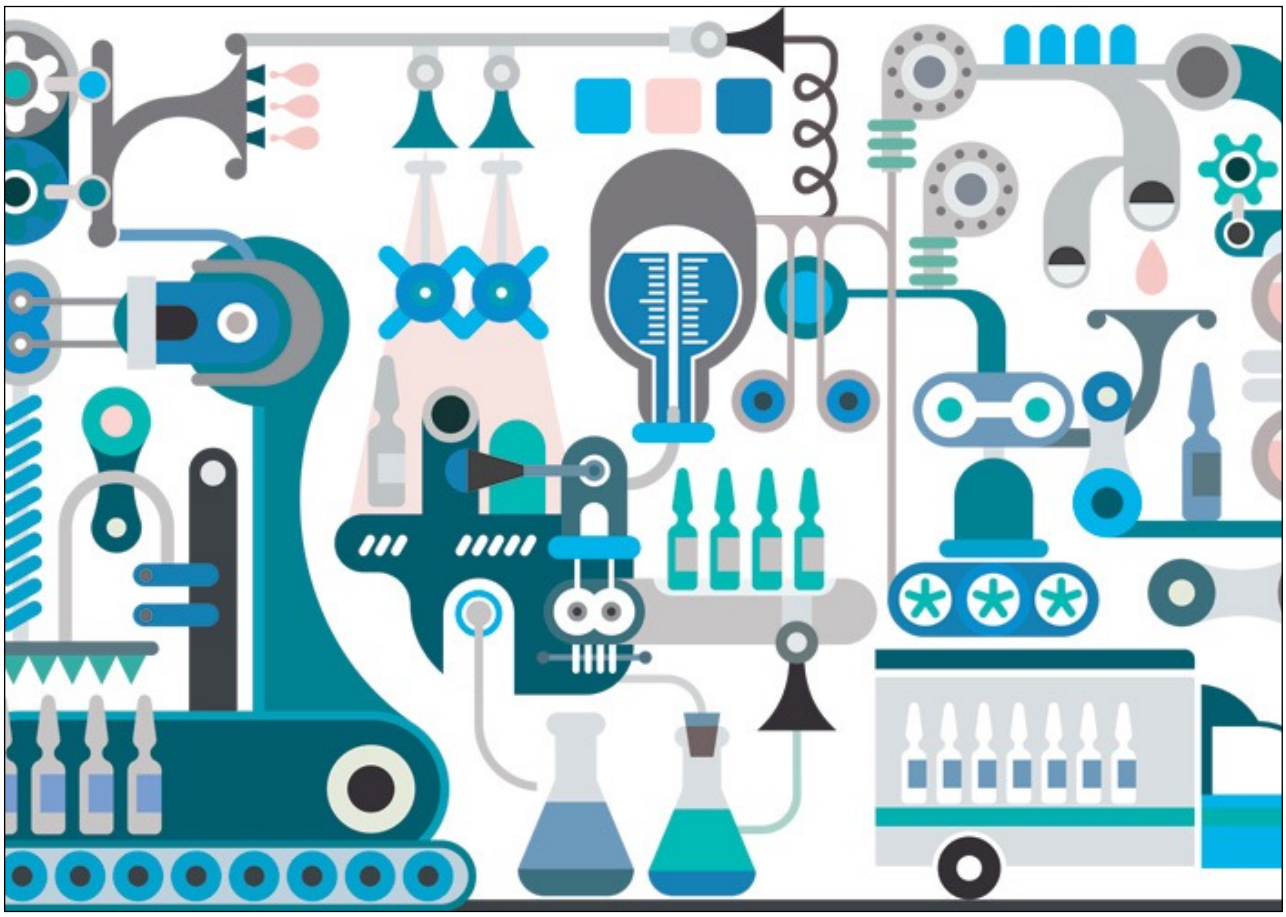
Hub & Spoke

Evidence-Based Policy Review

National Pharmacy Association - March 2016



Lead authors:
Mike Hewitson MPharm (Hons) MRPharmS
Gareth Jones BPharm (Hons), MRPharmS, DipPharmPrac

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1.1 About Us

The National Pharmacy Association (NPA) is a Trade Association which represents the interests of independent community pharmacy owners, covering 3,500 organisations and 6,600 pharmacies. Our members range from single site to large multi-site organisations, and are largely Small and Medium Enterprises (SME) under the UK Government definition, although some are larger. Our Association, established in 1921 is run by its members, which are practising community pharmacists through a Board of Management which is responsible for policy and representation.

We are a member of Pharmacy Voice, an umbrella body which represents all Trade Associations in our Sector.

1.2 The Role of the NPA

As a Trade Association the NPA has a duty of care to its members to understand the impact of Government policy on members interests and by extension to the impact on their patients and the public by virtue of member's professional obligations. The Office of Fair Trading broadly defines some Trade Association activities as[1]:

- representing to Government, the European Commission and other public bodies the interests of members on legislation, regulations, taxation and policy matters likely to affect them.
- promoting and protecting the interests of members in the media.
- collecting and disseminating statistics and market information and information about legislation and Government policy.
- promoting standards, codes of practice or standard terms and conditions of sale.
- providing a range of services of an advisory or consultancy nature on, for example, legal, accounting, training and environmental matters.
- providing advice of a more commercial nature.

Our Memorandum of Association lists representation as one of the principal objectives of the NPA[2]. This can be directly or via Pharmacy Voice, our umbrella organisation for other community pharmacy trade bodies.

[1] Understanding Competition Law, 2004. Office of Fair Trading. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284404/oft408.pdf Accessed 11/02/16

[2] Memorandum of Association, 26/06/13. National Pharmacy Association.

2.1 Executive Summary

Key Findings

- **Inter-company Hub & Spoke could result in serious unintended consequences, including inflationary pressures on medicines costs for the taxpayer, due to reduced competition and choice in the pharmaceutical wholesale/Hub market.**
- **Although Hub & Spoke could provide capacity to deliver more healthcare services through community pharmacy, the system is complex with a number of implementation problems, including the EU Falsified Medicines Directive and other professional and legal challenges.**
- **There is currently no basis for claims that Hub & Spoke will allow pharmacies to reduce their operating costs.**
- **We make key recommendations which will enable Hub & Spoke technology to operate more safely and effectively for those who wish to use it.**

Introduction

Diversity and innovation are key strengths of the independent community pharmacy sector. NPA members have given a mixed response to Department of Health proposals to allow all community pharmacy operators the choice to assemble medicines off-site by a third party. The National Pharmacy Association undertook an evidence based policy review to understand the opportunity and risks, barriers and enablers associated with the proposed change.

Methodology

An expert Task & Finish Group, consisting mainly of practicing community pharmacists, was convened to examine the evidence and consider the implications for practice. They considered:

- An NPA Member Consultation. 416 responses covering more than 1,000 pharmacies were received.
- Independent Literature Review performed by a leading academic at the University of Manchester.
- Expert witness programme featuring more than 20 leaders in this field. The expert witnesses provided experience from inside and outside the pharmacy sector, and from the UK and elsewhere in Europe.

The Group sought to understand:

- Terminology & modelling.
- Benefits to capacity, cost efficiency and safety.
- Cost implications for independent community pharmacy operators.
- Impact on medicines supply chain, patients & the public and legal & professional concerns.

Key Recommendations & Summary

The Group examined the subject matter in a fair and robust way, seeking to address issues holistically from the perspective of NPA members (the vast majority of whom are SMEs). We found some capacity benefit but no overall cost savings from Hub & Spoke, as well as a range of negative issues such as medicines waste, which could affect the viability of the model for members. We want to be clear that Hub & Spoke within the same legal entity is a very different proposition to an inter-company model, which has a different business case and commercial and professional considerations.

The task and finish group drew the following conclusions:

- Supporting service delivery:
    1. The Department of Health should commit to a new national clinical service such as Pharmacy First which would utilise additional capacity created by Hub & Spoke and give SMEs an incentive to invest.
    2. Policy commitments from Government would help with the uptake and implementation of Hub & Spoke: Original Pack Dispensing and greater use of electronic Repeat Dispensing are two prime examples.

- Supporting competition and choice for the provision of Hub services:
    3. Government must prevent restrictive distribution practices such as Direct to Pharmacy, Reduce Wholesale and quotas - or these schemes could act as a barrier to entry for a range of potential Hub providers.
    4. A set of national standards & KPIs should be developed for Hubs, to complement and enhance the GPhC inspection regime providing quality assurance and due diligence for SME customers to make free, fair and informed choices about Hub providers.

- Supporting constructive dialogue:
    5. Government should engage with the concerns of the SME sector, especially around the risks to procurement which has delivered more than £10bn savings for the taxpayer since 2005.
    6. The National Pharmacy Association should act as a constructive, but critical partner for stakeholders wishing to develop Hub & Spoke services for our members.

- Supporting members:
    7. The NPA should provide impartial advice and guidance to members wishing to pursue a Hub & Spoke model.
    8. The NPA should seek legal advice about the compatibility of pharmacy processes, including the provision of MDS and the EU Falsified Medicines Directive, with Hub and Spoke.
    9. The NPA should continue to monitor the economic and financial case for Hub & Spoke which will develop as the market forms.

3.1 Introduction

In October 2015, Rt Hon. Alistair Burt MP, Minister of State for Care and Support announced his intention to create a 'level-playing field' for all pharmacy operations to make use of off-site dispensing technology, otherwise known as Hub & Spoke[3]. To enable this, he has announced his intention to consult on changes to Section 10 Medicine Act, 1968 and Human Medicines Regulations 2012 which current restrict assembly of medicines for patients to the same legal entity. On 17th December 2015, Department of Health wrote an open letter to Pharmaceutical Service Negotiating Committee (PSNC) detailing a number of changes it would like to explore in connection with the provision of Community Pharmacy Services, these included the use of Large Scale Automated Dispensing, which can include Hub & Spoke technology and also Centralised Dispensing[4]. The letter stated "this could help pharmacies to lower operating costs and free up pharmacists to provide more clinical services and public health services". As a Trade Association representing 3,500 organisations, we have a duty of care to understand the technology and implications of UK Government intentions, especially with respect to SMEs.

Hub & Spoke is not a new concept, the first documented system in the UK was in Norwich in 2006[5], several large organisations have trialled operations of varying scales and levels of complexity. Prescription assembly must take place within the same legal entity under the current legal and Regulatory framework[6]. The Chief Pharmaceutical Officer, Dr Keith Ridge CBE clarified on 27th January 2016 that the Government wishes to "open (sic) up the option of Hub & Spoke to those who cannot currently access it"[7].

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[3] Government to consult on legal changes to permit widespread centralised dispensing. The Pharmaceutical Journal, Vol 295, No 7882, online | DOI: 10.1211/PJ.2015.20069571

[4] Community Pharmacy 2016/17 and Beyond. Department of Health & NHS England.

[5] Wright, M. How a central dispensary can improve patient care in community pharmacies. Pharmaceutical Journal 2006;276:720.

[6] Medicines Act, 1968. Section 10 (1) (b) (i) http://www.legislation.gov.uk/ukpga/1968/67/section/10 Accessed 11/02/16.

[7] Community Pharmacy 2016/17 and Beyond, a Foreword by Keith Ridge, Chief Pharmaceutical Officer. Department of Health & NHS England.

Terminology

This document uses a number of working definitions to ensure consistency and clarity.

Large Scale Automated Dispensing - an umbrella term used in the 17th December letter which encompasses two separate and distinct concepts: Hub & Spoke and Centralised Dispensing.

Hub & Spoke - Prescriptions are assembled in a central Hub before distribution to local 'Spokes' for onward distribution to the patient (this may include home delivery). Both the Hub & Spokes are Registered Pharmacies.

Centralised Dispensing - Prescriptions are dispensed at a central location and are sent either directly to the patient, or to a remote collection point, which may or may not be a pharmacy.

Assembly - The assembly of medicines against a prescription is controlled by Section 10 of the Medicines Act 1968. In relation to a medicinal product 'assembly' is defined by the Act as: enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied, or, where the product (with or without other medicinal products of the same description) is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it[8].

Short-Line Wholesaler - A wholesaler which concentrates on generics and fast moving products[9]. We also refer to this type of operation as a Regional Wholesaler.

Full-line wholesaler – A wholesaler which can supply the full range of products in the market. All pharmacies must contract with at least two of the three full-line wholesalers to access branded medicine supplied under limited distribution arrangements.

Monitored Dosage Systems (MDS) - A storage device containing a patient's regular medicines designed to improve compliance.

Buying group – A group of pharmacy owners that join together to negotiate with suppliers – leveraging their size as a collective to achieve higher discounts.

[8] Guidance for Responsible Pharmacists. General Pharmaceutical Council, 2010.

[9] Jargon Buster. AAH Pharmaceuticals. Accessed 13/02/16

3.2 Objectives

- Understand and agree consistent terminology.
- To take a holistic approach towards the issue of Hub & Spoke and understand the implications for NPA Members:
    - Strategic,
    - Economic,
    - Operational,
    - Financial.
- Understand how inter-company assembly of prescriptions impacts on professional practice, including the impact on patients and the public.
- Some organisations have a decade of experience in the deployment of the Hub & Spoke concept and associated technology. There is very little information in the SME sector, we will seek to reduce or close this information gap. This includes a review of published literature, and all other relevant evidence.

3.3 Our Approach

At its November 2015 Board Meeting, the NPA Board resolved to establish a Task & Finish (T&F) Group to examine the issue of Hub & Spoke with the above objectives. Membership of the group was dynamic, allowing for a broad base of opinions, experience and skills. Full biographies of the T&F Group members are included in Appendix 1.

The Task & Finish Group met three times during January & February 2016 in Manchester. A range of expert speakers and witnesses were invited to these meetings to give evidence on different aspects of Hub & Spoke. Members of the T&F Group were able to ask questions to help understand issues or clarify understanding. In addition to face to face sessions, evidence was submitted in the form of written submissions, video demonstrations and audio interviews.

In addition to the witnesses listed, we commissioned an independent literature review by Dr Ellen Schafheutle of Manchester University. A Member Consultation was also conducted to understand their attitudes towards the Hub & Spoke concept, this was accompanied by a video from the Chair of the group, and a briefing document. Full analysis can be found in the main body of this document.

Witness Programme

Name	Experience
Dr Richard Brown	Chief Officer, Avon LPC & BRR Consulting. Involved in development and deployment of Hub & Spoke for a national multiple. Oral evidence.
Dr Omar Shakoor	Pharmaceutical Services Director, Mawdsleys Brooks - pharmaceutical wholesaler. Oral evidence & group discussion.
Drew Warner	Project Manager, NPA. Former Network Change Manager at Dx, previously worked with City Link - logistics expert. Oral evidence.
Remy Croese	International Sales Manager at VMI Care - MDS automation supplier. Oral evidence.
Dr Ellen Schafheutle	Senior Lecturer in Law and Professionalism at University of Manchester & Director Centre for Pharmacy Workforce Studies. Literature review. Oral evidence & group discussion.
Fin McCaul	Pharmacist & Consultant to NPA Board, former Chairman of Independent Pharmacy Federation. Oral evidence & group discussion.
Chris Brooker	Consultant to Keith Ridge, and former advisor to Mawdsley Brooks. Oral evidence.
Cormac Tobin	Managing Director, Celesio UK. Q&A at Celesio Prescription Assembly Solutions Hub.
Chris Frost	Sales Director, AAH Pharmaceuticals. Q&A at Celesio Prescription Assembly Solutions Hub.
David Vanns	Director of Operations at HI Weldrick Ltd - medium pharmacy group operating a Hub & Spoke model. Written submission.
Dr Bharat Shah	Director at Sigma Pharmaceuticals - independent wholesaler. Oral evidence. Oral evidence.
Leyla Hannbeck	Chief Pharmacist, NPA. Relaying experience of Centralised Dispensing in Sweden. Oral evidence.
David Simons	Interim Chief Executive, NPA. Experience of Shop Direct Group. Oral evidence.
Noel Wardle	Solicitor Charles Russell Speechlys. Legal risks associated with Hub & Spoke. Oral evidence.
Andy Beesley	Medication Management Solutions. MDS automation technology supplier. Oral evidence.
Paul Mayberry	Managing Director, Mayberry Pharmacy Ltd. NPA Member currently operating a Hub & Spoke model in South Wales. Audio interview.
Willach Pharmacy Solutions	Manufacturer of automation and Hub & Spoke technology. Video of Dutch Hub & Spoke solution.
Jay Patel	Chief Innovation Officer, & Director. Day Lewis PLC. Written submission.

Name	Experience
Mike Dent	Director of Pharmacy Funding, PSNC. Ad hoc advice on cost modelling.
Glyn Walduck	Head of Claims, NPA Insurance. Ad hoc advice on insurance and accountability issues.

As part of the original press release to the trade media, an open call for evidence was made. A number of additional parties were also contacted to provide evidence:

- Dr Keith Ridge, Chief Pharmaceutical Officer
- Dr Will Cavendish, Director-General for Innovation, Growth & Technology NHS England
- A large pharmacy group
- Royal Pharmaceutical Society (currently reviewing position).

3.4 Member Consultation

NPA ran an online survey for two months between 11th December 2015 and 12th February 2016. The survey was accompanied by an explanatory video from the Chair of the Task & Finish Group, and a briefing paper to familiarise members with the terminology and concept. The survey was publicised via a number of channels, and resulted in a total of 416 responses, from members of all sizes and types, we believe that this is the largest sample of pharmacy owners opinions of the Hub & Spoke concept, and covers more than 1000 individual pharmacies.

Dr Ellen Schafheutle assisted with statistical analysis. Analysis was performed by NPA member segment, for further analysis 3 (11-100 branches) and 4 (100+ branches) were combined. Missing data are excluded in any cross-tabulation and related chi square analysis.

Pharmacy type – branch numbers

	n	%
Segment 1: Single independent	215	61.6
Segment 2: 2-10 branches	105	30.1
Segment 3: 11-100 branches	27	7.7
Segment 4: 100+ branches	2	0.6
Total	349	

Missing: 67 (16.1%)

It must be understood that these results reflect not only members initial concerns about a poorly defined concept, but also a reaction to the Department of Health/NHS England letter which was published days after the survey went live, and was a constant backdrop to members concerns.

Number of branches vs. positive/ negative attitude towards Hub & Spoke

	Single independent	2-10 branches	11+ branches	Total
Negative attitude towards Hub & Spoke	**135 (63.7%)**	51 (49.0%)	5 (17.2%)	191 (55.4%)
Positive attitude towards Hub & Spoke	77 (36.3%)	53 (51.0%)	**24 (82.8%)**	154 (44.6%)
Total	212	104	29	345

$X^2 = 24.670$; $p \leq 0.005$

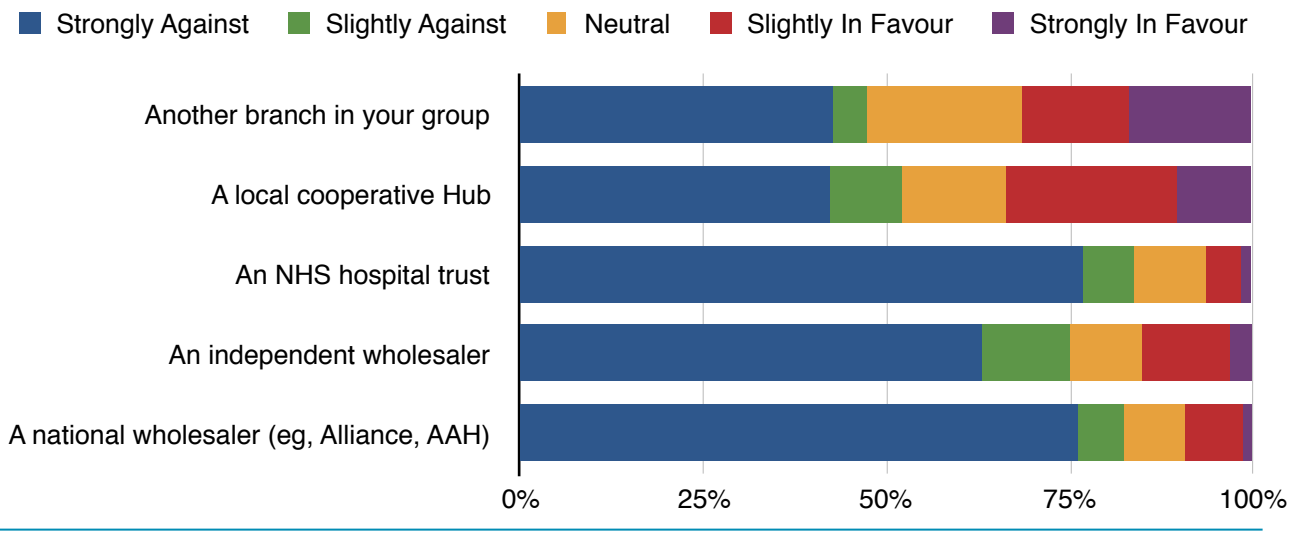
A clear relationship is observed between organisation size and their attitude (positive or negative) towards Hub & Spoke. Single independents are of particular interest because it is this group which the Government claims to be acting for in opening up the opportunity for cross-company Hub & Spoke.

Number of branches vs. positive/ negative attitude towards Hub & Spoke – detail

	Single independent	2-10 branches	11+ branches	Total
1 Never under any circumstances	**135 (63.4%)**	51 (48.6%)	5 (17.2%)	191 (55.0%)
2 Not at the moment, but might consider in the future	69 (32.4%)	44 (41.9%)	**15 (51.7%)**	128 (36.9%)
3 We are in the planning stages	3 (1.4%)	6 (5.7%)	4 (13.8%)	13 (3.7%)
4 We are currently operating a Hub & Spoke system	5 (2.4%)	3 (2.9%)	5 (17.2%)	13 (3.7%)
5 We have trialled but removed a Hub & Spoke system	1 (0.5%)	1 (1.0%)	0 (0)	2 (0.6%)

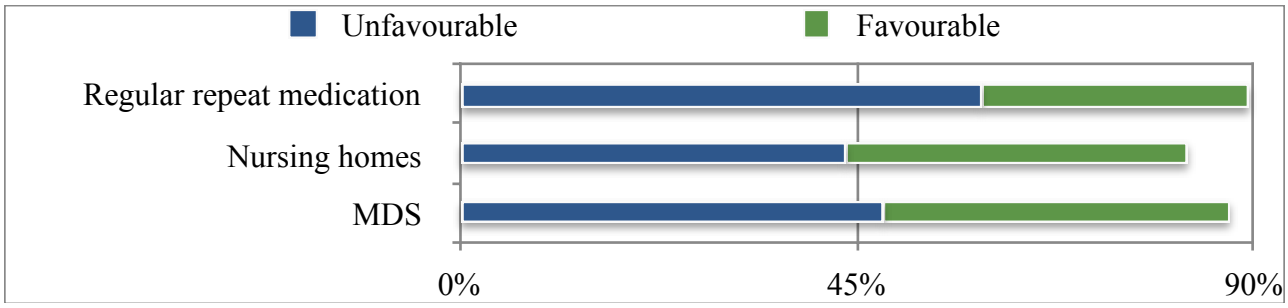
Members were asked about their preparedness for Hub & Spoke, unsurprisingly there was a high degree of resistance from small independents.

Members were asked about a range of Hub providers and how strongly they would favour each model. Overwhelmingly NPA members of all sizes were against National Wholesaler backed models, and NHS Trusts, but were less opposed to branches within the



same company (which would be allowed under current arrangements) or local co-operative Hubs.

When asked about workload shift, from a Spoke to a Hub, members were most opposed to moving regular repeat medication, and less opposed to the other options - MDS and Nursing Homes. In the graph below, neutrals were factored out.



Further analysis of this data revealed correlations between organisational size and attitude towards shifting two aspects of workload - nursing homes and MDS. Small independents are most opposed to shifting work than larger organisations.

Nursing homes depending on pharmacy type

	Single independent	**2-10 branches**	**11+ branches**	**Total**
1 Disagree	**102 (51.3%)**	39 (37.9%)	5 (17.2%)	146 (44.1%)
2 Neither disagree nor agree	34 (17.1%)	24 (23.3%)	5 (17.2%)	63 (19.0%)
3 Agree	63 (31.7%)	40 (38.8%)	**19 (65.5%)**	122 (36.90%)
Total	199	103	29	

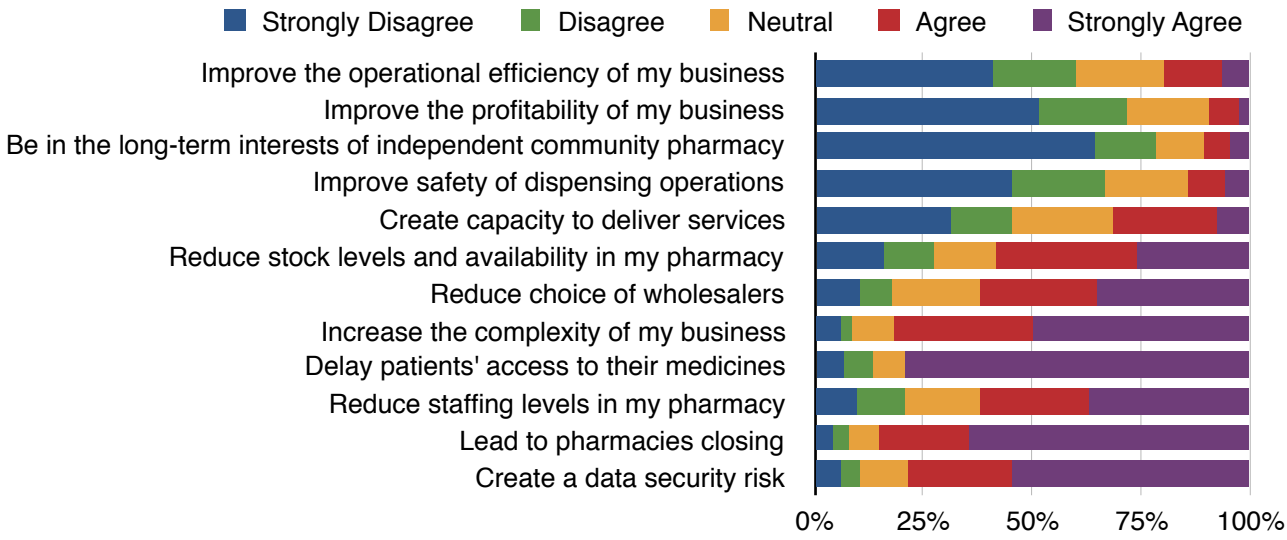
X^2= 17.424; p=0.002

MDS by pharmacy type

	Single independent	**2-10 branches**	**11+ branches**	**Total**
1 Disagree	**114 (53.3%)**	47 (45.6%)	7 (21.1%)	168 (48.6%)
2 Neither disagree nor agree	29 (13.6%)	14 (13.6%)	4 (13.8%)	47 (13.6%)
3 Agree	71 (33.2%)	42 (40.8%)	**18 (62.1%)**	131 (37.9%)
Total	214	103	29	346

X^2= 10.683; p=0.030

Members were asked a series of questions about the benefits and risks of Hub & Spoke. A number of significant relationships were observed between organisation size and attitudes towards Hub & Spoke.



Improve the operational efficiency of my business by pharmacy type

	Single independent	2-10 branches	11+ branches	Total
1 Disagree	**145 (67.4%)**	61 (58.1%)	8 (27.6%)	214 (61.3%)
2 Neither disagree nor agree	44 (20.5%)	20 (19.0%)	11 (37.9%)	75 (21.5%)
3 Agree	26 (12.1%)	24 (22.9%)	**10 (34.5%)**	60 (17.2%)
Total	215	105	29	349

$X^2 = 21.173$; $p \leq 0.001$

Improve the profitability of my business by pharmacy type

	Single independent	2-10 branches	11+ branches	Total
1 Disagree	**172 (80.0%)**	**73 (69.5%)**	**12 (41.4%)**	257 (73.6%)
2 Neither disagree nor agree	29 (13.5%)	22 (21.0%)	**13 (44.8%)**	64 (18.3%)
3 Agree	14 (6.5%)	10 (9.5%)	4 (13.8%)	28 (8.0%)
Total	215	105	29	349

$X^2 = 21.877$; $p \leq 0.001$

Be in the long-term interests of independent community pharmacy by pharmacy type

	Single independent	2-10 branches	11+ branches	Total
1 Disagree	**184 (85.6%)**	**80 (76.2%)**	**18 (64.3%)**	282 (81.0%)
2 Neither disagree nor agree	15 (7.0%)	13 (12.4%)	4 (14.3%)	32 (9.2%)
3 Agree	16 (7.4%)	12 (11.4%)	6 (21.4%)	34 (9.8%)
Total	215	105	28	348

X^2= 10.304; p=0.036

Members of all sizes appear to agree that Hub & Spoke is unlikely to be in the long term interests of independent pharmacy.

Improve safety of dispensing operations by pharmacy type

	Single independent	2-10 branches	11+ branches	Total
1 Disagree	**150 (70.1%)**	**77 (73.3%)**	**11 (37.9%)**	238 (68.4%)
2 Neither disagree nor agree	46 (21.5%)	12 (11.4%)	**9 (31.0%)**	67 (19.3%)
3 Agree	18 (8.4%)	16 (15.2%)	**9 (31.0%)**	43 (12.4%)
Total	214	105	29	348

X^2= 21.978; p≤0.001

Agreement across all membership sizes show a degree of skepticism towards claims that Hub & Spoke will improve safety of dispensing operations.

Create capacity to deliver services by pharmacy type

	Single independent	2-10 branches	11+ branches	Total
1 Disagree	**107 (50.0%)**	**45 (42.9%)**	7 (24.1%)	159 (45.7%)
2 Neither disagree nor agree	52 (24.3%)	27 (25.7%)	5 (17.2%)	84 (24.1%)
3 Agree	55 (25.7%)	33 (31.4%)	**17 (58.6%)**	105 (30.2%)
Total	214	105	29	348

X^2= 13.936; p=0.008

Finally members were asked about the impact of Hub & Spoke on three groups:

- patients
- their pharmacy business
- the pharmacy network.

Patients by pharmacy type

	Single independent	2-10 branches	11+ branches	Total
1 Negative	**185 (88.5%)**	**88 (83.8%)**	18 (69.2%)	291 (85.6%)
2 Neutral or positive	24 (11.5%)	17 (16.2%)	**8 (30.8%)**	49 (14.4%)
Total	209	105	26	340

X^2= 7.362; p=0.025

My pharmacy company by pharmacy type

	Single independent	2-10 branches	11+ branches	Total
1 Negative	**189 (89.2%)**	83 (79.0%)	**16 (57.1%)**	288 (83.5%)
2 Neutral or positive	23 (10.8%)	22 (21.0%)	12 (42.9%)	57 (16.5%)
Total	212	105	28	345

X^2= 20.521; p≤0.005

The community pharmacy network overall by pharmacy type

	Single independent	2-10 branches	11+ branches	Total
1 Negative	**195 (91.1%)**	93 (88.6%)	**20 (71.4%)**	308 (88.8%)
2 Neutral or positive	19 (8.9%)	12 (11.4%)	8 (28.6.9%)	39 (11.2%)
Total	214	105	28	347

X^2= 9.631; p=0.008

3.5 Modelling

There are several different models of Hub & Spoke provision. We have used a consistent definition of a true Hub & Spoke model as consisting of a Spoke which is a Registered Pharmacy with an NHS contract, and a Hub which is a Registered Pharmacy (which may or may not have an NHS contract), but there are a number of options in terms of who may provide the Hub service.

Option 1 - Vertically integrated provider (VIP). This is typically a large multiple such as Boots or Lloydspharmacy which has its own wholesale & logistics operation.

Option 2 - Regional wholesaler. This would likely require a company with its own logistics infrastructure, which would not have to rely on third party couriers for delivery[10].

Option 3 - Co-operative. Using a consortia approach several providers can join together to either create a new Registered Pharmacy to use as a Hub, or can use an existing pharmacy in a Peer to Peer approach.

Exclusions - Other options such as NHS Foundation Trusts as providers are possible, but were not considered in any detail. As Hub & Spoke is currently allowed within the same legal entity, we did not consider companies providing Hub services from their own facility, although we did take evidence from an NPA member, Paul Mayberry who has operated his own Hub for a number of years. The Centralised Dispensing model where prescriptions are sent directly to a patient from a Registered Pharmacy acting as a Hub is also out of scope because it is not a true Hub & Spoke model.

Buying Groups could be a further group of providers, but these could fall into any of the three options defined above.

The focus of the Task & Finish Group was on issues arising from inter-company assembly of prescriptions.

Each of the above options has its own pros and cons, which we will consider briefly in the table overleaf.

[10] Shah B. Oral Evidence to Task & Finish Group. 08/02/16

Option	Pros	Cons
Vertically Integrated Provider	- Extensive knowledge and technical capability. - Existing logistics infrastructure. - Economies of scale. - Understand risks. - Readiness. - Some risks can be managed contractually e.g. data. - Consistency. - Safety	- Systemic & individual impact on procurement. - Open to manipulation of Contractual Funding. - Asymmetric relationship. - Unacceptable to large number of NPA members. - Potential reduction of competition in wholesale market. - Lack of resilience if small number of Hubs. - Turnaround times. - Locked in to other services?
Regional Wholesaler	- Flexibility. - Potentially lower cost. - Closer to the customer - faster turnaround time? - Smaller impact on procurement. - Generates competition for Hub services.	- Need RW with own logistics channel (not open to all RWs). - Technical knowledge & capability. - Regionality - equity of access across country? - Variability. - Understanding of professional risks? - Lack of resilience. - Unacceptable to many NPA members. - Reduce viability of Buying Groups?
Co-operative	- No systemic impact on procurement. - Most acceptable option to NPA members. - Could be very local option - faster turnaround times? - Flexibility. - Tax benefits via Enterprise Investment Scheme. - Could use existing local capacity e.g. large pharmacy with robotics. - Could work well in urban centres.	- Technical knowledge & capability. - New logistics infrastructure likely. - Small economies of scale. - Understanding of professional risks? - Regionality - equity of access across country. - Variability - more difficult to manage & control risks. - Readiness? 12 - 24 months minimum. - Remote & rural operations unlikely. - Local competition & trust. - Safety?

This list is based on evidence given to the T&F Group by a number of witnesses, from discussions between the Group, the NPA Member Consultation and the Literature Review.

We express no opinion at this stage on the preference of an individual model, risks and benefits are discussed later in this document.

3.6 Operational Impact

Several witnesses gave evidence on the impact of Hub & Spoke on the operation of a pharmacy. This list is not intended to be exhaustive, but is indicative of some of the benefits and drawbacks of a Hub & Spoke model, and is written from the perspective of the Spoke pharmacy.

The model below was adapted from Slack, et al. Five strategic performance objectives[11].

Quality	• May improve accuracy of dispensing process. • Could improve safety or capacity of space constrained pharmacies. • Could introduce new process risks. • Could increase capacity at Spoke for service delivery & quality improvement. • 'Ownership' of problems can be left in limbo between Hub & Spoke. • Staff engagement with change process important.
Speed	• Patients will have to wait longer for prescriptions. • Impact could be variable - dependent on geography. • Track & trace of prescriptions in process could become more complicated.
Cost	• Will introduce new costs, with few offsets. • Cost of Hub service. • Impact on procurement margin. • Training. • Obtain & record patient consent. • Change of process - creating inefficiencies during transition. • Could increase medicines prices & service costs. • IT upgrades may be required. • Due diligence on Hub providers - including legal costs to check contract terms & conditions. • May require increased storage for prescriptions.
Dependability	• Small number of Hubs could decrease system resilience. • Reduced stock levels could increase supply disruption. • Heavily reliant on IT infrastructure. • Heavily reliant on logistics infrastructure. • Could provide additional on-demand capacity for pharmacies affected by staff shortages, sickness, holiday, etc.
Flexibility	• Restrictive Distribution Practices e.g. DTP, Reduced Wholesale Agreements barrier to providers - reducing flexibility. • Large providers offer less flexibility than small providers. • Could make it more difficult to change wholesalers and PMR suppliers. • Increase in business complexity which could reduce the opportunity for ad-hoc variation.

[11] Slack N, et al. Five strategic performance objectives. Operations Management, fifth edition, 2007. Harlow. FT Prentice Hall.

3.7 Understanding the Opportunity

Positive impacts of Hub & Spoke have been claimed in a few broad categories[12]:

1. Free capacity to deliver more services.
2. Delivery of operational efficiencies.
3. Improved safety of dispensing operations.

We set out to understand the supporting evidence for these claims.

Capacity to deliver services

We began our first evidence session with Dr Richard Brown, who had been involved in the development and deployment of a Hub & Spoke operation with a national pharmacy operator. From his experience he felt that it was possible to increase capacity to deliver more services, and to improve customer service using a Hub & Spoke model[13]. Dr Brown highlighted three areas which were important to patients/customers when choosing a pharmacy:

1. Waiting times.
2. Availability of product.
3. Provision of advice.

In branches where waiting times were already high, because of capacity constraints (both physical and human), it is possible to move planned work off-site for assembly - this helps to reduce waiting times for patients who need medicines more quickly[14]. In addition, Dr Brown had direct experience of pharmacies operating a Hub & Spoke model increasing their prescription volume as a result of the extra capacity and time with patients it could create[15], although a member of the group questioned whether prescription volumes could continue to rise against a stated backdrop of increased prescription duration in the December letter.

In the opinion of Dr Brown the biggest potential benefit of Hub & Spoke was to create more opportunity for pharmacists to spend time with patients and to deliver services. He talked about the opportunity to achieve higher delivery of national Advanced Services, locally commissioned services and private services such as those underpinned by Patient Group Directions. Dr Brown gave an estimate of the financial worth to an individual

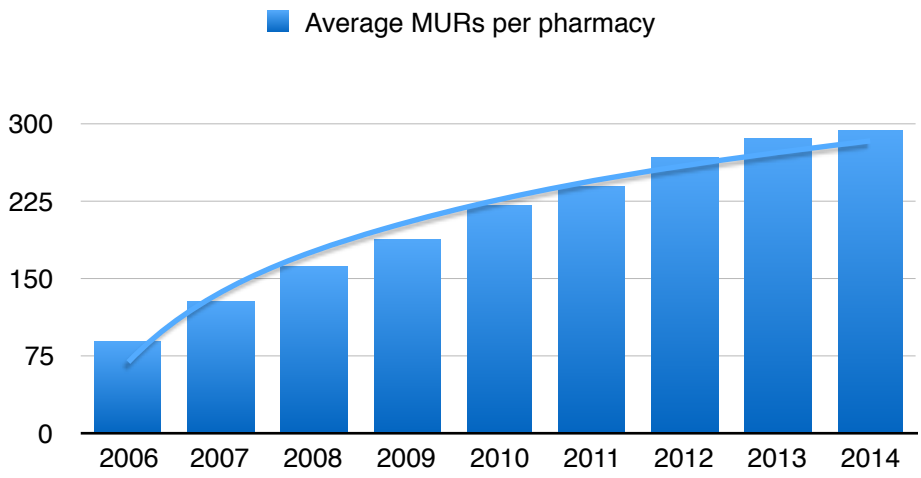
12 Schafheutle E. A literature search of 'Hub and Spoke' services used in the supply of medicines by community pharmacies – to inform the NPA consultation response. 22/1/16. Original Evidence.

13 Brown R. Oral Evidence to Task & Finish Group. 29/01/16

14 Ibid

15 Ibid

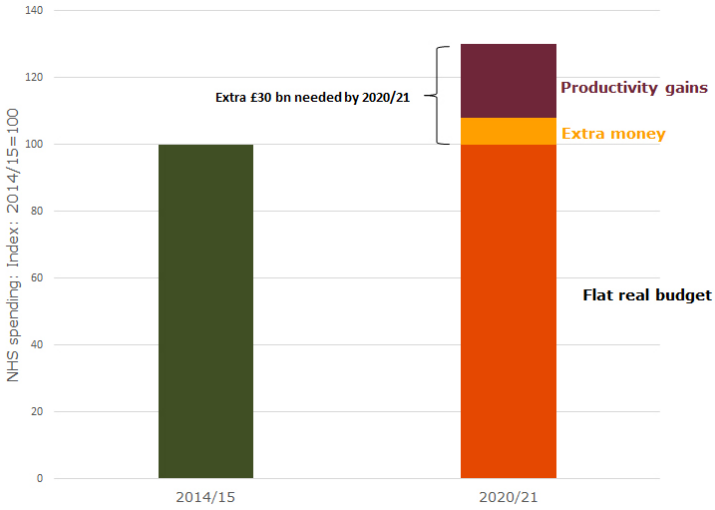
pharmacy of around £30,000 per annum, members of the group pointed out that the 'average pharmacy' currently conducted 292 MURs per year out of a potential of 400[16], and questioned both the figure, and whether this showed that there was no issue with capacity in service delivery at present. The problem was that there weren't enough services as there was great variability in local commissioning.



Source: HSCIC General Pharmaceutical Statistics 2005/6 - 2014/15

NHS 2020 - Demand growth

The NHS continues to experience growth in demand for services[17] because of the growing, ageing and ailing population. Prescription volume for example has risen by 48% since 2005[18], and continues to rise. Coupled with rises in labour costs brought on by the introduction of the National Living Wage and pensions auto-enrolment, it is possible that pharmacy needs to find ways to work more efficiently, especially in times of straitened resource. The figure to the right shows the predicted shortfall of NHS funding by 2020/21. Fin McCaul talked about the burden of Long Term Conditions on his CCG, and about the opportunity for



Source: Kings Fund

[16] HSCIC, General Pharmaceutical Statistics England 2005/6-2014/15.

[17] Kings Fund. How much money does the NHS need? 29/01/15.

[18] HSCIC, General Pharmaceutical Statistics England 2005/6-2014/15.

community pharmacy to play a much greater role in the care of patients, including tackling the problem of 50% of medicines being used incorrectly, and medicines related hospitalisation[19]. He also talked about his concern for the independent sector should Hub & Spoke only be open to large organisations who could then begin to spend more time with patients. At this point a member of the Group suggested that advanced skill mix was another way of creating the sort of 'headroom' to deliver services and offer the direct patient care which Mr McCaul was referring to. The Group was clear that the clinical relationship with the patient which currently exists at the Spoke pharmacy was important to deliver the type of services which could be needed in future, the type of disconnected, distance model offered by centralised dispensing ran contrary to Government health policy, and was universally opposed by the Group.

Monitored Dosage Systems

It has been suggested that MDS offers a big opportunity for Hub & Spoke, several witnesses brought expert knowledge of this aspect of automation/Hub & Spoke.

Dr Richard Brown stated his opinion that MDS offered the single biggest opportunity with Hub & Spoke. In practice currently, MDS is very labour intensive, removing huge amounts of capacity in a typical community pharmacy - he suggested that automation of these processes could offer a clear benefit.

Mr Remy Croese, International Sales Manager at MDS automation supplier, VMI Care gave evidence to the group on his company's MDS pouch system which was operating successfully in a number of European companies including Netherlands, Sweden and Germany.

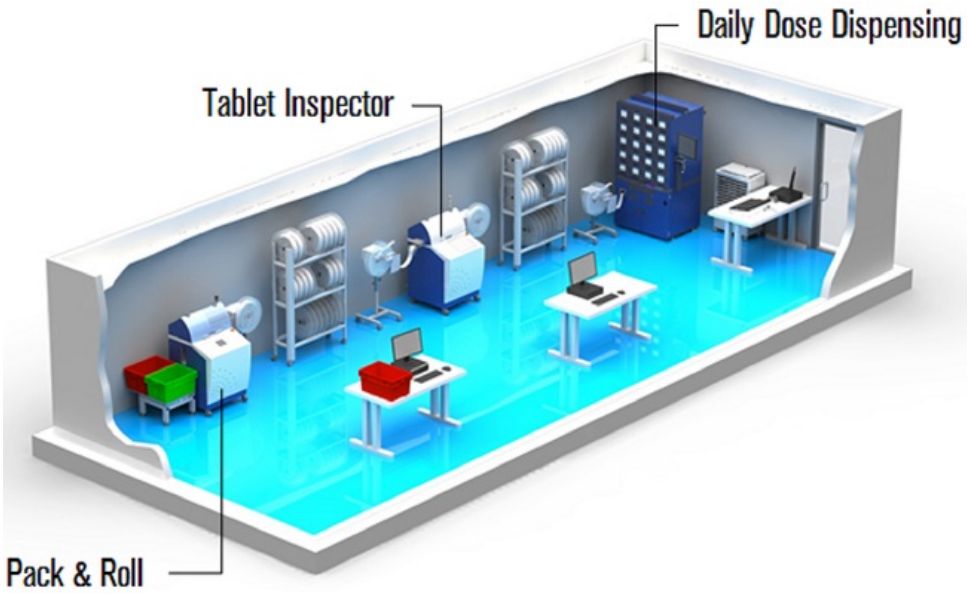
In his experience the automated pouch system could reduce preparation times per patient from 20-25 minutes to around 2-3 minutes per patient. Meanwhile, error rates for their system, which has a full photographic and electronic audit trail, were approximately 1 error in 8 million pouches. This would represent a significant improvement in the speed and safety of MDS systems.

Mr Croese was asked about the compatibility of their system with the Falsified Medicines Directive, he responded that their system was fully compliant with FMD, although members of the Group challenged this assertion. This assertion was later challenged by Noel Wardle on two grounds, firstly the compatibility with the terms of the MHRA Wholesale Dealers License, and secondly the compatibility with the EU FMD Delegated Act.

[19] McCaul F. Oral Evidence to Task & Finish Group. 29/01/16.

Andy Beesley of Medication Management Solutions, a company based in Cheshire gave evidence to the Group on automated MDS solutions. Mr Beesley expressed an opinion that co-operative Hubs were possible, although, it must be noted he was not coming from a legal perspective, but a financial one based on the cost of the technology. During his evidence Mr Beesley talked about the lack of published evidence in this area, citing the cost of research as one barrier to academic studies, and commercial sensitivities. He talked from a practical perspective as his company had been responsible for 30 installations of automated equipment in the UK. In his experience an average pharmacy was supplying MDS for around 75 patients per month. Automation had the potential to save around 60 hours work each month for the average pharmacy which would allow the pharmacy team to do other things. The Group questioned the capital costs of an automated solution which ranged from around £36-180k plus, Mr Beesley stated his belief that a Return on Investment would be delivered automated MDS technology from around 250 MDS patients[20].

Source: VMI Care.



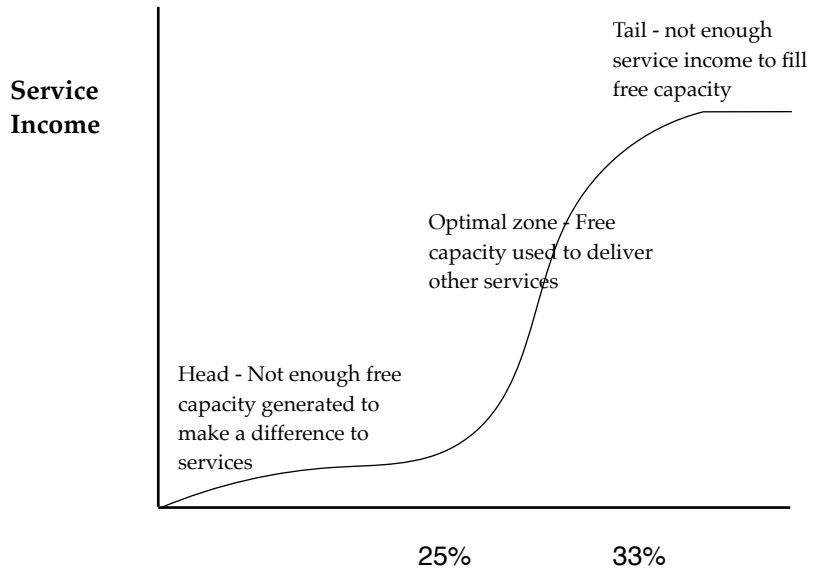
Quantifying a capacity benefit

When asked about the size of the opportunity afforded by Hub & Spoke, Dr Brown said that he felt an optimum of 25 - 33% of existing workload could be moved safely from a Spoke pharmacy. He explained that it was important to achieve significant critical mass for it free enough of a capacity to make a difference to the operation of the branch, but that beyond ~ one third of volume, there were not enough additional services and opportunity

[20] Beesley A. Oral Evidence to Task & Finish Group. 08/02/16.

to make use of the capacity created[21]. Cormac Tobin agreed during a Question & Answer session that there were not enough services available at present to make use of the additional capacity created by Hub & Spoke, and added that a high demand service like a national Pharmacy First (Common/Minor Ailments) service would be deliverable with the capacity created[22]. A graphical representation of this concept is seen below (not drawn to scale).

Figure 1: Hub & Spoke Efficiency Curve



In the literature review commissioned from the University of Manchester, the researcher was able to find documented suggestions that 40 - 50 % of dispensing volume could be moved to a Hub[23]. Meanwhile the Chief Pharmaceutical Officer, Keith Ridge believes "there are now large centralised dispensing facilities in England. It could be that such facilities will be capable

Examples of some items which cannot by supplied by a Hub:

- Controlled Drugs
- Fridge Items
- Acute or urgently required items
- Specials

[21] Brown R. Oral Evidence to Task & Finish Group. 29/01/16

[22] Tobin C. Oral Evidence to Task & Finish Group 08/02/16

[23] Scott C. Ready for a new dispensing model? Pharmacy Management & Business in Practice 2015

of dealing with two-thirds of dispensing volume in community pharmacy"[24].

In the absence of further quantitative data it is reasonable to suggest that a figure of 25 - 50% of dispensing volume is the best, evidence based-assessment of the potential volume shift that might be achievable using Hub & Spoke.

Direct Cost Savings

The Group set out to understand the opportunity the evidence to support the assertion in the December letter that Hub & Spoke would allow pharmacies to lower their operating costs.

The Group identified that the business case for a large company wishing to centralise costs, is different to an entity outsourcing some of its activity (and associated costs) to another provider. Unless staffing levels within the Spoke are reduced with the outsourced arrangement, the Hub merely adds additional variable cost for the SME.

Dr Brown presented some data which suggested that the unit assembly cost is lower for a fully automated Hub & Spoke system than either manual Hubs or the status quo. The Group questioned whether these were like for like comparisons, for example including infrastructure or logistics costs. Drew Warner, a general logistics expert provided some thoughts on how this cost model might work for a vertically integrated wholesaler. Mr Warner felt that the existing infrastructure national wholesalers had in place, including distribution trunking would give them the best opportunity for making a Hub & Spoke operation work. This is relevant to the issue of cost savings because non-vertically integrated Hub providers would have to create this infrastructure and charge it back to the customer - the Spoke[25]. Cormac Tobin of Celesio confirmed "Prescription Assembly Solutions (Hub & Spoke) and cost savings do not go together"[26].

The Group could not find any evidence to support Government claims that Hub & Spoke will allow pharmacies to lower their operating costs. This issue is explored further in Section 3.10.

[24] Ridge K. Role of pharmacists is set to grow and grow. Published 15/09/15. Department of Health.

[25] Warner D. Oral Evidence to Task & Finish Group. 29/01/16.

[26] Tobin C. Oral Evidence to Task & Finish Group 08/02/16.

Operational Efficiencies

Stockholding at Spoke

During his evidence, Dr Brown talked about the availability of product as being a major factor in a patient's choice of pharmacy, he felt that this was interesting because one of the benefits which had been suggested for Hub & Spoke operations is a reduced stockholding in the Spoke pharmacy. He suggested that there were two issues: lack of availability of product could be counterproductive as it was of high importance to patients, and secondly that the quantum of any potential reduction in stockholding could be smaller than anticipated[27]. An opinion was expressed that the introduction of Hub & Spoke could reduce stockholding at 1600 Lloydspharmacy branches[28]. Dr Shakoor felt that one of the main supposed benefits of Hub & Spoke was the ability to reduce stock holding, however, he felt that in order to maintain an acute prescription service, stock levels would not necessarily reduce[29]. A member of the Group suggested that if stock turnover is lower in a Spoke because of volume being moved to a Hub, there was the potential for an increase in medicines waste at the Spoke pharmacy because of out of date and slow moving lines. Drew Warner, a logistics expert commented that the potential for stock reduction was likely to be greater in urban conurbations than in rural area[30], the Group did not explore the reasoning behind this statement. Bharat Shah, Director of Sigma Pharmaceuticals a Short-Line wholesaler felt that it was unlikely that Spoke pharmacies would be able to significantly reduce their stockholding[31].

Case Study: Mayberry Pharmacy Group

Paul Mayberry an NPA member, operates a small independent group in a discrete geographical locality, he has operated his Hub since 2011 for 6 pharmacies adding the 7th in the last 12 months.

On the subject of stock management he estimates:

- 50% reduction in stock holding at Spokes.
- Without a corresponding increase at the Hub.

[27] Brown R. Oral Evidence to Task & Finish Group. 29/01/16

[28] Scott C. Ready for a new dispensing model? Pharmacy Management & Business in Practice 2015

[29] Shakoor O. Oral Evidence to Task & Finish Group. 29/01/16

[30] Warner D. Oral Evidence to Task & Finish Group. 29/01/16

[31] Shah B. Oral Evidence to Task & Finish Group 08/02/16

A case study from the Mayberry Pharmacy Group can be found above[32], members of the T&F Group questioned whether the level of stock reduction achieved by this group was reproducible because of his unique geography. Mr Mayberry said that there had been a corresponding cashflow improvement because of the lower stock holding.

Taking into account conflicting evidence on the size of the opportunity for stock reduction, and the risk of consequences relating to stock reduction, it would seem appropriate to exercise caution in accepting this as a clear benefit of Hub & Spoke.

Staffing Levels at Spoke

The Department of Health letter refers to Hub & Spoke as an opportunity to 'lower their operating costs'. We have already discussed the potential to grow revenue through service income, however, we must consider the Government's claim that Hub & Spoke will allow pharmacy owners to lower their operating costs. The only variable cost which Hub & Spoke could affect at the Spoke pharmacy is staffing, the assumption being that workload shifts from Spoke to Hub, and there is a corresponding reduction in headcount at the Spoke, thus producing a cost saving. Dr Richard Brown strongly cautioned against this approach, stating that it could be counterproductive - and could lead to even less time with patients and to deliver services than the current status quo. He added that in some circumstances this could lead to pharmacists checking their own work which could make processes less safe[33]. Paul Mayberry said that he had not reduced his staffing levels at his Spoke pharmacies, but had instead focused them on different activities such as talking to patients and delivering services - this had a positive impact on his business, he was very clear that Hub & Spoke should not be about reducing staffing levels, but freeing them to do other things[34]. The University of Manchester Literature Review did not reveal any further evidence on the impact of Hub & Spoke on staffing levels in Spoke pharmacies.

One member of the Group who had invested heavily in developing their pharmacy team to a high skill-mix felt particularly concerned about the logic of cost efficiencies driven by reduction in staffing levels at the Spoke. In their opinion it was possible to create headroom to deliver services, even in high volume businesses through a highly qualified team, and thus rejected the premise that Hub & Spoke could deliver cost efficiencies, particularly at the expense of staffing levels.

Although it might be possible to reduce staffing levels at Spoke pharmacies, this is a highly risky and potentially destructive option which defeats the purpose of freeing pharmacy teams to spend more time delivering care to patients.

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[32] Mayberry P. Audio Evidence to Task & Finish Group. 09/02/16

[33] Brown R. Oral Evidence to Task & Finish Group. 29/01/16

[34] Mayberry P. Audio Evidence to Task & Finish Group. 09/02/16

Safety

Patient safety is often cited as a benefit of automated dispensing Hubs. While it is true that automation can have some safety benefits there is a crucial difference between *accuracy* and *validity*, which is important to understand.

Hub & Spoke relies on the quality of data entry at the Spoke pharmacy, this was highlighted as a critical step by Dr Brown, and by the Celesio team during the Group's visit to their automated Hub[35]. The term 'Garbage In, Garbage Out' (GIGO) is common in I.T. and relates to the both *accuracy* and *validity*. When an operator at the Spoke asks for an item, they have a high percentage chance of receiving the item that has been asked for i.e. *accuracy* of stock picking is good. If the operator asks for the wrong item, they have an equally high chance of receiving that item - which would be *accurate* against the data input, but would not be *valid*. In this circumstance the responsibility would lie with the Spoke pharmacy - which is important as it underlines the importance of a final accuracy check at the Spoke before hand out to the patient.

While automated technology can improve the accuracy of the assembly task, it will not impact on other areas of the dispensing process such as data entry, taking in and handing out of the prescription, and will only impact items assembled at the Hub - and will therefore not affect Controlled Drugs and fridge items for example. There are other technologies which could positively impact on the accuracy of the assembly process - these include barcode accuracy scanning which is a feature on some PMR systems, and could be a potential benefit of the Falsified Medicines Directive - this is not an exclusive benefit of Hub & Spoke. Fin McCaul stated that he had seen the benefits of technology - observing a 50% reduction in dispensing errors since the introduction of a dispensing robot in his pharmacy. With effective use of EPS the error rate on labelling (incorrect patient names, address, product strength, etc) has also reduced errors[36].

One further reason for the patient safety claim is that in some large multiples currently operating an intra-company Hub & Spoke model, the Superintendent Pharmacist can force Spokes to undertake a vigorous quality management process prior to being allowed to order prescriptions from the Hub. Part of this process is a data validation exercise which requires dispensary staff to accurately enter 5000 prescription items onto the PMR system without making a mistake. This could be a time consuming and costly process, but in a large organisation it is not unfeasible to put a gateway step into the commissioning process at the Spoke. Unfortunately when considering inter-company Hub & Spoke models where the Hub and the Spoke have different Superintendent pharmacists, it is impossible to enforce this step - which could reduce the safety of inter- company systems versus existing models.

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[35] Brown R. Oral Evidence to Task & Finish Group. 29/01/16.

[36] McCaul F. Oral Evidence to Task & Finish Group 29/01/16.

While Hub & Spoke systems could have a positive advantage in terms of positive accuracy checking, it would be difficult for a Hub to play any quality assurance function in screening out errors of omission i.e. where items are missed from a prescription, usually by a surgery, but potentially by a Spoke. While an audit trail would exist to show what items were supplied from the Hub, these types of error are often only found at the point of hand out to the patient. As bags may arrive back at the Spoke as sealed units, a final accuracy/reconciliation check at the Spoke could be difficult, requiring bags to be opened which could undermine some of the safety benefits of the automated system. A common issue with EPS prescriptions is for multiple prescriptions for the same patient to become separated within the pharmacy, this could become a real issue for prescriptions with extended periods of treatment or many different prescribed items. Reconciling these back at the Spoke pharmacy could be a difficult task, as well as auditing where specific bags are within the system.

One final issue which the Group considered was the difference between relative and absolute risk. While it may be true that a fully automated Hub may be more accurate in terms of stock picking, yielding a lower error rate than a manual process in a busy Spoke pharmacy (i.e. a lower *relative* risk), they may still make a large number of errors by courtesy of the volume of workload they handle (this is *absolute* risk). David Simons raised this issue during his evidence[37].

Hub & Spoke may have some advantages over manual prescription assembly for the *accuracy* of drug picking, this is only one task in the dispensing process. The same improvement is achievable through barcode scanning technology integrated to PMR systems, and could be achievable in the near future through implementation of the EU Falsified Medicines Directive.

Data entry at the Spoke is *the* critical process to make Hub & Spoke work safely - while intra-company Hub & Spoke models can reasonably enforce quality improvements in this activity, this would be extremely difficult to replicate between companies and is a key concern for the Group.

Spoke pharmacies would need to perform a final accuracy or reconciliation check to confirm products supplied by the Hub.

[37] Simons D. Oral Evidence to Task & Finish Group. 09/02/16.

3.8 Understanding the Risks

Negative impacts of Hub & Spoke fall broadly into themes[38]:

1. Legal & professional issues
2. Impacts on procurement & the medicines supply chain.
3. Risks to patients & the public.

We set out to understand evidence surrounding these issues.

Legal & Professional Accountability

Noel Wardle, Partner at CharlesRussellSpeechlys, gave evidence to the Group about the legal and professional implications of inter-company Hub & Spoke. The advice below was given informally, and should not be relied upon by members. NPA may need to commission formal legal opinions.

Patient Consent

In the opinion of Mr Wardle, operators of Spoke pharmacies would have to obtain explicit, written consent from each patient to allow the off-site assembly of prescriptions, because this would involve the transmission of personal data to a third party. Although this would only have to be obtained once for each patient, it would not be permissible to make a general notice in the pharmacy or practice leaflet. This has workload implications for Spoke pharmacies.

Criminal Liability

Mr Wardle said that it was important that under criminal law it was the person, rather than the organisation which was accountable. This could include staff at the Hub, which might represent an expansion of criminal liability.

Department of Health is currently consulting on amendments to Section 67 of the Medicines Act, 1968 which would introduce a statutory defence for inadvertent dispensing errors. Mr Wardle explained that inter-company Hub & Spoke arrangements could invalidate the proposed statutory defence, where, for example a pharmacist at a Spoke failed to notify a patient that an error occurred at a Hub or if the Hub failed to notify the Spoke. The draft Statutory Instrument details a number of conditions which a

[38] Schafheutle E. A literature search of 'Hub and Spoke' services used in the supply of medicines by community pharmacies – to inform the NPA consultation response. 22/1/16. Original Evidence.

pharmacist or pharmacy technician or member of staff acting under the supervision of the pharmacist would need to satisfy. Part 67C (5) (a) (i) states:

> (5) Condition B is that—
> (a) before the defendant was charged, an appropriate person, on becoming aware that the product was not of the required nature or quality—
> (i) promptly ensured that all reasonable steps were taken to ensure that the person to whom the product was intended to be administered was notified that the product was not of the required nature or quality[39].

Mr Wardle was asked if the Responsible Pharmacist at the Hub had a Duty of Care towards the patient, in the event of an obvious clinical error. He responded that the Hub Responsible Pharmacist would have a duty of care to address any obvious clinical issue. A member of the Group who had previously been a Responsible Pharmacist at a Hub expressed concern about the ability of the Responsible Pharmacist at the Hub to exercise that Duty of Care whilst dealing with large volumes of prescriptions. Other members of the Group felt that his would lead to duplication of effort which could blur professional accountability between Hub & Spoke.

Civil Liability

In a service relationship, as would exist between a Hub and a Spoke, contracts will be important. For example in the case of a Hub which does not hold an NHS Contract, it would be necessary to bind the Hub provider to the NHS Terms of Service, Information Governance requirements, etc. A member of the group asked about the implications of events during December and January 2016 at a large internet pharmacy, when the contractor was unable to supply patients for a period of time, would a Hub hold liability in this circumstances? Mr Wardle replied that responsibility would still rest with the Spoke pharmacy.

The Group asked Mr Wardle about the need for an accuracy check at the Spoke pharmacy before the point of hand out to the patient, Mr Wardle felt that a final accuracy check/ reconciliation was important at this point because the supply was being made 'under the supervision of the pharmacist' at the Spoke, who has a Duty of Care to the patient. Mr Wardle said that this was different to the situation where a locum pharmacist on a previous day had checked a prescription for hand-out to the patient because of the transfer across legal entities.

[39] The Pharmacy (Preparation and Dispensing Errors) Order 2015. Draft Statutory Instruments. UK Government

Monitored Dosage Systems

Mr Wardle was asked about the compatibility of Hub & Spoke with the Falsified Medicines Directive. He responded that it is still too early to tell, however he did raise a concern over the treatment of MDS systems assembled by a Hub. Under FMD, the supplying pharmacy will need to check the tamper-evident seals on the packaging, but this would not be possible if the product is removed from its original packaging, which would be required to assemble MDS at a Hub. He added that it would be difficult for a Hub to perform an authentication scan at the point of assembly and claim that this was 'at the time of the supply to the patient', as directed in the Delegated Act.

In addition Mr Wardle discussed the supply of products from a Hub to a Spoke, which takes place by way of wholesale dealing. To comply with the terms of the MHRA Wholesale Dealers License (WDL) the wholesaler must act in accordance with the Product License, which Hub assembled MDS could not do because the product had been removed from its original packaging, which was outside of the Product License and therefore the terms of the WDL.

NHS Payment Issues

Mr Wardle explained that a Hub which does not have an NHS contract, could only supply a Spoke, and could not supply third party collection points or patients directly. This was due to a Court of Appeal decision involving Dispensing Appliance Contractors. It was ruled that the Spoke had to make a material contribution to the process of supply of the medicine. This is relevant to where the prescription is sent for payment.

A number of important legal issues have been identified which could have a bearing on the viability of inter-company Hub & Spoke. These will need to be examined prior to the Government consultation which is scheduled to run between March and April 2016.

Impact on Procurement & Supply Chain

During his evidence Bharat Shah, Director of one of the largest short-line wholesalers in the UK declared that Hub & Spoke would lead to consolidation in the short-line wholesale market.

Members of the Group expressed a concern about a potential lack of competition to supply Hub services, with a risk that only a small number of vertically integrated operations could currently enter the market. Dr Shah was asked which organisations were best placed to provide Hub services, he felt that large multiples and short-liners with their own logistics channels were likely to be the most successful providers. Dr Shah expressed an opinion that it would take in excess of 12 months to set up co-operative ventures.

A member of the Group with significant experience of the short-line wholesale market asked about the impact of Hub & Spoke on Buying Groups, Dr Shah said that it was unlikely to be positive. In all likelihood Buying Groups would have to align with a single national wholesaler, which would lead to big disadvantages for the independent sector. He felt that Buying Groups as they currently stand would not be in a position to be Hub providers themselves. In addition, as many Buying Groups are dependent on wholesale rebates to support their activities this could lead to a reduction in leverage for commercial negotiations. Dr Shah suggested that the pricing of generics might rise as a result of Hub & Spoke which might impact the sustainability of independent pharmacy businesses.

Picking up this argument, Dr Shah went on to say that providers of Hub services would need to recover the significant investment they would need to make in automation (and possibly logistics), the only way to do this would be to pass the cost on to the customer. He said that this could be through a reduction in procurement margins, while a member of the Group commented that this would be unfair on customers who chose not to use the Hub - a fairer way to apportion the cost would be on an item of service basis - but agreed that the cost would need to be recovered via some mechanism. Dr Shah estimated that the setup costs for a Hub might be in excess of £5m and financial instability in the pharmacy and wholesale sector could reduce investment without a stable financial outlook.

Dr Shah expressed a concern that the introduction of Hub & Spoke could see a reduction in service level of some wholesale operations from twice to once daily delivery. He also expressed a concern about restrictive distribution practices, such as Direct to Pharmacy which could act as a barrier to entry for some Hub providers.

A member of the Group asked about equity of access to Hub providers, particularly in rural locations. Dr Shah responded to say that there was a risk of regional variation, as there was likely to be less competition and choice outside of urban areas. A Group member agreed, stating that there were no regional wholesalers in his vicinity so his choice would be restricted to national providers and would therefore have to accept their terms and conditions if he wished to use a Hub & Spoke model. Doctor dispensing

practices also expressed a similar concern about the imposition of less favourable trading terms by Hub providers - "small contractors, particularly those in very remote locations may also fear the impact on their wholesalers business terms"[40].

Community pharmacy has an important role in procurement of medicines for primary care, which has yielded savings in excess of £10bn since 2005[41]. Chris Frost, National Sales Director for AAH Pharmaceuticals stated in an article for P3 Magazine that Hub & Spoke could change the procurement model for independents, who would procure on a basket approach as opposed to an individual item basis[42]. This is a fundamental and significant change, as independent pharmacies currently use a range of wholesalers including the short-line market to procure medicines at the lowest cost, members of the Group with operations of all sizes commented that their sustainability was largely built with a heavy reliance on short-line wholesalers for procurement margin. Dr Shah commented that one of the advantages for wholesalers of a Hub & Spoke model would be to 'lock in' customers - suggesting that there could be a risk of reduced competition in the wholesale market, especially if pharmacies become reliant on their Hub to meet capacity requirements.

To better understand the potential impact on competition, the group applied Porter's five forces model (which considers business strategy and seeks to identify profitable business opportunities) to the business model of the existing full-line wholesalers. Porter's model considers the forces that drive competition in a sector – and seeks to identify where there is less competition and therefore where it is more attractive to do business[43].

Force	Implications
Threat of a new entry	The threat of new entry into the wholesale market is already low as a result of DTP and limited wholesaler schemes and the cost of providing a nationwide twice-daily delivery. The investment required in order to provide a Hub service adds a further barrier to entry.
Bargaining power of suppliers	The DTP and limited wholesaler schemes have reduced the bargaining power of suppliers in the patent-protected market. The power of generic suppliers could be reduced as well, if only the largest wholesalers offer Hub services.

40 Gladwin, C. Hub and spoke dispensing: what it means for you. Resources to help dispensing practices understand the implications. 11-11-2015.

41 Cumulative Category M Savings 2005-2014. Pharmaceutical Services Negotiating Committee.

42 Scott C. Ready for a new dispensing model? Pharmacy Management & Business in Practice 2015

43 Porter M. The five competitive forces which shape strategy. Harvard Business Review. Jan 2008, Vol. 86 Issue 1, p78-93.

Force	Implications
Bargaining power of customers	The bargaining powers of customers is already weak as they must purchase the vast majority of their patent-protected products from one of the three big wholesalers. Hub and Spoke models will only deliver efficiencies if they include the majority of medicines – and so this will drive purchasing of generics from these wholesalers, further reducing the bargaining power of customers.
Threat of substitutes	The limited scope for pharmacy to decide which medicine to supply means there is little opportunity for substitution.
Rivalry amongst existing competitors	All pharmacies must contract with at least one of WBA and AAH – the existing level of competition is not very high.

Garry Myers, a member of PSNC, raised a concern about the effect of a new model on the Department of Health's ability to monitor the margin being received by the network and thus deliver the agreed global sum. There is a risk to Government that the margin for independents is reduced, and this will be reflected in higher drug costs. This situation would have a negative impact on the independent sector, and would increase costs for the tax payer.

System Resilience

Although stockholding at Spoke pharmacies has already been discussed as a potential benefit of Hub & Spoke, we must understand the risks of any reduction in near-patient stockholding. In particular, whether this increases the risk of patients running out of medicines.

David Simons, interim Chief Operating Officer at the National Pharmacy Association gave the Group the benefit of his experience with general logistics businesses. In particular he questioned the resilience of any system which relied on a small number of Hubs. He spoke of the experience in Boots where a retail distribution Hub burnt down in the run-up to Christmas 1997. A single aerosol canister exploding resulted in a £15m insurance claim and £30m of lost retail sales[44]. While a financial loss is a potential threat to pharmacy operators, it is the impact on patients and the public which concerned the Group.

In an article on this incident the author Dr Peck goes on to explain "we tend to think of supply chains in terms of simple linear process of goods and information flows passing swiftly through an efficient 'logistics pipeline', this is rarely the reality….supply chains are in fact messy, complex interacting networks that link organisations, industries and economies. Only when we recognise them for what they are can we really begin to

[44] Peck H. Resilience - surviving the unthinkable. Cranfield School of Management. Logistics Manager March 2004.

understand the nature and magnitude of the risks". Dr Peck calls out outsourcing as a particular risk: "Outsourcing, possibly more than any of the other major business trends mentioned here has added to the complexity and interconnectivity of supply chain networks. Therefore managers should be aware that in adopting outsourcing to deal with a known risk, the likelihood is that they are trading it for a host of previously unknown ones. Not least the short-term dislocation caused by the changes in staff, working practices, and the integration or upgrading of IT systems….Corporate risk assessment tends to focus on risk management from a single firm, rather than a network perspective, as such it has largely failed to keep pace with the reality of networked global supply chains. Leading insurers are actively seeking better ways to assess these risks, even so, insurance is unlikely ever to cover the full costs of supply chain failures"[45].

Supply chain risks are a feature of the current medicines supply chain - which can and frequently do result in market disruption due to product becoming unavailable. Hub & Spoke could increase the sensitivity of the supply chain to disruption. This could be via two mechanisms:

- reduction in the number of short-line wholesalers.
- reduction in stockholding near to the patient.

Although the medicines supply chain operates a *Just in Time* model, pharmacies and wholesalers will each hold their own stock, which can provide a buffer against short-term issues such as bad weather. Any reduction in either the number of pharmacies or wholesalers or the individual levels of stockholding at either level will reduce the buffer available, which could lead to short term availability problems, or cost spikes. This is a potential unintended consequence of Hub & Spoke which represents a strategic, operational and financial risk to NPA members.

A recent example of a critical failure of a large scale automated dispensing facility happened in December 2015 & January 2016 at *Pharmacy2U*, the largest single dispensing contractor in the country. Dr David Geddes, Head of Primary Care Commissioning at NHS England wrote to all GP Practices, NHS England local teams and community pharmacies explaining that technical issues at *Pharmacy2U* had lead to them being unable to supply medicines to patients over the Christmas period[46]. In this instance patients were referred back to their local community pharmacy[47]. Although this is not strictly a Hub & Spoke model, it highlights the risk associated with a large number of patients being served from a single site. A number of national newspapers ran this story which

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[45] Peck H. Resilience - surviving the unthinkable. Cranfield School of Management. Logistics Manager March 2004.

[46] Geddes D. Important note regarding services provided by 'Pharmacy2U' over Christmas and New Year. Correspondence. NHS England. 23/12/15.

[47] The Pharmaceutical Journal. Service disruption at Pharmacy2U prompts action by NHS England and Pharmacy Regulator. PJ December 2015 online, online | DOI: 10.1211/PJ.2015.20200366

underlines the risk to the reputation of NPA members. Another example of catastrophic failure of a large dispensing facility was the collapse of Pharmacy Plus in 2014. This company had been supplying care homes around the country, and went out of business in 2014 leading to thousands of vulnerable patients in institutional settings looking for pharmacy cover at short notice[48].

Noel Wardle, Partner at Charles Russell Speechlys during his evidence session pointed out that legal responsibility for failure to supply against a prescription could rest with the Spoke pharmacy[49]. In the event that the Hub did not hold an NHS Contract, it could be necessary to bind the Hub to the NHS Terms of Service via a contractual mechanism[50].

Risks of Transition

Leyla Hannbeck, Chief Pharmacist at the National Pharmacy Association, discussed the experience of the Swedish health system, which has undergone a radical transformation, towards deregulation and centralised dispensing operations. Ms Hannbeck spoke about the early days of the new system, when there were a large number of logistical problems with the service, resulting in many complaints and patient safety incidents. To mitigate these problems a national customer service centre was established to deal with these problems, but this has since been closed for budget reasons[51]. Paul Mayberry also noted that customer service levels dropped during the first few months following the introduction of the Hub[52]. David Vanns noted that there was risk that patients can be left 'in limbo' with neither the Hub or the Spoke taking ownership when problems arose[53].

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[48] Horti S. Pharmacies scramble to help care home patients after supplier collapses. Chemist & Druggist 22/05/15. Accessed 22/02/16.

[49] Wardle N. Oral Evidence to Task & Finish Group. 09/02/16.

[50] Ibid.

[51] Hannbeck L. Oral Evidence to Task & Finish Group. 09/02/16.

[52] Mayberry P. Audio Evidence to Task & Finish Group. 09/02/16.

[53] Vanns D. Written Evidence to Task & Finish Group.

3.9 Enablers

After examining the evidence, it is clear that there are a number key enablers which would help the development and deployment of the Hub & Spoke concept.

Planned Workload

It would be difficult for a pharmacy to shift unplanned or urgent workload because of the expectations of the patient around accessibility and convenience of product. Hub & Spoke works best for planned workload, such as regular repeat prescriptions and MDS. Therefore a move towards NHS Repeat Dispensing would encourage the use of Hub dispensing as the product could be ready and available at the Spoke pharmacy on a planned date and time. Furthermore EPS Repeat Dispensing would reduce the need for additional data entry at the Spoke pharmacy.

Uptake of the NHS Repeat Dispensing service has been variable. There are however a number of benefits including[54]:

- Reduced administrative burden for practices
- Less footfall into a practice.
- Less administration for prescribers, and more control e.g. easier to cancel Repeat Dispensing cycles.
- Less administration for patients and carers.
- Reduced need for Urgent & Emergency care providers to issue regular medicines at unplanned times.

Electronic Repeat Dispensing should be more widely promoted by the NHS and General Practice. A shift of work towards Repeat Dispensing will help pharmacies to plan their workflow, which could enable a move towards Hub dispensing.

Original Pack Dispensing

Split packs are likely to cause a problem with the operation of an automated assembly Hub, where a prescription calls for a quantity other than a readily available manufacturer's original pack, prescriptions could be deferred to the Spoke pharmacy for completion (thus increasing waste and reducing efficiency at the Spoke pharmacy). It was suggested that manufacturers could increase their range of pack sizes to accommodate common issues. This could increase the range of SKUs (Stock Keeping Units) held at a Hub and could make supply of medicines more costly as it could increase processing and packaging costs for manufacturers. Unless a concerted effort is made to reduce split-pack

[54] Electronic Repeat Dispensing Guide. NHS England. May 2015.

prescribing, Spoke pharmacies could see increased stock wastage if Hubs are not able to persuade manufacturers to increase their range of pack sizes. Hubs would be unable to supply part packs because of the Falsified Medicines Directive which requires the Authentication scan to take place at the point of supply to the patient (and does not allow for this to happen in to different legal entities). In its stakeholder briefing issued on 27th January, the Department of Health suggested that 90-day prescribing, where appropriate, would support more efficient working[55]. This type of prescriptive and disconnected logic belies the reality of 28 day pack sizes, and could increase waste.

Promotion of Original Pack Dispensing will support uptake of Hub & Spoke. Due consideration must given to the cost of split packs and waste to Spoke pharmacies.

Contractual Protections

A service relationship, such as the provision of Hub services to another company will need to be governed contractually. As there is potential for an asymmetric relationship between Hub & Spoke by virtue of size and resources it is essential that contracts are fair and balanced towards the Spoke operator. In its recent Enterprise Bill the UK Government discussed the issue of fair treatment for SMEs in connection with its proposal to introduce a Small Business Commissioner. Anna Soubry, Minister of State for Small Business, Industry and Enterprise noted that "small business owners can struggle in their commercial dealings with larger firms. These businesses can feel they are treated unfairly where they have weaker bargaining power….Disputes between two firms can be a drain on both parties, but the biggest impact is likely to be on the small firm"[56].

While we have no reason to believe that any potential Hub provider would act unfairly, the proposed change to legislation will allow a number of different providers to emerge. This could lead to inconsistencies between providers, which would create further uncertainty and risk for NPA members.

As a Trade Association, NPA should take the lead on framing a standard contract for Hub services which protects members interests. It should at least review the Terms & Conditions for major Hub providers as part of its Insurance arrangements to ensure that members are adequately covered for any new or enhanced risks.

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[55] Community Pharmacy 2016/17 and beyond - proposals. Stakeholder briefing. 27/01/16. Accessed 22/02/16.

[56] Soubry A. Foreword to Enterprise Bill 2015 - A Small Business Commissioner. Department for Business, Innovation and Skills. July 2015.

Professional Standards

Some organisations who intend to provide Hub services to different legal entities have been engaged in the development and deployment of this technology for up to a decade. It would take considerable investment of time, money and intellectual resource for new providers to be in a position to market a service. This is a concern for the National Pharmacy Association because competition will drive up service levels and drive down prices for our members. There is also a risk to members where new providers do not fully appreciate the risks and their responsibilities to NPA members and their patients, or where responsibility and accountability is unclear to members.

Although Hubs would have to be registered with the General Pharmaceutical Council as Registered Premises, and subject to its Inspection and Quality Assurance regime, this may be insufficient for cross-company Hub & Spoke. In April 2015 GPhC published Guidance for Registered Pharmacies providing services at distance, including reference to Hub & Spoke services. While guidance from the Regulator is welcome in this area, it was published prior to the announcement from the Minister in October 2015 of his intention to amend legislation to allow inter-company assembly of prescriptions - updated guidance will be required to take this into account. GPhC's definition of a Hub & Spoke service is different to ours, for example allowing for delivery of prescriptions from the Hub to non-Registered premises[57], to which the National Pharmacy Association maintains strong objections on grounds of patient safety and professional accountability. The likely scale and complexity of some Hub & Spoke models will at least require more regular inspection by the GPhC, however this alone may not be enough to provide quality assurance for Superintendent Pharmacists.

We call for the General Pharmaceutical Council to urgently review its guidance to take account of a likely change to the law allowing for cross-company assembly of prescriptions, and to take into account the professional concerns of the National Pharmacy Association and its members, when it does so.

Superintendent pharmacists would have to be in a position to make an informed, risk assessment of the suitability of a Hub provider. This duty is enshrined in the General Pharmaceutical Council Standards for Registered Premises, where Superintendents would have to:

- comply with their professional and legal obligations.
- use their professional judgement in the best interests of patients and the public[58].

[57] Guidance for Registered Pharmacies providing pharmacy services at a distance including on the internet. General Pharmaceutical Council. April 2015.

[58] Standards for Registered Premises. General Pharmaceutical Council. September 2012.

This professional responsibility would apply, even where part of the service is provided by another Registered Pharmacy, and cannot be delegated, even by a contractual relationship[59].

To support Superintendent pharmacists to make a safe and fair choice between a range of providers of Hub services, they will need access to accurate and up-to-date information on the performance of the Hub. Key Performance Indicators (KPIs) are a common quality management tool within most businesses,

To provide the Superintendent pharmacist of an SME with sufficient information to make their decision about a Hub provider, a set of common KPIs should be developed, which should be freely available to potential Spoke pharmacies.

As a Regulator GPhC's remit is to safeguard patients and the public, including the development of Standards and professional guidance, but this would not address variation between providers of Hub services. Inter-company assembly of prescriptions is a new area of professional practice, and so to safeguard patients and the public, as well as our members, from 'cowboy operators', we believe that a set of common Industry Standards should be developed. British Standards Institute (BSI) specialises in the development of business Standards, and has an international reputation. We believe that the development of a Publicly Available Specification or PAS would be in the interests of all stakeholders in the use of this nascent technology and capability.

Publicly Available Specifications "allow an agreed level of good practice, and quality to help establish trust in an innovative product or service"[60]. Benefits of a PAS include[61]:

- Improve productivity
- Increase efficiency
- Reduce costs
- Maintain quality
- Accelerate innovation
- Meet Regulatory obligations
- Build trust with customers
- Can be used as the basis for a British or International (ISO) Standard.

A number of these features appear pertinent to the needs and concerns of NPA members. Although this type of Standard is not enforceable it would help to improve consistency between Hub providers, allowing members to make a free and informed choice about using a Hub provider. An example of the sort of detail which could be built into a

[59] Wardle N. Oral Evidence to Task & Finish Group. 09/02/16.

[60] What is a PAS? British Standards Institute. Accessed 18/02/16.

[61] Ibid.

Standard, including KPI information for superintendents to assess and monitor accuracy and technical issues with Hubs, including turnaround times, etc.

We believe that it is necessary to insist on a quality standard for Hub providers, over and above GPhC Registration to reduce variation between Hub providers and give members the confidence in the quality of a given provider.

Service Gap

The Task & Finish Group has heard from many different witnesses who have Spoken about the opportunity for Hub & Spoke to release capacity within a Spoke pharmacy. Most have suggested that this spare capacity should be filled with service delivery. When examining the financial impact to a typical SME business, it has become apparent that the current level of services available is insufficient to offset increases in overall cost. Cormac Tobin made a strong case for a national Minor Ailments service, as it was impractical for companies like his to bid piecemeal for locally commissioned services. Mr Tobin felt that a new national service was absolutely critical to give contractors the confidence to keep investing in their businesses[62]. Pharmaceutical Services Negotiating Committee (PSNC) has published its proposals for a new clinical service driven contract[63] which could fill capacity created by Hub & Spoke.

During his evidence, Fin McCaul, former Chairman of the Independent Pharmacy Federation and a member of a CCG Board, talked about some of the opportunities for service development. He Spoke about the management of a number of Long Term Conditions, including hypertension where only half of patients in his CCG were diagnosed, while only half of those patients were controlled. Mr McCaul felt that opportunities such as these could only be pursued with the additional capacity created by Hub & Spoke[64]. Members of the Group disagreed that new capacity could only be created with Hub & Spoke, citing their experience of advanced skill mix.

A new service commitment from Department of Health/NHS England would give NPA members more confidence to examine the capacity opportunity afforded by Hub & Spoke.

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[62] Tobin C. Oral Evidence to Task & Finish Group. 08/02/16.

[63] Community Pharmacy Review 2016/17: A summary of PSNC's service development proposals to the Department of Health and NHS England. Accessed 21/02/16.

[64] McCaul F. Oral Evidence to Task & Finish Group. 29/01/16.

3.10 Barriers

EU Falsified Medicines Directive

The EU Falsified Medicines Directive seeks to reduce the risk of counterfeit medicines reaching patients. It contains a number of measures, including a proposal to serialise individual packs and require a process of product authentication at the point of supply to the patient. All packs must incorporate tamper evident seals, and these must also be verified before supply. This legislation therefore requires significant changes to dispensing processes - and presents a particular challenge to Hub and Spoke models.

The European Union published the final part of this legislation in February, and this establishes the implementation date as February 2019. A key requirement of the recently published Delegated Act (Article 25) is that: "Persons authorised or entitled to supply medicinal products to the public shall verify the safety features and decommission the unique identifier of any medicinal product bearing the safety features they supply to the public at the time of supplying to the patient". This means therefore that the pack will be scanned and a tamper check must take place when the product is being supplied to the patient. There remains a degree of uncertainty over the precise meaning of the phrase "at the time of supplying to the patient". However, it seems unlikely that a check of safety features made at a Hub hundreds of miles away, and days or weeks before the medicine reaches the patient, could be deemed to be compliant with the EU legislation. It seems likely therefore that these checks must take place in the Spoke. This may require the pack from the Hub to be opened. This would introduce a problem with respect to governance/ accountability, as the Hub will probably only take responsibility for the accuracy of the dispensing if their sealed bag remains intact. It would also nullify any potential efficiency gain for the Spoke pharmacy if they were required to handle and authenticate the product.

Noel Wardle raised a specific concern about the compatibility of Hub prepared MDS with the Delegated Act: the Authentication scan could not take place at the Hub because this was unlikely to be 'at the time of supply to the patient', and could not take place at the Spoke as it would be impossible to verify the authenticity of the contents of an MDS pack without being able to check the tamper evident seals on the original packs, even if an aggregated barcode on the final product is allowed.

In summary, the EU Falsified Medicines Directive could fatally undermine the financial case for Hub and Spoke and presents legal challenges which may be difficult to overcome.

The National Pharmacy Association will seek expert legal opinion on the compatibility of Hub & Spoke assembly models with the Falsified Medicines Directive.

Financial Viability

The Group examined the financial impact of Hub & Spoke on the viability of an 'average' pharmacy. The inputs for this session were informed by the evidence of multiple witnesses throughout the evidence programme. In understanding the impact on the finances of a pharmacy business, the Group acted as the expert. Task & Finish Group members operate pharmacy businesses of all scale and type, and are used to analysing the financial impact of policy and changes in the business environment on the viability of individual pharmacies. The assertion in the December letter from NHS England and the Department of Health that 'Hub & Spoke could help pharmacies to lower their operating costs' needed to be examined in light of the evidence presented to the Group by multiple expert witnesses.

The approach taken by the Group was to examine the positive and negative impacts on the profitability of an individual pharmacy at Profit & Loss Account level. We recognise that there are multiple methodologies for performing this type of exercise, however, for Hub & Spoke to make financial sense to a typical SME, a simple, relatable approach was required. The Group weighed positive and negative financial impacts of Hub & Spoke on an 'average' pharmacy.

It must be recognised that as private enterprises employing significant personal or corporate capital (sometimes in the form of secured bank debt), Directors of companies have a fiduciary duty under the 2006 Companies Act to act promote the success of their company, and to exercise due diligence[65]. Directors failing to fulfil proper financial due diligence with respect to Hub & Spoke could be negligent in their conduct.

Positive Impacts of Hub & Spoke on Profitability of SMEs

From evidence given to the Group, these fell into three broad categories:

- Increased service income
- Reduced staff costs
- Increased retail income

The Group set out to analyses the likelihood, quantum and inter-dependability of these positive effects.

Increased service income. This was mentioned by Dr Richard Brown and Cormac Tobin as the biggest potential benefit of Hub & Spoke to pharmacy businesses. The Group discussed the size of the opportunity, agreeing a figure in the low thousands of pounds per pharmacy, largely stemming from the ability of SMEs to achieve their maximum national Advanced Service income from MURs and NMS. Locally commissioned services

[65] Section 172 & 174 Companies Act, 2006. Accessed 21/02/16.

were discussed, but in light of decommissioning, complexity of access (tendering, regionality, etc) and falling revenues, this was largely discounted as insignificant to most pharmacy businesses.

Positive factors affecting service income:

- Removal of upper limit on MUR provision.
- New nationally commissioned services.

Negative factors affecting service income:

- Decommissioning of national Advanced Services.
- Decommissioning of local services.

Reduced staff costs. For an SME pharmacy business, the only variable cost which Hub & Spoke can affect is staffing costs i.e. staffing levels are reduced at the Spoke which frees resource to be invested elsewhere in the business.

Dr Richard Brown and Paul Mayberry cautioned against reducing staffing levels at the Spoke pharmacy because it reduced any capacity created for additional services - Dr Brown also suggested that this could in some circumstances lead to pharmacists self-checking their own work, which could be a patient safety risk. Jay Patel, wrote "in many cases in the pharmacy there often aren't enough staff to remove", questioning whether there was even an opportunity to reduce staffing levels in a typical pharmacy business.

The Group modelled an 'average pharmacy', dispensing around 6000 items per month, and employing 2 FTE dispensers. Including pensions, national insurance and other employment costs, the maximum saving would be around 0.25-0.5FTE, at the Spoke pharmacy. The impact is smaller than might be expected because the Spoke would still need to retain dispensing operations such as data entry, taking in and giving out the prescription, as well as adding new tasks such as reconciling assembled prescriptions received back from the Hub. In addition, because of annual leave, and contingency including sickness & maternity cover, it is often not possible to drop to a single dispensary FTE.

The inter-dependability of service income with appropriate staffing levels lead the Group to the position that it was likely that benefits could be wholly or at least partially exclusive i.e. you can achieve one or the other but not both.

Positive factors affecting staff savings:

- Large numbers of dispensary staff.
- Advanced skill mix e.g. Pharmacy Technicians, including Accuracy Checking Technicians.

Negative factors affecting staff savings:

- Low cost staff model e.g. Dispensary Assistants.

- Contingency risks e.g. maternity & sickness cover.

Retail income. The Group considered the opportunity to drive increases in retail revenue based on increased availability of staff to assist customers. Several members of the Group felt that this was could equally be driven by changes to skill mix in the pharmacy, increased training or retail refits. This was not accepted as a clear financial benefit of Hub & Spoke, although the Group modelled the impact of increased profit driven by improvements in retail income, should it be subsequently shown. At best this could add a low number of thousands of pounds to the profitability of an average pharmacy business.

Stockholding. It had been suggested that one potential financial impact of Hub & Spoke could be on the stockholding at individual Spoke pharmacies. Again the Group was cautioned about reductions in stockholding at Spokes by several witnesses, because of the importance of convenience and stock availability for patients who present with acute or urgent prescriptions at the pharmacy. One member of the Group, with significant experience in community pharmacy and short-line wholesaling said that stock levels constantly fluctuated in pharmacies, Hub & Spoke would only add to the complexity of getting the balance right. Even in the event of a reduction in Spoke stockholding being possible or desirable, any cashflow impact on an individual pharmacy business would be temporary and a one-off release. It was therefore decided to discount this as a financial benefit for the purposes of financial modelling.

A concern was also raised about the potential for increased medicine waste resulting from items dispensed at the Hub that are not collected from the Spoke. If a medicine is not collected currently, the packs can be returned to stock. It is not clear what could be done with Hub dispensed medicines that are not collected. There does not appear to be a legal mechanism to allow the Spoke to return the medicine to the Hub. It is not clear if it would be possible to put Hub-dispensed medicine into pharmacy stock. Without a solution to this problem, there is a risk of increased medicine waste.

Summary. On balance the Group found the maximum financial benefit of Hub & Spoke to an individual pharmacy business of no more than £10-15k. With the likeliest outcome in the region of £8-10k for an average pharmacy business.

Negative Impacts of Hub & Spoke on Profitability of SMEs

From evidence given to the Group, these fell into three broad categories:

- New direct costs.
- Indirect costs.
- Process & transformation costs.

The Group set out to analyses the likelihood, quantum and inter-dependability of these negative effects.

New direct costs. The biggest single cost of introducing Hub & Spoke for an SME is likely to be the direct cost of purchasing the service from their provider. Hub providers will need to recover the significant investment they have made in automation and infrastructure, and could look to recover this in a variety of ways: item of service payments, subscription, minimum purchase levels or through attrition of purchase margin; or a combination of methods.

The Group considered its 'average' pharmacy dispensing 6000 items, seeking to move 33% of its workload to a Hub. This would equate to a volume transfer of 24,000 items per year, even at a very optimistic price of 30p/item this would mean direct costs of around £8k/year - roughly equal to the financial opportunity generated by Hub & Spoke.

Positive factors affecting direct costs:

- Collective bargaining e.g. buying groups.
- Changes to funding delivery e.g. increases to Period of Treatment where Hub funded on per item basis.

Negative factors affecting direct costs:

- Lack of competition and choice of Hub provider.
- Charging model e.g. increases to Period of Treatment where Hub funded on cost per pack basis.
- Manipulation of contractual funding e.g. retained margin.

New indirect costs. The Group considered the wider implications to an SME pharmacy business of Hub & Spoke. One area of major concern was the risk of Hub & Spoke reducing competition and choice in the wholesale market. This is unlikely to be a problem until a critical mass of pharmacies had moved towards a Hub & Spoke model, but could ultimately lead to higher medicines costs for pharmacies and the taxpayer. Chris Frost stated in an article for P3 Magazine that Hub & Spoke that Hub & Spoke would 'change the procurement model for independent pharmacy operators to a basket model'. SMEs use shortline wholesalers because a financial benefit to do so exists - competitive pricing for individual lines, and the ability to shop around - which is what provides SMEs with the leverage the to drive procurement costs down, especially through buying groups.

The Group therefore considered very modest reductions in gross purchase margin up to -2%, which would have a significant negative impact on our average pharmacy model. This could easily be achieved through the reduced ability for independents to 'spot' buy products which are on offer or increasing in price. Other impacts could be around an increase in stock wastage e.g. for split packs.

Positive factors affecting indirect costs:

- Competitive market for Hub providers.

Negative factors affecting indirect costs:

- Consolidation of shortline wholesalers.
- Complexity of pricing model.
- Loss of ability to leverage collective bargaining.

Process & transformation costs. Hub & Spoke will add some costs to a pharmacy business, not least is understanding how the model works, and what needs to be done to put the Spoke pharmacy in a position where they can begin to use it. The Group identified a number of areas of new costs relating to the setup and ongoing process costs of Hub & Spoke:

- Due diligence to select Hub provider.
- Rewriting all existing pharmacy SOPs to take account of new model.
- Staff training.
- IT upgrade costs.
- Physical premises upgrades e.g. Rx storage.
- Data validation (to ensure staff are competent to begin ordering product from Hub as there may be no/limited opportunity to return).
- Redundancy costs where staffing reductions are possible.
- Obtaining explicit, written patient consent.

The cost to support change of business process is significant, and although many of these costs are one-off, they could easily be repeated, for example if a pharmacy chose to change Hub provider, or where staffing changes at the Spoke.

The group estimated these costs at a minimum of £10k for an average pharmacy.

Positive factors affecting process & transformation costs:

- Support materials e.g SOPs provided by Hub partner (although this could increase some risks for the Spoke).
- Understanding of Hub & Spoke model by SME.

Negative factors affecting process & transformation costs:

- Staff at Spoke - resistance/lack of understanding.
- Single independent cannot spread cost of Superintendent tasks across estate.

Summary. The Group found that the costs of Hub & Spoke were likely to be significant and could easily top £20k for an average pharmacy. The negative impacts, unlike the positive, did not appear to have a high degree of interdependency, meaning that the average pharmacy would face most if not all of the financial downside. Many of the costs were highly dependent on the degree to which competition and choice operates in the market for Hub provider, and the impacts on the wholesale market overall. In the event of a very small number of Hub providers emerging to service the SME sector, the negative financial impacts of Hub & Spoke could be greater, even for those who don't choose to operate the

model as wholesale entities could look to recover their investment from purchase margin from all customers.

Overall Financial Impact of Hub & Spoke on the Financial Viability of an SME

Existing Hub & Spoke models see the centralisation of cost within the same legal entity,. The proposed change to legislation, opens up the option to SMEs who cannot currently operate a Hub & Spoke model would require a different business case. We heard from one experts that one of the upsides for a large operator was to reduce the capital investment required to increase dispensing capacity at some branches who were becoming capacity constrained. Within a small organisation which may not even have a capital budget, the opportunities to offset this type of cost may be marginal.

The financial upsides of Hub & Spoke are marginal, especially because of the interdependency of positive factors which limit the quantum of the overall saving. The financial downsides on the other hand are complex and highly variable. The key factor appears to be the level of competition and choice between Hub providers which will drive microeconomic benefits for individual businesses.

Product Availability

The 2003 Office of Fair Trading investigation into the pharmacy market entry arrangements identified the main reasons for patients choosing a pharmacy[66]:

1. Location.
2. Convenience/speed.
3. Knowledgable staff.

From the perspective of the patient it is important that Hub & Spoke should not introduce any new delays in the availability of their medicines, or this could adversely affect the reputation of the business or impact on patients choice of pharmacy. From evidence given to the Group, we believe that there is a risk that Hub & Spoke could slow patient's access to their medicines by two mechanisms:

1. It could jeopardise twice daily deliveries to Spoke pharmacies from mainline wholesalers[67].
2. Turnaround times from Hubs for assembled products will be slower.

The likelihood of these impacts will only become apparent as Hub providers begin to market the service and the technological, logistical and competitive features of the service are tested.

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[66] Office of Fair Trading. The control of entry regulations and retail pharmacy services in the UK. January 2003.

[67] Shah B. Oral Evidence to Task & Finish Group 08/02/16.

NPA will maintain a watching brief on proposed service levels from Hub providers, and will challenge any threat to twice daily delivery from mainline wholesalers.

A number of proprietary pharmaceutical manufacturers have entered into restrictive distribution arrangements with full-line wholesalers. These can be either Direct to Pharmacy or Reduced Wholesale schemes which limit the choice of NPA members to purchase products from any wholesaler. This type of distribution arrangement may reduce the ability of shortline wholesalers or independent co-operatives to enter the market as providers of Hub services, and could limit their usefulness and efficiency as branded products would have to be added to prescriptions at the Spoke. This is of paramount concern to NPA as the SME sector is best served through a competitive market for Hub services.

We believe that these restrictive distribution arrangements are against our members interests, and are a barrier to a true level-playing field for the provision of Hub & Spoke services to organisations of all size and type. We urge the Government to act to ensure a level playing field.

We understand that some CCGs have looked at medicine ordering processes and found that there is an increase in waste if the order lead-time is increased. It is inevitable that ordering lead-times will need to increase with Hub and Spoke to build in the time taken for the Hub to process a prescription and supply the items to the Spoke. It is difficult to predict precisely what this cost will be – it depends on the uptake of Hub and Spoke and the Hub delivery times which will influence the prescription ordering lead-time. This could be a significant additional cost to the tax payer.

Short term strategies employed by local medicines management teams could reduce the opportunity for Hub & Spoke.

4.1 Summary

The NPA Task & Finish Group has undertaken an extensive review of all available evidence for Hub & Spoke, we believe our approach has been thorough and robust, and the final output balanced for a range of views.

The Group has been able to agree consistent terminology, which has subsequently been adopted by Pharmacy Voice Professional Practice Group.

We have established NPA members level of baseline support and understanding for the Hub & Spoke concept by all sizes of organisation. This shows a high degree of skepticism as to the potential benefits, and a degree of concern as to the potential risks. This is critical because these respondents are largely practising, front-line pharmacists and Superintendents who would need to make this system work if it is to be promoted.

The independent Literature Review commissioned by NPA has shown a lack of quality published scientific papers to support the Hub & Spoke concept. This wasn't surprising because of the nature of the system and the commercial positions of companies who have invested heavily in its development, but it does show the difficulty of making clear, evidence based-claims for efficiency and other benefits. The expert-witness approach we have taken has been successful in elucidating the key issues which could affect NPA members.

The largest benefit of Hub & Spoke observed, was around the potential to use capacity to deliver more services, but it would not be financially viable against the current level of service opportunities available. We heard from influential leaders that the sector needs a new nationally commissioned service to give pharmacy owners a reason to invest in Hub & Spoke. We saw the potential for automated MDS solutions to reduce labour intensive processes, and later became aware of serious legal issues which could prevent this. We were unable to find evidence of a clear cost saving for the SME sector - the business case is different for inter-company Hub & Spoke compared with existing intra-company arrangements. While a patient safety benefit is claimed, this is not exclusive to Hub & Spoke, and may be causally related to the environment and process changes which enable Hub & Spoke. These effects could be achieved with the integration of FMD authentication scanning with PMR systems.

When considering risks of Hub & Spoke the Group became concerned about a reduction in competition and choice in the pharmaceutical wholesale market, where infrastructure requirements, along with restrictive distribution practices could limit the number of potential Hub providers. This could easily lead to higher drug costs for the taxpayer which has benefited to the tune of £10bn since 2005 from competitive purchasing of medicines driven by non-vertically integrated SMEs. The Minister has stated that he wants a level playing field for all pharmacies to be able to use Hub & Spoke, we are

concerned that basic equity extend beyond the question of legislative change, which in itself is far from straightforward. We have heard from legal experts who have raised grave concerns over the compatibility of inter-company Hub & Spoke with both UK and EU law. The recent failure of a large scale automated dispensing operation underlines why it is important to consider risks as real and indeed likely. The consequences of a Hub failing could be disastrous for patients and the public, not to mention damaging to the reputation and finances of NPA members.

The Group looked at how Hub & Spoke could be made to work, and has suggested some reasonable steps to support competition and choice in the Hub market, as well as supporting SMEs to make a fair assessment of potential Hub partners. The NHS has the power to promote Original Pack Dispensing and electronic Repeat Dispensing to enable pharmacies to be more efficient, and plan their workload, but it has to do more than talk about it. Policy makers must not make the mistake that only large wholesalers will offer Hub services, a range of providers could and indeed should be encouraged to emerge to drive up service levels and drive down costs. For the purposes of inter-company Hub & Spoke, we believe that additional quality assurance beyond GPhC registration is required. A set of national standards should be developed to help SMEs to choose appropriate Hub partners and to ensure consistency between providers to make it easier to move provider.

A number of barriers were identified, including the basic cost model - at this moment it is difficult to see an inter-company Hub & Spoke model as being anything more than an additional cost for an SME. If Government truly wishes to support the use of inter-company Hub & Spoke models it has to use its powers to remove restrictive distribution practices such as Direct to Pharmacy, Reduced Wholesale Agreements and quotas as an essential prerequisite for SMEs to be able to choose from a range of Hub providers.

To close the review, we must re-iterate that the Group repeatedly stressed the importance for individual businesses of being able to choose to operate this model or not, based on their needs. Inter-company Hub & Spoke is more complex than existing intra-company models because of the transfer across legal entities, due consideration must be given to this crucial difference. We believe that Superintendent pharmacists and business owners need to make a free and informed choice about the model, including the risks as well as the benefits. It is not in the interests of the taxpayer, or SMEs for the choice of Hub provider to be limited to a few large organisations, a vibrant, dynamic market is essential or else the concept will fail.

4.2 Policy Recommendations

The Task & Finish Group would like to make the following recommendations to the NPA Board.

- Supporting service delivery:
    1. The Department of Health should commit to a new national clinical service such as Pharmacy First which would utilise additional capacity created by Hub & Spoke and give SMEs an incentive to invest.
    2. Policy commitments from Government would help with the uptake and implementation of Hub & Spoke: Original Pack Dispensing and greater use of electronic Repeat Dispensing are two prime examples.

- Supporting competition and choice for the provision of Hub services:
    3. Government must prevent restrictive distribution practices such as Direct to Pharmacy, Reduced Wholesale and quotas - or these schemes could act as a barrier to entry for a range of potential Hub providers.
    4. A set of national standards & KPIs should be developed for Hubs, to complement and enhance the GPhC inspection regime providing quality assurance and due diligence for SME customers to make free, fair and informed choices about Hub providers.

- Supporting constructive dialogue:
    5. Government should engage with the concerns of the SME sector, especially around the risks to procurement which has delivered more than £10bn savings for the taxpayer since 2005.
    6. The National Pharmacy Association should act as a constructive, but critical partner for stakeholders wishing to develop Hub & Spoke services for our members.

- Supporting members:
    7. The NPA should provide impartial advice and guidance to members wishing to pursue a Hub & Spoke model.
    8. The NPA should seek legal advice about the compatibility of pharmacy processes, including the provision of MDS and the EU Falsified Medicines Directive, with Hub and Spoke.
    9. The NPA should continue to monitor the economic and financial case for Hub & Spoke which will develop as the market forms.

4.3 Acknowledgements

The Chair of the Group would like to extend his thanks to a number of important contributors and supporters.

Firstly to the members of the Group for their hard work, diligence and insight into a complex and important issue.

Secondly to our expert witnesses who have provided their knowledge, understanding and skills to help the Group reach its conclusion.

We would like to thank Professor Rob Darracott of Pharmacy Voice for making key personnel available to us at an incredibly busy time.

Finally we would like to thank NPA members for contributing to the Member Consultation.

Appendix 1: Task & Finish Group Members

- Mike Hewitson MPharm (Hons), MRPharmS (Chair)

Currently Chair of the Pharmacy Voice Professional Practice Group, and a member of the NPA & Pharmacy Voice Boards, and a member of the Pharmaceutical Services Negotiating Committee representing NPA. Formerly Vice-Chair of the National Pharmacy Association & Chair of NPA Practice & Policy Committee and co-author of Bow Group policy paper on Pharmacy Services.

- Dr Nitin Sodha MRPharmS MBA FRSA

Currently Chair of Worcester LPC, LexonUK, and Managing Director of Knights Chemist Ltd. Vice Chair of NPA and Chair of Policy and Practice Committee, NPA.

- Rajesh Patel MBE, BSc, FRPharmS

A former NPA Chairman and former member of the PSNC Negotiating Team. He also represents the NPA in Europe as the Head of the UK Delegation to the PGEU. He is a non-executive director of National Pharmacy Association Insurance Company. He has recently been appointed as an external advisor to the School of Pharmacy at Manchester University.

- Claire Ward LLB (Hons), MA

Currently Chair of Pharmacy Voice, Non-Executive Director of Sherwood Forest Hospitals NHS Foundation Trust and Director of Capewells Ltd. Formerly Chief Executive of the Independent Pharmacy Federation and Member of Parliament for Watford, which included five years served as Government minister in posts including the Ministry of Justice and Government Whips Office.

- Nick Kaye BPharm MRPharmS

Superintendent S.Kaye & son Ltd, Vice Chair of Cornwall & Isle of Scilly Local Pharmacy Committee, Chair Peninsula Local Practice Forum, member South west local Practice Forum, Director NPA within NPA chair of Professional Development, Member Alliance Healthcare European Pharmacist Forum, member of PV professional practice group.

- Jay Badenhorst BPharm MRPharmS

Managing Director of Whitworth Chemists Ltd, Chairman for Tees LPC and an appointed Honorary Fellow for Durham University, School of Medicine, Pharmacy and Health.

- Garry Myers BPharm (Hons) MRPharmS MIPharmM

Currently Vice-Chair PSNC Funding & Contract Planning sub-committee and Independent Pharmacy Contractor member of the PSNC Negotiating Team. PSNC Committee member and Regional Representative for East Midlands & South Yorkshire. Member of Derbyshire LPC and Independent Pharmacy Contractor based in North East Derbyshire and Sheffield.

Supported by:

- Gareth Jones BPharm (Hons), MRPharmS, DipPharmPrac

Public Affairs Manager, National Pharmacy Association. Member of the UK delegation to the Pharmaceutical Group of the European Union, DH Supply Chain Forum and a number of Pharmacy Voice working groups.

- Fin McCaul MRPharmS

Former Chairman of the Independent Pharmacy Federation, and now advisor to the NPA Board. Fin is a practicing pharmacist in Greater Manchester, and is on the Board of Bury CCG where he is the lead for Long Term Conditions.

- Elizabeth Wade - MSc, PGCert, BA

Director of Policy, Pharmacy Voice. Formerly held senior roles in NHS management, academia and membership organisations including as Deputy Director of Policy - NHS Confederation, Senior Fellow - Health Services Management Centre University of Birmingham, and Head of Primary Care Commissioning for a London PCT.

- Kim Tran Packham MPH, BPharm, Dip Mgt

Senior Policy and Programmes Adviser at Pharmacy Voice. Australian community pharmacist and formerly Professional Services Special Projects Manager at the Pharmacy Guild of Australia (New South Wales Branch).

Appendix 2: Literature review

A search of existing literature on 'Hub and Spoke' services used in the supply of medicines by community pharmacies - to inform the NPA consultation response

Dr Ellen Schafheutle 28 January 2016
(Centre for Pharmacy Workforce Studies, Manchester Pharmacy School, University of Manchester)

Background

Community pharmacists provide increasing levels of clinical, patient-centred services to patients in their local areas, whilst dispensing volumes continue to rise and the healthcare system works under increasing financial pressures. The UK government is planning to consult on amending medicines legislation, which would allow all pharmacies (not just those part of the same legal entity) the use of 'Hub and Spoke' pharmacies. 'Hub and Spoke' in pharmacy refers to centralised dispensing models, where the assembly, dispensing and labelling of medicines take place in a central 'Hub,' and dispensed medicines are then transported to 'Spokes,' i.e. individual community pharmacies, from which they are collected by, or delivered to, patients.

Such models have been in use by a number of pharmacy multiples in the UK, but changes to medicines legislation would mean that all pharmacies, including smaller chains and independents, could use these systems/ models. Whilst it is advocated that centralised dispensing will make the dispensing process more efficient and increase patient safety, as well as free pharmacists to use their clinical skills more effectively, concerns have been voiced over the impact this change to medicines regulation may have on independent community pharmacies.

The NPA has therefore established a task and finish group to look at 'Hub and Spoke' dispensing, so that they can better understand the risks and opportunities for independent community pharmacies. The NPA is thus keen to gain a detailed understanding of Hub and Spoke, so that they can be in a position to make recommendations to the NPA Board, and ultimately to NPA members, and thus inform the NPA response to the up-coming DH consultation.

So that the task and finish group's recommendations are informed by the best available evidence on what has been tried and how effective it has been, the NPA commission a brief search of existing literature in this area of practice.

The **aim of the literature** search was to identify published evidence (research, evaluation and otherwise = 'grey') on 'Hub and Spoke' dispensing in the supply of medicines in community pharmacy to establish what is known on:

- Different models/ approaches to 'Hub and Spoke' and where they exist (i.e. which countries and healthcare systems)
- Effects of such approaches on
    - Patient safety
    - Pharmacy organisation, workload and staffing

- Reimbursement systems/ models, costs, and specifically the impact on the viability of smaller or independent community pharmacies

Methods of searching

To inform my thinking, I conducted a search of the ***Pharmaceutical Journal***.

I then searched a database/ search engine called **Scopus**, as this captures a wide range of (mainly) peer reviewed research evidence published in academic journals. Scopus is valuable as it lists a broad range of journals and allows a relatively flexible approach to searching, which was important for two reasons: Firstly, I did not expect to find a lot of published (and peer reviewed) literature on 'Hub and Spoke' and particularly its impact on independent community pharmacy. Secondly, I expected other countries to be using a variety of different terms for 'Hub and Spoke' dispensing, such as centralised dispensing (possibly automated dispensing) etc. It was therefore important to identify these terms for further searches. (Due to limited time, I did not expand my search to other academic databases, such as Embase, Medline, PubMed; however, there is considerable overlap between Scopus and these databases.)

In **Scopus**, using the search option 'Article Title, Abstract, Keywords,' I used the following search terms: "Hub &/and Spoke" AND pharmacy/ medicine(s)/ supply; automat* AND dispens* AND community; telepharmacy AND community/ dispensing/ supply/ medicine(s); decentrali* AND dispens*; centralised dispensing; satellite AND pharmacy AND community.

Please note: I excluded anything which was concerned with hospital pharmacy; this could be revisited at a later stage, as quite a few studies will have been published on automation, (de)centralised dispensing etc., and some of their findings and messages may well be relevant or at least informative for community pharmacy.

Following this search using Scopus, I broadened my search using **Google Scholar** and then **Google**. This allowed further searching of academic peer-reviewed publications and other types of papers and study/ evaluation reports, the so-called 'grey literature.' Whilst these types of publications do not have the same rigour and credibility (due to the lack of the quality control/ review system which is ensured through the peer review system in academic journals), this was still valuable for this relatively new and emerging area; academic publications tend to be published with considerable delays. I used the same search terms as listed above, to identify publications and websites from a much broader range of backgrounds, such as companies who offer 'Hub & Spoke' services, descriptions and/or evaluations of services and opinion pieces and commentaries on potential impacts.

Search findings

I provide a summary and overview of the papers and other publications I identified as relevant to the search aims; all papers are referenced in the bibliography at the end.

There have been a number of mostly commentaries and opinion pieces in the **Pharmaceutical Journal** (PJ) recently, all prompted by the possibility of a consultation around changes to the legislation around Hub and Spoke.[1-6] Some focus on the potential for positive impact, such as improved safety, accuracy and efficiency of dispensing, the

freeing up of highly trained staff, in particular pharmacists, for more clinical, patient centred services and in deed a positive impact on patients.[1,2] Others are more cautious and raise the importance of clarity on where accountability lies, and the potential of threatening profitability of community pharmacies and possibly destabilising the community pharmacy network as a whole.[3,4] Some other articles were also found in the PJ, dating further back, identifying the need and potential of learning from the model in place in hospitals, where "dispensing is undertaken by support staff and dispensing robots."[7]

Several of the articles emphasise the importance of evaluating the effects of the introduction and use of Hub & Spoke models. For example, in one article the Royal Pharmaceutical Society (RPS) calls for an evaluation of the automated Hub services in operation by Boots, so this may be good to watch out for.[8]

There was one further article, dating back to 2006, which may be valuable, as it **describes the running of a central dispensary in Norwich**, which supplies to four Spokes.[9]

Scopus

As noted earlier, I generally excluded any studies which related to hospital pharmacy; however, I came across a **systematic review of 'decentralised dispensing devices'** which I thought may still be of interest.[10] It identified eight studies as meeting their inclusion criteria, and the authors found that pharmacists' time checking dispensed medicines and resolving drug distribution problems reduced, whereas time spent on clinical activities increased because of a reduction in time spent on technical functions.[10]

Use of the search terms **'telepharmacy'** identified a few other potentially relevant studies. However, these studies are more about the use of remote technology to access a pharmacist's (clinical) input into services.[10] So these studies were more about a 'reverse type Hub and Spoke' model, which is more akin to a model of **remote supervision**, where the central telepharmacy (Hub) has an on-site pharmacist, whereas the Spokes are staffed by registered technicians. Studies have looked at differences in dispensing errors between pharmacist staff and remote community pharmacies (Canada), but did not find much difference/ impact in either site.[11,12] Other studies focussed on increasing access to rural populations which are underserved by usual, pharmacist-staffed community pharmacies; or out-of-hours, e.g. nights. However, they are not relevant to the topic under investigation here.

The description of the **Canadian model** of 'telepharmacy,' a company called MedCentre, can be found in the FIP journal of 2011.[13] The authors argue that this model is economically viable (and indeed reduces running costs), whilst offering various improvements and potential benefits, including pharmacists becoming much more accessible healthcare professionals and the opportunity to integrate much better into the overall care model ("at a fraction of the cost").[13]

'Automated dose dispensing' (ADD) appears to be mainly defined as "medicines being packed in unit-dose bags according to administration times," so most studies are related to unit dose dispensing. Some of this may still be relevant, esp. when studies investigate the impact on workflow, workload or patient safety in individual ('Spoke') community

pharmacies. Here are some examples, which you may find relevant, informative or valuable:

Finland: starting an automated dose dispensing service in community pharmacy, whereby individual community pharmacies buy unit-dose bags from one 'Hub' pharmacy.[14] 325 patients enrolled in 110 community pharmacies. They looked at medicines reconciliation and medication review and found that 593 changes were made to patients' medications. Reasons for these changes included: generic substitution, treatment related reasons and technical changes. The authors concluded that medications were not always appropriate or up-to-date when patients were enrolled. This study did not look at any other measures.

Netherlands[15,16] In their introduction to the study,[15] this paper offers valuable insights into some of the existing evidence:

"ADD has been introduced aiming to improve medication safety and treatment adherence, particularly in elderly patients with multiple medications. Additional ***advantages of ADD*** *are a reduced workload for the pharmacy dispensing staff and nurses administering the medication, avoidance of old stockpiles of medication at home, and decreased medication costs.[12] Early studies have confirmed that automated medication dispensing systems minimize medication dispensing errors and save time for the pharmacy dispensing staff. [13]–[16] Low error rates between 0.07‰ and 0.10‰ of automated dose dispensing machines have been observed during a 6-months follow-up period. [17] Other studies focused on treatment adherence and medication knowledge of the patient. [7], [9], [11], [18] Kwint et al showed that ADD users have a substantially higher self-reported adherence compared to non-ADD users (91% versus 58%).[7]"*[15]

"In addition to these positive effects, ADD may also introduce new types of medication errors. [8], [17], [19], [20] Two studies have shown that patients using ADD are at ***increased risk*** *of receiving inappropriate medicines like long-acting benzodiazepines, anticholinergic medicines, and three or more psychotropic medicines. [5], [19] […] These studies focused on incidents occurring in the medication administration phase. Overall insight into medication incidents related to ADD across the full range of phases of the medication process (from prescribing to dispensing, storage and administration) is still missing."*[15]

This study looked at both ADD in hospital – to hospital inpatients as well as patients in nursing homes – and **community pharmacies**, which is what I will focus on here. The authors write that *"especially community pharmacies tend to purchase this service [ADD] from a pharmacy that is specialised in ADD (the latter will be referred to as the ADD supplier [Hub]). The […] pharmacist will always remain responsible for entering the prescriptions into the pharmacy information system. Subsequently, the pharmacist transmits the ADD file electronically to the ADD supplier [Hub]. Using this ADD file the ADD supplier fills the ADD bags. In the next step […] in the community pharmacies the* ***ADD bags are dispensed directly to the patient and the community pharmacist provides counselling*** *about the medicines and how to use the ADD bags. […] When an alteration (e.g. new or changed prescription) occurs the pharmacist has two options: the alteration can be effectuated in the next ADD supply or the pharmacist collects the ADD bag from the patient and manually changes the ADD content."*[15]

In this study, the authors investigated incidents reported through a national reporting system, and they specifically focussed on those relating to ADDs. *"Healthcare providers working in community pharmacies submitted 3,685 (24.4%) incidents […]. In total 268 (****1.8%****)*

***incidents were related to ADD**: 227 (227/3685=6.2%) incidents from community pharmacies."*
The causes of these incidents in community pharmacy were: **an alteration of the medication regimen (24.2%, n=55)**. *"Examples of alterations were the addition of a new medicine to, a change in the strength, dosage, or administration time of a medicine and stopping the use of a medicine. For 16 incidents (7.0%) a switch to another brand or generic label caused the incident. In 10 incidents (4.4%) a discharge from or admission to hospital or nursing home led to an incident. For 116 (51.1%) incidents the researchers could not deduce the immediate causes from the reports."*[15]
Harm to the patient: *"In three community pharmacy-based incidents the healthcare providers reported serious temporary harm to the patient: one patient was admitted to hospital, another patient was feeling groggy and could not stand anymore, and in the third incident there was merely an indication of dizziness."* [15]
The authors concluded that: *"A low proportion of reported medication incidents was related to ADD. […] From our analysis we have an indication that the immediate cause of an incident was often a **change in the patient's medicine regimen or relocation**. The changes in the patient's medicine regimen contributed to incidents occurring in the phase of adjusting the content of the ADD bag. **Such adjustments were time consuming and had to be done manually and under pressure of time by the pharmacy team**."* [15]
They also added a paragraph on **'implications for practice:'** *"ADD has implications for the workflow of the pharmacy and these new operations also need to be accompanied with prospective risk analysis and with health technology assessment (HTA). The absolute percentage of incidents related to ADD may seem low, but the use of ADD will increase further and it is **necessary to pay attention to this new type of incidents in healthcare**. In the implementation of ADD, healthcare providers may have focused on the advantages, but **new technologies can also have unintended consequences**. This descriptive study will help healthcare providers to become more aware of the most vulnerable aspects of ADD so that they can take targeted measures to reduce their unintended consequences."*[15]
"To reduce the reoccurrence of ADD incidents it should be considered to perform double checks on the entering of the prescriptions and orders into the pharmacy information system, postpone alteration of patients' medication regimen when possible, avoid manual adjustments of ADD bags, follow training in the processing of ADD and to report ADD incidents adequately." [15]
Another study investigated *"Effects of medication review on drug-related problems in patients using automated drug-dispensing systems."*[16] The abstract of this (which is all I can access) can be found in the list of references below.

There are a number of studies which have looked at the impact of the **introduction of automated dispensing**, i.e. robotics, **within individual community pharmacies**, but not off-site. I add only a few examples, because I assume it is not of interest to the topic under investigation, as it is not off site dispensing, i.e. Hub & Spoke. [17-19]

Centralised dispensing brought up a paper from **South Africa** which may be of interest.[20] A Google search located two earlier articles published in South Africa's Pharmaceutical Journal, which describe the processes of centralised dispensing[21] and some of the felt benefits.[22] A key for a decision to enrol a patient for centralised dispensing is that they

have to be **clinically stable** (so they are comparable to patients on regular repeat prescriptions in the UK/ England). The **key difference** is that in this South African model the **driving force came from dispensing in the public sector (hospital) and moving dispensing of regular, established medicines to 'Spokes'**, i.e. individual community pharmacies. Other drivers were increased burden of disease (comparable to our increasing dispensing volumes), and pharmacist and other pharmacy staff shortages (which we no longer face). The aims were to: *"reduce pharmacists' workload, (by relieving pharmacy staff from repetitive and time consuming tasks that detract from patient-focussed elements), decongest health facilities (hereafter referred as facilities) and improve the patient experience by reducing waiting times."*[20] Some of the detail described in these three papers, as well as the benefits the author describe, may be of interest/ relevance to the UK:
"Initial implementation. […] This being a unique project, there were no other experiences on which to base a model of delivery. […] The pharmacies have found that the CDU processes introduced new work into their busy lives. There is a certain amount of administration related to the dispatch of prescriptions to the CDU, the reception of the dispensed medicines, the issue to the patients and the management of non-collected medicines. However, the time taken by performing this work is much less than that previously taken by dispensing the medicines. And the advantage is that much of this work can be performed in the early morning or late afternoon, times when the waiting rooms are clear of patients, thus less pressure on the staff."[22]
Another identified challenge was that of missed appointments and thus uncollected medicines parcels.[20]
Benefits: Significantly decreased waiting times,[22] pharmacy staff who experience a less pressurised work environment,[22] resulting in pharmacists' ability to serve more than double the people they served prior to CDU,[20] and increased time for patient counselling.[20]

Google Scholar and Google

First of all, it is worth drawing attention to the guidance published by the GPhC: *"Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet"* published in April 2015, following consultation. This includes a number of references to 'Hub and Spoke'.[23] Examples of the pharmacy services covered by this guidance include: *"a 'Hub and Spoke' pharmacy service, where medicines are prepared, assembled, dispensed and labelled for individual patients against prescriptions at a central 'Hub' registered pharmacy."* This GPhC guidance defines 'Hub and Spoke' as where *"The dispensed medicines are supplied by the 'Hub' to 'Spokes' or delivered direct to patients in their homes or to care homes. The 'Spokes' may be other registered pharmacies; or nonregistered premises, where patients drop off their prescriptions and from where they collect their dispensed medicines."* Under the heading 'regular audit,' the guidance recommends to consider: *"suitability of communication methods with patients, and between staff and other healthcare providers, including between Hubs and Spokes and with collection and delivery points*." - Under 'accountability of staff' the guidance states: *"When parts of a pharmacy service take place at different locations (such as in a 'Hub and Spoke' or 'click and collect' service) you must be clear about which pharmacist is accountable and responsible for each part of the service, and which pharmacy technician and other staff are involved."*

Other than duplicates of what has been presented above, much of what in particular Google located is not evidence based and not uncommonly rather opinion based or even biased. I will focus on including items below which have the potential of at least offering some valuable insights or reflections that may be worth consideration.
A number of websites and 'articles' (or blogs) define and describe what is meant by different distribution models in pharmacy practice, but their value and insight are limited, e.g.

- http://www.talyst.com/newsroom/blogs-general/pharmacy-practice-and-distribution-models/

An article, using some references, on the 'safety of automated dispensing systems,'[24] but I don't think this is relevant for the purpose of this search.
Descriptions of automation (robots) in individual community pharmacies – quotes on the impact this has had on the individual organisation – listed by the company selling these robots (advertising/ biased? http://www.arx-ltd.co.uk/case-studies/) – also do Hub-and-Spoke (http://www.arx-ltd.co.uk/case-study/centralised-hub-and-spoke-for-community-pharmacy-mayberrys/) – ARX
Another company "availability of centralised and decentralised automated dispensing machines increases demand" (http://www.technavio.com/pressrelease/availability-centralized-and-decentralized-automated-dispensing-machines-increases 31 May 2011)

Commentaries

Various other commentaries have been published in the pharmacy press, besides those mentioned under the PJ above. Similar potential benefits and concerns are raised to those mentioned earlier; here are just a couple of examples; the latter commentary being from an independent contractor.[25,26]

An interesting view can be found from **dispensing practices**, which draw comparison with the impact on independent community pharmacy contractors.[27] The authors write: *"Dispensing practices will share many independent pharmacy sector concerns; in particular the effect of reducing dispensing fees on the wider practice service provision, and the potential for dispensing patients to opt to use non GP-owned Hub dispensing services. If Hub services gain excessive market share, they may also be able to impose unfavourable trading terms on the Spoke operation."* [27]
"Small contractors, particularly those in very remote locations may also fear the ***effect on their wholesalers' business terms*** *if dispensary stocks are significantly reduced – although wholesalers say they will retain a role as a 'stock room' for practices."*[27] The Dispensing Doctors Association are getting involved in discussions. They have put together a 'dispensary management zone' *"to enable members to consider the following areas, and their implications for practice:*

- Time line of Hub and Spoke developments
- Defining Hub and Spoke and different models
- Business and ROI consideration
- Considerations affecting cost-effectiveness

- Legal considerations and professional expectations
- Potential professional benefits
- Professional concerns: Devaluing the dispensing fee
- *Professional concerns: 'Amazon-isation' of dispensing"*[27]

However, access to the above listed resources is restricted to DDA members.

Description of what 'Hub & Spoke' might look like, published by Pharmacy Management & Practice:[28]

Some quotes from the text: *"The use of automation and robotics to support the dispensing process and take some of that volume out from pharmacy – allowing the pharmacist to then concentrate on patient care – just feels like it's going to be an inevitable outcome."* [28]

They say some of their pre- community pharmacy distribution is already automated, so that would simply extend to the patient rather than the pharmacy.[28]

<u>Heading: Implications for multiples</u>

These figures may be valuable/ of interest for the NPA: *"The key point is that it frees up pharmacist time. If you can* ***take 40 to 50 per cent of volume out of the pharmacy to provide additional services****, then that is our biggest win. For me, that is the primary goal and has always been the driving force behind looking at off-site dispensing over the years."* – suggesting that repeat Rx's can be dispensed through an automated process.

"Such a system would also have a ***commercial benefit in reducing the stock-holding requirement*** *across Lloydspharmacy's 1,600 pharmacies."* [28]

The author also suggests that automation will **improve dispensing accuracy** (by removing the human element and thus chance of error), whilst the pharmacist is still needed for the clinical check, but the rest of the time would be freed for other services.

*"Realistically though, not all prescriptions would be fulfilled off-site. '****You still have 30 per cent of prescriptions that are acute, and there will always be a number of repeat scripts that you are not going to be able to do remotely*** *for whatever reason.'"* [28]

"Clearly, a change in the dispensing model would also affect other members of the team, such as technicians." [28]

<u>Heading: Implications for independents</u>

Please note, however, that these were written from the perspective of pre-announcement to consult on potential changes to legislation. The positives that are sited are otherwise similar to those above for multiples.

"Independent pharmacies can already more easily ***lever the role of a highly trained technician*** *to do the same [as Hub-and-Spoke automation], he suggests. 'There's no reason why – if they do it in the right way – that good independents with the right supporting team around them can't free up the same amount of time.'"* [28]

"There could be ***further areas to consider. Would automated dispensing change the wholesale system and the relationship between wholesaler and pharmacist for good?*** *[…] It would involve* ***changes to the purchasing model. 'Pharmacies would be purchasing on a basket basis rather than an individual product basis****. And how that changes the wholesale model is an interesting one.'"*[28]

Systems that offer 'Hub and Spoke' services/ solutions for community pharmacy

Finally, below please find some systems that I have come across online that offer 'Hub and Spoke' services/ solutions for community pharmacy. Many of these are either more like advertising of a system, or a description of its implementation and use; there seems little published in terms of impact – either on patients safety, access, pharmacy workload and workflows, or indeed a differential impact on multiple vs. independent community pharmacies.

UK

- Centralised Hub and Spoke for community pharmacy Mayberry's – South Wales (http://www.arx-ltd.co.uk/case-study/centralised-hub-and-spoke-for-community-pharmacy-mayberrys/) claims various benefits, mainly cost related – it's more of an advert, but contact may provide further detail/ insights
- Further articles: [29,30]
- Hub & Spoke for compliance aids, as presented at Pharmacy show (http://www.medmanagement.co.uk/compliance-aid-hub-spoke-improving-profit-for-pharmacy-groups/)[31]
- Adverts: http://www.pharmasysgroup.com/pharmacy-chains/
- Research and Markets: Global Automated Dispensing Machines Market 2015-2019 - Centralized and Decentralized Dispensing Machines is a Key Market Driver (http://www.businesswire.com/news/home/20150731005678/en/Research-Markets-Global-Automated-Dispensing-Machines-Market)

Canada

- PharmaTrust[13] – but seems to be more about remote Spokes and telepharmacy, rather than the UK model, which would retain a pharmacist at each Spoke

Netherlands

- 'Willach's Local Central Filling'
    - http://www.willach-pharmacy-solutions.com/en/News/News/New-hub-and-spoke-robotic-dispensing-solution-for-community-pharmacies-successfully-launched.php
    - http://www.willach-pharmacy-solutions.com/en/brochures/PDF-new/EN_CaseStudy_Local_Central_Filling_Oosterheem_Service_Pharmacy.pdf
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Appendix 3: Member Consultation Questions

1. Have you ever considered adopting a Hub & Spoke system in your business?
- Never under any circumstances
- Not at the moment, but might consider in the future
- We are in the planning stages
- We are currently operating a Hub & Spoke system
- We have trialled but removed a Hub & Spoke system

Please comment on your choice:

2. Hub & Spoke assembly operations can be provided in a number of different models. Would you be in favour or against a service provided by each of the following?:

Another branch in your group
- Strongly against
- Slightly against
- Neutral
- Slightly in favour
- Strongly in favour

A local cooperative Hub in which your pharmacy owned a share
- Strongly against
- Slightly against
- Neutral
- Slightly in favour
- Strongly in favour

An NHS hospital trust
- Strongly against
- Slightly against
- Neutral
- Slightly in favour
- Strongly in favour

An independent wholesaler
- Strongly against
- Slightly against
- Neutral
- Slightly in favour
- Strongly in favour

A national wholesaler (eg, Alliance, AAH)
- Strongly against
- Slightly against
- Neutral
- Slightly in favour

- Strongly in favour

Comments:

3. I would consider moving the following elements of workload to a Hub & Spoke arrangement:

Regular repeat medication
- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Nursing homes
- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

MDS
- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Other (please specify):

4. How far do you agree or disagree with the following statements?:

Hub & Spoke will.....

Improve the operational efficiency of my business
- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Improve the profitability of my business
- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Be in the long-term interests of independent community pharmacy
- Strongly disagree
- Disagree

- Neither disagree nor agree
- Agree
- Strongly agree

Improve safety of dispensing operations

- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Create capacity to deliver services

- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Reduce stock levels and availability in my pharmacy

- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Reduce choice of wholesalers

- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Increase the complexity of my business

- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Delay patients' access to their medicines

- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Reduce staffing levels in my pharmacy

- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree

- Strongly agree

Lead to pharmacies closing

- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Create a data security risk

- Strongly disagree
- Disagree
- Neither disagree nor agree
- Agree
- Strongly agree

Other (please state):

5. Finally, do you think the overall impact of Hub & Spoke will be positive or negative for the following groups?:

Patients

- Very Negative
- Negative
- Neutral
- Positive
- Very Positive

My pharmacy company

- Very Negative
- Negative
- Neutral
- Positive
- Very Positive

The community pharmacy network overall

- Very Negative
- Negative
- Neutral
- Positive
- Very Positive

Other (please specify)

6. If you have any other comments on the development of Hub & Spoke services please feel free to share them:

7. Please enter your details:

Pharmacy name:
Member number:
Name:
Telephone number:
Email address:

Appendix 4: Witness Question Prompts

Hub and Spoke task & finish group

1. **Benefits and risks**

In your experience, what are the key benefits of a Hub and Spoke system? Please provide evidence to support your view:
What are the key risks of a Hub and Spoke system? Please provide evidence to support your view:

2. **Modelling**

Various models of H&S operation have been suggested, what type of model would you favour and why?

Do you have any comments about what scale of Hub & Spoke operation would be viable?

In your opinion, which entities are best placed to provide a Hub services? Would the Hub need to be a Registered Pharmacy?

3. **Financial viability**

What impact do you think Hub and Spoke has on the cost-base of an independent community pharmacy?

4. **New benefits or risks**

Please describe any new risks or benefits created by Hub and Spoke?

5. **Stakeholder Impact**

In your opinion what are the positive and negative impacts of Hub & Spoke on the following stakeholders:

	Positive	Negative	Comments
Buying Groups			
Mainline Wholesalers			

	Positive	Negative	Comments
Shortline Wholesalers			
Patients			

6. **Service levels**

How reliable is the technology which is used to deliver Hub & Spoke services? Do you have any metrics to support this?
Would the introduction of Hub & Spoke lead to any reduction of stock-holding at the Spoke?

7. **Costs**

Do you have any information which would help SME considering adopting a Hub & Spoke model to understand the impact on their cost-model? e.g. what would it cost to purchase Hub services?