are likely to suffer severe resource constraints, the stability and longevity of the former type would make it far easier for such firms to engage with bodies such as the ASHNs. Different firms have different capacity and capability to engage with the NHS/DH within projects, and on an on-going basis between projects. The NIC and NTAC both developed processes, networks and resources to support innovation. There were some clear successes, with both organizations presenting sets of case studies to showcase successful innovations. However these types of organizations are also resource constrained, just as SMEs are, and so face the problem of how to scale up their work and influence to achieve a significant impact on the health economy. For example, in the final months of NTAC's operation, policies had to be put in place to prioritise resources as demand for their advice grew.

The new AHSNs shift accountability for innovation in the health service to the regional level. This may improve ease of access for SMEs, and lower costs of engagement with central functions with responsibility for innovation, notably by having a 'one stop shop' for all stages of the innovation cycle. The AHSN's capacity to cope with the scale of the task will presumably depend on them encouraging more NHS people to engage actively in innovation and by fostering local synergies through better coordination. For example, NHS innovation project champions may be able to work more effectively with suppliers which are local, and to coordinate better with and more readily influence local NHS colleagues. The latter stages of the innovation cycle would presumably require ASHNs to develop national coordination processes too.

Two observations from the analysis of the fifteen innovation projects are notable, and worth further consideration in research, and in policy development. First, 'pull' projects are not necessarily successful. Innovation is inherently uncertain and failure may be the appropriate outcome. The lack of success may however reflect some failure in the process which could be remedied. Second, the importance of DH/NHS engagement in 'push' innovation projects is clear. A finer grained understanding of such projects (product type, stage of innovation process, project support, type of SME) could help NHS/DH actors to target their support more effectively. It could also help SMEs to help themselves through a better understanding of the various ways in which they could gain commitment from innovation champions and prospective adopters.

Our review of documentary and primary data concerning policy and practice in innovation in the medical devices sector shows that attention

is being paid to creating an environment that is conducive to innovation, and to supporting the development and adoption of specific technologies or solutions. The adoption of forward commitment procurement and establishment of ASHNs are two particular important 'environment-building' initiatives. Whilst they add opportunity, they however also add complexity to the innovation environment. Specific FCP calls and other competitive calls are examples of efforts to encourage innovation of devices and other health technologies. How well these have, and will, support SME participation in the sector is not clear. The costs of sustained engagement are high, and small firms may need to partner with others to compete, and to use intermediaries such as trade associations and Chambers of Commerce to engage with health networks.

In contrast to the environment and the technology level, there is less evidence of attention to supporting SMEs operating within the MD sector, focusing on sustaining innovation and innovativeness in the longer term, and not just support in relation to a specific technology. Companies have to engage with many different stakeholders. Whilst there may be stability in terms of who to work with in medical disciplines, the management arrangements of healthcare providers and related specialist organizations continue to experience frequent, radical change. The impact on firms is greater the smaller and 'younger' they are, and yet policy measures do not seem to differentiate between SME firms.

Finally, the analysis summarised in Table 2 presents a further possible point of intervention which, it seems, is not yet recognised and addressed by policy measures. Using constructs and measures from organizational psychology team literature, the survey of the fifteen cases highlights collaborative arrangements (including boundedness, stability, interdependence) within interorganizational innovation projects. There is a considerable body of research on collaboration and partnerships within and between the public and private sectors. This could usefully be extended to interorganizational innovation projects to help SME and NHS/DH managers within projects and those responsible for facilitating innovation improve the likelihood of project success, better health outcomes and SME prosperity.

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Abstract

Healthcare providers are under ever increasing pressure to deliver more technologically advanced care without increasing costs. Innovation is essential (Darzi, 2008), and for this healthcare providers rely on innovation within commercial companies. SMEs have an important part to play in this sector (NHS Supply Chain Parliamentary Brief, 2013). Collaboration between SME suppliers and the NHS for innovation forms the focus of this paper. We examine the academic literature on interorganizational innovation including academic insights from the areas of forward commitment procurement (Environmental Innovation Advisory Group, 2003-2008), pre-commercial procurement (Bos & Corvers, 2007), innovation and SMEs. We then explore practice, first from a policy and business sector perspective. Second, we present evidence from fifteen cases of interorganizational innovation projects involving SMEs and UK healthcare providers. Our findings show much effort is being put into creating opportunities for more interorganizational innovation of medical devices. Working across organizational boundaries presents added complexity to the innovation environment and process, and the challenge of developing high-quality cross-boundary group interaction.

Riassunto

Le organizzazioni che producono cure mediche affrontano oggi una crescente pressione verso una maggiore innovazione tecnologica a parità di costo del servizio. Poiché l'innovazione è cruciale (Darzi, 2008), queste organizzazioni si appoggiano alla capacità di innovare delle imprese commerciali ed in particolare delle PMI, che hanno un ruolo importante da giocare in questo ambito (NHS Supply Chain Parliamentary Brief, 2013). Il focus di questo lavoro è la collaborazione tra PMI e il National Health Service (NHS) britannico nella realizzazione di innovazione in sanità. Esaminiamo la letteratura accademica sull'innovazione tra organizzazioni, includendo le prospettive che sono emerse in diversi filoni, quali le richieste di manifestazione di interesse (Environmental Innovation Advisory Group, 2003-2008), il pre-commercial procurement (Bos & Corvers, 2007) e l'innovazione nelle PMI. Esploriamo poi la pratica dell'innovazione inter-organizzativa, prima da una prospettiva di policy e poi dalla prospettiva business. In secondo luogo, presentiamo una serie di casi di innovazione inter-organizzativa che coinvolgono PMI da un lato e organizzazioni che producono cure mediche dall'altro. I nostri risultati dimostrano che un forte livello di impegno è presente nel Regno Unito per creare innovazione nei dispositivi medici attraverso collaborazioni inter-organizzative. Tuttavia, il coordinamento tra organizzazioni diverse aggiunge complessità all'ambiente e ai processi di innovazione, ponendo quindi la sfida di realizzare interazioni di alto profilo tra organizzazioni diverse.

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